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An innovative 3D hydroxyapatite patient-specific implant for maxillofacial bone reconstruction: A case series of 13 patients

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A R T I C L E   I N F O

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A B S T R A C T

The study aimed to evaluate and discuss the use of an innovative PSI made of porous hydroxyapatite, with interconnected porosity promoting osteointegration, called MyBone Custom® implant (MBCI), for maxillofacial bone reconstruction.

A multicentric cohort of 13 patients underwent maxillofacial bone reconstruction surgery using MBCIs for various applications, from genioplasty to orbital floor reconstruction, including zygomatic and mandibular bone reconstruction, both for segmental defects and bone augmentation.

The mean follow-up period was 9 months (1–22 months). No infections, displacements, or postoperative fractures were reported. Perioperative modifications of the MBCIs were possible when necessary. Additionally, surgeons reported significant time saved during surgery. For patients with postoperative CT scans, osteointegration signs were visible at the 6-month postoperative follow-up control, and continuous osteointegration was observed after 1 year. The advantages and disadvantages compared with current techniques used are discussed.

MBCIs offer new bone reconstruction possibilities with long-term perspectives, while precluding the drawbacks of titanium and PEEK. The low level of postoperative complications associated with the high osteointegration potential of MBCIs paves the way to more extensive use of this new hydroxyapatite PSI in maxillofacial bone reconstruction.

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1. Introduction

Maxillofacial reconstruction surgery presents a multifactorial challenge, both in the process and the expected outcome. The complexity of facial bones and soft tissues adds to the surgery's difficulty, while each defect's unique characteristics further complicate the procedure. Additionally, the success of these surgeries hinges on achieving satisfactory functional and esthetic results, since facial deformities can severely affect the patient's quality of life.

Conventional techniques, such as autologous bone graft (utilizing fibula, iliac crest, or scapula free flaps) and osteotomies have long been considered the gold standards for most maxillofacial reconstructions (Bedogni et al., 2021; Chepurnyi et al., 2021). However, autologous graft can be associated with resorption and donor-site morbidity. Additionally, in cases of large or complex defects, applying autologous grafts may be impractical (Beuriat et al., 2016). With regards to osteotomies, they require advanced surgical skills, while stability may be challenging to achieve (Haas Junior et al., 2017) and the esthetic outcome is not always predictable (Kerkfeld et al., 2022; Lee et al., 2018; Matsushita et al., 2015). To tackle such challenges, customized implant development has emerged over the past two decades (Brie et al., 2013; Kerkfeld et al., 2022; Kim et al., 2009; Staffa et al., 2007).

Computer-aided design (CAD) has improved the planning of reconstructive surgeries, enabling precise preoperative evaluation and simulation. Computer-aided manufacturing (CAM) and advances in additive manufacturing technologies have further facilitated the translation of 3D surgical planning into physical objects, such as patient-specific implants (PSIs). A variety of materials have been described in the literature for craniomaxillofacial PSI manufacturing, including poly-ether-ether-ketone (PEEK) (Alasseri and Alasraj, 2020; Atef et al., 2022; Järvinen et al., 2019; Kim et al., 2009; Shi et al. 2022), porous polyethylene (Medpor) (French et al., 2020; Landry et al., 2021), polycaprolactone and tricalcium phosphate (mPCL-TCP) (Castrisos et al., 2022), titanium (Bedogni et al., 2021; Le Clerc et al., 2020; Haroun et al., 2023; Mommaerts, 2021), and, less frequently, bioglass (e.g. Bioverit) (Falkhausen et al., 2021; Gebel et al., 2022). Polymethyl methacrylate (PMMA) and bioceramics, such as hydroxyapatite (HA), are also frequently used in PSIs, but limited to cranial defect surgeries (Beuriat et al., 2016; Brie et al., 2013; Staffa et al., 2007; 2012; Thayaparan et al., 2021). Nevertheless, HA is the closest to natural bone among these materials. It is considered to have excellent biocompatibility and osteoconductive properties (Brie et al., 2013).

The combination of additive manufacturing techniques, such as stereolithography (SLA), and bioceramics, including HA, offers a unique opportunity to create implants specifically designed to facilitate bone tissue regeneration. Indeed, these implants present the HA's osteointegration properties, while the additive manufacturing procedure provides precise control over the lattice structure and macroporosities.

This study investigated the outcomes of maxillofacial reconstruction surgeries using 3D-printed porous HA implants in a series of 13 patients.

2. Case series

2.1. Patient selection

From February 2021 to May 2023, 13 patients underwent maxillofacial bone reconstruction with MyBone Custom Implants (MBCIs), a porous hydroxyapatite patient-specific implant (HA-PSI). The surgeries took place in different hospitals in Belgium, France, and the Netherlands. Patients' informed consents were obtained to use their medical records and images. Reasons for surgery were diverse (esthetic, congenital deformity, trauma etc.), described in Table 1 together with patients' demographics.

Table 1
Patient demographics.

Patient no.	Sex	Age	Indication	Etiology
1	F	21	Genioplasty	Major mandibular retrusion
2	F	25	Genioplasty	Esthetic
3	M	20	Genioplasty	Esthetic, minor retrogenia
4	F	35	Genioplasty	Major retrogenia
5	M	18	Genioplasty	Esthetic
6	M	47	Mandibular reconstruction	Pseudoarthrosis subsequent to mandibular fracture
7	M	26	Mandibular apposition	Esthetic, mandibular asymmetry
8	F	34	Mandibular apposition	Esthetic, mandibular asymmetry, previously failed PEEK reconstruction
9	M	Unk	Zygoma reconstruction	Dislocated zygoma fracture
10	F	33	Bilateral zygoma augmentation	Pronounced medial face hypoplasia
11	F	33	Bilateral zygoma augmentation	Esthetic
12	M	50	Orbital floor	Anophthalmic socket syndrome
13	M	52	Orbital floor and zygoma augmentation	Left zygomatic asymmetry; left orbital floor enlargement and slight asymmetry

2.2. Digital chain for medical images and computer-aided design (CAD)

A systematic workflow was developed for the processing of DICOM (Digital Imaging and Communication in Medicine) images, the design and conception of the MBCI, and its manufacture by additive manufacturing (Fig. 1). Whenever possible, the overall shape of the PSI was determined through the mirroring the contralateral side. Alternative techniques, such as projection or physical modeling on 3D-printed models, were employed as needed. A collaborative approach involving both the manufacturer and the surgeon was adopted to define the PSI's overall shape, margins, screw positioning (taking into account surrounding tissues, such as nerves), and porous HA properties (pore size, orientation etc.) (Biscaccianti et al., 2022; Vidal et al., 2023) (Fig. 1.1-1.2b). Following validation of the PSI's shape by the surgeon, 3D gyroid porosities, involving a triply periodical minimal surface (TPMS), were integrated into the final volume using CAD software (Autodesk Netfabb, USA) (Fig. 1.2c).

2.3. Additive manufacturing

All MBCIs have been manufactured by CERHUM SA (Liège, Belgium). The manufacturing, including the virtual porosity implementation, the additive manufacturing process, and the post-treatment, have been previously described (Van Hede et al., 2022). The dimensions and shape of each HA-PSI were controlled by 3D scanning (GOM; Atos, Germany) to ensure conformity with the approved 3D design (Step 4 of Fig. 1.4). Each MBCI was provided in duplicate. The steam sterilization (134 °C, 18 min) was performed by the different hospitals.

