Int. J. Oral Maxillofac. Surg. 2017; xxx: xxx–xxx
https://doi.org/10.1016/j.ijom.2017.11.008, available online at https://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Clinical Paper
Pre-Implant Surgery

Titanium and polyether ether ketone (PEEK) patient-specific sub-periosteal implants: two novel approaches for rehabilitation of the severely atrophic anterior maxillary ridge

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Abstract. The aim of this study was to assess two new protocols for single-stage rehabilitation of the severely atrophic maxillary ridge using customized porous titanium or polyether ether ketone (PEEK) sub-periosteal implants. Ten patients with a severely atrophic anterior maxillary alveolar ridge were divided randomly into two groups (five patients in each) to receive customized sub-periosteal implants fabricated via CAD/CAM technology: group 1, porous titanium implants; group 2, PEEK implants. Prosthetic loading with fixed acrylic bridges was performed 1 month postoperative. The implants were followed-up for 12 months and evaluated for the presence of any sign of radiographic bone resorption, mobility, infection, prosthetic fracture, or implant exposure. The immediate postoperative period was uneventful except for one case complicated by wound dehiscence in group 1. At 12 months, all implants were functionally stable and the patients were comfortable with the prostheses. No signs of radiographic bone resorption, mobility, infection, or prosthetic fracture were observed. Within the limitations of this study, the application of customized porous titanium and PEEK sub-periosteal implants produced through CAD/CAM technology appears to be an acceptable method for single-stage prosthetic rehabilitation of the severely atrophic edentulous anterior maxilla. This study was awarded the best case study at the academy of osseintegration annual meeting 2017, Orlando, Florida.

Key words: polyether ether ketone; titanium; sub-periosteal implant; anterior maxilla.

Accepted for publication

0901-5027/000001+07

Rehabilitation of the severely atrophic maxillary ridge presents a huge challenge, since this requires first-stage bony reconstruction surgery followed by second-stage root-form endosseous implant installation. Several grafting materials and procedures have been introduced to augment the atrophic ridge. However, graft rejection, staged surgery with increased costs, and wound dehiscence remain possible complications that may lead to subsequent failure of the augmentation procedure. In addition, the time factor and surgical morbidity of a second surgical site in the case of autogenous bone grafting are not accepted by many patients[1].

The sub-periosteal implant is an earlier type of dental implant that was introduced in 1940 by Dahl[2]. Since then, several methods for the placement of sub-periosteal implants have been investigated. Many authors have reported the successful rehabilitation of atrophic maxillary ridges in a one-step procedure with maxillary dentures supported by sub-periosteal implants. However most long-term follow-up studies and retrospective studies have not favoured sub-periosteal implants[3,4]. With the rise of the root-form osseointegrated endosseous dental implant, clinical research on sub-periosteal implants has diminished. Generally speaking, several factors have contributed to the failure of sub-periosteal implants, including the material used to manufacture the implant, as well as the method of fabrication, lack of fixation, lack of osseointegration, surgical technique, and stress shielding.

Over the past decade, rapid advances have been made in computer-aided design/computer-aided manufacturing technology (CAD/CAM). Computer numerical control (CNC) machines have facilitated the creation of complicated three-dimensional (3D) metallic structures in place of the casting procedure. However, there are many types of milling, turning, and milling/turning CNC machines with different capabilities and numbers of working axes, and the design of the prototype will indicate the type of machine required to produce the final product. The production of a prototype with a CNC machine requires an expert in CNC programming and is high cost, making this technology more suitable for high accuracy production than for prototyping. Electron beam melting (EBM) has recently been introduced and is a fast and successful method for the fabrication and prototyping of specific parts from 3D CAD models. Several studies have recommended the use of EBM in the creation of patient-specific metallic implants (with physical properties close to human bone) from CAD models obtained using computed tomography (CT) image processing software.

The aim of this observational study was to introduce and assess a new protocol for single-stage rehabilitation of the severely atrophic maxillary ridge with customized porous titanium and polyether ether ketone (PEEK) sub-periosteal implants constructed using EBM technology.

Patients and methods

A single-institution observational clinical study was designed and implemented. Patients suffering multiple missing maxillary anterior teeth with deficient vertical and horizontal bone were selected. Approval was obtained from the research ethics committee and all patients provided informed consent for the procedures to be followed throughout the study.

