



Faculty of Engineering of the University of Porto

Biomechanics of female trauma during childbirth

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Contents

Abstract	vii
Resumo	ix
Acknowledgements	xiii
List of figures	xv
List of tables	xxiii
Nomenclature	xxv
I Motivation	1
1 Introduction	3
1.1 Anatomy of the female pelvis	3
1.1.1 Pelvic floor	4
1.1.2 Perineum	6
1.2 Description of labor and delivery	7
1.2.1 Stages of labor	7
1.2.2 Mechanisms of labor	8
1.3 Childbirth-related injuries	10
1.4 Biomechanics of childbirth	13
1.4.1 Finite element models	14

1.4.2	Constitutive modeling	17
1.4.3	Experimental tests	25
1.5	Finite element-based machine learning	29
1.6	Thesis outline and specific aims	33
II	Modeling and simulation in childbirth biomechanics	49
2	A biomechanical perspective on perineal injuries during childbirth	50
2.1	Introduction	53
2.2	Methodology	55
2.2.1	Anatomic modeling of the female pelvis	55
2.2.2	Mechanical characterization	57
2.2.3	Simulations of vaginal delivery	59
2.3	Results	62
2.4	Discussion	67
3	Computational modeling of vacuum-assisted delivery: biomechanics of maternal soft tissues	76
3.1	Introduction	79
3.2	Methodology	80
3.2.1	Biomechanical model	80
3.2.2	Numerical simulations	82
3.2.3	Mechanical characterization	85
3.3	Vacuum-assisted delivery simulations	88
3.3.1	Analysis of the maternal structures	88
3.3.2	Effect of the contraction duration and resting stages	90
3.3.3	Impact of the number of pulls	92
3.4	Discussion	94
3.5	Conclusions	98

III Artificial intelligence in childbirth biomechanics 103

4 A finite element-based machine learning framework to predict the mechanical behavior of the pelvic floor muscles during childbirth 104

4.1	Introduction	107
4.2	Related work	110
4.2.1	Childbirth biomechanical simulations	110
4.2.2	FEM-based ML biomechanical applications	111
4.3	Materials and methods	112
4.3.1	Biomechanical model	112
4.3.2	Finite element simulations of childbirth	114
4.3.3	Dataset generation	115
4.3.4	Machine learning pipeline	117
4.4	Results	122
4.4.1	Hyperparameter optimization	122
4.4.2	Case 1 – Single-output prediction for maximum stretch level . .	124
4.4.3	Case 2 – Multi-output prediction for multiple fetal descent levels	126
4.4.4	Real-time performance and time gains	129
4.5	Discussion	130
4.6	Conclusions	133

5 Patient-specific surrogate model to predict pelvic floor dynamics during vaginal delivery 140

5.1	Introduction	143
5.2	Related work	145
5.2.1	Biomechanics of childbirth	145
5.2.2	FEM-based ML in biomechanics	147
5.3	Methodology	148
5.3.1	Conceptualization	148

5.3.2	Computational model	149
5.3.3	Mesh-morphing	151
5.3.4	FEM simulations of vaginal delivery	153
5.3.5	Artificial intelligence pipeline	154
5.3.6	Clinical data	159
5.4	Results	161
5.4.1	Hyperparameter tuning	161
5.4.2	Effect of dataset size	162
5.4.3	Prediction of nodal coordinates	162
5.4.4	Stretch prediction	165
5.4.5	Real-time performance	165
5.4.6	Clinical validation	166
5.5	Discussion	167
5.6	Conclusions	171

IV Experimental mechanics for tissue characterization 179

6	Experimental characterization of the nonlinear viscoelastic properties of human female perineal tissue	180
6.1	Introduction	183
6.2	Methods	185
6.2.1	Sample collection and storage	186
6.2.2	Specimen preparation	187
6.2.3	Experimental protocol	188
6.2.4	Histological assessment	191
6.2.5	Calibration of the constitutive parameters	192
6.3	Results	196
6.3.1	Relaxation tests	196

6.3.2	Ultimate tensile tests	197
6.3.3	Histological assessment	198
6.3.4	Calibration of constitutive parameters	200
6.4	Discussion	201
V	Final remarks	211
7	General discussion	213
7.1	Discussion	213
7.2	Major findings	218
8	Conclusions and future work	221
8.1	Conclusions	221
8.2	Future work	223
9	Scientific outputs	227
9.1	Data availability commitment	227
9.2	Original research articles	227
9.3	Oral presentations	229
9.4	Poster presentations	230
9.5	Collaborations	231
	Appendices	235
A	Co-authors consent form	235

Abstract

The second stage of labor can be highly traumatic for women, often causing injuries to the pelvic floor muscles and perineum. These lesions may lead to long-term complications, such as pelvic organ prolapse, sexual dysfunction, urinary and anal incontinence, which can significantly reduce quality of life. Beyond physical trauma, childbirth is also associated with psychological distress, further amplifying its adverse effects. Given these concerns, improving the prediction and prevention of obstetric injuries is essential for enhancing maternal well-being and reducing childbirth-related anxiety. This thesis aims to improve computational models of vaginal delivery and investigates innovative approaches to accelerate the simulation process, facilitating integration into clinical practice.

A detailed finite element model was developed to simulate vaginal delivery, incorporating the pelvic floor muscles, perineum, and fetal head. A key focus was the inclusion of often-overlooked perineal structures such as the bulbospongiosus and ischiocavernosus muscles, the transverse perineal muscles, the perineal body, and the external anal sphincter. Simulations conducted in Abaqus[®] revealed that the inclusion of these structures significantly influenced the results. The regions most impacted during delivery were near the urogenital hiatus, which experienced a maximum stretch of 2.9, and the connection between the perineal body and the external anal sphincter. These findings underscore the importance of including such structures in future computational models.

This model was adapted to simulate vacuum-assisted delivery, a common obstetric procedure whose biomechanical impact remains insufficiently understood within the medical community. The results indicated that the muscle regions affected during vacuum-assisted delivery were similar to those involved in normal vaginal delivery. Additionally, prolonged contractions with extended resting periods facilitated maternal muscle recovery, whereas extracting the fetus with fewer pulls increased muscle stress and the force applied by the obstetrician. This analysis can contribute to the development of clinical guidelines from a biomechanical perspective.

To accelerate simulation outcomes, given that numerical simulations are often highly time-consuming, a finite element-based machine learning approach was implemented. A dataset comprising thousands of simulations with varying muscle material properties was used to train machine learning models. This approach yielded promising results, with artificial neural networks outperforming tree-based models in predicting muscle stress levels during vaginal delivery. Building on this, a patient-specific surrogate model was developed using a mesh-morphing algorithm to adjust the pelvic floor geometry, including a broad spectrum of women’s anatomical dimensions. The model predicts the coordinates of specific pelvic floor nodes to calculate muscle stretch. Among the tested models, the random forest algorithm demonstrated the best performance, achieving a mean absolute error of 0.086 mm. Notably, results were obtained in under 11 seconds, significantly outperforming traditional methods and making the approach suitable for clinical use. The feasibility of implementing this methodology in a clinical setting was also evaluated, including the development of a comprehensive pipeline and the identification of key requirements for successful integration.

Reliable finite element simulations depend not only on advanced modeling techniques but also on precise material properties, particularly for soft tissues such as the perineum. To refine these simulations, mechanical testing on *post-mortem* human female perineal samples provided insights into the perineum’s mechanical behavior. The perineal body was found to exhibit nonlinear hyperelastic and viscous properties, with a stress relaxation of approximately 40%. Histological analysis revealed a dense network of collagen fibers aligned with the direction of tissue stretching. Experimental data were used to calibrate the material parameters of a visco-hyperelastic constitutive model, leading to strong agreement between experimental and numerical results. These parameters can be used in future studies to improve the fidelity of finite element simulations, facilitating the simulation of physiological processes involving the perineum.

In conclusion, this thesis presents a multidisciplinary approach combining computational modeling, artificial intelligence, and experimental testing to improve our understanding of childbirth biomechanics. The results offer insights for future research aimed at improving maternal outcomes and informing clinical practices in obstetrics.

Resumo

O segundo estadio do parto pode ser traumático para a mulher, muitas vezes resultando em lesões nos músculos do pavimento pélvico e no períneo. Estas lesões podem conduzir a consequências a longo prazo, como o prolapso dos órgãos pélvicos, disfunção sexual ou incontinência, levando a uma redução significativa da qualidade de vida das mulheres. Para além do trauma físico, o parto também está associado a sofrimento psicológico, potenciando os seus efeitos adversos. Tendo em conta estas preocupações, existe uma necessidade urgente de prevenir e prever lesões obstétricas, de modo a melhorar o bem-estar materno e reduzir a ansiedade associada ao parto. Esta tese tem como objetivo melhorar os modelos computacionais existentes para simular o parto e investigar abordagens inovadoras para acelerar os resultados obtidos com estas simulações, facilitando a implementação destas metodologias na prática clínica.

Foi desenvolvido um modelo de elementos finitos detalhado para simular o parto vaginal, incluindo os músculos do pavimento pélvico, o períneo e a cabeça do feto. Um dos principais focos deste modelo foi a inclusão das estruturas do períneo, que geralmente não são representadas, como os músculos bulboesponjoso e isquiocavernoso, os músculos transversos superficiais e profundos do períneo, o corpo do períneo e o esfíncter anal externo. As simulações realizadas no Abaqus[®] demonstraram que a inclusão destas estruturas teve um impacto significativo nos resultados obtidos. As regiões mais afetadas durante o parto foram identificadas próximas do hiato urogenital, que sofreu um alongamento de 2.9, e a região do corpo do períneo que se liga ao esfíncter. Os resultados demonstram a importância de incluir as estruturas definidas em futuros modelos computacionais.

Este modelo foi posteriormente utilizado para simular um parto assistido por ventosa, um procedimento obstétrico comum, mas que ainda levanta questões na comunidade médica. Os resultados indicaram que as regiões musculares afetadas neste tipo de parto são semelhantes às de um parto vaginal. Além disso, foi demonstrado que contrações de maior duração e tempos de repouso mais longos facilitam a recuperação dos músculos do pavimento pélvico, enquanto a extração do feto com menor número de puxadas da ventosa leva a tensões mais elevadas nos músculos e à necessidade de o obstetra aplicar

maior força durante a extração. Esta análise poderá permitir desenvolver indicações clínicas específicas de uma perspectiva biomecânica.

De forma a obter resultados mais rápidos através das simulações numéricas, as quais geralmente têm um elevado custo computacional, foi implementada uma abordagem de aprendizagem computacional baseada em elementos finitos. Foi criado um conjunto de dados com informações obtidas a partir de milhares de simulações do parto vaginal, cujas diferenças estão nas propriedades mecânicas utilizadas para caracterizar os músculos do pavimento pélvico. Foram também treinados diferentes modelos para prever as tensões nos músculos durante o parto. Esta abordagem culminou em resultados promissores, com as redes neurais artificiais a obterem melhores resultados do que os modelos baseados em árvores na previsão das tensões no pavimento pélvico. Tendo em conta esta abordagem inicial, foi posteriormente implementado um modelo surrogado específico para o paciente, utilizando um algoritmo de transformação da malha para ajustar a geometria do pavimento pélvico, permitindo incluir as dimensões de um grande conjunto de mulheres. O modelo de floresta aleatória obteve a melhor performance na previsão das coordenadas de nós específicos do pavimento pélvico, com um erro absoluto médio de 0.086 mm. O modelo permite obter resultados em menos de 11 segundos, sendo significativamente mais rápido do que as abordagens tradicionais, e representando um tempo de espera aceitável para a prática clínica. A viabilidade de implementar esta abordagem em ambiente clínico foi também avaliada, incluindo o desenvolvimento de uma metodologia e a identificação dos principais requisitos para uma integração bem-sucedida.

O desenvolvimento de simulações de elementos finitos fidedignas depende não só de técnicas de modelação avançadas, mas também de propriedades mecânicas precisas, nomeadamente de tecidos moles, como o períneo. Para refinar estas simulações, ensaios mecânicos realizados em tecidos de cadáveres de mulheres permitiram obter um maior detalhe sobre o comportamento mecânico do períneo. O corpo do períneo demonstrou propriedades não lineares hiperelásticas e viscosas, com uma relaxação das tensões de aproximadamente 40%. A análise histológica revelou que o corpo do períneo apresenta uma densa rede de fibras de colagénio, preferencialmente alinhadas com a direção do alongamento. Os dados experimentais foram utilizados para calibrar os parâmetros constitutivos de um modelo visco-hiperelástico, tendo sido obtida uma boa correlação entre os resultados numéricos e experimentais. Estes parâmetros podem ser futuramente utilizados para melhorar a caracterização dos tecidos nos modelos de elementos finitos, facilitando a simulação de processos fisiológicos que envolvem o períneo.

Em suma, esta tese apresenta uma abordagem multidisciplinar que combina modelação computacional, inteligência artificial e ensaios mecânicos, com o objetivo de melhorar o conhecimento atual na área da biomecânica do parto. Os resultados obtidos oferecem novos detalhes que poderão ajudar na investigação futura, visando melhorar a saúde materna e informar os obstetras na prática clínica.

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List of Figures

1.1	Anatomical planes of reference and directional terms in human anatomy.	4
1.2	Anatomical representation of the pelvic diaphragm, including the pelvic floor muscles.	5
1.3	Anatomical representation of the perineal region.	7
1.4	Cardinal movements of labor. (a) Before engagement. (b) Engagement, flexion, descent. (c) Descent, rotation. (d) Complete rotation, early extension. (e) Complete extension. (f) Restitution (external rotation). (g) Anterior shoulder delivery. (h) Posterior should delivery.	9
1.5	Different levels of perineal tears. 1 – First-degree perineal laceration, involving only the vaginal epithelium of perineal skin. 2 – Second-degree laceration extending to the perineal muscles (bulbospongiosus and superficial transverse perineal muscles). 3A – Third-degree laceration including less than 50% of the external anal sphincter. 3B – Third-degree laceration including more than 50% of the external anal sphincter. 3C – Third-degree laceration including the external and internal anal sphincters. 4 – Fourth-degree laceration affecting the perineal body, entire anal sphincter complex, and anorectal mucosa.	12
1.6	Pipeline for the implementation of a FEM-based ML approach.	30
2.1	Anatomy of the bony pelvis, pelvic floor and perineum.	54
2.2	Geometric model of the PFM (coccygeus, iliococcygeus, pubococcygeus and puborectalis muscle) and perineum (perineal body, external anal sphincter, ischiocavernosus, bulbospongiosus, superficial transverse and deep transverse perineal muscles). The urogenital hiatus consists of the space through which the urethra and the vagina pass. The left figure corresponds to a superior view of the female pelvis and the right figure to an inferior view.	56

2.3	Boundary conditions and paths defined on the FE mesh. The light blue lines represent the fixed nodes. The red lines demonstrate the different paths established to calculate the stretch and measure the maximum principal stress on the distinct structures. (a) Path 1, 2 and 3. Path 1 corresponds to the levator hiatus. (b) Urogenital hiatus represented by Path 4. Inferior view of the perineal body, Path 5 and 6. (c) Superior view of the perineal body, Path 7.	60
2.4	Evolution of the fetal head in relation to the PFM from the initial position (0 mm of fetal descent).	61
2.5	Stretch of the PFM in Path 1 (simulations 1 and 2) and urogenital hiatus in Path 4 (simulation 2) during the vertical displacement of the fetal head.	62
2.6	Maximum principal stress (in MPa) measured on the paths defined on the PFM (Path 1, 2 and 3), for simulations 1 and 2.	63
2.7	Maximum principal stress distribution (in MPa) observed in the most affected region of the PFM for (a) simulation 1, without the perineum, and (b) simulation 2, with the perineum. In simulation 2, the vertical displacement (in the y-axis direction) of the PFM is nearly 10 mm greater than in simulation 1.	64
2.8	Maximum principal stress (in kPa) measured on the path defined on the urogenital hiatus (Path 4). The position of the fetal head at the instance of maximum stretch (approximately 84 mm) for simulation 2 is presented.	65
2.9	Stretch and maximum principal stress (in kPa) measured in different paths of the perineal body along the vertical displacement of the fetal head. In the stretch representation, Path 6 and 7 overlap since the stretch is equal for both cases.	66
2.10	Transverse and anteroposterior diameters of the external anal sphincter during the vertical displacement of the fetal head.	67

3.1	Geometric model of the PFM, in red, and perineum. The perineal body is presented in gray, the external anal sphincter in brown, the ischiocavernosus and bulbospongiosus muscles in dark red, the superficial transverse perineal muscle in blue, and deep transverse perineal muscles in pink. The blue lines correspond to two paths defined on the levator hiatus, path 1, and the urogenital hiatus, path 2 (the space through which the urethra and the vagina pass). The dark brown line corresponds to the fixed nodes of the PFM, while the yellow line corresponds to the constrained nodes of the ischiocavernosus and superficial transverse perineal muscles. The left figure corresponds to a superior view of the female pelvis and the right figure to an inferior view.	81
3.2	Representation of the FE model of the fetal head and vacuum cup. The vacuum cup is positioned at the flexion point of the fetal head, showing the distances to the anterior and posterior fontanelles. The black arrow at the tip of the vacuum cup indicates the direction of the imposed displacement.	82
3.3	Dynamics of the VAD simulation. Lateral and anterior views of the fetal head descent corresponding to the vertical displacement of the vacuum cup from 0 to 100 mm.	84
3.4	Force-deflection curve obtained from the anteroposterior compression test for the fetal head FE model, compared to the experimental curves by Loyd (2011).	88
3.5	Stretch of the levator hiatus (PFM) and urogenital hiatus (perineum) during the vertical displacement of the vacuum cup.	89
3.6	Maximum principal stress (in kPa) along the vertical displacement on the vacuum cup measured on Path 2. The results include the FE model of the perineum for vertical displacements of 37.5 mm and 82.5 mm, highlighting the stress distribution and identifying the most critical regions.	90
3.7	Time evolution of the maximum principal stress in the fetal head (left axis) and the vertical displacement of the vacuum cup (right axis) during the simulated VAD. The shaded blue areas indicate resting phases, while the white areas represent pulling phases.	91

3.8	Maximum principal stress (in MPa) along the vertical displacement of the vacuum cup measured on the PFM path for the different cases under study. The vertical dashed line indicates the displacement at which the resting stage is defined.	92
3.9	Maximum principal stress (in MPa) along the vertical displacement on the vacuum cup considering the fetal extraction with two, three and four pulls.	93
3.10	Force (in N) applied on the vacuum cup to extract the fetal head along its vertical displacement through the birth canal with two, three and four pulls.	94
4.1	(a) Geometric model of the PFM (coccygeus, iliococcygeus, pubococcygeus and puborectalis muscle) and pelvic bones. The blue line represents the fixed nodes of the PFM. (b) FE mesh of the PFM. Identification of path used for stress analysis.	113
4.2	Maximum principal stress range for all simulations performed at 20, 35, 50 and 65 mm of fetal descent. The bold line represents the mean, and the shaded area the minimum and maximum values.	117
4.3	Pipeline describing all steps performed from data generation to model evaluation.	118
4.4	Hyperparameter sensitivity analysis for the ANN model.	121
4.5	Box plot demonstrating the mean absolute error for each region of the PFM path. The distinct regions are represented in the left upper corner.	125
4.6	Box plot presenting the predicted and true values for each node of the test set simulations (ANN model).	125
4.7	Maximum principal stress (MPa) distribution in a FE simulation of childbirth, considering 50 mm of fetal descent.	126
4.8	Box plot demonstrating the mean absolute error for each region of the PFM path at four different levels of fetal descent.	128
4.9	Mean predicted and true values for each node of the test set simulations for 50 mm of fetal descent (ANN model).	129
5.1	Pipeline for implementing an AI framework in a clinical setting.	149

5.2	FE model used to simulate vaginal delivery. (a) PFM with the fixed nodes represented in blue and the path defined to retrieve results shown in black. (b) Fetal head in the vertex presentation and occipito-anterior position.	150
5.3	Example of distinct types of mesh morphing. Representation of the transverse diameter (1) and the anteroposterior diameter (2) of the levator hiatus. The fixed nodes selected to perform the morphing operation are represented by crosses. A - Transverse diameter adjustment. B - Adjustment of the anteroposterior diameter. C - Adjustment of both transverse and anteroposterior diameters.	152
5.4	(a) Range of target variables x, y, and z for all simulations. (b) Variation of the target variable y for each time step for all simulations.	156
5.5	MRI in the axial plane showing the levator hiatus of the LAM highlighted in green, the anteroposterior diameter in blue, the transverse diameter in orange, and the circumference of the levator hiatus excluding the attachment to the pubic symphysis in red.	160
5.6	Evolution of the mean absolute error (MAE) across varying percentages of data for the ML models under analysis.	162
5.7	Box plot demonstrating the (a) MAE for each time step and (b) MAE for each coordinate and time step of fetal descent.	163
5.8	(a) Box plot demonstrating the MAE for each region of the PFM path. The distinct regions are represented in the left upper corner. (b) Distribution of the error.	164
5.9	Three-dimensional reconstruction of a FE simulation: representation of predicted nodal coordinates (on the left) and true nodal coordinates (on the right) for all nodes along the path across 21 time steps.	164
5.10	Box plot presenting stretch MAE for each time step of the fetal descent.	165
5.11	Stretch evolution over time for subjects A, B and C.	167

6.1	Diagram presenting the four main steps of the applied methodology. 1 – Excise perineal sample, collect and freeze. 2 – Slide samples and create dog-bone shape specimens. 3 – Specimen clamping and insertion into the test machine. 4 – Run genetic algorithm, calibrate parameters and fit experimental curve.	186
6.2	Sample preparation steps: The initial perineal sample (1) was cut and inserted into the cryostat machine (2) to produce sections that were placed on microscope slides (3).	187
6.3	(a) Representation of the perineal specimen dimensions and its integration into the testing system, including the 3D-printed clamps, holders arms, and the specimen with black markers. (b) Specimen positioned in the 3D-printed clamps and machine grips, immersed in PBS bath, prepared for testing.	189
6.4	Displacement-controlled profile for the cyclic loading and relaxation test protocol.	190
6.5	Finite element model used for simulating experimental tests, integrated with a genetic algorithm for calibrating the constitutive model parameters. The finite element model consists of a eighth-symmetry of the specimen. (a) Full specimen mesh. (b) Eighth-model with symmetry planes. (c) Applied boundary conditions and direction of the applied stretch.	193
6.6	Representative cyclic loading and unloading response of the tissue prior to the relaxation tests, illustrating the evolution of Cauchy stress across repeated cycles. The pink line represents a spline interpolation fitted to the peak stress values of each cycle.	196
6.7	Average response of the relaxation tests: (a) Cauchy Stress (kPa) and (b) Normalized Stress (current stress/peak stress) of all the experiments (dashed lines).	197
6.8	Average Cauchy stress-stretch curve from the ultimate tensile tests. Averaged response: mean $\pm$ SD (standard deviation).	198

6.9	(a) Representative histological section stained with Sirius Red. (b) Post-processed histological section of perineal specimens at 20x magnification. Blue and green tones represent fibers oriented in the horizontal direction, while red tones represent fibers oriented in the vertical direction. (c) Polar histogram of the collagen fibers. Radial distance represents fiber density, while the angle, in degrees, indicates fiber orientation. Shaded bars show the distribution of fiber densities across directions.	199
6.10	Calibration of the constitutive model parameters using experimental data. (a) Fitting to the minimum, mean, and maximum stress-relaxation test curves. (b) Fitting of the minimum, mean and ultimate tensile test curves.	201

List of Tables

2.1	Material parameters used to characterize the pelvic floor and perineal muscles.	58
2.2	Comparison of the mechanical characterization of the pelvic floor and perineal muscles across distinct studies.	59
3.1	Material parameters used to characterize the pelvic floor and perineal muscles.	87
4.1	Dataset example including features and target for two different simulations.	116
4.2	Grid search hyperparameter values for each algorithm.	120
4.3	Optimal hyperparameter values selected for each algorithm.	123
4.4	MSE and MAE calculated for the ML models used.	124
4.5	MSE, MAE, NMSE and NMAE calculated for each fetal descent instant for the different selected models.	127
4.6	Measurement of the time required to predict stress values and load each model for the two cases, including also the total time needed (model load with prediction).	130
5.1	Dataset example including features and target for two different simulations.	157
5.2	Grid search hyperparameter values for each algorithm.	158
5.3	Optimal hyperparameter values selected for each algorithm.	161
5.4	Performance metrics for each ML model selected.	163

5.5	Measurement of the time required to make predictions and load the ML model.	166
5.6	Measurements of the anteroposterior (AP) and transverse (T) diameters of the levator hiatus, as well as the circumference of the hiatus, obtained from MRI.	166
6.1	Constitutive parameters obtained from the genetic algorithm optimization.	201

Nomenclature

Acronyms

AI	Artificial Intelligence
ANN	Artificial Neural Network
DIC	Digital Image Correlation
DM	Dummy Regressor
FE	Finite Element
FEM	Finite Element Method
FN	Fixed Nodes
HGO	Holzapfel-Gasser-Ogden
LAM	Levator Ani Muscles
MAE	Mean Absolute Error
MAPE	Mean Absolute Percentage Error
ML	Machine Learning
MN	Moving Nodes
MRI	Magnetic Resonance Images
MSE	Mean Squared Error
NMAE	Normalized Mean Absolute Error
NMSE	Normalized Mean Squared Error
OASIS	Obstetric Anal Sphincter Injuries
PBS	Phosphate-buffered Saline
PFM	Pelvic Floor Muscles

PINNs	Physics-informed Neural Networks
RF	Random Forest
SDG	Sustainable Development Goals
SVR	Support Vector Regression
TD	Target Distances
TPS	Thin Plate Spline
VAD	Vacuum-Assisted Delivery
WHO	World Health Organization
XGBT	Extreme Gradient Boosting

Symbols

$(\nabla)^\infty$	∇ at $t \rightarrow \infty$ responsible for the thermodynamic equilibrium state
$(\nabla)_f$	Fiber contribution of ∇
$(\nabla)_{iso}$	Isochoric contribution of ∇
$(\nabla)_m$	Ground matrix contribution of ∇
$(\nabla)_{vis}$	Viscous contribution of ∇
$(\nabla)_{vol}$	Volumetric contribution of ∇
α	Number of parallel elements in the Maxwell model
β_α	Free-energy viscous parameter
χ	Motion
$\mathbf{\Gamma}_\alpha$	Internal variables that characterize the non-equilibrium state of the deformation
σ	Cauchy stress tensor
$\hat{y}$	Predicted values
κ	Bulk modulus
$\mathbb{c}$	Spatial elasticity tensor
$\mathbb{C}$	Material elasticity tensor
$\mathbb{I}$	Fourth-order identity tensor
$\mathbb{P}$	Fourth-order projection tensor

$\mathcal{D}_{\text{int}}$	Internal dissipation
ν	Poisson ratio
Ω	Region at the current configuration
Ω_0	Region at the reference configuration
$\bar{\lambda}$	Fiber stretch
$\bar{I}_1$	Modified first invariant of the right Cauchy-Green strain tensor
$\bar{I}_2$	Modified second invariant of the right Cauchy-Green strain tensor
$\bar{I}_3$	Modified third invariant of the right Cauchy-Green strain tensor
$\bar{I}_4$	Modified fourth invariant of the right Cauchy-Green strain tensor
$\bar{I}_5$	Modified fifth invariant of the right Cauchy-Green strain tensor
Ψ	Strain-energy density function
τ_α	Relaxation time viscous parameter
:	Tensor contraction
$\mathbf{A}_0$	Second-order structural tensor
$\mathbf{a}_0$	Fiber direction in the reference configuration
$\mathbf{C}$	Right Cauchy-Green deformation tensor
$\mathbf{F}$	Deformation gradient tensor
$\mathbf{I}$	Identity tensor
$\mathbf{P}$	First Piola-Kirchhoff stress tensor
$\mathbf{S}$	Second Piola-Kirchhoff stress tensor
$\mathbf{X}$	Position vector at the reference configuration
$\mathbf{x}$	Position vector at the current configuration
θ	Level of activation of the muscles
Y_α	Configurational free-energy of the viscoelastic solid
A	Material constant of the Martins constitutive model
a	Material constant of the Martins constitutive model
B	Continuum body
b	Material constant of the Martins constitutive model

c	Material constant of the Martins constitutive model
c_{10}	Material constant of the Holzapfel-Gasser-Ogden constitutive model
D	Constitutive parameter associated with the volumetric contribution
E	Young modulus
F_e	Least squares evaluation function
J	Jacobian
k_1	Material constant of the Holzapfel-Gasser-Ogden constitutive model
k_2	Material constant of the Holzapfel-Gasser-Ogden constitutive model
N	Number of data points
P	Arbitrary point
P_i^e	Cauchy stress in the direction of the applied stretch from the experimental data
P_i^Ψ	Cauchy stress in the direction of the applied stretch from the numerical simulation
t	Time coordinate
T_0^M	Maximum muscle tension produced by the muscle at resting length
y	True values
$\bar{\mathbf{C}}$	Distortional component of the right Cauchy-Green strain tensor
$\bar{\mathbf{F}}$	Distortional component of the deformation gradient
$\otimes$	Tensor product
$\mathbf{Q}_\alpha$	Isochoric non-equilibrium stress tensor arising from viscous effects

Part I

Motivation

Chapter 1

Introduction

This chapter introduces the fundamental concepts of childbirth biomechanics. It begins with an anatomical overview of the female pelvis, highlighting its role during labor and delivery. This is followed by a brief description of the mechanisms of vaginal delivery. The discussion then addresses the prevalence and types of childbirth-related injuries, emphasizing their clinical relevance. An overview of existing research in computational childbirth biomechanics is provided, with particular focus on finite element modeling, mechanical behavior, and the experimental characterization of maternal tissues. Finally, the chapter explores the integration of machine learning techniques to enhance simulation efficiency and support clinical decision-making.

1.1 Anatomy of the female pelvis

The pelvis consists of the pelvic bones and interacts with the terminal parts of the vertebral column. The region of the pelvis below the level of the pelvic brim is the lesser (or true) pelvis and the part above the pelvic brim is the greater (or false) pelvis. The lesser pelvis encloses the pelvic cavity while the greater pelvis forms the lower part of the abdominal cavity and includes the right and left iliac fossae. The bowl-shaped pelvic cavity enclosed by the lesser pelvis consists of the pelvic inlet, walls, and floor. The perineum lies inferior to the floor of the pelvic cavity and forms the boundaries of the pelvic outlet. The size and shape of the pelvis can vary significantly among individuals, particularly in women, where differences in pelvic dimensions can influence factors such as childbirth [1].

Given the frequent use of anatomical terminology throughout this thesis, Figure 1.1 illustrates the standard human anatomical planes and directional terms for reference.

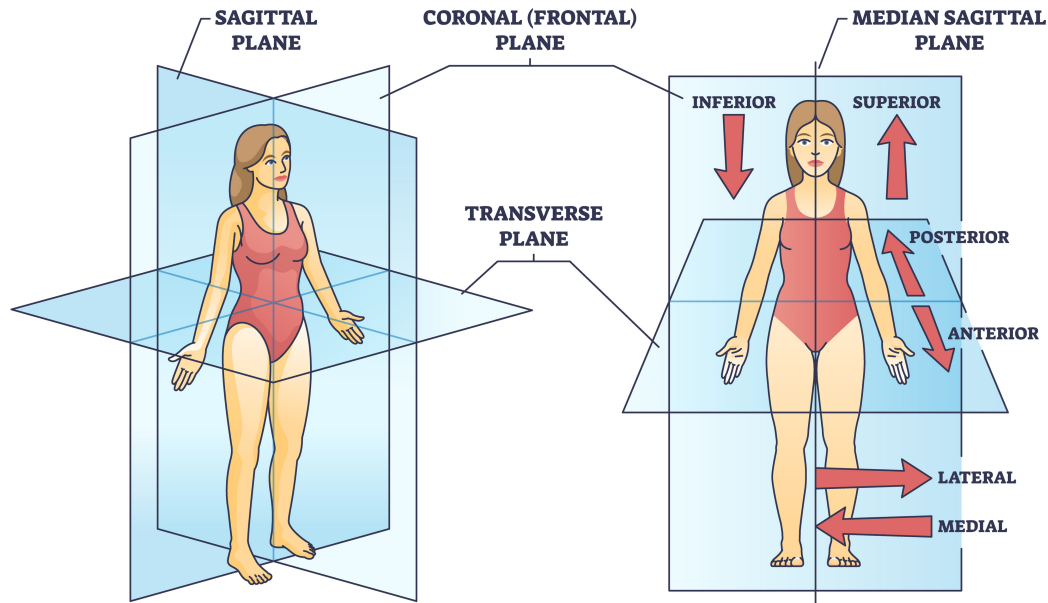


Figure 1.1: Anatomical planes of reference and directional terms in human anatomy.

1.1.1 Pelvic floor

The pelvic floor is formed by muscles and fascia, separating the pelvic cavity above from the perineum below. It consists of the pelvic diaphragm and, in the anterior midline, the perineal membrane along with the muscles in the deep perineal pouch. The pelvic diaphragm, the muscular component of the pelvic floor, also designated as pelvic floor muscles (PFM), is funnel-shaped and formed by the levator ani muscles (LAM) and the coccygeus muscles.

The LAM attaches to the pelvic wall and converges at the midline through connective tissue. Anteriorly, the muscles are separated by a U-shaped defect called the urogenital hiatus, which allows the urethra and vagina to pass through the pelvic diaphragm. The LAM can be subdivided into three main groups:

- **Pubococcygeus muscles** – originates from the body of the pubis and extends posteriorly to attach along the midline, reaching as far as the coccyx.
- **Puborectalis muscles** – a portion of the levator ani that originates from the pubis and descends on each side to form a sling around the terminal part of the gastrointestinal tract.
- **Illiococcygeus muscles** – the posterolateral part of the LAM, which joins the same muscle on the opposite side at the midline to form a ligament extending from the anal aperture to the coccyx.

The coccygeus muscles are triangular and complete the posterior part of the pelvic diaphragm. They are attached to the tips of the ischial spines and the lateral margins of the coccyx and sacrum [1]. A representation of the anatomy of the pelvic diaphragm is presented in Figure 1.2.

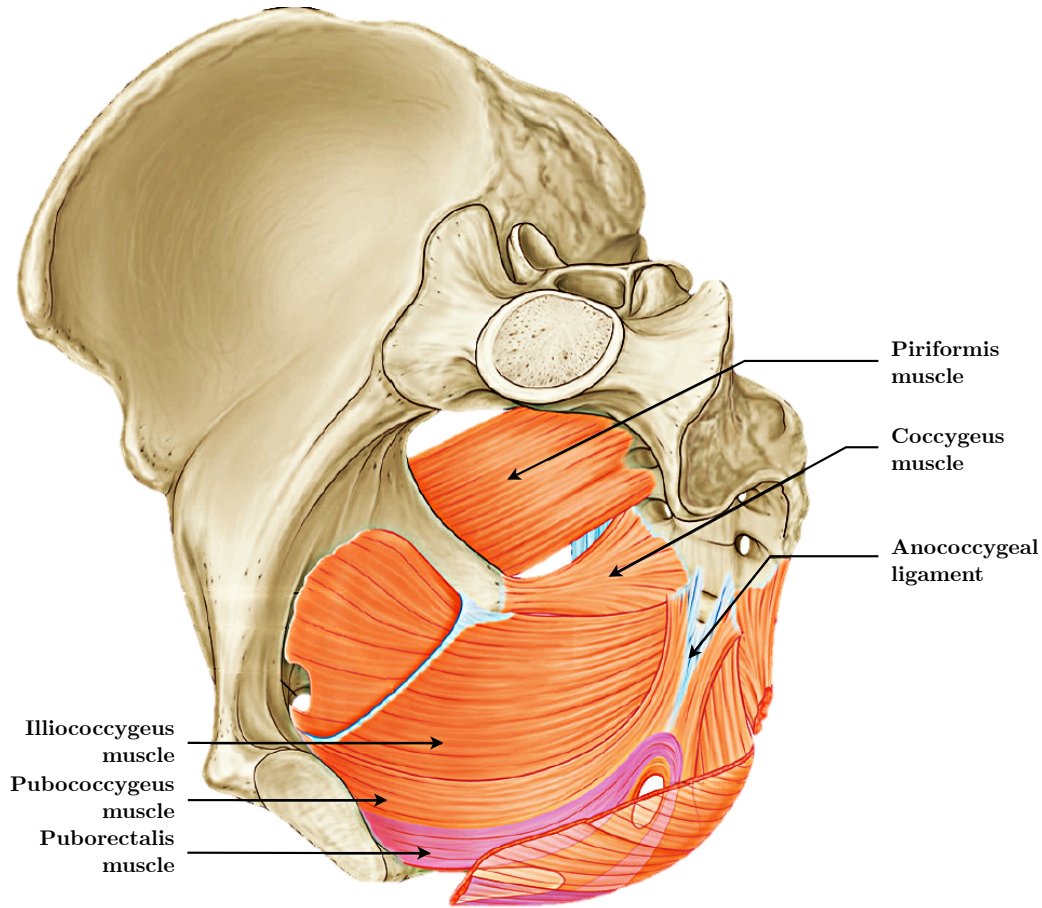


Figure 1.2: Anatomical representation of the pelvic diaphragm, including the PFM (adapted from [1]).

The female pelvic floor plays a critical role in maintaining continence and supporting pelvic organs, especially during activities that involve increased intra-abdominal pressure, such as coughing, lifting, or physical exercise. It must provide this essential support while also exhibiting sufficient flexibility to accommodate physiological processes like childbirth. Among the PFM, the LAM is particularly relevant, acting as a key structural and functional component. During labor, the LAM undergoes substantial stretching and mechanical stress to allow the passage of the fetus. However, this process places the muscle at risk of sustaining injuries, many of which are non-visible and challenging to diagnose, leading to long-term consequences. A detailed discussion of these childbirth-related injuries will be provided in Section 1.3.

1.1.2 Perineum

The perineum is a diamond-shaped region located inferior to the pelvic floor. Its margins are defined by the inferior border of the pubic symphysis at the anterior point, the tip of the coccyx at the posterior point, and the ischial tuberosities at the lateral points. The roof of the perineum is formed by the LAM, which separate the pelvic cavity from the perineum.

The perineum is divided into two regions: the urogenital triangle, associated with the openings of the urinary and reproductive systems, and the anal triangle, which contains the anus and the external anal sphincter. These triangles are defined by an imaginary line connecting the two ischial tuberosities. The urogenital triangle lies anterior to this line, while the anal triangle is posterior.

The urogenital triangle is filled by a thick fibrous sheet designated as perineal membrane. This structure has a free posterior border anchored at the midline to the perineal body and is laterally attached to the pubic arch. The deep perineal pouch lies adjacent to the perineal membrane and contains a layer of skeletal muscle along with neurovascular structures. Together, the perineal membrane and deep perineal pouch contribute to the pelvic floor and provide structural support for elements of the urogenital system within the pelvic cavity.

Anteriorly, in the urogenital triangle, a U-shaped defect in the muscles, known as the urogenital hiatus, allows the passage of the urethra and vagina. The size of the urogenital hiatus can vary significantly among women, and its dimensions are typically characterized by the urogenital area, the anteroposterior diameter, and the transverse diameter.

The superficial perineal pouch, located between the perineal membrane and the membranous layer of the superficial fascia, contains three pairs of muscles: the ischiocavernosus, bulbospongiosus, and superficial transverse perineal muscles.

- **Ischiocavernosus muscles** – anchored to the medial margin of the ischial tuberosity and related ischial ramus and passes forward to attach to the sides and inferior surface of the related crus (the crus are two erectile tissue structures).
- **Bulbospongiosus muscles** – anchored posteriorly to the perineal body and course anterolaterally over the inferior surface of the related greater vestibular gland and the bulb of the vestibule to attach to the surface of the bulb and to the perineal membrane.
- **Superficial transverse perineal muscles** – these muscles follow a course parallel to the posterior margin of the inferior surface of the perineal membrane.

The superficial transverse perineal muscles attach to the ischial tuberosities and extend medially to the perineal body in the midline, stabilizing it.

The perineal body is an important connective tissue structure that serves as an attachment point for the PFM and the perineum. It is located in the midline, along the posterior border of the perineal membrane, to which it is also attached. The posterior end of the urogenital hiatus in the LAM is connected to it. The deep transverse perineal muscles, external anal sphincter, superficial transverse perineal muscles, and bulbospongiosus muscles of the perineum also connect to the perineal body [1]. Figure 1.3 demonstrates the anatomy of the perineal region.

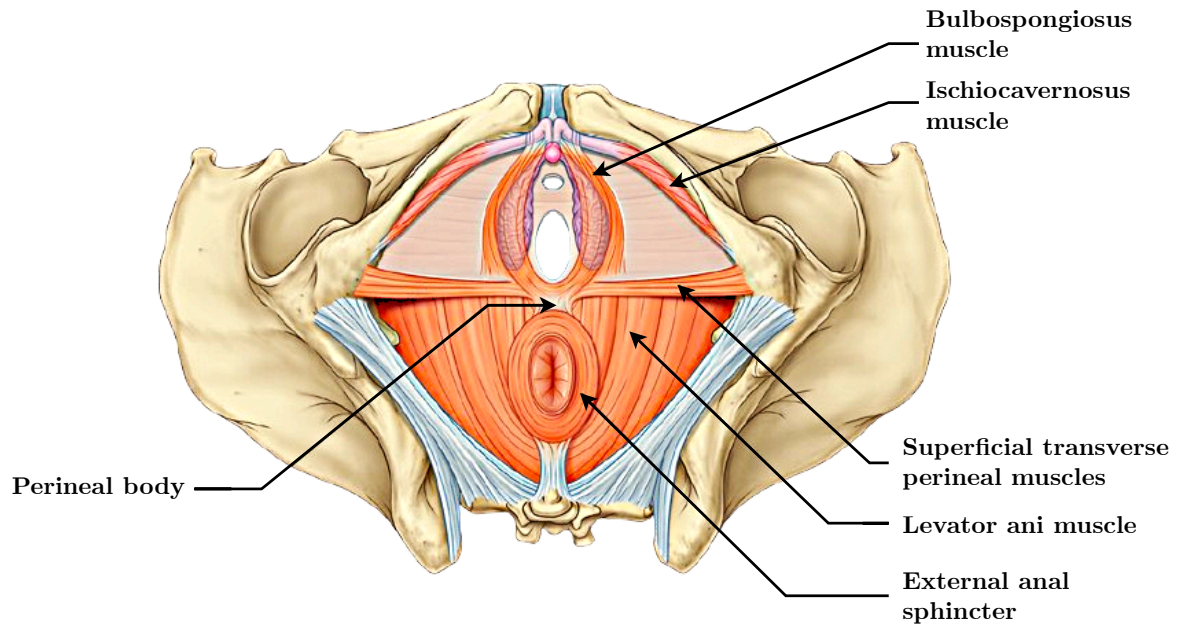


Figure 1.3: Anatomical representation of the perineal region (adapted from [1]).

During vaginal delivery, the perineum undergoes significant stretching to facilitate the passage of the fetus, making it highly susceptible to trauma. Perineal injuries, which may include tears and lacerations, are common and can range from minor to severe. These injuries may result in chronic perineal pain and contribute to pelvic floor dysfunction over the long term. The clinical implications of perineal trauma sustained during childbirth will be further discussed in Section 1.3.

1.2 Description of labor and delivery

1.2.1 Stages of labor

Labor is defined as the process by which the fetus is expelled from the uterus [2]. It begins with regular uterine contractions with effect on the cervix in form of cervical

dilatation and softening, and ends with the delivery of the newborn and the expulsion of the placenta. Clinically, labor is divided into three principal stages. The first stage, also called the stage of cervical effacement and dilation, begins with spaced uterine contractions and ends when the cervix is fully dilated (approximately 10 cm). The second stage, or stage of fetal expulsion, occurs after complete cervical dilation and ends with the delivery of the newborn. Lastly, the third stage, also known as the stage of placental separation and expulsion, involves the delivery of the placenta [3].

The second stage of labor is characterized as the phase that culminates in fetal delivery. During this stage, the mother experiences abdominal pressure and uterine contractions, which facilitate the expulsion of the fetus. The progress of labor is assessed by evaluating the presenting part. This involves measuring the relationship between the leading edge of the presenting fetal part and the level of the maternal ischial spines. The position of the presenting part relative to the plane of the ischial spines determines the fetal station [4]. When the bony portion of the fetal head or the breech aligns with the level of the ischial spines, the station is designated as “0”.

Although the duration may vary depending on factors such as the mother’s pushing efforts and uterine contractions, the second stage of labor lasts in average from 30 minutes to 3 hours in primigravid women and from 15 minutes to 2 hours in multigravid women. The median duration is 50 minutes in primiparous women and 20 minutes in multiparous women [5]. Epidural use increases the mean duration by 20 to 30 minutes. In nulliparous women, a prolonged second stage of labor is widely diagnosed when it exceeds 3 hours with regional anesthesia or 2 hours without regional anesthesia [6]. Conversely, the second stage is considered precipitous if it lasts less than 30 minutes [7].

1.2.2 Mechanisms of labor

The cardinal movements of labor describe the change in position of the fetal head while passing through the birth canal (Figure 1.4). This process can be divided into seven steps: engagement, descent, flexion, internal rotation, extension, external rotation or restitution, and expulsion [2]. During labor, these movements show temporal overlap. For example, during the engagement, there is both flexion and descent of the head simultaneously. Uterine contractions are also important, especially after the head has descended into the pelvis [3].

Engagement refers to the passage of the widest diameter of the presenting part of the fetus below the plane of the pelvic inlet. In a cephalic presentation with a well-flexed fetal head, this diameter corresponds to the biparietal diameter. Engagement is a key clinical milestone, as it indicates that the maternal pelvis is sufficiently large to allow the fetal head to pass through the narrowest part of the pelvis. Descent

follows as the fetus moves through the pelvic inlet towards the pelvic floor, driven by forces such as amniotic fluid pressure, uterine contractions, maternal abdominal effort, and fetal body extension. Flexion of the fetal head occurs due to the resistance of pelvic tissues, allowing the smallest suboccipitobregmatic diameter to present. Internal rotation then reorients the head to the anteroposterior position, facilitating further descent. The base of the occiput contacts the pubic symphysis, and the head is delivered through extension, followed by external rotation to align with the shoulders. Expulsion completes the process as the shoulders and body are fully delivered [2, 3].

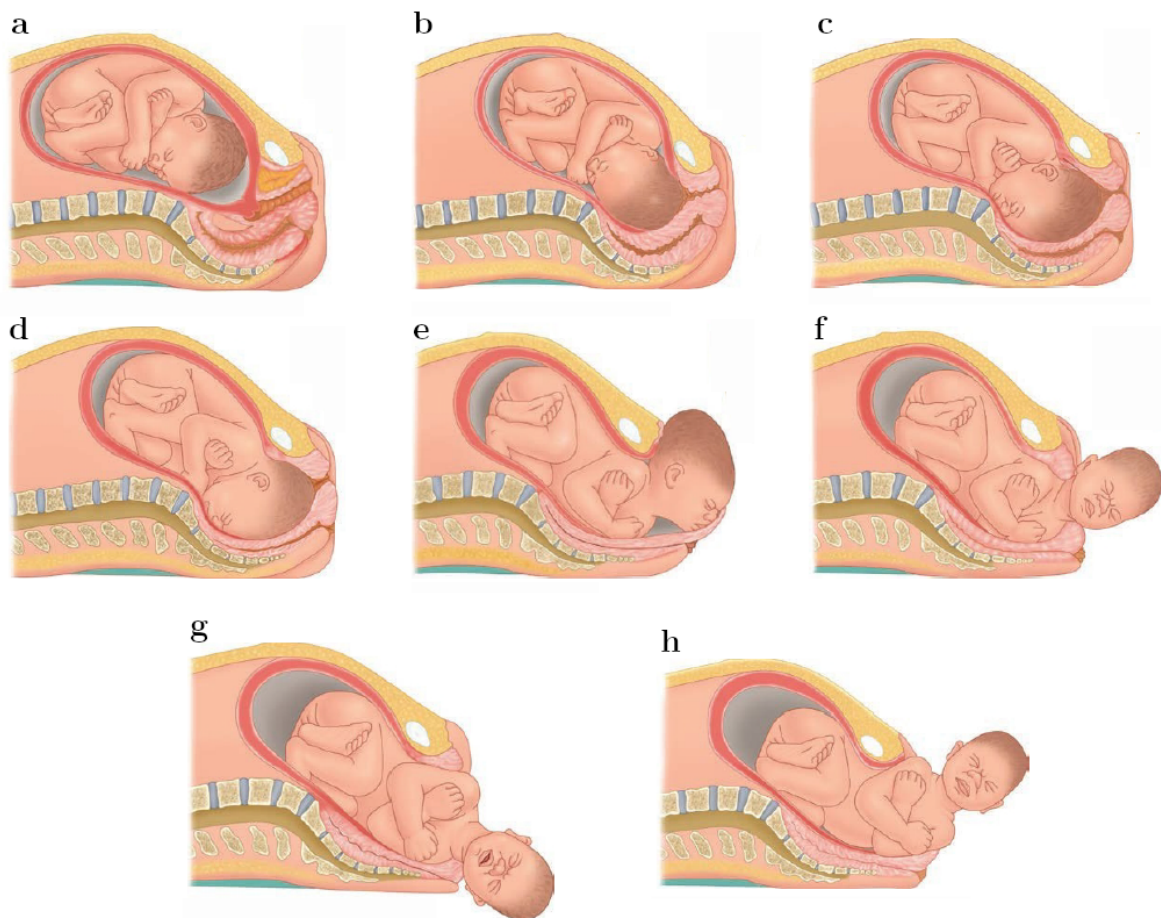


Figure 1.4: Cardinal movements of labor (adapted from [3]). (a) Before engagement. (b) Engagement, flexion, descent. (c) Descent, rotation. (d) Complete rotation, early extension. (e) Complete extension. (f) Restitution (external rotation). (g) Anterior shoulder delivery. (h) Posterior shoulder delivery.

The diameters of the pelvis play a crucial role in determining the success of vaginal delivery and can vary significantly among women. These measurements are taken at the pelvic inlet, midpelvis, and outlet, helping predict potential delivery outcomes. The pelvic inlet is characterized by the anteroposterior, transverse, and two oblique diameters. The midpelvis, also known as the midplane or the plane of least pelvic dimensions, is measured at the level of the ischial spines. At this level, the interspinous

diameter, which represents the narrowest pelvic dimension, is particularly important as its size is a critical factor in cases of obstructed labor [3].

Understanding the normal stages and mechanisms of labor is crucial, as deviations from this process can have significant clinical implications. Prolonged labor, malpresentation, or malposition of the fetus can interfere with the natural progression of childbirth, leading to increased maternal distress. These abnormalities increase the risk of maternal injuries, such as perineal tears, pelvic floor trauma, and uterine rupture. Furthermore, they may also require medical interventions, such as instrumental delivery or cesarean section, which carry additional risks and recovery challenges. Early recognition and management of these variations is essential to minimize maternal morbidity and ensure safe delivery outcomes.

1.3 Childbirth-related injuries

According to the World Health Organization (WHO), every day in 2020, approximately 800 women died from preventable causes related to pregnancy and childbirth, meaning that a woman dies around every two minutes [8]. The Sustainable Development Goals (SDG) place a strong emphasis not only on reducing maternal mortality, but also on improving maternal health outcomes beyond survival. Maternal mortality remains a predominantly regional issue, with the highest rates occurring in low- and middle-income countries. In addition to mortality, maternal morbidity poses a significant challenge. The WHO estimates that around 15% of all pregnant women will experience long-term complications requiring specialized care [9].

Childbirth is a traumatic event that can lead to long-term consequences as urinary or fecal incontinence, and pelvic organ prolapse, significantly decreasing women's quality of life [10]. Clinical and epidemiological findings indicate that women who undergo vaginal delivery are at an increased risk of developing pelvic floor disorders [11].

There are different types of lesions that can occur, including injuries at the perineum level. Studies indicate that the incidence of perineal trauma can be over 90% in women who deliver vaginally [12]. Perineal tears are classified from first to fourth degree, depending on the anatomical structures involved in the tissue damage. The most common perineal injury reported is a second-degree tear. Third- and fourth-degree tears, commonly designated as obstetric anal sphincter injuries (OASIS), affect a significant proportion of postpartum women (ranging from 1% to 11% [13]), and are associated with increased rates of both immediate and long-term morbidity [14]. The different levels of perineal tears are demonstrated in Figure 1.5 and can be classified as [15]:

- **First degree** – involve the fourchette (small fold of tissue that secures the labia minora), perineal skin, and vaginal mucous membrane, but not the underlying fascia and muscle. These include periurethral lacerations, which may bleed profusely.
- **Second degree** – injury to perineum involving perineal muscles but not involving the anal sphincter. These tears may be midline, but often extend upward on one or both sides of the vagina, forming an irregular triangle.
- **Third degree** – injury to the perineum involving the external anal sphincter. It can be divided into three levels.
 - A: Less than 50% of the external anal sphincter is torn.
 - B: More than 50% of the external anal sphincter is torn, with the internal anal sphincter remaining intact.
 - C: Both the external and internal anal sphincters are torn.
- **Fourth degree** – injury to the perineum involving the anal sphincter complex (external and/or internal). Extend completely through the rectal mucosa to expose its lumen and involves disruption of both sphincters.

In addition to perineal injury, another type of lesion that may occur is pelvic floor trauma, typically involving damage to the LAM. Childbirth is particularly challenging for the pelvic floor due to the passage of the fetal head [10]. The LAM plays a major role in this process since it is the most substantial soft tissue structure [16]. At rest, the LAM keeps the urogenital hiatus closed and maintains the pelvic floor and pelvic organs in the correct orientation. The puborectalis bundle is of particular functional importance since it is involved in the continence mechanisms and contributes to maintain balance.

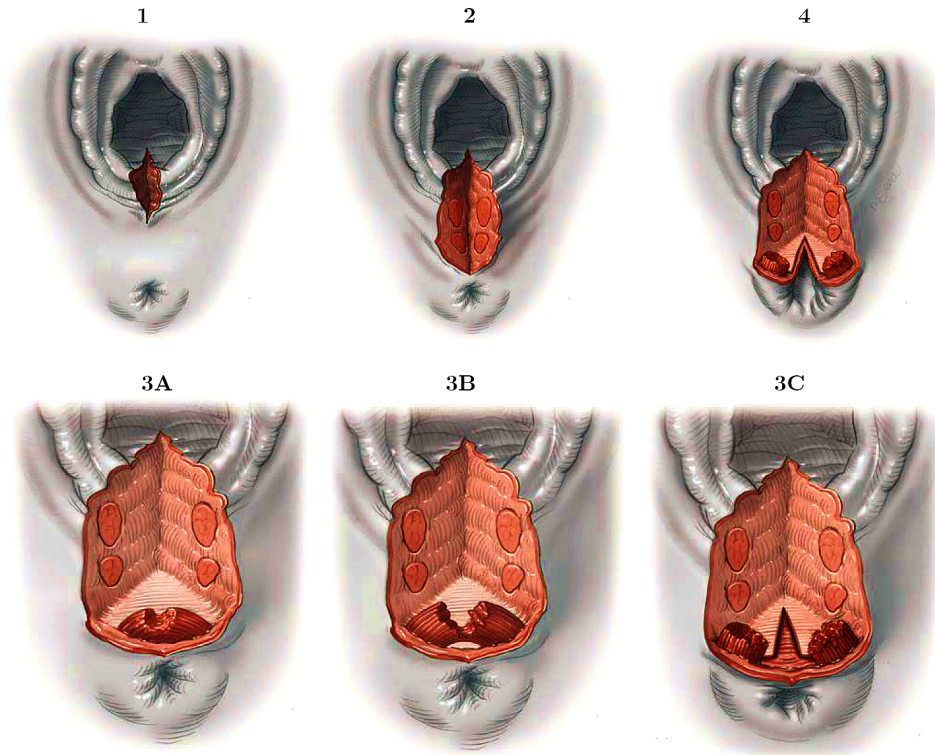


Figure 1.5: Different levels of perineal tears. 1 – First-degree perineal laceration, involving only the vaginal epithelium of perineal skin. 2 – Second-degree laceration extending to the perineal muscles (bulbospongiosus and superficial transverse perineal muscles). 3A – Third-degree laceration including less than 50% of the external anal sphincter. 3B – Third-degree laceration including more than 50% of the external anal sphincter. 3C – Third-degree laceration including the external and internal anal sphincters. 4 – Fourth-degree laceration affecting the perineal body, entire anal sphincter complex, and anorectal mucosa (adapted from [3]).

