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Midpalatal Suture Maturation Assessment on Panoramic X-rays and its correlation with Cervical Vertebrae Maturation

Research Dissertation
Integrated Master in Dental Medicine of the University of Porto

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List of Abbreviations

MPS - Midpalatal suture

RME - Rapid Maxillary Expansion

SARME - Surgically Assisted Rapid Maxillary Expansion

MARPE - Microimplant-Assisted Rapid Palatal Expansion

PGS - Pubertal growth spurt

HWR - Hand-wrist radiograph

CVM - Cervical vertebrae maturation

BGS - BOKA Grading System

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Abstract

Introduction: Maxillary constriction is often associated with esthetic and functional impairment. To correct transverse maxillary discrepancies, maxillary expansion is needed. Midpalatal suture maturation indicators and skeletal age assessment methods using the cervical vertebrae maturation have been proposed to allow clinicians to decide between orthodontic/orthopedic or surgical treatment.

Aim: The aim of this study is to validate the use of the BOKA Grading System as an indicator of the midpalatal suture maturation, by comparing it to Baccetti's cervical vertebrae maturation method, which is described in the literature as effective in determining the skeletal age of individuals undergoing maxillary expansion.

Methods: A dentistry student and an orthodontics specialist were trained to use the Baccetti's cervical vertebrae maturation method and the BOKA Grading System. They independently assessed 77 lateral cephalograms and 77 panoramic x-rays, from patients of the Orthodontic Department of the Faculty of Dental Medicine of the University of Porto, on 2 different occasions. The intraobserver and interobserver agreement, as well as the concordance between BOKA and Baccetti methods were evaluated using the Weighted Cohen's Kappa Coefficient. The two scales were recoded, based on three possible clinical decisions (A- patient favorable to the orthodontic/orthopedic maxillary expansion; B- patient whose orthodontic/orthopedic treatment success is doubtful; C: patient unfavorable to the orthodontic/orthopedic maxillary expansion) so that the methods could have the same number of categories.

Results: BOKA Grading System showed good/very good agreement, both in the evaluation of interobserver error (kappa= 0,874) and intraobserver error (kappa = 0,869 for observer 1 and kappa =0,794 for observer 2). The percentages of intraobserver agreement were higher for the observer 1, but lower for the observer 2. Regarding the Baccetti's method, kappa was ≥ 0,80 for interobserver and intraobserver error evaluation and the percentages of agreement were higher than 75%. The concordance between the BOKA and Baccetti's method was moderate (k=0,486; % of agreement=55,8%).

Conclusions: Both BOKA Grading System and Baccetti's method have good to very good reproducibility. BOKA Grading System isn't a sufficiently reliable method to be used alone in the assessment of the midpalatal suture maturation stage.

Resumo

Introdução: A constrição maxilar está associada a problemas estéticos e funcionais. A correção das discrepâncias maxilares transversais exige a realização de expansão maxilar. Para que os clínicos possam decidir entre realizar um tratamento ortodôntico/ortopédico ou cirúrgico, foram propostos indicadores de avaliação da maturação da sutura palatina mediana, bem como da maturação das vértebras cervicais.

Objetivo: O objetivo deste estudo é validar a utilização do Sistema de Classificação BOKA para a avaliação da maturação da sutura palatina mediana, ao compará-lo com o método de avaliação da maturação das vértebras cervicais proposto por Baccetti, que está descrito na literatura como adequado na determinação da idade esquelética de indivíduos sujeitos a expansão maxilar.

Metodologia: Uma estudante de medicina dentária e um especialista em Ortodontia, foram treinados para usar o método de Baccetti e o Sistema de Classificação BOKA. Os mesmos analisaram independentemente um total de 77 telerradiografias de incidência de perfil e 77 ortopantomografias, de pacientes do Departamento de Ortodontia da Faculdade de Medicina Dentária da Universidade do Porto, em 2 ocasiões distintas. O erro interexaminador e intraexaminador, bem como a concordância entre os dois métodos, foram calculados recorrendo ao Coeficiente Kappa de Cohen ponderado. As escalas de BOKA e de Baccetti foram recodificadas de acordo com três possíveis decisões clínicas (A- paciente favorável à realização de expansão maxilar não cirúrgica; B- paciente cujo sucesso de tratamento não cirúrgico é duvidável; C- paciente não favorável à realização de expansão maxilar não cirúrgica), para que as escalas tivessem o mesmo número de categorias.

Resultados: O método BOKA Grading System demonstrou uma correlação boa/ muito boa tanto para o erro interobservador (k=0,874) como para o erro intraobservador (k=0,869 para o observador 1 e k=0,794 para o observador 2). As percentagens de concordância foram superiores para o observador 1, relativamente ao observador 2. Para o método de Baccetti, o valor de Kappa foi superior a 0,80 para os erros interobservador e intraobservador, sendo as percentagens de concordância superiores a 75%. A concordância entre os métodos BOKA e de Baccetti mostrou-se moderada (k=0,486; % de concordância=55,8%).

Conclusões: Os métodos BOKA Grading System e de Baccetti têm uma reprodutibilidade boa a muito boa. O método BOKA Grading System não é suficientemente válido para ser utilizado de forma isolada na avaliação da maturação da sutura palatina mediana.

Keywords

Transverse maxillary deficiency, Maxillary expansion, Midpalatal suture, Midpalatal suture maturation, BOKA Grading System, Cervical Vertebrae Maturation, Baccetti's CVM method

Introduction

The midpalatal suture (MPS) connects the palatal processes of the maxilla. (1) It has the shape of a line from an anterior to posterior view and the shape of a triangle from inferior to posterior, with the vertex pointing to the nasal cavity. (2)

The mineral density of the MPS has a wide interindividual and intrasutural variation, although it usually increases with age. Its obliteration is under the control of hormonal, genetic and mechanical factors. (3, 4) It is professed that the closure of the MPS come around 14 to 15 years old in females and 15 to 16 years old in males. (5) Nevertheless, studies showed that MPS often fail to show a marked degree of closure before the third decade of life (6-8), showing that chronological age is not a reliable indicator of MPS closure.

Protrusion of the maxillary teeth, posterior crossbites and/or crowding are some of the manifestations of transverse maxillary discrepancy, which is a common malocclusion among adolescents and adults. (9, 10)

Maxillary constriction is often associated with several problems that include occlusal disharmony and esthetics, and functional difficulties as narrowing of the pharyngeal airway, increased nasal resistance and alterations in the tongue posture, resulting in mouth breathing. (5, 11) To correct these transversal discrepancies, maxillary expansion is needed. (9, 12)

According to the available literature, rapid maxillary expansion (RME) appears to be the treatment of choice for growing adolescents, although its success rate diminishes significantly when performed on mature teenagers and adults. (13) This can be explained by the increased rigidity of the craniofacial structures, the presence of the synostosis in the MPS and greater resistance to the distribution of expansion forces by the center of resistance in adult patients. (14, 15) So, when RME is not feasible, surgically assisted rapid maxillary expansion (SARME) can be the choice. (13, 16-18) Between the available SARME techniques, one of them consists of a LeFort I osteotomy simultaneous with surgical rupture of the MPS, so that the resistance to the lateral forces applied by the expansion appliances, usually anchored to the first molars and first premolars, decreases. A relatively recent non-surgical technique called microimplant-assisted rapid palatal expansion (MARPE), was developed in order to apply the forces to micro-implants and not to the teeth and periodontium, thus optimizing the mechanical forces applied to circummaxillary sutures and avoiding the osteotomies. (19)

To help clinicians to decide whether conventional RME or SARME/MARPE is necessary and to improve the outcome and stability of the treatment (20, 21), indicators of MPS maturation have been proposed. That includes MPS morphology assessment on occlusal radiographs (2, 6, 8, 14, 22-27) and CBCTs, which have become increasingly relevant. (28) During 2018, a qualitative method of evaluation of the MPS through panoramic radiographs, called “BOKA Grading System”, was developed.

