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TECHNICAL NOTE

An innovative orbital implant positioner for the proper restoration of eye-socket defects

Marco Mandolini[1] · Agnese Brunzini[1] · Manila Caragiuli[1] · Alida Mazzoli[2] · Mario Pagnoni[3]

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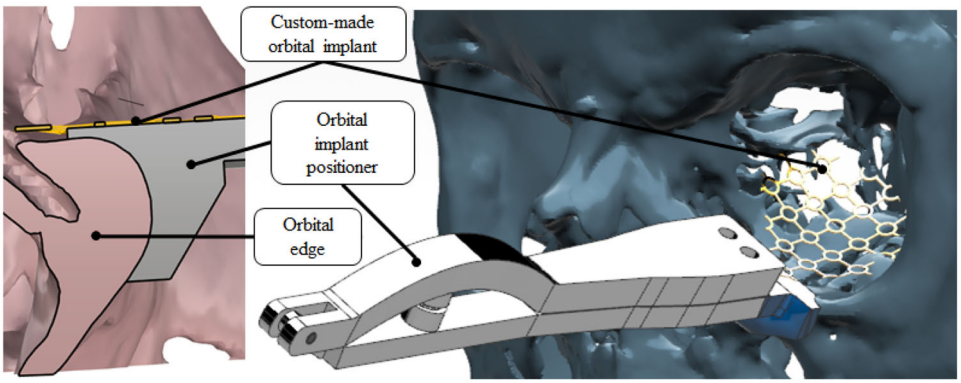
Graphic abstract



Fractures to the orbital walls and floor must be appropriately managed to avoid severe conditions. This results in particularly challenging anatomical reconstructions. The main issues are the implant's proper shaping, placement, and orientation onto the eye socket. A new, customized implant-shaping mould has already been developed to shape patient-specific implants. However, it still does not address the implant positioning in the fractured orbital cavity. This present research aims to design, develop, and assess an innovative implant positioner to be used with the optimized version of the aforementioned implant-shaping mould. The new medical device was designed to be used with titanium meshes and deantigenated bone implants. It is easy to use, has a low cost, and is reusable several times. It is composed of (1) two coupled and hinged handles that allow the grasping of the implant, and (2) the positioner itself that permits proper implant placement and orientation. Selective laser sintering was used to print the mould and the new device in polyamide. Promising results for implant shaping, positioning, and orientation accuracy were obtained. An accuracy of 0.1 mm and 1.3 mm was, respectively, achieved for the implant shape and its placement in the mediolateral direction. The mean malrotation angle around the orbital rim was about 6°.

✉ Marco Mandolini
m.mandolini@univpm.it

[1] Department of Industrial Engineering and Mathematical Sciences, Università Politecnica Delle Marche, Via Brecce Bianche 12, 60131 Ancona, Italy

[2] Department of Materials, Environmental Sciences and Urban Planning, Università Politecnica Delle Marche, Via Brecce Bianche 12, 60131 Ancona, Italy

[3] yourFACE, Clinica Ars Biomedica, Via Luigi Bodio 58, 00191 Rome, Italy

Introduction and literature review

Facial bone fractures are related to the orbital walls and floor and often involve damage to the contents and soft tissues of the eye socket [1]. These fractures may lead to several conditions [2], such as severe functional impairment that must be managed appropriately [3].

Every surgical approach requires implants that are inserted within the orbital cavity to restore the skeletal cavity, orbital volume, functionality, and aesthetics of the eye [4]. Thus, the implant must guarantee an accurate approximation of the orbital bones, restore extraocular muscle functionality, and it must not increase the rate of surgical complexity [5].

The ocular prosthesis is critical for adequate volumetric repair. One of the main problems in designing well-fitting orbital prostheses is the obtaining of an accurate midfacial plane to restore facial symmetry [6]. Among non-resorbable synthetic alloplastic materials, high-density porous polyethylene and titanium are the easiest to handle. They allow the achieving of precise three-dimensional (3D) anatomical reconstructions. For this reason, they are frequently used in manufacturing implants for the orbital floor [7]. Despite the use of many surgical techniques and implant materials, the limited intraoperative view makes anatomical reconstruction challenging [7].