Therefore, when the LAM stretches beyond its limits, injuries may occur. LAM trauma affects 6–40% of women undergoing vaginal delivery, particularly nulliparous individuals [17]. One common form of injury is LAM avulsion, the most frequent type of macroscopic levator trauma, which leads to persistent morbidity and requires future surgical intervention in 10–20% of patients [18]. Avulsion is characterized by the traumatic detachment of the puborectalis muscle from its bony insertion at the pubic bone. Other abnormalities may affect distinct portions of the muscle, such as the iliococcygeus, though these are less relevant to functional anatomy [16]. These injuries significantly impact levator hiatal dimensions, pelvic organ support, and contraction strength.

The prevalence of such injuries is increasing due to the rising maternal age at first birth [19]. Imaging studies conducted before and after childbirth have demonstrated that vaginal delivery is a direct cause of this trauma. In cases involving large perineal

tears, pelvic floor muscle damage can often be diagnosed immediately after delivery. However, levator ani avulsions are frequently hidden and challenging to diagnose clinically [20]. Ultrasound scans performed before and after childbirth have confirmed that the hiatus enlarges following vaginal delivery, indicating that the passage of the fetal head is the primary risk factor for LAM damage. This hypothesis is further supported by the almost absence of such damage in cases of cesarean sections [19].

We can conclude that, despite advancements in obstetric care, childbirth-related injuries remain significantly challenging to diagnose and prevent. These injuries can result from a wide range of factors, making them difficult to predict in clinical practice. To address this issue and contribute to improving maternal healthcare, biomechanical models provide valuable insights. By analyzing the mechanical factors involved, biomechanics can help identify risk factors, enhance decision-making, and ultimately develop more effective strategies for preventing and managing childbirth-related injuries. This topic will be further explored in the next section.

1.4 Biomechanics of childbirth

Biomechanics is a branch of bioengineering that applies engineering principles and mechanical techniques to the study of biological systems, offering solutions to clinical challenges across various human body systems. Computational biomechanics, particularly the use of the finite element method (FEM), has become increasingly relevant in medicine, as it enables the analysis of mechanical stresses and strains. This approach uses mesh discretization to simplify complex geometries into simpler elements, allowing their interactions to be studied through numerical simulations. In the context of female pelvic biomechanics, computational biomechanics has provided crucial insights into the complex phenomena occurring during vaginal delivery [21]. Understanding the mechanical behavior of human pelvic organs and their supporting structures is essential for maintaining pelvic floor integrity and preventing pelvic floor disorders.

Computational models are promising resources to quantitatively analyze the physiology of labor in ways that were not previously conceivable [22]. Childbirth simulations can overcome limitations of physical childbirth models or invasive evaluations, offering insights into the mechanisms of vaginal delivery and associated maternal and fetal injuries. These models can mimic the geometries of bony structures, soft tissues (as PFM and perineum), and the fetus. Mechanical properties can also be included to describe the mechanical behavior of the tissues by using constitutive models with parameters that match experimental data [23].

1.4.1 Finite element models

One of the first attempts to computationally model vaginal delivery consists of the development of a three-dimensional model based on magnetic resonance imaging (MRI) to predict LAM stretch during childbirth. This model, which allowed for a mechanical analysis of vaginal delivery, included the pubococcygeus, puborectalis, and iliococcygeus muscles. Anatomical and geometric data were used to create 24 individual muscle bands, reflecting the parallel-fibered structure of the levator ani. To simulate vaginal delivery, a fetal head, approximated as one of three different-sized spheres, was incrementally advanced through the pelvis. The medial pubococcygeus muscle was identified as the most susceptible to injury, with stretch ratios increasing proportionally to fetal head size [24]. Following this approach, Parente *et al.* (2008) [25] developed a finite element (FE) model that integrated pelvic bones, PFM, and the fetus, using cadaveric measurements to improve anatomical precision. The model simulated the key movements of childbirth, such as engagement, descent, flexion, internal rotation, and extension. The numerical simulations demonstrated that PFM undergo significant deformations, reinforcing the importance of computational modeling in childbirth biomechanics.

Since the fetus plays a crucial role in the mechanics of vaginal delivery, some studies have explored childbirth simulations to predict muscle trauma, focusing on fetal characteristics and positioning. The position of the fetal head is a key determinant of delivery success. When the fetus is not in the occipito-anterior position, which is considered the most common and safest, it is classified as a malposition. One common malposition is the occipito-posterior position, in which the fetal face is oriented toward the anterior region of the pelvis. This is typically associated with more difficult labor and an increased risk of trauma to the PFM. Biomechanical simulations have examined how occipito-posterior cases affect stretch-related injuries compared to occipito-anterior ones. Findings indicate that malpositioning leads to significantly higher stretch values in the PFM, potentially increasing the risk of injury [26]. Another critical factor is fetal head flexion, an essential aspect of the cardinal movements of labor. Parente *et al.* (2010) [27] investigated its role and found that increased flexion reduces opposing forces against the fetal head, potentially facilitating delivery and minimizing pelvic floor strain.

Although the fetal head is a key component of vaginal delivery and childbirth simulations, it is often oversimplified. Some studies approximate it as a sphere, as previously mentioned, while others use anatomical measurements but still treat it as a rigid, non-deformable structure. In reality, the fetal head is highly deformable, consisting of bones connected by sutures and fontanelles, dense collagenous structures that allow it

to mold and adjust to the birth canal. Given their crucial role in childbirth, models have been developed to simulate fetal head molding by incorporating the skin, skull, brain, sutures, and fontanelles [28]. Recent studies have characterized these structures using a visco-hyperelastic constitutive model, providing a detailed mechanical description [29]. These studies determined that considering a deformable fetal head with accurate mechanical properties reduces reaction forces and pelvic floor muscle stretching, highlighting the importance of precise mechanical characterization for reliable simulations.

As computational models evolved, researchers began to incorporate more realistic representations of soft tissue behavior. Muscles, for example, exhibit both passive and active behaviors, allowing them to contract. However, the active behavior of muscles is often overlooked in their characterization. To address this gap, a constitutive model was developed to include the active response of the PFM, aiming to understand its impact on the delivery process. Testing different activation levels determined that increased muscle activation was associated with greater resistance to fetal descent, suggesting that it may difficult fetal progression and prolong labor [30]. Building on this insight, further refinements in muscle characterization included the introduction of a structural damage model, which quantified muscle damage and revealed that even an uncomplicated vaginal delivery could cause injuries. The puborectalis component of the LAM was identified as particularly susceptible to damage [31, 32].

In addition to understanding muscle damage, it is essential to consider the time-dependent nature of soft tissue behavior. Given that soft tissues are typically viscoelastic, meaning their response evolves over time, incorporating this aspect into pelvic floor modeling allows the simulation of labor with different durations. These simulations revealed that prolonged labor leads to reduced tissue stresses, potentially lowering the risk of injury [33]. Moreover, the relaxation properties of tissues were found to contribute to lower damage levels, supporting the theory that delayed pushing during the second stage of labor could offer benefits [32].

Another crucial factor in childbirth is the influence of maternal characteristics and obstetric interventions. One such intervention is the episiotomy, a technique involving an incision in the perineum to prevent natural tearing and facilitate delivery. From a biomechanical perspective, numerical simulations have shown that a mediolateral episiotomy reduces the stress on the LAM, thus aiding the birthing process [34]. In cases involving fetal malposition or alternative incision techniques, research confirms the protective role of episiotomy in minimizing pelvic floor damage. Specifically, when simulating an episiotomy during a malpositioned birth, there was a reduction in the damage values to levels similar to those observed in normal deliveries. Furthermore,

the simulations reveal that the likelihood of macroscopic levator trauma is significantly reduced with an episiotomy. When comparing different episiotomy techniques, studies suggest that, from a mechanical perspective, multiple smaller incisions do not provide any advantage over a single, larger incision [35, 36]. More recently, with a focus on maternal factors, Borges *et al.* (2021) investigated the impact of maternal birthing positions, showing that flexible sacrum positions, such as kneeling, standing, and squatting, enhance pelvic mobility and may reduce the risk of obstructed labor [37].

While most computational models have primarily focused on the PFM, some studies have attempted to incorporate additional structures within the pelvic cavity that play a role in the second stage of labor. These include the uterus, abdomen, soft tissues, and pelvis [38]. Such models of the pelvic cavity do not necessarily have to be used solely to analyze the impact of vaginal delivery on the muscles, as other important structures may also be affected during childbirth. For example, a FE model of a pregnant woman, which includes muscles, ligaments, and pelvic organs, was used to simulate the descent of the fetal head through the birth canal. This model revealed that the uterosacral ligaments experience elevated stress during this process, which may contribute to urogenital prolapse [38]. Recently, Chen *et al.* (2021) emphasized that most childbirth computational models lack essential maternal soft tissues, such as the vagina and superficial perineal structures, highlighting the need for a more comprehensive representation of maternal structures to improve the accuracy of the results [23]. These structures are often overlooked, as the focus is typically on the pelvic floor, where non-visible injuries that can lead to long-term consequences may occur. However, perineal lacerations and OASIS are also common and can cause significant trauma, affecting women on multiple levels. Recent studies incorporating the superficial perineal structures to simulate vaginal delivery have concluded that their inclusion significantly influences pelvic floor dynamics and must be considered in future computational models [39, 40].

The most recent studies on childbirth computational modeling have explored diverse approaches. Chen *et al.* (2023) proposed a universal method to derive the curve of Carus for the second stage of labor, from fetal head engagement in the pelvis to delivery, accounting for various fetal head sizes [41]. This approach aims to standardize simulations across different computational models, enabling direct comparison and reproducibility. Furthermore, recognizing that most models consider either uterine expulsion forces or pelvic structures, but not both, Tao *et al.* (2024) introduced a framework that models the uterus and pelvis as an integrated system [42]. Their approach simulates maternal tissue behavior, allowing for fetal delivery driven by active uterine contractions.

In summary, over the past two decades, computational models of vaginal delivery have evolved from simple mechanical representations to advanced simulations that integrate detailed anatomical, biomechanical, and obstetrical factors. These advancements have significantly enhanced our understanding of pelvic floor biomechanics. However, to further advance the field and achieve the ultimate goal of using these models in clinical practice to aid in medical decision-making, significant future work remains to be done. This includes incorporating additional anatomical structures to study distinct types of lesions, in particular the perineal region and its connection to the pelvic floor, exploring the possibility of adjusting the geometry of different structures to create patient-specific models, and investigating specific obstetrical interventions that continue to raise questions within the medical community, such as vacuum-assisted delivery (VAD) and its biomechanical impact.

1.4.2 Constitutive modeling

Constitutive modeling defines the mechanical behavior of materials through mathematical models based on physical principles and experimental data. The accuracy of these models is essential for reliable computational simulations, especially in biomechanics, where the complex macro- and microstructural organization of soft tissues governs their nonlinear, anisotropic, and time-dependent mechanical behavior, directly impacting physiological function. A robust constitutive model must not only capture the mechanical response of tissues, whether *in vivo* or *ex vivo*, but also rely on parameters that can be determined experimentally, while maintaining fundamental mathematical principles [43].

Soft tissues are characterized by nonlinear, anisotropic, hyperelastic, and viscoelastic behaviors. Their capacity for large deformations results in a nonlinear stress-strain response [43], while their high water content leads to nearly incompressible behavior [44]. Hyperelastic models, whether isotropic or anisotropic, are commonly used to characterize these stress-strain responses, described by a strain-energy density function Ψ that physically represents the energy stored in the body per unit volume due to deformation [45]. Furthermore, inelastic effects such as viscoelasticity and damage play a significant role in soft tissue mechanics. A common approach involves complementing a hyperelastic baseline model with inelasticity formulations, such as the generalized Maxwell model, to describe viscoelastic behavior.

Large deformations are particularly relevant in the soft tissues of the female pelvic floor, notably during childbirth and physiological activities that increase abdominal pressure, such as laughing, sneezing, or coughing. To accurately model these deformations, hyperelastic models are widely employed. Common isotropic formulations

to model the pelvic floor behavior include the Neo-Hookean, Mooney-Rivlin, and exponential models [46, 47, 48, 49]. Transversely isotropic constitutive models such as Martins, Holzapfel-Gasser-Ogden (HGO), and Humphrey-Yin [26, 34, 50] have also been used. These models describe materials composed of an isotropic matrix reinforced by one or more families of fibers. When a single fiber family is aligned along a preferential direction, the material exhibits significantly greater stiffness along the fiber direction compared to the transverse directions. This represents the simplest form of material anisotropy, known as transverse isotropy, where the response remains isotropic in directions orthogonal to the preferred fiber orientation [45]. Given that PFM are skeletal muscles composed of organized fiber bundles embedded in a ground substance [51], transversely isotropic models are more appropriate to characterize this material. Additionally, some studies have incorporated viscoelasticity using the generalized Maxwell model to characterize the time-dependent response of these muscles [29, 32, 33].

In the context of this thesis, it is essential to introduce key concepts from continuum mechanics, including the transversely isotropic hyperelastic Martins and HGO constitutive models, as well as the generalized Maxwell model for viscoelasticity. These concepts, however, are explored in greater detail in the existing literature [45, 52, 53, 54].

Consider a continuum body B with an arbitrary point $P \in B$. As the body moves in space from one instant of time to another, it occupies a continuous sequence of geometrical regions $\Omega_0, \dots, \Omega$. The regions which are occupied by the continuous body B at a given time t are known as the configurations of B at that time t . The region Ω_0 corresponds to the reference (or material) configuration of the body, providing a material or Lagrangian description of kinematic quantities. The region Ω , which is occupied by the body at the current time, is called the current (or spatial) configuration and provides a spatial or Eulerian description of kinematic quantities.

$\mathbf{X}$ is the position vector (material coordinates) of point P in region Ω_0 (reference configuration) at time $t = 0$. The motion of body B to a new region Ω (current configuration) is mapped through a vector field χ . At time t , the point $P \in \Omega$ is described by its spatial coordinates $\mathbf{x} = \chi(\mathbf{X}, t)$. The deformation gradient $\mathbf{F}$ can be expressed as:

$$\mathbf{F} = \frac{\partial \mathbf{x}}{\partial \mathbf{X}} \quad (1.1)$$

As the deformation gradient is not a symmetric tensor, it is possible to introduce the right Cauchy-Green tensor $\mathbf{C}$, a strain measurement in the material coordinates, as:

$$\mathbf{C} = \mathbf{F}^T \mathbf{F} \quad (1.2)$$

The deformation gradient $\mathbf{F}$ and the right Cauchy-Green tensor $\mathbf{C}$ can be expressed by a multiplicative decomposition of $\mathbf{F}$ into *volume-changing (dilational)* and *volume-preserving (distortional)* parts, as following:

$$\mathbf{F} = (J^{1/3} \mathbf{I}) \bar{\mathbf{F}} = J^{1/3} \bar{\mathbf{F}}, \quad \mathbf{C} = (J^{2/3} \mathbf{I}) \bar{\mathbf{C}} = J^{2/3} \bar{\mathbf{C}} \quad (1.3)$$

The terms $J^{1/3} \mathbf{I}$ and $J^{2/3} \mathbf{I}$ are associated with volume-changing deformations, while the modified deformation gradient $\bar{\mathbf{F}}$ and the modified right Cauchy-Green tensor $\bar{\mathbf{C}} = \bar{\mathbf{F}}^T \bar{\mathbf{F}}$ are associated with volume-preserving deformations of the material.

A material for which dilational changes require a much higher exterior work than volume-preserving changes is called nearly incompressible material, for which the compressibility effects are very small. To avoid numerical complications in the FE analysis of nearly incompressible materials (as most soft tissues), it is often advantageous to perform this multiplicative decomposition of $\mathbf{F}$ and to separate the numerical treatments of the volumetric and isochoric parts.

The strain-energy density function Ψ can be written in a decoupled representation $\Psi = \Psi(\mathbf{C})$ (per unit reference volume). It is based on the kinematic assumption of Equation 1.3 and is expressed as:

$$\Psi(\mathbf{C}) = \Psi_{vol}(J) + \Psi_{iso}(\bar{\mathbf{C}}) \quad (1.4)$$

where $\Psi_{vol}(J)$ and $\Psi_{iso}(\bar{\mathbf{C}})$ correspond to the volumetric (or dilational) elastic response and the isochoric (or distortional) elastic response of the material, respectively.

In isotropic hyperelastic materials, the strain-energy function Ψ can be expressed in terms of the modified strain invariants $\bar{I}_a$, $a = 1, 2, 3$, defined by:

$$\bar{I}_1 = tr \bar{\mathbf{C}} \quad (1.5)$$

$$\bar{I}_2 = \frac{1}{2} [tr(\bar{\mathbf{C}})^2 - tr(\bar{\mathbf{C}}^2)] \quad (1.6)$$

$$\bar{I}_3 = det \bar{\mathbf{C}} = 1 \quad (1.7)$$

By analogy with the decoupled representation, and considering that $\bar{I}_3$ is constant, the strain-energy function can be expressed as:

$$\Psi(\mathbf{C}) = \Psi_{vol}(J) + \Psi_{iso}[\bar{I}_1(\bar{\mathbf{C}}), \bar{I}_2(\bar{\mathbf{C}})] \quad (1.8)$$

As previously mentioned, the PFM is considered transversely isotropic and is typically modeled with a single family of fibers. For a material reinforced by only one family of fibers, the stress at a material point depends not only on the deformation gradient $\mathbf{F}$ but also on the single preferred direction of the fibers, which is called fiber direction. The direction of a fiber at point $\mathbf{X} \in \Omega_0$ is defined by a unit vector field $\mathbf{a}_0(\mathbf{X})$, $|\mathbf{a}_0| = 1$. The fiber under a deformation moves with the material points of the continuum body and arrives at the deformation configuration Ω . This motion can alter both the direction and length of the fiber. Therefore, to account for changes in length, the stretch λ must be defined along its direction $\mathbf{a}_0$ as the ratio between the length of a fiber element in the deformed and reference configuration. The following expression relates the fiber directions in the reference and the current configurations:

$$\bar{\lambda}\mathbf{a}(\mathbf{x}, t) = \bar{\mathbf{F}}\mathbf{a}_0(\mathbf{X}) \quad (1.9)$$

Consequently, since $|\mathbf{a}| = 1$, the fiber stretch depends on the fiber direction of the undeformed configuration $\mathbf{a}_0$ and on the strain measure right Cauchy-Green tensor $\bar{\mathbf{C}}$.

$$\bar{\lambda}^2 = \mathbf{a}_0 \cdot \bar{\mathbf{F}}^T \bar{\mathbf{F}} \mathbf{a}_0 = \mathbf{a}_0 \cdot \bar{\mathbf{C}} \mathbf{a}_0 \quad (1.10)$$

Due to the directional dependence on the deformation, expressed by the unit vector field $\mathbf{a}_0$, the strain-energy function depends explicitly on both the modified right Cauchy-Green tensor and the fiber direction on the reference configuration. Hence, Ψ can be expressed as a function of the two arguments $\mathbf{C}$ and $\mathbf{a}_0 \otimes \mathbf{a}_0$, which corresponds to a second-order structural tensor and will be denoted as $\mathbf{A}_0 = \mathbf{a}_0 \otimes \mathbf{a}_0$, where $\otimes$ denotes the tensor product.

$$\Psi = \Psi(\mathbf{C}, \mathbf{A}_0) \quad (1.11)$$

In the same way that isotropic hyperelastic materials can be expressed in terms of the invariants, the full description of a transversely isotropic material requires the additional definition of the invariants $\bar{I}_4$ and $\bar{I}_5$, called pseudo-invariants:

$$\bar{I}_4(\bar{\mathbf{C}}, \mathbf{A}_0) = \bar{\mathbf{C}} : \mathbf{A}_0 = \bar{\lambda}^2 \quad (1.12)$$

$$\bar{I}_5(\bar{\mathbf{C}}, \mathbf{A}_0) = \bar{\mathbf{C}}^2 : \mathbf{A}_0 \quad (1.13)$$

The invariant $\bar{I}_4$ is the square of the stretch measure for the family of fibers and have a clear physical interpretation. For simplicity, in order to minimize the number of material parameters, the reduced form of the strain-energy function is given by:

$$\Psi(\mathbf{C}, \mathbf{A}_0) = \Psi_{vol}(J) + \Psi_{iso}(\bar{I}_1, \bar{I}_4) \quad (1.14)$$

Lastly, to describe the viscoelastic effects according to the generalized Maxwell model, a finite number of internal variables, associated with the irreversible (dissipative) effects of the material, are introduced in the reference configuration as $\bar{\Gamma}_\alpha = 1, \dots, m$. The tensorial variables $\bar{\Gamma}_\alpha$ depend on the deformation history and characterize the non-equilibrium state of the deformation process and $m \geq 1$ corresponds to the number of relaxation processes associated with the viscoelastic behavior.

Considering the viscoelastic effects, the strain-energy function can be written in the decoupled form according to the volumetric and isochoric decomposition:

$$\Psi(\mathbf{C}, \mathbf{A}_0, \bar{\Gamma}_1, \dots, \bar{\Gamma}_m) = \Psi_{vol}^\infty(J) + \Psi_{iso}(\bar{\mathbf{C}}, \mathbf{A}_0, \bar{\Gamma}_\alpha) \quad (1.15)$$

valid for some closed time interval $t \in [0, T]$ of interest. Here and elsewhere the superscript $(\bullet)^\infty$ refers to a function which represents the elastic response to sufficiently slow processes. The isochoric contribution can be further split into a thermodynamic equilibrium state, Ψ_{iso}^∞ , and into configurational free energies, $\Psi_{iso\alpha}$, responsible for the thermodynamic non-equilibrium state:

$$\Psi_{iso}(\bar{\mathbf{C}}, \mathbf{A}_0, \bar{\Gamma}_\alpha) = \Psi_{iso}^\infty(\bar{I}_1, \bar{I}_4) + \sum_{\alpha=1}^m Y_\alpha(\bar{\mathbf{C}}, \mathbf{A}_0, \bar{\Gamma}_\alpha) \quad (1.16)$$

The additional term corresponds to the dissipative term, responsible for the viscoelastic contribution and extending the decoupled strain-energy function of Equation 1.4 to the viscoelastic regime. The scalar-valued functions Y_α represent the so-called configurational free energy of the viscoelastic solid and characterize the non-equilibrium state (the behavior of relaxation and creep).

The stress response can be derived directly from the Clausius-Planck inequality, in which the internal dissipation $\mathcal{D}_{\text{int}}$ is given by:

$$\mathcal{D}_{\text{int}} = \mathbf{S} : \dot{\mathbf{C}}/2 - \dot{\Psi} \geq 0 \quad (1.17)$$

where $\mathbf{S}$ represents the second Piola-Kirchhoff stress tensor that can be defined in the decoupled form:

$$\mathbf{S} = 2 \frac{\partial \Psi(\mathbf{C}, \mathbf{A}_0, \mathbf{\Gamma}_1, \dots, \mathbf{\Gamma}_m)}{\partial \mathbf{C}} = \mathbf{S}_{\text{vol}}^{\infty} + \mathbf{S}_{\text{iso}} \quad (1.18)$$

with the definition of the isochoric contribution as:

$$\mathbf{S}_{\text{iso}} = \mathbf{S}_{\text{iso}}^{\infty} + \sum_{\alpha=1}^m \mathbf{Q}_{\alpha} \quad (1.19)$$

where the internal tensor variables $\mathbf{Q}_{\alpha}$, $\alpha = 1, \dots, m$, are the non-equilibrium stresses arising from the viscous effects.

The volumetric and isochoric contributions can be described by:

$$\mathbf{S}_{\text{vol}}^{\infty} = J \frac{d\Psi_{\text{vol}}^{\infty}(J)}{dJ} \mathbf{C}^{-1}, \quad \mathbf{S}_{\text{iso}}^{\infty} = J^{-\frac{2}{3}} \mathbb{P} : 2 \frac{\partial \Psi_{\text{iso}}^{\infty}(\bar{\mathbf{C}})}{\partial \bar{\mathbf{C}}} \quad (1.20)$$

where $\mathbb{P} = \mathbb{I} - \frac{1}{3} \mathbf{C}^{-1} \otimes \mathbf{C}$ corresponds to the fourth-order material projection tensor.

The additional internal tensor variables $\mathbf{Q}_{\alpha}$, $\alpha = 1, \dots, m$ have been introduced and may be interpreted as non-equilibrium stresses in the sense of non-equilibrium thermodynamics. As can be seen in Equation 1.19, the isochoric second Piola-Kirchhoff stress is decomposed into an equilibrium part and a non-equilibrium part characterized by the elastic response of $\mathbf{S}_{\text{iso}}^{\infty}$ and the viscoelastic response $\sum_{\alpha=1}^m \mathbf{Q}_{\alpha}$, respectively. Based on this, it is possible to define:

$$\mathbf{Q}_{\alpha} = J^{-2/3} \mathbb{P} : \bar{\mathbf{Q}}_{\alpha}, \quad \bar{\mathbf{Q}}_{\alpha} = 2 \frac{\partial Y_{\alpha}(\bar{\mathbf{C}}, \bar{\mathbf{\Gamma}}_{\alpha})}{\partial \bar{\mathbf{C}}} \quad (1.21)$$

These internal variables are governed by evolution equations that define the way the viscoelastic process evolves:

$$\dot{\mathbf{Q}}_{\alpha} + \frac{\mathbf{Q}_{\alpha}}{\tau_{\alpha}} = \beta_{\alpha} \dot{\mathbf{S}}_{\text{iso}} \quad (1.22)$$

Closed form solutions of the linear differential evolution equations may be presented by the convolution integrals:

$$\mathbf{Q}_\alpha = \exp(-T/\tau_\alpha) \mathbf{Q}_\alpha^{0+} + \int_{t=0+}^{t=T} \exp\left[-\frac{(T-t)}{\tau_\alpha}\right] \beta_\alpha \dot{\mathbf{S}}_\alpha dt \quad (1.23)$$

where τ_α and β_α are the viscous parameters and represent respectively the relaxation times and non-dimensional free-energy factors.

To apply the constitutive model in a FE context an iterative solution of Newton's type is frequently applied. However, it is also necessary to calculate the elasticity tensor. The fourth-order elasticity tensor $\mathbf{C}$ measures the change in stress which results from a change in strain and is referred as the elasticity tensor in the material description (or the Lagrangian elasticity tensor). The elasticity tensor may be written in the decoupled form based on the same decoupled structure of the strain-energy function demonstrated on Equation 1.4 and with analogy to Equation 1.18 and 1.19.

$$\mathbf{C} = 2 \frac{\partial \mathbf{S}(\mathbf{C}, \mathbf{A}_0, \mathbf{\Gamma}_1, \dots, \mathbf{\Gamma}_m)}{\partial \mathbf{C}} = \mathbf{C}_{vol}^\infty + \mathbf{C}_{iso} = \mathbf{C}_{vol}^\infty + \mathbf{C}_{iso}^\infty + \mathbf{C}_{vis} \quad (1.24)$$

Finally, for the FE implementation, the stress and elasticity tensors are often required in the current configuration. Thus, to obtain the stress tensor in the current configuration, known as Cauchy stress tensor, $\boldsymbol{\sigma}$, a push-forward operation can be applied to $\mathbf{S}$ as follows:

$$\boldsymbol{\sigma} = J^{-1} \mathbf{F} \mathbf{S} \mathbf{F}^T \quad (1.25)$$

The push-forward operation in the material elasticity tensor, $\mathbf{C}$, results in the spatial (or Eulerian) elasticity tensor, $\mathbb{C}$, as:

$$\mathbb{C}_{abcd} = J^{-1} F_{ai} F_{bj} F_{ck} F_{dl} \mathbf{C}_{ijkl} \quad (1.26)$$

In summary, the primary inputs required for the implementation of the constitutive model are the deformation gradient, $\mathbf{F}$, and the specific material parameters that characterize the tissue behavior. As previously discussed, the HGO and Martins constitutive models have been successfully used in several studies to capture the nonlinear, transversely isotropic behavior of the PFM [26, 32, 33, 55, 56]. The strain-energy functions corresponding to these models are presented below.

- **HGO constitutive model**

The strain-energy function of the HGO constitutive model is defined, as described in Equation 1.4, by the volumetric and isochoric contributions. The HGO model defines the isochoric equilibrium state strain-energy function, Ψ_{iso} , considering a further decomposition into a part associated with the isotropic behavior of the ground substance, $\bar{\Psi}_m$, and the family of fibers, $\bar{\Psi}_f$:

$$\bar{\Psi}_m = c_{10} (\bar{I}_1 - 3) \quad (1.27)$$

$$\bar{\Psi}_f = \frac{k_1}{2k_2} \left\{ \exp \left[k_2 (\bar{I}_4 - 1)^2 \right] - 1 \right\} \quad (1.28)$$

where c_{10} and k_1 are stress-like material parameters, and k_2 is a dimensionless parameter.

The volumetric contribution, Ψ_{vol} , is responsible for establishing the quasi-incompressibility and is defined as:

$$\Psi_{vol} = \kappa \left(\frac{J^2 - 1}{2} - \ln(J) \right) \quad (1.29)$$

where κ denotes the bulk modulus. In many FE formulations, the bulk modulus is alternatively expressed in terms of the material parameter D , defined as:

$$D = \frac{2}{\kappa} \quad (1.30)$$

- **Martins constitutive model**

The strain-energy function of the Martins constitutive model can be decomposed into three distinct components: the strain energy stored in the isotropic matrix embedding the muscle fibers, $\bar{\Psi}_m$, the strain energy stored in each muscle fiber family $\bar{\Psi}_f$, and the strain energy associated with the volumetric changes, Ψ_{vol} , given by Equation 1.29.

$$\bar{\Psi}_m = c \left\{ \exp \left[b (\bar{I}_1 - 3) \right] - 1 \right\} \quad (1.31)$$

where c and b are constitutive parameters related to the isotropic part.

In this model, the fiber contribution $\bar{\Psi}_f$ can be divided into a passive part $\bar{\Psi}_f^{PE}$ and an active part $\bar{\Psi}_f^{SE}$ responsible for muscle contraction.

$$\bar{\Psi}_f^{PE} = A \left\{ \exp \left[a \left(\bar{\lambda} - 1 \right)^2 \right] - 1 \right\} \quad (1.32)$$

$$\bar{\Psi}_f^{SE} = \theta T_0^M \int_1^{\bar{\lambda}} \left[-4 \left(\bar{\lambda} - 1 \right)^2 + 1 \right] d\bar{\lambda} \quad (1.33)$$

where $\bar{\lambda}$ represents the stretch ratio of the muscle fibers, T_0^M is the maximum muscle tension produced by the muscle at resting, $\theta \in [0, 1]$ defines the level of activation, and A and a are constitutive parameters related to the muscle fibers.

1.4.3 Experimental tests

The constitutive models presented in Section 1.4.2 require specific constitutive parameters to accurately characterize the behavior of the biomechanical models discussed in Section 1.4.1. These parameters are typically determined through experimental testing, where tissues are subjected to mechanical tests to obtain data that describe their behavior.

Experimental testing in biomechanics is particularly challenging due to the limited availability of biological tissues. Even when such tests are feasible, ethical and logistical constraints arise, particularly in the study of soft tissues in sensitive contexts as childbirth. Direct experimentation on human tissues during pregnancy is neither practical nor ethical due to the significant risks to both mother and fetus. As a result, *post-mortem* examinations remain one of the few viable options, though they come with limitations such as tissue degradation, altered mechanical properties, and restricted sample availability.

To overcome these challenges, researchers often utilize animal models to investigate the mechanical behavior of human pelvic floor components. Several animals, including cows, pigs, dogs, deer, sheep, and horses, develop pelvic floor disorders, with characteristics and risk factors that are comparable to those in humans [57]. Among these, sheep are considered the most suitable models for pelvic floor research. They have been extensively studied due to their tendency to develop spontaneous pelvic organ prolapse, sharing the same risk factors as humans and exhibiting a similar pelvic architecture [58, 59]. While these models provide valuable insights, they cannot fully capture the complexity of human anatomy and physiology, potentially leading to discrepancies in tissue characterization.

Beyond these approaches, *in vivo* methods are emerging, namely the use of pressure transducers, imaging techniques, or a combination of both to assess tissue properties [60]. The most commonly reported methods for characterizing the pelvic floor

include dynamometers, elastomers, shear-wave elastography (SWE), and ultrasound imaging [61, 62, 63, 64]. However, these techniques are relatively recent, and their implementation and validation still rely on the characterization of individual tissues through well-established *ex vivo* tests.

An alternative to animal models and *in vivo* methods is the use of human cadaveric tissue. Although this approach may raise ethical concerns, it remains one of the most widely adopted methods for characterizing the mechanical properties of soft tissues. Unlike conventional engineering materials, biological tissues have a complex organization, specialized functions, and highly nonlinear behavior. Their biomechanical response is governed by both active and passive components: active properties relate to a tissue's ability to generate force via muscle contractions, whereas passive properties describe its resistance to deformation and capacity to transmit loads [60]. To evaluate passive properties, tissues are typically dissected and subjected to mechanical testing *ex vivo*. For pelvic floor tissues, uniaxial tensile testing is the most commonly applied method [65, 66, 67], although biaxial stretching [68, 69] and stress relaxation tests [70] are also used. Conducting *ex vivo* tests on soft biological tissues, particularly human *post-mortem* samples, presents several challenges:

- **Tissue storage:** ideally, tissues should be tested immediately after dissection to ensure their mechanical properties are preserved. However, this is often not feasible. As a result, tissues must be carefully stored to maintain their integrity. Freezing is the most commonly used method, as it has minimal impact on the mechanical properties when performed correctly. Specimens are typically frozen at temperatures below -18°C , which helps to preserve their structure and function [71, 72, 73].
- **Hydration during tissue preparation and testing:** proper hydration of tissues is essential throughout both preparation and testing to preserve their mechanical properties. Insufficient hydration can lead to an overestimation of tissue stiffness and strength [74]. The most commonly used hydration mediums are saline solutions, such as phosphate-buffered saline (PBS), which not only maintain hydration but also protect against humidity [73]. Typical hydration methods include spraying the tissue during preparation and using an immersion bath during testing [75].
- **Attaching the samples to the testing machine:** securing soft tissue samples to testing systems presents a challenge, particularly when the samples have small dimensions. Currently, there is no standardized procedure for the mechanical testing of biological tissues. A common issue encountered during testing is the unintended slippage of samples from the clamping system, which can lead to

inaccuracies in strain and force measurements [76, 77]. Increasing clamping pressure to prevent slippage may seem like a solution, but it often results in premature tissue failure. The most common strategies to mitigate this problem involve modifying the clamp geometry according to the tissue or incorporating additional materials, such as sandpaper or adhesive, to enhance grip [77, 78].

- **Stress calculations:** stress calculation relies on precise measurement of the tissue's cross-sectional area, a task inherently challenging due to the nature of soft tissues. Measurement techniques for cross-sectional area can be categorized into contact and non-contact methods. Contact approaches include calipers, micrometers, geometric approximations (where the cross-section is assumed to be round, rectangular, or elliptical and dimensions are obtained using calipers), and molding techniques. However, these methods are prone to significant errors due to the deformable nature of soft tissues, which can be easily altered during measurement [75]. Non-contact methods include laser-based techniques and three-dimensional scanning approaches. While laser-based systems are generally more accurate than contact methods, they struggle to detect concavities and complex surface features of the specimen. Additionally, non-contact techniques, although often offering improved precision, tend to be slower, more expensive, and less readily available in standard laboratory settings [79].
- **Strain measurements:** various techniques can be employed to measure strain during testing, with non-contact methods being particularly common through the use of video analysis systems [75]. One widely used approach involves applying high-contrast markers to the specimen's surface and tracking their movement using digital video cameras. However, this method has notable limitations: markers may become lost from view due to the large deformations typical of soft tissues, and their position can shift during testing, especially when water baths are used to maintain tissue hydration [80]. An alternative is markerless strain measurement, an optical technique that utilizes digital image correlation (DIC) to assess surface strain by comparing variations in intensity patterns on the specimen's surface [81]. DIC is advantageous since it can capture strain heterogeneity across the tissue surface. Nevertheless, its application to soft tissues remains challenging due to the substantial deformations involved. Additionally, the use of speckle patterns required for DIC presents similar issues to marker placement. The simplest and most commonly reported method for estimating strain is the clamp-to-clamp approach. This involves measuring the initial distance between the clamps and recording the displacement of one clamp relative to the other during testing, allowing strain to be calculated by dividing the change in length by the initial distance. While this method is safer, more cost-effective, and easy

to implement, it assumes a homogeneous strain distribution and may result in strain overestimation. Near the middle of the sample, away from the clamps, strains are more uniform and better reflect the sample behavior [75]. The choice of the most appropriate technique largely depends on the specific tissue being studied and the equipment available in the laboratory.

Combining mechanical testing with microstructural analysis provides a more comprehensive understanding of soft tissue behavior. Microstructural analysis involves examining the microscopic arrangement of tissue components, such as collagen and elastin fibers, which play key roles in determining the tissue's mechanical properties. Techniques such as histological assessments, scanning electron microscopy, and optical microscopy are commonly used to visualize these components. For instance, histological analysis can estimate the average content of collagen and elastin, offering insights into how these components influence mechanical behavior [82]. Integrating mechanical testing with microstructural analysis offers a holistic view of soft tissue behavior. This combined approach provides valuable information on the relationship between tissue structure and function, supporting the development of accurate constitutive models.

In the field of childbirth biomechanics, the focus is often placed on the pelvic floor and vagina, while other crucial tissues involved in the process, and susceptible to injury, receive less attention. One such area is the perineum, particularly the perineal body and perineal muscles, which can sustain severe injuries during childbirth. These injuries contribute significantly to maternal morbidity and long-term complications, yet they remain poorly characterized in the literature.

Several studies have attempted to non-invasively estimate the mechanical properties of the perineal body, primarily using elastography techniques [83, 84]. However, these methods provide only the elastic properties of the tissue and fail to capture its complex mechanical behavior. Animal models, such as ewes and sows, have also been used to investigate the microstructure and elasticity of the perineal body through uniaxial tensile tests [85, 86]. To the best of my knowledge, only one study has performed tensile tests to determine the load-deformation properties of *post-mortem* human female perineal tissues, alongside histological assessment [87].

Despite these contributions, none of these studies provide a comprehensive analysis of the perineum's hyperelastic and viscoelastic properties, key factors that critically influence its mechanical behavior, particularly during childbirth. Improved data on perineal tissue mechanics can significantly enhance our understanding of how the perineum responds under stress. This knowledge can guide the development of more accurate models of tissue behavior, leading to better predictions of injury risk and ultimately improving patient outcomes. By capturing the full range of mechanical

properties, from elasticity to time-dependent behavior, biomechanical models can better inform healthcare professionals regarding the management of childbirth, including the prevention of perineal trauma and the optimization of delivery techniques.

1.5 Finite element-based machine learning

Driven by the need to achieve real-time responses for integrating biomechanical simulations into clinical practice, researchers have focused on strategies to reduce computational time. These strategies include increasing computational power through improved hardware, graphics processing units, or parallel processing, as well as employing model reduction techniques [88]. However, these techniques are often insufficient to ensure results in near real-time, which is a crucial requirement for most clinical applications. Therefore, machine learning (ML) algorithms have gained relevance due to their capacity to deliver robust, fast, and real-time responses for biomechanical simulations.

ML, a subset of artificial intelligence (AI), focuses on developing algorithms and methods that enable machines to solve complex problems, specially those that traditional programming techniques struggle to address. ML analyzes large datasets to uncover underlying structures and patterns, allowing for the development of models that can predict outcomes or behaviors based on previous data. Within the field of ML, two main types of learning exist: supervised and unsupervised learning. In supervised learning, the model is trained on a dataset in which each observation is paired with its corresponding ground truth, forming a labeled dataset. The algorithm then learns to identify key characteristics that distinguish the observations. Supervised learning can be divided into classification, where the probability of an observation belonging to a specific category is predicted, and regression, which involves predicting continuous values [89]. For the purpose of this thesis, all subsequent information will be focused solely on regression problems.

A promising approach to integrating ML algorithms with biomechanical simulations for faster response times is to use a finite element-based machine learning (FEM-based ML) approach. This method involves training ML models on data generated through FE simulations. While generating these simulations is computationally expensive and represents the main limitation of this method, it is primarily an upfront time investment. Once the dataset is created, the trained ML model can drastically reduce the time required to obtain results. The core idea is to build a dataset from FE simulations conducted for multiple cases of the problem under study and then use this dataset to train a ML model. When a new case arises that falls within the range of

the trained cases, the model can predict the outcome without requiring a complete simulation, significantly reducing computational costs. Over time, as this approach is applied repeatedly, the initial time investment in dataset creation is outweighed by the efficiency gains in subsequent predictions. A pipeline for the implementation of a FEM-based ML approach is demonstrated in Figure 1.6.

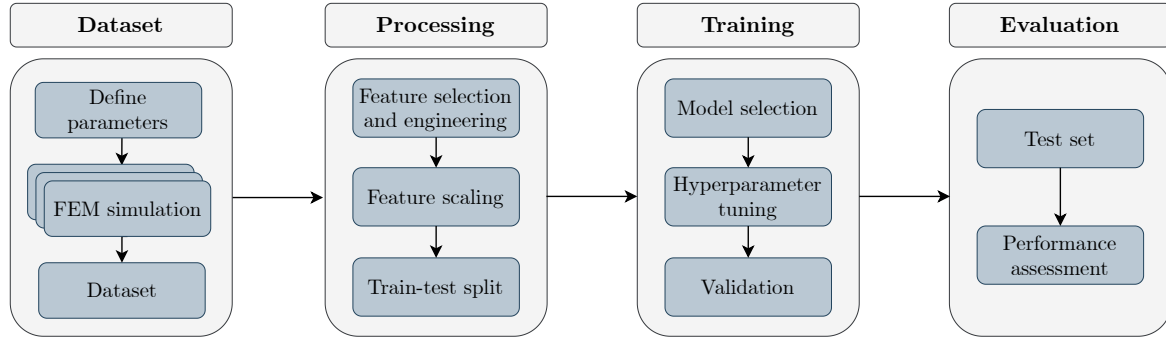


Figure 1.6: Pipeline for the implementation of a FEM-based ML approach.

A recently published review concluded that the three main types of regression algorithms used for generating fast and real-time simulations of anatomical structures are tree-based algorithms, specifically random forest (RF) and extreme gradient boosting (XGBT), as well as support vector regression (SVR), and artificial neural networks (ANNs) [88].

- Tree-based algorithms are a type of supervised ML models that build decision trees to divide the feature space into distinct regions, allowing for a structured representation of complex relationships between input features and target variables. While decision trees are relatively simple models that may not perform well for many complex problems, ensemble tree-based methods, such as bagging or boosting, leverage multiple trees to enhance model performance. Examples of such algorithms include RF and gradient boosting methods.
 - The RF model combines multiple decision trees to create a robust model. The algorithm works by selecting a subset of features, training a decision tree on them, and then repeating the process multiple times [90, 91]. One potential drawback of this model is that it can be computationally expensive when working with a large number of trees [92].
 - XGBT improves predictive performance by sequentially adding trees that correct the errors of previous ones. It integrates techniques to prevent overfitting and has been widely applied in domains such as computer vision and bioinformatics [93, 94].

- SVR models map input data into a high-dimensional feature space to identify a hyperplane that best fits the data while maximizing the margin from the nearest data points. SVR effectively handles nonlinear data, is robust to outliers, and performs well in high-dimensional spaces. However, its computational complexity and sensitivity to parameter selection, particularly the choice of kernel function, can be challenging [95].
- ANNs are inspired by the function of the human brain, particularly its neurons. A neural network consists of an input layer, one or more hidden layers, and an output layer. The connections between neurons have associated weights, which are adjusted during training to minimize the error between the network's predictions and the actual labels [96]. The versatility of ANNs, along with their ability to learn from large datasets and handle highly nonlinear data, make them powerful tools for various applications. However, careful implementation is necessary to prevent overfitting.

Numerous studies in the literature have adopted this approach within the biomechanical domain, particularly in scenarios involving the liver, stomach, femur, heart, or breast. These studies aim to predict variables as deformation, pressure, mechanical properties, external forces, and stress.

Neural networks have been applied in distinct approaches, such as predicting stress values in musculoskeletal structures and stress distribution in the aorta. For instance, a FE model of the tibio-femoral joint was used to simulate different loading and motion scenarios. Reaction forces were used as input features, and the von Mises stress was the primary output [97]. In another approach, patient-specific image data and characteristics served as direct inputs for the ML model, replacing the traditional FE calculation process. The model was trained to predict aortic wall stress distributions, achieving highly accurate predictions with normalized mean absolute error (NMAE) of less than 0.5% [98].

To predict myocardial stress, decision trees and XGBT have been used to train a dataset derived from simulations of left ventricular mechanics. The features used in the model include mechanical properties and the centroid coordinates of the elements. This approach reduced the stress prediction time from 20 minutes to just 5 seconds [99]. In the context of arterial health assessment, FEM-based ML has also been applied to predict the risk of plaque rupture. A parametric model for arterial geometry was developed, and a database of 2D FE simulations was used to predict the maximum von Mises stress, a critical indicator of plaque rupture risk. By integrating geometry, material properties, and boundary conditions, the ML models achieved stress predictions with an error of less than 10% [100].

FEM-based ML has also been applied in other relevant studies, such as to predict the deformation of breast tissues under compression using RF and XGBT models by simulating the real-time biomechanical behavior of the breast tissue [101]. In the domain of liver biomechanics, ML algorithms were trained using tens of thousands of biomechanical simulations, including one hundred different liver geometries. These algorithms utilized features such as node coordinates, forces, material properties, and distances, and were tested across various scenarios. This innovative approach enables the simulation of the mechanical behavior of any liver and the prediction of its displacement field [102].

Recent studies are increasingly exploring more complex approaches. Deep learning is being applied in areas such as cardiovascular fluid mechanics, soft tissue mechanics, and bone biomechanics to improve simulation accuracy and reduce computational time [103, 104]. Another promising approach involves physics-informed neural networks (PINNs), which incorporate boundary conditions, material properties, and the governing partial differential equations to constrain the network. However, PINNs require large datasets and are limited by the range of available data [103]. Autoencoders, another type of neural network, can be used for dimensionality reduction and feature extraction, enabling the simplification of high-dimensional data while preserving essential features [105].

In the field of childbirth biomechanics, FEM-based ML techniques remains largely unexplored. Childbirth simulations are inherently complex, as demonstrated by the FE models described in Section 1.4.1. To integrate these simulations into clinical practice and provide clinicians with real-time feedback, computational efficiency must be improved. To the best of my knowledge, the only existing approach applying ML to childbirth simulations is a recent study that developed deep learning architectures to predict soft tissue deformation. However, this study relied on a mass-spring model rather than a FE approach, limiting the mechanical quantities that can be directly predicted [106].

Thus, a critical gap in the literature has been identified concerning the time-consuming nature of childbirth FE simulations. Based on existing research, FEM-based ML appears to be a promising approach in this field, with the potential to significantly reduce the time required to obtain results. Such a transformation would not only enhance the efficiency of simulations but also offer a way to personalize obstetric care by tailoring predictions and recommendations to individual patients. ML algorithms could enable data-driven decision support, offering healthcare professionals the ability to make timely, informed choices based on real-time simulation outputs. In this way, obstetric care could move toward a more personalized approach, ensuring better outcomes for

both mother and fetus.

1.6 Thesis outline and specific aims

As highlighted in the previous sections, maternal morbidity is an emerging concern, exacerbated by the increasing trend of advanced maternal age. Addressing this challenge requires innovative strategies to improve maternal outcomes and overall healthcare quality. Enhancing maternal healthcare has the potential to provide significant societal benefits, including improving women's long-term quality of life, reducing healthcare burden and costs, and promoting the development of innovative tools for clinical applications. In this context, the primary goal of this thesis is to advance the field of childbirth biomechanics through a multidisciplinary approach that combines numerical simulations, computational methods (such as AI algorithms), and experimental techniques. By integrating these different approaches, this work contributes to the development of a predictive tool to assist obstetricians in anticipating and preventing childbirth complications, thereby improving maternal outcomes.

This thesis is organized as follows: Chapters 2 and 3 focused on numerical simulations to computationally characterize the labor process. Building on these models, Chapters 4 and 5 investigate methods to accelerate the results obtained from FE simulations and translate biomechanical insights into clinically applicable tools. Chapter 6 addresses the mechanical characterization of soft tissues, providing experimental data to improve the fidelity of the numerical models. A general discussion of the thesis is presented in Chapter 7, followed by concluding remarks and suggestions for future work in Chapter 8. Finally, the main scientific contributions of the thesis are summarized in Chapter 9.

Aim 1 – Develop a FE model of the PFM and perineum for childbirth simulations

Although extensively studied, childbirth biomechanical models often omit the perineal structures, which play a critical role in the labor process. These structures are particularly prone to perineal lacerations and OASIS, making their inclusion essential for a comprehensive understanding of childbirth biomechanics. The objective of Chapter 2 was to develop a detailed FE model of the PFM and perineum, based on medical imaging data, literature, and expert advice from obstetricians. This model aims to accurately replicate the biomechanical behavior of these structures during vaginal delivery, enabling the identification of the most affected regions.

The first aim of this thesis is to address the following research questions:

- Does the inclusion of perineal structures influence the simulation results for the PFM?
- Which regions of the perineum experience the greatest impact during vaginal delivery from a biomechanical perspective?

Aim 2 – Assess the impact of VAD on maternal soft tissues

Childbirth computational models are powerful tools for simulating various obstetric procedures, particularly those that are understudied and raise unanswered clinical questions. One such procedure is VAD, a common intervention associated with a significant risk of long-term morbidity. Most numerical studies on assisted delivery have primarily focused on the fetal head, often overlooking the impact on maternal tissues. Building on this gap, the main objective of Chapter 3 is to investigate the effects of VAD on maternal structures, using the FE model of the PFM and perineum developed in Chapter 2. The study aims to identify regions most susceptible to injury, explore how variations in contraction duration and resting periods influence maternal tissues, and assess the impact of the number of pulls required for fetal extraction. Ultimately, this work seeks to provide clinicians with deeper insights into the dynamics of VAD, contributing to the inclusion of biomechanical evidence in clinical guidelines.

The following research questions are essential for the second aim of this thesis:

- Which regions of the perineum experience the greatest stress during VAD?
- Does prolonged application of the vacuum cup increase the risk of maternal trauma?
- How do variations in contraction duration and resting phases influence maternal musculature?
- From a biomechanical perspective, is a lower or higher number of pulls more beneficial for maternal structures during fetal extraction?

Aim 3 – Implement a FEM-based ML framework for childbirth simulations

The computational simulations performed in Chapters 2 and 3 highlighted the feasibility of using FE models to simulate the childbirth process and quantify distinct aspects of labor. However, despite their potential, these simulations are computationally intensive and time-consuming, making them impractical for real-time clinical application. The time required to obtain results limits their usefulness for immediate clinical decision-making. To address this challenge, Chapter 4 investigates the use of a FEM-based ML approach to accelerate outcome predictions. By leveraging ML al-

gorithms, this method seeks to predict the stress in critical regions of the PFM during vaginal delivery more efficiently than traditional FE simulations. The primary goal of this study is to demonstrate the viability of integrating AI techniques with childbirth biomechanical simulations, delivering faster and reliable results.

The following research questions guide the third aim of this thesis:

- Can a FEM-based ML approach accurately predict mechanical stress in childbirth simulations?
- How much computational time is saved by using this approach compared to conventional FE simulations?

Aim 4 – Pipeline to integrate a patient-specific surrogate model into clinical practice

The biomechanical properties of maternal tissues are influenced by multiple factors, including pelvic geometry, pelvic floor muscle dimensions, and the diameters of the levator and urogenital hiatus. These factors shape an individual's unique anatomical profile and can vary significantly between women. Additionally, the mechanical properties of these muscles can also have considerable variability. Most childbirth computational models rely on average maternal dimensions and mechanical characterization, limiting their ability to deliver patient-specific results that reflect individual characteristics. To address this, Chapter 5 builds upon the FE model of the PFM from Chapter 2 and the FEM-based ML approach introduced in Chapter 4 to propose a patient-specific approach for predicting the pelvic floor muscle stretch during vaginal delivery. By leveraging FE modeling and ML, the aim of this chapter is to develop a predictive framework that accounts for individual anatomical and mechanical property variations. The focus is on establishing the necessary steps and requirements for clinical implementation, ensuring fast and accurate predictions within a clinically relevant timeframe.

To accomplish its fourth aim, this thesis addresses the following research questions:

- Do variations in anatomical dimensions and material properties influence the successful completion of childbirth simulations?
- Which ML model provides the best prediction of nodal coordinates based on the available data?
- Is the developed algorithm appropriate for testing with real clinical data?

Aim 5 – Experimental characterization of perineal tissues for integration in biomechanical models

The perineal region undergoes substantial deformation during childbirth, yet its biomechanical behavior remains poorly characterized. The perineal body, a crucial structure for maintaining perineal integrity, plays a key role in childbirth-related trauma. Chapter 6 aims to characterize the hyperelastic and viscoelastic mechanical behavior of the perineal body through experimental testing. This is achieved through uniaxial tensile tests and stress-relaxation tests on *post-mortem* female tissue. The primary objectives are to establish a robust experimental protocol for testing this soft biological tissue, analyze its mechanical response, and calibrate the material parameters of a constitutive model based on the experimental results. This characterization will provide a deeper understanding of the biomechanical behavior of the perineal region and essential data for future computational models and numerical simulations, thereby improving the characterization of pelvic tissues.

This thesis's fifth aim focuses on the following research questions:

- Does the perineal body exhibit pronounced hyperelastic behavior?
- Does the perineal body exhibit viscous behavior?
- Is the perineal body composed of collagen fibers? If so, what is their preferential direction?
- Can the experimental data be fitted to a constitutive model that accurately represents the identified characteristics?

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Part II

Modeling and simulation in childbirth biomechanics

Chapter 2

A biomechanical perspective on perineal injuries during childbirth

A biomechanical perspective on perineal injuries during childbirth

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Abstract

Background and Objective: Childbirth trauma is a major health concern that affects millions of women worldwide. Severe degrees of perineal trauma, designated as OASIS, and LAM injuries are associated with long-term morbidity. While significant research has been conducted on LAM avulsions, less attention has been given to perineal trauma and OASIS, which affect up to 90% and 11% of vaginal deliveries, respectively. Despite being widely discussed, childbirth trauma remains unpredictable. This work aims to enhance the modeling of the maternal musculature during childbirth, with a particular focus on understanding the mechanisms underlying the often overlooked perineal injuries.

Methods: A geometrical model of the PFM and perineum (including the perineal body, ischiocavernosus, bulbospongiosus, superficial and deep transverse perineal muscles) was created. The muscles were characterized by a transversely isotropic visco-hyperelastic constitutive model. Two simulations of vaginal delivery were conducted with the fetus in the vertex presentation and occipito-anterior position, with and without the perineum.

Results: The simulation that considered the perineum exhibited higher stresses over an extended area of the PFM, which suggests that including additional structures can impact the obtained results. The maximum stretch of the urogenital hiatus was 2.94 and the maximum stress was 23.86 kPa. The perineal body reached a maximum stretch of 1.95, which was more pronounced near the urogenital hiatus, where perineal tears may occur. The external anal sphincter's transverse diameter decreased by 51% and the maximum principal stresses were observed in the area close to the perineal body, where OASIS can occur.

Conclusions: The present study emphasizes the importance of including most structures involved in vaginal delivery in its biomechanical analysis and represents another step further in the understanding of perineal injuries and OASIS. The superior region of the perineal body and its connection to the urogenital hiatus and anal sphincter have been identified as the most critical regions, highly susceptible to injury.

Keywords: Perineal trauma; Biomechanics of labor; Finite element method; Computational modeling.

2.1 Introduction

The second stage of labor is widely associated with childbirth trauma. The occurrence of severe perineal tears and LAM avulsions can lead to long-term adverse outcomes such as incontinence and pelvic organ prolapse, which can greatly impact a woman's quality of life. Studies indicate that the incidence of perineal trauma can be over 90% in women who deliver vaginally [1]. Third- or fourth-degree tears, designated as OASIS, affect a significant proportion of postpartum women, ranging from 1-11% [2]. Similarly, LAM trauma is known to occur in 13-36% of women [3].

