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Design and medical devices

Redesign of a device for pelvic floor muscle training

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Abstract

Pelvic floor disorder represents an increasing problem as a result of the aging global population. Although these disorders are not life-threatening, it significantly impacts life quality, specifically in the female population, where their incidence is more significant. These disorders are often associated with weakening or weaker pelvic floor muscles, so their first line of treatment is usually conservative treatments. Conservative treatments are mainly composed of lifestyle changes and pelvic floor muscle training regimens. For the execution of these regiments, several devices can be used.

This dissertation embraces an ongoing project at the University of Porto, by Dr. Alice Carvalhais and Dr. Renato Natal Jorge, developing a state-of-the-art pelvic floor muscle training exercise and its associated device. The designer's role was to redesign the functional prototype resolving conflicts in its previous design and ultimately developing a more user-friendly solution.

The development of this dissertation was started with a review on the subjects of the pelvic floor female anatomy, disorders, treatments, and market research on pelvic trainer devices. This initial investigation gave viable insight on the matters addressed during this dissertation and improved communication within the workgroup. Finally, several solutions were created and tested through product development, using a co-design methodology involving project inventors, Dr. Alice Carvalhais and Dr. Renato Natal Jorge, and volunteer users.

At the end of this dissertation, all project goals' were met, resolving previous design conflicts and creating a user-friendly device. All volunteers considered the new design a significant improvement of the prior model, especially its new support system incorporated in an undergarment, which added a great sense of comfort during exercise execution.

Keywords: Redesign, Training Device, Female Pelvic Floor Muscles disorders, Conservative treatments

Resumo

As disfunções do pavimento pélvico representam um problema crescente, como resultado do envelhecimento da população mundial. Embora estas disfunções não sejam fatais, têm um impacto significativo na qualidade de vida do paciente, especificamente na população feminina, onde a sua incidência é mais significativa. Estas disfunções estão frequentemente associadas ao enfraquecimento, ou a fracos músculos do pavimento pélvico, pelo que a sua primeira linha de tratamento é geralmente a dos tratamentos conservadores. Os tratamentos conservadores são principalmente compostos por mudanças de estilo de vida e regimes de treino dos músculos do pavimento pélvico. Para a execução destes regimes, podem ser utilizados vários dispositivos.

Esta dissertação envolve-se num projeto em curso na Universidade do Porto, pela Dra. Alice Carvalhais e pelo Dr. Renato Natal Jorge, desenvolvendo um exercício de treino de músculos do pavimento pélvico inovador assim como o dispositivo a ele associado. Nesta dissertação o papel do designer foi o de redesign do protótipo funcional, resolvendo conflitos no seu design atual e, ao mesmo tempo desenvolvendo uma solução mais intuitiva para o seu utilizador.

Para o desenvolvimento desta dissertação, foi realizada uma investigação inicial sobre os temas da anatomia feminina do pavimento pélvico, disfunções e tratamentos, foi também desenvolvida uma pesquisa de mercado sobre dispositivos de treino dos músculos do pavimento pélvico. Esta investigação inicial permitiu um melhor entendimento sobre os temas abordados assim como uma melhoria na comunicação no seio do grupo de trabalho. Finalmente, foram criadas e testadas várias soluções no desenvolvimento do projeto, utilizando uma metodologia de co-design que envolveu os inventores do projeto, Dr. Alice Carvalhais e Dr. Renato Natal Jorge assim como vários usuários voluntários.

No final desta dissertação, todos os objetivos do projeto foram alcançados, resolvendo os conflitos da conceção anterior e criando um dispositivo de fácil utilização. Todos os voluntários consideraram uma melhoria significativa do modelo anterior, especialmente o seu novo sistema de suporte, incorporado em roupa interior, o que lhes acrescentou uma grande sensação de conforto durante a execução dos exercícios de treino dos músculos pélvicos.

Palavras-chave: Redesign, dispositivo de treino, Músculos do pavimento pélvico, Tratamentos Conservadores.

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List of Abbreviations

PFD - Pelvic Floor Dysfunctions

PFM - Pelvic Floor Muscle

PFMT - Pelvic Floor Muscle Training

POP - Pelvic Organ Prolapse

SUI - Stress Urinary incontinence

UUI - Urgency Urinary Incontinence

UI - Urinary Incontinence

Chapter 1- Introduction

This dissertation describes the development of a device redesign for Pelvic floor Muscle training (PFMT); the device was incorporated in a project created and developed by two professors of the University of Porto, Dr. Alice Carvalhais and Dr. Renato Natal Jorge. In 2013 the project started developing a state-of-the-art exercising method and its associated device, and in 2020 its patent was published under the Patent Cooperation Treaty, international publication number W.O. 2020/121247 A1. This project starts with the device functional prototype, identifying in an early stage of the project possible improvements, and then developing and searching throughout the dissertation process for viable new solutions. This dissertation also had the cooperation of its inventors throughout the entire process.

Motivation

Female pelvic floor disorders, although invisible, form an extensive and well-hidden problem; in the U.S. only, it is estimated to affect nearly 25% of the women population (Jennifer M. Wu et al., 2014). These dysfunctions can occur due to weakness or injury of the Pelvic muscles and ligaments. Thus if the Pelvic Floor Muscle (PFM) can't perform its functional support of the female cavity and assist continence, it can lead to one or several of the most common dysfunctions in women, such as urinary incontinence (UI), anal incontinence, pelvic organ prolapse (POP), and pelvic pain (Petros, 2010).

The first line of treatment for women who suffer from these conditions in the medical community is conservative treatment. This type of treatment can avoid a surgical correction or even improve their results. The main recommendations within these treatments are lifestyle changes and PFMT regimens (Paul Abrams et al., 2018). PFMT is recommended both as prevention and treatment for UI and pelvic floor prolapses. The training consists of a program of repeated voluntary contractions varying in intensity and duration, taught by a healthcare professional (Lamin, Parrillo, Newman, & Smith, 2016). Several devices, such as intravaginal cones and electrical stimulation devices, offer support for PFMT (Paul Abrams et al., 2018).

Even though these treatments are less invasive and help improve pelvic symptoms in prolapses and reduce UI, many women don't know this, so the care percentage for these conditions is low. For example, in the U.S., only 25% of affected women seek care for UI, according to the National ambulatory and Hospital Medical Care surveys (Fante, Silva, Mateus-

Vasconcelos, Ferreira, & Brito, 2019; Lukacz, Santiago-Lastra, Albo, & Brubaker, 2017).

Therefore, despite their high prevalence and high incidence, conditions such as UI are still majorly undiagnosed and undertreated. Devices such as those being developed in the dissertation hope to help women improve their conditions and create exercising methods more stimulating through biofeedback.

Objectives

The redesign approach to developing a new product offers many advantages, such as improvements in quality and efficiency of the product design process. In this case, the designer arrives in the middle of its design process, still allowing to incorporate this approach in its development. Overall, in the redesign, the focus is on resolving conflicts in the current device and its previous design capabilities. These conflicts are resolved by replacing components, components attributes; or modifying the original design structure (Li, Kou, Cheng, & Wang, 2006). By identifying design conflicts and functional dependencies in the functional prototype at an early stage of the dissertation, the workgroup defined several goals for the project. The objectives defined where:

- Enhancement of the support system.
- Enhancement of the rod and joint system.
- Enhancement of the weights and weight support system.
- Overall decrease of components.
- Overall improvement in aesthetics.
- Easier transportation

Methodology and Structure

It was essential to establish a methodology to guide the development of this dissertation. As a starting point, a bibliographic revision was conducted on Female pelvic anatomy, Female pelvic dysfunctions, and treatments. This revision allowed all intervenients to be familiar with the concepts related to the project. After the bibliographic revision, two more investigations were conducted, market research of existing supportive devices in conservative treatments and management as well as an informative review of the previous project. After that, to guide the project through its development phase, it was decided that "The Design thinking"

was the best fitting, explored in the project development chapter. Throughout the whole dissertation, several conventional investigation tools were used, including surveys and interviews. In addition to the conventional tools, tools commonly used in design processes were also used during the development phase, such as brainstorm sessions, mockups, prototyping techniques, and 3D printing.

The content of this dissertation is organized into four moments, Introduction, Literature review, Project development, and Conclusions.

Chapter one is where context, motivation, objectives, methodology, and structure are explored to guide the product development and dissertation.

Chapter two, the Literature review, explores concepts of female pelvic anatomy and female pelvic dysfunctions and treatments for context and informative purposes. Presentation of the general contextualization of the project motivation is followed by an analysis of how design can help develop medical products. And finally, extensive research of conservative treatment supportive devices is conducted, where comparative studies are made regarding material, color, number of components, and exercise levels.

Chapter three, Project development, starts by analyzing the design development methodology adopted on the project. After that analysis, the chapter splits into two moments, the ideate phase, where the process to find the project goals explores ideas and first solutions. The second moment is where all testing and prototype phases are developed. Together both moments represent all the decision-making processes of the project development.

Chapter four, Conclusions, were conclusions, constraints of the project, and recommendations for future works are presented.

Chapter 2-Literature Review

Female pelvic floor disorders form an extensive problem and sometimes a well-hidden one. In the United States, 11% of adult women sooner or later require surgery for pelvic floor disorder, including POP and UI (Lien, Mooney, DeLancey, & Ashton-Miller, 2004). Female pelvic floor disorders often coexist. In a study conducted on 5000 parous Swedish women, 46% had at least one disorder, and almost a third had two or more disorders (Gyhagen, Åkervall, & Milsom, 2015).

These types of disorders in women are multifactorial, and several risk factors have been identified, including parity, age, high impact sports, chronic straining, hormonal status, and childbirth-related injuries (Paul Abrams et al., 2018). Even Though not life-threatening, the influence of these disorders on the quality of life of those affected cannot be underestimated, and indeed may be devastating (Baert, 2010).

The pathophysiology of pelvic floor disorders is not entirely understood. Still, associated symptoms are commonly explained by altered pelvic floor function of pelvic floor tissue components such as fascia, ligaments, nerves, and muscles. Skeletal muscles are a significant component of the pelvic floor and have an important role in continence and organ support (Butrick, 2009; Mannella, Palla, Bellini, & Simoncini, 2013).

Most conservative treatment targets pelvic PFM function through voluntary and involuntary contraction and relaxation called PFMT. The training consists regiment of endurance, power, and relaxation exercises. (Abrams et al., 2018)

Therefore, to understand the extent of the problem and how it can be helped with devices such as the one being developed during this dissertation. It is important to explore the fundamentals of female anatomy and functions and the pelvic floor disorders (PFD) that could benefit from conservative treatments such as PFMT.

2.1 The Female Pelvis Anatomy

The female pelvic cavity is defined by its bones, organs, ligaments, and muscles, all playing an essential part in the pelvic function. The pelvic bone function is to protect the internal organs and distribute the weight from the upper part of the body and support the torso and leg muscles. Since women have a wider and circular shape to facilitate labor, they also are more prone to a weaker pelvic floor (Corton, 2005; Herschorn, 2004).

The female pelvic cavity comprises organs with very distinctive functions that can be affected by PFD. Those are:

- The female bladder, located on the lower abdominal part, is a hollow muscular organ that serves as a reservoir for urine (Shermadou, Rahman, & Leslie, 2020).
- The urethra is a tubular organ that extends between the urethral orifice (in the bladder) and the urinary meatus (opening in the female urethra). Its muscle configuration allows the constriction of the urethra, contributing to urinary continence (Hoyte & Damaser, 2016; F. H. J. E. H. Netter, New Jersey, 1990).
- The uterus is a highly muscular organ capable of bearing a child, located at the center of the female pelvic cavity, and is the central anatomical landmark of the female internal genitalia and pelvic anatomy (Hoare & Khan, 2020; McEvoy & Tetrokalashvili, 2019).
- The vagina is a fibromuscular canal with a range in length from 8 to 10 cm, and about 4 centimeters of diameter that lies between the urinary bladder and the rectum and is supported primarily by the transverse cervical ligaments (cardinal ligaments) and the levator ani muscle (Hoare & Khan, 2020; Pernoll & Benson, 2001).
- The rectum connects with the exterior through the anus. Another important structure for continence is located in the anal canal, where its muscular structures regulate defection and the internal and external sphincter (Bennett, 2008; Pernoll & Benson, 2001).

The organ's structural organization of the pelvic cavity relies simultaneously on the action of the connecting tissue (fascia) and the ligaments and muscles. It is imperative for the pelvic cavity organs to work correctly to maintain these structures' integrity (Hoyte & Damaser, 2016). This means that POP can be developed if the female pelvic floor anatomic structures are affected, and incontinence can occur during sudden rises in abdominal pressure and motions associated with daily physical activities (Ashton-Miller & DeLancey, 2007).

PFM plays a critical role in maintaining continence, specifically the levator ani muscle and the endopelvic fascia. The levator ani muscle is a structure of striated muscles composed of; the iliococcygeus, the pubococcygeus, and the puborectalis muscles. When there is a sudden rise in intra-abdominal pressure, these muscles must contract, which contributes to the maintenance and modulation of the intra-abdominal pressure (Ashton-Miller & DeLancey, 2007; "Female Pelvic Floor," 2017; Herschorn, 2004). In the central area of the levator ani muscle, three tubular structures perforate, the urethra, the vagina, and the rectum. Each passes through the pelvic floor at a different angle, which enhances the sphincter-like action of these muscles (Hoare & Khan, 2020; Pernoll & Benson, 2001).

Although these muscles present different fiber directions, which normally would mean they move in different directions, these muscles can only be contracted together, thus having an intricated action that lifts the PFM upper into the pelvic cavity, elevating the pelvic organs and constricting the urethra, vagina, and rectum (Hoyte & Damaser, 2016). In women without UI, these contractions happen simultaneously or precede the increase in intra-abdominal pressure as an unconscious automatic co-contraction (Bø & Sherburn, 2005).

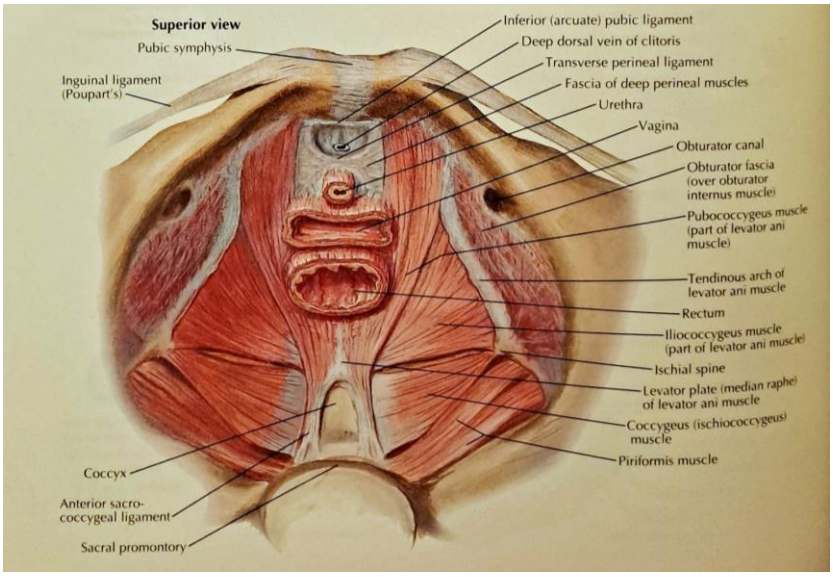


Figure 1-Pelvic floor muscles illustration, adapted from (F. H. Netter, 2014)

2.2 The Female PFM disorders

Female PFD is the term used to define a range of clinical conditions that affect and undermine women´s quality of life at all ages worldwide. These conditions include dysfunctions such as UI, anal incontinence, pelvic organ prolapse, sexual dysfunction, and chronic pain syndromes (Richard C Bump & Norton, 1998; MacLennan, Taylor, Wilson, & Wilson, 2000).

This review focused on the most common female PFD composed of UI, fecal incontinence, and POP (Hong & Ding, 2019), and their management.

POP refers to the partial or total descent of the pelvic organs through or under the vagina. This disorder happens due to the absence and fragility of the pelvic organs and pelvis's support mechanism (levator ani muscle, ligaments and fascia). There are different types of prolapse types depending on the structures that bulge into the vagina (Richard C. Bump et al., 1996; Lacima & Espuña, 2008).

Fecal Incontinence is a PFD that manifests by the inability to control the release of gases or feces, and it is classified according to three types of symptoms: passive fecal incontinence, urgency fecal incontinence, and mixed fecal incontinence (Lacima & Espuña, 2008).

UI is a dysfunction that manifests by any involuntary leakage of urine (Lacima & Espuña, 2008). There are two main subtypes of UI: Stress urinary incontinence (SUI) and Urgency urinary incontinence (UUI). These two subtypes are common and often coexist as a combination of symptoms, known as Mixed incontinence (Aoki et al., 2017; Wyndaele & Hashim, 2017).

- UUI is the complaint of urinary leakage related to the sudden desire to void with difficulty to defer (Aoki et al., 2017). Distinct from urge, a physiologic desire to void consequent to bladder filling, urgency is a pathological sensation and the main symptom in overactive bladder (Abrams , 2017). Opposed to this condition, SUI is not related to neurologic conditions. The International Continence Society and International Urogynecology Association define the complaint of urinary leakage related to coughing, sneezing, or physical exertion as SUI symptoms. In SUI, an unexpected rise in intra-abdominal pressure induced by effort is not followed by a sufficiently substantial increase in urethra pressure leading to a reverse of gradient pressure between the bladder and urethra, which results in urine leakage (Abrams et al., 2018; Haylen et al., 2010; Wyndaele & Hashim, 2017). The leakage can be serious even with a minimal rise in intra-abdominal pressure (Wyndaele & Hashim, 2017).
- Among middle-aged and young women, the main risks unequivocally associated with the condition are Body Mass Index, age, parity, and mode of delivery. Although all these risks are associated with UI, the association with SUI is bigger than UUI (Abrams, 2017).

2.3 Pelvic floor Disorders Management

For the three dysfunctions being reviewed, management is usually initiated by lifestyle changes appropriate to the condition in question and conservative treatments. Conservative treatments such as PFMT can improve POP and symptoms of fecal incontinence and UI, only if this initial management fails to improve the condition that specialized management is considered, including non-surgical and surgical treatments and medication, is considered (Abrams, 2017).

Conservative treatment targets PFM strengthening through a series of exercises. The theory for strength training is that by altering the disability of the PFM (timing and strength of muscle contraction, structural support), leakage may reduce or be stopped. In this way, the patient can sufficiently function and have an increased quality of life (Bø & Sherburn, 2005). Besides UI, fecal incontinence, and POP, training the PFM may benefit other PFD as pelvic pain and sexual disorders. PFMT is also recommended during the late stages of pregnancy and early post-natal, as it can decrease UI symptoms, improve muscle coordination, and deliver strong and flexible muscles for labor (Bø & Sherburn, 2005; Mørkved & Bø, 2014).

By reviewing these dysfunctions management and pathophysiology, it's clear that weak PFM is one of the main causes. Based on that, devices like the one being developed can help in their management by training the PFM to enhance its function by improving muscle strength and endurance.

2.4 Conservative treatments for Pelvic Floor Disorders

PFM training history

Conservative treatments are present in most PFD management. The first author to start talking about PFM exercises was Arnold Kegel, a Gynecologist from The University of Southern California, in 1948 (A. Marques, Lynn Stothers, & Andrew Macnab, 2010a). Dr. Kegel designed a perineometer device that helped evaluate PFM strength and guide users on the correct way to perform the exercises. He also showed that this exercise could help prevent cystocele, rectocele, and SUI (Huang & Chang, 2021). Dr. Kegel ultimately started to prescribed Kegels or PFM exercises as a program of isometric contraction of the PFM to close the external sphincter helping recover continence in women with SUI (Lamin et al., 2016).

Since 1950, PFM exercises have started to be recommended to compensate for PFD, reducing POP and UI symptoms. In 1948 biofeedback was introduced, and results of PFMT began to be studied. Researchers studied the impact on anatomical conditions and pelvic floor functions. The studies confirmed that the use of Kegel exercises changes PFM function (Marques et al., 2010a).

Figure 2- Original Kegel perineometer for aiding the learning of "progressive resistance exercises of lax perineal musculature" adapted from (Kegel, 1948)

2.5 Biofeedback and PFMT

Biofeedback is a mind-body technique where individuals can learn to change their physiology to enhance physical, mental, emotional, and spiritual health. Similarly, as with other physical therapy interventions, biofeedback requires the patient's active participation and regular practice between training sessions. This self-regulation technique allows patients to voluntarily control what was previously thought to be involuntary body processes (Frank, Khorshid, Kiffer, Moravec, & McKee, 2010). Nowadays, biofeedback is one of the most common methods in clinical practice to retrain PFM, displaying for the incontinent women through visual signs and/or sounds which muscle is to be worked on (Barbosa, Lós, Silva, & Anselmo, 2011).

PFMT

Distinct from nerves, muscles have a considerable ability to self-repair, and therefore, with proper stimulus, significant muscle function improvement can occur. Exercises and effective PFMT regimens can play an important part in this process (Marques, Stothers, & Macnab, 2010b).

PFMT comprises a series of endurance, coordination, and strength exercises by contracting and relaxing the PFM. Generally, the programs should combine three principles. The overload principle is where the targeted muscle should work more than it usually does. The principle of specificity requires the exercise to replicate the natural functional movement as close as possible. And the reversibility principle implies that the benefits attained by the exercise are reversible if the patient doesn't follow the training program (Marques et al., 2010a). Nevertheless, PFM voluntary contraction can be difficult to learn for women, even without PFD, with up to 70% of women not knowing how to contract the PFM correctly (Tibaek & Dehlendorff, 2014). Considering having biofeedback in devices can help women understand and train with the correct PFM contraction.

2.6 Stigma and Conservative treatments

Conservative treatments are the first line of treatment in all types of UI and other PFD. Surgical treatments are avoided as they leave scars and present several risks. Conservative treatments don't leave any marks (Scars) or irreversible outcomes that could be highly stigmatizing for women who are already suffering from a stigmatizing condition as it is. Stigma can complicate the patient's relationship with treatment, especially with PFD. Due to PFM location, its association to fecal incontinence and UI, and its impact on sexual experiences, patients end up avoiding coming forward with their symptoms and ultimately seeking help (Ramírez, Andreae, & Lemke, 2019).

It is perhaps because of the stigma that UI has such low care rates as only 25% of women seek treatment, and less than half of that receives treatment (Paul Abrams et al., 2018; Bø & Sherburn, 2005; Lukacz et al., 2017). Some of the reasons people do not seek help are low expectations in treatments, not regarding UI as abnormal or serious, thinking it's a normal part of aging, thinking it's something to cope with on their own and embarrassment (UK & THOM). However, UI is an invisible condition that can affect self-esteem, cause suffering, and affect social integration. Acts of criticism and ridicule from people close to them can make their withdrawal from activities, leading to psychological distress such as depression, anxiety, and ultimately unhappiness with life itself (Heintz, DeMucha, Deguzman, & Softa, 2013). Some testimonies from women suffering from this condition state that if their continence care routines were ineffective and that they did not believe they were normal. It was also mentioned that a lack of education on the matter leads to multiple women not knowing whether they suffer or not from it, and therefore not seeking health treatment for it (Bradway & Barg, 2006).

Nevertheless, Design can help decrease stigma perception with different approaches to design that try to promote fairness and equality by creating products accessible to all users and applying mainstream design values.

2.7 Design tools and approaches to reduce stigma and improve the usability

Objects aren't just products in a consumer's society. Objects present themselves as symbols and often express the identity of their user. Donald Norman presents this theory about reflective design, where he explores the messages and the meaning of a product or its uses. He also explores how owning a specific type of object in today's society almost every time has something to do with a social affirmation, with how owning that particular object is perceived by others (Norman, 2004).

However, some objects have the opposite effect identifying their users as disabled people. This is the case with several support products. To better understand how a product can become stigmatizing, it is essential to understand why such similar groups of products with similar functions are perceived so differently from society. For example, why are products such as hearing-aid devices, adult diapers, leg prosthetics so different from a pair of glasses? All these products represent support devices to help improve the quality of life of their users; the only difference is that having a poor vision is perceived as something "normal" whilst the other support products referenced above are used for needs that are not considered as "normal" (Bispo, 2018).

Support products often seem to assume that their end-user presents a diminished functional capacity of what's considered "normal"; for that reason, standard products are not adequate to them. Nevertheless, the functionality of a support product shouldn't be differentiated from the functionality of non-support products. Supportive products should be defined in their context of use and not by their physical aspects or function (Bispo, 2018).

The function itself doesn't have to be changed for the product to be less stigmatizing or more inclusive. For instance, in 2020, Nike launched their first maternity collection suited to all stages of pregnancy and postpartum. The function of the sports clothes doesn't change, and pregnant women stop feeling left out from the brand. Another good example is the Bradley timepiece. The Bradly watch is a tactile watch designed for blind people created by a group of students in 2014; although it was designed for the blind, people who don't suffer from this impairment can also use it. Both these types of designs perfectly demonstrate one of the approaches that could help reduce the perception of stigma, encouraging equality by designing products that all users can access.

Figure 3-Nike maternity collection, adapted from News.Nike

Figure 4-Bradley timepiece, adapted from Dezeen

Inclusive design emerges through a multidisciplinary approach to design, extracting the full potential of collaborations between designers, researchers, educators, and industry. The end goal is to create products and services that can meet the entire consumer society and diverse user's needs (Clarkson, Coleman, Keates, & Lebbon, 2013).

"The design of mainstream products and/or services that are accessible to, and usable by, as many people as reasonably possible on a global basis, in a wide variety of situations and to the greatest extent possible without the need for special adaptation or specialized design." (Persson, Åhman, Yngling, & Gulliksen, 2015).

Achieving this extension of the initial concept end user to a broader range of users can be challenging. Although this may seem like a good starting point, product success is highly affected by the end-users choice at the early stages of product development. If the end-user is a particular group, then the needs of that group should be the priority. However, if the design focuses on these needs, it may end up excluding other end users.

This outcome can be prevented by using the exclusion design principle. This principle states that identifying the user skills set demanded by the product makes it possible to establish the end-users who will not be able to use it, regardless of the cause of the functional disability. This information is vital to re-designing the product as it provides information that may help include a broader range of end-users that otherwise would be unnecessarily excluded (Clarkson et al., 2013).