Tailored implants are necessary for the precise restoration of an orbital defect. For such implants, computer-aided design and additive manufacturing techniques are needed [8, 9]. Kwon et al. [10] proposed a 3D-printed patient-specific guide made of a template and a press to shape an orbital wall implant. The solution can provide an accurate surgical implant shape. Nevertheless, implant placement is still crucial for successfully restoring the pre-injury symmetry and shape of the fractured floor. Schreurs et al. [11] developed an instrument for orbital implant positioning consisting of a coupling device, a spring-loaded retractor, and an insertion handle. The tool was tested on 10 human cadavers showing a reduction in rotational deviation to a visual approach based on the surgeon's expertise. The use of intraoperative navigation can improve the accuracy of implant positioning by moving a trackable pointer along the implant contour. At the same time, its position is compared to the preoperative plan. Zong et al. [12] compared the reconstruction of an orbital wall fracture using a computer-assisted navigation system (CASNS) and a conventional freehand method. A navigation probe enabled the surgeon to verify whether the position of the implant matched the preoperative plan. The mean surgery time was not significantly different in the two groups because the time required for the registration process was recovered by rapidly assessing the correct implant location. The CASNS provided a more significant restoration of the orbital cavity volume and an accurate reconstruction of the orbital wall. In another study, Schreurs et al. [13] embedded the implant-positioning instrument with reflective markers for a real-time assessment of the orbital implant position during implant insertion. The procedure improved the accuracy of implant positioning and decreased the duration of the navigation time and the number of implant-fitting trials since feedback on implant positioning is provided during the implant insertion and not only afterwards. Despite these benefits, the expense of the equipment required for intraoperative navigation limits its availability. Thus, a freehand approach is still commonly practised relying on the surgeon's expertise in orbital reconstruction [14].

Mandolini et al. [6] have already developed a patient-specific mould for implant shaping. However, it still does not address the correct placement of the prosthesis in the orbital cavity. However, implant positioning is crucial in restoring anatomical shape and symmetry. For this reason, our research aims to design and develop an innovative device for correct and accurate implant placement and orientation onto the fractured orbital floor. Besides, the functionality of the customized implant-shaping mould is optimized. The implant positioner was designed to simplify and speed up the surgical procedure. Proper implant positioning and fitting also reduce the surgery failure rate and improve a patient's comfort and satisfaction.

Materials and methods

The underpinning methodology used for developing the medical device is a simplified version of the engineering design approach presented in Haik et al. [15]. The paper presents the procedure for conceiving, designing, prototyping, and validating the medical device. This methodology applies to fractures of orbital cavities (walls and floor).

1. *Implant design*: 3D modelling of the (floor or wall) orbital implant was carried out by employing the mirroring imaging technique, which consists of mirroring the healthy side of the skull over the contralateral part. The design procedure, described in [6], applies only to unilateral defects that do not cross the midline, such as orbital fractures [16]. Here the resulting shape is larger than [6] because a small "tongue" must be added to grasp (and orient) the implant through the positioning device (Fig. 1b).
2. *Mould design*: 3D modelling of the system was used for realizing the implant. This device, which allows the deforming of a sheet of biocompatible material, is used by the surgeon during surgery. The equipment comprises a die and a punch whose deforming surfaces reflect the implant shape [6, 8]. Here the mould possesses a new feature to constrain the implant during its deformation (Fig. 1b). It consists of two small pins whose diameter and interaxial distance depend on the implant pattern.

