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Original Article

Validity of PEEK Patient Specific Implant (PSI) Containing Autogenous Bone Graft For Maxillary Reconstruction Following Lesion Enucleation - A Pilot study

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Abstract

Aim: The aim of this study is to evaluate the clinical and radiographic outcomes of PEEK/ PSI containing autogenous bone graft after enucleation of unilateral maxillary lesion encroaching maxillary sinus. **Subjects and Methods:** This study was conducted on ten patients (4 males and 6 females) with unilateral maxillary cysts encroaching the maxillary sinus. The age of the patients ranged from 15 to 59 with a mean of 33.1 years. All cases underwent surgical enucleation followed by immediate grafting with autogenous bone/xenograft mix in a PEEK /PSI to reconstruct the alveolar process and the maxillary sinus floor. **Results**: the results of this study demonstrated that pain intensity score according to the Visual Analogue Scale for the ten patients revealed: a minimum of 6 and a maximum of 10 with a mean of 7.2 preoperatively and a minimum of 0 and a maximum of 4 with a mean value of 1.8 one week postoperatively. According to radiographic results, Case number 5 was excluded from the statistical analysis of the radiographic results, as the PSI and the graft were removed 1 month postoperatively. Immediate postoperative bone density for 9 patients revealed: a minimum of 203.81 HU and a maximum of 413.79 HU with a mean of 318.79 HU. 4 months postoperative bone density for 9 patients revealed: a minimum of 274.75 HU and a maximum of 487.14 HU with a mean of 369.43 HU. **Conclusion:**The statistical analysis of the bone density immediately and 4 months postoperatively is considered to be very statistically significant.

Keywords: PEEK - PSI - autogenous bone graft - maxillary reconstruction - lesion enucleation.

1. Introduction

Surgical ablation of large maxillary lesions usually results in considerable hard and soft tissue deficits that ultimately affect the final esthetic and functional outcomes. Reconstruction of such defects; whether primarily or secondarily; should offer good long-term outcomes[1]. However, primary bony reconstruction becomes potentially complicated in large lesions encroaching or involving the maxillary sinus where a communication with the maxillary sinus lining may be unavoidable[2].

Reconstruction of such maxillary defects can be accomplished using autogenous bone grafts either intra-oral or extra-oral according to the size of the defect and the amount of the bone graft needed. Different bone substitutes - including allograft, xenograft and alloplast - remain to be another viable option[3].

Recently, polyetheretherketone (PEEK) material has been introduced into the field of the maxillofacial reconstruction with promising results due to its excellent biocompatibility and mechanical properties[4]. Computer

aided design and manufacturing (CAD/CAM) systems allow precise fabrication of PEEK patient specific implant (PSI)[5].

In the current research, PSIs made of PEEK will be used to contain the bone graft within, separate the graft material from the maxillary sinus cavity and reconstruct the bony defect for future implant rehabilitation.

2. Subjects and Methods

2.1. Pre-surgical preparation

History data was gathered including personal data, medical and surgical history, and family history. Then clinical data included lesion aspiration, radiographic examination and endodontic treatment where necessary.

Computed tomography (CT) of the maxilla-midface was ordered using a multislice helical CT machine. All images were obtained in a DICOM format. A PSI was designed using Mimics software to reconstruct the sinus floor based on the other healthy side then; it was constructed intodental PEEK material by milling technique (figure 1).

2.2. General operative procedures:

All cases underwent surgery under general anesthesia with nasotracheal intubation. A three-incision mucoperiosteal pyramidal flap was reflected properly. The flap was extended to the sound bone on both sides to allow adequate exposuse of the surgical site. Enucleation of the lesion and apicectomy with retrograde MTA apical seal of the endodontically treated involved teeth were carried out (figure 2). The lining of the sinus was removed with the lining of the cyst. Marrow cancellous bone from the anterior iliac crest was harvested using a 7mm trephine bur and bone curettes. The harvested bone was grinded using bone grinder machine and then mixed with 1gm bovine xenograft Packing of the bone graft into the maxillary defect was done to reconstruct the alveolar process. PSI was seated in place and fixed with titanium 1.5 mm micro-screws to cover the graft (figure 2). The soft tissue flap was repositioned and sutured in place with 3-0 resorbable polyglycolic acid interrupted and horizontal mattress sutures.