Particularly in this project, the main target group, which shows the most prevalence and incidence of SUI and other PFD, is adult women. Besides SUI, which is normally treated with conservative methods, other PFD also benefits from these treatments and may also be considered in the end-user group. Most of the incidence and prevalence are in new mothers as childbirth increases the risk for this type of dysfunctions, and the oldest age groups (Jundt, Peschers, & Kentenich, 2015; Kepenekci et al., 2011; Jennifer M Wu, Hundley, Fulton, & Myers, 2009).

A study conducted in the US demonstrates (Attachment 1) that these numbers are likely to increase over the next years (Jennifer M Wu et al., 2009).

Having shown that the main concerns with this device are function and accessibility to as many users as possible, it's also important to identify what tools design provides that could help improve the overall performance and usability of the product. But firstly, it is essential to understand two concepts functional design and usability.

So, what is Functional design? Functional design is the part that makes all objects around us comprehensible and usable, and communication seems to be the primary concern (Norman, 2004). Usually, designers only focus on the correct usage of their product, assuming that the end-user will act as intended if everything works properly. But they forget that there are three mental images to every object. Firstly, the image in the designer's head, the "*designer's model,"* secondly the image perceived by the person using the product *"user's model,"* and finally the image of the product itself and any written material such as manuals and advertisement provided called *"system image."* Ideally, the *designer's model* and *users' model* should be similar, and as a result, the user can understand the product correctly. Misunderstanding and miscommunication of a product can create complicated relations between the user and the product. (Norman, 2004, 2016).

Designers are often presented with several considerations when creating interactive devices or services, often leading to miscommunication. Thus, it is important for the design of devices nowadays to be sociable, considering the people with whom they interact and show understanding and tolerance with the user. Liz Sanders believes that a product should fulfill three requirements: be useful, usable, and desirable (Elizabeth B-N Sanders, 1992). What is the difference between usable and useful, then? Usefulness comes from creating a product that can meet the customer's needs; usable comes from creating a product that's easy to understand and interact with (Van Gorp & Adams, 2012). A product's usability can be also be defined by five components learnability, efficiency, memorability, errors, and satisfaction (Nielsen, 2012); which designers should also consider when designing products for people's support or rehabilitation.

"Taming complexity is a partnership between those who design and those who use." (Norman, 2016).

There are two types of product development, innovation, and improvement; in this dissertation, product improvement will guide the approach as innovation is already present in the device concept and state-of-the-art exercise.

Improvements to a product come first and foremost from observing how users interact with what exists today, finding out difficulties, and overcoming them(Li, Kou, Cheng, & Wang, 2006). A perfect example of these enhancements is Designer Teddy Schuyers Ostomy Bag, where she identified problems, such as leaking, skin irritation, the release of gas, and bag movement. She also determined that many users did not like the colors of the bags offered by clinical designs, usually white, pale, or Caucasian skin.

Identifying these difficulties allowed the designer to create a series of ostomy bags that permitted users to comfortably wear them without problems during several daily activities while exercising and during sexual intercourse. At the same time, she also provided a range of colors different from the ones being sold by clinical companies.

Figure 5-Teddy Shuyers Ostomy Bag, adapted from DrivenxDesign

Identifying difficulties can come from understanding the product's history and knowing how it got to where it stands now. Designs that disregard the past can find themselves in an unanticipated or unwanted state (Norman, 2016). Therefore, when working in the field of human-centered design, it is essential to understand the past and the present; what can be done now? What actions are possible? But the present can also give the designer important intel in how to design in support of people (Still & Crane, 2017). Approaches to Design such as human-centered design and participatory design, bringing several design tools that help improve product usability. In these approaches, non-designers, who are potential users, participate in co-design activities such as mockups and prototype testing. Designers, observing user interactions with the objects and hearing user opinions, helps them identify where to improve and where changes can be made. (Elizabeth B. N. Sanders, Brandt, & Binder)

This intel is provided by human behavior; it is also called a signifier. Signifiers are a powerful tool that allows designers to identify signs of correct behavior, whether intentional or non-intentional. This tool helps designers provide a clearer and more natural communication channel between the user and them. Some signifiers suggested in *"Living with complexity"* that can be very helpful during this project development are "*Usage patterns"* and "*Desire lines*," these signifiers can transform simple and appealing items into complicated ones if neglected. Designers need to observe people's behavior by doing so; these signifiers start becoming

more visible and help identify more easily where change is needed and, therefore, improve solutions (Norman, 2016).

Desire Lines can be easily seen in architectural landscaping. Take, for instance, the Ohio State University Campus Architects; although their sideways pattern may seem random before their paving, Architects waited for students to create their organic paths in the grass. Doing this avoided making sideways that would end up not being used by the students.

Figure 6- Ohio State University Campus, adapted from OSU.edu

These traces can be used to simplify the user's life creating devices that communicate naturally with them. But other than identifying their correct natural behavior, designers can identify errors or miscommunications of their product during development.

In the same way as Inclusive design, other methodologies such as universal design have the same goal: to create design approaches that recognize and respect the needs of a diverse range of users. This approach also provides a series of criteria that guide and evaluate the design universality. The seven principles (Clarkson et al., 2013) are:

1. *"Equitable use"*- meaning that the design should be useful and saleable to users with various abilities.
2. *"Flexibility in use"*- meaning that the design should incorporate various individual preferences and abilities.
3. *"Simple and Intuitive use"*- meaning that the use of the design should be understandable and straightforward regardless of the user's knowledge, experience, or language skills.
4. *"Perceptible information"*- meaning that the design should communicate the necessary information efficiently so it can be used regardless of the ambient conditions or users' sensory abilities.
5. *"Tolerance for error"*- meaning the design should minimize the dangers of incorrect or accidental actions.
6. *"Low Physical Effort"*-Meaning that the design should be used easily with minimum fatigue.
7. *"Size and Space for Approach and Use"*- Meaning the design should have appropriate space and size to fit different types of bodies, postures, or mobility.

The design tools and approaches reviewed improve knowledge of the product, how it communicates, and how to make it accessible to more diverse end-users. Therefore, must be considered throughout this redesign process.

2.8 Device for exercising the PFM, WO 2020/121247 A1

As mentioned in the previous Chapter, knowledge of the past, present, and future is fundamental to any project development (Norman, 2016). To better understand its history, it was essential to analyze the components and structures of the device for exercising the PFM, WO 2020/121247 A1, and how they function together. This will give a starting point and help define the main goals for this project.

The previous invention consisted of a device to exercise the PFM in women through the vaginal canal. The device helps treat or prevent disorders related to the variation of the muscular function of this anatomical area.

This invention aimed to overcome some disadvantages of previous existing devices demonstrated on PFM training, such as the impossibility to increase or decrease the extra weight during the training session without removing the device, and finally, the resistance force applied to PFM contraction not being in the direction of the fibers of the levator ani muscle but rather in a perpendicular direction, for example, the US 2010/0051036 A1 (Ira Kushnir, 2010). The technique of vaginal cones also promotes the application of different resistance forces (through weights), but for use in an orthostatic position (standing up), and therefore with the same disadvantages previously mentioned.

To effectively overcome the disadvantages, the device proposes to exercise de PFM, allowing the addition of external weights, to monitor and quantify the resistance inflicted on the muscles exercised, eliminating the need to remove the device during the training session. In addition to the previous advantages, the device also enhances the cephalic and anterior displacement of the urethra, vagina, and rectum, promoting these structures' closure (Carvalhais, 2020).

The main component (A), shown in Figure 7 and Figure 8, contains a cylindrical body (C), a vertical rod (H), two crosspieces (7), and two supports (9). The body (C) shape is similar to a menstrual tampon, composed of an intravaginal portion with a rounded tip (1), a middle part (2), and an extravaginal portion (3). The (1 and 2) sections of the body (C), were specially adapted to be in contact with de levator Ani muscle (21) hence applying a resistance force in the perpendicular direction onto those muscles fibers and opposed to its contraction (arrow 1), as shown

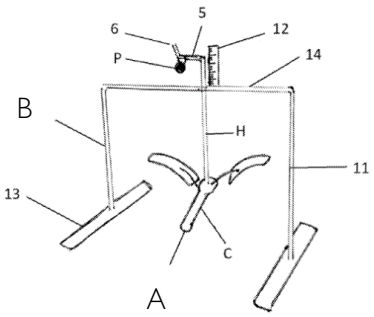


Figure 7- Antero-lateral view of the device of the invention, reflecting the relation between the components(A) and components (B) (Carvalhais & Natal Jorge, 2020).

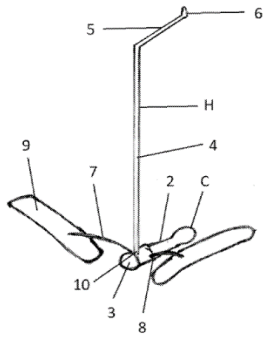


Figure 8 - Posterior-view of the Component (A) reflecting the relation between the components (Carvalhais & Natal Jorge, 2020).

in Figure 9. the extravaginal portion (3) of the body (C) there is a hole (10) fitting for the insertion of the rod (H), and on each side, a hole (8) fitting to assemble the crosspieces. The rod has four sections connecting to the body through the lower section in the hole (10) to connect mechanically with the extravaginal section (4) of the body (C). The lower region forms an internal angle, preferably of 100° with the intermediate section (5). The middle section and the upper area (6) form a 45° angle preferably to fit the external weights(P); the weights enhance the resistance to PFM contraction and generate a dislocation of the rod (H) in the mid-sagittal plane of the user.

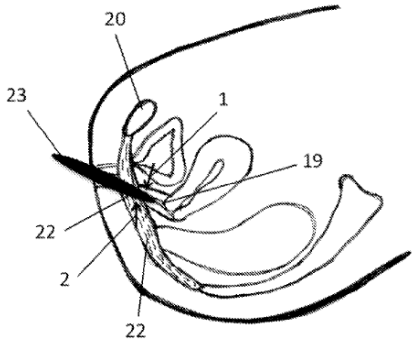


Figure 9 - -Resistance force (arrow1), resulting from the action of the present device, when the resistance is directly applied on the levator ani muscle, happening in the direction of the contraction of this muscle (arrow 2) (Carvalhais & Natal Jorge, 2020).

The supports (9) have a rectangular shape and are slightly curved, with a concave side, so that is to be endorsed by the anteromedial region of the user´s thighs (interior part of the user's thighs). Both supports are connected to the rigid beam (7), through the lateral holes (8), of the body (C) to connect with the extravaginal section (3) of the body (C). The connection is made by a 3D articulation, allowing the rotation in any of the three orthogonal axes.

The secondary component (B), as shown in Figure 7, contains two vertical beams (11), a graduated ruler (12), two support bases (13), and a horizontal beam (14).

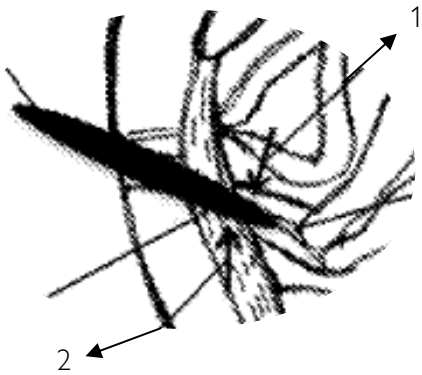


Figure 10- Zoom of Figure

The vertical beams (11) are adaptable in length and rigid, each of them comprising an upper and lower end.

The horizontal beams (14) are also rigid but with a circular adjustable length, section arranged at the upper end of each vertical beam.

The support base (13) has a substantially rigid rectangular shape and is mounted on each lower end of the vertical beams (11).

The ruler (12) can be graduated in mm or cm and is placed perpendicular and vertically at the midpoint of the horizontal beam. The graduated ruler (12) allows quantification evaluations of the dislocation of the rod (H), allowing monitoring of different types of muscle contractions performed against resistance.

The configuration of the secondary component (B), with an inverted "U" shape, ensures that the body (C) does not move longitudinally in the vaginal canal during the execution of the exercises.

The weights (P) are placed, when needed, in the intermediate section (5) of the rod (H); the weights are placed externally to the user´s body through a ring in the upper part of the weight.

Subsequently, there is no need to remove the body (C) after his insertion in the vaginal canal to change the load applied to the device. The weights (P) have a different load according to the needs and goals. Each of them can fluctuate between 5 and 40g, with a 5g gradient, using more than one weight at a time.

Material

Reviewing the Patent WO 2020/121247 A1, it's clear that the adequate material is a rigid material compatible with the vaginal mucosa, lubricants, and sanitizing products. As the device can be used at home or in a physiotherapy context, it must be sanitized or covered (ex: condoms) so that it can be used easily by different users and still be hygienic.

Advantages

The application of this device is especially advantageous for reinforcing the PFM, in particular, the levator ani muscle, by being able to adjust to the type of contraction (isometric, concentric, eccentric) and type of strength performance being developed (hypertrophy, endurance, power), appropriate to the precise dysfunctions of each patient.

Main differentiating features

- Possibility of assessment, qualitative and quantitative monitoring of the training sessions to strengthen the PFM.
- Target action to the levator ani muscle by the type of contraction (isometric, concentric, eccentric) in response to the resistance force.
- Adjustment of the load and type of force applied to the intended target (hypertrophy, endurance, power), specific for the dysfunctions of each patient.
- Application of different loads, without the need to remove the body of the device from the intravaginal region of the user, during the exercise.
- Maintenance of the correct positioning of the device thanks to the concave supports resting on the user's thighs.

2.9 Market Research (Currency data retrieved from Morningstar on 11/07/21)

Before starting the project development phase, it is important to frame this product on a specific market segment. This phase allows gathering a general in-depth knowledge of products already out there and of the market itself. For this purpose, more than 38 pelvic floor trainers (Attachment 2) and devices that are not directed to the training itself but rather for organ support were analyzed. Progressively the analyzed field was restricted to pelvic floor trainers, using a comparative study to analyze different categories such as components, type of exercise, color, biofeedback, material, and price. In the final stage of this research, a more in-depth analysis was made to the devices more similar to the pelvic floor trainer in development. This process allows understanding of the industrial tendencies and technical solutions to consider throughout the development phase.

Management solutions

There are several management solutions for UI and POP. Tampon-like pessaries present these stress incontinence solutions that work by pressing against the vaginal wall and closing the urethra enough to prevent involuntary urine loss. Some examples of that management solutions are

Material- Santoprene, thermoplastic rubber, non-latex hydrophobic polymer

Price: 80$ (67,36 €)

Figure 11- Coniform, adapted from Contiform international.

Material: the raw material used in Contam is a toxicologically and dermatologically harmless foam.

Price: £12.59 (14,74 €)

Figure 12-Contam, adapted from stressnomore

Material: Non-absorbent Hypoallergenic medical-grade plastic.

Price: 299 $ (251,75 €)

Figure 13-Uresta, bladder support device for women, adapted from Biomeds

Material: Santoprene.

Price: starter pack £19,99 (23.40€)

Figure 14- Diveen set, adapted from Bbraun.

Material: Medical Grade Silicone. Price: £59 (69.06€)

Figure 15-Efemia, incontinence device, adapted from Efemia

Material- state-of-the-art silicone, (Surgical, 2011).

Figure 16-Milex pessaries, adapted from Coopersurgical

The other available solutions are disposable and reusable absorbent continence products. The disposable absorbent continence products can be divided into two subgroups, Bodyworns, and underpads. Bodyworns are products worn by the user, such as inserts, diapers, pull-ups, and pouches that have sub-dived groups for different types of incontinence severity. Underpads are placed beneath the user, such as Bedpads and Chairpads. The reusable absorbent continence products are also divided into Bodyworns and underpads and present the same products in the same sub-groups. The only difference is the type of material, which is washable (P. Abrams & Society, 2016).

Pelvic Floor Trainers - competitor analysis

Concept- Elvie

Elvie is an intravaginal device Kegel exercises, training through a series of 4 levels of exercises with different types of contractions. The device is inserted like a menstrual tampon.

Figure 17-Elvie, pelvic floor trainer, adapted from Mifarma

Table 1-Technical specifications, Elvie

Brand/ Manufacturer	Minna Life
Material	Medical Grade Silicone
Dimensions (height,with,length)	N/D
Price	Aprox 126,27 €
Color	Blue
App	Yes

Concept- K-Goal

K-Goal is an adaptable intravaginal device that provides biofeedback through vibration; the Kegel exercises consist of a series of contractions, without any additional weights, that are measured and stored in the device app. The device is inserted like a menstrual tampon.

Figure 18-K-goal, pelvic floor trainer device, adapted from Kgoal

Table 2-Technical specifications, K-Goal

Brand	Minna life
Material	Medical Grade Silicone
Dimensions (height,with,length)	N/D
Price	Aprox. 126,27 €
Color	blue
App	yes

Concept- Perifit

Perifit device is a Kegel exerciser with pressure sensors to monitor your contractions in an app. The app lets you play videos games with the contractions of the PFM; also monitors and stores progress in five categories strength, endurance, frequency, release, and accuracy. The exercises are realized through contractions and without any additional weights. The device is inserted like a menstrual tampon.

Figure 19-Perifit, pelvic floor trainer, adapted from Perifit

Table 3-Technical specifications, Perifit

Brand/ Manufacturer	Perifit
Material	Medical Grade Silicone
Dimensions (height,with,length)	N/D
Price	Aprox 192,68 €
Color	Pink and greenish blue
App	Yes

Concept- Joy On

Intravaginal device for Kegel exercises. The exercises consist of contracting the device inside the vagina using the PFM. It comes with an app that provides real-time feedback and stores progress, and provides a series of exercises through games. The device can also offer four levels of massage modes; its insertion method is similar to a normal menstrual tampon.

Figure 20-Joy On, pelvic floor trainer, adapted from joyonproduct

Table 4-Technical specifications, Joy On

Brand/ Manufacturer	Joy on
Material	Medical grade silicone
Dimensions (height,width,length)	210mm x 33 mm x 33 mm
Price	Aprox 42,21 €
Color	pink
App	Yes

Concept- Aquaflex and Intimich pelvic health I 2.0

Both concepts are composed of cones, and these cones are intravaginal devices for Kegel exercises. During exercises, the device inside the vagina should be retained using the PFM; the device also provides four different weights that can be added as the muscles get stronger. The device is inserted like a menstrual tampon.

Figure 21- Aquaflex pelvic cones, adapted from stressnomore

Table 5-Technical specifications, AquaFlex cones

Brand/ Manufacturer	Neen
Material	N/D
Dimensions (height,with,length)	Small cone- 60mm x 22m Large cone-60mm x 26mm
Price	Aprox 36,23 €
Color	white
App	No

Figure 22- Intimich pelvic health I 2.0, adapted from Afrodisia

Table 6-Technical specifications, Intimich pelvic health I 2.0

Brand/ Manufacturer	Intimich
Material	Medical grade silicone
Dimensions (diameter)	22 mm peso 35g, 18 mm peso 20g, 15 mm 10g, 10 mm peso 5g
Price	Aprox 24,75 €
Color	Pink and light purple
App	No

Concept- Pixie cups and Joy on

The Pixies cups and the Joy on PFM trainers are composed of an intravaginal device for Kegel exercises. The exercises consist in retaining the device inside the vagina using the PFM. It comes with six different devices, each with a different weight, to use progressively as the muscles strengthen. The Pixie cups also offer an electronic guide of exercises, opposed to the Joy On, which provides an app for the exercises that monitor progress. The insertion method is similar to a menstrual tampon.

Table 7-Technical specifications, Pixie Cup

Brand/ Manufacturer	Pixie cup
Material	Medical grade Silicone
Dimensions (height,with,length)	N/D
Price	Aprox 33,73 €
Color	white, yellow,orange,green,dark blue,black
App	Yes

Figure 23- Pixie Cup, pelvic floor trainers, adapted from Amazon

Table 8-Technical specifications, Joy On, pelvic trainers

Brand/ Manufacturer	Joy on
Material	Medical grade Silicone
Dimensions (Diameter)	30 mm
Price	Aprox 29.54 €
Color	Gradiente of white to red
App	Yes

Figure 24-Joy On, pelvic floor trainers, adapted from Amazon

Concept- The Intimich pelvic health II and Je Joul

Both concepts are composed of 3 sets of intravaginal balls for Kegel exercises. The exercises consist in retaining the device inside the vagina using the PFM. It also provides three different sets of balls with progressive weights to choose from as the muscles get stronger. The device is inserted like a menstrual tampon.

Table 9-Technical specifications, Intimich pelvic health II

Brand/ Manufacturer	Intimich
Material	Medical grade silicone
Dimensions (with, height)	34 mm x 120 mm Peso 60 g, 34 mm x 168 mm Peso 120 gr, 35 mm x 175 mm Peso 115gr
Price	Aprox 42,69€
Color	Pink
App	No

Figure 25- Intimich pelvic health II, Kegel balls, adapted from Desejo Supremo

Table 10-Technical specifications, Je Joul

Brand/ Manufacturer	Ami
Material	Medical grade silicone
Dimensions (height,diameters)	115 mm x 39 mm 160 mm x 34mm 147 mm x 29mm
Price	Aprox 72,57€
Color	Purple,black,pink
App	No

Figure 26-Je joul, kegel balls, adapted from Wahaao

Concept- Sensa tone

The Sensa tone is an intravaginal device that sends electrical pulses through the pelvic muscles to strengthen them. It comes with a treatment plan for each of the four programs (A- Urge incontinence, B- stress incontinence, C- Mixed incontinence, D-after Care). The device is inserted like a menstrual tampon.

Table 11-Technical specifications, Sensa Tone

Brand/ Manufacturer	Body clock
Material	N/D
Dimensions (height,with,length)	120mm x 30mm x 15 mm
Price	Aprox 63,16€
Color	white
App	No

Figure 27-Sensa Tone, pelvic floor stimulator, adapted from Win-Health

Concept- Super Kegel

The Super Kegel is an external device placed between the glutes, and with their contractions works not only the PFM but also the buttocks and lower limbs.

Table 12-Technical specifications, Super Kegel

Brand/ Manufacturer	Altsales
Material	ABS
Dimensions (height,with,length)	241,3 mm x 152,4 x 101,6 mm
Price	Aprox 16,86€
Color	Blue (available in red, orange, green purple, and yellow)
App	No

Figure 28-Super Kegel, adapted from Wallmarkl

Most similar Competitor Devices

Concept- Kegel8

The Kegel8 are three sets of intravaginal devices for Kegel exercises, and it comes with an app guide. The exercises consist of an Isotonic exercise; the device is placed inside the vaginal canal, with an optimal length to reach the PFM without going too high. If it is correctly done during the exercise, the tail will indicate through its downward movement providing live visual feedback. Kegel8 provides three different devices changing its head diameters and weight, allowing the user to choose the best fit for them or change as the muscles get stronger (Karol, 2005).

Figure 29-Kegel8, pelvic floor trainer, adapted from amazon

Table 13-Technical specifications, Kegel8

Brand/ Manufacturer	Kegel8
Material	Santoprene,Medical grade silicone
Dimensions (height,diameters)	lengh-170mm insertable lenght-80 mm diameters 27 mm ,29mm,32 mm
Price	Aprox 35,06 €
Color	Blue gradient
App	Yes

Concept- Educator

The Educator is an intravaginal device for learning the correct way to do Kegel exercises. During the exercise, the intravaginal device, resting on the PFM, will move when the PFM contract and subsequently lifting the device inside the vaginal canal. The external indication rod will show through its downward movement, providing live visual feedback if the exercises are being correctly done. Although similar, this concept does not offer the possibility of adding any weight or resistance during exercise, therefore serving for limited training. The device's main focus is educating the user on the correct way of doing the kegel exercises, contrary to the device in development.

Figure 30- Educator, pelvic floor contraction educator, adapted from fisaude.pt

Table 14-Technical specifications, Educator

Brand/ Manufacturer	Neen
Material	N/D
Dimensions (lenght, diameter)	Lenght aprox. 90mm Diameter aprox.27 mm
Price	Aprox 27,96 €
Color	white
App	No

Concept: Kegelmaster

The Kegelmaster is an intravaginal device with two separates parts joined together. Inside these two parts, the user can choose what type of resistance they want for the exercise through a series of springs with different resistances. The exercises are executed by contracting and relaxing the PFM and subsequently the device and the springs inside. The device is inserted closed, then inside the knob is loosened so the springs can create the resistance. For the device to be removed, the knob must be tightened to lock it and then safely taken out of the vagina. Each time the user wants to change the resistance they have to remove the device.

Figure 31- Kegelmaster- pelvic floor trainer, adapted from amazon

Table 15-Technical specifications, Kegelmaster

Brand/ Manufacturer	Kegelmaster
Material	Springs stainless steel
Dimensions (lenght,diameters)	overal lenght: 167,64 mm, insertable lenght: 74,93mm, width of insertable section: 26,92 mm
Price	Aprox 109,56 €
Color	Blue
App	No

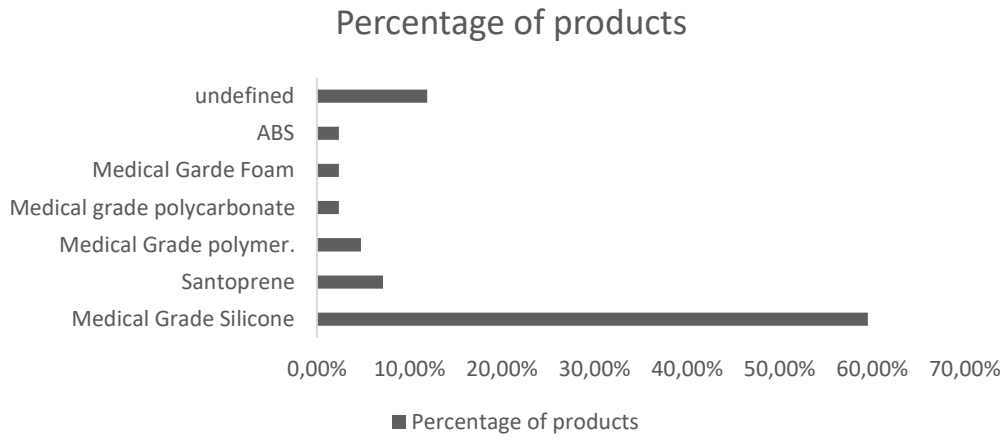
Figure 32- Kegelmaster, assembly, adapted from amazon

2.10 Comparative studies

A comparative study was developed to extract most of the information from the previous research; a comparative study of more than 40 devices was conducted, from pelvic floor trainers to incontinence leak supports and more than 20 brands/manufacturers. Some of the specifications were not always available by the brands or resellers; therefore, it was impossible to fill in all criteria. All dimensions were converted to millimeters to simplify comprehension, as all the prices to euros, with exchange rates of USD= 1,1815 euros GBP=0,8540 euros – according to exchange rates available daily in Morningstar Inc, at 13 of July 2021. All collected data for the following comparative graphics is in Attachment 2-Market research.

