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ORIGINAL ARTICLE

Patient satisfaction of orbital prosthesis fabricated by the aid of rapid prototyping technology versus conventional technique in orbital defect patients: A crossover randomized clinical trial

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ABSTRACT

Purpose: This study is to compare two types of orbital prosthesis fabrication techniques, the indirect rapid prototyping (RP) technology versus the conventional technique regarding; patient satisfaction and dimensional accuracy.

Material and Methods: Eight patients with orbital defects (age range 10–45 years) were selected to be included in a cross-over randomized trial. The patients were divided into two equal groups: Group A patients (n=4) received an orbital prosthesis constructed by conventional technique followed by another one constructed by RP technology. Group B patients (n=4) received the same treatment as the first group but in a reversed order. Patient satisfaction was evaluated through questionnaire while dimensional accuracy in comparison to the normal side was calculated for both techniques. Numerical data were analyzed using Kolmogorov-Smirnov and Shapiro-Wilk tests. For parametric data; Paired t-test was used to compare between prostheses and the normal side. For non-parametric data; Wilcoxon signed-rank test was used to compare between the two techniques.

Results: Orbital prostheses made by aid of RP technology showed statistically significant higher mean satisfaction score than the conventional technique ($P \leq 0.05$), both prostheses showed insignificant less eye fissure height dimensions in comparison to normal side but conventional technique showed significant less eye fissure length.

Conclusion: Rapid prototyping technology improved patient`s satisfaction regarding the orbital prosthesis and it was proved to be superior than conventional technique in dimensional accuracy. (*Int J Maxillofac Prosthetics 2019;1:27-32*)

INTRODUCTION

Over the last 40 years cancer survival rates have raised as a result of improvements in the diagnostic tools and the surgical techniques[1] however, quality of life (QOL) studies indicated high levels of emotional disturbance and impaired relationships for head and neck cancer patients.[2] One of the most challenging defects is orbital defect as it results in multiple functional and psycho-social difficulties, as the most important sensory organ of communication and expression of feelings is lost.[3]

Prosthetic rehabilitation of such defects is beneficial for re-establishing patient's aesthetics and elevate their self-esteem again to be more involved in the society which is directly related to their level of satisfaction with the prosthetic rehabilitation.[4] The conventional method used to restore such facial disfigurement prosthetically includes impression making to obtain plaster replica of the patient`s face on which wax is carved by hands to reproduce patient`s anatomy and contours typically in presence of patient to test fitting and sculpturing accuracy.[5] Although this method was shown to produce a highly esthetic satisfying outcome , it is a time consuming process which depends on exceptional artistic talent to make a mirror image of the healthy side.[6]

The 3D scanning technologies , computer aided designing and additive manufacturing technologies have proved their successful use in the field of maxillofacial surgery, which lead the researchers to start applying these technologies in the prosthetic field to overcome the conventional method shortcomings.[5] The use of additive manufacturing (AM) or rapid prototyping (RP) has the potential to offer significant advantages over traditional processing techniques with enormous potential for improvement in savings of time and cost of production, and consistency in quality.[7,8]

So many case reports have been published on the application of AM in anaplastology and its advantages in time saving and producing a highly esthetic prosthesis, however it all concluded that to depend totally on AM without manual modifications

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will not give a satisfying prosthesis as it is impossible to produce thin margin of silicone directly by additive manfacturing.[6,9] That`s why AM is used indirectly till now by producing a 3D model of the prosthesis in wax or in resin that is duplicated in wax to be modified manually.[10]

The evaluation of the esthetic outcome of the indirect RP technique was always done by reviewers or prosthodontists but no study has compared the indirect RP technique and conventional technique from the point of patient`s satisfaction. Shape accuracy and dimensions also were used to be assessed subjectively by the prosthodontists through likert scales. However, objective measurement of periocular landmarks is existing and is important for many specialties as ophthalmology, genetics, traumatology and anaplastology. The measurements are usually done between fixed anthropometric landmarks based on its standardized definitions according to Farkas who is considered to be the pioneer of modern craniofacial anthropometry, especially soft-tissue measurements.[11]

Therefore, this study is to evaluate both techniques the indirect rapid prototyping and the conventional method to find which one is superior from the patient`s point of view in addition to objective dimensional accuracy assessment of the prostheses fabricated by both techniques to compare them with the natural other side. It was hypothesized that RP technology will be more efficient in patients anatomy reproduction and will in turn improve patient`s satisfaction.

