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*ORIGINAL STUDY*

# Evaluation of prominence of straight plates and precontoured clavicle plates using automated plate-to-bone alignment

Alexander VAN TONGEL, Toon HUYSMANS, Bernat AMIT, Jan SIJBERS, Francis VANGLABBEEK, Lieven DE WILDE

*From the University Hospital Ghent, Ghent, Belgium*

**Hardware prominence after plate fixation for clavicle fracture is a common complication. The aim of the study was to perform a 3D analysis of the prominence of different types of superior clavicle plates. An automated fitting of 3 straight and 10 precontoured plates was performed on 52 3D-CT-scan reconstructed cadaver clavicles. The mean and maximum bone-plate distance and maximum prominence was significant higher with the straight plates compared to the precontoured plates. The mean and maximum bone-plate distance was significant higher with the precontoured DePuy-Synthes plates compared to the precontoured Acumed plates but when evaluating the maximum prominence there was no significant difference between the most commonly used 8-holes plates. To conclude, precontoured plates of the clavicula diminish significantly hardware prominence. There exists a difference in hardware prominence between different brands of precontoured plates but this difference is limited and in most cases not significant.**

**Keywords** : clavicle fracture ; hardware irritation ; precontoured plates ; 3D reconstruction ; automated fitting.

## INTRODUCTION

Approximately 2% to 5% of all fractures in adults involve the clavicle. More than two-thirds of these injuries occur at the diaphysis of the clavicle, and these injuries are more likely to be displaced as compared with medial- and lateral third fractures (*17,18*). Recent evidence suggests these specific subsets of patients may be at high risk for nonunion, shoulder dysfunction, or residual pain after nonsurgical management (*6,14,24,30*). In these patients, acute surgical intervention may minimize suboptimal outcomes. Internal fixation of clavicle fractures can be performed with either plate or intramedullary pin fixation with good result (*22*). Most complications in both groups are hardware-related. Irritation with subsequent removal of the hardware is the most common cause of additional surgery (*28,29*). Where intra-medullary devices are routinely removed upon fracture healing, the plates are also

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■ Alexander Van Tongel, MD, PhD, (Orthopaedic Surgeon).
■ Lieven De Wilde, MD, PhD (Orthopaedic Surgeon).
*Department of Orthopaedic Surgery and Traumatology, Ghent University Hospital, Gent, Belgium.*
■ Toon Huysmans, PhD (Engineer).
■ Bernat Amit, MD (Orthopaedic Surgeon).
■ Jan Sijbers, PhD (Engineer).
*Vision Lab Department of physics, Antwerp University, Belgium.*
■ Francis Vanglabbeek, MD, PhD (Orthopaedic Surgeon).
*Department of Orthopedic Surgery and Traumatology, Antwerp University Hospital, Belgium.*
Correspondence : Alexander Van Tongel, Department of Orthopaedic Surgery and Traumatology, Ghent University Hospital, De Pintelaan 185, 9000 Gent, Belgium.
E-mail : Alexander.vantongel@uzgent.be

frequently removed due to irritation. A second operation with plate debridement, removal or revision is required at best in one out of every ten patients treated, and in some studies even up to one out of every two patients (*2,5,6,11,12,20,21,23,25*).

To address this complication precontoured clavicle plates were introduced. The low profile and beveled edges of the plates were thought to have a better plate-bone contact resulting in a reduction of the incidence of irritating hardware prominence and the need for reoperation for hardware removal. The aim of this study is to determine the prominence of commercially available, straight versus precontoured superior claviclar plates, using a three dimensional 3D-CT scan reconstruction analysis and an automated plate-to-bone alignment.

## METHODS

### Fracture Fixation Plates Sets

First 3 straight plates (S) (6 – 7 and 8 holes) were created. The length, width and thickness of these plates were based on LCP Plates (DePuy-Synthes). The thickness of the plate was equivalent all over the plate (3.3 mm). The location of the holes were equivalent distributed over these custom plates (Fig. 1). Next 3 companies with precontoured plates (Acumed, DePuy-Synthes, Smith and Nephew) were contacted. Both Acumed and DePuy-Synthes provided us with accurate descriptions (STL files) of the three dimensional geometry of their plate sets for superior fixation of mid-clavicle fractures (Fig. 1). Note that, contrary to the Acumed plates which are only curved in the axial plane, the DePuy-Synthes plates are also (laterally) curved in the frontal plane. For each of these plates the plate-to-bone contact region and the position of all the screw holes were extracted automatically from the STL-file. Note also that concerning the thickness of the plate, in contrast to the straight plates, the thickness in precontoured plates is different at the side compared to the middle.