It is known that maxillary expansion has a greater effect before or during the pubertal growth spurt (PGS). (29, 30)

Chronological age, however, is not the best method to determine if an individual is going through PGS. (21, 31) Methods such as evaluation of secondary sex characteristics, height and weight, and dental development have been used as alternatives but showed no advantage. (20, 32) Hand-wrist radiograph (HWR) method, introduced in 1982 (20, 33, 34) is considered the gold standard (35), but it requires additional exposure to radiation. In that way, a method relying on the evaluation of the cervical vertebrae maturation (CVM) on cephalograms was created, since it is a routine exam in orthodontics. (34-39). Originally proposed by Lamparski, it suffered alterations by Hassel-Farman in 1995, Baccetti *et al.* in 2005 and Seedat and Forsberg in 2005. (40-47) Lateral cephalograms are routinely used in orthodontic practice

(34), thereby avoiding a second dose of radiation. (40, 48) It also seems to be consistent among patients and between various ethnic groups. (49)

The correlation coefficients between CVM parameters and HWR are relatively high.(20, 34, 35, 48, 50, 51)

The aim of this study is to assess the reliability and validate the use of the BOKA Grading System (BGS) - a method recently proposed and presented in orthodontic events - as an indicator of the MPS maturation in panoramic x-rays, by comparing it to Baccetti's CVM evaluation method (52), which is described in the literature as effective in determining the skeletal age of individuals subjected to maxillary expansion (34); helping to select the best treatment plan, without the need of additional radiation exposure. In addition, intraobserver and interobserver errors at the classification of panoramic radiographs with BOKA Grading System, and lateral cephalograms with Baccetti's CVM method were calculated.

Material and Methods

Type of study

This investigation project corresponds to a retrospective epidemiological study, with a descriptive and observational character.

Literature Review

Searches were conducted in the electronic databases PubMed, Scopus, and Scielo during January of 2019. All publications presented in databases contained a combination of MeSH and free terms, as followed:

- Keywords searched on Pubmed:
  - “Maxillary expansion”
  - “Midpalatal suture”
  - “(digital radiography AND suture) AND orthodontics”
  - "Cervical Vertebrae/growth and development" [Mesh]

- Keywords searched on Scielo:
  - Midpalatal suture maturation

- Keywords searched on Scopus:
  - “Midpalatal suture”

The following filters were utilized:

- articles published between the years of 2000 and 2019
- studies made in humans
- articles written in English, Portuguese or Spanish
- systematic reviews, reviews, meta-analysis, clinical trials, controlled clinical trials, randomized controlled clinical trials and journal articles

Afterward, duplicated results were removed from the combination of results obtained from all surveyed sources. After the removal of duplicates, the titles and abstracts that did not fit the established eligibility criteria were excluded. The resulting articles were evaluated and judged by their full texts. All relevant citations were collected in a bibliographic reference manager (EndNote, X9 version). (fig.1)

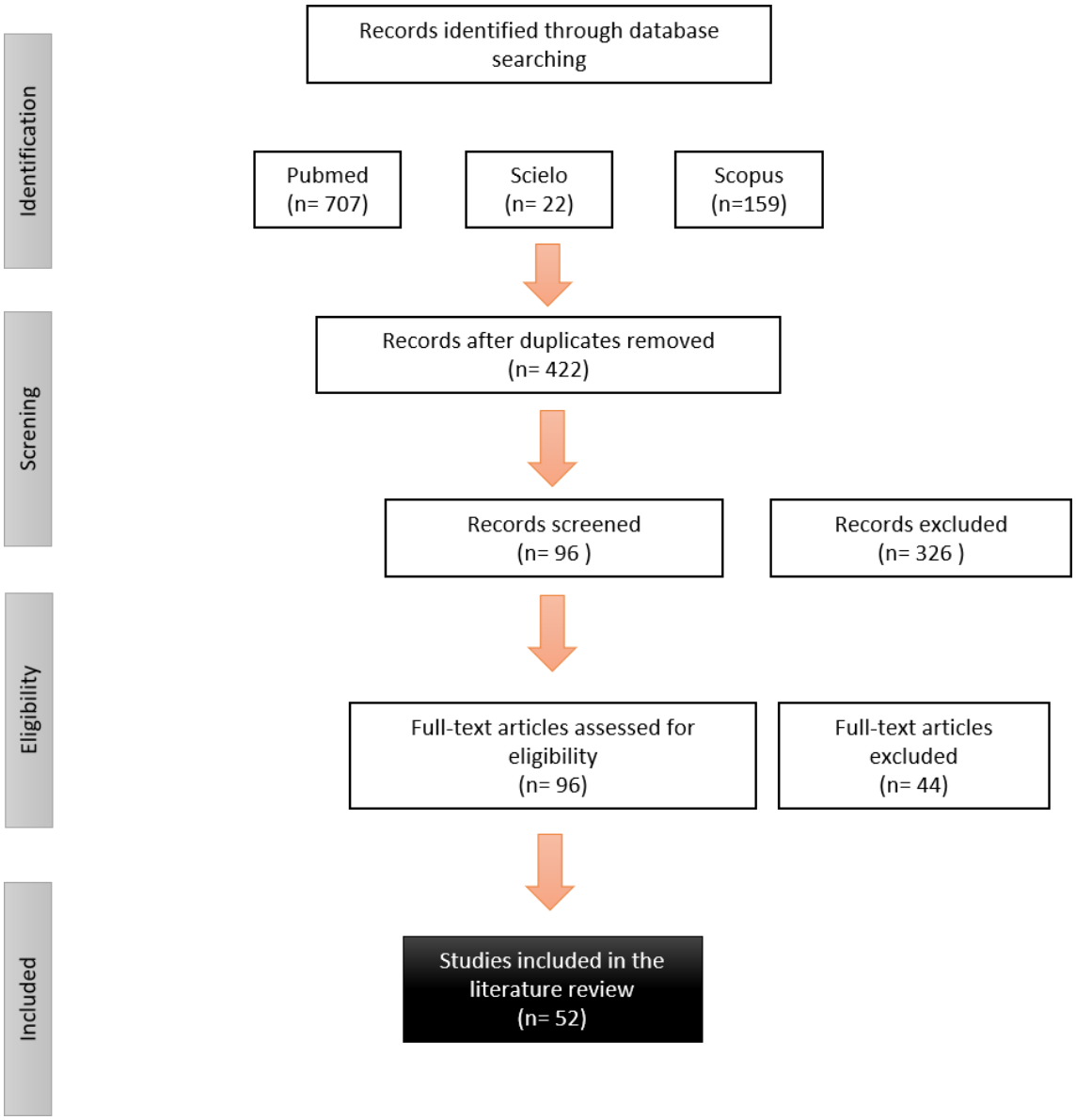


FIGURE 1- FLOW CHART WITH NUMBER OF RECORDS IDENTIFIED AND REMOVED AT EACH STAGE OF THE REVIEW

Sample

This retrospective study analyzed panoramic radiographs and lateral cephalograms from patients of the Orthodontic Department of the Faculty of Dental Medicine of the University of Porto, who had undergone radiographic exposure in line with normal clinical practice.

