Pre-operative Fitting of Osteosynthetic Plate for Clavicle Fracture using Rapid Prototyping

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1 The clinical problem

40 % of all clinically presented shoulder girdle injuries are clavicles fractures. Around 80% of those fractures are located in the mid third of the clavicle, the so called group I of the Allman classification [1]. In the majority of the cases, group I fractures are treated conservatively by supporting the shoulder with a shoulder immobiliser. In cases where the fracture shows >100% displacement, and a shortening of 1,5-2,0 cm, it is also justified to perform an open reposition and internal fixation [2].

In the Isala clinics, there were 44 open reduction internal fixation (ORIF) cases of group I clavicle fractures in 2012 and 2013. At least one out of four osteosynthetic plates did not fit the curvature of the clavicle according to the surgery reports, therefore it had to be altered by bending the plate perioperatively. Other cases described a rotation of the placement of the plate, where the lateral part of the plate was placed medial, and vice versa.

This alteration process takes time and the quality of alteration between surgeries may differ. Moreover, the unpredictable incision time due to the alteration process makes it rather difficult to create efficient operating schedules.

2 The solution

Preoperative planning is the solution to improve current efficiency and workflow in ORIF procedures. The perioperative alteration process can be avoided by performing the osteosynthetic plate selection and adjustment preoperatively instead. This is done by constructing a physical three-dimensional model of the fractured clavicle or by constructing a mirrored version of the contralateral clavicle. In this way, the osteosynthetic plate can be adjusted to fit onto the (modeled) clavicle.

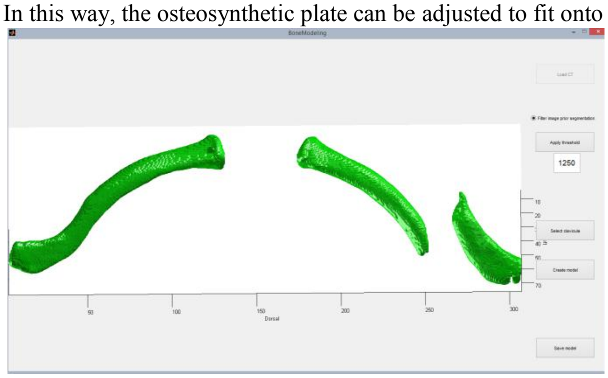

Figure 1. Three-dimensional surface mesh model created in Matlab.

First, a CT scan of both clavicles has to be made in order to create such models. From this scan, the clavicles can be segmented with the mathematical program Matlab and converted into a three-dimensional surface mesh model (see figure 1). The mesh model of the contralateral clavicle is mirrored, and subsequently the models are exported as stereolithography files (.stl). Thereafter, the segmented models are processed in the program Meshlab to clean the mesh and separate the fragments, resulting in a representative model of the fractured clavicle and one of the mirrored contralateral clavicle. The next step is to create physical models by means of a rapid prototyping technique. In this case the models are created by fused filament fabrication, using a 3D-printer (see figure 2), the bq Witbox.

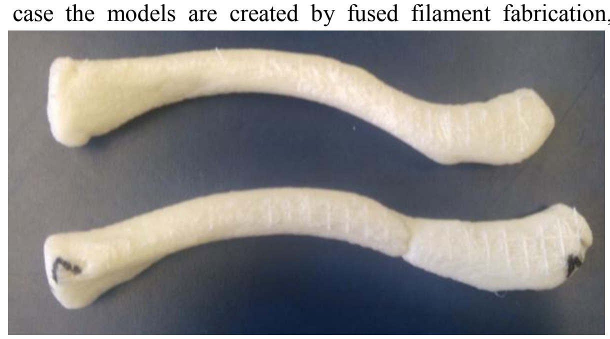

Figure 2. 3D-Printed models, the upper model is the mirrored contralateral clavicle and the one below the fractured clavicle.

The printed models can be used for planning of the surgery. The location of the plate on the clavicle can now be predetermined. Subsequently, different available plates can be tested in a way that the plate has a solid contact to the bone and that three screws on the medial and lateral fragment are able to penetrate both cortical layers of the clavicle. If a plate meets these requirements, a sterile version can be acquired during surgery. In case none of the available plates fit properly, one, of appropriate length, needs to be bent to fit onto the curvature of the clavicle. Because the plate becomes unsterile from bending, it has to be sterilized before using it in surgery.

For fitting plates two models are available, the fractured clavicle and the mirrored contralateral clavicle. For relatively fresh fractures, the fractured model is recommended, since not all clavicles are symmetric [3], and because (due to missing or loose fragments) the angle of the connecting parts can change, resulting in a different geometry. Fragments are commonly not used in the fixation, because they have been cut off from blood supply and are most likely to become devitalized, which interferes in the healing process of the bone. That is why fitting the plate is without the fragments. Older fractures are often paired with callus formation. Because callus is recognized as bone in the segmentation, the fractured model will be less representative to reality. Therefore it is recommended to use the mirrored contralateral model for planning in such cases.

A pilot study was carried out with this procedure, when a patient presented herself with pseudarthrosis after a clavicle fracture. Using the described method both models were printed. Since this concerned an older fracture with callus formation, the contralateral model was used to determine the best fitting plate. With tools present in the OR the plate was altered to fit the model, figure 3, and sterilized. During surgery no time was spend in altering the osteosynthetic plate and an improvement in workflow was observed. The accumulated time it took in the first case to prepare for surgery was around 4 hours.

3 Innovativeness

The pilot study showed that improvements in the fundaments of the conventional operation can be made. Usually a plate is selected based on the reposition of the fracture perioperatively. But because of a better orientation of the situation preoperatively, the plate will be based on that knowledge and the repositioning of the fracture can be based on the preshaped plate. Another advantage of pre-selecting a plate is that only the necessary surface of the bone has to be cleaned, which limits the damage to surrounding tissue.

Figure 3. The mirrored contralateral model of the pilot case and the resulting fixation plate after bending.

Also instead of using k-wires, the surgeon can use the plate to reposition and reconstruct the bone. This is possible when first one side of the fractured bone is attached to the plate and then subsequently the other part of the bone fixated the plate, as planned preoperatively.

In addition during the preparations, the type, length and angle of the screws can be predefined, which can also save time and avoid errors.

4 Conclusions

Through a pilot study it has been shown that the method has good prospects. The next step is to demonstrate the clinical relevance. With a clinical study, the gain in surgery time and the effect on the workflow of the surgeon can be investigated.

The expectations are that the average incision time will decrease. And maybe more important, the variability in incision time is expected to drop, resulting in tighter OR schedules. On top of that is it anticipated that the workflow will improve for the surgeon. In this investigation we have merely applied the method on the clavicle, but could easily be translated to other and different types of fractures, if clinically relevant.

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