Shape analysis for the design of a preformed osteosynthesis plate for accurate zygomatic reconstruction.

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1 Introduction

The zygoma is a bony structure, situated within the skull, between the maxillary bone, frontal bone, temporal bone, and sphenoid bone (Fig. 1). Aesthetic appearance of the face is affected by the zygoma, since it provides support to the lateral side of the face and its prominence defines the shape of the cheek. The zygomatic bone is a platform for transferring the pressure generated during chewing, but other muscles, associated with talking, swallowing, and facial expression, also attach to the zygoma and rely on it for proper function (Fig. 2) [1,2].

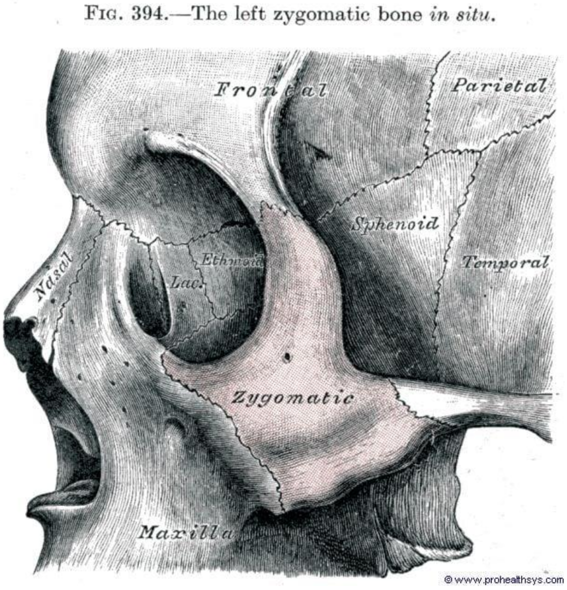

Fig. 1 Anatomy of left zygomatic bone [3].

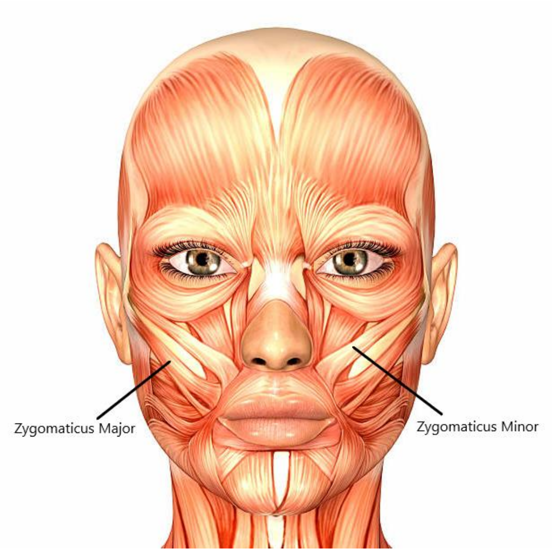

Fig. 2 Anatomy of the Zygomaticus muscles [4].

The location of the zygomatic bone determines its high predisposition to endure facial trauma. A fracture of the zygomatic complex can result in severe loss of function or cosmetic changes (Fig. 3) [5]. There is a noticeable increase in the number of maxillofacial injuries, which are usually the result of fights, road traffic accidents, contact sports or the introduction of mechanisation [6,7,8]. Fractures of the zygomatic bone are more common in males and are the second most common maxillofacial fractures [9,10]. Surgical treatment aims to recover the function and symmetry of the facial skeleton by repositioning the fractured, zygomatic bone to restore the original anatomy [11]. Factors to consider for proper reduction of the zygomatic complex are: anatomical shape, joint connections, innervation, bone thickness and alignment of teeth and their roots [12,13].

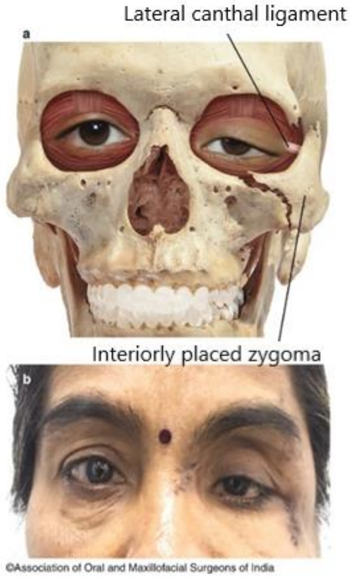

Fig. 3 Asymmetrical facial appearance caused by
zygomatic trauma [14].

Treatment of the fracture is possible through closed reduction, during which the treatment consists of setting the zygomatic bone in position without surgery, but also through open reduction and internal fixation, during which the bone is immobilised using either osteosynthesis plates, screws or rods to stabilise the bone [15]. An overview of some currently mostly used osteosynthesis plates is provided (Fig. 4).

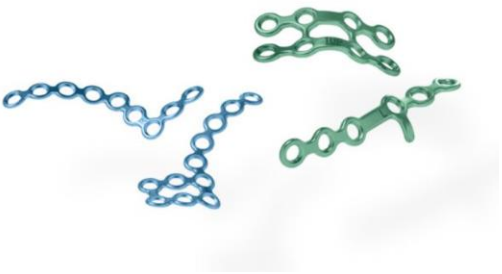

Fig. 4 Various shapes of osteosynthesis plates [15].

The selection for a specific osteosynthesis plate may be made based on fracture site, shape and size. Larsen and Thompson's classification divides fractures of the zygomatic bone into fractures showing minimal or no displacement and therefore not requiring intervention, fractures with significant displacement and interruption of the frontoparietal suture, comminuted fractures and fractures of all other types that require reduction but no fixation [16]. The operation and insertion of the plate are particularly challenging due to the variability in the location of the fractures and the fact that there are no rules or established guidelines for the insertion and positioning of conventional and preformed titanium plates [17]. Furthermore, the fixation of a plate also presents a significant challenge, as it needs to be carefully aligned and secured to ensure optimal stability, requiring precise surgical techniques and support during the healing process [18]. This means that each patient's case must be considered individually and its placement and fixation depends primarily on the surgeon's knowledge and decision, as well as the patient's anatomical possibilities. Consequently, fractures that are treated in the same manner may result in the plate being positioned at an angle or in a horizontal position (Fig. 5, 6) depending on the surgeon's decision and the optimal positioning for bone healing.

Fig. 5, 6 Intraoral vestibular approach used for reduction and fixation of zygomatic fracture [19]. Similar fracture, different technique.

During the surgical procedure, the conventional plate is contoured intraoperatively to the patient’s individual geometry, size and shape. Conventional plates often need to be bend to fit the fractured zygomatic bone. It alters its original mechanical properties, potentially leading to uneven distribution of forces. The stresses and strains in the plate may become concentrated in certain areas, affecting the stability of the fixation and potentially compromising the healing process [20]. Method of insertion and positioning of the plate, in turn can lead to subsequent problems with screw loosening, inflammation or even damage in the structure functionality of the zygoma [21]. In a study of zygoma reconstruction, the complication rate was 10% (35 patients) [22], and as high as 17% (8 patients) in another one [23]. The implication of these problems can be reoperation, which in itself is a risk the patient will face again, but there is also a higher economic cost. Tab. 1 includes the most important advantages and disadvantages of conventional plates [17,19,21].

Tab. 1 Advantages and disadvantages of conventional, two dimensional plates.

Pros of two dimensional plates	Cons of two dimensional plates
Greater Adaptability: Conventional plates can be manually adjusted during surgery to accommodate a wide range of anatomical variations, making them versatile.	**Increased Surgery Time:** The manual adaptation of conventional plates can extend the duration of the surgery, potentially leading to longer recovery times for patients.

Cost-Effectiveness: Conventional flat plates are cheaper than preformed counterparts, making them a preferred choice in situations where cost is a significant factor.	**Skill Dependency:** Achieving an optimal fit with conventional plates relies on the surgeon's skill and experience in contouring the plates, which may vary among practitioners.
	Inconsistency: The manual nature of adapting conventional plates introduces the possibility of variability and inconsistencies in plate contouring, which can affect the overall outcome.
	Extended Learning Curve: Achieving proficiency in contouring conventional plates requires a learning curve, and less experienced surgeons may face challenges in obtaining optimal results.
	Potential for Intraoperative Complications: Real-time adjustments with conventional plates carry a risk of intraoperative complications, such as misalignment or inadequate fixation, if not executed skilfully.
	Increased surgery time: Real-time adjustments increase the time of the operation while raising its cost. Time required for bending costs 10-20euro/min [24].
	Lack of guidance: A preformed plats has a defined shape and may guide the bone in position, a two-dimensional plate (that is bent on the surgery) is adapted to fit the result that is already obtained.

Due to the constant improvements in science, preformed plates have been developed yet for mandible and orbital reconstructions, matching the original anatomy of the patient. They are used more frequently, as they carry benefits. The most important advantage is that the complex shape, size and geometry of the fractured site is taken into consideration, when designing the preformed plate. This prevents the need for substantial bending during the surgery to customize the plate. Considering these aspects and according to several studies, preformed plates allow for shorter operating times, better stabilisation, and more accurate reduction [25]. Nevertheless, preformed plates must meet essential criteria such as proper fitting and desired mechanical properties, including residual stress and rigidity, to achieve those advantages. Preformed plates have demonstrated efficacy and dependability in the successful reconstruction of the mandible and orbit [25,26,27,28]. Utilizing preformed plates for mandibular reconstruction achieves mechanical stabilization, reduces the risk of fatigue fracture and eliminates the necessity for additional external incisions [29]. Moreover, preformed osteosynthesis plates were reported to have the most advantages in the orbital reconstruction study. They were characterized by high contour accuracy, ease of use and low cost [30]. The effective use of preformed anatomical plates in orbital and mandibular reconstruction, the advantages, along with their proven mechanical stabilization and reduced risk of complications, suggests their viability for zygoma reduction. Preformed plates, thanks to their shape and 3D complexity, can also act as clues for the surgeon, suggesting their desired position by navigating against characteristic lines or anatomical shapes. Advantages and disadvantages of preformed plates are shown in Tab. 2 [25,26,27,28,29,30].

