

UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

JORGE TOMASIO CABALLERO

**Facial anthropometrics landmarks used to obtain the occlusal
vertical dimension - a stereophotogrammetry study**

**Avaliação através de estereofotogrametria, de medidas faciais
antropométricas utilizadas para obtenção da dimensão vertical de
oclusão**

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Orientadora: Prof.^a Dr.^a Simone Soares.

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DEDICATÓRIA

A meus filhos Mia Isabella e Jorge Gustavo

A minha esposa: Roxana; esposa, companheira e amiga.

A meus pais, Jorge e Carla; e à minhas irmãs, Carla e Mariana.

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“O sucesso não é o fim, o fracasso não é fatal; é a coragem de continuar que conta.”

Winston Churchill

RESUMO

Restabelecer a dimensão vertical de oclusão (DVO), quando não há estabilidade oclusal e ausências múltiplas dentárias além de desgastes acentuados, é fundamental para atingir uma reabilitação oral satisfatória. Apesar da existência de vários métodos para determinar a DVO não há um método único e preciso. O presente trabalho se propôs a utilizar da estereofotogrametria para observar a relação entre medidas antropométricas da face e comparar as técnicas métricas para obtenção da DVO entre indivíduos de 20 a 65 anos. A análise foi realizada em 186 pacientes divididos em quatro grupos: G1 - 46 pacientes de 20 a 30 anos de idade; G2 - 35 pacientes de 31 a 40 anos de idade; G3 - 50 pacientes de 41 a 50 anos de idade; G4 - 55 pacientes de 51 a 65 anos de idade. As fotografias 3D foram obtidas utilizando o sistema portátil de câmera de estereofotogrametria Vectra H1 (Canfield Scientific, Inc, Fairfield, NJ, EUA). Pontos morfométricos foram estabelecidos na face previamente a captura da imagem e, através do software VAM elaboration (Canfield Scientific, Inc), medidas lineares de relevância para a avaliação da DVO foram mensuradas. Regressão linear múltipla avaliou a relação entre as medidas do terço inferior da face (Sn-Gn e Prn-Pg). O ANOVA foi aplicado para comparar as medidas de Sn-Gn com as medidas do canto externo dos olhos às linhas retas dirigidas lateralmente as comissuras, no sentido vertical (Exo R/L-Ch'R/L) nos grupos avaliados. O nível de significância de .05 foi considerado significativo. Através da regressão linear múltipla, 13 medidas lineares preditoras da DVO foram avaliadas e apenas 4 foram consideradas estatisticamente significativas para o modelo Sn-Gn: Exo R – Ch' R; ExoL – EndL x2; EndR – EndL x2 e sexo. Para o modelo Prn-Pg, três variáveis independentes apresentaram diferença estatisticamente significativa: Exo R-Ch' R; Exo L-Ch'L e Exo L-End Lx2. Os preditores ExoR-Ch'R e ExoL-EndoLx2 impactam significativamente a DVO, através da estereofotogrametria. Quando se comparou os grupos (ANOVA) e as medidas de Sn-Gn em relação ao canto externo dos olhos (ExoR/L) e a linha reta da comissura (Ch'R/L) e a pupila (PupilR/L) e a linha reta da comissura (Ch''R/L), ambas no sentido vertical, os resultados mostraram diferença estatisticamente significativa em todas as medidas exceto em PupilL-Ch''L. Conclui-se que o método de Willis, que estabelece a medida do canto externo do olho à linha da comissura direcionada lateralmente e que se encontra com a linha vertical do canto externo do olho, como método para

estabelecer a DVO só apresenta relevância na medida da pupila à comissura do lado esquerdo (PupilL/Ch'L), não encontrando respaldo nas demais medidas para estabelecimento da DVO com a estereofotogrametria.

Palavras-chave: Reabilitação Bucal; Fotogrametria; Imagem; Dimensão Vertical.

ABSTRACT

Restoring the occlusal vertical dimension (OVD) in occlusal imbalance, multiple dental absences, and severe wear is essential to achieving satisfactory oral rehabilitation. Despite several methods to determine the OVD, there is no single and precise. The present study aimed to use stereophotogrammetry to assess the relationship between facial measurements and compare metrics techniques to obtain OVD among individuals aged ranging 20 to 65 years. The analysis was performed on 186 patients divided into four groups: G1 - 46 patients aged between 20 and 30 years; G2 - 35 patients aged 31 to 40 years; G3 - 50 patients aged 41 to 50 years; G4 - 55 patients aged 51 to 65 years. Relevant anthropometrics landmarks relationship to OVD were pointed on the face, and 3D images were obtained using the Vectra H1 (Canfield Scientific, Inc, Fairfield, NJ, USA) portable stereophotogrammetry camera system. The linear measurements were measured by VAM elaboration software (Canfield Scientific, Inc). Linear regression analysis was performed to evaluate the relationships between the measurements of the lower third of the face (Sn-Gn and Prn-Pg). The ANOVA was applied to compare the Sn-Gn measurements with the measurements from the outer corner of the eyes to the straight lines of the commissures in the vertical direction (Exo R/L-Ch'R/L) in the evaluated groups. $P < .05$ was considered significant. Through multiple linear regression, 13 linear measures predictive of OVD were evaluated, and only four were considered statistically significant for the Sn-Gn model: Exo R – Ch' R; ExoL – EndL x2; EndR – EndL x2 and sex. For the Prn-Pg model, three independent variables showed a statistically significant difference: Exo R-Ch' R; Exo L-Ch'L, and Exo L-End Lx2. The ExoR-Ch'R and ExoL-EndoLx2 predictors significantly impact the OVD through stereophotogrammetry. Comparing the groups (ANOVA) and the Sn-Gn measurements concerning the outer corner of the eyes (ExoR/L) and the straight line of the commissure (Ch'R/L) and the pupil (PupilR/L) and the straight line of the commissure (Ch''R/L), both vertically, the results showed a statistically significant difference in all measurements except PupilL-Ch''L. It is concluded that the Willis method, which establishes the measurement from the outer corner of the eye to the straight line of the commissure as a method to obtain the OVD, only has relevance in the measurement of the pupil to the left straight line of the commissure (PupilL/Ch'L). Not finding support in the other measures to establish OVD with stereophotogrammetry.

Key words: Mouth Rehabilitation; Photogrammetry; Imaging, Three-Dimensional; Vertical Dimension.

