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No more rattling: biomechanical evaluation of a hexapod ring fixator free of play

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Abstract: Hexapod-ring-fixators have a characteristic rattling sound during load changes due to play in the hexapod struts. This play is perceived as unpleasant by patients and can lead to frame instability. Using slotted-ball-instead of universal-joints for the ring-strut connection could potentially resolve this problem. The purpose of the study was to clarify if the use of slotted-ball-joints reduces play and also fracture gap movement. A hexapod-fixator with slotted-ball-joints and aluminum struts (Ball-Al) was compared to universal-joint-fixators with either aluminum (Uni Al) or steel struts (Uni Steel). Six fixator frames each were loaded in tension, compression, torsion, bending and shear and mechanical performance was analyzed in terms of movement, stiffness and play. The slotted-ball-joint fixator was the only system without measurable axial play (<0.01 mm) compared to Uni-Al (1.2 ± 0.1) mm and Uni-Steel (0.6 ± 0.2) mm ($p \le 0.001$). In both shear directions the Uni-Al had the largest play ($p \le 0.014$). The resulting axial fracture gap movements were similar for the two aluminum frames and up to 25% smaller for the steel frame, mainly due to the highest stiffness found for the Uni-Steel in all loading scenarios ($p \le 0.036$). However, the Uni-Steel construct was also up to 29% (450 g) heavier and had fewer usable mounting holes. In conclusion, the slotted-ball-joints of the Ball-Al fixator reduced play and minimized shear movement in the fracture while maintaining low weight of the construct. The heavier and stiffer Uni-Steel fixator compensates for existing play with a higher overall stiffness.

Keywords: biomechanics; deformity correction; external fixation; fracture fixation; hexapod; initial laxity; lower extremities; play; stiffness.

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Introduction

Hexapod ring fixators allow complex limb reconstruction with low invasiveness and are commonly used for fracture reduction and deformity correction [1], limb lengthening [2], or for treatment of pediatric and adolescent long bone fractures [3].

Popular hexapod systems exhibit a characteristic rattling sound during load changes due to play in the junctions of the hexapod struts, as described by Smitham et al. [4]. This play is often perceived as unpleasant by patients, can lead to instability of the frame and can cause a complete frame collapse when combined with small strut angles, according to Henderson et al. [5]. Minimizing play in the strut connection may thus affect patient acceptability as well as the mechanical performance of hexapod fixator frames. But without a certain amount of joint-play a universal-joint hexapod would not be functional.

Fracture gap movement in hexapod fixators occurs as a result of a combination of construct stiffness and play. In general, fixator stiffness depends mainly on structural and material properties, while play is dependent on mechanical design properties.

Stiffness depends on ring-strut-angles and the lever arms of the Schanz screws (further referred as pins) and wires, and usually correlates with ring-, wire- and pin-diameters and the ring and strut material (e.g. aluminum, stainless steel or carbon fibre, see [6]). On the other hand, initial laxity and, therefore, play in the fracture gap mainly come from the moving parts of the ring-strut junctions (e.g. universal joints) and increase with lower ring-strut-angles [5]. Therefore, to reduce the overall movement in the fracture gap, one can either increase the stiffness of the components by changing structural or material properties or decrease play by changing the mechanical design of the joints.

Recently the use of slotted ball joints instead of universal joints has been suggested to reduce the play in strut connections (joint-play). Due to the novelty of the slotted ball joint design, our literature review revealed a lack of knowledge of their biomechanical behavior, besides a few case reports [7–9].

Thus, the aim of our biomechanical study was to quantify the effect of a slotted ball joint on the movement in the fracture gap of a hexapod system in a clinically relevant ring wire-pin configuration.

Materials and methods

Tests were conducted in a mid-shaft tibia fracture model to compare fracture-gap-stiffness and -play characteristics of currently available hexapod-style external fixators in axial, bending (anterior-posterior and medial-lateral), and torsional scenarios. To determine the level of mechanical laxity, or 'play', present in the various hexapod external fixators, a hysteresis curve was generated in axial, rotational and shear directions and analyzed in the respective load direction.

Specimens and study groups

Three hexapod fixators were analyzed (see Figure 1): The novel TrueLok Hexapod System (TL-Hex, Orthofix, Bussolengo Verona, ITA), which varies in design by using slotted ball joints instead of universal joints (further referred to as **Ball-Al**), the Taylor Spatial Frame (TSF, Smith & Nephew plc., Watford, UK), which was chosen as a base reference due to its longstanding application and sufficient documentation (further referred to as **Uni-Al**), and the Hoffmann Limb Reconstruction Frame Hexapod (LRF-Hex, Stryker Corporation, Kalamazoo, USA), which varies in strut material properties by using stainless steel instead of aluminum (further referred to as **Uni-Steel**).

