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The ideal patient specific implant. Part II: An eight step checklist for maxillary class I, II Brown defects

Sanjay Kumar Roy Chowdhury [a], Karan Padha [a,*], Sneha Singh [a], Pradeep Yadav [b], Ravi Prajapati [b]

[a] Department of Oral & Maxillofacial Surgery, AFDC, New Delhi, India
[b] New Delhi, India

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ABSTRACT

Patient specific implants (PSI) though considered the next frontier in Maxillofacial Reconstruction, the gold standard for Brown I, II maxillary defects still remains autogenous reconstruction. The authors in their previous papers have standardised the design of Patient Specific Implants for Brown I, II mandibular defects. In this paper they attempt to standardise the design of PSI for Brown I,II maxillary defects using a scientifically optimised design which has passed through a stringent set of parameters. They aim to address the complications like wound dehiscence, poor dimensional accuracy and unoptimised biomechanics due to lack of standardisation thus impeding it's widespread acceptance among the scientific community. This study presents an eight step checklist to be followed for designing of an ideal standardised patient specific implant and can serve as a go-to guide for the operating and designing team.

1. Introduction

Patient specific implants (PSI) are customised implants made according to patient's individual anatomic requirements. Though autogenous reconstruction of Brown I,II defects is still the gold standard, the advantages of Patient Specific implants namely being reduced duration of surgery, prediction of failure due to FEA analysis and biomechanical accuracy make it the prime alternative. The lack of widespread acceptance of PSI's can be explained by the lack of standardisation in design leading to complications like wound dehiscence, poor biomechanics and dimensional accuracy and thus subsequent failure. This study aims to standardise the design of PSI for Brown I, II maxillectomy defects using an optimised design and stringent parameters.

2. Material and methods

The authors present a design for a Brown II maxillectomy post Mucormycosis defect for which a patient specific implant was designed (Figs. 1–3).

2.1. Designing of the patient specific implant

The PSI can be divided into:

- Dental Implant Component
- Fixing plate
- Vertical Buttress Struts

The fixing plate should be designed by thickening a portion on the buccal surface on the maxilla and this design is known as "I style". The alternative design of the fixing plate is "L style". This design involves thickening of the fixing plate on the buccal as well as the inferior surface. According to Qin et al., the section modulus of "L style" fixation plate is almost double of the "I style" fixation plate.[1] However, "L style" fixation plate is not possible in the maxilla with an "I style" fixation plate more commonly used.

Transitional fillet area:

The transitional area between the body and fixing plate is known as the transitional fillet area. Its importance lies in its radius. According to Qin et al., the stress concentration on the transitional fillet area significantly reduces when the radius increases from 0 to 1 mm. Thus, the

* Corresponding author. AFDC, KG Marg, New Delhi, 110001, India.
E-mail addresses: skrchow@gmail.com (S.K. Roy Chowdhury), krnpadha@gmail.com (K. Padha), drsnehasingh192@gmail.com (S. Singh), pradeepyadav596@gmail.com (P. Yadav), raviprajapati52@gmail.com (R. Prajapati).

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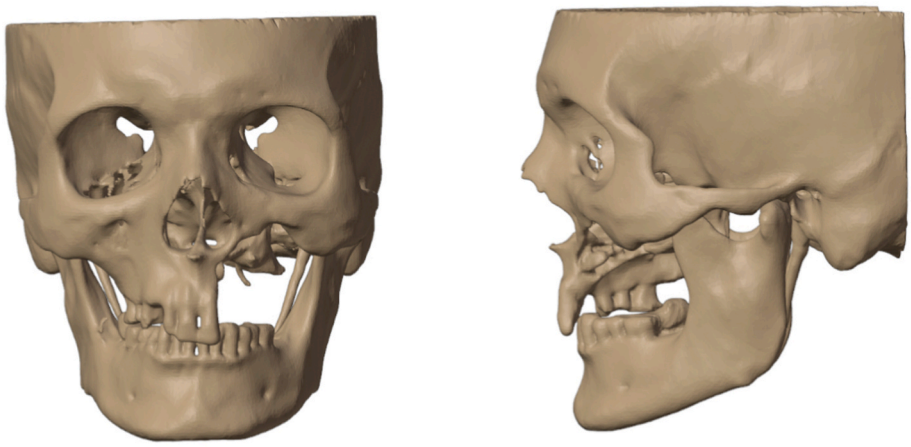

Fig. 1. Brown II Maxillectomy defect.