Material Selection

Most available products in the market tend to follow a constructive pattern transversal to many brands and manufacturers. All products in physiotherapy or personal health have been through a thorough process of investigation and development. All materials used in this field must be safe and well-considered. For that, a comparative study on materials was made. This study allowed identification of what materials are most used by companies already in the market.



Graphic 1 – Comparative study on all Materials of studied products.

As can be seen, in Graphic 1 – Comparative study on all Materials of studied products., the most used material is medical-grade silicone followed by Santoprene and medical-grade polymers.

Medical Grade silicone

Silicone is extremely versatile, and can be made into various forms varying on its intended applications. It is made of silicon, oxygen, carbon, and hydrogen. Being highly biocompatible and bio-durable when interacting with host tissues makes silicones widely used in medical device applications. Other characteristics that reinforce its utilization are: its capability to withstand repeated sterilization, its wide chemical and thermal stability, having hemocompatibility due to its hydrophobicity, and consequently maintaining blood properties. It also has a high permeability to gases such as oxygen, carbon dioxide, and moisture. Silicone is nontoxic, inert, and nonbiodegradable (Zare, Ghomi, Venkatraman, & Ramakrishna, 2021).

Some of its biomedical applications are:

- Coating, treatment, or assembly of a variety of medical devices.
- Implants and inserts to substitute a variety of body parts
- Catheters, drains, and shunts are used for medical treatment and short-term implants.
- Aesthetic implants
- Contact lenses

Santoprene

It is a non-hygroscopic thermoplastic vulcanizate (TPV) in the thermoplastic elastomer (TPE) family, designed for medical use and health care applications. This grade of Santoprene TPV is sheer-dependent and can be processed in conventional thermoplastics gear for injection molding or blow molding. It is recyclable within the manufacturer stream and polyolefin-based (Exonmobil, 2014).

Medical Grade Polymers

The most common medical grade polymers used in medical devices are Polyethylene, Polypropylene, Polystyrene, Polyester, PLA, and other bioabsorbable polymers, Polycarbonate, Polyvinyl Chloride, Polyethersulfone, Polyacrylate, Hydrogel, Polysulfone, Polyetheretherketone, Thermoplastic Elastomers (McKeen, 2014).

Designers and engineers must consider stresses, impacts, and loads the product might suffer during its use when choosing a material. Also, to be considered are physical properties such as transparency/opacity, aesthetics, color, water absorption, wear resistance, and mechanical properties such as impact resistance, tensile strength, tensile modulus, and elongation (McKeen, 2014).

In this case, the device in development will be for pelvic floor physical therapy interventions and made of a rigid material, as previously referred, with some flexibility to facilitate its assembly. Thus, it's crucial that besides its mechanical properties, it should be taken into consideration its Biocompatibility, as it will be in contact with the vaginal mucosa.

Medical grade silicone coating is still a viable solution if it is decided to sell as a personal use product.

Color

Everything from products to clothes and living spaces relies on color to give visual appeal, data codes, and meanings. The color itself is a feature of the product and plays an important part in experiences with everyday surroundings. Culture and experiences can change how color is perceived; consequently, color preferences may be individual and based on personal memories, physical body coloring, family traditions, or fashion. Color can also trigger memories and can aid recognition (DeLong & Martinson, 2013). In medical devices design, color can be a powerful tool, not necessarily in an attractive way but to improve user experience. For example, color can emphasize key interaction points (ex: buttons) or influence user interactions and help them follow the correct usage steps resorting to gradient color schemes. Nowadays, medical devices focus not only on safety but also on effectiveness, looking for ways to respond to user needs and improve usability and engagement. By considering the emotional, practical, and lifestyle challenges of product users, designers can create an experience that helps reduce usability barriers, and choosing the right color can play a crucial role in achieving this (Greenhalgh).

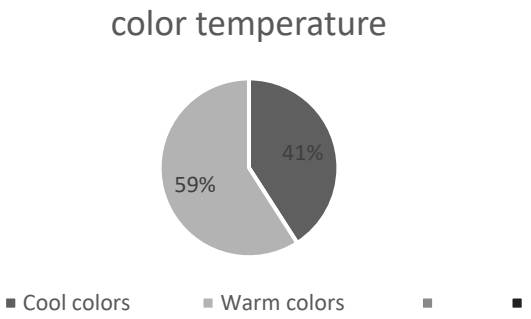
During Color consideration, it is essential to understand who will be using the product and what is appealing to them from a color point of view. The user will associate the product´s "appeal" with their values and characteristics. Those characteristics will be further associated with specific colors by the user. There are many ways to obtain this particular knowledge, for example, surveying the existing competitors' products, the environment in which the product will be used, cultural considerations, and sterilization methods required for the product in question (Stipe).

Color temperature

Warm colors, such as orange, red, yellow, pink, and violet, are often associated with positive emotions. For instance, yellow is regarded as happiness, sunlight, optimism, and pink, more associated with sunsets and a soothing sensation. Pink is also historically strongly associated with feminine connotations. In Medicine, warm colors are usually very present in pediatric and obstetrics/gynecology departments (Adams, 2017; Stipe). Although historically, medical products have been using shades of green, blues, and neutrals such as whites and greys, not only because these colors are often associated with peacefulness, serenity, and regeneration but also

for their association to cleanliness and sterilization. Nevertheless, warm colors seem to be more dominant in feminine products (Adams, 2017; DeLong & Martinson, 2013; Stipe).

The color itself has a particular influence on the emotional representation of rehabilitation equipment. Pleasant equipment can be helpful in the treatment and improve its therapeutic effect on patients helping them recover their daily functions as early as possible. Nowadays, the most common color schemes of rehabilitation equipment are pure achromatic colors. They commonly use white, grey, black, red, blue, green, and other colors. Generally, the use of cool colors such as green and blue still prevails in medical devices for their ability to relieve patients of negative emotions, such as tension and anxiety. Colors can bring different sensations and feelings in people and are one of the most important factors in designing rehabilitation devices (Liu, 2020).

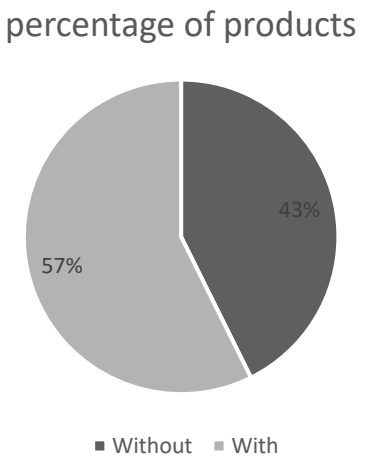


Graphic 2-Competitor's choice of color temperature

Graphic 3-Colors of the reviewed products

Evaluating the information gathered in the Competitor product analysis, detailed in Graphic 2 and Graphic 3, it is visible that although cool colors are still being used, such as whites, blues, and mint, in the specific market sector for feminine pelvic floor trainers, warm color prevails within the shades of pinks, purples, and violets. Some brands opt to use gradient colors instead of only one color to identify different levels of the exercises and help users distinguish the correct usage order of them. It is also visible that most physiotherapy-related brands continue to opt for cool colors as opposed to more commercial brands of pelvic floor trainers that opt for colors on the warm side, mainly pinks, and purples.

Exercises with weight or resistance

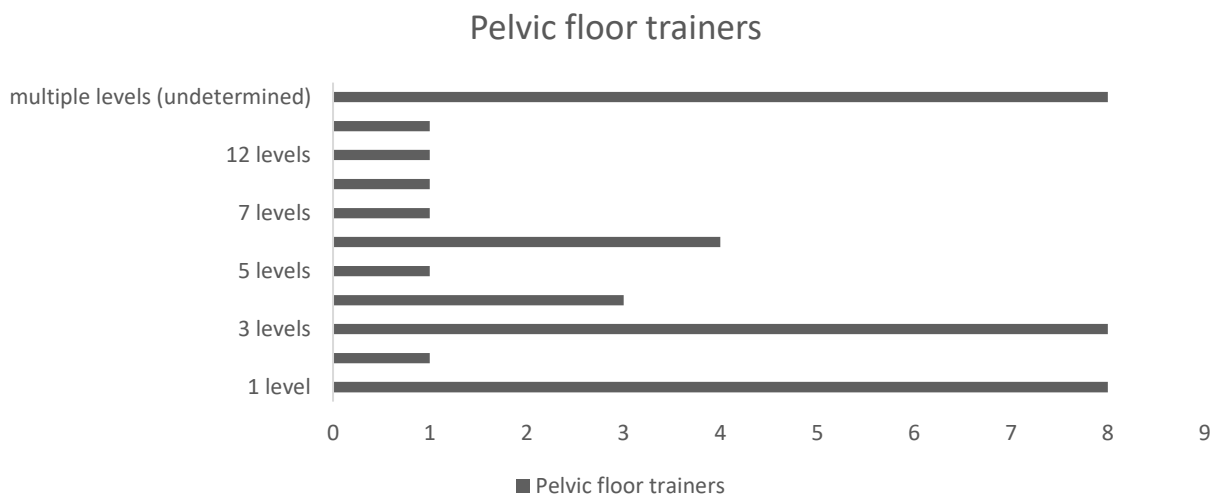


Graphic 4-Percentage of products using exercises with or without weights

Studying all the 39 pelvic trainer devices, it's evident that most of the market still relies mainly on two types of exercises. With weights, they mostly rely on the technique introduced by Pelvnik in 1985. A tampon-like weighted vaginal cone was introduced to help patients identify the correct muscles to contract and exercise them. For that, a set of cones with the same volume but with increasing weight were used; this technique was also developed as a way for the patients to be able to rely less on physiotherapists progressively. As the cones provided biofeedback, this allowed patients to monitor their progress on their own and self-treat UI in their homes (Cammu & Van Nylen, 1998).

The other type of pelvic floor trainers mostly relies on different types of voluntary contractions, such as timers, repetitions, and endurance exercises, existing exceptions that rely on resistance, for example, the Kegelmaster.

Exercising Levels



Graphic 5- Pelvic floor exercising level of the reviewed products

Regarding the levels of exercises, only 21,62% of them had just 1 level. Most of them provide the user with various alternatives, either resistance, weights, or exercises. Pelvic floor weakness and abilities to withstand exercises changes from person to person. Therefore, having different levels from beginner to more advanced ones gives the product a wider range of users and allows the user to keep using the product while advancing on training, providing a longer product life span.

Chapter 3-Project Development

Simon Herbert defines the act of designing as the process of changing previously existing conditions into ideal ones (Simon, 2019), and redesign by definition of the Oxford dictionary is to design again or differently. For that, it's vital to assess what functional changes are essential to prioritize. However, change has the power to propagate and can affect many parts of a design, creating the need to rework on other aspects so they can be implemented (Ahmad, Wynn, & Clarkson, 2013). When the previous design was presented, it had an excess of components to compensate for functional needs so that it could work as a whole. Therefore, the main focus of this project is to reduce components by improving their functionality and create a more user-friendly device.

3.1-Project Development Methodology

"Design Process at its best integrates the aspirations of art science and culture" – Jeff smith

Reducing and improving components without compromising their functional characteristics was the main goal, and it was necessary to choose a methodology that would best work for this purpose. This project's first phase started back in 2013, by a collaboration between Professor Alice Carvalhais and Professor Renato Natal, from the University of Porto, which makes fundamental for their cooperation during this process.

"Co-Design = Working Side by Side. Not Top Down. Not Bottom-up." - The Australian Centre for Social Innovation (TACSI)

Co-design is a methodology where multiple people actively engage in the design of enhancements, innovations, and impacts, gathering their collective experiences to build outcomes that are as good as they can be. It is focused not only on the end-user feedback but also on all the people involved in their development. The design process in co-design is a vessel for framing, redoing, actively test the defined solutions for learning and improving based on the results and feedback (Burkett, 2012). It's also vital in co-design to take the time to understand the problem through the user's eyes, not like in a statistically significant way, but in small groups and spending quality time with that group of people, mapping their experiences and identifying obstacles. The second phase of the learning process focuses on developing prototype interventions with key partners' collaboration and developing a quick response to support that dynamic.

The key point to this phase is to gather results to progress in further tests and create a series of design-redesign cycles, which will be perceptible through this chapter (Stoker & Evans, 2016).

For this process, the workgroup consisted of 8 female volunteer users of different ages and backgrounds and the expertise of Alice Carvalhais with a Ph.D. in physiotherapy and the expertise of Renato Natal Jorge with a Ph.D. in mechanichs and several years of experience in bioengineering. . Both of them worked on the first stage of this device and have published a Patent under the Patent Cooperation Treaty (PCT) (Carvalhais & Natal Jorge, 2020). These key partners will continue to assist in this second phase of improvements and problem solving, with their unique experience in their fields and with the device itself.

Co-design is a hybrid concept that pulls from product design thinking (Stoker & Evans, 2016). Design thinking, although it may seem a new concept, is as old as we humans are. Since the beginning, humans have been making things, designing things, everything since the earliest tools to today's most advanced technologies are products of design, i.e., a creative process to solve problems (Clarke, Amonkar, & Rosenblad, 2019).

There are many other design thinking definitions. For instance, for Bason (2018), design thinking is the design process and how it can guide the collaboration of different disciplines (Bason, 2018). Lupton (2011) describes it as being the process of ideation, research, prototyping, and user experience. A series of tools can be extracted and used throughout this process from all these different approaches, such as Brainstorming, interviewing, and focus groups. These creative process strongly leans on co-design and teamwork (Lupton, 2011)

Therefore, the methodology used in this dissertation is based on the design thinking process, more precisely the Stanford Design Thinking Process, having co-design at its center for the idea generation and prototype phases.

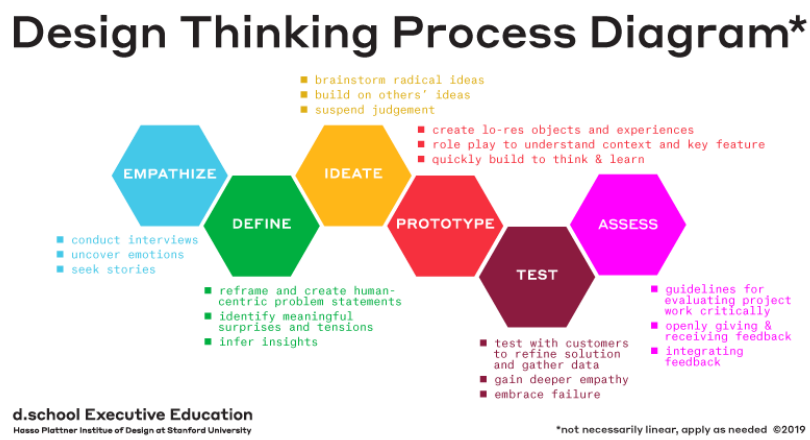


Figure 33- 5 steps design thinking model proposed by the Hasso-Plattner Institute of Design at Stanford adapted from (Tu, Liu, & Wu, 2018)

Before starting the design process, it was important to establish a good and strong relationship with all the people involved in this project. Therefore, regular contact was maintained to keep the project flowing. Regular meetings accompanied the process. These meetings were vital to help validate and share gathered information, explore what was already in the market as solutions to the problem, define main problems to be solved, brainstorm, and define concepts. So that all through this process every step was discussed, and every opinion heard.

Firstly, it was essential to understand the core problem the first device answered to and what ages would use it the most. For that understanding, a need emerged to conduct a series of searches and literature revisions focused on the female pelvic anatomy and pelvic floor dysfunctions. This revision allowed a better insight into the previous design and a better knowledge foundation to further work on it. The literature revision also included market research on devices for PFM training and female incontinence, which allowed to see what type of solutions were being used for materials, transportation, and training methods.

"Empathize" and "Define" was the second learning phase that allowed, with the use of insights and surveys from the workgroup and the previous device users, to define goals for the redesign of the existing device the main tasks for this project. Both learning phases provided insight into the user profile.

"Ideate" is the first step towards finding solutions to various problems resulting from the previous phase. The first experiment phase started with a series of brainstormings for each sub-problem. Brainstorming allowed all involved in the workgroup to participate with ideas and knowledge and also allowed interdisciplinary perspectives on a problem that embodies different knowledge and skills stets (Lewrick, Link, & Leifer, 2020). After the workgroup debated all the generated ideas, a few of them were selected to pass to the next phase using a few criteria such as long-term goals, impact on customer satisfaction, obedience to deadlines, the possibility of prototyping.

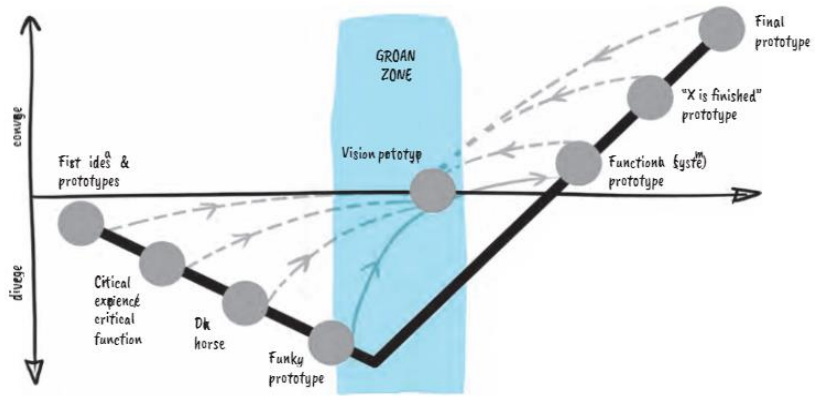


Figure 34- Prototype process followed based on the toolbox presented in (Lewrick et al., 2020)

"*Prototype*," "*Testing*," and "*Assess*" Prototypes allow making ideas tangible and more perceptible. A few ideas were materialized in the first series of prototypes, then in the second series, multiple volumetry and their functionality were studied. These second series are also known as critical experiment prototypes or critical function prototypes, used when the problems are not yet completely understood, and critical elements still need to be questioned, starting the cycle of design redesign.

In the following approach was used a "Darkhorse prototype" (Lewrick et al., 2020). This experiment allowed to test a reaction to an unusual approach to a solution; this concept entails a high risk of user rejection. Thus, it hasn't been technically feasible until now. For that, it was conducted a series of surveys that will further in this chapter demonstrate the public reaction to it. In this case, the "Darkhorse" was also a "funky

prototype" (Lewrick et al., 2020), as it combined ideas from the first series of experiments and brainstorm sessions.

Looking to the future, the "vision prototype" permitted the workgroup to use all feedback and knowledge of the previous phases to create the first prototype that tried to solve all the functional problems. Testing was a fundamental part of the process to help overcome the "Groan Zone"- a transition zone between problem exploration and problem-solving and refining the selected ideas to go further to a more functional and convergent phase (Lewrick et al., 2020).

The convergent and final phase leads up to the final prototype. In the first segment, the functional prototype was developed. This phase is where the last improvements on the core problems found in the previous stage were refined and retested, making the solution more perceptible and tangible. In the second segment, sub-functionalities were implemented. These sub-functionalities are required for the overall functional structure to work (Lewrick et al., 2020). They, too, were tested to see if all the sub-functionalities worked together, allowing the concept to be a step closer to the final Prototype.

The final prototype used the 3D Printer provided by the Faculty of Engineering of the University of Porto to print the final modification done to the last segment. This type of prototyping offers a more visually clean and working prototype of all the sub-functionalities together.

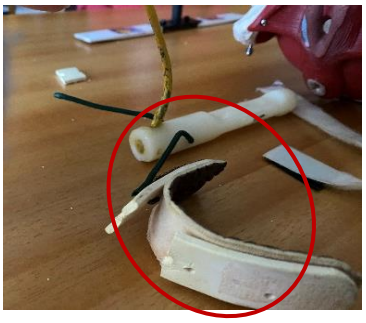
3.2 *"Emphasize"* and *"Define."*

After reviewing all literature, the second understanding phase began. In this phase, the main goal was to analyze and gather all previous information related to the previous device. A survey was developed for previous users to evaluate their experiences with the device to attain that information. This information was complemented by knowledge passed on by both its inventors.

The first meeting with the workgroup, Dr. Alice Carvalhais, and Dr. Renato Natal Jorge, was strictly to contextualize the evolution of the previous device and explain how each component worked and why it was developed. It was clear that many components were created to overcome some functional challenges existing from other parts.

Components that presented that functionality were both the crosspieces and supports. Those components were created because the rod's weight and the natural moisture characteristic of the vaginal canal would allow the device to slide off and fall and/or topple to the side.

The crosspieces worked by supporting the device in the interior region of the user's thighs. Although these components helped overcome some degree of the problem, avoiding the device toppling to its sides, the device continued to slide off. As a response to the problem that persisted, the supports were created, composed of two vertical beams, one horizontal beam, and two support bases.



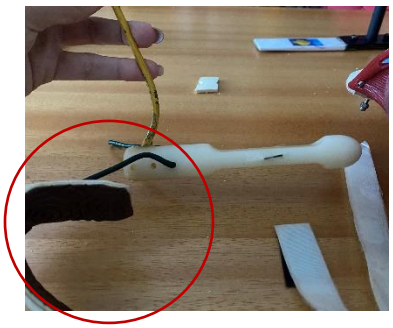


Figure 35- Side pieces and supports.

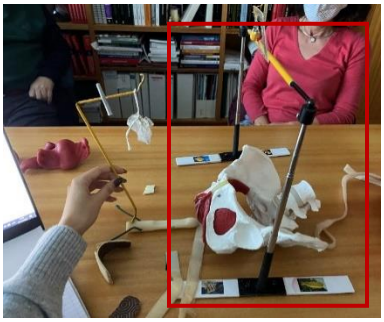


Figure 36-Supportive structure composed of 2 vertical beams, 1 horizontal beam and 2 support bases.

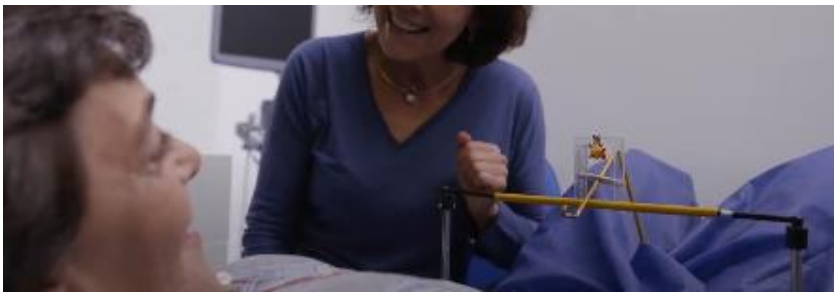


Figure 37-User and the device in physiotherapy consultation

These components were created to avoid the device sliding off from the user during exercises with resistance. Still, they also allowed the physiotherapist to monitor data and quantitatively evaluate the exercise through the ruler. As shown in Figure 38, component 1 with the beam and ruler avoids the device from sliding off during exercises with resistance.

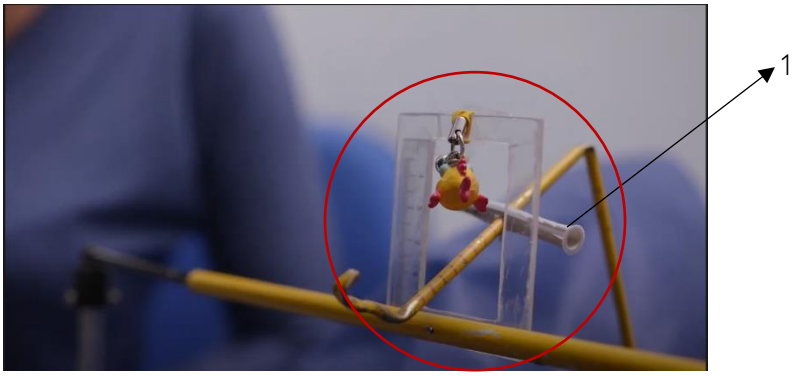


Figure 38-Positioning of the rod with the beams and ruler, component 1 function: to avoid the device from sliding off Adapted from Upin.up

What usually happened when the device started to slide off from the vaginal canal was that the rod would begin falling in the direction of the abdominal area, but with the use of the supporting beams and component 1, the rod wouldn't be able to pass through the ruler location, as component 1 exercised and barrier function.

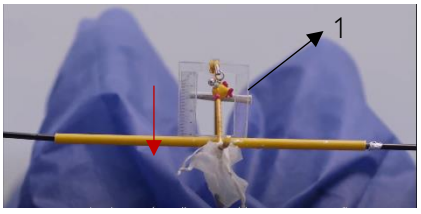


Figure 39- User's perspective of the ruler and beams, incorrect movement of the rod signaled by the red arrow. Adapted from Upin.up

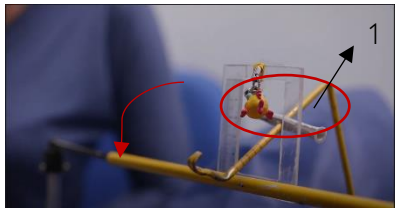


Figure 40- Component 1, incorrect movement of the rod signaled by the red arrow. Adopted from Upin.up

Both the beams and component 1 would serve as a barrier to this incorrect movement of the rod, preventing that the device would slide off and/or toddle sideways, Figure 39 and Figure 40. Benefits from this component were the visual feedback, the collected data, and a visual goal to overcome during exercises. As seen in both images, the exercise goal was to elevate the weight to that figurine hanging in the center of the ruler, Figure 41.

Figure 41-Figurine, Adapted from Upin.up

As for the initial components, composed of the rod, the cylindrical body, and weights, improvements were identified even if the component´s function wouldn't be compromised without those. Both the rod and weights were still in a rough prototyping phase and seemed to need more improvements from the initial components. The rod was still missing a proper joint with the cylindrical body and adequate support for the weights during training.