The naming scheme is therefore based on the type of joint used (universal or ball) and the main material used in the struts (aluminum or stainless steel). Another mentionable difference is that the Uni-Steel uses 6 mm ball threads with 2 mm lead while the Ball-Al and Uni-Al use regular M6 threaded rods with 1 mm lead.

The fixators were mounted on 300 mm glass fibre-reinforced resin tubes (Krüger und Sohn GmbH, Landshut, GER) with an outer diameter of 30 mm and wall thickness of 4 mm. Wire pairs were tensioned simultaneously to 1,300 N using the corresponding wire tensioners. Nut and screw tightening torque was set to 10 Nm using a torque limiter (Garant 65 6055_25, Hoffmann Group, Munich, GER) with an open-end wrench attachment (Garant 65 7850_I-27). Hexapod struts were chosen to be tested in close to full extension. All constructs were tested with Ø 180 mm aluminum full rings, Ø 5 mm stainless steel half pins and Ø 1.8 mm stainless steel wires. Rings were numbered one to four from proximal to distal. Ring spacing was 40 mm between rings 1-2 and 3-4 and 140 mm between rings 2-3. The simulated fracture gap was 20 mm. The first and fourth ring are fixed to the bone by two crossed wires, the second and third ring by one pin from anterior. Wires were mounted at a 60° angle and pins in the second hole from the anterior strut. Axial distances were measured from the center of the ring cross-sections to compensate for different ring thicknesses.

Mechanical testing

Mechanical testing was performed on a servo-hydraulic Instron 8874 testing machine (Instron Ltd, High Wycombe, UK) equipped with a Dynacell load cell (10 kN, 100 Nm, accuracy class 0.1) and 3D-motion was tracked using an Aramis 6M system (GOM GmbH, Braunschweig, GER). Components were only tested in elastic deformation using load and displacement limits. All constructs were pre-cycled axially for 1,000 cycles between 10 and 50 N to set the system and normalise wire-tension. Except for the wires and bone substitute, all components were reused after visual inspection to achieve a sample size of n=6.

Constructs were mounted between two universal joints to measure fracture-gap-stiffness and -play under axial and torsional loading (see Figure 2). Axial stiffness was measured at 0.5 mm/s until 300 N or a maximum of 5 mm compressive actuator displacement was reached. Axial play was measured at 0.5 mm/s between 50 N of compression and tension loading. Torsional stiffness was measured at 1°/s until 10° Nm or 10° angular displacement was reached, and torsional play was measured at the same rate between ±5 Nm torsional loading. The bending stiffness of the constructs was determined in a four point bending test setup with a support span of 600 mm and a load span of 300 mm (Figure 2). Stiffness was measured at 0.5 mm/s until 400 N (≙30 Nm) or 5 mm actuator displacement was reached. Tests were performed in both anterior-posterior (A-P) and medial-lateral (M-L) directions.

To quantify shear movement of the bone, the distal shaft was rigidly clamped to the machine frame and the proximal part was clamped to the actuator of the testing machine. Specimens were loaded in A-P and M-L directions. The rotational movement of the seesaw mounting component was blocked in this configuration. Shear play was measured at 0.5 mm/s until ±50 N or 5 mm actuator displacement was reached.

3D-motion-tracking

Optical marker adapters were attached to the bone surrogate fracture ends to measure pure relative displacements between the distal and proximal bone fragments (see Figure 3). Virtual cylinders were assigned to fit to the adapters in the Aramis software. This allows for the placement of measurement probes on positions unable to be directly seen by the camera system. The cylinder axis was defined as the shaft axis and the virtual fracture gap was set to 20 mm (see Figure 3 top left). The fracture gap movement could therefore be evaluated in all 6° of freedom. Machine load values were transferred via analog output to the camera system for synchronization and processing in the software of the camera system (Aramis). Stiffness and play were calculated using the relative displacements of the fracture gap.

SPSS Statistics 26 (IBM, Armonk, USA) and Excel 2010 (Microsoft, Redmond, USA) software were used for statistical evaluation. Normal distribution was tested using Shapiro-Wilk test and variance in homogeneity was tested using Levene-test. 2-tailed, unpaired t-tests with $p<0.05$ were used to check for significant differences between groups.

Results

Axial stiffness of the fixator frames ranged from mean values of 42 N/mm to 58 N/mm (see Figure 4), with the Uni-Steel system having the highest stiffness (p=0.001).