Tab. 2 Advantages and disadvantages of three dimensional, preformed plates.

Pros of three dimensional plates	Cons of three dimensional plates
Time Efficiency: Preformed plates can significantly reduce the surgery time as they are designed to fit specific anatomical structures, minimizing the need for extensive adjustments during the procedure.	**Limited Adaptability:** Without bending preformed plates may not accommodate the full range of anatomical variations, limiting their suitability for patients with unique or complex anatomies.
Predictable Fit: Since preformed plates are manufactured based on standardized anatomical dimensions, they are expected to provide a more predictable and accurate fit compared to manually adapted conventional plates.	**Anatomical fit:** Anatomical variation in the population might potentially lead to issues with plate fit and positioning during surgery.
Reduced Intraoperative Decision-Making: Surgeons may benefit from preformed plates as they eliminate the need for extensive intraoperative bending and contouring, leading to a more straightforward surgical process.	**Virtual planning challenges:** The segmentation step in the preoperative planning process may encounter difficulties in accurately representing the patient’s anatomy, especially in cases where there are anomalies or irregularities. Accurate virtual reconstruction of the pre-traumatized anatomy may be difficult and might lead to inaccurate simulation.
Consistent Quality: Preformed plates are produced under controlled manufacturing conditions, ensuring consistent quality and	**Cost:** Preformed plates can be more expensive due to the advanced manufacturing processes involved, potentially impacting the overall cost of the surgical procedure.

reducing the variability seen in manually adjusted conventional plates.	
Reduced Tissue Trauma: The preformed plates' precise fit can result in less manipulation of surrounding tissues, potentially reducing trauma and aiding in faster patient recovery.	
Guidance of positioning: The preformed plate can potentially guide the surgeon to position the zygomatic complex correctly by additional anatomical reference.	

In addition to these advantages, surgeons often prefer the use of preformed plates [31]. What makes them attractive is their demonstrated effectiveness in handling challenging scenarios, not only in orbital and mandibular reconstructions but potentially also in zygomatic reconstruction. The ability of preformed plates to address diverse anatomical challenges with a single plate stands out as a significant advantage, minimizing the reliance on additional plates [28]. Furthermore, the reduced risk of reoperation associated with preformed plates, attributed to their superior accuracy in repositioning, adds to their appeal [25]. If proven successful in zygomatic reconstruction, the use of preformed plates could become even more compelling for surgeons, providing a comprehensive solution. In such cases, the advantages of preformed plates may outweigh cost considerations, making them a preferred choice in complex maxillofacial surgeries. The advantages attributed to the use of preformed plates in the treatment of zygomatic fractures are currently grounded in assumptions, and the existing clinical evidence is not yet substantial. Given the absence of preformed plates, this highlights the opportunity for further research and development of preformed plates for zygoma reconstruction. Establishing a solid project base for future design is crucial to ensure the development of preformed zygoma plates.

The goal of this assignment is to provide the foundation for design of a preformed zygomatic reconstruction plate. In the first step, the requirements and desires of the design are listed. Preliminary designs are proposed based on the requirements and desires. The second step is to evaluate the average, normal anatomy and variability between patients in the anatomy of the zygomatic bone, since this is necessary to ensure that the shape of the preformed osteosynthesis plate may be accurately matched to the individual patients and in the general population. The feasibility of the preliminary designs is evaluated based on the information contained in the normative anatomical model.

2 Materials and Methods

2.1 Requirements and wishes

When starting a design project, one of the first steps is to create and analyse the requirements and wishes. Collaboration with surgeons at the Amsterdam Universitair Medische Centra, locatie AMC has resulted in generating information on the limitations and imperfections with the osteosynthesis plates being used today. After analysing the problems and participating in zygoma reconstruction operations, a list of requirements and wishes for a future improved and optimised design of an osteosynthesis preformed plate for zygoma reconstruction were developed.

2.2 Preliminary ideas

Preliminary design ideas were generated based on the requirements and wishes, to visualize potential shapes of a preformed zygoma bone plate. This approach allowed preliminary examination and discussion with surgeons if the concepts are practical, useful and implementable, especially in terms of the shape of the plate, before final decisions are made. The result of this design assignment can be used in the future as a basis for determining the final appearance and dimensions. In this way, the initial design process is a critical point in the development of the design, enabling an iterative approach to refining the final shape and dimensions.

2.3 Construction of statistical shape model

The shape of preformed osteosynthesis plate is based on the statistical shape model (SSM). The SSM represents the average three-dimensional shape and modes of variation in a population [32]. The 3D shape variation is described by the SSM by means of principal components (PCs) [33]. The use of statistical information, contained in the Statistical Shape Model (SSM), will allow to define the average surface of the zygomatic bone and the variances in its shape between patients [34]. To get a realistic SSM result it is necessary to follow specific steps (Tab. 3). SSM was derived from a dataset of 53 patients who had a unilateral zygomatic fracture, without involvement of other structures, that had a surgical intervention (primary open reduction and internal fixation of the zygoma) in the Amsterdam UMC, location AMC, between 2011 and 2023. SSM represents a diverse population and captures variations in the shape and anatomy of the zygoma bone [35]. Table 4 shows ratio of the patients and trauma side.

Tab. 3 Steps necessary to obtain correct Statistical Shape Model.

Step	Operation	Software used
Segmentation	• Atlas based segmentation	• Brainlab (.stl)
Preprocessing	• Remeshing • Initial template creation	• Meshmixer (.stl) • 3DMedX (.obj)
Initial correspondence mapping	• Mapping initial template on 10 datasets	• 3DMedX
Building final template	• Calculate average from initial correspondence mappings • Indicate area of interest	• MatLab
Final correspondence mapping	• Mapping final template on all datasets	• 3DMedX
Region overlay and selection	• Verify point correspondence • Create selection	• MeshMixer
Registering ROI's	• Procrustes alignment	• 3DMedX
Shape Model	• Building of Statistical Shape Model	• Scalismo, IntelliJ Idea

Tab. 4 Ratio of the patients.

Sex		Side of the fracture		Mean age at trauma
Male	Female	Right	Left	41 years 9 months
43	10	31	22	

2.3.1 Segmentation

The CT data of the patients were imported in Brainlab Elements (BrainLAB AG, 2001 Germany, www.brainlab.com). An atlas-based segmentation [36] of the unaffected side's maxilla and zygoma was performed. The two segmented parts of the ZMC (Fig. 7) were fused using a Boolean Union operation. The maxillary sinus was filled (Fig. 8) to eliminate the inner bony surface from the object, since the inner and outer surface in close proximity had resulted in inaccurate data processing in template registration for correspondence mapping.

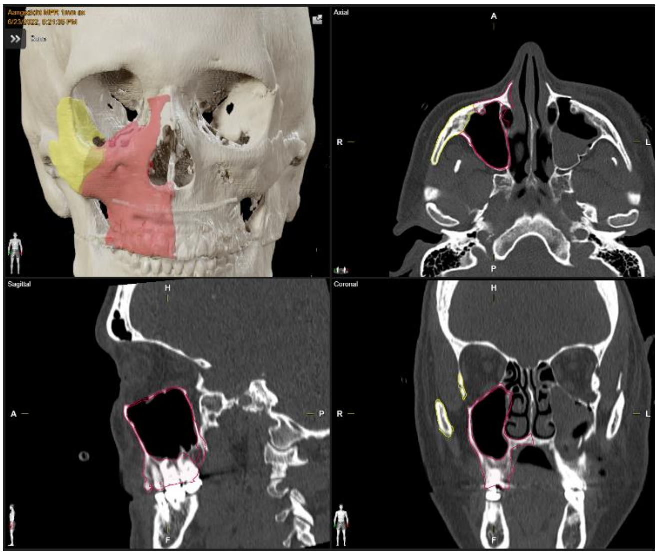

Fig. 7 Segmented parts of ZMC.

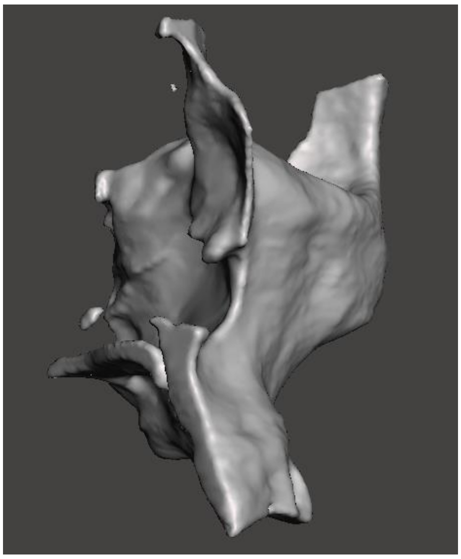

Fig. 8 Filled maxillary sinus.

A final check of the object's outline in the multiplanar views was performed and, if necessary, adjustments to the outline were made using the Smart Brush. Segmentation errors in the dentition and nasal cavity were not adjusted, since these regions were outside the region of interest for possible plate design. The final object was exported in STL format.

2.3.2 Pre-processing

Pre-processing of the STL files was performed in MeshMixer (Autodesk, 2020, California, www.meshmixer.com). Brainlab's exported meshes (Fig. 9) were remeshed to reduce the point density and standardize it among all meshes. To minimize possible deviations between original object and remeshed object, a target edge length of 0.75 mm was chosen (Fig. 10). The meshes were inspected, and the auto-repair function was used to prevent possible errors in subsequent steps because of errors in the mesh. A removal, of small bony structures not related to the zygomatic bone that had been erroneously incorporated in the model, was performed (Fig. 9). This all steps were done in order to obtain uniform results and reduce working time for all 53 data. The prepared objects were exported to the OBJ extension, due to the requirement for this extension by the program used for the next steps. One sample was selected from the first ten data sets to serve as the initial reference template in the subsequent point correspondence mapping. The selected sample was deemed to be the best representation of typical anatomy in the first ten samples. The demarcation cranial of the paranasal bone and lateral orbital wall are not based on anatomical boundaries but were created artificially by the atlas-based segmentation approach. An open edge was created at these locations to exclude influence of these artificial landmarks in the next steps. Open edges were also created at the teeth and medial edge of the paranasal bone to avoid influence of large variations in these areas later on.

