Dimensional Accuracy of Computer-Aided Design/Computer-Assisted Manufactured Orbital Prostheses

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Purpose: The aim of this research was to assess the dimensional accuracy of orbital prostheses based on reversed images generated by computer-aided design/ computer-assisted manufacturing (CAD/CAM) using computed tomography (CT) scans.
Materials and Methods: CT scans of the faces of 15 adults, men and women older than 25 years of age not bearing any congenital or acquired craniofacial defects, were processed using CAD software to produce 30 reversed three-dimensional models of the orbital region. These models were then processed using the CAM system by means of selective laser sintering to generate surface prototypes of the volunteers' orbital regions. Two moulage impressions of the faces of each volunteer were taken to manufacture 15 pairs of casts. Orbital defects were created on the right or left side of each cast. The surface prototypes were adapted to the casts and then flasked to fabricate silicone prostheses. The establishment of anthropometric landmarks on the orbital region and facial midline allowed for the data collection of 31 linear measurements, used to assess the dimensional accuracy of the orbital prostheses and their location on the face.
Results: The comparative analyses of the linear measurements taken from the orbital prostheses and the opposite sides that originated the surface prototypes demonstrated that the orbital prostheses presented similar vertical, transversal, and oblique dimensions, as well as similar depth. There was no transverse or oblique displacement of the prostheses. ***Conclusion:*** From a clinical perspective, the small differences observed after analyzing all 31 linear measurements did not indicate facial asymmetry. The dimensional accuracy of the orbital prostheses suggested that the CAD/CAM system assessed herein may be applicable for clinical purposes. *Int J Prosthodont 2010;23:271–276.*

Patients with a loss of orbital anatomy resulting from orbital exenteration commonly develop esthetic, functional, and psychologic disorders that significantly compromise their quality of life. Reconstructive surgery is only possible when local and systemic conditions are favorable. Some of the factors that often make reconstructive surgery impossible are the extension of the lesion and the affected tissues. Hence, it is not possible to surgically restore a normal anatomical appearance when the ocular portion of one's facial anatomy is lost or compromised.

A facial prosthesis is, most of the time, the only means of restoration that provides immediate esthetic results. The placement of a prosthesis with the combined efforts of a multidisciplinary team minimizes recurring hospitalization and decreases treatment cost, therefore allowing immediate social reintegration and improvement of the patient's quality of life.

Until very recently, the fabrication of a facial prosthesis depended solely on the technical and artistic skills of a specialist who would hand-sculpt the prosthesis. Hand-sculpting of an orbital prosthesis is based on the reversion of anthropometric landmarks and measurements taken from the unaffected contralateral side. Although based on precise data, this technique is subject to individual variations, and depends on the skill of the specialist in reproducing three-dimensional (3D) anatomical contours.

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The optical acquisition of 3D data from the surface of the face has been reported as an alternative when constructing models of facial prostheses.[1,2] Improvements in the image acquisition process in the medical field and advances in computer science have led to the development of specific software that, when applied to the images obtained from computed tomography (CT),[3–6] magnetic resonance imaging,[7] and surface scanning,[8–16] enabled virtual, 3D reconstructions of anatomical structures. Comparative studies on the images generated by these different image acquisition methods have concluded that they are all appropriate for creating 3D models that may be used in the reconstruction of lost ears.[17–19] Images can be digitally manipulated using specific CAD system software. By mirroring the unaffected side, the generated image may be used in the prosthetic rehabilitation of the affected side. The rapid prototyping process consists of transforming the image generated by the CAD system into a physical cast using a CAM system.

The purpose of this study was to assess the dimensional accuracy of orbital prostheses constructed by means of CAD/CAM technology applied to images acquired by CT and saved as DICOM files.

Materials and Methods

Cast Production

The study group comprised 15 volunteers (6 men, 9 women; age range: 25 to 30 years). None of them presented with congenital or acquired lesions in the craniofacial region. Two moulage impressions of the orbital regions of each volunteer were made using irreversible hydrocolloid (Jeltrate type II, Dentsply) with the following demarcation: the upper limit was 3 cm above the glabella, the lower limit was an imaginary horizontal line that ran below the ala nasi, and the lateral limit was a vertical line anterior to the tragus. The volunteers sat in a dental chair with a 60-degree inclination and no rotation of the head. This positioning has been recommended since it minimizes facial tissue deformation while recording a moulage impression. The 30 moulage impressions were cast in dental stone (Asfer type III, Asfer Ind. Química).