One hundred and nighty-eight radiographs (99 panoramic x-rays and 99 lateral cephalograms) were collected in February of 2019. X-rays were randomly selected from all the patients with radiographic records who attended the Orthodontic Department between 11th September of 2018 and 29th January of 2019.

After screening the radiographs and subjecting them to the inclusion and exclusion criteria, a total of 77 panoramic x-rays and 77 lateral cephalograms were selected to this study. The age of the subjects varied between 7 and 57 years old. The radiographs pertain to a total of 38 males and 39 females.

Inclusion and Exclusion Criteria

Inclusion criteria:

- no age limit
- individuals without previous orthodontic treatment or orthognathic surgery
- patients with the absence of congenital clefts of the lip or palate or craniofacial syndromes or grown related conditions, requiring orthognathic surgery
- lateral cephalograms with complete visualization of cervical vertebrae C2, C3, and C4
- lateral cephalograms and panoramic radiographs that were taken in the same year occasion

Exclusion criteria:

- individuals that had or were having orthodontic and/or orthognathic treatment
- central incisors with a history of trauma
- lack of central incisors, regardless of the cause
- palatal anomalies like palatal tori or others
- supernumerary teeth (mesiodens)
- mesially impacted maxillary canines superimposed beyond the maxillary central incisors
- radiographs of low quality, that impeded the right visualization of the morphological features of the cervical vertebrae C2, C3, and C4, as well as the midpalatal suture (grainy, pixelated images or incorrect positioning of the patient during radiographic exposure)

Radiographic Material and Methods

The radiographs of the sample were performed by the Gendex Orthoralix 9200 DDE Digital Cephalometric and Panoramic X-Ray device, model GEN-XRAY25, manufactured by *Gendex Panoramic*, with the following features:

- input voltage between 115V and 250V
- long term rating between 1A and 0,5A
- maximum momentary rating between 11A and 10A

Technique and positioning – panoramic x-rays

1. Patients were asked to remove any earrings, hair pins, dentures or removable orthodontic appliances.
2. Patients were placed accurately within the X-ray machine, using the various head-positioning devices and light-beam marker positioning guides.
   2.1. Light-beam guides:
      2.1.1. lining of the tragus with the inferior orbital notch
      2.1.2. midline
      2.1.3. maxillary canines
   2.2. They were instructed to place the tongue in the hard palate and not to move throughout the exposure cycle.

Technique and positioning – lateral cephalograms

1. Within the cephalostat, the patient's sagittal plane of the head was positioned vertical and parallel to the film and the Frankfurt plane horizontal. Teeth were in maximum intercuspidation.
2. The head of the patient was immobilized with plastic ear rods, that were inserted into the external auditory meatus.
3. The aluminium wedge was positioned to cover the anterior part of the film.

Ethical Considerations

The radiographs were chosen randomly, without any data that allowed identification of the patient. They were subjected to confidentiality and data protection according to the rules of Bioethics that this type of study entails. Only the gender and the age of the patients were collected.

The framework of this intervention did not jeopardize the well-being of the participants (there was not additional radiation exposure) since it is a retrospective study that uses data from complementary diagnostic exams that were performed on first orthodontic appointments and that are part of the clinical files of the Orthodontic Department patients. Therefore, none of the patients were subjected to unnecessary or additional radiation.

This research does not have any financial or economic purpose, having merely academic goals.

Ethical approval was obtained from the Ethics Commission (attachment 1) and the authorization for the treatment of personal data in investigation projects was obtained from the University of Porto (attachment 2). Authorization for Re-Use of Clinical Records for Research Purposes was also granted (attachment 3).

Data Collection and Analysis Protocol

The collection and analysis of the x-rays were carried out in the computers of the Orthodontic Department of the Dental Medicine Faculty of the University of Porto, using the NewSoft DS 14® (Imaginasoft®, Porto, Portugal) software. No changes were made in the contrast, brightness or size of the radiographs.

The evaluation of the radiographs collected was made by 2 examiners: a Dentistry student and an Orthodontics specialist, which had never used the CVM and the BOKA methods previously. Thereby, they were trained to employ them, using the teaching material from Baccetti *et al.* (52) and a PDF document of the BOKA Grading System, kindly given by the creators of the method (attachments 4 and 5). The training presentation included a detailed explanation of the morphological features of each stage in diagrammatic format, a written description of the radiographic features of each stage and a calibration exercise to ensure that both observers understood the method.

After the training period, the panoramic x-rays and lateral cephalograms of 77 patients were collected and the two examiners proceeded to the classification, according to the BOKA Grading System and the Baccetti's method, simultaneously. A second evaluation was made 2 weeks after.

The scores obtained for each radiograph were saved in an Excel 16® (Microsoft Office, New Mexico, U.S.A) file document and later the data was introduced in the SPSS® (Statistical Package for Social Science) version 24 for Windows® (IBM corp. New York, U.S.A), in order to allow the respective statistical analysis to be carried out. The Excel and SPSS files were stored on an external disc, protected by a password.

To proceed to the evaluation of the concordance between BGS and Baccetti's CVM method, the two scales were recoded, based on three possible clinical decisions, so that the methods could have the same number of categories: (table 1)

- category A: patient favorable to the orthodontic/orthopedic maxillary expansion
- category B: patient whose orthodontic/orthopedic treatment success is doubtful
- category C: patient unfavorable to the orthodontic/orthopedic maxillary expansion

BOKA Grading System	Baccetti's CVM Method	Recodification
Stage 1	Stages 1, 2 and 3	A
Stages 2 and 3	Stage 4	B
Stage 4	Stages 5 and 6	C

TABLE I - RECODIFICATION OF THE BOKA GRADING SYSTEM AND BACCETTI'S CVM METHOD

Statistical Methodology

Intraobserver and interobserver agreement

The calculation of the intraobserver and interobserver error was made using the Weighted Cohen's Kappa Coefficient.

BOKA Grading System showed good/very good agreement, both in the evaluation of interobserver error (kappa= 0,874) and intraobserver error (kappa = 0,869 for observer 1 and kappa =0,794 for observer 2). Regarding the Baccetti's method, kappa was ≥ 0,80 for interobserver and intraobserver error.

Thus, it was possible to assume that the existing error was compatible with the scientific application of the methodology.

Concordance between BOKA Grading System and Baccetti's CVM method

For the evaluation of the agreement between BOKA and Baccetti methods, the Weighted Cohen's Kappa Coefficient was used. This coefficient assumes the maximum value of 1 in the case of perfect agreement between the two measurements. The further away from 1, the less concordance. The cut-off points proposed by Altman in 1991 (53) were used as follows:

- ≤ 0,20 – low correlation
- 0,21 – 0,40 – reasonable correlation
- 0,41 – 0,60 – moderate correlation
- 0,61 – 0,80 – good correlation
- 0,81 – 1,00 – very good correlation

The Weighted Cohen's Kappa Coefficient was calculated using the package psych (Revelle, Illinois, U.S.A) (54), available in program R- version 3.3.2 (R Core Team, Vienna, Austria). (55)

A significance level of 5% was considered, which means that associations were considered statistically significant when the significance level was under 0,05 ($p<0,05$).

Calculation of the Sample Size

The minimum sample size required for the valid use of the Weighted Cohen's Kappa Coefficient was estimated by specifying a test power of 80% ($1-\beta= 0,80$; β being the Type II error) and a significance level of 5% ($\alpha= 0,05$; α being the Type I error), following the indicators of Bujang & Baharum of 2017 (56). A minimum of 74 radiographic was required. To assess the intraobserver error, 30 records were randomly selected from the whole sample.

