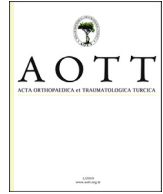




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Biomechanical comparison of humeral nails with different distal locking mechanisms: Insafelock nails versus conventional locking nails

Tunay Erden^{a,*}, Mehmet Kapicioglu^a, Abdullah Demirtas^b, Kerem Bilsel^a,
Fuat Akpinar^b, Hacer Kuduz^c

^a Bezmialem Vakıf University Medical School, Department of Orthopaedics and Traumatology, Istanbul, Turkey

^b Istanbul Medeniyet University, Department of Orthopaedics and Traumatology, Istanbul, Turkey

^c Department of Biomechanics, Faculty of Mechanical Engineering, Istanbul Technical University, Istanbul, Turkey



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ABSTRACT

Objective: The aim of this study was to compare the biomechanical resistance to rotational and axial forces of a conventional locking nail with a newly designed intramedullary humeral nail developed for humeral shaft fractures with a secure locking mechanism through the distal part of the nail.

Methods: InSafeLOCK humeral nail system (group 1, TST, Istanbul, Turkey) and Expert humeral nail system (group 2, DePuy Synthes, Bettlach, Switzerland) of the same size (9 × 300 mm) were examined. In total, 24 fourth-generation humerus sawbones were used in the experiment. Osteotomy was performed at the humerus shaft, and a defect was created by removing 1 cm of bone. After pre-loading 5000 cycles at a frequency of 2 Hz and a force of 50–250 N for axial loading and 5000 torsion torques between 0.5 Nm and 6.5 Nm at a 2 Hz frequency for torsional loading, the failure load values of each load were recorded. Distal interlocking was performed with an endopin in group 1, while a double cortex screw was used in group 2.

Results: All samples successfully passed the cyclic loading. The initial and final stiffness values were similar between the groups after axial loading ($p = 0.873$ and $p = 0.522$, respectively). The mean axial failure load values in groups 1 and 2 were 2627 ± 164 N and 7141 ± 1491 N, respectively. A significant difference was found in the axial failure load values ($p = 0.004$). Significant differences were observed between the initial and final torsional stiffness between the two groups ($p = 0.004$ and $p = 0.004$, respectively). No significant difference was found in the failure load values after torsional loading (11791 ± 2055 N.mm and 16997 ± 5440 N.mm) ($p = 0.055$).

Conclusion: These results provide a biomechanical demonstration of the adequate stability of both nails after axial and rotational loading. The reliability of the newly developed InSafeLOCK humeral nail system, which does not require fluoroscopic control and an additional incision for distal locking, supports its use in the clinic.

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* Corresponding author. Bezmialem Vakıf University Medical School, Department of Orthopaedics and Traumatology, Istanbul, Turkey. Tel.: +90 5546289045.

E-mail addresses: doktorerden@hotmail.com (T. Erden), kapicioglu@gmail.com (M. Kapicioglu), drademirtas@hotmail.com (A. Demirtas), kbilsel@gmail.com (K. Bilsel), fuatakipinar@yahoo.com (F. Akpinar), hacerbiomed33@gmail.com (H. Kuduz).

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Introduction

Humerus shaft fractures constitute approximately 3% of all fractures.¹ Currently, both surgical and conservative treatment options are available. Treatment may vary according to the fracture pattern, soft tissue damage, and sociocultural status of the patient.

The indications for surgical treatment include open fractures, polytrauma, vascular injury, unacceptable rotational or angular malalignment, pathological fractures, and floating elbows.² Many studies in the literature have compared surgical treatment

methods, but no consensus regarding the optimal treatment has been reached.^{2–7} Plate-screw osteosynthesis require exposure and radial nerve exploration, prolonging the surgical time.^{8,9} With the introduction of minimally invasive methods, the use of locked humeral nails has increased.

The use of locked intramedullary humeral nails is a less invasive approach than plate-screw osteosynthesis. However, intramedullary nails require an additional incision for distal locking, which carries a risk of neurovascular injury. The additional incision also prolongs the surgical procedure, requires more fluoroscopy exposure and results in a worse cosmesis. Therefore, the distal locking method of humeral nails must be improved.

