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Biodegradable magnesium vs. polylactide pins for radial head fracture stabilization: a biomechanical study

Ferdinand C. Wagner, MD[a,b,*], Larissa Polossek, MD[b], Tayfun Yilmaz, MD[a], Martin Jaeger, MD[a], Dirk Maier, MD, PhD[a], Matthias J. Feucht, MD, PhD[a,c], Norbert P. Südkamp, MD, PhD[a,b], Kilian Reising, MD, PhD[a,d]

[a]*Department of Orthopedics and Trauma Surgery, Medical Center, Faculty of Medicine, Albert-Ludwigs University of Freiburg, Germany*
[b]*G.E.R.N. Tissue Replacement, Regeneration & Neogenesis, Department of Orthopedics and Trauma Surgery, Medical Center, Faculty of Medicine, Albert-Ludwigs University of Freiburg, Germany*
[c]*Department of Orthopaedic Sports Medicine, Klinikum Rechts der Isar, TU Munich, Germany*
[d]*Department of Trauma Surgery, Asklepios Klinikum Hamburg, Germany*

Background: Biodegradable implants have gained increasing importance for the fixation of simple displaced radial head fractures to supersede implant removal and to minimize cartilage destruction. Commonly used polylactide pins still lead to higher rates of secondary loss of reduction compared with metal implants. Alternatively, implants made from a magnesium alloy meanwhile are available in a pin design that hypothetically could perform better than polylactide pins. Because biomechanical data of clinical applications are lacking, the goal of the present study was to biomechanically compare magnesium pins to polylactide pins using a Mason type II radial head fracture model.
Methods: Fourteen pairs of fresh-frozen human cadaver radii with a standardized Mason type II radial head fracture were stabilized either by two 2.0-mm polylactide pins (PPs) or two 2.0-mm magnesium pins (MPs). Biomechanical in vitro testing was conducted as 10 cycles of static loading at 0.1 Hz axially and transversally between 10 and 50 N. Afterward, loosening was tested by dynamic load changes at 4 Hz up to 100,000 cycles. Early fracture displacement was measured after 10,000 cycles. Afterward, maximum loads were raised every 10,000 cycles by 15 N until construct failure, which was defined as fracture displacement $\geq$2 mm.
Results: MP osteosynthesis showed a tendency toward higher primary stability on both axial (MP: 0.19 kN/mm, PP: 0.11 kN/mm; $P =$ .068) and transversal loading (MP: 0.11 kN/mm, PP: 0.10 kN/mm; $P =$ .068). Early fracture displacement was significantly higher following PP osteosynthesis (MP: 0.3 mm, PP: 0.7 mm; $P =$ .030). The superiority of MP was also significant during cyclic loading, represented in a higher failure cycle (MP: 30,684, PP: 5113; $P =$ .009) and in higher failure loads (MP: 95 N, PP: 50 N; $P =$ .024).
Conclusion: According to our findings, in simple radial head fractures, osteosynthesis with magnesium pins show superior biomechanical properties compared with fractures treated by polylactide pins. Prospective investigations should follow to evaluate clinical outcomes and resorption behavior.

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

*Reprint requests: Ferdinand C. Wagner, MD, Department of Orthopaedic Surgery and Traumatology, Medical Center, Faculty of Medicine, Albert-Ludwigs University of Freiburg, Hugstetter Straße 55, 79104, Freiburg, Germany.
E-mail address: ferdinand.wagner@uniklinik-freiburg.de (F.C. Wagner).

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Radial head fractures represent about one-third of the elbow joint's fractures in adults[18,24] and account for 1.7%-5.4% of all fractures.[11] The typical trauma mechanism is a fall on the outstretched pronated forearm. Minimally displaced radial head fractures (Mason type I) are treated conservatively with excellent long-term results,[10] but the treatment of Mason type II fractures is still discussed controversially.[1] However, it has been proven biomechanically that Mason type II fractures significantly compromise the stability of the elbow joint,[2] especially in valgus stress conditions.[15,16] Therefore, open reduction and internal fixation of Mason type II fractures is applied with good as well as excellent results in patients with high functional demands.[7,11] Osteosynthesis is obliged to enable early functional postoperative care to prevent stiffness and functional restrictions, which are the most common reasons for secondary surgery in primary conservatively treated Mason type I and II fractures.[8]

