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Biomechanical comparison of biodegradable magnesium screws and titanium screws for operative stabilization of displaced capitellar fractures

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Background: Displaced fractures of the humeral capitellum are commonly treated operatively and fixed by titanium screws (TSs) either directly or indirectly. In the case of direct transcartilaginous fixation, biodegradable screws with the ability to be countersunk can be favorable regarding implant impingement and cartilage destruction. Hence, the goal of this study was to biomechanically compare headless compression screws made from titanium with a biodegradable equivalent made from a magnesium alloy.
Methods: This biomechanical in vitro study was conducted on 13 pairs of fresh-frozen human cadaveric humeri, in which a standardized Bryan-Morrey type I fracture was fixed using 2 magnesium screws (MSs) or 2 TSs. First, construct stiffness was measured during 10 cycles of static loading between 10 and 50 N. Second, continuous loading was applied at 4 Hz between 10 and 50 N, increasing the maximum load every 10,000 cycles by 25 N until construct failure occurred. This was defined by fragment displacement >3 mm.
Results: Comparison of the 2 screw types showed no differences related to construct stiffness (0.50 ± 0.25 kN/mm in MS group and 0.47 ± 0.13 kN/mm in TS group, $P = .701$), failure cycle (43,944 ± 21,625 and 41,202 ± 16,457, respectively; $P = .701$), and load to failure (152 ± 53 N and 150 ± 42 N, respectively; $P = .915$).
Conclusion: Biomechanical comparison showed that simple capitellar fractures are equally stabilized by headless compression screws made from titanium or a biodegradable magnesium alloy. Therefore, in view of the advantages of biodegradable implants for transcartilaginous fracture stabilization, their clinical application should be considered and evaluated.

Institutional review board approval was not required for this basic science study.

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The Bryan-Morrey type I fracture (Hahn-Steinthal fracture) is a coronal shear fracture involving most of the capitellum and little or none of the humeral trochlea,[2] which is equivalent to a Dubberley type I A fracture[4] that does not exceed the lateral trochlear ridge. Currently, open reduction–internal fixation is favored over closed reduction and immobilization or fragment excision to achieve stable anatomic reduction for optimum elbow stability and early elbow range of motion.[4,11] The implants of choice for open reduction–internal fixation are headless cannulated screws[14] to facilitate stable anatomic reduction and to minimize cartilage destruction and implant impingement. In recent biomechanical studies, headless compression screws made from steel or titanium showed at least equal properties to conventional fixation material such as cortical lag screws for osteosynthesis of capitellar fractures with less articular affection.[6,7]

The properties of steel and titanium are poorly matched with those of bone, possibly leading to stress shielding or aseptic loosening.[9] Therefore, to date, biodegradable implants are gaining in importance to reduce articular degeneration due to long-term implant impingement and to supersede the necessity of implant removal. Commonly used biodegradable implants consist of polymers lacking in biomechanical strength[16] and being degraded by hydrolysis, resulting in possible acid environments, favoring foreign body reactions and infections.[13,15] An innovative alternative is magnesium-based implants. In 2013, the Magnezix compression screw (Syntellix, Hannover, Germany) was the first magnesium implant to be authorized for human application. It is composed of the magnesium alloy MgYREZr (magnesium–yttrium–rare earth–zirconium), which is completely degraded after about 1 year,[18] having mechanical properties more similar to those of bone than those of steel or titanium implants.[8] In a prospective randomized study, Windhagen et al[19] showed equivalent clinical outcomes for hallux valgus correction using Magnezix compression screws vs. equal screws made from titanium. Furthermore, successful application of Magnezix compression screws was reported in a trauma patient with an osteochondral fracture of the humeral capitellum.[1]

On the basis of the aforementioned successful application of the Magnezix compression screw, the hypothesis of this study was that the fixation of small fractures using titanium screws (TSs) or biodegradable magnesium screws (MSs) would show no significant difference in biomechanical properties. Therefore, the objective of this study was to conduct a biomechanical comparison of headless compression screws made from either titanium or biodegradable magnesium in a Bryan-Morrey type I capitellar fracture in a cadaveric model.