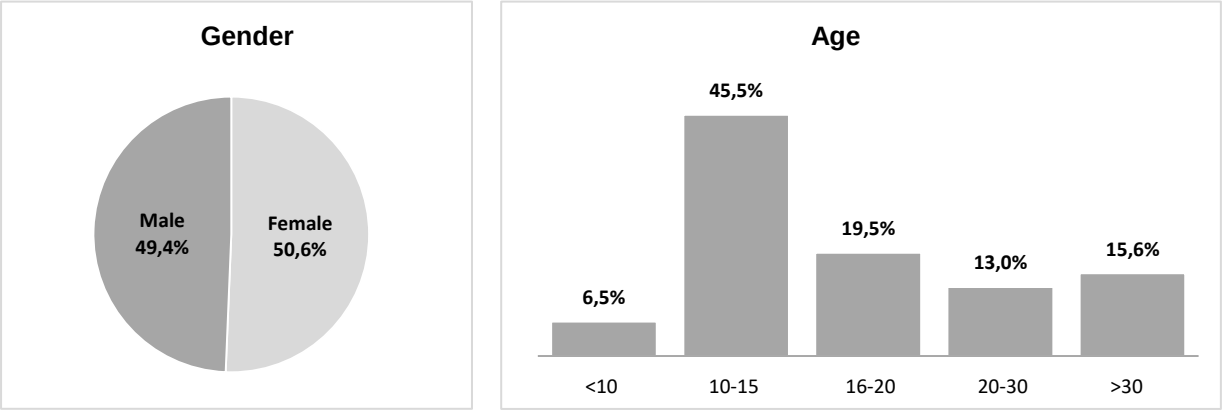
Results

Sample

The sample consisted of 77 patients, with ages ranging from 7 and 57 years old (mean age = 19,9 years old), mostly aged between 10 and 15 years old (45.5%) and between 16 and 20 years old (19,5%). About half are female (50,6%) and half male (49,4%). (table 2 and graph 1).

	Categories	n	%
Gender	Female	39	50.6%
	Male	38	49.4%
Age (years)	< 10	5	6.5%
Minimum = 7	10 - 15	35	45.5%
Maximum = 57	16 - 20	15	19.5%
Mean = 19.9	20 - 30	10	13.0%
Standard deviation = 12.1	> 30	12	15.6%

TABLE II – SAMPLE CHARACTERIZATION ACCORDING TO GENDER AND AGE (N=77)



GRAPH 1 – SAMPLE CHARACTERIZATION ACCORDING TO GENDER AND AGE (N=77)

Error Measurement

BOKA Grading System

The values of the Weighted Cohen's Kappa Coefficient for BGS showed good/very good agreement, both in the assessment of interobserver error (kappa= 0,874) and intraobserver error (kappa = 0,869 for observer 1 and kappa =0,794 for observer 2). The percentages of the intraobserver agreement were higher than 80% for the observer 1 but lower for the observer 2 (56,7%). (table 3, 4 and 5)

		Observer 2				Total
		Stage 1	Stage 2	Stage 3	Stage 4	
Observer 1	Stage 1	**27**	2	0	0	29
	Stage 2	0	**8**	0	0	8
	Stage 3	0	3	**5**	0	8
	Stage 4	2	2	3	**25**	32
	Total	29	15	8	25	77
Kappa = 0.874; % of agreement: 84.4% (65/77)						

TABLE III - DATA REGARDING THE STUDY OF THE INTEROBSERVER ERROR OF BGS (N=77)

		Second observation				Total
		Stage 1	Stage 2	Stage 3	Stage 4	
First observation	Stage 1	**10**	1	0	0	11
	Stage 2	0	**1**	2	0	3
	Stage 3	0	0	**5**	0	5
	Stage 4	1	0	1	**9**	11
	Total	11	2	8	9	30

Kappa = 0.869; % of agreement: 83.3% (25/30)

TABLE IV - DATA REGARDING THE STUDY OF THE INTRAOBSERVER ERROR OF BGS – OBSERVER 1 (N=30)

		Second observation				Total
		Stage 1	Stage 2	Stage 3	Stage 4	
First observation	Stage 1	**8**	1	1	0	10
	Stage 2	3	**1**	3	0	7
	Stage 3	1	1	**1**	3	6
	Stage 4	0	0	0	**7**	7
	Total	12	3	5	10	30

Kappa = 0.794; % of agreement: 56.7% (17/30)

TABLE V - DATA REGARDING THE STUDY OF THE INTRAOBSERVER ERROR OF BGS - OBSERVER 2 (N=30)

Baccetti's CVM Method

Regarding the Baccetti's method (tables 6, 7 and 8), the Weighted Cohen Kappa Coefficient was ≥ 0,80 for interobserver and intraobserver error evaluation and the percentages of agreement were higher than 75% (90% for the observer 1 and 83,3% for the observer 2).

		Observer 2						Total
		Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6	
Observer 1	Stage 1	**8**	1	5	0	0	0	14
	Stage 2	0	**2**	1	0	0	0	3
	Stage 3	0	0	**6**	0	0	0	6
	Stage 4	0	0	0	**7**	5	0	12
	Stage 5	0	0	0	1	**29**	2	32
	Stage 6	0	0	0	0	3	**7**	10
	Total	8	3	12	8	37	9	77

Kappa = 0.796; % of agreement: 76.6% (59/77)

TABLE VI – DATA REGARDING THE STUDY OF THE INTEROBSERVER ERROR OF BACCETTI'S CVM METHOD (N=77)

		Second observation						Total
		Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6	
First observation	Stage 1	**3**	0	0	0	0	0	3
	Stage 2	0	**1**	0	0	0	0	1
	Stage 3	0	0	**1**	1	0	0	2
	Stage 4	0	1	0	**8**	0	0	9
	Stage 5	0	0	0	1	**12**	0	13
	Stage 6	0	0	0	0	0	**2**	2
	Total	3	2	1	10	12	2	30

Kappa = 0.867; % of agreement: 90.0% (27/30)

TABLE VII- DATA REGARDING THE STUDY OF THE INTRAOBSERVER ERROR OF BACCETTI'S CVM METHOD – OBSERVER 1 (N=30)

		Second observation						Total
		Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6	
First observation	Stage 1	**3**	0	0	0	0	0	3
	Stage 2	0	**0**	0	0	0	0	0
	Stage 3	0	0	**2**	1	0	0	3
	Stage 4	0	1	0	**4**	1	0	6
	Stage 5	0	0	0	0	**14**	1	15
	Stage 6	0	0	0	0	1	**2**	3
	Total	3	1	2	5	16	3	30

Kappa = 0.834; % of agreement: 83.3% (25/77)

TABLE VIII - DATA REGARDING THE STUDY OF THE INTRAOBSERVER ERROR OF BACCETTI'S CVM METHOD - OBSERVER 2 (N=30)

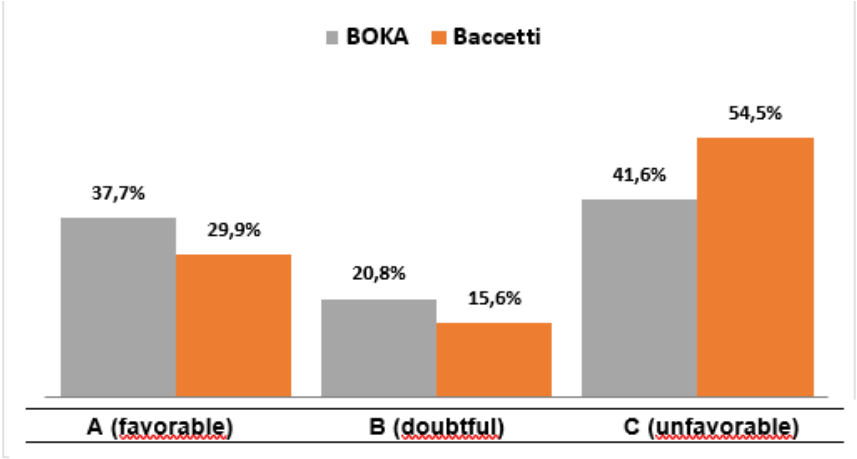
Concordance between BOKA Grading System and Baccetti's CVM Method

The results of the concordance study between the BGS and Baccetti methods (recoded) are presented in table 9 and graph 2. The value of the Weighted Cohen Kappa Coefficient (k= 0,486) shows the existence of a moderate agreement between the two scales (IC 95%: 0,315-0657). The percentage of agreement among the rankings was of 55,8%.