To date, standard implants for osteosynthesis of radial head fractures are metal implants, such as minifragmental screws and plates.[6,21] However, the mechanical properties of steel and titanium poorly match those of bones. This may lead to stress shielding or aseptic loosening.[17] Implant removal due to functional restrictions or hardware impingement is often required. Hence, biodegradable implants gain increasing importance to prevent these problems and to avoid secondary surgery. Currently, the vast majority of biodegradable implants used for fracture fixation are made from polymers lacking in biomechanical strength.[25] Magnesium-based implants are an innovative alternative and meanwhile are available in a pin design (Fig. 1, *a*). In this case, they are composed of the magnesium-alloy MgYREZr (magnesium–yttrium–rare earth–zirconium), which is completely degraded after about 1 year[27] and has mechanical properties more similar to those of bones.[13]

The first clinical outcomes using magnesium screws have been satisfactory,[19] and osteosynthesis stability has been proven biomechanically to be equal to titanium implants in a fracture model.[26] Therefore, the hypothesis of the present study was that pins made from a biodegradable magnesium alloy could have superior biomechanical performance than similarly shaped polylactide pins.

Because there are neither clinical nor biomechanical studies evaluating magnesium pins in human application, the goal of the present study was to conduct a biomechanical comparison of biodegradable polylactide and magnesium pins using a Mason type II radial head fracture in a human cadaver model.

Material and methods

As a biomechanical in vitro study, this test series was performed on 14 pairs of fresh-frozen human cadaver radii. The specimens were from 10 female and 4 male donors with a mean age of 77.9 years (range 64-93) and a body mass index of 24.0 (range 18.8-31.2). First, including all soft tissues, computed tomography scans were performed (Toshiba Aquilion ONE, Toshiba Medical Systems Europe, Zoetermeer, Netherlands) on all elbow joints to exclude prior fractures or other bony pathologies and to obtain information about bone mineral density (BMD) at the site of interest based on the work of Budoff et al.[4] Group differences in BMD thereby were precluded as well (mean values for BMD: 0.242 g/cm^3 in the PP group (polylactide pin) and 0.235 g/cm^3 in the MP group (magnesium pin) (P = .396). Subsequently, bones were stripped from all soft tissues, and a standardized Mason type II fracture was created referring to prior biomechanical studies.[5,25] The fracture was generated by a single-plane osteotomy with a water-cooled diamond-blade saw (EXAKT 300 CP; EXAKT Advanced Technologies GmbH, Nordstedt, Germany) with a blade thickness of 0.3 mm. Using an adjustable specimen clamp to avoid any freehand sawing, the exact fracture plane was determined prior to sawing. The result was a fragment, measuring one-third of the radial head's longest diameter, including the safe zone of the radial head circumference (Fig. 1, *c*). Ending tangentially to the radial shaft, the fragment had no bony support during testing.

The constructs then underwent pair-by-pair stable fracture fixation by two 2.0-mm polylactide pins (PP) (Polypin; Biovision, Ilmenau, Germany) or two 2.0-mm magnesium pins (MP) (Magnezix; Syntellix, Hannover, Germany) as shown in Fig. 1. Left and right radii were assigned to one of the groups following a randomization protocol. Both polylactide pins and magnesium pins were implanted strictly according to the manufacturer's manual. All pins were implanted parallel to the articular joint's surface, and the length was chosen ensuring the tip of each pin ended subchondrally. The resulting osteosynthesis was radiologically controlled in 2 planes (Fig. 2).

Constructs were shortened to 9 cm and embedded into a standardized carton cuboid in polymethylmethacrylate (PMME-Technovit 3040; Heraeus Kulzer GmbH, Wehrheim, Germany), leaving a free bone stock of 5 cm.

