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Tensioning device increases biomechanical stability of tuberosity fixation technique with cerclage sutures in reverse shoulder arthroplasty for fracture

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Background: Complex proximal humeral fractures in elderly patients are increasingly treated with primary reverse total shoulder arthroplasty. Many surgeons use cerclage sutures for tuberosity fixation in reverse total shoulder arthroplasty for proximal humeral fractures. In this study, we hypothesized that sutures fixated with a tensioning device would achieve higher initial fixation stability of the tuberosities compared with manually knotted cerclage sutures in a biomechanical model.

Methods: A 4-part fracture was created in 7-paired human cadaver proximal humeri. The tuberosities were reduced anatomically and fixed with 3 cerclage sutures in a standardized technique. Tightening was performed either manually ($n = 7$) or with a cerclage tensioning device with 50 Newton meter (N m) ($n = 7$). The humeri were placed in a custom-made test setup enabling internal and external rotation. Cyclic loading with gradually increasing load was applied with a material testing machine starting with 20 N m and increasing by 5 N m after each 100th cycle until failure (>15° rotation of the tuberosities). Motion of the tuberosities was measured with a 3-dimensional camera system.

Results: Overall, the knot group reached 1040 ± 152 cycles, and the device group reached 1820 ± 719 cycles ($P = .035$). Major fragment motion was detected in the humeral shaft axis and in the distal divergence of the tuberosities. After 900 cycles, the knot group showed increased rotation of both lesser and greater tuberosities in all 3 axes around the humeral shaft compared with the device group.

Conclusion: Biomechanical stability of the reattached tuberosities is significantly increased, and rotational movement of the tuberosities is decreased after tightening of the applied cerclage sutures with a tensioning device compared with manual knotting. However, transferability of these promising biomechanical results and their clinical relevance have to be verified with clinical studies.

Institutional review board approval was obtained from the University of Mannheim/Heidelberg (study no. 2018-628N-MA).

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Proximal humeral fractures (PHFs) account for 5% of all fractures.[23] Humeral head necrosis after PHFs represents a major problem of joint-preserving therapy approaches such as osteosynthesis or conservative treatment.[2,22,23,26] Therefore, arthroplasty is commonly used to treat PHFs in elderly patients with a high risk of avascular necrosis. Initially, hemiarthroplasty (HA) was the mainstay of treatment of PHFs that were not amenable to osteosynthesis. However, functional outcomes with HA are highly dependent on tuberosity healing, which is often difficult to achieve. The development of reverse shoulder arthroplasty (RSA) has provided an alternative treatment option for elderly patients with comminuted PHFs. Recent studies have demonstrated that the functional outcome after RSA in such a cohort is superior to HA.[10,16,30] Not only in HA but also in RSA tuberosity healing improves the functional outcome.[9,10,15,28] In addition, tuberosity healing may increase the compression force and decrease shear forces resulting in a more stable RSA and possibly better long-term results.[1,4,25] Insufficient tuberosity repair may lead to nonunion, malunion, or resorption.[22] The tuberosity healing rate depends on different factors and is reported to be between 37% and 87%.[9,29]

One important factor is the fixation technique. Most of the techniques and materials used for tuberosity reattachment in RSA are similar to those used in HA, although biomechanics differ.[3] Most surgeons prefer to use cerclage sutures as they have the advantages of not interfering with radiologic imaging, potentially easier handling, and no risk of metallosis. In our practice, we are using a new tensioning device to improve the stability of tuberosity fixation in RSA for PHFs. The aim of this biomechanical study was to analyze the initial stability of manually knotted cerclages compared with sutures fixated with a new tensioning device on a 4-part proximal PHF model treated with RSA. We hypothesized that cerclage sutures tightened with a tensioning device would achieve higher fixation stability of the tuberosities compared with manually knotted cerclage sutures in a biomechanical model.

Materials and methods

Institutional review board approval was granted and all donors had given informed consent to provide their bodies for scientific purposes.

In this experimental biomechanical study, 7 paired humeri from 7 men (mean age: 73.9 ± 16.6 years, mean body mass index: 24.3 ± 4.0 kg/m^2) were tested. All specimens had been double shrink-wrapped and frozen at −20°C for conservation. Before preparation, they were thawed overnight at 6°C.