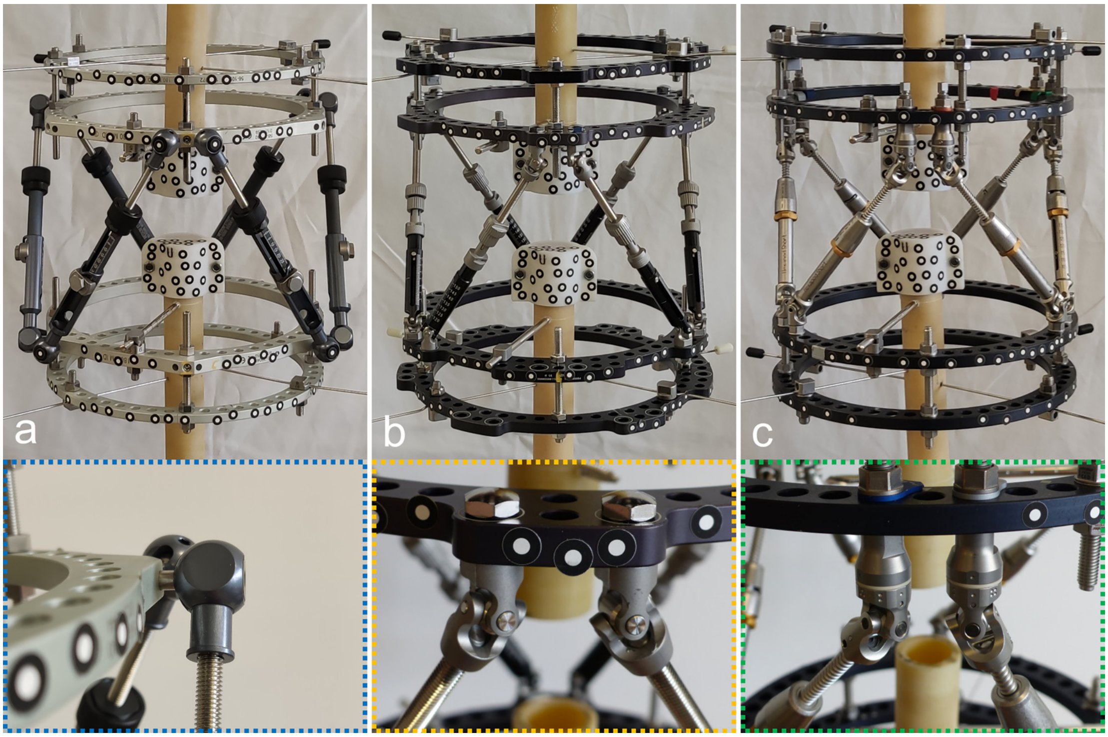

Figure 1: Ball-Al (a), Uni-Al (b) and Uni-Steel (c) hexapod ring fixators with close-up of the joint.

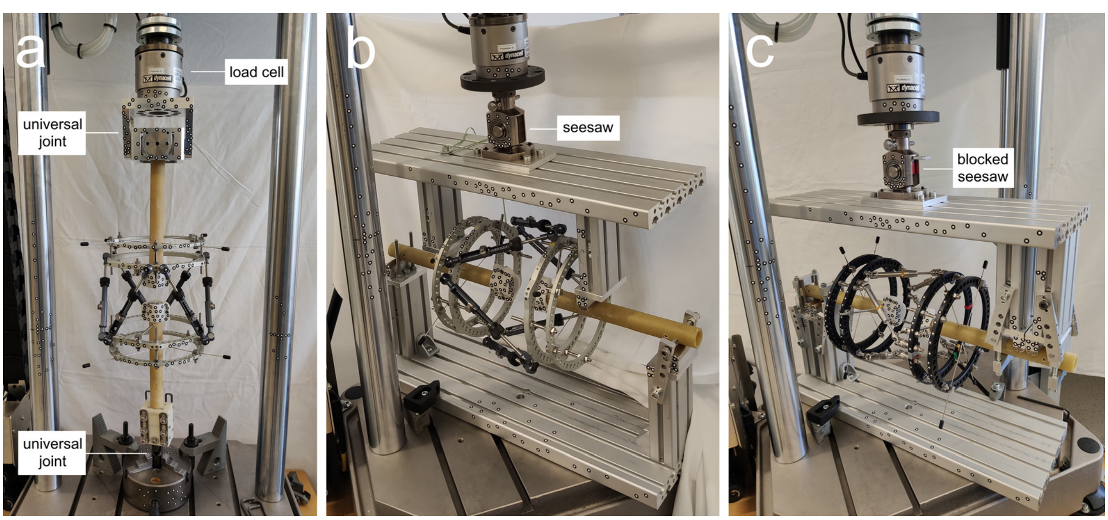

Figure 2: Axial and torsional test setup.
Fixator construct mounted between two universal joints (a). 4-Point-B ending setup. The seesaw allows rotation of the upper rollers (b). A-P- and M-L-Play with bone fragments fixed to the frame (distally) and actuator (proximally). The rotational movement of the seesaw was blocked (c).