The procedure of testing was carried out with the servohydraulic testing machine Amsler HC10 (Zwick/Roell, Ulm, Germany). Force was applied by a cylindric stamp axially and tangentially to the fragment according to prior research.[5,25] For axial loading, the radial shaft axis was placed vertically and mounted to the testing machine's load frame by a clamp (Fig. 3, *b*). During transverse loading, the specimens were placed in their cross axis, with a metal block supporting the radial head except from the fragment (Fig. 3, *a*). Force application parallel to the fracture plane was ensured in both settings, and any caudal support of the fragment was strictly avoided. First, static loading was conducted. After applying a

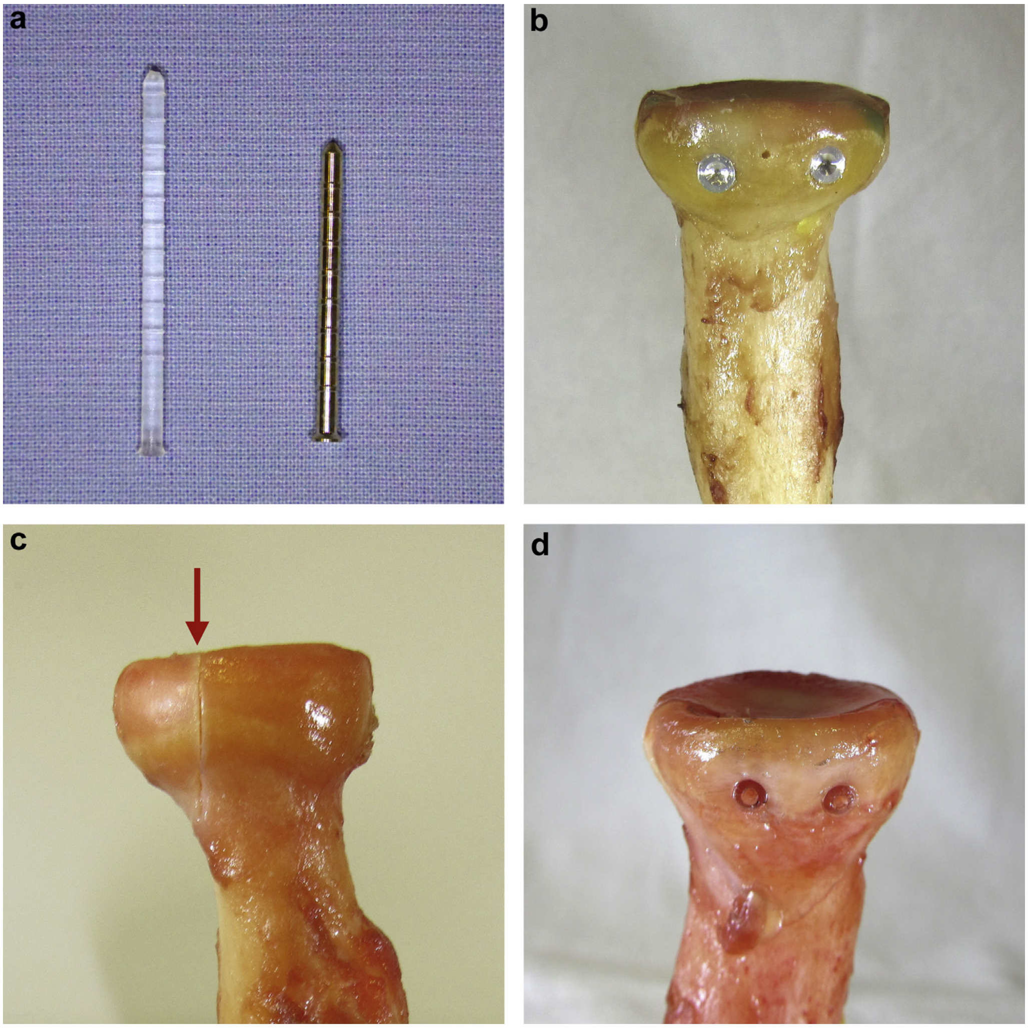

Figure 1 Implants and osteosynthesis. (**a**) Left: 2.0-mm Polypin (Biovision, Ilmenau, Germany); right: 2.0-mm Magnezix Pin (Syntellix, Hannover, Germany). Note: Polypins are shortened before implantation whereas Magnezix Pins are selected in 2-mm steps. (**b**) Construct with two 2.0-mm Magnezix Pins implanted. (**c**) Lateral view of a reduced fracture; the red arrow indicates the fracture line. (**d**) Construct with two 2.0-mm Polypins implanted.

