Original Article

Graftless technique in open maxillary sinus lifting using Poly-Ether-Ether-Ketone versus titanium meshwork for evaluation of bone quantity. Randomized clinical trials.

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ABSTRACT

Purpose:This research aimed to assess the amount of bone formation with PEEK (test group) in compared to Titanium Meshwork (control group) in maxillary sinus lifting using CBCT and assessment of the biocompatibility of the Meshwork and PEEK with the schneiderian membrane integrity. Materials and Methods: Patients were divided into two groups ; the test group had their maxillary sinuses lifted using PEEK, while the control group had their sinuses lifted using titanium mesh.Clinical examination includes assessment of biocompatibility of Schneiderian membrane ; Postoperative healing and radiographic examination using CBCT at 6 months to assess newly produced bone in both groups. Results : Although there was no significant difference in newly produced bone between both groups, the test group had stronger Schneiderian membrane biocompatibility than the control group. Conclusion: PEEK and titanium mesh are used as space-maintenance devices; however; in terms of application, the PEEK device demonstrated greater biocompatibility with the Schneiderian membrane.

Key Words : Open sinus lifting , Titanium mesh , PEEK , Schneiderian membrane
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INTRODUCTION

Bone loss in the posterior maxilla less than 4 mm necessitate augmentation for implant placement. The absence of maxillary molars causes increased osteoclastic activity of the sinus membrane, which results in resorption of the bone in the sinus cavity (Kempraj et al., 2020). After tooth extraction,pneumatization of the maxillary sinus is the major cause ; in such circumstances, implant-supported rehabilitation remains challenging. However, the preferred therapy in these circumstances is sinus augmentation(Dominiak et al., 2021). The use of bone grafting material, autologous blood, platelet-rich fibrin, other synthetic materials has been discussed. The optimal grafting material should be stable, have the capacity to increase surface area, promote the development of new bone, and be reasonably priced(Kempraj et al., 2020).

MATERIALS AND METHOD

In this study, twelve subjects developed maxillary sinus pneumatization with bone height remainsbelow 4 mm.All of the patients were not smokers and had never undergone sinus surgery. Furthermore, none of the sinuses exhibited any pathogenic abnormalities. Each patient was informed of the treatment's risks and advantages, and they provided signed consent. The tested group had their maxillary sinuses lifted with PEEK, whereas the control group had theirs lifted with titanium For the control group; a titanium mesh(stock-1mm)(Leibinger,Stryker Co. , Geneva , Switzerland) were utilized in all patients .For the test group; the PEEK device was milled

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using a 5-axis machine (EMAR MILLING MACHINE)sterilized in an autoclave {fig.1} .All of the patients in both groups received DUAL (EGYPT) dental implants.

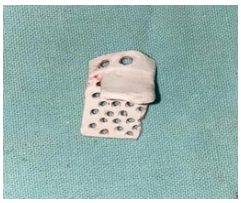

Fig 1: Showing the milling device of the PEEK

Preoperative preparation and radiographic examination:

Every patient had a full preoperative examination that comprised a radiological, clinical, and history review. As a primary survey, to rule out any pathological defects or lesion inthe region of interest, each patient had a preoperative digital panoramic radiograph with a 1:1 magnification then a CBCT was performed for each patient.

Surgical procedure:

1.First stage surgery

A local anesthetic consisting of 2% lidocaine HCl and 1:100,000 epinephrine was used to perform the procedure on the patient. The perioral spaces were prepped aseptically. In the edentulous region after making a crestal incision to expose the bone, the flap was raised carefully and stretched labially.As necessary, a vertical releasing incision will be donemesiallyand distally to fully reveal the maxillary sinus lateral wall and the mucosal flap was denuded subperiosteally. The floor, lateral wall, medial, and posterior walls of the sinus membrane were carefully removed and pulled up for the installation of PEEK in the test group and titanium meshwork in the control group using an electric-motor equipped with suitable saline for cooling.In control group; Before being applied into the sinus cavity, a 1 mm thick titanium mesh was first cut, adjusted in position, and its sharp protuberances were eliminated. The mesh was then attached to the sinus lateral wall above the osteotomy using two mini screws(fig. 2). For the test group, two mini screws were used to secure a 1 mm thick customized PEEK device to the sinus's lateral wall above the osteotomy. (fig. 3).

