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Surgical Site Adaptability and Outcomes of Patient Specific Implants used for the Reconstruction of Maxillofacial Defects: A Prospective Pilot Study

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ABSTRACT

Objectives: Major breakthrough in Craniofacial reconstructions emerged with the advent of Patient Specific Implants (PSI) which are designed with high precision and accuracy, leading to improved adaptability to such defects and a plethora of treatment options ranging from the reconstruction of simple alveolar defects to complex three-dimensional printing of maxilla or mandible en bloc. The aim of this study is to evaluate the surgical site adaptability and patient acceptance of patient specific implants used for reconstruction of maxillofacial defects.

Materials and Methods: This is a case series of patients operated in the Department of Oral and Maxillofacial Surgery of Saveetha Dental College. 3 patients with maxillofacial defects requiring reconstruction have been included. CBCT or CT analysis of the defects was done, based on which patient specific implants were designed using in - house Geomagic Freeform 3D designing software. Three-dimensional titanium printing of the designed implants was done in the in-house laboratory at Saveetha Dental College. Surgical procedure for placement was carried out. The variables assessed are the surgical site adaptability, postoperative VAS score, scale assessing the aesthetic result of the surgery and challenges faced intraoperatively.

Results: Prime advantage of patient specific implants is the surgical site adaptability achieved and the provision for future prosthetic rehabilitation. The mean VAS score was as follows: 1st day - 8.97, 3rd day - 6.5, 7th day - 3.5. The aesthetic rehabilitation score for the 1st and 3rd patient was 3.0 and the second patient was 4 (Chi-square test, $p>0.05$). The challenges observed were the need for additional soft tissue flaps in 2 cases, and the requirement to extend surgical site for access in large PSIs.

Conclusion: Patient specific implants prove to be an effective treatment option for reconstructing defects of maxillofacial skeleton owing to their superior surgical site adaptability and aesthetic outcomes.

Keywords: *Reconstruction, maxillofacial defects, patient specific implants, adaptation*

INTRODUCTION

Defects of the craniofacial skeleton need to be addressed meticulously as they impair not only the aesthetic appearance but also functions such as speech, mastication and deglutition. The etiology of these maxillofacial defects can be congenital anomalies such as crouzon's syndrome, Treacher's Collin syndrome, hemifacial microsomal, etc., and acquired defects due to trauma and pathology (1). The latter are however more common than the former due to resection surgery of maxilla or mandible for benign or malignant pathologies. Large defects, accompanied by a significant breach of bone continuity, lead to cosmetic deficiency, impaired chewing, swallowing and speech, deterioration of somatic health of severe psycho-emotional disorders and reduced quality of life. The main objectives of comprehensive treatment of such patients are to ensure adequate masticatory function and acceptable aesthetic outcomes (2).

The reconstruction of the resulting maxillofacial defects is extremely challenging and requires skilled surgeon. This can be attributed to the anatomical complexity of the region and the difficulty in establishing the natural anatomical contours, without hampering the functional abilities. The current gold standard for reconstruction of maxillofacial defects is autografts, namely vascularized free flaps and free grafts. In Spite of the enormous advantages and excellent literature evidence supporting this method, it has its own disadvantages like increased surgical time, donor site morbidity, graft resorption or rejection (3).

The advent of modern technological solutions such as Computer assisted designing and manufacturing systems now aid in virtual osteotomies, resections and planning of reconstruction. In the last two decades, patient-specific implants (PSIs) have become widespread with the advances in three-dimensional (3D) computer-aided design (CAD) and computer-aided manufacturing (CAM) technologies in different fields of medicine (4). Hip and knee arthroplasties in orthopedic surgery and cranial surgery are some of the implementations of PSIs. PSIs are also used in oral and maxillofacial surgery for reconstruction of orbital defects, facial contouring, reconstruction of the mandible, dental rehabilitation, temporomandibular joint prosthesis, and orthognathic surgery.

Patient specific implants are designed with high precision and accuracy, by mirror imaging the intact normal anatomy in case of unilateral defects or by creating de novo in case of bilateral defects. These PSIs exhibit improved adaptability to maxillofacial defects due to their precise designing protocols. Patient Specific implants have also opened up Plethora of treatment options - from reconstruction of simpler alveolar defects to complex reconstruction involving maxilla or mandible in toto.

Our team has extensive knowledge and research experience that has translated into high quality publications (5-14). This pilot study was conducted to evaluate the surgical site adaptability and patient acceptance outcomes of Patient Specific Implants.

