



Case Report

Mandibular Angle Augmentation using Customized PEEK Implants and Guides Generated with 3D Planning and Printing: Case Studies

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Citation: Arcas A, Vendrell G, Cuesta F, Bermejo L, Piqué N (2020) Mandibular Angle Augmentation using Customized PEEK Implants and Guides Generated with 3D Planning and Printing: Case Studies. Ann Case Report 14: 511. DOI: 10.29011/2574-7754.100511

Received Date: 20 October, 2020; **Accepted Date:** 26 October, 2020; **Published Date:** 31 October, 2020

Abstract

Mandibular angle augmentation is a procedure that, despite its obvious aesthetic and reconstructive indications, is not routinely performed, even by experienced surgeons. We present a case series of 10 patients treated with custom-made mandibular or inferior border prostheses for aesthetic concerns and sequelae following trauma or orthognathic surgery. Customized implants were designed with CAD/CAM technology, milled from Polyetheretherketone (PEEK) and 3D-printed implant placement guides were used. Ten patients (6 men and 4 women) were included; median age was 36.5 years (28-45 years). Indications for surgery were aesthetics (5 cases) and postoperative sequelae (4 orthognathic surgery and 1 mentoplasty).

No significant early complications occurred, except edema and small bruises. Three patients developed wound dehiscence and prosthesis exposure, which closed spontaneously after 2-3 weeks, except one case that required a slight reduction of the upper edge of the prosthesis. No prostheses required removal. After the initial healing period there were no exposures or any late-onset infections or prosthesis intolerance. The use of customized PEEK prostheses together with tooth-supported guides provides treatment that is safe, easier surgically and more reliable. More experience is needed to define bone beauty standards to achieve the desired aesthetic results.

Keywords: Customized implants; Mandibular angle augmentation; Polyetheretherketone (PEEK); Polyamide guides; 3D design; 3D printing

Introduction

Mandibular angle augmentation is a procedure that, despite its obvious aesthetic and reconstructive indications, is not routinely performed, even by experienced surgeons, for a number of reasons [1]. On the one hand, multiple complications, such as secondary infections or instability, arise from use of the materials of choice (traditionally, silicone or polyethylene) [2,3]. On the other, adapting standard implants to the patient's anatomy is very complex and therefore, difficult to achieve, which often caused asymmetrical results [1,2,4]. Finally, the intraoral approach, which provides very limited access, adds more difficulty to the

accurate positioning of the prostheses [2,4]. Recent advances in technology have led to a radical change in the approach to this type of surgery, as it not only allows us to use 3D planning but also to manufacture customized prostheses that adapt perfectly to the patient's anatomy [5-8]. Furthermore, the properties of the new materials that have been developed (such as Polyetheretherketone (PEEK) and titanium) for use in manufacturing these prostheses, have provided solutions to the problems of the old materials, in particular the issues with the high incidence of infection and lack of adaptation [2,8-12].

The new materials have provided improvements, especially with regard to better matching of shape, thanks to digital technology and new manufacturing techniques. With the use of customized implants, guides and plates, close collaboration between surgeons and biomedical engineers in industry is required [6-8,13]. In

this study, we present a series of 10 cases of patients treated with custom-made mandibular or inferior border prostheses for aesthetic concerns or sequelae following trauma or orthognathic surgery, illustrated with the types of customized implants that were designed with CAD/CAM technology and milled from PEEK, together with the 3D-printed implant placement guides that were used. The authors of this study bring their expertise to bear on designing and using customized guides for this type of surgery, which provide accuracy and ease in the placement of the prostheses while reducing surgical time and obtaining the designed symmetry.

Material and Methods

Patients

Ten patients who underwent surgery at the Department of Oral and Maxillofacial Surgery Maxilodexeus of Quirón Dexeus University Hospital (Barcelona, Spain) between December 2017 and August 2019 for mandibular angle augmentation for aesthetic improvement or for sequelae following orthognathic surgery or mentoplasty were included in this series. Aesthetic results were evaluated over the course of several visits, with follow-up at one week, 15 days and then monthly, where assessments were performed on potential postsurgical complications, objective aesthetic results and the personal satisfaction of the patients. The follow-up period was 12-18 months.