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LIST OF ABBREVIATIONS

3D	Three dimensional
VD	Vertical Dimension
OVD	Occlusal Vertical Dimension
RVD	Rest Vertical Dimension
IRD	Interocclusal Rest Distance



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1 INTRODUCTION

Rehabilitating total or partially edentulous patients who need to reestablish the occlusal vertical dimension (OVD) is a challenge for the dental surgeon.^{1,2} The metrics used to establish the OVD, based on the rest vertical dimension (RVD) are based on empirical data dictated by Willis in 1930.³ However, it should be noted that the thirds of the face must be balanced to maintain facial harmony, and the lower third is directly related to OVD.⁴

The OVD can be determined from the base of the nose (Subnasale - Sn) to the base of the chin (Gnathion - Gn) or from the tip of the nose (Pronasale - Prn) to the prominent region of the chin (Pogonion - Pg) in sagittal direction.¹ Adequate and practical methods have been used to determine the OVD nonetheless, they are controversial due to lack of scientific evidence.¹ To overcome the limitations of the proposed methods, we used a combination of techniques without scientific basis. Thus, with the onset of stereophotogrammetry (3D technology), anthropometrics landmarks established on the face can be evaluated and compared to the feasibility and reliability of this new tool. From classical anthropometry, which identifies facial points and performs measurements with calipers and cephalometric rulers, digital anthropometry captures facial landmarks and by using X, Y, and Z coordinates, linear distances, and angles are measured.⁵ Thus, classical anthropometry, in two dimensions, is being replaced by various methods of three-dimensional analysis (3D).⁵⁻⁷

Three-dimensional technology (3D) has been used in research a few years ago, and proved to be accurate, allowing for reliable and reproducible facial measurements;^{5,7-10} in addition to presenting advantages such as speed, simplicity of

use,^{5,7,8} data storage, non-invasive method with application in areas such as plastic surgery, maxillofacial surgery, orthodontics, forensic medicine, among others.⁹⁻¹²

Based on previous researches on OVD and the absence of studies that validate the methods available for its determination. Knowing that in the lack of a precise technique, the literature has a consensus on the methods association, in the present work, we sought to evaluate the use of anthropometrics landmarks to determine the OVD. Comparisons of measurements among individuals of different sex and age through stereophotogrammetry have not yet been performed and presented in the literature. In this way, we sought to assess which measures are reliable to establish normal parameters to rehabilitate patients who need to restore the OVD, according to the sex and age of the individuals studied. The null hypothesis to be tested states that the methods from the Subnasale (Sn) – Gnathion (Gn), Pronasale (Prn) – Pogonion (Pg), and Exocanthion (Ex) – Cheilion (Ch) measurements are parameters to determine the OVD.

2.1 Article 1

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3D stereophotogrammetry to determine the Occlusion Vertical Dimension

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ABSTRACT

Purpose: Evaluate, through stereophotogrammetry, facial anthropometrics landmarks measurements to determine the occlusal vertical dimension (OVD).

Methods: A hundred and eighty-six individuals (20 to 65 years) in both sexes were evaluated. Relevant anthropometrics landmarks relationship to OVD were pointed on the face, and 3D images were obtained using the Vectra H1 portable stereophotogrammetry camera system. The linear measurements were measured by VAM elaboration software. Linear regression analysis was performed to evaluate the relationships between the measurements of the lower third of the face (Sn-Gn and Prn-Pg) used to establish the OVD. $P < .05$ was considered as significant.

Results: Thirteen linear measurements were evaluated as predictors, and predictors with statistically significant differences for Sn-Gn were: Exo R – Ch' R; Exo L – End L x2; End R – End L x2 and sex. For the Prn-Pg, the independent variables presented Exo R-Ch' R; Exo L-Ch'L, and Exo L-End Lx2 as statistically significant differences.

Conclusions: The multiple regression model revealed that there is a prediction of measurements from the outer corner of the eyes to the commissure on the right side and from the outer corner of the eyes to the inner corner multiplied by two on the left side in both proposed models (Sn-Gn and Prn-Pg).

INTRODUCTION

In the rehabilitation of partially or edentulous patients, the restoration of the Occlusal Vertical Dimension (OVD) is an important phase and a challenge for professionals [1,2]. Restoration of OVD is indicated for multiple reasons; but it must be indicated respecting the physiology and function of the stomatognathic system. For it is not an immutable reference but a dynamic dimension, within a zone of physiological tolerance [3].

There is no single and precise method to determine the Occlusal Vertical Dimension, on the contrary, there are methods in the literature that, despite being adequate and convenient in clinical practice, are controversial due to the lack of scientific evidence. So, it is recommended to use a combination of techniques to overcome the limitations of each method and approach the appropriate OVD for each patient [1]. In the literature, pre-extraction and post-extraction methods are described, and among the post-extraction methods, anthropometric landmarks are indicated [1].

The assessment of facial morphology through measurements obtained from anthropometric points is essential for medical and dental disciplines [4]. Such specialties have been favored in recent years due to advances in technology, which allows performing three-dimensional analyzes of facial morphology through innovative instruments, among which stereophotogrammetry stands out [5,6,7].

Over time, OVD has usually been measured through conventional cephalometric analyses or anthropological tweezers. The drawback of cephalometry is radiation, while anthropological tweezers, despite presenting themselves as a simple technique, are subject to measurement errors [8,9].

Based on previous studies on OVD and verifying the absence of researches that validate measurements and techniques to determine the height of the lower third of the face; knowing that, in the absence of a precise method, the association of several methods is a consensus; the present study sought to evaluate the measurements of the Subnasale (Sn) - Gnathion (Gn) and Pronasale (Prn) - Pogonion (Pg) to determine the OVD, which, although they are routinely used, lack scientific basis. The null hypothesis to be tested is that anthropometrics distances on the face associated with Sn-Gn and Prn-Pg measurements can be used to determine the OVD in patients aged between 20 and 65 years of both genders using stereophotogrammetry.

MATERIAL AND METHODS

1 Sample selection

This study was conducted after approval by the institutional Review Board. Written informed consent was obtained from all participants under protocol number CAAE: 22075219.6.0000.5417.

A total of 186 volunteers individuals were enrolled in this study with age ranged 20 to 65 years. The inclusion criteria were: natural teeth individuals with occlusal stability and Angle Class I occlusion, Caucasian, Brazilian, single or 3-units' prostheses, individuals who do not present pathologies in the orofacial region, and individuals without craniofacial anomalies.

The exclusion criteria were: individuals who underwent orthognathic surgery, individuals with a history of craniofacial trauma, individuals with severe tooth wear and significant facial asymmetry, and who underwent plastic surgery.

2 – Acquisition of 3D images using Stereophotogrammetry

Vectra H1 stereophotogrammetry equipment (Canfield Scientific, Inc, Fairfield, NJ, EUA) and VAM elaboration software (Canfield Scientific, Inc) were validated to perform facial analysis [10,11]. The system has proven reliable in evaluating linear, angular, and surface area measurements and is accurate and reliable for clinical and research applications [6,10,11].

Using the VECTRA H1 handheld camera system and obtaining 3D images; the patient must be positioned correctly and the operator calibrated to capture the facial photographs [11].

3- Anthropometric points selected to analyze the linear measurements on the face

Sixteen anthropometric points [1,4,6,12-14] were identified and marked on the patients' faces [8,11] (Table 1). Linear distances established for measurement and comparison (Table 2) were obtained to evaluate the methods for determining OVD (Figure 1).