MATERIALS AND METHODS

Study setting

The study was carried out in an institutional setting with the advantage being a wide range of data availability in digital format and the disadvantage being assessment of patients in a single location only. The approval of the Institutional Ethics Committee was sought.

Study design

The study was designed to include all patients reporting with maxillofacial defects for reconstruction. Cases with previously failed autografts, free flap or patient specific implants, patients who have undergone radiotherapy were excluded from the study.

Sampling technique

The study was based on a Non probability convenience sampling. To minimize the sampling bias, all the patients requiring reconstruction of maxillofacial defects were included.

PSI Protocol

The study was carried out for a period of 4 months. 3 patients reported with maxillofacial defects for whom PSI was designed using Geomagic Freeform software, using the patient's CBCT or CT records. In case of unilateral defect, the normal side was used as a mirror image to design the PSI. The designed PSI was then converted to an STL format and printed using an in-house DMLS - 3D printer. Material used is medical grade titanium alloy. The printed PSIs were autoclaved at 132 C and taken for surgical placement. All the surgical procedures were carried out under General anesthesia with strict infection control and sterilization protocols. During surgical placement the adaptability of the PSI to the surgical site was assessed as follows: whether intraoperative modifications were required for the PSI or not. If yes, how much modification was done (measured in mm). Postoperatively VAS score was assessed during the 1st, 3rd and 7th postoperative days. Aesthetic rehabilitation score was evaluated during the end of 3rd month postoperatively.

The aesthetic result of surgery was analyzed on expert assessments using the following score scale: 5 points – changes are not visually noticeable, 4 points – changes in appearance are barely noticeable and do not affect the patient's quality of life, 3 points – there is an aesthetic deficit that does not require surgical correction, 2 points – there are aesthetic defects that require minor surgical corrections in the postoperative period, 1 point – there are significant aesthetic defects that require serious (often multi-stage surgical correction), and 0 points – the presence of severe aesthetic defects that cannot be eliminated (6).

Statistical analysis

The variables were coded and the data was imported to SPSS. Using SPSS Version 20.0, the statistical significance of associations was tested using the Chi-square test and results obtained.

RESULTS

Of the three patients (Table 1) for whom PSI was designed, 2 patients had bilateral maxillary defects after mucormycosis. Both the patients reported for reconstruction 6 months after the resection was done. The single case of mandibular PSI was a 22-year-old female with ameloblastoma of the left mandible. Resection of the left hemimandible followed by immediate PSI placement was done. The two cases of maxillary PSIs did not require any intraoperative modifications and had excellent surgical adaptability. The mandibular PSI required a modification of 2 mm.

The postoperative VAS score was assessed ranging from 0-10 (0 - no pain, 10-severe pain). The mean VAS score was as follows: 1st day - 8.97, 3rd day - 6.5, 7th day - 3.5. There was a clinically significant difference in the postoperative VAS score of all the 3 days. However, the values were not statistically significant (Chi-square test, $p>0.05$). The aesthetic rehabilitation score for the 1st and 3rd patient was 3.0 and the second patient was 4.0 (Chi-square test, $p>0.05$).

TABLE 1: Type of defect and surgical site adaptability

Patient No.	Age/ Sex	Type of defect	Surgical site adaptability
1	47 years / M	Bilateral maxillary defect post mucormycosis	Yes
2	24 years / F	Ameloblastoma of the left mandible. Resection and immediate placement.	No. 2mm modification
3	52 years / M	Bilateral maxillary defect post mucormycosis	Yes

DISCUSSION

Reconstructive surgeries are extremely challenging even to the most experienced surgeon particularly due to the complex anatomy, sensitivity of the involved systems, and uniqueness of each defect. The technologies, such as additive manufacturing (AM) also known as rapid prototyping (RP) or three-dimensional (3D) printing, are robustly growing and have positively infuenced the biomedical sector over the last decade allowing the surgeons and researchers to utilize them in manufacturing objects (15,16). According to Chernogorskyi et al., (16), PSIs allow you to accurately restore the mandibular contour in the mirror image of the healthy side, compensating for the existing mismatch in the shape of the grafts. Instead, when using traditional methods of defect replacement, there is often a need for contouring, correction of the mandibular shape, reproduction of the curvature of its contour using individualized polymer and ceramic plates, bone grafts and more. This was completely confirmed in their study based on the need for corrective surgery, which in the control group was twice as large. Aesthetic outcomes in the main group of patients, the satisfaction level and the assessment of changes in quality of life were probably better in patients with established PSI than in the conventional graft group. The current study also utilised the same aesthetic rehabilitation scale utilized by Chernogorskyi et al., (16) and similar outcomes were obtained.