Virtual Planning

On the patient's first visit, a thorough evaluation and physical examination of the maxillofacial skeleton was performed. Aesthetic predictions of the results that would be achieved after surgery were also made in 2D and 3D. After the patient agreed to the surgical treatment, a Computed Tomography (CT) scan of the mandible according to the DICOM (Digital Imaging and Communications in Medicine) standard was performed, with slice thickness of less than 1 mm in order to make a three-dimensional reconstruction of the maxillofacial skeleton using Mimics software (Materialise, Belgium). Together with engineers from Avinent Implant System (Santpedor, Barcelona, Spain) using 3-matic software (Materialise, Belgium), we then designed a customized prosthesis. After the design of the prosthesis was completed, a tooth-supported placement guide was designed which, depending on the surgeon's preference, had to be able to adapt to the prosthesis either directly or by means of a micro screw-retained platform. The prosthesis was manufactured from PEEK discs using a High-Speed Milling (HSM) process and the guides were 3D printed in Polyamide (PA2200) using an EOS-Formiga P110 printer at Avinent Implant System (Santpedor, Spain).

Surgical Technique

Surgery for placing the prosthesis through an intraoral incision was performed under general anesthesia. A subperiosteal plane was developed and the muscle insertions of the masseter and medial pterygoid muscles were detached in the region where the prosthesis was to be placed. We ensured that the size of the incision was proportional to the size of the prosthesis and then a tooth-supported guide was inserted, to allow the three-dimensional positioning of the prosthesis to be checked and make it easier to fasten it with screws. If the surgeon preferred, the guide could also be fastened with screws in order to facilitate manipulating the prosthesis and visualization, which helps to improve the fixing procedure as the guide is fastened throughout (Figures 1-4). After fastening the prosthesis, a two-layered closure was performed without the use of drains. Antibiotic treatment was administered for two days and the wound was carefully cleansed with chlorhexidine rinses and gel.

Results

Ten patients (6 men and 4 women) were included; median age was 36.5 years (range: 28-45 years). The indications for mandibular angle augmentation were aesthetics in 5 cases and for the rest of patients, postoperative sequelae: 4 following orthognathic surgery and 1 after mentoplasty. Surgery times were approximately 90 minutes and postoperative recovery was satisfactory. In all 10 patients the aesthetic results were satisfactory (patient satisfaction with aesthetics was excellent in 100% of cases). No significant early complications occurred in the patients, except edema and small bruises. Three patients developed wound dehiscence and prosthesis exposure, which closed spontaneously after 2-3 weeks of local cleaning and application of chlorhexidine gel, except in one case that required a slight reduction of the upper edge of the prosthesis. No prostheses required removal. After the initial healing period there were no exposures or any late-onset infections or prosthesis intolerance.

Case Description

Case Presentation 1

A 26-year-old patient with a class II dentofacial deformity for whom a Le Fort I osteotomy with mandibular advancement and repositioning (centering) was planned. Since there was an asymmetry involving the right ascending ramus, a customized mandibular angle implant was designed, which was inserted at the time of the orthognathic surgery to achieve facial symmetry. In addition to bimaxillary advancement, the procedure also achieved symmetry of both ascending rami, thanks to the custom-made prosthesis (Figure 1).