2.4. Surgery

The surgery features are presented in Table 2. The MBCIs were used in different facial areas: chin (n = 5), mandibular body (n = 1), mandibular angle (n = 2), zygomatic bone (n = 4), and orbital floor (n = 2). One patient underwent both zygoma augmentation and orbital floor reconstruction. In most cases, surgical access was intraoral (77 %). The MBCIs were fixed only with screws for 62 % of the patients. Plates were added for four patients and wire in one case to ensure overall implant stability. For one patient, MBCI was placed in compression only (no osteosynthesis material was attached to the implant). For four patients, breakage happened without the possibility of replacement with the spare MBCI. However, the issue was resolved by removing the small

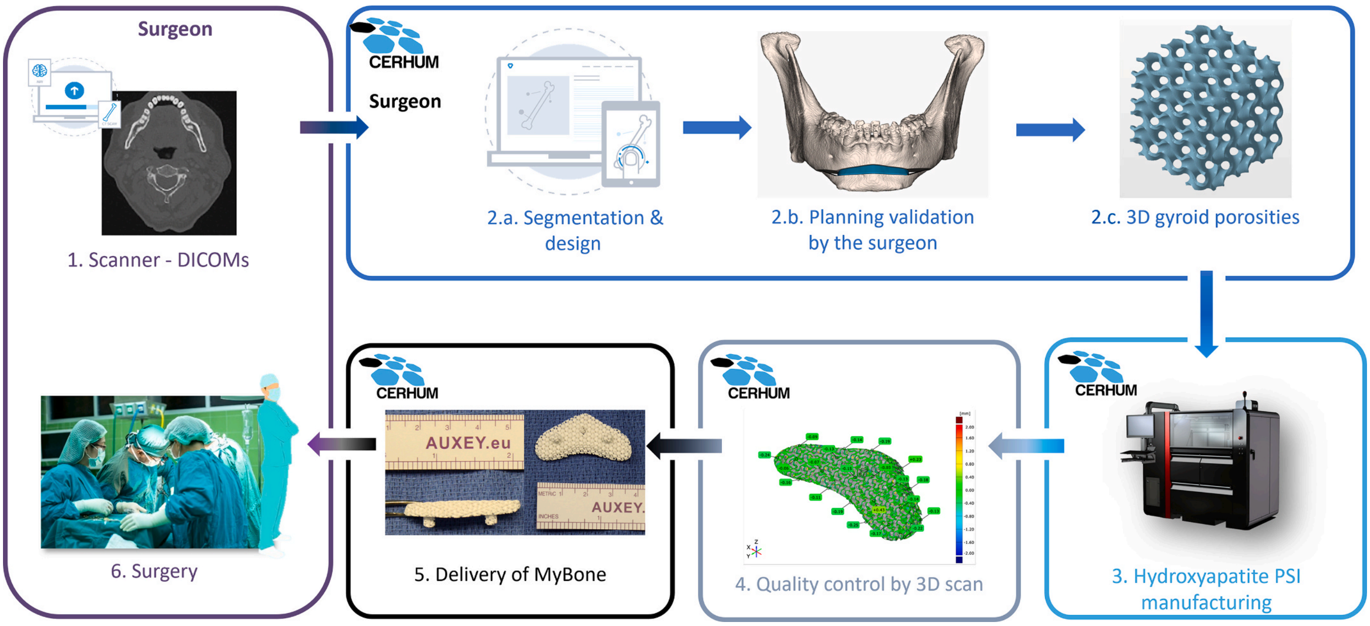

Fig. 1. Workflow illustrating the different steps for the design and manufacture of MBCI, from the patient's medical images to the surgery.

Table 2
Surgery and follow-up.

Patient no.	PSI site	Number of PSIs	Access	Fixation	Perioperative complications	Postoperative complications	Surgeon feedback	Follow-up (months)
1	Mandible symphysis	1	Intraoral	2 screws, plate and wire	Fractured implant	No		16
2	Mandible symphysis	1	Intraoral	1 central screw	No	No		22
3	Mandible symphysis	1	Intraoral	1 central screw and plate	Fractured implant	No	Saved 1 h and 15 min of operating time	5
4	Mandible symphysis	1	Intraoral	2 screws and plate	No	No		1
5	Mandible symphysis	1	Intraoral	1 central screw and plate	Fractured implant	No	Saved 1 h of operating time	1
6	Mandibular body	1	Cervical	Compression only	Adaptation of the PSI due to change in the anatomy	Exposure leading to implant removal		11
7	Mandibular angle	2	Intraoral	5 screws	No	No	Absence of preoperative adjustment need was satisfying	5
8	Mandibular angle	1	Intraoral	3 screws	No	No		11
9	Zygomatic bone	1	Intraoral	1 screw	Difficult fit due to significant scar tissue in the sinus, but acceptable outcome	No	Osteointegration signs on the 6-month and 1-year postoperative scans	18
10	Zygomatic bone	2	Intraoral	1 screw per implant	No	No		11
11	Zygomatic bone	2	Intraoral	1 screw per implant	No	No		7
12	Orbital floor	1	Transconjunctival	1 screw	Adaptation of the PSI due to too ambitious planning + fracture of a small part	No	Osteointegration signs on the 6-month postoperative scan	9
13	Orbital floor and zygomatic bone	2	Palpebral and intraoral	1 screw and 2 screws	No	No	2 h saved compared with zygoma osteotomy	4

fragment if not essential or by ensuring the stability of the fragment with additional osteosynthesis material. For two patients, adaptation of the MBCI was required to match the bone defect. For one patient, this was due to a difference in defect configuration between the preoperative imaging scans and the situation at the time of surgery. For the second patient, the planned PSI volume was too ambitious and required slight milling. In three cases, the surgeons highlighted the significant time saved in surgery — from 1 to 2 h — thanks to the MBCI (Table 2).

2.5. Outcome and follow-up

Follow-up data for all the patients are presented in Table 2. The follow-up period varied between 1 and 22 months (mean 9 months). No cases of PSI infection, breakage, displacement, or paresthesia were reported. For one patient, the MBCI had to be removed due to exposure. Osteointegration signs could be identified on postoperative imaging scans when available.

2.6. Case presentation

Nine clinical cases were selected among the 13 patients of this case series to illustrate the different types of maxillofacial bone defect treated with MBCIs, and to provide details regarding surgical procedures and postoperative observations. These cases are numbered as per Tables 1 and 2 They include segmental genioplasty, mandibular apposition and segmental reconstruction, maxillary/zygoma apposition and segmental reconstruction, and orbital floor reconstruction.

2.7. Major retrognathia — case 1

A 21-year-old woman presenting with major mandibular retrusion secondary to juvenile arthritis and total bilateral condylar resorption underwent a genioplasty accompanied with the interposition of an MBCI (Fig. 2A) to enhance chin projection and to provide good consolidation of the whole. The surgical intervention also involved a maxillomandibular osteotomy.

The MBCI was designed to incorporate two holes perpendicular to the patient's natural bone, allowing for the application of compressive strength using two screws (Ø 2.3 mm) that traversed the implant (Fig. 2B). Additional osteosynthesis material (Materialise, Leuven, Belgium) was used to fix the chin fragment and to maintain overall stability. The HA-PSI fractured during placement due to the critical thickness of the implant near the fixation holes, requiring additional wire fixation.

No complications were reported up to 17 months postoperatively. The esthetic outcome was deemed excellent (Fig. 2D), although it should be noted that the successful result was attributable not only to the implant but also to the repositioning of the jaws and the chin.

2.8. Minor retrognathia — cases 3 and 5

A 20-year-old man with retrognathia (Fig. 3A4) and an 18-year-old man with a relative progenia (Fig. 3B4) underwent modification of the chin using an MBCI for esthetic purposes. In the second case, this was coupled with maxillomandibular osteotomy.