#### *Study Population*

In this study, 52 clavicles from 52 distinct human Caucasian cadavers were dissected. This set of clavicles represented 32 male and 20 female specimens with a mean age of 71 years (range : 25 to 99 years). The population consisted of 50 (31 male, 19 female) right and 2 (1 male, 1 female) left clavicles.

### Data Acquisition and Preparation

Preparation of the clavicles was done in the anatomy lab of the University of Antwerp. All clavicles were scanned with a GE LightSpeed VCT (GE Medical Systems, Milwaukee WI, USA) with a spatial resolution of $500 \times 500 \times 600\ \mu m^3$ at the Antwerp University Hospital. The computed tomography (CT) reconstructions from the GE Lightspeed Volume CT system were automatically segmented by morphological image-processing operations. From the obtained segmented images, the outer boundary surface of each clavicle was extracted using the marching cubes algorithm (*13*).

Finally, all right clavicles were mirrored with respect to the sagittal plane and thereby brought into the coordinate space of the left clavicle.

#### *Common Reference Coordinate System*

In order to facilitate an automated plate-to-bone fitting procedure, all clavicles are placed in a common reference coordinate system following the three-steps procedure of Huysmans *et al* (*9,10*).

#### *Automated Plate-to-Bone Fitting*

The common reference coordinate system enables the automation of fitting a given plate to a given clavicle with optimal plate-to-bone contact while satisfying several constraints imposed by the surgical procedure. On the average clavicle a single point was placed manually on the superior part in the middle of the clavicular surface as defined in the reference system. A fracture was simulated by cutting the clavicle along the angular line of the cylindrical coordinate system that runs through the annotated point. This is followed by the calculation of the desired region of contact for the plate. This is a region of 100mm in length and 10mm in width defined along the axial line that runs through the annotated point (Fig. 2). The fracture line and the desired region of contact, as defined on the average clavicle, can be mapped using the correspondence to each of the 52 individual clavicles in the population, effectively simulating 52 fractured clavicles.

For a given clavicle, the automated plate fitting procedure proceeds in two steps. First, an initial alignment of the plate to the bone is obtained by aligning the center and principal axes of the contact region of the plate to the center and principal axes of the desired contact region of the bone, taking into account the medial and lateral sides of the plate. After this initialization, the plate and bone may intersect and other constraints, imposed by the surgical procedure, may not be satisfied. We therefore

