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Original Article

Comparison between PEEK with platelet-rich fibrin and PEEK alone in maxillary sinus augmentation: histomorphometric and clinical analysis: A Randomized Clinical Trial

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Abstract
Maxillary sinus pneumatization and resorption of the posterior alveolar bone complicate implant placement in the posterior maxillary area, where the implant placement procedure is very challenging. **Aim:** To assess the efficacy of the PEEK material that can maintain the Schneiderian membrane elevated and close the sinus window during the healing period, and to assess the quality and quantity of bone formation in maxillary sinus augmentation.
Subjects and methods: twenty-four patients with clinical and radiological diagnoses of maxillary sinus pneumatization with remaining bone height less than 5mm needing implants after lateral approach sinus augmentation surgery with age range 20-50 years. The patients in the study were divided into two equal groups. In twelve patients (tested group), the maxillary sinus was lifted using PEEK and PRF product after blood centrifuging. Twelve patients in the control group's maxillary sinus were lifted using the PEEK device alone
Results: Six months after Schneiderian membrane elevation using the PEEK device alone (control group) or with PRF (tested group) revealed an insignificant difference in the quantity (mm) using CBCT ($P>0.05$), while the significant difference in quality (Percentage of bone formation %) using histomorphometric analysis of the newly formed bone between both groups (P value<0.0001).
Conclusion: Custom-made PEEK novel design is a predictable method in sinus lift procedures with predictable results, irrespective of the presence or absence of PRF as it proved to be of little value as a sole augmentation material.

Keywords: Sinus augmentation, polyetheretherketone, PRF, CBCT.

Introduction

Maxillary sinus pneumatization usually complicates implant placement in the posterior maxillary area, which makes it a challenging procedure needing high skilled operators.

Schneiderian membrane has osteoprogenitor cells, which are stem cells that usually have the function of bone formation after lifting procedure; if it is fixed in a high position during the healing period to permit space for newly formed

bone.

The osteotome crestal technique and lateral approach (Caldwell-Luc approach) are the most used techniques in vertical sinus augmentation of the posterior maxilla.

The remaining bone height always determines which technique is used during the maxillary sinus lifting procedure, either lateral approach in case of bone height less than 4mm or crestal approach when bone height is more than 4mm allowing implant primary stability.

Boyne and James were the first ones to propose that elevating the Schneiderian membrane for maxillary sinus augmentation could serve as an option to repair this troublesome area. **(Boyne and James, 1980)**

The greatest risk associated with lifting surgery is Schneiderian membrane perforation; however, surgical guides and piezo surgery can reduce this risk.

Covering the maxillary sinus door after the lifting procedure is the best way to conserve the grafting material from its dislodgment out of the sinus during patient breathing or soft tissue encleftation. A collagen membrane may be needed also between the grafting material and the Schneiderian membrane especially if perforation occurs at the time of surgery.

A semi-crystalline poly aromatic thermoplastic polymer with outstanding mechanical properties and biocompatibility, PEEK (Poly-Ether-Ether-Keton) is suitable for usage in medical applications**. (Mounir *et al.*, 2019)**

Computer-aided manufacturing and design, or CAD/CAM, innovations can be used after software PEEK designing, however, there is not enough study about using PEEK materials inside the maxillary sinus.

A biocompatible autologous graft material called platelet-rich fibrin (PRF) is becoming more and more common in surgical practice. One of the most reliable procedures available is PRF-assisted maxillary sinus augmentation.**(Liu *et al.*, 2019)**

Hence, the proposed idea of maxillary sinus augmenting with PRF after sinus membrane elevation with lateral window coverage by PEEK in one computer-designed and milled process was researched in this study.

Subjects and Methods

Patients' details were entered into the database of the outpatient clinics run by Cairo University's Faculty of Dentistry's Department of Oral & Maxillofacial Surgery.

There were 24 patients in the research with maxillary sinus pneumatization who needed implants.

A total of 38 dental implants were placed.