The application of PSI is not only limited to the maxillofacial complex but also extends to the reconstruction of cranial defects. Zeggers et al., (17) in their study retrospectively evaluated 29 cases of craniofacial defects reconstructed using titanium or PEEK PSI. According to this study reconstruction of skull bone defects with PEEK and titanium patient specific implants gave a statistically significant improvement in quality of life. It also decreased pain and headache and gave aesthetically good results. In another study mandibular patient specific implants were used for jaw contouring for cosmetic purposes and the results were analyzed using Four FACE Q questionnaire (18). The results revealed that the surgical outcomes and patient satisfaction of those who received such jaw angle PSI were superior to that of the conventional stock silicone implants.

Lim et al. (19) have provided an outline of possible indications and contraindications for patient specific implants.

Indications

1. A continuity defect of the facial bone limited to hard tissue for which reconstruction has already been performed and there is no proper reconstruction option.
2. If there is a mild or moderate bone defect due to previous excessive bone preparation in a patient with facial osteoplasty.
3. In case of high esthetic requirements such as correction of fine skeletal asymmetry.
4. Areas that require functional load bearing, such as the mandible.
5. When simultaneous reconstruction with dental implants is required.

Contraindications

1. Cases requiring complex tissue reconstruction of hard and soft tissues.
2. Patients with hypersensitivity to titanium material.
3. Patients who require continuous follow-up through radiographic imaging such as CT or MRI (9).

Another promising material for the manufacture of patient specific implants is PEEK - Polyetheretherketone. PEEK has been widely employed for fabricating spinal fusions due to its radiolucency, chemical stability and superior sterilization resistance at high temperatures. PEEK can also be tailored into patient-specific implants for treating orbital and craniofacial defects in combination with additive manufacturing processes (20,21). The orbital volume correction was better when a PEEK PSI was used and the residual enophthalmos has also been reported to be lower than conventional titanium mesh for orbital reconstruction (21).

The adaptability of PSI was excellent intraoperatively in the current study samples. No major modifications were required. The challenges faced during the procedure was the requirement to extend the surgical site in order to obtain access for fixation of large PSIs for the maxillary cases. The ability to achieve adequate soft tissue coverage was also challenging and for both the maxillary cases, bilateral nasolabial flaps were harvested for adequate soft tissue coverage. Similar challenges have also been encountered in the case series by Alasseri and Alasraj (22).

The limitations of this study are the small sample size which is also a major factor for the clinically significant but statistically insignificant results. However, the clinical outcomes prove Patient Specific Implants to be a promising treatment modality for the reconstruction of maxillofacial defects.

CONCLUSION

Patient specific implants prove to be an effective treatment option for reconstructing defects of maxillofacial skeleton owing to their superior surgical site adaptability and aesthetic outcomes. Further research needs to be initiated in a large sample size, in order to provide stronger scientific evidence in this regard.

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CONFLICTS OF INTEREST

The authors declare no potential conflict of interest.

REFERENCES

1. Yagiz A, Dogru SC, Üzel M, Kocaelli H, Arslan YZ, Cansiz E. Design of Patient-Specific Maxillofacial Implants and Guides. Applications of 3D printing in Biomedical Engineering. 2021:121-31.
2. Kim MM, Boahene KD, Byrne PJ. Use of customized polyetheretherketone (PEEK) implants in the reconstruction of complex maxillofacial defects. Archives of facial plastic surgery. 2009.
3. Sharma N, Aghlmandi S, Dalcanale F, Seiler D, Zeilhofer HF, Honigmann P, Thieringer FM. Quantitative assessment of point-of-care 3D-printed patient-specific polyetheretherketone (PEEK) cranial implants. International Journal of Molecular Sciences. 2021 Aug 7;22(16):8521.
4. Järvinen S, Suojanen J, Kormi E, Wilkman T, Kiukkonen A, Leikola J, Stoor P. The use of patient specific polyetheretherketone implants for reconstruction of maxillofacial deformities. Journal of Cranio-Maxillofacial Surgery. 2019 Jul 1;47(7):1072-6.
5. Malli Sureshbabu N, Selvarasu K, V JK, Nandakumar M, Selvam D. Concentrated Growth Factors as an Ingenious Biomaterial in Regeneration of Bony Defects after Periapical Surgery: A Report of Two Cases. Case Rep Dent. 2019 Jan 22;2019:7046203.
6. Ahad M, Gheena S. Awareness, attitude and knowledge about evidence based dentistry among the dental practitioner in Chennai city. J Adv Pharm Technol Res. 2016;9(11):1863.
7. PradeepKumar AR, Shemesh H, Jothilatha S, Vijayabharathi R, Jayalakshmi S, Kishen A. Diagnosis of Vertical Root Fractures in Restored Endodontically Treated Teeth: A Time-dependent Retrospective Cohort Study. J Endod. 2016 Aug;42(8):1175–80.
8. Jangid K, Alexander AJ, Jayakumar ND, Varghese S, Ramani P. Ankyloglossia with cleft lip: A rare case report. J Indian Soc Periodontol. 2015 Nov;19(6):690–3.
9. Kumar A, Sherlin HJ, Ramani P, Natesan A, Premkumar P. Expression of CD 68, CD 45 and human leukocyte antigen-DR in central and