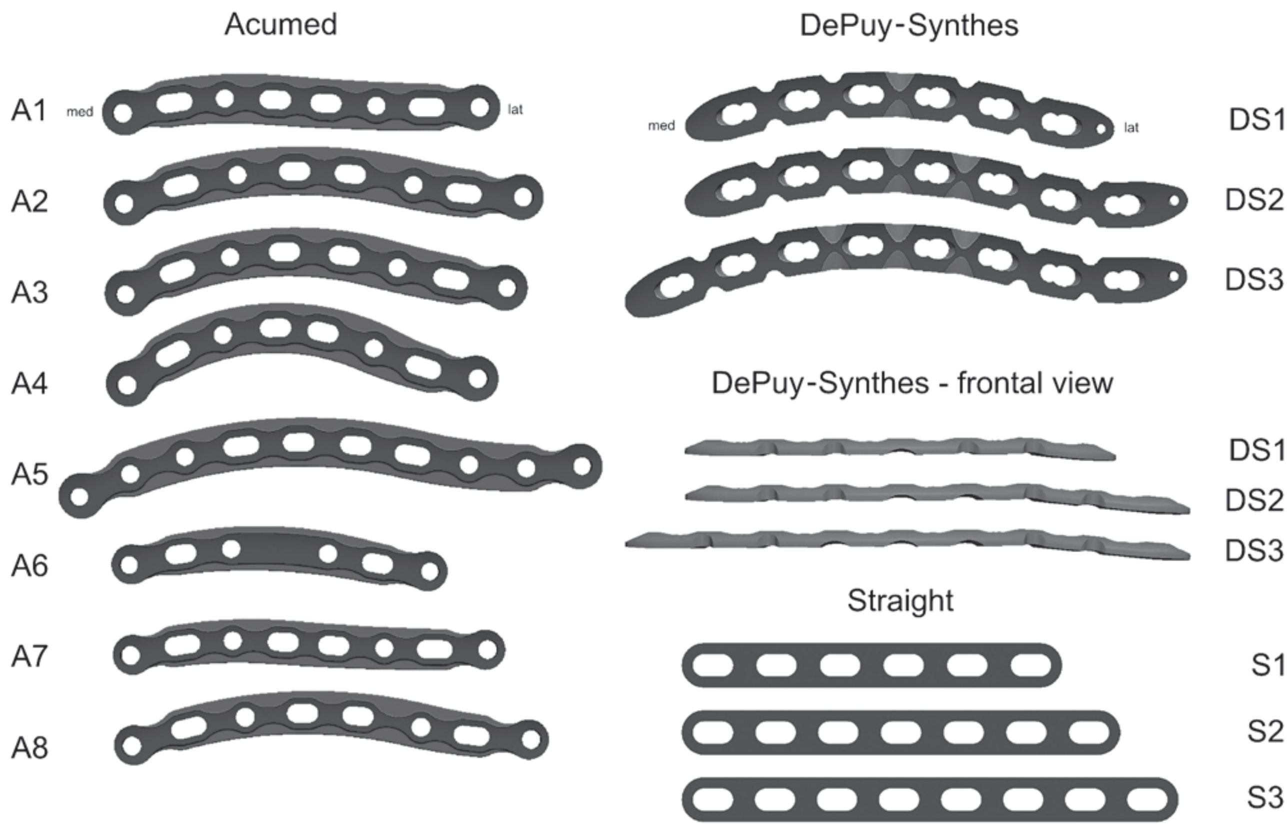


*Fig. 1.* — 13 different tested clavicula plates

introduced a second step. This step is an optimization that minimizes the distance between plate and bone, measured as the mean of squared distances from the contact region of the plate to the closest points on the bone. During this optimization the following constraints are also enforced : (a) avoid intersection of plate and bone, (b) ensure at least three screws on each side of the fracture with a minimum distance of 4mm from the fracture line, and (c) ensure that each screw catches enough bone, i.e. the centerline of the screw should be at least 3mm from the side of the bone. When the optimization does not succeed in satisfying all the constraints, the plate is considered a bad fit for that specific clavicle (Fig. 3).

The number of good and bad fits for every plate was measured. Next the plates were grouped in group A (6 holes), group B (7 holes), group C (8 holes). The plate of Acumed with 10 holes was excluded because no comparison could be made with an equivalent plate of Depuy-Synthes or straight plate. We did not grouped the plates concerning their length because during surgery the surgeon seems to be more guided by the number of holes

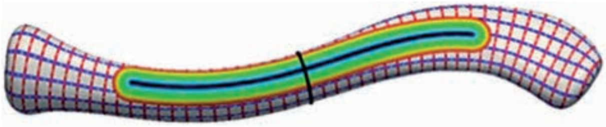

*Fig. 2.* — Calculation of desired region of contact for the plate

then by the length of the plate. Next the mean plate-to bone distance for the different plates on every clavicle was measured. The next step was to measure the maximum bone-plate distance for the different plates on every clavicle. These two distances are a measure of how tightly the plate fits to the bone (Fig. 4). At last the maximum hardware prominence for the different plates was measured as well. This was measured as the largest minimum distance between the plate and the bone. This measurement gives an estimate of the largest tissue displacement due to the plate (Fig. 4). The statistical analysis was performed using Chi$^2$ test, the Fisher's Exact test, Mann-Whitney U test and the Kruskal Wallis test.

