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Analysis of the accuracy of a novel preformed osteosynthesis plate for the reduction and fixation of zygomaticomaxillary complex fractures

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ABSTRACT

Introduction: There has been a shift toward surgical treatment of ZMC (zygomaticomaxillary complex) fractures with open reduction and subsequent fixation in the past decades. Anatomically preformed osteosynthesis plates, already used in the field of craniomaxillofacial surgery for the treatment of fractures of the mandible and the orbit, might be a suitable option for ZMC fractures as well.
Material and methods: A statistical shape model was created from 179 cranial CT scans. Based on this surface model, an anatomically preformed plate for the reduction and fixation of ZMC fractures was developed in 3 sizes (S, M, L). Virtual analysis of the accuracy of the plate was performed on a dataset consisting of 120 CT scans.
Results: Within a determined tolerance range of 0–1.5 mm, analysis revealed a high accuracy of the plate in 70–87 % of the CT scans. The S-sized plate has the highest overall accuracy, whereas the L-sized plate has highest accuracy at the "base" region which is essential for the placement of the plate.
Discussion: The newly developed plate can be placed via an intraoral approach and analysis of the plate has confirmed its accuracy to be sufficient to ensure an adequate fracture reduction and fixation. It thus might allow for a less extensive approach and less approaches/incisions necessary overall to reduce and fixate ZMC fractures.

1. Introduction

Due to its prominent location in the midface, the zygomaticomaxillary complex (ZMC) is commonly affected in cases of maxillofacial trauma (van Hout et al., 2013). Common causes of these fractures are motor vehicle accidents, assaults, falls, and sport-related injuries (van den Bergh et al., 2012). The main clinical features of ZMC fractures include aesthetic deformity with depression of the malar eminence, malocclusion/reduced mouth opening and neurosensory disturbances of the infraorbital nerve (Evans and Evans, 2008).

Conservative treatment and wire fixation have been the treatment of choice in cases of ZMC fractures for many decades. However, there has been a shift from conservative approaches and wire fixation toward surgical approaches in the past decades, especially in cases of displaced fractures (Rallis et al., 2015). These approaches are aiming at reduction of the fracture and sufficient fixation, with the surgical procedure being adapted to the fracture pattern (van Hout et al., 2016). In cases with only minimal displacement, adequate results can be obtained by a minimally invasive procedure with the ZMC being reduced through a small incision and no subsequent fixation. However, a large proportion of displaced ZMC fractures require post reduction fixation, applying titanium osteosynthesis plates (van Hout et al., 2016; Salentijn et al., 2014).

Reposition of the fracture can be challenging and for many decades, intraoperative control of the correct reposition relied solely on visual evaluation by the surgeon and team. Recent technological developments such as intraoperative cone beam computed

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tomography (CBCT) and computer aided surgery (CAS) provide the surgeon with extended options to ensure the correct repositioning of the fracture (He et al., 2013; Heiland et al., 2005). However, these approaches are limited to centers provided with respective technical equipment and only indicated in cases of complex fractures (Lübbers et al., 2011).

Internal fixation of ZMC fractures can be achieved using titanium osteosynthesis plates. The complex geometry of the ZMC demands extensive intraoperative contouring of commercial straight osteosynthesis plates to fit the patient's ZMC geometry (Wang et al., 2018). Contouring of titanium osteosynthesis plates can be time consuming and does not necessarily result in satisfying contour accuracy. Moreover, excessive or radical bending of the titanium plate potentially worsens the fatigue properties of the material (Martola et al., 2007; Probst et al., 2012). Whereas the access to these plates is excellent, as they can be stored sterile in the operating room, readily available to the surgeon and are available at moderate costs, their contour accuracy and ease of use can be considered moderate to poor.

Advancing technological options with the possibility of CAD/CAM (Computer-aided design/Computer-aided manufacturing) have enabled the production of patient specific implants (PSI). Such patient specific implants have been used for the treatment of defects of the calvaria since the 1980s, providing excellent results (Mankovich et al., 1986; van Putten and Yamada, 1992). PSI have been shown to provide excellent contour accuracy in the treatment of fractures of the orbit as well and moreover can reduce the duration of surgery. However, the production process is time-consuming and costly (Strong et al., 2013).

Anatomically preformed, industrially machined plates might strike a middle ground, as they can be stocked sterile in the operating room, provide a good contour accuracy, moderate cost and excellent ease of use. Such preformed plates are used by a variety of surgical disciplines, for example the Locking Compression Plate (LCP, Synthes) for the treatment of distal humerus fractures, that can serve as guidance for the reposition and enables reliable fixation (Rübberdt et al., 2008). In the field of cranio-maxillofacial-surgery, commercially available preformed osteosynthesis plates for the treatment of fractures of the mandible have been found to reduce the operating time, minimize the risk of plate failure owing to fatigue fractures and to facilitate the transoral application (Probst et al., 2012). Preformed titanium mesh implants for the treatment of fractures of the orbit have been found to provide very good contour accuracy and excellent ease of use whilst being available at moderate costs (Strong et al., 2013).