For case 3 (Fig. 3A), the HA-PSI was designed to contain a central screw and rods on either side of the fixation hole to hold the graft in place and prevent rotational movement (Fig. 3A1 and A2). A surgical cutting guide (Materialise, Leuven, Belgium) was used to cut the chin bone fragment. The rods allowed the surgeon to achieve good positioning and stability during the procedure. A screw (Ø 2 mm), going through the chin fragment and MBCI, and a plate (Materialise, Leuven, Belgium) were used to fix the chin fragment and maintain the overall bone and PSI stability (Fig. 3A3).

For case 5 (Fig. 3B), the HA-PSI was designed to fill the bone space after a clockwise rotation of the chin. A surgical cutting guide (Ennoia, Besançon, France) was used to cut the chin bone fragment. A custom-made plate and five screws (Ennoia, Besançon, France) were used to

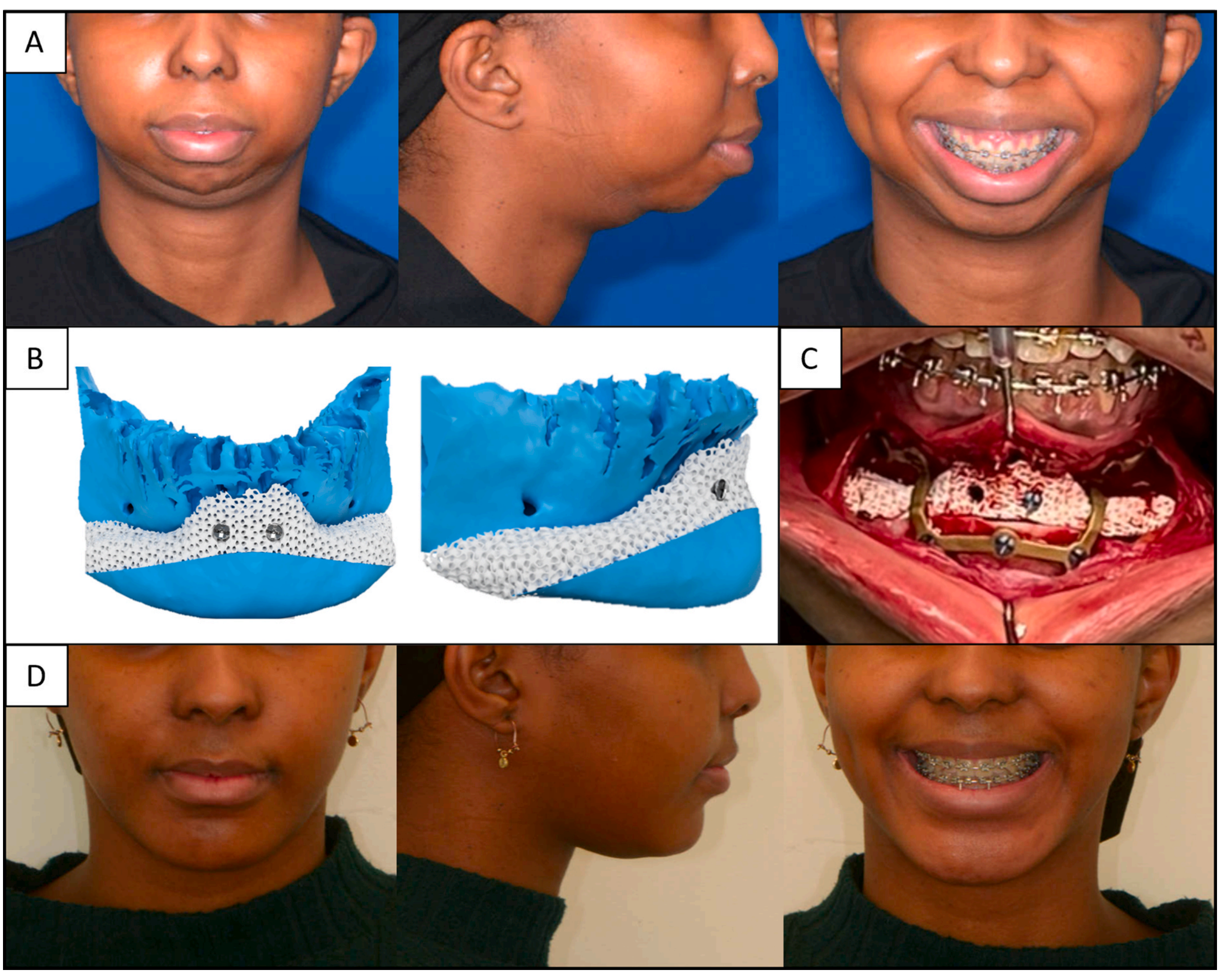

Fig. 2. Genioplasty — case 1: (A) preoperative photographs of the patient; (B) preoperative planning; (C) intraoperative view of the implant; (D) 1-year postoperative photographs of the patient.

