An Interactive, Fully Digital Design Workflow for a Custom 3D Printed Facial Protection Orthosis (Face Mask)

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Abstract. Sport-related injuries have an increased prevalence of maxillofacial fractures among professional (soccer) players. From professional players' perspective, these injuries can have career-detrimental effects when followed with prolonged recovery periods. Therefore, to facilitate an earlier training and competition return, and reduce the chances of re-injury, the use of face-protective orthosis, commonly known as a face mask, in rehabilitative management is of paramount importance.

To date, the fabrication of a customized face mask has been an entirely manual and time-consuming process. To mitigate the issues with conventional customized face masks, the authors have presented a fully digital "contactless design and production" workflow for the fabrication of a patient-specific face mask. This work aimed to integrate the existing tools of medical image processing software, computer-aided design (CAD), three-dimensional (3D) digitization, and additive manufacturing (AM) to provide a cost-effective, practitioner/patient-friendly solution for the design and manufacturing of patient-specific face-protective orthosis or face masks. Considering the functional and clinical aspects at the fractured site, a virtually designed face mask was fabricated in-house with carbon-reinforced polylactic acid composite material via material extrusion or Fused Deposition Modeling (FDM) technology. The face mask had a comfortable fit, required no alterations, was lightweight, and shortened the convalescence period for the patient. The results from the selected design case accurately represent the clinical scenario and shows the potential of the proposed workflow in similar facial fracture situations. With greater ease of fabrication and production validity, this study highlights an alternative approach applicable in clinical practice.

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1 Introduction

Sport-related injuries result from a variety of different mechanisms and often vary in location and pattern. These injuries account for 6 to 10% of maxillofacial traumas, with the most common association to the fractures of nose followed by zygomatic bones [1, 2]. In general, sport-related injuries have an increased prevalence of facial fractures in soccer and basketball players [3, 4]. From professional players' perspectives, especially in high contact sports, these injuries can have career-detrimental effects when followed with prolonged convalescence periods. Face-protective orthoses, commonly known as face masks, are patient-specific splints, that primarily protect the face and redistribute the impact forces during sport activities [5]. Therefore, to facilitate an earlier training and competition return, and reduce the chances of re-injury, the role of face-protective orthosis in rehabilitative management is of paramount importance [6].

Face masks can be either prefabricated or customized (also known as patient-specific). Over-the-counter or prefabricated face masks are commonly available in the market and fit a range of athletes during sports activities. However, the use of prefabricated face mask in the clinical treatment of athletes sustaining maxillofacial trauma is limited [7, 8]. These devices do not provide an individualized fit to the patient and, therefore, are considered inferior to customized face masks during the rehabilitation phase. On the other hand, customized or patient-specific face masks are solely designed for the individualized rehabilitative management of athletes with maxillofacial injuries [9]. Until now, the fabrication of customized face masks has been an arduous task. This fabrication method is an entirely manual, labor-intensive process comprising face impression or moulage (negative), plaster mold (positive) fabrication, adaptation of thermoplastic sheet onto the mold, and last, fine-tuning of the mask with cutting tools. This conventional approach, although widely used among clinicians, is time-consuming and unpleasant for the patient. Besides, this approach often requires frequent adjustments compromising both the comfort and function of the face mask [5, 9–11].

To address the challenges mentioned above and increase patient compliance, the integration of less invasive technologies into the clinical workflow is imperative. Medical image processing software and additive manufacturing (AM) technology have been applied in several medical applications, including the design and manufacturing of medical splints for ankle-foot or wrist [12–14]. Furthermore, advancements in digitization technologies such as three-dimensional (3D) face-scanning have made it conceivable to generate digital models of surface topography of human face [15]. The assimilation of these technologies contributes to patient-specific digital data in a contactless manner, and has the potential to change the conventional workflow for customized face mask. This work aimed to integrate the existing tools of medical image processing software, computer-aided design (CAD), 3D digitization, and AM to provide a cost-effective solution for the design and manufacturing of patient-specific face-protective orthosis or face masks. More specifically, a practitioner/patient-friendly "contactless design and production" approach was devised that enabled the clinicians with point-of-care manufacturing to fabricate a customized face mask for a patient operated at a distant hospital.