Considering these aspects, the aim of this study was to investigate the accuracy of a novel anatomically preformed osteosynthesis plate for the reduction and fixation of ZMC fractures.

2. Material and methods

2.1. Design of the plate

For the analysis of variation in size and shape of the zygomaticomaxillary complex (ZMC), a statistical shape model was created from 179 cranial CT scans. The dataset consisted of CT scans from 90 European (45 female, 45 male) and 89 Asian (42 female, 47 male) patients. An atlas segmentation using iPlan CMF (Brainlab AG, Munich, Germany) was performed to obtain three-dimensional triangular surface meshes. To ensure (pseudo-) homology throughout the sample, a two-step elastic registration procedure using a diffeomorphic image registration approach was employed (Fig. 1). The first step was based on diffeomorphic image registration using the R-package ANTsR software (Avants et al., 2008, 2015). Therefore, all surface meshes were converted to binary 3D image

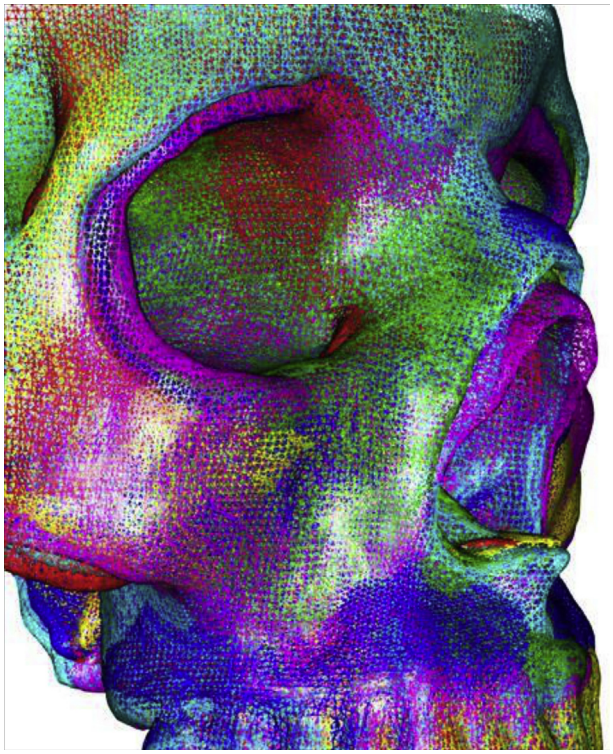

Fig. 1. Meshes superimposed by their corresponding vertices.

labels. A template specimen was then registered to all patients in the sample and the resulting transformation was applied to the surface mesh of said template specimen. As the result was already a close but not perfect match, an additional surface registration was added using an elastic free-form registration, penalizing mesh distortions (Amberg, 2011) to match the result of the first step perfectly to the target surfaces.

All statistical analyses were done using the statistical software R (R Core Team, 2015) and specifically the R-packages Morpho, mesheR, Rvcg and RvtkStatismo (Schlager, 2017). The region of interest (zygomaticomaxillary complex) was defined on the sample's mean (Fig. 2) and successively extracted automatically from all registered meshes, exploiting the identical mesh topologies (i.e. corresponding vertex indices). The vertices belonging to this region were then rigidly aligned using a Procrustes registration (Goodall,

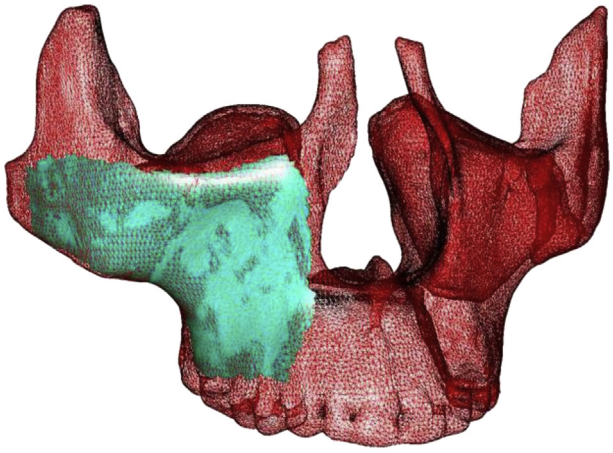

Fig. 2. Definition of the ROI (turquoise) on the sample mean.

1991) and a Principal Component Analysis (PCA) was computed on these aligned data. The first PC represents the major axes of variation. As the data were not standardized regarding size, the first PC is associated with allometric effects as well as sexual dimorphism. In order to model these effects, we regressed the shape of this region onto the first PC, calculating a surface model for the 20%, 50% and 80% quantile of the 1st PC-Scores. That way the resulting surfaces are not only varying isotropically but also incorporate the shape change associated with size. These surface models provided the base for the design of the plate in three sizes; S (small), M (medium) and L (large).

Designing the plate, particular attention was paid to matching the localization of the screw holes and bridges of the plate to the most frequent fracture lines in ZMC fractures. In these fractures, comminuted zones are frequently found in the area of the zygomaticomaxillary buttress and the facial maxillary sinus walls. Thus, an increased number of screw holes and bridges were incorporated into these areas of the plate (Fig. 3).