In this study, we aimed to biomechanically compare a conventional locking nail with a newly designed humeral nail that specifically includes a secure locking mechanism through the distal part of the nail. Our hypothesis was that the newly designed nail could be equally or more stable against axial and torsional forces.

Materials and methods

This biomechanical study was performed using a servo-hydraulic test device (MTS 858 Mini Bionix II, Eden Prairie, MN) to assess axial and torsional loading (Fig. 1). Twenty-four identical, synthetic, polyurethane, fourth-generation, left, 9 mm medullary canal diameter and 365 mm length, large-size humerus models (Sawbones 3404-4; Malmö, Sweden) were divided into 2 groups, each consisting of 12 specimens.

A newly designed, commercially available 9 mm × 300 mm InSafeLOCK humeral nail system.

(TST, Istanbul, Turkey) was used in group 1 (Fig. 2A, B). A 9 mm × 300 mm Expert humeral nail system (DePuy Synthes, Bettlach, Switzerland) was used in group 2 (Fig. 3A, B). All

implantation procedures were performed by the same orthopaedic surgeon who has more than 8 years of experience in shoulder and elbow surgery. In all cases, the implantation was performed after the intramedullary canal was carved using the nail. Post-implant osteotomy was performed at the same level in all specimens. To imitate a comminution, a transverse 1 cm bone piece was removed from all specimens (from 18 cm proximal to the distal humeral joint line). One dynamic (50 mm) screw and one static (40 mm) screw were used in all samples in both groups after guide-assisted drilling for proximal locking. The distal locking method was the main difference between the groups. In group 1, for the endopin (which was used for distal locking) holding point, the posterior cortex was drilled through the top of the nail (through the nail channel) with a 3 × 400 mm K-wire with a motor aid. The endopin (2.5 mm × 200 mm) was passed through with a screwdriver from the connection screw at the nail holder insertion site. The grooves on the tip of the endopin matched the grooves in the nail channel. The endopin was moved to the distal tip by clockwise rotation of the inserter.

Following distal locking, proximal locking was performed with two screws. The InSafeLOCK nail is an intramedullary nail used for humeral shaft fractures. The InSafeLOCK nail is cannulated and round. The same nail can be used on both the right and left sides. It is possible to use this nail with or without reaming. There are four screw holes in the proximal part of the nail, including one dynamic and three static screw holes.

The main difference between the nails is the distal locking system. The InSafeLOCK nail is specifically designed to contribute to the rotational stability, and the final 3 cm of the distal tip are angled 5° anteriorly to allow the nail to be easily distracted. At the posterior of the distal nail tip, an oval hole is specifically designed for the internally secured pin (endopin) (Fig. 4). In group 2, the distal part was clearly observed with fluoroscopy, and both cortices were drilled using an anterior-posterior (A-P) drill. Then, a nail fixed with a single 4-mm screw was passed through the posterior cortex. Post-implantation, direct radiographs were used to verify the implant placement in all specimens (Figs. 2B and 3B).

After the implantation procedures, two Kirschner wires were placed crossing the humeral condyles 2 cm proximal to the humeral joint line. The distance from the tip of the nail to the crossing Kirschner wires over the epicondylar area was 4 cm. The specimens were embedded in polyester cement. A 100-mm diameter and 5-cm high polyvinyl chloride (PVC) pipe was used for the scaffold. A custom-made centralizer was used during this procedure to allow the nail of the construct to be placed perpendicular to the base of the PVC pipe and its long axis to be passed through the centre of the PVC pipe.

Test protocol

The tests were performed by applying axial forces to 6 samples per group and rotational forces to 6 samples per group. All tests were performed within the elastic behaviour limits. The failure and stiffness values were calculated by a MATLAB R2016 (The Mathworks Inc., Massachusetts, USA) program using the load–displacement data obtained from the experiments using an MTS test machine.