The female pelvis comprises several components, including the bony pelvis, pelvic cavity, pelvic floor, and perineum. Within this complex region, the pelvic floor consists of a muscular sheet that serves primarily as a support structure. This sheet consists of distinct individual muscles, such as the pubococcygeus, iliococcygeus, and puborectalis muscles. The pubococcygeus originates from the pubis and attaches posteriorly to the coccyx. Additionally, the puborectalis, together with the pubococcygeus, arises from the pubis and descends inferiorly on each side to form a sling around the anus. Finally, the iliococcygeus originates from the tendinous arch and converges with the remaining muscle on the other side in the midline [4].

The perineum, which is an approximately diamond-shaped region situated below the LAM, encompasses several important structures. The perineal region comprises the ischiocavernosus, bulbospongiosus, deep, and superficial transverse perineal muscles. Central to this anatomical region is the perineal body, a crucial connective tissue that serves as an attachment site for both the PFM and the surrounding perineal structures. Within the perineum, the ischiocavernosus muscle attaches securely to the ischial tuberosity, while the bulbospongiosus muscle anchors posteriorly to the perineal body and extends anteriorly, attaching to the surface of the bulb and the perineal membrane. Additionally, the superficial transverse perineal muscles run parallel to the posterior margin of the inferior surface of the perineal membrane, anchoring themselves to the ischial tuberosities and extending medially to the perineal body [4]. Figure 2.1 presents the anatomy of the bony pelvis, pelvic floor and perineum.

The occurrence of birth trauma is related to many factors that can be included in a biomechanical analysis, namely women's parity, mode of delivery, duration of the second stage of labor, fetal position and/or presentation, or previous deliveries with injuries. Clinical studies argue that birth tears and OASIS might be indicators of LAM avulsions [5]. Although a widely discussed topic in the medical community, the occurrence of childbirth trauma for a specific delivery remains unpredictable. In a clinical environment, the quantification of the deformation and forces suffered by

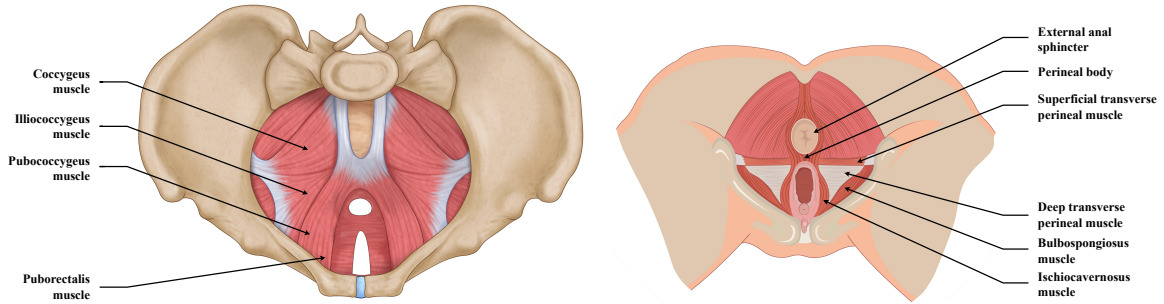


Figure 2.1: Anatomy of the bony pelvis, pelvic floor and perineum.

the muscles is not manageable, and the assessment is mostly qualitative, which does not guarantee the absence of injuries. The identification of specific lesions can be a challenge and requires additional and expensive examinations that are not part of the post-partum common assessment [6]. Thus, clinicians can benefit from insights that guide them in searching for specific lesions.

Computational models are valuable resources to quantitatively analyze the physiology of labor [7]. Childbirth simulations can overcome the limitations of traditional physical models or invasive evaluations, providing insights into the mechanisms of vaginal delivery and associated maternal and fetal injuries. Additionally, it is well-established in clinical practice that various maternal, fetal, and obstetric factors have an impact on the childbirth process, and these factors interact in a way that is difficult to quantify *in vivo*. Therefore, simulations allow for a deeper understanding of the impact of these different factors, and can inform modifications as needed in the future. Furthermore, a biomechanical understanding of the birth process is critical in the development of preventative strategies [8].

Most reported computational models used to simulate the effects of childbirth on maternal injuries focus mainly on the LAM. Previous studies have analyzed mechanical changes on the PFM during delivery [9], quantified muscle damage [10], evaluated the fetus trajectory [11], studied fetal head molding [12], investigated the influence of several obstetric procedures [13], and included time-dependent analyses [14]. Additionally, models of the pelvic cavity have been employed to evaluate the shape of the fetal head and investigate urogenital prolapse [15, 16].

However, none of the previously described models include the perineum in their analysis. Routzong *et al.* (2019) [17] created the first model including the pubovisceral muscle and superficial perineal structures. This study measured the stretch of the pubovisceral muscle and perineal body, concluding that superficial perineal structures play a critical role in female birth injuries and must be considered in computational simulations of vaginal delivery. In 2021, Cechova *et al.* [18] created a FE model includ-

ing both perineum and PFM, evaluating the stresses on the LAM and perineal body obtained due to the fetal head expulsion. Additionally, Chen *et al.* (2021) [19] identified the need to develop a complete representation of the maternal soft tissues since childbirth computational models lack essential anatomical structures as the vagina and superficial perineal structures.

The aim of this research is to conduct a thorough analysis of perineal injuries during childbirth. To achieve this, a FE model of the female pelvis, integrating the pelvic floor and perineum, was developed. The main goals are to accurately represent the dimensions of the levator hiatus in comparison to previous studies, gain a deeper insight into the influence of incorporating perineal structures in the FE analysis of childbirth, and identify the regions that are most susceptible to injury during delivery. Furthermore, conducting a comprehensive mechanical analysis of the different structures and analyze their interactions is crucial. This knowledge will enhance the understanding of the biomechanics of childbirth and contribute to the development of effective strategies to reduce the risk of childbirth-related injuries.

2.2 Methodology

2.2.1 Anatomic modeling of the female pelvis

A geometric model of the PFM, including the levator ani (pubococcygeus, puborectalis, and iliococcygeus) and the coccygeus muscles, was developed. The pelvic bones and the visible parts of the LAM (pubococcygeus and puborectalis muscles) were segmented from MRI of a 30 year-old healthy woman. The geometries were designed in Rhinoceros[®] software, and the illicococcygeus and coccygeus muscles were also included based on obstetrician advice and anatomical information from the literature [4, 20], as they were not visible in the images that were utilized.

In addition to the PFM, the perineum was also considered. Since the perineal region is hardly visible in MRI, the structures were designed according to descriptions from literature [4, 20]. Both superficial and deep perineal pouch were included, namely the perineal body, ischiocavernosus, bulbospongiosus, superficial and deep transverse perineal muscles. To accurately represent the perineum, the model incorporated the pelvic bones and PFM to aid in defining their insertions. The inclusion of the bones played a crucial role in delineating the boundaries of the perineal muscles, specifically the ischiocavernosus, bulbospongiosus, and superficial transverse perineal muscles. To achieve this, a three-dimensional model of the pelvic bones obtained from the same 30-year-old healthy woman's MRI was used. It is worth noting that the pelvic diameters closely align with the average values reported in the literature [21]. Consequently,

the dimensions of the muscles also approximate the average external measurements, as these dimensions are primarily defined by their insertions. A representation of the geometric model of the PFM and perineum can be seen in Figure 2.2.

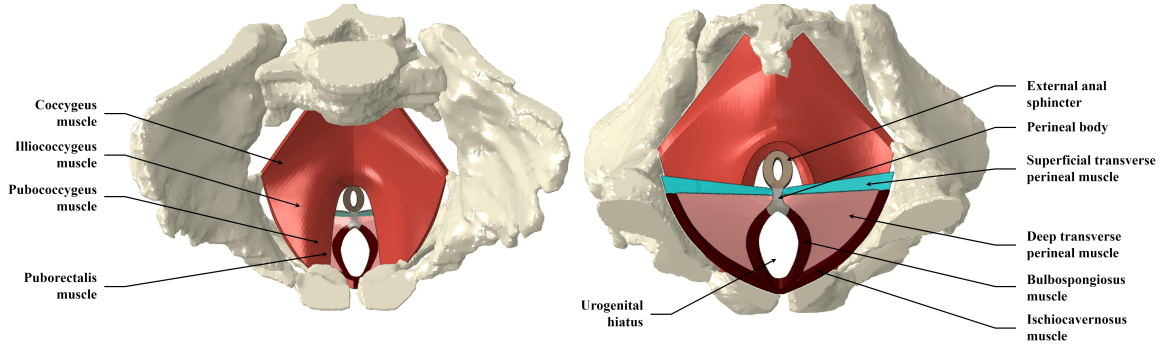


Figure 2.2: Geometric model of the PFM (coccygeus, iliococcygeus, pubococcygeus and puborectalis muscle) and perineum (perineal body, external anal sphincter, ischiocavernosus, bulbospongiosus, superficial transverse and deep transverse perineal muscles). The urogenital hiatus consists of the space through which the urethra and the vagina pass. The left figure corresponds to a superior view of the female pelvis and the right figure to an inferior view.

The superficial layer of the external anal sphincter, which inserts into the perineal body, was also included, joining the superficial transverse perineal muscle, the levator ani, and the bulbospongiosus muscle.

The geometrical model was exported to Abaqus[®] software to generate a FE mesh. A mesh composed of hexahedral solid elements was generated, comprising 5712 nodes and 3618 C3D8H elements for the PFM, and 7253 nodes and 4862 C3D8H elements for the perineum. The PFM was defined with varying thicknesses. The puborectalis and pubococcygeus muscles were determined to have a thickness of 6.5 mm [22], whereas the iliococcygeus and coccygeus muscles were modeled with a thickness of 3.6 mm [23]. Concerning the perineum, the thickness was defined as 4.0 mm for the bulbospongiosus, ischiocavernosus and perineal body, 2.0 mm for the superficial and deep transverse perineal muscles, and 6.0 mm for the external anal sphincter [24, 25]. Additionally, the transverse and anteroposterior diameters of the external anal sphincter opening were considered approximately 4.7 mm and 11.2 mm, respectively [26]. The levator hiatus was defined with a anteroposterior and transverse diameter of 5.7 cm and 3.2 cm, respectively [27, 28].

2.2.2 Mechanical characterization

The PFM and most of the perineal muscles (ischiocavernosus, superficial and deep transverse perineal muscles) were characterized by a transversely isotropic visco-hyperelastic constitutive model proposed by Martins *et al.* (1998) [29] and previously used by Parente *et al.* (2008) [9]. The viscoelastic contribution was implemented by Vila Pouca *et al.* (2017) [14].

Regarding the constitutive model, the strain energy density per unit volume is given by the following expression presented in Equation 2.1.

$$\begin{aligned} \Psi = & \underbrace{c\{e^{b(\bar{I}_1-3)} - 1\}}_{\bar{\Psi}_m} + \underbrace{A\{e^{[a(\bar{\lambda}_f-1)^2]} - 1\}}_{\bar{\Psi}_{fPE}} \\ & + \underbrace{\theta T_0^M \int_1^{\bar{\lambda}_f} -4(\bar{\lambda}_f - 1)^2 + 1 \, d\bar{\lambda}_f}_{\bar{\Psi}_{fSE}} + \underbrace{\frac{1}{D}(J-1)^2}_{\Psi_{vol}} \end{aligned} \quad (2.1)$$

where $\bar{\Psi}_m$ corresponds to the isotropic strain energy stored in the isotropic matrix, $\bar{\Psi}_{fPE}$ and $\bar{\Psi}_{fSE}$ represent, respectively, the passive and active parts of the strain energy stored in each muscle fiber, and Ψ_{vol} is related to the volume change. $\bar{I}_1$ is the first invariant of the right Cauchy-Green strain tensor with the volume change eliminated, $\bar{\lambda}_f$ represents the stretch ratio of the muscle fibers, T_0^M is the maximum muscle tension produced by the muscle at resting, $\theta \in [0, 1]$ defines the level of activation, and $J = \det(\mathbf{F})$ is the volume ratio, where $\mathbf{F}$ is the deformation gradient. c , b , A , a and D are constitutive parameters. In this work, only the passive behavior of the muscles were included, thus it was assumed $\theta = 0$ for all the simulations, considering that the muscles are fully relaxed due to anesthesia, which is seen in more than 60% of women who have vaginal birth according to the Centers for Disease Control [30].

The viscoelastic contribution is represented by the generalized Maxwell model. The implementation includes the addition of a dissipative potential to the strain energy function (Equation 2.2), describing the non-equilibrium state.

$$\Psi(\mathbf{C}, \mathbf{\Gamma}_1, \dots, \mathbf{\Gamma}_m) = \Psi_{vol}^\infty(J) + \Psi_{iso}^\infty(\bar{\mathbf{C}}) + \sum_{\alpha=1}^m Y_\alpha(\bar{\mathbf{C}}, \bar{\mathbf{\Gamma}}_\alpha) \quad (2.2)$$

The configurational free energy Y_α is a function of the modified right Cauchy-Green strain tensor, $\bar{\mathbf{C}}$, and a set of strain-like internal variables denoted by $\bar{\mathbf{\Gamma}}_\alpha$. The latter characterizes the relaxation and/or creep behavior of the material. The viscoelastic

behavior is modeled by $\alpha=1,\dots,m$ viscoelastic processes.

The second Piola-Kirchhoff stress can be decomposed into an equilibrium part and a non-equilibrium part characterized by the elastic response of the system and the viscoelastic response, respectively, as demonstrated in Equation 2.3.

$$\mathbf{S} = \mathbf{S}_{vol}^\infty + \mathbf{S}_m^\infty + \mathbf{S}_f^\infty + \sum_{\alpha=1}^m \mathbf{Q}_\alpha \quad (2.3)$$

where $\mathbf{S}_{vol}^\infty$, $\mathbf{S}_m^\infty$ and $\mathbf{S}_f^\infty$ denote the volumetric, matrix and fiber contribution of the second Piola-Kirchhoff stress tensor, and $\mathbf{Q}_\alpha$ correspond to the isochoric non-equilibrium stresses arising from the viscous effects:

$$\mathbf{Q}_\alpha = \exp(-T/\tau_\alpha) \mathbf{Q}_\alpha^{0+} + \int_{t=0+}^{t=T} \exp\left[\frac{-(T-t)}{\tau_\alpha}\right] \beta_\alpha \dot{\mathbf{S}}_\alpha dt \quad (2.4)$$

where τ_α and β_α consist of the relaxation time and free-energy parameters, representing the viscoelastic properties derived from the Maxwell model with α parallel elements.

The material parameters used to characterize the PFM and the perineal muscles are presented in Table 2.1.

Table 2.1: Material parameters used to characterize the pelvic floor and perineal muscles.

Hyperelastic parameters [31]	Viscoelastic parameters [14]			
$c = 0.0185$ MPa	$\beta_{m1} = 1.5$ (-)	$\tau_{m1} = 20$ s	$\beta_{f1} = 1.2$ (-)	$\tau_{f1} = 0.9$ s
$b = 1.1730$ (-)	$\beta_{m2} = 0.7$ (-)	$\tau_{m2} = 400$ s	$\beta_{f2} = 0.5$ (-)	$\tau_{f2} = 250$ s
$A = 0.0280$ MPa	$\beta_{m3} = 0.5$ (-)	$\tau_{m3} = 5000$ s	$\beta_{f3} = 0.3$ (-)	$\tau_{f3} = 3500$ s
$a = 0.6215$ (-)				

The perineal body and bulbospongiosus muscle were considered linear elastic ($E = 23.8$ kPa and $\nu = 0.49$) [32]. The Neo-Hookean model was used to characterize the external anal sphincter. A stress-strain curve of the human sphincter [33] was used as reference to define the material constant value, however the stiffness was increased to consider the presence of the surrounding structures that provide stability to the sphincter. Thus, the material constant was defined as $c = 0.1$ MPa. To define this value, a sensitivity analysis was performed and distinct values were tested until the behavior of the structure was as anatomically expected.

To facilitate a comparison between the present study and related work in the literature, Table 2.2 provides an overview of the constitutive models employed in this research for characterizing the pelvic floor and perineal muscles, as well as those utilized by Routzong *et al.* (2019) [17] and Cechova *et al.* (2021) [18].

Table 2.2: Comparison of the mechanical characterization of the pelvic floor and perineal muscles across distinct studies.

	Current study	Routzong <i>et al.</i> (2019) [17]	Cechova <i>et al.</i> (2021) [18]
Characterization	Visco-hyperelastic transversely isotropic	Hyperelastic and isotropic	Hyperelastic and isotropic
Constitutive model	Martins	Neo-Hookean	Ogden
Source	Human vaginal tissue	Not mentioned	Porcine muscle

2.2.3 Simulations of vaginal delivery

The simulations were performed in Abaqus[®] software to mimic the second stage of labor with the fetus in the occipito-anterior position and vertex presentation. Two distinct simulations were conducted: the first one, performed for comparison purposes, exclusively considered the PFM (Simulation 1), while the second included the perineal region (Simulation 2). Both simulations were performed with a duration of 100 minutes to replicate an average second stage of labor in nulliparous [34].

Regarding boundary conditions, the nodes on the extremities of the PFM were fixed. The nodes located at the extremities of the superficial transverse perineal muscles, as well as those of the bulbospongiosus muscles in proximity to the pubic symphysis, were also fixed. Furthermore, to accurately reflect the anatomical attachment of the external portion of the ischiocavernosus muscles to the ischium, the nodes corresponding to these muscles were fixed in the y-axis. The mentioned boundary conditions are illustrated in Figure 2.3.

In the simulation process, the interactions between the PFM, perineum, and fetal head were modeled using the standard Abaqus[®] contact algorithm. Kinematic contact conditions were imposed through the establishment of contact constraints between the aforementioned anatomical structures, recurring to the Augmented Lagrange method to facilitate surface interactions.

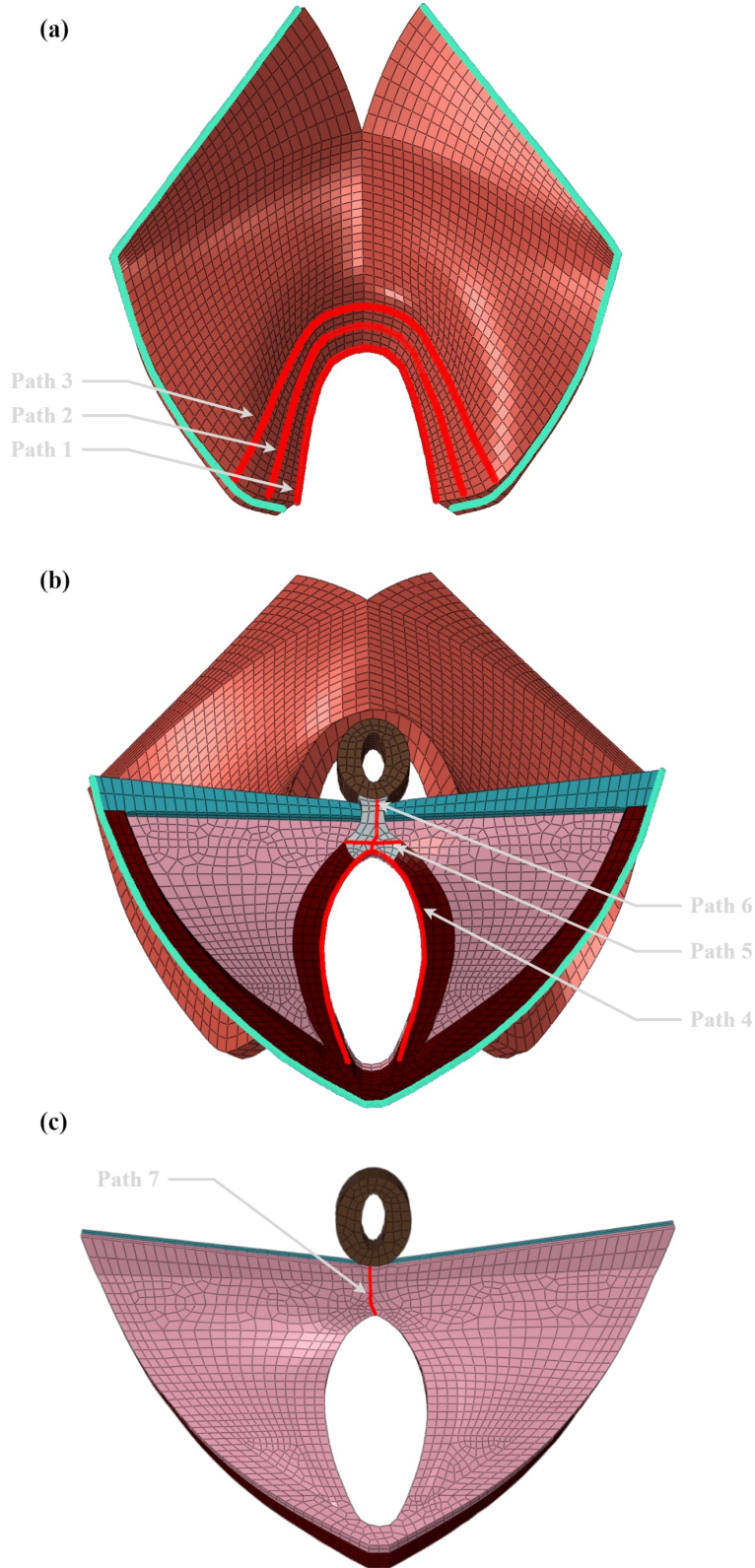


Figure 2.3: Boundary conditions and paths defined on the FE mesh. The light blue lines represent the fixed nodes. The red lines demonstrate the different paths established to calculate the stretch and measure the maximum principal stress on the distinct structures. (a) Path 1, 2 and 3. Path 1 corresponds to the levator hiatus. (b) Urogenital hiatus represented by Path 4. Inferior view of the perineal body, Path 5 and 6. (c) Superior view of the perineal body, Path 7.

The fetus head used was considered rigid and was anatomically modeled with dimensions in agreement with the literature for a full-term fetus: suboccipitobregmatic diameter, 10 cm; suboccipitofrontal diameter, 10.5 cm; occipito-frontal diameter, 12.0 cm; mentovertical diameter, 13.0 cm; and submentobregmatic diameter, 11.5 cm [9]. The descent and extension of the fetal head were controlled by a reference node, while the remaining degrees of freedom were left free. The trajectory of the fetal head was based on the cardinal movements of labor and on the Curve of Carus defined by Jing *et al.* (2012) [35]. This curve illustrates the anteroposterior movement in relation to the vertical displacement of the fetal head. In the present simulations, the vertical movement of the fetal head is considered up to 90 mm, which aligns with the average length of the birth canal. Simultaneously, the posterior displacement reaches approximately 45 mm. Although the pelvic bones were not included in the simulation, the boundary conditions applied to the PFM, specifically the fixed nodes near the pubic symphysis insertions, were sufficient to limit the movement of the head during the descent. The position of the fetal head along different stages of descent is presented in Figure 2.4.

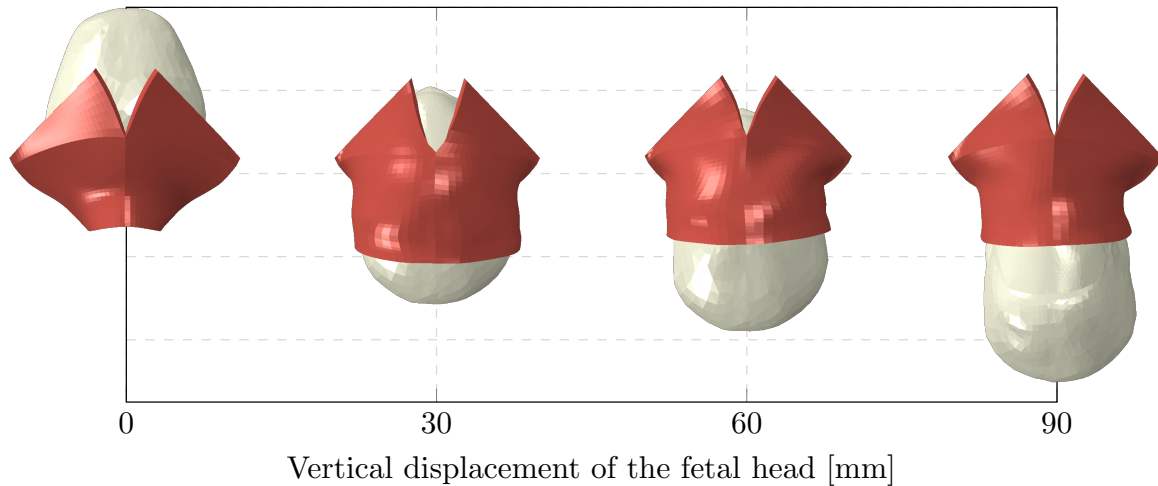


Figure 2.4: Evolution of the fetal head in relation to the PFM from the initial position (0 mm of fetal descent).

The maximum principal stresses were quantitatively assessed for both simulations. Additionally, the stretch on the PFM, urogenital hiatus and perineal body was also analyzed. To evaluate the stretch, which is defined as the ratio between the current and the original length, different paths were defined within these structures, as presented in Figure 2.3. This methodology allows for the measurement of length variations during the simulation, thus enabling the determination of stretch values in relation to fetal descent. Furthermore, to biomechanically analyze the region where the perineal tears may occur during vaginal delivery, a vertical and a horizontal path were established in the perineal body to evaluate the stretch and stresses.

2.3 Results

Figure 2.5 illustrates the stretch along the vertical displacement of the fetal head for the PFM and urogenital hiatus. The maximum stretch obtained for the PFM at Path 1 was determined to be 2.15, corresponding to a vertical displacement of 74.72 mm and 65.24 mm, in simulations 1 and 2, respectively. The urogenital hiatus displayed a maximum stretch of 2.94 at a vertical displacement of 84 mm, measured at Path 4, with these results only being obtained in simulation 2 as simulation 1 did not incorporate the perineum.

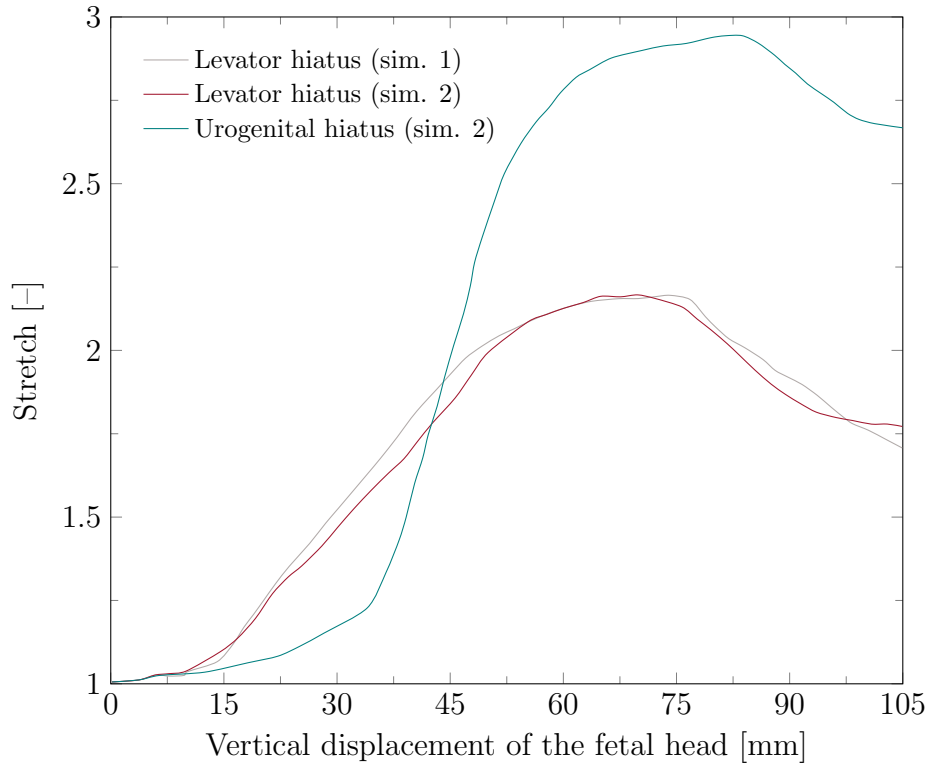


Figure 2.5: Stretch of the PFM in Path 1 (simulations 1 and 2) and urogenital hiatus in Path 4 (simulation 2) during the vertical displacement of the fetal head.

The measurement of the maximum principal stress for the PFM was taken at the respective time points for maximum stretch along Paths 1, 2 and 3, as shown in Figure 2.6. The highest stresses recorded for the PFM for simulations 1 and 2 were, respectively, 15.03 MPa and 11.75 MPa (Path 1), 9.41 MPa and 12.79 MPa (Path 2), and 5.67 MPa and 13.01 MPa (Path 3).

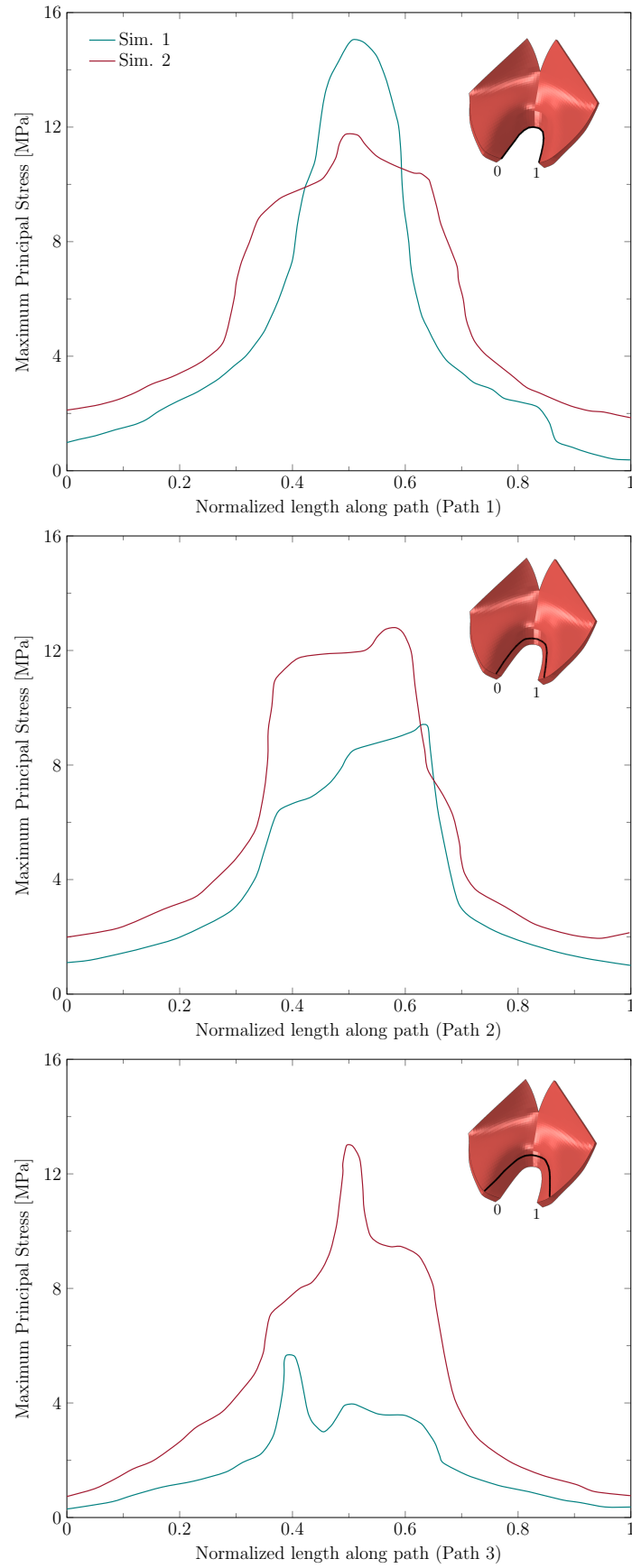


Figure 2.6: Maximum principal stress (in MPa) measured on the paths defined on the PFM (Path 1, 2 and 3), for simulations 1 and 2.

Figure 2.7 illustrates the distribution of maximum principal stress ranging from 5 to 15 MPa in the PFM during the moment of peak stretch in each simulation.

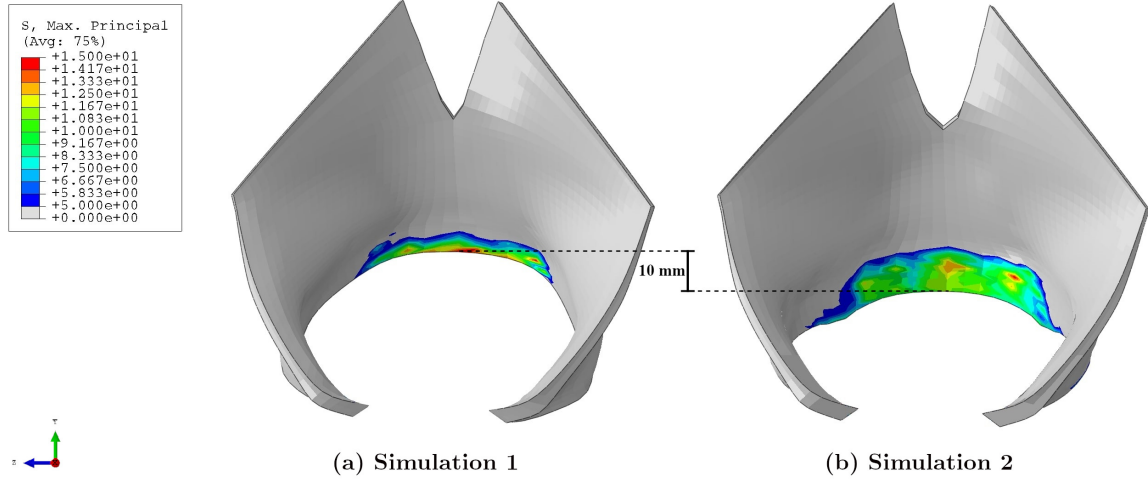


Figure 2.7: Maximum principal stress distribution (in MPa) observed in the most affected region of the PFM for (a) simulation 1, without the perineum, and (b) simulation 2, with the perineum. In simulation 2, the vertical displacement (in the y-axis direction) of the PFM is nearly 10 mm greater than in simulation 1.

The maximum principal stress was also measured in the urogenital hiatus, corresponding to Path 4, at the moment of maximum stretch (84 mm of fetal descent), registering a maximum value of 23.86 kPa, as demonstrated in Figure 2.8.

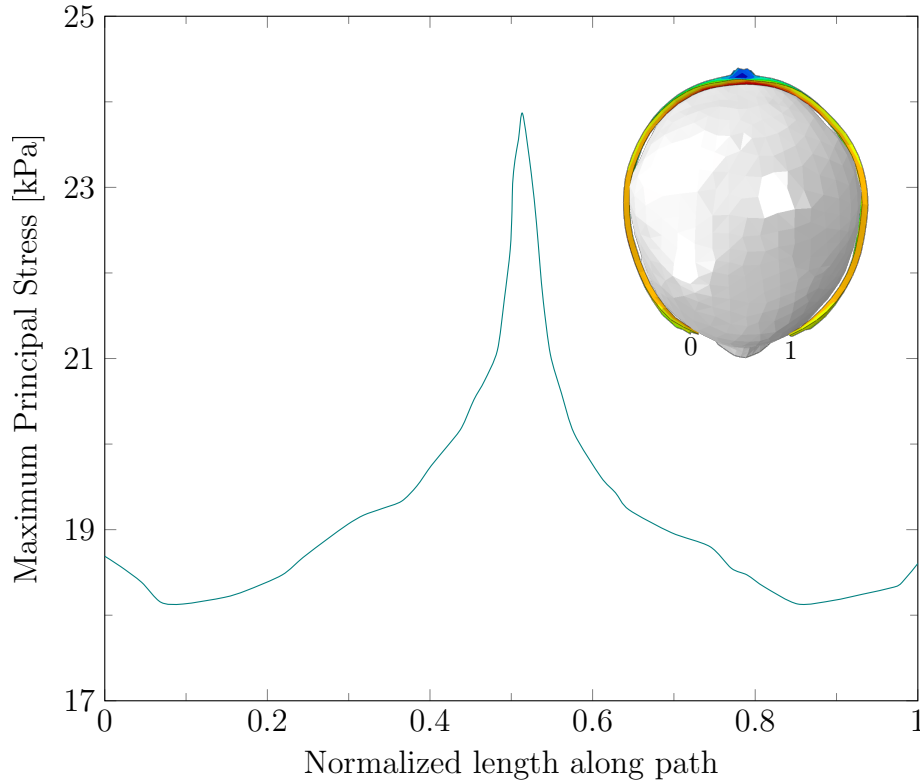


Figure 2.8: Maximum principal stress (in kPa) measured on the path defined on the urogenital hiatus (Path 4). The position of the fetal head at the instance of maximum stretch (approximately 84 mm) for simulation 2 is presented.

Three paths were defined in the perineal body to measure the stretch and stresses, as demonstrated in Figure 2.3. The results revealed that the maximum stretch for Path 5 was 1.95 and for Path 6 and 7 was 1.62, respectively, with corresponding vertical displacements of the fetal head at approximately 84 and 65 mm. Additionally, the maximum principal stresses for the perineal body were determined to be 13.96, 11.98, and 13.31 kPa, respectively, for Path 5, Path 6, and Path 7, with corresponding vertical displacements of approximately 82, 71 and 71 mm. The data gathered from these measurements is presented in Figure 2.9.

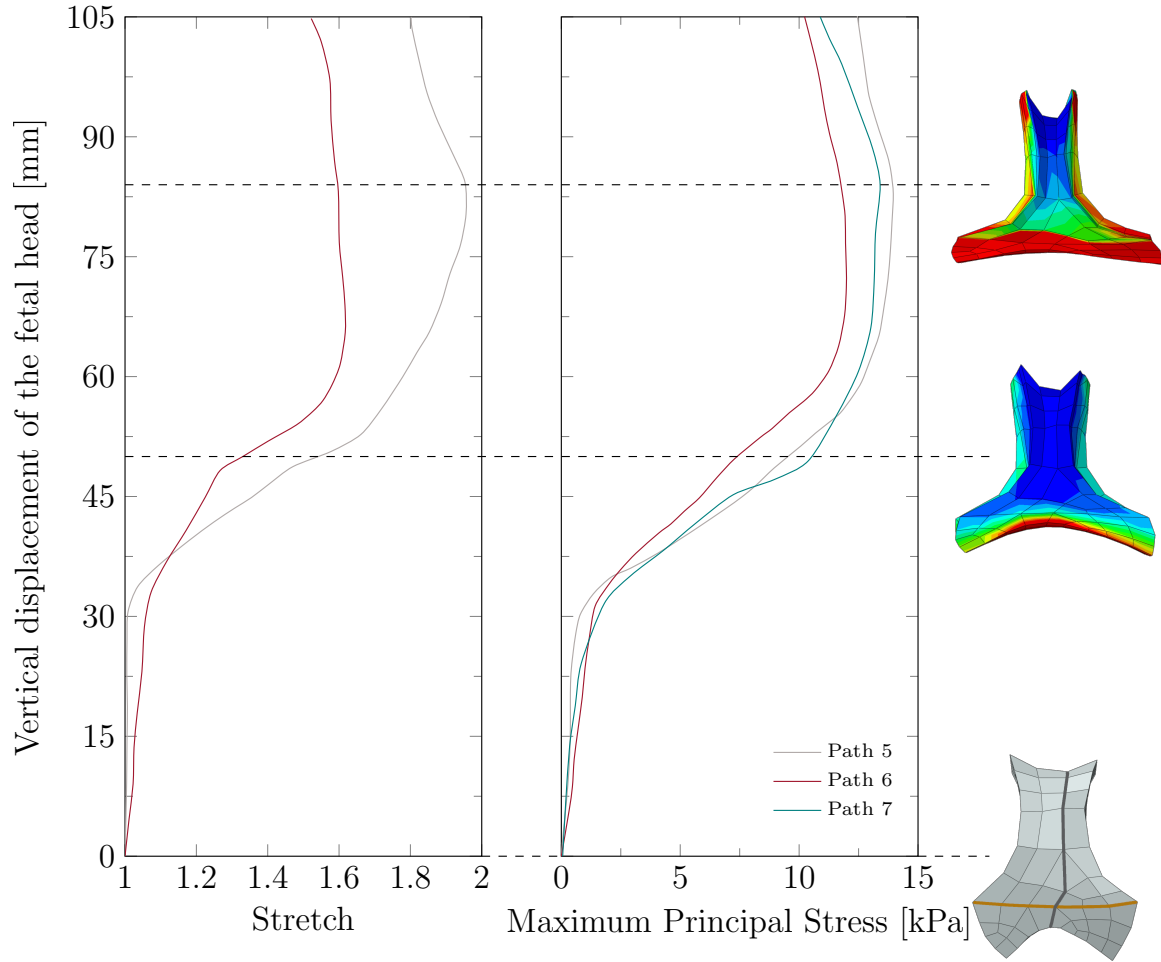


Figure 2.9: Stretch and maximum principal stress (in kPa) measured in different paths of the perineal body along the vertical displacement of the fetal head. In the stretch representation, Path 6 and 7 overlap since the stretch is equal for both cases.

As depicted in Figure 2.10, the variations in the diameters of the external anal sphincter were measured during fetal descent. Specifically, the anteroposterior diameter exhibited an approximate increase of 20%, reaching a maximum of 14.05 mm. Conversely, the transverse diameter exhibited a maximum decrease of approximately 51.4%.

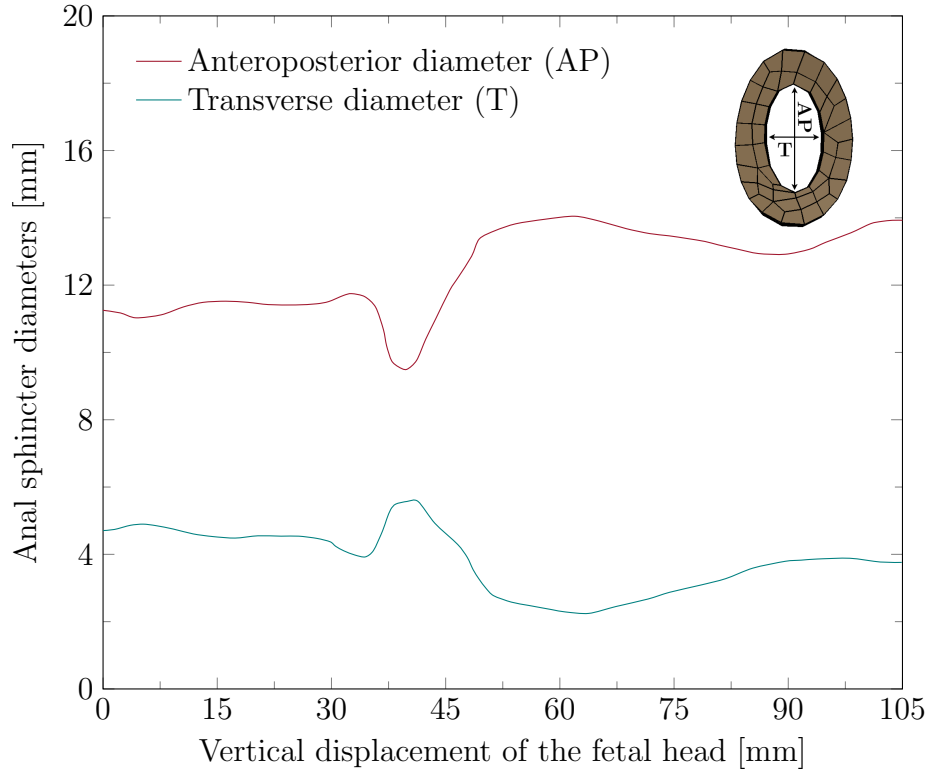


Figure 2.10: Transverse and anteroposterior diameters of the external anal sphincter during the vertical displacement of the fetal head.

2.4 Discussion

The mechanical behavior of the perineum during childbirth has not yet been properly investigated. Although several studies have addressed the biomechanics of childbirth, most focus only on pelvic floor disorders, neglecting prevalent injuries such as perineal lacerations or OASIS. The main goal of the present work is to create a FE model capable of simulating childbirth that contemplates the perineum and enables to identify the most critical regions. This model has the potential to enhance the current knowledge on the biomechanical behavior of the perineal structures.

The geometry of the PFM was enhanced in comparison to previous studies, with dimensions between the ranges detailed in the literature for the levator hiatus. In the present study, the amount of stretch obtained was considerably higher compared to previous studies used to simulate childbirth, such as Parente *et al.* (2008) [9], in which the stretch was approximately 1.63. This difference can be attributed to the different geometry used in the current work, as smaller dimensions were employed to model the levator hiatus in order to achieve a more realistic representation of the limited space available for the fetus to descend.

The present study demonstrates that including the perineal structures increases the area of the PFM subjected to higher stresses. By comparing the stress distribution within the muscle, as illustrated in Figure 2.7, it becomes evident that within a specific range of stresses, the impact extends to a larger area of the pelvic floor near the levator hiatus when the perineum is included. This difference can be attributed to the increase in the vertical displacement of the PFM (nearly 10 mm) in the presence of the perineum. The presence of perineal structures prevents the PFM from retracting as the fetal head passes through, as they impose additional constraints. This leads to a behavior that more closely approximates to the birthing process, as similarly noted by previous studies [17, 18].

Overall, the inclusion of perineal structures in the simulation of childbirth imposes additional constraints on the PFM due to the boundary conditions and interactions they create. This further emphasizes the importance of their consideration in future simulations. The first study that included perineal structures in vaginal delivery was presented by Routzong *et al.* (2019) [17] with the aim of determining the impact of these structures on the stretch ratios of the pubovisceral muscle and perineal body, along with assessing the angle of progression of the fetal head and perineal body. The present study adopts a more extensive analytical approach, conducting a comprehensive examination of the stretch in the levator and urogenital hiatus, as well as evaluating stress distribution in multiple critical areas of the perineum. In the model that included the perineum, the stretch of the perineal body determined in Routzong's study was 4.10, a significantly higher value compared to the results obtained in the current study. This difference could potentially be attributed to variations in the mechanical properties or kinematics of the simulation, as all maternal muscles were treated as hyperelastic and isotropic, with no distinction made between the material properties of the different muscles. The rotation of the fetal head was also defined differently in the two studies. Additionally, the authors observed a decrease in the stretch of the pubovisceral muscle when the perineum was included, whereas in our present study, the stretch remained approximately the same in both simulations. Since stretch is primarily influenced by mechanical factors and predominantly depends on the trajectory of the fetal head, we can conclude that the inclusion of the perineum in our study does not modify the trajectory of the fetal head.

Cechova *et al.* (2021) [18] concluded that including perineal structures in a childbirth simulation led to an increased level of stress in the LAM, which aligns with the findings of the present work. Furthermore, the mentioned study concludes that in the presence of the perineum, there is an increase in the downward displacement of the PFM, which also supports the presented results. In their simulation involving the LAM and perineum, the authors reported a maximum stress of 88.7 MPa in the pubovisceral muscle

and 119.6 MPa in the perineal body. Both of these values are considerably higher than those obtained in our study. This difference could be attributed to variations in the mechanical properties used to characterize the muscles. Table 2.2 presents a comparison of the mechanical characterization used for the pelvic floor and perineal muscles in the studies analyzed in the present work. Unfortunately, the authors did not provide information about the dimensions of the urogenital hiatus considered in their study. Therefore, it is not possible to analyze whether the differences in stresses could be due to distinct geometries. The results obtained in various studies are challenging to compare due to several factors. These include the variable inclusion or exclusion of structures in the models, uncertainty in the anatomical description of the pelvic floor, and the wide range of available mechanical properties and constitutive models.

Comparing different studies shows that there are many variations and unique factors to consider when using a FE model for simulating childbirth. For the practical integration of these models into clinical applications, the scientific community needs to agree on which structures to include, how to describe their biomechanical interactions, which constitutive models are most suitable for each, and general dimensions that can be adjusted later. This approach could lead to a generic model that can be customized for individual patients by simply changing pre-defined parameters to specific dimensions and material properties.

The perineal body, a critical area of the perineum, is subject to significant stretching and can incur perineal tears of varying degrees of severity during childbirth. In the simulations performed, it has been determined that the stretch on the perineal body is most pronounced near the urogenital hiatus, as a result of the pressure exerted by the fetal head. This region is particularly vulnerable to perineal tears and in certain cases, an episiotomy may be necessary to prevent excessive damage when pressure is too intense. The peak stress on the perineal body coincides with the instants of maximum stretch, with the most critical moment occurring between 6 and 9 cm of descent through the birth canal. Additionally, it was observed that the superior region of the perineal body experiences higher levels of stress compared to the inferior region. This observation could potentially assist in identifying concealed lacerations in the superior part of the perineum, which occasionally occur and remain unseen. The current study did not incorporate any damage criteria as no stress-strain curve that includes rupture was identified in existing literature for use in the characterization of this structure. However, the inclusion of such analysis would be pertinent to gain a deeper understanding of the damage mechanisms associated with perineal tears.

During vaginal delivery, the anus undergoes dilation and the rectum epithelium becomes visible, a phenomenon described as anal dilation [36]. Through the childbirth

simulations performed, the behavior of the external anal sphincter can be analyzed, and changes in diameters can indicate the possibility of occurrence of the described dilation. An increase of approximately 20% of the anteroposterior diameter and a decrease of 51.4% on the transverse diameter of the anal sphincter was registered during crowning. The excessive mechanical stress to which this muscle structure is subjected to can be responsible for facilitating the occurrence of anal sphincter injuries. Establishing a threshold for the level of stretch that results in rupture of the anal sphincter would greatly enhance our understanding of the relevant values, yet to the best of our knowledge, no such reference has been previously documented in the literature. In the simulations performed, the maximum principal stresses in the anal sphincter were observed in the area near the connection with the perineal body and transverse perineal muscle. This outcome is consistent with what was expected since OASIS occurs in this region.

The present work has several limitations. In the performed simulations, the fetal head was considered a rigid structure. Given that simulations become more computationally demanding when accounting for a deformable head, as demonstrated in previous research, this simplification was adopted to facilitate the convergence of the simulations [9, 13]. Additionally, the lack of mechanical properties to accurately characterize the perineal muscles can make their behavior not completely identical to reality. To address this, further mechanical testing is necessary to determine the mechanical properties of these structures. Another limitation is the limited knowledge among obstetricians regarding the dimensions and thickness of the perineal muscles, as they are often not visible in imaging examinations. Furthermore, there is not a consensus among the medical community regarding the anatomy of the perineal region, making it challenging to clinically validate the simulation's representation of the muscles' geometry and behavior during childbirth. This lack of consensus underscores the need for continued research and collaboration within the medical field to refine the understanding of perineal anatomy and its dynamic response to the complexities of childbirth.

Nevertheless, this study presents a FE model to simulate vaginal delivery, consisting of a step forward in the investigation of childbirth-associated injuries. This model incorporates complex constitutive models to accurately characterize the muscles and includes the consideration of viscoelasticity. This study presents the first attempt to analyze both stretch and stress in the critical areas that can be injured during childbirth (levator hiatus, urogenital hiatus, and perineal body). To summarize, biomechanically, the critical regions that have been identified include the perineal body near the urogenital hiatus, the superior region of the perineal body (which is sometimes overlooked), and the area connecting the anal sphincter to the perineal body and transverse muscles. As future work, the integration of a deformable fetal head into the

model would enable an examination of the perineum's influence on fetal head molding. Including other structures involved in vaginal delivery, namely the soft and body structures of birth canal and the uterus, would serve to enhance the model's results and facilitate more sophisticated analyses. Furthermore, this perineal model can be used to study the distinct degrees of perineal tears that occur during childbirth, as well as to analyze the impact of episiotomies on perineal muscle damage. Finally, further advancements in the geometry and characterization of the anal sphincter would allow for more detailed studies of OASIS.

Acknowledgments

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Chapter 3

Computational modeling of vacuum-assisted delivery: biomechanics of maternal soft tissues

Computational modeling of vacuum-assisted delivery: biomechanics of maternal soft tissues

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Abstract

Childbirth is a complex process influenced by physiological, mechanical, and hormonal factors. While natural vaginal delivery is the safest, it is not always feasible due to diverse circumstances. In such cases, assisted-delivery techniques, such as VAD, may facilitate vaginal birth. However, this technique can be associated with a higher risk of maternal injuries, potentially resulting in long-term conditions such as pelvic organ prolapse or incontinence. This study investigates the biomechanical impact of VAD on maternal tissues, aiming to reduce these risks. A FE model was developed to simulate VAD, incorporating maternal musculature, a deformable fetal head, and a vacuum cup. Twelve simulations were conducted, varying contraction durations, resting intervals, and the number of pulls required for fetal extraction. Results revealed that prolonged contraction durations, coupled with extended resting intervals, lead to a reduction in pelvic floor stress. Elevated stress levels were observed when fetal extraction involved two pulls, with an 8.43% decrease in maximum stress from two pulls to four. The peak stress recorded was 0.81 MPa during a 60-second contraction, followed by a 60-second rest period. These findings indicate that longer maneuvers may reduce trauma, as extended pulls allow muscles more time to relax and recover during both contraction and rest phases. Furthermore, an increased number of pulls extends the duration of the maneuver, facilitating fetal rotation and improved adjustment to the birth canal. This study offers crucial insights into the biomechanics of childbirth, providing clinicians with valuable information to enhance maternal outcomes and refine assisted delivery techniques.

3.1 Introduction

Childbirth, though a natural process, is often associated with significant physical trauma for women. The spectrum of childbirth-related injuries ranges from levator ani avulsion to perineal lacerations, all of which can have a profound impact on a woman's quality of life. Among the techniques used to aid vaginal delivery, VAD is a common intervention to facilitate the birth process when it is not progressing naturally. VAD rates vary by country, ranging between 10% to 15% in the United States, and 10% to 13% in the United Kingdom [1].

Despite its common occurrence, VAD raises serious concerns regarding maternal pelvic floor dysfunction. Substantial evidence indicates that instrumental deliveries significantly increase maternal morbidity, including perineal trauma and long-term urinary and fecal incontinence [2]. Notably, studies indicate that around 30% of women who underwent VAD reported new-onset incontinence of any kind [3], and that maternal soft tissue trauma can range between 21% and 36% [2], underscoring the clinical significance of these complications. Of particular concern is the technique's association with LAM injuries, with avulsion rates reported as high as 34% in vacuum extractions [4]. Additionally, VAD is linked to a higher rate of third- and fourth-degree perineal lacerations (10%) compared to spontaneous vaginal deliveries (2%) [5]. Although forceps deliveries are associated with an even higher incidence of maternal complications, their use has declined substantially in recent decades. As VAD becomes the predominant operative vaginal delivery technique, there is a growing need for further investigation into its short- and long-term maternal outcomes.

From a clinical perspective, there are still some unanswered questions. Obstetricians are uncertain about how long vacuum extraction should last, how long the vacuum cup should be in place, and the biomechanical effects of its duration on the pelvic floor and perineum. Additionally, the acceptable number of pulls is also unknown, and most guidelines are based on observational studies. The relationship between the number of pulls and adverse outcomes remains unclear [6]. Given the significant impact of assisted vaginal birth on maternal health and the lack of conclusive evidence on the specific risks associated with vacuum extraction, there is an urgent need for extensive studies to elucidate the biomechanical factors underlying childbirth-related injuries.

Computational models offer significant value in the quantitative analysis of the physiology of labor. Childbirth simulations can overcome the limitations of traditional physical models and invasive procedures, providing a deeper understanding of the mechanisms involved in vaginal delivery and the resulting maternal and fetal injuries [7]. Several computational models have been developed to simulate normal vaginal deliv-

ery. Previous research has explored mechanical changes in the PFM during delivery, quantified muscle damage, assessed the trajectory of the fetus, studied fetal head molding, examined the effects of various obstetric procedures, and conducted time-dependent analyses [8, 9, 10, 11, 12, 13]. Additionally, models of the pelvic cavity have been used to evaluate the shape of the fetal head and investigate urogenital prolapse [14, 15]. More recently, childbirth computational models have incorporated perineal tissues in the analysis of maternal injuries to improve the ability to predict distinct lesions [16, 17].

Although there are numerous studies in the literature on VAD, FE simulations of this delivery method have not been properly addressed. Only a handful of studies have focused on simulating assisted delivery. For example, Lapeer *et al.* (2014) [18] used a FE analysis to simulate vacuum extraction during delivery, while Huang *et al.* (2022) [19] examined the effects of different sizes of vacuum extractors during delivery. In the area of forceps delivery, Su *et al.* (2016) [20] investigated the influence of forceps blade angles on the fetal head. However, these studies primarily focused on the deformations or stresses on the fetal head induced by these procedures and neglected to evaluate their effects on maternal tissues.