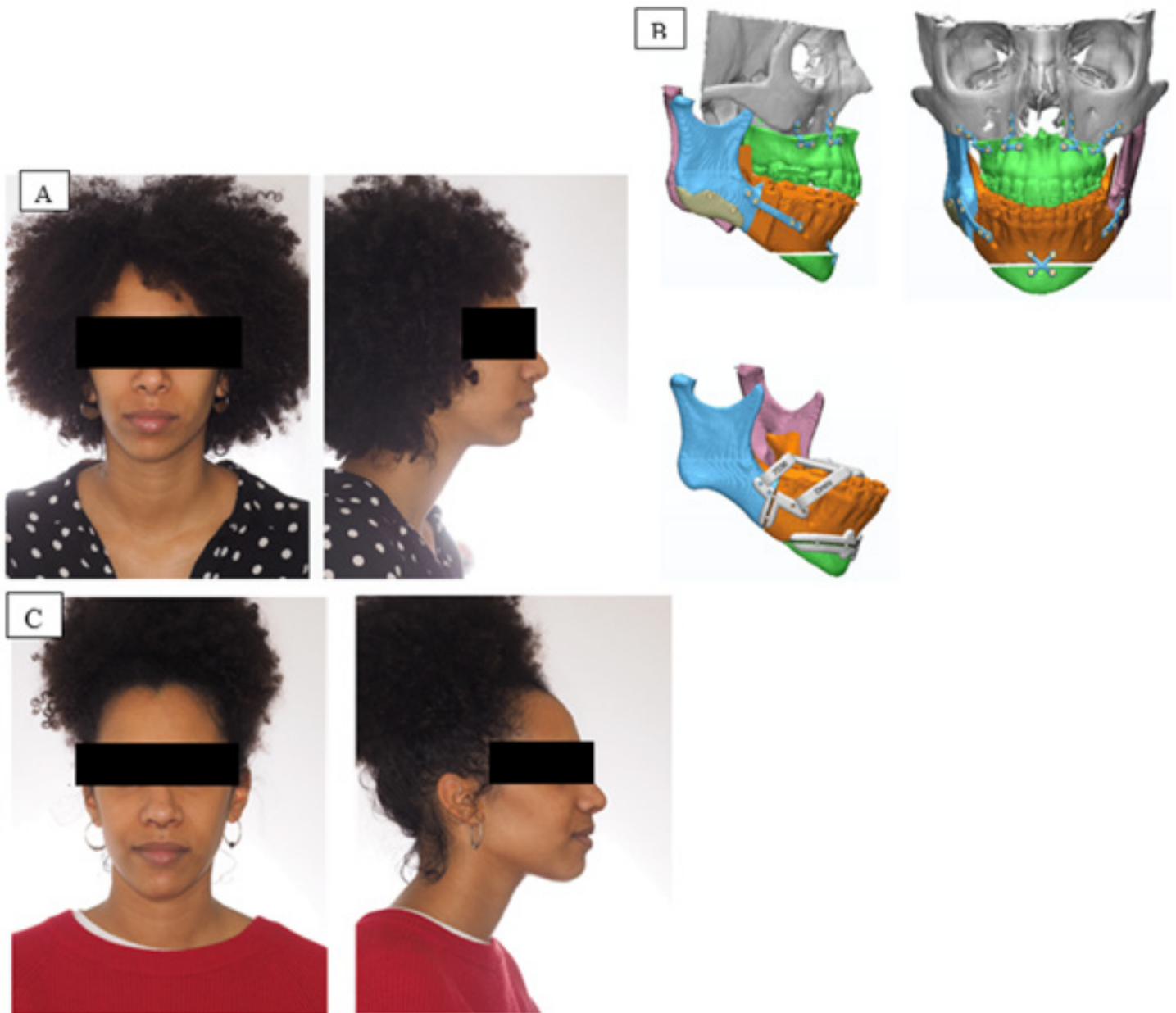


Figure 1: Results of mandibular angle surgery (case 1). **A)** Preoperative profile; **B)** Customized implants and guides; **C)** Postoperative profile.

Case Presentation 2

A 32-year-old patient who came to see us after undergoing a previous procedure for the insertion of a silicone chin and mandibular angle implant that did not achieve the expected projection. The clinical examination led us to suspect a malposition of the implant, which was confirmed on the CT scan. Using general anaesthesia we removed the old prostheses; two PEEK mandibular angle implants were then placed using custom tooth-supported guides and advancement genioplasty was performed with customized guides and plates (Figure 2).