Table 1. List of anthropometric landmarks

Anthropometric landmarks	Definição
Endocanthion (En)	The point at the inner commissure of the eye fissure (left and right);
Exocanthion (Ex)	The point at the outer commissure of the eye fissure (left and right);
Pogonion (Pg)	The most anterior of the chin;
Pronasale (Prn)	The most protruded point of the apex nasi;
Subnasale (Sn)	The midpoint of the angle at the columella base where the lower border of the nasal septum and the surface of the upper lip meet;
Tragion (T)	The notch on the upper margin of the tragus (left and right);
Gnathion (Gn)	The lowest median landmark on the lower border of the mandible;
Cheilion (Ch)	The point located at each labial commissure (left and right);
Cheilon'(Ch')/(Ch'')	The point located in the line of at each labial commissure (left and right);
Pupil (Pup)	The center of the eye (left and right)

Table 2. List of the linear measurements (predictors) evaluated

Linear measurements	
End – Ch (right and left)	Distance between the Endocanthion to the Cheilion
Exo- Ch´ (right and left)	Distance between the Exocanthion to the Cheilion´
Exo R - End L	Distance between the Exocanthion right to the Endocanthion left
Exo L - End R	Distance between the Exocanthion left to the Endocanthion right
T – Exo (right and left)	Distance between the Tragion to the Exocanthion
Pupil -Pupil	Distance between the pupil right and left
Exo - end x2 (right and left)	Distance between the Exocanthion to the Endocanthion multiplied by 2
Pupil - Ch" (right and left)	Distance between the pupil to the Cheilion´

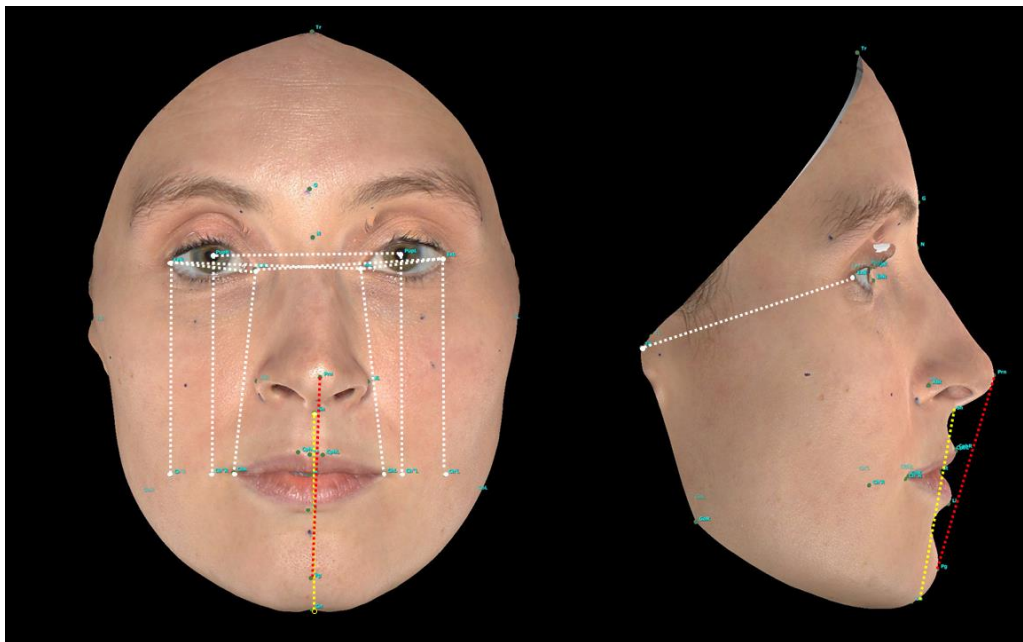


Figure 1. Linear measurements predictors in white and the occlusal vertical dimension measurement defined by two different linear measurements, in yellow (Sn-Gn) and red (Prn-Pg).

4. Statistical analysis

Linear regression analysis was performed to analyze the relationships between the measurements of the lower third of the face (Sn-Gn and Prn-Pg) and the following

measurements as predictors: End – Ch (right and left); Exo- Ch´ (right and left); Exo R - End L; Exo L - End R; T – Exo (right and left); Pupil -Pupil; Exo - End x2 (right and left); Pupil - Ch" (right and left). $P < .05$ was considered as significant. Multiple linear regression with a stepwise backward approach was used to estimate equations for the optimal linear measurement to determine the occlusal vertical dimension. All data were analyzed using JAMOVI v.1.2 (The jamovi project, Sidney, Australia).

RESULTS

The study evaluated thirteen predictors (Table 2), and the dependent variables were the linear measurements in the lower third of the face used to determine the occlusal vertical dimension, the distance between the Subnasale to the Gnathion (Sn-Gn), and the distance between the Pronasale to Pogonion (Prn-Pg). The bivariate regression with the predictors was assessed ($p \leq 0.2$), twelve predictors were included in the multiple regression initial model, and the age was excluded from this analysis. Two multiple linear regression was applied, first to the Sn-Gn, and second to the Prn-Pg measurements.

The multiple linear regression model had performed with the whole predictors determined to the dependent variables Sn-Gn (Table 3) and Prn-Pg (Table 4). However, eight (8) of them were excluded (Pupil R - Ch" R; Pupil L - Ch" L; End R – ChR; End L – ChL; Exo R - End L; Exo L- End R; TR-ExR and TL-ExL) due to the variance inflation factor (VIF) > 5 . Stepwise backward model of the multiple regression model had assessed only the significant predictors of the literature to Sn-Gn (Table 5) and to Prn-Pg (Table 6).

Table 3. The first multiple linear regression model to the Sn-Gn linear measurement

Predictor	Estimate	SE	t	p
Intercept ^a	-3.4931	7.5164	-0.465	0.643
Exo R - Ch´R	0.6580	0.1543	4.265	< .001*
Exo L - Ch´L	0.1503	0.1508	0.997	0.320
Pupil -Pupil	-0.1110	0.1620	-0.685	0.494
Exo R - end R x2	-0.0781	0.1266	-0.616	0.538
Exo L - end L x2	0.3138	0.1208	2.598	0.010*
End R- End L x2	0.1435	0.0773	1.857	0.065
Sexo:				
M – F	2.0374	0.7337	2.777	0.006*

^a Represents reference level

Table 4. The first multiple linear regression model to the Prn-Pg linear measurement

Predictor	Estimate	SE	t	p
Intercept ^a	-5.8638	9.0563	-0.6475	0.518
Exo R - Ch´R	0.3790	0.1859	2.0394	0.043*
Exo L - Ch´L	0.4977	0.1817	2.7396	0.007*
Pupil -Pupil	0.0128	0.1952	0.0655	0.948
Exo R – End R x2	-0.1972	0.1526	-1.2926	0.198
Exo L – End L x2	0.3833	0.1456	2.6333	0.009*
End R- End L x2	0.0637	0.0931	0.6839	0.495
Sexo:				
M – F	1.1323	0.8840	1.2809	0.202

^a Represents reference level

Table 5. Stepwise backward model of the multiple regression model had assessed the significant predictor of the literature (Sn-Gn dependent variable)

Predictor	Estimate	SE	t	p
Intercept ^a	-5.0972	7.3652	-0.692	0.490
Exo R - Ch´R	0.6627	0.1528	4.337	< .001*
Exo L - Ch´L	0.1310	0.1491	0.879	0.381
Exo L - End L x2	0.2119	0.0725	2.923	0.004*
End R - End L x2	0.0990	0.0462	2.142	0.034*
Sex:				
M – F	1.9086	0.7120	2.681	0.008*

^a Represents reference level

Table 6. Stepwise backward model of the multiple regression model had assessed the significant predictor of the literature (Prn-Pg dependent variable)

Predictor	Estimate	SE	t	p
Intercept ^a	-3.125	8.1457	-0.384	0.702
Exo R - Ch´R	0.420	0.1840	2.281	0.024*
Exo L - Ch´L	0.463	0.1801	2.573	0.011*
Exo L - End L x2	0.212	0.0862	2.462	0.015*
Sexo:				
M – F	1.283	0.8492	1.511	0.133

^a Represents reference level

The two significant predictors of the literature (Sn-Gn and Prn-Pg) using for OVD were evaluated using multiple linear regression. If $p < 0.05$ this means that at least one predictor is significant to evaluate the measure in question, in this case, both measurements were, but the adjusted R for the Sn-Gn measure is greater, that is, 53% of this set of predictors (Table 7).