MATERIALS AND METHODS

A crossover randomized clinical design was used, patients were divided into two groups as follows; Group A (patients received an orbital prosthesis constructed by conventional technique followed by another one constructed by aid of rapid prototyping technology) and Group B (patients received an orbital prosthesis constructed by aid of RP technology followed by another one by the conventional technique). The research proposal has been reviewed and approved by the research ethics committee, faculty of oral and dental medicine, Cairo university.

A total of eight patients with orbital defects with age ranging between 10-45 years were consecutively included in this study where every patient received two orbital prosthesis using both conventional and RP techniques. Patients were selected to meet certain inclusion criteria as: resection defects with no recent surgical intervention in the orbit or recent radiotherapy for at least 6 months and the bony walls of the orbit should be lined with skin. On the other hand, patients with orbital defects occluded by local or distant tissue flap and patients with serious systemic problems or conditions (including psychiatric disease) were excluded.

For all included patients, an impression has been made for the orbital defect and the normal orbit. The patient was positioned in a semi-supine position and facial hair (eye brows and eyelashes) was protected by a light application of petroleum jelly before the application of the light polyvinyl silicone elastomer material (elite P&P light body fast set, Zermak, Italy). The material was applied cautiously with no pressure at all on soft tissue to avoid deformation of tissues ,and then a piece of gauze was placed before the application of plaster to prevent separation between the two materials .An adequate amount of plaster was mixed with slurry water to decrease its setting time, the mix was fluey in consistency and was spread over the entire impression surface by a brush to a thickness of about 0.25 inch not to exert pressure on tissues by the excess weight of plaster. Then a fragmented tongue depressor was added inside the plaster to prevent impression deformation and another amount of plaster was added.

The impression was poured with an extra hard stone to obtain the orbital cast which was duplicated to be used for the alternative technique. In the following visit, proper selection and adjustment of stock eye shill has been done in presence of the patient. Since the trial was a cross over randomized clinical trial, the randomization process at this stage determined which prosthesis to start with. A computer-generated two column tables of random numbers using www.random.org was used to produce the random allocation sequence of the participants. When a conventional technique was selected, the major anatomy sculpturing has been started manually to produce a wax pattern of the prosthesis. While for orbital prosthesis by aid of RP, a 3D model of the patient`s face has been obtained by Planmeca ProMax 3D ProFace (Fig 1). Two high resolution standardized photos were taken for the patient from frontal and profile views for calibration. STL file editing was done by special 3D modelling software (Z brush pixologic software) to design the orbital prosthesis through mirroring image of the normal side on the defect side and model subtraction (Fig 2).

The final orbital design was 3D printed by fused deposition modeling machine (Felix FDM) to produce a resin orbital replica (Fig 3), which was duplicated into wax pattern using conventional dental impression replication technique. For all patients, texturing was added manually and refinement of the margin position and thickness has been done. Flasking of the final wax pattern and wax elimination was done following the conventional technique. In the following visit the matching skin shade was tried including intrinsic coloration of silicon elastomer material (bredent multisil-Epithetik kit, Germany) which was packed in the flask. Deflasking was done later followed by finishing and extrinsic coloration in presence of the patient.

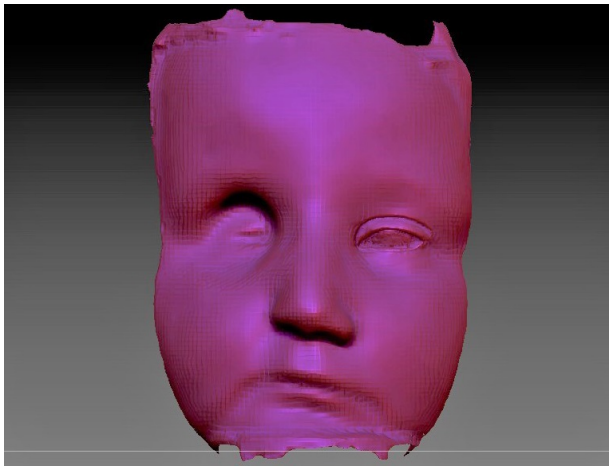

Fig 1. Proface STL file.