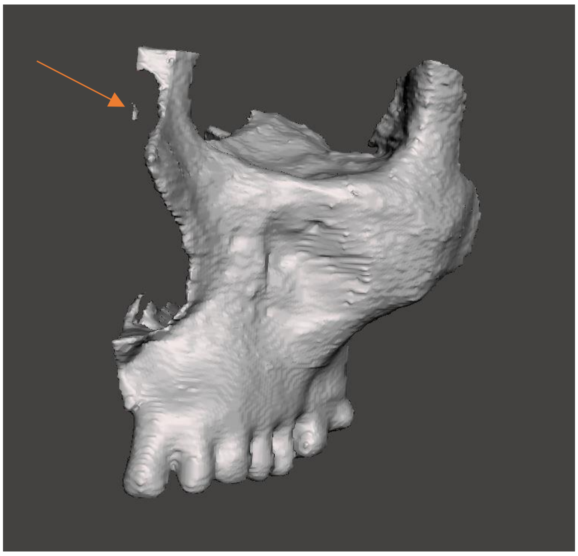

Fig. 9 Raw object.

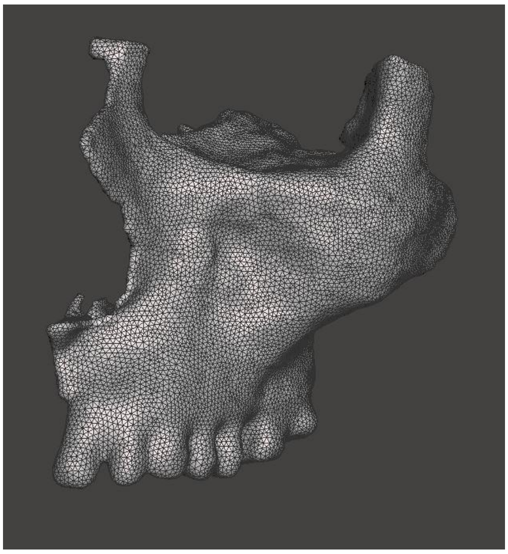

Fig. 10 Object remeshed and repaired.

2.3.3 Initial correspondence mapping

The alignment of all 53, pre-processed data was performed in 3DMedX (3DMedX, 2023, Netherlands, www.3dmedx.nl), where the first step was to import the objects together with the selected reference object. The Iterative Closest Point function, used to align the moving object to the target object, requires the selection of the four extreme and distant landmarks in both objects to be the same (Fig. 11, 12).

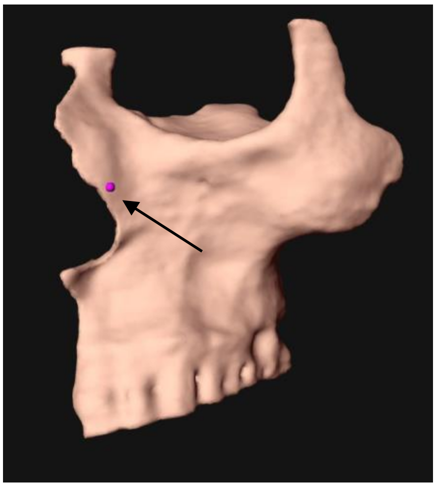

Fig. 11 Target object with landmark on paranasal area.

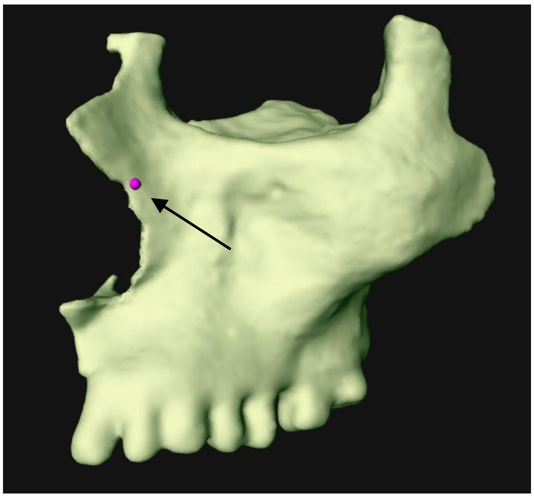

Fig. 12 Moving object with landmark on paranasal area.

Through iteration, it finds the closest point in the target set and minimises the distance between points, ensuring convergence to the optimal alignment (Fig. 13) [37]. In this way, all the objects were processed in succession with the reference selected beforehand. The aligned objects were saved in the same OBJ extension.

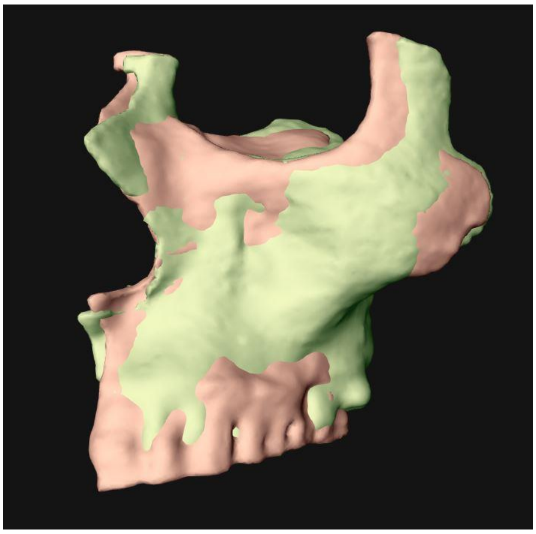

Fig. 13 Moving object aligned to the target object.

To achieve correspondence between meshes, the first mesh template, which is a mesh file, of the reference data, was created (Fig. 14). Using the right lateral view, an area of the patient's teeth had to be selected to be excluded as it is not an area of interest and may cause some inconsistencies. After ignoring the selected parts, it was necessary to indicate the four extreme and distant landmarks, in the moving object and the target object, and then register the previously generated mesh template. Therefore, the correspondence was performed, using MeshMonk algorithm, for the first 10 objects, overlaying reference mesh template (Fig. 15). MeshMonk uses a combination of rigid and non-rigid registration, based on the ICP algorithm [38]. The number of iterations as well as other values should be set in specific order (Fig. 16).

Fig. 14 Mesh template (blue) and target object.

Fig. 15 Overlaying – correspondence performance.

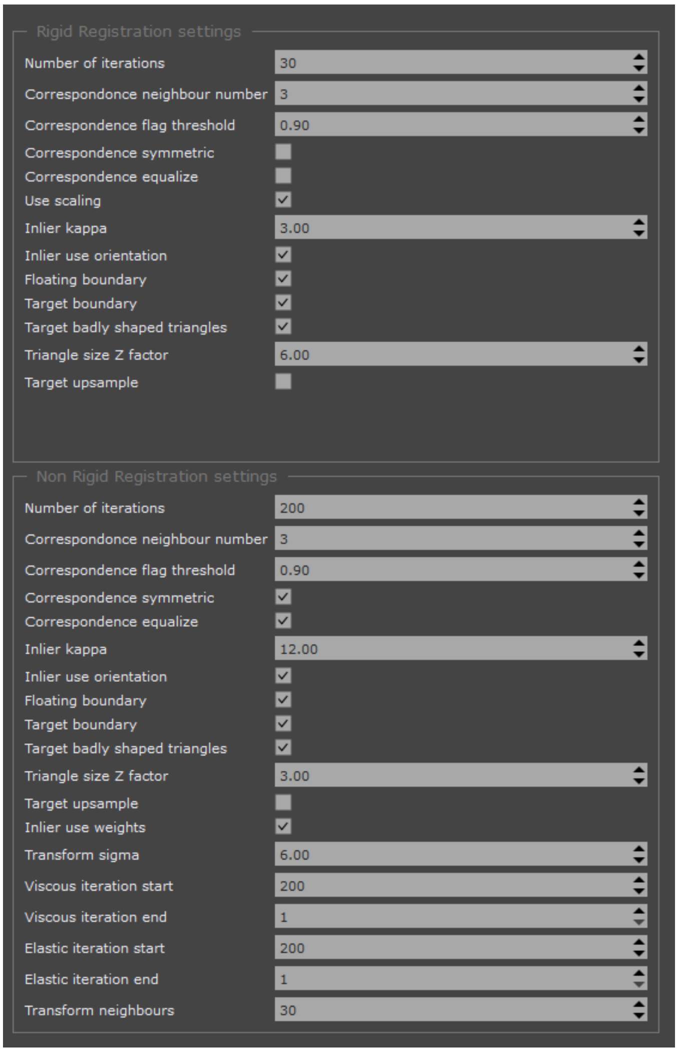

Fig. 16 MeshMonk settings.

2.3.4 Building correspondence template

The accuracy of the registration process is dependent on the similarity between template and target object. Ideally, a template should be used that is a good representation of the average shape of the average anatomy; a final template may be generated as a more accurate representation of the average shape [39,40]. The initial correspondence mappings of the first 10 data sets were imported in OBJ format in Matlab (MathWorks, 1970, California, www.mathworks.com), and the average position of each vertex was calculated. The average model was exported as the final template to be used for point correspondence mapping on all the data. The finished mesh files, having the same number of nodes, were exported to OBJ.

2.3.5 Region overlay and selection

A region of interest was delineated on the final template model as a selection of the area of interest. The colour scheme was created based on easily identifiable areas of the patient's craniofacial region, such as the zygomatic process (blue), infraorbital (red), paranasal (grey), zygomatic arch (black), and zygomatic prominence (green); the additional area possibly of interest for anatomical fit was indicated as yellow (Fig. 17). It was decided to restrict the surface and later on extract it to avoid problems in the construction of the SSM, as the zygomatic bone has a complex shape with hard to similarly define end bone areas on each patient.