The primary objective of this study is to investigate the effects of VAD on maternal tissues, with particular emphasis on the PFM and perineum. A key focus is to identify the regions most susceptible to injury, offering a clearer understanding of the biomechanical impact of VAD on these critical structures. The study also explores how variations in the duration of contractions and resting periods between pulls influence maternal tissue outcomes, along with the correlation between the number of pulls required for successful delivery and the degree of tissue trauma. By employing a computational approach, this work aims to provide insights that could inform clinical practice and improve maternal health outcomes.

3.2 Methodology

3.2.1 Biomechanical model

A FE model of the PFM, perineal structures, and fetal head was used to simulate VAD. The model of the PFM and perineum was developed in a previous study by Moura *et al.* (2024) [17], including the levator ani and coccygeus muscles, perineal body, ischiocavernosus, bulbospongiosus, superficial and deep transverse perineal muscles, and the superficial layer of the external anal sphincter. The PFM mesh comprises 5712 nodes and 3618 hexahedral elements (C3D8H), while the perineum has 7253 nodes and 4862 C3D8H elements. Hybrid elements were used in this study because the

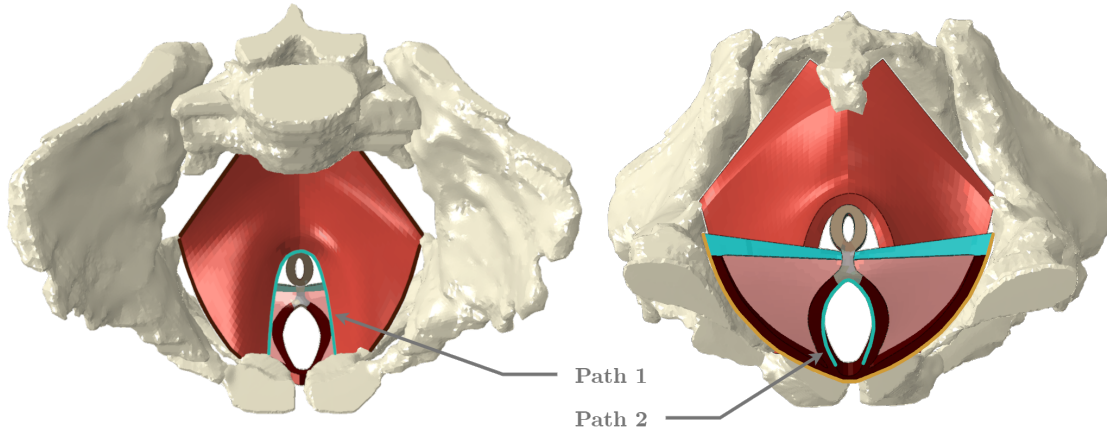


Figure 3.1: Geometric model of the PFM, in red, and perineum. The perineal body is presented in gray, the external anal sphincter in brown, the ischiocavernosus and bulbospongiosus muscles in dark red, the superficial transverse perineal muscle in blue, and deep transverse perineal muscles in pink. The blue lines correspond to two paths defined on the levator hiatus, path 1, and the urogenital hiatus, path 2 (the space through which the urethra and the vagina pass). The dark brown line corresponds to the fixed nodes of the PFM, while the yellow line corresponds to the constrained nodes of the ischiocavernosus and superficial transverse perineal muscles. The left figure corresponds to a superior view of the female pelvis and the right figure to an inferior view.

modeled tissues are hyperelastic and nearly incompressible. In such cases, standard elements can suffer from volumetric locking. The hybrid formulation introduces an additional degree of freedom to enforce incompressibility through a pressure variable, which significantly enhances numerical stability. The complete FE model used is presented in Figure 3.1, and further details can be found in the aforementioned work.

The fetal head was modeled with dimensions consistent with the literature for a full-term fetus [8]. It was represented as a deformable structure consisting of 4388 nodes and 19537 tetrahedral elements (C3D4H). To manage the complexity of the numerical simulations, the head was modeled as a single unified structure rather than being divided into separate components. This approach allows the head to undergo deformation while minimizing contact conditions and interactions that could hinder the convergence of the numerical simulations.

Lastly, the FE model of the vacuum cup corresponds to the Kiwi Omnicup[®] Complete Vacuum Delivery System (Laborie Medical Technologies, New Hampshire, USA). A diameter of 60 mm and a height of 20 mm were the defined measurements. The mesh is composed of 7146 of type C3D4 and 13553 nodes. The vacuum cup was modeled as a rigid structure. Figure 3.2 shows the FE model of the fetal head and vacuum cup, with the vacuum cup positioned on the flexion point of the fetal head. This point is located on the sagittal suture, 6 cm behind the anterior fontanelle and 3 cm anterior

to the posterior fontanelle. The center of the cup is aligned with the flexion point, and with a diameter of 60 mm, its brim reaches the posterior fontanelle.

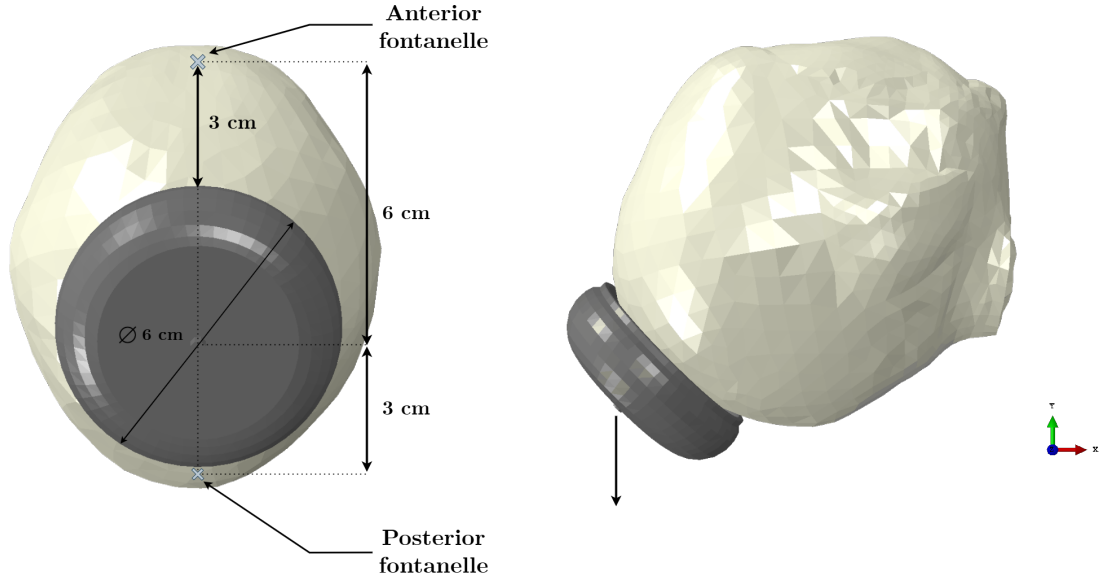


Figure 3.2: Representation of the FE model of the fetal head and vacuum cup. The vacuum cup is positioned at the flexion point of the fetal head, showing the distances to the anterior and posterior fontanelles. The black arrow at the tip of the vacuum cup indicates the direction of the imposed displacement.

3.2.2 Numerical simulations

The FE simulations were performed in Abaqus/Standard[®] software under a static analysis to mimic a VAD with the fetus in the vertex presentation and occipito-anterior position.

Boundary conditions and interactions

The following boundary conditions were applied to the simulations: the nodes at the extremities of the PFM and the superficial transverse perineal muscles, as well as those of the bulbospongiosus muscles near the pubic symphysis, were fixed. The external nodes of the ischiocavernosus muscles, which attach to the ischial bone, were fixed along the vertical direction to reflect this attachment. The boundary conditions are represented in Figure 3.1.

During the simulations, interactions between the PFM, perineum, fetal head and vacuum cup were established using the standard Abaqus[®] contact algorithm. The Augmented Lagrange contact method was used to define the contact between these structures and to facilitate surface interactions. A tie constraint was established between

the fetal head and the vacuum cup to ensure they remain connected throughout the simulation.

Vacuum-assisted delivery dynamics

In a VAD, the vacuum cup is typically introduced when the fetal head is at a station between +1 and +3, indicating an advanced but stalled stage of labor. This scenario corresponds to the early stages of the FE simulations usually performed to replicate childbirth. In the present study, the simulation begins with the engagement of the fetal head into the PFM. This process has a duration of three hours to mimic the conditions of prolonged labor, where vacuum extraction is often indicated. After this phase, the assisted delivery simulation starts. As the fetal head is not visible from the outside, the vacuum cup must be inserted through the perineum. The initial engagement of the fetal head on the PFM is crucial, as the muscles already experience some degree of deformation when the vacuum cup is introduced, facilitating its proper placement. The next step involves positioning the vacuum cup alongside the perineal region into the vagina and through the PFM on the fetal head, enabling control over its descent.

The movements of the vacuum cup are controlled by a reference node, which defines its descent and rotation. Consequently, the initial phase of the simulation focuses on “delivering” the vacuum cup by maneuvering it through the PFM and the urogenital hiatus. Once this stage is completed, the simulation advances to the extraction of the fetal head. The different stages of the VAD simulation can be seen in Figure 3.3.

A total of twelve simulations of VAD were performed, each designed to replicate realistic clinical scenarios. Key parameters were varied, including the contraction duration, during which the obstetrician pulls the fetal head, the resting period between contractions, and the total number of pulls required to extract the fetus. Since the uterus is not included in the FE model, uterine contractions are represented indirectly by prescribing specific fetal descent dynamics, applying a downward displacement during the pulling phase and maintaining the head position during the resting phase. Based on cardiotocographic data and input from experienced obstetricians, the duration of uterine contractions typically ranges from 60 to 90 seconds, with rest intervals between contractions varying from 60 to 180 seconds. Using this information, extreme values were selected for the simulations performed: contraction durations of 60 and 90 seconds, and resting intervals of 60 and 180 seconds. Furthermore, scenarios involving two, three, and four pulls were tested. The combination of these parameters resulted in twelve distinct simulation setups.

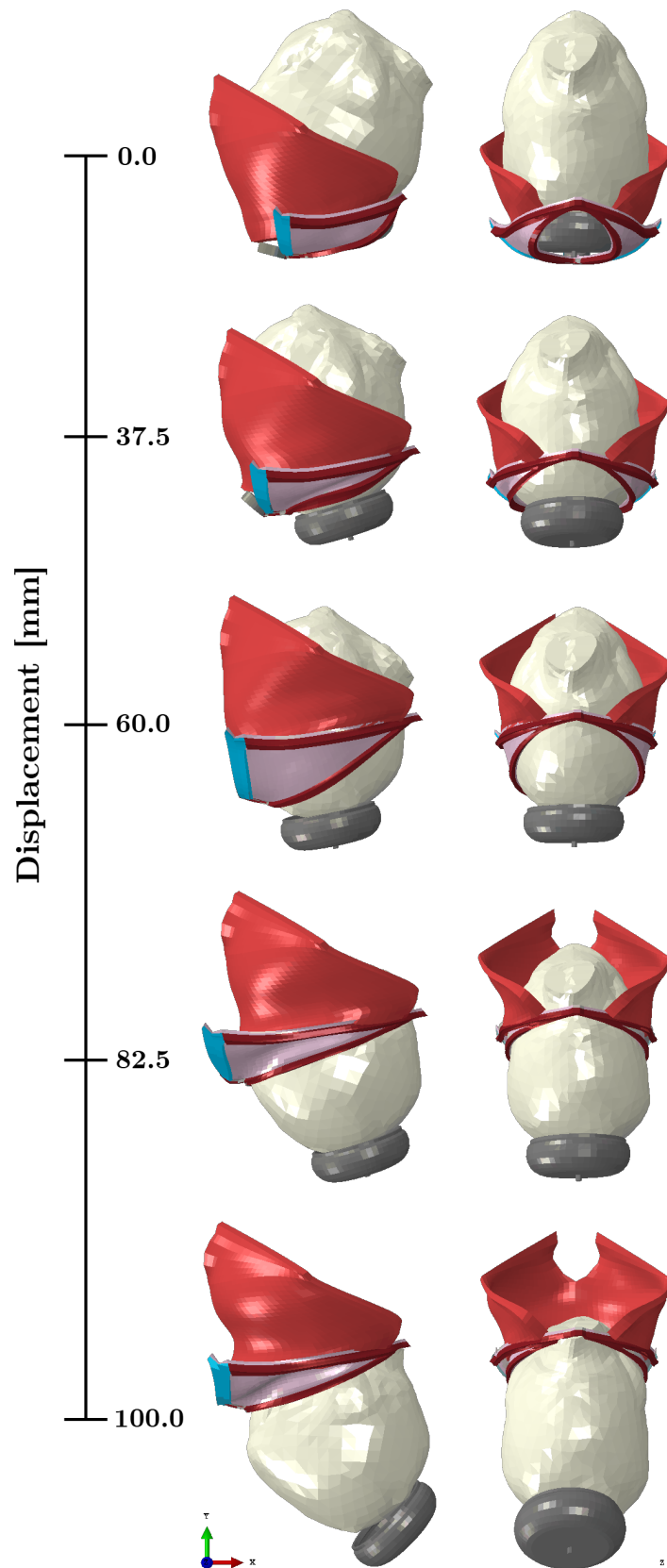


Figure 3.3: Dynamics of the VAD simulation. Lateral and anterior views of the fetal head descent corresponding to the vertical displacement of the vacuum cup from 0 to 100 mm.

Calculations

The maximum principal stress was analyzed along two predefined paths in the PFM: one in the inferior portion corresponding to the levator hiatus, and another along the urogenital hiatus, as illustrated in Figure 3.1. Stress values were recorded throughout the vertical displacement of the vacuum cup. Stretch was also evaluated along these paths, defined as the ratio between the current length and the original length. The forces applied to the vacuum cup during fetal extraction were measured, considering only the force component in the y-direction, as the head is pulled along this axis.

Maximum principal stress and forces were chosen as the primary variables for comparing results across the different cases. Since the geometry of the muscles and fetal head remains unchanged in all simulations, the resulting stretch and deformation of the maternal muscles are expected to remain constant.

3.2.3 Mechanical characterization

The PFM and most of the perineal muscles, namely the ischiocavernosus, superficial and deep transverse perineal muscles, were characterized by a transversely isotropic visco-hyperelastic constitutive model [21]. The strain energy density function is given by Equation 3.1.

$$\Psi = \bar{\Psi}_m + \bar{\Psi}_f + \Psi_{vol} \quad (3.1)$$

where $\bar{\Psi}_m$ corresponds to the isotropic strain energy stored in the isotropic matrix (Equation 3.2), $\bar{\Psi}_f$ represent the strain energy stored in each muscle fiber (Equation 3.3), and Ψ_{vol} is related to the volume change (Equation 3.4).

$$\bar{\Psi}_m = c \left\{ e^{b(\bar{I}_1 - 3)} - 1 \right\} \quad (3.2)$$

where $\bar{I}_1$ is the first invariant of the right Cauchy-Green strain tensor with the volume change eliminated, and c and b are constitutive parameters related to the isotropic part.

$$\begin{aligned} \bar{\Psi}_f = & \underbrace{A \left\{ e^{[a(\bar{\lambda}_f - 1)^2]} - 1 \right\}}_{\bar{\Psi}_{f_{PE}}} \\ & + \underbrace{\theta T_0^M \int_1^{\bar{\lambda}_f} \left[-4(\bar{\lambda}_f - 1)^2 + 1 \right] d\bar{\lambda}_f}_{\bar{\Psi}_{f_{SE}}} \end{aligned} \quad (3.3)$$

where $\bar{\Psi}_{f_{PE}}$ and $\bar{\Psi}_{f_{SE}}$ represent, respectively, the passive and active parts of the strain energy stored in each muscle fiber, $\bar{\lambda}_f$ represents the stretch ratio of the muscle fibers, T_0^M is the maximum muscle tension produced by the muscle at resting, $\theta \in [0, 1]$ defines the level of activation, and A and a are constitutive parameters related to the muscle fibers.

$$\Psi_{vol} = \frac{1}{D} (J - 1)^2 \quad (3.4)$$

$J = \det(\mathbf{F})$ is the volume ratio, $\mathbf{F}$ is the deformation gradient, and D is a constitutive parameter.

In this work, only the passive behavior of the muscles were included. While muscles retain some residual tone even under anesthesia, it was assumed $\theta = 0$ for all the simulations, as a reasonable approximation for a relaxed state. This condition is observed in more than 60% of women who have vaginal birth, according to the Centers for Disease Control [22].

The viscoelastic contribution is represented by the generalized Maxwell model [12]. The implementation includes the addition of a dissipative potential to the strain energy function (Equation 3.5), describing the non-equilibrium state.

$$\Psi_{vis} = \sum_{\alpha=1}^m Y_{\alpha}(\bar{\mathbf{C}}, \bar{\mathbf{\Gamma}}_{\alpha}) \quad (3.5)$$

where Y_{α} represents the dissipative potential, which is a function of the modified right Cauchy-Green strain tensor, $\bar{\mathbf{C}}$, and a set of strain-like internal variables denoted by $\bar{\mathbf{\Gamma}}_{\alpha}$. The latter characterizes the relaxation and/or creep behavior of the material. The viscoelastic behavior is modeled by $\alpha=1, \dots, m$ viscoelastic processes.

The perineal body and bulbospongiosus muscle were considered linear elastic ($E = 23.8$ kPa and $\nu = 0.49$) [23]. The Neo-Hookean model was used to characterize the external anal sphincter, with a material constant defined as $c = 0.1$ MPa, as explained

in Moura *et al.* (2024) [17]. The material parameters used to characterize the PFM and the perineal muscles are presented in Table 3.1.

Table 3.1: Material parameters used to characterize the pelvic floor and perineal muscles.

Hyperelastic parameters [24]	Viscoelastic parameters [12]			
$c = 0.0185$ MPa	$\beta_{m1} = 1.5$ (-)	$\tau_{m1} = 20$ s	$\beta_{f1} = 1.2$ (-)	$\tau_{f1} = 0.9$ s
$b = 1.1730$ (-)	$\beta_{m2} = 0.7$ (-)	$\tau_{m2} = 400$ s	$\beta_{f2} = 0.5$ (-)	$\tau_{f2} = 250$ s
$A = 0.0280$ MPa	$\beta_{m3} = 0.5$ (-)	$\tau_{m3} = 5000$ s	$\beta_{f3} = 0.3$ (-)	$\tau_{f3} = 3500$ s
$a = 0.6215$ (-)				

As previously mentioned, the fetal head was considered a deformable structure. The head was characterized using a linear elastic constitutive model, with a Young's modulus of 1.1 MPa and a Poisson's ratio of 0.25. To calibrate the parameters used in this characterization, an anteroposterior compression test performed by Loyd (2011) [25] was replicated. The Young's modulus was optimized until the numerical curve matched the experimental curves, which were obtained from neonates aged 37.5 weeks, 1 day, and 3 days. The setup of the compression simulations was replicated according to the experimental tests. The head was placed between two rigid plates, and a displacement of 5.0 mm was applied in the anteroposterior direction. The resulting force-deflection curve is presented in Figure 3.4, alongside data from the literature for comparison.

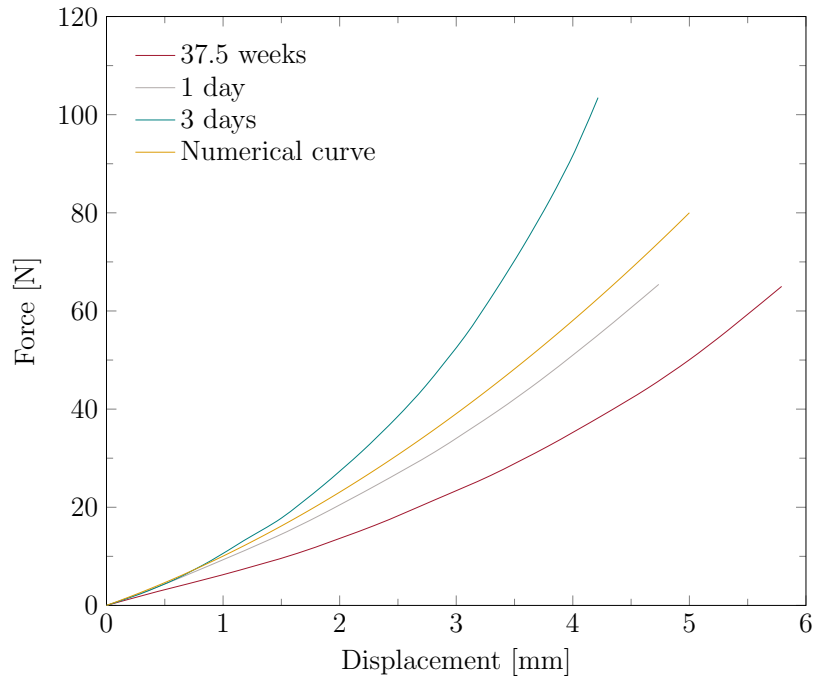


Figure 3.4: Force-deflection curve obtained from the anteroposterior compression test for the fetal head FE model, compared to the experimental curves by Loyd (2011).

3.3 Vacuum-assisted delivery simulations

3.3.1 Analysis of the maternal structures

Figure 3.5 illustrates the stretch measured on the levator hiatus and urogenital hiatus during the vertical displacement of the vacuum cup. The maximum stretch of the levator hiatus reached 2.09 at a descent of 69.91 mm, while the perineum exhibited a stretch of 3.01 at a descent of 79.51 mm.

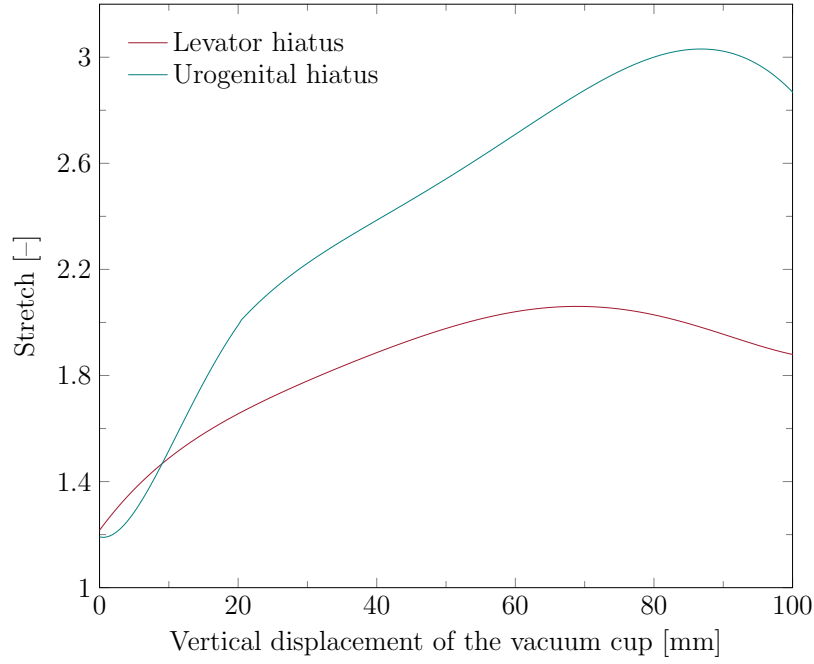


Figure 3.5: Stretch of the levator hiatus (PFM) and urogenital hiatus (perineum) during the vertical displacement of the vacuum cup.

The maximum principal stress on the urogenital hiatus was also evaluated. As the bulbospongiosus muscle and perineal body were modeled without viscoelastic properties in this study, the stress distribution in these structures remains unchanged across the different cases under analysis. Consequently, Figure 3.6 shows the stress results on the urogenital hiatus obtained for all cases during the vertical displacement of the vacuum cup.

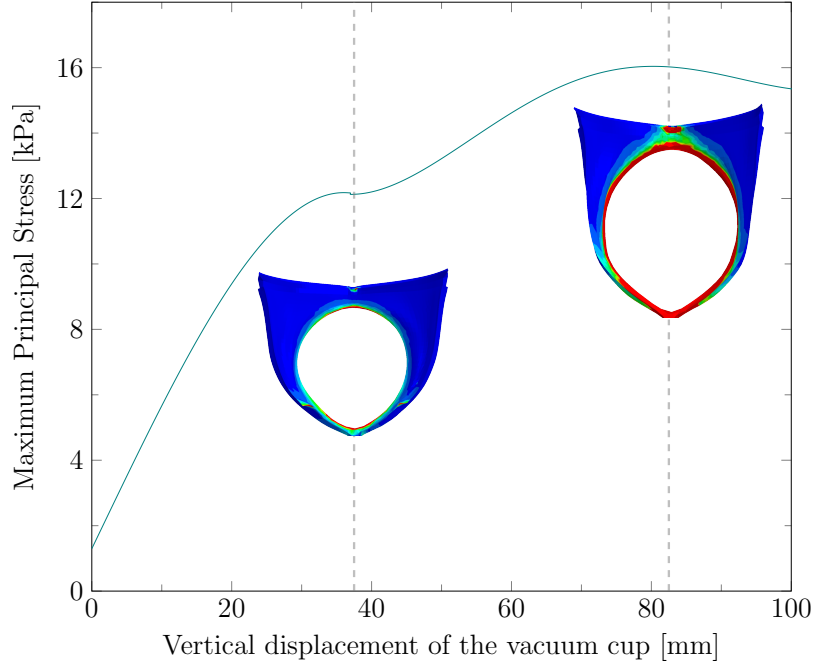


Figure 3.6: Maximum principal stress (in kPa) along the vertical displacement on the vacuum cup measured on Path 2. The results include the FE model of the perineum for vertical displacements of 37.5 mm and 82.5 mm, highlighting the stress distribution and identifying the most critical regions.

Based on the analysis of the maternal structures, the following results will focus on the vertical displacement of the vacuum cup between 55 and 80 mm, as this range represents the most critical interval for the pelvic floor.

3.3.2 Effect of the contraction duration and resting stages

Figure 3.7 shows the time evolution of the maximum principal stress at the levator hiatus and the vertical displacement of the vacuum cup. The plot represents a VAD simulation with three pulls, 90 seconds of contraction and 180 seconds of rest. The results reveal a notable reduction in stress during the resting phases, particularly in the second rest period with a stress relaxation of 19.22%, underscoring the muscle recovery effect facilitated by the intervals between contractions.

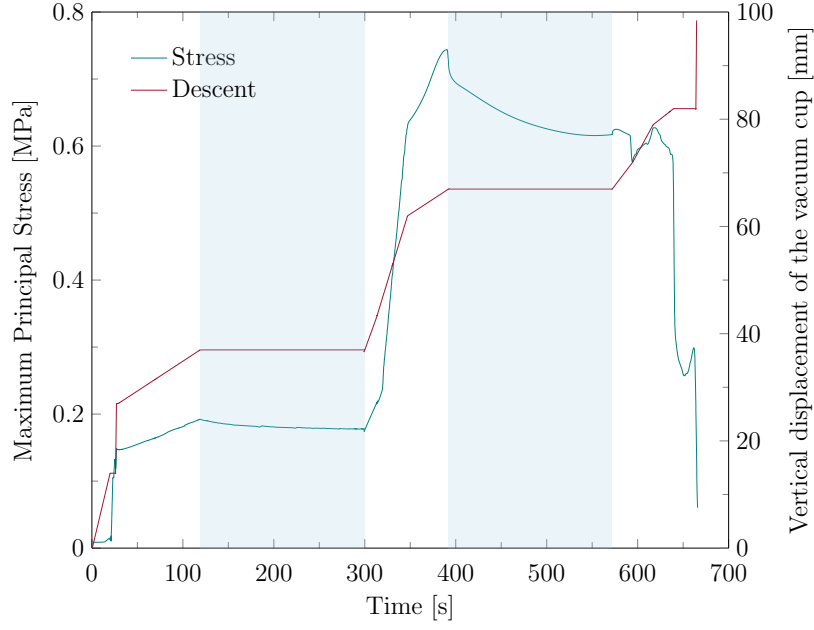


Figure 3.7: Time evolution of the maximum principal stress in the fetal head (left axis) and the vertical displacement of the vacuum cup (right axis) during the simulated VAD. The shaded blue areas indicate resting phases, while the white areas represent pulling phases.

To investigate the effect of contraction duration and resting periods on the PFM, the maximum principal stress on the levator hiatus was measured along the vertical displacement of the vacuum cup, as shown in Figure 3.8. The results demonstrate that shorter contraction and resting times result in higher stress values, whereas longer contraction and resting periods lead to lower stress levels. The highest recorded stress was 0.78 MPa, observed in the simulation with 60 seconds of contraction and 60 seconds of rest, corresponding to a fetal descent of 67.03 mm.

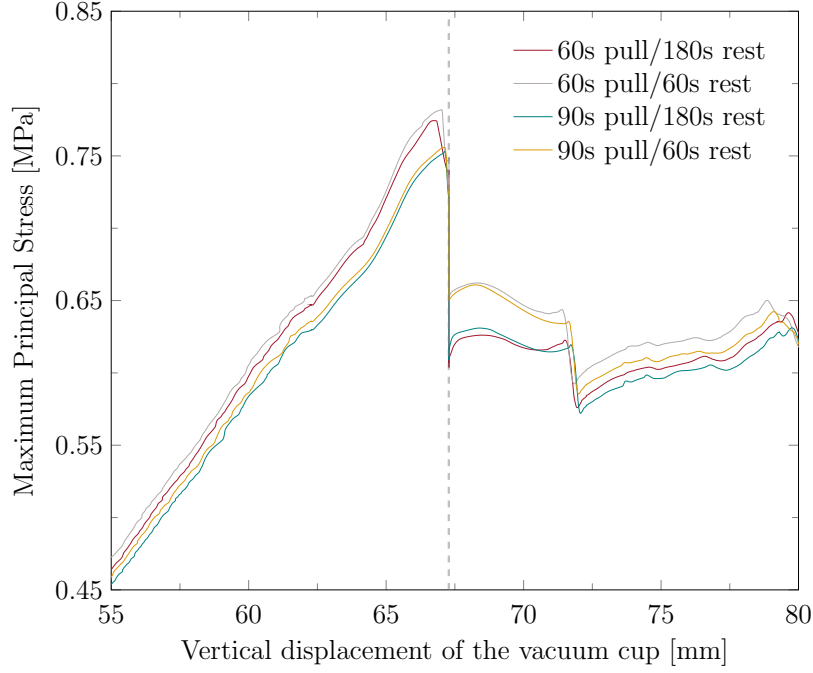


Figure 3.8: Maximum principal stress (in MPa) along the vertical displacement of the vacuum cup measured on the PFM path for the different cases under study. The vertical dashed line indicates the displacement at which the resting stage is defined.

The force applied to the vacuum cup to extract the fetus was measured in the y-direction, corresponding to the vertical displacement of the vacuum cup from the moment it is attached to the fetal head. The maximum recorded force was 130.10 N at a vertical displacement of 63.69 mm, during a contraction phase lasting 60 seconds, followed by a resting phase of equal duration. The descent moment can be associated with the moment of maximum stretch of the levator hiatus. The results show a similar trend to the maximum principal stresses observed across the different simulated cases.

3.3.3 Impact of the number of pulls

As the highest stress values were recorded in the 60s contraction and 60s rest scenario, the impact of the number of pulls was analyzed for these specific contraction and rest durations. Figure 3.9 illustrates the maximum principal stress observed during the VAD simulations, comparing fetal extraction scenarios with two, three, and four pulls. The results indicate that using only two pulls leads to higher stress on the muscles, with a maximum stress of 0.81 MPa for a vertical displacement of 66.28 mm, compared to three pulls, which result in a maximum stress of 0.78 MPa for a displacement of 66.82 mm, and four pulls, which lead to a maximum stress of 0.76 MPa for a displacement of 67.54 mm.

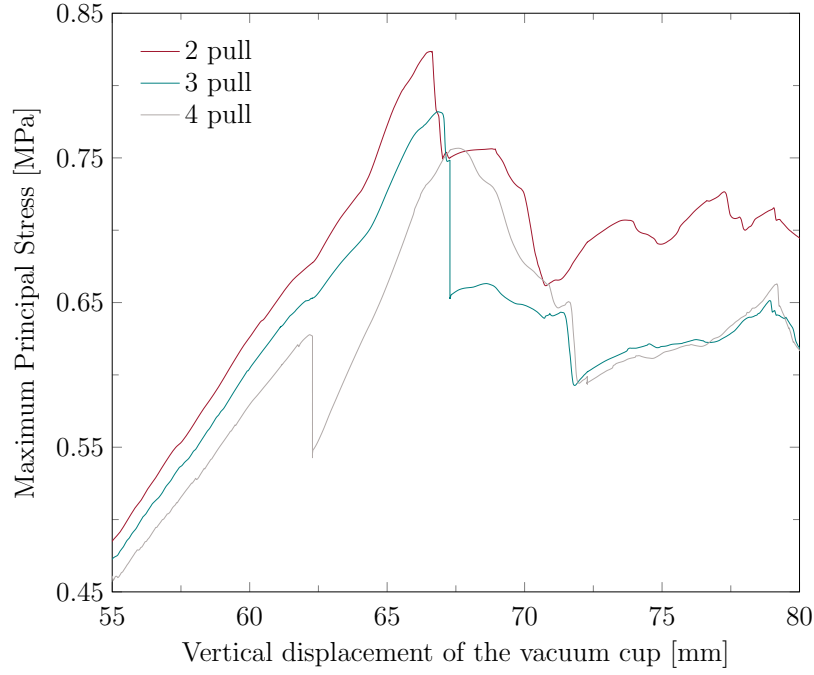


Figure 3.9: Maximum principal stress (in MPa) along the vertical displacement on the vacuum cup considering the fetal extraction with two, three and four pulls.

The force applied to the vacuum cup to extract the fetus was measured in the y-direction along its vertical displacement for two, three, and four pulls (Figure 3.10). The maximum forces recorded were 136.99 N, 130.10 N and 123.63 N, corresponding to vertical displacements of 64.24 mm, 63.69 mm, and 66.98 mm, respectively.

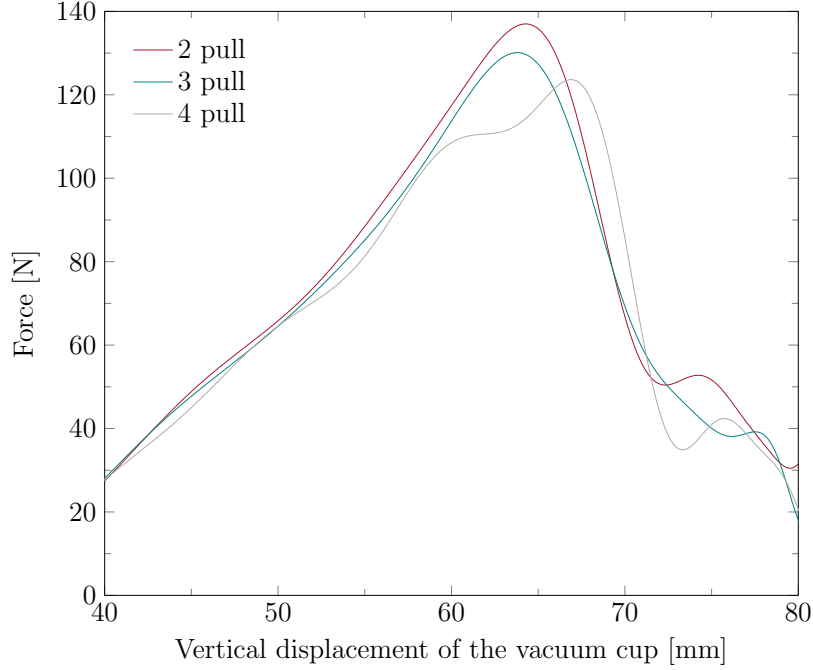


Figure 3.10: Force (in N) applied on the vacuum cup to extract the fetal head along its vertical displacement through the birth canal with two, three and four pulls.

3.4 Discussion

Assisted delivery is a widely used obstetric technique designed to facilitate labor progression when complications arise that hinder natural delivery or when the birth needs to be accelerated due to imminent fetal compromise. Among these techniques, vacuum-assisted birth is commonly used, although it is associated with high rates of pelvic floor trauma and perineal lesions. Despite its widespread use, the biomechanical effects of VAD on maternal tissues remain poorly understood. This study seeks to address this knowledge gap by examining the mechanical impact of this technique on maternal tissues. The novelty of this work lies in the biomechanical analysis of VAD, with a focus on specific controllable factors that may play a critical role in the prevention of pelvic floor dysfunction.

When analyzing the maternal structures, the levator hiatus was found to stretch to approximately twice its initial length, consistent with the findings of Moura *et al.* (2024) [17], where vaginal delivery was simulated using the same FE model of the PFM and perineum. Similarly, the urogenital hiatus stretched approximately three times its initial length in both studies. These results suggest that VAD does not significantly impact muscle stretch, as this is primarily a geometrical feature influenced by fetal head size and the intrinsic dimensions of the muscles. However, in the VAD simulations, the maximum stretch occurred at an earlier stage, indicating that the use of the cup

might induce faster and earlier muscle opening compared to normal vaginal delivery. This earlier stretch might have clinical implications, potentially increasing the risk of muscle injury or contributing to long-term pelvic floor dysfunction, as reported in previous clinical studies.

For the analysis of the maternal structures, it is crucial to identify the regions subjected to higher stress levels, as these are more prone to injury during VAD. The perineum representation in Figure 3.6 highlights that during maximum perineal stretch, the most affected regions are the anterior area near the attachment to the pubic symphysis and the middle posterior region connecting to the perineal body. Additionally, the region of the perineal body adjacent to the anal sphincter also experiences significant stress, indicating a potential risk for OASIS. These findings are consistent with the literature, which commonly reports perineal tears in the posterior region and OASIS at the connection with the anal sphincter. Regarding the PFM, the highest stress concentrations are observed in the central portion of the muscle and at the attachment points to the surrounding structures, as reported in previous numerical studies.

Distinct contraction and resting stages were simulated to evaluate their impact on the maternal muscles. The results show that the highest muscle stresses were observed for a contraction duration of 60 seconds combined with a resting stage of 60 seconds. This scenario induces higher stresses as the shorter resting time limits the muscles' ability to recover and adapt, resulting in a more abrupt descent. This effect can be attributed to the viscoelastic properties of pelvic floor tissues, which require adequate time to recover following deformation. Interestingly, Figure 3.8 shows that the stress levels for the 60s contraction–180s rest case are nearly identical to those of the 60s contraction–60s rest case during the contraction phase. However, after the resting stage, the stresses significantly decrease, with a reduction of approximately 21.71%, and approach the values observed in the 90s contraction–180s rest case. This suggests that the duration of the resting stage has a greater influence on muscle stress recovery than the contraction duration itself. Clinically, this highlights the importance of optimizing contraction-to-resting time ratios during labor management to protect the maternal muscles. Chill *et al.* (2024) [26] concluded that a shorter duration of VAD can increase the risk of OASIS since an increased procedure time may afford perineal tissues the opportunity to stretch and accommodate to the fetal head. This is in line with our findings that longer deliveries might be beneficial to the PFM, as the stresses are lower.

Another objective of this study was to determine whether the number of times the obstetrician must pull to deliver the fetus affects the maternal muscles. This analysis focused on the PFM, and the results revealed that the number of pulls significantly

influences muscle stress. Specifically, the stresses on the muscles were found to be higher when the fetus was extracted with only two pulls compared to four pulls, with an 8.43% difference in the maximum stress values between these two scenarios. This indicates that fewer pulls result in more intense muscle effort, which may increase the risk of injury. These findings are consistent with the results observed for the variations in the contraction and resting stages. When the fetal head is extracted using a higher number of pulls, there is more time for the muscles to relax between pulls, allowing for better adjustment and leading to lower stress.

Additionally, the force applied to the vacuum cup was analyzed across different number of pulls. The results showed that a higher force was required for extraction with two pulls compared to the other cases. The increased force required in these scenarios could potentially lead to a higher risk of maternal trauma, such as perineal tears or pelvic floor damage, as well as a higher risk of cup detachment from the fetal head, which may increase the risk of intracranial bleeding. Therefore, obstetricians may benefit from considering a more gradual approach to assisted delivery, with careful attention to the timing and number of pulls applied. Literature indicates that a traction force of 115 N to 125 N is sufficient for successful delivery and that this traction should not exceed 135 N [27]. The values obtained in the present study fall within this range, thereby supporting the validity of the FE model and the approach implemented.

The findings of this study provide valuable insights for obstetric practice regarding the biomechanical implications of VAD. From a mechanical perspective, with a focus on maternal health, the study concludes that longer contraction durations and extended rest periods are beneficial for maternal muscles. These intervals allow muscles more time to adapt and stretch, thereby reducing the risk of potential injuries caused by abrupt deformations. Since these factors can sometimes be influenced by medication, in situations where there is no immediate risk to the fetus or the mother, these recommendations may help achieve the best possible outcomes in what is already a challenging and potentially traumatic scenario. Additionally, the finding that a higher number of pulls can benefit maternal muscles offers a practical clinical guideline. Obstetricians could aim to avoid excessive force during individual pulls and instead utilize more contractions, optimizing relaxation time for the muscles and minimizing excessive deformation.

However, it is important to balance these benefits against potential risks to the fetus, such as hypoxia, which may arise from prolonged delivery times. Future research should explore this balance in greater detail, with a focus on developing clinical guidelines that prioritize both maternal and fetal well-being. To establish clinical guidelines, a structured approach is required, beginning with the integration of real-world clinical

data, followed by model calibration and validation against observed outcomes such as perineal lacerations and pelvic floor injuries. Once validated, the model can be used to simulate a range of clinical scenarios, assess the impact of varying delivery forces, define risk thresholds, and guide safer obstetric practices.

Although the tridimensional model presented in this work has specific dimensions corresponding to an average of the literature, both the PFM, the perineal structures and the fetal head can be modified to adapt to the geometric features of a specific woman with the mesh morphing algorithm implemented in Moura *et al.* (2024) [28]. After gathering the relevant dimensions on pre-birth ultrasounds, the simulations can be performed patient-specifically and provide insights to the clinicians. Additionally, when combined with patient-specific data, these models can be used to define quantitative criteria for proposing optimal delivery conditions and assessing the risk of potential injuries. With proper validation against clinical data, quantitative thresholds could be established, for example, the maximum extraction force beyond which the risk of injury significantly increases, the maximum muscle stretch that can occur without causing injury, and the stress values beyond which the likelihood of postpartum pelvic floor disorders or perineal lacerations becomes significant. To reduce model uncertainties, capturing the dynamics of labor using MRI, as demonstrated by Ami *et al.* (2016) [29], could be a valuable approach, along with obtaining *in vivo* mechanical properties using recent techniques such as shear wave elastography.

This approach could serve as a decision-support tool, enabling obstetricians to evaluate the potential mechanical outcomes of different delivery strategies in a personalized manner. By identifying patients at higher risk of pelvic floor trauma, tailored labor management protocols could be implemented to mitigate these risks. Additionally, patient-specific models could assist in optimizing the use of pharmaceutical agents or physical therapy as preventive measures in the prenatal period. Future developments in this field, particularly when combined with ML algorithms, could further enhance the predictive capabilities of such models, ultimately contributing to more individualized and safer obstetric care.

The proposed work presents several limitations. Firstly, although the fetal head is modeled as a deformable structure, it is represented as a single entity without distinguishing between cranial bones, sutures, fontanelles, or brain tissue. Incorporating these anatomical components could potentially allow for greater deformation of the fetal head, thereby reducing maternal muscle stretch. However, this would significantly increase the complexity and computational cost of the simulations. The model also omits the fetal body, which would likely not affect the results of the simulations performed but could be important for simulating other maneuvers or delivery strate-

gies in the context of VAD. Another limitation lies in the vacuum cup model used for the simulations, as only one specific type was considered despite the existence of multiple designs, sizes, and materials. Assessing different cup models could help determine their biomechanical impact. Additionally, the placement of the vacuum cup depends on both the head's size and shape, yet only one fetal head model with fixed dimensions was tested. Simulations with varying head geometries would provide a broader understanding of this effect. The interaction between the fetal head and the vacuum cup is also simplified, as the suction mechanism of the cup is not modeled. Furthermore, the FE model does not account for additional surrounding structures and fluids, which could influence the delivery process. Lastly, another limitation of this study is the absence of a dedicated mesh sensitivity analysis within the current simulation setup. Although the muscle model used has been previously validated for childbirth biomechanics, mesh density can affect localized stress values. Consequently, finer discretization may reveal additional detail in regions of high strain.

3.5 Conclusions

This study presents a novel approach to analyzing the impact of assisted delivery techniques on maternal tissues. By addressing critical, previously unanswered clinical questions, this approach could shift clinicians' perspectives and guide the development of new guidelines that integrate biomechanical insights. The findings offer valuable knowledge on the biomechanics of assisted delivery, emphasizing the importance of optimizing techniques to minimize maternal trauma. These insights have the potential to influence clinical guidelines and future research directions, ultimately contributing to improved maternal health outcomes. Future research should expand to include other relevant structures, such as the uterus and cervix, and provide a more detailed characterization of the fetus, allowing for a comprehensive analysis of the process as it affects fetal tissues as well. Moreover, simulating the fetus in various positions, particularly the occipito-posterior position, would provide valuable insights into positional effects and enhance the ability to model a wider range of clinical scenarios. Nonetheless, this study represents an important step forward in advancing the current understanding of childbirth biomechanics and in developing tools that could enable clinicians to make more precise, case-specific decisions for improved outcomes.

Acknowledgements

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Part III

Artificial intelligence in childbirth biomechanics

Chapter 4

A finite element-based machine learning framework to predict the mechanical behavior of the pelvic floor muscles during childbirth

A finite element-based machine learning framework to predict the mechanical behavior of the pelvic floor muscles during childbirth

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Abstract

The medical community has been focusing on gaining a deeper understanding of birth trauma, which affects millions of women worldwide. Maternal lesions can be challenging to diagnose and expensive to examine. To better comprehend the mechanism of injuries occurring in the PFM, biomechanical simulations can be a valuable tool. However, utilizing the FEM to conduct simulations can be a time-consuming process. To overcome this issue, the present study aims to develop a ML framework to predict stresses on the PFM during childbirth by training ML algorithms on FEM simulation data. To generate the dataset for the ML algorithm's training, childbirth simulations were performed using different material properties to characterize the PFM. Four ML algorithms were employed, namely RF, XGBT, SVR, and ANN, considering two scenarios: (1) stress prediction for the maximum stretch level of the muscle, and (2) for multiple levels of fetal descent. Results showed that the ANN performed best in the former, with a mean absolute error (MAE) of 0.191 MPa. In the latter, XGBT provided lower errors for 20 and 35 mm of fetal descent, with MAE values of 0.002 and 0.028 MPa, respectively. Nevertheless, the ANN yielded better predictions for 50 and 65 mm, with MAE values of 0.214 and 0.187 MPa, respectively. The present work represents the first attempt to use FEM-based ML algorithms with childbirth simulations to obtain near-real-time predictions in routine clinical procedures.

Keywords: Biomechanics of labor; Pelvic floor injuries; Computational modeling; Artificial intelligence; Real-time biomechanics.

4.1 Introduction

Childbirth trauma during the second stage of labor is a prevalent concern, affecting an extensive number of women worldwide. Research indicates that perineal trauma occurs in up to 90% of birthing women [1]. Additionally, LAM trauma, which can impact 6-40% of women undergoing vaginal delivery, particularly nulliparous individuals, is also a prevalent injury arising from childbirth [2]. One form of LAM trauma consists of LAM avulsion, which leads to persistent morbidity and the necessity of future surgical intervention for 10-20% of patients [3]. Thus, the consequences of childbirth trauma can be long-lasting and manifest in both physical and psychological forms [4]. Physically, women may suffer from long-term conditions such as pelvic organ prolapse, urinary incontinence or sexual disorders [5, 6]. Psychologically, the trauma can lead to the development of post-traumatic stress disorder or a decreased desire to have more children [7].

Despite being a highly debated subject, pelvic floor trauma remains omitted from the standard protocol for evaluating pelvic floor trauma postpartum. Unlike genital tears, LAM injury is much more difficult to identify, requiring additional and thorough examinations. The optimal time to perform these exams seems to be within 6-12 weeks after birth, and accurately identifying these lesions can be a challenge [2]. Therefore, the current method of assessment is largely qualitative, as the quantification of mechanical factors such as deformation and forces is not feasible. Clinicians would benefit from having a means of predicting the likelihood of LAM injury without having to conduct additional exams on every patient, which consumes time and additional resources.

Researchers have employed a variety of strategies to identify the risk factors associated with childbirth-related injuries and predict their occurrence. One approach involves utilizing statistical analysis of retrospective data to determine correlations between the incidence of difficult labor and specific maternal and fetal characteristics. Although this method provides valuable insights into the risk factors, it fails to underlie these injuries' mechanisms or causative factors. Another approach consists of using physical birth simulators, which aid healthcare providers in managing a range of labor scenarios. However, these models have limitations in their ability to represent patient-specific information and crucial details to the mechanics of the birth process, such as the soft tissue geometry and its mechanical properties. Moreover, computational models can offer a more detailed understanding of the mechanisms responsible for fetal and maternal injuries during the birthing process. These models overcome the constraints of the previously described methodologies by incorporating patient-specific data, three-dimensional geometries, and complex mechanical properties of biological tissues. In the past years, researchers have leveraged the advancements in computer

technology to develop numerical models that can thoroughly investigate the biomechanics of childbirth [8].

One of the most widespread methods used as a basis to perform computational simulations is the FEM. This method works by dividing a complex system into smaller elements and then solving partial differential equations to analyze the behavior of each element [9]. In the context of biomechanics, the FEM facilitates the comprehension of the response of structures and tissues to external stimuli, enabling to retrieve information that would otherwise be impossible to obtain [10]. Despite demonstrating success in several applications and producing results that cannot be obtained through other means, the FEM is known for being computationally expensive, leading to time-consuming simulations. This drawback is incompatible with its application in clinical settings, as the simulations must be capable of delivering results promptly or even in real-time, due to critical and urgent nature of some medical decisions (including labor).

Driven by the necessity of achieving real-time responses to incorporate biomechanical simulations in a clinical setting, researchers have been focusing on strategies to decrease the computational time, such as: accessing powerful computer resources (improved hardware and different solutions as using graphics processing units or parallel processing algorithms) and model reduction techniques [10]. However, despite the advancements in the FEM and the techniques available to fasten results, these are still not enough to guarantee results in near real-time, which is a crucial requirement in most clinical applications. Therefore, ML algorithms have gained relevance due to their capacity to deliver robust, fast, and real-time responses for biomechanical simulations.

AI encompasses various approaches aimed at endowing machines with intelligence, including the development of expert systems. ML consists of a subset within the realm of AI. ML is a field of computer science that studies algorithms and methodologies for automating solutions to complex problems that are difficult to solve using traditional programming techniques. It can provide insights into structures and patterns from large datasets, enabling the creation of models by learning from existing data to predict outcomes or behaviors. Within ML, there are two primary types of learning: supervised and unsupervised. In supervised learning, the machine is given a dataset with correct answers that correspond to the data points, constituting a labeled dataset. The algorithm then learns the distinguishing features within each data point. Supervised learning is further categorized into classification problems, involving the categorization of items into distinct classes, and regression problems, which involve predicting values of a continuous variable [11].

A recent published review by Phellan *et al.* (2021) [10] concluded that the three main types of regression algorithms used to generate fast and real-time simulations of anatomical structures are tree-based algorithms (namely decision trees and RF), SVR, and ANNs. In the field of tree-based algorithms, a RF is a supervised learning method that combines multiple decision trees to create a robust model. The algorithm works by selecting a subset of features, training a decision tree on them, and then repeating the process multiple times [12, 13]. One potential drawback of RF is that it can be computationally expensive when working with a large number of trees [14]. Still in the field of tree based algorithms, XGBT is a widely used algorithm due to its high performance. The base model are also decision trees, and it improves these trees through the incorporation of new trees that correct errors from previous ones [15]. This model includes several techniques to prevent overfitting and has been used in several fields such as computer vision and bioinformatics [16]. Another type of model is the SVR, which works by finding a function that approximates the relationship between the input variables and a continuous target variable, while minimizing the prediction error. SVR seeks to find a hyperplane that best fits the data points in a continuous space. This is achieved by mapping the input variables to a high-dimensional feature space and finding the hyperplane that maximizes the margin (distance) between the hyperplane and the closest data points. As main advantages, SVR can handle nonlinear data, is robust to outliers and can also handle high-dimensional input spaces. However, this algorithm can be computationally expensive, and can be sensitive to the choice of parameters and to the kernel function used [17]. Lastly, ANNs are a type of ML model based on the function of the human brain, more specifically on its neurons. The structure of a neural network includes an input layer, one or more hidden layers, and an output layer. The connections between neurons have associated weights, which are adjusted during the training process to minimize the error between the network's predictions and the labels [18]. The versatility and ability of ANNs to learn and make predictions based on large amounts of data are some of their key strengths. However, it is important to have caution in their implementation to avoid overfitting [19].

In FEM-based ML algorithms, FEM simulations are used to generate a large dataset that can be used to train ML models. Although the FE simulations are still computationally expensive to generate, a trained ML algorithm significantly reduces the time required to predict the desired outcomes. This methodology works as a viable alternative to solving partial differential equations of the FEM and uses data obtained from FE simulations to train supervised ML models, thereby enabling the determination of output variables based on a defined set of input variables. Literature indicates that the utilization of ML models in biomechanical simulations can fasten the results without compromising their performance, namely in the fields of computer-aided surgery,

cancer detection, and cardiovascular diseases. Despite extensive research in the field of biomechanics of childbirth, to the best of our knowledge, no studies have yet utilized FEM-based ML algorithms to analyze the mechanics of labor. The integration of ML techniques with childbirth computational simulations can lead to the development of new methods of predicting and preventing trauma to the woman and fetus. By providing patient-specific, real-time results, healthcare professionals would be able to make informed decisions that could improve the outcomes of labor.

The present study implements a ML framework to predict stresses on crucial regions of the PFM during vaginal delivery. This approach enables determining the stresses that a specific maternal tissue suffered, by incorporating as input distinct material properties to characterize the muscles. The main goal and contribution of this study is to address the current limitations in traditional FE childbirth simulations by integrating ML techniques. Previous studies have relied on conventional FE analysis, which requires a substantial amount of time to generate results. The present study proposes a novel approach that combines ML techniques with data generated through FE childbirth simulations, aiming to achieve faster results. This advancement enables the potential for patient-specific decision-making in a clinical setting.

4.2 Related work

The current work focuses on two different areas: firstly, childbirth computational models and simulations, and secondly, the application of FEM-based ML in the context of biomechanical applications.

4.2.1 Childbirth biomechanical simulations

Childbirth computational simulations can overcome limitations of physical childbirth models or invasive evaluations, offering insights into the mechanisms of vaginal delivery and associated maternal and fetal injuries. These models can mimic the geometries of bony structures, soft tissues (as PFM), and the fetus [8]. The first three-dimensional computational model used to simulate vaginal delivery appeared almost 20 years ago, when Lien *et al.* (2004) [20] developed a model of the LAM to calculate its stretch during childbirth. Posteriorly, Parente *et al.* (2008) [21] created a FE model that simulates the pelvic bones, PFM, and fetus, to evaluate the stretch and deformations of the pelvic floor induced by the passage of the fetus, during vaginal delivery. Since then, several analysis have been made resorting to these computational models, namely the impact of an occipito-posterior position instead of the common occipito-anterior [22], the effect of fetal head flexion [23], the influence of pelvic floor muscle contraction

on vaginal delivery [24], the incorporation of viscoelasticity [25, 26], the study of fetal head molding [27], the analysis of obstetrical procedures such as episiotomies [28], the quantification of muscle damage [29, 30], the study of uterine contraction [31, 32], the inclusion of perineal structures in the FE models [33], among others. All these studies were performed with complex FE models leading to time-consuming computational simulations.

4.2.2 FEM-based ML biomechanical applications

In the field of FEM-based ML, ML algorithms can be trained by using biomechanical simulations generated with FEM. Although FEM-based simulations are computationally expensive to generate, a trained ML algorithm can significantly reduce the time required to obtain results. Numerous studies in the literature have adopted this approach within the biomechanical domain, particularly in scenarios involving the liver, stomach, femur, heart, or breast. These studies aim to predict variables as deformation, pressure, mechanical properties, external forces, and stress.