Table 7. The model fit of multiple linear regression to the two dependent variables according to the significant predictors of the literature

	Model Fit measures			Overall Model Test			
	R	R ²	Adjusted R ²	F	df1	df2	p
Sn-Gn	0.739	0.546	0.533	43.3	5	180	< .001
Prn- Pg	0.667	0.445	0.433	36.3	4	181	< .001

DISCUSSION

In the present study, linear facial measurements were associated with classical measures to determine the OVD, Sn - Gn (Subnasale - Gnathion) and Prn - Pg (Pronasale - Pogonion); through multiple linear regression in patients aged between 20 and 65 years old, of both sexes, through stereophotogrammetry. Among the 13 predictors analyzed, 4 and 3 significantly impacted the OVD for Sn–Gn and Prn-Pg models, respectively. The multiple regression model revealed that there is a prediction of measurements from the outer corner of the eyes to the commissure on the right side

and from the outer corner of the eyes to the inner corner multiplied by two on the left side in both proposed models (Sn-Gn and Prn-Pg). Therefore, the null hypothesis was accepted, as the coefficient of determination showed that 53% and 43% of the OVD results measured by the Sn-Gn and Prn-Pg models are explained by this set of predictors, respectively.

The methods used to determine the OVD from craniofacial measurements are among the most described in the literature [14-19]. In addition, the authors claim that there is a relationship between craniofacial distances capable of predicting OVD. Nevertheless, most of them evaluate in 2D, using calipers and rulers, and not through 3D technology that has already proven accurate [11,20].

The models proposed are in congruence with the literature, Sn-Gn, Prn-Pg [1,17,21]. The results presented reveal that for each mm that is increased in the Exo R–Ch'R measure, we increased the OVD by 0.66mm for the Sn-Gn model and 0.42mm for the Prn-Pg model. This result is corroborated by Alhajj et al., [14] which evaluated whether the Prn-Pg and Sn-Gn distances correspond to the distance measured from the outer corner of the eye to the labial commissure in a straight line (Exo-Ch'). The authors concluded that the Exo-Ch' measure could be used as a reliable method to predict the OVD, however, it would be better to correlate it with Prn-Pg distance [14]. This result agrees with Sakkar et al., which reported that the Prn-Pg distance was more correlated with intraoral changes than the Sn-Gn distance, although facial measurements are not ideal for predicting OVD, the Prn-Pg distance is more reliable than the Sn-Gn distance [15]. Contrary to the above, Nagpal et al., evaluated the reliability of different craniofacial measurements used to predict OVD, comparing them with the distance (Sn-Gn) at rest and occlusion and concluded that the distance from the outer corner of the eye to the corner of the mouth can be used as an adjunct in

determining the OVD [17]. The present work, when applying a regression analysis, aimed to be more precise in the evaluation of craniometric measurements associated with the height of the lower third of the face.

Analyzing the sex is possible to infer that in the models presented, in which the female sex is the reference, from woman to man, there is an increase of 1.90 mm in the Sn-Gn model and 1.28 mm in the Prn-Pg model. It shows that the OVD values are higher in males, in agreement with Majeed et al., which evaluated the craniofacial measures correlation and OVD in the Saudi Arabian population using a caliper. The authors measured the OVD of Sn-Gn and found that the OVD mean in male (69.25 ± 5.54) was higher than in female (57.41 ± 5.32) [19]. Thus, it is relevant to note that in all studies with anthropometric measures of the face, differences in gender and ethnicity must be considered, and the results analyzed with caution [19,22].

The age variable was not considered for the multiple regression since, in this kind of test, it is evaluated if the predictors are minimally related to the outcome.

The distance from the outer and inner corners of the eyes on the left side, multiplying by two, presented equality in the two proposed models (Sn-Gn, Prn-Pg). It means that, each mm increased in the Exo L-End L x 2 measurements, we increased 0.21 mm in both models.

Interestingly, in the Prn-Pg model, both sides (right and left) of the distances from the outer corner of the eyes to the commissure, following a straight line, proved to be predictors of OVD, which corroborates what was observed by Alhaji et al. in the Yemeni population, in which there is a correlation between the measured distance from the outer corner of the eye to the angle of the mouth and Prn-Pg [14].

It is still important to emphasize that the establishment of a superior relationship between the OVD and the left facial measurements (Prn-Pg) instead of the right facial

measurements in dentate and edentulous individuals was advocated by Chou et al. [23]

In the Sn-Gn model, when the distance from the right inner canthus of the eye to the left inner canthus of the eye is multiplied by 2, the regression model proved to be a predictor of OVD. Therefore, it is inferred it is relevant for professionals to choose a starting point to measure the OVD, either the Prn-Pg or Sn-Gn distance, and from one of these measures to establish, according to the predictors, which significantly impacted and apply it while measuring the OVD.

It is important to note that the predictors identified as those that significantly impacted the OVD are all based on fixed points and not on soft tissue that presents a high degree of unpredictability [24,25].

The present study has limitations related to the sample size, the population studied, which is mixed race, and the difficulties of comparison with studies that evaluate through stereophotogrammetry, which are still scarce in the literature. However, the results must be interpreted with caution. Several authors showed that the Prn-Pg model is the one reliable for taking the OVD, in agreement with Jakstatet al., which investigated the movement of the skin markings due to the contraction of the mimic muscles and concluded that the Prn point proved to be the least mobile landmark. In the present study, the Sn-Gn model presented a coefficient of determination of 53% explained by this set of predictors, different from the 43% revealed by the Prn-Pg model [26].

These two models presented for obtaining the OVD, based on predictors, are relevant because the professional can choose one of them and consider which predictors are statistically significant.

CONCLUSION

The current study result suggests that in the Sn-Gn model, the predictors: sex, distances from the outer corner of the eye to labial commissure of the right side (ExoR-Ch'R); right to left inner corner of the eye multiplied by 2 (End R-End Lx2) and outer corner to the inner corner of the eye at left side multiplied by 2 (ExoL-EndL x 2) significantly impacts the OVD. As for the Prn-Pg model, the predictors of the outer corner of the eye and labial commissure of the right and left (ExoR-Ch'R) (ExoL-Ch'L) sides and exocanth and endocanth left multiplied by 2 (ExoL-End L x 2) significantly impact the OVD.

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Authors contributions

Authors 1 and 2: Contributed to data acquisition and interpretation, performed all statistical analyses, drafted and critically revised the manuscript

Authors 3, 4 and 5: Contributed to conception, design, interpretation, performed all statistical analyses, drafted and critically revised the manuscript

Author 5: Contributed to conception, design, interpretation, performed, drafted and critically revised the manuscript

“All authors gave their final approval and agree to be accountable for all aspects of the work.”

Declaration of Conflicting Interests

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2.2 Article 2

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Is there a relationship between the Willis method and the same measure to determine Occlusal Vertical Dimension using stereophotogrammetry?

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CLINICAL RESEARCH

Is there a relationship between the Willis method and the same measure to determine Occlusal Vertical Dimension using stereophotogrammetry?