Compared with the Baccetti's method, the BGS led to a higher percentage of patients classified in category A (favorable to orthodontic/orthopedic maxillary expansion) - 37,7% vs 29,9%; and in category B (doubtful)- 20,6% vs 15,6%. On the contrary, the BGS classified fewer patients in category C (unfavorable to orthodontic/orthopedic maxillary expansion) compared to the Baccetti's method – 41,6% vs 54,5%.

		BACCETTI			Total
		A (favorable)	B (doubtful)	C (unfavorable)	
BOKA	A (favorable)	**17**	5	7	29 (37.7%)
	B (doubtful)	3	**2**	11	16 (20.8%)
	C (unfavorable)	3	5	**24**	32 (41.6%)
	Total	23 (29.9%)	12 (15.6%)	42 (54.5%)	77
Kappa = 0.486 (IC95%: 0.315-0.657); **% of agreement: 55.8%** (43/77)					

TABLE IX- CONCORDANCE BETWEEN BGS AND BACCETTI'S CVM METHOD (N=77)



GRAPH 2 – CLASSIFICATION ACCORDING TO BOKA AND BACCETTI RECODED SCALES (N=77)

Discussion

State of Art

According to the available literature, orthodontic/orthopedic correction of the transverse maxillary deficiencies do not represent a challenge as long as it is performed before or during the PGS (30), probably because the midpalatal suture is not completely fused. (29) However, as skeletal maturity increases, bony interdigitation increases as the craniofacial sutures, including MPS, fuse. In 2009, David *et al.* (2) verified that the prognosis of RME worsened as the synostosis of the various sutures of the face happens. The most important sutures are the midpalatal suture, the frontonasal suture, zygomaticomaxillary suture, and zygomaticotemporal suture, in a descendent way. (2) In these cases, patients must be submitted to surgical disjunction (18) or to MARPE, which tries to perform a rapid maxillary expansion, applying forces to palatal micro-implants, in order to avoid a surgical disjunction procedure. (19)

In that way, in orthodontics and dentofacial orthopedics, the timing of the treatment onset may be as critical as the selection of a specific treatment protocol. (52)

Multiple studies demonstrated that chronological age, however, is not the best method to determine an individual skeletal age (21) and that there isn't a significant relationship between the chronological age and the presence of bone interdigitation in MPS, since its mineral density has a wide interindividual and intrasutural variation. (3) This agrees with a study conducted in 2004 by Knaup *et al*. (7), made to determine the histological difference in width and obliteration of the midpalatal suture with age. The results showed a tendency to a bigger obliteration with age, but the differences between the age groups were not statistically significant.

It is also important to notice, as highlighted in a study conducted by Ball *et al.* (49) in 2011, that are differences between early, average and late maturing children. Children with advanced skeletal age have a corresponding early PGS, and those with delayed skeletal development experience their PGS later. So, individuals with the same chronological age may have different growth patterns regarding the onset, duration, speed, direction and amount of residual growth. (21)

To overcome the limitations of chronological age, several methods for MPS morphology assessment, as well as skeletal maturity indicators have been proposed over the years. (8, 25)

A successful diagnostic tool, that allows the clinician to decide whether conventional RME or SARME/MARPE is necessary, must be valid and reliable, even as reproducible. (20)

The method we hoped to validate with this study, the BOKA Grading System, proposes the assessment of MPS morphology through the visualization of it in panoramic x-rays, a two-dimensional diagnostic tool. In the past, the same was attempted by means of occlusal radiographs. However, the literature on the subject is not conclusive. Some authors advocate the use of occlusal radiographs, but others do not.

In 2001, Wehrbein *et al.* (8) demonstrated that whenever the midpalatal suture was visible in occlusal radiographs, histologically there was a gap between the maxillary bones or, sometimes, small areas of interdigitation. When not visible on x-rays, the suture had wide areas of interdigitation. On the other hand, a compact vomer or structures from the external nose may overlap the midpalatal suture and lead to a false radiological interpretation of the real morphological characteristics. This also happens when the suture doesn't run parallel to the X-ray path in its main course.

In 2007, Malmstrom *et al*. (26) concluded that occlusal radiographs are the best choice to prove the suture opening and to control the treatment process. Digitalization of those radiographs allows to measure its radiographic density and quantify the occurred changes.

In 2008, Filho *et al.* (22) conducted a study to validate the use of occlusal radiographs in the evaluation of bone neoformation after rapid maxillary expansion. The presence of mew ossified suture after maxillary expansion is a sign that the disjunctor apparatus can be removed. The radiographic images showed reliability for the assessment of the best time to remove the expander. A similar conclusion was found in 2009, by Martins *et al.* (23) and in 2013, by Melo *et al*. (25), who analyzed the bone neoformation in the MPS through the process of RME, by means of density readings in occlusal radiographs, to understand when to remove the disjunction apparatus. Sannomiya *et al.* (24) in 2007 and Gurgel *et al*. (14) in 2012, also had similar conclusions, but for SARME.

On the other hand, in 2004, Ennes *et al.* (6) evaluated the ossification degree of the midpalatal suture in human skulls in different age groups, comparing histological images with occlusal radiographs of those sutures. They concluded that the proximity of the margins of the MPS, observed in occlusal radiographs didn't relate to the degree of bone ossification observed macroscopically and microscopically. In 2007 Guyen *et al*. (27) subjected the palates of 20 cadavers to occlusal radiographs and histological evaluation. They concluded that there was not a direct relation between these two anatomies and that in all the individuals with more than 70 years old, the ossification of the midpalatal suture was incomplete.

Sample and Methodology

In the present study, BGS - a two-dimensional method of assessment of the MPS maturation in panoramic x-rays, developed in 2018 and presented in various orthodontic events – was evaluated for its validity and reproducibility.

We selected 77 lateral cephalograms and 77 panoramic x-rays, from patients of the Orthodontic Department of FMDUP, that varied between 7 to 57 years old, in a total of 38 males and 39 females. These radiographs were selected randomly, to overcome the problem of authors preselecting images that are the ideal representation of each stage. (45) Instead, our selection was made based solely on the exclusion and inclusion criteria, regardless of the image representativeness of a concrete stage. This led us to the conclusion that many lateral cephalograms were not easily staged, even after proper training.