peripheral giant cell granuloma, giant cell tumor of long bones, and tuberculous granuloma: An immunohistochemical study. Indian J Dent Res. 2015 May;26(3):295–303.

10. Manohar J, Abilasha R. A Study on the Knowledge of Causes and Prevalance of Pigmentation of Gingiva among Dental Students [Internet]. Vol. 10, Indian Journal of Public Health Research & Development. 2019. p. 95. Available from: http://dx.doi.org/10.5958/0976-5506.2019.01859.x
11. Sekar D, Mani P, Biruntha M, Sivagurunathan P, Karthigeyan M. Dissecting the functional role of microRNA 21 in osteosarcoma. Cancer Gene Ther. 2019 Jul;26(7-8):179–82.
12. Girija SA, Jayaseelan VP, Arumugam P. Prevalence of VIM- and GIM-producing Acinetobacter baumannii from patients with severe urinary tract infection. Acta Microbiol Immunol Hung. 2018 Dec 1;65(4):539–50.
13. Maheswari TNU, Venugopal A, Sureshbabu NM, Ramani P. Salivary micro RNA as a potential biomarker in oral potentially malignant disorders: A systematic review. Ci Ji Yi Xue Za Zhi. 2018 Apr;30(2):55–60.
14. Subashri A, Maheshwari TNU. Knowledge and attitude of oral hygiene practice among dental students. J Adv Pharm Technol Res. 2016;9(11):1840.
15. Honigmann P, Sharma N, Okolo B, Popp U, Msallem B, Thieringer FM. Patient-specific surgical implants made of 3D printed PEEK: material, technology, and scope of surgical application. BioMed research international. 2018 Mar 19;2018.
16. Chernogorskyi DM, Voller MV, Vasilyev AS, Chepurnyi YV, Kopchak AV. Clinical efficacy of patient-specific implants manufactured by direct metal laser sintering (DMLS) technology in patients with mandibular defects. J Diagn Treat Oral Maxillofac Pathol. 2020;4(9):162-77.
17. Zegers T, ter Laak-Poort M, Koper D, Lethaus B, Kessler P. The therapeutic effect of patient-specific implants in cranioplasty. Journal of Cranio-Maxillofacial Surgery. 2017 Jan 1;45(1):82-6.
18. Mommaerts MY. Patient-and clinician-reported outcomes of lower jaw contouring using patient-specific 3D-printed titanium implants. International Journal of Oral and Maxillofacial Surgery. 2021 Mar 1;50(3):373-7.
19. Lim HK, Choi YJ, Choi WC, Song IS, Lee UL. Reconstruction of maxillofacial bone defects using patient-specific long-lasting titanium implants. Scientific Reports. 2022 May 9;12(1):7538.
20. Chepurnyi Y, Chernogorskyi D, Kopchak A, Petrenko O. Clinical efficacy of peek patient-specific implants in orbital reconstruction. Journal of oral biology and craniofacial research. 2020 Apr 1;10(2):49-53.
21. Liao C, Li Y, Tjong SC. Polyetheretherketone and its composites for bone replacement and regeneration. Polymers. 2020 Nov 29;12(12):2858.
22. Alasseri N, Alasraj A. Patient-specific implants for maxillofacial defects: Challenges and solutions. Maxillofacial Plastic and Reconstructive Surgery. 2020 Dec;42:1-8.