Prebending of Osteosynthesis Plates Versus Screw and Cerclage Fixation for Os Acromiale or Acromion Fracture; the 3D Technique and Mechanical Testing

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Abstract: Three-dimensional applications are on the rise in medicine, mainly to make treatment more patient specific. This study compares the in vitro outcome parameters of 2 surgical techniques: hollow screws with cerclage fixation (HC) versus patient-specific plate osteosynthesis (PO). The techniques were tested on scapulae of 5 fresh-frozen cadavers as a treatment for symptomatic os acromiale or acromion fracture, to assess ultimate failure strength, stiffness, and fracture pattern. An existing osteosynthesis plate is preoperatively shaped by a printed 3-dimensional model of the acromion of the cadaver. The strength for the PO group [mean, 254.08 ± 130.35 N (range, 118.12 to 404.19 N); $P = 0.10$] was significantly different from the HC group [mean, 166.68 ± 65.39 N (range, 91.02 to 226.34 N)]. There was no significant difference between stiffness of the PO group [mean, 13.38 ± 4.99 N/mm (range, 7.02 to 19.22 N/mm); $P > 0.10$] and stiffness of the HC group [mean, 10.22 ± 6.26 N/mm (range, 6.73 to 21.38 N/mm)]. The fracture pattern of the HC is characterized by the screws ripping from the inferior bone cortex, whereas in the PO the posterior screws tear at the superior spine. From ultimate failure strength results can be concluded that patient-specific PO provides a stronger repair construct than cannulated screws and cerclage.

Key Words: hollow screws with cerclage, plate osteosynthesis, os acromiale, acromion fracture, 3D model, biomechanical testing

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Os acromiale is a defect in the formation of a bony connection between ossification centers of the acromion during development. A defect of the ossification center of the mesoacromion is most common. The overall prevalence of os acromiale ranges from 1% to 30%. Between 41% and 62% of the cases occur bilaterally.[1] Surgery is indicated for a symptomatic os acromiale not responding to conservative treatment.[2,3]

Acromion fractures are uncommon and occur most of the time together with fractures of the ipsilateral glenoid, neck, and body of the scapula because of high-energy injuries. Surgery is indicated for symptomatic nonunion, displaced fractures, or acromion fractures in combination with other lesions of superior shoulder complex. Also less displaced acromion fractures but with reduced subacromial space need a surgical intervention.[4] One of the currently recommended surgical techniques for os acromiale and acromion fracture is based on cannulated or hollow screws with cerclage fixation (HC).[4,5] However this technique is not infallible, as reported in foregoing studies. Secondary to loss of fixation, the majority of the shoulders included, resulted in nonunion of symptomatic os acromiale. In addition, surgeons have experienced a lack of space in thin acromia for the 3.5 or 4.5 mm hollow screws, used for the HC technique.[3] Therefore we explored the potential of 3-dimensional (3D) applications to obtain a higher repair strength and to make the surgical treatment for os acromiale or acromion fracture more patient specific.

Our study focuses on the comparison between the existing cannulated screws with cerclage fixation technique and a new patient-specific plate osteosynthesis (PO) technique. We build further on prior research where a comparison was made between a surgical technique with screws only and a technique of HC. Spiegl et al[6] studied the difference in ultimate failure strength, stiffness, and fracture pattern between 2 treatments in a pull measurement on scapulae of fresh-frozen cadavers and demonstrated that cannulated screws with cerclage fixation was more resistant against high forces than the technique with screws only.[6]

Our research will use a similar study design to compare the existing technique using 2 hollow screws with cerclage and a new technique in which a customized prebended osteosynthesis plate based on a 3D model is used. Almzayyen et al[7] showed in a previous study that the technique of using a precontoured distal clavicle plate could be used for acromial fractures.

This noninferiority trial is based on the assumption that the PO technique has the same ultimate failure strength and stiffness as the HC. It is expected that both techniques will not distort. The screws of the PO, the front screws in particular, are expected to hold until the end of the measurement. The hollow screws are expected to tear out of the bone.

MATERIALS AND METHODS

Overview

Five pairs of fresh-frozen scapulae from human cadavers were tested in a biomechanical study at time zero after surgery. For logistic simplicity, the right acromia were considered as intervention group for the PO and the left acromia as comparative group for the hollow screws with cerclage wire.