This investigation used a greater sample than most of the studies found in the literature. (2, 4, 8, 21-26, 33, 41, 42, 44). However, the sample was not uniform in relation to the number of individuals in each age and gender group, in order to allow to take conclusions regarding the relation between CVM and BGS stages with chronological age and gender. In a study conducted by Gray *et al*. (32) in 2016, the general vertebrae shape changes were similar in both genders, although girls were more advanced than boys, reaching each development stage earlier. The design of the present study didn't enable to acknowledge such conclusions, by means of establishing an affinity between the different stages of the BGS and CVM methods with a certain chronological age or determine if females reach PGS and thus MPS fusion, earlier than their male counterparts.

The avoidance of bias was assured by having the observers staging the panoramic x-rays and lateral cephalograms in digital format directly and not from tracings of anatomic structures, that could affect the reproducibility of both methods analyzed. (21) But the x-rays were not cropped to show only the area of interest (the MPS and the cervical vertebrae), leaving structures as the teeth, that could mislead in the classification.

Training is necessary to obtain high diagnostic accuracy and intraobserver agreement in the visual assessment of BGS and CVM methods. So, our observers received proper training before staging the x-rays. Nevertheless, it should be noticed that the number of examiners was low and that both participated in the design and construction of the study, although none of the observers had research-level experience or ever used the BGS or the CVM method.

For the statistical analysis, it was used the Weighted Cohen's Kappa Coefficient instead of a correlation test, because it was utilized ordinal data (qualitative stages) in our study. To proceed to the evaluation of the concordance between BGS and Baccetti's CVM method, the two scales were recoded, since they were measuring the maturation of different anatomic structures, which have not the same morphological development, impeding the establishment of a direct correlation between them. In that way, the recodification was done based on possible clinical decisions. That also allowed to have the same number of categories on both scales.

Furthermore, it was used the Weighted Cohen's Kappa Coefficient to assess intraobserver and interobserver agreement and quantify the disagreement, providing an accurate assessment of Baccetti's CVM method and BOKA Grading System reproducibility.

Validity and reliability of the BOKA Grading System

Reliability is a measure of the reproducibility. If a method is reliable, results obtained by the same examiner in different occasions, or by distinct observers should be similar. The results showed a good/very good agreement in the classifications between the two observers and the ones made by the same observer two weeks apart, demonstrating that BGS seems to be a reproducible method of evaluation. To notice that the percentage of agreement was significantly higher for the observer 1 (the dentistry student) than for the observer 2 (the Orthodontics specialist), raising the question "Does the clinical experience affect the classification of panoramic x-rays according to the BGS?".

The stages that observers disagreed the most was between stage 2 and 3, and 3 and 4 (table 4), which can lead to a misdiagnose and inadequate treatment plan, especially between stages 2 and 3.

Baccetti's CVM method is based on the fact that cervical vertebrae go through morphological changes at different development stages and mature in a consistent and predictable way with periods of acceleration and deceleration that mimic the overall somatic growth pattern. (49) It includes six stages: two prepubertal (stages 1 and 2), two pubertal (stages 3 and 4) and two postpubertal (stages 5 and 6). (43)

The results of our study showed a good/very good agreement in the classifications between the two observers and the ones made by the same observer two weeks apart, demonstrating that Baccetti's method seems to be a reproducible method of evaluation. This is in accordance with some studies on the literature. In a study conducted by Zhao *et al.* (47) in 2012, the reliability of Baccetti's method was proved statistically with strong interobserver and intraobserver agreement. A study made in 2014, by Perinetti *et al*. (43) also stated that the visual assessment of the CVM stages appears to be accurate and repeatable if the examiners receive training and precise guidelines. Rainey *et al.* (20), in 2016, classified the intraobserver and interobserver reliability of Baccetti method to assess the mandibular growth as substantial. The staging was greatly influenced by the quality of the radiographs.

Nevertheless, other studies in the literature state the opposite, making hard to draw conclusions about reproducibility of Baccetti's CVM method. In a study conducted by Nestman *et al*. (42) in 2011, it was concluded that the interobserver agreement, regarding to Baccetti's method is high when describing the lower borders of C2, C3 and C4 as flat or curved, but low when assessing the shape of C3 and C4 bodies, leading to an overall poor reproducibility. In 2015, Engel *et al*. (44) and Rongo *et al.* (21) concluded that the reliability and thus reproducibility of CVM method were questionable and that additional biologic indicators should be considered. Inter-observer reproducibility of the CVM method was low to moderate, and intra-observer reproducibility was substantial in a study conducted by Sohrabi *et al*. (46) in 2016. Gabriel *et al*. (41) in 2009, concluded that the CVM method is too variable to be used as a strict clinical guideline for assessing skeletal maturity and timing of orthopedic treatment, because there were more disagreements than agreements between observers (agreement was below 50%) and the same observer only agreed with himself or herself in 62% of cases.

There are various reasons to explain the high variability of the intraobserver and interobserver values: small samples and number of examiners, radiographs that are not selected randomly, but instead

preselected on the basis of ease of stage determination, authors that have research-level experience and that perform as observers in their studies. Cropped images may also diminish the similarity of the test environment to the usual clinical situation in which an orthodontist will see a full lateral cephalogram, thus affecting the reliability and reproducibility of the CVM method. (20) Our study doesn't make these mistakes, except for the limited number of observers.

Our observers disagreed the most between stages 1 and 3, and stages 4 and 5 (table 6), which can lead to a misdiagnose and treatment plan. Classification between stages 4 and 5 requires carefulness because may lead to the loss of the opportunity for proper treatment. (43)

To notice that the percentage of agreement was a little bit higher for the observer 1 (the dental student) than for the observer 2 (the orthodontics specialist). A study performed by Rongo *et al.* (21) concluded that orthodontic clinical practice has no influence on the intraobserver and interobserver reproducibility of the method, although a deep training of the use of CVM method is critical. Furthers studies should be made on the subject.

***

Although BGS seems to be a reproducible method, our study failed to prove its validity and reliability, since the values of concordance between BGS and Baccetti's CVM method, described in the literature as valid in the determination of skeletal age and, consequently, in the choice between RME and SARME/MARPE (20, 34, 35, 48, 50, 51), were only moderate. This discloses that the use of this method alone is not enough in the decision process.

Compared with the Baccetti's method, the BGS led to a higher percentage of patients classified in category A and fewer in category C. This could mean that BGS method underestimates the maturation stage of the MPS, thus leading to a false perception of the ability of a non-surgical procedure to achieve maxillary expansion in a specific patient. Potential complications of choosing RME for the treatment of patients with an advanced skeletal age are the relapse of the maxillary expansion, pain and tissue swelling, as well as necrosis of the palate, tipping of the molars and root resorption, fenestration of the buccal cortex, bone loss and subsequent gingival recessions. (3, 5, 17)

It should be noticed that the lack of scientific literature regarding the BGS, made its recodification difficult. More clinical studies are needed in order to enable researchers and orthodontics practitioners to interpret this classification method and to use it in clinical practice. Moreover, by converting a scale with more stages into one with fewer, information deficit might occur, due to loss of discriminative capacity at the intermediate stages. This may explain why the agreement between the two scales was not ideal.

Final considerations

If, in the future, the BOKA method proves to be valid in the evaluation of the maturation of the midpalatal suture, its use in orthodontic practice may be valuable, since the panoramic radiographs are routinely performed in the Dental Medicine consultations. Thus, in the presence of individuals with the need of maxillary expansion, they will not be exposed to additional radiation for the evaluation of the most indicated therapeutic modality.