Specimen preparation

For specimen preparation, the humeri were dissected while preserving the rotator cuff tendons inserting to the greater (GT) and lesser tuberosity (LT). To imitate a 4-part fracture pattern, first the anatomic neck was sawn off using an oscillating saw. In addition, 10 mm lateral to the bicipital groove the GT and LT were divided vertically with the oscillating saw. Finally, the GT and LT fragments were horizontally separated from the metaphysis with the saw while leaving the tendon-to-bone insertions of the rotator cuff intact. The infraspinatus tendon and the subscapularis tendon were grasped by modified Mason Allen stitches as they were used for load application in the cyclic biomechanical testing. For biomechanical testing, the distal part of the humeri was embedded in a neutral position.

Implantation of the prosthesis and tuberosity fixation

All operations were performed by the same surgeon (JS). In all cases, a consistent implant system (Univers Revers; Arthrex, Naples, FL, USA) with 135° humeral inclination was used and all stems were implanted press-fit. After fixation of the humeral stem, the tuberosities were first repositioned with a clamp and then sutured to the metaphysis of the prosthesis with 2 horizontal sutures (Fibertape long; Arthrex), which were passed through the infraspinatus and subscapularis tendon-to-bone insertion. In addition, a figure-of-eight cerclage suture (Fibertape long; Arthrex) was applied between the humeral shaft and tendon-to-bone insertion of subscapularis and infraspinatus in all cases. Tightening of the cerclage sutures was realized either manually with 7 knots ($n = 7$) and maximal tension or with a cerclage tensioning device (Arthrex) with 50 Newton meter (N m) ($n = 7$) in a standardized fashion. The cerclage technique and the used tensioning device are shown in Fig. 1.

Biomechanical analysis

To test the stability of the tuberosity fixation, the muscular traction of the inserting muscle groups was simulated in a custom-made setup. In order to obtain an exact simulation of the muscular forces, the samples were clamped in the testing device at an angle of 30° abduction, because in this position the rotator cuff vectors are directed into the center of the glenoid.[23] A passive deltoid muscle force with a dead weight of 1 kg ensured the contact pressure between both components of the prosthesis. The torque-controlled transmission of force into the tendons of the subscapularis and infraspinatus muscles was applied via previously inserted pull strings. The muscle pulls of the subscapularis and infraspinatus tendons were actively simulated with a testing machine imitating rotational movements of up to ±7.5°. The tensile forces started at 20

N m and were increased continuously after every 100 cycles by 5 N m until failure. The test setup is illustrated in Fig. 2. Fixation failure was defined by a relative rotation of the tuberosities of more than 15° in relation to the shaft of the humerus.

Any motion between the tuberosities and the humeral shaft was measured with a 3-dimensional camera device (ARAMIS; GOM GmbH, Braunschweig, Germany). The rotation was measured in 3 axes (*x*, *y*, and *z*), as shown in Fig. 3. The *x*-axis reflected the humeral shaft axis. The *y*-axis was set perpendicular to the *x*-axis, pointing from posterior to anterior. The *z*-axis crossed the *x*-axis perpendicularly, pointing from lateral to medial.

Statistical analysis

Statistical analysis was performed with JMP (SAS Institute, Cary, NC, USA) using the Wilcoxon rank test. Quantitative variables were described by means, standard deviations, minimums, and maximums. Normal distributions were tested by the Shapiro-Wilk test and confirmed graphically by a histogram. *P* values $\leq$.05 were considered to be significant.

Results

For statistical analysis, 5 fresh frozen paired human humeri were included. Two pairs were disregarded in the analysis. In one pair, abnormally poor bone quality resulted in an early loss of reduction as the horizontal sutures in both groups cut through the tuberosities with tensile forces of 20-40 N m, that is, during the first 400 cycles. In the second pair, mechanical failure with proximal cerclage cutout of the vertical cerclage at the tendon-to-bone insertion was observed due to a pre-existing cuff tear arthropathy with chronic fatty degeneration of the rotator cuff. As the vertical cerclage is inserted through the rotator cuff more medially than the horizontal cerclages, it fails first in case of poor tendon quality. The manually knotted group reached 1040 ± 152 cycles, and the tensioning device group reached 1820 ± 719 cycles (*P* = .035). The rotation of the GT and LT with increasing load around the *x*-, *z*-, and *y*-axis is illustrated in Figs. 4–6, respectively. Major fragment motion was detected in the humeral shaft axis (*x*-axis) (Fig. 4) and in the opening of the distal ends of the tuberosities (*z*-axis) (Fig. 5).