First the scapulae were removed from the cadavers, afterwards they were scanned so a 3D model of them could be made. The 3D models were used to perform a patient-specific bending of the Depuy-Synthes (DepuySynthes Trauma, West Chester) distal clavicular osteosynthetic plates, to fit the right side scapulae. The distal clavicular osteosynthetic plates were used off-label. All the scapulae were cemented in a mold in order to be fixed at a universal testing machine. In all scapulae was first an os acromiale simulated between the mesoacromion and meta-acromion and then the predefined surgery technique was applied in each group. Next all scapulae were fixated at the universal testing machine and biomechanical tests for ultimate force, failure pattern, and stiffness were executed. The outcome measurements were based on the

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graphs produced by the testing machine and statistically analyzed with the Wilcoxon signed-rank test.

Details of each methodological step are described below and can be seen in Figure 1.

Scanning and Printing 3D Models of the Scapulae

Using a Conebeam computed tomography scan in the Jessa Hospital (Hasselt, Belgium), all 5 pairs of scapulae from fresh-frozen cadavers were scanned according to a protocol developed by Dr Bijnens (Table 1). The Digital Imaging and Communications in Medicine images of the scapulae of the PO group were processed in INVesalius (freeware), Rhinoceros 5 and Netfabb Professional and Meshmixer. Thereafter, 3D models of the scapulae were printed with a Makerbot 2X Printer in ABS material. Locking compression distal clavicular osteosynthesis plates of Depuy-Synthes (with 3 medial screws and 6 distal corner stable screws) were bent to fit the printed models, creating patient-specific plates. This bending, with plate bending instruments of Depuy-Synthes, took 20 to 30 minutes to achieve the right fit, tortion, and intended fracture reduction. The clavicular plates were used off-label.

Preparing the Scapulae

Twenty-four hours before the test the scapulae were thawed at room temperature and were dissected. The surrounding muscle tissue was removed. The acromion was visually inspected for any preexisting abnormalities or an existing os acromiale.

TABLE 1. Protocol for 3D Print PACS

Position	Patient in supine position Shoulder in the middle Humerus in exorotation
Field of view	From the acromion until tip of the scapula
Resolution	PACS: axial: ST 0.5/GAP 0.25 bone Cor/Sag 2/2 bone

Cor indicates coronal; PACS, picture archiving and communication system; Sag, sagittal; ST, slice thickness; 3D, 3 dimensional.

Creating a Mold for the Scapulae

The inferior portion of the scapulae was removed by cutting parallel with the inferior border of the spina scapula 1 cm below the glenoid. An additional piece of the medial border was removed.

With bone cement (Hi-fatigue G Bone Cement, 41.75 g polymer powder, 40 mL/cadaver) and 5 minutes mortar (Lugato; 400 mL/cadaver) the cadaver scapulae were locked in a custom-made mold in such a way that the glenoid fossa and