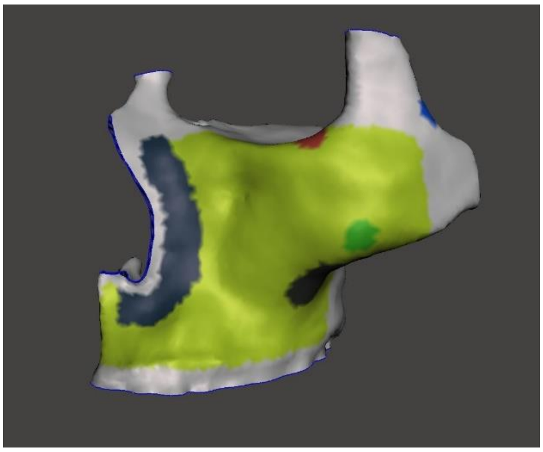

Fig. 17 The area of interests, limited by the template.

This template was also used in the visual assessment of point correspondence, since the different colours assigned to specific vertices of the reference object made it possible to overlay the template on the point corresponding models and verify that the same areas of vertices were coloured as the reference areas (Fig. 18). Objects should have the same mesh, and consequently the marked areas should appear in the same anatomically selected locations.

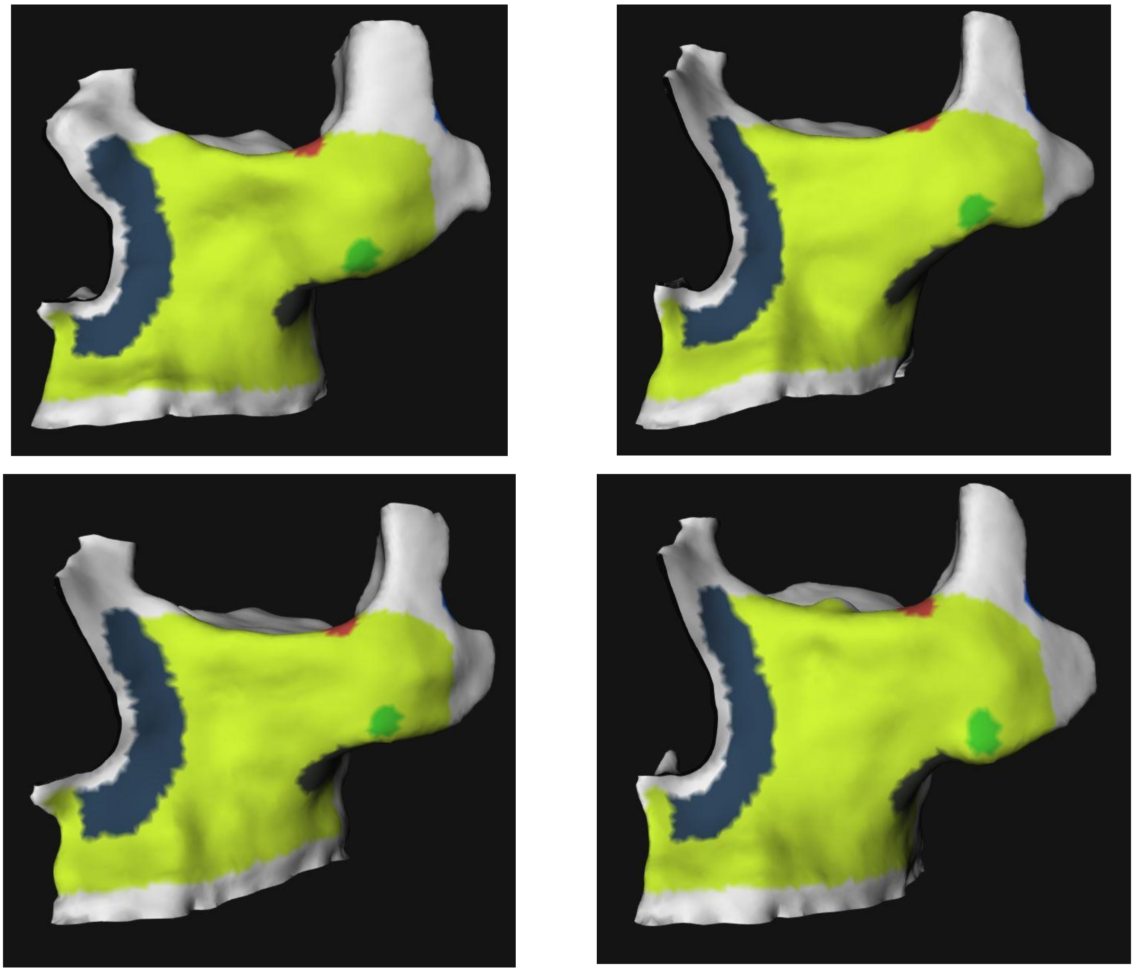

Fig. 18 Template overlayed on random objects.

Since the MeshMixer has possibility to select vertices based on their colour similarity, it was used to extract the surface, of zygomatic bone, bounded by the template (Fig. 19). This was done in order to obtain an area of interest, for placement of preformed plate, for every 53 available data and was later used to obtain mean shape of this area (Fig. 20). Using the selection tab "Expand mode" and "Vertex colour similarity", it was necessary to select the area to be deleted. The surface with the area of interest was exported to the OBJ extension, as the next step took place again in 3DMedX. Skipping this step and sequentially moving to SSM resulted in an unrealistic result.

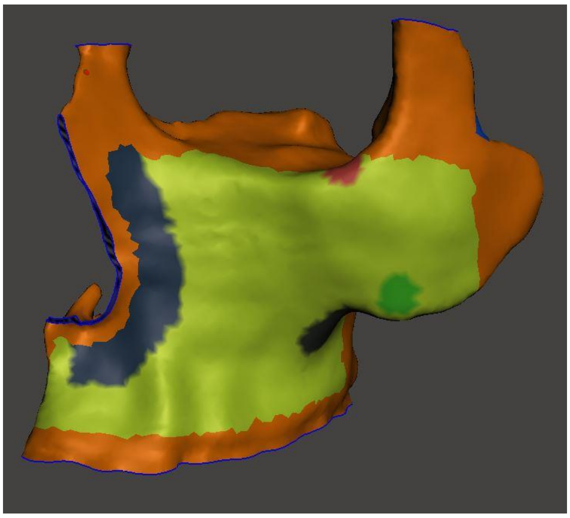

Fig. 19 Selection of area to extract in MeshMixer.

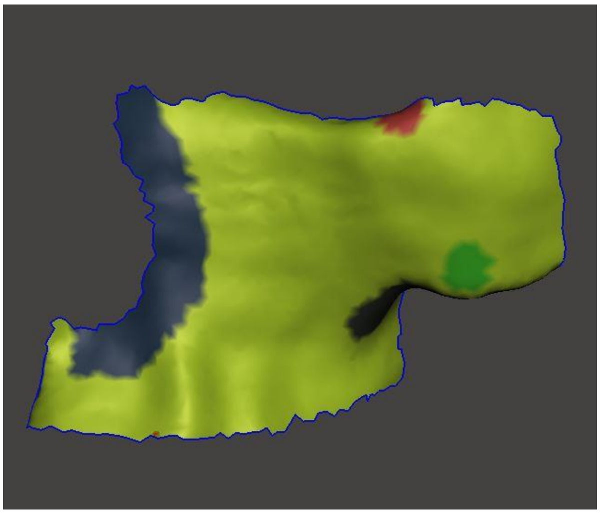

Fig. 20 Extracted area of interest.

2.3.6 Registering ROI's

Using the general Procrustes alignment algorithm, a final alignment of all objects (Fig. 21,22) was performed. Procrustes analysis (Commandeur, 1991) is a rigid shape analysis that uses translation, and rotation to find the best fit between two landmarked shapes [41].

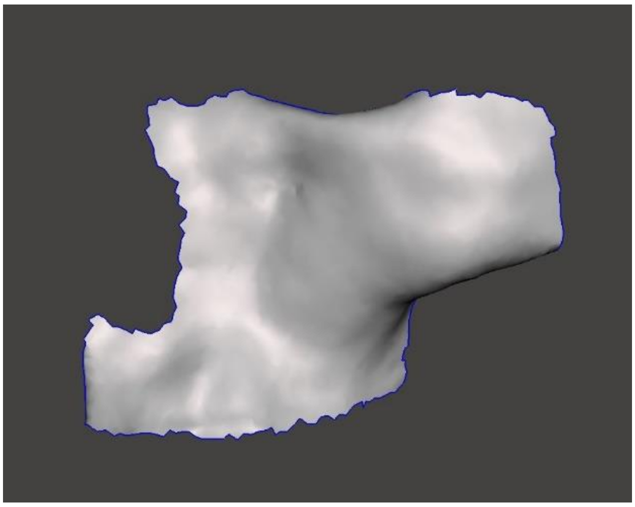

Fig. 21 Final object completed before SSM.

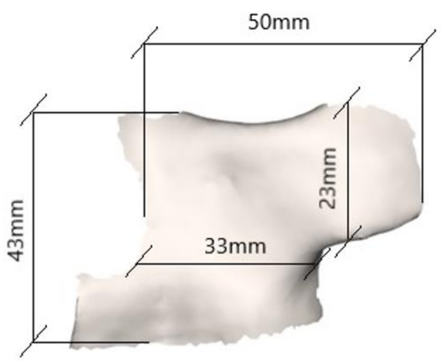

Fig. 22 Dimensions of the final object.

To perform alignment, it was needed to select the moving object, i.e. the object that will be aligned, and the target object, i.e. the one according to which the data will be aligned (Fig. 23, 24). Initial rigid registration, based on ICP algorithm might be performed. Exported to STL, the objects are ready for SSM creation after all the above steps.