The lateral branch of the plate serves as a guide for the reposition of the fracture. The target position of the nasal and basal parts of the plate is the maxillary bone, thus, these parts can serve as a guide for the placement of the plate onto the local bone. The nasal and basal parts of the plate will be referred to as “base” of the plate in this article.

The prototype of the plate was fabricated from titanium with a thickness ranging from 0.4 to 1.0 mm. The screws used for the fixation of the plate have a diameter of 1.5 mm. If these screws fail to provide sufficient grip in the bone, “emergency”screws with a diameter of 1.8 mm are available.

2.2. Analysis of the accuracy of the plate

Virtual analysis of the accuracy of the plate was performed on 120 cranial CT scans, which had not been included in the creation of the statistical shape model. As studies report significant differences in the proportions of the face between Caucasians and Asians (Le et al., 2002), the dataset included 60 Caucasian and 60 Asian patients. Half of the population was female, half was male, age of the included persons ranged from 19 to 91 years. CT data of the European population was obtained from our own institution (University Medical Center Freiburg, Freiburg, Germany), CT data of the Asian population was provided by the Shanghai Ninth People's Hospital, Shanghai, China.

DICOM data of the CT scans and STL data of the plates were imported into the 3D measurement data evaluation software GOM Inspect (GOM GmbH, Brunswick, Germany). One plate of each size (S, M, L) was positioned on the right and left side of every CT scan via 3 point alignment and subsequent best-fit alignment.

For manual 3-point alignment, the measuring points 1, 6 and 10 (Fig. 4) and the corresponding parts of the bony surface were selected. These points were chosen, as they can easily be marked on the cranial bony surface and, moreover, are located on the “edges” of the plate, facilitating the virtual positioning of the plate. As manual 3 point alignment does not allow for the optimal positioning of the plate, subsequent best-fit alignment was performed. Manual marking of the bottom side of the plate and the surface of the ZMC region by the investigator enables the software to determine the position of the plate with maximum alignment.

After best-fit alignment, the distance between the bottom side of the plate and the bony surface was measured. The computed distance is visualized in the software by a color scale. To evaluate the distance between the plate and the bony surface, 21 measuring points were specified on the plate (Fig. 4). These 21 points result from the number of bridges connecting the screw holes. It was decided to place the measuring points on the bridges, as they provide a larger contact surface on the cranial bony surface and positioning of the measuring points is easier on the bridges.

For the analysis of the accuracy, a tolerance range of 0–1.5 mm of distance between the bottom side of the plate and the bony surface was determined. Fitting was evaluated at all measuring points, with particular attention paid to the “base” points (point 4–6) and the repositioning arm (point 7–10). All measuring results were exported into Excel (Microsoft Corporation, Redmont, WA, USA) and statistical analysis was performed using STATA 14.1. (StataCorp LLC, College Station, Texas, USA).

3. Results

3 CT scans had to be excluded from the final analysis due to the nasal bridges of the plate ranging into the nasal region and/or incomprehensible measurement values, potentially caused by thin bony walls of the maxillary sinus, leading to imprecise depiction of these structures in the CT data. 117 CT datasets with 3 measurements performed on the right and left side of each CT scan resulted in 702 measurements included in the final statistical analysis.

3.1. Analysis at all measuring points

Statistical analysis revealed fitting of all sizes of the plate in 70 %–87 % of the patients, considering the tolerance range of

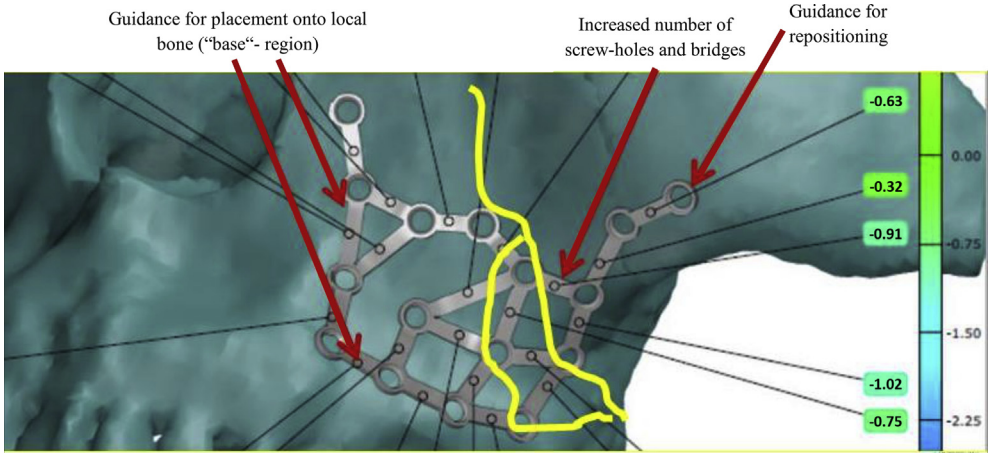

Fig. 3. Preformed plate after alignment in the 3D measurement data evaluation software GOM Inspect.