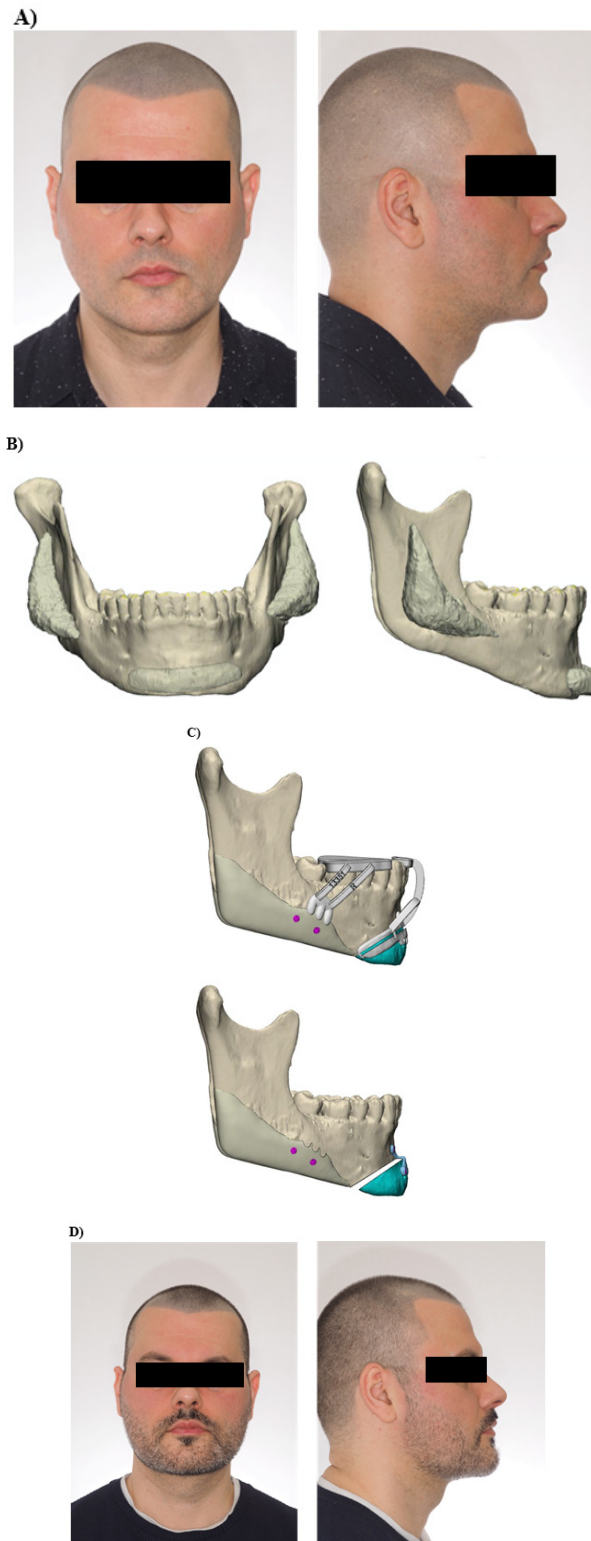


Figure 2: Results of mandibular angle surgery (case 2). **A)** Preoperative profile; **B)** Silicone prosthesis previously implanted to the patient; **C)** Customized implants and guides; **D)** Postoperative profile.

Case Presentation 3

A 41-year-old patient with hemifacial microsomia, who had undergone orthognathic surgery 15 years ago. She came to us seeking facial projection to improve aesthetic appearance. Two mandibular angle and inferior border prostheses were implanted, in addition to a chin prosthesis to obtain greater projection of the entire inferior mandibular border (Figure 3).