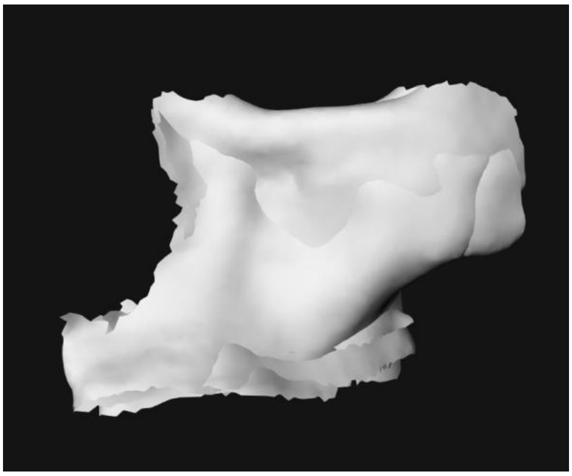

Fig. 23 Data before Procrustes alignment.

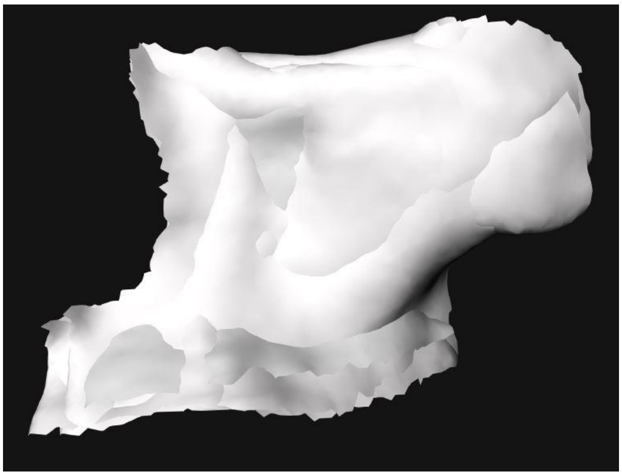

Fig. 24 Data aligned.

2.3.7 Shape model

Based on the Scalismo (Graphics and Vision Research group, University of Basel, Basel, www.scalismo.org) tutorial [42], a statistical shape model (Appendix 1) was built in IntelliJ Idea (JetBrains s.r.o., 2001, Prague, www.jetbrains.com). The 53 prepared objects were placed in a single folder, which is the input folder when building the SSM. Once the input folder was inserted into the pre-prepared code, it could be run to obtain the statistical shape model. In addition, a code for variations was constructed to visualise the smallest and largest shape deviations, i.e. the areas with the smallest and largest differences in shape between patients. The variations between the reference - the result of the statistical shape model, i.e. the average shape of the area of interest - and the individual patient data, from which the SSM was created, were shown. Once the SSM is created and the model is obtained, it needs to be exported with an STL extension so that the dimensions can be extracted and final concept of the preformed plate might be performed.

2.4 Evaluation of statistical shape model

In the process of developing a statistical shape model, an important step is to evaluate the compactness, generalisation and specificity. This includes analysing the correctness of the model's geometry and its ability to accurately represent the diversity of structures. This evaluation also includes checking whether the model adequately represents the variability of the training data [43]. In the context of the results obtained, an important aspect is the use of principal components, which are key components of the statistical shape model. These components make it possible to describe the dominant sources of variability in the data. The evaluation process also includes an analysis of the model's effectiveness in the context of prediction and its overall usefulness in practical applications. Evaluation of these aspects is important both to confirm the validity of the created model and to adapt it to specific research or clinical needs [44].

3 Results

3.1 Requirements and wishes

Recognizing the critical role that surgeons play in medical interventions, understanding their unique needs, preferences, and the limitations they encounter during procedures becomes paramount in shaping the future of medical product design. Therefore, through careful analysis of surgeons' needs, problems and product capabilities, requirements and wishes have been created which are the basic information of a future design (Tab.5) [45].

Tab. 5 Overview of requirements and the wishes for future design of preformed zygoma plate.

Requirements	Wishes
• The product should have at least two fixation points on the dislocated zygomatic complex and two on the unaffected bone.	• The product should be as cheap as possible.
• The product should reduce the zygomatic complex in the correct anatomical position.	• The duration of the surgery should be reduced thanks to the product.
• The product should require only one intraoral incision.	• The product should make it easier for the surgeon to insert the hook into the right position.
• The product should fit as many patients as possible.	• The product should be one plate.
• The product should have increased rigidity, so it is not going to bend under insertion or manipulation forces.	• The product should be as small as possible.
• The product should withstand forces associated with daily activities and the external forces produced between the body parts, as pressure, muscle, friction .	• The product should guide the surgeon to enter it in the appropriate position.
• The product should keep the zygoma in the correct position, as previously decided.	• The implementation of the product should be as easy as possible.
• The product should not cause iatrogenic damage.	• The screws used to fixate the product should be an already existing osteosynthesis screw.

• The product should be designed for the zygoma.	

Three surgeons were interviewed, and as a result, three requirements that were most significant and of greatest importance to surgeons, in the future design of a preformed plate for zygoma bone, were identified. It was decided to present them in an intelligent and measurable way to easily meet long-term goals in the assignment.

Description 1 : **The product should reduce the zygomatic complex in the correct anatomical position.**

Scale: The reduction will be expressed in millimetres given a specific reference point.

HTD: Simulation of reduction of zygomaticomaxillary complex, during which the reduction value can be calculated.

Must do: Accuracy of reduction > 2 mm – reduce the fracture within 2 mm compared to the plan position or restore functions and symmetry.

Plan: Accuracy of reduction > 1 mm – reduce the fracture within 1mm compared to the plan position or restore functions and symmetry.

Wish: Every reduction succeeded.

Rationale: To guarantee good healing and avoid complications after surgery, accurate reduction and fixation of displaced zygomatic fractures are necessary [46].

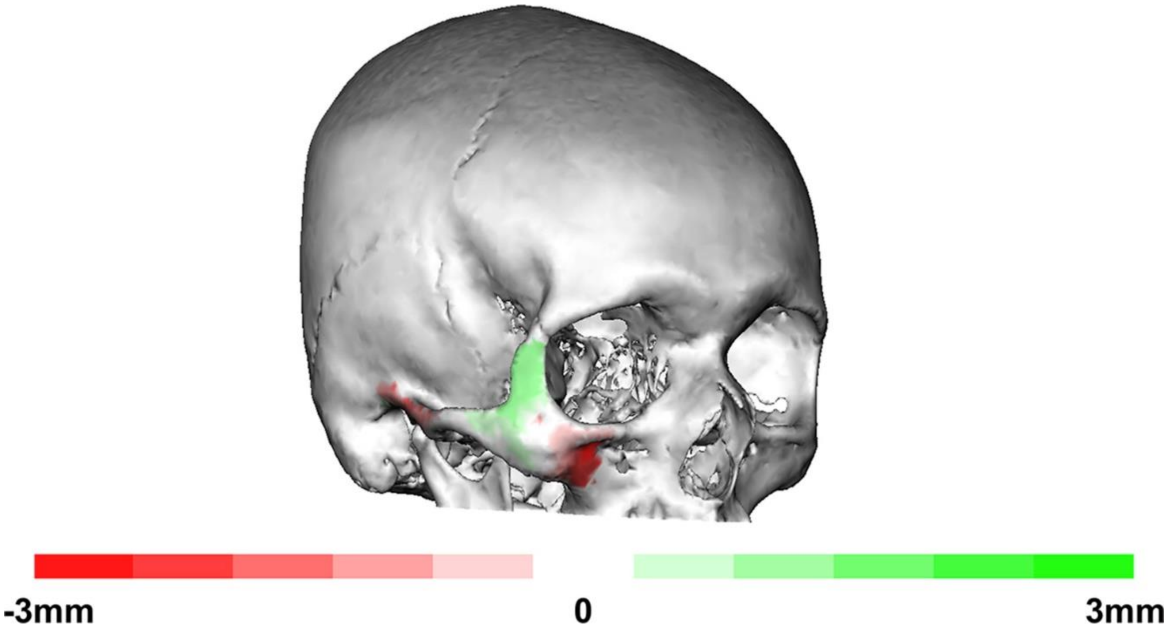

Fig. 25 The accuracy of reduction.

Description 2: **The product should fit as many patients as possible.**

Scale: The product's suitability will be evaluated through virtual assessment, comparing the designed plate fit with 3D models generated from scans of each patient's zygomatic bone.

HTD: Virtual simulation of insertion of the plate. There cannot be visible exceeded contacts between plate and the bone. Must do: Fit to the anatomy of the patients - fits 50% of patients. Plan: Fit to the anatomy of the patients - fits 75% of patients. Wish: Fit to the anatomy of the patients - fits 90% of patients. Rationale: A distance between plate and bone of less than 1.5 mm was defined as sufficient fitting [29].
Description 3 : **The product should require only one intraoral incision.** Scale: Intraoral incision length will be expressed in millimetres in the mucobuccal fold just beneath the zygomatic buttress of the maxilla. HTD: The design of the device must have a maximum height and width of no more than 2cm. Must do: A device with a maximum height and width of no more than 2cm, without interfering with anatomical structures. Plan: A device of any maximum height and width, which placement will be possible with a 2cm long incision. Wish: A detachable device, with the ability to be joined after insertion, which placement will be possible with a 2cm long incision. Rationale: In order to perform the Keens procedure (intraoral incision), a 1-cm-long incision is created in the mucoperiosteal fold, which is located directly below the maxillary zygomatic fossa [47].

3.2 Statistical Shape Model outcome

The result of this particular Statistical Shape Model is the average shape, contour and dimensions of zygomatic bone, given the data collected from 53 patients. The resulting mean shape (Fig. 26, 27) and random variances in shape, between patients (Fig. 28), look realistic.

Fig. 26 Outcome of Statistical Shape Model – mean shape.

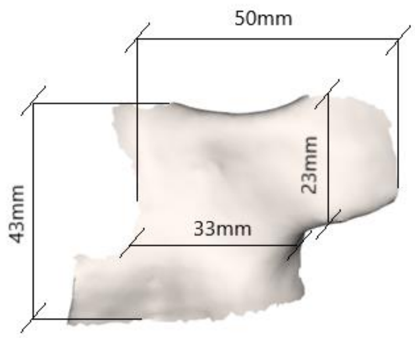

Fig. 27 Dimensions of mean SSM shape.