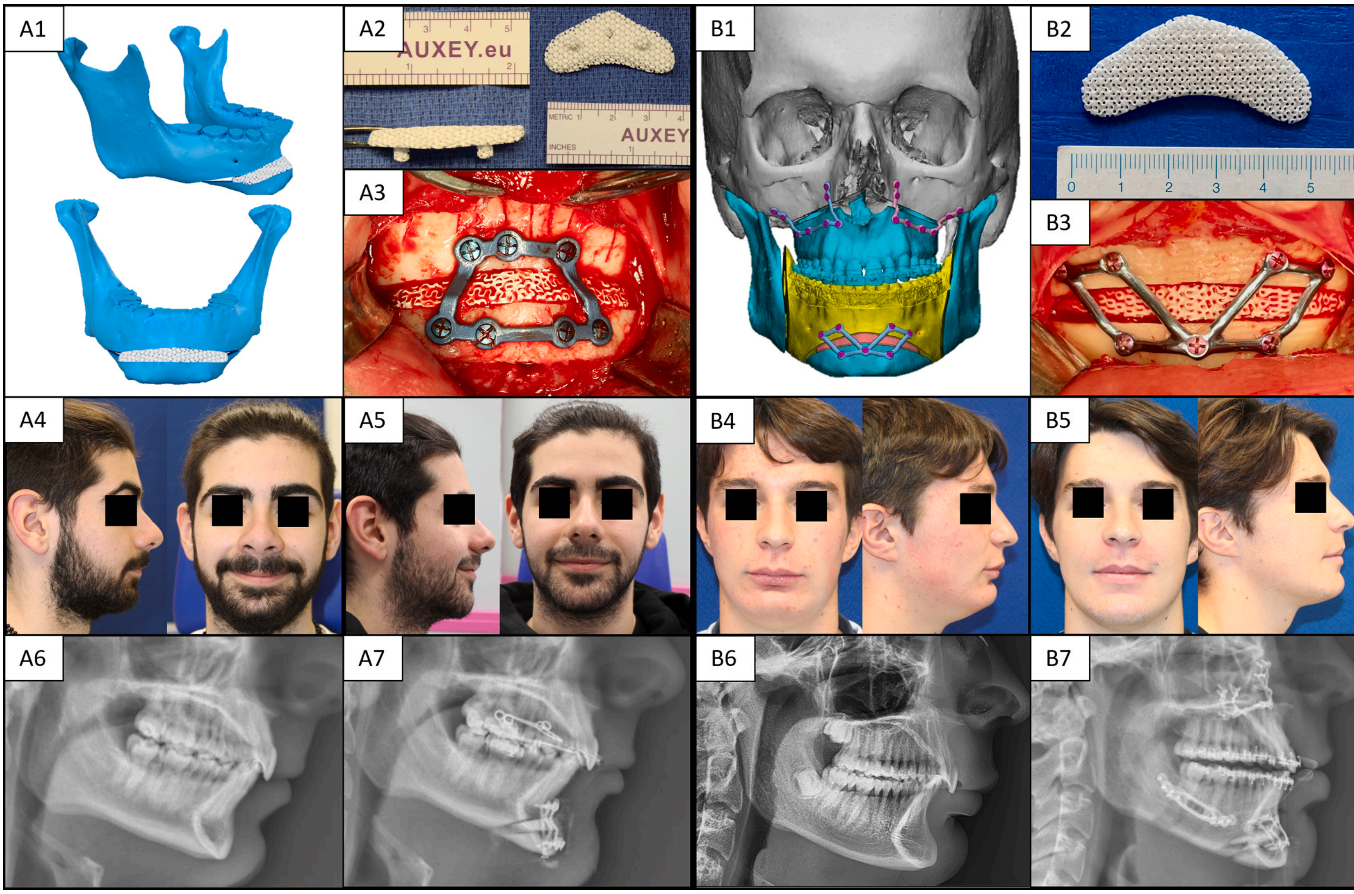

Fig. 3. Genioplasty — cases 3 and 5: (A1 & B1) preoperative planning and the MBCIs; (A2, A3, B2, & B3) intraoperative views of the implant; (A4 & B4) preoperative photographs of the patient; (A5 & B5) 1-month postoperative photographs of the patient; (A6 & B6) RX preoperative with sagittal view, showing the chin; (A7 & B7) 1-day postoperative RX with sagittal view, showing the MBCI in place.

fix the chin fragment and maintain the overall bone and PSI stability (Fig. 3B3).

For both cases, the esthetic result was deemed satisfactory (Fig. 3A5 and B5).

2.9. *Mandibular body segmental defect — case 6*

A 47-year-old man presented with severe mandibular pseudarthroses subsequent to mandibular fracture. The MBCI was initially designed to fit the mandibular defect (Fig. 4A). However, the intraoperative scenario differed from the preoperative planning. The external fixator, used to maintain the mandibular segments in place, moved and the two bone extremities joined, modifying the space left for the HA-PSI. The surgeon reshaped the MBCI to fit the new anatomical situation. A titanium mandible plate was added to secure the HA-PSI between the two bone segments (Fig. 4B and C). Cutaneous cervical access was chosen over an intraoral route to avoid contamination from the oral flora and damaging the weakened mucous membrane.

At the 3-month postoperative follow-up, the patient presented with mouth pain and edema, but no signs of exposure or infection were observed. At the 10-month follow-up, the HA PSI was slightly mobile and extensively exposed in the oral cavity, requiring subsequent removal. Remarkably, the patient did not report pain, and no infection signs were visible.

The failure of this bone reconstruction was probably multifactorial. Ambitious reconstruction involving scarred tissues, previous osteitis, and proximity to the dental root were a challenge from the start, which was worsened by tobacco abuse and poor buccal hygiene. This postoperative complication emphasized the importance of placing the MBCI in a healthy environment, with hermetic soft-tissue coverage. Therefore, removing any teethth that could be in contact with the MBCI is advised.

2.10. *Mandibular angle apposition — case 7*

A 26-year-old male patient presenting with mandibular asymmetry underwent an HA-PSI reconstruction procedure for mandibular apposition. The MBCI was designed to incorporate a posterior screw, oriented perpendicular to the bone graft for transjugal fixation, as well as an anterior screw, angled for buccal fixation. Additionally, three screw holes were included as backup for potential reinforcement during fixation. To facilitate placement and fixation, the MBCI was divided into two parts (Fig. 5A). During the surgical procedure, the vestibular cortical was slightly abraded with a drill to favor osteointegration. Then the two parts were positioned subperiosteally, and the anterior part was securely fixed via buccal access. Subsequently, the posterior part was fixed via the transjugal route. An additional hole was drilled in the anterior part using a 2.0 mm drill bit, and a new screw (Ø 2.0 mm) was inserted to achieve the desired stability. Xenograft particulates (BioOss; Geistlich, Roissy, France) and a platelet-rich fibrin (PRF)-type blood centrifugation mixture were used to remove the step between the bone and the anterior end of the HA-PSI.

At the 1-week postoperative follow-up, the patient exhibited edema and reported some residual pain in the masseter during mastication. Both are expected outcomes related to the surgical approach used. One way to avoid using the transjugal route would be to use an angled screwdriver.

The esthetic result (Fig. 5D) was satisfactory, although complete correction of facial asymmetry was not achieved due to chin deviation

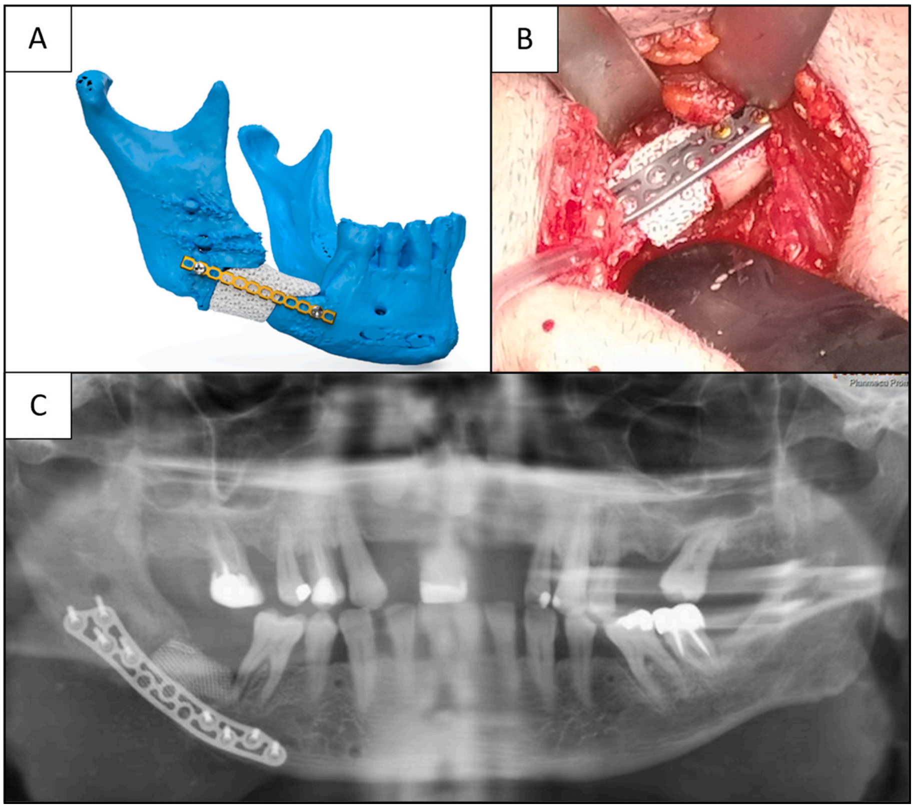

Fig. 4. Mandibular reconstruction — case 6: (A) preoperative planning; (B) intraoperative view of the MBCI; (C) 7-week postoperative RX, showing the MBCI in place.

and a slightly tilted occlusal plane. This result was expected and consistent with the surgeon's expectations, and the patient expressed overall satisfaction. The patient preferred to proceed only with the mandibular angle correction in the first phase, allowing simpler post-operative follow-up and a possibility of genioplasty in a second phase if necessary. The other possibility, refused by the patient, was bimaxillary orthognathic surgery necessitating an orthodontic treatment and more restrictive postoperative follow-up, notably regarding nutrition.