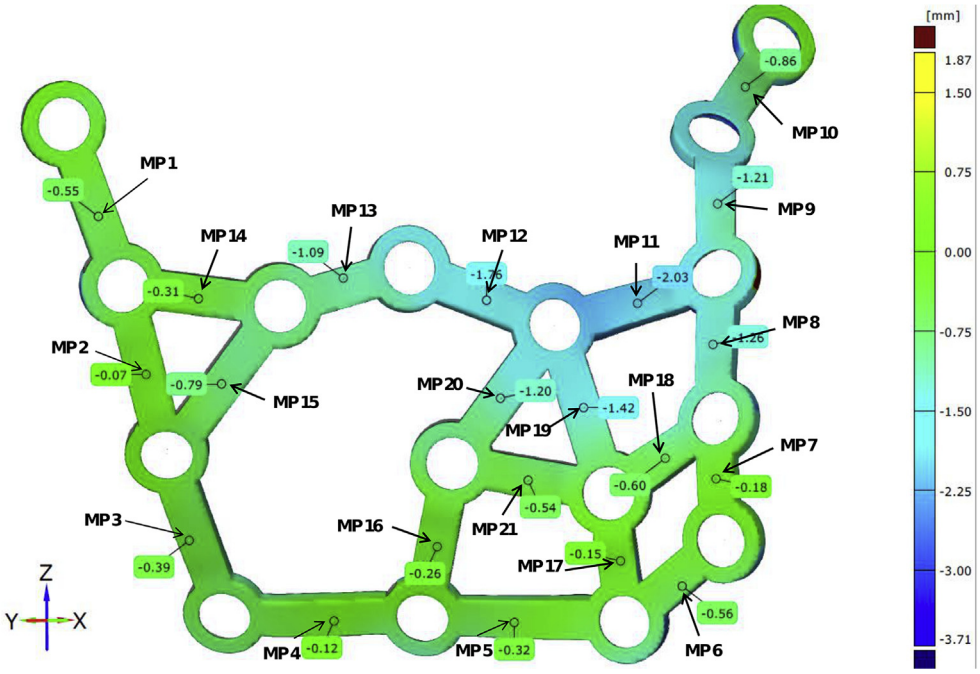

Fig. 4. View of the bottom side of the plate with color scaling and numbering of the measuring points (MP).

0–1.5 mm between the bottom side of the plate and the bony surface. Considering all measuring points, the S-sized plate had the highest accuracy. Significant differences at all measuring points, dependent on the size of the plate, were found for the side of the cranium ($p = 0.000$) and gender of the patient ($p = 0.000$). Pairwise comparison revealed significant differences between the three sizes of the plate within the determined range of tolerance of 0–1.5 mm. Significant differences were found between sizes M and L ($p = 0.023$), S and L ($p = 0.000$) as well as S and M ($p = 0.000$). If the tolerance range is expanded, significant differences are not only found regarding the side of the cranium ($p = 0.000$) and gender of the patient ($p = 0.005$) but also regarding the ethnic group ($p = 0.032$). Expanding the tolerance range, significant differences regarding the size of the plate are only found between sizes L and S ($p = 0.006$). Considering all measuring points except for those that can be contoured/bended (point 1, 9 and 10), the analysis revealed a mean distance of 0.947 mm and a median distance of 0.76 mm for the S-sized plate. For the M-sized plate, a mean distance of 1.075 mm and a median distance of 0.82 mm were found and for the L-sized plate a mean distance of 1.18 mm and a median distance of 0.93 mm were found. Mean and median distances at all measuring points are given in Table 1. A box plot depicting the results of the analysis of the accuracy at all measuring points is given as Fig. 5.

Table 1
Accuracy at all measuring points.

plate and side	n measuring points	mean	median	SD
plate S	4872	1.007 mm	0.78 mm	0.84
plate S right	2436	0.94 mm	0.74 mm	0.87
plate S left	2436	1.065 mm	0.83 mm	0.87
plate M	4872	1.04 mm	0.79 mm	0.86
plate M right	2436	0.97 mm	0.75 mm	0.79
plate M left	2436	1.12 mm	0.84 mm	0.91
plate L	4872	1.13 mm	0.86 mm	0.93
plate L right	2436	1.07 mm	0.81 mm	0.91
plate L left	2436	1.18 mm	0.92 mm	0.94

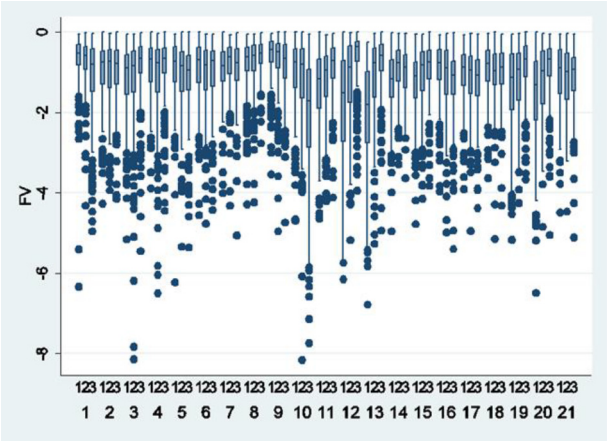

Fig. 5. Statistical analysis of all measuring points. Top row: 1 = plate L; 2 = plate M; 3 = plate S, Bottom row: measuring points 1 to 21.