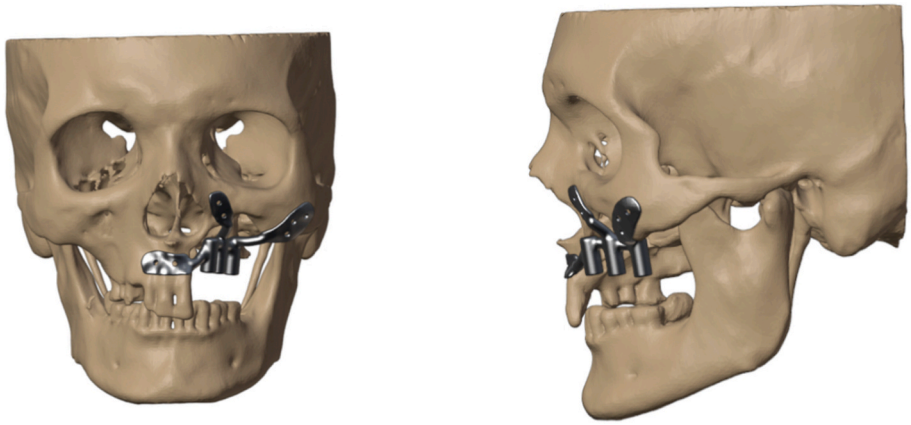

Fig. 2. PSI design.

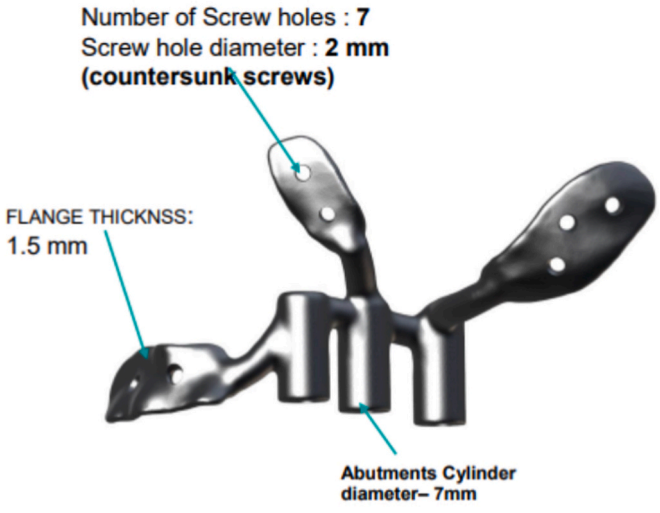

Fig. 3. PSI design.

transitional fillet radius should always be 1 mm or more or optimal stress distribution.

Countersink fixation holes:

The countersink fixation holes of PSI can be designed in two ways:

"II style": Countersink holes in a straight line.

"X style": Countersink holes in a staggered distribution and at an angle of 45°.

According to Qin et al., the section modulus of staggered countersink holes at 45° angulation is significantly greater than the holes in a straight line. Thus, countersink fixation holes should always be designed in a staggered distribution with an angulation of 45°.