2 Materials and Methods

In this section, an interactive digital design workflow for customized face-protective orthosis or face mask is introduced for athletes with sports-related injuries of the maxillofacial region. The entire workflow has been established using a procedural methodology, including four phases, each involving several steps. An overview of the schematic representation of the digital workflow is displayed in Fig. 1.

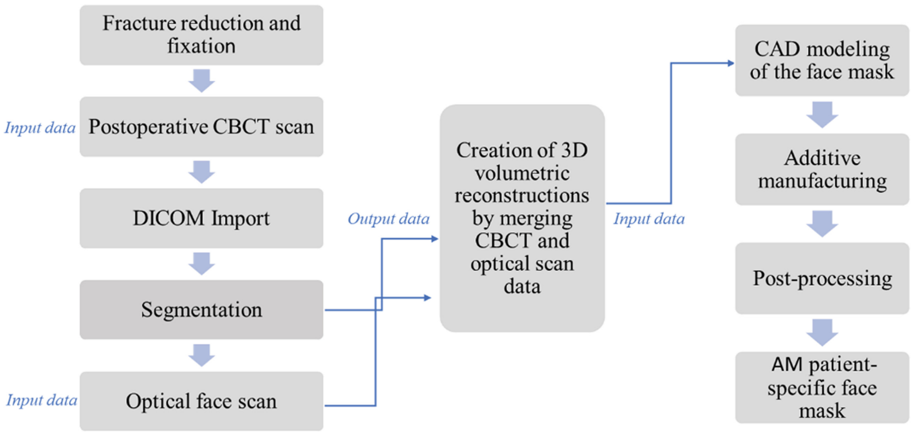

Fig. 1. An overview of the schematic representation of the digital workflow.

2.1 Clinical Case Fracture Treatment

The workflow started with an appropriate clinical case selection, referred to the Department of Cranio-Maxillofacial Surgery, University Hospital Basel, to discuss the treatment option for the fabrication of a patient-specific face mask. The patient was a professional soccer player of the Austrian First League who suffered an injury to the face during sport activity. He experienced a fracture of the right zygomaticomaxillary complex (ZMC) region, which was treated by immediate open reduction and internal rigid fixation. The digital imaging and communications in medicine (DICOM) dataset from immediate postoperative cone-beam computed tomography (CBCT) provided by the operating hospital were imported into Materialise Interactive Medical Image Control System (MIMICS) medical software (MIMICS Innovation Suite v. 20.0, Materialise, Leuven, Belgium). Following this, Hounsfield unit (HU), which expresses the grayscale, was adjusted accordingly using the thresholding method. Subsequently, a semiautomatic segmentation of the region of interest was performed, and the respective bony and soft tissues 3D volumetric reconstructions were generated, which were consequently exported and saved in a standard tessellation language (STL) file format. The 3D volumetric reconstructions confirmed adequate reduction with three-point fixation of the ZMC region with titanium miniplates at the right frontozygomatic suture, right infraorbital, and right zygomatic buttress regions (Fig. 2).