Materials and methods

In this biomechanical in vitro study, this test series was performed on 13 pairs of fresh-frozen human cadaver humeri. The cohort consisted of 5 male and 8 female specimens, with a mean age of 77 years (range, 64-92 years) and body mass index of 24.2 kg/m^2 (range, 18.8-31.2 kg/m^2). Because of the hypothesis of similar results between the groups, a prospective power analysis was conducted in alignment with the results of Koslowsky et al.[7] Power calculations were carried out on the resulting effect sizes using G*Power (Heinrich Heine University, Düsseldorf, Germany), resulting in a sample size of 13 to achieve power > 0.8.

All specimens were initially examined by computed tomography (Toshiba Aquilion ONE; Toshiba Medical Systems Europe, Zoetermeer, The Netherlands). Thereby, prior fractures or other bony pathologies were excluded, and bone mineral density (BMD) calculations were conducted on the site of interest, ruling out any between-group differences in this aspect. Because of the significant correlation of Hounsfield units to BMD,[12] BMD was calculated from Hounsfield unit measurements at the humeral capitellum using 0.903 as a calculation factor, as published by Budoff et al.[3] Afterward, the samples were stripped from all soft tissues, and a standardized Bryan-Morrey type I fracture was created in accordance with prior biomechanical in vitro studies.[5-7] The fracture was created with a water-cooled diamond blade saw–type cut grinder (model 011; Patho-Service, Hamburg, Germany) with a blade thickness of 0.4 mm. In the lateral view, the fragment size was exactly one-half the anteroposterior (AP) diameter of the lateral distal humerus, ensuring that the cartilage-surface part of the capitellum was included in the fragment. The coronal fracture plane proximally was tilted 20° anteriorly to the humeral shaft axis. Completion of the fracture in the sagittal fracture plane was generated in the AP direction through the tip of the trochlea's lateral border, in line with the humeral shaft axis. The water-cooled saw contained an accurately adjustable specimen clamp to avoid any freehand sawing and to determine the exact fracture plane prior to sawing. The produced Bryan-Morrey type I fracture is shown in Figure 1, *a-c*. Proximally, the fracture ended tangentially to the humeral shaft. Thus, any bony fragment support during testing was avoided.

Pair-by-pair fracture stabilization was performed using either two 2.7-/3.6-mm Magnezix headless compression screws (Syntellix) with a shaft diameter of 2.1 mm or two 3.0-/3.8-mm HBS (Headless Bone Screw) standard (KLS Martin, Tuttlingen, Germany) with a shaft diameter of 2 mm. Both implants were similar to the original Herbert screw with a cannulated shaft and a self-tapping head (Fig. 1, *d*). Left and right humeri were assigned using