Patients

To be included in the study sample, the patients had to meet the following inclusion criteria: no systemic disease that may affect bone healing, no local pathosis that may interfere with bone healing, and no history of any grafting procedure at the designated edentulous ridge. Furthermore, the anterior maxillary alveolar ridge had to present inadequate vertical and horizontal dimensions, making it impossible to place root-form dental implants with a diameter of at least 3 mm and a length of at least 8 mm. With regard to the number of missing teeth in the anterior maxillary alveolar ridge, the minimum was three and the maximum was all six anterior teeth.

A total of 10 patients were included. These patients were divided randomly into two equal groups with five patients in each: group 1 patients received patient-specific titanium sub-periosteal implants; group 2 patients received patient-specific PEEK sub-periosteal implants.

Each patient was interviewed in order to obtain a comprehensive history, including full medical and dental history. Preoperative digital panoramic radiographs (1:1 magnification) were ordered for each patient for primary assessment.

Virtual planning

The selected patients underwent multislice CT examinations, with the following parameters: bony window, zero gantry tilt angle, slice thickness of 0.5 mm, and slice interval of 0.5 mm in order to acquire accurate bony dimensions for the area planned for implantation (Fig. 1). Further processing of the DICOM files (Digital Imaging and Communications in Medicine) was performed using the specialized DICOM image processing software Mimics (Materialise, Leuven, Belgium), and reconstructed 3D models of the anterior maxilla were made. These 3D models were used to design the sub-periosteal implants of the required shape and size, consisting of the main implant framework and the projecting single piece abutments, using 3Matic software (Materialise) (Figs 2–4). Finally the 3D printing files for the designed sub-periosteal implants were sent to the 3D printing laboratory (Camplex Pty Ltd, South Yarra, Victoria, Australia) for printing on an EBM machine (Arcam AB, Stockholm, Sweden): group 1 implants were made from medical grade 23 titanium Ti–6Al–4V ELI (extra low interstitial) and group 2 implants from PEEK.

Implant microtopography

In order to enhance the osseointegration capability, the whole implant body (group 1, titanium) and the endosseous fixing screws were subjected to a two-stage acid-etching protocol: first stage in H_2SO_4 for 72 h and second stage in HCl for 30 h[3]. The acid-etching creates a regular microroughness on the titanium surface (Fig. 5), which subsequently increases the osseointegration of the titanium with the bony surface. Finally the implants were cleaned in an ultrasonic bath of absolute ethyl alcohol solution for 50 min to ensure the removal of any residuals on the implant surface and then sterilized in a dental class B autoclave.

Operative procedures

The local anaesthetic applied was 2% mepivacaine with 1:100,000 adrenaline for haemostasis (Scandonest 2%; Septodont, Saint-Maur-des-fossés, France). Each 1.8-ml cartridge contained 36 mg of mepivacaine hydrochloride and 18 μg of adrenaline.

Scrubbing and draping of the patient was performed in the standard fashion using povidone–iodine surgical scrub (Betadine; Pharco, Alexandria, Egypt). A pyramidal flap was raised using three incision lines. The crestal incision was performed more towards the palatal aspect of the crest of the ridge, with the incision made between the two teeth bounding the edentulous area. Two oblique releasing incisions were then made at the distal ends of the crestal incision.

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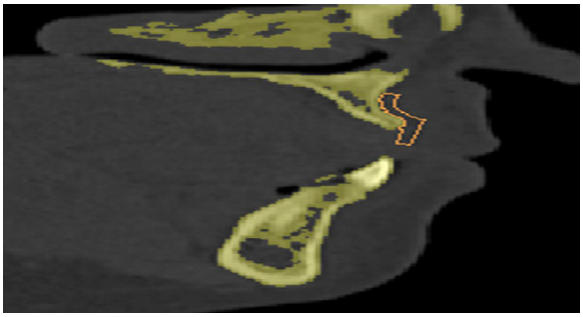

Fig. 1. Preoperative cross-sectional view of a CT scan showing the deficient ridge.