As can be seen, the weights were supported by a hanging fabric bag and consisted of fishing lead weights. The weights would be changed during the exercise by opening the fabric bag and changing the weight inside.

Figure 42- Weights being hanged in the rod

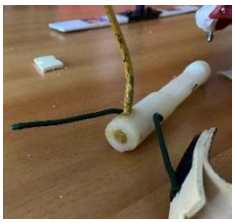


Figure 43- Joint of the rod with the cylindrical body

After this meeting, a survey was written to understand users' experience with the previous device and their suggestions to improve it. Answers are in Attachment 4, not all previous testers were able to be contacted, so the results are limited to the ones the survey reached.

Analyzing the results, it was clear that no one rated high on any categories, although most people found it comfortable and intuitive. In the written questions, suggestions were almost all answered, addressing the same point: fewer components, smaller size, and better aesthetics. In meetings, it was also discussed the device's ability to be used in a personal use context. This was also addressed In the survey, and despite positive results, still, 40% of users said they wouldn't buy it for personal use.

Crossing all information gathered, in the market research, meetings and surveys, gives a starting point to define the goals for this project. Market research allowed the group to understand the present competitor products on the market, understand the market tendencies and identify where the device presents a disadvantage when compared to others. The survey gave valid intel on what people would change and what expectations they had to improve the device. Finally, understanding the process and decisions made until today in the development of the existing device, making it easier to understand difficulties that could be overcome in this redesign.

The goals defined for the redesign of the device for the training of the PFM are:

- Enhancement of the support system.
- Enhancement of the rod and joint system.
- Enhancement of the weights and weight support system.
- Overall decrease of components.
- Overall improvement in aesthetics.
- Easier transportation

3.3 "Ideate" phase

The device behind this redesign is unique in various ways, not only by how the exercises are executed but also by its functionality.

In the Ideate phase, the main concern is to find possible solutions to the goals defined in the previous stage. For this phase, a series of tools are used, such as brainstorming, mockups, and looking for possible solutions already available in the market. These processes will help generate new ideas that could be used to solve each sub-problem.

Weights

Although there are several devices with exercises related to weight, none places the weight out of the intravaginal device. Most Devices present the weight integrated inside the device, and only a few allow the same device to combine different weights. Most of them provide different devices, with each having an associated weight.

Figure 44-Kegel Master, adapted from amazon

Examples of devices that provide different resistances are Kegelmaster, in this particular case, the resistance comes in the form of springs, Intimich pelvic health I 2.0, which provides four weights of (35g,20g,10g,5g) and finally, The AquaFlex cones, also providing four weights (20g,20g,10g,5g).

Figure 45- Intimich pelvic health I 2.0, adapted from desejosupremo

It's crucial to study what types of weights are usually provided by similar products. Only by defining what will be the maximum weight can be decided how many weights the device will provide to reach as many users as possible. This study was conducted in Attachment 2-Market Research. However, the maximum weight found in this study was 138 g; information from the previously conducted studies on this particular device from Dr. Alice Carvalhais and Dr. Renato Natal Jorge showed that most people didn't pass the 50 g in this type of exercise.

With this in mind, a series of 4 possible concepts were developed in order to adapt the previous weights was define what weight each would have.

Figure 46- The AquaFlex cones, adapted from stressnomore

Concept 1 – Concept one consisted of weights with a shape similar to a raindrop. That weight would be inserted inside the tip of the rod and covered with a transparent cap that would allow the user to see which weight was used; for change during exercise, the user would only have to remove the cap and change the weight, Figure 47. This concept would only rely upon color to identify the weight level.

Concept 2 – Concept 2 is like the previous one that included the weight inside the rod. The difference stands in that instead of removing the cap and changing the weight, the last portion of the rod would be removable and adjusted according to the exercise level. The Tips would also identify the weight level through its tactile design, represented in Figure 48.

Concept 3- Concept 3 adopts the idea of caps, and instead of the weight being inside the rod, the weight here is presented inside a removable cap that would be changed during the progress on the exercises, Figure 49. Like concept 1, the weight would only rely upon color to be identified.

Concept 4 - In this concept, the idea was to visually create a progression of the exercise through the transparency in the tip of the rod combined with the stackable weight balls, Figure 50. Again, the weight identification is only relying on color.

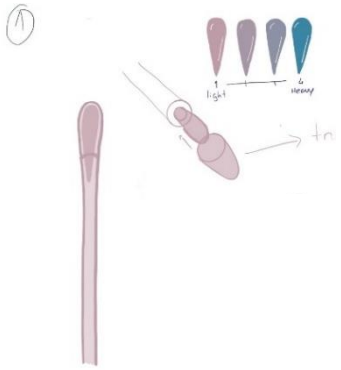


Figure 47- Concept 1: Weight drops

Figure 48- Concept 2: different tips different weights

Figure 49- Concept 3:, weight caps

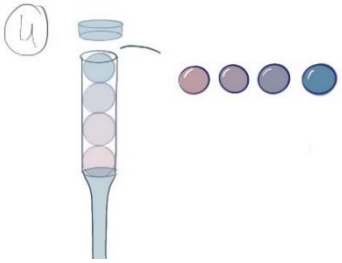


Figure 50- Concept 4: stackable weight balls

Although all concepts at first seem to have great potential, some problems were identified when debated in meeting with all partners. With the first three concepts, the main concern was the implications to the rod that changing its tip would have and, more importantly, the impossibility of combining weights. If these concepts were adopted, the user would be restricted to only four levels of weights.

Concept 4 also had the same concerns about its effect on the rod itself; even though the weights were in theory stackable, their volumetry would affect their stability, risking them falling off during exercises.

It was necessary to change the approach to the weights, being defined that the weights should not affect the integrity of the rod or its tip and that the weights would be combinable to allow more possibilities of exercises and weight levels.

Another concept surges, Concept 5: ring weights.

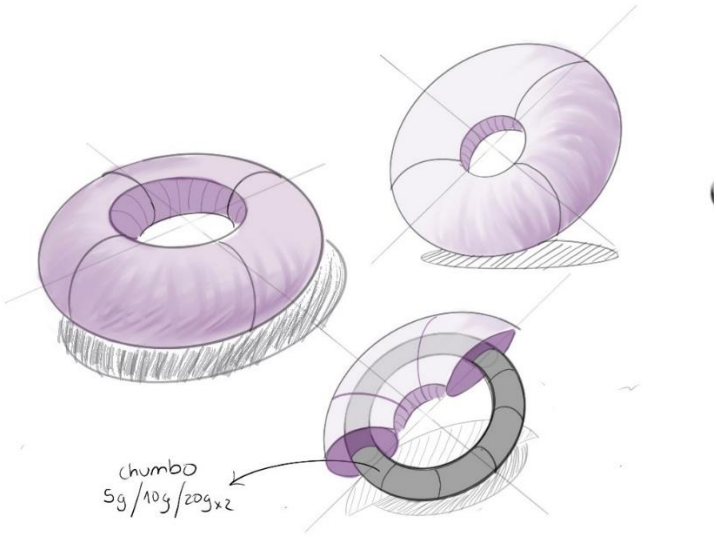


Figure 51- Concept 5: Ring weights

The ring weight would be lead coated with silicone, each ring representing a specific weight identifiable through its color, Figure 51. The silicone would give extra adherence to the rod, allowing the concept of stackable weights to function and expanding the number of weight levels the device can present. The concept was created to incorporate four weights, two of 20g, one of 10g, and one of 5g, Figure 52. Together they will provide the user with ten weight combinations (levels) with a maximum weight of 50g.

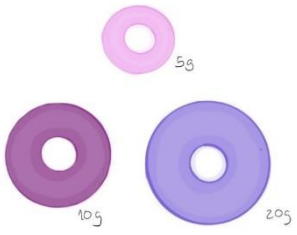


Figure 52-Ring weighs

Rod

Only two competitors presented similarities to the concept of the device, that similarity being only the rod. The rod only offers the function to visually indicate the correct contraction of the PFM, not being used to sustain resistance weight as in this case. Analyzing both rods from Kegel8 and Educator both presented different solutions. Kegel8 doesn't have a removable rod; instead uses an indicator clip to put the rod in the correct angulation for proper use. As for the Educator, this device presents a more attractive solution that allows the rod itself to be disassembled and to be disassembled from the intravaginal device.

Figure 53- Kegel8, indicator clip, adapted from "etspeaksfromhome" review

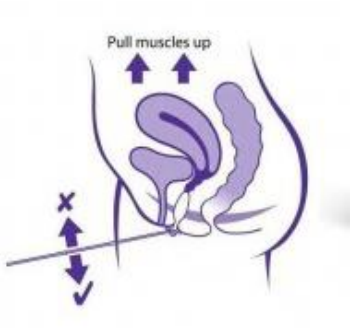


Figure 54- Educator rod function, adapted from Fisaude

Figure 55- Educator disassembled

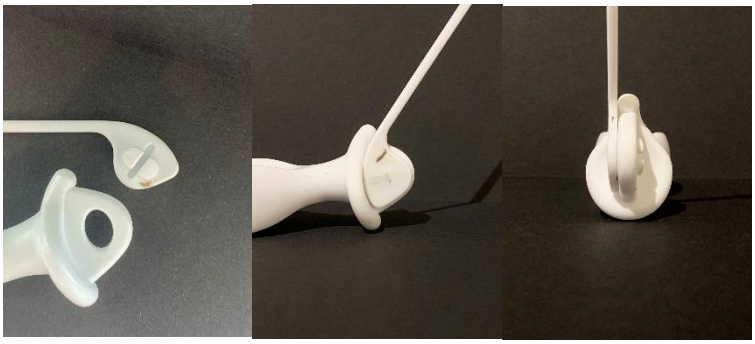


Figure 56- Educator joint between the rod and intravaginal device.

As shown in Figure 56, the Educator joints use a snap-fit joint; this type of joint is commonly used in polymer applications, as it allows the joint to be disassembled multiple times. There are several types of snap-fits adequate for this type of application. Some of its advantages are the ability to be disassembled, the insertion force being smaller than the pullout force, and can be easily printed in 3D machines (Serisier, 2017).

Figure 57- Assembled Educator

Figure 58- Zoom of snap fit joint of the rod

As shown in Figure 55, the rod can also be disassembled, but as was previously mentioned, the rod only has an educative function. If weight was applied at the rod's tip, the joints wouldn't hold the weight and would instantly disassemble.

After carefully analyzing existing market solutions, it was important to understand the physics and mechanical considerations the design should obey for the rod to work properly. The rod was previously tested several times to define its optimal length and angulation. It was also imperative that the gravity center in which the weights were located stayed the same. For that, a strict model for drawing was created where the design could freely change shape but maintaining these critical features, Figure 59.

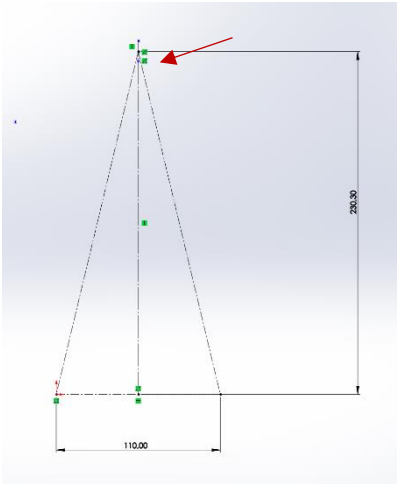


Figure 59- Drawing model for new design of the Rod, red arrow pointing to the gravity point where weights should be located.

Figure 60-Shapes study

From those drawings, several models emerge, as can be seen in Figure 60; from that, it was decided that the best models to follow through the prototyping phase were the ones with the more arched shape due to the rod proximity with the pubic bone. A more arched shape will better contour the female anatomy, Figure 61, avoiding any possible contact between them.

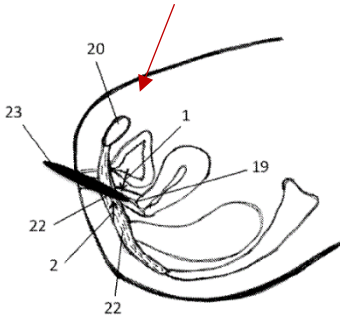


Figure 61- Relation of the intravaginal device and the public bone, pubic bone indicated by the red arrow (20).

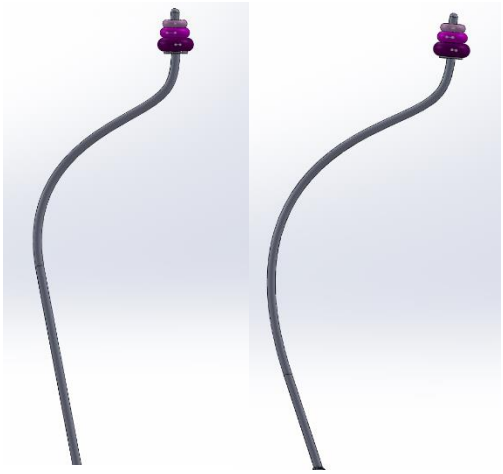


Figure 62- Chosen models to follow through prototyping.

Weight Supports

Weigh supports couldn't be design detached from the rod itself, but this concept emerged by not interfering internally with the rod and maintaining its vertical direction to the gravity center.

Figure 63- Drawings for Plate concept for supporting weights.

This plate-like concept will accommodate the rings with stability and provide a strong support structure for the weights to be lodged. As opposed to the other market solutions, this design allows users to visualize progress and quickly change weights during exercises.

Figure 64- 3D concept model of the supporting plate for the ring weights

Rod Joints

Before moving for the prototype phase of the rod, one more sub-problem still had to be met with a solution, the rod joints. By studying the solutions available in the market, it was decided that a similar approach would be made to this rod using a snap-fit joint. Snap-fit joints can have rounder or squarer indentations.

For the first prototyping, it was agreed to test a rounder concept, Figure 65. But by changing the joint of the rod, the cylindrical body now must incorporate a socket for the snap.

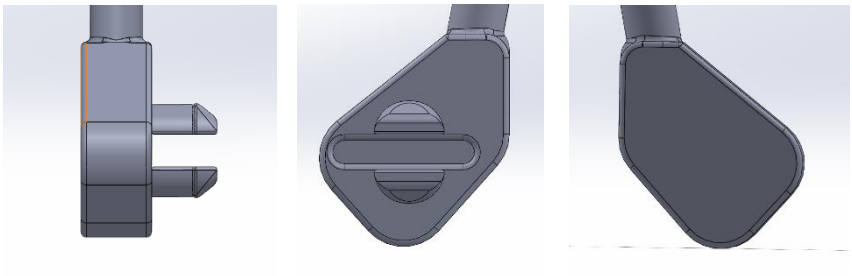


Figure 65- Different views from a 3D concept model Snap fit

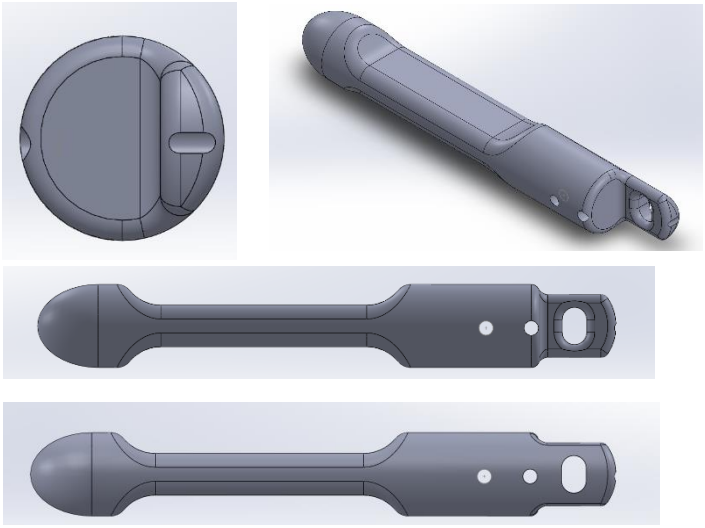


Figure 66- Different views from a 3D concept model of the snap-fit socket.

The socket was created through a negative space of the snap-fit (Figure 66).

Support

Enhancements to each component of the device were defined and discussed in the first meetings. The cross-pieces and the beams support system were the main components to create stability for all the other components to work properly (Figure 67 and Figure 68). Simplifying these structures was one of the main goals for the reduction of components and improving device transportation. This would simplify the device itself and would also be able to compete with simpler solutions already in the market of personal use PFMT devices.

As previously mentioned, this training method is entirely different from what is already in the market. Although some similar solutions were found to other components in this particular support system, there aren't any. The only reference to what the requirements were for the support to work correctly was the previous support system in the device.

As already was analyzed, the support consisted of two cross pieces that supported the device against the inner tights. So, it was considered designing a support system that had enough strength against the inner tights to avoid the sliding-off effect and avoid the device being toppled to its sides.

Figure 67- Supportive beams system

Figure 68- Cross-pieces, thighs support system

An imprint mold was created using air clay to better understand the shapes that would more organically adapt to the inner-tight area. Air clay is a super soft clay that can easily adapt to different shapes.

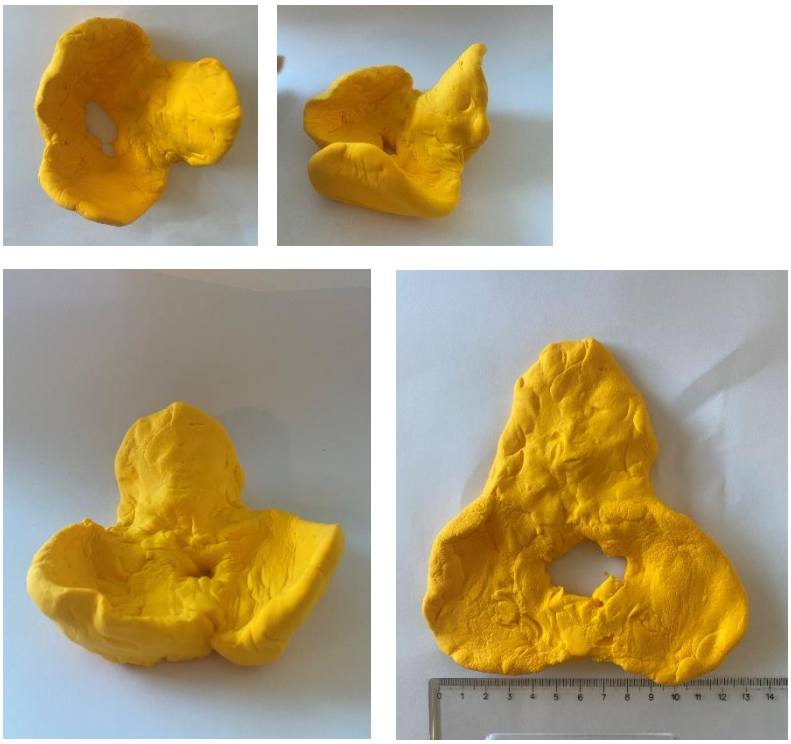


Figure 69- Air clay inner thighs imprint model. Different Views.

This model helped the ideate process by allowing several shapes to be extracted from it, and that would help to idealize and to sketch up new possible concepts for the support system. From this model were then extracted three shapes that led to 3 different concepts.

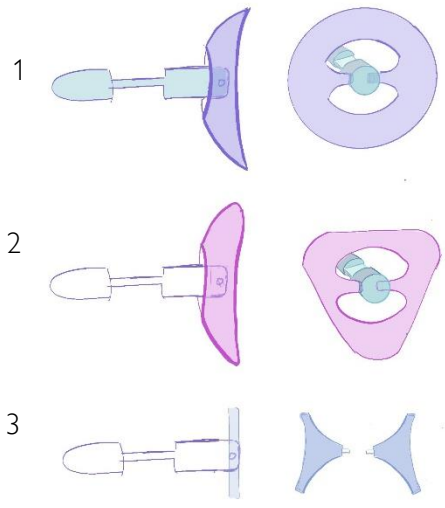


Figure 70-Three different shape concepts extracted from the air clay model. Concept 1, 3 and 3

This type of tool in design, called sketch modeling, is a powerful tool to explain a concept to the other work-group members. In cases such as this one, a 2D image may not be enough for the designer to express its ideas or concepts. That's where the next tool comes in. Mockups are an excellent tool to create quick and easy 3D concept models that make communication easier. So, three mockups were created, firstly in plasticine, but later in foam with an internal wire, which allowed the models to have similar material properties to their final material and similar shape to its sketch concept.

These three shaped concepts were to rely only upon material properties to create pressure around the intravaginal insertion point (vaginal canal). The pressure would be located in the inner thighs and crotch area; as for the joint between the support and the intravaginal device, the holes that were previously there for the previous support system would be adapted for this new one. This would create an axis allowing the device to move during the exercises.

Figure 71- Foam circular concept model 2. Different views.

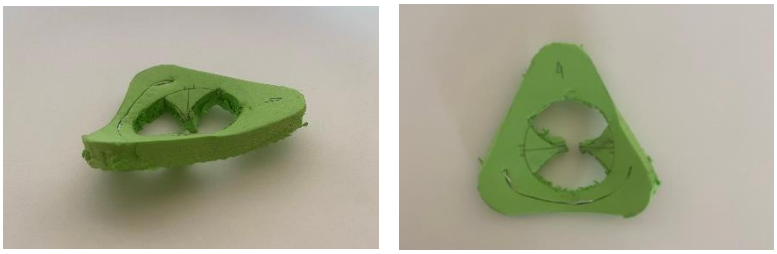


Figure 72- Foam triangular concept model 3. Different views.

In this Mockup stage, the third concept had already been abandoned due to its fragilities. After presenting both concept models, concerns about the material capability with some level of flexibility to withstand the device weight and the strength of the contractions start rising. So, a new solution that wouldn't rely solely on its material properties began being searched.

Given the difficulties of the first three concepts, a new solution was created. Although relying on the shape studies previously done, this new solution also incorporated a system that can be seen in several day-to-day products such as laundry hanging clamps, car keys, and paper clamps. This system would be composed of torsion springs that would work in a radial direction. Two concepts for the system were created, as can be seen in Figure 73. Both concepts presented two main parts, the central part, where the intravaginal device would be inserted and engaged, and the two side parts, with two silicone applications that would be placed against the inner tights section.

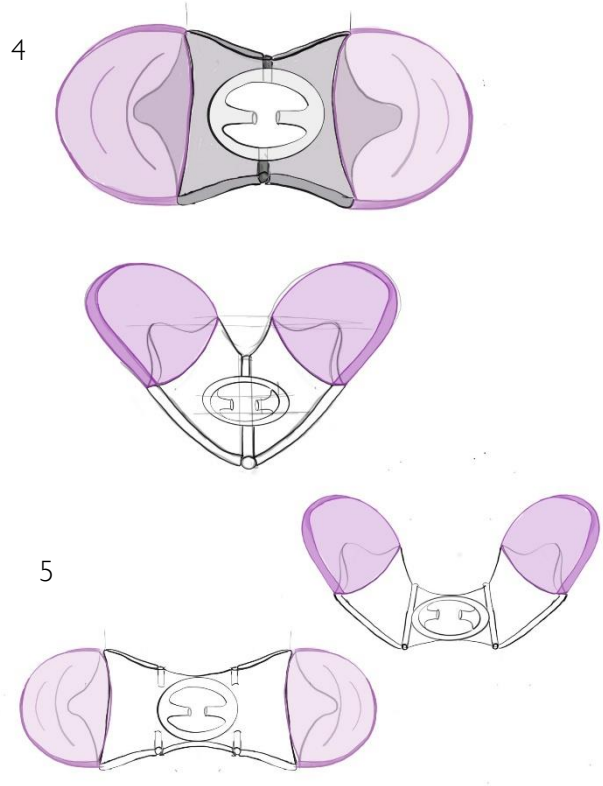


Figure 73-Support system concept 4 and 5

Equally, to what was done for the previous model, a mockup was created using foam and wire.

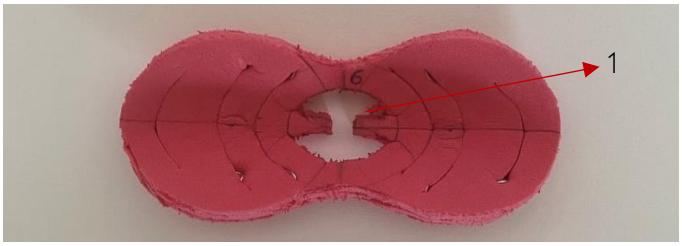


Figure 74-Foam mockup concept model 4, (1- insertion and engaging point of the intravaginal device).

The foam model helps the concept movement be more perceivable and for clearer communication during the discussion session. The mechanism would be similar to a laundry hanging clamp, but instead of the natural position of the spring being the clamp closed, it would be open. This would allow the pressure executed by the spring to go back to its natural position, creating support in the inner tights.

Figure 75-Natural state of the spring

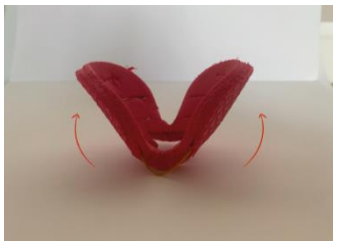


Figure 76-Support position when in contact with the inner thighs.

Although the concept seemed promising given the additional weight of the exercises, for the device to work as expected, the weight of the device itself plus the strength of the contractions, the solution would require several extra springs. However, that could also bring problems, such as the correct positioning of the support. The positioning would have been compromised due to the force of the springs pushing against the inner thighs.

It was then decided to use all that was learned from the previous concepts to create an adaptation that would be incorporated into an undergarment. This would create a strong support system for the solution and add user privacy during training.

The final concept for the support part uses cycling shorts as an inspiration, creating an adaptation of the foam they present in the pubic area. The goal was for that new concept to be able to engage the device and give the stability necessary for the users to execute the exercise without any of the previously detected problems.

Based on the concept studies of form previously done, the next shape emerges with an adaptation of the air clay and foam concepts.

This final concept would become the last idea discussed before advancing to the next phase. Considering how different the view was from all existing solutions in the market, the concept could be regarded as the "dark horse" and the "Funkie" prototype. The dark horse and "Funky" prototype are a concept presented in "The Design Thinking toolbox" by (Lewrick et al., 2020). The dark horse concept is defined in the book as the prototype that allows testing user reaction and reception to the possible product; as for the "Funkie" prototype, this prototype appears through the combination of the initial experiments and closes the exploration process.