After 900 cycles, the mean rotation around the humeral shaft axis (*x*-axis) of the greater tuberosities was 0.9° ± 0.7° for those cerclages fixed with the tensioning device and 3.3° ± 2.9° for those knotted manually (*P* = .11). The lesser tuberosities showed a mean rotation of 0.2° ± 0.3° for the device group and 1.5° ± 0.7° for the knot group (*P* = .47). In general, the difference in rotation of the GT between the device group and the knot group was not significant for all load cycles in the *x*-axis (Fig. 4). After 900 cycles, the mean distal opening (*z*-axis) of the greater tuberosities was 0.4° ± 0.5° for those cerclages fixed with the tensioning device and 3.0° ± 1.9° for those knotted manually (*P* = .03). The lesser tuberosities showed a mean rotation of 0.1° ± 0.3° for the device group and 3.9° ± 4.0° for the knot group (*P* = .18). The device group also showed less rotation for both tuberosities for the tilting around the cup of the prostheses (*y*-axis) compared with the knot group after 900 cycles (Fig. 6).

Discussion

It is well established that bony healing of the tuberosities in an anatomic position is the most important single factor for a good clinical outcome after primary HA for PHFs.[6,11,22] Resorption or loss of reduction of the tuberosities leads to dysfunction of the rotator cuff and significant functional limitations.[6,17,24] Not only in HA but also in RSA successful tuberosity healing improves patient satisfaction,

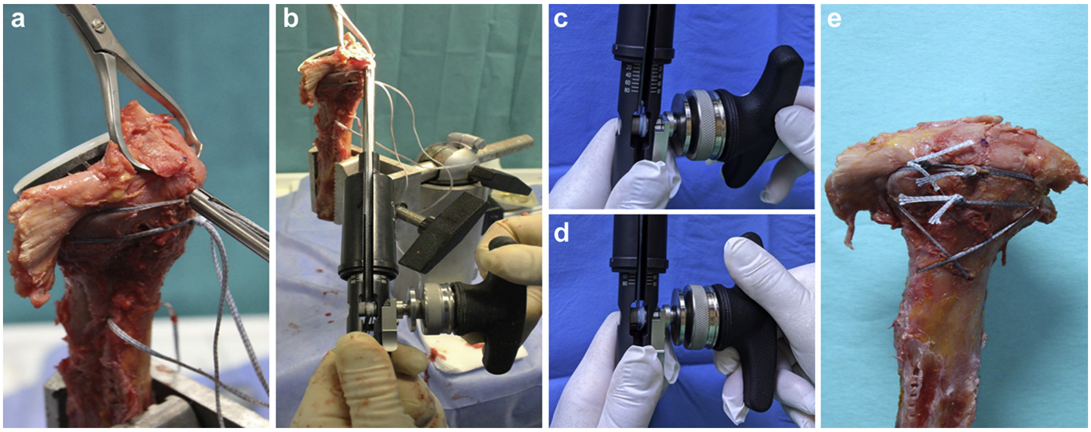

Figure 1 Technique of tuberosity repair with the tensioning device. In the tensioning device group, all sutures are tightened with a tensioner with 50 Newton meter. A clamp is used to achieve and maintain an anatomic reposition of the tuberosities before tightening the cerclage sutures (**a**). After each knot, the sutures are inserted in the tensioning device and tension of 50 Newton meter is applied (**b, c, d**). The tuberosity fragments are reconstructed horizontally around the neck of the prosthesis with 2 cerclage sutures. This construct relies on anatomic relationships to restore the geometry of the proximal humerus. In the vertical plane, a figure-of-eight technique reduces the tuberosities to the shaft (**e**).