3.2. Analysis at the "base"-region

If the analysis is limited to the "base" region (measuring points 4, 5 and 6), the L-sized plate shows the highest accuracy (83.7%). If the 3 measuring points are evaluated separately, best fitting at point 4 is found for the S-sized plate (87.5%) and at point 5 (85.3%) and 6 (84 %) for the L-sized plate. On the left side, the L-sized plate showed best fitting (83%), on the right side, the S-sized plate showed best fitting (85 %). No differences were found regarding gender, with the L-sized plate showing best fitting in both genders. The same applies for the ethnic groups.

Significant differences, dependent on the size of the plate, were found for the side of the cranium ($p = 0.048$) and the gender of the patients ($p = 0.000$). Pairwise comparison of the 3 sizes of the plate revealed significant differences between the sizes L and M ($p = 0.001$) as well as M and S ($p = 0.022$). No significant differences were found between sizes S and L ($p = 0.554$). Mean and median

distances between the bony surface and the bottom side of the "base" region of the plate, considering the 3 sizes of the plate, are given in Table 2. Box plots depicting the results of the analysis of the accuracy at the "base" region are given as Fig. 6.

3.3. Analysis at the lateral branch

Analysis of the lateral branch of the plate (measuring points 7 to 10) revealed best fitting for the L-sized plate (85.1%) and the M-sized plate (85.4%). If the 4 measuring points are evaluated separately, best fitting at point 7 is found for the M-sized plate (90.9%), at point 8 for the S-sized plate (96.9%) and at point 9 for the L-sized plate (90.5%). Measuring point 10 showed poor fitting for the S-sized plate (42.6%) and better fitting for the L- and M-sized plate (78.8%/72.8%). However, this part of the lateral branch can be bent/contoured.

In male patients, sizes L and M (both 83.4%) showed the best fitting, in the female population the M-sized plate showed the best fitting (87,5 %). Regarding the side of the cranium, sizes M (right 85.5%; left 84.9%) and L (right 85.7%; left 84.4%) showed the best fitting. In the European population, size L showed best fitting (87,9 %), in the Asian population, size M showed best fitting (84.1%).

Significant differences, dependent on the size of the plate, were found regarding gender ($p = 0.002$). Pairwise comparison revealed significant differences between sizes L and S ($p = 0.000$) as well as sizes S and M ($p = 0.000$). There were no significant differences between sizes M and L ($p = 0.973$). Mean and median distances between the bony surface and the bottom side of the lateral branch of the plate, considering the 3 sizes of the plate, are given in Table 3. Box plots depicting the results of the analysis of the accuracy at the lateral branch are given as Fig. 7.

3.4. Application of the plate

A clinical case is included in this article for visualization of the application of the plate. Fig. 8 shows a CT scan of the patient with the virtually placed ZMC-plate. The ZMC is approached via an incision in the vestibular fold of the upper jaw (Fig. 9a). After visual evaluation of the fracture, the plate is placed (Fig. 9b) and fixated to the "base" region (Fig. 9c) to ensure a stable localization of the plate. This way, the plate can serve as guidance for the repositioning of the zygomatic bone and fracture fragments of the facial maxillary sinus wall (Fig. 9d). Once the fracture fragments are positioned as desired by the surgeon (Fig. 9e), they can be fixed to the plate using osteosynthesis screws (Fig. 9f).

4. Discussion

The ZMC is frequently affected in cases of maxillofacial trauma. Exact reduction and rigid fixation of displaced ZMC fractures are critical to avoid functional and esthetic impairment. Potential consequences of inadequate reduction include enophthalmos, hypophthalmos, loss of malar projection/flattening of the malar eminence, and midfacial widening (Ellis and Perez, 2014).

There is an ongoing controversy on the size and number of plates required for adequate fixation after reduction of displaced ZMC fractures, with the decision on the adequate surgical procedure being determined by the fracture features, i.e. displacement, comminution and stability after reduction (Covington et al., 2012; Ellis and Perez, 2014; Hollier et al., 2003).

The ideal surgical approach to the ZMC fractures should allow for a good exploration of the fractured segments at minimal potential for further injury to facial structures and good postoperative cosmetic results, i.e. avoidance of visible extraoral scars. An intraoral incision can provide exposure of the zygomaticomaxillary buttress, whereas the zygomaticofrontal suture can be accessed and plated via a transconjunctival approach and plates to the inferior orbital rim can be placed via a subciliary, subtarsal or transconjunctival approach. Considering cosmetic aspects, intraoral and/or transconjunctival approaches can be considered favorable, whereas subciliary or subtarsal approaches should be avoided, as they can result in visible scars, scleral show, lid retraction, and ectropion (Ellis and Perez, 2014).