Axial load test

Six specimens per group were subjected to a dynamic axial load test. The nail was loaded, and the force was transmitted to the entire humerus. After pre-loading (2 Hz, 10 N–50 N, 10 cycles), the system was released to control the system stability, and the initial stiffness values were measured by applying an axial force of up to 250 N at a frequency of 2 Hz at 50 N/s. Then, 5000 cycles at a

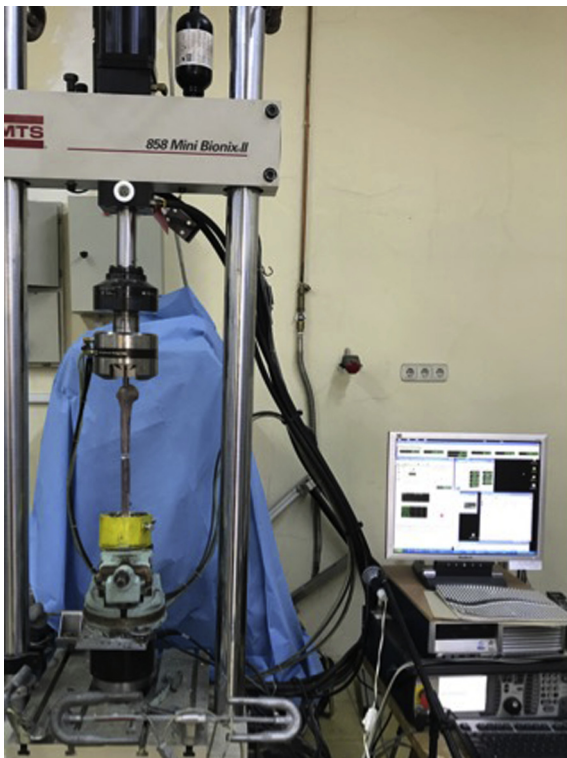


Fig. 1. A specimen on the MTS machine and the control system.

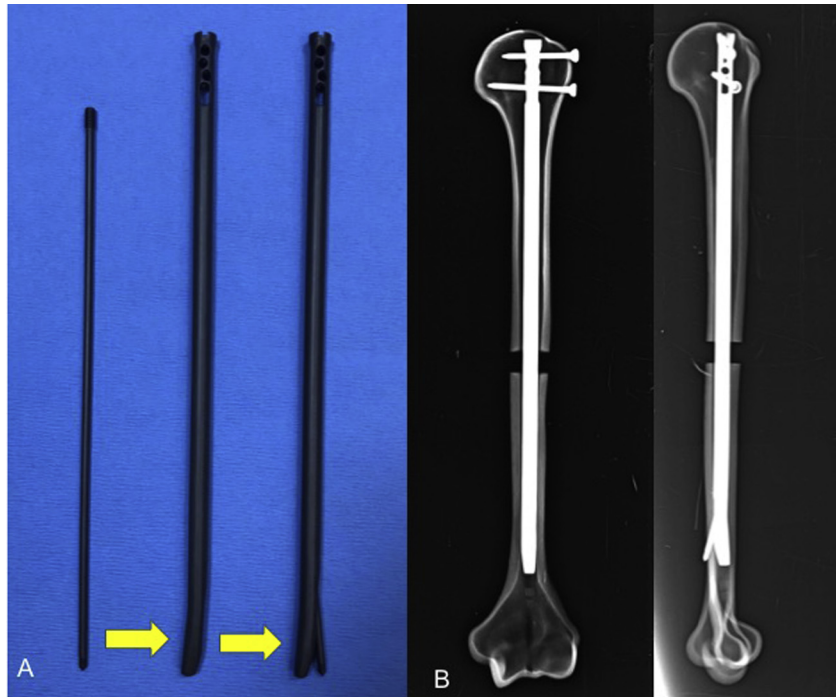


Fig. 2. A: InSafeLOCK humeral nail (TST) and Endopin B; X-ray view of a post-application InSafeLOCK nail.