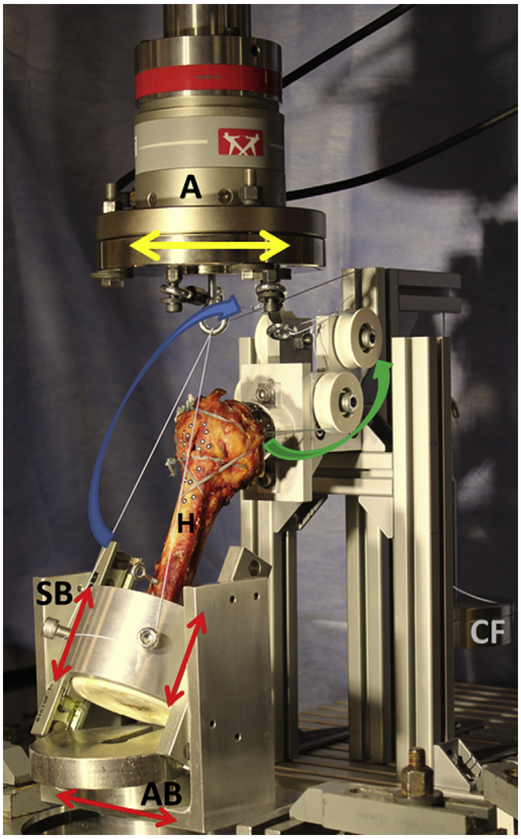

Figure 2 Custom-made test setup in the material testing machine: the embedded humerus (H), was fixed to the sliding bars (SB) and the axle bearing (AB), enabling movement in all 3 directions [↕]. The glenosphere was fixed to the framework. The sutures of the grasped tendons were connected to the actuator (A) of the material testing machine rotating clockwise and anticlockwise [↕] applying a rotational force [↑]. The delta force was imitated through a central force (CF) [↑].

yields better functional outcome,[5,15,18,28,29] and might contribute to the avoidance of complications.[5,8,20]

This biomechanical study investigated the biomechanical stability of cerclage sutures that were either manually knotted or tightened with a tensioning device in a PHF model treated with RSA. A decreased rotation of the reattached tuberosities in the device group compared with the knot group could be observed for all 3 axes. Regarding the load-to-failure measurements, a significantly higher stability of the cerclages tightened with the tensioning device could be shown.

From a clinical point of view, the applied cyclic loading forces in the initial phase are low and simulate the loading in the initial postoperative rehabilitation protocol with passive and limited mobilization of the shoulder. Thus, any differences in the stability of the reattached tuberosities might influence tuberosity healing in an anatomic position.

In a biomechanical model, Frankle et al[14] demonstrated that nonanatomic tuberosity reconstruction in HA leads to significant impairment in external rotation kinematics and an 8-fold increase in torque requirements. Furthermore, Bono et al[7] simulated the displacement of the GT in a cadaver model and measured the necessary deltoid force to achieve 90° of abduction. After malreduction of the GT that had been displaced 5 mm, the required deltoid abduction force was significantly increased.[7] However, several other biomechanical factors influence the stability of the reattached tuberosities such as prosthesis design,[29] fixation technique,[3,13] and fixation material.[12,21]

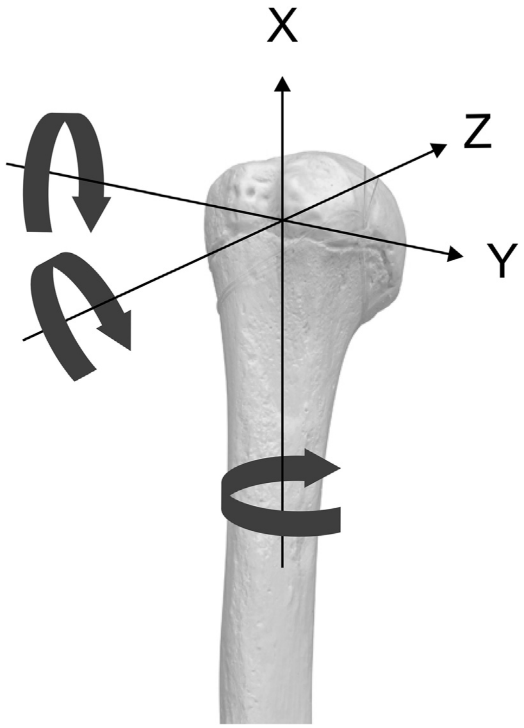

Figure 3 Coordinate system with the center of rotation in the humeral head for motion description of the tuberosities. The *x*-axis refers to the humeral shaft axis, the *y*-axis (posterior to anterior) detects the tilt of the tuberosities, and the *z*-axis (from lateral to medial) represents the opening of the distal ends of the 2 tuberosity fragments.