Similarly, the rotational stiffness (mean values ranging from 1.6 Nm/deg to 2.1 Nm/deg) was highest for the Uni-Steel frame compared to both other frames (p=0.000).

Bending stiffness of all constructs was 60–70% higher in the anterior-posterior direction compared to the medial-lateral direction. The stiffness of the Uni-Steel frame was again significantly larger than the two other frames in both bending directions (p≤0.036). During the A-P bending tests all frames demonstrated a non-linear deformation response until up to 1.5 mm of displacement. This was likely due to mounting limitations leading to slipping of the bone fragments during small loads.

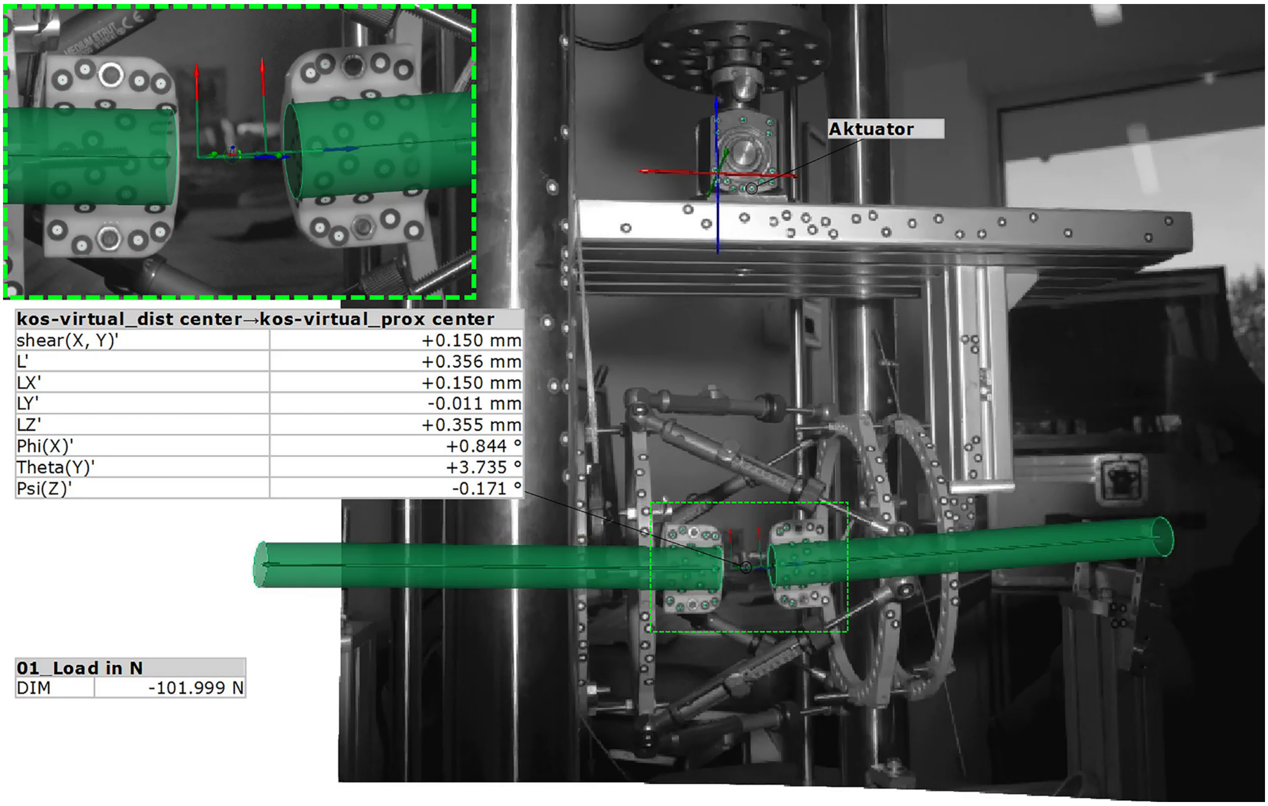

Figure 3: 3D-motion tracking software with virtual fracture gap.