2.11. Zygoma segmental defect — case 9

A 56-year-old male patient presented with a dislocated right zygomatic fracture involving the orbital floor, resulting from craniofacial trauma. The patient had previously undergone open reduction and internal fixation. An MBCI was used for a second reconstructive surgery to reposition the right zygomatic complex. Mobilization of the right zygomatic complex involved four osteotomies: frontozygomatic process, infraorbital rim, lateral sinus, wall and zygomatic arch. The MBCI was designed to incorporate two screw fixations in contact with the patient's maxilla and zygoma (Fig. 6A). A space on the superior area of the MBCI was left to allow passage for the infraorbital nerve. The screw placement was guided using a drilling guide. The MBCI was fixed using a 7 mm self-tapping screw (Ø 2.0 mm) on the medial side of the graft, anchoring it to the lateral sinus wall. Patient-specific plates (KLS Martin, Huizen, Netherlands) were used to fix the bone segments after osteotomies and repositioning (Fig. 6B and C).

The MBCI was carefully covered by periosteum and the wounds were closed tightly. The repositioning of the zygoma complex along with the placement of the MBCI successfully restored the projection of the zygoma. Osseointegration signs were visible on the edges of the MBCI in contact with the patient's bones when comparing the immediate and 6-month postoperative scans (Fig. 6D and E). Additionally, the comparison between the 6-month and 1-year postoperative scans (Fig. 6E and F) showed an increase in osseointegration and additional bone formation around the MBCI.

2.12. Zygomatic bone augmentation — case 10

A 33-year-old female patient presenting with a pronounced medial face hypoplasia underwent HA-PSI reconstruction for zygomatic augmentation (Fig. 7A) through a placement via Le Fort I and bimaxillary orthognathic surgery. Each MBCI was designed to contain one screw (Ø 2.0 mm) fixation (Fig. 7B).

In this case, the use of an MBCI allowed us to avoid performing a Le Fort III, which is a complex procedure associated with morbidity and requiring significant postoperative care (Schlieder and Markiewicz, 2022).

2.13. Anophthalmic socket syndrome — case 12

A 50-year-old male patient diagnosed with anophthalmic socket syndrome underwent HA-PSI reconstruction to restore the internal volume of the right anophthalmic orbit and improve the prosthetic eye positioning. The MBCI was designed to contain one screw fixation (Fig. 8A and B).

During the surgery, the MBCI volume was reduced by milling due to overly ambitious planning. During the screw placement, a small portion of the HA-PSI fractured, necessitating the creation of a new hole. However, this was successfully accomplished with ease, and the final stability was achieved with one screw (Ø 1.5 mm).

By the 6-week follow-up, no complications were reported, the surgical wound had healed well, and the esthetic result was satisfactory, with a notable improvement in the palpebral fold esthetic. The eye appeared less hollow and had enhanced support from the ocular orthosis. According to the surgeon, the result obtained was at least as good as what could have been achieved with alternative materials, such

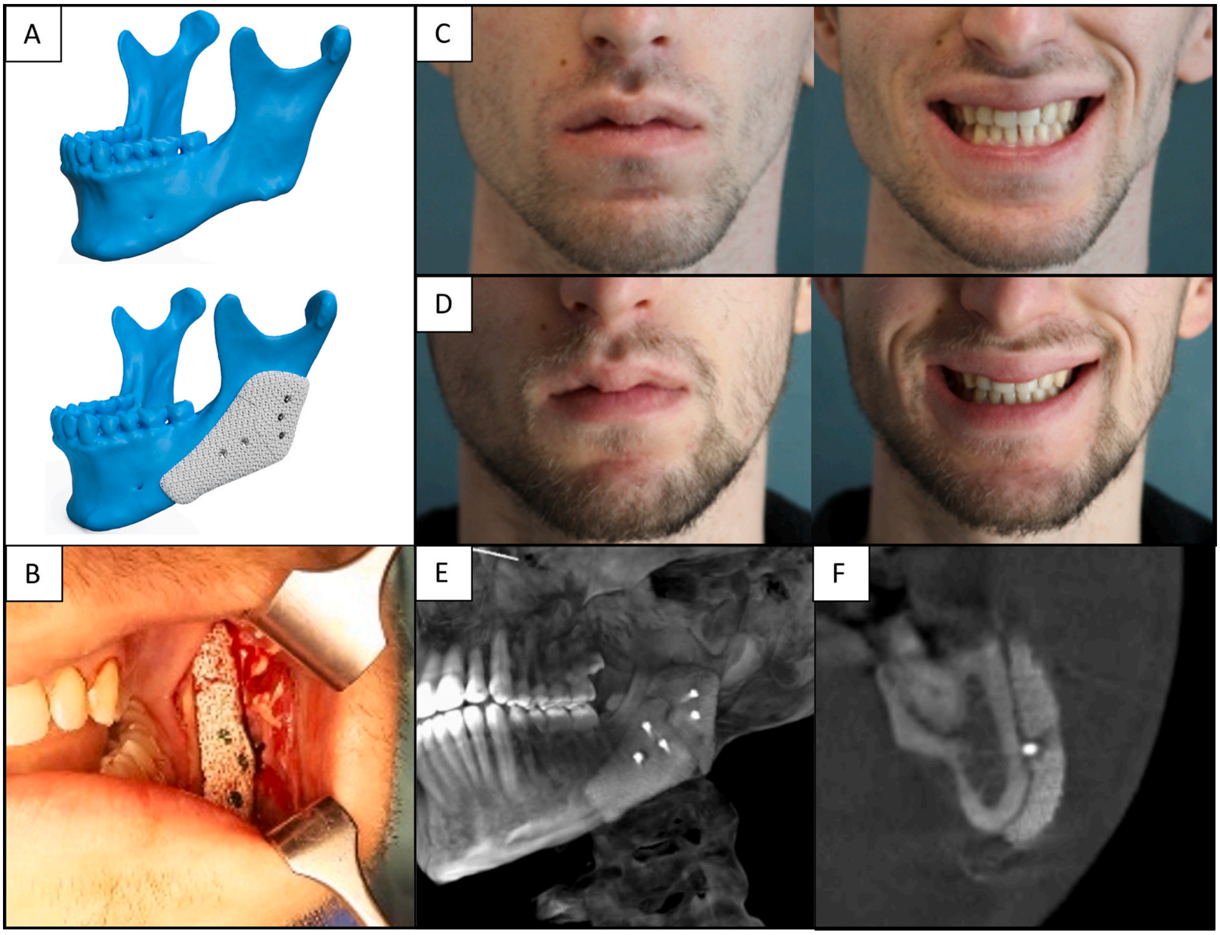

Fig. 5. Mandibular augmentation — case 7: (A) 3D reconstruction of the defect and the planned HA-PSI; (B) intraoperative view of the MBCI; (C) preoperative photographs of the patient; (D) 1-month postoperative photographs of the patient; (E &F) postoperative cone-beam CT with sagittal and coronal views, respectively, showing the MBCI in place.

as titanium or PEEK. Additionally, osseointegration signs were visible on the edges of the MBCI in contact with the patient's bone on the 6-month postoperative scan (Fig. 8C).

2.14. *Simultaneous orbital floor and zygomatic bone reconstruction — case 13*

A 52-year-old male patient with a history of zygoma fracture presented with left zygomatic asymmetry and enlargement along with slight asymmetry of the left orbital floor. The patient refused the classical zygomatic osteotomy and expressed a preference for HA-PSI over porous titanium due to previous observations of poor tolerance and inflammation experienced with titanium plates.

The MBCI for the orbital floor was designed to contain one screw fixation (Ø 2.0 mm) (Fig. 9A). The MBCI for the zygoma was designed to contain two screw fixations (Ø 1.6 mm). Palpebral and buccal access were employed for the orbital floor and zygomatic bone reconstruction, respectively. The positioning and fixation of the zygoma implant were relatively easy while the orbital floor implant required more surgical manipulation. The latter broke during placement and was replaced by the duplicate, which was successfully fixed but remained slightly unstable. Consistency between the preoperative planning and the postoperative result was very satisfying, as shown in Fig. 9D.