Calculation of section modulus and maximum bending stress of the fixation plate:

$W = I/d$

W: Section Modulus
I: Second axial moment of the area
d: Distance of the farthest point to the neutral axis

$\sigma = M/W$

σ: Maximum bending stress
M: Bending moment
W: Section Modulus

If bone reduction is required for fixation of the plate, then the amount of bene reduction can be calculated by:

$Q = 0.75\ \pi\ t\ R^2$

Q: Volume of bone grinding
t: Height of fixing plate
R: Transitional fillet radius

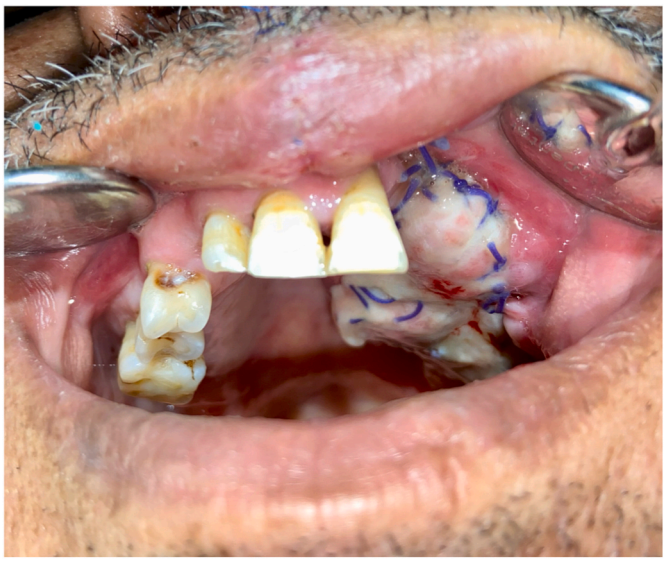

Fig. 4. Healing temporalis muscle providing soft tissue coverage over the PSI.

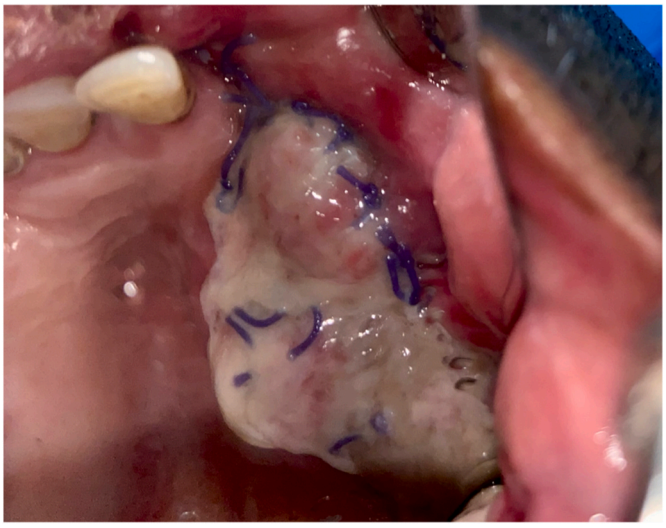

Fig. 5. Healing temporalis muscle providing soft tissue coverage over the PSI.

2.2. The importance of porosity in design optimisation

According to Luo et al., inducing porosities in titanium implant leads to a significantly lighter implant while maintaining rigidity with the most obvious changes during optimisation being reduction of the structural weight with increase in scaffold porosity.[2]

Scaffold porosity of the implant can be calculated:

$(1- V_{struts}/V_{overall}) \times 100$

V_{struts} = Volume of struts
$V_{overall}$=Volume of external contour

2.3. Importance of submerging dental implant component

According to Goodson et al., the limited biological width/barrier of mucosa between the contaminated oral environment and the mandibular PSI leads to a subsequent risk of catastrophic metalwork infection and wound dehiscence.[3] This important caveat can be tackled by scanning the dental implant and integrating it's hex into the PSI. The dental implant component can then be submerged with adequate biological