Regarding the fixation technique, no gold standard has been established yet and several techniques are reported in the literature.[3,13,19] In the clinical practice, both wire and cerclage sutures are used for the reattachment of the tuberosities. In order to prevent metallic wear in case of contact between the cerclage and the prosthesis and to avoid radiologic interference, many surgeons prefer cerclage sutures. Moreover, cerclage sutures are easier to handle and can be effortlessly passed through holes in the prosthesis. However, Knierzinger et al[21] showed in a PHF model with 7 paired humeri higher stability for wire cerclages after RSA compared with nonabsorbable Ethibond (Ethicon, Somerville, NJ, USA) cerclage sutures. Yet, in our eyes, this model has 2 weaknesses making it unrealistic for in vivo use. On the one hand, the cerclages were not attached to the prosthesis although Frankle et al[14]

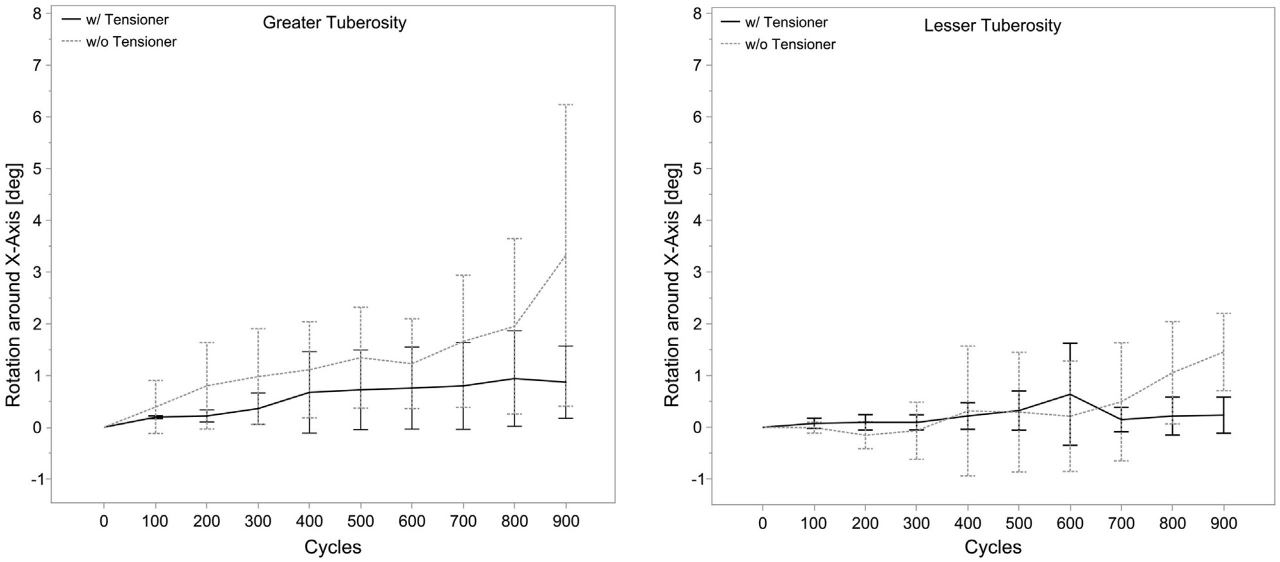

Figure 4 Mean and standard deviation (range bars) for the rotation of the greater (left) and lesser tuberosity (right) around the *x*-axis up to 900 cycles. *deg*, degrees; *w/*, with; *w/o*, without.