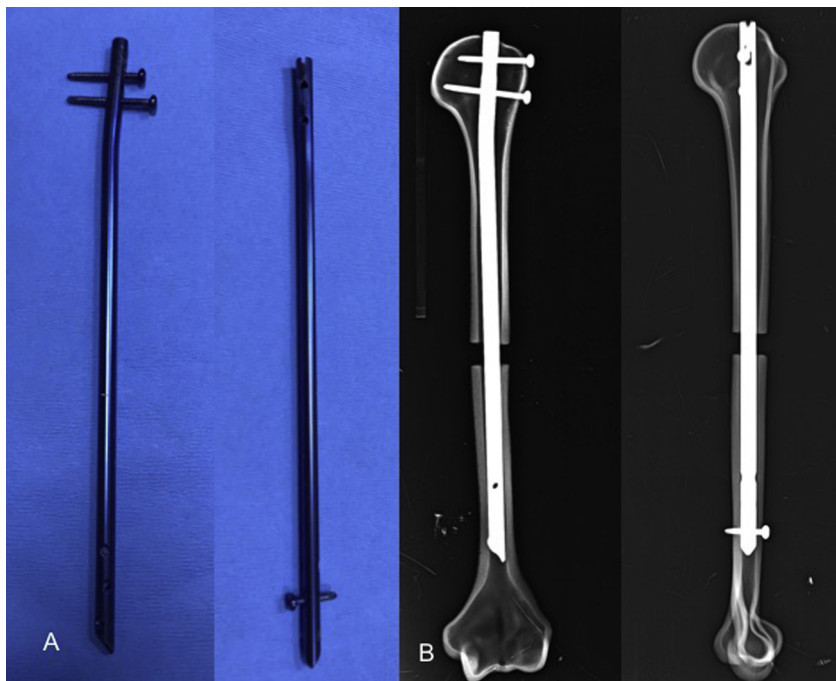


Fig. 3. A: Expert humeral nail (DePuy and Synthes) B: X-ray view of a post-application Expert humeral nail.

frequency of 2 Hz and a force of 50–250 N were repeated. The load to failure determination test was initiated after the cyclic loading by transferring the force from the control to the displacement-controlled protocol, and the force was applied at a rate of 15 mm/min until damage occurred. After 5000 cycling loads, the amount of displacement and durability (initial and final stiffness) and the

highest failure load value of each load were recorded. Axial stiffness was calculated from the slope of the linear part of the load–displacement curve. Stiffness can be expressed as $k = f/\delta$, where k = Stiffness (N/mm (for the axial loading test) or N.mm/degree (for the torsional loading test)) (F = Force, axial load applied to the test specimen, T = Torque, moment (torsion load) applied to

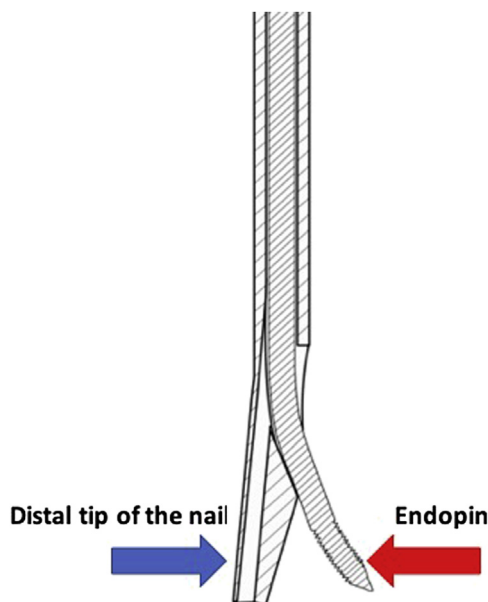


Fig. 4. Distal tip of the InSafeLOCK humeral nail.

the test specimen, δ = Displacement after axial (mm) or torsional loading (degree ($^{\circ}$)).

Rotational load test

The specimens were rotated through the nail such that the anatomic axis of the humeral nail formed the rotation centre. To facilitate the construction of the test fixture, a force used to generate torque was applied to the holder at the head of the humeral nail and clamped in the upper jaw of the test device. After pre-loading (2 Hz, 0.5 to 6.5 Nm, 10 cycles), the system was loosened. Then, a torsional moment to 6.5 Nm was applied at a rate of 0.2 Nm/s, and the system was evacuated to 0.5 Nm to measure the initial stiffness values. Then, 5000 torsion torques between 0.5 Nm and 6.5 Nm at a 2 Hz frequency were applied and discharged to 0.5 Nm. After the first 10 (baseline) and every 1000 cyclic loadings, the change in stiffness and rotation were recorded. The torsional stiffness was calculated from the slope of the linear part of the load–displacement curve. After 5000 cycles were completed, the torque-controlled load was terminated, and angle-controlled loading was started to determine the failure point. The failure test with 10°/min angular overload was continued until failure occurred, and the failure values of all cases were recorded.