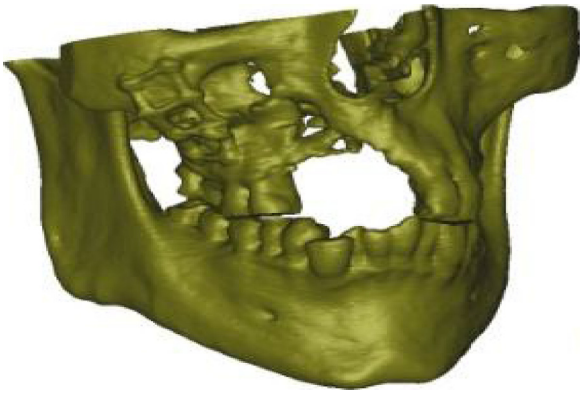

Fig. 2. Preoperative 3D reconstruction of a cone beam CT scan showing the severely deficient ridge (titanium group).

After bone exposure, the implants were installed and fixed with 2.0-mm grade 5 titanium screws (Figs 5 and 6). The layer was then closed with 3–0 Vicryl.

Postoperative instructions were given and medications were prescribed: placement of an ice pack for 10 min every 30 min for 24 h; amoxicillin–clavulanic acid for 10 days; diclofenac potassium for 4 days; strict oral hygiene measures in the form of regular antiseptic chlorhexidine gluconate 0.1% mouthwash use for 14 days. Regular brushing was started at 1 week postoperative.

The sutures were removed after 10–14 days, following which impressions were made for prosthetic fabrication. Loading with acrylic bridges after relining with cold-cured acrylic and temporary cementation was started about 1 month postoperative (Figs 7–10). The patients were followed up every month for 12 months.

Results

Ten patients were included in the study, eight male and two female, who ranged in age from 18 to 55 years (Table 1). The immediate postoperative follow-up within the first month before prosthetic loading was uneventful and without complications for all patients, with the exception of one patient in the titanium group who showed wound dehiscence and exposure of the implant. However, with strict oral hygiene measures and removal of the uncovered rim of the implant with a high-speed carbide fissure bur under copious irrigation, the exposed alveolar bone was totally covered after 2 months and prosthetic loading was started.

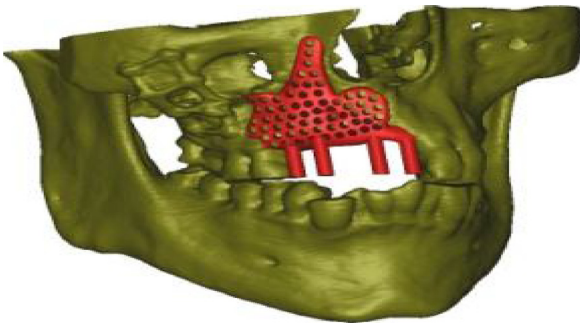

Fig. 3. Preoperative 3D reconstruction of a cone beam CT scan showing the virtual adaptation of the titanium implant to the severely deficient ridge (titanium group).

In the titanium group, 1–2 mm of the platform around the projecting abutments was exposed for almost all of the implants. However this did not interfere with prosthetic loading or affect patient satisfaction in any way (Figs 7 and 9).

The patients were followed up for 12 months. At the final follow-up, all implants were functionally stable and were not showing any signs of mobility, infection, or prosthetic fracture.

When the 1-year postoperative panoramic radiograph was compared to the immediate postoperative panoramic radiograph, no obvious changes were observed regarding the level of supporting bone in relation to the sub-periosteal implants.

Discussion

The initial trials of sub-periosteal implants by Goldberg and Gershkoff suggested fabrication without taking a bony impression[4]. The framework was waxed up on a trimmed cast according to alveolar ridge mapping with a probe to exclude the mucosal thickness. Since this was an impractical and inaccurate technique, taking a bony impression became unavoidable.

Advances made in CT scanning and image processing software have facilitated the production of virtual 3D models of the mandible with good levels of accuracy. All of the implants fabricated in the present study showed an adequate fit to the bone surface. CAD allowed the whole maxillary surface area to be included: buccal, lingual, and even beyond the alveolar bone. Increasing the surface area is advantageous, as it allows the forces to be distributed over a large area. This is in contrast to the impression technique, which provides only a limited area to work on. In addition, with the computer-guided technique, the need for a first-stage bony impression procedure is reduced.