Reproducibility of the Impression Technique

To limit the number of volunteers and make the most of the CT images, the right and left orbital regions of each individual were analyzed. In view of that, two impressions of the face of each volunteer were obtained so that one would be used to manufacture a prosthesis for the right side and the other, for the left. Due to the fact that there are no reports investigating the reproducibility of the technique for obtaining moulage impressions of the face, it was necessary to conduct a prior check using the values of the 31 measurements taken from both sides of each of the two moulage casts from the same individual. Cronbach alpha ($P \leq .05$) revealed that data from all 15 volunteers demonstrated excellent intraoperatory reproducibility, with high confidence levels. No significant difference was observed between the measurements obtained from the casts derived from the first and second moulage impressions.

A parallelometer (Bio-Art 2, Bio-Art Equipamentos Odontológicos) was used to determine a horizontal frontal plane (Fig 1). The casts were fixed to the plate of the parallelometer by means of three screws and the ensemble was then transferred to a smooth glass plate for stabilization with plaster of Paris (Asfer Ind. Química). This enabled maintenance of the position obtained after the cast had been removed from the parallelometer.

Each of the two casts of the 15 volunteers received a simulated orbital exenteration, one on the right side and the other on the left, using a power drill (Skil/Bosch, Robert Bosch) and a hole saw 3 cm in diameter (HSS Bimetal, Starrett). To standardize the site at which the orbital exenteration would be simulated, the most prominent point of the upper eyelid was chosen as the center of the injury.

Establishment of Landmarks and Linear Measurements

Eight anatomical landmarks were established, and 31 linear measurements, grouped in sequence and two-by-two, were taken for each of the 30 casts on the right and left sides by the same operator.[20]

The landmarks consisted of the facial midline (glabella [G], nasion [N], and subnasale [Sn]) and the orbit (endocanthion [En], exocanthion [Ex], orbitale superius [Os], palpebrale superius [Ps], and orbitale inferius [Oi]) (Fig 2).

Linear Measurements

The anthropometric landmarks were grouped as follows:

- Group A (Sn): A1 = Sn-En, A2 = Sn-Ex, A3 = Sn-Os, A4 = Sn-Oi, A5 = Sn-Ps
- Group B (N): B6 = N-En, B7 = N-Ex, B8 = N-Os, B9 = N-Oi, B10 = N-Ps
- Group C (G): C11 = G-En, C12 = G-Ex, C13 = G-Os, C14 = G-Oi, C15 = G-Ps
- Group D (En): D16 = En-Ex, D17 = En-Os, D18 = En-Oi, D19 = En-Ps
- Group E (Ex): E20 = Ex-En, E21 = Ex-Os, E22 = Ex-Oi, E23 = Ex-Ps

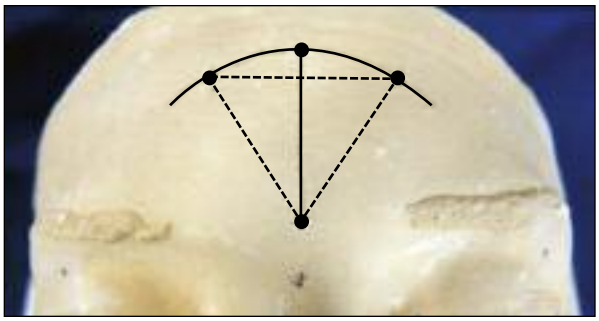


Fig 1 Establishment of the frontal plane for stabilization of the cast.

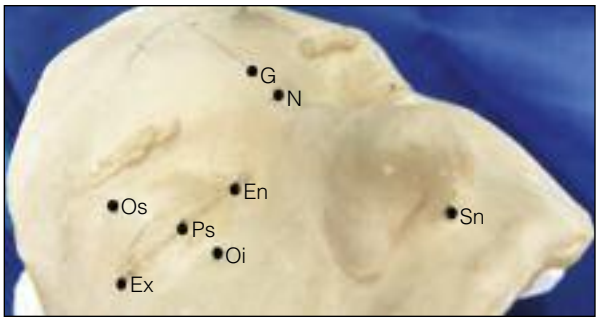


Fig 2 Anthropometric landmarks.