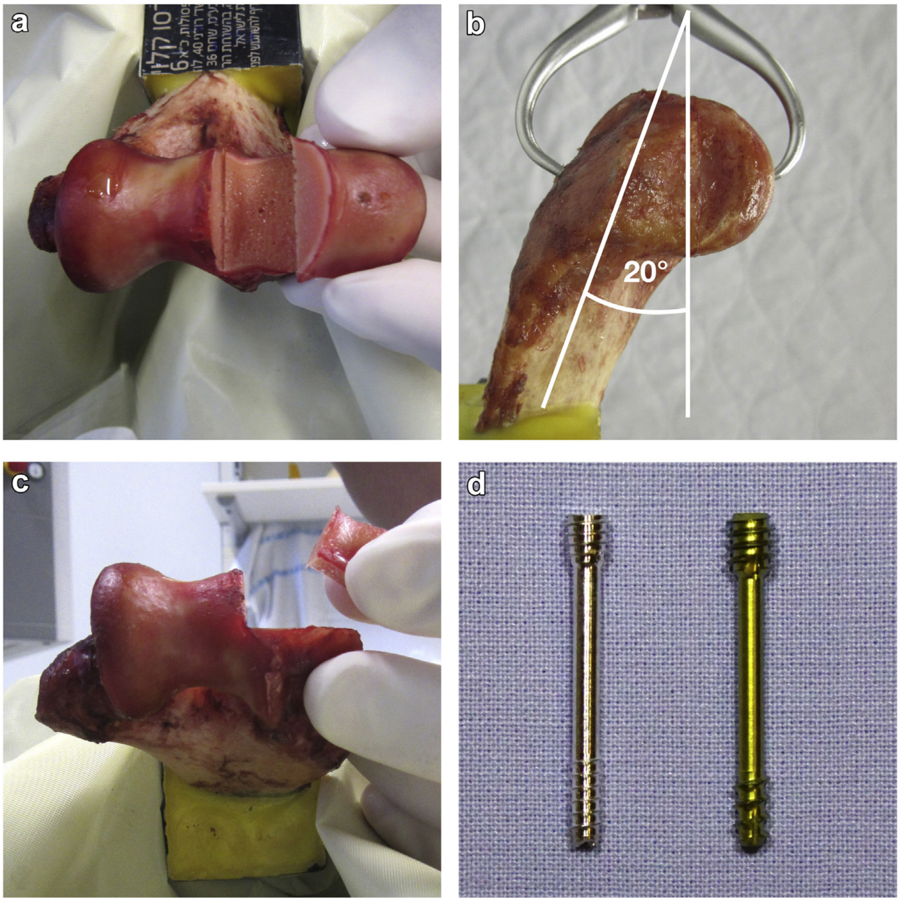

Figure 1 Fracture pattern and implants. (**a-c**) Resulting Bryan-Morrey type I fracture. The sagittal fracture plane medially was ensured to include the trochlear ridge (**a, c**), and the coronal fracture plane was angulated 20° to the humeral shaft axis (**b**). (**d**) Cannulated headless compression screws: 2.7-mm Magnezix compression screw *(left)* and HBS (Headless Bone Screw) standard *(right)*.

a randomization protocol. All osteosynthesis procedures were conducted by the same surgeon following the manufacturer's instructions and using the appropriate surgical equipment provided by the manufacturer. Radiologic controls ensured anatomic reduction and correct implant positioning (Fig. 2). Every fracture was stabilized by 2 screws implanted directly from the capitellar joint surface in a slightly converging AP direction (Fig. 3, *a, c*).

Biomechanical testing was carried out with the Amsler HC10 servo-hydraulic testing machine (Zwick/Roell, Ulm, Germany). Bone was cut to 10 cm of length and then embedded 5.5 cm in polymethyl methacrylate (PMME-Technovit 3040; Heraeus Kulzer, Wehrheim, Germany) into a standardized carton cuboid. Perpendicular positioning of the fracture plane was strictly ensured to enable loading parallel to the fracture plane for maximum stress on the osteosynthesis during testing. A schema of the test setup is shown in Figure 4.

Testing was conducted by applying sinusoidal load changes on the fragment, parallel to the fracture planes. First, 10 static load changes between 10 and 50 N were applied at 0.1 Hz to obtain information about construct stiffness. Afterward, dynamic testing was carried out by sinusoidal load changes between 10 and 50 N at 4 Hz. The peak of the load changes was increased every 10,000 cycles by 25 N until construct failure, which was defined as fragment displacement >3 mm. Primary loads of 50 N were chosen according to pretests, ensuring continuous loading at subfailure levels during the first 10,000 cycles. Raising the maximum load by 25 N every 10,000 cycles was chosen to address stiffer constructs that were assumed to result from donors with higher BMD levels.

Fragment displacement was monitored by means of an ultrasound-based motion analysis system (CMS 20; Zebris Medical, Isny im Allgäu, Germany), which has been well established in biomechanical motion tracking.[10,17] Data acquisition was based on the transmission of ultrasound waves in all 3 *df* with an accuracy of 0.1 mm, and data were recorded using WinBioMechanics software (version 0.1.2; Zebris Medical). Figure 4 shows 1 sample including the mounted ultrasound transmitter and receiver.