So, to test user reaction, a blind survey was passed on to several women of all ages and backgrounds. The survey did not present any image or sketch as it could induce user answers, which could be vital for future considerations. This tool allows the workgroup to understand how the end-user would be open to the idea of a product like this and how receptive it would be.

In the surveys, user's response was positive, with around 90% of users saying they would buy or considered buying a device that would incorporate an undergarment. Furthermore, more than 90% thought they would feel less exposed in physiotherapy and domestic use contexts.

Note: The survey was written both in English and Portuguese, and full results can be consulted in Attachment 4.

Having found a possible viable solution to all components, the work team decided to move to the next phase.

3.5 Prototype, testing, and Assess phase

This next phase is one of the most critical phases in project development. This phase allows not just to give ideas a tangible and functional 3D model but also to identify possible issues that otherwise would not be detected or caught in later stages, making it more challenging to reassess and retest that solution.

In the initial phase, the main concern was resolving the support issue. Therefore, the first prototype to envision one of the solutions was the supporting component. This component was quickly prototyped by using a bra sponge and sawing a flexible O-ring with a similar diameter to the intravaginal device.

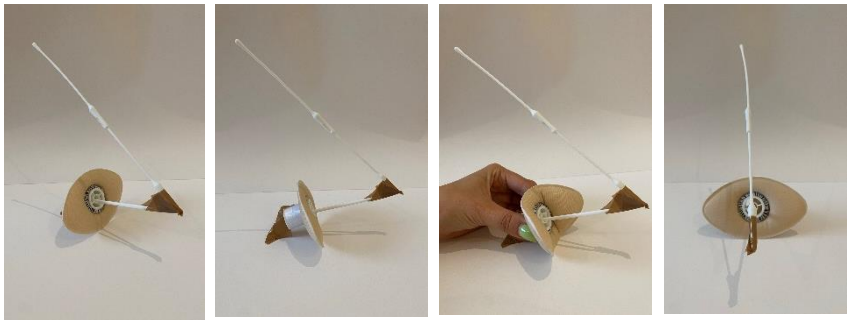


Figure 77- testing of concept 1 of the support part, different views.

Testing the support part with a similar shape and diameter object to see if the fitting was enough to be implemented in the undergarment, as shown in Figure 77. Although the O-ring was slightly smaller than the intravaginal device diameter, its material properties allow it to accommodate and secure it. The sponge flexibility was not compromised with the application of the O-ring. For testing purposes, the support part was inserted in a pair of shorts, not created by the author, only to be regarded as demonstrative and as support for the testing process.

Figure 78- Undergarment with support part 1 size small

In the first usability testing session, the shorts were tested in a young adult woman and an adult woman with all the previous components besides the cross-pieces and the supporting beams. Both tests gave positive feedback, presenting solid results in the toppled effect and sliding-off problem. With this new support, the rod, with or without any weight, stayed secured entirely.

Although the feedback was positive, the young woman did not present a significant movement of the rod, so it was not possible to perceive if the O-ring was constricting the device movement in any way. In the adult women tester, the rod movement was easily perceived, so to understand how the O-ring might affect the rod movement, further test with different women was necessary. This first testing raised the question, does the support system affects rod movement in women with weaker pelvic floor or smaller displacements?

For further testing, three more pairs of shorts were prototyped; now, two of the prototypes were size small, and two were medium size; each pair had two different O-ring diameters, as shown in Figure 79. This second testing phase would allow understanding of how the O-ring size influenced the rod movement and if a wider O-ring would improve that, and at the same time maintain its support capability.

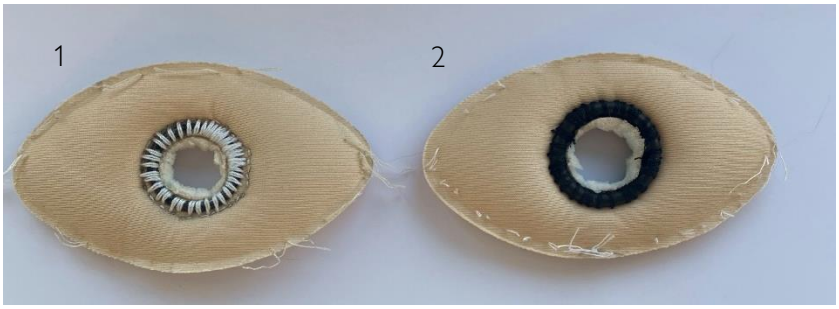


Figure 79-Second testing phase, comparison between the first and second O-ring size

Note: all shorts were washed between tests. The shorts were tested in two different colors, beige and black.

Even though two medium-size shorts were added to guarantee every volunteer had a size option, the shorts were of stretching material as they maximize the prototype's support effect and accommodate more body types.

This second phase was composed of volunteers who were asked to test the device in a realistic controlled physiotherapy environment. This type of testing allows the designer to see the users' interactions with the product in an anticipated form and harness vital information for its development. In this case, and due to the world's situation, with a global pandemic and limited capacity in interior spaces, the user trials were conducted by Dr. Alice Carvalhais. Dr. Alice Carvalhais would become an intermediate between user and designer; the volunteer's users also shared a relationship with the Intermediate as they were volunteers in the previous trials. Given the nature of these user trials, the intermediate relationship with users allowed the users to feel comfortable and safe in the testing environment.

Note: For register purposes, after all trials, a small interview was conducted and later transcribed. All interviews and user narration are detailed in Attachment 4.

The second testing phase results couldn't clarify if the smaller o-ring were effectively constricting the rod movement. Nevertheless, the tests were vital in understanding that stability could be compromised if the user used the wrong short size, as seen in the interview with subjects 1M and 1C, who tested concept 1.1. and 1.2 stated that they felt more movement freedom on the broader o-ring (1.2), but it could provide proper support than the small o-ring (1.1) provided. In another interview with subject 1L, the smaller o-ring proved again effective in its supporting session.

Therefore, the wider o-ring proved ineffective in providing enough strength to secure the device during exercises. The smaller o-ring still raised doubts about the movement constriction of the rod.

Reviewing both previous tests results, it was clear that the support needed to allow more movement freedom while providing the necessary support. For that, adaptations were made to the concept incorporating two snap points, which added an axis. The two snap points' addition permitted the device to rotate on that axis and still be secured.

Figure 80- Concept 1

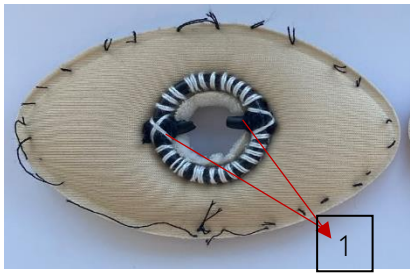


Figure 81- Concept 2, (1-inserted snaps)

Concept 2 used the same o-ring from concept 1.2 so that the intravaginal device had enough space to move freely.

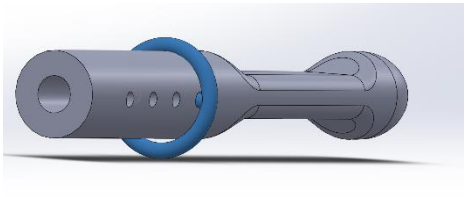


Figure 82- Intravaginal device and the concept 2

Note: Once more, two sizes of shorts were available with the new and old concept.

Figure 83- Testing model for concept 2

Figure 84- Zoom of the support o-ring

In this third stage of the testing phase, the volunteers had a comparative testing session between concepts 1.1, 1.2, and 2. It still wasn't visible if both these concepts were restricting in some manner the whole rod movement. For users, the rod moved freely, but the expertise of Dr. Alice Carvalhais on the matter and her previous contact with each subject showed her that with this concept, the movement wasn't entirely occurring, proving that the axis wasn't fully functional.

The axis in concept 2 wasn't as efficient as expected, so it was decided that new changes were going to be made in the axis emerging the Concept 3 that comes from both ideas of concepts 1.1 and 2. In this new concept, instead of the device rotating on the snaps, the o-ring of concept 1.1 would rotate in new incorporated lateral snaps that would engage in two lateral beams to create a new axis.

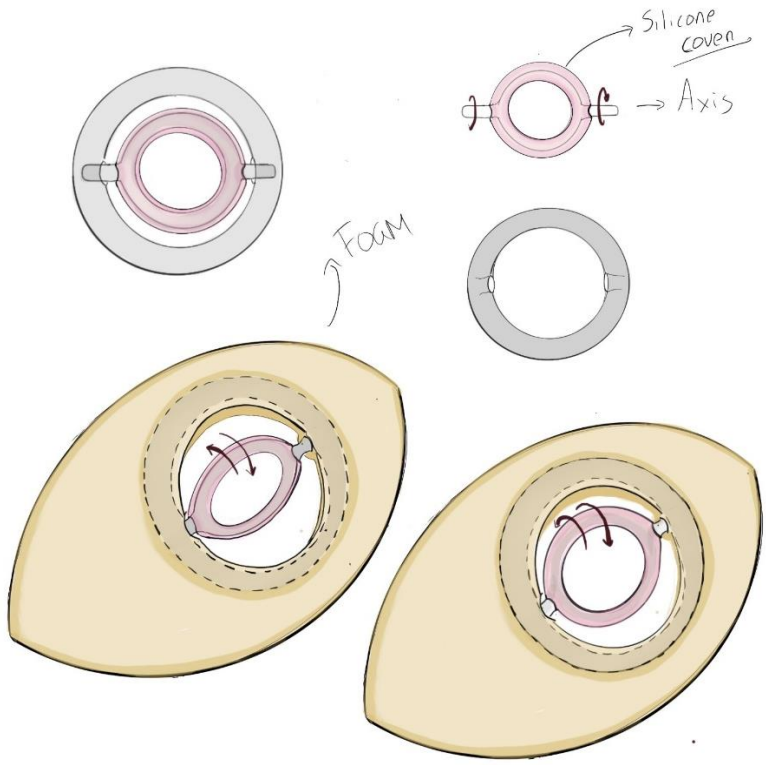


Figure 85-Concept 3 drawings

Figure 86- Sequential images of the concept 3 support prototype

The prototype was composed of two side beams inserted in the foam material and an o-ring joint with two lateral hollow joints. The solution for the rod to have freedom of movement was attained by changing the axis to the lateral part of the support. As previous test results proved, the o-ring used in concept 1 was the best diameter to give the proper stability for exercises. Therefore, this concept gave freedom of movement through the axis and support through the o-ring structure.

Figure 87- Final support concept disassembled

Figure 88- O-ring movement

Incorporation of the support part 3 in the testing shorts:

Figure 89- Testing prototype 3

The results for this final testing phase were positive. The support allowed the rod to move freely and performed its supportive function at the same type.

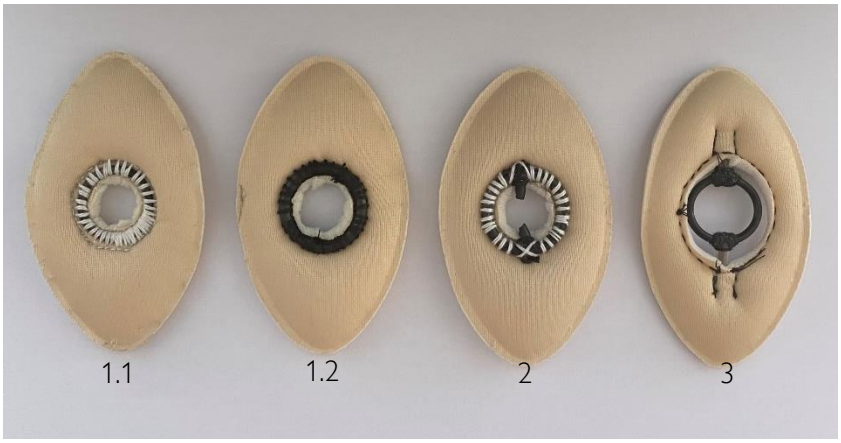


Figure 90-Concept evolution from prototype 1.1 to prototype 3

All four concepts have been through several evaluation processes, where different volunteers tested the support part. Throughout the whole process, volunteers helped identify problems that needed reassessment. All these design redesign cycles culminated in the final support concept.

During the evaluation process, the volunteers were also asked to give their opinions on the most significant improvement from the previous model to the new one. All eight volunteers were unanimous that the most significant improvement was introducing the support system in the undergarment. The volunteers considered the new support much easier to use and carry, but the undergarment's comfort during training sessions was the most valued improvement.

A reflection of that feedback are the testimonies below:

"The shorts give great comfort in the sense of the exposure"- subject 1A

"I can be more comfortable because I´m dressed"- Subject 1G

"Simple and practical (…) more comfortable and more intimate"- Subject 1M

"it would be a great advantage as more women could be doing the exercises together because the person would feel completely covered!"- Subject 1I

"I think the beams complicated..."- 1I

After gathering positive feedback from both the surveys and the volunteers on the support solution and finding a viable functioning solution, the workgroup decided to start the prototyping phases for the other components.

Rod and intravaginal device prototyping phase

As defined in the *"Ideate"* phase 2, shapes would move to this phase and generate two functional prototypes. The literature revision specifies that the device should be made of rigid material, so the prototypes used materials with similar specifications. Before testing the entire resolved rod with the joint designed, it was decided to create just a functional prototype with the new shape and weight system. This allowed the workgroup to determine which of the shapes would best fit with the angulation of the intravaginal device.

Figure 91- Shape 1 prototype

Figure 92 -Shape 2 prototype

As shown in Figure 91 and Figure 92, both present an arched shape; the main difference is the point where that arch is initiated. Analyzing the relative location of both rod shapes, in relation to the intravaginal device and the pubic bone, it was agreed that the best shape would be the second one. During the testing phases of the support component, it was also discovered that the intravaginal device was considered too big and consequently not clear enough until what point was the correct insertion. It was then decided before testing the new rod and weight support system to reduce the length of the rod.

Figure 93- Functional prototype of new rod shape and weight support system.

No functional problem was found when both subjects 1I and 1A tested the rod or new length of the intravaginal device. However, Dr. Alice Carvalhais thought about some modifications for the intravaginal device to make its insertion more comfortable. Therefore, the device adopts more soft lines between the flatter area and the insertion tip, resembling more the natural lines of the human finger, allowing the device to be more easily inserted inside the vaginal canal.

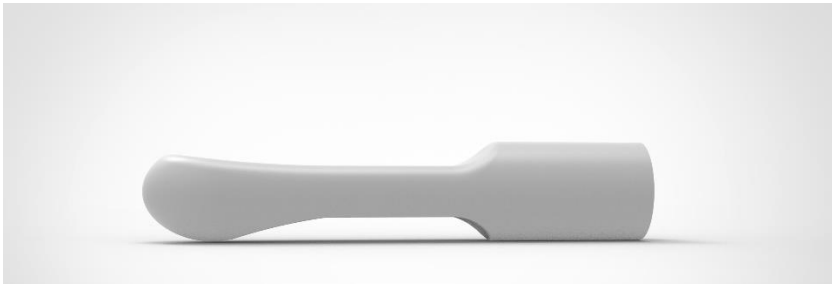


Figure 94-Intravaginal device 3

After addressing the functionality of the chosen shape and support system, the project moved to incorporate the next component, the rod joint. For prototyping the entire rod, rapid prototyping method was used. This method was chosen as it allows translating CAD models into physically detailed models using 3D printing technologies. The rod joint presents specific functional details and material properties that need to be tested.

Figure 95- Full rod prototype

Figure 96- Rod Joint lateral view

Figure 97- Rod joint prototype front view

After printing the rod joint and rod, some concerns were raised by Dr. Renato Natal Jorge. The concerns were with the rod thickness, which seemed to be thin and fragile; the flexibility of the indentations in the joint snap-fit system; and the ability of the round snap-fit not to rotate in the intravaginal engaging hole. The intravaginal device for that snap-fit concept was never printed due to the concerns raised after 3D printing the first rod.

It was then discussed a redesign of the rod joint into a geometric form that would remove those concerns; regarding the rod, 3D printing in a different material was tested to see if the thickness was effectively fragile or just a problem with the material in which it was printed. Two new snap-fit indentations were designed to see which would work best.

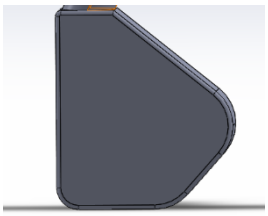


Figure 98-Lateral view

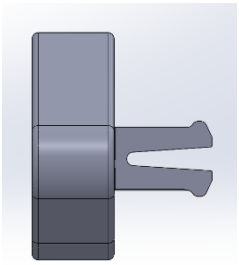


Figure 99- Indentation model 2

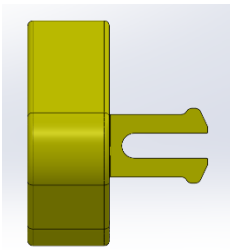


Figure 100- Indentation model 3

For testing the functionality of the snap-fit, the intravaginal device with an engaging hole was also printed.

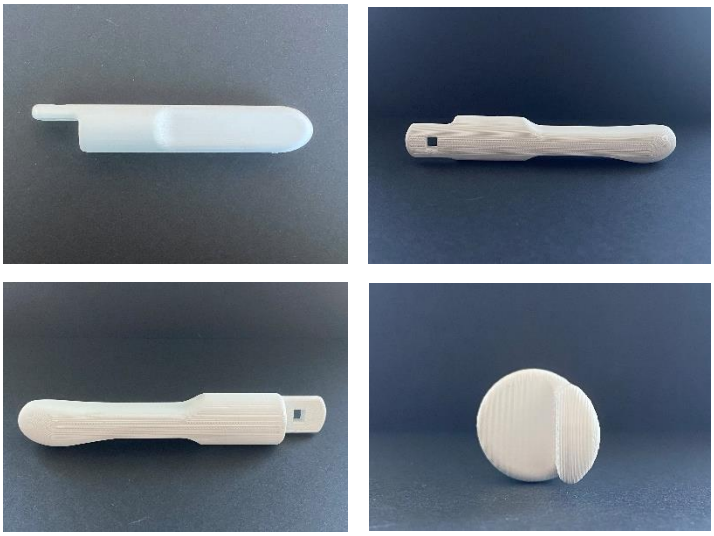


Figure 101- New intravaginal model, with engaging hole for the snap-fit 2 and 3

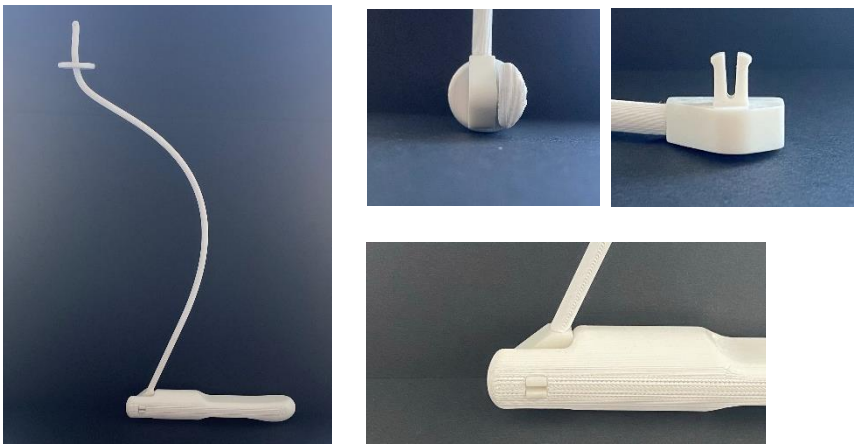


Figure 102- Prototype 3, snap-fit 2

Figure 103-- Prototype 3, snap-fit 3

Between the two snap-fits, snap-fit 2 showed the best flexibility, although as shown in both Figure 102 and Figure 103, the rod was printed backward but did not affect the testing of the snap-fits. However, the rod still presented the same fragility and instability due to its thin thickness.

Now knowing which snap-fit indentations worked better, adaptations could be made to increase the rod thickness. These adaptations meant that the piece that was accommodating the snap-fit indentation had to be enlarged. Because the rod must stay centered with the intravaginal device, if the rod was to broaden its thickness, it would be much more difficult to still provide the engagement hole in the device, as shown in Figure 104.

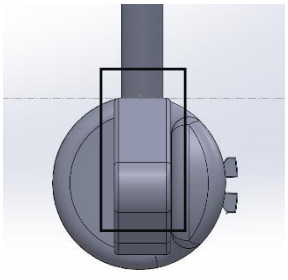


Figure 104- Simulation of a larger joint piece

A new concept surges to meet the criteria mentioned before. This concept moves the indentations of the snap-fit to the base of the intravaginal device and the engaging hole to the rod's base.

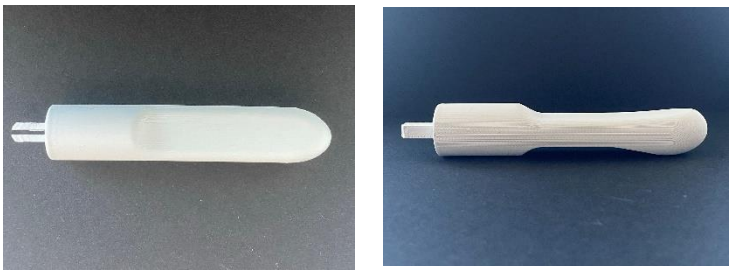


Figure 105- New intravaginal device with snap-fit indentations

One of the disadvantages of having the indentations longer is that they become more fragile and at risk of getting broken. To avoid that risk, a protection cap was created.

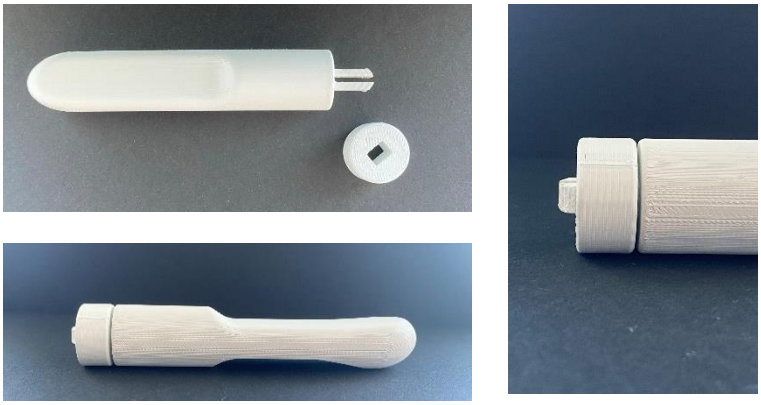


Figure 106- Protection cap and intravaginal device.

As for the rod, the new adaptations allow it to broaden its thickness to make it more stable and less fragile.

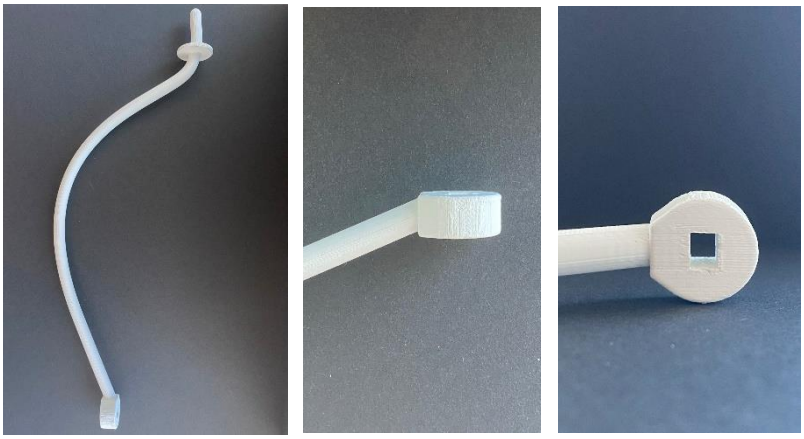


Figure 107-New rod and engaging hole joint.

Figure 108- Joint and intravaginal device evolution

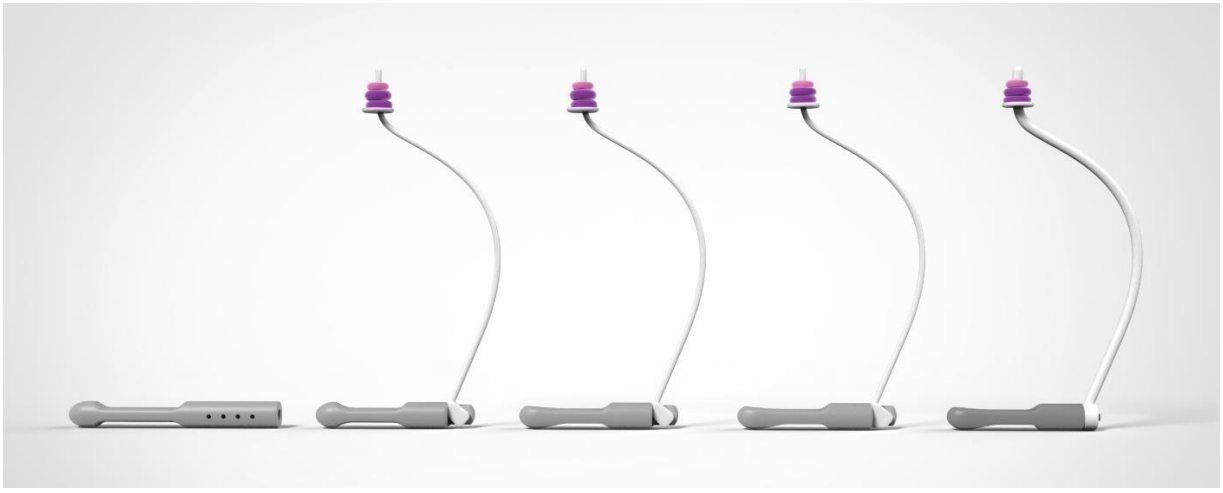


Figure 109- Full concept evolution

Final Full Concept prototype

After going through several design redesign processes, the final prototype surges with all components working in sync.

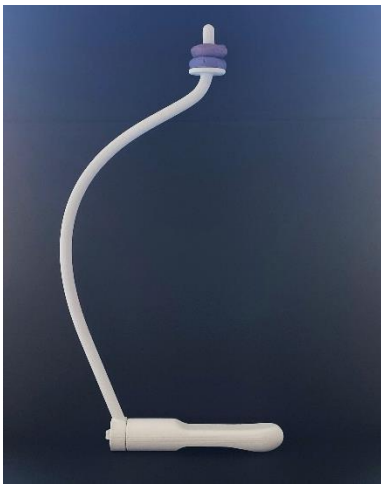


Figure 110-Assembled final prototype

Figure 111- Pelvic Floor exercising kit, final prototypes

Looking at the comparison between previous complete concept prototypes and the new functional prototype as shown in Figure 112 and Figure 113, it is clear significant reduction of components was achieved during this dissertation by implementing the newly developed solutions.