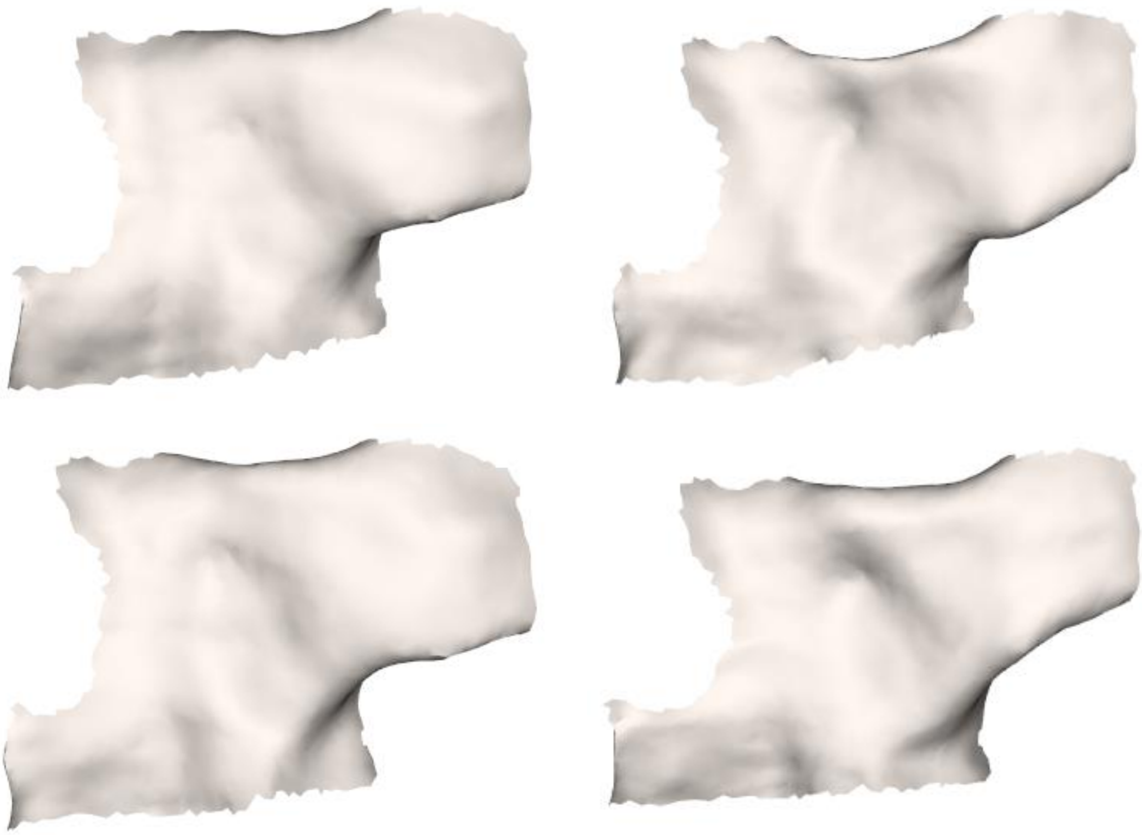

Fig. 28 Variances in statistical shape model – random possibilities.

3.2.1 Validation of the model

The evaluation of the statistical shape model used three fundamental methods: compactness, generalisation and specificity. The generalisation (Fig. 29) is an important parameter, as it shows of whether the model has been trained with an adequate amount of data. A substantial decrease (no bigger differences than 10^{-3}mm [48]) in generalisation with the inclusion of a single mesh suggests the enough amount of training data. Considering the graph below, as the amount of training data increased, the value of root mean square error [49] decreased significantly until it no longer reached differences greater than 10^{-3}mm.

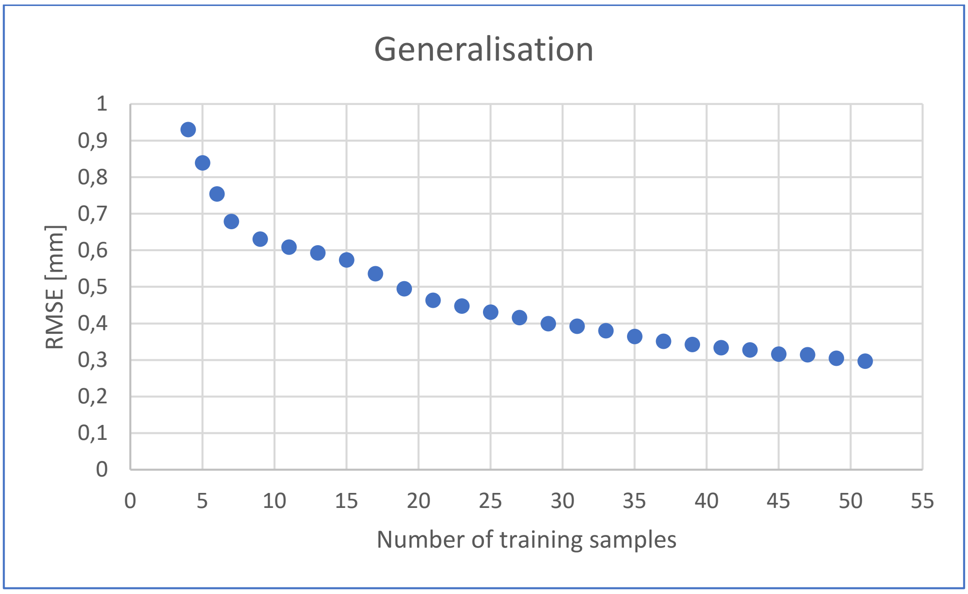

Fig. 29 Generalisation of statistical shape model.

Compactness shows how many percent, a given component, is able to define an instance [40]. It was discovered that the first 14 principal components had eigenvalues that above the 90% of the simulated eigenvalues (Fig. 30). This suggests that these components accounted for the majority of the data variability.

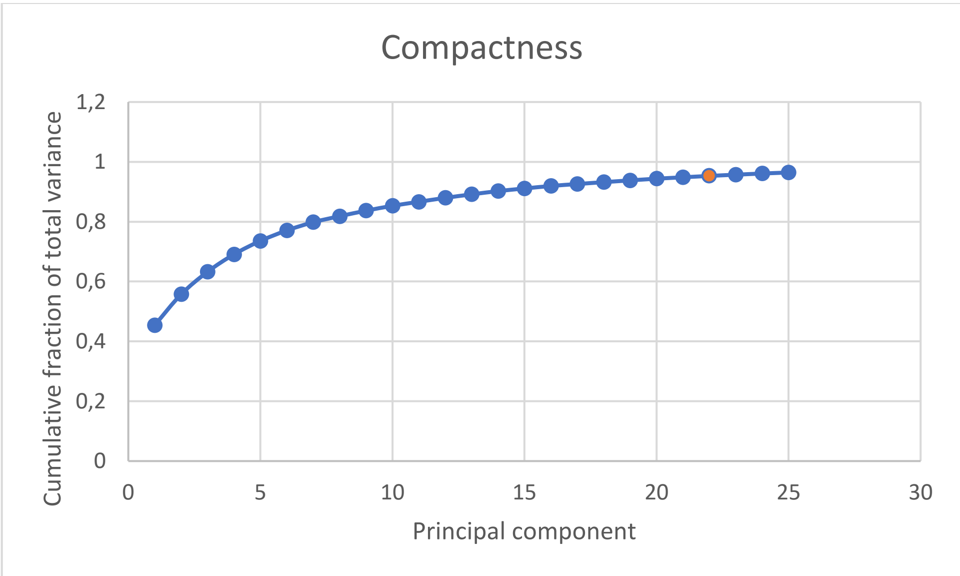

Fig. 30 Compactness of statistical shape model.

Specificity is the ability to create realistic new meshes (Fig. 31). It create new meshes out of the known information about variance in the model and then check this to the closest training mesh, to show if it is a realistic new mesh. The decrease suggests suggest that the model is learning and becoming more specific in capturing the shape variations present in the training data. And later stabilisation that the model has likely captured a significant portion of the relevant shape information and the specificity would not change much adding training data.

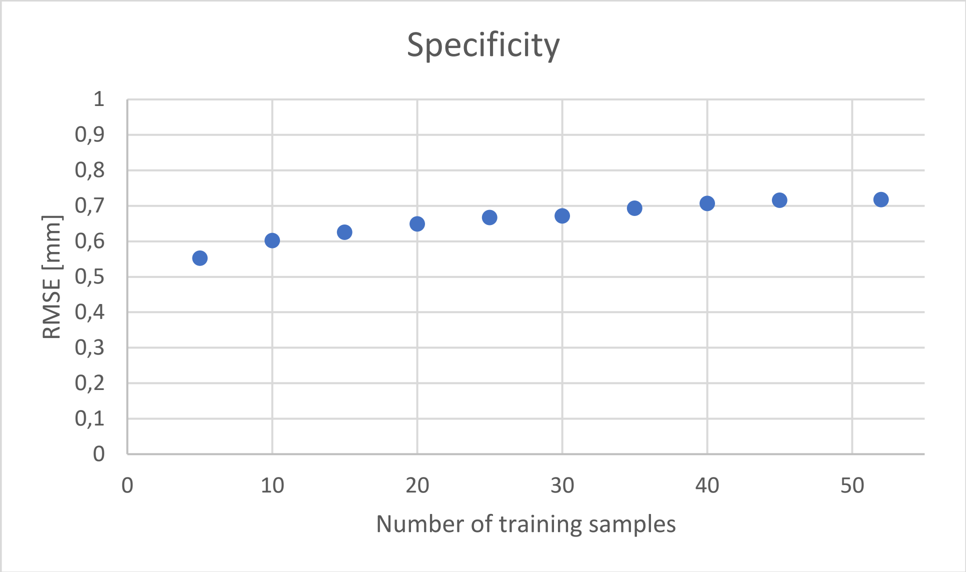

Fig. 31 Specificity of statistical shape model.