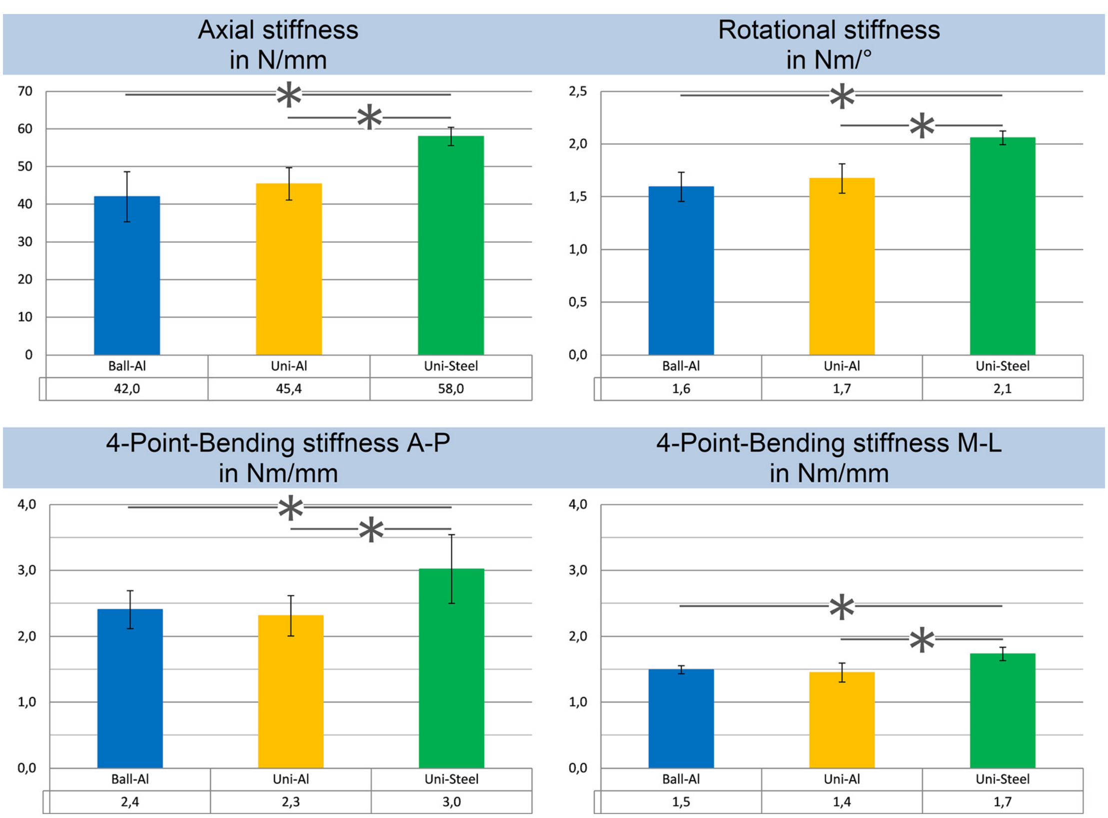

Figure 4: Stiffness results in axial, radial, A-P and M-L directions.
(t-test: 2-Tailed, unpaired, $p<0.05$).

Fracture gap-play, that was defined as >20% deviation from the linear range, was consistently lowest in the Ball-Al frame and largest in the Uni-Al frame for all translational load directions (see Figure 5). The play in shear was negligible for both the Ball-Al and the Uni-Steel frames. In contrast, the Uni-Al demonstrated considerable play in all translational loading directions, particularly in shear, demonstrating more than 8-fold larger play than for the other fixator frames.

Strikingly, the gap-play in the axial direction was almost nonexistent for the ball joint fixator (see Figure 6).

The resulting fracture gap movement is a combination of gap-play and stiffness. To compare the systems, we calculated the mean axial fracture gap movement with standard deviations for each system accounting for different partial weight-bearing levels (see Figure 7)

Due to its lack of gap-play, the Ball-Al frame exhibited with the least initial axial gap movement. For loads larger than 10 kg, the Uni-Steel demonstrated consistently smaller gap movement compared to both aluminum constructs. Comparing the two aluminum constructs, the ball joint resulted in smaller gap movement until up to 60 kg loading, and showed somewhat larger gap movement at larger load levels.

Considering an 80 kg patient at 50% (40 kg) weight-bearing, the systems displayed a mean fracture motion of 9.5 ± 1.8 mm (Ball-Al), 10.0 ± 1.0 mm (Uni-Al) and 7.5 ± 0.5 mm (Uni-Steel). At 25% (20 kg) weight-bearing Ball-Al, Uni-Al, and Uni-Steel systems showed mean fracture motions of 4.8 ± 0.9 mm, 5.6 ± 0.6 mm and 4.1 ± 0.4 mm, respectively.

The Uni-Steel construct tested was, with a mass of 1938 g, about 29% heavier than the 1,549 g Ball-Al, which was the lightest fixator construct. The 1752 g mass of the Uni-Al fixator fell neatly between those two.

Discussion

When comparing hexapod fixator frames that used different joints connecting the struts to the frame, we found that the slotted ball joints of the Ball-Al fixator significantly reduced play while maintaining similar stiffness to Uni-Al fixator. This result in less fracture gap movement compared to similar models in a relatively lightweight construct.