2.3. Postoperative care and Medications

- Ice packs for the first 24 hrs
- Ampicillin 1500 mg intramuscular injection twice daily for three days.
- Diclofenac sodium 75 mg intramuscular injection twice daily for two days.
- Dexamethasone Sodium Phosphate 4 mg intramuscular injections every 6 hours for the first postoperative day, half the dose every 6 hours .
- Methylprednisolone Acetate 40 mg intramuscular injection two vials as 80 mg with the last half dose of Epidrone.
- Chlorohexidine Gluconate 0.1% mouthwash started the day after surgery 5 times daily for 2 weeks.

2.4. Postoperative clinical follow up:

Three days post-operatively the patient was recalled, to evaluate pain, abnormal swelling, hemorrhage, infection or any surgical complications and general condition was assessed. Follow ups were then scheduled once weekly for the first month, then monthly for 3 months.

2.5. Postoperative records:

- A score of pain intensity was recorded one week postoperatively using the same visual analogue scale used preoperatively.
- A CT scan was ordered postoperatively immediately and after 4 months following the same preoperative parameters.
- Measuring of the bone density at three different sites (anterior, middle and posterior) on the axial cuts in relation to a fixed reference point was done on the immediate postoperative C.T. and on the 4 months postoperative C.T (figure 3).

3. Results

3.1. Demographic data:

Personal, surgical and pathological data of the cases are summarized in table 1.

3.2. Pain intensity score (Visual Analogue Scale) (VAS):

- Pain intensity score according to the Visual Analogue Scale for ten patients revealed: a minimum of 6 and a maximum of 10 with a mean of 7.2 preoperatively and a minimum of 0 and a maximum of 4 with a mean value of 1.8 one week postoperatively (table 1).

3.3. Radiographic results (bone density):

- Case number 5 was excluded from the statistical analysis of the radiographic results, as the PSI and the graft were removed 1 month postoperatively.
- Immediate postoperative bone density for 9 patients revealed: a minimum of 203.81 HU and a maximum of 413.79 HU with a mean of 318.79 HU.
- 4 months postoperative bone density for 9 patients revealed: a minimum of 274.75 HU and a maximum of 487.14 HU with a mean of 369.43 HU (table 2, 3).

P value and statistical significance: The two-tailed P value equals 0.0076. By conventional criteria, this difference is considered to be very statistically significant (table 4).

4. Discussion

Surgical removal of huge maxillary cystic lesions that intrude into the maxillary sinus leads to loss of soft and hard tissues with subsequent functional and esthetic problems.

Adequate reconstruction for maxillary intra-bony defects becomes more presice and more easier after introduction of the CAD/CAM software and patient specific implants (PSIs)[6]. These computer guided PSIs not only reconstruct the maxillary defect precisely with proper contour and facial symmetry, but also decrease the intra-operative time and effort.

During the past decade, PEEK has been used for PSIs fabrication in the maxillofacial field with promising results[7]. Thus, PEEK was chosen in the present study for its good mechanical and chemical properties, biocompatibility, durability and light weight.