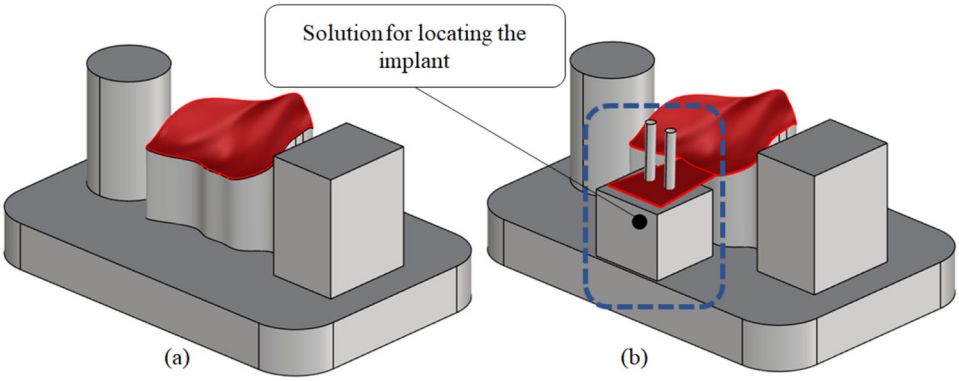


Fig. 1 Implant and mould die in the original (**a**) and the new design (**b**)

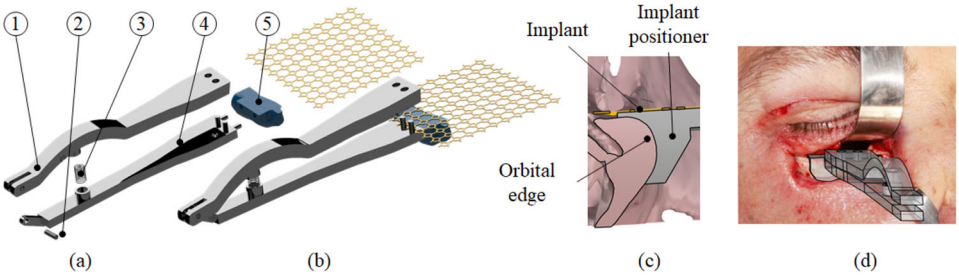


Fig. 2 **a** Medical device exploded, **b** assembled, and **c** cross-section views; **d** simulation of the medical device for a transcutaneous approach (① upper handle; ② pin; ③ spring; ④ lower handle; ⑤ positioner)

The pins and the flat surface of the die define the reference system required to orient the implant into the orbital cavity through the positioner.

3. *Implant positioner conceptualization and design*: device development from the users' requirements—identification to detailed design [15]. Users' requirements were defined through a specific questionnaire distributed among 23 practitioners. The most relevant requirements were biocompatibility, cost, sterilizability, safeness, corrosion-resistance, suitability for orbital floors/walls and deantigenated/titanium implants. The quality function deployment (QFD) method defined the technical specifications. Multi-functionality, production cost, and weight were the three most relevant specifications. Out of eight concepts developed by three design teams, two were selected (and integrated into a single idea) for the following embodiment design phase that is presented in the next section.
4. *Physical prototyping*: 3D printing of the mould, device, and orbital cavity through a powder-bed process. Physical prototypes were used to validate the presented procedure (Sect. Physical prototyping).
5. *Validation of the approach*: experimental tests to assess the accuracy of the implant shape (obtained from the mould) and position/orientation (positioned into the orbital cavity by the positioner). The first goal was to assess the difference between the implant's nominal (designed) and actual (shaped) surfaces. The second goal was to evaluate errors in placing the implant within the orbital cavity (linear and angular deviation). Section Results and discussion presents the validation process in detail.

Implant positioner conceptualization and design

The product concept that solves the design problem consists of five components (Fig. 2a). Two handles (1 and 4), which rotate around a pin (2), are used by the surgeon to grasp the device. A compression spring (3) keeps the device open (Fig. 2b). When the surgeon's fingers press the device, the implant is blocked. The lower handle is designed with four small pins. The vertical pins are in contact with the implant and establish the relative orientation between the device and the implant itself. The pins' diameters and interaxial distance are dependent on the implant shape (hole pattern). The relative position and orientation between the pins and the implant are the same between the implant and the mould. In the case of implants made of deantigenated bone, the flat sheet must be drilled before it is shaped into the mould. The two horizontal pins fix the implant positioner (5). Its front shape copies the orbital rim, allowing it to uniquely place and orient the device into the orbital cavity (Fig. 2c). To guarantee accessibility in transconjunctival surgeries, the implant positioner width was set to around 22 mm. A larger positioner can be conceived of in the case of transcutaneous surgeries (Fig. 2d), or according to the patient's mediolateral orbital rim dimensions. The lower handle and the implant positioner establish the correct orientation and position of the implant inside the orbital cavity. After the surgery, the implant will