Inclusion criteria:

Patients range in age from 20 to 50

Posterior edentulous ridges with pneumatized maxillary sinus and remaining bone height less than 5mm

Physical status ASA- I and II

Exclusion criteria:

General contraindications to implant surgery.

Insufficient oral hygiene and motivation.

Pregnant or nursing.

Cannot open the mouth sufficiently to accommodate the surgical procedure.

Systemic disorders such as; chronic sinusitis, bleeding tendency, bone metabolism-related conditions, uncontrolled diabetes mellitus… Subjected to irradiation in the head and neck area.

Patients with any systematic disease that may affect normal healing.

Group allocation:

(Control group): maxillary sinus was lifted using the PEEK design alone

(Tested group): maxillary sinus was lifted using PEEK and PRF product after blood centrifuging.

Pre-operative examination:

The patient's medical history was examined to rule out the existence of any underlying conditions that may make the sinus lifting treatment more difficult.

The patient's dental records were examined to rule out the possibility of untreated dental caries or gingivitis that might affect the healing or may appear similar to the post-operative pain and complicate the prognosis.

Preoperative examinations with panoramic views and dental cone-beam computed tomographic scans were performed. Available bone volume, bone quality, and any existing sinus pathology were evaluated on these radiographs. The bone height of the remaining alveolar ridge was less than 5mm. Patients were consecutively treated with sinus floor elevation by the lateral window approach.

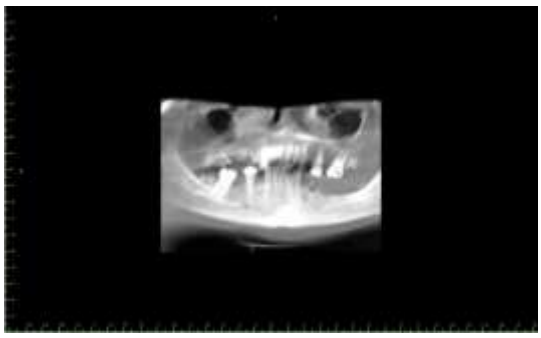

Figure 1: pre-operative panoramic radiograph shows pneumatized right maxillary sinus

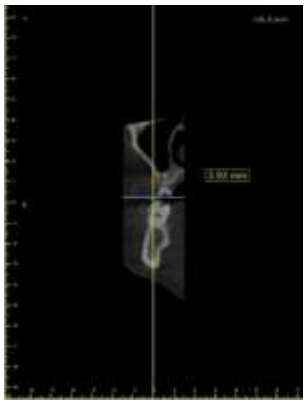

Figure 2: coronal cut of pre-operative CBCT shows 1mm remaining bone height.

Pre-operative virtual planning:

Pre-operative CBCT image was used for planning, designing through DICOM (digital imaging and communications in Medicine) file and measuring the residual bone height. 3-Matic is a Windows-based program that is used to make changes to Standard Tessellation Language mesh files directly.

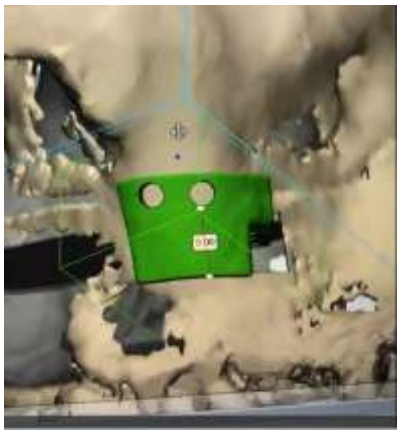

Figure 3: figure show digital planning of the future PEEK device attached to the maxilla through the pre-planned Caldwell-Luc approach and small window trimmed to facilitate implantation of the graft material.

Managed through Materialise software designing, non-cutting edges design was used safely during the surgical procedure of sinus lifting and fixed to the maxilla using mini-screws to cover the window after the Caldwell-Luc operation instead of preventing soft tissue encleftation into the maxillary

sinus by covering the entrance with a membrane.