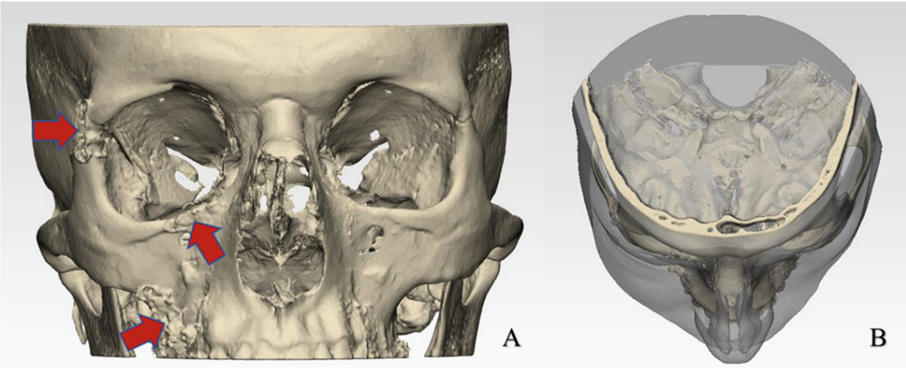

Fig. 2. Postoperative CBCT 3D volumetric reconstructions A: Bony 3D volumetric reconstruction showing titanium miniplates fixation at right frontozygomatic suture, infraorbital region, and zygomatic buttress regions. B: 3D volumetric reconstructions of soft and bony components with noticeable soft tissue swelling (right side).

2.2 Computational Image Data Acquisition and Virtual Model Registration

An accurate visualization of anatomical bone and soft tissue components is an essential step for the design of a patient-specific face mask. As the immediate postoperative CBCT dataset does not corroborate with the soft tissue component because of postoperative swelling, a 3D optical face scan (Vectra M3 3D Imaging system, Canfield Scientific, New Jersey, USA) was scheduled after the swelling had subsided. Prior to data acquisition, the optical scanner was calibrated following the manufacturer's instructions. After the scanning procedure was completed, the digitized surface geometry of the face was transferred as polygonal STL (triangular mesh) containing over 200,000 points and 474,180 triangle elements. The mesh generated was of high quality, and no further post-processing procedures were required. To register the face's surface topography generated from a 3D optical scan dataset to the native anatomical bony structures generated from the postoperative CBCT dataset, superimposition via a best-fit alignment method was executed (3-matic medical v. 13.0, Materialise, Leuven, Belgium). Using an iterative closest point (ICP) algorithm, surface registration protocol (n-point and global registration) was accomplished between the 3D volumetric reconstruction of CBCT soft tissue component and 3D optical face model (Fig. 3A, 3B). The registration protocol was based on the selection of similar anatomical points on the healthy (non-operated) side of the face, unaffected by postoperative swelling. Integrating 3D volumetric reconstructions of bony anatomical structures with a 3D optical face scan allowed an accurate representation of the patient's maxillofacial region, which served as a reference for the digital designing of face mask (Fig. 3C).

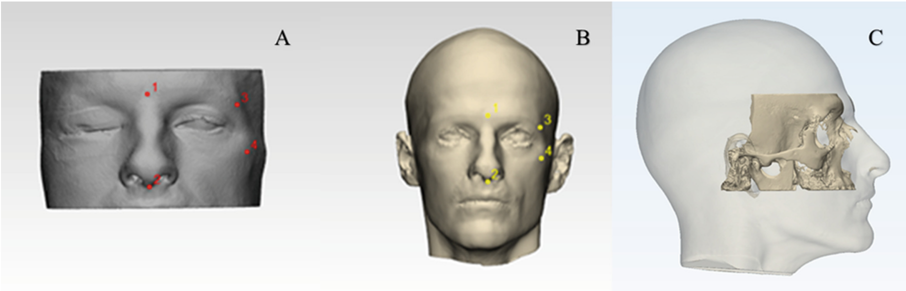

Fig. 3. Illustration of the subsequent steps of the computational medical image registration protocol. A: Selection of points on the 3D volumetric reconstruction of soft tissue component from postoperative CBCT. B: Selection of points on the 3D optical face scan model. C: Profile view of the patient after registration of a 3D optical face model on the 3D volumetric reconstruction of the bony component from postoperative CBCT.