preload of 10 N, 10 sinusoidal load changes between 10 and 50 N were applied at 0.1 Hz both axially and afterward tangentially. Finally, high cycle loading was carried out under axial loading. Load changes therefore were applied at 4 Hz between 10 and 50 N. Maximum forces were raised every 10,000 cycles by 15 N until construct failure. During fatigue testing, loading frequency was raised to 4 Hz to avoid problems due to specimen decomposition over time. As the mechanical properties of bone are strain rate dependent, construct stiffness was measured before fatigue testing at 0.1 Hz only. Construct failure was defined as fragment displacement $\geq$2 mm, which was monitored by the testing machine's mean stamp position. Articular steps $\geq$2 mm are the subject of treatment discussions,[1,7] whereas isolated injuries with articular steps <2 mm (Mason type I) are usually treated conservatively with good clinical results.[10] Hence, secondary displacement $\geq$2 mm has to be regarded relevant and has already been the cutoff in previous biomechanical research.[22,25]

Final outcome parameters were construct stiffness during static loading, displacement after 10,000 cycles, and both failure cycle and failure load during cyclic loading. For statistical analysis, a Wilcoxon signed-rank test was run to detect group differences. Statistical significance was set at P <.05.

Results

In the PP group, the mean stiffness under axial loading was 0.15 $\pm$ 0.10 kN/mm (median: 0.11; minimum: 0.06; maximum: 0.39). In the MP group, a mean of 0.25 $\pm$ 0.21 kN/mm (median: 0.19; minimum: 0.06; maximum: 0.71) was recorded. This difference was not significant (P = .068).

Under transversal loading, 0.09 $\pm$ 0.03 kN/mm (median: 0.10; minimum: 0.04; maximum: 0.13) was measured in the PP group and 0.12 $\pm$ 0.05 kN/mm (median: 0.11; minimum: 0.04; maximum: 0.20) in the MP group,

