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Full length article

The design, production and clinical application of 3D patient-specific implants with drilling guides for acetabular surgery

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ABSTRACT

An innovative procedure for the development of 3D patient-specific implants with drilling guides for acetabular fracture surgery is presented. By using CT data and 3D surgical planning software, a virtual model of the fractured pelvis was created. During this process the fracture was virtually reduced. Based on the reduced fracture model, patient-specific titanium plates including polyamide drilling guides were designed, 3D printed and milled for intra-operative use. One of the advantages of this procedure is that the personalised plates could be tailored to both the shape of the pelvis and the type of fracture. The optimal screw directions and sizes were predetermined in the 3D model. The virtual plan was translated towards the surgical procedure by using the surgical guides and patient-specific osteosynthesis. Besides the description of the newly developed multi-disciplinary workflow, a clinical case example is presented to demonstrate that this technique is feasible and promising for the operative treatment of complex acetabular fractures.

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Introduction

Operative treatment of complex acetabular fractures is challenging [1]. The goal of surgical treatment of the fractured acetabulum is to restore the articular surface and provide a stable fixation, which allows immediate postoperative exercising. Proper fracture reduction might be demanding due to the large forces needed to manipulate the bone fragments, the soft tissue involvement, and the limited surgical access to position reduction clamps. After the reduction, we are faced with the challenges for stable fracture fixation. Unfortunately, no uniform osteosynthesis plate is available that fits the shape of each pelvis and the variability of the fracture patterns perfectly. In current routine, the plates require multiple intra-operative bending and contouring

manoeuvres and adjustments, in order to adequately fit an individual pelvis. Occasionally, the shape of the plate is suboptimal to buttress comminuted quadrilateral plate or posterior wall fractures. The optimal screw positions might be challenging to determine and hard to verify with fluoroscopy. Taken all this into account, it is obvious that preoperative planning is mandatory to achieve optimal results in acetabular fracture surgery. ‘Plan your operation, and operate your plan’ is one of the adages taught during our surgical training.

Recent developments in three-dimensional (3D) imaging technology expand the capabilities for planning surgical treatment. 3D visualisation and virtual planning of surgery has been used for preoperative planning and postoperative evaluation of complex cranio-maxillofacial reconstructions for years [2,3]. Mandibular or maxillary defects that often resulted from tumour resections can be reconstructed by using free vascularised fibula flaps. Three-dimensional preoperative planning of this procedure was reported to be successful for an accurate translation of the virtual planning towards the actual surgery by the use of custom made plates and surgical cutting/drilling guides [2]. Based on this

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validated approach, as applied in our hospital, we explored whether it would be feasible to use patient-specific plates and drilling guides for acetabular fracture surgery. Refining the preoperative planning of acetabular fracture surgery with the development of patient-specific implants and drilling guides may improve the surgeon's efficiency and the quality of the reduction and fixation. So far, there have been no reports on the design, production and application of personalised implants used in conjunction with surgical drilling guides for treating these injuries. Our aim was to develop custom made reconstruction plates with matching drilling guides for acetabular surgery. We assessed the feasibility, accuracy, and efficiency of this innovative procedure through a clinical case.

Design, production and clinical application of 3D patient-specific implants with drilling guides

Patient

A 48-year-old healthy male patient was transferred to the emergency department, arriving from another hospital, after falling from his bicycle onto his left hip. At physical examination he had functional impairment and pain in his left hip but without

neurovascular compromise. He was admitted at the level 1 trauma centre for operative treatment of a displaced fracture of the left acetabulum (Fig. 1). A CT scan of the pelvis demonstrated a both column fracture of the left acetabulum (AO/OTA fracture and dislocation classification type C3.3).

3D model and plate designs

A 3D model of the fractured pelvis was created based on the CT data (slice thickness of 1 mm), using ProPlan CMF 2.1 (Materialise, Leuven, Belgium) software. In order to obtain an adequate 3D model, a threshold-based bone segmentation (automatic) was performed. In addition the individual fragments were checked and adjusted (manual) where necessary. After the segmentation process each bony fragment was labelled and assigned a different colour. The uninjured side of the pelvis was mirrored over the injured side as a supportive model for restoring the pelvic integrity. Using the translational- and rotational tools in the virtual planning software, each individual fragment was repositioned in order to reduce the fracture. The anatomically reduced pelvis was discussed and authorised in a multidisciplinary meeting with surgeons, technical physicians, and engineers (Fig. 2). Subsequently, patient-specific implants were designed on the reduced pelvis in 3-Matic

Fig. 1. Pelvic radiograph AP view (A) and 3D reconstruction (B) of a left acetabular fracture (type AO/OTA 62-C3.3). The CT scan showed a mild protrusion of the femoral head due to a displaced acetabular fracture involving the iliac wing, extending to the acetabular roof, reaching up to the quadrilateral plate, and involving both the anterior and posterior columns.