Statistical analysis was carried out using SPSS software for Mac OS (version 24; IBM, Armonk, NY, USA). Group comparison was performed using the Wilcoxon signed rank test, and a correlation was drawn between previously determined BMD and construct stiffness by a Spearman correlation. The level of significance was set at $P < .05$.

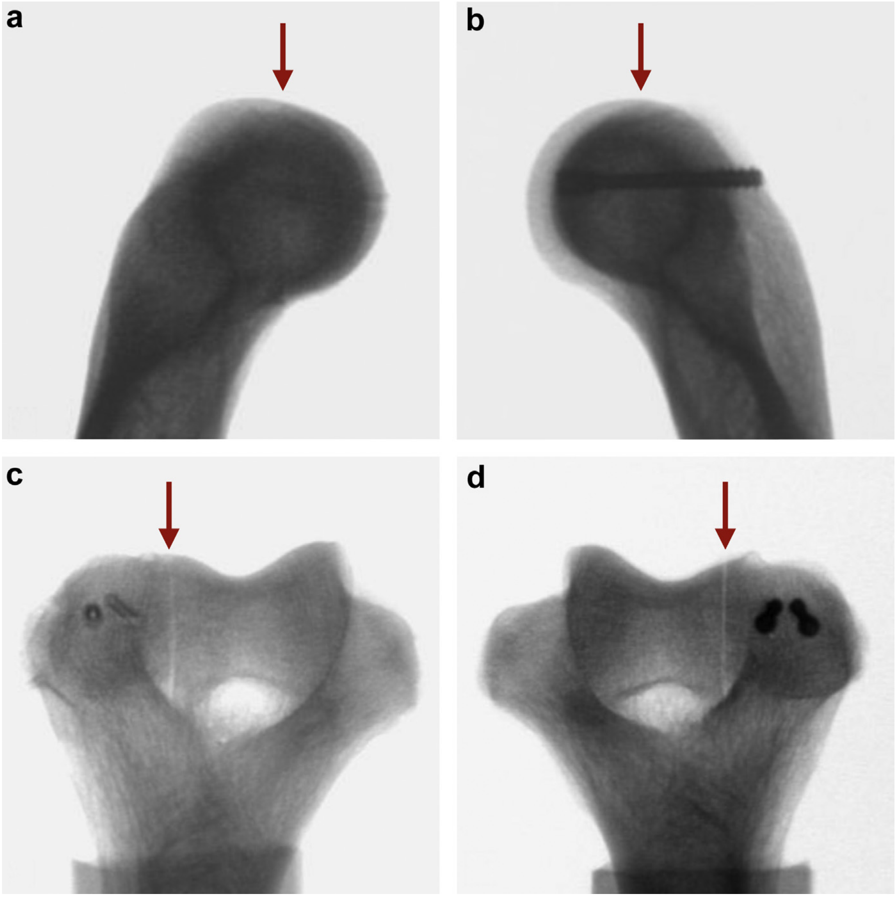

Figure 2 Radiologic controls: anteroposterior (**a**) and lateral (**c**) views of magnesium screw construct and anteroposterior (**b**) and lateral (**d**) views of titanium screw construct. The ← indicate the fracture line.

Results

With a BMD of 189.4 ± 77.8 mg/cm^3 (median, 176.1 mg/cm^3; minimum, 81.3 mg/cm^3; maximum, 345.0 mg/cm^3) in the MS group and 191.6 ± 85.9 mg/cm^3 (median, 163.4 mg/cm^3; minimum, 62.3 mg/cm^3; maximum, 370.2 mg/cm^3) in the TS group, there was no statistical difference between the groups ($P = .701$). In the MS group, mean stiffness under static loading was 0.50 ± 0.25 kN/mm (median, 0.41 kN/mm; minimum, 0.32 kN/mm; maximum, 1.22 kN/mm). In the TS group, a mean value of 0.47 ± 0.13 kN/mm (median, 0.48 kN/mm; minimum, 0.20 kN/mm; maximum, 0.77 kN/mm) was recorded. This difference was not statistically significant ($P = .701$).