3.2.2 Variation in the model

What can be noticed first (Fig. 32,33) is that certain areas show significantly smaller variation values (< 0.20mm) than other areas that vary significantly in shape between patients (up to 4.53mm). The minimum values (blue), which indicate little changes in contour and shape between patients, spread out starting with the zygomatic arch, infraorbital foramen and paranasal, which shows a bit more values than the other ones. Thanks to that, those are also the locations that are most favourable for the design of preformed zygomatic plates. The maximum variations in shape (red) are located in the area of the teeth and zygomatic bone, estimating greater discrepancies in the anatomy.

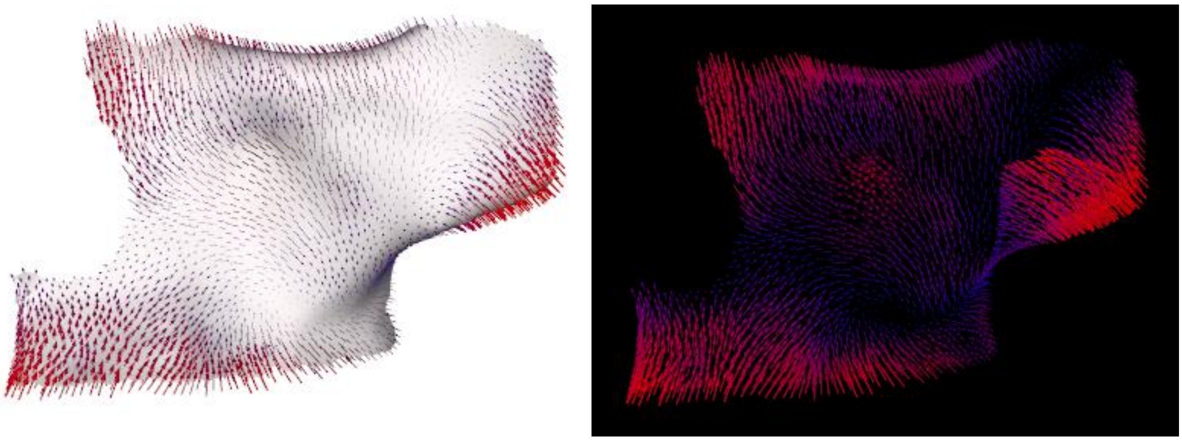

Fig. 32, 33 Outcome of smallest (blue) and largest (red) variations between mean SSM and individual data.

3.3 Principal components

To learn more about the data set's shape variability and changes in shape, principal component analysis was made. Of the overall collection, the first component explained 45.4%, and the first 10 components explained 85.3% of the variance.

Each principal component describes one or more physical processes. Most of them are based on many variables; component 0 corresponds to the overall size of the model, component 1 to the overall width, especially within the maxilla and infraorbital foramen, component 2 to the distance between the teeth and orbit, component 3 to the width and anatomical angle of the zygomatic arch, component 4 to the angle of position between the zygomatic arch and the teeth part, component 5 height of the maxilla and infraorbital foramen, component 6 height of the zygomatic bone, component 7 width and size of the dental part, component 8 width within the teeth and orbit, component 9 height of the orbit and size of the paranasal, component 10 width and bulge of the central part of the sample.

The identification of three principal components, with most impact (Fig. 34,35,36), in both directions of standard deviations (value -2 red, 2 blue) further refines understanding of the shape variations within the dataset and offer valuable insights into the primary modes of anatomical variation.

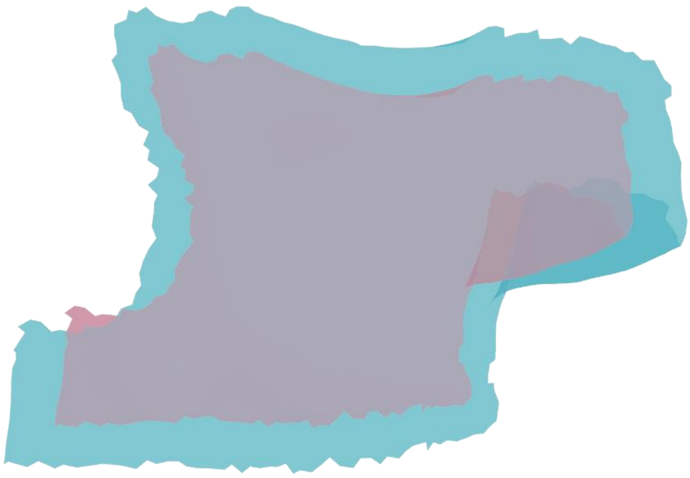

Fig. 34 Principal component 0, in both directions of standard deviations (value -2, 2) [mm].

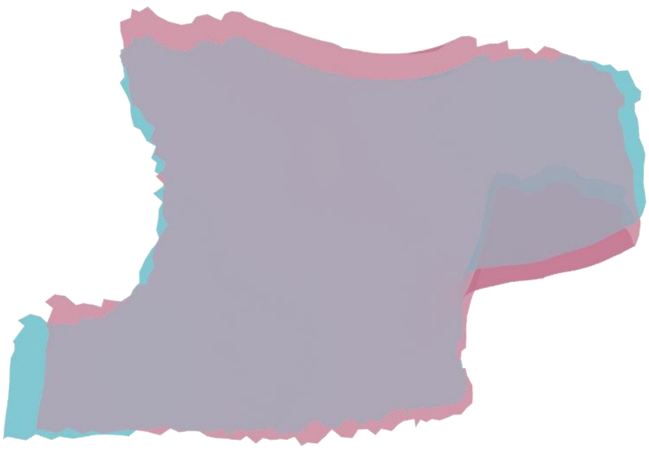

Fig. 35 Principal component 1, in both directions of standard deviations (value -2, 2) [mm].

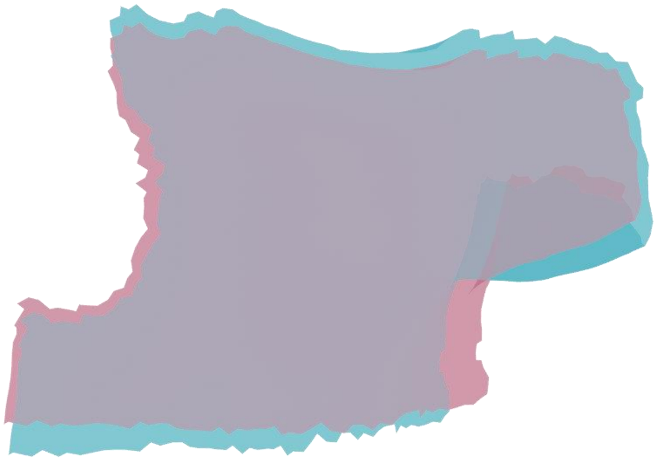

Fig. 36 Principal component 2, in both directions of standard deviations (value -2, 2) [mm].

These findings shows the ways in which the first three principal components contribute to the observed shape variations, providing a possibility for understanding the anatomical diversity present in the dataset.

3.4 Preliminary ideas

The aim of this assignment was to establish a foundational framework, including the relevant dimensions and details of the zygomatic bone and the specific area of interest. This work would lay the foundation for the potential future development of a preformed osteosynthesis plate made specifically for the zygomatic bone. Throughout the examination of the requirements and wishes, preliminary concepts were conceived.

The use of SSM allows the study of potential changes beyond the normative model. By examining the statistical trends observed in SSM, preliminary designs can take into account broader fracture patterns, as well as the range of patient-specific anatomical conditions. In addition, SSM plays a key role in assessing the feasibility of preliminary designs. Using a normative anatomical model, the SSM provides a baseline for evaluating the practicality and feasibility of proposed concepts. This systematic evaluation ensures that preliminary designs are consistent with expected anatomical changes, minimizing the risk of intraoperative changes and increasing the overall efficiency of the design process.

The first idea (Fig. 37) is a larger version of the simple plate. Given that the fracture site is on the zygomatic bone, within the zygomatic arch, it was decided to design the plate to have two fixation points. One on the right side of the fracture, where the size of the plate is small, due to the area close to the orbit; while two more, for better stability, on the opposite side, in the maxillary area, at a point above the presence of the tooth roots.

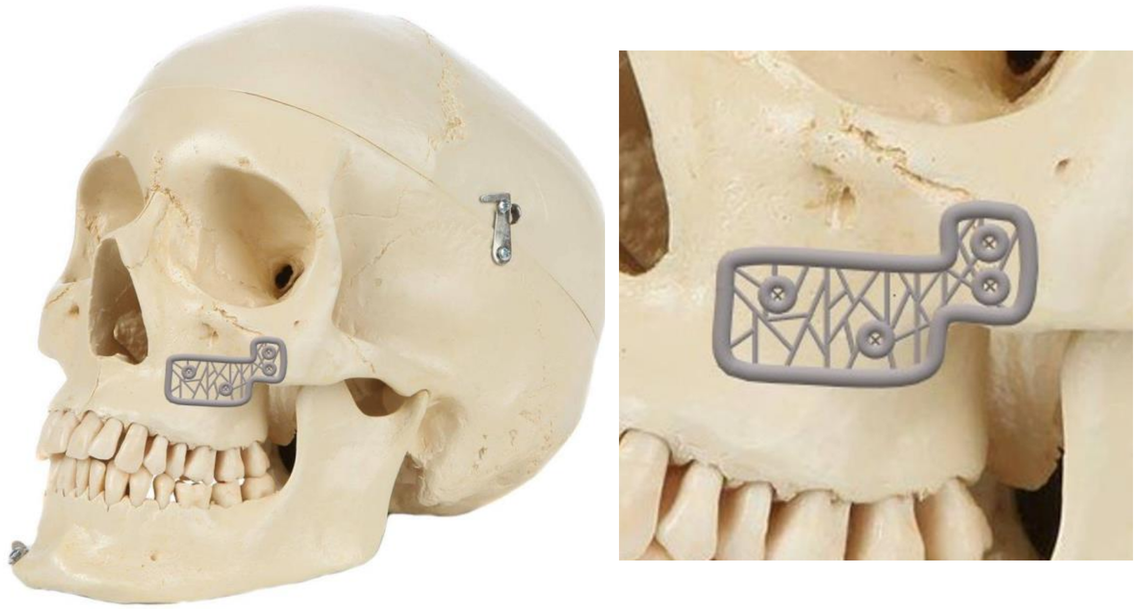

Fig. 37 I preliminary design of preformed osteosynthesis plate for zygomatic bone

Included in the requirements and wishes that were discussed at the beginning of the project was the wish to create an additional, so-called 'hook' to help stabilise the bone and allow surgeons to easily locate the correct insertion of the plate. This is located on the zygomatic arch and bends underneath it to form a short hook. What we can notice on the variations figure is that the indicated area shows a slight deviation and therefore a slight difference in shape between patients. The whole design is based on a scaffold, which makes the plate lighter and uses less material.