Fig. 2. Preoperative planning of the fractured pelvis, which is created by using the MIMICS 19.0 software. The fractured left acetabulum is virtually reduced. Patient-specific implants with drilling guides were designed for fracture fixation.

11.0 (Materialise, Leuven, Belgium), Solidworks professional 2017 (Dassault Systèmes Solidworks Corp., Waltham, MA, USA) and Geomagic for Solidworks (3D systems, Rock Hill, SC, USA) software (Fig. 3). Taking the fracture pattern into account, an anterior and posterior plate were designed in the most optimal position on the virtually reduced acetabular fracture to achieve stable internal fixation. Reinforcements for the quadrilateral plate and the posterior wall were incorporated in the design of the implants. Drilling guides were designed to redirect the screws to the right position during the operation. The guides were developed to fit on top of the implant. They had additional bone supporting extensions that enabled a peroperative visual check for correct placement. In addition, the guides were supplied with holes for k-wire fixation once the correct position was achieved. The direction of drilling was guided by a stainless steel (316 L) milled drill sleeve, which could be inserted into supporting cylinders on the guide. The preoperative planning required a close collaboration between the surgeon, technical physician and medical engineer, as this workflow relies heavily on an adequate representation of the real life condition in the virtual model. In the virtual environment plates and screws can be placed in all possible positions, but in

reality soft tissues may interfere with the reduction and narrow the working space.

Production process

The designed guides were saved as a stereolithography (STL) file for 3D printing. The implant file was converted into a STEP file (standard exchange product of model data-file) and sent to the regional milling company (Witec Medical) that manufactured our self-designed implants (Fig. 4). The drilling/positioning guides were 3D laser-printed from medical certified polyamide powder. The implant was milled, using a 5-axis milling machine, out of a commonly used medical grade titanium alloy (Ti-6Al-4V). The implants and guides were post-processed and packaged for hospital sterilisation according to routine standards, including the 134 °C autoclave steam sterilisation process.

Operation

The patient was operated under general anaesthesia in a supine position. A preperitoneal approach according to Stoppa was used to

Fig. 3. Preoperative planning of the screw positions and lengths (mm).

Fig. 4. Patient-specific plates and drilling guides.

Fig. 5. A/B. Intraoperative image through a Stoppa approach with a clear view of the anterior plate, which is placed over the pelvic rim. The plate fixation is performed by using the drilling guide. C/D. Intraoperative view on the posterior plate through a Kocher-Langenbeck approach. Fixation of the plate with a drilling guide.

Fig. 6. The postoperative X-rays (A. AP pelvis, B. obturator view) showing the position of the patient-specific implants for the reconstruction of a type C3.3 acetabular fracture.

anteriorly expose the fracture site. There was a fracture dislocation of the anterior column and the quadrilateral plate was medially displaced. To properly expose and reduce the fractures we opened the first ilioinguinal window along the iliac crest. Subsequently, we were able to reduce the fractures by placing the collinear reduction clamp. In addition, two pelvic reduction clamps were placed over the anterior column. The patient-specific implant with guide was positioned over the pelvic rim and temporarily fixated with K-wires through the guide (Fig. 5). The pelvic brim plate is curved and was designed with an extension to support the quadrilateral surface and buttress the medial wall of the acetabulum. Our personalised plate gave some advantage with the reduction because the quadrilateral surface extension and the brim plate were incorporated in one design. Unlike most commercially available plates for acetabular osteosynthesis, which solely provide separate quadrilateral surface plates with an angular shape. One of the major disadvantages of these separate plates is that they may be difficult to attach because the fixation screws point in the direction of the acetabulum or have little grip due to the fracture