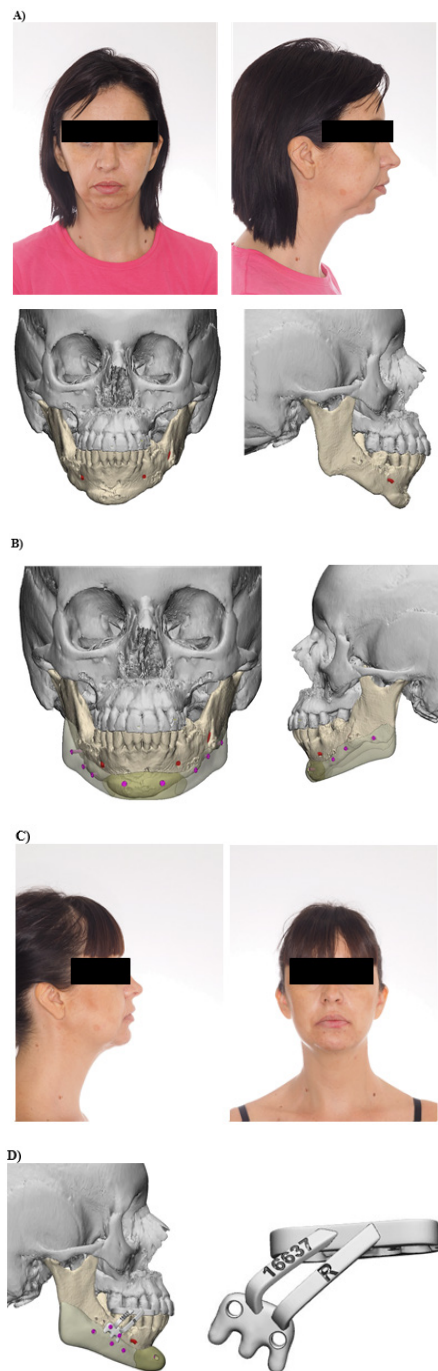


Figure 3: Results of mandibular angle surgery (case 3). **A)** Preoperative profile; **B)** Customized implants and guides. **C)** Postoperative profile. **D)** Detail of the PEEK implant with guide temporarily fastened with screws to facilitate placement of the prosthesis.

Case Presentation 4

A 43-year-old patient with a history of bilateral mandibular osteotomy. The ascending ramus was displaced resulting in loss of soft tissue support as well as a lack of projection of the mandibular angle and inferior border. A procedure was performed under general anesthesia to place two customized angle and inferior border prostheses that provided projection and balance to the two sides of his face (Figure 4).