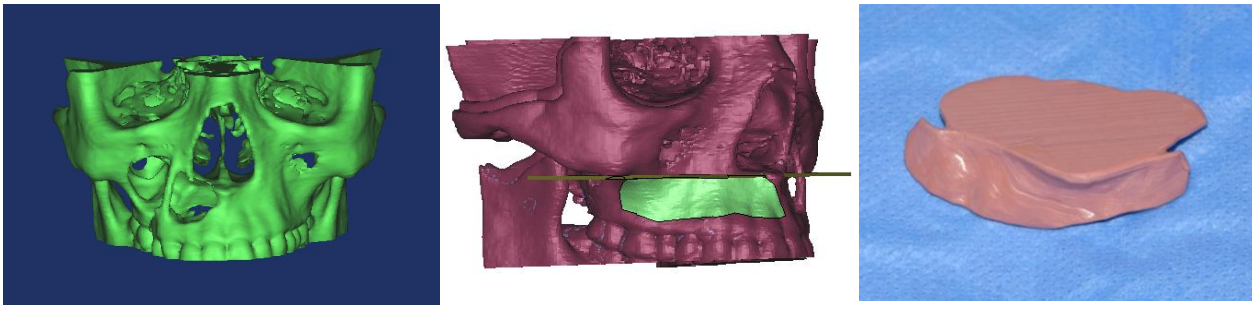

Figure 1: The PSI design and printing.

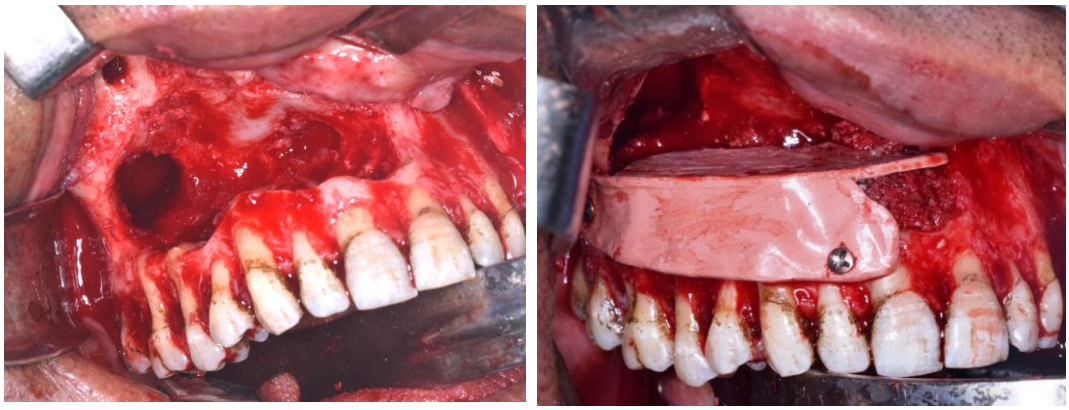

Figure 2: Complete cystic enucleation (Lt) PEEK PSI fixed in place to cover the graft (Rt)

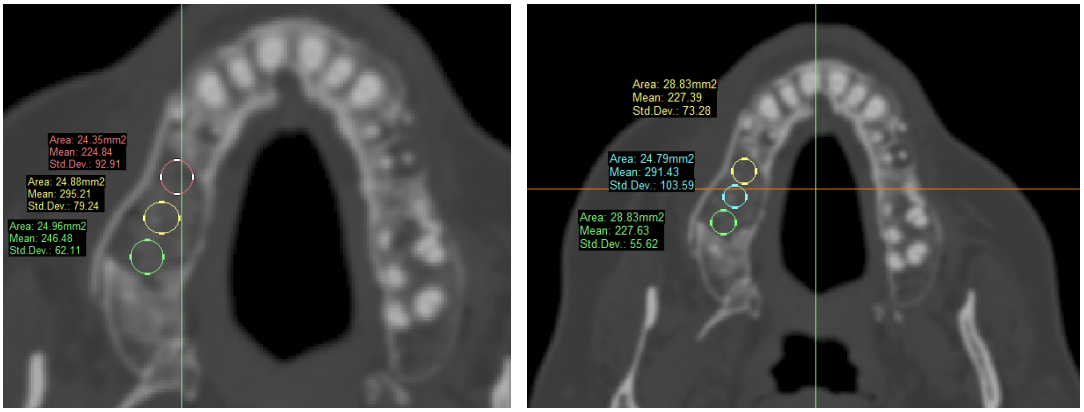

Figure 3: Immediate (Lt) and 4 months postoperative C.T. (Rt)

Table 1: The demographic data of the patients

Case No.	Age	Gender	Affected side	Involved teeth	Pathology report
1	15	Male	Right	7543	IPC
2	35	Female	Right	7643	IPC
3	18	Female	Left	3467	IPC
4	51	Female	Right	7632	IPC
5	29	Female	Left	45	IPC
6	40	Male	Right	7654321	ICW
7	27	Male	Left	4567	ICW
8	59	Male	Right	32	RC
9	35	Female	Left	23456	IPC
10	22	Female	Right	65432	IPC

IPC: inflammatory periodontal cyst. ICW: infected cyst wall. RC: residual cyst.