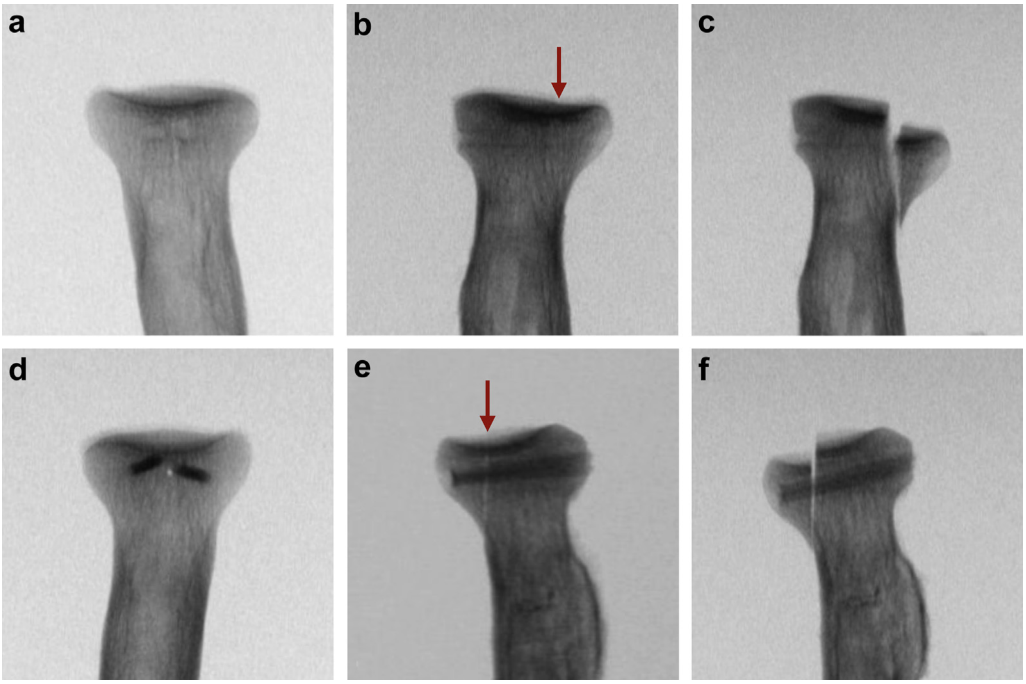

Figure 2 Radiologic controls. (**a**) Anteroposterior and (**b**) lateral view of a construct with two 2.0-mm Polypins implanted. The red arrow indicates the fracture line. (**c**) Corresponding radiologic control after construct failure. (**d**) Anteroposterior and (**e**) lateral view of a construct with two 2.0-mm Magnezix Pins implanted. The red arrow indicates the fracture line. (**f**) Corresponding radiologic control after construct failure.

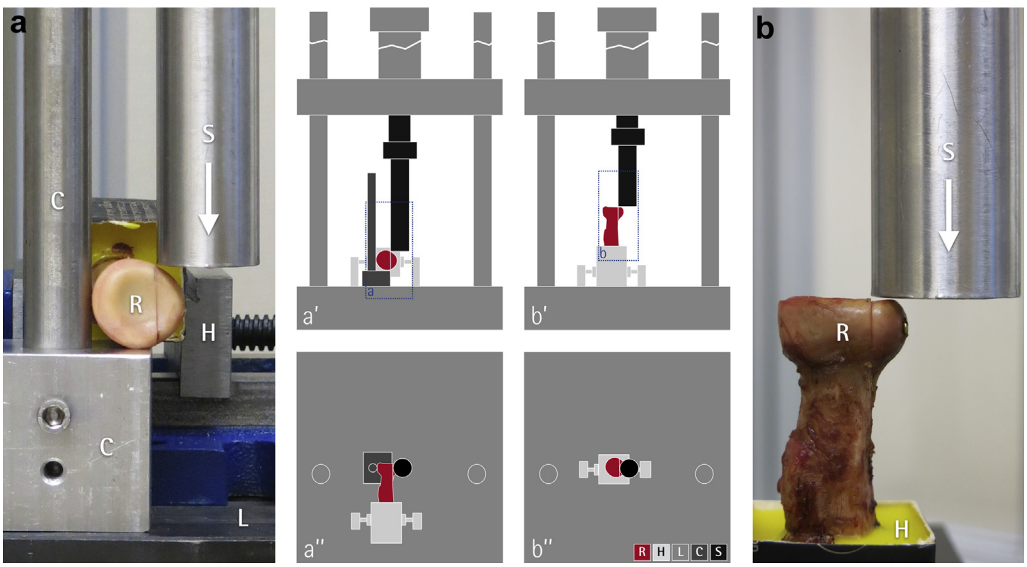

Figure 3 Test setup. (**a**) Experimental setup of transversal loading that is shown schematically in (a') and (a''). (**b**) Experimental setup of axial loading that is schematically shown in (b') and (b''). R: specimen including the radial head with the fracture plane being mounted parallel to the loading direction, which is indicated by the white arrow. H: the sample holder securely mounting the cemented specimen to the load frame L. C: counter bearing preventing the radial head from evasive movement during loading. S: the stamp, mounted to the servohydraulic testing machine.

respectively. Again, no significant differences were noted ($P = .068$).

After 10,000 cycles, a fragment displacement of 1.0 ± 0.7 mm (median: 0.7; minimum: 0.2; maximum: 2.0) was recorded in the PP group and 0.5 ± 0.5 mm (median: 0.3; minimum: 0.1; maximum: 2.0) in the MP group, respectively. This difference was significant ($P = .030$).

Under cyclic loading, construct failure in terms of implant loosening with fragment displacement ≥ 2 mm was recorded after $11{,}810 \pm 15{,}249$ (median: 5113; minimum:

1; maximum: 50,500) cycles in the PP group and 29,510 ± 17,294 (median: 30,684; minimum: 1; maximum: 60,031) in the MP group, respectively. This difference was significant ($P = .01$).

With a failure load of 65.0 ± 23.5 N (median: 50.0; minimum: 50.0; maximum: 125.0) in the PP group compared with 89.6 ± 24.7 N (median: 95.0; minimum: 50.0; maximum: 140.0) in the MP group, this significant difference was also reflected ($P = .02$). All results are shown in Table I as a data sheet.