Table 1 Bill of materials of the medical device

	Qty	Material	Mass (g)	Manufacturing process	Cost (€)	Dimensions (mm)
1. Upper handle	1	AISI 316L	37	Investment casting	1.80	20×33×102
2. Pin	1	AISI 316L	0.2	Bought-in	0.10	2×2×7
3. Spring	1	AISI 316L	0.1	Bought-in	0.15	4×4×7
4. Lower handle	1	AISI 316L	27.0	Investment casting	1.50	18×30×102
5. Positioner	1	PA12	0.8*	Selective laser sintering	4.00*	13×18×22*
Total			65.1		7.55	

*Indicates values that depend on the specific device

have (theoretically) the same position and orientation as that established during pre-planning.

From a manufacturing standpoint, the device consists of standard (1, 2, 3, 4) and custom-made parts (5). The formers do not depend on the patient. Thus, it can be reused after sterilization for several patients (they need to be assembled only the first time). The implant positioner is patient-specific. It must be designed and manufactured for every patient.

Considering the shape and specifications of the device (AISI 316L stainless steel), standard parts can be bought-in or realized by employing investment casting, sintering, and machining, to allow for an affordable solution. The implant positioner can be additively manufactured in PA12 through selective laser sintering. This technology allows realizing high-precision parts (±0.3% and a lower limit of ±0.3 mm) at a low cost. The manufacturing cost was estimated using LeanCOST (Hyperlean Srl). The total cost presented in Table 1 refers to production of the first device (assembly, sterilization, and packaging are not considered). After that, because the standard components are sterilized, the cost decreases to around 4.00 € (plus the sterilization and packaging cost). Further information is available in Table 1.

Physical prototyping

A 3D printer (ZPrinter 450, by 3D systems) was used to realize the custom-made mould (Fig. 3a), the orbital implant positioner (Fig. 3b), and the skull of a patient with a floor fracture on the left orbital cavity (Figs. 3c and 3d). The latter was manufactured by merging the implant positioner with the lower handle. The device components (lower and upper handles, spring, and pin) were assembled as shown in Sect. Implant positioner conceptualization and design. A commercial flat titanium mesh (0.2 mm thick) for orbital cavities was used for the experimental tests. The implant's final shape was achieved by deforming the implant using a mould. The implant was then externally cropped to define its contour.

Results and discussion

Test 1: Implant shape accuracy

The first validation of the medical device consisted of evaluating the implant's accuracy realized through the custom-made mould and then cut to adjust its contour. Because the implant has a textured surface, to facilitate 3D scanning and acquire a continuous shape, the implant was covered with a thin layer of scotch tape (around 0.05 mm thick). A high-precision (accuracy of 40 μm) laser scanner (Range 7 by Konica Minolta) was used for digitizing the implant. CloudCompare (cloudcompare.org), an open-source 3D point-cloud and mesh-processing software, was used to compare the nominal (reference) and the scanned models after a proper alignment through the three-point and best-fitting methods. The deviation between these is given in Fig. 4. The resulting colour-coded scale describes a mean distance of about 0.1 mm (standard deviation of 0.1 mm).

Test 2: Implant position and orientation accuracy

The second validation aimed to evaluate accuracy in placing and orienting the medical device and the implant into the orbital cavity. The test plan consisted of three (Case 1, Case 2, and Case 3) fractured orbital cavities (with the related orbital implant and device), three testers (Tester A, Tester B, and Tester C) and two trials (1°, 2°) for each tester and device, for a total of 18 tests (Table 2 and Fig. 5c). Testers used the medical device to simulate implant insertion into the 3D-printed skull. The same 3D laser scanner was used for digitizing the device's position once the tester felt confident about the achieved position and orientation of the device on the orbital rim. Each tester was asked to stay still during the rapid scan (5 s long).