Figure 112- Previous functional prototype.

Figure 113- New functional prototype.

3.7 Aesthetic Considerations

Color is often wrongly considered only an aesthetic aspect, but it is much more than that. A color is a powerful tool that can help communication between product and user. The color itself can serve as an indicator of correct usage and correct usage steps. Throughout the whole testing and prototype phases, the workgroup was able to rely on user trials to help during project development and study usage patterns and ultimately desire lines. But these two tools can give much more than just the natural intuitive way people will interact with the product. It can also emphasize what will be the most common errors during its usage.

One of the most common errors observed during the whole development phase was the difficulty in understanding the correct way to assemble the rod with the intravaginal device. Its assembly was often done backward; And also, after the final modifications on the intravaginal device, understanding what its top and bottom side were.

The user's difficulty with the assembly of the product was overcome with two marks of color. The marks were placed in the rod and on top of the intravaginal device. This allowed the user to intuitively understand that, if the marks match, the assembly was correctly done. The color used was a light pink similar to the colors presented in the weights. Pink is often related to femininity, but it is also a warm color commonly associated with positive and calming emotions (Adams, 2017).

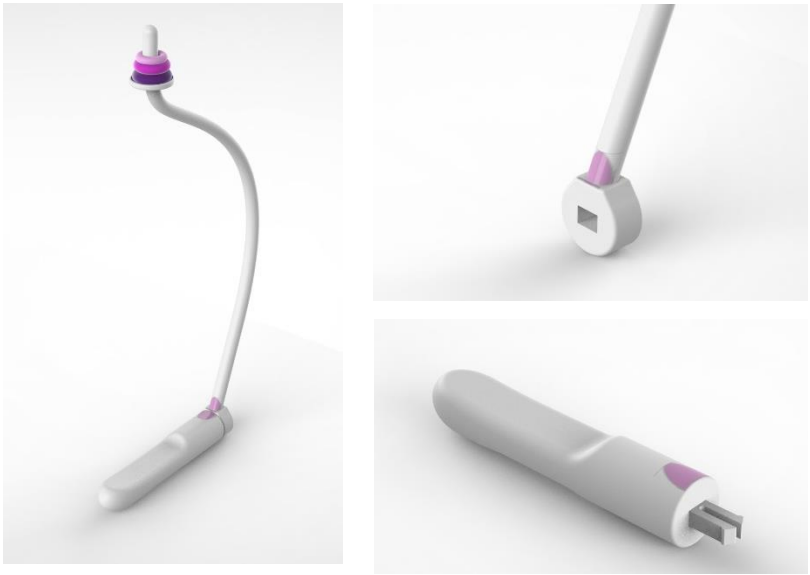


Figure 114- Correct assembly indicators

Most of the product is absent of color, except for the weights. It was decided to be left in white color as this product will be used in physiotherapy sessions, and it is important to transmit a sense of cleanness to the user. White is often used in sterilized environments, and as previously reviewed in chapter 2, most rehabilitating products opt to combine neutral colors with brighter ones in the literature revision. So, it was decided to leave all color representation on the exercise's weights, which would also help to indicate their correct usage steps.

Figure 115- Usage of a color gradient to indicate correct usage steps.

As shown in Figure 115, the gradient of colors allows the user to understand that the darker colors will represent the heaviest weight and the lighter colors, the lighter weights. This color usage allows the user to comprehend the correct usage pattern from lighter to heavier intuitively. It was also considered that colors might be difficult to see for people who suffer from color blindness. Still, even though color blind people might not be able to identify which color it is, they will understand their difference through luminance and hue contrast (Seungji & Yong Man, 2003; Van Beveren, 2021). So, three colors with significant luminance contrast were selected.

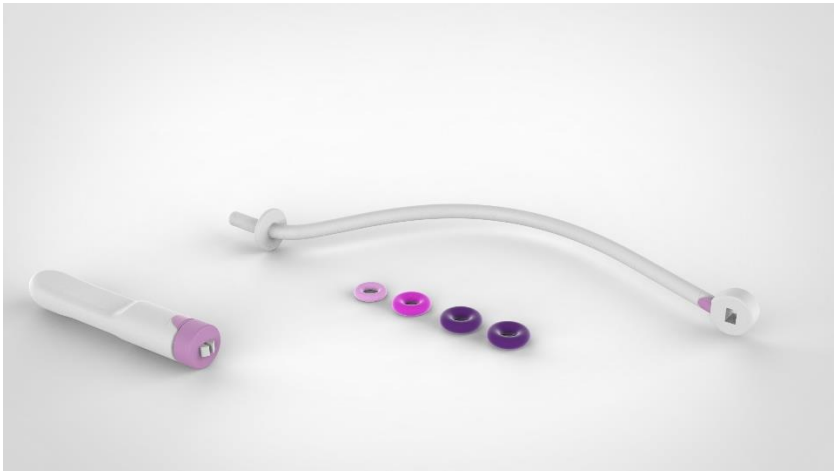
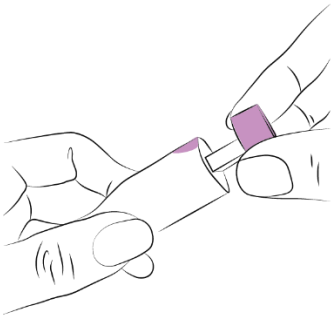


Figure 116- Pelvic floor muscle training Kit, rendered

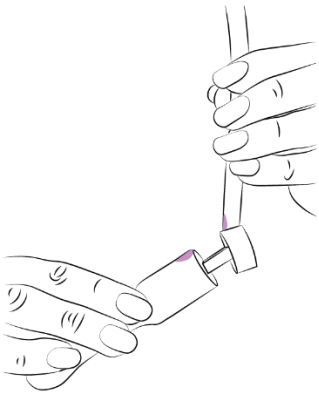
3.7- Device instructions

1- Dress the undergarment.

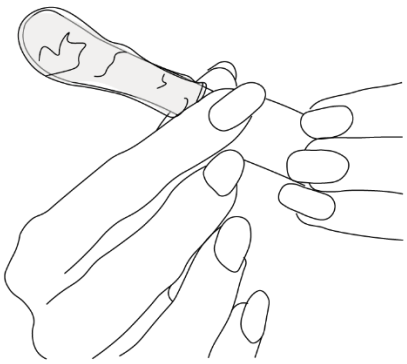
2- Take the protection cap off.



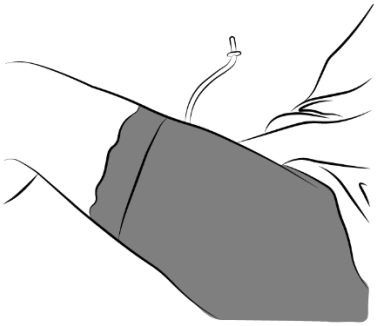
3- Connect the intravaginal device and the rod.



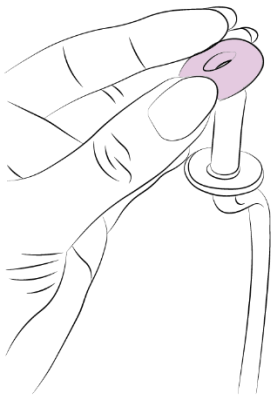
4- Insert the condom.



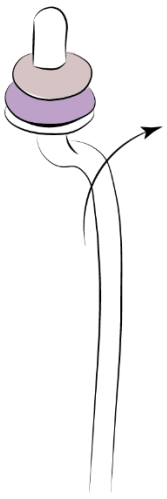
5- Insert the intravaginal device with the rod.



6- Insert weights in its support.



7- Exercise correct movement.



*When in Physiotherapy context

Chapter 4-Conclusion

4.1 Conclusion

This dissertation takes over the redesign of a pelvic floor muscle training device for an ongoing project at the University of Porto.

The project started with a brief analysis of the female pelvic cavity anatomy and pelvic floor disorders, which allowed all involved to be acquainted with concepts and terms and the current situation regarding conservative treatments. This review allowed easier communication between all involved in the workgroup and proved helpful during the development of solutions for the project. Also, in this first project phase, the market research that was conducted provided vital intel on the market preferences and proved very helpful in understanding what solutions were being used by other devices that could be used or implemented in this project.

As could be seen in the project development chapter, mockups and prototypes were one of the most important tools to allow the workgroup to analyze and detect errors; other than these tools, testing was fundamental. But it's essential to consider the situation in which this dissertation was developed, the ongoing global pandemic affected people's freedom to socialize and gather together, which resulted in restrictions within public and closed spaces. The use of tools such as surveys helped overcome those limitations. For this project, it was defined that the testing would occur with limited people in the room, naming Dr. Alice Carvalhais the intermediate between user and designer. These tests were conducted only on volunteer users, who also agreed to record an interview at the end of every testing session. In this way, despite the whole project team not being present, communication between user and designer existed indirectly.

During the testing phase, several conclusions could be made of the device:

- That the new support system, other than its supporting function, also corrected the device positioning inside the women, but further testing may be necessary to validate this affirmation thoroughly.
- The previous intravaginal device's size and shape weren't the most appropriate and, therefore, was also redesigned during this dissertation's development.
- All testers agreed that using an undergarment was one of the most valuable improvements from the previous device.
- The newly adapted weight system was more stable than the previous one.

In conclusion, finding a new solution for each sub-problem ultimately reduced the number of components from eleven parts plus external weights to four parts plus four weights and improved the transportation of the device. Therefore, all goals defined at the beginning of the project were met.

4.2 Future works recommendations:

- Development of a specific undergarment to incorporate the support developed. Information gathered on the surveys may be helpful in its development
- Addition of a quantifying mechanism for the rod movement.
- Development of an app for progress monitoring, exercise catalog, games, and instruction manual.
- Despite the achieved enhancement of the support system, this could still be further developed into more final prototypes.
- Conduct a study on which medical-grade polymer works best for the specific mechanical considerations of the project.
- Conduct more detailed and extensive studies.

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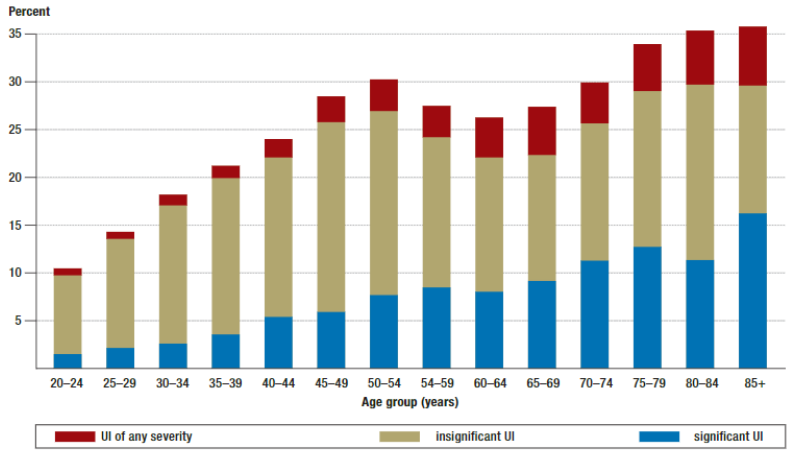
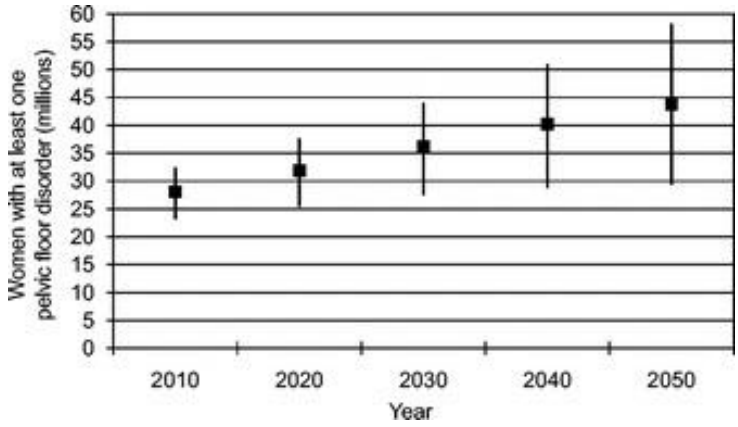
Attachments

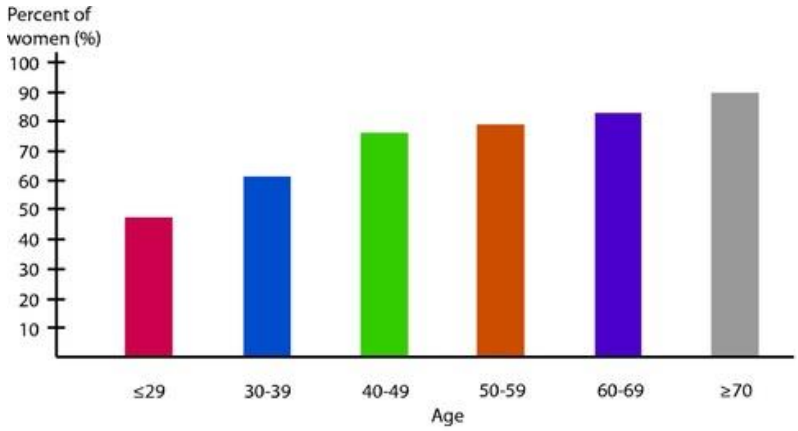
Attachment 1-Prevalence of Urinary Incontinence in Women



Graphic 6- Prevalence and significance of urinary incontinence in women by ages, Source: (Jundt et al., 2015)



Graphic 7- Forecasting and prevalence of pelvic floor dysfunctions in women (US). Source: (Jennifer M Wu et al., 2009)



Graphic 8- Prevalence of Pelvic Floor Disorders by age in women. Source: (Kepenekci et al., 2011)

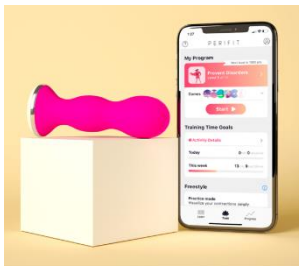
Attachment 2- Comparative study Market research

Table 16- Comparative Market research (underlined products explored in the dissertation)

Product Name	Brand/ Manufacturer	Dimensions (mm) heigh,width,legth	Base Material	Waterproff	Components	Number of components	Color	resorts to app support	Concept	Transportation aside packaging	levels of exercises	Biofeedback	Price	price in euros
Elvie	Chiaro	80x35x30 mm	Medical Grade Silicone	yes	charger, box, device		3 mint	yes	Kegel exercise, no extra weights (contractions)	plastic box	4 levels in the app	through the app	199	199,00 €
Kegoal	Minna Life	N/D	100% phthalate-free and Class VI medical grade silicone	yes	device,charger		2 Sky Blue	yes	Kegel exercise, no extra weights (contractions)	none	multiple levels on app	through the app, tactil feedback	149 $	126,27 €
Kegg Keagle Ball	Lady Technologies	N/D	old-plated stainless steel, medical-grade silicone	N/D	device,charger,box		3 white, gold	yes but as a guide	Kegel exercise , no extra weights fertility tracker (hold in)	plastic box	1 level	vibration	275 $	233,05 €
Venus Balls	Whoop.de.doo	N/D	Czech glass,hypoallergenic medical-grade silicone	yes	balls,bag		2 white,red,black	no	kegel exercise, vibration stymulation (hold in)	SWISSCOTTON bag	3 levels,each device different weigh	none	per balls 89	89,00 €
Pericfit	Pericfit	N/D	medical grade silicone	yes	device,charger		2 Pink, mint	yes	kegel exercise, no extra weights (contractions)	none	multiple levels(games,exercises	through the app	199 $	192,68 €
Educator	Neen	N/D	N/D	yes	device,wand		2 white	no	Kegel exercise (contractions)	none	1 level	visual	33 $	27,96 €
Aquaflex cones	Neen	Small cone- 60mm x 22m Large cone-60mm x 26mm	N/D	yes	two cones, 4 weights of (5g, 10g, 20g, 25g) , box		2 white, mint	no	kegel with weights (hold in)	plastic box	weights combinations	none	33,99 £	36,23 €
Kegel8	Kegel8	length 170mm insertable lenght 80 mm diameters 27,29,32 mm	medical grade silicone, Santoprene	yes	device		1 gradient of blue	yes , guide only	kegel with weights (hold in)	none	3 levels, each device different weigh,	visual	29,99 £	35,06 €
Kegel1Smart	Intimina	N/D	medical grade silicone	yes	device		1 pink	no	kegel with vibration (contractions)	none	cotina de exercicios	vibration	73,19	73,39 €
Intimich pelvic health II	Intimich	34 mm x 120 mm Peso 60 gr , 34 mm x 168 mm Peso 120 gr, 35 mm x 175 mm Peso 115gr	medical grade silicone	yes	devices (60,120,115 g), bag		3 pink	no	kegel with weights (hold in)	satin bag	3 levels	none	170,76	170,76 €
Intimichic Pelvis Health 1.2.0	Intimich	22 mm peso 35g, 18 mm peso 20g, 15 mm 10g, 10 mm peso 5g	medical grade silicone	yes	cone 15g , weights (5g, 10g, 20g, 25g) , bag		pink, available in light purple	no	kegel with weights (hold in)	fabric bag	5 levels	none	24,75	24,75 €
JE JOUE	Ami	147 mm/160 mm/115 mm , diameters 29 mm/34 mm/ 39 mm	medical grade silicone	yes	3 kegel balls		purple, Available in pink and black	no	kegel with weights (hold in)	none	3 levels	none	72,57	72,57 €
Utopia	Calexotics	93 mm x 38mm , 81mm x 33mm, 50 mm x 33mm	medical grade silicone	yes	3 sets of kegal balls (45g,60g,80g), bag		6 pink	no	kegel with weights (hold in)	fabric bag	3 levels	none	N/D	N/D
Bolas Ben Wa	N/D	171 mm lengh, 46mm with	medical grade silicone	yes	6 balls , (39.6g, 59.5g, 79 .3g, 90.7g, 119g, 138.9g), bag, two adaptors		6 black to of pink gradient	no	kegel with weights (hold in)	velvet bag	6 levels	none	30,99$	26,16 €
Pelvic weight set	Pixie Cup	N/D	medical grade silicone	yes	6 devices , (45g, 60g, 75g, 90g, 105g, 120g)		white, yellow,orange,green,da rk blue,black	yes but as a guide	kegel with wheights (hold in)	none	6 levels	none	39,95 $	33,73 €
Pelvic floor exercise weights	Kegel	N/D	medical grade silicone	yes	6 devices, (30g, 40g, 50g, 70g, 105g, 130g), bag		7 blue to green gradient	yes as a guide	kegel with weights (hold in)	bag	6 levels	none	29.99 $	25,32 €
Kegel weights	Lpy on	30 mm diameter	medical grade silicone	yes	7 devices(25g, 40g, 60g, 80, 100g, 125g,150g ,) bags		8 white to red gradient	yes, monitoring process	kegel with weights (hol in)	bag for 1 , bag for all the rest	7 levels	none	34,99 $	29,54 €
Kegel exercise system	Intimate Rose	152.4 mm x 50.8 mm x 101.6mm	medical grade silicone	yes	6 devices , (25g, 40g, 60g, 85g, 105g, 125g)		6 white to purple gradient	no	kegel with weights (hold in)	none	6 levels	none	49,99 $	42,21 €
kegel	Lpy on	210mm x 33 mm x 33 mm	medical grade silicone	yes	device, bag, cable USB		1 pink	yes, exercises and games	kegel without weights (contractions)	bag	multiple levesl (games and exercises)	through the app	49,99 $	42,21 €
Kegel Balls	Abandship	172.72 mm x 35,56 mm x 35,56 mm	medical grade silicone	yes	3 device, (30g, 45,35g, 102.05g), charger, emote		5 pink , purple	no	kegel with weights, vibration (hold in)	none	3 levels of weights	none	29.99 $	25,42 €
kegels balls	Al'ofa	210 mm x 139,9 mm x 55.1 mm	medical grade silicone	yes	4 devices 55g, 75g, 100g, 60g, remote, charger		gradient from white to pink	no	kegg with weights	none	4 levels of weights	none	39,99 $	36,23 €
Kegel	Better Angel YC	150.11 mm x 130,05mm x 39,87mm	medical grade silicone	yes	device , batterys		2 black	yes, monitoring and games	kegel without (contractions)	none	multiple levels(games)	through the app	48,99 $	41,36 €
Kegel	Sensua	167.89mm x 135.89mm x 43,9mm	medical grade silicone	yes	4 devices (45.36g, 88g, 102g, 66.3g), Charger		5 pink	no	kegel with weights	none	4 levels	none	31,995	27,01 €
kegel exercise Balls	Man Nuo	N/D	medical grade silicone	yes	8 devices, (30g, 45g, 65g, 85g, 95g, 105g, 115g, 125g)		8 pink to red gradient	no	kegel with weights (hold in)	none	8 levels	none	23,09 $	19,49 €
Kgel	Folove	140mm x 65mm x 35 mm	medical grade silicone	yes	device,charger,bag		3 pink	yes	kegel without weights (contractions	none	1 level	N/D	76,99 $	65,00 €
kegel balls	Al'ofa	120mm x32mm	medicalgrade silicone	yes	2 devices, 2 remotes, charger		5 purple and light pink	no	kegel with weights (hold in), vibrations	none	2 levels	none	20,64 $	17,43 €
Kegel Balls	Lovemmy	183 mm x 35 mm	medical grade silicone	yes	device, remote, charger		1 purple	no	kegel without weights (contractions), vibration	none	1 level	none	19,99 $	16,88 €
Kegel Master	Kegel Master	overal lenght: 167,64 mm, insertable lenght: 74,93mm, width of insertable section: 26,32 mm	medical grade stainless steel stainless steel with zinc electroplating	yes	device,8 springs, bag		10 blue	no	kegel with progressive resistance	fabric bag	15 levels of spring combinations	none	129,95 $	109,56 €
Super Kegel	Ntoales	241,3 mm x 152,4 x 101,6 mm	ABS	N/D	device, exercise charts		2 blue	no	external kegel	none	1 level	none	19,99 £	16,86 €
Epi-No	Epi-No	N/D	medical grade silicone	yes	device, lub		2 blue	no	Kegel exercises with a pressurized balloon and a pressure display handle	none	multiple levels (different pressures)	visual, through the pressure display	120,88	120,88 €
Kegel Pro	Grizabs	N/D	N/D	yes	device,bag		2 white	no	kegel without weights	fabric bag	1 level	none	47,995	40,46 €
Sensa tone	body clock	120mm x 30mm x 15 mm	N/D	N/D	device, bag , cable, batterys		4 white	no	mild electrical pulses through the pelvic floor muscles	fabric bag	multiple levels of electronic stimulation for each dysfunction	none	€53,96	63,18 €
Gyneflex	N/D	N/D	Medical grade polymer	yes	device, exercise manual		2 pink	no	resistance kegel exercise	none	1 level	none	N/D	N/D
Natratone	Natratone	N/D	Medical grade Polycarbonate	yes	device, box		2 white	no	kegekl without weights	box	1 level	none	109.99 $	92,72 €
Vivi stimulator	Aneros	length 139.7 mm insertable Length 63.5 mm	medical garde silicone	yes	device, charger		2 red	yes	pelvic floor stimulation through vibration	none	12 vibration paterns	none	110,01	110,01 €
Laielle	Intimina	N/D	medical grade silicone	yes	balls (28g,38g, 48g)		1 pink	no	kegel with weights	none	1 available devices	none	12,5	12,50 €
Nova Ball	Svakom	Single Ball : Ø36X135 mm Double Ball (big): Ø32X170 mm Double Ball (small): Ø28X162 mm	medical grade silicone metal balls	yes	3 sets of balls (43g 75g 95g), bag		4 pink, violet, green	no	kegel with weights	Fabric bag	3 levels	none	595	49,76 €
Taxa de cambio a 13/07/21 USD= 1,1815 euros GBP=0,8540 euros	a 13/07/21 fonte:Morningstar	morningstar.pt/pt/	N/D - non disclosed											

2.1-Representative images of the competitor products analysis

Table 17- Representative images of the competitor analysis

1-Elvie 	5-Perifit 	9-AquaFlex cones 
2-Kgoal 	6-Educator 	10-Intimichic Pelvis Health II 
3-Kegg Keagle Balls 	7-Kegel8 	11-Intimichic Pelvis Health I 2.0 
4-Venus Balls 	8-KegelSmart 	12-JE JOUL 

13-Utopia 	17-Kegel weights 	21-Kegel balls (Al'ofa) 
14-Bolas Bem Wa 	18-Kegel Exercise system 	22-Kegel (Better Angel YC) 
15-Pelvic wight set 	19-Kegel 	23-Kegel (Sensua) 
16-Pelvic Floor exercise weights 	20-Kegel Balls 	24-Kegel exercise balls 

25-Kgel 	29-Super Kegel 	33-Gyneflex 
26-Kegel balls (al'ofa) 	30-Epi-No 	34-Natratone 
27-Kegel Balls (Lovemmy) 	31-Kegel pro 	35-Vivi Stimulator 
28-Kegelmaster 	32-Sensa Tone 	36-Laselle 

37-Nova Ball

2.2-Webgrafia images and Market Research

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40. https://mysecretluxury.com/aneros-vivi-kegel-exerciser (accessed in 12/07/21)
41. https://www.intimina.com/laselle?utm_source=TnL5HPStwNw&utm_medium=Linkshare_cps&utm_campaign=433030&utm_content=10&ranMID=41390&ranEAID=TnL5HPStwNw&ranSiteID=TnL5HPStwNwgzK4mpKgo6S_AZPMQqfSdQ;
https://www.intimina.com/laselle?utm_source=TnL5HPStwNw&utm_medium=Linkshare_cps&utm_campaign=433030&utm_content=10&ranMID=41390&ranEAID=TnL5HPStwNw&ranSiteID=TnL5HPStwNw-gzK4mpKgo6S_AZPMQqfSdQ (accessed in 12/07/21)
https://www.intimina.com/laselle?utm_source=TnL5HPStwNw&utm_medium=Linkshare_cps&utm_campaign=433030&utm_content=10&ranMID=41390&ranEAID=TnL5HPStwNw&ranSiteID=TnL5HPStwNw-gzK4mpKgo6S_AZPMQqfSdQ%20%20acedido%20a%2012/07/21 (accessed in 19/08/21)
42. https://www.svakom.net/Nova (accessed in 12/07/21)

Attachment 3- Surveys Results

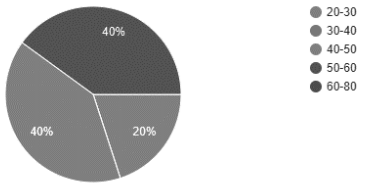
3.1-Survey 1 "A sua experiência com o dispositivo de treino dos músculos do pavimento pélvico"

Answered in Portuguese.