- Group F (vertical): F24 = Os-Ps, F25 = Os-Oi, F26 = Ps-Oi
- Group G (depth): G27 = N-En, G28 = N-Os, G29 = N-Oi, G30 = N-Ps, G31 = N-Ex

A digital caliper (CD-6" CX-B, Mitutoyo Sul Americana) was used to make all measurements except for the depth measurements, which were recorded with a digital comparator (COMP 25 mm, Mitutoyo Sul Americana). One observer was responsible for recording all measurements in millimeters. To assess the reproducibility of the measurements, the 31 linear measurements of the right and left sides of 10 casts were taken by the observer twice, with a 1-week interval between measurements. The data gathered were then submitted to statistical analysis using Cronbach alpha ($P \leq .05$).

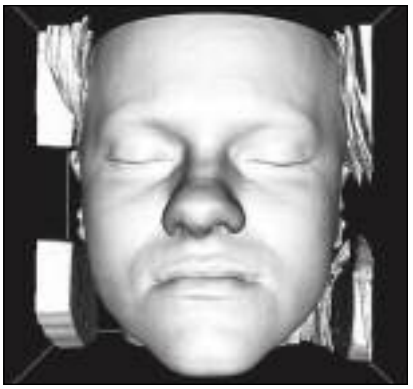


Fig 3 Image of a 3D reconstruction recorded as a DICOM file.

Reconstruction of 3D Data and Rapid Prototyping

The volunteers who comprised the study sample underwent 3D CT (Light-Speed 16 Pró, GE Medical Systems) of the face. The images were saved as DICOM files (Fig 3) and processed using InVesalius Software (CTI–Information Technology Center) to obtain slices that showed the soft tissues used in the reconstruction of the 3D models.

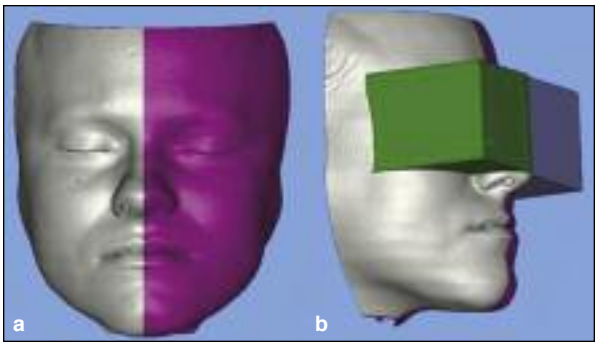
The models were saved as STL files (triangular mesh) and sent to Magics Software (Magics X SP2 v.1.1.17, Materialise), where the 3D reconstructions of the face were split in two at the facial midline, creating two STL files, one for the right side and one for the left. A reference parallelepiped was created using the CAD system Rhinoceros Software v. 4.0 (Robert McNeel & Associates) and SolidWorks Software v. 2008 (Dassault Systèmes) on the STL files of the right and left hemifaces to guide prototyping (Figs 4a and 4b).

Using Magics Software once again, the parallelepiped was superimposed on the midline at the orbital region, thus allowing the region to be mirrored. The left side was mirrored by the right and vice versa, and the resulting 3D reconstruction was saved onto the STL file (Figs 5a and 5b).

The file was then sent to the rapid prototyping machine, which constructed the prototypes of the orbital region using Polyamide (Robotec) by means of selective laser sintering (Sinterstation 2000, 3D Systems) (Fig 6).

Fabrication of the Silicone Prostheses

The prototypes were carefully cut and placed onto the casts where the orbital injuries had been simulated (Fig 7a). A bevel was created with wax (Epoxiglass Ind. e Com. de Produtos Químicos) on the edge of each prototype, which was then removed from the cast and placed in a no. 6 flask. Dental stone (Asfer type III) was poured into the flask, and silicone (MDX4-4210, Dow Corning) was prepared according to the manufacturer's instructions in a ratio of base and catalyst of 1 to 10 by weight. Pigments were added to the silicone to make it less transparent and facilitate the location of the anthropometric landmarks.



Figs 4a and 4b **(a)** Medial section of the virtual model. **(b)** Parallelepiped superimposed onto the orbital region.