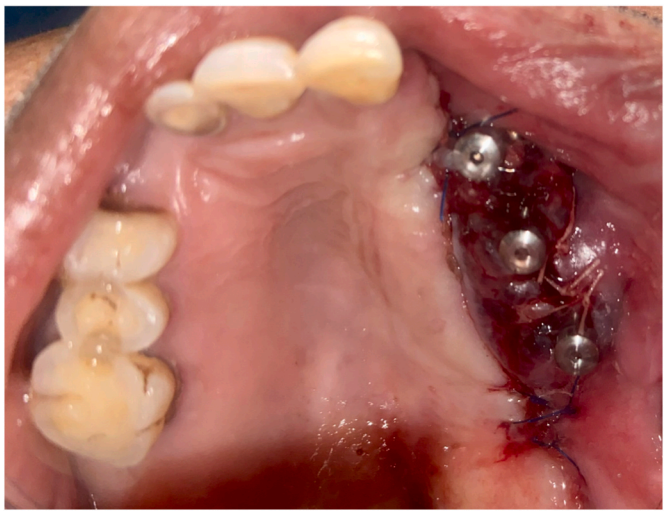

Fig. 6. Exposure of the dental components after three months and attachment of gingival formers.

width of tissue covering the PSI. Sculean A et al. in their study conducted on soft tissue wound healing around teeth and dental implants concluded that it takes 6–8 weeks of healing for formation of biological width and maturation of barrier function around transmucosal implants.[4] Salvi GE et al. in their study on temporal sequence of hard and soft tissue healing around titanium dental implants concluded that collagen fibers of the mucosa are organised after 4–6 weeks with the implanto-mucosal seal being fully functional at 6–8 weeks.[5] Thus, according to the studies quoted and also according to the authors experience, the PSI should be kept submerged for at least 6–8 weeks before second stage surgery thus allowing adequate time for healing and stabilisation of the soft tissue component. In the case presented Temporalis pedicled flap was used to provide soft tissue coverage for the PSI (Figs. 4–6).

2.4. Importance of FEA analysis

FEA analysis uses nodal points to solve equation for stress with colors representing load distribution for visualization purposes with blue signifying minimum stress and red signifying maximum stress. Computed tomography (CT) data with a slice thickness of 1 mm is

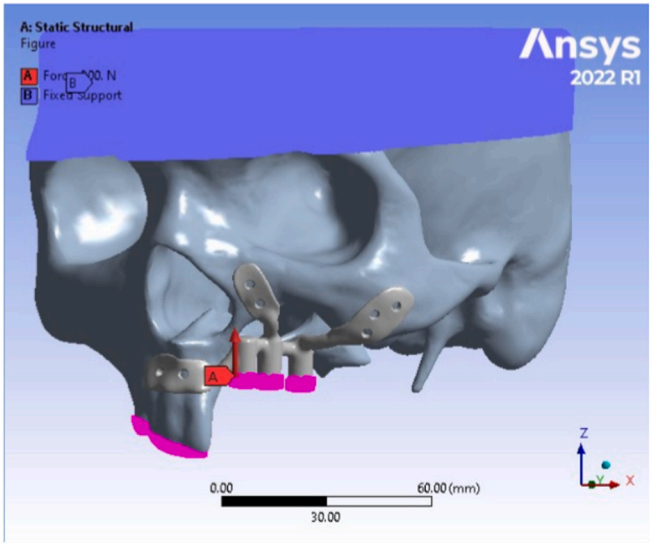

Fig. 7. Boundary condition under typical loading condition 300 N.

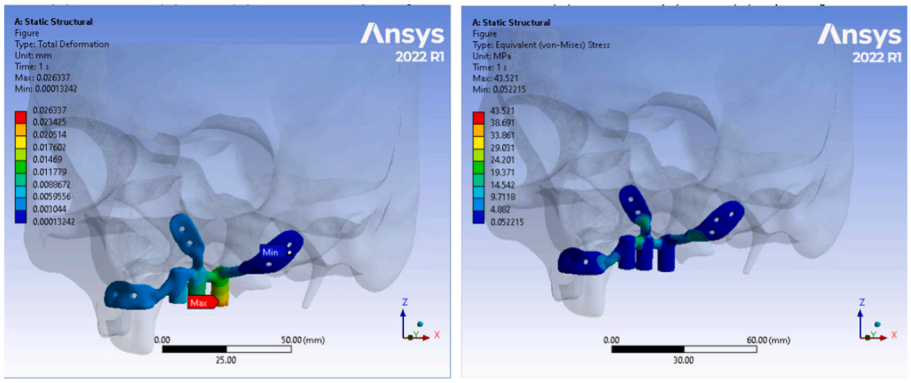

Fig. 8. FEA analysis of the PSI.