Because this is the first study to evaluate the diagnostic reliability and validity of the BOKA Grading System, comparison with previous articles is not possible. In that way, further studies are necessary to prove not only the efficacy of BGS but also to validate the results of the present study. Future studies should include a larger number of observers, with different degrees of clinical experience. It would be also interesting to make a longitudinal study, that allowed to observe the changes on the x-ray image of the MPS and cervical vertebrae over the years and establish a correlation between the stages of the two scales. It would be important, after more research on the topic, to try to validate the use of the BGS, by means of clinical cases of maxillary expansion, in which the decision between RME and SARME/MARPE was made using BGS method.

Nevertheless, the study of MPS maturation in panoramic x-rays must be made with caution, once panoramic radiographs deliver a two-dimensional image of a three-dimensional structure, representing

only a small part of the whole anteroposterior length of the MPS. Structures overlapping the MPS and its running path, when not parallel to the x-ray, may lead to an incorrect BGS classification. Radiographic diagnosis is also influenced by the degree of post-acquisition image sharpness and clarity. In this study, no changes were made in the contrast, brightness or size of the radiographs, which may have impaired its correct interpretation.

It is important, when performing CVM staging, to standardize the patient's head position, to avoid small variations that might impair the reliability of measurements and consequently interfere with the diagnosis. A study performed in 2013 by Torres *et al.* (39) demonstrated that with a 15º upward head inclination and 15º downward head inclination, the stages obtained were significantly higher, thus having the potential to influence the type of treatment indicated for the patient.

We have also noted that, with aging, the vertebrae undergo degenerative changes, which can lead to their erroneous classification in an inferior CVM stage.

Conclusion

According to the limitations of the present investigation, it was possible to conclude that:

- the intraobserver and interobserver agreement of both BGS and Baccetti's CVM method were good to very good, showing that these methods are reproducible.
- BOKA Grading System showed only a moderate concordance with Baccetti's CVM method. In that way, it doesn't seem to be sufficiently reliable to be used alone in the assessment of the MPS maturation stage, and to decide between orthodontic/orthopedic or surgical treatment of transverse maxillary deficiencies.

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I express my appreciation as well to all the other people that accompanied me during this academic journey and in the elaboration of the thesis.

Attachments

Attachment 1 - Ethical approval from the Ethics Commission

TÍTULO DO PROJETO :

"Evaluation of the maturation of the midpalatal suture in panoramic x-rays and its correlation with cervical vertebrae maturation"

RELATORES:

Prof. Dr. Álvaro Azevedo

Dra. Felicidade Lourenço

PARECERES:

- ___X_Parecer favorável (final)
  - Os relatores são favoráveis à realização do projeto tal como apresentado

- ___Parecer favorável condicional
  - Os relatores consideram o projeto adequado no geral, mas solicitam a reformulação de aspetos pontuais do mesmo ; após a alteração ser efetuada (e documentada por comunicação escrita dirigida à CE demonstrando que foi feita), o parecer torna-se favorável, sem ser necessária reapreciação.

- ___Pedido de esclarecimento/reformulação
  - Os relatores consideram que há informação essencial em falta que não permite a adequada apreciação ética do projeto.

- ___Parecer desfavorável (final)
  - Os relatores consideram que o projeto não é adequado do ponto de vista ético.

2019/01/07

Prof. Dr. Álvaro Azevedo

Dra. Felicidade Lourenço

Attachment 2- Authorization for the treatment of personal data in investigation projects from the University of Porto

U.PORTO	Unidade de Proteção de Dados	DATA: 17/01/2019

TICKET N.º 2018121115002439

Nome	Ana Catarina Remoaldo Vaz
Número Mecanográfico	201405409
Unidade Orgânica	Faculdade de Medicina Dentária (FMDUP)
Título do Tratamento/Estudo	Evaluation of the maturation of the midpalatal suture in panoramic x-rays and its correlation with cervical vertebrae maturation

Sumário do Pedido

No âmbito da unidade curricular de "Monografia de Investigação ou Relatório de Atividade Clínica", integrada no plano de estudos do Mestrado Integrado em Medicina Dentária da FMDUP, pretende a requerente levar a cabo um estudo clínico sem intervenção destinado a validar a utilização do método BOKA para a avaliação da maturação da sutura palatina mediana em radiografias panorâmicas. Além disso, o estudo visa comparar o método supracitado com o método de avaliação da maturação das vértebras cervicais proposto por Baccetti.
Os únicos dados a serem utilizados serão as radiografias panorâmicas e telerradiografias em incidência de perfil de pacientes do Serviço de Ortodontia da Faculdade de Medicina Dentária da Universidade do Porto (FMDUP); as quais foram previamente realizadas quando os indivíduos em causa se deslocaram à Faculdade no âmbito de consultas de Ortodontia. Os pacientes cujas radiografias vão ser analisadas são escolhidos aleatoriamente, sem que qualquer dado que os permita identificar (nome, número do processo, etc.) acompanhe os dados radiográficos recolhidos.

Conclusões

Apesar de a requerente ter acesso ao processo clínico dos pacientes, apenas extrairá, para fins de investigação, medições e características médicas das radiografias. Sendo residuais as probabilidades de identificação dos participantes no estudo em causa a partir da análise dos dados supramencionados, somos do parecer que os mesmos podem considerar-se anonimizados tendo em conta os meios suscetíveis de ser razoavelmente utilizados para identificar direta ou indiretamente uma pessoa singular.

a Encarregada de Proteção de Dados
da Universidade do Porto

Susana Rodrigues Pereira
Doutora Susana Rodrigues Pereira

Attachment 3 – Approval for Re-Use of Clinical Records for Research Purposes from RAI

U.PORTO
FACULDADE DE MEDICINA DENTÁRIA

AUTORIZAÇÃO RAI-FMDUP 08000019

Pedido para a reutilização de registos clínicos para fins de Investigação

Investigador: ***Ana Catarina Remoaldo Vaz***

E-mail: up201405409@fmd.up.pt Tlm: 913387334

O seu pedido para reutilizar registos clínicos para fins de investigação foi registado com o número em epígrafe, e foi por mim **autorizado**, no uso dos poderes legais em que estou investido como Responsável pelo Acesso à Informação (RAI) da Faculdade de Medicina Dentária da Universidade do Porto.

A presente autorização, que tem um âmbito estritamente jurídico e natureza imperativa, no domínio do acesso e reutilização da informação de saúde, dos registos clínicos, à guarda legal e institucional da FMDUP, **não dispensa o necessário e pertinente parecer da Comissão de Ética e autorização do Director da FMDUP**. Por isso mesmo, da comunicação da presente deliberação, será dado conhecimento ao Exmo. Senhor Director e à Exma. Senhora Presidente da Comissão de Ética, já que a **investigação deve ser abordada numa perspectiva integrada, onde a requerente deve ser a primeira a assumir, que o Estatuto de Investigador significa um conjunto de direitos e obrigações, quer de natureza jurídica, quer de natureza ética, quer, ainda, com o necessário enquadramento na estratégia institucional**.

O presente pedido de reutilização de registos clínicos para fins de investigação, intitulado: ***"Midpalatal suture maturation assessment on panoramic X-rays and its correlation with cervical vertebrae maturation"*** subsume-se no fenómeno da reutilização para fins de I&D, consagrado quer na Lei 26/2016, de 22 de Agosto, quer na Directiva 2013/37/EU, de 26 de Junho, do Parlamento Europeu e do Conselho.

Aproveito esta oportunidade para a felicitar por ter feito este pedido de reutilização de registos clínicos para fins de Investigação & Desenvolvimento, o que significa estar a exercer um direito que tem enquanto investigadora, e ainda, para a informar, que a reutilização de documentos do sector público, neste caso registos clínicos, sem autorização da entidade competente, o RAI, é uma contra-ordenação prevista e punida nos termos do artigo 398, da Lei 26/2016, de 22 de Agosto.