ABSTRACT

Statement of problem: 'Willis' method using a Willis gauge, is one of the methods to determine the occlusal vertical dimension (OVD). Using stereophotogrammetry there is no study verifying if there is relationship between Willis's method and the values to determine the OVD.

Purpose: Based on Willis method as an auxiliary to restore occlusal vertical dimension the present study aimed to compare the measurements from Exocanthion and pupil of the eye to cheillion in straight line in both sides with Subnasale (Sn) to Gnathion (Gn) and evaluate the relationship by stereophotogrammetry.

Material and methods: A hundred and eighty-six individuals age range 20 to 65 years old were divided in 4 groups. Ten facial landmarks were marked on the face of each patient, a photo was captured. Paired t-test was performed to analyze the correspondence of the measurements proposed by the Willis metrical method. The ANOVA one-way was performed to evaluate the differences between the lower third of the face among ages. The statistical analysis was performed with significance at the level of 0.05.

Results: The Willis gauge from Exocanthion R/L – Ch'R/L comparing to Pupil R/L-Ch''R/L presented differences statistically significant ($P<.001$). Comparing the difference between the Sn-Gn and ExoR-Ch'R ($P=0.021$), ExoL-Ch'L ($P<.001$), Pupil R-Ch''R ($P=.002$), all of them presented statistically significant differences, except Pupil L-Ch''L. The ANOVA one-way was performed to evaluate if differences were observed among ages in all measurements in

the Willis metrical method. The differences were in ExoR-Ch'R ($P=0.012$) (G2/G3) and Pupil R-Ch''R ($P=0.002$) (G1/G3, G2/G3).

Conclusion: The use of Willis compass based on the description of the literature and based in the method used by clinicians is different from the measures using stereophotogrammetry. Only the measure Pupil L-Ch''L can be useful to establish the OVD. Differences were presented among ages only in ExoR-Ch'R and PupilR-Ch''R showing that the left side is more stable than right side.

CLINICAL IMPLICATIONS

Empirical methods to establish OVD are described in the literature. Willis's method is one of them used as an auxiliary to restore OVD, however this method was not evaluated by stereophotogrammetry, a non-invasive and precise tool to measure anthropometric distances on the face.

Keywords: Occlusal Vertical Dimension, Rest Vertical Dimension, Photogrammetry, Anatomic Landmarks.

INTRODUCTION

'Willis' method¹ is one of the methods to determine the occlusal vertical dimension. It consists in measure the distance from the pupil of the eye to the rima oris, and this distance is presumed to be equal to the vertical measurement from subnasale (Sn) to the Gnathion (Gn), when the teeth are in occlusion.² Restoring the lower facial height is a relevant procedure for health, esthetic, and quality of life in edentulous and partially dentate patients.

The majority methods proposed were based in caliper and rules³⁻⁵ and they did not show precise, because the soft tissue has to be considered and promotes distortion.^{6,7} Nowadays the 3D technology is rising quickly and the stereophotogrammetry is a new, non-invasive, portable tool and proved to be reliable.⁸⁻¹⁰ Studies using stereophotogrammetry and the face's anthropometric landmarks to help restore the OVD are sparse.

Based on Willis method as an auxiliary to restore occlusal vertical dimension the present study aimed to compare the measurements from pupil of the eye/from outer canthus of the eye to cheillion in straight line in both sides with Subnasale (Sn) to Gnathion (Gn). The null hypotheses to be tested is that no differences between these two measurements are presented and the Willis method can be used to restore occlusal vertical dimension using stereophotogrammetry.

MATERIAL AND METHODS

1) Sample selection

Ethics Board Committee approved the study under number: 22075219.6.0000.5417. The present study adopted a minimum clinical difference of 3 mm in soft tissue alteration¹¹ with a standard deviation of 3.51 mm¹² and a significance level of 0.05. Based on the sample calculation, at least 27 patients per group were established. A hundred and sixteen patients ranging from 20 to 65 years participated in the study.

The inclusion criteria were: Brazilian Caucasian; dentate patients who presented occlusal stability maintained by natural teeth, no orofacial anomalies and pathologies. The exclusion criteria were: patients who underwent orthognathic surgery, presented previous craniofacial trauma, the extensive prosthesis (occlusal stability maintained by prosthesis), malocclusion, severe wear, and plastic surgery on the face. Four groups divided in ages were established:

G1: 46 patients age from 20 to 30 years;

G2: 35 patients age from 31 to 40 years;

G3: 50 patients age from 41 to 50 years;

G4: 55 patients age from 51 to 65 years.

2 – Acquisition of 3D images by stereophotogrammetry

A Vectra H1 camera (Canfield Scientific, Inc, Fairfield, NJ, EUA), and the VAM elaboration software (Canfield Scientific, Inc), were used to acquisition and measures the distances between specific facial landmarks.¹³ The images were captured sequentially in the right, frontal, and left positions, and 10 anthropometrics landmarks pointed in the face before the capture (Figure 1, Table 1).¹⁴⁻¹⁸

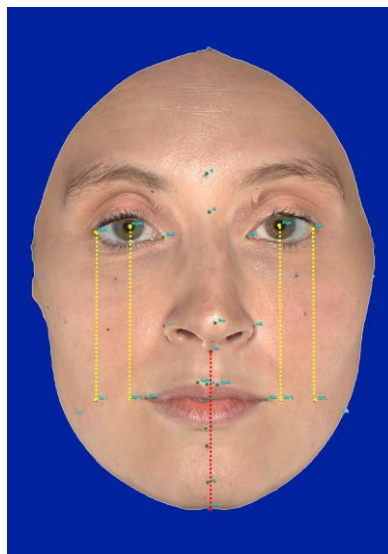


Figure 1 – Anthropometrics landmarks

Table 1 – List of anthropometrics landmarks

Anthropometric landmarks	Definition
Exocanthion (Ex R/L)	The point at the outer commissure of the eye fissure (right and left);
Subnasale (Sn)	The midpoint of the angle at the columella base where the lower border of the nasal septum and the surface of the upper lip meet;
Gnathion (Gn)	The lowest median landmark on the lower border of the mandible;
Cheilion (Ch R/L)	The point located at each labial commissure (right and left);
Cheilion' (Ch' R/L)/(Ch''R/L)	The point located in the cheilion, projecting a straight line laterally at each labial commissure (right and left);
Pupil (Pup R/L)	The center of the eye (right and left)

Table 2 – List of the linear measurements

Linear measurements	
Exo- Ch' (right and left)	Distance between the Exocanthion to the Cheilion'
Pupil - Ch'' (right and left)	Distance between the Pupil to the Cheilion''
Sn-Gn	Distance between Subnasale to Gnathion

3. Statistical analysis

Paired t-test was performed to analyze the correspondence of the measurements proposed by the Willis metrical method between the gouge and the literature and with the lower third of the face (Sn-Gn). The ANOVA one-way was performed to evaluate the differences between Sn-Gn in all groups. All data were analyzed using JAMOVI v.1.2 (The jamovi project, Sidney, Australia).

RESULTS

The first assessment performed in the study was to analyze the correspondence of the measurements in the method proposed by Willis¹ in the literature (Pupil-Ch'') and by the gauge utilization (Ex-Ch'). The results showed that the description of the method in the literature was different than the usual evaluated by the clinicians using the Willis gauge (Table 3).