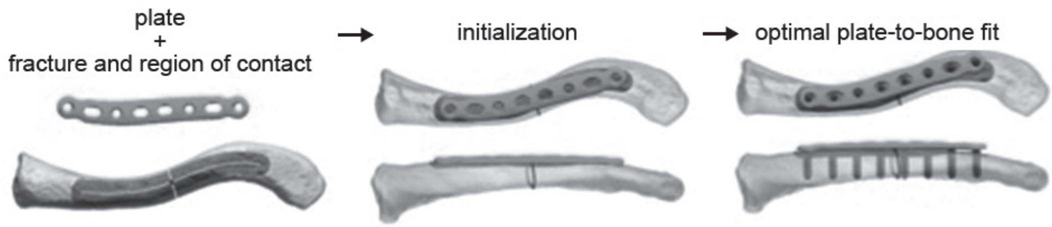


***Fig. 3.*** — Optimalization of the plate-bone fit

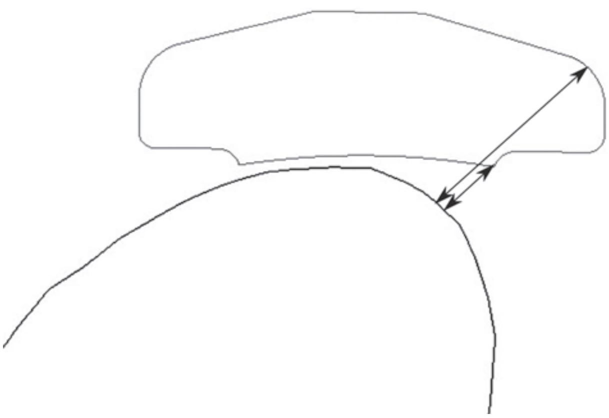

***Fig. 4.*** — Measurement of plate-bone distance and prominence

## RESULTS

In 65 out of 728 cases a bad fit was observed (Table I). There are significant more bad fits with the straight plates compared to the precontoured plates in group A ($p < 0.001$), B ($p = 0.004$) and C ($p < 0.001$). There is no statistical difference between the number of bad fits between precontoured plates in group A ($p = 1.000$) and C ($p = 0.695$).

In 663 cases the bone-plate distance could be measured. The mean bone-plate distance of the different plates can be seen in Table I. The mean bone-plate distance is significant higher with the straight plates compared to the precontoured plates in group A ($P < 0.001$), B ($p < 0.001$) and C ($p < 0.001$). The mean bone-plate distance is significant higher with the precontoured DePuy-Synthes plates compared to the precontoured Acumed plates in group A ($p < 0.001$) and in group C ($p < 0.001$).

The mean maximum distance of every plate can be seen in Table I. The mean maximum distance is significant higher with the straight plates compared to the precontoured plates in group A ($p < 0.001$), B ($p < 0.001$) and C ($p < 0.001$). The mean maximum bone-plate distance is significant higher with the precontoured Depuy-Synthes plates compared to the precontoured acumed plates in group A ($p < 0.001$), and C ($p < 0.001$).

The mean maximum hardware prominence of every plate can been seen in Table I and figure 5. The mean prominence is significant higher with the straight plates compared to the precontoured plates in group A ($p < 0.001$), B ($p < 0.001$) and C ($p < 0.001$). The mean maximum hardware prominence is significant higher with the precontoured DePuy-Synthes plates compared to the precontoured Acumed plates in group A ($p < 0.001$), but not in group C ($p = 0.054$).

## DISCUSSION

This study determines the prominence and its maximal location of two commercially available precontoured superior claviclar plates (DePuy-Synthes and Acumed) versus a straight plate. To the best of our knowledge this is the first study that evaluates the prominence of several different types of clavicular plates using a 3D-CT-scan reconstruction analysis and an automated plate-to-bone alignment. Superior plate fixation of the clavicle presents several unique demands, due to the complex, highly variable, bony architecture of the clavicle and its immediate subcutaneous location (*16*). Several types of plates have been used to fix the broken clavicle (*21,25,27*). The use of pelvic reconstruction plates