In their treatment algorithm, Ellis and Perez (2014) propose to start the surgical procedure with a transoral approach and

Table 2
Accuracy at "base" region.

plate	mean	median	SD
plate S	1.00 mm	0.76 mm	0.82
plate M	1.09 mm	0.80 mm	0.91
plate L	0.91 mm	0.71 mm	0.75

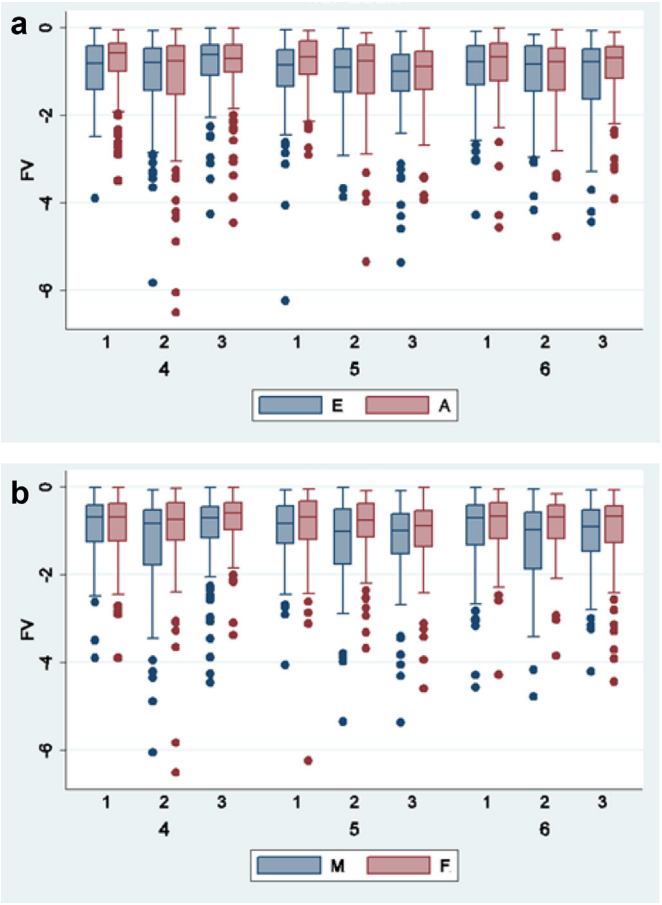

Fig. 6. a/b Statistical analysis of "base" region points 1 = plate L; 2 = plate M; 3 = plate S; 4 = measuring point 4; 5 = measuring point 5; 6 = measuring point 6 E = European; A = Asian; M = male; F = female.

Table 3
Accuracy at lateral branch.

plate	mean	median	SD
plate S	1.11 mm	0.78 mm	1.10
plate M	0.86 mm	0.62 mm	0.80
plate L	0.84 mm	0.63 mm	0.71

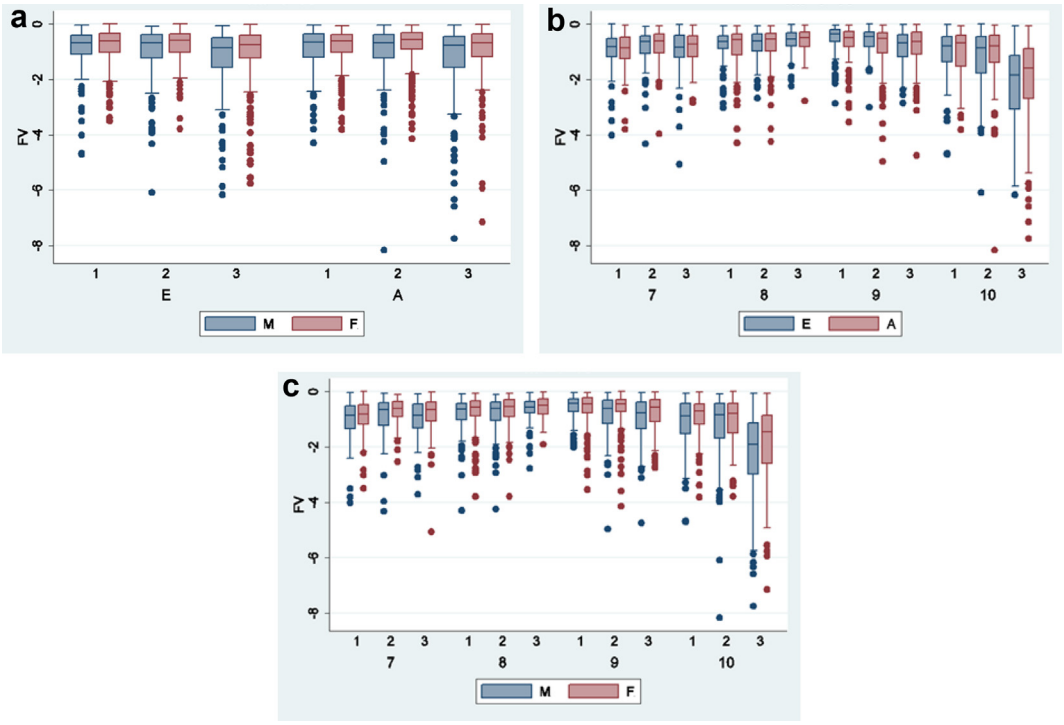

Fig. 7. a-c Statistical analysis of lateral branch 1 = plate L; 2 = plate M; 3 = plate S; E = European; A = Asian; M = male; F = female; 7 = measuring point 7; 8 = measuring point 8; 9 = measuring point 9; 10 = measuring point 10.