Under cyclic loading, construct failure in terms of implant loosening with fragment displacement >3 mm was recorded after 43,944 ± 21,652 cycles (median, 38,584 cycles; minimum, 20,097 cycles; maximum, 90,010 cycles) in the MS group and after 41,202 ± 16,457 cycles (median, 42,010 cycles; minimum, 2554 cycles; maximum, 60,069 cycles) in the TS group. This difference was not significant ($P = .701$). With a failure load of 151.9 ± 52.5 N (median, 125 N; minimum, 100 N; maximum, 250 N) in the MS group compared with 150.0 ± 42.1 N (median, 150 N; minimum, 50 N; maximum, 200 N) in the TS group, there was also no significant difference ($P = .915$).

The failure mode was distal screw cutout in all TS constructs and 11 of 13 MS constructs (Fig. 3, *b*). The 2 remaining MS constructs showed implant breakage close to the screw head (Fig. 3, *d*). With BMD values of 344.9 mg/cm^3 and 288.1 mg/cm^3, these 2 constructs had the highest values in the MS group and failed after 71,099 and 60,536 cycles, respectively.

The Spearman correlation between BMD and construct stiffness was significant in the MS group ($P = .012$, $R = 0.669$) but nonsignificant in the TS group ($P = .098$, $R = 0.478$). Both groups showed a significant correlation between BMD and both failure cycle ($P < .001$, $R = 0.828$ for MS group and $P < .001$, $R = 0.857$ for TS group) and failure load ($P = .001$, $R = 0.787$ for MS group and $P < .001$, $R = 0.829$ for TS group). All results are shown in Table I as a data sheet.