According to the surgeon's assessment, using the MBCI saved approximately 2h of surgery compared with classical zygomatic osteotomy.

At the 10-week follow-up, the patient reported an improvement compared with the previous intervention, although some pain and slight scleral show remained. The latter was partially due to the scarring reaction from the mediopalpebral approach necessary for removing the previous osteosynthesis material. Additionally, the patient reported the disappearance of the associated cephalgia and cervicalgia (attributed to the preoperative diplopia), which was his main request.

3. Discussion

PSIs have been extensively discussed in the literature, particularly in the context of maxillofacial bone reconstruction due to the complex anatomy and the importance of esthetic and functional outcomes for the patient (Alasseri and Alasraj, 2020; Scolozzi, 2012). Their higher costs compared with conventional techniques are often leveraged by their numerous advantages (Rodríguez-Arias et al., 2022), such as reduced surgical time (Rodríguez-Arias et al., 2022; Rubio-Palau et al., 2016; Scolozzi, 2012), which minimizes the risk of infections (Rodríguez-Arias et al., 2022; Shilo et al., 2018), and the precise fitting (Alasseri and Alasraj, 2020), which offers stable fixation (Alasseri and Alasraj, 2020; Thayaparan et al., 2021) and optimal bone contacts, contributing to faster healing (Charbonnier et al., 2021). Furthermore, preoperative planning enables the preservation of the surrounding tissue, such as neurovascular structures (Rubio-Palau et al., 2016; Vidal et al., 2020).

These features contribute to improved surgical outcomes on multiple fronts, not to mention enhanced functional restoration and esthetic results — critical considerations in maxillofacial surgery that can profoundly impact a patient's self-esteem and overall quality of life

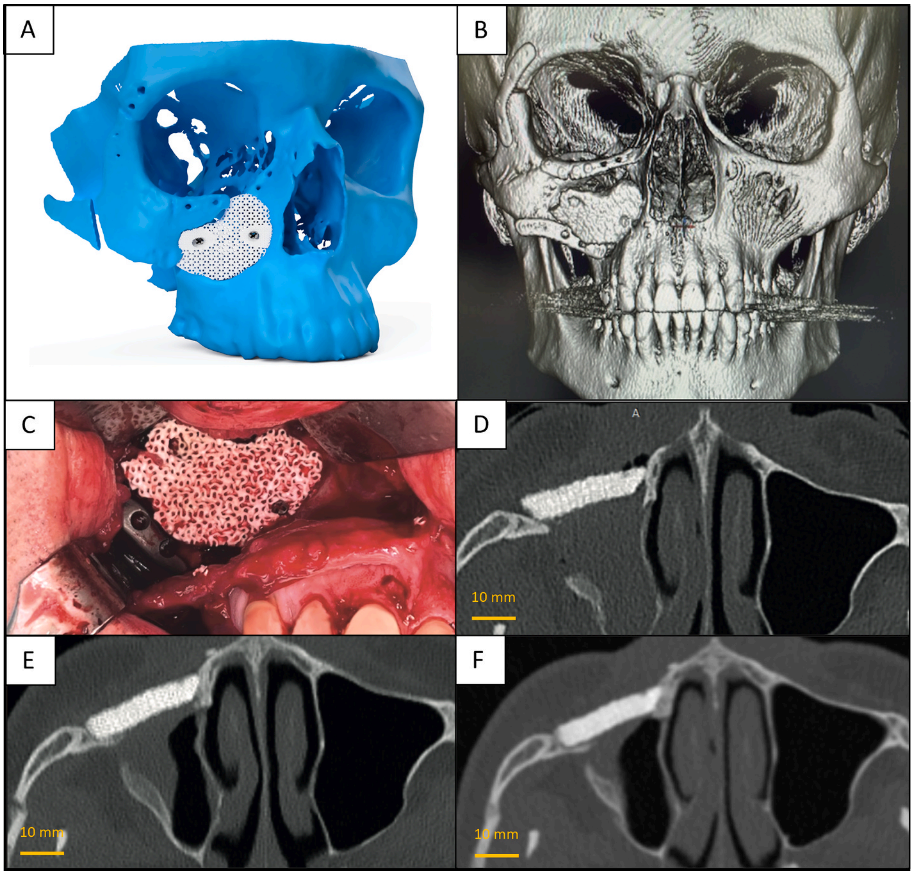

Fig. 6. Zygomatic fracture — case 9: (A) preoperative planning (MBCI only); (B) 3D view of the patient facial bones 1-day postoperatively, showing the PSI in place; (C) intraoperative view of the MBCI; (D–F) 1-day, 6-month, and 1-year postoperative CT scans, respectively, showing the MBCI in place and evidence of osteointegration on the edges.

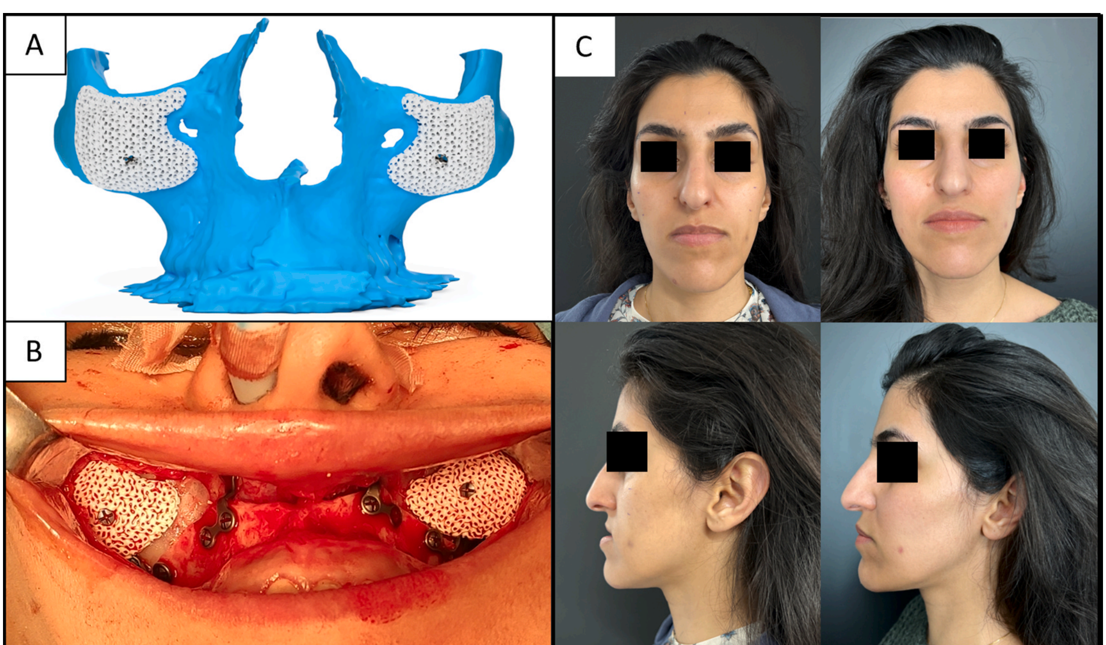

Fig. 7. Zygomatic augmentation — case 10: (A) preoperative planning; (B) intraoperative view of the implants; (C) postoperative photograph prior to the surgery (left) and 6 months postoperatively (right).