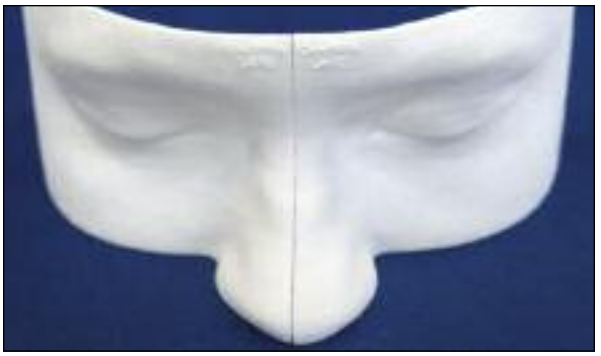
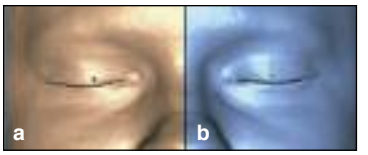
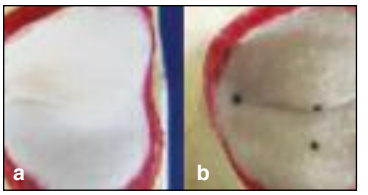


Fig 6 Right and left prototypes of the same volunteer.



Figs 5a and 5b **(a)** Magics Software image prior to mirroring. **(b)** Mirrored image to be sent to the rapid prototyping machine.



Figs 7a and 7b **(a)** Prototype and **(b)** silicone prosthesis adapted to the cast.

After manipulation, the silicone rested for 30 minutes before investment and flask closure. The flasks remained closed for 24 hours at room temperature and were then placed in a dry oven for 15 minutes at 100°C.

The orbital prostheses were placed onto the casts and fixed with wax to avoid dislocation when collecting data (Fig 7b). A support made of plaster of Paris was placed on the posterior part of the simulated orbital exenteration so that the weight of the digital caliper would not dislocate the prosthesis.

Results

Cronbach alpha indicated that data collected by the investigator evidenced excellent reproducibility of the measurements with high levels of confidence, and data collection proceeded reliably ($P \leq .05$).

Facial Symmetry

The same data allowed the authors to assess the facial symmetry of the casts by comparing the 31 linear measurements of the right and left sides of the 30 casts. The Wilcoxon signed-ranked test revealed a significant difference between the right and left sides of 10 of the 30 casts analyzed ($P \leq .05$), indicating facial asymmetry. This previous analysis was conducted exclusively to observe if asymmetry was already present in this study group.

Dimensional Accuracy of the Orbital Prostheses

Dimensional accuracy was assessed by comparing the orbital prosthesis to the unaffected opposite side, which served as a model for it. Statistical analysis using the Mann-Whitney test ($P \leq .05$) did not evidence any significant difference between the position of all the landmarks on the prosthesis and that of the facial landmarks outside it, located below the prosthesis (group A: Sn), at the same level as the area of the prosthesis (group B: N), and above it (group C: G).

Dimensional accuracy was assessed in the areas of the orbital prosthesis represented by group D (inner corner), group E (outer corner), group F (vertical), and group G (depth). These groups corresponded to the transverse, oblique, and vertical dimensions, as well as depth of the prosthesis, respectively. Statistical analysis using the Mann-Whitney test ($P \leq .05$) did not indicate a significant difference between the measurements of the stone casts and those of the orbital prostheses in groups D, E, F, and G.

All linear measurements were also analyzed collectively, comparing the data gathered from the unaffected side of the stone cast with those from the orbital prosthesis. The Wilcoxon signed-ranked test ($P \leq .05$) indicated a significant difference between most of the pairs of variables. Thus, when the linear measurements were considered collectively, only three prostheses were statistically similar to the stone casts.

Discussion

The recording facial moulage technique was developed to minimize possible deformations in the soft tissues of the orbital region.[21,22] The different positioning assumed during CT did not account for any discrepancy between the facial countours.[23] Due to the fact that there are no studies investigating the reproducibility of this technique, the two casts of the same volunteer were tested previously. No significant differences were observed between the two casts of each of the 15 individuals ($P \leq .05$), which means that the technique for making impressions of the face demonstrated excellent reproducibility, and was thus considered reliable for use in this study.