2.3 3D Modeling of Patient-Specific Face Mask in CAD Software

Following the computational medical image registration protocol, modeling of the face mask was accomplished in an open-source CAD software (Meshmixer v.3.5.474, Autodesk Inc.). Anatomical and functional requirements were taken into consideration during this design phase. The maxillofacial skeleton has areas of strength (maxillofacial buttresses or pillars) and areas of weakness (in-between walls). The components of the buttress system in the exemplary case consist of vertical (zygomaticomaxillary) and horizontal (frontal bar, infraorbital rim) buttresses. These regions have increased bone thickness and act as a supporting base for the design of the face mask. The STL (triangular mesh) file from the 3D optical face model was used for the digital modeling of the face mask. Using Meshmixer's *select* tool feature, the region of interest (ROI) was highlighted using *unwarp brush* tool. A specific selection mode, limited to symmetry, was turned on during this phase, to allow equivalent boundary extensions of the face mask (Fig. 4A). The smooth boundary of the mask was then defined using the expand mode filter for geodesic distance (Fig. 4B). Keeping the *select* tool on, the edit functionality was used, and the mask surface was extracted. Next, using the *offset* tool, a clearance of 2 mm was created. (Fig. 4C). This was necessary to have an adaptation space between the face and inner surface of the face mask to prevent over-compression of the mask on the patient's face and also to allow sufficient space for the padded lining. The extracted surface of the mask was separated from the 3D optical face model STL. Next, the thickness of the mask was defined. Using the edit mode feature and keeping the surface connected functionality on, the *offset* tool was used to extrude the mask surface and modeled to a thickness of 3 mm (Fig. 4D). To refine the boundaries of extruded mask, *smooth boundary* tool was used, keeping the shape-preserving functionality on (Fig. 4E). Further refinement of the mask was accomplished using the *sculpt* tool, limited to surface only functionality. This fine-tuning of the mask overlaying the fractured regions was limited to the outer surface with a selective increase in the thickness. Lastly, using *Boolean subtraction* tool, four rectangular retentive grooves (dimensions: 5 mm × 2 mm) were bilaterally designed onto the frontal and zygoma region of the mask to secure the fastening band (Fig. 4F). These grooves are for assembling and disassembling the face mask, making it adjustable during the rehabilitation phase of the patient. The modeled mask file was at last exported in STL file format.

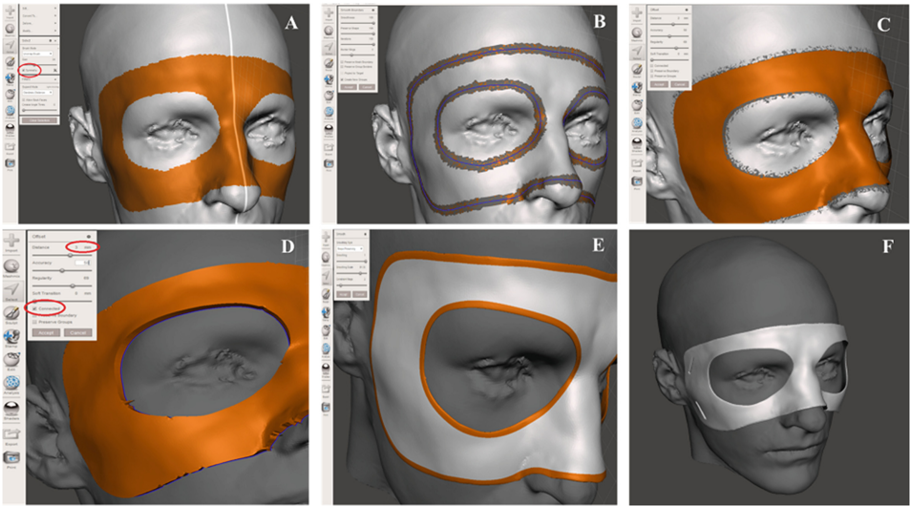

Fig. 4. Illustration of the subsequent steps of 3D modeling workflow. A: Selection of the region of interest (ROI), B: Defining smoothed boundaries, C: Creation of gap between mask and face, D: Extraction of the mask's surface to add thickness, E: Shape-preserving symmetrical boundary refinement of extruded mask, F: Creation of rectangular pattern retention grooves.