Discussion

Because of the trend toward biodegradable implants for the stabilization of small articular fragments, the aim of the present study was to conduct biomechanical comparison of osteosynthesis in displaced radial head fractures using polylactide pins or magnesium pins.

The main finding was that osteosynthesis with magnesium pins show better biomechanical properties compared with fractures treated with polylactide pins in simple radial head fractures. This was reflected in a tendency toward higher primary stability, significantly less early fracture displacement, and a higher durability under high cycle loading conditions with higher failure loads, respectively. The tendency toward higher primary stability and significantly less early fracture displacement might enable early functional postoperative care following magnesium pin osteosynthesis, which partly is handled more restrictively following polypin osteosynthesis.[23] The higher durability under high cyclic loading conditions might prevent secondary loss of reduction prior to consolidation and thus might reduce degenerative changes and prolonged pain. These assumptions are obliged to be proven by prospective clinical trials, as direct conclusions cannot be drawn by the present biomechanical findings.

Regarding the literature, there are 4 biomechanical in vitro investigations available on radial head fractures. Koslowski et al[12] biomechanically compared 4 different fixation methods in a Mason type III sawbone fracture model. Testing comprised load-to-failure measurements as shear stress vertical to the radial shaft axis in 2 perpendicular directions. They postulated significantly higher stability using fine-threaded wires, miniscrews, and Kirschner wires compared with the application of miniplates. Axial loading was not performed. Shi et al analyzed 3 different screw positions at a Mason type II Synbone fracture model.[22] Using 2 headless compression screws each, they described best results for divergent screw positioning compared with parallel positioning or convergent crossing screws. A Mason type II fracture model in human cadaver radii was used in 2 prior studies.[5,25] Burkhart et al[5] compared headless compression screws to cortical lag screws. They performed both axial and transversal loading, then continuous loading up to 1000 cycles with load changes from 10 to 100 N, followed by load-to-failure testing. They concluded similar biomechanical stability in both groups.

Using a similar experimental setup as Burkhart et al,[5] in an own prior investigation, polylactide pins and titanium lag screws were compared on 8 pairs of fresh-frozen human cadaver radii.[25] The fractures stabilized with polylactide pins showed inferior biomechanical stability than those treated by titanium lag screws. This was demonstrated through less primary construct stiffness and significantly lower failure loads within the polypin group.

The present loading protocol comprised load changes between 10 and 50 N for the first 10,000 cycles followed by an increase of maximum loads by 15 N every 10,000 cycles. Changing the loading protocol to the protocol of Burkhart et al[5] was done for 2 reasons. First, the above-mentioned prior research[25] indicated 50 N to be the adequate sub–failure level for continuous loading following polypin osteosynthesis, and second, high cyclic loading was implemented to gain information about long-term fracture displacement rather than primary failure loads. Because of these changes, absolute values could not have been directly compared to the results of Burkhart et al. After 1000 cycles, they recorded a median displacement of 0.36 mm following lag screw osteosynthesis and 0.87 mm following headless compression screw osteosynthesis. After 10,000 cycles, the present study showed a displacement of 0.7 mm following polypin osteosynthesis and 0.3 mm following magnesium pin osteosynthesis. The loading protocol difference prohibited a comparison of the failure loads, and stiffness values were not provided by Burkhart et al. Comparing the present stiffness values to the results of Shi et al[22] and our own prior research,[25] with 0.25 ± 0.21 kN/mm under axial loading, the magnesium screw group could compete with the stiffest screw configuration (divergent screws) of Shi et al (0.21 ± 0.03 kN/mm) and with the lag screw group of our previous research (0.29 ± 0.11 kN/mm), whereas the present polypin group resulted in a stiffness of 0.15 ± 0.10 kN/mm, which was in the range of the significantly less stiff parallel screw configuration of Shi et al (0.15 ± 0.02 kN/mm) and the polypin group of our previous research (0.19 ± 0.09 kN/mm). The lower standard deviation values of Shi et al might reflect the Synbone fracture model (Malans Synbone Company, Zizers, Switzerland) with equal size and density of the specimen, whereas our investigations were run on human cadaver specimens with interdonor variations in size and BMD contributing to higher standard deviations, which was also seen in the results of Burkhart et al.[5]

In summary, respecting the methodologic differences of the available research, magnesium pin osteosynthesis biomechanically enqueues between lag screw and polypin osteosynthesis in Mason type II fractures and might be able to compete with the latter, which should be addressed in pending research.