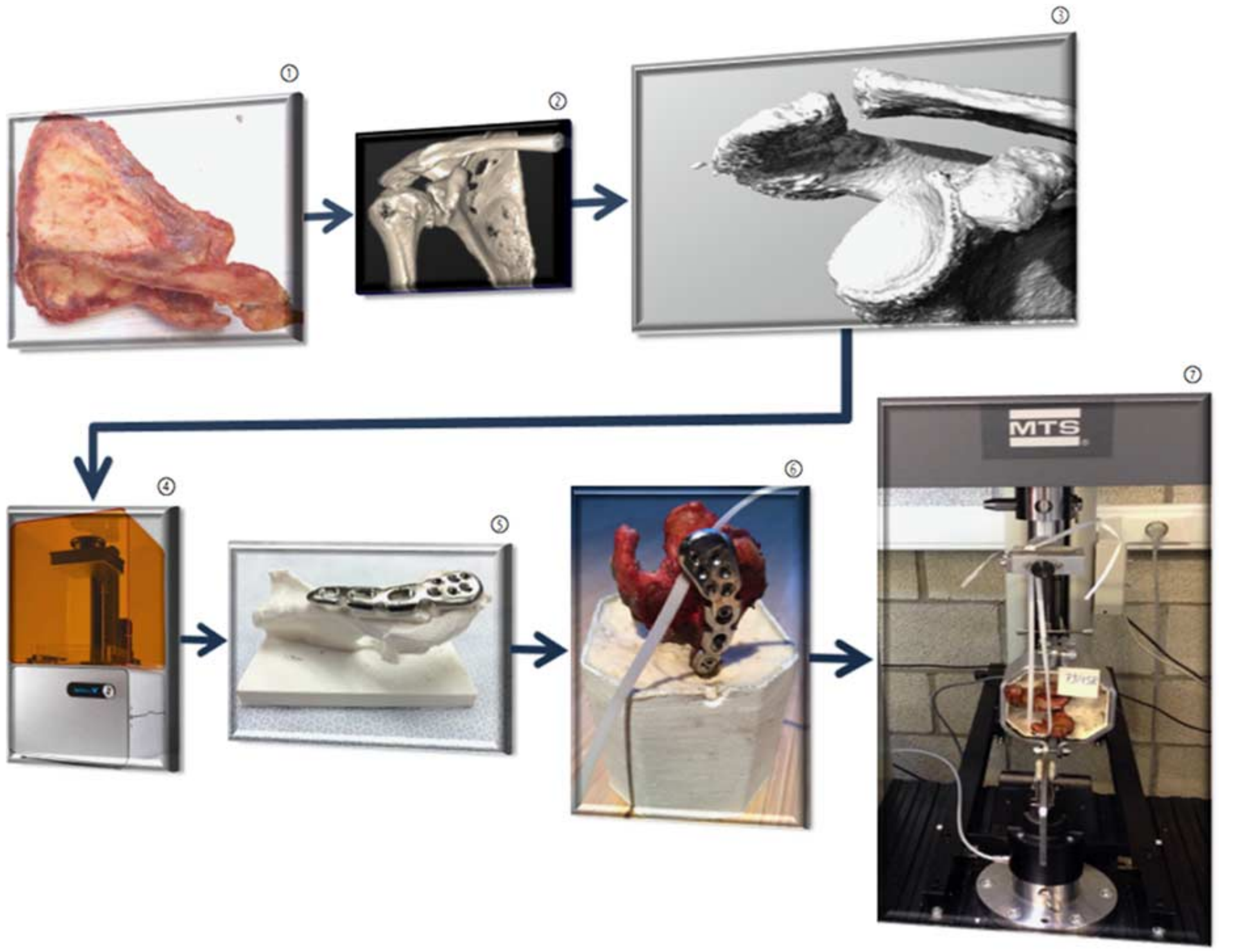

FIGURE 1. Study design. 1, Scapula of fresh-frozen cadavers. 2, Three-dimensional (3D) computed tomography scan according to a protocol. 3, A 3D processing: segmentation and digital planning to STL file. 4, A 3D printing. 5, A 3D model of patient-specific bended osteosynthesis plate. 6, Plate osteosynthesis technique. 7, Biomechanical testing. full color online

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the acromion protruded above the rim, while the acromion was in a horizontal position. Next the mold with the scapula was fixated to the universal testing machine (MTS Exceed Series 10 Electromechanical Universal Test Systems with a load cell of 2 kN) through a mechanical grip.

Simulated Os Acromiale

On the acromia of the right shoulders, the clavicular plate was first fixated with 6 tangential, 2.7 mm locking screws. After this, an os acromiale was simulated in each scapula with an oscillating saw. The os acromiale was always created in the frontal plane on the anterior side of the acromion. According to existing literature[1,6] about the meso-type os acromiale, its location falls within an average distance of 42% from the anterior-posterior length of the acromion, seen from the anterior protrusion. All osteotomies were simulated like this, after the position for each specimen was determined at which 42% of the total anterior-posterior length was reached.[2]

Surgery Techniques

Afterwards the osteotomy of the right scapulae was fixed by using the compression technique of the *Association for the Study of Internal Fixation* with 1 cortical screw.[8] Two locking screws were placed posterior of the first cortical screw. The length of the distal screws was defined by the measured thickness of the acromion minus 1 mm.

The contralateral shoulders (left side) were treated with 2 cannulated 4.0 mm screws (DepuySynthes) in an anterior-posterior direction in combination with a cerclage wire. The 1 mm cerclage wire was placed around the superior acromion in a figure-of-eight configuration. Both loops were tensioned simultaneously and in the same direction creating a similar tension. The hollow screws were placed in an anterior-posterior direction as recommended by Spiegl et al[6] because of the technical simplicity and the anatomic preference according to the size of the anterior fragment (Fig. 2).