In the specific context of stress prediction, Lu *et al.* (2013) [34] demonstrated the efficacy of a neural network for predicting stress values in musculoskeletal structures. By using a simplified model of the tibio-femoral joint, simulations across various loading and motion scenarios were performed. Input features consisted of reaction forces, while the desired output was von Mises stress. In another application, deep learning was employed to estimate stress distributions in the aorta. This involved utilizing patient image data and characteristics as direct inputs to a deep learning model, thus replacing the conventional FE calculation process. The model's training aimed to generate aortic wall stress distributions, achieving accurate predictions with an average error under 0.5% [35]. Moreover, Dabiri *et al.* (2019) [36] adopted a distinct approach by creating a FE-based ML platform to simulate left ventricular mechanics. Using decision trees and XGBT as ML models, the aim was to predict myocardial stresses. Input features included mechanical properties and elements' centroid coordinates. This approach reduced stress prediction time from 20 minutes to 5 seconds. In the context of arterial health assessment, FEM-based ML has also been used for plaque rupture risk prediction. A parametric model for arterial geometry was created and a database of 2D FE simulations was employed to predict maximum von Mises stress, a key indicator of plaque rupture risk. By incorporating geometry, material properties, and boundary conditions, the deep learning models used achieved stress predictions with an accuracy of under 10% [37].

In addition to stress prediction, FEM-based ML has been applied in other relevant studies, such as deformation prediction. Martínez-Martínez *et al.* (2017) [38] intro-

duced a data-driven method to simulate the real-time biomechanical behavior of breast tissue. The primary objective was to anticipate the deformation of breast tissues under compression using models like extremely randomized trees and RF. In the domain of liver biomechanics, ML algorithms were trained using tens of thousands of biomechanical simulations, including a hundred different liver geometries. These algorithms utilized features such as node coordinates, forces, material properties, and distances, and were tested across various scenarios. This innovative approach enables the simulation of the mechanical behavior of any liver and the prediction of its displacement field [39].

4.3 Materials and methods

4.3.1 Biomechanical model

A FE model was used to simulate vaginal delivery. Initially, a geometric model of the PFM comprising the LAM (pubococcygeus, puborectalis, and iliococcygeus) and the coccygeus muscle, was generated using Rhinoceros[®] software. Part of the LAM (pubococcygeus and puborectalis muscles) was segmented from MRI of a 30 year-old healthy woman, while the iliococcygeus and coccygeus muscles were included based on obstetrician advice and anatomical information from the literature [40, 41]. The levator ani and coccygeus muscle were the only muscles considered in the model due to their roles in the development of pelvic floor dysfunctions.

Furthermore, a three-dimensional model of the pelvic bones, obtained from previous MRI studies conducted in the research group, was used to assist in delimiting muscle insertions. The iliococcygeus originates from the tendinous arch on each side and converges in the midline, while the puborectalis, along with the pubococcygeus, arises from the pubis and descends inferiorly on each side to form a ring around the anus. More specifically, the pubococcygeus originates from the pubis and attaches posteriorly to the coccyx.

The geometries were initially created in Rhinoceros[®] software as surfaces and then exported in an appropriate format to be imported into Abaqus[®] software as a Part. The FE mesh was subsequently created using Abaqus' Mesh Module after partitioning the geometry to ensure a more uniform distribution of the elements. The mesh comprised 8501 nodes and 5892 hexahedral solid elements of type C3D8H [42]. The thickness of the puborectalis and pubococcygeus muscles were determined to be equal to 6.5 mm [43], while the iliococcygeus and coccygeus muscles were modeled with a thickness of 3.6 mm [44], according to the cohorts of the referred studies. A mesh quality analysis was performed using Abaqus software. It was determined that the percentage of nodes

with a face corner angle below 40° was 0.34% and above 140° was 0.46%. This metric measures the skewness of the mesh, and the angles should not be too small or too large. In addition, only 0.75% of the elements had an aspect ratio greater than 4. Figure 4.1 presents the described model.

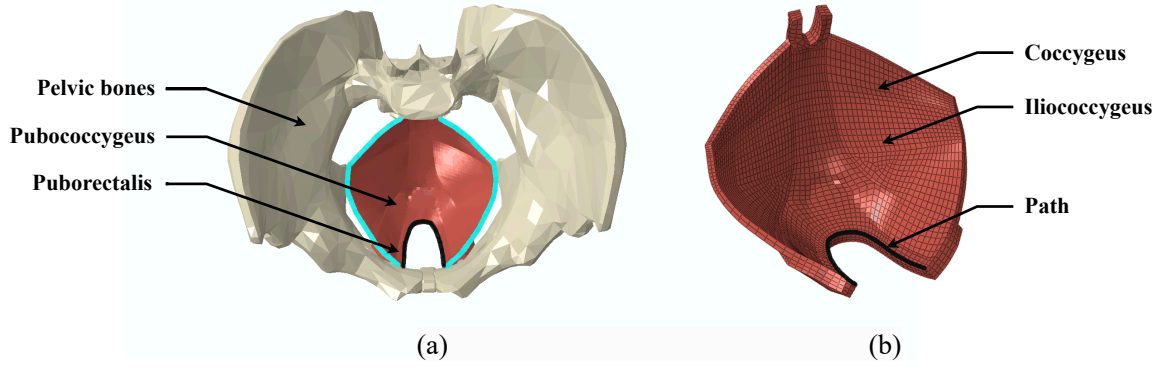


Figure 4.1: (a) Geometric model of the PFM (coccygeus, iliococcygeus, pubococcygeus and puborectalis muscle) and pelvic bones. The blue line represents the fixed nodes of the PFM. (b) FE mesh of the PFM. Identification of path used for stress analysis.

The PFM were characterized by a transversely isotropic visco-hyperelastic constitutive model proposed by Martins *et al.* (1998) [45]. Martins constitutive model considers the tissue's nonlinearity, anisotropy, incompressibility, and hyperelasticity. The strain energy function describes the microstructure of the tissue, which includes an extra-cellular matrix providing strength and resilience, as well as the passive and active behavior of the fibers, as represented in Equation 4.1. The viscoelastic contribution was posteriorly implemented by Vila Pouca *et al.* (2017) [26].

$$\begin{aligned} \Psi = & \underbrace{c \{e^{b(\bar{I}_1 - 3)} - 1\}}_{\bar{\Psi}_m} + \underbrace{A \{e^{[a(\bar{\lambda}_f - 1)^2]} - 1\}}_{\bar{\Psi}_{f_{PE}}} \\ & + \underbrace{\theta T_0^M \int_1^{\bar{\lambda}_f} -4(\bar{\lambda}_f - 1)^2 + 1 \, d\bar{\lambda}_f}_{\bar{\Psi}_{f_{SE}}} + \underbrace{\frac{1}{D}(J - 1)^2}_{\Psi_{vol}} \end{aligned} \quad (4.1)$$

where $\bar{\Psi}_m$ corresponds to the isotropic strain energy stored in the isotropic matrix, $\bar{\Psi}_{f_{PE}}$ and $\bar{\Psi}_{f_{SE}}$ represent, respectively, the passive and active parts of the strain energy stored in each muscle fiber, and Ψ_{vol} is related to the volume change. c , b , A , a and D are constitutive parameters. $\bar{I}_1$ is the first invariant of the right Cauchy-Green strain tensor with the volume change eliminated, $\bar{\lambda}_f$ represents the stretch ratio of the muscle fibers, T_0^M is the maximum muscle tension produced by the muscle at resting,

$\theta \in [0, 1]$ defines the level of activation, and $J = \det(\mathbf{F})$ is the volume ratio, where $\mathbf{F}$ is the deformation gradient. In this work, only the passive behavior of the muscles were included, thus it was assumed $\theta = 0$ for all the simulations, considering that the muscles are fully relaxed due to anesthesia [46].

To simplify the FE simulations, the fetus head used was considered rigid and was modeled with dimensions in agreement with the literature for a full-term fetus, as thoroughly detailed in Parente *et al.* (2008) [21].

4.3.2 Finite element simulations of childbirth

A set of 2744 simulations were performed, varying the material properties of the Martins constitutive model, used to characterize the PFM, as described in section 2.2.1. Janda (2006) [47] obtained a set of stress-strain curves from uniaxial and equibiaxial tests performed on PFM of fresh cadaver specimens. Based on these curves, Parente *et al.* (2009) [22] performed an iterative process by varying the constitutive model constants until obtaining an adequate approximation, reaching a range of values for the material parameters of the Martins constitutive model. Following an iterative approach, each parameter was varied while analyzing the stress-strain curves generated, ensuring that they remain within the range of curves defined by Janda. Thus, in the present study, the c , b and A material constants presented in Equation 4.1 varied in specific ranges: $\{0.01, 0.045\}$, $\{1.0, 1.35\}$ and $\{0.01, 0.052\}$, respectively, using 14 intervals to limit the number of simulations. The parameter a was kept constant and equal to 0.6215, as Parente *et al.* (2009) [22] also did not vary this parameter due to its significant impact on the results obtained with the equation and the lack of information available regarding its influence. This resulted in 2744 distinct simulations, of which 1715 were successfully completed. The set of simulations took approximately 403 hours to run, using a Supermicro Workstation, Dual Epyc Milan 7315 32C/64T with 128 Gb DDR4 RAM.

Abaqus[®] software was used to perform simulations that mimicked the second stage of labor, with the fetus in the occipito-anterior position and vertex presentation. The simulations were designed to replicate an average second stage of labor in nulliparous women and lasted for 100 minutes [48]. To describe the fetal trajectory, all fetal movements were enforced by a reference node that allows controlling the descent and the movements of flexion/extension, while the remaining degrees of freedom were left free. Due to the significant computational expense and prolonged duration required to execute the simulations, the descent of the fetal head was limited to a maximum of 65 mm, instead of 90 mm. This restriction was chosen as it approximately aligns with the point of maximum muscle stretching, and it is expected that the maximum

stress would be observed at this point or earlier, as established in previous studies [21, 22, 27].

Regarding boundary conditions, the nodes on the extremities of the PFM, demonstrated in a blue line in Figure 4.1, were fixed. Additionally, during the simulation, the interaction between the PFM and the fetal head was modeled using the standard Abaqus® contact algorithm. Kinematic contact conditions were imposed through the establishment of contact constraints between the aforementioned anatomical structures, recurring to the Augmented Lagrange method to facilitate surface interactions.

To assess the effect of the fetal descent on the PFM, the maximum principal stresses are generally obtained along a specified node path defined in the urogenital hiatus, as demonstrated in previous studies [49, 50] and represented in Figure 4.1. In the present work, the maximum principal stresses were measured at the referred path during the vertical displacement of the fetal head (0 to 65 mm).

4.3.3 Dataset generation

The dataset was generated with data retrieved from the FE simulations described in Section 4.3.2. To generate the dataset, 46 nodes of the PFM near the urogenital hiatus, as illustrated in Figure 4.1, were included for each simulation. This specific path has been commonly employed in prior studies for result collection, given that it is the area where stress and stretch on the pelvic floor typically exhibit higher values. Consequently, this approach simplifies the problem, enabling a less computationally expensive analysis. Thus, each node of the path corresponds to an observation of the dataset, which results in a total of 1715×46 observations, considering all simulations successfully performed. Only information from the simulations that converged was used to ensure a properly validated dataset.

To effectively train a supervised ML model, the data must be properly organized. This includes expressing the data in the form of an input matrix, which comprises the features used for training, and an output matrix, which consists of the target variable to be predicted. Therefore, each individual sample, represented by a row in the matrix, corresponds to a node of the FE mesh, with each column corresponding to a selected feature. An example of the dataset can be seen in Table 4.1. The choice of features is not fixed and must be made based on the problem and the relationship with the target variable. The following features were chosen to represent the input data:

- **Node number:** Number of the node in the FE mesh. It can be used as an identifier, for tracking or verification purposes.
- **Node position:** Position of the node in the node path composed of 46 nodes.

It provides information about the relation between each node and others, and can also give insights into stress distribution on the path.

- **x, y, z:** Initial coordinates of the node in a three-dimensional space, providing spatial information.
- **c, b, A:** Material parameters of the Martins constitutive model. Understanding how material properties can influence stress distribution.

Table 4.1: Dataset example including features and target for two different simulations.

node_number	node_position	x	y	z	c	b	A	S_Max_Principal
14659	0	-62.442	-16.784	9.836	0.010	1.275	0.019	1.446
14658	1	-66.698	-17.311	9.628	0.010	1.275	0.019	1.008
14657	2	-71.058	-17.808	9.485	0.010	1.275	0.019	0.606
14656	3	-75.368	-18.317	9.183	0.010	1.275	0.019	0.617
⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
14659	0	-62.442	-16.784	9.836	0.010	1.300	0.010	1.298
14658	1	-66.698	-17.311	9.628	0.010	1.300	0.010	0.917
14657	2	-71.058	-17.808	9.485	0.010	1.300	0.010	0.512
14656	3	-75.368	-18.317	9.183	0.010	1.300	0.010	0.523
⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮

Thus, the selected variables resulted in 8 variables used as input. As target, the objective is to predict the maximum principal stress (S_Max_Principal) at each node. With this purpose, two distinct approaches were tested:

- Case 1 – Obtain the maximum principal stress at each node for the instant of maximum stretch (65 mm). This results in a single target and was used as an initial demonstration of the feasibility of the implemented algorithm.
- Case 2 – Predict the maximum principal stresses at each node for multiple steps simultaneously (20 mm, 35 mm, 50 mm and 65 mm), resulting in a multi-objective approach.

Upon obtaining the output data from the FE simulations, which were used as true values, an analysis of the range of the stresses can be conducted. Figure 4.2 shows the stress range for four distinct descent levels. The bold line represents the mean, while the shaded area shows the range of values between the minimum and maximum for all simulations. This analysis facilitates the identification of the range of values that the algorithm needs to predict. The figure included at the left upper corner represents the fetal position in relation to the muscles at each level of fetal descent.

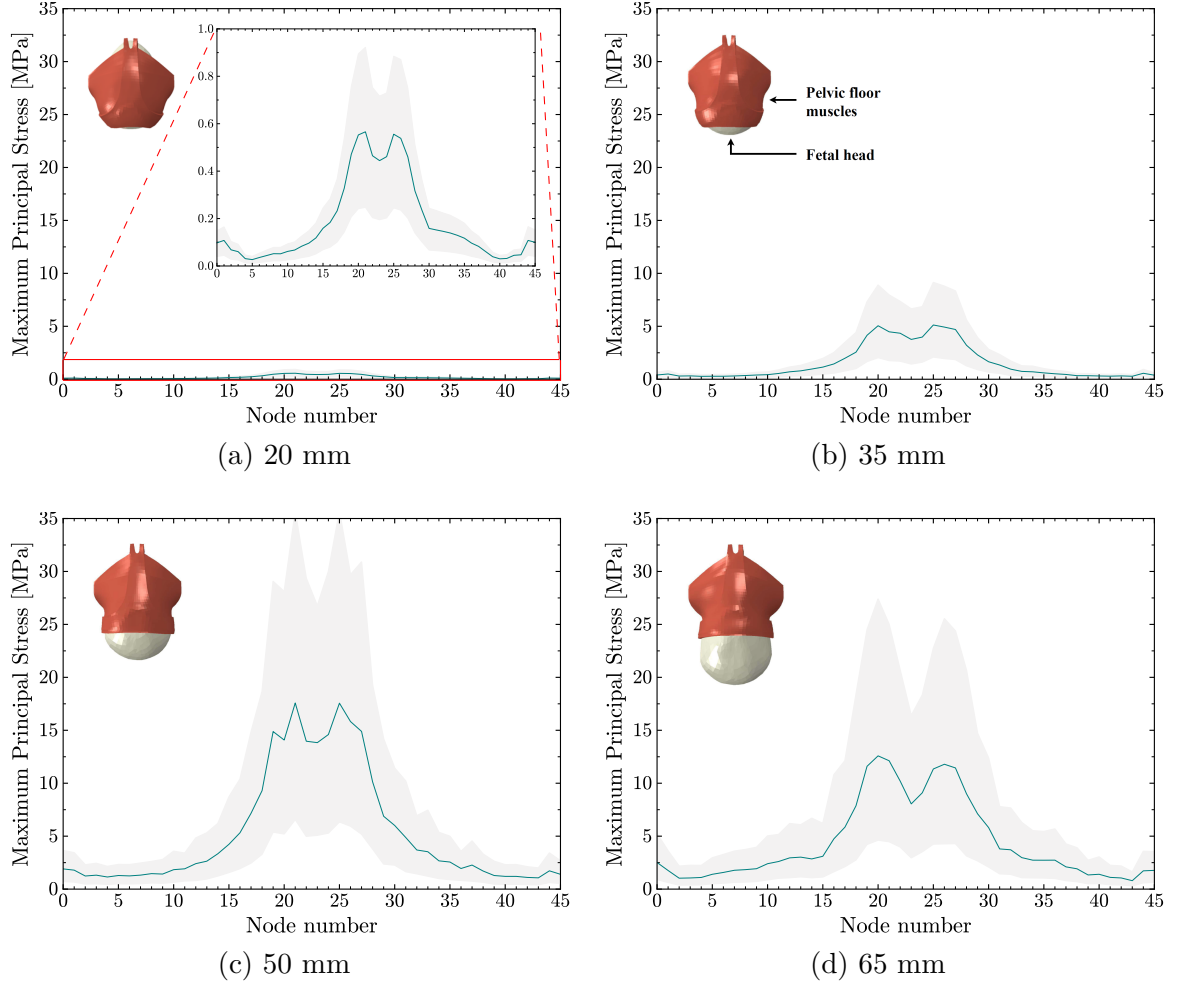


Figure 4.2: Maximum principal stress range for all simulations performed at 20, 35, 50 and 65 mm of fetal descent. The bold line represents the mean, and the shaded area the minimum and maximum values.

4.3.4 Machine learning pipeline

A ML pipeline, demonstrated in Figure 4.3, was established. The process of data generation starts with defining the range of material parameters, as elaborated in subsection 4.3.2. Subsequently, FE simulations were performed, involving variations in material properties within the predefined range. Upon completion of the simulations, the dataset was created, incorporating the specified features (outlined in subsection 4.3.3). Data pre-processing was then implemented, which included feature scaling, grouping the nodes to ensure that nodes belonging to the same simulation are not separated into the training or test sets, and splitting the dataset into training and test sets. Following this, a process of hyperparameter tuning with cross-validation was performed to obtain the best set of hyperparameters for each model. Subsequently, the models were trained using the obtained parameters. Finally, the model's performance was evaluated using well-established metrics and an error estimate was determined

using the test set.

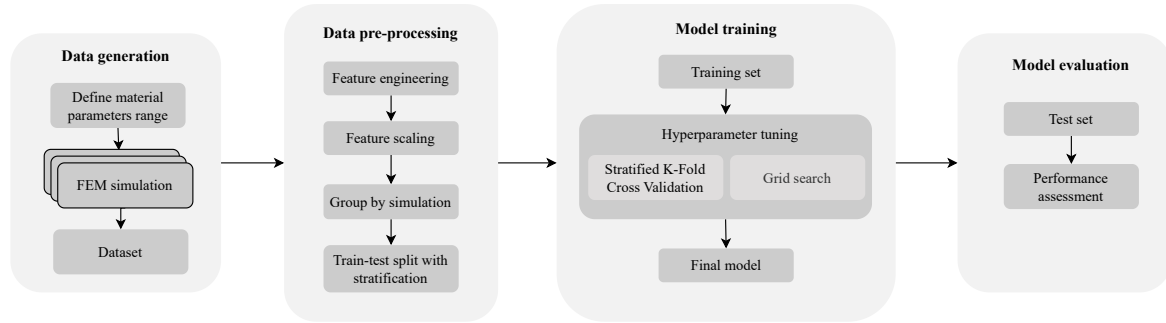


Figure 4.3: Pipeline describing all steps performed from data generation to model evaluation.

In this study, four types of models were considered: two tree-based algorithms (RF and XGBT), SVR, and ANNs, based on the reported in Phellan *et al.* (2021) [10]. The same hardware used to run the simulations, mentioned in Section 4.3.2, was used to train the models. The following sections explain the data pre-processing, model selection, validation, and evaluation processes in detail.

Data pre-processing

Following the common ML framework, the dataset was divided into two subsets, the training and test sets. However, randomly generating splits of the dataset is not the optimal solution for most problems, as the proportions of the features or classes can be extremely different. Thus, a sophisticated approach to perform this operation is to incorporate stratification, which guarantees that the distribution within the training and test sets is similar. This technique is crucial to prevent bias during the model evaluation process and to improve performance metrics. In the present study, as it is a regression problem, the aim was to ensure that there is a homogeneous distribution of the features values that vary between each simulation (the material parameters c , b , and A). One of the benefits of utilizing stratification is that it is used to mitigate overfitting by improving the generalization error. Thus, *StratifiedShuffleSplit* method from *scikit-learn* open-source software library [51] was implemented to divide the data in training and test sets.

Before splitting the data into training and test sets, a data transformation process was performed to maintain the consistency of the simulations. This was achieved by ensuring that all nodes within each simulation belonged either to the training or test set. This approach helps the ML model to learn the relationships and dependencies between variables and reduces the possibility of overfitting due to noise or any other anomalies in the data.

Furthermore, a pre-processing technique for scaling was implemented in the dataset, as ML algorithms generally perform better when features are on a similar scale or close to normal distribution. The *scikit-learn* library's *StandardScaler* function was used for this purpose. Although other scaling algorithms were tested during the training process, the method described produced the best results.

Hyperparameter optimization with cross-validation

Hyperparameter tuning consists of a fundamental procedure to obtain a powerful ML model, especially for algorithms with many hyperparameters, such as tree-based models or neural networks [52]. The traditional way of selecting these parameters is through manual testing, but this approach is not efficient when the model has a large number of hyperparameters, as it becomes time-consuming. To overcome this, automatic optimization techniques have been developed to find the optimal architecture of an ML model. These techniques reduce the amount of human effort required, improve the performance of ML models, and make the models and research more reproducible [52].

One of the most widely-used methods for hyperparameter tuning is grid search, which is considered an exhaustive search method that evaluates all combinations provided in the grid. This procedure was implemented in the present work and Table 4.2 shows the values set for each hyperparameter. For the parameters not mentioned, the default value was used. The ANN architecture was designed to be simple, consisting of two hidden layers, since the increase in architecture complexity did not improved the model's performance.

Table 4.2: Grid search hyperparameter values for each algorithm.

Algorithm	Hyperparameters	Search values
RF	max_depth	3, 5, 10, 50, 100, 200, None
	max_features	sqrt, 1.0
	min_samples_leaf	0.3, 0.5, 1, 2
	min_samples_split	0.5, 1, 2, 3, 4
	n_estimators	20, 100, 200, 500, 1000
XGBT	n_estimators	10, 20, 25, 50, 100, 200
	max_depth	3, 5, 9, 10, 11, 20, 100, 200, None
	eta	0.1, 0.2, 0.22, 0.3
	lambda	1, 2, 5, 10
SVR	C	1.0, 2.0, 3.0
	gamma	scale, auto
	kernel	rbf, linear, sigmoid
ANN	batch_size	64, 128, 256
	epochs	80, 100, 150
	learning_rate	0.001, 0.008, 0.01, 0.05, 0.1
	activation_function	ReLU, sigmoid
	hidden layer 1	60, 62, 64, 66
	hidden layer 2	68, 70, 72, 74

To determine the optimal parameters for each model, a combination of hyperparameter optimization and cross-validation was employed. The *StratifiedKfold* and *GridSearchCV* methods were used, both from *scikit-learn* library, considering a five-fold cross-validation. To ensure consistency with the train-test split process, nodes from the same simulation were assigned exclusively to a single fold.

To illustrate the impact of hyperparameters on the model's performance, a sensitivity analysis was conducted. Different values were explored for each hyperparameter within the specified search space. The ANN model was trained using all possible combination of hyperparameters, and the resulting MAE was recorded for each combination. Figure 4.4 displays the mean MAE and standard deviation for each hyperparameter under study, while keeping the studied hyperparameter constant and modifying all other parameters.

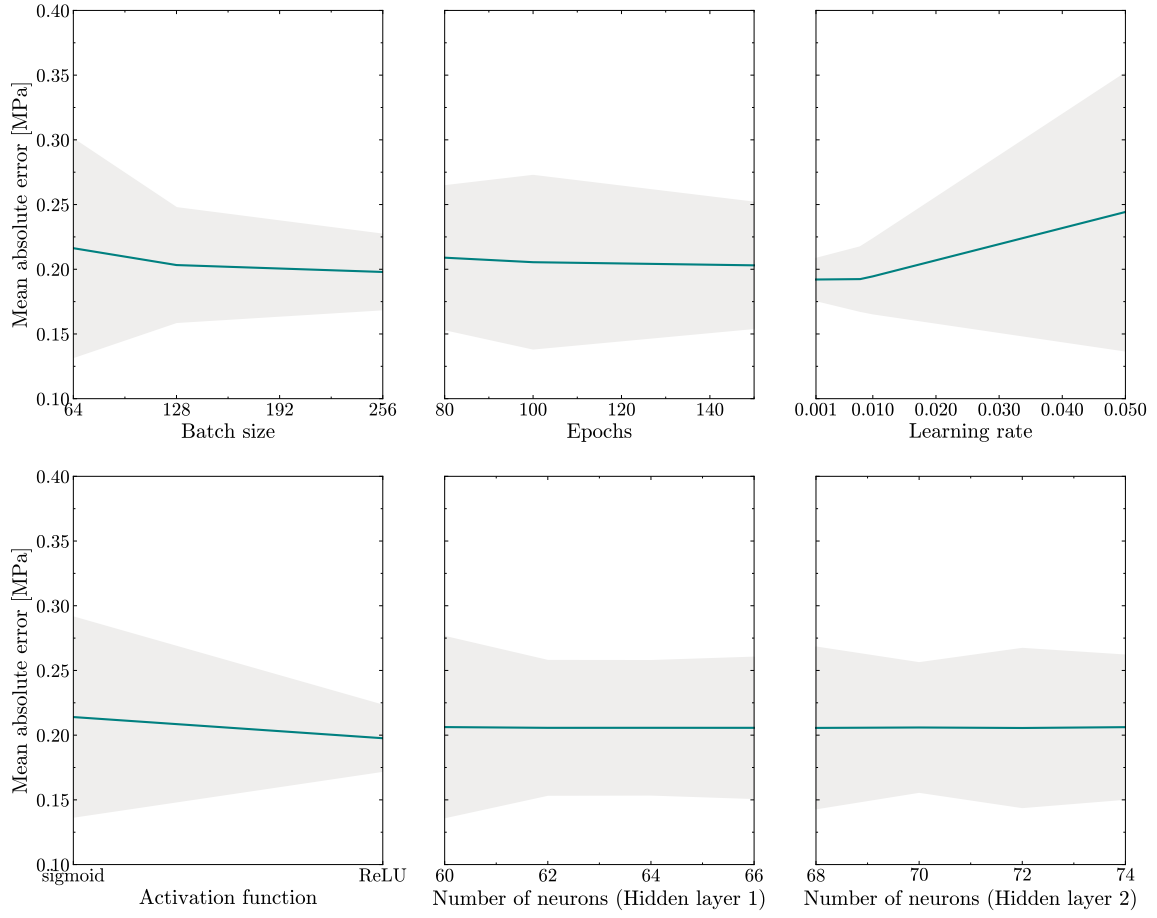


Figure 4.4: Hyperparameter sensitivity analysis for the ANN model.

Performance metrics

Performance metrics are required to quantify the results obtained while training and evaluating a ML algorithm [10]. In the current study, the results were evaluated through two commonly used metrics in applications that use ML algorithms to simulate biomechanical behavior: the mean squared error (MSE) and the MAE.

The MSE is a common metric used for validation and testing purposes, calculated as the average of the squared differences between the values generated by the ML model and the corresponding labels, as presented in Equation 4.2. The MSE is simple to use and since it is used in many scientific publications, it allows performance comparison with other proposed ML methods.

$$MSE = \frac{1}{N} \sum_{i=1}^N (y_i - \hat{y}_i)^2 \quad (4.2)$$

where y correspond to the reference values, $\hat{y}$ to the predicted values, and N to the

number of data points.

Another commonly used metric in regression problems is the MAE, which calculates the magnitude of the difference between the predicted value and the true value (Equation 4.3).

$$MAE = \frac{1}{N} \sum_{i=1}^N |y_i - \hat{y}_i| \quad (4.3)$$

Regarding its advantages, MAE has the same unit as the original data, is robust to outliers as it gives equal weight to all errors and is easy to interpret and compare to other models, making it a useful metric for evaluating models.

The aforementioned metrics can also be normalized. The normalized mean squared error (NMSE) and absolute error (NMAE) are presented in Equations 4.4 and 4.5, as defined in [10].

$$NMSE = \frac{MSE}{\max(y_i) - \min(y_i)} \times 100\% \quad (4.4)$$

$$NMAE = \frac{MAE}{\max(y_i) - \min(y_i)} \times 100\% \quad (4.5)$$

4.4 Results

This section presents the results obtained for each model and case study. All results presented refer to the test set to provide an indication of the performance of the models on unseen data that is different from the data used for training.

4.4.1 Hyperparameter optimization

Table 4.3 demonstrates the hyperparameters selected for each model for both cases 1 and 2. The SVR model was only used in case 1, thus no values were chosen for case 2.

Table 4.3: Optimal hyperparameter values selected for each algorithm.

Algorithm	Hyperparameters	Case 1	Case 2
RF	max_depth	100	100
	max_features	sqrt	sqrt
	min_samples_leaf	1	1
	min_samples_split	3	1
	n_estimators	500	500
XGBT	n_estimators	25	25
	max_depth	11	11
	eta	0.22	0.22
	lambda	10	2
SVR	C	3.0	–
	gamma	scale	–
	kernel	rbf	–
ANN	batch_size	256	256
	epochs	100	100
	learning_rate	0.008	0.0085
	activation_function	sigmoid	sigmoid
	hidden layer 1	62	66
	hidden layer 2	72	74

The RF architecture consisted of an ensemble of 500 trees, each with a maximum depth of 100. To form a leaf node, at least one sample was required, and for an internal node to split, a minimum of 3 samples were required in case 1 and 1 sample in case 2. Moreover, the XGBT architecture comprised 25 trees in the ensemble, with a maximum depth of 11. The model was trained with a learning rate of 0.22, and an L2 regularization parameter of 10 was used for case 1, and 2 for case 2. The SVR model utilized an RBF kernel with a kernel coefficient set to *scale* and a regularization parameter of 3.0. The ANN has been designed with a batch size of 256 and is trained over 100 epochs using a learning rate of 0.008 for case 1 and 0.0085 for case 2. The activation function used is sigmoid. The ANN has the following architecture: an input layer with 8 neurons representing the features; two hidden layers with 62 and 72 neurons for the first case, and 66 and 74 neurons for the second case; and an output layer producing a single output for case 1 and four outputs for case 2.

An ablation study was conducted on the ANN to assess the influence of the two defined layers on the model’s performance. The findings suggest that training with each layer independently results in a higher mean absolute error. This indicates that the employed model has a suitable architecture for addressing the problem under study.

4.4.2 Case 1 – Single-output prediction for maximum stretch level

The results for the prediction of maximum principal stresses at a fetal descent of 65 mm are demonstrated in Table 4.4, which presents the MSE, MAE, NMSE and NMAE. Furthermore, the errors for the Dummy Regressor model (DM) were also included, which corresponds to an important tool for comparing the performance of other regression models. This model provides a baseline for comparison by predicting the target variable using the mean of the training data.

Among the models evaluated, the ANN yielded the most favorable outcomes, achieving an MSE of 0.112 MPa² and an MAE of 0.191 MPa. Conversely, the SVR model registered the highest error, with a MSE of 0.444 MPa² and a MAE of 0.356 MPa. For this reason, the latter was not considered in Case 2.

Table 4.4: MSE and MAE calculated for the ML models used.

	DM	RF	XGBT	SVR	ANN
MSE [MPa ²]	17.76	0.131	0.123	0.444	0.112
MAE [MPa]	3.235	0.207	0.203	0.356	0.191
NMSE [%]	66.76	0.492	0.462	1.669	0.413
NMAE [%]	12.16	0.782	0.763	1.338	0.718

Since the values demonstrated in Table 4.4 correspond to a mean for all nodes of the pelvic floor path, Figure 4.5 presents a box plot in which the path was divided in five regions to analyze the MAE in each region.

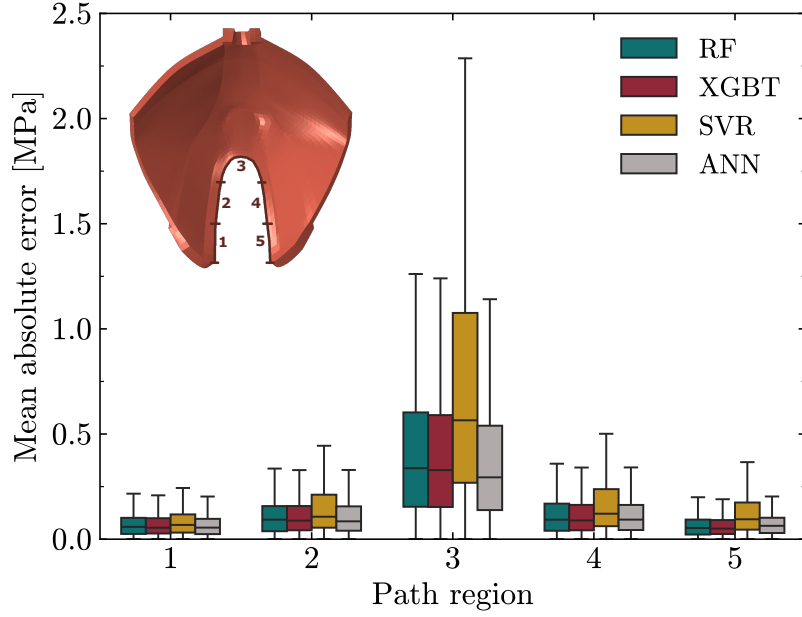


Figure 4.5: Box plot demonstrating the mean absolute error for each region of the PFM path. The distinct regions are represented in the left upper corner.

Figure 4.6 illustrates a box plot of the maximum principal stress for each node in all simulations within the test set, presenting both predicted and true values using the ANN model.

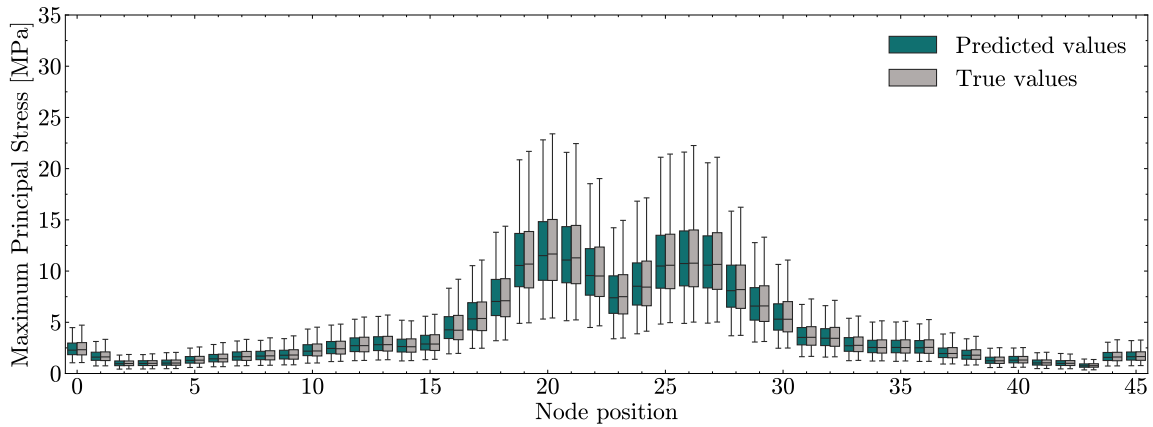


Figure 4.6: Box plot presenting the predicted and true values for each node of the test set simulations (ANN model).

An example of the maximum principal stress distribution for a simulation of vaginal delivery with fetal head descent of 50 mm is presented in Figure 4.7.

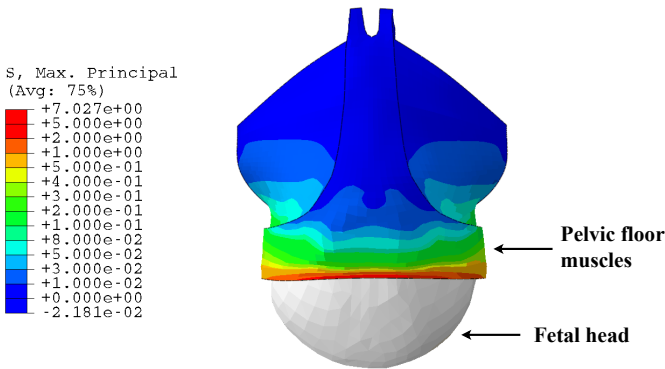


Figure 4.7: Maximum principal stress (MPa) distribution in a FE simulation of childbirth, considering 50 mm of fetal descent.

4.4.3 Case 2 – Multi-output prediction for multiple fetal descent levels

Table 4.5 displays the MSE, MAE, NMSE and NMAE computed for each fetal descent level, along with the mean errors for predicting the four values simultaneously. The results demonstrate that XGBT model is more suitable to predict lower stress values, whereas the ANN model performs better in predicting stress in the highest ranges.

Table 4.5: MSE, MAE, NMSE and NMAE calculated for each fetal descent instant for the different selected models.

	Fetal descent	DM	RF	XGBT	ANN
MSE [MPa ²]	20 mm	0.034	3×10^{-5}	2×10^{-5}	8×10^{-5}
	35 mm	2.988	0.004	0.003	0.004
	50 mm	35.34	0.185	0.167	0.153
	65 mm	17.76	0.132	0.129	0.105
	Mean	14.03	0.080	0.075	0.066
MAE [MPa]	20 mm	0.143	0.003	0.002	0.006
	35 mm	1.360	0.032	0.028	0.035
	50 mm	4.555	0.242	0.230	0.214
	65 mm	3.235	0.206	0.208	0.187
	Mean	2.323	0.121	0.117	0.111
NMSE [%]	20 mm	3.794	0.003	0.002	0.010
	35 mm	34.79	0.047	0.035	0.047
	50 mm	102.1	0.537	0.482	0.439
	65 mm	66.76	0.496	0.485	0.417
	Mean	51.86	0.271	0.251	0.228
NMAE [%]	20 mm	16.15	0.339	0.226	0.677
	35 mm	15.84	0.373	0.326	0.407
	50 mm	13.16	0.699	0.664	0.628
	65 mm	12.16	0.774	0.782	0.712
	Mean	14.33	0.546	0.499	0.606

A box plot demonstrating the MAE for five distinct pelvic floor path regions, as previously described, and for each level of fetal descent, is illustrated in Figure 4.8. The path region is similar to the one represented in the left upper corner of Figure 4.5.

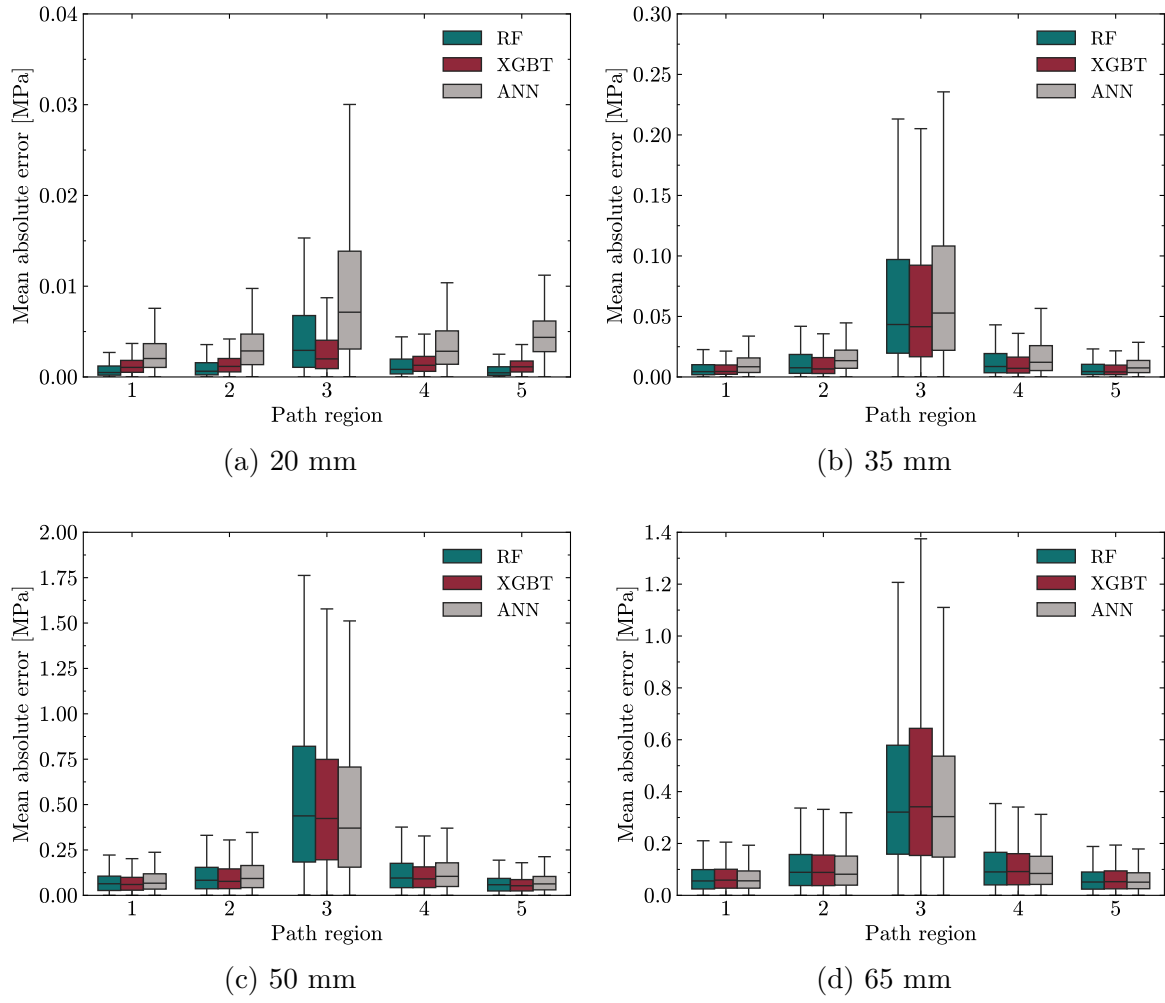


Figure 4.8: Box plot demonstrating the mean absolute error for each region of the PFM path at four different levels of fetal descent.

Figure 4.9 demonstrates the maximum principal stress for each node at 50 mm of fetal descent, corresponding to all the simulations in the test set, for the predicted and true values with the ANN model.

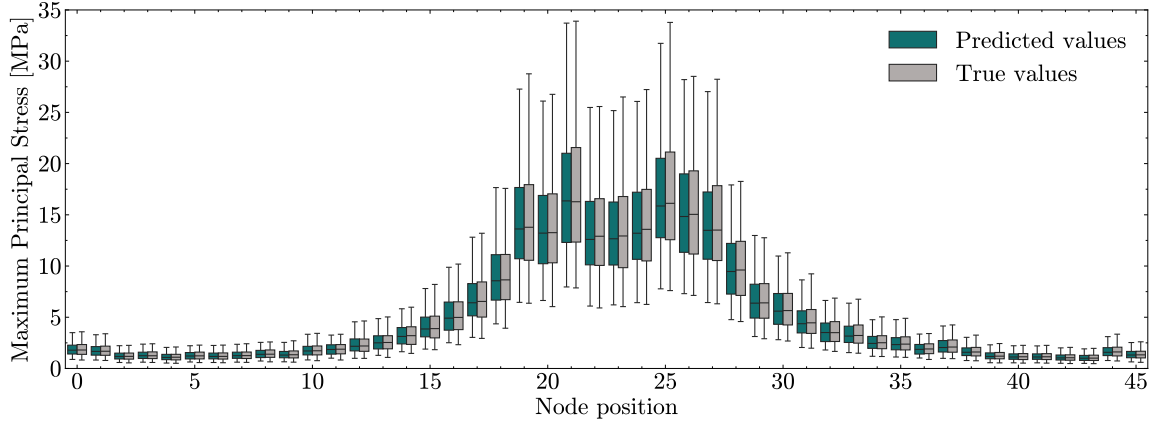


Figure 4.9: Mean predicted and true values for each node of the test set simulations for 50 mm of fetal descent (ANN model).

To analyze the significant difference between the ML models, the Wilcoxon rank sum test was conducted. In this test, the values obtained from each fold in the k-fold cross-validation were used, employing the optimal hyperparameters for each model. The results of the test indicate a significant difference ($p\text{-value} < 0.05$) between the SVR model and all other tested models (RF, XGBT, and ANN). Additionally, a significant difference also exists between the ANN model and the RF model, with a $p\text{-value}$ of 0.028. However, no significant differences were observed between the ANN and XGBT models, as well as between the RF and XGBT models.

4.4.4 Real-time performance and time gains

In computer engineering, a real-time system is defined as a system where responses must happen within a precise range of time, usually expressed in milliseconds or a few seconds for biomechanical applications [10]. The classification of a system as real-time depends on its application, since some authors expressed their results in milliseconds but others also consider a few seconds as real-time.

Table 4.6 displays the time required to predict stress values for a simulation in the two cases implemented, as well as the time necessary to load the different models, which can be relevant for certain applications. The values presented represent the mean of ten subsequent measurements.

Table 4.6: Measurement of the time required to predict stress values and load each model for the two cases, including also the total time needed (model load with prediction).

	Predict		Model load		Total	
Model	Case 1	Case 2	Case 1	Case 2	Case 1	Case 2
RF	0.041 s	0.044 s	1.765 s	3.155 s	1.806 s	3.199 s
XGBT	0.014 s	0.022 s	0.111 s	0.185 s	0.125 s	0.208 s
ANN	0.120 s	0.117 s	0.301 s	0.313 s	0.422 s	0.429 s

4.5 Discussion

Childbirth simulations are widely used by researchers to investigate the effects of vaginal delivery. FE simulations allow researchers to model childbirth considering different factors and specific scenarios. Nonetheless, these simulations are computationally expensive, becoming impractical to use in real-time decision-making. One potential solution is to utilize FEM-based ML algorithms, wherein a model is trained using data from a set of FEM simulations. This approach facilitates the prediction of particular outputs when the model is sufficiently trained with appropriate data. The primary objective of this study was to establish an initial framework that uses ML algorithms to predict stresses on the PFM during vaginal delivery.

In the present work, two distinct approaches were utilized: case 1 aimed to predict a single stress at the moment of maximum muscle stretch, while case 2 aimed to predict multiple stresses throughout fetal descent. In the prediction of the maximum principal stress for the instant of maximum stretch, the XGBT algorithm outperformed the RF, demonstrating higher predictive capabilities and faster prediction and loading times. XGBT's sequential addition of decision trees correcting previous errors contributed to its superior performance. Furthermore, SVR did not provided promising results for stress prediction, it required time-consuming hyperparameter tuning and still yielded considerably higher mean absolute error compared to other models, making it unsuitable for this specific application. The ANN outperformed all other models, as neural networks excel in modeling highly nonlinear and complex relationships, resulting in better predictions. Some disadvantages consist of the fact that training a neural network is computationally intensive, and hyperparameter tuning is complex and time-consuming due to the large number of hyperparameters involved.

The box plot shown in Figure 4.5 indicates that the error is higher in region 3 of the pelvic floor path, which corresponds to the area of highest stress. On the other hand, errors are lower in the other regions since stresses are also lower. The ANN model

performed the best, with a median error value of less than 0.4 MPa. Additionally, the plot indicates a right-skewed data distribution, suggesting that most of the values are concentrated in the lower part of the box, and the median is closer to the first quartile. A right-skewed distribution indicates that the model has smaller error for most of the data points and larger error for extreme cases. Thus, this distribution can impact the analysis of the overall model's performance, possibly leading to a misinterpretation of its performance.

Regarding the second case, results indicate that the XGBT model performed better for predicting fetal head descent at 20 and 35 mm, while the ANN model had lower error values for higher stresses, corresponding to a descent of the fetal head of 50 and 65 mm. Therefore, it can be concluded that the XGBT model is more suitable for predicting values in a narrow range, whereas the ANN model may be more appropriate for predicting higher stresses. In Figures 4.8a and 4.8b, it is evident that the neural networks had significantly higher error compared to the other models. One possible explanation for this might be that the stress data for 20 mm and 35 mm are relatively closer and may exhibit a more linear or structured relationship, as the stress values are lower. Therefore, it may be easier to model them using a tree-based approach. Conversely, the stress values in the higher range groups may have more complex and nonlinear relationships, which may require a more flexible modeling algorithm. From a clinical perspective, predicting higher stress values is more relevant, thus using an ANN may be more suitable.

To assess the generalization ability of the model, a second test set was employed, consisting of new data that had not been previously seen by the model, and which utilized material parameters of the Martins model with different intervals than those used in generating the training data. The resulting MAE for the ANN model in case 1 was 0.34 MPa, indicating that the model is capable of performing reasonably well on new data and has demonstrated good generalization ability.

The time required to make predictions using the pre-trained models was measured (Table 4.6), and the results indicated that the XGBT model is the fastest. This model demonstrated error values only slightly higher than those of the ANN and proved to be better at predicting stress values within a lower range. Therefore, it may be preferable to use this model for applications that require a rapid response, and where the error value can be overlooked. For example, in the current study, as the stresses have high values in case 1, a difference of 0.012 MPa in the error will not significantly impact the results obtained, so a fast model response can be more relevant. However, in other contexts such as surgery, it may be more important to keep the error as low as possible. It can be concluded that the selection of the appropriate model may depend on several

factors, and finding a balance between the obtained error and the prediction time is necessary. The RF model takes approximately twice as long to make predictions as the XGBoost model and has a very high model loading time, making it unsuitable for real-time applications. It is also possible to conclude that, despite taking a considerable amount of time to run the FE simulations and generate the dataset, once the model is trained, it can predict stresses based on a specific set of parameters in less than 4 seconds, in the worst-case scenario.

The number of simulations that were run was determined by defining the intervals between the material parameters of the Martins constitutive model. For each parameter, a range of 14 values was defined based on their minimum and maximum values. This level of discretization was deemed sufficient to impact the results, leading to a total of 2744 simulations ($14 \times 14 \times 14$). Based on the performance obtained, it appears that additional data is not necessary as the error is already quite low for the range of stress values in the dataset. Moreover, conducting more simulations would be time-consuming. Similarly, while it would have been possible to select more parameters for the grid search during hyperparameter optimization, this would have increased the model training time when the results were already satisfactory, making it less computationally efficient.

The applied methodology could be used in clinical practice if muscle properties were measured more frequently. There are already some non-invasive techniques that allow obtaining the elastic properties of tissues in the pelvic region, such as SWE. However, this type of examination is not commonly performed. To overcome this issue and acquire a comprehensive understanding of the mechanical behavior of the PFM, standard measurement protocols should be incorporated into regular prenatal appointments, especially towards the later stages of pregnancy, as the properties of the tissues may undergo changes over time. It is worth noting that the current study relied on synthetic data generated through FE simulations. Ideally, ML models should be trained using real clinical data. However, obtaining *in vivo* measurements is challenging and involves collecting several authorizations. Furthermore, due to the large amount of data required, the process would be time-consuming and could take several years to complete the dataset. Therefore, using biomechanical simulations in data generation can overcome these challenges, as long as the limitations of the models are acknowledged and that the models are validated using parameters and dimensions derived from clinical data.

4.6 Conclusions

The current work represents an advance in the field of childbirth computational simulations using AI tools. In this work, a FEM-based ML framework was developed, utilizing data from FE simulations. Distinct ML models were trained to analyze and determine the most appropriate model for predicting maximum principal stress, based on the material properties of the PFM as input. The ability to predict, in this case, the stresses experienced by the woman on the pelvic floor immediately before or during childbirth could aid in medical decision-making.

The present study has several limitations. The biomechanical simulations conducted to generate the dataset only considered fetal descent up to 65 mm, approximately the moment of maximum stretch, instead of the usual 90 mm, to reduce the time needed to create the dataset. This assumption was made based on the fact that stresses generally decrease after 65 mm of fetal descent, thus the maximum stress during childbirth is still adequately captured. Moreover, to ensure simulation convergence, a rigid head was utilized instead of a deformable head, which might have resulted in a higher stress range. Additionally, only one geometry was utilized for the PFM, which implies that the trained models are not suitable for all geometries. During the training process, the use of feature engineering and selection mechanisms such as creating new features by combining existing ones or ranking the importance of features based on their contribution to the model's performance, can enhance the results obtained.

Nevertheless, this work has successfully demonstrated the feasibility of implementing a ML approach coupled with FE analyses to predict pelvic floor stress during vaginal delivery. The implemented approach is significantly quicker than standard FE simulations, making it suitable for implementation in clinical applications. Therefore, the proposed methodology provides the beginning of a solution that can be potentially incorporated in more sophisticated software, aiding physicians in identifying muscle injuries as a preventive process.

As future work, a model capable of making predictions for a wide range of geometries representative of most women will be created, enabling to predict the stretch, damage, or other critical biomechanical factors for each woman, essential for determining possible maternal injuries. Additionally, the inclusion of perineal structures in the childbirth simulations can help predict other important injuries, while using a deformable fetal head will lead to more reliable stress values. The inclusion of additional nodes of the FE mesh, beyond the initially selected 46 nodes selected, will also be addressed. With this, other features can be explored, such as boundary conditions, connectivity between nodes and elements, element shape and contact between

the nodes and elements with the fetal head. Mechanisms of feature selection will be employed to explore these features and improve model's performance.

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Chapter 5

Patient-specific surrogate model to
predict pelvic floor dynamics
during vaginal delivery

Patient-specific surrogate model to predict pelvic floor dynamics during vaginal delivery

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Abstract

Childbirth is a challenging event that can lead to long-term consequences such as prolapse or incontinence. While computational models are widely used to mimic vaginal delivery, their integration into clinical practice is hindered by time constraints. The primary goal of this study is to introduce an AI pipeline that leverages patient-specific surrogate modeling to predict pelvic floor injuries during vaginal delivery. A FEM-based ML approach was implemented to generate a dataset with information from FE simulations. Thousands of childbirth simulations were conducted, varying the dimensions of the PFM and the mechanical properties used for their characterization. Additionally, a mesh morphing algorithm was developed to obtain patient-specific models. ML models, specifically tree-based algorithms such as RF and XGBT, as well as ANNs, were trained to predict the nodal coordinates of nodes within the pelvic floor, aiming to predict the muscle stretch during a critical interval. The results indicate that the RF model performs best, with a MAE of 0.086 mm and a mean absolute percentage error of 0.38%. Overall, more than 80% of the nodes have an error smaller than 0.1 mm. The MAE for the calculated stretch is equal to 0.0011. The implemented pipeline allows loading the trained model and making predictions in less than 11 seconds. This work demonstrates the feasibility of implementing a ML framework in clinical practice to predict potential maternal injuries and assist in medical-decision making.

Keywords: Finite element simulations; Mesh morphing; Pelvic floor stretch; Vaginal delivery; Machine learning; Real-time biomechanics.

5.1 Introduction

The WHO estimated that in 2020, around 800 women died each day globally due to pregnancy-related complications. This translates to one maternal death every two minutes worldwide, with the majority of these fatalities occurring in low and lower-middle-income countries. The Sustainable Development Goal target is to decrease maternal mortality to less than 70 maternal deaths per 100,000 live births by 2030 [1]. Regarding morbidity, the WHO estimates that approximately 15% of all pregnant women will experience a long-term complication requiring specialized care [2]. In agreement, it has been reported that 6-40% of vaginal births may result in trauma to the LAM, leading to long-term consequences such as urinary and fecal incontinence or pelvic organ prolapse [3]. Consequently, there is a need to minimize pregnancy-related risks by predicting potential complications and implementing preventive measures.

Over the last few decades, FE simulations have emerged as a crucial tool in the study of the biomechanics of childbirth. The FEM allows for a comprehensive understanding of how structures and tissues respond to external stimuli, providing critical information about their mechanical behavior [4]. Childbirth computational simulations can overcome limitations of physical childbirth models or invasive evaluations, offering insights into the mechanisms of vaginal delivery and associated maternal and fetal injuries [5]. These models can mimic the geometries of bony structures, soft tissues, and the fetus. Mechanical properties can also be included to describe the mechanical behavior of the tissues by using constitutive models with parameters that match *in vivo* experimental data [6].