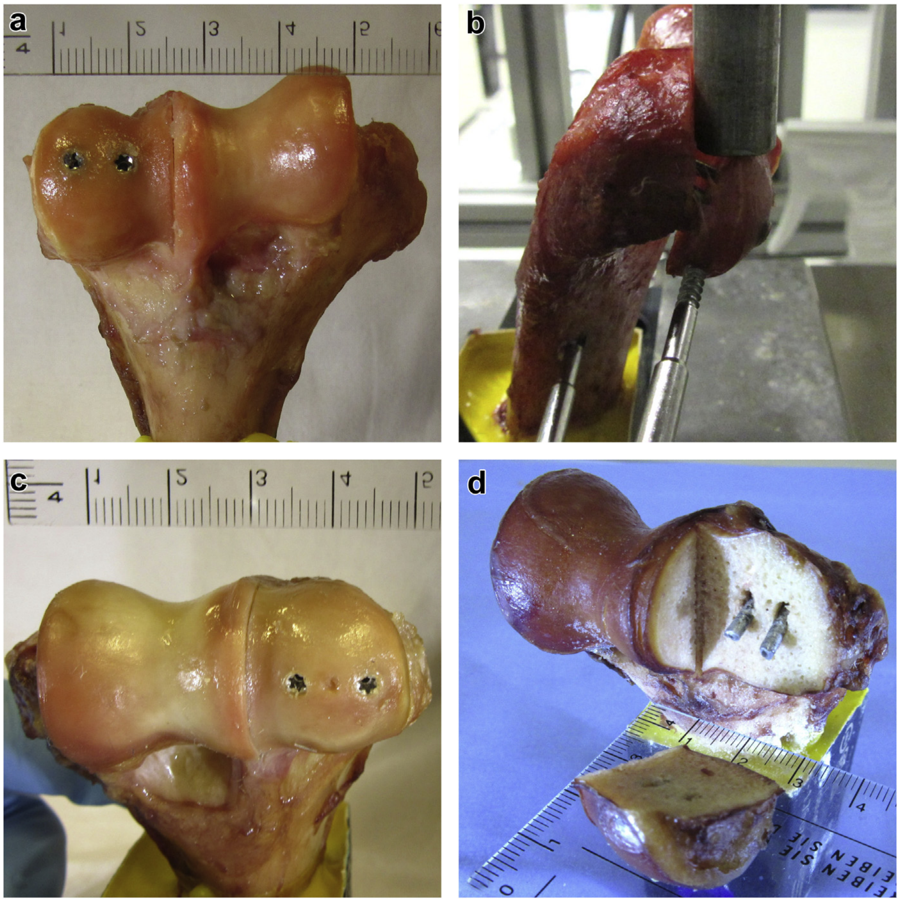

Figure 3 Constructs and failure mode. (**a**) Titanium screw construct with 2 headless screws buried under the cartilage surface. (**b**) Distal screw cutout—the most observed failure mode in this study—in a titanium screw construct. (**c**) Magnesium screw construct. (**d**) Screw breakage, which occurred in 2 magnesium screw constructs after 71,099 and 60,536 cycles.

Discussion

The main finding of this study was that simple capitellar fractures stabilized by biodegradable headless compression screws consisting of a magnesium alloy showed similar biomechanical properties to fractures treated by equally designed TSs. In both groups, a significant correlation was recorded between BMD and both failure cycle and failure load. It is interesting to note that a correlation between BMD and primary construct stiffness was seen only in the MS group whereas TS construct stiffness was not dependent on the specimens' BMD. This aspect could support the assumption that the mechanical properties of magnesium implants are more similar to those of bone than steel or titanium implants, which was previously stated by Luthringer et al.[8]

Another difference in mechanical properties between titanium and magnesium implants was observed related to failure mode. All TS constructs failed because of distal screw cutout, whereas this failure mode occurred in 11 of 13 MS constructs. The 2 remaining constructs showed screw breakage close to the screw head. Deeper data analysis pointed out that the 2 constructs resulting in screw breakage had the highest BMD rates among the constructs in the MS group (344.9 mg/cm^3 and 288.1 mg/cm^3, with a group average of 189.4 mg/cm^3). As construct stiffness correlated significantly with BMD in the MS group, this construct stiffness consequently leads to the highest stress rates at the bone-implant interface. The 2 constructs failed after 71,099 and 60,536 cycles; this implant failure might play an inferior role under in vivo conditions, in which bone consolidation eases maximum loads at the bone-implant interface over time and thus might prevent screw breakage.

To date, there exist 3 biomechanical studies investigating capitellar fractures. In 2002, Elkowitz et al[6] analyzed 3 different fixation methods for Bryan-Morrey type I capitellar fractures. First, they compared 6 pairs of fractures treated by 2 partially threaded 4.0-mm screws inserted as lag screws in either an AP or posteroanterior manner with countersunk screws in the AP position using an embedded cadaveric model. Each specimen underwent