Table 3- Paired t test between the measurements utilized with the Willis compass and the Willis description of the metric method

Willis Compass measures	Mean±SD	Willis Method metric description	Mean±SD	p
Exo R - Ch'R	68.6±4.16	Pupil R - Ch'' R	70.2±4.19	< .001*
Exo L - Ch'L	67.9±4.24	Pupil L - Ch'' L	69.7±4.24	< .001*

*Statistical differences (p≤0.05)

Following the pertinent comparisons in each individual, the second analysis was the difference between the measurements and the lower third of the face (Sn-Gn). The results showed statistical differences in the majority of measurements, except in the Pupil L- Ch'' L (Table 4).

Table 4- Paired t test between the measurements proposed to Willis to verify the lower third of the face which was determined by the measure Sn-Gn

Willis Method Measures Mean±SD	Lower Third of the face (Sn-Gn)		p
Exo R - Ch'R	68.6±4.16	69.3±5.81	0.021*
Exo L - Ch'L	67.9±4.24	69.3±5.81	< .001*
Pupil R - Ch'' R	70.2±4.19	69.3±5.81	0.002*
Pupil L - Ch'' L	69.7±4.24	69.3±5.81	0.218

*Statistical differences (p≤0.05)

The ANOVA one-way was performed to evaluate if there were differences among ages in all measurements in the Willis metric method. The results showed statistical differences in two measurements, ExR-Ch'R between G2 and G3 and in Pupil R-Ch''R among G1 and G2 compared with G3 (Table 5).

Table 5- ANOVA one-Way among the groups divided by ages (G1, G2, G3 and G4) in all measurements

Measures	G1 (n=45)	G2 (n=36)	G3 (n=51)	G4 (n=54)	F	df1	df2	p
Sn - Gn	69.1±6 ^a	68.5±4.84 ^a	70.5±5.78 ^a	68.8±6.23 ^a	1.21	3	98.8	0.31
Exo R - Ch'R	67.7±4.02 ^{ab}	67.2±3.81 ^a	69.8±4.13 ^b	69±4.24 ^{ab}	3.85	3	97.7	0.012*
Exo L - Ch'L	67.2±4.04 ^a	67.3±3.79 ^a	68.5±3.98 ^a	68.3±4.86 ^a	1.37	3	98.1	0.25
Pupil R - Ch'' R	69.2±3.77 ^{ac}	68.7±3.53 ^{ac}	71.5±4.34 ^b	70.8±4.34 ^{abc}	5.17	3	98.7	0.002*
Pupil L - Ch'' L	68.7±3.95 ^a	68.7±3.36 ^a	70.5±4.17 ^a	70.3±4.85 ^a	2.70	3	99.5	0.05

*Statistical differences (p≤0.05)

DISCUSSION

The present study based on the method proposed by Willis¹ to determine the OVD from the rest vertical dimension (RVD) and compared, through stereophotogrammetry, the relationship between the measurements obtained from the Subnasale (Sn) to the Gnathion (Gn) in 186 individuals separated into four age groups ranging from 20 to 65 years. The null hypothesis was partially rejected. The measurements taken by the Willis compass, used clinically, and compared with the dimension proposed by Willis from the pupil of the eye to the rima-oris line (commissure line in a straight line to meet with the vertical of the pupil) revealed a statistically significant difference, except for the left side. Considering that the measurement is commonly verified, by professionals, from the external corner of the eye (Exo R/L) to the line of the laterally projected commissure in a straight line (Ch'R/L) compared with the method proposed by Willis (Pupil R/L – Ch"R/L), there was a statistical difference on both sides, right and left.

It is relevant to emphasize that prosthesis experts use the Willis compass to measure the distance from the outer corner of the eye (Exo R/L) to the commissure, tilting the tool, which alters the measurements significantly. Even if the instrument has stems that can compensate and adjust the trajectory in a straight line, the correct way to obtain the values is by tracing a straight vertical line from the outer corner of the eye (Exo R/L) to the lateral projection of the commissure in a straight line (Ch'/Ch").

The study by Alhajj et al.,¹⁶ contrasts with the present study, as the authors concluded that the distance from the outer corner of the eye to the labial commissure seems to be a reliable method to predict the OVD, being better to correlate it with the distance Pronasale (Prn) to the Pogonion (Pg). Brar et al.,³ also stated that the distance between the pupil and the labial commissure (the authors call it the stomion), but not in a straight line, can be used clinically as a guide to verify the OVD. Basnet et al.,⁴ also define the Rima oris point as the point located at the corner of the mouth. When correlating facial measurements with the

OVD, they concluded that the measured distance between the pupil and the rima oris correlated with OVD more than other craniofacial measurements. Basnet et al., established the Prn-Pg landmarks as points for taking the OVD.⁴

Comparing the measurements from exocanthus (R/L) to commissure (Ch'R/L), and pupil center (Pupil R/L) to commissure (Ch"), only the Pupil L-Ch"L measurements did not show a statistically significant difference. One alert lights on, most of the professionals are right-handed because approximately 90% of the population prefers the right side, and they evaluate the OVD by taking on the patient's right side.¹⁹ However, the left side is the side that is more compatible to aid in the establishment of OVD. Evaluating the established groups aged between 20 and 65 years, the left side (ExoL-Ch"L and PupilL-Ch"L) was again more stable concerning the height of the lower third of the face (Sn-Gn).

The authors who evaluated such anthropometric relationships^{3,16} did not refer to the evaluated sides (right or left). This reference is significant because Kazemi Ashtiani et al.,²⁰ compared the dimensions of the right and left sides in skulls and observed that the orbit measurements on the left side were bigger concerning the right side. In general, the left side of the face and body seems to be larger and wider than the right side, as reported in the literature,²¹⁻²³ a hypothesis also confirmed in measurements performed from computed tomography scans of the chest and pelvis.²³ Studies evaluating such differences in the face through stereophotogrammetry are scarce in the literature.

However, the literature evaluates such differences between the facial s and cerebral hemispheres. It explains that such hemispheres are functionally asymmetric due to the morphogenetic link between the brain and the craniofacial appearance. Different patterns of neural innervation for the upper versus lower face, depending on the nature of the neurological control of the two sides of the face by the two cerebral hemispheres, reveal the

complexity of facial muscle control. The mobility of facial expression also presents facial asymmetry.²⁴

Studies suggested that the left side of the face is more expressive of emotions: an asymmetry that probably stems from the dominance of the right hemisphere for emotional expression.²⁵⁻²⁷ Such functional asymmetry in facial expression may have some relation to the dimensional balance between the left and right hemiface.²⁸

Finally, evaluating the groups, the right side showed a statistically significant difference in the ExoR-Ch'R measurement between the individuals of the G2 group (31 and 40 years old) and G3 (41 to 50 years old) and the PupilR-Ch'R measure the group G3 showed a difference to G1 (20 and 30 years old) and G2. The present study did not assess gender and was concerned with evaluating the Willis method for taking OVD. The changes presented between groups G2 and G3 and between G1 and G3 caused surprise because such changes were expected in the G4 group. But it must be considered that the groups were dentate patients with occlusal stability and physiological wear. However, the changes in the groups lead us to infer that a G3 group is a transitional group, reaching menopause and andropause for women and men and revealing significant hormonal changes.²⁹

According to Othman et al. and Majeed et al., ethnic and gender differences are critical when dealing with craniofacial measurements, so such results should be considered with caution when trying to extrapolate to the general population.^{5,30}

The limitations of the present study include the Caucasian population, no differences between sex were evaluated, and the need for longitudinal studies that follow individuals to verify the aging process and the changes that occur in the measures in the individual in the different decades of life.