One of the major limitations of the described FE models is that they have generally been created to match the geometry of a single representative individual within a population. This presents a significant limitation, as anatomical differences among women may result in distinct mechanical responses. While models of the pelvic floor could be developed on a subject-specific basis, creating new meshes and models for multiple geometries can be time-consuming and inconsistent. Therefore, mesh-morphing techniques can be employed to modify the body's shape without the necessity of creating an entirely new mesh. This involves generating a new shape for the structure under study by updating nodal positions while maintaining the same topology, thereby preserving the mesh quality. In biomechanical applications, morphing can be utilized by adapting a template mesh to a subject-specific geometry obtained from magnetic resonance or other imaging modalities [7, 8, 9]. The generation of new shapes involves deforming the baseline model's mesh by updating nodal positions, requiring minimal computational time compared to any re-meshing procedure [7].

Despite successfully overcoming certain limitations with mesh-morphing methods to create patient-specific models, incorporating biomechanical simulations into clinical practice remains challenging due to their high computational costs. However, this obstacle can be addressed by leveraging AI techniques. Recent technological advancements have significantly strengthened the bond between medicine and engineering, leading healthcare professionals to recognize the potential for technology to enhance diagnostic accuracy, aid medical decision-making, guide personalized treatment approaches, assess lesion likelihood, and offer valuable support during surgical procedures. In the field of obstetrics, studies have already been conducted to predict distinct risks during pregnancy, such as determining the most suitable birth method [10] and addressing factors associated with preterm birth or the risk of its occurrence [11, 12].

Nevertheless, these studies have relied only on clinical datasets or statistical information, lacking the integration of biomechanical data. The use of AI techniques with FEM simulations enables the inclusion of information from personalized biomechanical models. This information can then be used by ML models to learn complex relationships and identify patterns that may not be evident through clinical statistical datasets alone. In addition, while the integration of clinical data is always beneficial, the generation of synthetic data has the advantage of considering the majority of possible scenarios, which can be limited with clinical data due to its unavailability. Therefore, to fasten the results and apply biomechanical simulations in a clinical setting, surrogate models can be used to replace expensive computational models, allowing for real-time outcomes [4]. A surrogate acquires knowledge of soft tissue behavior resorting to a supervised ML approach that utilizes data from previously generated numerical simulations. These simulations provide a comprehensive understanding of the biomechanical properties and behavior of soft tissues. Although researchers have used surrogate modeling in the field of biomechanics, its application to childbirth simulations has only been investigated by Moura *et al.* (2024) [13], who employed ML models to predict the stress on the PFM during vaginal delivery. However, the referenced study lacks a patient-specific methodology and the prediction of additional pertinent variables concerning childbirth-related injuries, as well as a comprehensive framework for implementing this approach.

In this context, the present study proposes an innovative approach to address this gap by developing an AI framework for predicting the risk of PFM injuries during vaginal delivery. The main goal is to train ML models to predict the PFM stretch during childbirth, indicating the potential risk of lesion. The development of this framework consists of a preliminary step toward the implementation of patient-specific, near real-time computational simulations in a clinical environment. These biomechanical simulations aim to offer clinically relevant information about potential birth injuries

based on the specific characteristics of the patient, including geometry and mechanical properties.

In summary, the main contributions of this paper are:

1. A dataset consisting of synthetic data that spans the anatomical spectrum of material properties relevant to characterizing the female PFM. In addition to mechanical characterization, this dataset integrates muscle dimensions derived from ultrasound and MRI measurements obtained from literature.
2. A mesh-morphing approach that facilitates the creation of patient-specific simulations. This approach is not limited to the PFM but can be extended to other anatomical structures as needed. The implementation of this technique enhances the adaptability of biomechanical simulations, providing a valuable tool for personalized patient assessment.
3. A deeper understanding of the behavior of ML models when applied to biomechanical childbirth simulation data. This knowledge can assist in the selection and more efficient optimization of ML models for future applications.
4. Development of an innovative framework for predicting the risk of PFM injury during vaginal delivery that includes the intersection of AI techniques and biomechanical simulations, bridging the gap between biomechanics and clinical practice to improve diagnostic accuracy and personalized treatment approaches.

The structure of this article is as follows: Section 5.2 provides a brief state-of-the-art in childbirth biomechanics and FEM-based ML. Section 5.3 presents a detailed description of the proposed methodology, including the conceptualization of the developed framework, the computational model utilized, FE simulations conducted, and the implemented ML pipeline. In Section 5.4, the main results are presented. Section 5.5 includes in a discussion of these results, and finally, in Section 5.6, the proposed work is summarized, outlining potential future research directions.

5.2 Related work

5.2.1 Biomechanics of childbirth

Childbirth simulations have been extensively used to analyze the biomechanics of labor and gain a better understanding of this physiological process. One of the first three-dimensional computational models used to calculate LAM stretch during vaginal delivery was introduced by Lien *et al.* (2004) [14]. The authors concluded that the medial pubococcygeus muscle experiences the most significant stretch during labor,

with an elevated risk of injury. Subsequently, numerous advancements have been made in the analysis of vaginal delivery and the understanding of the physiology of the female pelvic floor.

Geometric and anatomical models of the PFM and fetal head have been created using MRI data and cadaveric measurements. These models facilitate numerical simulations of the second stage of labor, revealing that the PFM undergo significant deformations during the passage of the fetal head. The presentation and position of the fetal head, as well as the degree of head flexion, have also been investigated to assess their impact on maternal injuries [15, 16]. Additionally, other biomechanical models incorporate the main women's organs involved in the birthing process, resulting in a comprehensive yet simplified model of the pelvic cavity [17].

Since mechanical characterization is essential for FE simulations, distinct constitutive models have been tested to characterize the PFM. Parente *et al.* (2010) [18] analyzed the influence of muscle contraction during vaginal delivery, focusing on the activation of the PFM. Other studies have incorporated damage models to define the mechanical behavior of the PFM, aiming to analyze potential injuries inflicted on the muscles. Additionally, researchers have explored viscoelasticity to enable a time-dependent analysis, providing insights into the biomechanical impact of delivery duration [19, 20, 21].

Computational models have also been employed to investigate the effects of obstetrical procedures on the PFM. Oliveira *et al.* (2016) [22] conducted a biomechanical analysis of the impact of episiotomy during vaginal delivery, examining the influence of different fetal positions on this procedure [23]. The analysis also integrated multiple types of episiotomies to provide a comprehensive understanding of their effects [24].

Still within the field of childbirth biomechanics but more focused on the behavior of the uterus, Vila Pouca *et al.* (2019) [25] implemented a chemo-mechanical constitutive model to investigate uterine contractions during fetal expulsion. Subsequently, Fidalgo *et al.* (2022) [26] analyzed the impact of irregular uterine activity during vaginal delivery using an electro-chemo-mechanical constitutive model. This particular constitutive model has also been employed to examine the mechanical effects of a Maylard scar during a vaginal birth following a previous caesarean section [27].

The computational models discussed have overlooked the incorporation of superficial structures in the perineum. Routzong *et al.* (2019) [28] introduced the first model that incorporates superficial perineal structures to assess the stretch of the pubo-visceral muscle and perineal body. The findings emphasized the crucial role of the perineal structures in female birth injuries, highlighting the necessity of considering them in computational simulations of vaginal delivery. Recognizing the importance

of a comprehensive representation of soft tissues, Chen *et al.* (2021) [6] identified the need to develop a complete model. Consequently, recent computational models have addressed this gap by including perineal structures and conducting a thorough analysis of their impact [29, 30].

While being a well-established domain, the commonality among these studies, apart from acquiring biomechanical knowledge regarding childbirth, is that they all rely on complex numerical simulations that are computationally expensive and require a significant amount of time to obtain the desired results.

5.2.2 FEM-based ML in biomechanics

Recently, due to the success of AI techniques in enhancing medical diagnostics, treatment planning, and patient outcomes, researchers have explored the application of FEM-based ML in biomechanical applications. Despite the computational expenses associated with FEM simulations, a trained ML algorithm can substantially decrease the time needed to obtain results. There is evidence in the scientific literature supporting that ML can help to accelerate the biomechanical simulations, obtaining real-time responses. This approach has been widely adopted in several studies, particularly those focusing on the liver, stomach, femur, heart, or breast, aiming to predict variables such as deformation, pressure, mechanical properties, external forces, and stress.

In studies aimed at predicting stresses, Lu *et al.* (2013) [31] demonstrated the effectiveness of a neural network in predicting stress values in musculoskeletal structures. A simplified model of the tibio-femoral joint was used and simulations were conducted across various loading and motion scenarios. The input features were the reaction forces, while the desired output was von Mises stress. In another application, deep learning was employed to estimate stress distributions in the aorta. This involved using patient image data and characteristics as direct inputs to a deep learning model, thereby replacing the conventional FE calculation process. The model's training aimed to generate accurate aortic wall stress distributions [32].

Additionally, Dabiri *et al.* (2019) [33] implemented a distinct approach by developing a FEM-based ML framework to simulate left ventricular mechanics. Decision trees and extreme gradient boosting were utilized as ML models to predict myocardial stresses. The input features included mechanical properties and elements' centroid coordinates, resulting in a significant reduction in stress prediction time from 20 minutes to 5 seconds. In the context of arterial health assessment, FEM-based ML was also applied for plaque rupture risk prediction. A parametric model for arterial geometry was created, and a database of 2D FE simulations was employed to predict the maximum von Mises stress, a crucial indicator of plaque rupture risk. The deep learning models

incorporated geometry, material properties, and boundary conditions, achieving stress predictions with an accuracy of under 10% [34].

These ML techniques have also been applied in other relevant studies, namely with the aim of predicting nodal coordinates, displacement, or deformation. In a study by Martínez-Martínez *et al.* (2017) [35], a data-driven method was introduced to simulate real-time biomechanical behavior in breast tissue. The primary goal was to predict the deformation of breast tissues under compression, employing models like extremely randomized trees and RF. In the field of liver biomechanics, ML algorithms were trained using thousands of biomechanical simulations, including different liver geometries. These algorithms incorporated features such as node coordinates, forces, material properties, and distances. The testing involved different scenarios, demonstrating the versatility of this approach [36].

More recently, Moura *et al.* (2024) [13] presented a FEM-based ML approach to predict the stresses on a specific region of the PFM during vaginal delivery. This study marks the first attempt to integrate AI techniques with FE simulations of childbirth. However, the study assumed the moment of maximum stretch of the PFM and calculated the stretch for that moment, without conducting a time frame analysis. Additionally, a single geometry was utilized for the muscles, rather than adopting a patient-specific approach. The main conclusions of the mentioned study were the proof of concept of applying FEM-based ML in the context of childbirth and the demonstration of the near-real-time application of the implemented methodology.

Building upon previous references, the present study introduces a novel framework designed to predict the behavior of the PFM during childbirth. The goal is to achieve nearly real-time results and provide valuable support in medical decision-making.

5.3 Methodology

5.3.1 Conceptualization

This work aims to establish a framework for implementing FEM-based ML techniques in clinical obstetric practice to aid in medical decision-making, as demonstrated in Figure 5.1.

In the AI pipeline, the dataset is initially generated through FE simulations. This process involves selecting the range of material parameters and pelvic floor diameters for inclusion in the simulations. Based on the defined diameters, mesh-morphing operations are performed, and a predefined number of FE simulations are conducted, providing essential information for dataset generation. Subsequently, data pre-processing

is performed, including feature selection, scaling, grouping nodes to ensure nodes from the same simulations are not separated into training or test sets, and division of the dataset into training and test sets. Following dataset pre-processing, a hyperparameter optimization algorithm with cross-validation is implemented. To assess the readiness of the model for clinical use, performance metrics are employed.

In the clinical setting, the goal is to make this framework patient-specific. During a prenatal appointment, each woman would undergo specific examinations to obtain mechanical properties and levator hiatus diameters, to be used as input for the ML model. As the model is already trained, the calculations occur in a few seconds, allowing the obstetrician to determine the maximum stretch of the patient's pelvic floor during childbirth and the approximate moment at which it occurs.

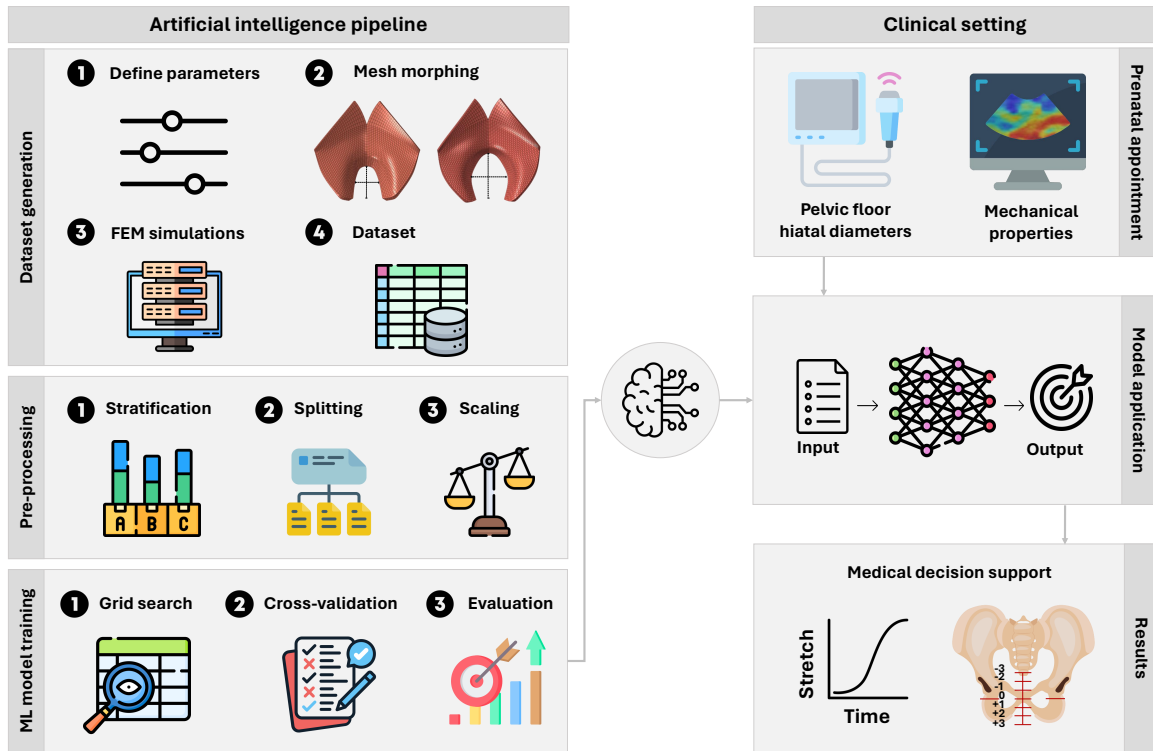


Figure 5.1: Pipeline for implementing an AI framework in a clinical setting.

The subsequent sections provide a comprehensive description of each step outlined in the AI pipeline.

5.3.2 Computational model

A FE model of the PFM and fetal head developed in previous studies was used to simulate vaginal delivery [30]. The PFM consists of the LAM (puborectalis, pubococcygeus, and iliococcygeus) and the coccygeus muscle. The FE mesh includes 5712

nodes and 3618 C3D8H hexahedral elements and was defined with varying thickness. The puborectalis and pubococcygeus muscles were defined with a thickness of 6.5 mm [37], while the iliococcygeus and coccygeus muscles were modeled with a thickness of 3.6 mm [38]. To simplify the FE simulations, the fetal head used was considered rigid and was modeled with dimensions in agreement with the literature for a full-term fetus, as thoroughly detailed in Parente *et al.* (2008) [39]. Figure 5.2 shows the FE model of the PFM and fetal head.

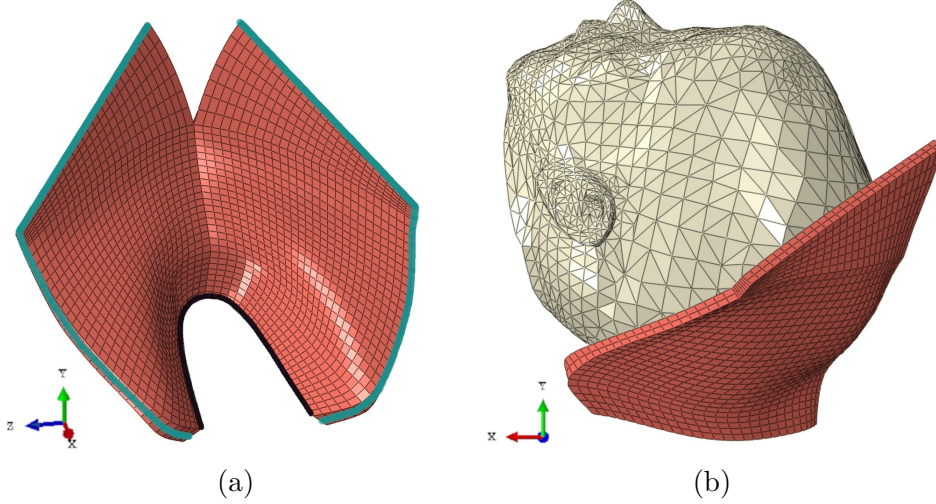


Figure 5.2: FE model used to simulate vaginal delivery. (a) PFM with the fixed nodes represented in blue and the path defined to retrieve results shown in black. (b) Fetal head in the vertex presentation and occipito-anterior position.

The PFM were characterized by a transversely isotropic visco-hyperelastic constitutive model proposed by Martins *et al.* (1998) [40]. The constitutive model encounters the nonlinearity, anisotropy, and hyperelasticity of the tissues. The viscoelastic contribution was posteriorly implemented by Vila Pouca *et al.* (2017) [20]. The strain energy function is equal to:

$$\Psi = \bar{\Psi}_m + \bar{\Psi}_f + \Psi_{vol} \quad (5.1)$$

where $\bar{\Psi}_m$ corresponds to the isotropic strain energy stored in the isotropic matrix, $\bar{\Psi}_f$ the strain energy stored in each muscle fiber, and Ψ_{vol} is related to the volume change.

The isotropic strain energy of the isotropic matrix is given by:

$$\bar{\Psi}_m = c \{ e^{b(\bar{I}_1 - 3)} - 1 \} \quad (5.2)$$

where c and b are constitutive parameters, and $\bar{I}_1$ is the first invariant of the right Cauchy-Green strain tensor with the volume change eliminated.

The strain energy stored in each muscle fiber can be divided in its passive ($\bar{\Psi}_{f_{PE}}$) and active ($\bar{\Psi}_{f_{SE}}$) parts, as follows:

$$\bar{\Psi}_f = \bar{\Psi}_{f_{PE}} + \bar{\Psi}_{f_{SE}} = \left[A \{ e^{[a(\bar{\lambda}_f - 1)^2]} - 1 \} \right] + \left[\theta T_0^M \int_1^{\bar{\lambda}_f} -4(\bar{\lambda}_f - 1)^2 + 1 \, d\bar{\lambda}_f \right] \quad (5.3)$$

where $\bar{\lambda}_f$ represents the stretch ratio of the muscle fibers, T_0^M is the maximum muscle tension produced by the muscle at resting, and $\theta \in [0, 1]$ defines the level of activation. In this work, it was assumed $\theta = 0$ for all the simulations, considering that the muscles are fully relaxed due to anesthesia [41].

Finally, the strain energy related to the volume change can be written as:

$$\Psi_{vol} = \frac{1}{D} (J - 1)^2 \quad (5.4)$$

where $J = \det(\mathbf{F})$ is the volume ratio, and $\mathbf{F}$ is the deformation gradient.

The viscoelastic contribution is represented by the generalized Maxwell model. The implementation includes the addition of a dissipative potential to the strain energy function (Equation 5.5), describing the non-equilibrium state.

$$\Psi(C, \Gamma_1, \dots, \Gamma_m) = \Psi_{vol}^\infty(J) + \Psi_{iso}^\infty(\bar{\mathbf{C}}) + \sum_{\alpha=1}^m Y_\alpha(\bar{\mathbf{C}}, \bar{\Gamma}_\alpha) \quad (5.5)$$

The configurational free energy Y_α is a function of the modified right Cauchy-Green strain tensor, $\bar{\mathbf{C}}$, and a set of strain-like internal variables denoted by $\bar{\Gamma}_\alpha$. The latter characterizes the relaxation and/or creep behavior of the material. The viscoelastic behavior is modeled by $\alpha=1, \dots, m$ viscoelastic processes.

5.3.3 Mesh-morphing

To facilitate the generation of distinct geometries for the PFM without the need for creating entirely new meshes, a mesh-morphing algorithm was developed using Python language. The algorithm was based on the 3D point set warping function algorithm [42].

The process begins by defining fixed nodes within the pelvic floor FE mesh, which remain unchanged during the morphing process, and identifying the moving nodes

that will be adapted based on the specified distances. Subsequently, landmarks are calculated according to these defined distances. Figure 5.3 presents the fixed nodes and distances to be changed along with examples of the transformation.

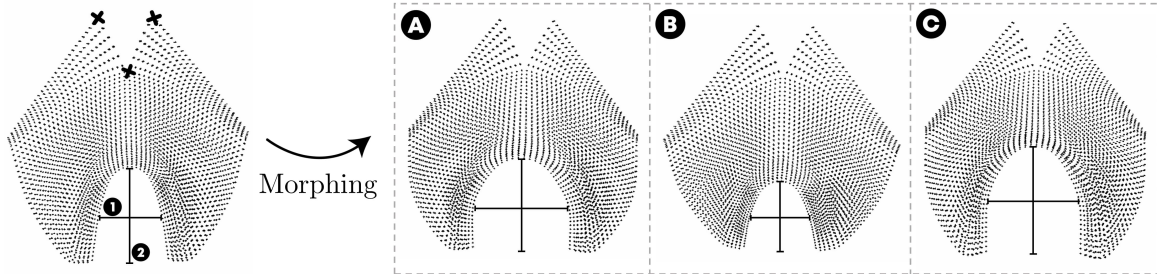


Figure 5.3: Example of distinct types of mesh morphing. Representation of the transverse diameter (1) and the anteroposterior diameter (2) of the levator hiatus. The fixed nodes selected to perform the morphing operation are represented by crosses. A - Transverse diameter adjustment. B - Adjustment of the anteroposterior diameter. C - Adjustment of both transverse and anteroposterior diameters.

In the morphing algorithm, a transformation matrix is computed by solving a linear system of equations between the input and output matrices. To compute the input matrix, a matrix is first defined that includes the distances between the fixed nodes, the moving nodes, and the landmarks. The input matrix also includes mathematical operations to account for the translation component and homogeneous coordinates. The Thin Plate Spline (TPS) method is then applied to this matrix to smooth the deformation, resulting in the input matrix. In contrast, the output matrix exclusively includes the landmarks.

After calculating the transformation matrix, a new input matrix is defined, taking into account not only the moving nodes but also the entire FE mesh of the PFM. The TPS method is then applied to this matrix, and the morphed mesh is obtained by multiplying the transformation matrix with the input matrix. This process generates the morphed mesh, effectively achieving the desired geometrical changes while preserving the overall topology and mesh structure. The described process is presented in Algorithm 1.

Algorithm 1 Outline of the morphing algorithm.

Input: Source pelvic floor FE mesh;

Output: Morphed pelvic floor FE mesh;

- 1: Define fixed nodes (FN), moving nodes (MN) and target distances (TD);
- 2: **for** (each distance TD) **do**
- 3: Compute landmarks L ;
- 4: **end for**
- 5: Define output matrix U based on calculated landmarks L and FN;
- 6: Calculate matrix D with distances between MN, FN and L ;
- 7: Apply TPS method to matrix D to obtain input matrix I ;
- 8: Solve linear system of equations to compute transformation matrix T :

$$IT = U$$

- 9: Calculate matrix D^* with distances between source mesh, FN and L ;
- 10: Apply TPS method to matrix D^* to obtain new input matrix I^* ;
- 11: Compute morphed mesh M :

$$M = T \times I^*$$

5.3.4 FEM simulations of vaginal delivery

Childbirth simulations were performed in Abaqus[®] software to mimic the second stage of labor with the fetus in vertex presentation and occipito-anterior position. Variations in each simulation included adjusting the material properties to characterize the PFM and the initial geometry of the muscle to achieve a patient-specific characterization.

The material parameters were adjusted according to the literature. Janda (2006) [43] obtained stress-strain curves from uniaxial and equibiaxial tests on PFM from fresh cadaver specimens. Subsequently, Parente *et al.* (2009) [15] used an iterative process of adjusting the constitutive model constants to obtain an accurate approximation within the range of values for the material parameters of the Martins constitutive model. Each parameter was varied while analyzing the stress-strain curves generated, ensuring that they remained within the range of curves defined by Janda. Therefore, in the present study, the material constants c and b in Equation 5.3 were varied within certain ranges: $\{0.02, 0.045\}$ and $\{1.0, 1.35\}$, respectively, using 10 intervals to limit the number of simulations.

Additionally, the two main diameters of the levator hiatus (anteroposterior and transverse) shown in Figure 5.3 were adjusted according to the literature. The specified ranges were $\{46.0, 74.2\}$ and $\{24.8, 54.8\}$ for the anteroposterior and transverse diameters, respectively, also using 10 intervals [44, 45, 46, 47, 48].

The combination of all parameters resulted in 10000 simulations. However, an additional constraint was implemented to ensure that the ratio between the transverse diameter and the anteroposterior diameter always remained between 0.55 and 0.85. This constraint aimed to prevent anomalous geometries and was defined based on calculated ratios from the literature. After this filter, a total of 6897 simulations were performed, of which 5618 were successfully completed. The unsuccessful simulations did not converge due to numerical problems.

The simulations aim to replicate an average second stage of labor in nulliparous women with a duration of 100 minutes [49]. The fetal head trajectory remained the same in all simulations, regardless of muscle geometry, and is controlled by a reference node. Initially, all displacements (x, y, and z) are controlled until the head is fully fitted within the muscles. Subsequently, the degrees of freedom are unrestricted, so that only descent can be imposed. This means that the head can adjust in anteroposterior and lateral directions, especially considering the different geometries of the muscles.

During the simulations, the interaction between the PFM and the fetal head was modeled using the standard Abaqus[®] contact algorithm. The contact conditions were imposed recurring to the Augmented Lagrange method to facilitate surface interactions. Regarding boundary conditions, the nodes on the extremities of the PFM were fixed, as demonstrated in Figure 5.2. The simulations were performed on a Supermicro workstation, Dual Epyc Milan 7315 32C/64T with 128 GB DDR4 RAM.

5.3.5 Artificial intelligence pipeline

Dataset generation

The dataset was generated using information retrieved from childbirth simulations. To create the dataset, only 49 nodes of the PFM were utilized, delineating a path at the levator hiatus, as illustrated in Figure 5.2. These nodes were selected since they are used to calculate the stretch in previous childbirth simulations analyses. In addition, this region is considered the most critical area of the muscle, where higher stresses and increased muscle strain typically occur. Each node of this path corresponds to an observation of the dataset.

For each simulation, results were collected for each time instant between a fetal head descent of 50 mm and 80 mm. This specific range was chosen with the objective of

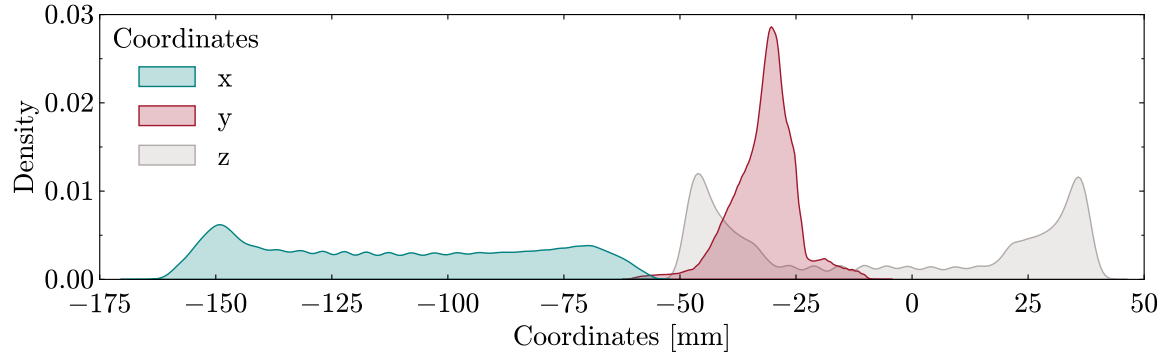
calculating the maximum stretch of the muscle and determining the moment at which it occurs. Based on prior simulations, it is established that the maximum stretch will take place within the specified range. Since different simulations may have a distinct number of increments, a resample algorithm was implemented to ensure that all simulations share the same number of time steps, set at 21.

In summary, for each simulation, data are recorded for each of the 49 nodes over 21 time steps, documenting their displacement over time. Thus, the dataset has the following dimension: $S \times N \times T$, where S is the total number of simulations, N is the number of nodes, and T is the number of time steps, resulting in 5 780 922 observations. For the effective training of a supervised ML model, it is essential to appropriately structure the dataset. This involves organizing the data into an input matrix, containing the features used for training, and an output matrix, comprising the target variable to be predicted. Consequently, each individual sample, represented by a row in the matrix, corresponds to a node within the FE mesh. Each column in the matrix corresponds to a specific selected feature.

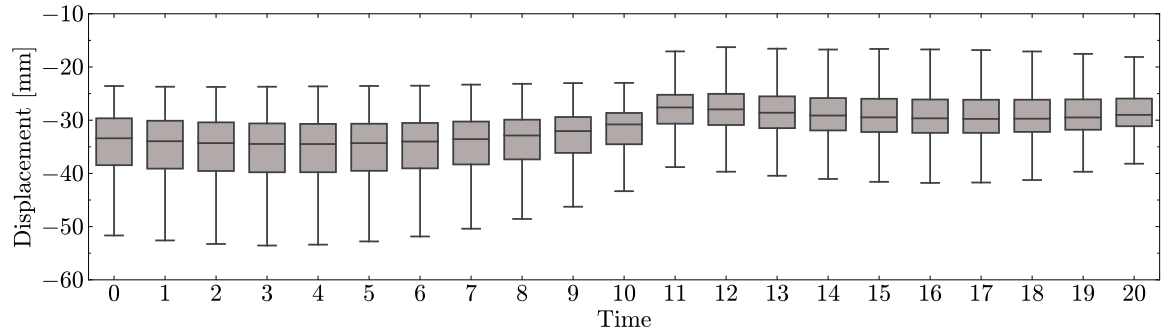
Regarding the features, their selection is not rigid and should be determined based on the problem under study and the relation with the target variable. The chosen features to represent the input data include: time (time step during a particular simulation), node position (position of each node in the path), initial coordinates (x , y , and z coordinates of each node for each simulation), material parameters (constitutive parameters c and b of the Martins constitutive model), diameters (initial diameters AP and T of the FE model), and length (initial length of the path for each simulation).

Besides the features that are mandatory to incorporate since they provide patient-specific characteristics (material properties and diameters), the relevance of the other features was tested to analyze if they are essential during the training of the model. Therefore, a manual feature selection procedure was performed, and the performance of the models was evaluated excluding the initial coordinates, node position, and path length. Furthermore, to explore the potential of using additional features based on the initial data to improve model training, feature engineering was used, focusing in particular on the definition of geometric features, such as the coordinates of neighboring nodes, the distance from the lateral node, or the direction of displacement at each node during all time steps.

The target of the ML model is the coordinates x , y , and z of each node, resulting in a multi-output problem. Figure 5.4a illustrates the density and range of each target for prediction, while Figure 5.4b displays the distribution of the y -coordinate at each time step (the x and z coordinates exhibit negligible variation across different time steps).



(a)



(b)

Figure 5.4: (a) Range of target variables x , y , and z for all simulations. (b) Variation of the target variable y for each time step for all simulations.

An illustration of the dataset is provided in Table 5.1.

Table 5.1: Dataset example including features and target for two different simulations.

time	node	position	x_i	y_i	z_i	c	b	AP	T	length	x_f	y_f	z_f
0	0		-67.780	-20.224	9.666	0.010	1.275	48.82	27.8	99.165	-70.761	-26.754	19.281
0	1		-69.815	-20.460	9.571	0.010	1.275	48.82	27.8	99.165	-74.012	-28.750	21.432
⋮	⋮		⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
0	48		-68.118	-20.756	-22.081	0.010	1.275	48.82	27.8	99.165	-70.834	-27.214	-32.135
⋮	⋮		⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
20	0		-67.780	-20.224	9.666	0.010	1.275	48.82	27.8	99.165	-71.368	-23.680	21.721
20	1		-69.815	-20.460	9.571	0.010	1.275	48.82	27.8	99.165	-74.645	-24.175	25.298
⋮	⋮		⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
20	48		-68.118	-20.756	-22.081	0.010	1.275	48.82	27.8	99.165	-72.437	-24.934	-33.556
0	0		-62.213	-20.224	11.847	0.025	1.280	57.28	33.8	130.559	-63.343	-24.646	20.704
0	1		-64.760	-20.460	12.523	0.025	1.280	57.28	33.8	130.559	-66.661	-26.059	23.698
⋮	⋮		⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
0	48		-68.118	-20.756	-22.081	0.025	1.280	57.28	33.8	130.559	-62.893	-25.391	-33.549
⋮	⋮		⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
20	0		-62.213	-20.224	11.847	0.025	1.280	57.28	33.8	130.559	-61.675	-22.705	21.292
20	1		-64.760	-20.460	12.523	0.025	1.280	57.28	33.8	130.559	-64.708	-23.487	24.951
⋮	⋮		⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
20	48		-68.118	-20.756	-22.081	0.025	1.280	57.28	33.8	130.559	-62.813	-24.743	-33.167

Data pre-processing

Following the AI pipeline described in Figure 5.1, the data underwent pre-processing before initiating the model training. To train a ML model, the dataset has to be divided into train and test sets. In this case, the splitting process was performed considering that all nodes of each simulation belong exclusively to either the training or the test set. The split ratio used in the current study was 90% for training and 10% for testing. This approach aims to prevent data leakage, overfitting, and enhance the model's generalization capability.

To reduce bias in the model evaluation process and improve performance metrics, a stratification algorithm was used to ensure equal representativeness of features in each set. The goal was to ensure that there was a homogeneous distribution of features that varied between each simulation (material parameters and diameters). Therefore, the *StratifiedShuffleSplit* method from the *scikit-learn* open source software library was implemented to split the data into training and test sets.

In addition, a pre-processing technique for scaling the dataset was implemented, as ML algorithms generally perform better when features are on a similar scale or close to a normal distribution. The *StandardScaler* function of the *scikit-learn* library was used for this purpose. Although other scaling algorithms were tested during the training process, the method described provided the best results.

ML model training

The regression algorithms used were selected according to a recently published review by Phellan et al. (2021) [4], which analyzed papers that included the FEM and ML in the context of real-time biomechanics. According to the authors, there are three main types of regression models used to generate fast and real-time simulations of anatomical structures: tree-based algorithms, SVR, and ANNs. Therefore, three types of models were considered in this study: RF, XGBT, and ANNs. It is worth noting that the *scikit-learn* library was used to implement the ML models, and since the problem under analysis corresponds to a multi-output problem, some algorithms cannot yet handle this condition. For this reason, the support vector regressor was not implemented in the current study.

Since the selected models have a wide range of hyperparameters that can be chosen, a hyperparameter optimization algorithm was implemented. The method used was the grid search, which consists of an exhaustive search method that evaluates all combinations provided in a pre-defined grid. The grid used for this hyperparameter procedure is presented in Table 5.2. For the parameters not mentioned, the default value was used. Due to the extensive volume of data and lack of computational power, the hyperparameter tuning process was conducted using only 10% of the data.

Table 5.2: Grid search hyperparameter values for each algorithm.

Algorithm	Hyperparameters	Search values
RF	max_depth	10, 50, 100, 200, None
	max_features	sqrt, log2, 1.0
	min_samples_leaf	1, 5, 25, 50
	min_samples_split	0.5, 1, 2, 3, 4
	n_estimators	20, 100, 200, 300, 500
XGBT	max_depth	6, 15, 25
	eta	0.1, 0.22, 0.25, 0.3
	lambda	1, 2, 3, 5
ANN	batch_size	512, 1024, 2048
	epochs	100, 150, 200
	learning_rate	0.001, 0.005, 0.08, 0.01
	activation_function	ReLU, sigmoid
	hidden layer 1	50, 100, 180, 200, 220, 250
	hidden layer 2	50, 100, 180, 200, 220, 250
	hidden layer 3	50, 100, 180, 200, 220, 250

To determine the optimal parameters for each model, a combination of hyperparameter optimization and cross-validation was implemented. The methods *TimeSeriesSplit* and *GridSearchCV*, both from the *scikit-learn* library, were used, considering a twenty-fold cross-validation strategy. Given that each simulation consists of 21 consecutive time steps, a time series data approach was applied in the cross-validation process to consider temporal dependencies. The choice of twenty folds was based on the defined number of time steps. Initially, only information related to the first time step is available. Therefore, the training process involved training the second time step solely with data from the first time step, then training the third time step with data from the first and second time steps, and so forth.

Performance metrics

Performance metrics are required to quantify the results obtained while training and evaluating a ML algorithm [4]. In the current study, the results were evaluated through two commonly used metrics in applications that use ML algorithms to simulate biomechanical behavior: the MSE, presented in Equation 5.6, and the MAE, in Equation 5.7.

$$MSE = \frac{1}{N} \sum_{i=1}^N (y_i - \hat{y}_i)^2 \quad (5.6)$$

$$MAE = \frac{1}{N} \sum_{i=1}^N |y_i - \hat{y}_i| \quad (5.7)$$

where y correspond to the reference values, $\hat{y}$ to the predicted values, and N to the number of data points.

The mean absolute percentage error (MAPE), shown in Equation 5.8, was also used as performance metric:

$$MAPE = \frac{1}{N} \sum_{i=1}^N \left| \frac{y_i - \hat{y}_i}{y_i} \right| \times 100 \quad (5.8)$$

5.3.6 Clinical data

To demonstrate the applicability of the ML algorithm and the developed framework, MRI data were collected from nulliparous women to be used as input parameters for determining stretch over time and the time required to make a prediction.

MRI was used to identify levator ani hiatus dimensions in 20 nulliparous women. The study was approved by the Ethics Committee of the Institute for Mother and Child

Care (n.2021/28_1/2). Informed consent was obtained from all individual participants included in the study. The research has been performed in accordance with the Declaration of Helsinki. A high-resolution axial 3 Tesla MRI scanner (Phillips Achieva TX series) was used to acquire images in the supine position. The imaging parameters were as follows: repetition time 5331 milliseconds, 375 phase encodes, 24 cm field of view, and 2 mm slice thickness, no gap in axial, coronal and sagittal projections. MRI sequences were performed at rest, the women were asked not to contract the pelvic floor during imaging and had not received bowel or bladder preparation. The participants had to micturate 30 minutes before the examination.

3D Slicer software was used to identify levator ani hiatus dimensions [50]. Midsagittal plane was tilted to coincide with a line originating from the back of the inferior tip of the pubis to the apex of the anorectal angle [51]. Levator ani hiatus width, height, and length were identified in the axial image in the plane parallel to puborectalis. This process is illustrated in Figure 5.5.

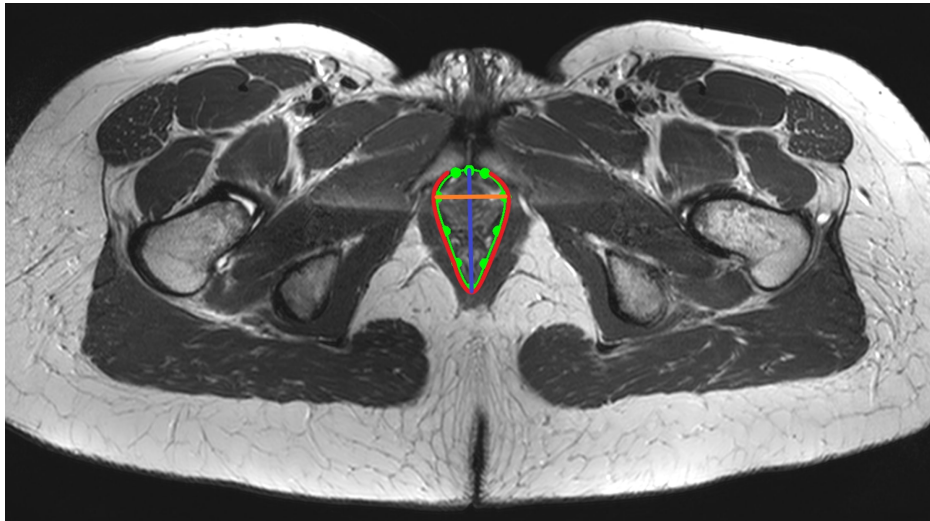


Figure 5.5: MRI in the axial plane showing the levator hiatus of the LAM highlighted in green, the anteroposterior diameter in blue, the transverse diameter in orange, and the circumference of the levator hiatus excluding the attachment to the pubic symphysis in red.

5.4 Results

5.4.1 Hyperparameter tuning

The process of hyperparameter tuning described in subsection 5.3.5 was implemented to obtain the best hyperparameters for each ML model tested, as presented in Table 5.3.

Table 5.3: Optimal hyperparameter values selected for each algorithm.

Algorithm	Hyperparameters	
RF	max_depth	None
	max_features	1.0
	min_samples_leaf	5
	min_samples_split	2
	n_estimators	300
XGBT	max_depth	25
	eta	0.25
	lambda	2
ANN	batch_size	2048
	epochs	200
	learning_rate	0.005
	activation_function_1	ReLU
	activation_function_2	sigmoid
	hidden layer 1	200
	hidden layer 2	220
	hidden layer 3	220

The RF architecture comprised an ensemble of 300 trees, each with a maximum depth where nodes are expanded until all leaves are pure or until all leaves contain fewer than min_samples_split samples. To create a leaf node, a minimum of 5 samples were necessary, and for an internal node to split, at least 2 samples were required.

Furthermore, the XGBT architecture consisted of a maximum depth of 25. The model was trained using a learning rate (*eta*) of 0.25, and an L2 regularization parameter (*lambda*) of 2 was applied. In this model, a multi-output tree strategy was employed for training multi-target models. This recently implemented strategy enables the use of multi-target trees instead of employing a separate model for each target.

The ANN has been designed with a batch size of 2048 and is trained over 200 epochs using a learning rate of 0.005. The ANN has the following architecture: an input layer with 10 neurons representing the features; 3 hidden layers with 200, 220, and 220 neurons, respectively; and an output layer producing three outputs. The activation

function used was ReLU for the first hidden layer and sigmoid for the other two layers. The influence of the number of layers in the network was also examined, with three layers considerably outperforming the results obtained with only one or two hidden layers.

5.4.2 Effect of dataset size

To assess how the percentage of data impacts the performance of the selected ML models, a study on the convergence of algorithms was conducted. The MAE was calculated while varying the initial percentage of available data, ranging from 10% to 100%. This analysis is a crucial step in understanding whether the amount of data used is sufficient or if acquiring more data would be beneficial. Figure 5.6 illustrates the evolution of the MAE for the ML models used.

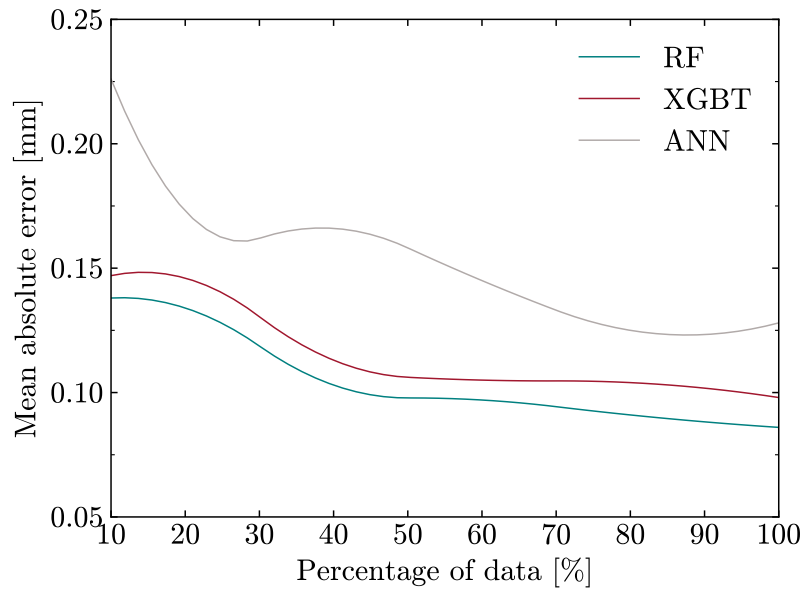


Figure 5.6: Evolution of the mean absolute error (MAE) across varying percentages of data for the ML models under analysis.

5.4.3 Prediction of nodal coordinates

The results obtained for the prediction of the nodal coordinates are presented in Table 5.4, which presents the MSE, MAE, MAE for each target coordinate, and MAPE. Furthermore, the errors for the DM model were also included, which corresponds to an important tool for comparing the performance of other regression models. This model provides a baseline for comparison by predicting the target variable using the mean of the training data.

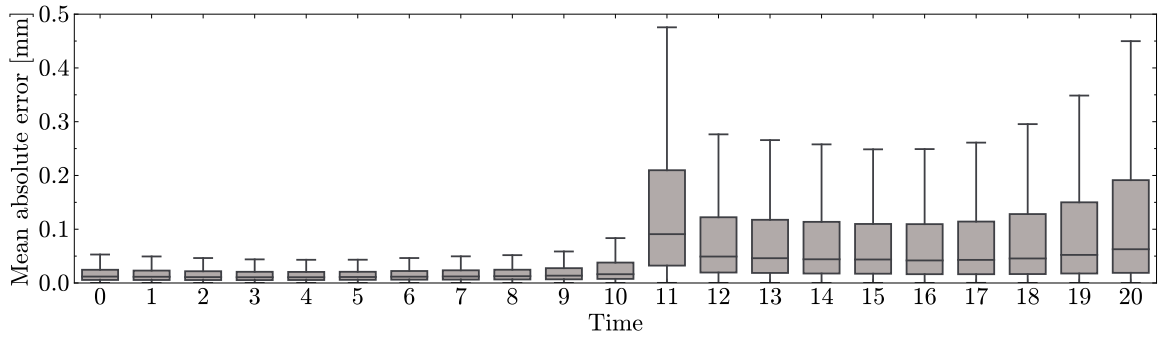
Among the models evaluated, the RF yielded the most favorable outcomes, achieving

a MAE of 0.086 mm. The MAE obtained corresponds to 0.052% of the maximum nodal coordinate from the whole dataset (-166.51 mm).

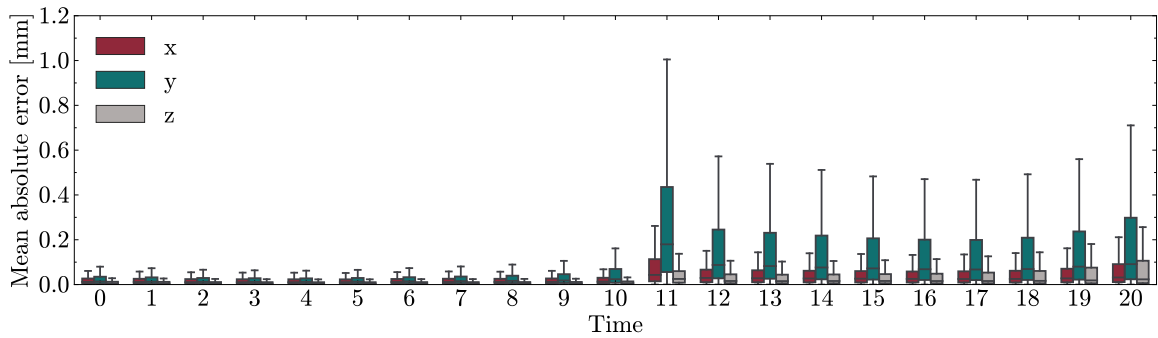
Table 5.4: Performance metrics for each ML model selected.

Model	MSE [mm ²]	MAE [mm]	MAE _x [mm]	MAE _y [mm]	MAE _z [mm]	MAPE [%]
DM	697.7	21.17	26.29	5.195	32.08	75.10
RF	0.195	0.086	0.055	0.159	0.043	0.387
XGBT	0.268	0.098	0.061	0.182	0.050	0.472
ANN	0.201	0.128	0.116	0.192	0.075	0.931

As the values in Table 5.4 represent the mean across all nodes of the pelvic floor path and all time steps, a more detailed analysis of the error was conducted. This involved examining the MAE for each coordinate, individual time step, and distinct regions of the node path. Figure 5.7a illustrates the MAE for each time step for the RF model, which yielded the best results. The errors for each target are shown in Figure 5.7b, with the y-coordinate exhibiting higher errors across all time steps.



(a)



(b)

Figure 5.7: Box plot demonstrating the (a) MAE for each time step and (b) MAE for each coordinate and time step of fetal descent.

The MAE calculated for five distinct regions of the pelvic floor are demonstrated in Figure 5.8a, with the highlighted regions displayed in the upper right corner. Figure 5.8b illustrates the percentage of nodes within a specific MAE range, representing the distribution of the error. The percentage of nodes with an absolute error of less than 0.1 mm is 82.04%, and 98.63% are under 1 mm.

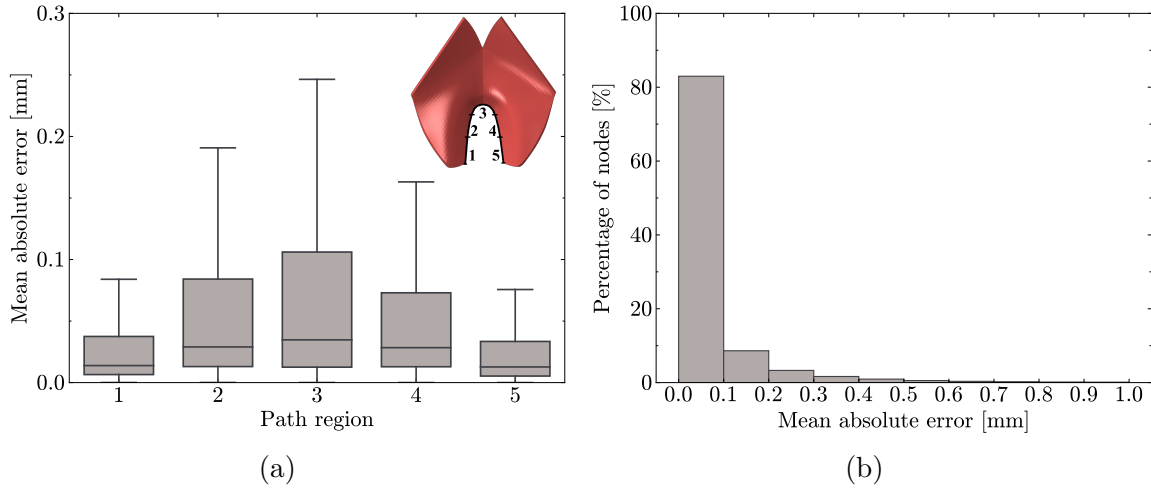


Figure 5.8: (a) Box plot demonstrating the MAE for each region of the PFM path. The distinct regions are represented in the left upper corner. (b) Distribution of the error.

A three-dimensional reconstruction of a FE simulation is presented in Figure 5.9, illustrating the pelvic floor path at each position between 50 and 80 mm of fetal descent. Predicting the coordinates of each node enables the reconstruction of the path at each time step.

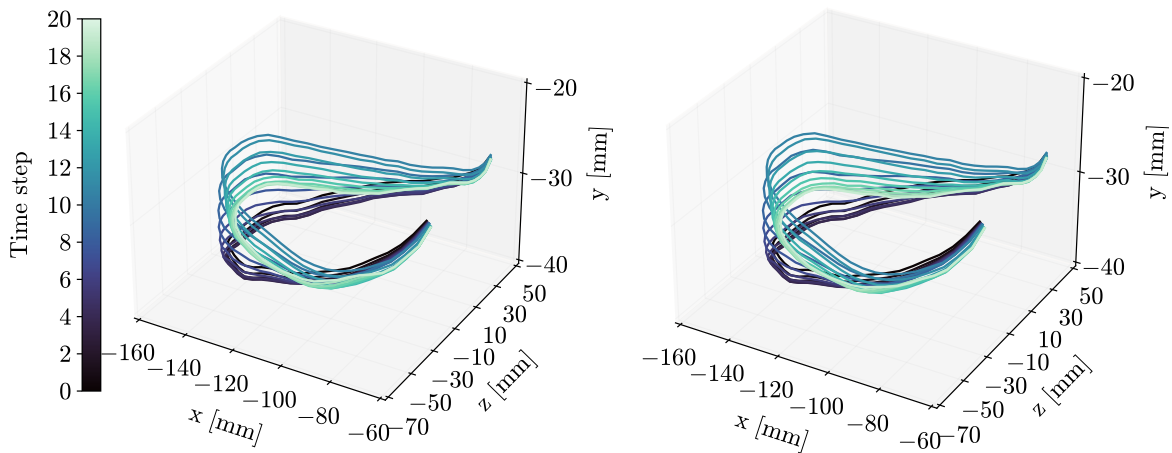


Figure 5.9: Three-dimensional reconstruction of a FE simulation: representation of predicted nodal coordinates (on the left) and true nodal coordinates (on the right) for all nodes along the path across 21 time steps.

5.4.4 Stretch prediction

The main goal of the present study is to predict the stretch of the PFM during the critical part of the vaginal delivery process and to determine the moment at which the maximum stretch occurred. Therefore, based on the predict coordinates, the MAE for the calculated stretch is equal to 0.0011. The specific MAE for each time step is presented in Figure 5.10.

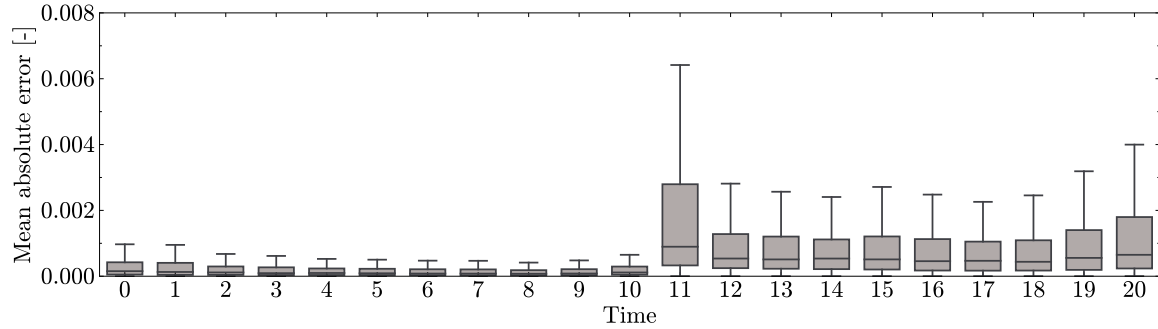


Figure 5.10: Box plot presenting stretch MAE for each time step of the fetal descent.

Furthermore, the percentage of times that the instant of maximum stretch was correctly predicted, with a tolerance of one time step, was calculated. It was concluded that 92.17% of the time, the instant of maximum stretch is predicted accurately.

5.4.5 Real-time performance

In computer science, a real-time system is characterized by the need for responses to occur within a specific time frame, usually measured in milliseconds or a short span of seconds in the context of biomechanical applications [4]. The categorization of a system as real-time depends on its intended use, as some researchers report their results in milliseconds, while others recognize a few seconds as falling within the realm of real-time.

Table 5.5 illustrates the time required to predict the results of a simulation, along with the time required to load the model, which can be critical in certain applications such as surgical interventions. The values given are the average of ten consecutive measurements.

Table 5.5: Measurement of the time required to make predictions and load the ML model.

Model	Predict	Model load	Total
RF	0.028 s	10.74 s	10.77 s
XGBT	0.005 s	4.108 s	4.113 s
ANN	0.045 s	1.954 s	1.999 s

5.4.6 Clinical validation

To validate the ML model, three out of the twenty MRIs were utilized to demonstrate the applicability of the proposed framework. The subjects were selected to represent a range of anteroposterior diameters, including small, medium, and large sizes. Although MRI is not commonly performed during prenatal appointments, these images were utilized solely as a validation tool to demonstrate the applicability of the implemented algorithm, due to the absence of real ultrasound images. Nonetheless, this kind of exam can also be used to define the levator hiatus dimensions, if available.

These diameters were given as input parameters to the trained ML model, along with synthetic mechanical properties, as we lacked any clinical data to provide real values. Table 5.6 presents the anteroposterior and transverse diameters measured on the MRI, and the circumference of the pelvic floor hiatus (also used as feature in the training of the ML model).

