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Comparison of Aesthetic Outcomes of Different Methods of Reconstruction of Maxillofacial Defects: A Clinical Trial

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The craniofacial skeleton includes complex structures such as the cranium, temporomandibular joint, mandible, dentition, palate, and the sensory organs that forms the major basis of form and function. The aim of this study is to compare the aesthetic outcomes of different methods of reconstruction of maxillofacial defects. The study is a prospective single-center clinical trial that was designed based on the guidelines published by the Consolidated Standards of Reporting Clinical Trials (CONSORT) statement. The results of the study reveal that there is a significant difference between the preoperative and postoperative scores of Face Q scale, speech articulation test and nutritional status. Further, the scores have shown significant improvement over the postoperative period from the 1st to the 6th month. According to this, patient specific implants can be a promising treatment modality in improving the quality of life of patients with maxillofacial defects. In future, research must focus on validating the results in a larger population and exploring new materials for patient specific implants.

Keywords: craniofacial skeleton, Consolidated Standards of Reporting Clinical Trials, Implants, preoperative and postoperative scores.

1. Introduction

The craniofacial skeleton includes complex structures such as the cranium, temporomandibular joint, mandible, dentition, palate, and the sensory organs that forms the major basis of form and function [1]. Ablative surgeries, trauma, and congenital conditions lead to defects of the craniofacial skeleton that need to be addressed meticulously as they impair not only the aesthetic appearance but also functions such as speech, mastication and deglutition. Large defects, accompanied by a significant breach of bone continuity, lead to

cosmetic deficiency, impaired chewing, swallowing and speech, deterioration of somatic health, severe psycho-emotional disorders and reduced quality of life [2]. The etiology of these maxillofacial defects can be congenital anomalies such as Crouzon syndrome, Treacher Collins syndrome, hemifacial microsomal, etc., and acquired defects due to trauma and pathology [3]. The latter are however more common than the former due to resection surgery of maxilla or mandible for benign or malignant pathologies [4].

The main objectives of comprehensive treatment of such patients are to ensure adequate masticatory function and acceptable aesthetic outcomes. The practice of reconstructive surgery revolves around the use of autologous or allogeneic grafting techniques. However, craniofacial reconstruction due anatomical complexity of the region and the difficulty in establishing the natural anatomical contours, without hampering the functional abilities is extremely challenging and requires skilled surgeons. The current gold standard for reconstruction of maxillofacial defects is autografts, namely vascularized free flaps and free grafts, coupled at times with tissue engineering [5]. 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 [4]. 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 [6]. Patient Specific Implant are 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 [7]. These Patient specific implants exhibit improved adaptability to maxillofacial defects due to their precise designing protocols. Patient Specific implants have also opened up a plethora of treatment options - from reconstruction of simpler alveolar defects to complex reconstruction involving maxilla or mandible in toto.

The aim of this study is to compare the aesthetic outcomes of different methods of reconstruction of maxillofacial defects.

2. MATERIALS AND METHODS:

Study design

The study is a prospective single-center clinical trial that was designed based on the guidelines published by the Consolidated Standards of Reporting Clinical Trials (CONSORT) statement.

Eligibility Criteria

Inclusion Criteria

- Patients with maxillary / mandibular / combined defects

- Patients having cranial defects
- Patients undergoing resection for benign pathologies and planned for immediate reconstruction / delayed reconstruction
- Patient undergoing occlusal rehabilitation for defects of alveolar bone
- Patients undergoing guided bone regeneration

Exclusion Criteria

- Patients who have undergone radiotherapy
- Cases with only soft tissue defect reconstruction

Setting and Location

The study participants were recruited from the outpatients reporting to the Department of Oral and Maxillofacial Surgery, Saveetha Dental College and Hospitals, Chennai. The study began in April 2022 and the last patients were recruited in December 2023.

Outcome measures

Four face Q questionnaire was used for the assessment of aesthetic outcomes. It consists of a calibrated subjective assessment scale that assesses the aesthetic perception of the individual based on different regions of the maxillofacial region.

Statistical Analysis

All statistical analysis was performed using Statistical Package for Social Science (SPSS, version 17) for Microsoft Windows. The data were normally distributed and therefore parametric tests were performed. The data was expressed as Mean and SD. Inter group comparison done using Two - way ANOVA. Intragroup comparison done using repeated measures ANOVA and Bonferroni test. A two-sided p value < 0.05 was considered statistically significant.

3. RESULTS:

Graph 1: Distribution of different methods of reconstruction of maxillofacial defects.