Outcome measures

In all samples, the initial and final stiffness values before and after axial and rotational loading and the highest force/torque values causing failure were measured. The failure criteria included a sudden decrease in the force/displacement curve during axial and rotational loadings, fracture (of the bone or screw) at any point, plastic deformation in the screw (lateralization of the force/displacement curve), and closure of the osteotomy line (≥ 1 cm displacement).

Statistical analysis

The statistical analyses were performed using SPSS version 22 (IBM SPSS Statistics for Windows, Armonk, NY; IBM Corp., Released

2013). First, a Kolmogorov–Smirnov test was used to determine which variables to use for the data analysis and whether the variables fit a normal distribution, but the data were not normally distributed. Therefore, non-parametric tests were used. The Mann–Whitney U test was used to examine the differences between the groups. The statistical significance level was set at $p < 0.05$. The median (min–max) values and the mean $\pm$ standard deviation values are provided as the descriptive statistics (Tables 1 and 2).

Results

During the axial and rotational cyclic loading processes, no failure occurred in any samples, and all samples successfully passed the cyclic loading phase. Failure occurred in all cases in group 1 after axial loading (Fig. 5), which resulted in the closure of the 1-cm osteotomy defect. In group 2, plastic deformation of the distal screw was found to be the result of failure in all axial loading specimens (Fig. 6). The mean axial failure load values in groups 1 and 2 were 2627 ± 164 N and 7141 ± 1491 N, respectively. A significant difference was observed in the axial failure load values between the groups, indicating that the samples in group 2 were more stable ($p = 0.004$). The initial and final stiffness values under axial forces were similar between the groups ($p = 0.873$ and $p = 0.522$, respectively) (Table 1).

All specimens in group 1 that underwent rotational loading exhibited failure due to a spiral fracture in the distal humerus (Fig. 7). In group 2, transverse fractures developed around the distal screw in 4 specimens, while in 2 specimens, failure occurred due to the horizontal curvature of the load/displacement curve after plastic deformation in the nail guide (Fig. 7). Significant differences were observed in the initial and final torsional stiffness values between the two groups ($p = 0.004$ and $p = 0.004$, respectively; Table 1). The mean torsional failure in group 1 load was 11791 ± 2055 N.mm, while that in group 2 was 1 and 16997 ± 5440 N.mm. However, no statistically significant difference was found in the failure load values after torsional loading ($p = 0.055$) (Table 1).

Discussion

The main purposes of intramedullary fixation are to provide stabilization following anatomical reduction and allow for healing by preserving the load transfer on the extremity.¹⁰ However, an optimal treatment option for internal fixation is not available to date, and although numerous studies in the literature have compared the detection methods, methodological discussions continue.^{11–15}

Biomechanical studies in the literature have shown that excellent levels of resistance can be achieved against forces generated during movement when intramedullary nails with appropriate metrics are used for humerus shaft fractures.^{16–18} In this study, a 1-cm gap was formed in the humerus shaft to simulate a multi-segmented fracture or bone defect, and the stability of locked humeral nails with two different distal locking mechanisms after fixation was compared in the presence of axial and rotational forces.

The Expert humeral nail had a high failure load value compared to the InSafeLOCK humeral nail in the failure tests after axial cyclic loading. The main reason for this finding is that the distal locking screw used in group 2 has a double cortex attachment. In group 1, the load was transferred from the bone-endopin interface to the posterior cortex, and failure occurred due to the collapse of the posterior cortex. In group 2, the load was transferred directly from the distal screw to the double cortex, and the screw failed due to