The Uni-Steel construct, however, showed significantly higher stiffness values in all described testing conditions and less play than the other universal joint fixator (likely due

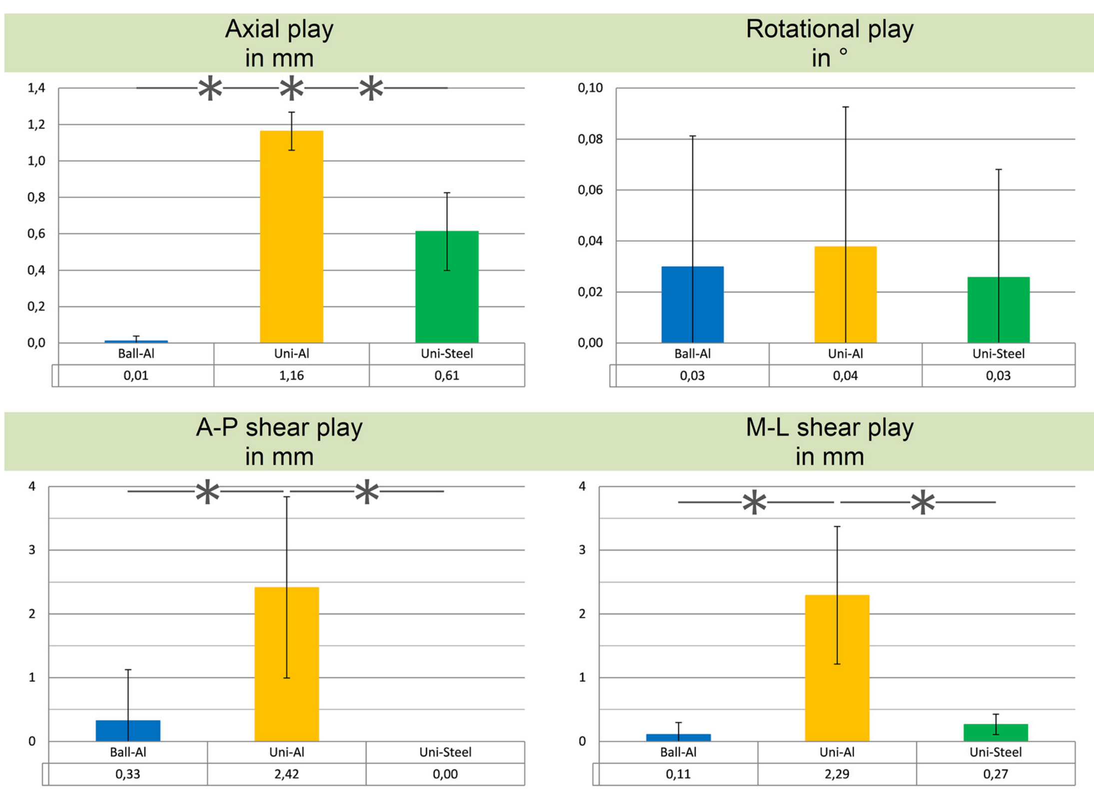

Figure 5: Fracture-gap-play results in axial, radial, A-P and M-L directions. In each case play was evaluated in load direction. (t-test: 2-Tailed, unpaired, $p<0.05$).