Fixating the Scapulae at the Universal Testing Machine and the Biomechanical Testing

The acromion was fixed at the universal testing machine with a polypropylene wire (0.40 mm height, 4.80 mm width). For the PO group the wire was fixated parallel to the dorsal rim of the acromion, 1 cm of the anterior protrusion and between the 2.7 mm screws. For the hollow screws group the wire was fixated between the bone and the cerclage wire. The ends of the wire were attached to the mechanical grip with a knot.

The acromion was fixed in a reverse position compared with the normal anatomic position; in this way the acromion was horizontal and parallel to the bottom of the testing machine and perpendicular to the mechanical grip.

The polypropylene wire ensured a distributed load on the anterior acromion, which simulates the attachment of the deltoid muscle as accurately as possible. Using this test setup perpendicular tensile forces were applied on the anterior acromion in a superior to inferior direction, in accordance with the forces in a human body. The tensile generated force pulled on the wire with a speed of 60 mm/min (Fig. 3). Because of lacking existing literature about mechanics of the acromion, this load protocol is based on biomechanical studies of the clavicle. This is reasonable, because of the similar bending forces on the clavicle by the action of the deltoid muscle.[9]

Determining the Outcomes and Statistical Analysis

The ultimate force where the acromion or the internal fixation technique failed, the fracture pattern and the stiffness were the biochemical test outcomes.

The ultimate forces where the surgical techniques fail, were determined by the graphical representation of the results produced by the universal testing machine in which the x-value represents stretching at the time of failure expressed in millimeters and the y-value ultimate failure expressed in newton. The first clear peak on the chart was considered as ultimate failure strength. Prior small peaks or disturbances were disregarded.

Stiffness was calculated by dividing ultimate failure by the stretching at the same time of failure for every scapula separately. The maximum rigidity was derived from the previously defined point that represents the ultimate failure strength.

The paired measurement data of the strength and stiffness at the time of failure for the 2 surgical techniques were analyzed with the Wilcoxon signed-rank test. This test started with a ranking procedure (Table 2). The absolute value of the differences in strength and stiffness, between right and left strength were organized from smallest to largest. To each value was assigned an ordinal number.

Then, the sum of the ordinal numbers for the group with a positive difference were calculated. This is the group for which the measured strength or stiffness is greater with the plate osteosynthesis than the hollow screws with cerclage. The regions of rejection for $n=5$ are $(-\infty; 0)$ $(15; +\infty)$. Given the limited number of observations the maximum achievable significance level was 10%.

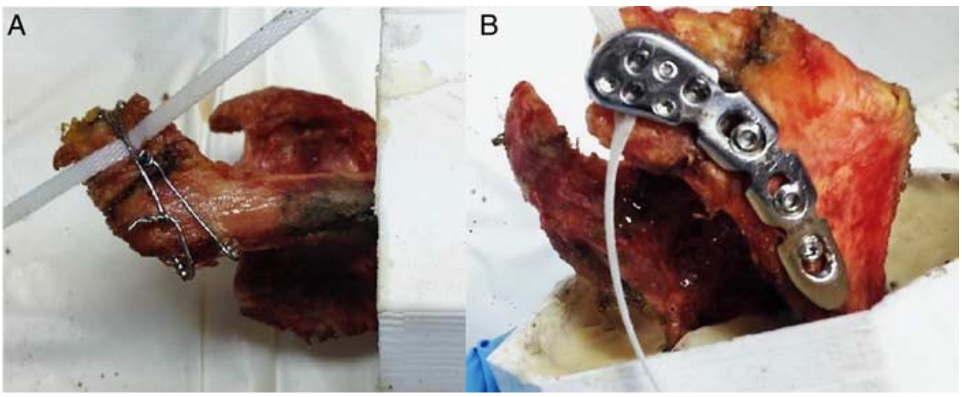

FIGURE 2. Surgical techniques. A, Combination of hollow screws with cerclage wires fixation. The screws were placed into an anterior-posterior direction on a left acromion and the cerclage wires around the screws form a figure-of-eight. B, Prebended osteosynthesis plate. A clavicle osteosynthesis plate was used to bend in the shape of the os acromiale, fixed by divergent and cortical screws. full color online