The inner part of the design should be part away from the lateral side of the nose with through and through multiple rounded edge perforations that mimic a meshwork to allow the passage of the osteoprogenitor cells, produced by the Schneiderian membrane which play a notable role in osteogenesis during sinus augmentation procedure.

To enable exact opening during the Caldwell-Luc procedure of the maxillary sinus, a surgical guide window was created. A small window was trimmed on the outer surface of the design for both groups to be standardized and to allow PRF charging in a confined area maintaining its stature after the Schneiderian membrane preventing its spread all over the sinus by the effect of the membrane movement during breathing of the patient.

Design processing and sterilization: Machines with five axes were used for milling PEEK blocks. **(EMAR MILLING MACHINE)**, and the PEEK device was sterilized using the autoclave before the surgical procedure. The resin 3-D printed surgical guide was sterilized in a (2%) glutaraldehyde solution (Cidex) a night before the surgery.

Surgical procedure:

Stage 1:

- The operation was performed on both groups under local infiltration anesthesia with (2% Lido- HCl with (1:100,000) epinephrine) administered in the buccal vestibule and palate mucosa.
- A crestal incision was made on the mid-crest of the gingiva that was joined to the edentulous ridge. To reveal the bone, the mucosa was gently raised and extended labially. A mesial and distal vertical releasing incision was made as necessary. Denuding the mucosal flap sub-periosteally allowed for full exposure of the alveolar ridge and the maxillary sinus lateral wall.
- The surgical guide was placed and adapted after flap elevation at the pre-planned site and fixed by drilling at the site of screws and screwing it using two mini-screws.
- The sinus membrane was gently lifted after the lateral access window was opened using an electric motor attached to a specialized bur and appropriate cooling of sterile saline solution.
- Surgical guide removal.
- An open sinus-raising kit was used to place PEEK after carefully detaching and pushing up the medial, posterior, lateral, and floor of the sinus membrane.
- The PEEK device was screwed using the same holes that have been used for the surgical guide fixation.
- For the control group PEEK device was placed alone depending on the osteoprogenitor cells for bone formation

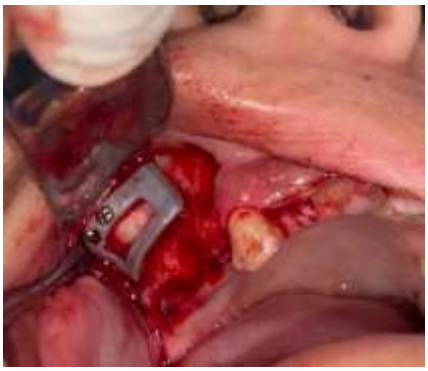

Figure4: photograph show two-sided flap reflection and surgical guide fixed to the maxilla.

For intervention group:

- After the fixation of the PEEK device; the PRF was applied through the outer window of the device.
- For both groups, the flap was sutured using a 3-0 vicryl suture.

Figure 5: photograph shows PEEK device attached to the maxilla of an intervention group and PRF application through the small window

Figure 6: indirect photograph shows flap closure using 3-0 vicryl suture

Post-operative instructions include:

- Avoid traumatization of the surgical site.
- 30 minutes for a whole day, apply ice packs for 10 minutes.
- Avoid sneezing and prescription of nasal drops.
- Post-operative medication including antibiotics, analgesics, and Chlorhexidine gluconate 0.2% mouthwash 3 times daily for 14 days.

Follow-up:

Follow-up after one week, and weekly for the first month, then monthly till 6 months was performed to observe any signs of flap dehiscence or any other complication.

Stage 2:

After six months post-operatively; CBCT was requested to evaluate the quantity of gained bone and for measurement of the length to place dental implant.

Surgical steps:

A mucoperiosteal flap was performed to allow PEEK device removal and a core biopsy was taken from the crest of the ridge for histomorphometric analysis using a trephine bur with a gauge of 3.3mm. For routine bone histologic evaluation, core specimens are placed in 10% neutral buffered formalin and delivered to the pathology lab.