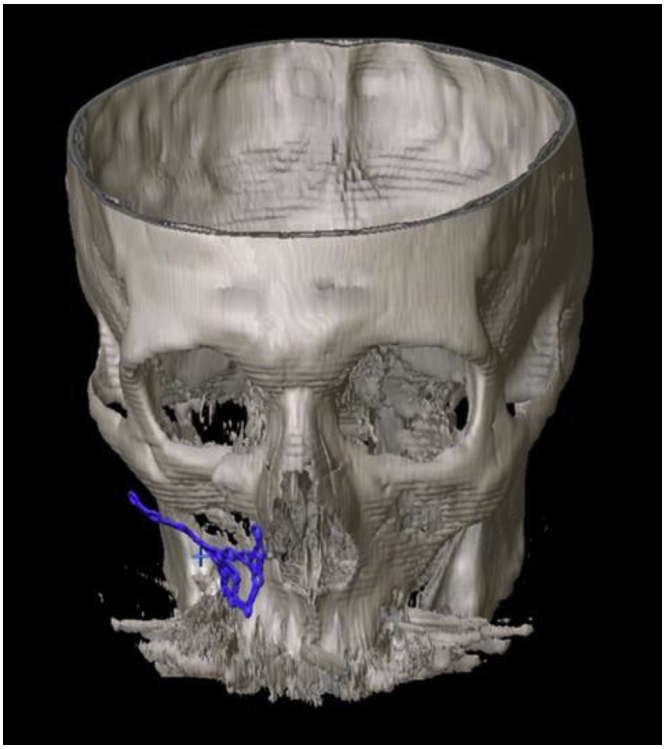

Fig. 8. CT scan with virtually placed ZMC-plate.

reduction of the zygomaticomaxillary buttress, as this is considered a key point for the alignment of displaced zygoma fractures. From a biomechanical standpoint, placing plates at this location will have the greatest mechanical advantages in maintaining the position of the zygoma (Ellis and Kittidumkerng, 1996; Fujioka et al., 2002). Further surgical approaches should be added only if required for adequate fracture reduction and/or fixation (Ellis and Perez, 2014).

Many investigators consider it essential taking into account deforming muscle forces acting on the reconstructed ZMC when planning and performing post reduction fixation. However, Dal Santo et al. (1992) report the masseter muscle force to be significantly reduced even 4 weeks post surgery and question a major role of masseter muscle force in post reduction displacement of ZMC fractures.

Several experimental and clinical studies have been performed to investigate the adequacy of different rigid fixation techniques of ZMC fractures (Deveci et al., 2004). Many investigators consider 3-point fixation the gold standard for ZMC fracture fixation, arguing this to be the optimum method to achieve stable post-reduction fixation (Covington et al., 2012; Makowski and Van Sickels, 1995; Yonehara et al., 2005). Stable internal fixation can help to maintain the position of the fractured bone segments, however, potential complications and esthetic consequences of applying a combination of different surgical approaches should be kept in mind. Limiting the surgical approaches to those absolutely necessary can minimize the risk of injuring anatomical structures like the lower eye lid or the facial nerve and reduce the potential of an unfavorable cosmetic outcome (Ellis and Perez, 2014).

Several reports have demonstrated that fractures relatively stable once reduced may be adequately fixated using one single plate (Ellis and Perez, 2014; Hollier et al., 2003). According to Fujioka et al. (2002) one-plate fixation of the zygomaticomaxillary buttress can provide sufficient rigidity with the achievement of three-point alignment, given, that the fracture is not comminuted. Correspondingly Yonehara et al. (2005) state that stable fixation can be achieved with miniplate fixation of the zygomaticomaxillary buttress, anterior maxillary wall and, if necessary, zygomaticofrontal suture. Deveci et al. (2004) however report the fixation of the frontozygomatic suture (FZS) to be most vital in resisting rotation of the zygoma under masseteric chewing forces