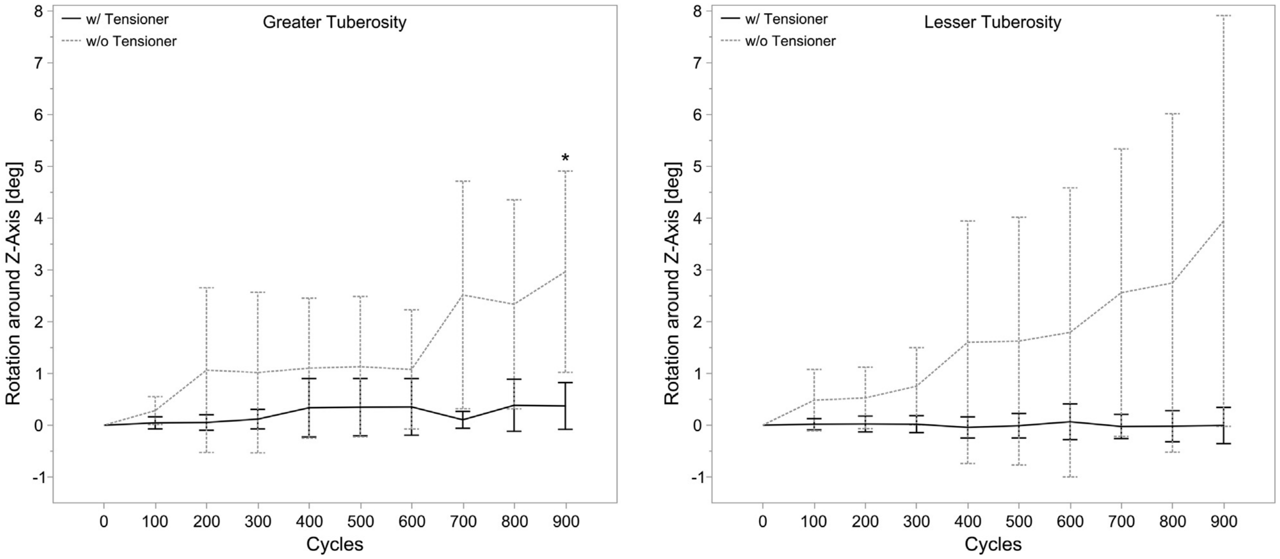

Figure 5 Mean and standard deviation (range bars) for the rotation of the greater (left) and lesser tuberosity (right) around the *z*-axis up to 900 cycles. Significant differences ($P < .05$) are marked with an asterisk. *deg*, degrees; *w/*, with; *w/o*, without.

had already shown in 2001 that when a horizontal circumferential fixation was added and wrapped through the medial hole in the prosthesis in an HA model, an additional 15° of rotation could be tolerated before a certain threshold was reached. On the other hand, in this study, no additional vertical cerclage was used to fixate the tuberosities to the humeral shaft. The importance of a vertical cerclage has been described before and should always be considered to increase stability.[3,13] During biomechanical testing of the prepared specimens in our study, we observed that as soon as the vertical cerclage failed, subsequently the displacement of the tuberosities that were still held together by intact horizontal cerclages occurred.

De Wilde et al[31] performed a biomechanical study that investigated the stability of tuberosity reattachment in an HA model with 2 different techniques: reattachment of the tuberosities with cerclage sutures passed through holes in the rim of the prosthesis in combination with a vertical cerclage to the humeral shaft was compared with a circumferential tension band wiring of the tuberosities. The authors reported no significant difference regarding the rotation of the tuberosities for the 2 fixation techniques.

Concerning the mechanical properties, similar results for sutures with different mechanical properties compared with a titanium alloy wire were recently reported in a biomechanical study.[12] The authors investigated 3 different types of sutures—Ethibond No. 2 (Ethicon), Orthocord No. 2

(DePuy Mitek, Raynham, MA, USA), and FiberWire No. 5 (Arthrex)—and a 0.8 mm titanium alloy cerclage wire for the reattachment of the tuberosities using a fracture prostheses in ovine specimens. Nevertheless, they reported a higher elongation of the sutures compared with the wire. Renner et al,[27] who compared 1.2 mm cerclage wires with FiberWire No. 5 (Arthrex) cerclage sutures for non-displaced periprosthetic humerus fractures, reported a significantly increased tightening force of wire cerclages compared with cerclage sutures. In contrast, cerclage sutures showed significantly higher load-to-failure values. Therefore, they concluded that the suture construct may compensate for its elasticity with the greater surface area to distribute the load on the bone and may thus cut less into the soft periosteum and bone.