Introduction: Questionário no âmbito da usabilidade e experiência do utilizador com o dispositivo de treino dos Músculos do Pavimento Pélvico desenvolvido pela Prof. Alice Carvalhais e pelo Prof, Renato Natal Jorge.

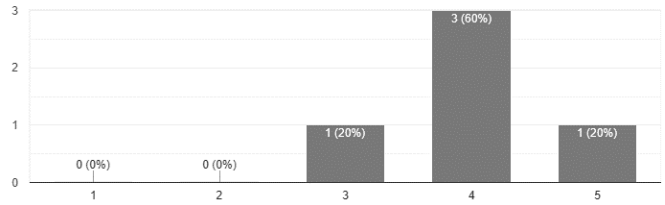
Faixa etária

5 respostas



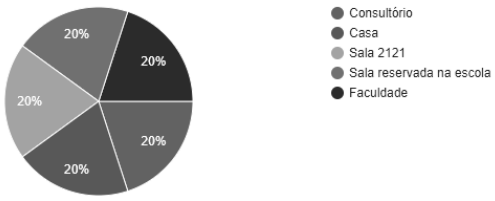
Avalie a sua experiencia com o dispositivo de 1 a 5

5 respostas



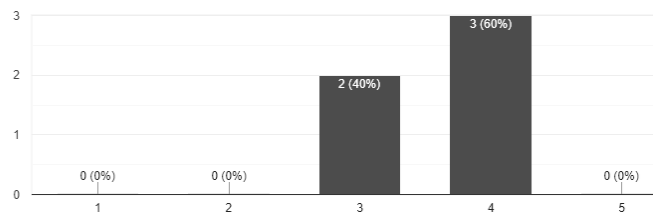
Em que ambiente testou o dispositivo ?

5 respostas



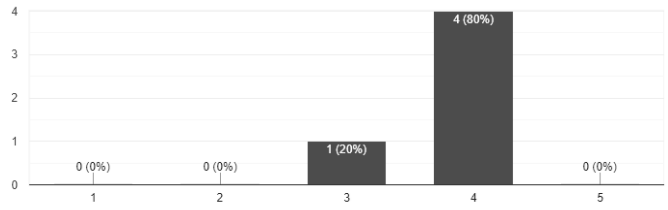
Avalie o dispositivo nas seguintes categorias : Conforto

5 respostas



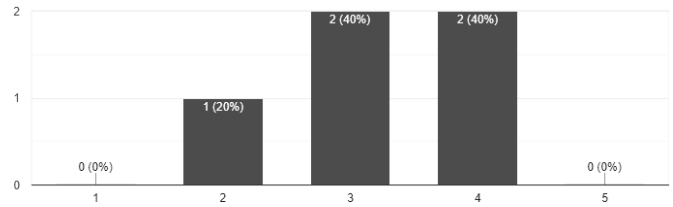
Facilidade de utilização (sem assistência)

5 respostas



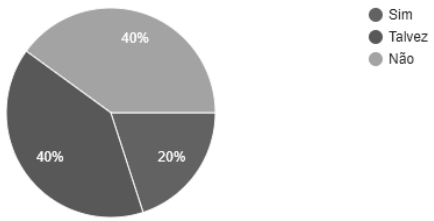
Transporte do dispositivo (para uso pessoal ou consulta fisioterapêutica)

5 respostas



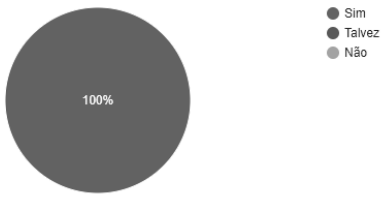
Compraria este dispositivo para uso pessoal ?

5 respostas



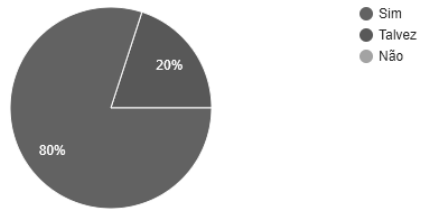
O dispositivo é complementado com diferentes níveis de exercícios associados a diferentes cargas de pesos que são colocadas na vareta e que se move durante o exercício. Sente que esta estimulação visual da contração muscular e consequente movimento da vareta , a incentiva ultrapassar os desafios do exercício?

5 respostas



Recomendaria este produto a outras pessoas?

5 respostas



O que o mudaria neste produto ? e porquê ?

3 respostas

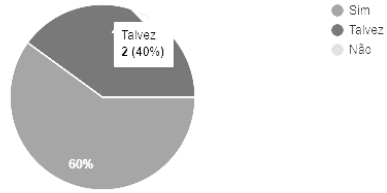
mais simples, menos peças

Modernizava e coloria, para ajudar na utilização

Tamanho

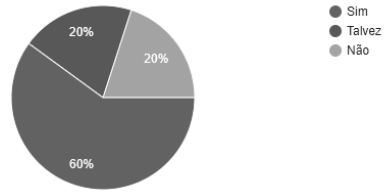
Caso o dispositivo fosse incorporado numa cueca reduzindo assim o seu número de peças para apenas (vareta, sonda, cueca e pesos). Considera que iria melhorar a sua experiencia ?

5 respostas



Considerando a proposta da questão anterior considera que se sentiria mais confortável por ter a área intima menos exposta ?

5 respostas



3.2-Survey 2 "Dispositivo de treino dos músculos do pavimento pélvico, preferências de mercado"

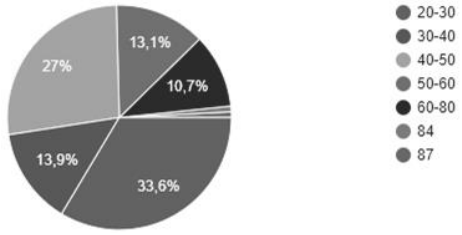
Survey answered in Portuguese.

Introduction: Questionário desenvolvido para uma dissertação de mestrado em Design de Produto e Industrial da FEUP/FBAUP. Este questionário servirá apenas para avaliação de preferências de mercado, no setor de dispositivos para treino funcional do pavimento pélvico e roupa interior, para otimização de um dispositivo de

treino funcional do pavimento pélvico. (Nota: a informação é confidencial e meramente para tratamento estatístico)

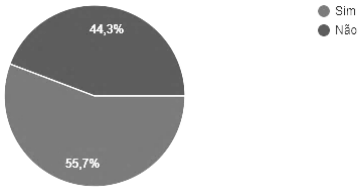
Faixa etária

122 respostas



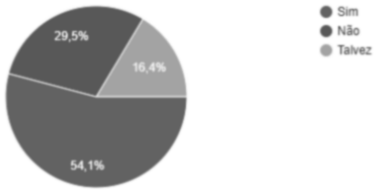
Alguma vez experienciou perdas involuntárias de urina ? (Por exemplo , ao tossir, fazer esforço, espirrar, ou associado a uma necessidade súbita e repentina de urinar)

122 respostas



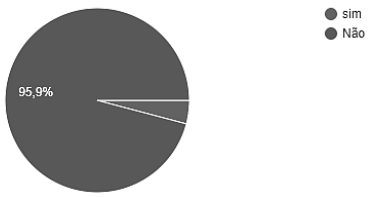
Sabia que com a utilização dos dispositivos de treino do pavimento pélvico melhora a força dos mesmos , e em alguns casos (dependendo da gravidade) pode reduzir a perda involuntária de urina, melhorar prolapsos dos órgãos pélvicos e melhorar a sua função sexual?

122 respostas



Alguma vez comprou dispositivos de treino dos músculos do pavimento pélvico como por exemplo bolas Kegel ?

122 respostas



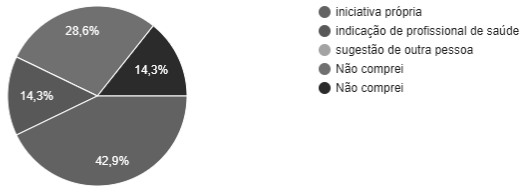
Nome do dispositivo que comprou.

4 respostas

Não recordo o nome mas eram uns "pesos" que ia colocando par treinar os músculos e que tinham diferentes tamanhos e pesos
Nao lembro. Pompp
Bolas de kegel
-

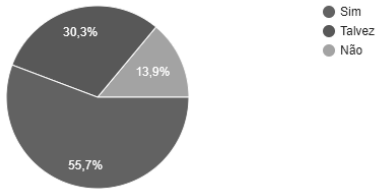
Comprou-o por...

7 respostas



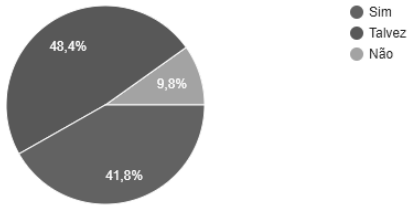
Se comprou ou algum dia comprar, o transporte e arrumação do mesmo vai ser um fator que vai pesar na sua decisão de compra?

122 respostas



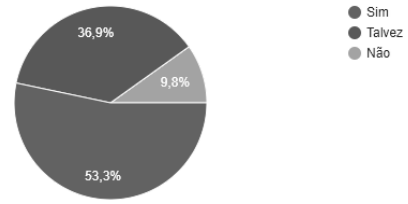
Se um dispositivo para treinar os músculos do pavimento pélvico fosse apresentado incorporando uma peça de roupa interior , consideraria comprá-lo?

122 respostas



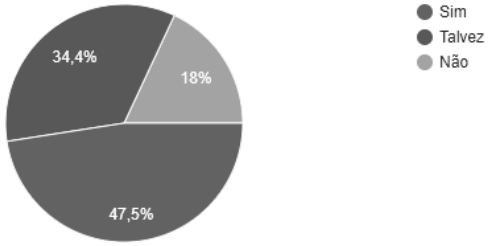
Sentir-se-ia menos exposta com a utilização deste novo dispositivo com roupa interior incorporada, por exemplo nas consultas de fisioterapia?

122 respostas



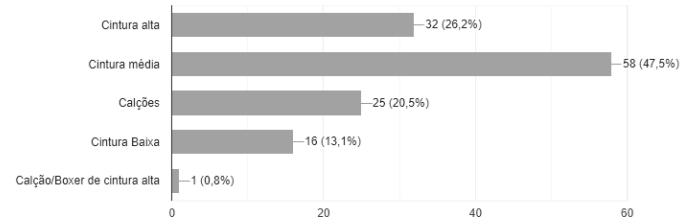
e no uso em domicilio?

122 respostas



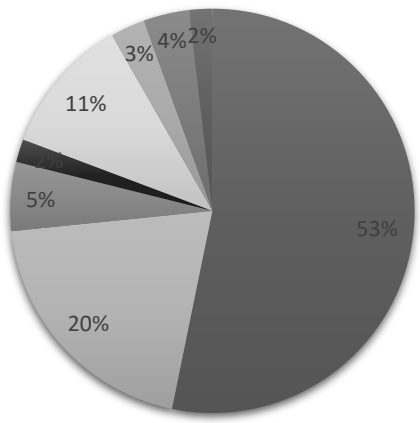
Que tipo de roupa interior preferiria que fosse incorporada no dispositivo (tendo em consideração a variedade de tamanhos que teria que servir)

122 respostas



Que cor gostaria de ver na cueca?

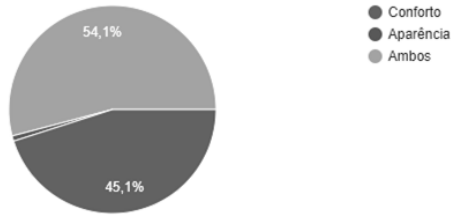
122 respostas



preto | bege, tons neuros | azul | azul escuro | tons de pele | rosa | vermelho | todas

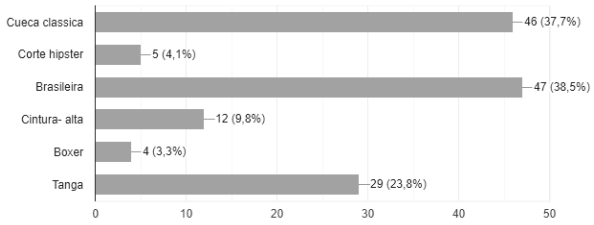
O que normalmente procura em roupa interior para o dia a dia?

122 respostas



Que tipo de cueca normalmente compra ?

122 respostas



Que cores normalmente procura?

122 respostas

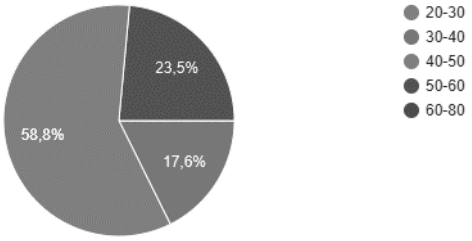
3.3- Survey 2.1 ”Pelvic floor trainer device, market preferences”.

English version and results

Introduction: Survey developed for a master thesis in product and industrial design, this survey will only serve as a market preference search and evaluation for the development of a pelvic floor trainer device. (Note: this is an anonymous survey your privacy is valued, the information it’s just for statistics purposes)

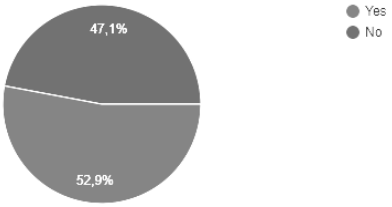
How old are you ?

17 respostas



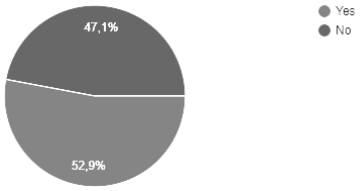
Have you ever experienced involuntary urine leakage ? (for example: while coughing, sneezing, heavy physical exercise, because of a sudden urge to urinate ... etc)

17 respostas



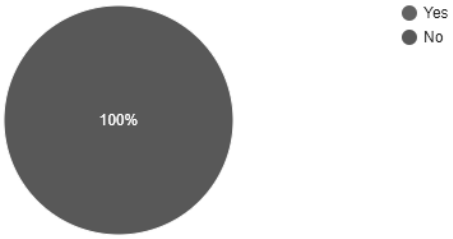
Do you know that pelvic floor trainers can improve your pelvic muscles strength and in some cases (depending on the severity) reduce your involuntary urine leakage, improve pelvic organ prolapses and your sexual function??

17 respostas



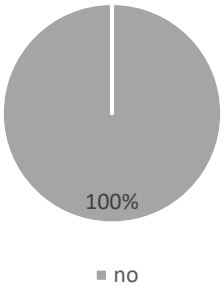
Have you ever bought pelvic floor trainers like for example kegel balls?

17 respostas



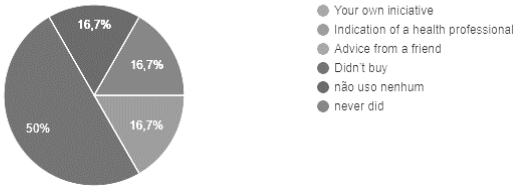
Can you name the device you use ?

6 respostas



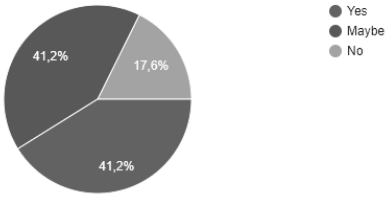
Why did you buy it ?

6 respostas



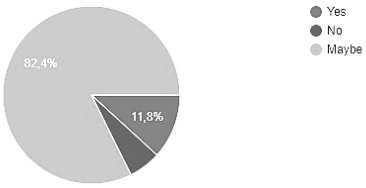
If you bought or are considering buying one sometime in the future , will transport and storage be a factor that will weigh in your purchase decision?

17 respostas



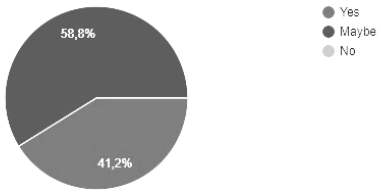
If a device for pelvic floor trainer was presented to you incorporated in underwear would you consider buying it?

17 respostas



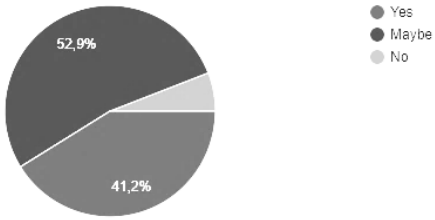
Would you feel less exposed if this was used in physiotherapy treatments? (This underwear would reduce the exposure of the intimate area during the exercise.)

17 respostas



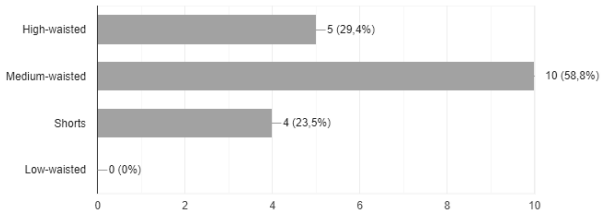
And in domestic use?

17 respostas



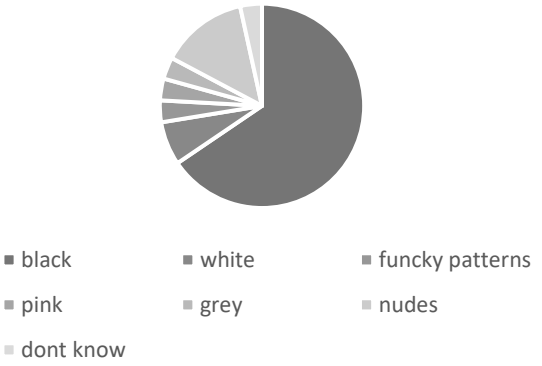
What type of underwear would you prefer it was incorporated in the device (having in consideration the range of different bodies it would have to fit)

17 respostas



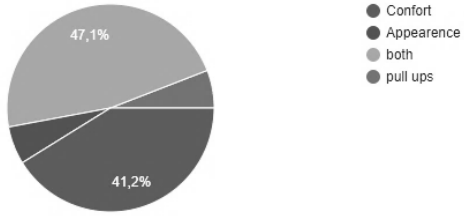
What type of color would you like to see it with ?

17 respostas



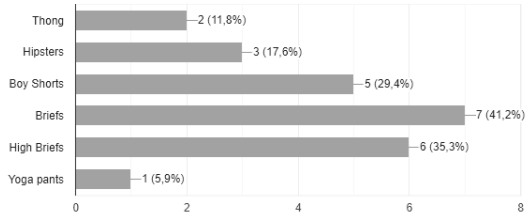
What do you look for in everyday underwear?

17 respostas



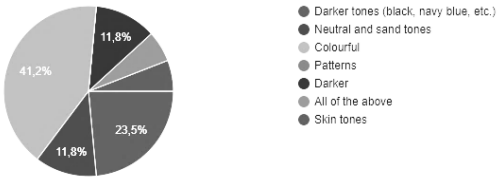
What type of pants do you purchase more ?

17 respostas



Do you normally go for what type of colors?

17 respostas



Attachment 4- Interview Transcripts and Users Narrations

4.1 Participante 1- 52 anos, SUI symptoms (08/06/21)

Concept 1.1

Entrevistadora- Relativamente ao dispositivo anterior o que é que acha foi melhoria ou não, comparativamente a esta nova opção?

Participante 1G- Maior conforto ehm… posso estar mais á vontade porque estou vestida, não estou preocupada em que os arames que estão aqui à volta caiam, não tenho nada com que me preocupar ehm… e o facto de ter a cueca é mais confortável.

Entrevistadora- E o facto de não ter aqui a referência que dá indicação, ou ainda não ter?

Participante 1G- Não me faz falta, porque eu acho que vejo o… , não é se estiver a olhar para lá vejo o peso a subir e portanto sei que estou em contração assim como quando relaxo vejo…

Entrevistador- … a descer, e se quiseres quantificar essa deslocação?

Participante 1G- é mais difícil, pronto precisa ali de qualquer coisa para… mas acho que consigo ter a noção da contração.

Entrevistadora- sim… noção da contração e não a quantidade de contração…ok. E relativamente á colocação do peso, sentes que ele pode cair ou sentes que ele está seguro?

Participante 1G- Não, não! Sinto que está seguro, não há medo de… o outro era pior dava a sensação que podia cair.

Entrevistadora- E o peso aqui, portanto achas que sentes a vareta a oscilar de um lado para o outro?

Participante 1G- Não, não. Está estável.

Entrevistadora- Ok. Muito obrigada.

Participante 1G- De nada.

2 teste – (08/06/21)

Entrevistadora- Continuação paciente 1G, sem a cueca relativamente á quantidade de movimento da vareta. Achou?

Participante 1G- que o movimento é o mesmo, mas que a vareta fica mais instável.

Entrevistadora- pois… era mais por causa da quantidade do movimento.

Participante 1G- pronto… a quantidade do movimento é o mesmo

4.2- Participante 1B- 60 anos POP diagnostic (12/06/21) Concept 1.1, 1.2, and 2

Entrevistadora- Primeira tentativa com o dispositivo sem a cueca, por causa da posição da vareta e provavelmente por influência do retocele a inclinação da vareta fica alterada! Vamos fazer agora segunda testagem com a cueca. A primeira introdução sem a cueca foi fácil?

Participante 1B- Fácil, fácil!

Entrevistadora- Vamos passar para a introdução com a cueca, portanto primeiro colocou a cueca depois colocou o dispositivo na cueca. Ok…relaxou… foi fácil?

Participante 1B- Fácil.

Entrevistadora- Ok! Então agora vamos lá, isso…outra vez, perfeito. Sentes magoar? Sentes?

Participante 1B- não...

Entrevistadora- Vou tirar mais um bocadinho, nesta posição ora faz. Isso…com calma, contrai…vai ao máximo segura e relaxa. Ok, vamos colocar agora o peso. Agora quero que vejas se ao colocar esta carga aqui se sentes instabilidade?

Participante- Claro…

Entrevistadora- Portanto, esta foi a cueca preta. (repete exercício), na cueca 1.2 cai para o lado quando colocado o peso. Foi desconfortável?

Participante 1B- Não, não foi desconfortável.

Entrevistadora- ok, obrigada. Com a cueca a questão de a vareta ficar muito posicionada para lá já não aconteceu, já conseguiu levantar contra gravidade. Alteramos para a cueca bege mas concept 2 já não se inclinou mas de qualquer das maneiras vamos agora testar a cueca bege tamanho 1.1. Portanto substituindo agora para a cueca bege concept 1.1, qual a diferença? alguma diferença?

Participante 1B- Não senti grande diferença.

Entrevistadora- Ok, portanto, a funcionar na mesma contra gravidade. Alguma sugestão de melhoria?

Participante 1B- Não tenho porque também não tenho referências.

Entrevistadora- Se a tivesses que usar num tratamento de fisioterapia sentias-te mais confortável? Era-te indiferente?

Participante 1B- Mais confortável se calhar…

4.3- Participante 1C- 57 anos nullipara (12/06/21)
concept 2

Entrevistadora- Primeira colocação sem cueca sem nada. Fácil de introduzir? Fácil de sentir o movimento?

Participante 1C- sim…sim, não tive dificuldade.

Entrevistadora-Estamos então com a cueca bege tamanho 1, a colocação sózinha da cueca e a colocação do dispositivo, foi fácil?

Participante 1C- Foi.

Entrevistadora- Ok! então vá movimento de contração correta, exatamente…, sem levantar rabo.

Participante 1C – Aii agora esta me…

Entrevistadora – esta quê?

Participante 1C- Senti aqui qualquer coisa, mas foi um pequeno ajuste.

Entrevistadora- Então vá, (execução do exercício) então agora vou colocar a carga. Colocar peso. (execução do exercício novamente, mas com carga) sentes escorregar para os lados?

Participante 1C- Não, não está a cair, mas está a virar.

Entrevistadora- Que engraçado… pode ser a tua orientação, não olha ponha as pernas alinhadas antes de começar. Isso agora começa. Ok, portanto, vamos trocar a cueca, portanto esta é a que tem a anilha mais apertada, vamos passar para a cueca que tem a anilha um bocadinho mais alargada.

Participante 1C- vamos lá então. Tiro esta?

Entrevistadora- Portanto sem peso nenhum estamos com a cueca bege 1.2, ora, portanto faz lá o movimento. Relativamente à cueca anterior sentes alguma diferença?

Participante 1C- Sim, sinto menos presa.

Entrevistadora- Agora vamos colocar o peso. Ok e agora (executa o exercício) isso. Agora o que quero que vejas é se pelo facto de estar menos presa vai cair? Pronto ok! Tem mesmo que ficar mais presa. E até onde é que inseriste?

Participante 1c- Até ao…

Entrevistadora- Não, mas não vai. Ela vai rodar, certo?

Participante 1C- Vai.

Entrevistadora- Portanto tinha que ser a cueca 1.1. Essa é o tamanho mais largo tinha que ser a outra. Ok, agora pergunta. Relativamente a esse sistema que experimentaste haveria alguma sugestão que te lembrarias

de fazer de melhoria obviamente ou de alteração? Relativamente à cueca gostavas de uma coisa mais curtinha mais caviada?

Participante 1C-Acho que é melhor…

Entrevistadora-Sentirias mais confortável se tivesses que fazer esse exercício num gabinete de fisioterapia? Estavas mais tranquila a fazer e mais à vontade a fazer o exercício assim?

Participante 1C- Sim, sim. A fazer com cueca.

Entrevistadora- e mesmo em casa?

Participante 1C- Em casa é indiferente é só pela exposição.

4.4- Participante 1M – (15/06/21)
Concept 1.1 e 1.2

Entrevistador- Como é que foi a colocação da cueca e depois a introdução do dispositivo?

Participante 1M- Foi simples e prático.