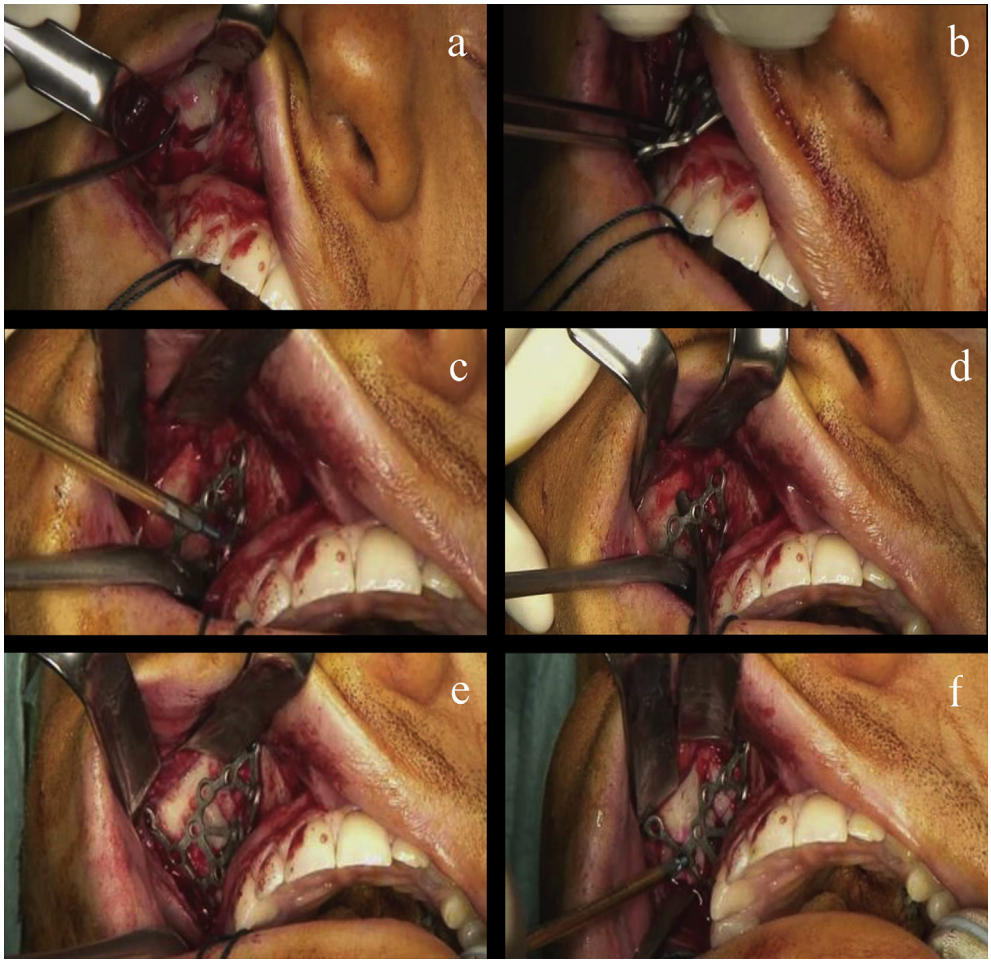

Fig. 9. Visualization of the application of the plate.

and report satisfactory rotation resistance placing miniplates at the FZS.

The newly developed plate can be inserted via an intraoral approach. Once the "base" part of the plate is fixed on the alveolar bone of the maxilla, the position of the plate is predetermined. The plate stabilizes the fracture at the zygomaticomaxillary buttress and provides a three-dimensional shape that can serve as a guide for the reduction of the anterior maxillary wall. It thus might allow for a less extensive approach and less incisions/approaches necessary overall to reduce and fixate the fracture and moreover has the potential to reduce the duration of surgery. Analysis of the plate has confirmed its accuracy to be sufficient to ensure an adequate fracture reduction.

It would be of interest, if the newly developed plate is applicable in cases of bilateral ZMC fractures as well. Surgical treatment of bilateral fractures of the midface is generally challenging, as orientation at an unaffected side is not possible, an aspect that excludes the application of PSI as well (Herlin et al., 2011; Watzinger et al., 1997). In these cases, the anatomically preformed plate might serve as guidance for the reposition and provide the surgeon with a better support.

There is no conclusive answer to the question of which amount of accuracy is required in anatomically preformed osteosynthesis plates. A certain amount of asymmetry is found in every face and considered a "normal", physiologic condition (Ferrario et al., 1994). It would be very difficult, if not impossible, to calculate the extent of facial asymmetry no longer considered esthetic. Asymmetry of the maxillofacial skeleton can be compensated by soft tissue to a certain amount (Ferrario et al., 1993). However, the amount of change of the soft tissue due to changes of the underlying bone is individually different and difficult to predict (Kocadereli, 2002). Further studies would be required to investigate if the level of accuracy determined in our study is sufficient or might even be too restrictive.

Statistical analysis of the 3 sizes of the plate revealed significant differences between genders but not between ethnic groups. This finding deviates from what would have been expected, as literature reports differences in the shape of the cranium between male and female as well as Caucasian and Asian people (Ferrario et al., 1994, 1993; Le et al., 2002; Schlager and Rüdell, 2017). Significant differences between the ethnic groups were only found after expanding the tolerance range.

Analyzing the accuracy of the plates, we were also aiming at determining if 3 sizes of the plate are required or if one size might be dispensable. Considering the whole ZMC-region, the analysis revealed highest accuracy for the S-sized plate. Highest accuracy at the "base" region was found for the L-sized plate and at the lateral branch of the plate for the M- and L-sized plate.

Accuracy at the "base" part is essential for reliable positioning of the plate. Thus, the M-sized plate might be considered dispensable, as it had high accuracy "only" at the lateral branch, a part of the plate can be bent/contoured.

5. Conclusion

Statistical analysis confirmed an adequate accuracy of the preformed ZMC-plate. The newly developed plate can be placed via an intraoral approach. It provides the surgeon with a guide for the repositioning and reduces the need for additional approaches to achieve a satisfactory functional and esthetical outcome. It thus might contribute to reducing the duration of surgery and saving anatomical structures.

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Conflicts of interest

The authors declare that they have no conflict of interest.

Informed consent

Informed consent was obtained from all individual participants included in this study.

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