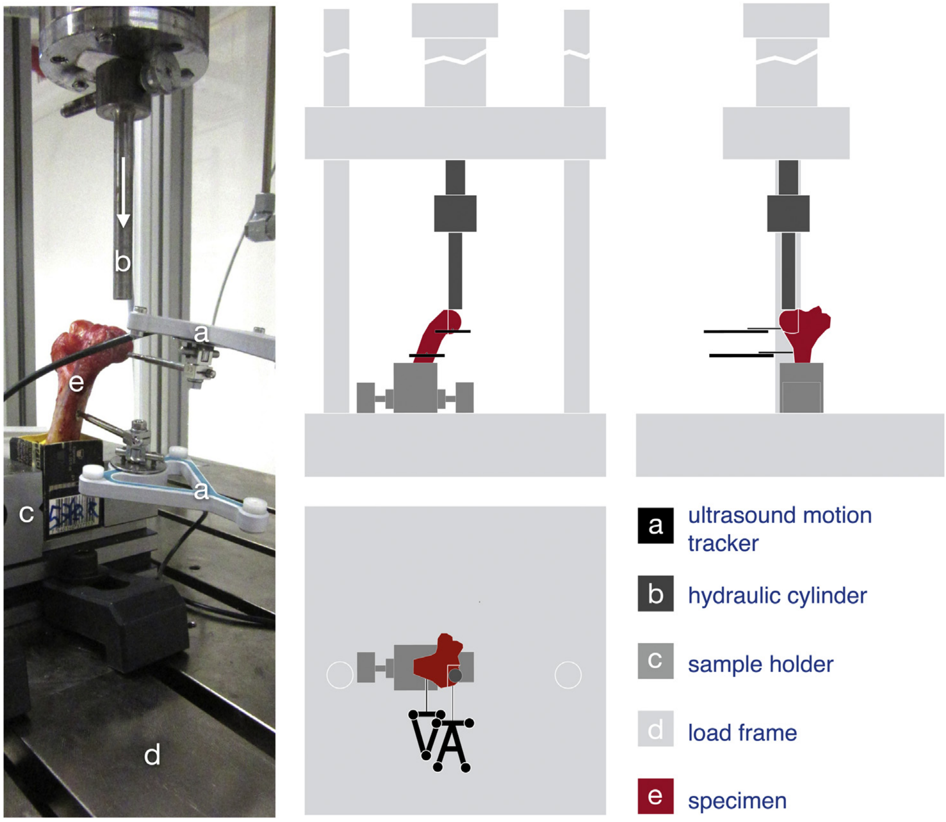

Figure 4 Photograph *(left)* and schema *(right)* of test setup. (a) Ultrasound transmitter and receiver, which recorded the relative motion of the fragment 3-dimensionally. The loading direction is indicated by the *arrow*. (b) Hydraulic cylinder, transmitting the loading force solely to the fragment. (c) Sample holder, stiffly mounting the cubic cemented specimen to the load frame. (d) Load frame. (e) Mounted specimen.

Table I Overall results of MS and TS constructs

Implant	Average	SD	Median	Minimum	Maximum	*P* value
Stiffness, kN/mm						.701
MS	0.50	0.25	0.41	0.32	1.22	
TS	0.47	0.13	0.48	0.20	0.77	
Failure cycle, n						.701
MS	43,944	21,652	38,584	20,097	90,010	
TS	41,202	16,457	42,010	2554	60,069	
Failure load, N						.915
MS	151.9	52.5	125	100	250	
TS	150.0	42.1	150	50	200	
BMD, mg/cm^3						.701
MS	189.4	77.8	176.1	81.3	345.0	
TS	191.6	85.9	163.4	62.3	370.2	

MS, magnesium screw; *TS*, titanium screw; *SD*, standard deviation; *BMD*, bone mineral density.

No significant differences in construct stiffness, failure cycle, or failure load were recorded. As a result of pair-wise comparison, BMD measurements showed no significant difference between the groups. The correlation between BMD and construct stiffness was significant in the MS group ($P = .012$, $R = 0.669$) but nonsignificant in the TS group ($P = .098$, $R = 0.478$).

2000 continuous load changes up to 75 N at 3 Hz, followed by load-to-failure testing. The posteroanterior group showed less displacement (0.32 mm vs. 0.92 mm) with statistical significance, and this technique was then compared in a second step in 6 matched pairs with Acutrac headless compression screws (Acumed, Beaverton, OR, USA) inserted in an AP position. The Acutrac screw is a fully threaded, self-tapping screw with a tapered headless shape. The headless compression screw constructs showed less displacement (0.14 mm vs. 0.38 mm) without statistical significance. Failure loads did not differ significantly in any of the test series.

In 2003, in a subsequent investigation of 6 pairs of embedded cadaver humeri with the same fracture model, Elkowitz et al[5] compared the formerly tested Acutrac headless compression screw with a Herbert screw design that gains interfragmentary compression by being partially threaded with a differential pitch. After 2000 cycles of continuous loading, the Acutrac group showed significantly less displacement than the Herbert screw group: 0.17 mm vs. 1.57 mm. The failure load was significantly higher in the Acutrac group as well, at 154 N vs. 118 N.