Table 5.6: Measurements of the anteroposterior (AP) and transverse (T) diameters of the levator hiatus, as well as the circumference of the hiatus, obtained from MRI.

Model	AP	T	Circumference
Subject A	47.26 mm	34.29 mm	91.81 mm
Subject B	58.45 mm	27.21 mm	117.40 mm
Subject C	68.64 mm	28.64 mm	123.10 mm

Figure 5.11 demonstrates the prediction of the stretch values along the vertical displacement of the fetal head for subjects A, B and C. The stretch took approximately 113, 129 and 134 milliseconds to be predict for the three patients, respectively.

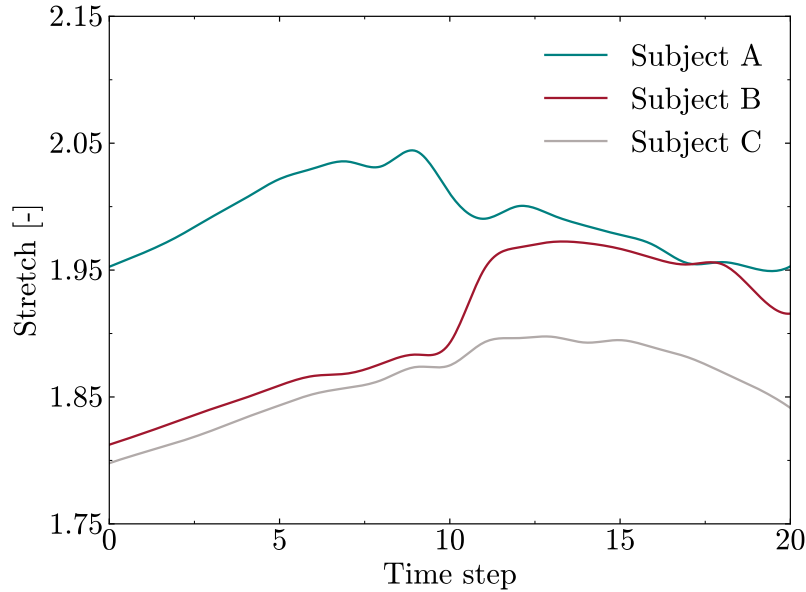


Figure 5.11: Stretch evolution over time for subjects A, B and C.

The maximum stretch is achieved around time step 12 in subjects B and C, corresponding to approximately 70 mm of fetal descent, which can be attributed to a station between 4 and 5 according to the American College of Obstetricians and Gynecologists classification system [52]. Subject A experienced a greater stretch due to the smaller initial dimensions of the pelvic floor, and the maximum stretch occurred around time step 9, with a fetal descent of approximately 65 mm, corresponding to station 4.

5.5 Discussion

Computational biomechanical simulations can be a valuable tool to improve the current knowledge of the biomechanics of vaginal delivery. Nevertheless, these simulations are time-consuming and often not directly applicable to individual patients, making their implementation in clinical practice challenging. The current study proposes a FEM-based ML approach to predict injuries related to childbirth during vaginal delivery on a patient-specific basis. The main objectives of this study are to establish a framework for the implementation of an AI pipeline in a clinical setting and to illustrate the feasibility of using ML models to assess the biomechanical behavior of the PFM in near real-time.

Distinct ML models were trained to determine the most favorable results. The selection of models was based on the review paper authored by Phellan *et al.* (2021) [4], which indicated that tree-based algorithms, SVR, and ANNs are frequently used in FEM-based ML approaches. In the prediction of nodal coordinates, the RF algorithm yielded the best results, outperforming both XGBT and ANN. RF demonstrated superior

prediction capacity, showcasing its strength in handling large datasets and maintaining robustness against overfitting. While XGBT also achieved a notable performance, RF's ensemble learning approach provided more accurate predictions. The ANN, although a powerful tool for capturing intricate nonlinear relationships, trailed behind RF and XGBT in this scenario. Despite its potential, ANN's performance may have been hampered by its computational intensity during training and the complexity associated with hyperparameter tuning, which often requires significant computational resources and time. Since the amount of data is significantly large, the hyperparameter tuning performed with the ANN model was limited to the computational resources available, which might have influenced the results negatively.

The amount of data used, resulting from the number of simulations defined, was analyzed for the three models employed. It was observed that as the percentage of data increased, there was an improvement in the outcomes, characterized by a decrease in error of 37.6%, 33.3%, and 43.3% from 10% to 100% of data for the RF, XGBT, and ANN models, respectively. This indicates that although the dataset has a large number of observations, its size is suitable for the problem under study. The volume of observations within the dataset deserves attention, indicating its suitability for the objectives of the study. While it is possible that further expansion of the dataset could potentially yield even better results, it is important to recognize that the current dataset already allows for a considerable good performance of the models, with approximately 98.6% of the nodes exhibiting an error of less than 1 mm. Achieving a balance between dataset expansion and computational demands is crucial. While additional data may theoretically lead to decreased errors, the implications of handling increasingly large datasets, particularly in terms of computational resources and model complexity, require careful consideration.

In the detailed examination of the RF model results, which yielded the most favorable outcomes, the box plot in Figure 5.7 shows an increase in MAE at the 11th time step compared to the other steps. This behavior can be explained by the fact that initially, as the PFM begins to open and stretch, it moves downward. However, as the muscle continues to open and the fetal head descends further, this movement tends to reverse. This change in muscle behavior may account for the observed increase in error, as the ML model was unable to fully capture the shift in nodal displacement direction. After this time step, the muscle behavior stabilizes, leading to a decrease in error. Additionally, it is evident that the error after step 11 remains higher than in the previous steps. This can be attributed to a greater distance between each path, as illustrated in Figure 5.9, indicating that the coordinates undergo more significant variations compared to the initial time steps. Despite the integration of specific features aimed at enhancing this aspect and providing additional information to the models regarding

muscle behavior, such as the coordinates of neighboring nodes, distance to the lateral node, or the direction of displacement at each node, no improvement in the obtained results was observed.

Furthermore, the MAE was analyzed for distinct regions of the pelvic floor path to illustrate its distribution. As expected, a higher error was observed in the middle region of the PFM, corresponding to path region 3 as shown in Figure 5.8a, since this region undergoes greater stretch, resulting in higher coordinate variations. In previous studies conducted by the research group, this region also exhibited higher errors when analyzing the distribution of stresses [13]. Figure 5.8b illustrates the distribution of nodes for a MAE ranging from 0 to 1 mm. It can be concluded that over 80% of the nodes exhibit an error smaller than 0.1 mm, while more than 98% of the cases have errors under 1 mm. The MAE for the stretch was also analyzed since its calculation corresponds to one of the main goals of the current work. The range of the stretch values calculated in the test set was between 1.48 and 2.41, and the MAE obtained for the mean of all time steps was equal to 0.0011, which is particularly low in comparison with the values being predicted.

In comparison to the literature, Martínez-Martínez *et al.* (2017) [35] used a FEM-based ML approach for modeling the mechanical behavior of the breast tissues. The authors obtained a mean nodal error of 0.046 mm and reported that 92% of the nodes had errors below 1 mm. In a similar study conducted by Pellicer-Valero *et al.* (2020) [36], employing a comparable approach for biomechanical modeling of the liver using FEM-based ML, the errors in predicting nodal coordinates were below 0.6 mm for simpler cases. These errors are consistent with the results obtained in the current study for all time steps, and the percentage of samples with errors under 1 mm is also approximately 98%. The analysis of the two studies mentioned, which focused on predicting nodal coordinates, lead to the conclusion that the results of the current work fall within the range typically observed in the literature.

The proposed framework was designed for integration into a clinical setting. However, in practice, specific examinations would need to be incorporated into standard prenatal obstetrical appointments, which are not currently part of the defined protocol. One possible approach to acquire the mechanical properties of the PFM would be through shear-wave elastography. Nevertheless, given that this technique is not yet utilized in clinical practice, and the associated equipment or technologies could be costly, an alternative would be to utilize a more subjective measurement, such as manual palpation. This alternative method would provide a quantitative classification using a predefined scale that describes the level of tissue stiffness. Subsequently, a range of material parameters would be used to characterize the muscles corresponding to the

defined stiffness. In terms of measuring pelvic floor dimensions to obtain personalized geometry, it would be crucial to include transperineal ultrasound in routine prenatal care, as it can provide information on the dimensions and thickness of the PFM. While this information can also be obtained from MRI, it is an expensive examination and is typically performed only in very specific cases. Additionally, measuring levator hiatus dimensions in high-risk patients, particularly nearing childbirth, should be part of the assessment to identify potential injuries. Concerning the implementation of the presented framework in clinical practice, stretch prediction serves as just one of the indicators of potential injury, in cases where muscles are overstretched. However, incorporating additional biomechanical variables, such as stresses or forces, into the analysis as target variables could offer a more comprehensive understanding of childbirth outcomes. This framework could also aid in defining critical biomechanical thresholds for potential injury, which would enable the implementation of classification ML problems to directly determine the probability of injury.

The time required for predictions using pre-trained models was measured (Table 5.5). The findings reveal that the XGBT model outperforms the other models, providing the quickest prediction of target values for a single simulation. While exhibiting marginally higher errors compared to RF, which demands nearly sixfold more time for predictions and over twice the loading time, a thoughtful consideration should be performed to select the most suitable model for specific applications. When smaller error is a priority and load time is a secondary concern, RF is the preferred option. Conversely, in scenarios where real-time response is critical and there's room for a slightly wider prediction range, XGBT is the optimal choice. This highlights the need to balance performance and time efficiency when selecting the appropriate model. Furthermore, despite the significant duration required for running FE simulations and generating the dataset, once trained, the model showcases remarkable performance, providing results in under 0.045 seconds in the worst-case scenario.

The current study has several limitations. Firstly, the geometry is only considered patient-specific for the PFM. The fetus is assumed to have the same dimensions in all simulations, impacting the stretch obtained. To address this, the analysis should incorporate the different diameters of the fetal head as input parameters. Additionally, in an effort to shorten the simulation process and dataset generation, only two diameters of the PFM were varied. While these diameters are crucial measurements of the muscle and the region most affected during vaginal delivery, other distances, such as the distance between the two ischial spines defined by the coccygeus muscle insertions, could be included in the analysis for a more personalized model. However, both issues mentioned are constrained by the computational cost of running each simulation. Adding even a single parameter can increase the number of simulations

by a factor of ten, consequently increasing the overall time required to generate the complete dataset. To overcome this limitation and include more input parameters in the dataset, there is a need to reduce the time required to run the simulations. This could be achieved by decreasing their complexity, using reduced-order models, or implementing similar techniques. Furthermore, the dataset was exclusively derived from synthetic data. Ideally, while synthetic data should still be included for training, measurements and material properties of the muscles should also be obtained from patients to establish a dataset including the widest range of cases possible. Another limitation is the large amount of generated data, making it challenging to process for hyperparameter tuning. Consequently, only 10% of the dataset was utilized for defining these hyperparameters. To address this limitation, future efforts could explore techniques for handling large datasets or allocate additional computational resources.

Despite the outlined limitations, the proposed framework has shown promising feasibility for implementation in clinical practice, as evidenced by the low errors achieved. This underscores its potential for improvement, adaptation to various clinical scenarios, and integration into real-world applications.

5.6 Conclusions

In this paper, we present an AI-based computational pipeline designed to predict the mechanical behavior of the pelvic floor during vaginal delivery. A variety of ML models were trained to identify the most appropriate one for predicting pelvic floor stretch, using different geometries for the muscles and distinct mechanical properties as input. This study successfully demonstrates the feasibility of implementing an AI framework in a clinical setting using ML techniques and FE simulations. The implemented approach is significantly faster than performing an individual vaginal delivery simulation for a specific patient. The ability to predict the mechanical behavior of muscles, particularly the stretch experienced by women before childbirth, has the potential to aid in medical decision making. The proposed methodology represents a fundamental step toward creating a solution that could be integrated into medical software to assist obstetricians in identifying potential injuries or analyzing the optimal mode of delivery.

As future work, the focus should be to decrease the necessary time to run each simulation in order to obtain a more complete dataset. While a FEM-based ML approach aids in decreasing the time to obtain results, the simulations still need to run to generate the dataset. A complete dataset for childbirth simulations needs the inclusion of multiple factors, such as measurements of the pelvic floor and pelvic bones, fetal head

dimensions, fetal positioning, material properties, and other relevant parameters. The most viable approach to create a dataset with all this information from FE simulations is to expedite the simulations, enabling the execution of hundreds of thousands of simulations within an acceptable time frame. Therefore, future efforts should prioritize the implementation of reduced-order models or low-fidelity outcomes.

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Part IV

Experimental mechanics for tissue characterization

Chapter 6

Experimental characterization of
the nonlinear viscoelastic
properties of human female
perineal tissue

Experimental characterization of the non-linear viscoelastic properties of human female perineal tissue

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Abstract

The female perineum plays a critical role in several physiological processes. During childbirth, this region undergoes significant stretching, resulting in perineal trauma in over 90% of vaginal deliveries. Despite advances in obstetric care, predicting and preventing such injuries remains challenging. Computational models offer a non-invasive approach to investigate female pelvic biomechanics. However, their reliability depends on a deeper understanding of perineal mechanics, an area that remains understudied. This study addresses this gap by characterizing the mechanical behavior of the human female perineal body. Perineal samples were obtained *post-mortem* from six women and subjected to stress-relaxation tests and ultimate tensile tests up to failure. A genetic algorithm and finite element simulations calibrated the material parameters of a visco-hyperelastic model to fit the experimental data. Stress-relaxation tests demonstrated a 40% stress reduction after 900 seconds, highlighting the tissue's time-dependent behavior. The ultimate Cauchy stress was 224.70 ± 131.69 kPa at a stretch of 1.97. Histology revealed preferential fiber alignment with the direction of physiological stretching. Three ranges of material parameters were calibrated, enabling the data to be used in future computational simulations. The findings provide valuable insights into the mechanics of the female perineum, facilitating more accurate simulations. This study contributes to ongoing efforts to enhance the understanding, prevention, and management of pelvic floor dysfunctions.

6.1 Introduction

The perineal region forms a diamond-shaped area bound by the pubic symphysis, the tip of the coccyx, and both ischial tuberosities. Within this region lies the perineum, located centrally between the commissure of the labia and the anus. The main anatomical structure in the perineum forms the perineal body, a structure composed of dense connective tissue and interspersed with muscle fibers. It serves as an attachment point for several key muscles, including the pelvic floor muscles (PFM), the external anal sphincter, the deep and superficial transverse perineal muscles, and the bulbospongiosus muscles [1]. As a region that undergoes significant stretching during childbirth, studies indicate that the incidence of perineal trauma may exceed 90% in females who deliver vaginally [2]. Third- or fourth-degree perineal tears, classified as obstetric anal sphincter injuries (OASIS), affect a substantial proportion of postpartum women, with an incidence ranging from 1% to 11% [3]. Perineal trauma is associated with considerable postnatal morbidity, including pelvic organ prolapse and urinary incontinence, and patients are at increased risk of recurrent severe perineal lacerations in subsequent deliveries [4].

Several factors contribute to the risk of perineal trauma during childbirth. While certain aspects, such as ethnicity, nulliparity, and maternal age, are unchangeable, other factors must be considered: these include fetal macrosomia, the use of epidural anesthesia, prolonged second stage of labor, instrumental delivery, and the practice of episiotomy [5]. Even a modest reduction in perineal trauma would positively impact a significant number of women, leading to lower childbirth costs and reduced demand for extended medical care [6]. Despite extensive discussions in the medical field, childbirth-related trauma remains difficult to predict to date. Identifying specific injuries often requires costly post-delivery examinations that are not typically part of the standard care process. As such, healthcare providers could benefit from non-invasive quantitative methods to help identify potential injury sites or predict the types of injuries that may occur. Early detection and monitoring could facilitate timely interventions, thereby reducing the risk or severity of pelvic floor disorders, which often manifest years or even decades after delivery and significantly impact women's quality of life.

Computational models provide a quantitative approach to analyze the physiology of labor, overcoming the limitations of physical models and invasive procedures [7]. Finite element simulations are often used to replicate the biomechanical behavior of the distinct structures involved in childbirth, providing a deeper understanding of the mechanisms of vaginal delivery and the associated risks of injury [8]. A critical aspect of these models is the mechanical characterization of the soft tissues involved, which often exhibit complex, non-linear behavior. Nevertheless, owing the complexity of

the mathematical models required to accurately capture this behavior, or the lack of experimental data, researchers often rely on simplified assumptions, such as focusing only on linear elastic or isotropic hyperelastic properties. While these simplifications facilitate modeling, they severely limit the accuracy of computational models. This limitation can be mitigated by performing mechanical experiments to obtain precise, tissue-specific properties that allow for more realistic simulations.

However, even when experimental tests can be conducted to characterize tissues, ethical and logistical challenges arise, particularly when dealing with soft biological tissues in sensitive contexts as childbirth. Direct experimentation on the human perineum during pregnancy is neither feasible nor ethical due to the significant risks it poses to both mother and fetus. This leaves *post-mortem* examination as one of the few viable options, although it has its own limitations, such as potential tissue degradation, changes in mechanical properties, or limited sample availability. Contemporary research also involves the use of animal models to mimic the mechanical behavior of human pelvic floor components [9, 10]. While these models offer valuable insights, they cannot fully replicate the complexity of human anatomy and physiology, potentially leading to discrepancies in tissue characterization.

Several studies have attempted to non-invasively estimate the mechanical properties of the perineal body, primarily using elastography techniques. For instance, Chen *et al.* (2015) [11] measured the mechanical properties of the perineal body in 20 nulliparous women, estimating its elastic modulus. Similarly, Li *et al.* (2024) [12] quantified the perineal body elasticity using transperineal shear wave elastography. However, these methods only capture the elastic properties of the tissue, which does not fully encompass its complex mechanical behavior. As previously mentioned, animal models are commonly used in research due to their anatomical similarities to the human female pelvic region, with ewe and porcine tissues often selected. Kochova *et al.* (2019) [13] investigated the microstructure and elasticity of the perineal body by conducting uniaxial tension tests on pregnant and postmenopausal ewes. More recently, Lallémant *et al.* (2024) [14] performed uniaxial tensile tests on sows' perineal body tissue to gain further insights into the mechanical properties contributing to perineal tears during childbirth. Furthermore, Kochova *et al.* (2019) [15] conducted the only study, to our best knowledge, which performed tensile tests to determine the load-deformation properties of human female *post-mortem* perineal tissues, alongside histological assessment. Despite these contributions, all of these studies lack a detailed analysis of the hyperelastic and viscoelastic properties of the perineum, critical factors that significantly influence its mechanical behavior.

Therefore, the primary goal of this study was to thoroughly characterize the hyper-

elastic and viscoelastic mechanical behavior of the human female perineum, specifically focusing on the perineal body. This was achieved through uniaxial tensile tests and stress-relaxation tests on *post-mortem* tissue. The experimental data were then used to calibrate the material parameters of a visco-hyperelastic constitutive model, providing a detailed representation of the tissue's mechanical properties. The data obtained contribute to a deeper understanding of the biomechanical behavior of the perineal region and enable more accurate mechanical characterization of these tissues in computational models. Ultimately, this study provides a valuable reference for the mechanical properties of pelvic tissues, supporting simulations of aging-related dysfunctions and pelvic floor disorders, and offering insight into factors that contribute to tissue vulnerability in elderly women.

In summary, the main contributions of this paper are:

- Development of a experimental protocol tailored to perineal tissue, addressing the challenges of its softness and small dimensions, while providing standardized procedures for collection, storage, and preparation that may also be adapted to other delicate soft tissues.
- A deeper understanding of the mechanical behavior of perineal tissue. This includes an analysis of its deformation characteristics, stress-strain relationship, relaxation behavior over time, and its maximum load-bearing capacity before failure.
- Mechanical characterization of the perineum using a visco-hyperelastic anisotropic constitutive model. The determined material parameters can be used for finite element simulations to accurately model the mechanical behavior of the perineal body.
- Establish a reference dataset of the mechanical properties of the human female perineum. This dataset can be used for future studies and computational modeling, particularly for applications such as understanding postpartum dysfunction, as pelvic organ prolapse, and developing interventions for pelvic tissue disorders.

6.2 Methods

The protocol begins with sample collection and storage, followed by specimen preparation for experimental testing, including uniaxial tensile and relaxation tests. The final step involves calibrating the material parameters. A summary of the methodology is presented in Figure 6.1.

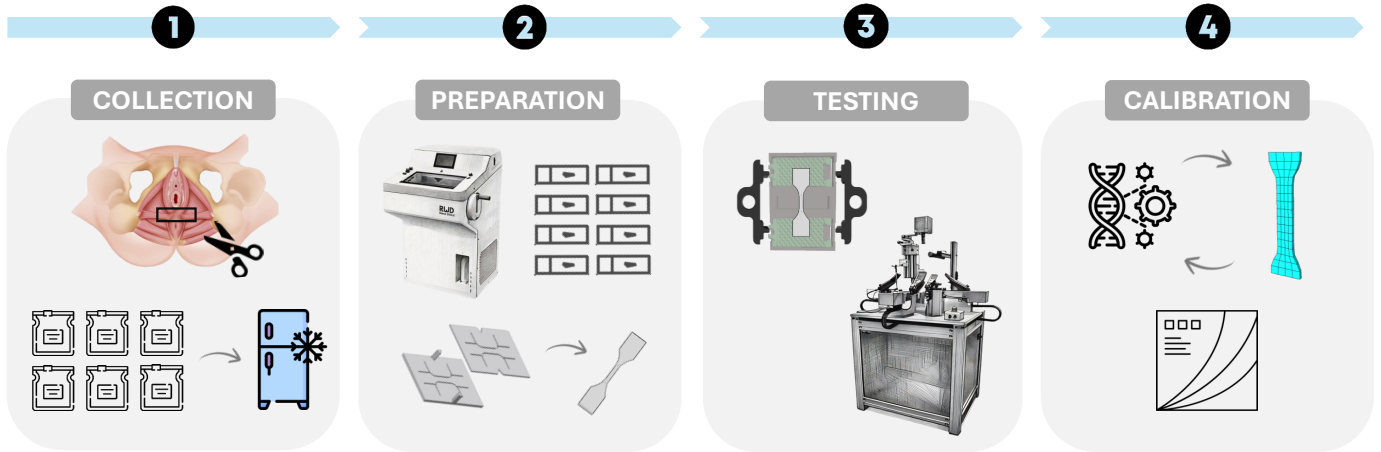


Figure 6.1: Diagram presenting the four main steps of the applied methodology. 1 – Excise perineal sample, collect and freeze. 2 – Slide samples and create dog-bone shape specimens. 3 – Specimen clamping and insertion into the test machine. 4 – Run genetic algorithm, calibrate parameters and fit experimental curve.

6.2.1 Sample collection and storage

Perineal samples were obtained from six females who while alive had provided written informed consent to participate in a *post-mortem* body donation program. The study was reviewed and approved by the Ethics Committee of the Medical University of Graz (36-197 ex 23/24) through an expedited review process. All experiments were performed in accordance with relevant guidelines and regulations. Tissues were obtained from females aged 72 to 101 years at the time of death (87 ± 9.8 , mean $\pm$ standard deviation). The following clinical data is known from the donors: height (162.9 ± 2.7 cm), weight (70.7 ± 15.6 kg), body mass index (26.6 ± 5.4 kg/m²).

The samples were collected *post-mortem*, pre-cooled at 4°C for 1 hour and stored frozen at -80°C for 7-120 days. During sample collection, first skin and subcutaneous tissue were removed, then surrounding structures were identified for guidance, and the perineal body was dissected up to a depth of 20 mm. The region of interest in anterior-posterior orientation was defined as between the inner vaginal wall and the inner rectal wall. Laterally the region of interest was extended to approximately 30 mm per side to avoid damage of the perineal body during dissection. The orientation of the perineal body was marked with surgical suture.

To ensure uniform sample preparation for mechanical testing, the perineal samples were thawed at room temperature for only as long as necessary to enable cutting. The region of interest, the perineal body, was then carefully dissected. The areas closest to the vaginal wall and the anal sphincter were identified, and all samples were refrozen at -80°C in such a way that the sphincter region was flat and facing downward. This

ensured that all specimens would be cut in the same direction. During the process, the samples were kept constantly hydrated with PBS.

6.2.2 Specimen preparation

To maximize the number of specimens retrievable from each sample and ensure uniform sample thickness, a Leica CM1950 Cryostat was used to cut each frozen sample into 0.6 mm sections, the maximum value within the trimming thickness range of this instrument. The specimens were embedded in optimal cutting temperature (OCT) compound to provide structural support and stability and to prevent damage. The sections were kept hydrated with PBS before and immediately after cutting. Each section was placed on a glass microscope slide, numbered sequentially from 1 to the total number of sections, starting from the sphincter side, and then returned to the freezer at -80°C until it was time for specimen preparation for testing. This process is demonstrated in Figure 6.2.



Figure 6.2: Sample preparation steps: The initial perineal sample (1) was cut and inserted into the cryostat machine (2) to produce sections that were placed on microscope slides (3).

On the day of testing, each specimen was thawed, a process that only took a few minutes due to their small thickness. The specimens were then cut into a dog-bone shape using a customized dog-bone punch created for this purpose. As each sample measured approximately 25 to 30 mm per side, the final dimensions of each specimen were 22 mm in total length, 12 mm in gauge length, 3 mm in width, and 0.6 mm in thickness, as shown in Figure 6.3a. The samples were hydrated with PBS throughout the preparation phase.

Following the shaping process, each specimen was placed on a preparation table. A vinyl polysiloxane dental impression material was then applied to both the top and bottom surfaces of the specimen. Once the material solidified, it was carefully cut

to register the cross-sectional area, which was subsequently scanned for further analysis. This methodology was implemented in accordance with the same principles of standardized soft tissue testing described by Scholze *et al.* (2020) [16].

To prevent slippage during testing, custom-designed 3D-printed clamps were employed, following the approach outlined by Scholze *et al.* (2020) [16]. The testing setup included a preparation table, clamps featuring flat pyramid structures optimized for securing thin soft tissue samples, and holder arms designed to attach the clamps and specimen securely to the testing machine, as demonstrated in Figure 6.3a. The clamps and preparation table were fabricated using polylactic acid filament, while the holder arms were made from thermoplastic polyurethane for increased flexibility.

Before placing the specimen in the testing machine, a set of black markers was drawn in the middle of each specimen using tissue marker dye. These markers were essential for using a video extensometer to obtain precise strain measurements. By measuring strain directly on the specimen's surface with the integrated digital extensometer of the Zwick/Roell biaxial testing machine, this technique eliminates potential errors caused by machine deformation or material slippage, ensuring more accurate data collection.

6.2.3 Experimental protocol

The study was conducted in two phases. The first phase involved performing relaxation tests, during which each specimen was subjected to strains of 75% and 150% of its gauge length to evaluate the viscoelastic mechanical properties of the perineal body. The selection of these stretch values was based on preliminary tests with a limited number of samples while considering realistic stretch values during birth [17]. In the second phase, ultimate tensile tests were carried out to determine the failure mechanical properties of the tissue.

After completing all sample preparation steps, seventeen specimens were allocated for stress-relaxation tests and seven for ultimate tensile tests. For the former, two to three specimens were tested per donor, while for the latter, at least one specimen was tested per donor. All tests were conducted using a Zwick/Roell biaxial tester machine equipped with four 100 N load cells, each with a resolution of 0.002 N. The machine was operated in uniaxial mode, calibrated, and controlled using the testXpert III software. The complete set up of the testing machine is presented in Figure 6.3b.

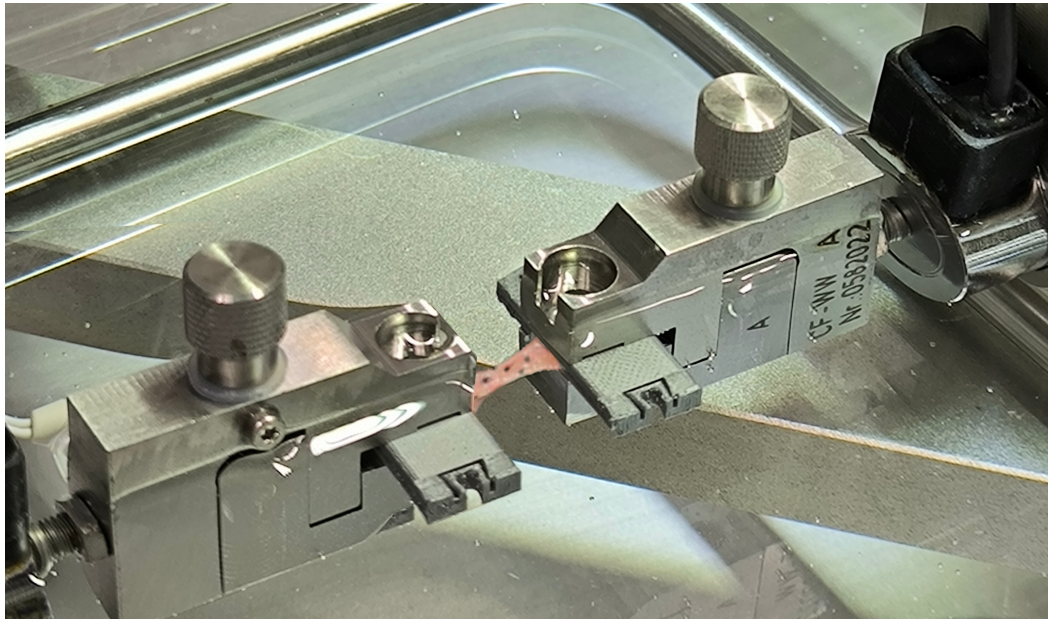
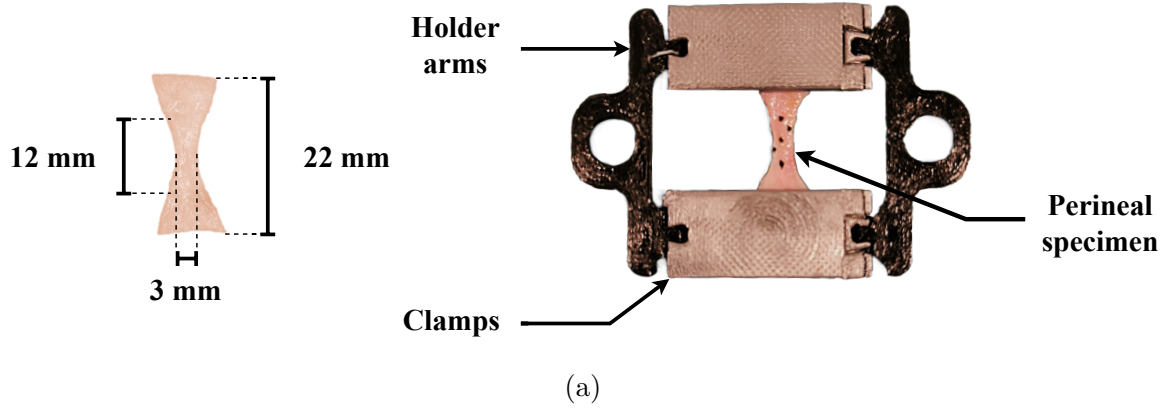


Figure 6.3: (a) Representation of the perineal specimen dimensions and its integration into the testing system, including the 3D-printed clamps, holders arms, and the specimen with black markers. (b) Specimen positioned in the 3D-printed clamps and machine grips, immersed in PBS bath, prepared for testing.

For stress calculations, molds of the cross-sections were scanned at 600 DPI using a commercial scanner (CanoScan LiDE 400). The resulting images were then processed using ImageJ software, where a threshold was applied to differentiate the dental impression material from the remaining area formed by the specimen's shape. This remaining area corresponds to the specimen's cross-section, and its area was automatically calculated by the software. The engineering stress (or first Piola-Kirchhoff stress, P) was calculated, which is given by the force in the current configuration divided by the area in the non-deformed reference configuration. To calculate the Cauchy stress tensor, σ , the following equation was considered:

$$\sigma = \frac{1}{J} P F^T \quad (6.1)$$

where J is the Jacobian, assumed to be 1 since we are assuming an incompressible behavior of soft tissues which is a valid approximation due to the water amount [18], and F is the deformation gradient for the purely isochoric uniaxial deformation.

In the uniaxial case, which is the formulation considered in the present work, the Cauchy stress is given by:

$$\sigma = \frac{f}{A_0} \lambda \quad (6.2)$$

in which f corresponds to the applied force, A_0 is the cross-sectional area in the undeformed (reference) configuration, and λ is the stretch ratio in the direction of the applied load.

Relaxation tests

The relaxation tests were displacement-controlled and followed a defined protocol involving seven loading and six unloading cycles at 75% strain, applied at a rate of 3 mm/min. The preconditioning served the purpose to create a more realistic baseline and account for preconditioning as soft tissues in the living body are also being loaded periodically. After the cycles, the displacement was held constant for 900 seconds [19]. The sample was then stretched to 150%, and another set of seven loading and six unloading cycles to 75% was performed. At 150%, the displacement was again held constant for 900 seconds. After the relaxation test, the sample was stretched until failure, with force-displacement data recorded at 0.1-second intervals. A representation of the protocol implemented is presented in Figure 6.4.

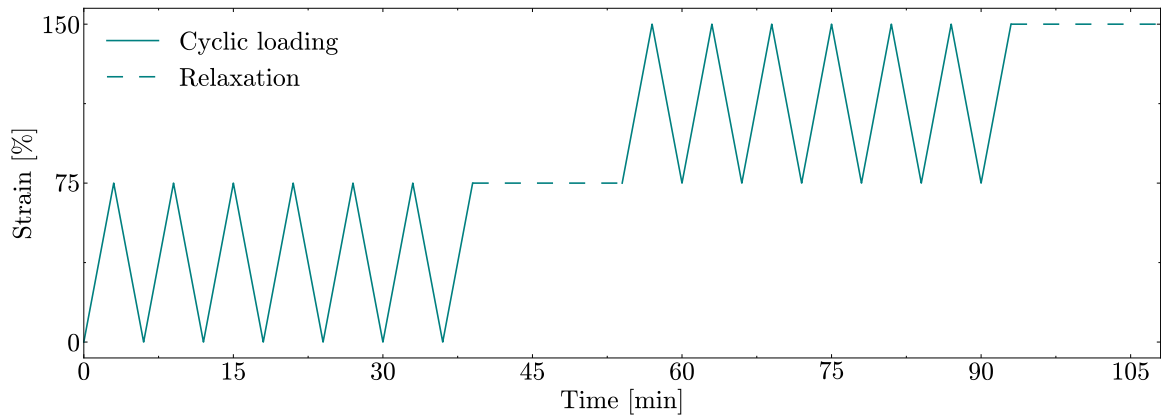


Figure 6.4: Displacement-controlled profile for the cyclic loading and relaxation test protocol.

Ultimate tensile tests

Similarly, the ultimate tensile tests were also displacement-controlled, with specimens stretched until failure at a rate of 1 mm/min, and force-displacement data were acquired at 0.1 second intervals. For the ultimate tensile test, preconditioning of the samples was not performed before testing. Throughout the mechanical tests, the specimens were kept hydrated in a 37° C bath containing PBS.

6.2.4 Histological assessment

Samples for histology were taken adjacent to the center of the dog-bone sample. Samples were fixed with 4% formaldehyde for 24h and then stored in PBS at 4°C until further processing. Tissue samples were processed with a KOS Rapid Tissue Processor (Milestone SRL, Valbermo, Italy) using the pre-programmed setup for Histoprocessing (Fixation: 4% formaldehyde, Dehydration: Ethanol-Isopropanol- Wax). After paraffin embedding, 5-µm sections were obtained using a rotary microtome (Leica RM2255, Nussloch, Germany).

Sirius red staining for collagen was performed according to routine procedure (Weigert's hematoxylin 15 min; Picro-sirius red 60 min) [20]. Brightfield imaging was performed under controlled conditions, maintaining consistent brightness and contrast settings across all samples to ensure reliable comparability. Similarly, Masson-Goldner-Trichrome staining was performed according to standard protocol (Weigert's hematoxylin 2 min; Goldner staining solutions 5 min each). After dehydration in graded solutions of alcohol, slides were cover slipped in DPEX mounting media (Electron Microscopy Science, Hatfield, PA, USA). Throughout the process, xylol was replaced with Histolab Clear (Sanova, Vienna, Austria). Images were taken using a digital slide scanner (Slideview VS200, Olympus, Tokyo, Japan) or a camera-equipped microscope (BX-43, Olympus, Tokyo, Japan) using a 20x dry lens.

Evaluation of histological stains

Collagen fiber orientation was evaluated employing Fiji [21] with the ImageJ plugins Colour Deconvolution 2 [22, 23] and OrientationJ [24] on Sirius red-stained sections. All imaged sections were evaluated using the same color parameters and consistent fiber thickness using a custom-written macro. The derived histograms of fiber orientation were used to calculate the fiber orientation mean and standard deviation using Python, which were used as an input for the computational model.

Muscle content was evaluated qualitatively due to variance in staining intensity in Masson-Goldner stained sections. Sections were categorized as containing low,

medium, or high muscle fiber content.

6.2.5 Calibration of the constitutive parameters

The experimental data were used to calibrate the material parameters of a visco-hyperelastic constitutive model. Finite element simulations were conducted in Abaqus[®], modeling a specimen that replicated the geometry and boundary conditions of the experimental setup. The material parameters were iteratively optimized to reproduce the mechanical response of the specimen, and the resulting stress–relaxation and stress–stretch curves were extracted from the simulations. The optimization procedure was implemented in MATLAB, while the finite element analyses were executed in Abaqus[®]. Simulation results were automatically transferred to MATLAB for analysis, establishing an Abaqus[®]–MATLAB interface for automated parameter calibration. The simulated curves were then compared with the experimental results to evaluate and refine the calibration. The optimization was performed using a previously developed genetic algorithm [25]. The different components of this process, including the constitutive model, finite element simulations, and optimization algorithm, are described in detail in the following sections.

Finite element simulation

To obtain numerical data, simulations were conducted to replicate the experimental protocol of the mechanical tests. The geometrical model used for parameter calibration, shown in Figure 6.5, represents the specimen from the experimental tests, with dimensions detailed in Figure 6.3a. To simplify the analysis, only one-eighth of the specimen was modeled, leveraging symmetry boundary conditions. The final mesh comprises 592 elements of type C3D8H. The fibers were assumed to have a principal orientation aligned with the direction of the applied stretch. The Cauchy stress in the direction of the applied load was used as the comparison variable with experimental data, and the average response of all finite elements within the gauge length was considered.

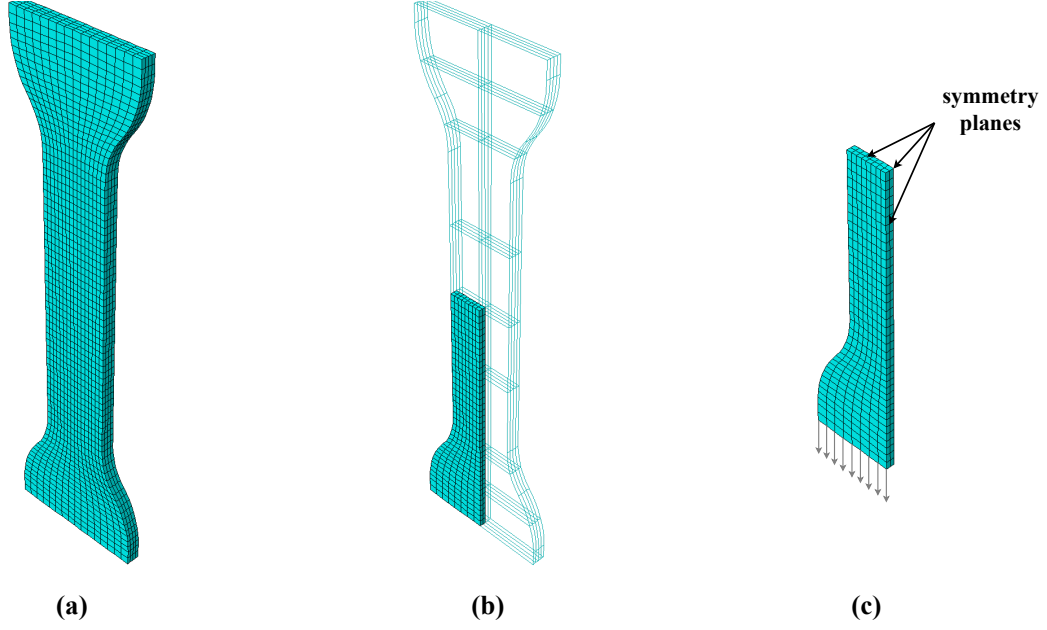


Figure 6.5: Finite element model used for simulating experimental tests, integrated with a genetic algorithm for calibrating the constitutive model parameters. The finite element model consists of a eighth-symmetry of the specimen. (a) Full specimen mesh. (b) Eighth-model with symmetry planes. (c) Applied boundary conditions and direction of the applied stretch.

Material model

Based on the experimental data obtained, a transversely isotropic hyperelastic response with viscoelastic behavior was assumed. The HGO constitutive model model was considered for the hyperelastic behavior and the generalized Maxwell model for the viscous effects [26, 27]. The constitutive behavior was implemented in Abaqus[®] using a previously defined user-defined material subroutine (UMAT). The strain-energy function is given by Equation 6.3.

$$\Psi = \bar{\Psi}_m + \bar{\Psi}_f + \Psi_{vol} \quad (6.3)$$

where $\bar{\Psi}_m$ is the isochoric matrix contribution (Equation 6.4), $\bar{\Psi}_f$ the collagen fibers contribution (Equation 6.5), and Ψ_{vol} the volumetric contribution (Equation 6.6).

$$\bar{\Psi}_m = c_{10} (\bar{I}_1 - 3) \quad (6.4)$$

$$\bar{\Psi}_f = \frac{k_1}{2k_2} \left(\exp \left[(\bar{I}_4 - 1)^2 \right] - 1 \right) \quad (6.5)$$

$$\Psi_{vol} = \frac{1}{D} (J - 1)^2 \quad (6.6)$$

where $c_{10} > 0$ and $k_1 > 0$ are stress-like material parameters, and $k_2 > 0$ is a dimensionless parameter. $\bar{I}_1 = \text{trace}(\bar{\mathbf{C}})$ is the first invariant of the isochoric right Cauchy-Green strain tensor, given by $\mathbf{C} = \mathbf{F}^T \mathbf{F}$, where $\mathbf{F}$ is the deformation gradient, and $\bar{I}_4 = \bar{\lambda}^2$ is an invariant arising directly from the anisotropy that is equal to the square of the stretch in the fiber direction. Regarding the volumetric contribution, $J = \det(\mathbf{F})$ corresponds to a measure of the volume variation, and D is a constitutive parameter that allows to describe the tissue as near-incompressible, with a value of $1 \times 10^{-5} \text{ MPa}^{-1}$ used.

The viscoelastic contribution is represented by the generalized Maxwell model. The implementation includes the addition of a dissipative potential to the strain energy function (Equation 6.7), describing the non-equilibrium state.

$$\Psi_{vis} = \sum_{\alpha=1}^m Y_{\alpha}(\bar{\mathbf{C}}, \bar{\mathbf{I}}_{\alpha}) \quad (6.7)$$

The configurational free energy Y_{α} is a function of the isochoric right Cauchy-Green strain tensor, $\bar{\mathbf{C}}$, and a set of strain-like internal variables denoted by $\bar{\mathbf{I}}_{\alpha}$. The latter characterizes the relaxation and/or creep behavior of the material. The viscoelastic behavior is modeled by $\alpha=1, \dots, m$ viscoelastic processes.

The second Piola-Kirchhoff stress tensor, given by $\mathbf{S} = J\mathbf{F}^{-1}\boldsymbol{\sigma}\mathbf{F}^{-T}$, can be decomposed into an equilibrium part and a non-equilibrium part characterized by the elastic response of the system and the viscoelastic response, respectively, as demonstrated in Equation 6.8.

$$\mathbf{S} = \mathbf{S}_{vol}^{\infty} + \mathbf{S}_m^{\infty} + \mathbf{S}_f^{\infty} + \sum_{\alpha=1}^m \mathbf{Q}_{\alpha} \quad (6.8)$$

where $\mathbf{S}_{vol}^{\infty}$, $\mathbf{S}_m^{\infty}$ and $\mathbf{S}_f^{\infty}$ denote the volumetric, matrix and fiber contribution of the second Piola-Kirchhoff stress tensor, and $\mathbf{Q}_{\alpha}$ correspond to the isochoric non-equilibrium stresses arising from the viscous effects:

$$\mathbf{Q}_{\alpha} = \exp(-T/\tau_{\alpha})\mathbf{Q}_{\alpha}^{0+} + \int_{t=0+}^{t=T} \exp\left[\frac{-(T-t)}{\tau_{\alpha}}\right] \beta_{\alpha} \dot{\mathbf{S}}_{\alpha} dt \quad (6.9)$$

where τ_{α} and β_{α} consist of the relaxation time and free-energy parameters, representing the viscoelastic properties derived from the Maxwell model with α parallel elements.

Genetic algorithm

The algorithm begins by generating a random population of five elements, where each element represents a unique set of material parameters. The fitness of each element is evaluated using a specific evaluation function, and the fittest element is retained for the next generation, which is produced through a crossover operation. The population is then checked for diversity. If there is insufficient diversity, the population is reinitialized randomly, except for the fittest individual, who is retained for the next generation. This iterative process continues until the algorithm converges.

In the present work, the elements of the population were the material parameters of the constitutive model described in the previous section, and the fitness of each element was evaluated using a least squares evaluation function, F_e , between the experimental data and the solution from the numerical simulation.

$$F_e = \sqrt{\sum_{i=1}^n \frac{(P_i^e - P_i^\Psi)^2}{n-2}} \quad (6.10)$$

where n is the number of considered experimental points and P_i^e and P_i^Ψ are respectively the Cauchy stresses in the direction of the applied stretch from the experimental data and from the numerical simulation in Abaqus[®].

Calibration

To calibrate the visco-hyperelastic material, the viscous properties of the Generalized Maxwell model were initially determined using the mean normalized relaxation curve obtained from the relaxation part of the experiments. In the calibration process, only the relaxation of the tissue was considered, not including the cyclic loading procedure performed prior to the stress-relaxation test. Normalization ensures that stress-relaxation is expressed as a percentage, independent of the absolute values and the hyperelastic parameters, which are unknown at this stage. The normalization was performed by dividing each data point by the maximum value of the relaxation curve.

Once the viscous parameters were successfully determined, the next step involved calibrating the hyperelastic properties. This was done by comparing the model's predictions with the absolute values obtained from the Cauchy stress – stretch experimental data. By fitting the model to the mean of the experimental curves, the hyperelastic parameters were determined, completing the material calibration process.

6.3 Results

The data acquired during the relaxation and ultimate tensile tests is available at [Zenodo](#) repository [28]. The dataset includes the samples that were considered in the results presented in this study.

6.3.1 Relaxation tests

Of the seventeen samples tested, thirteen successfully completed the protocol. Specimens were excluded if they ruptured during the first 75% loading cycle or exhibited insufficient relaxation during the relaxation period. The latter were excluded primarily because they consisted mostly of fat tissue. Since the majority of specimens failed during the first loading cycle at 150% strain, relaxation data was collected at the 75% strain level.

The stress response during these loading and unloading cycles is illustrated in Figure 6.6. The stress decreased from the first peak to the final one by 78.3%, highlighting the material's response to cyclic loading.

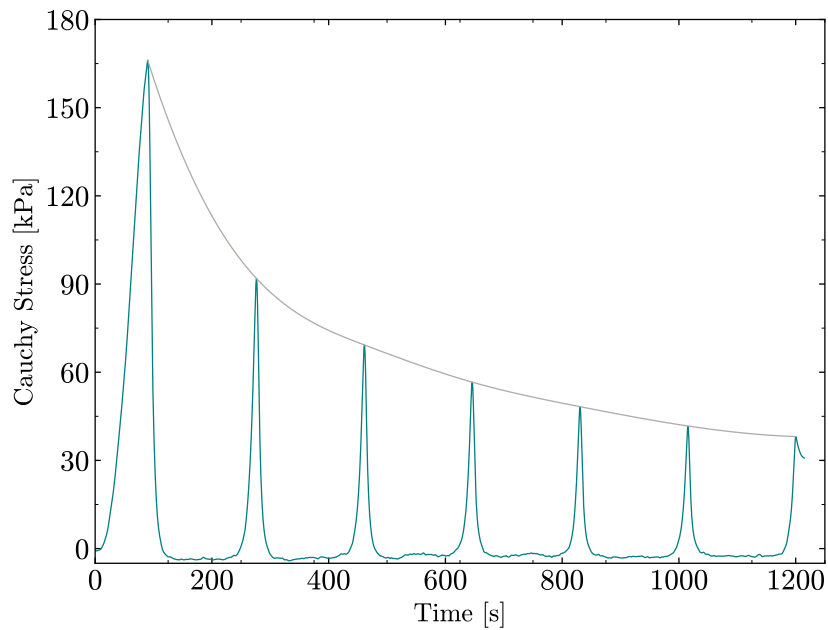


Figure 6.6: Representative cyclic loading and unloading response of the tissue prior to the relaxation tests, illustrating the evolution of Cauchy stress across repeated cycles. The pink line represents a spline interpolation fitted to the peak stress values of each cycle.

Following the seventh loading cycle, the displacement was held constant at 75% strain for 900 seconds. The Cauchy stress-time curve for the experiments, along with its

averaged response, is presented in Figure 6.7a. Additionally, the results are presented in terms of normalized stress (Figure 6.7b), calculated as the ratio of the current stress to the peak stress. By the end of the 900-second period, the material demonstrated an average stress-relaxation of 39.76%, highlighting its time-dependent behavior.

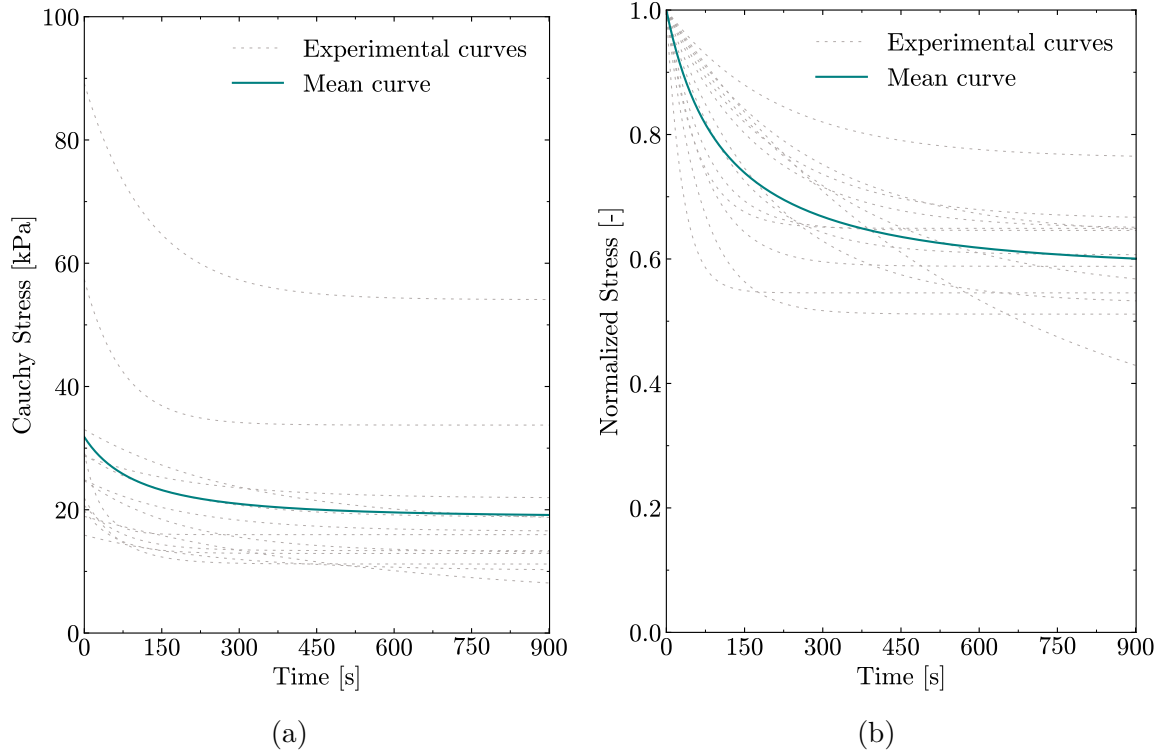


Figure 6.7: Average response of the relaxation tests: (a) Cauchy Stress (kPa) and (b) Normalized Stress (current stress/peak stress) of all the experiments (dashed lines).

6.3.2 Ultimate tensile tests

For ultimate the tensile tests, the displacement of the actuators was used to calculate stretch and stress, as the markers measured with the video extensometer deformed strongly resulting in insufficient quality for reliable analysis. Of the seven samples tested, five successfully completed the protocol, while the other two slipped during testing, which made the data collected nonviable. From the force-displacement data, the ultimate tensile displacement was determined to be 11.43 mm, while the ultimate tensile force reached 0.291 ± 0.182 N. The results are represented in terms of Cauchy stress (calculated in kPa) as a function of stretch, as shown in Figure 6.8. The maximum Cauchy stress for the average curve was determined to be 224.70 ± 131.69 kPa, corresponding to a stretch of 1.966.

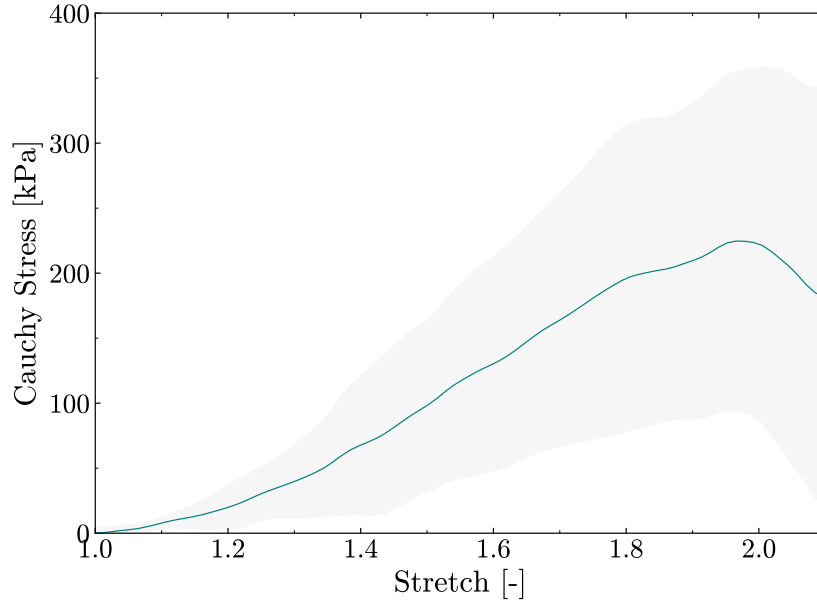
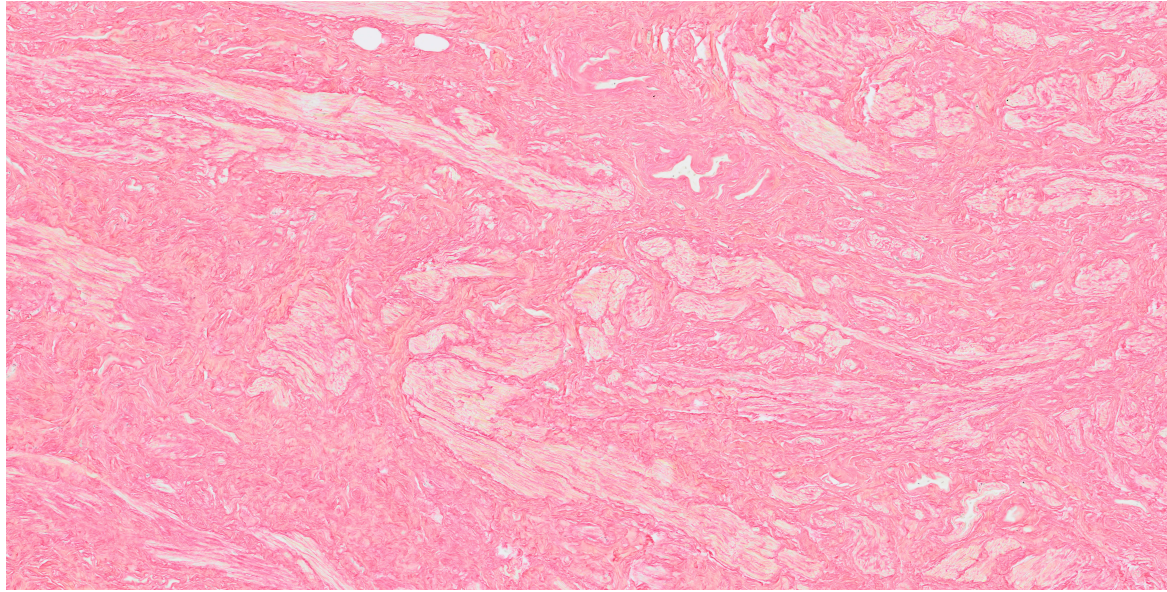


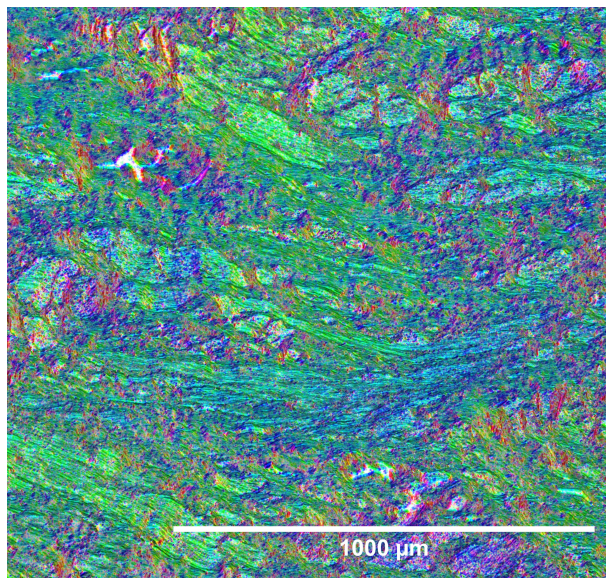
Figure 6.8: Average Cauchy stress-stretch curve from the ultimate tensile tests. Averaged response: mean $\pm$ SD (standard deviation).