The second (Fig. 38), similar to the first, with an additional extension, allows for better stabilisation, through more fixation points and will further assist in navigating the positioning of the plate in relation to the bone prominence and zygomatic arch. The variation in shape value indicates low variation between patients at the plate area. All created on the basis of scaffolding, allowing the plate to be lighter and using less material.

Fig. 38 II preliminary design of preformed osteosynthesis plate for zygomatic bone

The third plate (Fig. 39) differs significantly in concept from the previous two. It can join more extensive fractures also those arising in the orbit. The idea of the hook has been retained due to the possibility of localising the insertion of the plate by surgeon’s. The upper part of the plate overlaps the orbit to create a similar hook as the one below. The variations on the orbit are a bit larger than minimal, which may suggest a bit greater difference in this area between patients.

Fig. 39 III preliminary design of preformed osteosynthesis plate for zygomatic bone.

Furthermore, as part of the project evaluation, a grading of the preliminary design was undertaken. By analysing the preliminary designs and their alignment with the project requirements and wishes, a clear selection of a design, with the highest potential for success was established.

Concepts were considered based on Harris profile. Based on the graphs, the strengths and weaknesses of the preliminary designs are shown, where -2 means not possible/not able and +2 possible/able [50]. Table 6 below shows the ratings awarded. What can be seen is that the I Preliminary design has the most chances to became successful as preformed zygoma plate, according to requirements and wishes performed in cooperation with surgeons.

Tab. 6 Grading of preliminary designs – Harris profile.

	Preliminary design I				Preliminary design II				Preliminary design III			
	-2	-1	+1	+2	-2	-1	+1	+2	-2	-1	+1	+2
Requirement 1			■					■		■		
Requirement 2				■				■				■
Requirement 3				■			■			■		
Requirement 4				■				■				■
Requirement 5				■				■				■
Requirement 6				■				■			■	
Requirement 7			■					■			■	
Requirement 8		■				■				■		
Requirement 9				■				■			■	
Wish 1			■			■						■
Wish 2				■				■				■
Wish 3				■				■				■
Wish 4				■				■		■		
Wish 5			■			■						■
Wish 6				■				■				■
Wish 7				■			■				■	
Wish 8				■				■				■
Result	27				23				18			

4 Discussion and recommendations

Even if there is no actual proof of concept, reasonable assumptions can be made about its functionality. An important aspect was to create a basis for the design of the plate, starting with the requirements that were set as necessary for the design, creating a statistical shape model, thus obtaining information on the required dimensions for the usability of the product and checking variations in shape, which affects the shape of the plate. Combined, this gives us the basic data needed for a correct design of the final product. The requirements and wishes created and analysed can be a suitable basis for future understanding and implementation of the rest of the project.

4.1 Requirements and wishes

A detailed approach to requirements and wishes, which were developed in collaboration with surgeons, provides a solid foundation for the design of a preformed zygomatic bone plate. These requirements and wishes reflect an understanding of the research problem, the challenges surgeons face, and the desired additional solutions for an optimal solution. It is recommended that the preformed osteosynthesis plate for zygomatic reconstruction be designed based on the obtained requirements and wishes. This ensures that the design process is not only technically reasonable, but also takes into account the real problems and limits of conventional plates faced by surgeons.

4.2 Statistical shape model outcome

4.2.1 Validation of SSM

An important outcome aspect is the realistic shape of the statistical model and its dimensions. This allows the conclusion to be drawn that the study was carried out correctly. Evaluation of the SSM using parameters such as generalisation, compactness and specificity allows analysis of model validation. The generalisation results in which the mean squared error decreased and the difference was no greater than 10^{-3}mm as the number of training data increased, suggests that the model was trained with enough data. This shows that for the selected limited surface 53 patient data are sufficient to create a model that accurately captures the variability and characteristics present in a given dataset. Compactness, where the high percentage of variability was explained by the first 14 principal components indicates the model's ability to capture most of the variability in the data, ensuring its reliability. Specificity shows that the model has learned relevant shape information and is able to generate realistic representations of shape changes, strengthening its reliability. In conclusion, these key indicators collectively confirm the reliability and credibility of the model, inspiring confidence in the results and outcomes obtained from its application.

4.2.2 Variation in SSM

Considering the mean SSM and shape variance between patients, it can be deduced that the area of interest for the insertion of a preformed plate shows little variation between patients. But it is necessary to take care about the places of screw insert, as some places, chosen before for screws, shows slight differences between patients. The wrong place of insert might later cause problems according to fit of the plate. Consequently, the outcome should provide an opportunity to design an osteosynthesis preformed plate to match the average shape of a larger number of patients.

4.3 Materials and methods

When starting to create the code in IntelliJ, it was necessary to correctly prepare the input data. Adequate segmentation was required, as any artefacts or holes caused problems with the mesh. The meshes of the selected craniofacial region themselves had to be remeshed beforehand to have a uniform size. Failure to meet both resulted in the inability to create a correspondence between the meshes. Equally importantly, not every input file extension was compatible with Scalismo. STL had a problem during correspondence, similar with PLY. The best extension was VTK, which, however, by mandatory web conversion could give false positive correspondence results, which was analysed through other 3D software and visualisation of the mesh. In the process of carrying out the work, an equally important aspect was the precise layout of the SSM steps. Further problems when obtaining correspondence results, confirmed by results from other software, suggested a change in the way the first stage of data preparation was carried out. Additional problems occurring during the creation of the SSM, with too extensive segmentation, i.e. primarily unrealistic shapes, further confirmed this. The 3DMedx programme proposed solutions that worked better during the preparation of the ICP, correspondence and the MeshMonk algorithm. From the segmented part of the patient's craniofacial, it was decided to extract one surface, with a smaller area of interest, based on the template previously made in the 3DMedx programme, and then proceed with the next steps towards obtaining a realistic SSM. Those information can be useful when creating correspondence for such complex shapes.

4.4 Principal components

PCA was used to describe the mean shape and variability of the data set. This representation is fundamental for ensuring that the model adequately captures the anatomical variations present in the zygomatic bone dataset. Due to the complex variance between components, interpretation was relatively difficult. In addition to the fact that each component was responsible for two or more major physical processes, it was noted that they consisted of many additional, smaller processes. As a result, it was problematic to attribute further physical process to the components as they represent a smaller and smaller percentage of the overall variance in the data set. It was decided to focus on first three, with most influence.

4.5 Preliminary design

The first two proposed plates in the initial design phase coincide with areas of low variance in the variation figure, which may positively influence the future success of the design of preformed plates for the zygomatic bone. In practice, this means that the variation analysis in the zygomatic bone area has shown characteristics that can be used for the subsequent development of the final designs of these plates. This, in turn, can translate into more precise and effective solutions, increasing the likelihood of success in their creation process. The third design, which shows slight shape changes in the orbital area, may suggest future necessary refinements and a closer look at the orbital area, towards finding a suitable shape, or matching the proposed one. The preliminary ideas might be also used as a basis for determining the final appearance and dimensions of the plate.

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Appendix 1

```
import scalismo.common.DomainWarp
import scalismo.geometry.{EuclideanVector, _3D}
import scalismo.statisticalmodel.dataset.{Crossvalidation,
DataCollection, ModelMetrics}
import
scalismo.statisticalmodel.dataset.DataCollection.TriangleMeshD
ataCollection
import scalismo.mesh.{MeshMetrics, TriangleId, TriangleMesh}
import scalismo.image.{DiscreteImage, DiscreteImage3D}
import scalismo.statisticalmodel.PointDistributionModel
import scalismo.io.ImageIO
import scalismo.io.StatisticalModelIO
import
scalismo.io.StatisticalModelIO.writeStatisticalTriangleMeshMod
el3D
import scalismo.io.{MeshIO, StatisticalModelIO}
import scalismo.ui.api.ScalismoUI
import scalismo.ui.api.LandmarkView
import scalismo.utils.Random

import scala.util.Try

object SSMNEW extends App {
  scalismo.initialize()
  implicit val rng: scalismo.utils.Random =
scalismo.utils.Random(42)
  val ui = ScalismoUI()

  val meshesDir = "procrust_data"
  val dataFolder = "datasets"

  val meshFiles = new java.io.File(dataFolder + "/" +
meshesDir + "/")
    .listFiles.filter(file => !file.isDirectory).sortBy(f =>
f.getName) //no more than just files from folder, no more
folders etc

  val meshGroup = ui.createGroup("meshFiles")

  val meshes = meshFiles.map(meshFile => {
    MeshIO.readMesh(meshFile).get
  })
  val referenceMesh = meshes.head

  val dc =
DataCollection.fromTriangleMesh3DSequence(referenceMesh,
meshes)
  val modelFromDataCollection =
PointDistributionModel.createUsingPCA(dc)
```

```
  ui.show(meshGroup, modelFromDataCollection, "ModelDC")
}
```