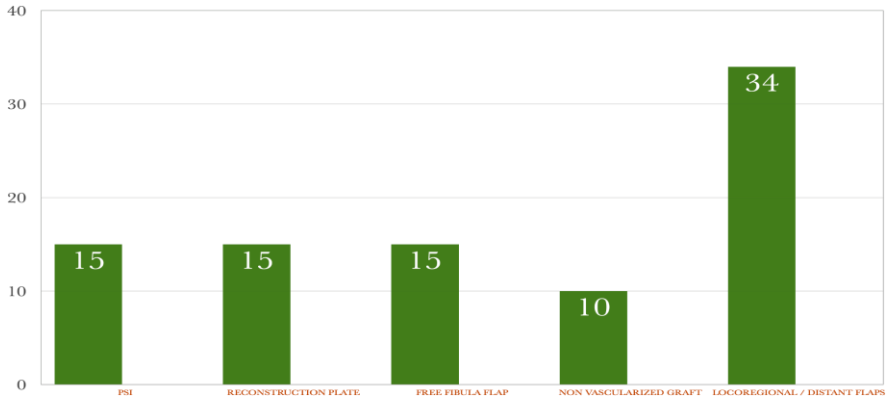

Table 1: Postoperative 1st month vs 6th month comparison of Face Q Appearance scale

Pair	p-value
Patient specific implants	<0.001*
Free fibula flap	<0.001*
Non vascularized grafts	0.067
Other locoregional flaps / distant flaps	0.078
Reconstruction plate	0.073

Adjustments for multiple comparisons: Bonferroni test; * indicates a significant difference at $p \leq 0.05$.

Figure 1: Immediate Patient specific implant reconstruction for segmental mandibular defect with disarticulation in a case of benign odontogenic neoplasm

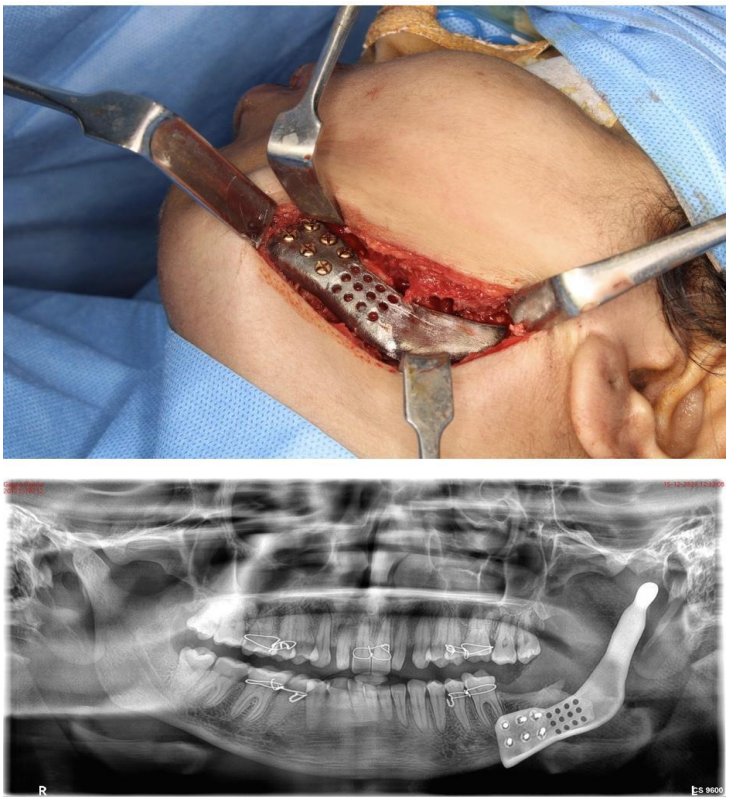

Figure 2: Immediate Free fibula flap reconstruction for segmental mandibular defect with disarticulation in a case of benign odontogenic neoplasm

Figure 3: Case of osteomyelitis of right mandible - segmental resection and reconstruction plate fixation

4. 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 influenced the biomedical sector over the last decade allowing the surgeons and researchers to utilize them in manufacturing objects [2]. According to Chernogorskyi et al., [6], 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.

In our study population, the defects were either maxillary or mandibular or alveolar defects. Combined defects were not encountered in any of the cases. The design was done by mirroring the normal side. The difficulties were encountered in designing in case of maxillary PSI as mirroring of the normal side was not possible in these cases due to destruction of anatomy in the contralateral side as well. The next challenge was in incorporating the prosthetic component in the patient specific implant for patients whose defect included the dentate segment. The custom abutments were scanned and incorporated with designing, to facilitate an easier prosthetic fabrication in the postoperative period.