CONCLUSION

Based on the findings of this clinical study, the following conclusions were drawn:

1. The use of Willis compass based on the description of the literature and based in the method used by clinicians is different from the measures using stereophotogrammetry.
2. Only the measure Pupil L-Ch''L can be useful to stablish the OVD. Differences were presented among ages only in ExoR-Ch'R and PupilR-Ch''R showing that the left side is more stable than right side.

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3 DISCUSSION

In the present study, 186 patients aged between 20 and 65 years old, of both sexes were evaluated and linear facial measurements were associated with classical measures to determine the OVD, Sn - Gn (Subnasale - Gnathion) and Prn - Pg (Pronasale - Pogonion), through stereophotogrammetry.

In the first paper, multiple linear regression was applied. Among the 13 predictors analyzed, 4 and 3 significantly impacted the OVD for Sn-Gn and Prn-Pg models, respectively. The multiple regression model revealed that there is a prediction of measurements from the outer corner of the eyes to the commissure on the right side and from the outer corner of the eyes to the inner corner multiplied by two on the left side in both proposed models (Sn-Gn and Prn-Pg).

Analyzing the sex is possible to infer that in the models presented, in which the female sex is the reference, from woman to man, there is an increase of 1.90 mm in the Sn-Gn model and 1.28 mm in the Prn-Pg model. It shows that the OVD values are higher in males, in agreement with Majeed et al., which evaluated the craniofacial measures correlation and OVD in the Saudi Arabian population using a caliper. The authors measured the OVD of Sn-Gn and found that the OVD mean in male (69.25 ± 5.54) was higher than in female (57.41 ± 5.32).¹² Thus, it is relevant to note that in all studies with anthropometric measures of the face, differences in gender and ethnicity must be considered, and the results analyzed with caution.^{10,12}

Several authors showed that the Prn-Pg model is the one reliable for taking the OVD, in agreement with Jakstatet al., which investigated the movement of the skin markings due to the contraction of the mimic muscles and concluded that the Prn point proved to be the least mobile landmark. In the first paper, the Sn-Gn model presented

a coefficient of determination of 53% explained by this set of predictors, different from the 43% revealed by the Prn-Pg model.¹³

These two models presented for obtaining the OVD, based on predictors, are relevant because the professional can choose one of them and consider which predictors are statistically significant.

The second paper evaluate the method proposed by Willis³ to determine the OVD from the rest vertical dimension (RVD) and compared, through stereophotogrammetry, the relationship between the measurements obtained from the Subnasale (Sn) to the Gnathion (Gn).

The measurements taken by the Willis compass, used clinically, and compared with the dimension proposed by Willis from the pupil of the eye to the rima-oris line (commissure line in a straight line to meet with the vertical of the pupil) revealed a statistically significant difference, except for the left side. Considering that the measurement is commonly verified, by professionals, from the external corner of the eye (Exo R/L) to the line of the laterally projected commissure in a straight line (Ch'R/L) compared with the method proposed by Willis (Pupil R/L – Ch"R/L), there was a statistical difference on both sides, right and left.

It is relevant to emphasize that prosthesis experts use the Willis compass to measure the distance from the outer corner of the eye (Exo R/L) to the commissure, tilting the tool, which alters the measurements significantly. Even if the instrument has stems that can compensate and adjust the trajectory in a straight line, the correct way to obtain the values is by tracing a straight vertical line from the outer corner of the eye (Exo R/L) to the lateral projection of the commissure in a straight line (Ch'/Ch").

Evaluating the two studies presented, it seems that one is contrary to the other, which is not truthful. The first work aims to assess predictors through multiple

regression to support taking the vertical dimension of occlusion. In the second one, the purpose was to evaluate how the method proposed by Willis is adequate and correctly used for obtaining the vertical dimension of occlusion.

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ANNEX A – Aprovação Comitê de Ética

USP - FACULDADE DE
ODONTOLOGIA DE BAURU DA
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PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação através de estereofotogrametria das medidas craniofaciais utilizadas para a obtenção da dimensão vertical de oclusão entre adultos jovens de sexos e idades diferentes.

Pesquisador: Simone Soares

Área Temática:

Versão: 2

CAAE: 22075219.6.0000.5417

Instituição Proponente: Universidade de Sao Paulo

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.718.125

Apresentação do Projeto:

Idem parecer 3.642.048

Objetivo da Pesquisa:

Idem parecer 3.642.048

Avaliação dos Riscos e Benefícios:

Idem parecer 3.642.048

Comentários e Considerações sobre a Pesquisa:

Idem parecer 3.642.048

Considerações sobre os Termos de apresentação obrigatória:

Idem parecer 3.642.048

Recomendações:

As recomendações foram acatadas pelo pesquisador responsável.

Conclusões ou Pendências e Lista de Inadequações:

Sugiro aprovação.

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 13/11/2019, com base nas normas éticas da Resolução CNS 466/12. Ao término da pesquisa o CEP-FOB/USP exige a

Endereço: DOUTOR OCTAVIO PINHEIRO BRISOLLA 75 QUADRA 9
Bairro: VILA NOVA CIDADE UNIVERSITARIA **CEP:** 17.012-901
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Telefone: (14)3235-8356 **Fax:** (14)3235-8356 **E-mail:** cep@fob.usp.br

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Continuação do Parecer: 3.718.125

apresentação de relatório final. Os relatórios parciais deverão estar de acordo com o cronograma e/ou parecer emitido pelo CEP. Alterações na metodologia, título, inclusão ou exclusão de autores, cronograma e quaisquer outras mudanças que sejam significativas deverão ser previamente comunicadas a este CEP sob risco de não aprovação do relatório final. Quando da apresentação deste, deverão ser incluídos todos os TCLEs e/ou termos de doação assinados e rubricados, se pertinentes.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1354296.pdf	30/10/2019 15:54:06		Aceito
Outros	oficio_resposta.pdf	30/10/2019 15:53:49	Simone Soares	Aceito
Outros	Aquiesc_resp_clinica.pdf	18/10/2019 19:03:38	Simone Soares	Aceito
Outros	Aquiesc_graduacao.pdf	18/10/2019 19:03:04	Simone Soares	Aceito
Outros	Aquiesc_pos_grad.pdf	18/10/2019 19:02:37	Simone Soares	Aceito
Outros	Aquiesc_diretor.pdf	18/10/2019 19:01:54	Simone Soares	Aceito
Cronograma	Cronograma.docx	18/10/2019 19:01:14	Simone Soares	Aceito
Outros	Checklist.pdf	02/09/2019 15:39:17	Simone Soares	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Departamentoaquiescencia.pdf	06/08/2019 14:54:12	Simone Soares	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Doutorado_FINAL.docx	05/08/2019 17:45:50	Simone Soares	Aceito
Declaração de Pesquisadores	Declaracaodecompromisso.pdf	05/08/2019 17:44:40	Simone Soares	Aceito
Orçamento	Orcamento.docx	05/08/2019 16:27:22	Simone Soares	Aceito
Folha de Rosto	CEP_Jorge.pdf	05/08/2019 14:36:37	Simone Soares	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.docx	04/06/2019 10:20:10	Simone Soares	Aceito

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Continuação do Parecer: 3.718.125

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

BAURU, 21 de Novembro de 2019

Assinado por:

**Ana Lúcia Pompéla Fraga de Almeida
(Coordenador(a))**

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ANNEX B – Termo de Consentimento Livre e Esclarecido



Universidade de São Paulo Faculdade de Odontologia de Bauru

Departamento de Prótese e Periodontia

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Convidamos _____ o _____ (a) Senhor(a) _____ para participar da pesquisa **“Avaliação através de estereofotogrametria das medidas craniofaciais utilizadas para a obtenção da dimensão vertical de oclusão entre adultos jovens de sexos e idades diferentes”**

O perfil facial influencia na estética, fonética e função, e a perda dos dentes causa no perfil facial uma influência negativa, a qual as próteses totais de diversos tipos, tem o objetivo de devolver a proporção facial adequada.