Table I Overall results of the polylactide pin constructs (PP) and the magnesium pin constructs (MP).

Variable	Average	SD	Median	Minimum	Maximum	*P* value
Stiffness axial, kN/mm						.068
PP	0.15	0.10	0.11	0.06	0.39	
MP	0.25	0.21	0.19	0.06	0.71	
Stiffness transversal, kN/mm						.068
PP	0.09	0.03	0.10	0.04	0.13	
MP	0.12	0.05	0.11	0.04	0.20	
Displacement 10,000 cycles, mm						.030*
PP	1.0	0.7	0.7	0.2	2.0	
MP	0.5	0.5	0.3	0.1	2.0	
Failure cycle, n						.009
PP	11,810	15,249	5113	1	50,500	
MP	29,510	17,294	30,684	1	60,031	
Failure load, N						.024*
PP	65.0	23.5	50.0	50.0	125.0	
MP	89.6	24.7	95.0	50.0	140.0	
Bone mineral density, g/cm^3						.396
PP	0.243	0.041	0.232	0.191	0.349	
MP	0.235	0.038	0.237	0.162	0.293	

SD, standard deviation.
There were no significant differences recorded in construct stiffness both axially and transversally. Following magnesium pin osteosynthesis, significantly less displacement was recorded after 10,000 cycles, and both failure cycle and failure load were significantly higher.
* *P* values $< .05$.

A higher rate of secondary displacement following absorbable polylactide pin osteosynthesis compared with miniscrew osteosynthesis has also been reported clinically.[9,23] Although no significant differences were observed comparing functional outcomes, residual pain was reported in 15.8% of the patients following polylactide pin osteosynthesis and just 8.5% following miniscrew osteosynthesis, respectively.[23] One explanation of the authors was a different postoperative protocol of prolonged immobilization following polypin osteosynthesis, which was possibly leading to stiffness as there was no relation seen between pain and limitation of excursion to secondary displacement.

The present study ties onto these findings, with better results following magnesium pin osteosynthesis compared with polylactide pin osteosynthesis, possibly enabling early functional postoperative care as this is mandatory to prevent stiffness and functional restrictions, which are the most common reasons for secondary surgery in primary conservatively treated Mason type I and II fractures.[8]

Although the present results demonstrate significantly less early implant loosening and a higher durability under continuous loading following magnesium pin osteosynthesis, a significant difference from polypin osteosynthesis in primary construct stiffness was not reached ($P = .068$). Although magnesium pin constructs either failed by pin loosening, more specifically cut out, or a complete breakage of the pin, in polypin osteosynthesis, intermediate failure types including pin deviation or pin kinking were observed as well. This observation might lead to the assumption that the polypin's stiffness is more susceptible to continuous loading. Deeper statistical analysis of this assumption could not be realized because of the limited group size and the biomechanical setup. On the other hand, a clinical implication of the observed primary stiffness following polypin osteosynthesis might make it an adequate biodegradable alternative in situations where early functional care is not prescribed because of accompanying injuries requiring prolonged immobilization.

Particularly in elbow extension and pronation, most of the upper limb's weightbearing is transferred through the radiohumeral joint.[20] Axial loading of the present test setup was conducted to simulate this force transmission. Transverse loading was conducted to simulate shear forces transferred through the proximal radioulnar joint as well as postoperative adhesions interfering during forearm pronation and supination. Loads were chosen because of pretests at subfailure levels and were applied parallel to the fracture plane on the fragment only. This force application model was chosen both for being predescribed in the literature[5,25] and for gaining higher selectivity with maximum stress on the osteosynthesis, though lacking in the reflection of physiological loading conditions.