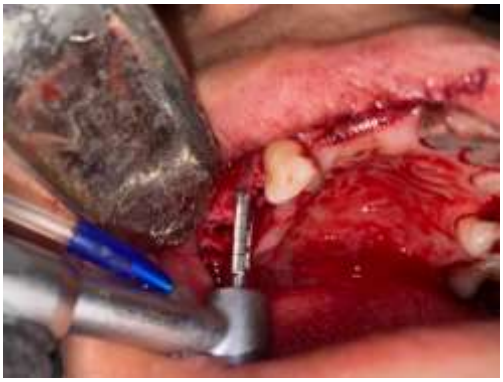

Figure 7: photographic image shows PEEK removal and core biopsy taken using trephine bur

with gauge 3.3mm after 6 months of PEEK placement.

Histomorphometric and histopathological analysis of the specimens were performed using Hematoxylin and Eosin stains to reveal the newly formed bone content, while Masson trichrome staining was utilized to distinguish between the recently generated tissue and the old native bone.

Complete drilling above 3.3mm till the chosen implant size and the DUAL implant were used.

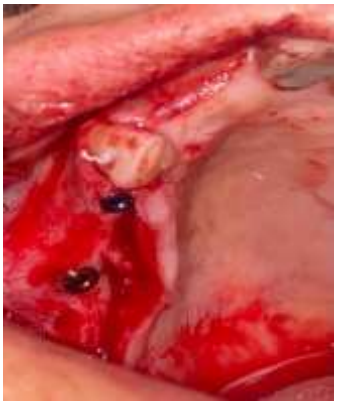

Figure 8: photograph after PEEK removal and DUAL implant placement.

Follow-up:

For the first week, then monthly till three months and exposure time.

Stage 3:

Three months after implant placement exposure and dental impression have been taken to deliver the final prosthesis for each case.

Figure 9: photographic image shows delivery of dental prosthesis 3-months after implant placement.

Follow-up:

Follow-up every 3 months after delivery of the final prosthesis was performed.

Statistic evaluation

The statistical analysis was performed using Microsoft Excel 2016, GraphPad Prism, and SPSS

20®.

All quantitative data were examined for normalcy using the Shapiro-Wilk and Kolmogorov normality Test. They were subsequently presented as means and standard deviation (SD) values. All data were presented in (8) tables & (6) graphs.

Tests used:

- "Shapiro Wilk and Kolmogorov were used for normality exploration."
- To compare the two groups, independent (t) tests were utilized.

The original bone height and the post-operative bone height were compared using a paired (t) test.

Results

Analytical results:

A. Bone height and quantity (mm) using CBCT:

1. (Tested group): Maxillary sinus lift PEEK and platelet rich fibrin by Caldwell luc approach.

(Paired t test) was used to compare them, and the results showed a significant rise in bone height from (3.19 1.17) to (10.29 5.65) with an increase of (7.11) as P = 0.0001.

2. (Control group): Maxillary sinus lift using PEEK alone by caldwell luc approach.

Comparison between them was performed by using Paired (t test) which revealed significant increase in bone height from (3.35 ± 1.01) to (12.34 ± 2.77) with increase (8.98) as P=0.0001.

3. Comparison between tested and control group.

Using an independent t test to compare the two groups, it was determined that there was no significance between them (P>0.05).

Table (1) and Figure (10) show the mean and standard deviation for both groups for original bone height, post-operative bone height, and amount of bone increase.

Table 1: Mean and standard deviation of original, postoperative bone height (mm) and amount of bone gained in both groups, comparison between them using independent t test.

	Tested group		**Control group**		**Difference (Independent t test)**				
					MD	SED	95% CI		P value
	M	SD	M	SD			L	U	
Original bone height	3.19	1.17	3.35	1.01	0.16	0.63	-1.24	1.57	0.80
Post-operative bone height	10.30	5.65	12.34	2.77	2.04	2.57	-3.69	7.76	0.45
Amount of bone gain	7.11	5.14	8.99	1.90	1.88	2.24	-3.11	6.86	0.42

M: mean SD: standard deviation MD: mean difference SEM: standard error mean CI: confidence interval L: lower arm U: upper arm
**Significant difference as P<0.05*