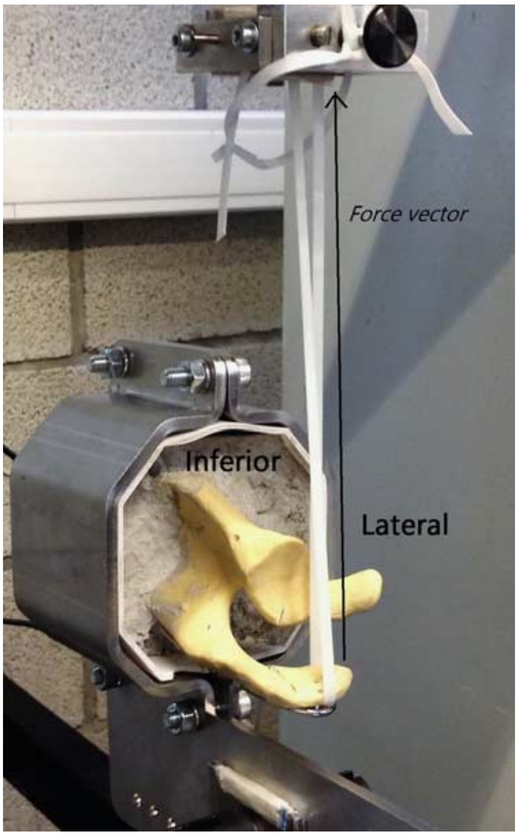

FIGURE 3. Test setup. A polypropylene rope was fixed in parallel to the dorsal acromion edge 1 cm from the anterior protrusion. The 2 ends were clamped and tied to the upper part of the testing machine. The force vector is parallel to the surface of the acromion. full color online

RESULTS

The strength and stiffness data for all specimens are reported in Table 3. The strength for the PO group [mean, 254.08 ± 130.35 N (range, 118.12 to 404.19 N); $P = 0.10$] was significantly different from the HC group [mean, 166.68 ± 65.39 N (range, 91.02 to 226.34 N)].

There was no significant difference between stiffness of the PO group [mean, 13.38 ± 4.99 N/mm (range, 7.02 to 19.22 N/mm); $P > 0.10$] and that of the HC group [mean, 10.22 ± 6.26 N/mm (range, 6.73 to 21.38 N/mm)].

The fracture pattern, registered with video recording, is typical for each technique. We observed in all left acromia treated with the hollow screws and cerclage technique that the anterior part of the os acromiale bent against the posterior part. This happened already at small forces in the beginning of the measurement. As the power increased in size, the ends of the hollow screws in the posterior part of the os acromiale pushed to inferior and gradually tore out of the bone. This bone avulsion of the screws could be observed for each acromion in the inferior direction. However, the hollow screws retain their shape during the test. The cranially positioned cerclage was always bent. The screws, which are placed in the marrow channel of flat bone crack through the inferior cortex of the posterior part. In the right acromia treated with the PO technique we observed that the anterior part of the os acromiale bent caudally against the posterior part at relatively small forces; which was similar for the hollow screws with cerclage technique. With increasing forces the plate pleated temporarily. The postchecking with the help of the 3D models revealed however that the plates did not bend permanently. The 6 anterior angular stable screws on the anterior fragment did not release. The 3 posterior screws, however, were pulled from the bone at the level of the scapular spine except for 2 of 5 acromia where the screws were pulled out along the sides. In these 2 cases the screws were placed surgically at about 1 mm from the edge of the bone, while for the other acromia the screws were placed more centrally in the bone (Fig. 4).

TABLE 2. Wilcoxon Signed-rank Test

$\|d_i\|$	Negative d_i	Negative f_i	Positive d_i	Positive f_i	Ordinal Number
Strength (N)					
15.28	−15.28	0	15.28	1	1
36.99	−36.99	0	36.99	1	2
37.35	−37.35	0	37.35	1	3
169.55	−169.55	0	169.55	1	4
177.85	−177.85	0	177.85	1	5
Stiffness (N/mm)					
0.54	−0.54	1	0.54	0	1
5.47	−5.47	0	5.47	1	2
9.27	−9.27	0	9.27	1	3
10.90	−10.90	1	10.90	0	4
12.49	−12.49	0	12.49	1	5

d_i indicates difference PO–HC; f_i, frequency; HC, hollow screws with cerclage; PO, plate osteosynthesis.

DISCUSSION

On the basis of forces at failure, the PO technique performs better than the hollow screws with cerclage technique. There are to date no studies which demonstrated the same result. In a study with a similar study design Spiegl et al[5] compared the performance of the cannulated screw technique with or without a tension band in biomechanical tests. They demonstrated that HC was more resistant against high forces than the technique with screws only.