Não hesite em me contactar, para o endereço rai@fmd.up.pt ou para o Tlm: 967 020 912, para esclarecer qualquer dúvida.

Com os melhores cumprimentos, votos de sucesso na investigação, e na expectativa que a mesma venha a contribuir para a sociedade do conhecimento que todos, legitimamente, almejamos.

Considere-me, sinceramente, ao seu dispor

Porto, 07/03/2019

Américo dos Santos Afonso

Faculdade de Medicina Dentária da Universidade do Porto
Rua Dr. Manuel Pereira da Silva, 4200-393 Porto PORTUGAL

Attachment 4 – BOKA Grading System for the classification of the Midpalatal suture maturation

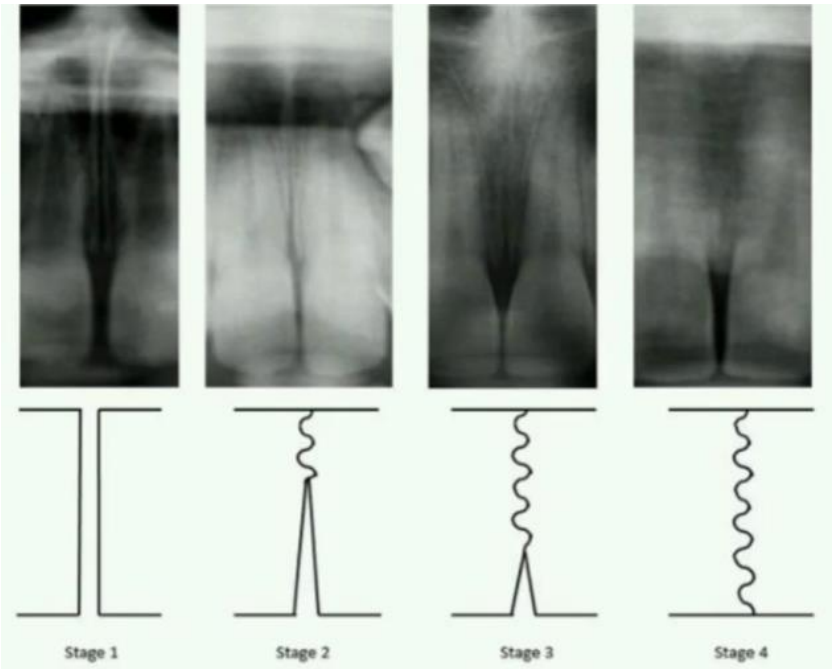

FIGURE 2- STAGES OF THE BOKA GRADING SYSTEM FOR THE MATURATION OF THE MIDPALATAL SUTURE

Stage 1: The Midpalatal suture is straight with parallel high-density lines and little or no interdigitation. It appears as a complete radiolucent line from the floor of the nasal cavity inferiorly through the crestal bone between the maxillary central incisors.

Stage 2: The Midpalatal suture has interdigitated less than half the distance from the floor of the nasal cavity inferiorly to the crestal bone between the maxillary central incisors, but it is not completely radiolucent as in stage 1.

Stage 3: The Midpalatal suture has interdigitated more than half the distance from the floor of the nasal cavity inferiorly to the crestal bone between the maxillary central incisors, but it is not fully fused as in stage 4.

Stage 4: The Midpalatal suture is fully interdigitated from the nasal floor inferiorly down the crestal bone between the maxillary central incisors.

Attachment 5 - Cervical Vertebrae Maturation (CVM) Method by Baccetti *et al.* 2005 (52)

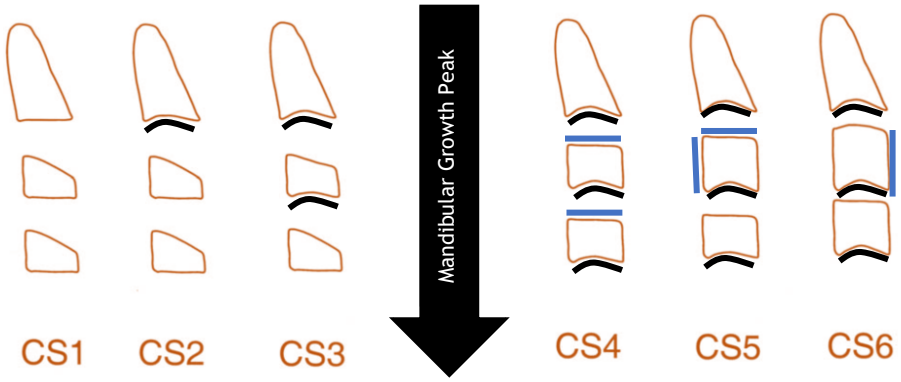

FIGURE 3- STAGES OF CERVICAL VERTEBRAE MATURATION METHOD. ADAPTED FROM BACCETTI *ET AL*. 2005

Cervical Stage 1 (CS1): The lower border of all the three vertebrae (C2, C3 and C4) are flat. The bodies of both C3 and C4 are trapezoid in shape (the superior border of the vertebral body is tapered from posterior to anterior). The peak in mandibular growth will occur on average 2 years after this stage.

Cervical Stage 2 (CS2): A concavity is present at the lower border of C2. The bodies of both C3 and C4 are still trapezoid in shape. The peak in mandibular growth will occur on average 1 year after this stage.

Cervical Stage 3 (CS3): Concavities at the lower border of both C2 and C3 are present. The bodies of C3 and C4 may be either trapezoid or rectangular horizontal in shape. The peak in mandibular growth will occur during the year after this stage.

Cervical stage 4 (CS4): Concavities at the lower border of C2, C3 and C4 are now present. The bodies of both C3 and C4 are rectangular horizontal in shape. The peak in mandibular growth has occurred within 1 or 2 years before this stage.

Cervical stage 5 (CS5): The concavities at the lower borders of C2, C3 and C4 are still present. At least one of the bodies of C3 and C4 is squared in shape. If not squared, the body of the other cervical vertebra is still rectangular horizontal. The peak in mandibular growth has ended at least 1 year before this stage.

Cervical stage 6 (CS6): The concavities at the lower borders of C2, C3 and C4 are still evident. At least one of the bodies of C3 and C4 is rectangular vertical in shape. If not rectangular vertical, the body of the other cervical vertebra is still squared. The peak in mandibular growth has ended at least 2 years before this stage.

Declaration of authorship

DECLARAÇÃO

Monografia de Investigação/Relatório de Atividade Clínica

Declaro que o presente trabalho, no âmbito da Monografia de Investigação/Relatório de Atividade Clínica, integrado no MIMD, da FMDUP, é da minha autoria e todas as fontes foram devidamente referenciadas.

16 / 05 / 2019

Ana Catarina Ramos Alves Vaz
O / A investigador(a)

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Advisor's Authorization for final delivery of the thesis

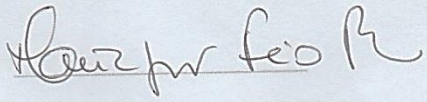
PARECER

(Entrega do trabalho final de Monografia)

Informo que o Trabalho de Monografia desenvolvido pelo(a) Estudante Ana Catarina Bernardo Vaz com o título: Midpalatal Suture Maturation Assessment on Panoramic X-rays and its correlation with Cervical Vertebrae Maturation está de acordo com as regras estipuladas na FMDUP, foi por mim conferido e encontra-se em condições de ser apresentado em provas públicas.

16/05/2019

O(A) Orientador(a)



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