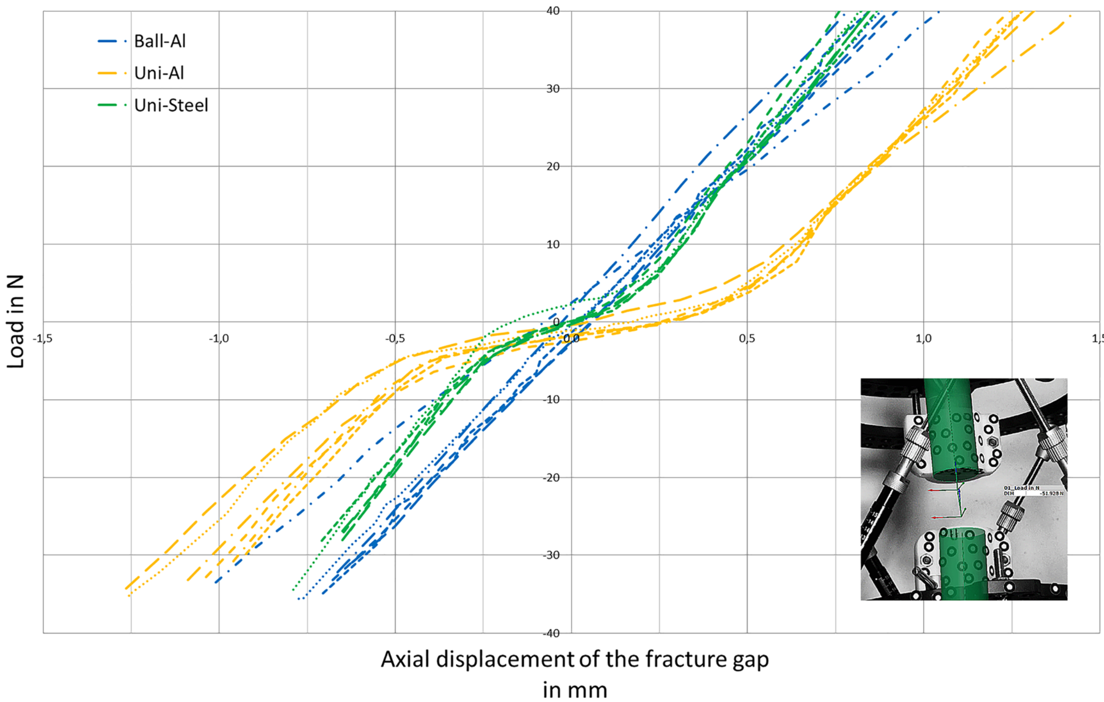

Figure 6: Axial load displacement curves of all constructs with noticeable plateaus (i.e. play) for the Uni-Al and Uni-Steel, and almost linear behavior for the Ball-Al.

to tighter tolerances), compensating for higher axial play under higher loads. One major explanation is the use of mainly stainless steel components for the hexapod struts, resulting in significantly higher stiffness values but also a noticeably higher weight. The components (rings, threaded rods, nuts, screws and wires) were chosen to be similar enough to be comparable among all three fixator constructs.

The Uni-steel relies on a traditional ring-design to mount hexapod struts, pins and wires all onto a single hole-line (see Figure 1). This results in a compact system, but also 15 out of 52 mounting holes being no longer accessible for pin- and wire-mounting after strut placement. In contrast to that the Uni-Al and Ball-Al have separate offset mounting spots for the struts for less interference with the pin/wire-mounting spots. The Ball-Al and Uni-Al options therefor only have six inaccessible mounting holes after strut placement. The surgeon must consider these compromises for each individual patient and injury scenario. For example, a stiff yet heavy fixator might be appropriate for a heavier patient while a lighter patient might benefit from a play-free and lighter construct for the same level of partial weight-bearing. A lower construct weight may also be a deciding factor in pediatric applications. The potential benefit of an increase in patient acceptance due to the lack of rattling sounds associated with less play has yet to be evaluated.

In terms of axial play, the Ball-Al construct showed significant differences compared to the other two constructs, allowing almost no measurable play in the shaft direction. This difference may potentially lead to increased patient comfort [10]. The measurable play heavily depends on strut lengths and angles, which could explain instability due to low strut angles [5] and the potential for a total collapse of the hexapod construct. Strut lengths and therefore strut angles are generally longer (steeper) for the Ball-Al compared to the other options for the same ring distances; this is likely due to the mounting position being external to the ring perimeter. The ball joint's center of rotation is therefore within the ring plane instead of being offset to it, as it would with universal joints mounted on top or below the ring. In combination with the reduced overall play, this feature could potentially further reduce the risk of frame collapse.

The measured axial stiffnesses are approximately 50% lower than values found in the literature [5, 8, 9]. Other than the different measuring techniques and component-spacing configurations the utilized ring size has probably the greatest influence on these differences. We aimed to simulate a "worst case" scenario by using 180 mm rings, instead of 155 mm like most of the referenced publications. This greater diameter increases the lever arm of all pins and wires by 16%, resulting in lower