Table I. — Number of bad fits and measurement of plate-bone distance and prominence

| plate | bad fit | mean mean plate-bone distance (+/- SD) | mean maximum plate bone distance (+/- SD) | mean prominence (+/-SD) |
|---|---|---|---|---|
| S1 | 13 | 1,26 (+/- 0,29) | 4,22 (+/- 1) | 6,22 (+/- 0,91) |
| S2 | 11 | 1,42 (+/- 0,38) | 4,98 (+/- 1,36) | 7,28 (+/- 1,4) |
| S3 | 15 | 1,63 (+/- 0,42) | 5,51 (+/- 1,39) | 7,66 (+/- 1,43) |
| DS1 | 1 | 1,12 (+/- 0,36) | 3,48 (+/- 1,15) | 5,11 (+/- 1,08) |
| DS2 | 1 | 1,13 (+/- 0,36) | 3,51 (+/- 0,95) | 5,20 (+/- 0,84) |
| DS3 | 4 | 1,24 (+/- 0,35) | 3,93 (+/- 1,23) | 5,49 (+/- 0,97) |
| A1 | 1 | 0,98 (+/- 0,32) | 3,40 (+/- 1,1) | 5,21 (+/- 0,82) |
| A2 | 2 | 1,02 (+/- 0,55) | 3,20 (+/- 1,42) | 5,25 (+/- 1,19) |
| A3 | 3 | 0,93 (+/- 0,29) | 3,19 (+/- 0,96) | 5,13 (+/-0,84) |
| A4 | 5 | 1,08 (+/- 0,24) | 3,79 (+/- 0,74) | 5,70 (+/-0,62) |
| A6 | 0 | 0,75 (+/-0,27) | 2,41 (+/- 0,93) | 4,58 (+/- 0,62) |
| A7 | 2 | 0,93 (+/- 0,29) | 3,17 (+/- 1,07) | 5,12 (+/- 0,82) |
| A8 | 2 | 0,94 (+/- 0,38) | 3,01 (+/- 1,22) | 4,98 (+/- 0,93) |

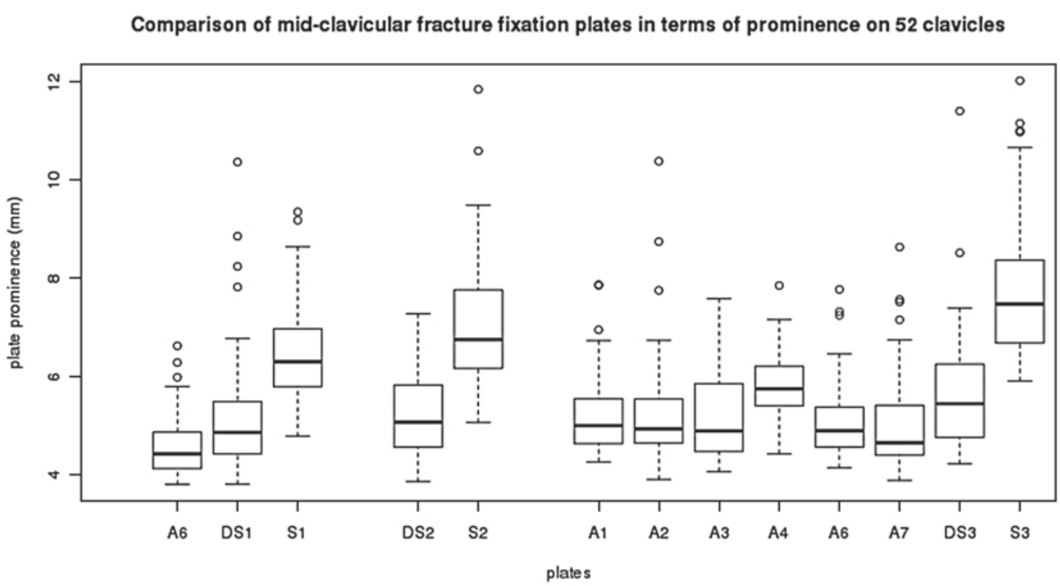


*Fig. 5.* — Box-plot of the prominence of the different plates

has been proposed because they are easier to contour and can provide a better plate-bone contact then non-contoured locking plates. But contouring is time consuming and reconstruction plates are mechanically weaker then angularly stable implants (*4,7,19,21,26*). This is the reason why we opted to study only angular stable implants.