6.3.3 Histological assessment

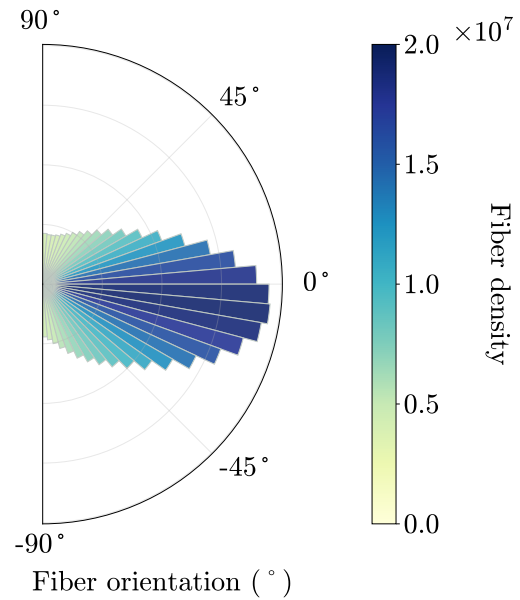
Histological analysis was performed on all specimens included in the stress-relaxation and ultimate tensile test results. Figure 6.9a presents the original histological section of the sirius red staining, while 6.9b presents the color-coded visualization after orientation analysis based on sirius red staining of the perineal specimens. Fiber orientation was analyzed employing Fiji [21] with the ImageJ plugins Colour Deconvolution 2 [22, 23] and OrientationJ [24]. Blue and green tones indicate fibers oriented in the horizontal direction, and red tones represent fibers oriented in the vertical direction.



(a)



(b)



(c)

Figure 6.9: (a) Representative histological section stained with Sirius Red. (b) Post-processed histological section of perineal specimens at 20x magnification. Blue and green tones represent fibers oriented in the horizontal direction, while red tones represent fibers oriented in the vertical direction. (c) Polar histogram of the collagen fibers. Radial distance represents fiber density, while the angle, in degrees, indicates fiber orientation. Shaded bars show the distribution of fiber densities across directions.

The histological assessment enabled the analysis of fiber density and orientation in the examined tissues. The preferential fiber direction is illustrated in Figure 6.9c, with the majority of fibers predominantly aligned horizontally, corresponding to the direction of tissue stretching. The mean orientation of the fibers is approximately 19 degrees. In

the qualitative evaluation of muscle content assumed *in vivo*, most specimens exhibited medium fiber content, while two showed high fiber content, and one displayed low fiber content.

6.3.4 Calibration of constitutive parameters

The micro-genetic algorithm developed by Vila Pouca *et al.* (2020) [25] was used to calibrate the constitutive parameters of the Holzapfel-Gasser-Ogden (HGO) constitutive model, which was coupled with the generalized Maxwell model to account for viscous effects and capture the visco-hyperelastic behavior. Figure 6.10 presents the calibrated constitutive model with the experimental data. Due to the variability observed in both the hyperelastic and viscoelastic responses, parameter calibration was performed for three cases: minimum, mean and maximum stress relaxation, as well as the corresponding stresses from the tensile tests. This approach enabled the derivation of three sets of parameters, each representing distinct types of tissue behavior. The calibrated parameters are presented in Table 6.1.

The mean squared error for the viscoelastic response is 1.31×10^{-5} , 4.49×10^{-5} and 7.27×10^{-5} for cases 1, 2 and 3, respectively. For the hyperelastic calibration, the errors obtained were $1.66 \times 10^{-5} \text{ MPa}^2$, $8.02 \times 10^{-6} \text{ MPa}^2$ and $1.08 \times 10^{-6} \text{ MPa}^2$ for the same cases.

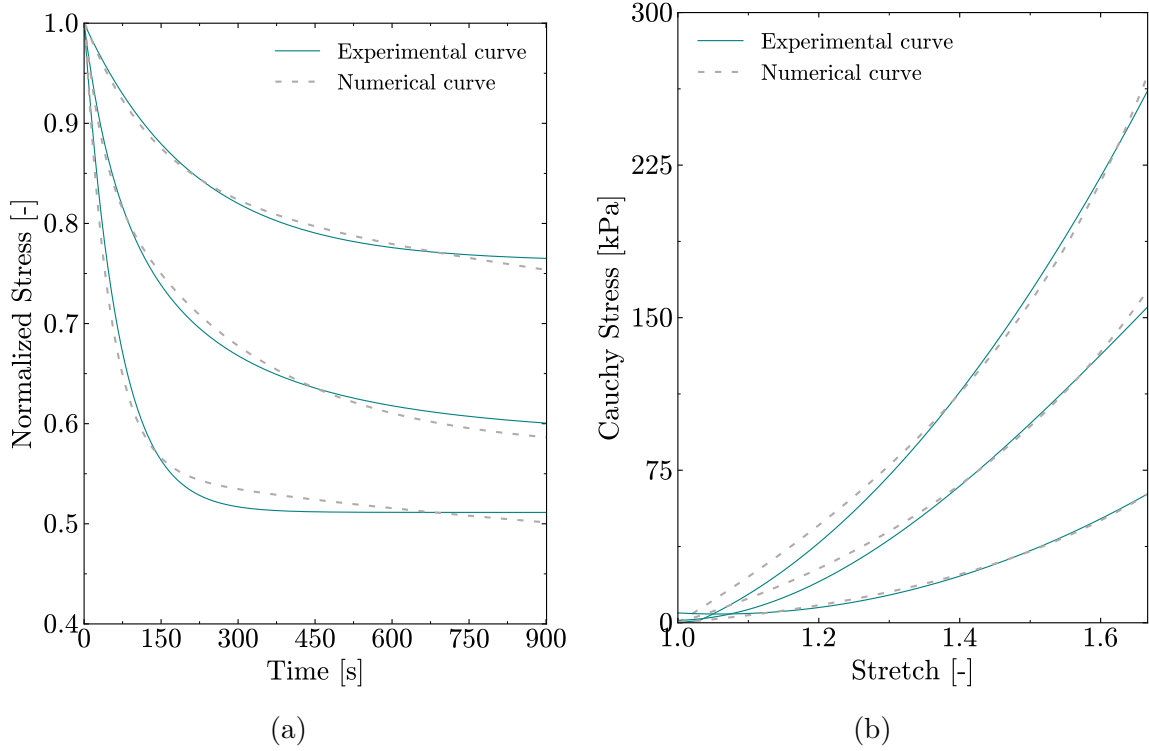


Figure 6.10: Calibration of the constitutive model parameters using experimental data. (a) Fitting to the minimum, mean, and maximum stress-relaxation test curves. (b) Fitting of the minimum, mean and ultimate tensile test curves.

Table 6.1: Constitutive parameters obtained from the genetic algorithm optimization.

	Hyperelastic parameters			Viscoelastic parameters			
	c_{10}	k_1	k_2	β_1	τ_1	β_2	τ_2
Minimum	22.0 kPa	8.60 kPa	0.292 [-]	0.99 [-]	48.94 s	0.23 [-]	1177.81 s
Mean	6.20 kPa	9.30 kPa	0.094 [-]	0.24 [-]	33.29 s	0.51 [-]	291.25 s
Maximum	0.75 kPa	3.30 kPa	0.108 [-]	0.24 [-]	130.78 s	0.30 [-]	1424.24 s

6.4 Discussion

This study presents an experimental approach to investigate the hyperelastic and viscoelastic properties of the female perineum, a critical structure within the pelvic cavity that plays a fundamental role in various physiological processes. Accurate mechanical characterization of the perineum can be essential for developing reliable biomechanical models that simulate the mechanical behavior of the pelvic cavity, providing insights into tissue vulnerability and contributing to the prediction, prevention, and management of pelvic organ prolapse and other age-related pelvic floor dysfunctions. The present study conducted uniaxial tensile and stress-relaxation tests on *post-mortem*

perineal tissue samples to explore the tissue's mechanical behavior. The findings presented here aim to enhance the understanding of perineal biomechanics, providing valuable insights that could help unveil the mechanisms underlying pelvic floor disorders, supporting the development of preventive strategies and therapeutic interventions to promote long-term maternal health. The raw mechanical characterization data is available to interested researchers at [Zenodo](#). Given the specificity of the data, assistance can be provided for its interpretation and usage, along with the necessary documentation. This will ensure that others can accurately utilize the dataset for further analysis and development in the field.

The relaxation test results indicate that the perineal body exhibits viscoelastic behavior, as evidenced by the high stress relaxation when a constant displacement is maintained for 900 seconds. Specifically, the stress decreased by approximately 40% during this period, as illustrated in Figure 6.7. Viscoelasticity is a critical property of biological tissues, particularly in the female pelvis, as it allows tissues to accommodate larger deformations with reduced risk of damage [29]. This characteristic is especially relevant during childbirth, where the relaxation of pelvic tissues facilitates progressive dilation as labor advances [30]. However, to the best of our knowledge, no stress-relaxation curves for the perineal body are currently available in the literature for direct comparison of its viscoelastic behavior.

The ultimate tensile tests revealed that the specimens exhibited non-linear hyperelastic behavior, as demonstrated by the stress-stretch curve (Figure 6.8). The specimens demonstrated high deformability, with a non-linear relationship between force and displacement. Limited data exist in the literature regarding the mechanical failure properties of the perineum. Kochova et al. (2019) [15] reported ultimate strain and engineering stress values of 1.4 and 171.5 kPa, respectively, for the postmenopausal human female perineal body. In contrast, the specimens tested in the current study exhibited a lower ultimate strain of 0.95 before failure, while the ultimate tensile engineering stress, approximately 120 kPa, was within a comparable range. These discrepancies may arise from differences in sample dimensions, as the present study utilizes specimens with smaller width and thickness. Additionally, the experimental setup differs, as our study uses a phosphate-buffered saline (PBS) bath during testing to prevent the sample from drying throughout the process. Another possible explanation is that, despite both studies involving elderly women, the mean age in our study is higher.

The mechanical properties obtained from the tensile tests in this study can also be compared to those reported in animal models, which are often used as surrogates for human tissues in biomechanical research. For instance, Lallemand *et al.* (2024) [14]

performed uniaxial tensile tests on porcine perineal tissues, identifying the vagina and anal mucosa as the stiffest tissues, while the internal and external anal sphincters were more extensible and less stiff. The stress values reported for latter structures fall within a similar range to those observed in our human tissue specimens. This suggests that certain porcine tissues may serve as reasonable analogs for studying the mechanical behavior of human perineal structures, although differences in anatomy and tissue composition must be considered. Additionally, Kochova *et al.* (2019) [13] conducted tensile tests on the perineal body of postmenopausal ewes, reporting stress values that are comparable to those obtained in our study. However, the ewe tissue exhibited slightly higher rigidity and sustained greater strain before failure. These comparisons highlight the potential utility of animal models for preliminary investigations into perineal biomechanics, while also underscoring the importance of human tissue data for accurate characterization. Despite the similarities, the observed differences in mechanical behavior between human and animal tissues emphasize the need for caution when extrapolating findings from animal studies to human clinical applications.

The histological analysis of the perineal specimens provided valuable insights into the structural composition and fiber orientation of the tissue, which are critical factors influencing its mechanical behavior. The Sirius Red collagen staining revealed a dense network of collagen fibers, predominantly aligned along the direction of tissue stretching, as illustrated in the polar histogram (Figure 6.9c). This preferential fiber orientation aligns with the anatomical function of the perineal body, which undergoes significant stretching during childbirth. The alignment of fibers in the direction of loading likely contributes to the tissue's ability to withstand high stress, as observed in the ultimate tensile tests. However, the high variability in fiber density, observed directly from the measurements, and in fiber orientation across specimens may also explain the differences in mechanical responses, such as the stress relaxation behavior observed in the relaxation tests. The presence of well-organized collagen fibers supports the tissue's viscoelastic properties, allowing it to reduce stress over time, which is crucial for accommodating the large deformations experienced during childbirth. These histological findings complement the mechanical data, providing a more comprehensive understanding of the perineal body's biomechanical behavior. In future work, the constitutive model could also be extended to account for collagen fiber dispersion using the HGO formulation. Incorporating fiber orientation heterogeneity could allow a more physiologically realistic representation of the tissue's anisotropic mechanical behavior and improve the predictive accuracy of the simulations.

The calibration of material properties demonstrated the feasibility of fitting numerical simulations to experimental data to achieve accurate mechanical characterization. In this study, the minimum, mean, and maximum tissue responses were calibrated

based on the variability in the mechanical behavior of the same tissue across different women, with these responses representing the lowest, average, and highest experimental curves, respectively. This variability can be primarily attributed to inter-individual differences among donors, including age-related physiological changes and variations in tissue composition. All specimens were obtained from elderly women, a population in which pelvic tissue quality is affected by factors such as reduced collagen cross-linking, altered elastin content, and progressive remodeling of the extracellular matrix. In addition, the absence of detailed obstetric or clinical histories further contributes to the heterogeneity observed across samples. These donor-related factors influence the microstructure and viscoelastic behavior of pelvic tissues, introducing variability that reflects the natural physiological diversity of the studied population rather than methodological inconsistencies. This underscores the critical need for patient-specific models to account for anatomical and mechanical differences unique to each individual. In the calibration process of the relaxation tests, a small deviation from the experimental curves is observed in the numerical results, with a faster initial decay followed by an approach to an equilibrium value slightly lower than the experimental data. The inclusion of an additional time constant within the Maxwell model framework was considered to address this discrepancy. However, the overall trend remained unchanged. Despite this, the numerical curves show very good agreement with the experiments, and the associated errors are minimal. Additionally, the relaxation curves exhibited slight variations across stress levels, suggesting a transition from a predominantly single-mode to a multi-mode relaxation behavior at higher stresses. This observation indicates that the tissue displays stress-dependent viscoelastic effects, which could be more accurately represented by models incorporating variable or non-linear relaxation spectra [31]. The values reported in Table 1 correspond to the optimal parameters obtained from the calibration of the constitutive model through a genetic algorithm for each specimen. The genetic algorithm provides point estimates rather than statistical confidence intervals. While parameter variability could in principle be assessed via repeated calibration runs or sensitivity analysis, this was beyond the scope of the present study. Therefore, the reported values represent single optimal estimates. Nevertheless, significant advancements in experimental mechanics are still required to effectively capture the hyperelastic and viscoelastic behavior of tissues *in vivo*. Addressing this challenge is essential for improving the fidelity of models used and potentially implementing them in clinical applications.

The primary limitation of this study is that all specimens were obtained from elderly female donors, whose perineal tissue may exhibit mechanical properties substantially different from those of younger, nulliparous, or pregnant women. Age-related changes, including reduced collagen content, altered elastin structure, and hormonal variations,

are known to influence the mechanical behavior of soft tissues. Consequently, caution is warranted when extrapolating these results to younger populations. Previous research has explored the impact of aging on the biomechanical properties of soft tissues, particularly pelvic tissues. For instance, Chanterreau *et al.* (2014) [32] demonstrated that aging and potential trauma contribute to changes in the mechanical behavior of pelvic floor tissues, resulting in increased stiffness in most of the tissues tested. These findings are crucial as they could facilitate the development of mathematical models that relate the mechanical properties of younger and older tissues [33]. Such models would allow researchers to extrapolate the characteristics of younger tissues based on the more readily available samples from elderly individuals.

Additional limitations must be acknowledged in this study. First, the small sample size (eighteen samples from six individuals) limits its generalizability and the ability to account for inter-individual variability in tissue properties, which may have led to biased or incomplete conclusions. Second, the perineal tissue samples were frozen prior to analysis, a common preservation method that may alter the mechanical and structural properties of biological tissues. Nonetheless, literature suggests that this influence is minimal [34, 35]. Regarding the freezing process, the tissues were stored frozen for a relatively long period, which may have slightly influenced their mechanical properties and contributed to some variability between samples. In addition, the occurrence of one or more freeze–thaw cycles could also have had an effect on tissue integrity and mechanical behavior [36]. Third, although the perineal body contains muscle fibers, only the passive properties of the tissue were analyzed. However, this scenario can be compared to cases where women receive epidurals during labor, which lead to muscle relaxation. Furthermore, the mechanical properties were tested in only one direction. While this aligns with the primary anatomical stretching direction of the tissue, it may limit the acquisition of critical information regarding tissue heterogeneity. Future work should focus on testing the tissue in the transverse direction and also under biaxial loading, allowing for a more comprehensive validation of the anisotropic response of the tissue. Also, the use of a standardized geometry in the finite element simulations for parameter calibration may be considered a limitation, as small geometric variations exist between specimens, and the model does not fully capture the unique geometry of each individual specimen. The absence of histological assessment throughout the experimental protocol also represents a limitation. Since microstructural analysis was not performed at different stages, particularly after preconditioning, it is not possible to determine with certainty whether any microstructural damage occurred in the tissue. Moreover, all experiments in this study were performed at a single deformation rate. Therefore, rate-dependent viscoelastic effects, which may influence tissue stiffness at different loading rates, were not assessed. Nonetheless, previous studies have

demonstrated that tissue stiffness can vary with loading rate due to rate-dependent viscoelastic behavior [37]. Lastly, the marker data could not be incorporated into the ultimate tensile test analysis, which may have led to less precise measurements. As the samples demonstrated stress concentration near the grips, causing damage to the areas near the clamps, it would have been more accurate to measure the stress data at the midsection of the samples.

Despite these limitations, this study presents a pipeline for acquiring experimental data from *post-mortem* tissues and integrating it into a computational model for biomechanical simulations. Our findings demonstrate that the perineal body exhibits a highly non-linear, time-dependent viscoelastic response when subjected to mechanical stress. By fitting experimental data to a constitutive model using Abaqus[®] finite element software, we successfully characterized the tissue's mechanical behavior. Incorporating realistic tissue characterization into computational models can help identify regions of the pelvic floor that are most susceptible to stress or deformation, particularly in elderly women who are at increased risk of pelvic organ prolapse and other pelvic floor dysfunctions. This predictive capability could inform the development of targeted interventions, such as individualized pelvic floor rehabilitation programs, supportive devices, or preventive strategies to reduce the progression of prolapse and associated complications. Furthermore, integrating these models into clinical training and decision-making could improve healthcare providers' understanding of the biomechanical factors contributing to pelvic floor dysfunction, ultimately supporting better prevention, management, and care for aging women.

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Part V

Final remarks

Chapter 7

General discussion

7.1 Discussion

Childbirth-related injuries represent a significant health concern that affects millions of women globally. The incidence of perineal trauma during vaginal delivery can exceed 90%, while pelvic floor injuries impact between 6% and 40% of women, as discussed in Chapter 1. These injuries can lead to long-term complications such as pelvic organ prolapse, urinary and fecal incontinence, sexual dysfunction, and psychological distress. In fact, up to 20% of women who experience LAM trauma may require subsequent surgical intervention. This highlights the urgent need for strategies to predict and prevent such injuries, enabling timely medical intervention. This thesis aims to enhance the understanding of the mechanisms involved in vaginal delivery and related trauma, with a focus on how this knowledge can be applied in clinical practice by obstetricians. The hypothesis of this research is that a FE model, adaptable for different labor-related applications and integrated with experimental data, can be used to train ML models capable of delivering patient-specific predictions in a clinical setting.

The first aim of this work was to develop a FE model of the PFM and perineum to simulate vaginal delivery and identify the most affected regions. The model, which includes the PFM and key structures of the perineal region, was developed using MRI of a young, healthy woman, as well as input from obstetricians and anatomical literature, with a focus on achieving realistic dimensions for the main structures. The inclusion of perineal structures, as opposed to previous studies that only focused on the PFM, introduces additional constraints on the PFM due to boundary conditions and structural interactions, resulting in a more anatomically realistic scenario. In simulations that include the perineum, the stress distribution across the PFM is spread over a larger area with lower concentration, suggesting that focusing solely on these muscles may

overlook the full extent of the potential injury area. This highlights the importance of incorporating the perineal structures when simulating childbirth. The critical regions identified in the study include the perineal body near the urogenital hiatus, the superior region of the perineal body, and the connection between the perineal body and the anal sphincter. These findings align with clinical evidence, as perineal tears and OASIS are commonly observed in these regions. An interesting finding is that stress levels are higher in the superior region of the perineal body compared to the inferior region. This area is challenging to visualize externally and is often overlooked. The indication of potential damage here underscores the need for obstetricians to carefully assess it for possible injuries.

The FE model developed can be used to simulate distinct obstetric scenarios, such as different labor positions, fetal malpositions, precipitated or prolonged labor, and obstetric procedures. This aligns with the second aim of the thesis, which is to utilize the FE model to simulate a common obstetric procedure, particularly VAD, and assess its impact on maternal soft tissues. The study also aims to demonstrate how these models can directly address clinical questions that remain unanswered from a quantitative perspective. One such question was whether the regions most affected during VAD coincide with those identified in normal vaginal delivery. The analysis supported this, revealing maximum stress in the perineal body near the anal sphincter and at the opening of the urogenital hiatus. Additionally, when comparing the two delivery methods, the maximum stretch in VAD simulations occurred at an earlier stage, suggesting that the use of the vacuum cup may lead to earlier and potentially faster muscle opening compared to normal vaginal delivery. Since VAD is often associated with an increased risk of injury, this could be a contributing factor.

The impact of VAD duration, particularly the contraction and resting stages during vacuum cup application, remains poorly understood from a biomechanical perspective. To address this, distinct contraction and resting stages were simulated to assess their effect on the tissues, using contraction durations of 60 and 90 seconds, and resting periods of 60 and 180 seconds. Shorter contraction and rest periods resulted in higher muscle stress, as the muscles had less time to recover and adapt. This behavior is consistent with the viscoelastic properties of the PFM. Additionally, the resting stage duration had a more significant effect on muscle stress than the contraction duration. To ensure adequate muscle relaxation and allow for proper adjustment to large deformations, longer resting periods between contractions are recommended. The observed effects of varying the number of pulls required to extract the fetus is in agreement with these results. Fewer pulls led to higher muscle stress and required the obstetrician to apply greater force on the cup. Such increased force raises the risk of maternal trauma or cup detachment, which could compromise fetal safety.

Based on the findings of the VAD simulations, the following guidelines are recommended for obstetricians, with a primary focus on maternal outcomes and biomechanical factors. (1) To minimize the risk of maternal trauma, it is crucial to maximize the duration of rest between contractions. Prolonging the rest phases allows maternal tissues to recover, reducing the likelihood of excessive stress or injury. (2) In situations where there is no immediate threat to the fetus or mother, medications could be considered to extend the contractions, potentially facilitating a smoother and more controlled delivery process. (3) Obstetricians should aim to avoid excessive force during individual pulls. Instead, distributing the effort over multiple contractions can reduce the intensity of each pull, thereby minimizing the risk of maternal tissue damage. The application of the FE model for VAD simulations highlights the potential of biomechanical modeling in guiding obstetric care. This model can be further extended to inform clinicians across multiple obstetric procedures beyond VAD and to address specific clinical questions that are challenging to explore with other methods.

In the context of guiding obstetric care, the primary objective of these FE models is to be used as a decision-support system in clinical settings. To achieve this, simulations must deliver fast or near real-time responses. This aligns with the third aim of this thesis, which is to develop an ML framework based on FE simulations of childbirth to provide faster results. In this approach, ML models are trained using data from FE simulations to act as surrogate models, predicting mechanical variables such as stress, displacements, and forces. In the implemented framework, nearly three thousand simulations of vaginal delivery were conducted, considering only the PFM and fetal head. The differences between these simulations were the variation of the material parameters of the constitutive model used to characterize muscle behavior. The primary goal was to ensure that, regardless of muscle properties within a physiologically relevant range reported in the literature, the ML model could predict stress in the PFM without requiring additional simulations. In practice, this means that by assessing a woman's specific tissue behavior, it would be possible to estimate the stress on her muscles. To develop the proposed framework, a dataset was generated with data from the FE simulations, and four ML models (RF, XBGT, SVR, and ANNs) were tested for stress prediction across different levels of fetal descent. All models, except for SVR, delivered promising results, with the ANN outperforming the others by yielding results in under 0.5 seconds and demonstrating strong generalization to unseen data. These findings confirm the feasibility of an FEM-based ML approach for childbirth simulations, laying the foundation for more advanced and sophisticated solutions.

However, despite the necessity of obtaining results within a time frame acceptable for clinical practice, it is equally crucial for the models to be patient-specific to ensure

they accurately adapt to individual patient profiles. Although the FE model is already established and the FEM-based ML approach has been evaluated for childbirth simulations, there is currently no standardized pipeline for its practical integration into clinical workflows. Therefore, the fourth aim of this thesis was to develop a patient-specific surrogate model capable of predicting pelvic floor behavior and to propose a pipeline that bridges the computational approach with clinical practice.

Personalization was introduced through the implementation of a mesh-morphing algorithm, which enables modifications in the dimensions of the PFM, specifically the diameters of the levator hiatus. This algorithm was integrated into a simulation environment, where each simulation received as input a unique set of dimensions and material properties corresponding to a specific patient. As a result, approximately 5600 simulations were successfully completed, leading to the creation of a dataset containing nodal position and coordinates, material properties, and pelvic floor dimensions. Within this framework, ML models were trained to predict the nodal coordinates of each node in a defined region of the pelvic floor, predicting the displacement of the muscles during part of the simulation. Among the ML models tested, the RF model demonstrated the best performance. Given the model's computational load and prediction time, this approach delivers results in less than 11 seconds. However, if a slight compromise in performance is acceptable, the XGBT model provides comparably accurate predictions while reducing inference time to just 4 seconds, offering a viable alternative for real-time applications.

The idea behind this pipeline involves a woman attending a routine prenatal appointment at the end of her pregnancy, where the obstetrician measures the pelvic floor hiatal dimensions through ultrasound and assesses the mechanical properties of the muscles, currently possible only through a qualitative approach. Using this data, a pre-trained ML model would generate clinical predictions related to delivery, such as the maximum stretch the muscle will undergo, which fetal station might present the greatest risk, and other key indicators. These indicators could be customized based on predefined factors that obstetricians would prioritize when training the models. One advantage of this approach is its flexibility, allowing focus on the most relevant factors defined by obstetricians. While this is still an initial concept that requires further refinement and validation, it holds potential as a data-driven support system to aid obstetrical care.

Throughout the research conducted for this thesis, a major limitation identified in the literature was the absence of detailed mechanical properties for the regions involved in the childbirth process. While vaginal tissues and the pelvic floor have been well-characterized, the perineal region remains poorly described for accurate representation

in FE simulations. This gap in the literature led to the fifth aim of the thesis, which was the experimental characterization of human female perineal tissues.

It was anticipated, based on existing knowledge of soft tissues, that the perineal tissues, especially the perineal body, would exhibit nonlinear behavior and viscoelastic properties. In Chapter 6, a series of tests were conducted to determine whether the behavior of the perineum matched these expectations. Using *post-mortem* female human perineal tissue, a testing protocol was developed to investigate both the hyperelastic and viscoelastic properties of the tissue. In addition to these mechanical tests, the specimens were also prepared for histological analysis to examine their microstructure.

The results from the relaxation tests highlighted a clear viscoelastic behavior, with a significant reduction in stress, approximately 40%, under a constant displacement maintained for 900 seconds. This stress relaxation was consistent with typical viscoelastic responses observed in soft tissues. Furthermore, the ultimate tensile tests confirmed a nonlinear hyperelastic behavior, as anticipated. These findings aligned with the initial hypothesis, providing strong evidence that the perineal body exhibits a pronounced visco-hyperelastic response. Additionally, histological analysis of the tissue revealed a dense network of collagen fibers, predominantly oriented along the horizontal direction, which corresponds to the direction of tissue stretching.

This thorough characterization of the perineum enabled the calibration of a visco-hyperelastic constitutive model based on the experimental data obtained. The model demonstrated good correlation with the experimental results, providing reliable parameters for simulating perineal tissue behavior in FE analyses. This model holds promise for future studies, especially in understanding and predicting the mechanical response of perineal tissues during labor and other physiological or pathological conditions.

In conclusion, this thesis demonstrates the importance of multidisciplinary research in addressing complex health challenges, particularly childbirth-related injuries. By integrating principles from biomechanics, computational modeling, ML, experimental testing, and clinical obstetrics, this work has enhanced our understanding of the mechanisms of vaginal delivery and unveiled techniques that can be further explored in the future. This holistic approach not only underscores the importance of collaboration across diverse scientific fields but also highlights the potential for innovative technologies to improve patient care. As we continue to refine and validate these models, the synergy between computational modeling and clinical practice will undoubtedly lead to more effective strategies for preventing and managing childbirth-related injuries, ultimately improving maternal health outcomes.

7.2 Major findings

The major findings of this thesis, which address the research questions, are as follows:

- The inclusion of perineal structures in FE simulations of vaginal delivery significantly influences the behavior of the PFM and alters the simulation outcomes. Therefore, their inclusion is essential for future simulations. The analysis highlights critical regions, particularly the perineal body adjacent to the urogenital hiatus and the area surrounding the external anal sphincter, which is connected to both the perineal body and the transverse perineal muscles (Chapter 2).
- The areas most susceptible to trauma during VAD include the anterior perineum near its attachment to the pubic symphysis, the posterior perineal region where the bulbospongiosus muscle connects to the perineal body, and the junction between the perineal body and the external anal sphincter. Longer contraction durations and extended resting periods between contractions benefit the maternal muscles by allowing time for adaptation and relaxation. Therefore, prolonged application of the vacuum cup does not increase the risk of maternal trauma. Conversely, extracting the fetal head with fewer, more forceful pulls demands greater muscular effort, thereby increasing the risk of tissue injury (Chapter 3).
- A FEM-based ML approach proves effective in accelerating results in childbirth biomechanical simulations. The implemented framework allows for the prediction of stress on the most critical region of the pelvic floor in under 0.5 seconds, representing a 99.99% reduction compared to a conventional FE simulation. Among the models tested, ANNs outperformed tree-based models in predicting higher stress values, with a MAE of 0.19 MPa. Additionally, the trained model demonstrates strong generalization capability when applied to previously unseen data (Chapter 4).
- Demonstration of the feasibility of implementing a pipeline that integrates AI techniques with biomechanical simulations to predict patient-specific pelvic floor muscle stretch during vaginal delivery. Mesh-morphing techniques are effectively incorporated into this pipeline to personalize the muscle geometry. Of the simulations defined for dataset generation, 81% were completed successfully. The RF model yielded the best performance, with a MAE of 0.086 mm. The proposed method significantly reduces computational time compared to conducting full vaginal delivery simulations for each individual patient, as demonstrated by testing the algorithm on real clinical data (Chapter 5).

- The perineal body exhibits a highly nonlinear, time-dependent viscoelastic response, with stress relaxation of approximately 40%. Histological analysis reveals a dense network of collagen fibers, predominantly aligned horizontally, corresponding to the direction of tissue stretching. The mechanical behavior of the tissue can be characterized by three distinct ranges of material parameters, determined from experimental data, which can be used to biomechanically describe the behavior of perineal tissues (Chapter 6).

Chapter 8

Conclusions and future work

8.1 Conclusions

This work focuses on using a non-invasive approach to study childbirth-related injuries, consisting of a multidisciplinary approach that leverages simulation techniques, AI, and experimental mechanics to improve the current understanding of childbirth biomechanics. The primary aim is to enhance childbirth computational models by incorporating perineal structures, investigating their mechanical properties through experimental testing, and evaluating the impact of a common obstetric procedure, thereby demonstrating the model's versatility across different applications. Additionally, the study seeks to highlight the potential of using long-established simulation methods in novel approaches by integrating recent techniques, such as ML algorithms, to generate faster outcomes with the potential for clinical translation.

This research underscores the need to incorporate all relevant anatomical structures, such as the perineal tissues, into FE simulations of vaginal delivery, as their inclusion significantly impacts simulation outcomes. Different tissues, including those of the perineum, exhibit unique mechanical behaviors, highlighting the importance of thoroughly studying their characteristics to ensure that simulations reflect the true dynamics of childbirth. Additionally, the findings suggest that advanced simulation techniques, combined with ML and personalized models, can offer valuable insights into obstetric procedures, helping clinicians make more informed decisions and potentially contributing to the development of clinical guidelines for safer delivery practices. Overall, this work represents a step forward in improving computational models of childbirth and their applications, contributing to the ongoing effort to reduce childbirth-related injuries and improve maternal outcomes. However, despite its main findings, this work has several limitations and unresolved questions that require further investigation.

To conduct childbirth computational simulations, several simplifications and assumptions were made. One key challenge in modeling the perineal structures lies in the lack of consensus within the medical community regarding the precise anatomy of the perineal region. There is limited literature on the specific dimensions and thicknesses of the different structures involved. Moreover, observing these structures through medical imaging, particularly MRI, is difficult, making it challenging to clinically validate the geometry and behavior of the muscles during childbirth. A more detailed medical examination using specialized imaging techniques focused on the perineum is needed to enhance computational models. Furthermore, the fetal head was modeled as either a rigid structure or as a single deformable entity, without considering internal structures such as the skull, brain, sutures, and fontanelles. This simplification may influence the simulations, as phenomena such as fetal head molding were not considered. The absence of other anatomical structures, besides the pelvic floor and perineum, is another simplification that could be addressed by incorporating additional structures. Their inclusion would improve the model's representation of the second stage of labor. However, it is important to note that this would substantially increase the simulation's complexity and may introduce convergence issues that could be challenging to address. Lastly, during the simulation of VAD, the connection between the fetal head and the vacuum cup was modeled as a tied constraint, without accounting for the suction mechanism. Although this is a simplification, its impact would be more significant if a deformable fetal head with sutures and fontanelles were considered.

The FEM-based ML approach for generating faster outcomes also involved several simplifications. To predict stress and displacement in the pelvic floor, only a path with 49 nodes was considered, as this region typically experiences the highest impact during simulations. While this simplification aligns with the primary focus of the analysis, incorporating the full geometry of the muscles and predicting mechanical factors across all nodes could provide deeper insights and result in a more robust approach. However, this would require the models to make accurate predictions for a significantly larger number of nodes, thereby generating a considerably larger dataset. This, in turn, would increase the time required for both model loading and training, introducing additional challenges related to computational efficiency and scalability. Furthermore, as this was a preliminary study, the analysis was limited to the pelvic floor, although the same approach could be applied to other structures. Also, only a specific period of the simulation was used for prediction, as this is when the muscles are most affected. However, to extend this approach to all labor scenarios, the full simulation timeline must be considered to account for unexpected events. Another limitation lies in the fact that ML models were trained on synthetic data, rather than clinical data directly provided by patients. While the generated data was created

based on the literature, this approach needs to be validated with clinical data.

Regarding the experimental tests conducted, the tissues were collected solely from elderly women, whose mechanical properties may differ from those of younger or pregnant women, potentially influencing the results. Another limitation is the small sample size, which restricts the generalizability of the findings and may introduce bias. Increasing the sample size would be essential to strengthening the validity of our results. The experiments were performed only in the uniaxial direction, limiting insights into tissue heterogeneity. Lastly, the use of invasive techniques for stress and strain measurements may have caused tissue damage prior to testing.

Despite these limitations, this study demonstrates the potential of using biomechanical tools as decision-support systems to assist clinicians, contributing to advancements in the literature and the publication of relevant findings in multiple journals. It is hoped that the work can be used as a reference for future research in the field, contributing to the development of new strategies and obstetric guidelines aimed at preventing maternal injuries. This thesis aligns with the 2030 Agenda for Sustainable Development through the SDG, particularly SDG 3: Good Health and Well-being, which aims to ensure healthy lives and promote well-being. Additionally, it supports SDG 5: Gender Equality by aiming to improve the quality of maternal healthcare and ensure that women receive safe and effective childbirth experiences. Furthermore, the study's emphasis on interdisciplinary collaboration and innovative technologies also reflects the objectives of SDG 9: Industry, Innovation, and Infrastructure, as it seeks to advance medical technologies and foster innovation in healthcare systems.

8.2 Future work

In the field of computational modeling and simulation, there is significant potential to advance our understanding of the complex physiological processes involved in labor and delivery. While focusing only on the pelvic floor and perineum may be sufficient for studying specific injuries and predicting delivery outcomes, incorporating additional anatomical structures into the model would provide a much more comprehensive and accurate representation of the entire childbirth process. Including key elements such as the uterus, cervix, and pelvic organs would enhance the predictive capability of these models by enabling the simulation of the fetal trajectory from the uterus, through the cervix, and down the birth canal.

This approach would contribute to a deeper understanding of the interactions between different anatomical structures and their role in a successful vaginal delivery. Many of the necessary structures for this type of simulation already exist in FE models (for

example, the uterus, cervix, and pelvic organs). However, these models are often used in isolation, without considering the full system dynamics. Therefore, future research should prioritize integrating these individual models into a single system that would enable the simulation of a complete vaginal delivery.

Although initial steps have been taken to improve the time efficiency of FE simulations, much work remains to be done in this area. Future research should focus on exploring additional strategies to further accelerate FE simulations, thereby reducing the time required to create datasets with multiple parameters and enabling the incorporation of patient-specific variability. Data from biomechanical simulations can also be integrated with predictive models based on demographic and clinical factors such as body mass index, fetal size beyond the head, maternal age, pre-existing conditions, and ultrasound imaging, to enhance the interpretation and applicability of the simulation results.

Furthermore, when predicting stress and deformations in the PFM using FEM-based ML approaches, it is essential to consider the entire muscle, or even surrounding structures, rather than focusing only on pre-defined critical areas. In this context, graph neural networks show promising potential and should be investigated in future studies, as they can incorporate the full geometry and provide predictions for each node in the FE mesh.

In the field of biomechanical characterization of soft tissues, there is a need to develop non-invasive methods for obtaining the mechanical properties of tissues during pregnancy, particularly in the pelvic region, where significant changes occur due to hormonal and physiological alterations. These changes are crucial for understanding how tissues adapt to the growing fetus and prepare for labor. Monitoring these variations over time could improve our understanding of the biomechanical behavior of tissues during labor. Researchers should focus on developing reliable, non-invasive tools, such as advanced imaging techniques or biophysical sensors, to measure the hyperelastic properties of tissues *in vivo*.

Although non-invasive methods are preferable, experimental tests on *post-mortem* tissues can also provide valuable data. Investigating the pelvic floor and perineal tissue properties of younger women, preferably pregnant women, could help establish baseline data for comparison with samples from older individuals. This approach would clarify whether *post-mortem* tissues from elderly women, which are more readily available, exhibit properties comparable to those of younger tissues, or whether age-related differences make them unsuitable for generalization. Additionally, such experiments would support the validation of non-invasive methods, helping to bridge the gap between experimental findings and clinical applications.

The primary goal of researching childbirth biomechanics is to provide clinically relevant information that can assist obstetricians in making more informed clinical decisions. Over the years, biomechanical simulations of childbirth have been extensively studied, and the field has advanced significantly. However, we have now reached a point where researchers should shift their focus toward developing practical, clinically implementable tools that can be directly integrated into obstetric practice. To achieve this, future research must address several critical gaps that go beyond the issues outlined in the preceding paragraphs. Firstly, it would be beneficial to explore advancements in other scientific fields, such as increased computational power, more sophisticated AI models, innovative sensors for clinical data collection, and novel experimental testing methods. Secondly, validating biomechanical models is particularly important to ensure they accurately replicate real-world scenarios. Access to clinical data is essential in this context, as it offers the most reliable means of assessing whether the computational models are making accurate predictions.

To further enhance the accuracy and clinical relevance of biomechanical simulations, it is crucial to establish new guidelines and integrate specific examinations into routine prenatal appointments. Collaborating with hospitals to collect key patient-specific parameters, such as pelvic and muscle geometry, or soft tissue properties, would significantly strengthen the predictive power of these models. Incorporating such standardized assessments would not only address current limitations in simulation input data but also lead to more personalized and informed obstetric care.

Another important aspect that researchers should begin to prioritize is addressing the ethical and regulatory concerns necessary for clinical translation. Future work should focus on developing clear ethical guidelines and regulatory pathways for integrating biomechanical simulations and AI tools into real clinical settings. Key questions, such as how to effectively communicate simulation outputs to clinicians and how to validate these tools to ensure they meet clinical safety standards, need to be carefully considered and addressed. Ultimately, these efforts would help transform biomechanical simulations from purely research tools into valuable aids for clinical decision-making and individualized childbirth planning.

Chapter 9

Scientific outputs

9.1 Data availability commitment

In alignment with the principles of open science, I am committed to providing access to the FE models, datasets, algorithms, and experimental data generated throughout my research. The algorithms developed during this research are available in [Github repository](#), while the experimental data are hosted on [Zenodo repository](#). These resources are shared to promote transparency and encourage further advancements in the field. To ensure reproducibility and support future research, I will also provide any necessary additional documentation, including detailed descriptions of the model setup, characterization, data collection methods, and any assumptions made during the process. This commitment seeks to foster collaboration and improve the accessibility of research tools for the scientific community, with the goal of advancing knowledge in childbirth biomechanics and enhancing maternal healthcare.

9.2 Original research articles

R. Moura, M. Borges, M.C.P. Vila Pouca, D.A. Oliveira, M.P.L. Parente, N. Kimmich, T. Mascarenhas, & R.M. Natal Jorge. “A numerical study on fetal head molding during labor,” *International Journal for Numerical Methods in Biomedical Engineering*, 37(1), e3411, 2020. <https://doi.org/10.1002/cnm.3411>

M. Borges, **R. Moura**, D.A. Oliveira, M.P.L. Parente, N. Kimmich, T. Mascarenhas, & R.M. Natal Jorge. “Effect of the birthing position on its evolution from a biomechanical point of view,” *Computer Methods and Programs in Biomedicine*, 200, 105921, 2020. <https://doi.org/10.1016/j.cmpb.2020.105921>

R. Moura, M. Borges, D.A. Oliveira, M.P.L. Parente, N. Kimmich, T. Mascarenhas, & R.M. Natal Jorge. “A biomechanical study of the birth position: A natural struggle between mother and fetus,” *Biomechanics and Modeling in Mechanobiology*, 21(3), 937–951, 2022. <https://doi.org/10.1007/s10237-022-01569-2>

D.A. Oliveira, **R. Moura**, & D. Fidalgo. “Biomechanik der Geburt,” *Die Gynäkologie*, 56(10), 660–670, 2023. <https://doi.org/10.1007/s00129-023-05138-1>

R. Moura, D.A. Oliveira, M.P.L. Parente, N. Kimmich, & R.M. Natal Jorge. “A biomechanical perspective on perineal injuries during childbirth,” *Computer Methods and Programs in Biomedicine*, 243, 107874, 2022. <https://doi.org/10.1016/j.cmpb.2023.107874>

R. Moura, D.A. Oliveira, J.P.S. Ferreira, M.P.L. Parente, N. Kimmich & R.M. Natal Jorge. “A finite element-based machine learning framework to predict the mechanical behavior of the pelvic floor muscles during childbirth,” *Expert Systems with Applications*, 250, 123953, 2024. <https://doi.org/10.1016/j.eswa.2024.123953>

R. Moura, D.A. Oliveira, M.P.L. Parente, N. Kimmich, L. Hynčák, L.H. Hympánová, L. & R.M. Natal Jorge. “Patient-specific surrogate model to predict pelvic floor dynamics during vaginal delivery,” *Journal of the Mechanical Behavior of Biomedical Materials*, 160, 106736, 2024. <https://doi.org/10.1016/j.jmbbm.2024.106736>

D.A. Oliveira, **R. Moura**, C. Rocha, M.P.L. Parente, T. Mascarenhas & R.M. Natal Jorge. “Developing a Biomechanical Model to Study OASIS,” In *Computer Methods in Biomechanics and Biomedical Engineering II*, 58-66. Wafa Skalli; Sébastien Laporte; Aurélie Benoit, 2024.

R. Moura, D.A. Oliveira, N. Kimmich, R.M. Natal Jorge & M.P.L. Parente. “Computational modeling of vacuum-assisted delivery: biomechanics of maternal soft tissues.” *Biomechanics and Modeling in Mechanobiology*. 2025 Aug; 24(4):1435-1446. doi: 10.1007/s10237-025-01977-0.

D. Fonseca, D.A. Oliveira, **R. Moura**, C. Rocha, M.P.L. Parente & R.M. Natal Jorge. “Biomechanical Impact of Recurrent Childbirth on the Female Pelvic Floor.” *International Journal for Numerical Methods in Biomedical Engineering*. 2025 Jul; 41(7):e70053. doi: 10.1002/cnm.70053.

R. Moura, D.A. Oliveira, M.R. Carvalho, T.M. Pirker, N. Hammer, M.P.L. Parente

& A. vom Sheidt. “Experimental Characterization of the Nonlinear Viscoelastic Properties of Human Female Perineal Tissue,” Under review in *Scientific Reports*, 2025.

9.3 Oral presentations

R. Moura, M. Borges, D.A. Oliveira, M.P.L. Parente, T. Mascarenhas, R.M. Natal Jorge. *Biomechanical impact of distinct fetal positions on pelvic floor dysfunctions*, 46th IUGA Annual Meeting, *online edition*, 2021, 9 – 12 December

R. Moura, M. Borges, D.A. Oliveira, M.P.L. Parente, T. Mascarenhas, R.M. Natal Jorge. *Biomechanical analysis of the maternal-fetal interaction during a malposition childbirth*, 5th Meeting of the Young Researchers of LAETA, Lisbon, Portugal, 2022, 5 – 6 May

R. Moura, D.A. Oliveira, M.P.L. Parente, T. Mascarenhas, R.M. Natal Jorge. *Development of a finite element model to simulate childbirth-related injuries*, 27th Congress of the European Society of Biomechanics, ESB 2022, Porto, Portugal, 2022, 26 – 29 June

R. Moura, M. Borges, D.A. Oliveira, M.P.L. Parente, T. Mascarenhas, R.M. Natal Jorge. *Biomechanical interaction between mother and fetus during vaginal delivery*, 8th European Congress on Computational Methods in Applied Sciences and Engineering, ECCOMAS 2022, Oslo, Norway, 2022, 5 – 9 June

R. Moura, M. Borges, D.A. Oliveira, M.P.L. Parente, T. Mascarenhas, R.M. Natal Jorge. *Fetal position during childbirth: biomechanical effect on the pelvic floor muscles and maternal pelvis*, 9th World Congress of Biomechanics, WCB 2022, *online edition*, 2022, 10 – 14 July

R. Moura, D.A. Oliveira, M.P.L. Parente, T. Mascarenhas, R.M. Natal Jorge. *Modeling a female pelvic floor and foresight biomechanical injuries during vaginal delivery*, Virtual Physiological Human Conference, VPH2022, Porto, Portugal, 2022, 6 – 9 September

R. Moura, D.A. Oliveira, M.P.L. Parente, T. Mascarenhas, R.M. Natal Jorge. *Impact of perineal structures in the biomechanical analysis of childbirth*, 18th International Symposium on Computer Methods in Biomechanics and Biomedical Engineering, CMBBE 2023, Paris, France, 2023, 3 – 5 May

R. Moura, D.A. Oliveira, M.P.L. Parente, R.M. Natal Jorge. *A machine learning-based prediction of pelvic floor stress during vaginal delivery*, VII ECCOMAS Young Investigators Conference, YIC2023, Porto, Portugal, 2023, 19 – 21 June

R. Moura, D.A. Oliveira, M.P.L. Parente, R.M. Natal Jorge. *Predicting pelvic floor injuries during childbirth using machine learning and finite element simulations*, International Conference on Computational Bioengineering, ICCB 2023, Viena, Austria, 2023, 20 – 22 September

R. Moura, D.A. Oliveira, M.P.L. Parente, R.M. Natal Jorge. *Predicting Pelvic Floor Stretch during Childbirth: a Machine Learning Framework*, The 9th European Congress on Computational Methods in Applied Sciences and Engineering, ECCOMAS 2024, Lisbon, Portugal, 2024, 3 – 7 June

R. Moura, D.A. Oliveira, M.P.L. Parente, R.M. Natal Jorge. *Patient-specific surrogate model to predict childbirth-related injuries*, 29th Congress of the European Society of Biomechanics, ESB 2024, Edinburgh, Scotland, 2024, June 30 – July 3

R. Moura, D.A. Oliveira, M.P.L. Parente, R.M. Natal Jorge. *Artificial intelligence framework for predicting pelvic floor muscle behavior during childbirth*, 19th International Symposium on Computer Methods in Biomechanics and Biomedical Engineering, CMBBE 2024, Vancouver, Canada, 2024, July 30 – August 1

R. Moura, D.A. Oliveira, M.R. Carvalho, M.P.L. Parente, A. vom Scheidt, R.M. Natal Jorge. *Characterizing the mechanical behavior of the human female perineal tissue*, 30th Congress of the European Society of Biomechanics, ESB 2025, Zurich, Switzerland, 2025, 6 – 9 July

9.4 Poster presentations

R. Moura, D.A. Oliveira, M.P.L. Parente, T. Mascarenhas, R.M. Natal Jorge. *Predicting pelvic floor stresses during vaginal delivery: a machine learning approach*, 28th Congress of the European Society of Biomechanics, ESB 2023, Maastricht, Netherlands, 2023, 9 – 12 July

R. Moura, D.A. Oliveira, M.P.L. Parente, N. Kimmich, R.M. Natal Jorge. *Vacuum-assisted birth and maternal trauma: biomechanical perspectives*, IUGA/EUGA Joint Meeting, 50th IUGA Annual Meeting, Barcelona, Spain, 2025, 18 – 21 June

9.5 Collaborations

Throughout the development of this PhD thesis, several key collaborations were established, significantly contributing to the research:

- **University Hospital Zurich:** Co-supervision by Dr. Nina Kimmich, who provided valuable clinical insights and expertise in medical applications throughout all steps of the work.
- **Graz Medical University:** Collaborative work within the Division of Macroscopic and Clinical Anatomy, led by Dr. Annika vom Scheidt, focusing on the performance of experimental tests on perineal tissues.
- **New Technologies Research Centre, University of West Bohemia:** Data exchange and collaborative research efforts, enhancing the validation of the developed methodologies.

These collaborations played an important role in enriching the interdisciplinary nature of the thesis, offering a combination of clinical, experimental, and numerical perspectives.

Appendices

Appendix A

Co-authors consent form

Chapter 2 co-author consent form

Dulce Alves de Oliveira, Marco Paulo Lages Parente, Nina Kimmich, and Renato Manuel Natal Jorge, the undersigned, as co-authors of the paper entitled "A biomechanical perspective on perineal injuries during childbirth" submitted to the journal *Computer Methods and Programs in Biomedicine*, agree to the inclusion of its contents, including figures and tables, in the Ph.D. thesis of Ana Rita da Silva Cruz Moura, entitled "Biomechanics of female trauma during childbirth".

Signed,

Dulce Oliveira

Dulce Alves de Oliveira

22/04/25

Date

Marco Parente

Marco Paulo Lages Parente

23/04/2025

Date

NK

Nina Kimmich

23/04/25

Date

Renz

Renato Manuel Natal Jorge

23/04/2025

Date

Chapter 3 co-author consent form

Dulce Alves de Oliveira, Nina Kimmich, Renato Manuel Natal Jorge, and Marco Paulo Lages Parente, the undersigned, as co-authors of the paper entitled "Computational modeling of vacuum-assisted delivery: biomechanics of maternal soft tissues" submitted to the journal *Biomechanics and Modeling in Mechanobiology*, agree to the inclusion of its contents, including figures and tables, in the Ph.D. thesis of Ana Rita da Silva Cruz Moura, entitled "Biomechanics of female trauma during childbirth".

Signed,

Dulce Oliveira

Dulce Alves de Oliveira

22/04/25

Date

N.K.

Nina Kimmich

23/04/25

Date

Renato

Renato Manuel Natal Jorge

23/04/2025

Date

Marco Parente

Marco Paulo Lages Parente

23/04/2025

Date

Chapter 4 co-author consent form

Dulce Alves de Oliveira, João Pedro Sousa Ferreira, Marco Paulo Lages Parente, Nina Kimmich, and Renato Manuel Natal Jorge, the undersigned, as co-authors of the paper entitled "A finite element-based machine learning framework to predict the mechanical behavior of the pelvic floor muscles during childbirth" submitted to the journal *Expert Systems With Applications*, agree to the inclusion of its contents, including figures and tables, in the Ph.D. thesis of Ana Rita da Silva Cruz Moura, entitled "Biomechanics of female trauma during childbirth".

Signed,

Dulce Oliveira
Dulce Alves de Oliveira

22/04/25
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João Ferreira
João Pedro Sousa Ferreira

30/04/2025
Date

Marco Parente
Marco Paulo Lages Parente

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Nina Kimmich
Nina Kimmich

23/04/25
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Renato Manuel Natal Jorge

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Chapter 5 co-author consent form

Dulce Alves de Oliveira, Marco Paulo Lages Parente, Nina Kimmich, Luděk Hynčák, Lucie Hájková Hympánová, and Renato Manuel Natal Jorge, the undersigned, as co-authors of the paper entitled "Patient-specific surrogate model to predict pelvic floor dynamics during vaginal delivery" submitted to the journal *Journal of the Mechanical Behavior of Biomedical Materials*, agree to the inclusion of its contents, including figures and tables, in the Ph.D. thesis of Ana Rita da Silva Cruz Moura, entitled "Biomechanics of female trauma during childbirth".

Signed,



Dulce Alves de Oliveira

22/04/25

Date



Marco Paulo Lages Parente

23/04/2025

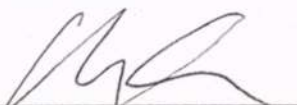
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Nina Kimmich

23/04/25

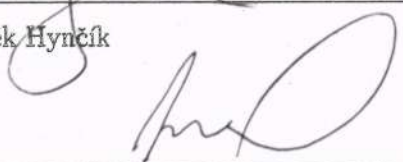
Date



Luděk Hynčák

24/04/25

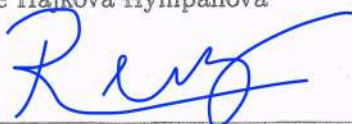
Date



Lucie Hájková Hympánová

24.4.2025

Date



Renato Manuel Natal Jorge

23/04/2025

Date

Chapter 6 co-author consent form

Dulce Alves de Oliveira, Mariana Rocha Carvalho, Teresa Marie Pirker, Niels Hammer, Marco Paulo Lages Parente, and Annika vom Scheidt, the undersigned, as co-authors of the paper entitled “Experimental characterization of the nonlinear viscoelastic properties of human female perineal tissue” submitted to the journal *Scientific Reports*, agree to the inclusion of its contents, including figures and tables, in the Ph.D. thesis of Ana Rita da Silva Cruz Moura, entitled “Biomechanics of female trauma during childbirth”.

Signed,

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