2.4 Material Extrusion Additive Manufacturing and Post-processing of Patient-Specific Face Mask

The STL file of the virtually designed face mask was imported into the slicing software (MakerBot Print v. 4.5.0.1729, MakerBot Industries, USA) of a 3D printer. The face mask was fabricated in PLA filament reinforced with short carbon fibers (in a weight fraction of 30%) (Patona 1.75 mm Black Carbon Fiber PLA filament, Patona International S.L.U, Germany) using a desktop Fused Deposition Modeling (FDM) 3D printer (MakerBot Replicator+, MakerBot Industries, USA), with the following settings: infill: 40%; layer height: 0.2 mm; shells: 3; nozzle diameter: 0.6 mm, extrusion temperature: 220 °C. For optimal printing, the generation of both raft and support structures were selected in the slicing software. After manual removal of support structures, the surface of the face mask was smoothed using 1000 grit sandpaper, and two layers of carbon-fiber fabric 200 g/m^2 (HP-T200/120C, HP-Textiles, Schapen, Germany) were adhered on the inner side of the mask for additional reinforcement.

In succession, to achieve a glossy smooth surface finish, the mask was coated with a layer of an epoxy resin material (Epoxy Resin 4305, DD composite, Germany), and left to dry. Custom graphics were later added for aesthetic purposes. Finally, a padded foam lining was adhered to the undersurface of the face mask.

3 Results

Figure 5 shows the result of the described interactive fully digital workflow – from computational 3D planning/designing, additive manufacturing to the realization of patient-specific face mask in a professional soccer player. Due to the nature of the maxillofacial fracture pattern, in this case, the customized face mask was fabricated as a one-piece structure, which provided optimal protection to the operated site. Results from subjective assessment by the patient were entirely satisfactory. According to these results, the face mask had a comfortable snug-fit requiring no alterations, was impact-resistant, and provided a significant earlier return to his athletic practice sessions. The digitally contoured ocular apertures gave an unobstructed view during sport activity. Overall, this in-house fabricated face mask was sturdy, lightweight (50 gm), and aesthetically pleasing.

Fig. 5. Interactive digital workflow. A. 3D computer-aided design and planning B. FDM printed carbon-reinforced PLA face mask C. A professional soccer player with a customized face mask during his sport's practice session.

4 Discussion

Recently, the use of face-protective orthosis or face masks by professional athletes has significantly increased. While several over-the-counter options for face masks already exist, these masks are not as efficient as custom-made masks due to diverse patterns of maxillofacial injuries [7]. Patient-specific face masks are more comfortable and provide a better fit. However, the traditional fabrication method for custom-made masks come with some disadvantages, the most significant being the unpleasant fabrication process. This conventional method is an entirely manual process, starting with a negative impression (sometimes called moulage) of the face taken with materials such as plaster, alginate, or silicon rubber. Next, a positive replica of the face is made from the impression using plaster or dental stone. Subsequently, a thermoplastic sheet material is heated, and together with the positive replica is placed in a vacuum former. Once set, the sheet is removed from the mold and adjusted to the dimensions of the mask using a heated knife or a grinding/cutting tool. Finally, holes are cut for the eyes, nostrils, mouth as required, and retention grooves are made for straps. Although this conventional process is widely used among clinicians, the process requires frequent iterations, resulting in a time-consuming process where much material and prosthetic clinic time is invested [8, 9]. However, such procedures can be outsourced to an external company, but this fabrication process is expensive and requires long lead times. Therefore, to increase efficiency from conventional methods and outsourcing, a novel in-house, fully digital workflow for the design and manufacture of a patient-specific face mask was devised.