In the current study, the FACE Q scores for the appearance scale showed significant improvement from the preoperative period till the 6th month postoperative period. The nutritional status of patients improved over time. In the immediate postoperative period there was a dip in the nutritional score of patients, as some patients were kept on nasogastric tube feed to avoid the surgical site infection in the postoperative period. Eventually after the removal of the nasogastric tube, the nutritional status showed significant improvement, which can be attributed to the prosthetic rehabilitation as well. Such statistically significant scores were particularly observed in cases of reconstruction with patient specific implants or free fibula flap.

The surgical outcomes were not statistically significant in cases where locoregional / distant flaps or reconstruction plates were used. This can be attributed to the challenges in the prosthetic rehabilitation of such patients, which adversely affects the function and aesthetics.

The application of PSI is not only limited to the maxillofacial complex but also extends to the reconstruction of cranial defects. Zeggers et al., [7] 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 [8]. 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. [9] have provided an outline of possible indications and contraindications for patient specific implants. Another promising material for the manufacture of patient specific implants is PEEK - Polyetheretherketone. PEEK can be tailored into patient-specific implants for treating orbital and craniofacial defects in combination with additive manufacturing processes [10, 11]. 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 [11].

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 inorder 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.

According to Chepurnyi et al., [10], the mean difference between intact and damaged orbital volumes when pre bent titanium plates were used was 1.6-2.4 cubic centimeters. This increase in orbital volume of >2.4 cc could result in significant functional and aesthetic sequelae such as diplopia and enophthalmos. According to the authors, similar values were reported by many other authors as well. Further, the use of these conventional plates was not only associated with poor functional and aesthetic outcomes, but also had time consuming intraoperative adaptation and increased blood loss during the surgery. The residual enophthalmos postoperatively was also very low and the clinical efficacy of PSI in restoring the shape of damaged orbit was extremely high [10]. In a study by Alasseri et al.,[12] PEEK was used to fabricate 8 of the 10 PSIs used. Zygoma was reconstructed using a separate PSI. For secondary deformities of orbits the authors used titanium PSI. They observed that PSIs require minimal adjustments that were easily made intraoperatively. Another advantage of PSI is that navigational guides and rulers could be incorporated into the implant. As the pointer traverses along the trajectory guides, the navigation system can confirm that certain points are in the correct position and also that the trajectory is correct. This enables accurate positioning of the implant, alleviating the need for intraoperative CT scans and the dose of radiation patients are exposed to [13].

The most reported limitation using PSI was the difficulty in inserting larger implants with minimal surgical access. This forces the surgeon to extend the surgical approach. Further, the intraoperative difficulties such as scar tissue from previous surgery, lack of tissue compliance to accommodate both the implant and retractor, further complicate the insertion and adaptation of the implant [13, 14]. According to Kotecha et al.[15], though some studies have reported the advantages of PSI over conventional implants in reducing operative time and improving postoperative orbital volume and enophthalmos, statistically significant difference was not observed in their meta-analysis. Rana et al., [16] point out that the techniques of planning and designing a PSI require a lot of training and the learning curve is very steep particularly in PSIs for orbital fractures. Moreover the time taken for designing and milling hinder its usage in cases requiring immediate intervention within 24 hours.

In spite of all the limitations pointed out, there is a better future for PSI in orbital reconstruction, as these limitations are negligible when compared to the benefits associated with PSI usage. The surgical site access can be overcome by designing larger PSIs as 2-3 components connected with connectors facilitating easy placement [17,18]. According to Schlittler et al., [19], the need for revision surgeries was high when conventional plates were used for complex orbital fractures. They point out that PSI will be the future of orbital reconstruction alleviating the need for revision surgeries[19,20].

There are not many studies that compare the outcomes of patient specific implants with other methods of reconstruction of maxillofacial defects. Hence, this study is novel in its design and conceptualisation.

5. CONCLUSION:

The results of the study reveal that there is a significant difference between the preoperative and postoperative scores of Face Q scale, speech articulation test and nutritional status. Further, the scores have shown significant improvement over the postoperative period from the 1st to the 6th month. According to this, patient specific implants can be a promising treatment modality in improving the quality of life of patients with maxillofacial defects. In future, research must focus on validating the results in a larger population and exploring new materials for patient specific implants.

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