By repositioning of the tuberosities with a clamp and using a tensioning device, the tightening force of cerclage sutures can be increased and might be comparable to those of a wire cerclage; however, this was not the focus of this study.

In our study, a loosening of the initial stability of the reattached tuberosities was observed in both groups during the cyclic loading irrespective of the fixation technique. Possible explanations could be either the elongation of the sutures over time or the unavoidable creation of a small gap between the cancellous bone of the tuberosities and the cup of the prosthesis.

As mentioned above, 2 paired humeri were disregarded in the analysis as cerclage failure occurred in both groups. In our eyes, this is neither a problem of the cerclage sutures nor an issue of the tightening technique but a biological problem. In practice now and then there are cases in which tuberosity repair is simply not possible due to biological reasons such as extremely poor bone quality or severe cuff tear arthropathy.

Another important factor influencing tuberosity repair is the prosthesis design.[29] In our study, we decided to use prostheses with an anatomic humeral inclination of 135° as we supposed that an extra-anatomic humeral inclination of 155° could compromise sufficient tuberosity due to the bulkiness of the metaphysis of the prosthesis when implanted with 155°. This assumption was confirmed in pretests showing increased vertical and horizontal gap formation between the fixated tuberosities when the prosthesis was implanted with 155° humeral inclination, as shown in Fig. 7. This can be explained by the fact that if implanted with 155° and a 39 mm cup the most medial and most lateral border of the metaphysis has a range of 4.2 cm, whereas the 135° design with the same features only measures 3.7 cm.

Limitations

This biomechanical cadaveric study has various limitations. First, the primary outcome parameter was the initial biomechanical stability after tuberosity repair; therefore, the study did not take into account the biological healing process underlying several influencing factors. However, a stable initial fixation is an essential requirement for successful tuberosity healing. Second, the sample size of the specimens was limited. Third, the used 4-part PHF model in a laboratory environment also reflects a limitation, considering the vast individual fracture variations in reality. Fourth, cyclic loading only simulated active internal and external rotation while excluding any abduction or flexion although this might have affected the results. Fifth, although the distribution of the specimens in the 2 test groups was performed at random (pairwise left and right), the bone mineral density was not measured.