Even though operative treatment of Mason type II fractures might still be discussed controversially,[1] this fracture model was chosen for being very easily reproduced, predescribed,[5,25] and a recognized indication for polypin implantation.[9] To date, there is 1 randomized clinical trial of Mason type II fractures dividing into operative or nonoperative treatment and it is yet to be completed.[3] Retrospective studies showed significantly more secondary displacement and varus-valgus joint instability[7] or rather more functional limitations and a higher incidence of osteoarthritis[11] following nonoperative treatment compared with operative treatment of Mason type II fractures. On the other hand, a favorable clinical outcome was reported following conservative treatment of Mason type II fractures as well,[1] though lacking in an operative control group in this case. Summarizing, high clinical evidence is still lacking in this field. In our clinical proceeding, Mason type II fractures are operatively stabilized where associated injuries such as tears of the medial ulnar collateral ligament raise the demands on the radiocapitellar column as a secondary stabilizer against valgus moments. In these patients, secure stabilization plays a critical role in allowing early postoperative motion so that it prevents posttraumatic and postoperative stiffness.[8] Magnesium pins evidently provide more stability compared with polylactide pins according to the present biomechanical findings and thus might enable the required early functional postoperative care, still meeting the criteria of biodegradable transcartilaginous fixation of small articular fractures. Nevertheless, prospective clinical studies have to follow as an immediate conclusion can never be drawn by a simplified biomechanical test setup.

A limitation of the present study is the absence of soft tissues such as joint capsule and ligaments during biomechanical testing as they play a decisive role in the elbow joint's stability. In addition, because the load was applied isometrically, the effect of joint movements, leading to shear stress and bending forces as well as varus-valgus moments, was not analyzed in this setting and would have reflected physiological conditions more precisely. Simplification of both fracture model and test setup was applied for optimum reproducibility and feasibility.

Furthermore, as a characteristic of in vitro testing, bone healing factors influenced by blood supply and cancellous bone contact or resorption behavior of the biodegradable implants could not have been taken into account. Suggesting 100,000 cycles of radial head loads to represent more than 6 postoperative weeks, there might have been a beginning consolidation influencing construct stiffness and implant loosening in physiological conditions. As the present results demonstrate, the biomechanical superiority of magnesium pin osteosynthesis already takes effect in the early postoperative period with a tendency toward higher primary stability and significantly less early fracture displacement compared to polylactide pin constructs. Nevertheless, because there are case series reporting cystic lesions following magnesium implant application,[14,28] prospective clinical trials are obliged to follow, comparing the resorption behavior of magnesium and polylactide implants.

With 14 pairs of fresh-frozen human cadaver radii, the small sample size is another drawback of the present study, which always is a compromise between ethical feasibility and statistical power. The group size of 14 approved our hypothesis and is in line with or superior to comparable biomechanical studies.[5,12,22,25]

Investigating on cadaveric specimens also means dealing with aged donors, in this case with a mean age of 77.9 years. BMD values were analyzed at each radial head to preclude group differences, which was also ensured by conducting a matched-pair investigation. Even though BMD values are assumed to be below average at the age of 77.9 years, a comparison to a representative cohort was impossible because of the lack of reliable data about BMD values at the radial head.

Comparing the surgical procedures, there is no difference in application of polylactide or magnesium pins as they are both impacted after drilling one 2.0-mm hole per pin. Because of equal shape and size, neither exposure, surgical approach, or the surgeon's experience should influence the primary outcome or reduction quality. Both implants can be used in small fragments and can be placed beyond the safe zone that makes them advantageous over bulkier implants. However, one drawback of magnesium pins still are their high cost. In the present study, implant costs of the magnesium pin group were about 60% higher than in the polylactide pin group.

As the present biomechanical study has yielded promising results using magnesium pins for the osteosynthesis of simple radial head fractures, clinical investigations should follow to compare the functional outcome and to monitor fracture healing, resorption behavior, secondary displacement, and osteoarthritis following early functional postoperative care.

Conclusion

According to our findings, in simple radial head fractures, osteosynthesis with magnesium pins show superior biomechanical properties compared with fractures treated by polylactide pins, and might permit early functional postoperative care. Prospective investigations should follow to evaluate clinical outcomes and resorption behavior.

Disclaimer

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