Several materials have been reported in the literature for the fabrication of sub-periosteal implants, including stainless steel, cobalt, chrome, and titanium[5,6]. Grade 5 titanium has almost replaced all other materials in the fabrication of craniofacial implants because of its biocompatibility, corrosion resistance, mechanical strength combined with low weight, and osseointegration properties[7]. In the present study, grade 23 titanium Ti–

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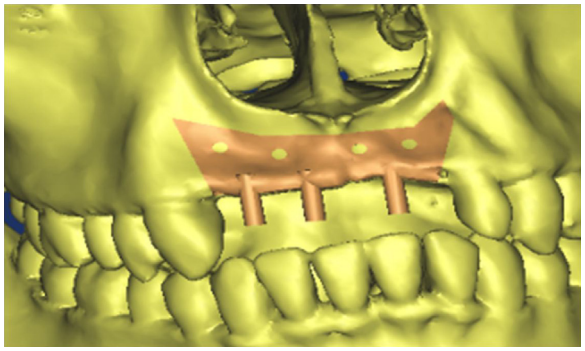

Fig. 4. Preoperative virtual design of the sub-periosteal implant (PEEK group).

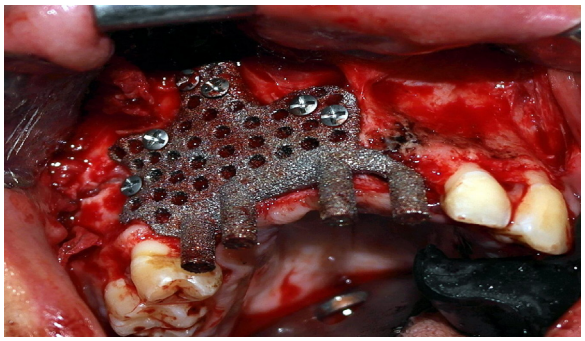

Fig. 5. Customized titanium implant fixed in place using microscrews.

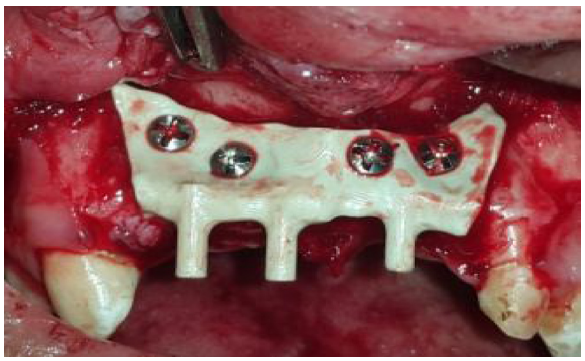

Fig. 6. Customized PEEK implant fixed in place with microscrews.

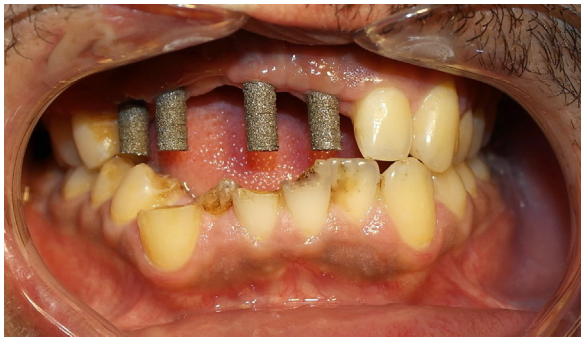

Fig. 7. Healing at 1 month postoperative—titanium group.

6Al–4V ELI was used in group 1; this is basically the same alloy as grade 5, but has a lower oxygen content, which improves the ductility and the fracture toughness, with little reduction in strength. Fracture toughness is one of the most important properties that should be considered during the fabrication of medical devices, since it shows the ability of the material to withstand fractures when it contains a crack. This is why Ti–6Al–4V ELI is recommended for use in fracture-critical medical devices[8].

Surgical grade Vitallium (cobalt, chrome, molybdenum alloy) was the most commonly used material for the fabrication of sub-periosteal dental implants due to the easier casting procedure compared to titanium alloys[9,10]. Titanium alloys are reactive, particularly at high temperatures, taking up oxygen and nitrogen from the atmosphere and hydrogen if moisture is present. Hence when titanium devices are manufactured by casting, the environment has to be purged with an inert gas like argon[11,12], which makes the casting procedure of titanium extremely sensitive and requires specific casing machines. In addition, not all designs can be produced by casting.