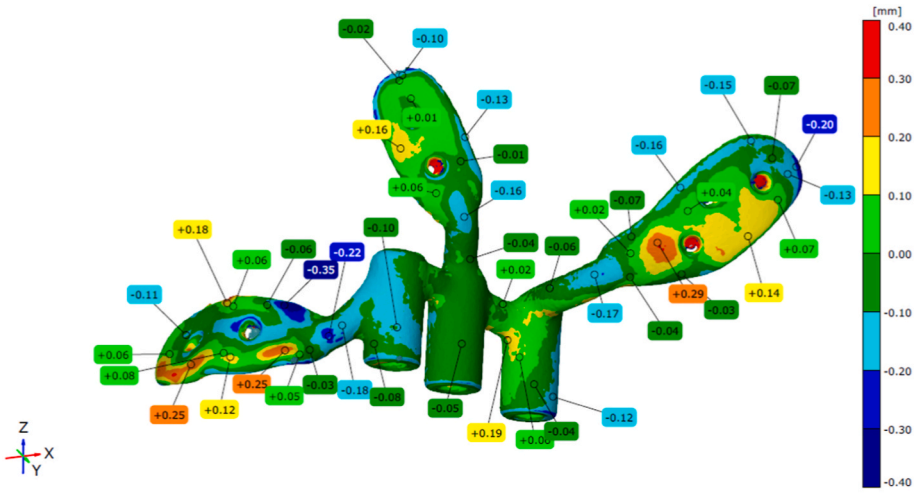

Fig. 9. GOM analysis of the PSI.

acquired and Finite element analysis (FEA) pre-processing and post processing is done in Ansys 2022 R1. In finite element analysis, meshing is the preprocessing step in which discretization of the infinite number of elements in the anatomical model into finite number of elements is done. The mesh formed 6045857 elements and 8385255 nodes from the anatomical model that included the maxilla and the implant. Quadratic tetrahedral elements (C3D10) were assigned as the element type. The implanted maxilla was subjected to biting and chewing simulations with a compressive force of 300 N. All of the following teeth were considered: The right maxillary central incisor, right maxillary lateral incisor, right maxillary canine, right maxillary first premolar and right maxillary second premolar. The displacement for maxillary bone was found to be 0.006787 mm whereas for the maxillary implant it was 0.026377 mm. von Mises stress on the implant was measured to be 43.521 MPa, which was much lesser than the allowable limit of 830 MPa. The maxillary bone experienced von Mises stress of 10.75 MPa, which was much lesser than the permissible limit of 113 MPa, indicating that the PSI design was biomechanically and functionally stable (Figs. 7 and 8).

2.5. Importance of GOM analysis

GOM Analysis is used for generating report for surface analysis and deviation. Green, Yellow, Orange and Red representing scanned implant surface outside designed implant surface. Light Blue, Dark Blue representing scanned implant surface inside designed implant surface. A 3D scanner is used to scan the finished 3D printed model, and then GOM software is used to register the manufactured implant with the original CAD design so as to compare for surface deviations. Maximum deviation of 0.29 mm was observed for the maxillary PSI which was lesser than the acceptable limit of ± 0.4 mm as per quality standards (Fig. 9).