The surgical pre-planning geometries were aligned with the digital scans using CloudCompare. The orbital cavity shape was used to align the compared geometries. The validation consisted of assessing the accuracy in the placing and orienting of the device. The former was evaluated by

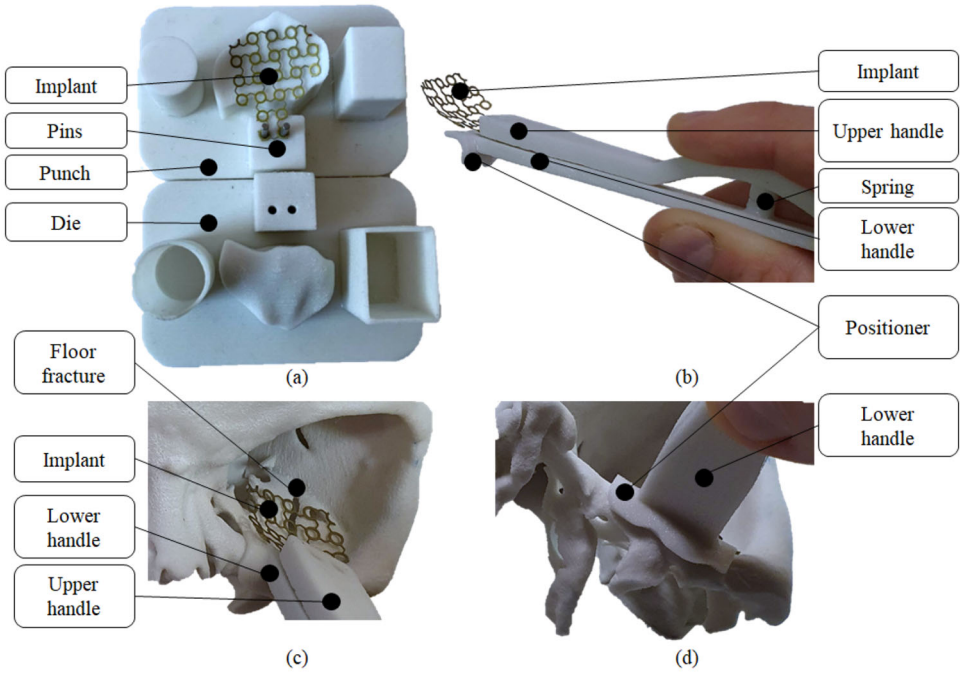


Fig. 3 **a** Mould (die and punch) and shaped implant, **b** implant positioner fixed in the implant, **c** implant placed into the orbital cavity, **d** implant positioner placed in contact with the orbital rim of the phantom skull

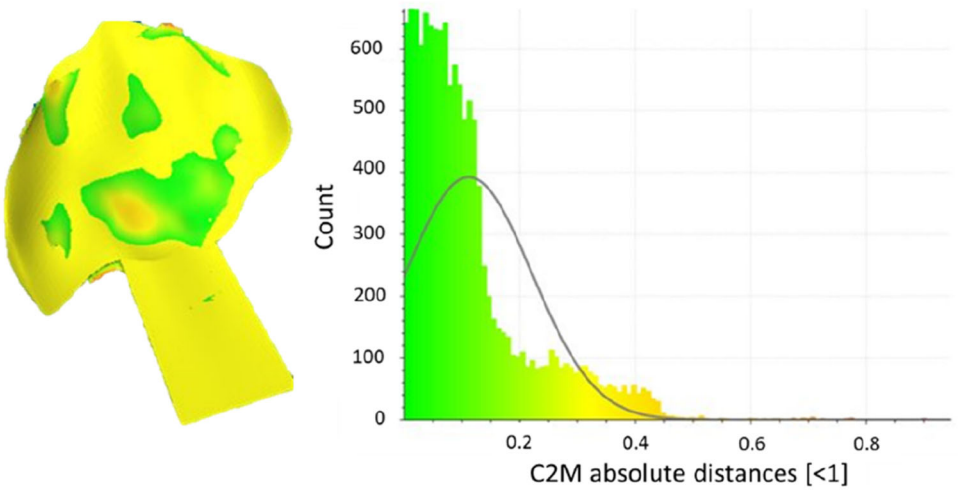


Fig. 4 Distance between the shaped implant and the reference CAD model

measuring the distance between the geometries along a direction perpendicular to the medical device axis (see measuring plane in Fig. 5a). The orientation was evaluated by measuring the angular deviation between geometries, taken on a plane perpendicular to the lower-handle face and passing through the medical device axis (Fig. 5b).