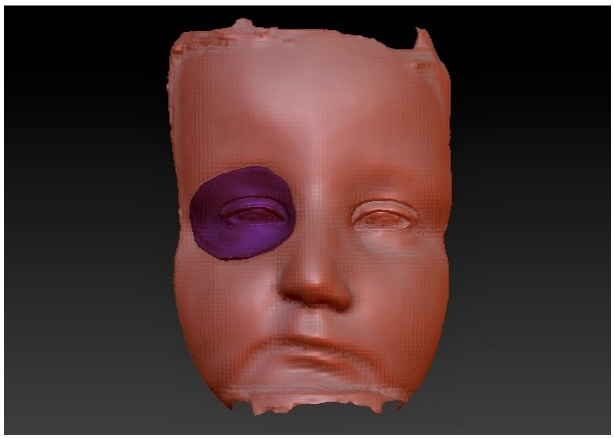

Fig 2. Designing process of orbital prosthesis.



Fig 3. Resin rapid prototyped orbital model.

The finished orbital prostheses were delivered to each patient and a high resolution frontal standardized photo was taken while the patient wearing the orbital prosthesis. The primary outcome (patient satisfaction) data was collected one week and 3 months after prosthesis insertion through questionnaire (Table 1). The questionnaire was composed of 7 questions about satisfaction, comfort and reaction with each type of the prosthesis.[2] For each question, a score has been given from 0-4, where 0 is not satisfied at all and 4 is very satisfied. The score was calculated as an average satisfaction of all the 7 questions.

Table 1. Patient satisfaction questionnaire.

1- How satisfied are you with the appearance of the prosthesis?
O Very satisfied O Quite satisfied O Moderately satisfied O Slightly satisfied O Not at all satisfied
2- Do you think others could notice that you are wearing prosthesis?
O Almost never notice O Noticed once O Sometimes notice O Often notice O Almost always notice
3- How comfortable is your prosthesis?
O Not at all comfortable O Slightly comfortable O Moderately comfortable O Quite comfortable O Very comfortable
4- How many hours do you wear your prosthesis each day?
O Less than 3 hours O 3-6 hours O 7-8 hours O 9-12 hours O More than 12 hours
5- What circumstances do you wear your prosthesis?
O Home O Work O Social occasions O All circumstances O Non
6- Do you think the prosthesis treatment was worthwhile?
O Very worthwhile O Worthwhile O Neutral O Not worthwhile O Not worthwhile at all
7- How much do you recommend this treatment to others?
O Strongly not recommend O Not recommend O Neutral O Recommend O Strongly recommend

Dimensional accuracy data comparing the orbital prosthesis and the normal side was collected by measuring linear distances between fixed anthropometric landmarks using Adobe Photoshop software. On the photo, a total of 8 landmarks were identified, 4 on each side according to the standardized definitions.[12] Endocanthion [En], exocanthion [Ex], palpebral superiors [Ps], and palpebral inferiors [pi] were identified and a total of 4 linear measurements were taken for the evaluation of each orbital prosthesis, 2 on the side of the orbital prosthesis and 2 on the normal side [eye fissure length (ex-en) , eye fissure height (ps-pi)] (Figs 4, 5).

Numerical data were analyzed using Kolmogorov-Smirnov and Shapiro-Wilk tests. For parametric data; Paired t-test was used to compare between prostheses and the normal side. For non-parametric data; Wilcoxon signed-rank test was used to compare between the two techniques.