Moreover, the elastic modulus of dense casted titanium is much higher than that of human bone and it is twice as heavy as natural dense cortical bone. These differences result in stress shielding and subsequent bone resorption upon loading, which is one of the main causes of sub-periosteal implant exposure over time, and subsequent implant failure[13,14]. Hence porous titanium produced with a 3D additive manufacturing technology was used in the present study. This 3D additive manufacturing is a fast prototyping process in which metallic parts are fabricated by melting the metal powder layer by layer, guided by a 3D model (in STL format) of the part to be produced.

There are currently two main technologies for the production of porous titanium: selective electron beam melting technology (EBM) and selective laser sintering technology (SLS). The reason for using EBM rather than SLS is that EBM is superior for the production of porous titanium parts, due to the use of a high energy electron beam to melt the powder rather than a laser beam – the high energy electron beam ensures complete melting of the metal powder. In addition, the vacuum processing in EBM increases the purity of the parts produced due to the elimination of the oxygen and chemical impurities[14].

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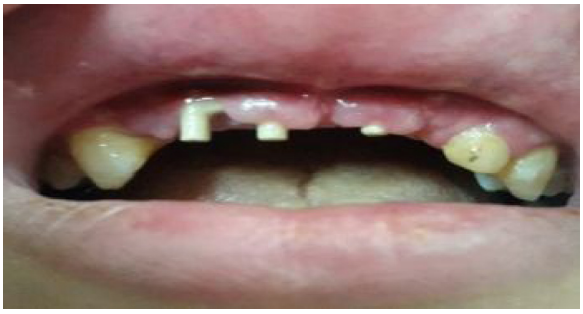

Fig. 8. Healing at 1 month postoperative—PEEK group.

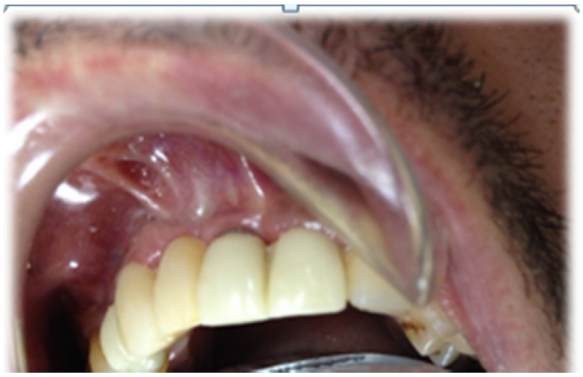

Fig. 9. Loading with a fixed cemented prosthesis—titanium group.

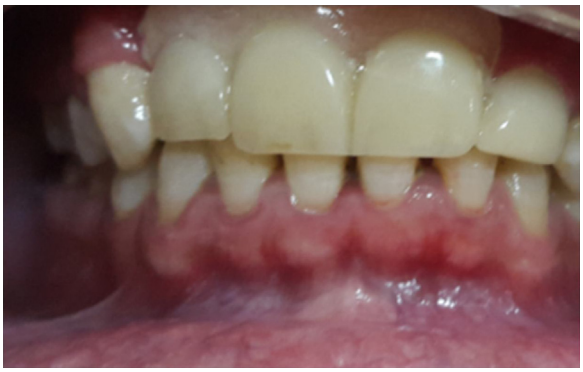

Fig. 10. Loading with a fixed cemented prosthesis—PEEK group.

EBM allows one-step fabrication of porous custom titanium implants with comparable structural and mechanical properties to the cortical bone, unlike casted titanium. Parthasarathy et al. also recommend the use of EBM for the fabrication of patient-specific custom implants, since EBM allowed the production of craniofacial implants with predictable mechanical properties[15]. They stated that ''the fabrication of titanium devices with porosities as high as 50% to 70% satisfy the mechanical strength requirements needed for craniofacial applications''.

Linkow et al. were the first to perforate the metal framework of the sub-periosteal implant to allow fibrointegration of the periosteum through these struts[7,8]. The sub-periosteal titanium implants used in the present study were meshed with 2.3-mm holes to allow fixation of the implants with 2.0-mm titanium screws and also to allow bone in-growth through the perforations, not only fibrointegration. Hence it may be hypothetically claimed that this study has introduced an osseointegrated sub-periosteal implant due to the use of porous titanium in its fabrication.