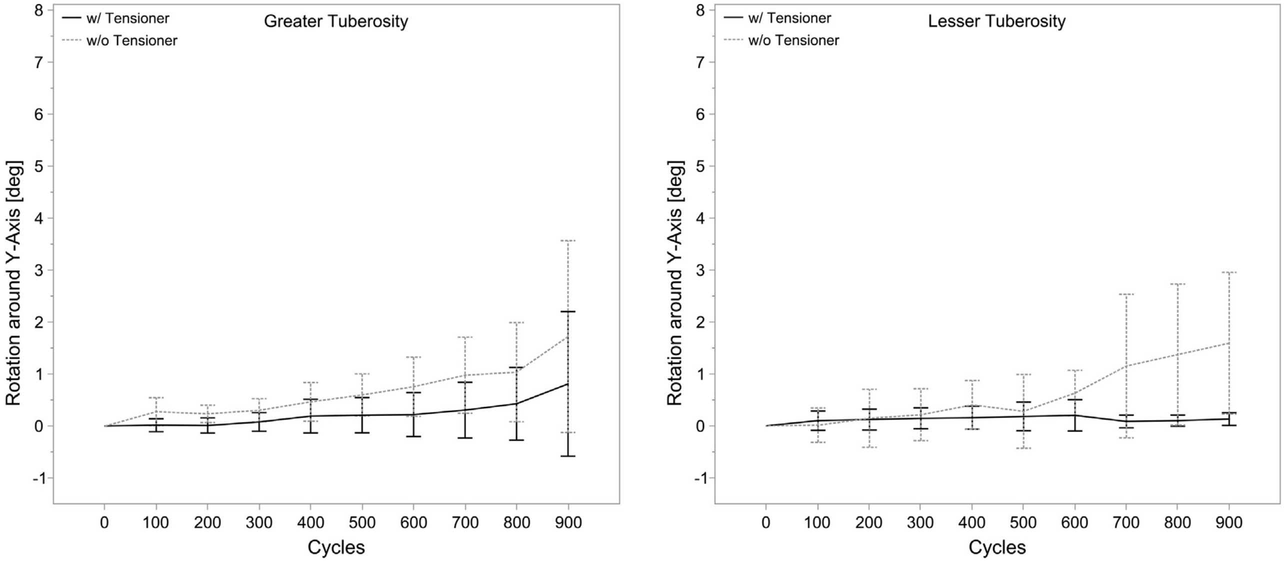

Figure 6 Mean and standard deviation (range bars) for the rotation of the greater (left) and lesser tuberosity (right) around the *y*-axis up to 900 cycles. *deg*, degrees; *w/*, with; *w/o*, without.

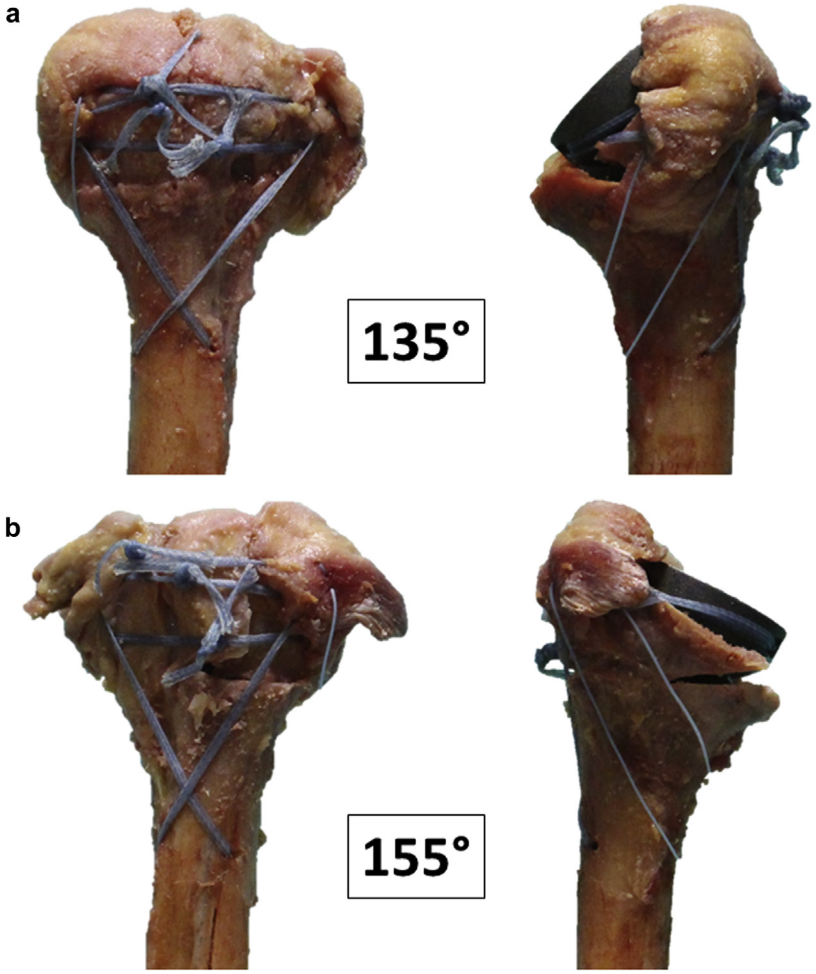

Figure 7 Exemplary images of paired cadaver humeri after implantation of a reverse prosthesis with 135° humeral inclination on the right (**a**) and 155° humeral inclination on the left side (**b**). The 135° design allows an exact anatomic reduction of the tuberosities (**a**), whereas the 155° prosthesis (**b**) shows a vertical gap and an overlapping of the malreduced tuberosities.

Conclusion

The use of a cerclage suture tensioning device shows promising biomechanical results for tuberosity fixation. Initial biomechanical stability of the reattached tuberosities is increased and rotational movement of the tuberosities is decreased after tightening of the applied cerclage sutures with a tensioning device compared with manual knotting. However, transferability of these promising biomechanical results and their clinical relevance have to be verified with clinical studies.

Disclaimer

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