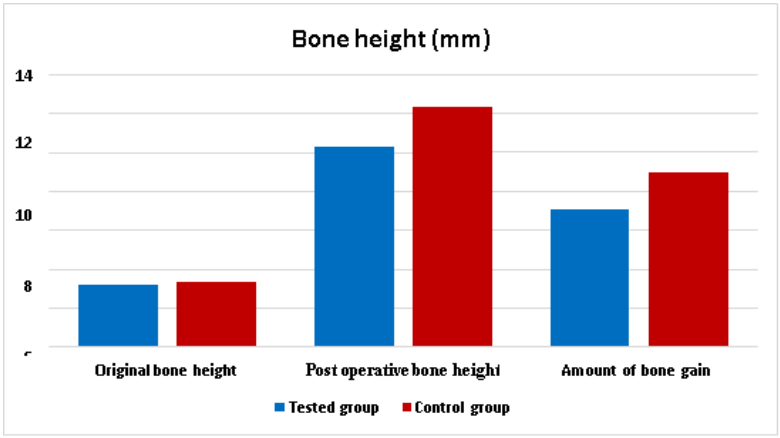

Figure 10: bar chart showing original, postoperative bone height (mm) and amount of bone gained in both groups.

Discussion

The posterior maxilla presents a unique and difficult site for the best dental implant insertion because of its relatively low bone quality and restricted bone volume caused by ridge resorption and sinus pneumatization. With the help of various techniques, the posterior maxillary bone volume was reconstructed using onlay grafts, sinus lifts, and Le-Fort-I osteotomies with bone grafts in between. One of the most reliable procedures, maxillary antrum augmentation, may be done with a variety of grafting materials, including autogenous, allograft, xenograft, and alloplastic bone, as well as more recently platelet concentrates. **(Meboldt and Klahn, 2018)**

It is still unknown if PRF can develop and preserve new bone under the two-stage approach, however, the augmentation therapy using PRF alone is a more secure and straightforward operation than the protocol employing a mixture of PRF and graft materials. This study attempted to use PRF as the only augmentation material in sinus lift surgery. **(Cortese *et al.*, 2016)**

Several investigations have revealed that simultaneous implant placement and an elevation of the antrum membrane resulted in the addition of new bone without the need for grafting material. However, it is still unknown how bone forms in the maxillary antrum without graft. Other studies have looked at the osteogenic potential of cells isolated and grown from the maxillary sinus lining, as well as their capacity to form bone in ectopic situations. On the other hand, it was suggested that new bone formation is caused by the sinus walls and septa, a mechanism similar to how extraction sockets build bone if a blood clot occurs.**(Bahaa-Eldin *et al.*, 2017)**

In the current project, the use of 3-dimensional X-ray (CBCT) exposed the patients to less radiation, however, with a low-quality image than multi-slice computed tomography (CT); Mimics Medical 21.0 can improve the quality and can resemble the same image produced by the CT scan, as facial CT scans facilitate the segmentation of the virtual construction of patient-specific implant devices. **(Atef *et al.*, 2022)**

Although computer-assisted sinus floor elevation is a potential alternative for more predictable and precise treatment, substantial preparation is necessary before starting the surgical phase. It takes time to plan the lateral window and implant virtually, However, difficulties that develop during surgery as a result of a lack of accuracy in the planning phase would need more surgical time to correct than the computer-guided surgical procedure, and the patient would be subjected to greater surgical trauma. In accordance, this study implemented the computer guided designing of both the surgical cutting guide and the sinus membrane elevation device to utilize the benefits of precision and reduce the possible hand risks.**(Testori et al., 2020)**

PEEK's biocompatibility and advantageous mechanical qualities are a result of the material's rapid evolution in the reconstructive and maxillofacial disciplines encouraging us to research its possible use in sinus lift procedures. PEEK implant is being employed more and more commonly for oral and craniofacial rebuilding of the deficient bones in the oral cavity, as has been amply documented in the literature. There have been several uses, including solely specialized implants for restoring face symmetry, resections and reconstruction, cranioplasties, and specialized augmentation of the alveolus. **(EL Morsy *et al.*, 2020)**