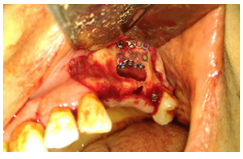

Fig 2: Clinical picture demonstrating the a aptation and fixation of titanium mesh.

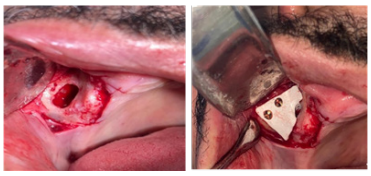

Fig 3: Clinical picture demonstrating the adaptation and then fixation of PEEK device

2.Second stage surgery :

The same preparation and local anesthetic technique were used for the second surgery. The flap was raised after a crestal incision was made.In both groups, implants placement in edentulous area The Schneiderian membrane compatibility was clinically evaluated by looking for any possible signs of inflammation, infection, flap dehiscence, and exposure to titanium mesh or PEEK.

Postoperative care:

After recovery, patients and guardians were given postoperative recommendations such as utilizing ice packs for 10 minutes every 1 hour the first day after surgery and practicing sharp oral hygiene measures with a toothbrush and antiseptic mouthwash. Patients were instructed not to exert any pressure into the nasal cavity following surgery (e.g., blowing their nose, sipping with a straw, spitting, or breathing down). Amoxicillin/sulbactam tablets (1g/kg every 12 hours for 5 days), Voltaren(75 mg/3ml ampoule every 12 hours for 2 days), Flagyl (500 mg/kg every 8 hours for 5 days, and mouthwash containing 0.2% chlorhexidine gluconate for two weeks are the medications that will be administered following surgery.

Results:

In the current investigation, 12 maxillary sinuses that were elevated using the lateral window method titanium mesh was used to lift the sinuses in the control group {fig 4, 5}, while the PEEK device was used to lift the maxillary sinuses in the testing group {fig 6,7}.

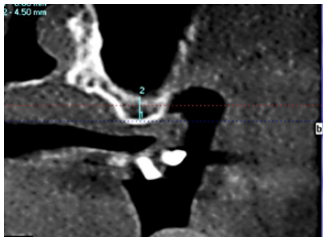

Fig 4: coronal cut showing the preoperative length of remaining height of bone in the control group

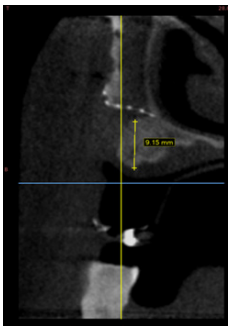

Fig5: coronal cut after 6 months postoperative showing the newly formed bone in the control group

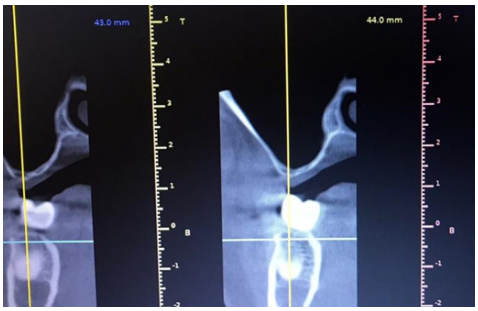

Fig6:coronal cut showing the preoperative length of remaining bone height in the test group

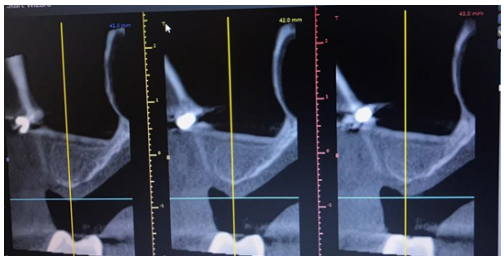

Fig 7: coronal cut showing the postoperative length of remaining bone height in the test group.