Table 2: Pain intensity scores

Case No.	VAS preoperatively	VAS one week postoperatively
1	8	2
2	6	1
3	10	4
4	7	0
5	7	3
6	6	1
7	6	2
8	7	0
9	8	3
10	7	2
Mean	**7.2**	**1.8**

Table 3: The bone density immediately and 4 months postoperatively

Case No.	Mean value of immediate postoperative bone density (HU)	Mean value of 4 months postoperative bone density (HU)
1	273.38	274.75
2	372.22	487.14
3	319.57	411.54
4	321.06	363.29
5	141.78	_____
6	413.79	426.06
7	203.81	312.46
8	260.66	291.67
9	338.5	365.44
10	366.15	392.60

Table 4: Statistical analysis of the bone density immediately and 4 months postoperatively

	Mean	Std. Deviation	P- value
Immediate post-operative	318.79	64.39	0.0076
4 months post-operative	369.43	68.63	

Also its reasonable cost compared to titanium could be another factor encouraging its use.

In the present study, C.T. scan was used for computer guided designing of the PSI. However, C.T. scan may be more expensive and expose the patient to higher dose of radiation than CBCT. Nevertheless, many authors have reported the use of the C.T. scan in the maxillofacial reconstruction as it has better resolution and fewer artifacts compared to CBCT[6–12].

During planning of the PSI design, the thickness was kept to the minimum (1 mm) as more thickness would be bulky and might increase the risk of soft tissue dehiscence. While less thickness may cause weakness of the PSI with increased probability of its fracture.

Few problems were encountered during fixing the PEEK PSI in place. In case number 4, a crack occurred during fixing the screw. This may be related to the thin thickness of the PSI and/or due to the mechanical properties of the used PEEK. Care should be taken during screwing to avoid this complication.

Mucosa thinning with appearance of the shadow of the PEEK PSI 2 months postoperatively in case number 2 may be attributed to the thickness of the PSI (1mm) and the nature of the mucosa in this area which is usually very thin. Also, the soft tissue dehiscence over the PEEK PSI showed in cases number 1 and 9 one month postoperatively may be attributed to the same reason and the type of the used PEEK.

Regarding infection, many authors reported infection rate of 7.6[7,11,13]. Comparably, in the present study case number 6 showed signs and symptoms of infection after 3weeks postoperatively with infection rate of 10%. This complication may be attributed to the bad oral hygiene measures of the patient and communication of the bone graft with the sinus environment due to rapid degradation of the PRF preparation when it is used as a membrane.

Case number 5 showed soft tissue dehiscence and loss of the bone graft due to its communication with the oral cavity after 2 weeks postoperatively. This was caused by a technical problem intra-operatively as the bone at the alveolar crest - the site of the bone graft packing – was removed during cyst enucleation leading to communication of the bone graft with the oral cavity.

Pain intensity score according to visual analogue scale ranged from 0 to 4 one week post-operatively. The different in scorning is probably related to patient's pain threshold and his expectations of the pain intensity following the surgical procedure. Although the VAS is considered as a simple procedure, some patients found difficulty with it due to their low socio-economic level.

Regarding radiographic results, the significant difference in bone density between immediate and 4 months postoperative C.T. is an indication of ongoing bone remodeling and calcification.

5. Conclusion

The technique can be considered as a promising solution to reconstruct the maxillary intra-bony defects without dispersion of the graft into the sinus cavity. However, soft tissue dehiscence and infection that occurred in some cases should be considered in the future modification on the surgical technique and the PSI design and material.

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