To our knowlegde only two studies evaluated the feasibility of clavicular osteosynthesis (*7,8*). Grechting *et al* fixed manually 4 different AO locking compression plates on 49 different clavicles. They positioned manually the plate on cadavers in an optimal surgical way on the superior surface of the clavicle (*7*). They defined a good fit of the plate if three screws could be safely applied through either side of a mid-shaft fracture. In case of comminution, or a butterfly fragment, two screws were also accepted. Huang *et al* used axial radiographs of 200 clavicles. Digitized representations of the 3 precontoured Acumed plates were freely translated and rotated along each clavicle to determine the quality of fit and the location of "best fit." (*8*). "Best fit" was defined as placement of the plate in a location that "best" matched the S-shaped curvature of the clavicle with minimum anterior or posterior plate overhang. Both methods, the clinical or radiological evaluation are prone to visual bias which is overcome using the fully automated technique of 'the best fit' to bone-plate alignment. To obtain an optimal reproduction of a real life situation, we ensured at least three bicortical screws on each side of the fracture with a minimum distance of 4 mm from the fracture line, and ensure that each screw is surrounded by enough bone (at least 3 mm). We defined this seen as the worst-case scenario. As described there are statistical significant ($p < 0.001$) less bad fits with the precontoured plates compared to the straight plates and this as well for 6,7 and 8 holes and not for both groups of precontoured plates. Nevertheless, in a clinical setting these straight plates can be useful for the surgeon because screws can be inserted in an oblique way and not in the pre-determined locking direction.

We also measured, without any human bias, the distance between the bone and the plate in a three-dimensional way. The mean maximum plate-bone distance with straight plates but also with precontoured plates is larger than compared to the results of Grechting *et al*. In our opinion this is can be explained by the different measurement techniques that are used (two-dimensional versus three-dimensional technique). This means that the study of Grechting measured a projection of the real length. Also we do not fully understand how an accuracy of 0.1 mm can be obtained clinically.

In our study, the mean maximum distance with the precontoured plates is significant lower than the straight plates. Next, the mean maximum distance of the Acumed plates is significant lower for to two subgroups (6 holes, 8 holes) compared to the DePuy-Synthes plate. A possible explanation can be found in the fact that the length of the Acumed plates is shorter than de DePuy-Synthes plate. As stated in the methods, we compared plates with the same numbers of holes and not the length because we think that during surgery the surgeon will be more guided by the number of holes then by the length of the plate.

Prominence of the plate can be a concern because this may lead to irritation of the soft tissues around the plate and as it is the most common reason for reintervention after clavicular plate osteosynthesis. This is the reason why we also studied the largest minimum distance between the plate and the bone (also taking the beveled edges into account). There was a statitiscal difference between the straight plates and the precontoured plates. The mean hardware prominence in straight plates is 7 mm and in precontoured plates 5.2 mm. From clincical point of view this 1.8 mm difference is probably relevant, knowing that a thin periost, platsyma and the skin only cover the superior part of the clavicle. It has been described that the normal thickness of myocutaneous platsyma flap is 2.2 mm (*1*). When evaluating the difference between Acumed plates and the DePuy-Synthes plates in the group with 8 holes, there is no significant difference which can be explained because the thickness of the DePuy-Synthes plate is less. The mean difference is also only 0,3 mm and probably clinical not relevant.

There are some weaknesses in this study. First we stimulated a transverse fracture in the middle of the clavicle. We did not take any comminution or different location of the fracture in the shaft into account and a perfect anatomical reduction was always considered as the ultimate surgical goal. A non perfect anatomical reduction, thus a reconstruction of the bone to the plane rather than vice versa, can probably influence both the prominence and the location. Second, we did not take the soft-tissue envelop around the plate into account, which can significantly influence the likelihood to provoke irritation.

Third, hardware irritation is still a subjective feeling and in this study is not possible to analyse the correlation between hardware prominence and the patients complaint.

## CONCLUSIONS

To conclude precontoured plates of the clavicula diminish significantly the hardware prominence. There exists a difference in hardware prominence between different brands of precontoured plates but this difference is limited and in most cases not significant. The studied precontoured plates are sufficiently anatomically curved and can cover the big variety of curves of the clavicle.

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