lines in the anterior column. This provided the rationale to integrate the pelvic brim and quadrilateral surface extension in one design. By pushing the plate with the extension to the pelvic rim we were able to press the quadrilateral surface back to its anatomical position. Due to the guide design it was possible to insert the fixating screws into the pilot holes immediately after drilling, without needing to remove the guide. Once all screws were inserted and the implant was properly fixated, the guide was removed from the implant. The screw directions and sizes were pre-determined in the preoperative planning and could be placed without peroperative measurements by using the guide. The screws were planned in such a way that they would not hamper the reduction of the posterior column. Furthermore, we planned a lag screw through the plate to catch the large posterior wall fragment. Unfortunately, it was not possible to reduce the fragment by placing lag screws. An intraoperative 3D run with the Orbic O-arm demonstrated that there was still incongruence in the joint due to the irreducible posterior wall fragment. It was therefore decided to remove this insufficient lag screw, close the anterior wounds and turn the patient to a lateral position. We followed our initial plan to perform a posterior reduction and plate fixation through a Kocher-Langenbeck approach. A trochanter flip osteotomy was performed to get good exposure posteriorly. The posterior column and wall were reduced by using a ball spike together with reduction clamps. Three free-hand lag screws had to be placed to keep the reduced posterior wall fragment in place. The anatomically contoured plate including the guide was positioned and the pre-planned screws were placed by using the drilling guide (Fig. 5). However, we experienced that there was more working space in the soft tissues on the anterior side than on the posterior side for the placement of a guide. The guide was removed and the wounds were closed. An animation video of the 3D planning, design, and clinical application of the patient-specific implants and drilling guides is included in the Supplementary materials. The actual total operation time for both the anterior and the posterior approaches was 5 h and 10 min. The actual blood loss during the procedure was approximately 2000 mL. Postoperative non-weight bearing of the left leg was allowed for 6 weeks.

Postoperative

A postoperative X-ray (Fig. 6) and CT scan were performed to assess the accuracy of the reduction and internal fixation. The CT scan revealed a good reconstruction of articular surface (Fig. 7). The fracture largely consisted of gaps instead of steps. The preoperative fracture gaps at the acetabular dome were respectively 16 mm (axial), 14 mm (coronal), and 12 mm (sagittal) in all planes. Postoperatively, the gaps had been reduced to respectively 2 mm (axial), 1.5 mm (coronal), and 0 mm (sagittal) in all planes. The procedure was evaluated by comparing the preoperative planning to the postoperative CT scan. To this end, the postoperative CT scan was superimposed on the virtually reduced pelvis on which the patient-specific implants were designed by using the 3-Matic software (Materialise, Leuven, Belgium). A good correlation was found between the preoperative planning of the custom made implants and the postoperative CT scan. The position and orientation of the anterior fixation plate on the pelvic ring showed a good match between the planning and the actual execution. The placement of the posterior plate deviated slightly from the planned position because it touched a free-hand lag screw, which was inserted to maintain the reduction of the large posterior wall fragment. With the aid of the drilling guides, all screws could be placed at once without peroperative measurement with an average deviation of 8.5° (sd 4.6, range 0.4–17.5) from the pre-planned position (Fig. 8). None of the screws interfered with each other or went into the hip joint cavity. The postoperative recovery of the

Fig. 7. Coronal, sagittal, and axial images from the preoperative (A) and postoperative (B) CT scan, demonstrating a nearly anatomical reconstruction of the fractured acetabulum.

patient was uneventful. Clinical follow up after 3 months demonstrated a good hip function at physical examination with 120° of flexion, 40° of extension, 50° of abduction, 40° of adduction, 40° of exorotation, and 30° of endorotation. The planned fracture fixation with custom made implants and drilling guides resulted in a Majeed score of 98 out of 100 at 3 months follow up.

Discussion

The rise of 3D imaging modalities has improved our understanding of the complex fracture patterns in acetabular injuries [4]. Recently, significant progress has been made in the application of 3D technologies for acetabular fracture treatment. These innovative techniques provided the development of 3D planning software, which enables a virtual simulation of the operation and implant selection [5,6]. These tools might also be useful for educational purposes [7]. Further advancements in this field have led to the use of 3D-printed pelvic models for acetabular fracture treatment. One of the first attempts was described 15 years ago by generating 3D wax models of the contralateral non-fractured hemipelvis in order to pre-bend the plates and plan the screw trajectories with some sort of template [8]. Ever since, 3D-printed pelvic models have been used as molds for pre-bending and fitting of plates prior to the actual surgery. Several preliminary clinical studies indicate that the use of 3D preoperative planning modules and 3D printed models can help to improve the outcome of acetabular fracture surgery [9–15]. It might provide opportunities to better understand the fracture pattern, prepare pre-bend implants and screw directions in advance, and simulate some parts of the operative procedure prior to the actual surgery. Although the use of pre-bend plates on printed models show

promising results, preoperatively produced custom made implants might be a future application for acetabular fracture surgery [16]. Recently, it has been demonstrated that the clinical application of these custom-made implants is associated with an anatomical fitting, a minimised time usage due to the lack of manual plate contouring, secure fixation, and a low rate of implant failure [16]. In line with the rapid developments in 3D visualisation, even virtual-reality-style interactive surgical planning with haptic devices or augmented reality has quite recently been proposed for the surgical planning of acetabular fractures [17,18].