We noticed differences in fracture pattern between the 2 surgical techniques. For the hollow screws with cerclage technique we observed that at the larger forces when the anterior part of the os acromiale is pleated to inferior, the rope begins to pull more and more to the cerclage itself instead of to the bone. In general, the weakness of the hollow screws with cerclage technique is in pulling the hollow screws through the bone which makes the bone crack. Despite this, the hollow screws with cerclage stay in the correct position. For the osteosynthesis technique the fracture is located posteriorly on the spine. The weakness of the PO is in releasing the posterior screws. From this observation, we can conclude that the bone is weaker than the osteosynthesis plate.

The age differences (62 to 103 y) and the paired design of this survey can be considered as a strength of this study, because the inclusion of scapulae of varying ages better reflects the patient population.

The study design had some weaknesses.

A first weakness we should mention is the fixation of the rope; from the moment the anterior part of the os acromiale is bent far to inferior, the rope starts to pull on the screws of the plate, as it did in the hollow screw configuration. Incidentally, the rope splitted in 3 scapulae at the moment of applying the screws in the bone, but they did not torn. The splitting of the rope could influence the strength of it, but the rope never broke.

TABLE 3. Results

			Group 1: PO			Group 2: HC		
Specimen	Age	Sex	Side	Strength (N)	Stiffness (N/mm)	Side	Strength (N)	Stiffness (N/mm)
747	103	Female	Right	128.37	19.22	Left	91.02	6.73
750	91	Male	Right	118.12	7.02	Left	102.84	7.56
2126	70	Male	Right	404.19	10.48	Left	226.34	21.38
7515	62	Male	Right	359.45	12.79	Left	189.90	7.32
7915	81	Male	Right	260.27	17.40	Left	223.28	8.13
Mean	81.4	—	—	254.08	13.38	—	166.68	10.22
SD	16.32	—	—	130.35	4.99	—	65.39	6.26

HC indicates hollow screws with cerclage; PO, plate osteosynthesis.

Given the limited number of observations the maximum achievable significance level was 10%. This is an important limitation for this analysis.

Another point of discussion applies to the attachment of the muscles to the acromion. In this study we used a rope which exerts a force onto the superior and anterior side of the acromion, whereas in the human body the lateral part of deltoid muscle arises from the superior surface of the entire acromion process. Consequently, the force in this test setup is not distributed in the same way as in the body, but the rope was fixed in such a position to mimic the force distribution as accurately as possible. When preparing the scapulae, the muscles and ligaments, which play a role in the strength and solidity of the acromion, are removed. Consequently, the forces of the humerus acting on the inferior surface of the acromion, when the arm elevates or abducts, could not be charged.

In addition, this study did not take into account the size of the scapulae, the bone density, and the differences in composition of the scapulae between left and right.

In practice, one notes that the left and right scapulae differ slightly in size and thickness, but the dominancy of the specimens was not known. Unpublished data on the variation in width and length for paired human acromia shows a difference of 3.33 mm in length and 2.45 mm in width in a total of 17 pairs of scapulae, which included the 5 of our study. Furthermore, a variability between scapulae from different patients could be deduced from these data, with a SD of 6.70 mm for length and 3.17 mm for width. This also explains why patient-specific osteosynthesis plates are necessary.

The trial design with the speed load on the anterior acromion are an oversimplification of reality. During the biomechanical testing, the scapulae were loaded to obtain a failure which simulates a worst-case scenario and not a cyclic loading to simulate repetitive small forces on the acromion. The load-failure protocol is however best suited for this study time zero after surgery, given that cyclic loading simulates a loosening over the time and would not take into account the subsequent healing.

Another difficulty was the determination of a specific point which represents consistently for each scapula, the point at which the surgical technique fails. In our study we determined this point observationally: based on the graphic representation of the results, we included consistently the first clear peak with the associated x-value and y-value. The occurrence of a minimal deflection before a clearly discernible peak was not accepted as a point of ultimate failure load but considered as noise in the graph which could be explained by a minimum shift of the rope.