Mangano et al. reported the success of custom-made blade implants fabricated from porous titanium through the SLS technology; they found no change in the marginal bone level after 2 years[16]. In the present study, there was no difference in the supporting bone beneath the implants at 1 year, as seen on the postoperative panoramic radiographs, and this might support the hypothesis of the elimination of stress shielding with the application of porous titanium devices.

In contrast to titanium, PEEK has very limited osteoconductive properties. Hence, several trials have been conducted to improve the bioactivity of PEEK implants. As such, PEEK-based materials are gaining increasing interest as possible alternatives to titanium-based materials in dental and orthopaedic prostheses and implants. PEEK has been explored for a number of applications in clinical dentistry. PEEK dental implants have shown lesser stress shielding compared to titanium dental implants due to the closer match of the mechanical properties of PEEK and bone. The elastic modulus of PEEK can be increased to up to 18 GPa

Table 1. Patient characteristics.

Patient number	Age, years	Sex	Cause of edentulism	Number of abutments	Implant material
1	31	Male	Aggressive periodontitis	4	PEEK
2	18	Female	Papillon–Lefèvre syndrome	6	Titanium
3	24	Male	Resection of benign lesion	4	Titanium
4	45	Female	Badly broken down teeth	3	PEEK
5	55	Male	Periodontitis	3	Titanium
6	45	Male	Periodontitis	3	PEEK
7	30	Male	Trauma	3	PEEK
8	22	Male	Post ablative surgery	5	Titanium
9	18	Male	Trauma	3	Titanium
10	37	Male	Periodontitis	5	PEEK

PEEK, polyether ether ketone.

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through reinforcement with carbon fibres. This elastic modulus is close to that of bone tissue (10–18 GPa), leading to a match in mechanical behaviour[17,18].

Furthermore, recent studies have worked to improve the bioactivity of PEEK implants at the nanoscale. A number of methods have been proposed to improve PEEK bioactivity, such as coating with synthetic hydroxyl apatite as an osteoconductive material[19,20], increasing its surface roughness and chemical modifications, and incorporating bioactive particles[21]. PEEK has a white colour and excellent mechanical properties, hence it has been proposed for other prosthodontic applications such as fixed prostheses[22] and removable prostheses[23]. The effects of surface modification of PEEK have been investigated for bonding with different luting agents[24] and extracted teeth[25]. In this study, it was hypothesized that the use of PEEK sub-periosteal implants would gain from the benefits of the mechanical properties of PEEK, which are closer to that of human bone than those of titanium, and the osseointegration properties of the surface-treated fixation screws[3].

Osseointegration is a pure histological fact and cannot be judged at radiographic levels of resolution. Furthermore, there is no objective method to determine whether or not there is bony osseointegration of the body of a sub-periosteal implant. However, from a clinical point of view, all of the patients in this study received fixed acrylic bridges and none experienced any sort of mobility. All were satisfied with their prosthesis throughout the 12-month follow-up period.

Trials aimed at producing osseointegrated sub-periosteal implants have been performed, but almost all of these studies have been experimental and have augmented the implant surface with various grafting materials and techniques. Hjørting-Hansen et al. showed incomplete osseointegration of sub-periosteal titanium implants fixated to the rabbit tibial bone surface and covered with expanded polytetrafluoroethylene (ePTFE) membranes[26].

In the present study, the outer surface of the implant facing the periosteum was left unpolished to minimize the possibility of wound dehiscence after surgery and implant exposure during function. However this hypothesis was not completely borne out, since wound dehiscence occurred in one patient and the abutment platform was exposed in almost all of the cases.

In conclusion, single-stage rehabilitation of the severely atrophic edentulous anterior maxilla with either customized porous titanium or customized PEEK sub-periosteal implants is a reliable method. However, studies with larger samples and longer follow-up periods are recommended to determine the long-term functional stability of these implants.

Funding

Self-funded.

Competing interests

None.

Ethical approval

Approved by the Ethics Committee of Cairo University.

Patient consent

Not required.

Acknowledgment. Authors would like to thank Dr Mohammedd Zain and Dr Mariam Roshdy for their great efforts.

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Please cite this article in press as: Mounir M, et al. Titanium and polyether ether ketone (PEEK) patient-specific sub-periosteal implants: two novel approaches for rehabilitation of the severely atrophic anterior maxillary ridge, *Int J Oral Maxillofac Surg* (2017), https://doi.org/10.1016/j.ijom.2017.11.008