It is still controversial whether a sealing membrane is required to cover the osteotomy window. Some writers advocated sealing the antrum door to prevent the tissue encleftation and the loss of the antrum content. In the literature, loss of cortication of the graft surface as well as minor encleftation through the sinus window was documented in the majority of the patients (radiographically and

histologically)". These were attributed to the fibrogenic nature of the periosteum after it had been lifted from the bone surface. **(EL Morsy *et al.*, 2020)**

Hence, membrane coverage of the maxillary sinus window during open sinus lifting is an essential step to preserve the grafting material from escapement out of the sinus or soft tissue enclefitation during the healing period. In accordance, to prevent the enclefitation of connective tissue not related to the bone formation process into the cavity, the lateral window had a cover with PEEK in the current investigation to experience the presurgical precise milling of the PEEK-membrane mimic and its ease of application with the mentioned benefits of PEEK. The membrane design was considered to be very thin and took the contour of the maxilla at the site of the window to be compatible with soft tissue healing.

It has been shown that titanium meshes improve bone volume in a highly predictable manner. Nonetheless, the stiffness of titanium meshes is a significant disadvantage, leading to the high rate of disintegration of soft tissue, sinus membrane perforation, and graft exposure. PEEK tensile strength and resiliency, on the other hand, are superior to human bone. **(EL Morsy *et al.*, 2020)**

In this investigation, PEEK. specific implant device was designed on specific software and milled using an axis milling machine. Its rigidity, biocompatibility, and smooth, rounded edge helped to keep the sinus membrane raised at the new level and preserve all the created space, allowing the inserting of the longest implant possible. The PEEK's holes allowed for direct interaction between the Schneiderian membrane's osteogenic property and the blood clots in the newly generated gap.

Bone histomorphometry, as documented by the Committee for American Society of Skeletal and Minerals Studies, has been and continues to be the tool to obtain essential information regarding bone constituents and the
effectiveness of novel agents that operate on the bone. In accordance, it was used in this study to assess the bone quality determined by the different bone cells, trabeculae and connective tissue amount. **(EL Morsy *et al.*, 2020)**

Even though PRF is easy to obtain, inexpensive, and capable of promoting natural bone regeneration, this study found no statistically significant difference between the control and tested groups in terms of the amount of newly formed bone in the presence or absence of PRF. This came in contrast with Simon Pieri et al who claimed significant bone gain when using PRF alone as an augmentation material, however with simultaneous implant placement which could have acted as the tented effect of the sinus membrane resulting in a different outcome with this study.

This confirmed the alleged fact that PRF is more useful as a booster or a scaffold to other bone substitutes which are better used together agreed with (Barbu et al., 2021)who stated that "PRFs alone are not suited for maxillary sinus augmentation due to their high rate of resorption in comparison to the process of bone growth in contrast to traditional bone grafting materials which sustain the volume of the augmentation site with little resorption". Hence, the rule of osteogenesis during the sinus lifting procedure remains keeping the Schneiderian membrane elevated at a constant height during the healing period along with the integrity of the sinus membrane. **(EL Morsy *et al.*, 2020)**

On the other hand, a statistical difference between both groups was recorded in the results of this study regarding the newly formed bone quality and bone trabeculae in favor of the control group. This may be attributed to the presence of the PRF which may have prevented the natural healing process of a naturally formed blood clot and its interaction with the sinus membrane.

In this study, only one case reported a post-operative dehiscence, in the intervention

group, which occurred 2 weeks after peek device placement. This lacked any scientific explanations hence the same selection criteria, preoperative planning, and surgical steps were implemented. However, after a comprehensive examination and review of the patient's medical history, it was determined that the patient had not followed the post-operative instructions for quitting smoking.

Conflict of Interest:
The authors declare no conflict of interest.

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Ethics:
This study protocol was approved by the ethical committee of the faculty of dentistry-Cairo university on: 1-10-21.

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