2.6. Importance of fabrication process

The importance of quality control of the titanium powder material in the printing process lies in the fact that after 30 repetitions, oxygen content increases from 0.11% in virgin powder to 0.15% after 30 cycles. Considering the oxygen content quality standard in 0.15%, 30 recycles is the limit. According to Du et, after 15 recycles, the powder suffers from shape distortion as well as so called “satellite effect” in which smaller particles stick to larger granules thus affecting the quality of the printing process.[6] The parameters of the 3D printing process that can be controlled during the manufacturing are

- Laser power
- Laser scanning speed
- Layer thickness

The density of the titanium implant increases with an increase in laser power. With an increase in scanning speed and layer thickness, the density decreases. Thus, the laser power should be high while the scanning speed should be low and layer thickness should be small. The importance of these parameters can be found in the study by Huo et al. in which, titanium failure occurred due to von Mises stress of 141 MPa inspite of yield strength of titanium being 800 MPa.[7]

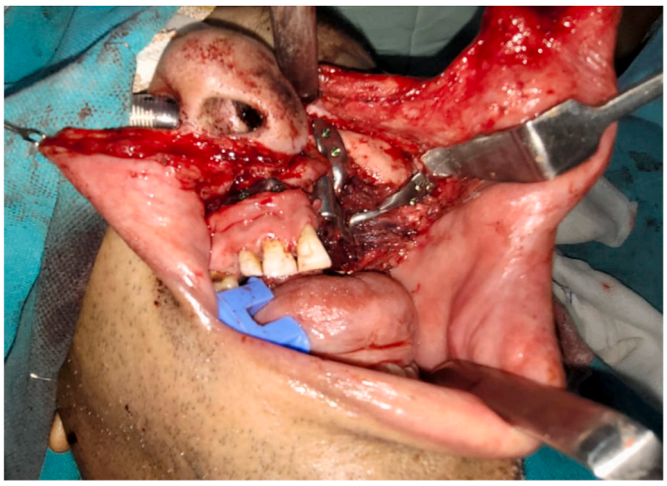

Fig. 10. PSI fixation after exposure of the defect.

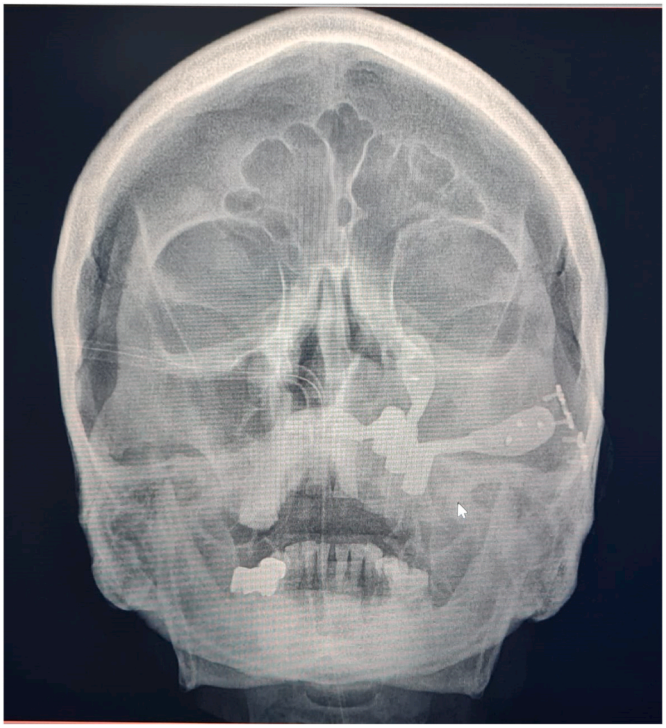

Fig. 11. Post of PA view.

3. Results

3.1. Analysis of case

The PSI was designed for reconstruction of a Brown II maxillectomy defect post Mucormycosis (Figs. 10 and 11).

The powder size was 30 μm with a layer thickness of 20–80 μm. Scanning speed was 4.5 m/s with the laser power being 100 W.