Sua participação consistirá em autorizar, uma avaliação bucal e três tomadas fotográficas utilizando uma câmera adequada 3D, em sessão única de 40 minutos em média, para a realização das medidas faciais.

Os participantes serão recrutados na Clínica I da Faculdade de Odontologia de Bauru da Universidade de São Paulo (FOB/USP), nas disciplinas de Prótese I e II, e após o atendimento serão então convidados a participar da pesquisa.

As fotografias e a avaliação serão realizadas no departamento de Prótese e Periodontia, as imagens serão imediatamente passadas para o computador próprio da pesquisa a qual apenas os envolvidos na equipe de pesquisa terão acesso, as imagens serão analisadas pelo software adequado e serão levadas em consideração apenas as medidas analisadas, sendo assim, as tomadas fotográficas não serão divulgadas e as mesmas serão descartadas.

Os pesquisadores envolvidos tentarão minimizar ao máximo qualquer tipo de risco, por exemplo o cansaço do paciente. Uma vez que os participantes autorizarem as tomadas fotográficas, todos os participantes passarão por uma avaliação bucal, juntamente com orientações de higiene, caracterizando benefícios diretos para os participantes. Caso durante a avaliação odontológica seja detectada alguma alteração bucal, o participante será encaminhado para o setor de Triagem.

Apenas a equipe de pesquisa estará no local reservado: “laboratório de prótese”, não podendo ter mais pessoas no local próprio para coletas das imagens. Se o participante se queixar de cansaço, em vista de minimizar esse risco, haverá uma cadeira no local para descanso, visando o conforto dos participantes e para que os mesmos fiquem a vontade para desistir de participar, porém fica assegurado, aos participantes, o direito a indenização caso algum dano dela decorra. Os gastos que forem gerados por este trabalho ficarão a cargo do responsável pelo projeto.

O benefício indireto resultante desse trabalho será a possibilidade de avaliar o perfil facial dos indivíduos de sexos diferentes e nas idades estabelecidas pela pesquisa (21 a 40 anos), observando se há relação entre as medidas que a literatura descreve para determinar a altura do terço inferior da face (Dimensão Vertical de Oclusão) com as mesmas medidas avaliadas pela fotografia 3D, visto que devolver proporção facial está diretamente ligada a estética, fonética e função.

O participante da pesquisa receberá uma via deste documento, assinado e rubricado por ele próprio e pelo pesquisador responsável. Para o desenvolvimento dessa pesquisa, sua participação é fundamental, mas não obrigatória, e todas as informações serão **CONFIDENCIAIS**, podendo ser publicadas apenas para fins científicos, portanto sem a

Rubrica do Pesquisador Responsável:

Rubrica do Participante da Pesquisa:



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Departamento de Prótese e Periodontia

identificação dos participantes. A qualquer momento poderá ser pedido mais informações ou até mesmo negar-se a continuar participando da pesquisa sem qualquer penalidade.

Desde já agradecemos a colaboração e nos colocamos à disposição para mais esclarecimentos que se fizerem necessários. Se restarem dúvidas, o participante poderá entrar em contato com o responsável pelo estudo (Jorge Tomasio Caballero), pelo telefone (14) 3235-8277, pelo e-mail jorgetc88@usp.br ou pelo endereço: Departamento de Prótese e Periodontia, da Faculdade de Odontologia de Bauru/USP, Alameda Dr. Octávio Pinheiro Brisolla, 9-75.

Para denúncias e/ou reclamações, entrar em contato com Comitê de Ética em Pesquisa-FOB/USP, à Alameda Dr. Octávio Pinheiro Brisolla, 9-75, Vila Universitária, ou pelo telefone (14)3235-8356, e-mail: cep@fob.usp.br.

Pelo presente instrumento que atende às exigências legais, o Sr. (a) _____, portador da cédula de identidade _____, após leitura minuciosa das informações constantes neste TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO, devidamente explicada pelos profissionais em seus mínimos detalhes, ciente dos serviços e procedimentos aos quais será submetido, tais como a avaliação bucal e as fotografias, não restando quaisquer dúvidas a respeito do lido e explicado, DECLARA E FIRMA seu CONSENTIMENTO LIVRE E ESCLARECIDO concordando em participar da pesquisa proposta. Fica claro que o participante da pesquisa ou seu representante legal, pode a qualquer momento retirar seu CONSENTIMENTO LIVRE E ESCLARECIDO e deixar de participar desta pesquisa e ciente de que todas as informações prestadas tornar-se-ão confidenciais e guardadas por força de sigilo profissional (Art. 9º do Código de Ética Odontológica (Res. CFO-118/2012)).

Por fim, como pesquisador(a) responsável pela pesquisa, DECLARO o cumprimento do disposto na Resolução CNS nº 466 de 2012, contidos nos itens IV.3 e IV.4, este último se pertinente, item IV.5.a e na íntegra com a resolução CNS nº 466 de dezembro de 2012.

Por estarmos de acordo com o presente termo o firmamos em **DUAS VIAS** igualmente válidas (uma via para o participante da pesquisa e outra para o pesquisador) que serão **rubricadas em todas as suas páginas** e assinadas ao seu término, conforme o disposto pela Resolução CNS nº 466 de 2012, itens IV.3.f e IV.5.d.

Bauru, SP, _____ de _____ de _____.



Universidade de São Paulo Faculdade de Odontologia de Bauru

Departamento de Prótese e Periodontia

Assinatura do Participante da pesquisa

Jorge Tomasio Caballero
(Pesquisador responsável)

O **Comitê de Ética em Pesquisa – CEP**, organizado e criado pela **FOB-USP**, em 29/06/98 (**Portaria GD/0698/FOB**), previsto no item VII da Resolução nº 466/12 do Conselho Nacional de Saúde do Ministério da Saúde (publicada no DOU de 13/06/2013), é um Colegiado interdisciplinar e independente, de relevância pública, de caráter consultivo, deliberativo e educativo, criado para defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos.

Qualquer denúncia e/ou reclamação sobre sua participação na pesquisa poderá ser reportada a este CEP:

Horário e local de funcionamento:

Comitê de Ética em Pesquisa

Faculdade de Odontologia de Bauru-USP - Prédio da Pós-Graduação (bloco E - pavimento superior), de segunda à sexta-feira, no horário das 13h30 às 17 horas, em dias úteis.

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