The findings are given in Table 2.

Discussion of results

The mould concept proposed in this paper deformed the implant following the patient-specific shape. The deviation is lower than 0.1 mm, unlike that in Kwon et al. [10]. They reported a mean difference in length and depth between the plate and the decompressed implant of 0.6 mm and 1.2 mm, respectively. This slight deviation is mainly due to two causes. First, the titanium mesh tends to restore its original condition once removed from the mould due to the spring-back effect. Second, the implant rotates within the mould due to the mechanical tolerances between the pins and the mesh holes. However, the implant's stability under a pressure mechanism could be improved by designing two additional pins opposite the current ones. These could firmly hold the prosthesis on both sides, reducing the spring-back effect of titanium.

Concerning the implant-positioning device developed by Schreurs et al. [11, 13], the patient-specific interface of the positioner guarantees a proper coupling at the orbital rim to

Table 2 Measurements of linear and angular deviation of the medical device

Tester	Case	Trial	Distance (mm)	Angle (°)
Tester A	Case 1	1°	1.5	4
Tester A	Case 1	2°	0.3	7
Tester B	Case 1	1°	1.0	8
Tester B	Case 1	2°	1.8	10
Tester C	Case 1	1°	1.1	8
Tester C	Case 1	2°	1.6	5
Tester A	Case 2	1°	0.9	10
Tester A	Case 2	2°	0.6	6
Tester B	Case 2	1°	3.0	5
Tester B	Case 2	2°	4.1	8
Tester C	Case 2	1°	0.4	8
Tester C	Case 2	2°	0.8	5
Tester A	Case 3	1°	1.1	4
Tester A	Case 3	2°	0.5	4
Tester B	Case 3	1°	2.0	11
Tester B	Case 3	2°	0.5	6
Tester C	Case 3	1°	0.4	1
Tester C	Case 3	2°	2.4	2
Mean			1.3	6

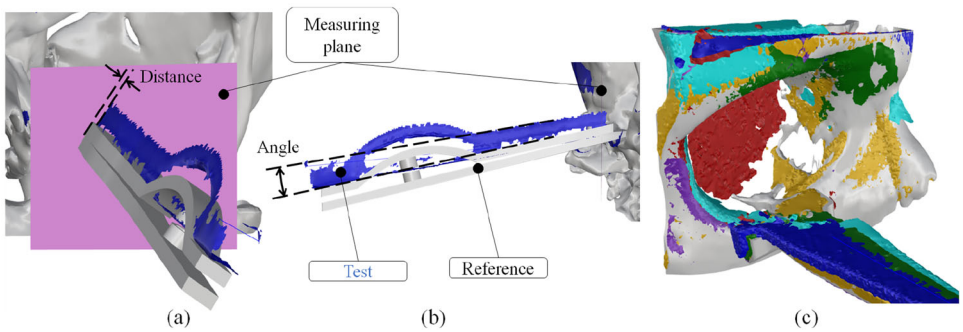


Fig. 5 Procedure to assess the accuracy in **a** placing and **b** orienting the medical device, **c** overlapped scans (six) for a specific orbital cavity

correctly place the implant. A mean value of 6° reflects the rotation angle of the implant positioner around the orbital rim (Table 2). This deviation angle is not an issue since the implant is fixed to the bone through specifically placed screws. The implant will fit the bone during fixation, and rotation will be removed. A mean distance of 1.3 mm is observed in the mediolateral direction (Table 2). No other deviations are observable because the positioner design prevents variations in any other direction. The findings suggest that the mould and implant positioner can improve the prosthetic implant's adequate positioning within the fractured orbit regarding accuracy and surgery costs.

The error in correctly placing the implant depends on the rim shape of the orbital cavity. As seen in Table 3, Cases 1 and 3 have an orbital rim that is more shaped than in Case 2, which determines a lower distance deviation. The deviation can be reduced by increasing the mediolateral length of the device.