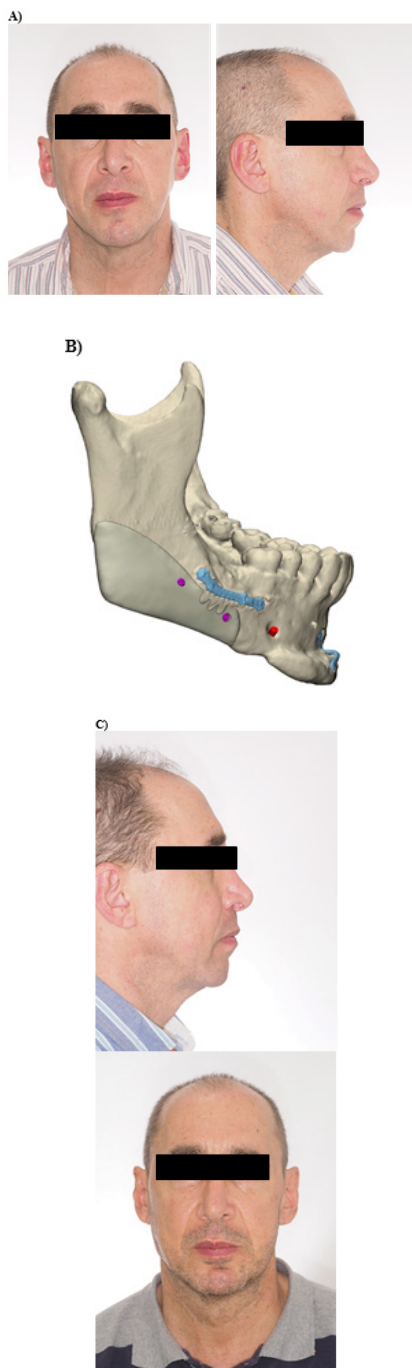


Figure 4: Results of mandibular angle surgery (case 4). **A)** Preoperative profile; **B)** Customized implants and guides; **C)** Postoperative profile.

Discussion

Maxillofacial surgery has undergone radical change with the advent of virtual 3D planning using computed tomography and planning software (such as Dolphin, Materialise), demanding better knowledge of anatomy, achieving greater accuracy and reducing the number of complications. This revolution has been made complete by the ability to manufacture customized guides and plates, which allow to perform personalized surgery on patients, providing all the benefits inherent to such procedures: more precision, less invasive surgery and less surgical time [2,6,7,14]. While jaw angle implants have been commercially available for almost 25 years, they have largely been neglected both in clinical practices and the medical literature [9]. Jaw angle implants can now reliably provide a companion to chin augmentation as well as offer the final solution to a more complete jawline augmentation that many patients seek today [9].

The materials currently used to produce these customized prostheses are mainly titanium and Polyether Ether Ketone (PEEK), the material used in our study. PEEK is a semi-crystalline thermoplastic biomaterial ((-C6H4-O-C6H4-O-C6H4-CO-)n) belonging to the Polyaryletherketones (PAEKs) polymer group family, that has attracted more interest than any other implantable material for medical devices in the last 20 years [15,16]. It has good mechanical strength, is non-allergenic and non-magnetic as well as having good biocompatibility and radiographic translucency, with elasticity similar to that of cortical bone [17]. PEEK currently has multiple applications in orthopedics and is a prime candidate to replace metallic implants and prostheses in orthopedics, spine and cranio-maxillofacial surgeries due to its excellent properties: it is resistant to high temperatures, chemicals and fatigue, is lightweight, has high yield strength and is durable [18-20].

Advantages of PEEK over titanium are its radiolucency, the ease with which it can be carved, ease of handling, with a non-porous surface that reduces the risk of bacterial biofilm formation and therefore, the risk of infection. This material has been used to manufacture prosthetics to replace human body parts, for example, in craniofacial or sinus cavities reconstruction and for minor to major defects or sequelae in the maxillo-mandibular complex, as well as in orthopedic and spine surgery [21-23]. PEEK prostheses have important advantages over conventional prostheses (silicone, polyethylene, polymethyl methacrylate, methyl methacrylate and calcium hydroxyapatite), which have been associated with asymmetry or irregular results, increased risk of infection, implant migration and instability [24]. These materials are highly porous, which increases the risk for infection, especially from the formation of biofilms that are highly resistant to antibiotics. Implant removal is frequently the only option, resulting in failure of the aesthetic treatment [24].

In addition, silicone implants placed subperiosteally may cause resorption of the underlying bone and formation of a fibrous capsule, resulting in implant instability and migration and leading to unsatisfactory results [24]. In our study, we present a series of cases of customized mandibular or inferior border prostheses made of PEEK, demonstrating for the first time that the use of PEEK prostheses in conjunction with placement guides designed and produced using 3D technology is a safe option that allows the desired aesthetic results to be achieved. At the same time, designing these custom prostheses poses a challenge to the surgeon because there are no patterns of facial skeletal “beauty”. In the design of the prosthesis, patient preference and the surgeon’s artistic ability and experience, which will enhance the final result, are particularly important [1]. In cases of sequela or asymmetry, it is easy to design the prosthesis, by mirroring the contralateral mandibular ramus [2].