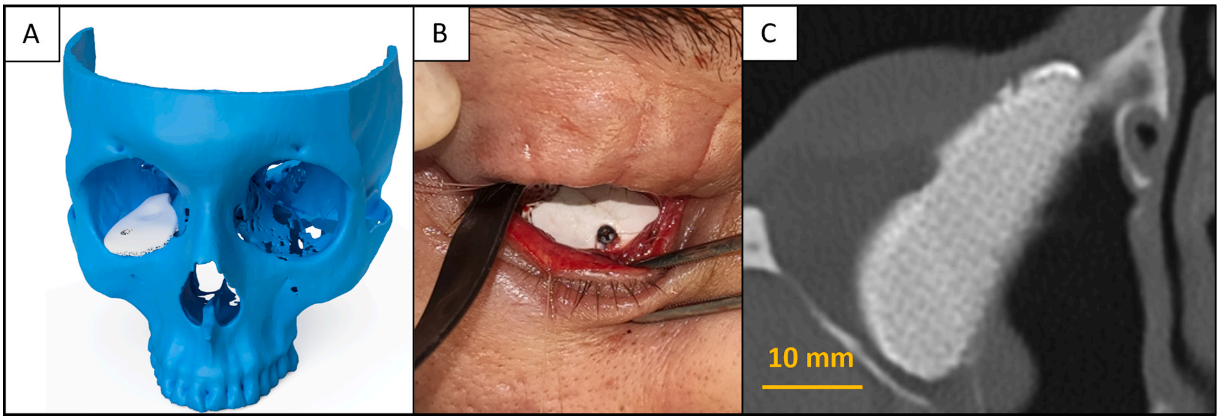

Fig. 8. Orbital floor reconstruction — case 12: (A) preoperative planning; (B) intraoperative view of the MBCI; (C) CT scan (sagittal view) of the MBCI at 6 months postoperatively.

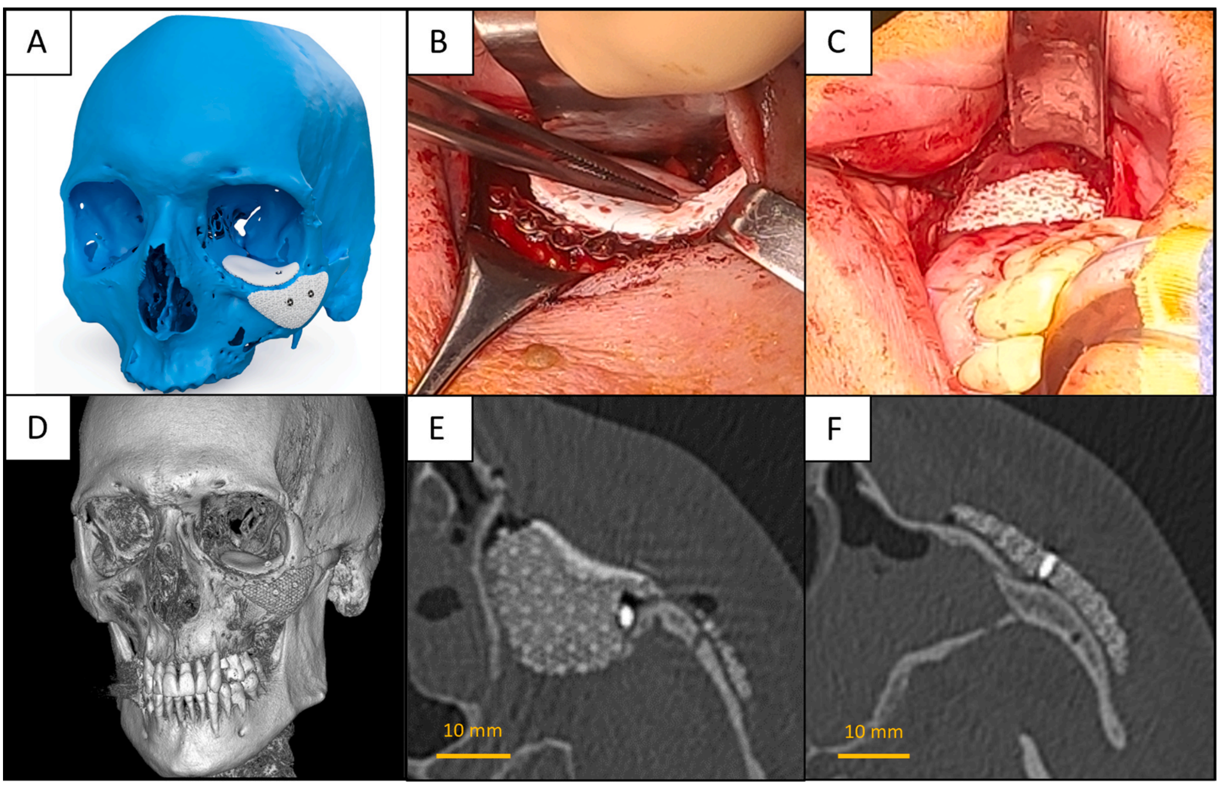

Fig. 9. Zygomatic and orbital floor augmentation — case 13: (A) preoperative planning; (B) intraoperative view of the orbital floor implant; (C) intraoperative view of the zygomatic implant; (D) 3D reconstruction of the immediate postoperative situation; (E & F) immediate postoperative axial views of the orbital MBCI and the zygoma MBCI, respectively.

(Alonso-Rodriguez et al., 2015; Thayaparan et al., 2021). The ability to present the patient with an anticipated esthetic outcome prior to the actual surgery is another valuable aspect of PSIs.

HA PSIs offer additional features that cannot be achieved with other alloplastic PSI materials, such as Medpor, PEEK, or titanium. First, HA possesses a composition similar to mineral bone (Hou et al., 2022) which makes it highly biocompatible and a long-term solution, since it will turn into bone (Kattimani et al., 2016). Unlike Medpor, PEEK and titanium will remain as foreign materials (Shilo et al., 2018) that may need to be removed at some point.

HA bone grafts have been commercialized for over 40 years, and have continued to demonstrate relevant clinical evidence regarding their long-term safety and efficacy as particulate bone grafts, bone cements, or cranial plates (Habraken et al., 2016; Hou et al., 2022; Kattimani et al., 2016; Moreira Filho et al., 2021; Wang and Yeung, 2017). This was confirmed in our study by the absence of reported adverse reactions from the material, which contrasts with titanium, for which allergic reactions and poor tolerance have been described in the literature (Kim et al., 2019). Titanium can also lead to discomfort with heat and cold sensation, depending on the weather (Ghantous et al., 2020; Spetzger et al., 2010). With regards to PEEK, very few adverse events have been reported, although in one study paresthesia was observed in six out of 24 patients (Järvinen et al., 2019). The long-term effects of this relatively new material have yet to be fully demonstrated. Lastly, cases of foreign body reaction have been reported with Medpor (Gosau et al., 2008; Vollkommer et al., 2019), but more extensive studies have reported low overall complications rates (French et al., 2020; Ridwan-Pramana et al., 2015).

None of the patients in this case series experienced infection, which is the most common complication of facial implants (Rayess et al., 2018), even though intraoral access was used in 77 % of the patients. In the literature, infection rates for PEEK PSIs have been reported at 8.3 % (24 patients), 14.3 % (14 patients), and 7.7 % (65 patients) (Järvinen et al., 2019); regarding Medpor, an infection rate of 27 % has been reported in cases of mandibular augmentation compared with 7.3 % globally (Ridwan-Pramana et al., 2015). A comparative study on titanium, PEEK, and HA PSIs for cranioplasty revealed higher rates of infection and subsequent explantations with titanium and PEEK, compared with HA (Morselli et al., 2019).

One patient in this case series presented with exposure of the PSI, which led to the material's removal. The potential reasons for the exposure have been discussed previously. Of note, it was the only MBCI that was placed directly under the mucosa of the buccal area. The infection was not the cause of the exposure, and probably took place after it — as an inert material close to the bacteria-laden buccal area, slight contact with those bacteria can rapidly lead to colonization of the HA-PSI.