Table 3 Summary of results for each case and tester

	Distance (mm)	Angle (°)
Case 1	1.2	7
Case 2	1.7	7
Case 3	1.2	5
Tester A	0.8	6
Tester B	2.1	8
Tester C	1.1	5

Indeed, because the implant positioner is patient-specific, its dimensions can be adjusted according to the specific mediolateral length of the orbital rim and the surgery planned by the surgeon (e.g., the transcutaneous approach grants more room than transconjunctival). In this way, the surgeon can achieve

a more stable position. The augmented size can better compensate for dimensional errors due to 3D printing technology, which cannot be neglected (around ±0.3 mm). Additionally, accuracy also depends on the user's skills. As presented in Table 3, the average mediolateral deviation ranges from 0.8 to 2.1 mm. This result means that trained clinicians, such as surgeons, can have the ability to position the implant with acceptable accuracy (less than 1 mm in lab tests). The average accuracy in orienting the implant does not highly depend on the orbital shape and testers.

It is worth noting that the results were obtained using rigid 3D-printed physical prototypes in a laboratory setting. Soft tissues (e.g., skin or orbicularis muscle) were not considered. Thus, further testing (e.g., on cadavers) is required to ensure that the device can function properly in a more realistic setting.

Although intraoperative navigation systems improve the accuracy of implant positioning, their use is limited due to expensive equipment, the availability of CT scans, and the time required for system preparation. Being easy to use and ergonomic, the proposed device can guide the surgeon to place the implant firmly and correctly, avoiding repetitive fitting trials and thus reducing surgery time and costs. Indeed, the proposed approach allows an autonomous fabrication of the product based on a widely available technology (3D printing). The possibility of manufacturing the device on-site reduces the time and cost related to the logistics. At last, the reduced surgery time positively impacts the National Healthcare System costs and patient's quality of life. The medical device was designed to be reused after proper sterilization. This reduces its cost because only the implant positioner is patient-specific. The system can also be helpful for education and training as students and younger surgeons can improve their skills in a pre-surgery environment.

Conclusions

The paper presents an innovative medical device for placing and orienting custom-made implants within fractured orbital cavities. The system was conceived to grasp an implant. This was realized through a customized mould, appropriately modified from previous research by the same authors. This device aims to support maxillofacial surgeons in precisely fixing custom-made orbital implants as planned before the surgery. The device was designed to be easy to use, affordable, reusable, and applicable for deantigenated bones or titanium implants for orbital floors and walls. Physical prototypes were realized to evaluate the system's accuracy and to correspond to the technical specifications.

The experimental tests demonstrate that the mould could precisely shape the implant as designed (the average Euclidian distance is lower than 0.1 mm). The device accuracy in placing the implant is acceptable for surgeons (1.3 mm in the mediolateral direction). Given its shape (contact between the positioner and the orbital rim), the device guarantees a precise position in the anteroposterior and superior-inferior directions. Rotation around the orbital rim (around 6°) does not represent a problem. The orientation is restored by the screws that fix the implant to the orbital bone.

In future work, we intend to improve system accuracy. First, the mediolateral dimensions of the device should be increased for a more stable orientation with the orbital rim. Second, augmented reality could support surgeons in placing and orienting the positioner. Specific targets must be attached to the device and maxilla in this case. A head-mounted display can be used by a surgeon to track the target and to inform of the precise location and orientation. Higher accuracy can compensate for the higher costs of this solution. Since the valuation was performed on phantom skulls, a clinical trial (e.g., on cadavers) must be performed to evaluate feasibility within a surgery room (soft tissues were not considered in this research).

Author contributions MM: conceptualization, methodology, and writing—original draft preparation; AB: writing—original draft preparation, investigation, and validation; MC: writing—original draft preparation, investigation, and validation; MP: conceptualization, supervision, and writing—review & editing; AM: writing—review & editing and validation.

Declarations

Conflict of interest The authors have no financial or proprietary interests in any material discussed in this article.

Ethical approval This study does not contain any studies with human or animal subjects performed by any of the authors.

Data or code availability The data generated in this study are available from the corresponding author upon reasonable request.

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