Results

Control group:

There was significant difference between (M = 2.9, SD = 0.5) and after (M = 9.5, SD = 1.1), according to the paired-t test results (t(5) = 23.7, p <.001).

Test group:

There was significant difference between(M=2.6 , SD=0.7) and after (M=11.2, SD=1.1), according to the paired-t test results(t(5)=22.1, p<.001).

Discussion:

The edentulous posterior maxilla is very difficult to restore; even with powerful posterior pressures, there is a limited amount of bone. Two main factors that contribute to bone loss are sinus pneumatization and ridge resorption(Larsen and Kennedy, 2019). When a maxillary sinus cyst was removed, bone formation from the sinus floor was marked after the formation of a blood clot-filled empty space. This demonstrated the efficacy of sinus elevation surgery without the need for a bone grafting material(Lundgren et al., 2004). Graftless maxillary sinus augmentation has the advantage of completely eliminating infectious issues. Graft infection is very difficult to treat with traditional antibiotics in a segregated setting, which is the primary reason graft removal is required(Urban et al., 2012) (Hatano, Sennerby and Lundgren, 2007) Titanium mesh was selected because it is naturally biocompatible and has the properties of being both sufficiently malleable to be easily altered and rigid enough to maintain its form. The results of Atef et al., who emphasized the use of titanium mesh as a space-maintaining instrument in graftless open sinus lift procedures(Atef et al., 2014). The biocompatibility and inertness of this peek material made it suitable for use in reconstructive procedures. In the medical profession, particularly in cranio-maxillofacial surgery, (CAD/CAM software) had made the generation ofanatomical models and implants tailored for patients a successfultechnique(Mounir et al., 2019a). One of titanium mesh's main drawbacks is the higher frequency of exposure brought on by its rigidity compared to a peek that was smooth and had a more rounded edge; this issue was less common in the PEEK group, which is consistent with (Mounir et al., 2019a) The study's findings demonstrated that both groups' newly created bone following maxillary sinus lifting differed significantly, however the PEEK (tested group) demonstrated greater biocompatibility with the Schneiderian membrane because of its resilience and smoothness. In the current investigation, the customized PEEK device was more time consuming; easily in its application and removal during the operation, which is consistent with (Mounir et al., 2019b), who removed the PEEK in anterior maxillary defect patients that were In contrast to the titanium mesh, which was difficult to remove because it might cause harm to the Schneiderian membrane, resulting in degeneration and tears(Elbanna and Helmy, 2018).

Conclusion:

PEEK and Titanium mesh are used to preserve space, although the PEEK device

is more biocompatible with the Schneiderian membrane because to its ease of application and removal, as well as being more time-consuming during surgery.

Recommendation

Conflict of Interest : there is no conflicts of interest.
Funding source: No funding

Ethical approval statement:Human subjects research protocols were carried out in accordance with the 1964 Helsinki Declaration and its later amendments, or comparable ethical standards, as well as the institutional and/or national research committee's ethical requirements. The Ethical Committee of the Faculty of Dentistry at Cairo University gave its approval to the study process (IRB number 34-5-24). Patient consent statement:Prior to their involvement, every participant in the research gave written informed consent. Clinical trial registration: The research project is included in the Clinical Trials registry. Registry of the US National Institutes of Health (NCT06846632) Authors contribution :A.Y. was responsible of randomization, allocation, outcome assessment, and supervising all surgical procedures. M.G. took care ofrecruitment and taking participant's consent, baseline data and outcome data collection, and performing clinical part of the trial.Y.A.Held responsible for thesis writing and final report of the research. M.T. handled the outcome assessment, and supervising all surgical procedures.

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