The osteointegration capability of the MBCI differentiates it from Medpor and PEEK PSIs. The body tolerates the latter well, but the lack of osteoconductive properties (Gunatillake and Adhikari, 2016; Kwarcinski et al., 2017; Persson et al., 2018) makes them more prone to biofilm formation (Sarfraz et al., 2022). Additional surface treatments are necessary to improve their bonding with bone cells (Dondani et al., 2023), yet they never reach the same level of osteointegration as HA. Titanium implants present osteointegration properties (Kwarcinski et al., 2017), but these are usually improved by an HA coating (Chamrad et al., 2021).

Aside from the intrinsic osteointegration properties of HA, MBCI osteointegration is enhanced by its interconnected macroporosity, based on gyroids (TPMS), which allows fast and significant bone growth (Bouakaz et al., 2023; Charbonnier et al., 2020, 2021; Van Hede et al., 2022; Paré et al., 2022). Available postoperative scans (cases 9 and 12) demonstrated the first signs of MBCI osteointegration at 6 months postoperatively and a continuing osteointegration process after 1 year.

From the medical imaging perspective, MBCI enables more precise and accurate evaluation than the other PSIs. Unlike titanium, which introduces artifacts (Spetzger et al., 2010), and Medpor and PEEK, which are translucent (Khorasani et al., 2018; Nieminen et al., 2008), HA presents the same radiopacity as bone, enabling easy positioning and osteointegration assessment on CT scans or X-rays (Brie et al., 2013; Staffa et al., 2012). Additionally, the porosity of the MBCI is visible on the CT scans, as highlighted for cases 9 and 12, and will allow us to measure the evolution of osteointegration deeper inside the material. This is in contrast with other ceramic PSIs, such as CustomBone (Finceramica, Faenza, Italy), which has a denser structure that hinders analysis of ossification by radiological images (Hardy et al., 2012).

Since all these PSIs are being made of different types of material, and manufactured by different types of technology, their prices vary accordingly. Moreover, a precise price comparison is difficult due to the cost variability among countries (Goodson et al., 2021), varying PSI sizes, and the lack of maxillofacial PSI price details in the scientific literature and public databases. However, it is generally accepted that polyethylene (e.g. Medpor) is the cheapest material (Paxton et al., 2019). As is the case for porous HA-PSI, the prices for PEEK and titanium can vary greatly depending on the size and design (Goodson et al., 2021; Haroun et al., 2023; Sarfraz et al., 2022). Nevertheless, cost comparisons relating to the use of different PSIs should be calculated holistically, taking into account surgery duration and postoperative care costs.

Concerning the overall surgical process when using MBCIs, this does not differ from the surgical steps conducted with the other PSIs, thus simplifying its acceptance by the medical community. Nonetheless, with regards to genioplasty, this is generally conducted without the use of a bone substitute material, leaving a gap that will remodel and disappear on its own (Chan and Ducic, 2016). In these cases, MBCIs improve the surgery outcomes, enabling better stability of the chin fragment and a more predictable esthetic result. As for titanium, Medpor, or PEEK PSIs, since these remain as foreign materials, they are more often used as onlays. However, there are some reports on the use of porous titanium and Medpor for segmental zygomatic (Le Clerc et al., 2020; Düzgün and Sirkeci, 2020) and mandibular bone reconstructions (Haroun et al., 2023).

HA-PSI also facilitates intraoperative adjustments, such as additional screw placements or shape modifications, as presented for cases 6, 7, and 12 in this study. While PEEK and Medpor allow for some degree of adjustment (Järvinen et al., 2019; Shilo et al., 2018), titanium implants pose difficulties in this regard (Kwarcinski et al., 2017; Shilo et al., 2018). On the other hand, HA-PSI workability makes it susceptible to fracture during placement or fixation. This occurrence was observed in some clinical cases in this study, although it never impeded the completion of surgery. As long as stability can be achieved, fractured parts of the HA-PSI can remain in place because they become integrated with the bone. Notably, no postoperative fracture was reported.

Once in place, MBCIs are protected from bending and present sufficient compressive strength. Additionally, the mechanical strength of porous HA implants increases with their osteointegration (Doi et al., 2016). Nevertheless, minimizing the HA-PSI fragility can be achieved by improving the PSI design to avoid weak areas and by increasing the HA density to increase its intrinsic mechanical strength (Trzaskowska et al., 2023).

These improvements can be sufficient for the clinical indications presented in this study. However, for large segmental mandibular bone reconstruction, for instance subsequent to tumor removal, the masticatory stresses that need to be sustained are very high. Porous HA-PSI will require extensive additional osteosynthesis material to ensure short- and mid-term stability, and to leverage the mechanical stresses. Osteosynthesis could be removed partially or totally afterwards, depending on the level of osteointegration achieved.

Nonetheless, HA-PSIs present an advantage for extensive maxillary and mandibular bone reconstruction in cases of dental rehabilitation. Dental implant placement in PEEK or Medpor is not feasible, since good osteointegration is necessary. Although the use of porous titanium PSIs is conceivable, it necessitates careful planning during the implant's design, since no modification will be possible (Haroun et al., 2023). In contrast, HA-PSIs allow for the drilling and placement of dental implants once they have achieved sufficient osteointegration. This characteristic offers considerably more flexibility in dental rehabilitation compared with the use of titanium implants.

Regarding dental rehabilitation, MBCI is also of great interest for alveolar ridge augmentation. Currently, vertical (as well as horizontal) bone augmentations remain a challenge. Xenograft, whose main component is hydroxyapatite, and synthetic HA are conventionally used materials for alveolar bone regeneration (Zhao et al., 2021). For this indication, HA-PSI would allow a more predictable bone augmentation while avoiding recourse to autograft (Blume et al., 2023; Perez et al., 2023). This will be the subject of a forthcoming publication, with experiments that focus on the use of MBCI for alveolar bone regeneration having already been conducted.

Limitations of this study included the low number of patients, the retrospective design, and the short follow-up periods for some of the cases. Although osteointegration signs were already detected at 6 months, this could be investigated further. Performing histological biopsies to study new bone formation is likely to be unacceptable for most patients; however, continuing the analysis with CT-scans over a longer period would generate interesting data regarding long-term osteointegration and bone remodeling inside and around the MBCI. Therefore, this study needs to be extended using clinical trials. The latter would also be useful to further compare MBCI with the other PSIs — made of titanium, PEEK, and porous polyethylene — with regard to intraoperative aspects, surgery outcomes, and costs.

4. Conclusion

To the best of our knowledge, this was the first study to report the use of porous 3D-printed hydroxyapatite PSIs for a wide range of patient-specific maxillofacial bone defect reconstructions.

Hydroxyapatite overcomes several drawbacks of PEEK and Medpor, such as lack of osteointegration and radiolucency, and titanium, such as cold/heat sensation, imaging artifacts, and impossible intraoperative modifications. In addition to these features, the main advantage of MBCI is its composition (similar to the mineral bone) and interconnected porosity, allowing significant osteointegration and colonization by new bone, while the other PSIs will remain as foreign materials.

This study provides evidence for the useful application of MBCIs for several maxillofacial applications (genioplasty, zygomatic and mandibular bone reconstructions, orbital floor reconstruction), both for apposition and segmental reconstruction. Signs of osteointegration were observed at 6 months and 1 year postoperatively, although patient follow-ups should be continued to investigate the evolution of osteointegration with time. The results pave the way for using MBCIs at larger scales. This will be further supported by subsequent studies on alveolar bone augmentation associated with dental implants.

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Declaration of competing interest

EC is a CERHUM employee. J-LN and GN have direct ownership in CERHUM. The other authors have no conflicts of interest.

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