In the present study, the dimensional accuracy of the orbital prostheses was assessed in two ways. First, the authors assessed the stability of the anthropomorphic landmarks located on the orbital prosthesis, namely the inner corner of the eye, outer corner of the eye, orbitale superius, palpebrale superius, and orbitale inferius, in relation to the glabella, nasion, and subnasale, located at different points along the facial midline. Stable landmarks along the facial midline have already been used as reference points to assess the position of anthropometric landmarks on the outer ear.[10]

Statistical analysis did not demonstrate any significant difference between the position of the landmarks located on the prosthesis and that of the landmarks located on the face (ie, subnasale, nasion, and glabella). This indicated that there was no significant displacement of the orbital prosthesis in the transverse or oblique directions.

Second, an assessment of the dimensional reproducibility of the area of the orbital prosthesis was made analyzing groups D (inner corner), E (outer corner), F (vertical), and G (depth). Groups D and E corresponded to dimensional reproducibility in the transverse and oblique directions; group F corresponded to dimensional reproducibility in the vertical direction. Statistical analysis showed no significant difference between the measurements of the casts and those of the orbital prostheses in these groups, which means that the dimensions of the orbital prostheses were stable in the transverse, oblique, and vertical directions.

Specific considerations were required to analyze group G. The proper superimposition of the mirrored image surfaces onto the opposite sides, the 1 mm thickness of the prototypes resulting from this image, and proper adaptation of the prototype to the exenterated area led to an absence of a significant difference between depth measurements of the prosthesis and the opposite side. This demonstrates that the methodology used in this study allowed the prosthesis to show similar anterior-posterior positioning to that of the unaffected side, which served as its model. It is worth drawing attention to the fact that a surgically compromised tissue base demands a careful adaptation of the prototype to the injured area to assure the best 3D orientation of the prosthesis.

When the 31 linear measurements were assessed collectively, a significant difference was observed between the orbital prosthesis and the unaffected opposite side in most cases. Nevertheless, in the event that the results are analyzed in terms of absolute values, the means of the differences are limited to decimals of millimeters. Such minute values indicate an extremely subtle difference between sides, which is barely discernible visually and does not characterize facial asymmetry.[24] The differences between the orbital prostheses manufactured using the CAD/CAM system and the opposite normal sides were similar to eventual differences once observed in the facial casts of normal individuals of the study group, and therefore, not clinically suggestive of facial asymmetry when using this system. In a clinical situation, the previous symmetry may not be known and the prosthetic rehabilitation presupposes to attain as much symmetry as possible in relation to the unaffected normal side. Hence, the system proposed meets the requirements for a proper facial rehabilitation.

The methodology used in this study was based on the observations that the surfaces generated by conventional molding with irreversible hydrocolloid and digitalization of 3D images produce equivalent models[23] and that the reformatting of images acquired by CT generates 3D models similar to the original anatomical structure, which can therefore be used to fabricate facial prostheses.[18] The results of the present study have confirmed that 3D images obtained from CT scans combined with the CAD/CAM system reduce the need for technical ability in sculpting and the amount of time it takes to manufacture an orbital prosthesis.[25] This technique also helps to manufacture higher-quality and more esthetically satisfactory facial prostheses.[15]

Considering that the esthetic quality and success of a facial prosthesis depend on its dimensional accuracy and resulting facial harmony, the results of this study demonstrated that the method used allowed for successful, esthetically pleasing orbital prostheses in the rehabilitation of an orbital exenteration.

Conclusion

The assessment of the dimensional reproducibility of orbital prostheses constructed from models based on reversed images obtained by the CAD/CAM system from CT scans of the face allowed the authors to conclude that the prostheses did not undergo dimensional changes in the transverse, oblique, or vertical directions. These dimensions remained stable in relation to the opposite side, which served as a model for the surface prototype.

Digital imaging processing and proper adaptation of the prototype to the cast allowed the resulting orbital prosthesis to reach the correct anterior-posterior positioning on the frontal plane of the face. The orbital prostheses were stable in relation to landmarks established along the facial midline, and did not undergo spatial displacement in the transverse or oblique directions.

A significant difference was observed between the measurements of the orbital prosthesis and those of the opposite side, which served as its model. The absolute values observed, however, demonstrated that the asymmetry was not clinically significant, which means that the CAD/CAM system assessed herein can be clinically used to produce dimensionally stable orbital prostheses.

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