Digitization technologies such as 3D face scanning and AM contributed to the contactless production of patient-specific digital data, which correlates to anatomical features [16, 17]. A device created from a patient's data makes a bespoke orthosis, which provides the best fit geometry. For a clinical fit patient-specific face mask, each clinical case should be assessed individually. One of the essential aspects that need consideration is adequate fixation of the fracture. A face mask designed over improperly reduced fracture site can cause more damage with fracture-dislocation when in contact with external forces. Several design criteria are also relevant to determine, which anatomical structures such as fractured bones and soft tissue lacerations need protection and which anatomical structures contribute to maximal support for the face mask. In the present clinical case, bilateral supraorbital rims, glabella, and contralateral non-injured zygoma region acted as supporting anatomical structures for the face mask. An elevated surface that helps in the distribution of forces away from the operated ZMC region protected the fractured region. Lateral and anterior field of view was maintained by contouring and widening the ocular region. As an ill-fitting face mask can cause discomfort to the patient, smooth boundary edges and padded lining were added to prevent abrasion of the underlying skin from mild movement. This image-based design workflow is minimally invasive, less stressful for the patient, and facilitates quick rehabilitation during the convalescence period by protecting the traumatized anatomic region.

In this study, we chose the option of using a biodegradable composite thermoplastic material, carbon-reinforced PLA, for the fabrication of a lightweight face mask. The addition of reinforced materials (such as carbon fibers) to PLA to form a thermoplastic composite, helps in matrix binding and transfers the load to the reinforcing fibers. This results in carbon-reinforced composites with high strength-to-weight ratio, excellent corrosion and wear resistance, and high dimensional stability [18]. In terms of utility and performance of the face mask, it can be ascertained that the AM manufactured carbon-reinforced PLA mask achieved a good balance between strength and weight reduction. The subjective assessment by the patient validates the high durability and friendly wear of the face mask. The complete workflow from planning to fabrication of mask was accomplished in less than one day. This shows that using an in-house AM setup not only results in a shorter overall turnaround time, but is also a relatively cost-effective production solution. The cost of the proposed in-house digital workflow is represented in a general scenario, for instance, the clinician already has the required equipment for the scanning and printing process, and the overall cost is lower due to less time and material consumption. Nevertheless, these cost-effective benefits should be further evaluated where clinicians verify the proposed workflow with conventional fabrication methods.

The medical application of AM is increasing with the potential integration of an automatic design process. Some novel concepts for substitutes in medical splints for orthopedic aids are already reported [13]. These digital solution platforms automatically generate a design, which is digitally validated through finite element simulations. Once a feasible structure is obtained, the design is manufactured. Such digital platforms can be exploited and expanded in the field of face masks by establishing a digital process chain.

Although the proposed workflow is based on a patient with a fracture of the zygoma region, this sequential methodology, with slight design alterations (for example: the selection of specific ROI), can apply to other fractures of the maxillofacial region that need protection during the convalescence periods. This digitized workflow enables design freedom in a virtual environment, and various modifications can be rapidly integrated before proceeding with manufacturing [13, 19]. The digitized approach provides an easier means of reproducibility in case of lost/damaged mask. Finally, incorporating digital technologies in a clinical environment allows the clinician to customize the patient's mask with minimal effort, increasing patient satisfaction, and an improvement in treatment efficacy.

5 Conclusion

In this article, we presented a fully digital workflow that combined state-of-the-art digitization technology with medical imaging and additive manufacturing to rapidly fabricate a custom-made face-protective orthosis for rehabilitative management in patients with sports-related maxillofacial injuries. To sum up, the exemplary case demonstrates how the unique properties of point-of-care manufacturing can be exploited in the field of orthoses and prostheses through the establishment of a digital process chain. This workflow has allowed an improvement of some characteristics of conventional custom-made masks as follows:

- Minimally invasive, contactless production method
- Decrease in lead times
- Easier reproducibility
- Cost-effectiveness

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