Entrevistador: Simples e prático muito bem … A sensação agora ao fazer o movimento, é confortável? é desconfortável? Alguma coisa...

Participante 1M- é mais confortável.

Entrevistador- Ok… O facto de ter a cueca para exercício feito por exemplo numa clínica de fisioterapia, mesmo sendo fechada em gabinete, seria mais confortável assim?

Participante 1M- Mais confortável e mais íntimo.

Entrevistador- E mais íntimo…Mesmo em casa, se fosse em casa, preferia estar a fazer os exercícios com cueca ou sem cueca?

Participante 1M- Com cueca!

Entrevistador: Ok… então agora vamos colocar a carga. Vários movimentos com o peso, isso… e quero que me diga se sente isso seguro, se acha que isso vai cair para os lados?

Participante 1M- Neste momento sinto seguro.

Entrevistadora- Ok… estamos com 40g, ok… é desconfortável? é confortável?

Participante 1M- É confortável.

Entrevistadora- Ok perfeito…, portanto temos que diminuir o comprimento do dispositivo! Agora estamos com a cueca 2 e com o peso, ora faça por favor. Isso… que sente? Ele vai começar a escorregar?

Participante 1M-Tá...tá

Entrevistadora- Tá a escorregar! Pronto ok! E em termos de liberdade de movimento acha que a outra cueca…

Participante 1M- A nível de liberdade de movimento tenho mais neste, mas é menos seguro sinto mais desequilibrado de um lado e do outro, o outro é mais apertado, mas…

Entrevistadora- Ou seja acha que sente menos deslocamento da vareta, é isso?

Participante 1M- Exatamente!

Entrevistadora- Ok, pronto obrigada.

4.5- Participante 1L- 29 anos (17/06/21)
concept 2

Entrevistador- Quantos anos?

Participante 1L- 29 anos.

Entrevistadora- 29 anos… A colocação da cueca foi confortável? foi difícil?

Participante 1L- Não, foi fácil e é confortável!

Entrevistadora- Juntamente com o dispositivo?

Participante 1L- Sim, sim foi fácil de inserir!

Entrevistadora-ok… movimento, alguma dor? algum desconforto?

Participante 1L- Não nenhum.

Entrevistadora- nenhum… então vamos colocar o peso, e eu vou colocar o que tenho aqui… que são…. aqui dentro estão 40 gramas, e eu vou colocar os 40g na vareta. Cueca tamanho 1. E agora vamos fazer a mesma coisa, o mesmo exercício, isso… até pode fazer com velocidade, rapidez. É desagradável? Não é desagradável?

Participante 1L- Não é desagradável.

Entrevistadora- Sente que o peso tem tendência a cair par algum dos lados?

Participante 1L- Não, neste momento sem olhar para ele, só com o facto do que estou a sentir… não sinto nada.

Entrevistadora- Ok! pode olhar para lá… isso, para ver o movimento com a carga, vá à posição de relaxamento, ok e agora contraia isso… e mantenha, mantem… e relaxa. Algum, desconforto?

Participante 1L- ele baloiça…ele desce (em simultâneo com a execução do exercício). Nenhum!

Entrevistadora- O facto de ter a cueca sente-se mais protegida? Mais resguardada? Mais à vontade em fazer o exercício? Imagine que estava numa clinica, não é, a trabalhar ehm… por algum, problema que tivesse ehm se tivesse que estar a fazer o exercício sentia-se mais confortável pelo facto de ter a cueca? Era-lhe indiferente?

Participante- ah não, prefiro com a cueca.

Entrevistadora- E se fosse em casa? Mesmo que estivesse na sua casa a fazer exercício?

Participante 1L- Preferia com cueca.

Entrevistadora- Também preferia com cueca, ok! ehm alguma sugestão na questão da cueca? Claro que isto é um modelo apenas de experiência, mas gostaria de ver nessa cueca alguma cor?

Participante 1L- Olhe eu gosto de preto, gosto de roupa escura por causa das roupas, não é, é o que se estraga menos. Ehm… não fio dental, porque não sei até que ponto seria confortável, mas uma tanga assim sem rendas mesmo de algodão… confortável para poder usar no dia a dia. Entrevistadora- Pronto, ok! pode tirar sózinha, o dispositivo primeiro e depois tirar a cueca, já está.

4.6- Participante 1I (23/06/21) SUI Symptoms Cocept model 3

Entrevistadora- relativamente ao dispositivo anterior o que é que achou em termos de colocação? Montagem do dispositivo? O que é que alterou, alterou para melhor? Para pior? O que é que gostou?

Participante 1I- Alterou para melhor, faz com que seja mais fácil o próprio colocar que as outras cintas nas coxas eram mais difíceis de segurar, é mais comodo não é

Entrevistadora- Comodo no sentido de exposição? Por exemplo?

Participante 1I- Também…

Entrevistadora- Sente que está mais protegida?

Participante 1I- Sim, menos exposta.

Entrevistadora- Durante o exercício é uma contribuição importante?

Participante 1I- Sim é!

Entrevistadora- Sentia-se mais confortável se tivesse que fazer o tratamento, por exemplo numa clinica, em fisioterapia ou no hospital na parte da fisioterapia mesmo que em gabinete, sentia-se mais cómoda, se tivesse essa cueca a ajudar o exercício?

Participante 1I- Sim, isso é, seria uma vantagem muito grande porque assim podiam estar outras senhoras a fazer na mesma sala o mesmo exercício que uma pessoa sente-se completamente tapada!

Entrevistadora-ok e se estivesse em casa? Imagine que vai fazer os exercícios para o quarto também acha que lhe daria algum conforto ter a cueca ou era indiferente?

Participante 1I-ehm… para mim era indiferente uma vez que já não tenho filhos pequenos, mas para quem tiver crianças pequenas que podem entrar a qualquer hora, sim… sim1 é muito mais confortável e seguro, no sentido de a criança não ver ali a mãe muito exposta.

Entrevistadora- Ok! Relativamente a uma estrutura que o componente anterior tinha, que era aquela barra em trapézio, e que este para já não tem nada. Há algo que sinta que lhe facilitaria no anterior relativamente a este ou não?

Participante 1I- Ehm… não. Eu acho que a barra complicava devido a ser colocar e tirar, e ter que se manter muito direitinha senão podia deslocar-se.

Entrevistadora- E a questão da referência do movimento, que nós na outra tínhamos a referência de um movimento e nesta para já não temos.

Participante 1I-mas eu acho que não faz diferença porque a gente ao fazer o exercício vê o movimento da vareta. E acho que é suficiente para se perceber se estamos a contrair bem ou não.

Entrevistadora- Ok! Relativamente à sonda em si, ela é desagradável? É confortável?

Participante 1I- É confortável, completamente confortável.

Entrevistadora- Alguma proposta, de alguma alteração?

Participante 1I- só se for o comprimento da sonda, como eu sou muito pequenina, ser um bocadinho mais curtinha. Se ela ficar mesmo na posição certa fica a forçar um bocadinho na ponta da vagina.

Entrevistadora- pronto, muito obrigada!

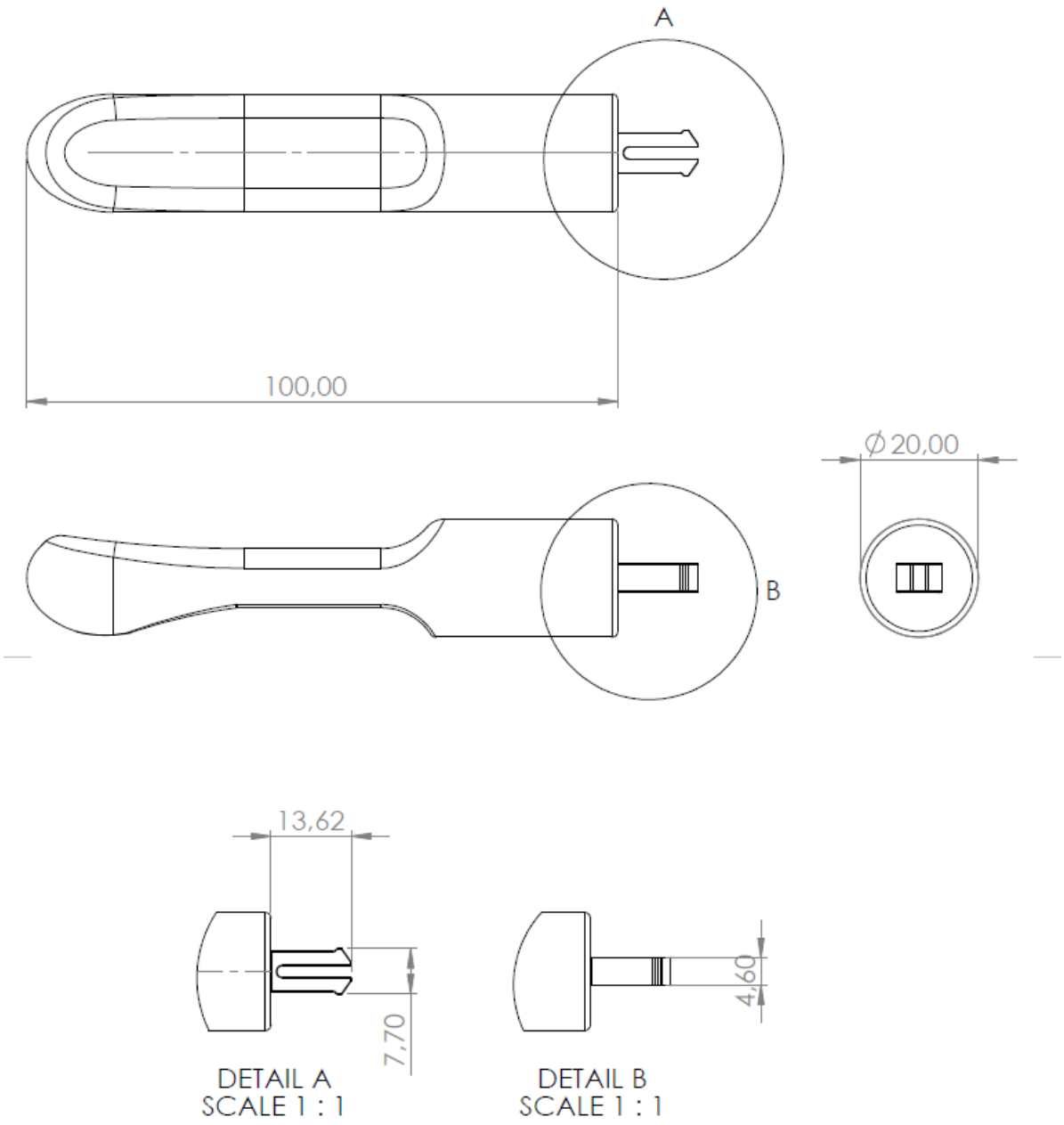
User narration

Participante 1A (30/06/21) cocnept 3- A cueca dá um conforto grande em termos de sensação de se estar menos exposta. A facilidade de colocação da sonda é grande e muito mais simplificada comparativamente ao trapézio que existia antigamente. O eixo de movimento se descer um bocadinho relativamente à posição em que estava facilita a rotação em torno desse eixo que não está centrado ao canal vaginal. Quanto á colocação da carga fica perfeitamente estável durante o exercício.

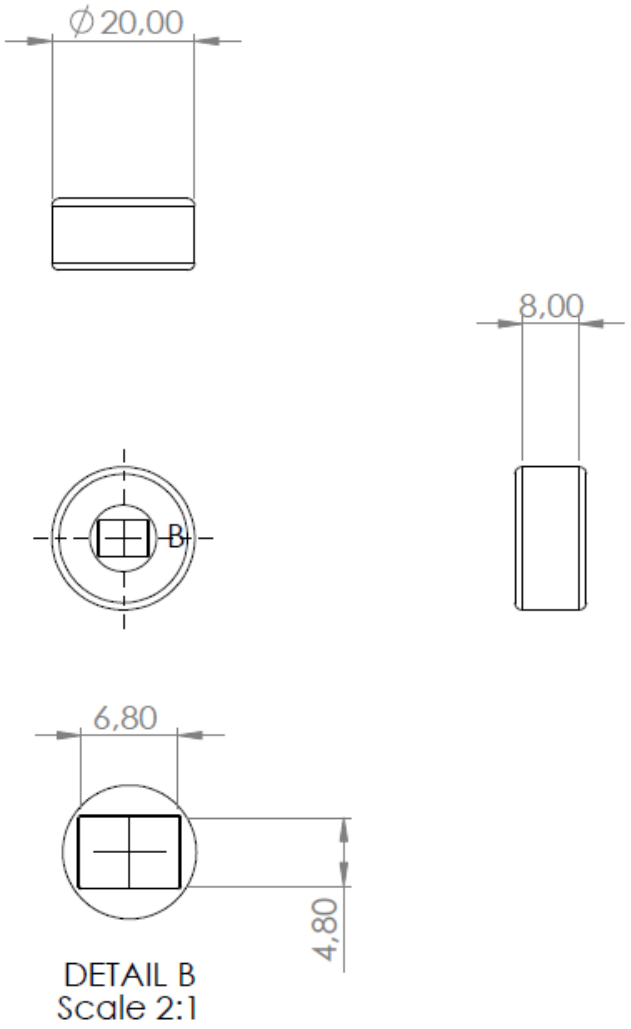
Participante 1D (13/05) concept 1.1- Efetivamente a cueca transmite uma sensação de conforto e segurança quer em casa como num gabinete, os primeiros protótipos 1.1. embora para mim resolvessem a situação de tombar com o peso, a movimentação da vareta era mínima. Outra das dificuldades que senti foi perceber até que ponto é que a sonda intravaginal tinha que entrar.

Attachment 5- Technical Drawings (all measures presented in millimeters)

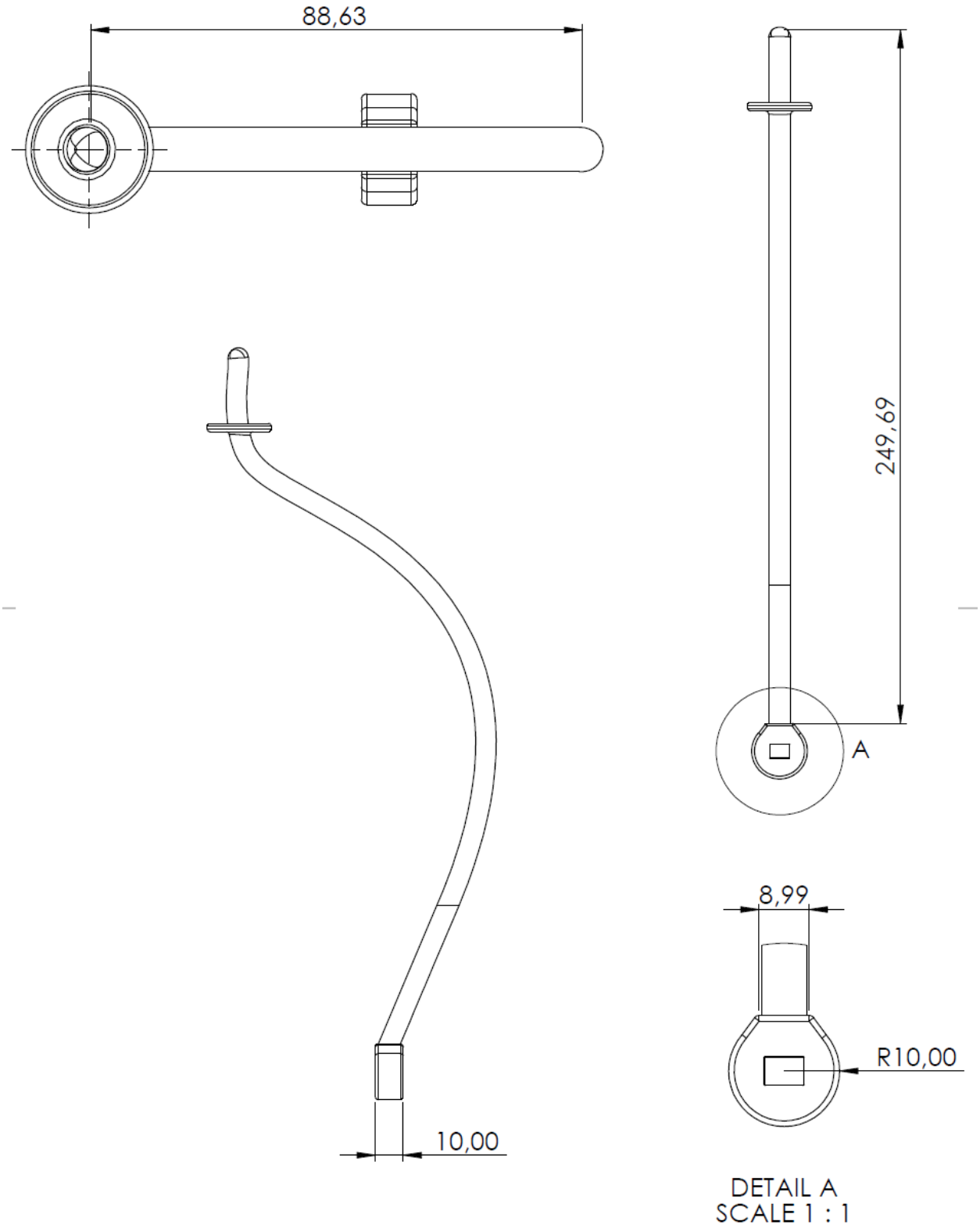
5.1-Technical Drawing- Intravaginal device (Final prototype general measures)



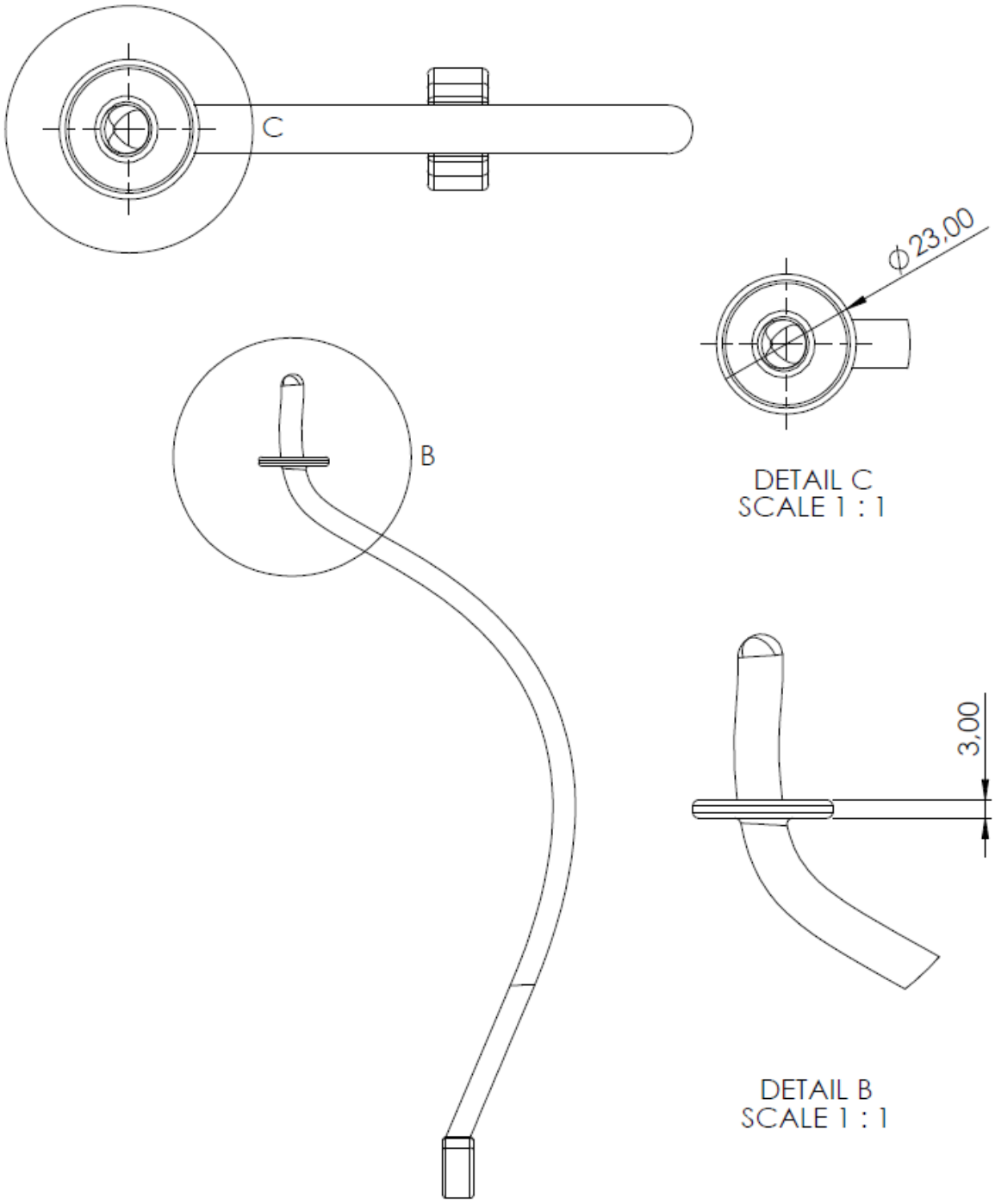
5.2-Technical Drawing- Protection Cap (Final prototype general measures)



5.3-Technical Drawing- Rod (Final prototype general measures)

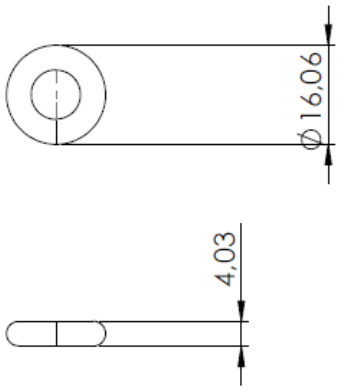


5.4-Technical Drawing- Weight support system Rod (Final prototype general measures)

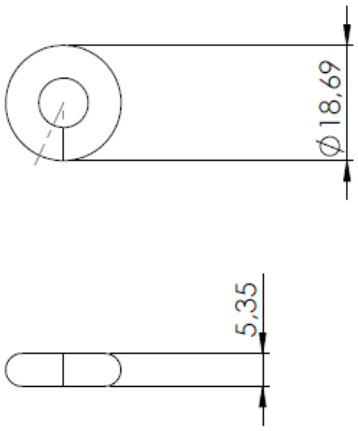


5.5-Technical Drawing- Ring weights (Final prototype general measures)

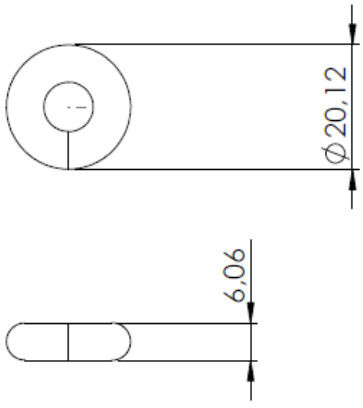
Weight ring 5g



Weight ring 10g



Weight ring 20g



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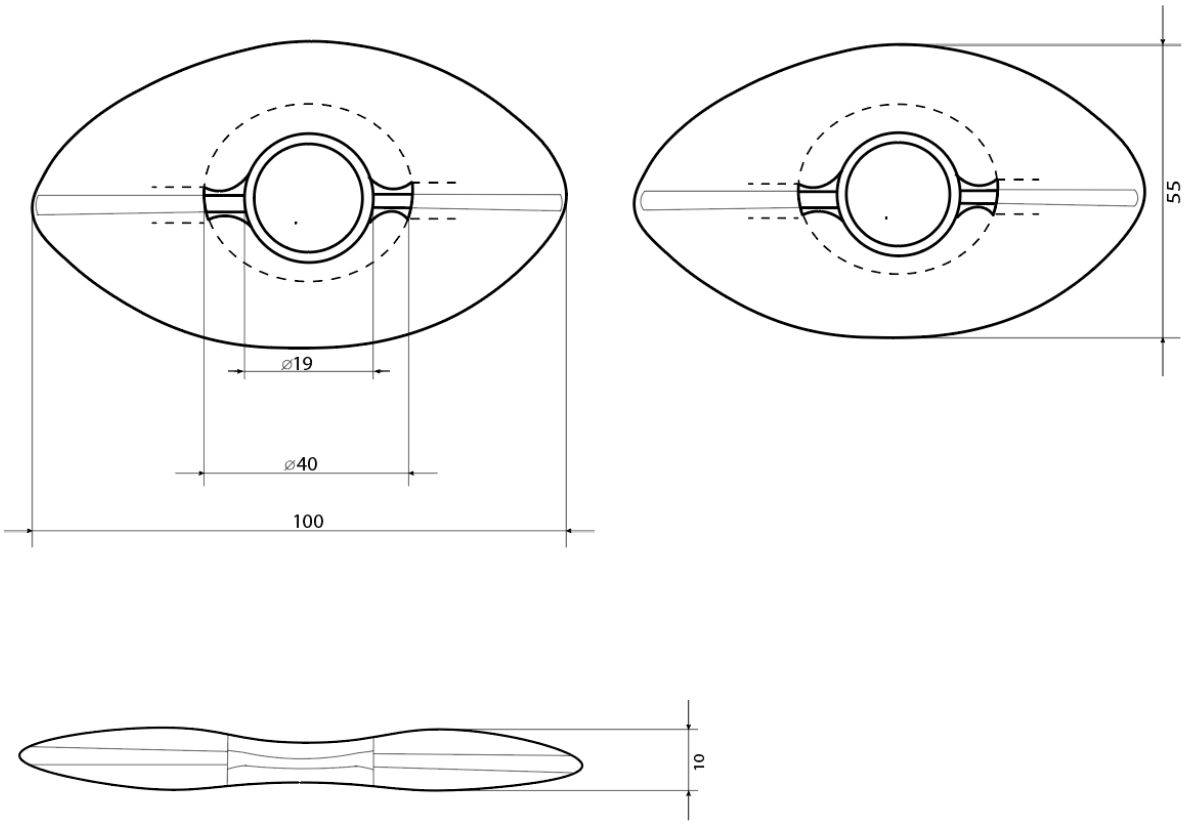
5.6-Technical Drawing- Underwear intravaginal support (Final prototype general measures)



Design and medical devices

Redesign of a device for pelvic floor muscle training

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