The challenge arises when we are required to design a prosthesis for aesthetic considerations, because we must calculate all three dimensions of the prosthesis and be able to predict how it will affect the soft tissues, especially the masseter muscle, whose thickness can mask alterations in the transverse and vertical dimensions and on which there are no studies regarding the correlation between soft and hard tissue augmentation. In this regard, it is worth noting Mommaerts’ study, in which a survey using photographs was conducted to determine the ideal male standard of beauty for the mandibular angle and inferior border, assuming a 1:1 ratio for prosthetic augmentation to soft tissue augmentation [2,25,26]. However, we still need to establish patterns for facial bone beauty for both men and women, as well as perform studies to conclusively determine what percentage of impact the soft tissues have. Surgically speaking, customized prostheses provide great advantages: their perfect adaptation to the patient’s anatomy greatly simplifies the surgical procedure and the surgeon can make technical modifications to facilitate placement.

In this regard, the authors of this study preferred to limit the extension of the lingual flange present in many conventional prostheses, which make them much more difficult to place. Conversely, they opted to visibly increase vestibular depth for three reasons: ease of handling, ease of fastening, as it allows placing screws more coronally, and greater prosthesis stability, especially in areas with great vertical growth where the masseter muscle can move the prosthesis. The use of customized tooth-supported guides that, as in the case of custom-made prostheses, have three guide slots to ensure exact placement of the prosthesis, makes the vestibular depth of the implant particularly important as it provides a fixation area that is closer to the occlusal plane. In our experience, especially when using an intraoral approach, placement of a customized prosthesis does not prevent errors in placement and symmetry. We must understand that we are dealing

with convex surfaces that are not very retentive, with limited visibility, where despite customization, positioning errors can occur, even if they are as small as a millimeter.

Experience has led us create a second option in which we fasten the guide with screws, greatly facilitating placement of the prosthesis, because all the surgeon needs to do is align the parts in the prosthesis with the slots in the guide to ensure placement goes as planned in all three planes of space (Figure 5). In our opinion, this guide is the key factor to facilitating and ensuring correct placement of the prosthesis. On the basis of the above, we can conclude that mandibular angle and inferior border augmentation are a surgical challenge when conventional prostheses are used, because of difficulties in adaptation, problems with the materials and placement difficulty. The use of customized prostheses, together with tooth-supported guides, provides treatment that is safe, easier surgically and more reliable. However, more experience and studies are needed to define bone beauty standards that will help us design the prostheses that will achieve the desired aesthetic results.

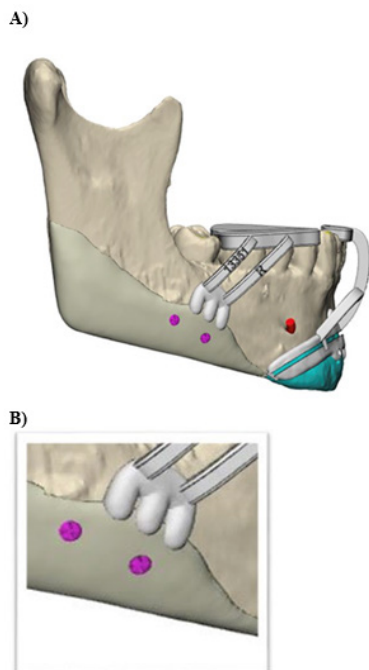


Figure 5: Detail of the PEEK implant. **A)** Positioning of the custom-made mandibular angle using a tooth-supported guide. **B)** Detail of how the guide and PEEK implant fit together.

Acknowledgements

Núria Piqué is a Serra Húnter Fellow. All authors have viewed and agreed this article.

Declaration of Interest

None.

Author's Contributions

All authors designed and carried out the study, performed the statistical analyses and contributed to the interpretation of the results and writing of the manuscript.

Funding

This research did not receive any specific grants from funding agencies in the public, commercial, or not-for-profit sectors.

Patient Confidentiality

Written informed consent for publication in print and electronic form from the patients was obtained.

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