The graphs of the individual tests did not always begin at zero. This can partly be explained by the fact that the pull rope was not each time equally tensioned before the start of the test with the tensile testing machine. The differing characteristics of the various acromia could be a more important explanation. In the tests for which graphs did not start at point zero, a greater stantepede force was required to stretch bone increasingly at a speed of 60 mm/min. Ultimately, this did not affect the study

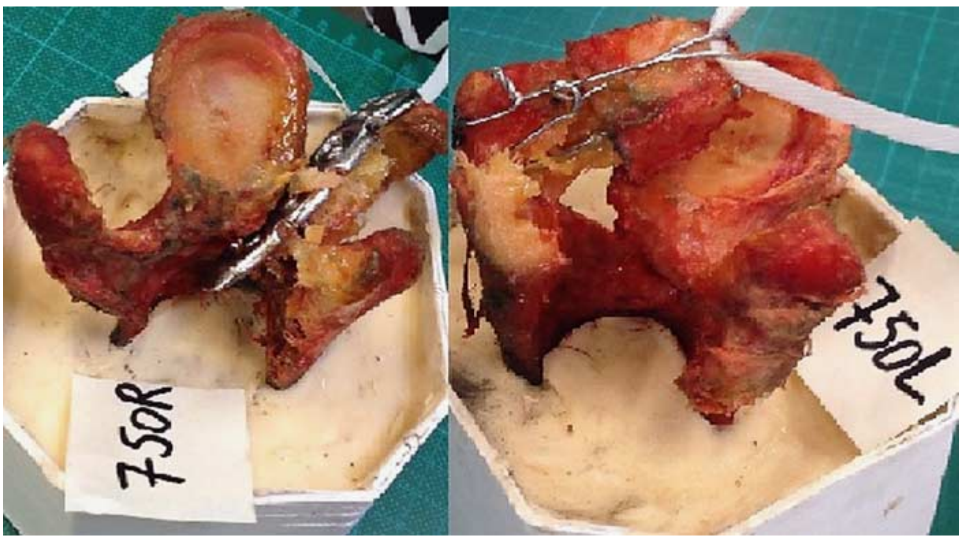

FIGURE 4. Fracture pattern. Prebended osteosynthesis (750R) plate; hollow screws with cerclage wires fixation technique (750L). full color online

results as only the values associated with the maximum power were used.

A final point of interest is the fact that the osteosynthesis plates were prebended on 3D models. The use of easy available free software without certification can be considered as a weak point. In contrast, the use of this freeware makes in-house printing possible, which allows the reduction of the leap-time, from trauma to 3D print, to 24 hours or maximum 48 hours, as is the case in our institution.[10] In this way this technique can be applied in acute trauma cases. The foregoing may possibly be legally relevant in clinical practice for the preoperative preparation and it is therefore important that the clinician is aware of this. A 3D printing can be integrated in the surgical procedure of a patient. A clinical advantage of a 3D model, is the provision of a better insight in complex fractures or deformities, as it represents the underlying lesions in a visual and tactile manner. This declares the lower consumption of materials and a less invasive procedure, because the 3D model allows a more thorough preparation of surgery. This improved preparation increases the self-confidence of the surgeon, which makes him operate more efficiently. Despite all these benefits, it should be mentioned that the PO is more expensive than the screw and cerclage technique. The total costs for the DupeySynthes materials, necessary for the HC technique, are approximately 540 euros compared with 900 euros for the PO technique. For this total amount, the digital preparation and in-house 3D printing are not taken into account. Besides the materials, further investigations are necessary to obtain an overview of all related costs.

CONCLUSIONS

The measurements on 5 pairs of scapulae show that the maximum strength is consistently higher in the PO technique. Accordingly, it can be concluded that the PO provides a stronger repair construct than cannulated screws and cerclage.

Contrary to the maximum strength, the stiffness, more specifically the strength per millimeter stretch, is not significantly different for both techniques. The fracture pattern at the point of failure is typical for each technique. The fracture is located posteriorly on the spine in the osteosynthesis technique. The screws in the hollow screws and cerclage technique crack through the inferior cortex of the posterior part.

This innovative surgical technique, based on 3D printing and a more patient-specific approach for acromial fractures and symptomatic os acromiale, seems a good alternative for the classic hollow screw and cerclage technique, especially due its higher repair strength. However it should be noticed that currently this new technique is still more expensive compared with the classic technique.

The benefit of in-house 3D printing is that a 3D print of the patient's acromion CT can be made to allow the surgeon to shape the osteosynthesis to fit the 3D model before the surgery, taking into consideration the attempted correction of the fracture or the lift of the mesoacromion, reducing the risk for further impingement. In our hands this will allow the whole staff to be well instructed and prepared. Once the plate is sterilized, less sterile instrument trays are needed, and the surgical time and anesthetic time will be reduced. The foregoing has been experienced in 6 clinical cases in our department so far.

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