RESULTS

Patient satisfaction scores and dimensional changes (difference) data showed non-parametric (non-normal) distribution while eye fissure height, length, and height/length ratio data showed parametric (normal) distribution. Data were represented as mean,

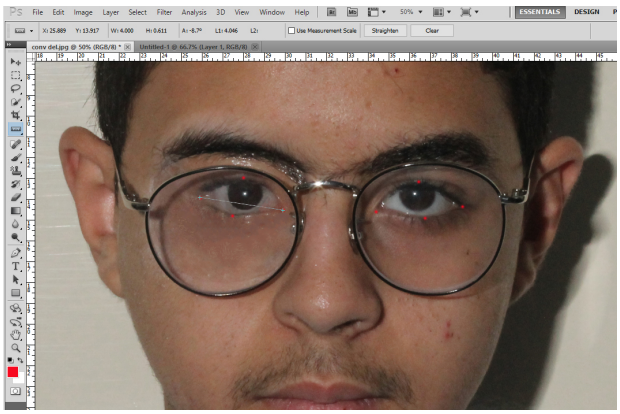

Fig 4. Eye fissure length (ex-en) for orbital prosthesis made by conventional technique.



Fig 5. Eye fissure length (ex-en) for orbital prosthesis made by aid of rapid prototyping.

standard deviation (SD), median, range and 95% confidence interval (95% CI) values. Orbital prostheses made by aid of RP technology showed statistically significantly higher mean score than orbital prostheses made by the conventional technique (P ≤ 0.05) (Table 2).

Regarding dimensional accuracy , for eye fissure length , orbital prostheses made by aid of RP technology showed statistically insignificantly lower mean measurements than the normal side, while orbital prostheses made by the conventional technique showed statistically significantly lower mean measurements than the normal side. For eye fissure height, both techniques showed statistically insignificantly lower mean measurements than the normal side and for eye fissure height/length ratio, orbital prostheses made by aid of RP technology showed statistically insignificant lower measurements than the normal side, while orbital prostheses made by the conventional method showed statistically insignificant higher eye measurements than the normal side (Table 3).

Table 2. Mean, standard deviation (SD) values and results of Wilcoxon signed rank test for the comparison between satisfaction scores in the two groups.

RP Technology		Conventional technique		P-value
Mean	SD	Mean	SD	
2.75	0.41	2.25	0.23	0.011*

RP: Rapid prototyping, *: Significant at P ≤ 0.05

DISCUSSION

The current study was aiming to compare the quality of the final prostheses made by two different techniques, and as there is an increasing interest in evaluating patient responses to facial prostheses,[13] it was decided to be the primary outcome. To overcome the subjectivity of the primary outcome which is the patient satisfaction, a complementary objective method of comparison between the two prostheses was needed to identify dimensional differences between the prostheses and the natural eye which will allow better interpretation of the primary outcome data.

To avoid the influence of tissues compressibility by the impression material on the prosthesis fit which in turn will affect the patient satisfaction, this confounder was controlled by processing both types of prostheses on a cast poured from the same impression. This was done by duplicating the original cast using polyvinyl siloxane duplicating material to be used for the intervention or the control based on the randomization process.

Three-dimensional surface data were acquired using Planmeca ProMax 3D ProFace unit which is a radiation-free process where laser beam scans facial geometry; simultaneously digital cameras in the revolving unit of the machine capture the color and texture of the face. The machine was tested for its accuracy in comparison to direct measurements from patient`s faces and the mean difference of that measurements was 0.42 mm which had no clinical significance in addition to high precision and reliability.[14]

Based on the results of this study and although both prostheses were judged very satisfactory ,there was a significant difference between orbital prosthesis made by both techniques regarding patient satisfaction in favor of RP technology and this could be due to the better reproduction of major anatomy and eye contours in the RP technology as a result of digital mirroring of the normal side in the designing process ,in contrast to the conventional technique which depends totally on the clinician skills and have a higher risk of difference due to human intervention.

For dimensional accuracy assessment digital anthropometry was done. Anthropometry is an objective measuring and proportioning method that is

Table 3. Mean, standard deviation (SD) values and results of paired t-test for the comparison between (ex-en), (ps-pi), (ps-pi/ex-en) measurements of the prostheses and normal side.