In 2012, Koslowsky et al[7] compared 4 different fixation techniques in a Bryan-Morrey type I fracture model with a Sawbones construct (Sawbones, Vashon Island, WA, USA). They compared constructs with two 2.2-mm fine-threaded wires, two posteroanteriorly inserted 2.7-mm lag screws, two AP inserted 3.0-mm headless compression screws (Herbert screws), and two 2.0-mm Kirschner wires. Ten specimens in each group underwent load-to-failure testing until displacement of 3 mm was reached, and 10 specimens underwent continuous load changes of 100 loading cycles between 2 and 250 N. On both cyclic loading and load-to-failure testing, Kirschner wire fixation showed significantly inferior results to the other fixation methods.

Because of the different loading protocols used by Elkowitz et al[6] and Koslowsky et al,[7] displacement values were not comparable. Our study conducted a high cyclic loading protocol with sinusoidal load changes between 10 and 50 N at 4 Hz. Every 10,000 cycles, maximum load was raised by 25 N until construct failure occurred, which was defined as fragment displacement >3 mm. Outcome parameters were primary construct stiffness and both failure load and failure cycle. With failure loads of 152 N in the MS group and 150 N in the TS group, our failure load values are in a comparable range to those of Elkowitz et al,[5] who recorded 154 N in the Acutrac group and 112 N in the Herbert screw group. With 329.5 N in the headless compression screw group, the higher load-to-failure values of Koslowsky et al[7] could be attributed to the use of Sawbones models instead of human cadaver humeri and the fact that the specimens used for load-to-failure testing did not previously undergo cyclic loading in their protocol.

Because this was a biomechanical cadaveric investigation, a limitation of this study, among others, is the small sample size. With a comparison of 13 samples per group, a compromise between ethical feasibility and statistical power is always necessary. A prospective sample size calculation was conducted with a requested power >0.8, as mentioned in the "Materials and methods" section. This sample size is higher than that seen in comparable biomechanical studies in the literature,[5-7] which was necessary to prove our hypothesis of similar biomechanical outcomes using bioabsorbable MSs vs. TSs for capitellar fracture fixation.

Another limitation is the lack of soft tissues, such as the joint capsule and ligaments. These play a decisive role in elbow joint stability. Furthermore, load bearing was conducted as isometric loading in a 20° position, perpendicular to the fracture planes, to obtain maximum stress on the osteosynthesis. There were neither joint movements, leading to rotational and bending forces, nor varus-valgus moments involved, which would have reflected physiological loading more precisely. Simplification of the fracture model and test setup is a common method in biomechanical in vitro testing for both the reproducibility and feasibility of consecutive test series and was also seen in previously conducted investigations.[5-7]

Furthermore, as a common disadvantage of in vitro testing, bone consolidation could not be reflected in our study. Failure after >40,000 cycles on average corresponded to a postoperative period of >6 weeks. In vivo, this period would have led to significant fracture consolidation, easing maximum loads on the osteosynthesis implants and potentially preventing construct failure as previously mentioned.

Dealing with cadaveric specimens also means investigating aged specimens with typically lower BMD values. In this test series, the mean age of cadavers was 77 years (range, 64-92 years). However, conducting a matched-pair investigation, analyzing the BMD values at the site of interest ensured the absence of significant differences between the groups. Because of the lack of reliable data on BMD at the humeral capitellum, our BMD findings could not have been compared with a regular cohort and were just taken as relative values.

Conclusion

Biodegradable MSs in a headless compression design showed equal biomechanical results to comparable TSs in the treatment of a simple shear fracture of the humeral capitellum. Owing to the advantages of biodegradable implants with the ability to be countersunk for transcartilaginous fracture stabilization, such as less implant impingement and cartilage destruction, as well as redundant implant removal, from a biomechanical point of view, their clinical application should be considered and evaluated.

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