It was aimed to bring the preoperative planning of acetabular fractures to a next level by designing and producing patient-specific implants within our team, by adding additional features to the plates, and by the application of drilling guides to insert the screws in the pre-planned positions. The plates were designed in such a way that they were personalised and tailored to the shape of the pelvis and the fracture type. No additional peroperative contouring was required during the operation, which is timesaving and avoids weakening of the metal due to repetitive plate bending. If the anatomically contoured plates do not fit, it might be a sign that the reduction should be improved any further. Additionally, the plates might be used as molds or references to correct minimal residual displacement of fragments. In our case the incorporated buttress plate for support of the quadrilateral plate was helpful in maintaining the reduction. It is possible to design different features or extensions of the custom-made plates in order to buttress different parts of the fracture, which may help to achieve and maintain an optimal reduction. Furthermore, a personalised plate with a guide gives the opportunity to place guided lag screws, which go through the plate and may contribute to the quality of the reduction. In our case, we planned a guided anterior lag screw in

Fig. 8. Images from the postoperative CT scan were overlapped with the preoperative planning to verify the orientation and position of the plates and screws. The implants extracted from the postoperative CT scan were labelled green. The implant designs extracted from the preoperative 3D model are shown in orange. A comparison of the pre- and postoperative data revealed that the preoperative planning was properly executed during the actual surgery.

order to reduce a posterior fragment, but unfortunately the grip strength of this screw was insufficient to reduce the posterior fragment. The drilling guides were helpful in placing the screws in the right directions. Especially in both column fractures, it is important to choose the directions of the anterior screws carefully so they will not impede the reduction of the posterior fracture fragments or vice versa.

3D technologies are meant to make surgery easier and more precise. We realise that these techniques come with a lot of efforts, time consuming software packages, and costly hardware tools. Surgeons and technicians must become familiar with their use. Lead time is a challenging aspect of incorporating these 3D techniques in acetabular fracture surgery. There is only a short time window of a few days between the injury and the operative treatment in which the 3D model and the patient-specific implants must be produced. Creating a 3D model and designing the implants requires close collaboration between technical physician, engineer and surgeons. It takes time to optimise this process and build up more experience. However, discussing the 3D fracture model with the whole team improved our understanding of the injury. It provided a moment of reflection and the possibility to discuss different approaches and treatment options. The whole process of preparing for the surgery by using a team judgement of the 3D fracture model was experienced as useful. Another challenge for the adoption of these techniques might be the time that is needed for the production process of the implants. The software to design the implants and to produce them must be adapted to each other. The reason we managed to complete the whole process in three days is that we established a regional collaboration between the

surgeon, the medical technician, engineer and the production facility. Our case demonstrates that it is feasible to develop a workflow for making custom made implants with drilling guides for acetabular surgery. With time this application will probably expand and become more accessible to everyone. At this stage, the lead time issue is still challenging, but we believe that the rapid developments in this field will allow these techniques to become part of our armamentarium for treating complex acetabular fractures in the coming decades. Although 3D techniques might be helpful, we should keep in mind that the most challenging step in the procedure is probably the fracture reduction, and the experience, skills and judgement of the surgeon are still very important elements in the outcome of the operative treatment.

We presented an innovative workflow, which enables a complete virtual design, production and application of patient-specific implants and drilling guides for acetabular fracture treatment. This technique is feasible, safe and appears to be effective. We were only able to present our initial experiences in the present study. A larger cohort is needed to further assess whether we shall benefit from this technique in maintaining a better reduction, reducing operation time, blood loss, radiation time, and improving patient's and surgeon's satisfaction. We believe this application might bring new opportunities for the treatment of complex acetabular fractures in the near future.

Conflict of interest

None of the authors have any conflicts of interest with regards to this research.

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Appendix A. Supplementary data

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