The transitional fillet radius was 1.5 mm with the bending stress being 107.14 MPa (Fig. 10). The design followed the principles of "I style" fixation plate with staggered countersink holes. Maximum von Mises stress on the implant was calculated to be 43.521 MPa which was much lower than the allowable limit of 550 MPa whereas the bending stress on the implant was 107.14 MPa.

Allowable bending stress calculation:

Width (B) = 4 mm

Radius (R) = 1.5 mm

Force (F) = 300 N

Section Modulus (W)=(B x H^2)/6 = 6.28 mm^3

Moment (M) = F x Distance = 300 x 10 = 3000 Nm

Bending stress (Max) = M/W = 107.14 MPa

Allowable bending stress = Bending stress (Max)/ Factor of safety = 1528.66/ 2 = 764.33 MPa

Hence, the bending stress on implant (107.14 MPa) was much lesser than allowable bending stress (764.33 MPa).

4. Discussion

The eight step checklist to be followed in PSI fabrication:

1. Two vertical buttress (preferably nasomaxillary and zygomatico-maxillary) should be engaged for optimal stress distribution.
2. Countersink holes should always be staggered with an angulation of 45°.
3. The transitional fillet radius should always be more than 1 mm.
4. Porosities should be included whenever possible for weight reduction corresponding to volume.
5. Manufacturing parameters to be evaluated:
   - Not more than 15 recycles of powder (Ideally none)
   - Laser power should be high
     - Layer thickness should be low
     - Scanning speed should be low
6. The dental implant component should always be submerged at first stage surgery.
7. FEA Analysis with maximum stress on implant being less than the allowable limit (The bigger the difference the better)
8. GOM Analysis with maximum deviation being within the acceptable limit of ± 0.4 mm

Patient specific implants form the next frontier in maxillofacial reconstruction with numerous advantages like biomechanical prediction and prevention of failure through FEA analysis, reduced duration of surgery, improved quality of life and integrated dental rehabilitation. However, the lack of standardisation and the complexity of the designing process has led to an array of PSI designs not optimised for maxillectomy defects thus leading to complications and subsequent reluctance in accepting PSI as a reconstructive option.

Through this paper, we have addressed the same and have provided an eight step standardised checklist as a guide for any surgeon planning to rehabilitate the Brown I,II maxillectomy defect.

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Ethical approval

All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from the individuals included in the study.

Declaration of competing interest

The authors have no conflicts of interest to declare that are relevant to the content of this article.

References

1 Qin Mian, Liu Yaxiong, Wang Ling, et al. Design and optimization of the fixing plate for customized mandible implants. *J Cranio-Maxillofacial Surg*. 2015;43(Issue 7), 1296-1302, ISSN 1010-5182.

2 Luo D, Rong Q, Chen Q. Finite-element design and optimization of a three-dimensional tetrahedral porous titanium scaffold for the reconstruction of mandibular defects. *Med Eng Phys*. 2017 Sep;47:176–183.

3 Goodson AM, Kittur MA, Evans PL, Williams EM. Patient-specific, printed titanium implants for reconstruction of mandibular continuity defects: a systematic review of the evidence. *J Cranio-Maxillo-Fac Surg*. 2019 Jun;47(6):968–976.

4 Sculean A, Gruber R, Bosshardt DD. Soft tissue wound healing around teeth and dental implants. *J Clin Periodontol*. 2014 Apr;41(Suppl 15):S6–S22.

5 Salvi GE, Bosshardt DD, Lang NP, et al. Temporal sequence of hard and soft tissue healing around titanium dental implants. *Periodontol*. 2000;68(1):135–152, 2015 Jun.

6 Du Ruxu, Su Yu-Xiong, Yan Yu, et al. A systematic approach for making 3D-printed patient-specific implants for craniomaxillofacial reconstruction. *Engineering*. 2020;6 (Issue 11):1291–1301.

7 Huo J, Dérand P, Rännar LE, Hirsch JM, Gamstedt EK. Failure location prediction by finite element analysis for an additive manufactured mandible implant. *Med Eng Phys*. 2015 Sep;37(9):862–869.