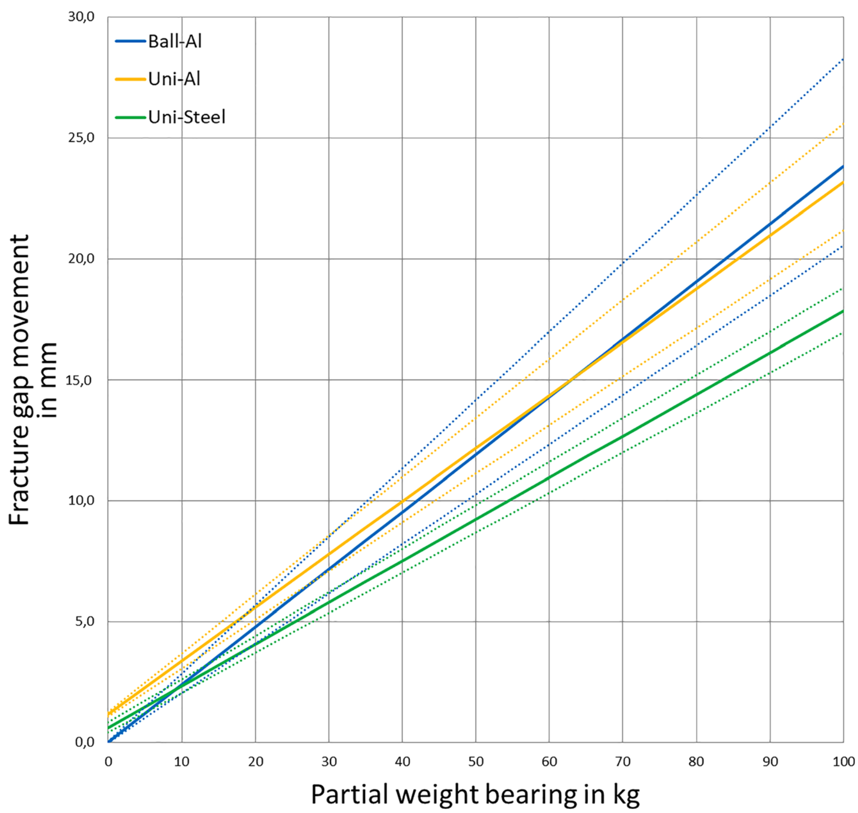

Figure 7: Axial fracture gap movement with standard deviations (dotted), resulting from stiffness and play as function of weight bearing level.

stiffness values. Khurana et al. [11] observed similar stiffness ratios of constructs using pins without wires (pin-only) when comparing 155–180 mm single-ring constructs. The same publication also showed markedly higher (20–150%) stiffness values for pin-only constructs compared to transverse wires.

Comparing traditional all-wire Ilizarov fixators to hexapod configurations (hybrid or pin-only), the hexapod showed similar or slightly higher axial stiffness values and noticeably higher torsional and bending stiffnesses [12]. The overall stability of all of the tested constructs in this study is therefore presumably at least on par axially and likely superior in torsion and bending to what's been previously demonstrated in all-wire Ilizarov fixators. Interestingly, Smitham et al. [4] minimized the play of an Uni-Al construct by adding a tensioned seventh strut and pretensioning the whole construct, and therefore preventing zero crossing.

The Uni-Steel uses a strut placement in its standard configuration that leads to differing strut lengths even in the straight ring position. In return the Uni-Steel allows "strut offsetting", which could potentially compensate for the lower number of usable mounting holes and the irregular standard configuration to some degree. This might have an effect on the mechanical properties, which was not considered in this study.

Another limitation of this study was the use of artificial bone surrogate for reproducibility and simplicity reasons. Muscle forces and soft tissue effects were therefore not taken into account. The examined fracture gap was an actual air gap lacking consideration of any callus formation. The hexapod systems were also only tested in a straight upright configuration to provide the most reproducible loading scenario and simplify the interpretation of findings. Hence, displacement values were probably considerably higher than in *in vivo* conditions. However, the ratio of fracture gap movements should be realistic and appropriate for the purpose of general comparison. One might also argue that play in the fracture gap may be desirable due to dynamisation and the subsequent stimulation of callus formation. That may be true for some fixator configurations and certain treatment times, but is undesirable, firstly, in the very early stages of healing and, secondly, in such an uncontrolled way that could even allow for inconsistent shear movement to occur during the treatment period. A proper way to encourage dynamisation would be to prohibit the unpredictability of the play entirely and induce controlled motion using special components. Whereby over-stiffening of the fracture site, that could lead to delayed- or non-union, was not a problem for our 5 mm pin-wire configuration, but it may become relevant for stiffer 6 mm pin-only constructs and smaller ring diameters. Our tests were also performed with all struts in close to full extension and therefore large strut angles, while, according to Henderson et al. [5], amounts of play may drastically increase for smaller strut angles.

Nevertheless, clinical investigations have yet to show whether the reduction of play in the axial fracture gap movement increases the wearing comfort for the patient or improves likelihood of fracture healing.

In conclusion, the slotted ball joints of the Ball-Al fixator were able to significantly reduce play while maintaining similar stiffness values to the comparable Uni-Al fixator. This led to less fracture gap movement maintained in a relatively lightweight construct, which may be especially beneficial for lighter patients or pediatric applications. In comparison, the heavier but stiffer (and with fewer usable mounting holes) Uni-Steel fixator compensates its existing play at relatively small loads.

As an outlook, a combination of play-optimized slotted ball-joints and stiffness-optimized stainless steel struts could reduce uncontrolled fracture gap movements even further. This could be meaningful clinically, especially for heavier patients who are dependent on larger ring sizes.

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