Tech.	Eye fissure length (ex-en)							Eye fissure height (ps-pi)							Eye fissure height/length ratio (ps-pi/ex-en)						
	Prosth.		Normal side		Difference		P-value	Prosth.		Normal side		Difference		P-value	Prosth.		Normal side		Difference		P-value
	Mean	SD	Mean	SD	Mean	SD		Mean	SD	Mean	SD	Mean	SD		Mean	SD	Mean	SD	Mean	SD	
RP	27.13	3.1	27.38	3.6	-0.25	1.44	0.638	9.38	0.9	9.5	1.56	-0.13	0.69	0.626	34.7	3.9	34.8	4.4	-0.02	0.79	0.931
Con.	25.88	2.8	27.38	3.6	-1.50	1.31	0.014*	9.25	1.3	9.5	1.56	-0.25	0.96	0.487	35.68	3.1	34.80	4.48	0.88	3.49	0.501

RP: Rapid prototyping, Con: Conventional, Prosth: prosthesis, *: Significant at P ≤ 0.05

used to assess the human morphology. Digital anthropometry is the evaluation and analysis on facial images instead of direct measurements on patient face according to Jayaratne, et al.[15] This technique was proved to be less disturbing for the patient, time saving and provides a permanent data of the face in addition to having same accuracy as direct measurements.[16]

Mild asymmetry between the two halves of the face is accepted and within the normal variation. Regarding the extent of facial asymmetry between the different parts of the face, significant variations have been reported by Farkas and Cheung who conducted a study on 308 normal Caucasian children to determine the degree of asymmetry using anthropometric analysis. According to this study, the most asymmetric third of the face (69.2%) was the upper third.[17] Ferrario et al. in 1994 used conventional cephalometric analysis to prove that there was a certain degree of normal soft tissue facial asymmetry in global populations. This asymmetry was most obvious in the tragus and gonion areas. According to Ferrario et al. the variations between the most symmetric and the most asymmetric people were less than 2.5 mm.[18] None of these studies provided comparison between the eye fissure length (ex-en), eye fissure height (ps-pi) and the ratio between them (ps-pi/ex-en) between the right and the left eye ,so four control persons of the patient`s ages have been selected to calculate the normal difference between right and left eye using digital anthropometry. Difference in eye fissure length (ex-en) ranged between 0.23-1.28 mm, while difference in eye fissure height (ps-pi) and eye fissure height/length ratio (ps-pi/ex-en) was 0.24-0.58 mm and 0.02-0.06 mm, respectively between the right and left eye of the same individual.

According to the results of this study, both techniques showed insignificant dimensional difference in comparison to the normal side .The only significant difference was between the orbital prosthesis made by the conventional technique and the normal side in eye fissure length (ex-en) measurement and this could be the reason behind less patient`s satisfaction to prostheses fabricated by conventional technique.

The results of this study could be considered consistent with the results of a study published by Eggbeer et al. who used a direct method and indirect method to fabricate a nasal prosthesis for a patient with nasal defects, the direct method was to fabricate the final prosthesis directly from additive manufacturing material, while the indirect method was to fabricate a mold of the designed prosthesis to be processed in conventional silicone. The material used in direct method was not proved to be biologically and mechanically acceptable. He concluded that the indirect method by rapid prototyping was judged by experts to be superior to the conventional methods in terms of position, shape and edge quality.[19]

According to the limitation of this study which is small sample size, rapid prototyping technology is very promising technology and provides orbital prostheses with a reliable high quality that can satisfy patients more in comparison to the conventional technique used. This satisfaction could be improved if this technology was developed enough to produce the prosthesis directly but this will require a dedicated digital system that can produce a prosthesis in a biocompatible material with properties similar to the silicone material used nowadays, and to be able to print different colors to produce a skin-matching prosthesis and these applications will require further research investigations.

CONCLUSION

Rapid prototyping technology is a promising technology and improved patient`s satisfaction regarding the orbital prosthesis and it was proved to be superior than conventional technique in dimensional accuracy.

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