Table 1

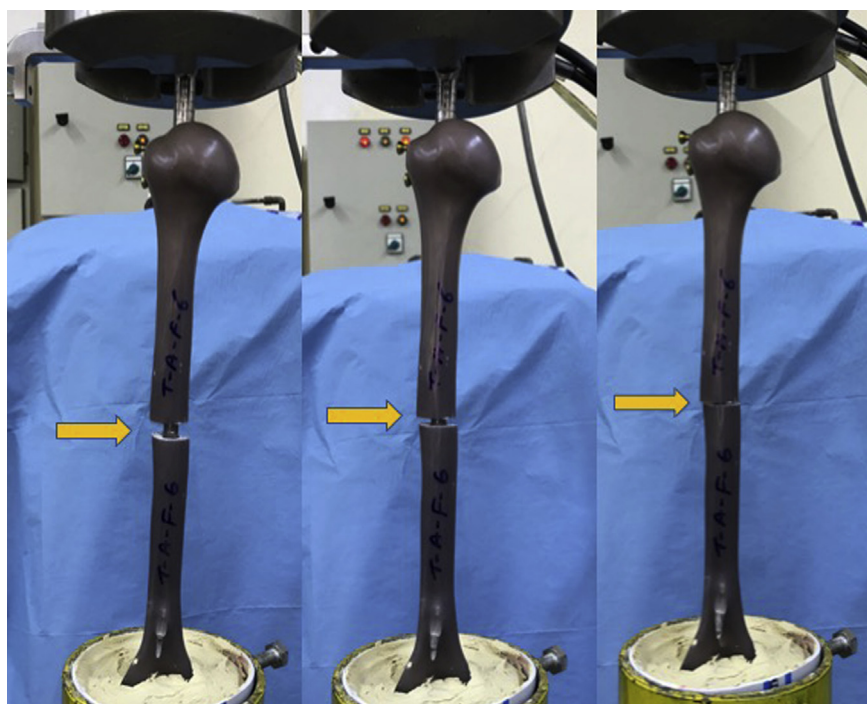
Summary of the mean and minimum–maximum values of the outcome parameters of the groups using the axial and torsional loading protocol.

	Axial forces			Torsional forces		
	Initial stiffness $\pm$ SD	Last stiffness $\pm$ SD	Failure load $\pm$ SD	Initial stiffness $\pm$ SD	Last stiffness $\pm$ SD	Failure load $\pm$ SD
Group 1	2707 $\pm$ 826 N/mm	4138 $\pm$ 1035 N/mm	2627 $\pm$ 1164 N	671.61 $\pm$ 78.3 N.mm/deg	770.8 $\pm$ 55.2 N.mm/deg	11791 $\pm$ 12055 N.mm
Group 2	2858 $\pm$ 294 N/mm	3780.3 $\pm$ 836.8 N/mm	7141 $\pm$ 1491 N	996.5 $\pm$ 88.6 N.mm/deg	1123.3 $\pm$ 60.4 N.mm/deg	16997 $\pm$ 15440 N.mm
P value	0.873	0.522	0.004	0.004	0.004	0.055

Table 2

Summary of the minimum–maximum and median values of the outcome parameters of the groups.

		Axial forces			Torsional forces		
		Initial stiffness	Last stiffness	Failure load	Initial stiffness	Last stiffness	Failure load
Group 1	Minimum	1802 N/mm	2808 N/mm	2340 N	575 N.mm/deg	715 N.mm/deg	8758 N.mm
	Maximum	4025 N/mm	5428 N/mm	2822 N	789 N.mm/deg	842 N.mm/deg	14508 N.mm
	Median	2558 N/mm	4295 N/mm	2646 N	667 N.mm/deg	753 N.mm/deg	11462 N.mm
Group 2	Minimum	1626 N/mm	2923 N/mm	4261 N	887 N.mm/deg	1044 N.mm/deg	7972 N.mm
	Maximum	5180 N/mm	5097 N/mm	8553 N	1094 N.mm/deg	1193 N.mm/deg	24430 N.mm
	Median	2807 N/mm	3679 N/mm	7534 N	1025 N.mm/deg	1118 N.mm/deg	16975 N.mm

**Fig. 5.** Failure due to closure of osteotomy defect after axial loading in group 1.

plastic deformation, suggesting that the double cortical strength is greater than the strength of the distal screw. The force required for plastic deformation to occur in the distal screw was significantly higher than the strength required for the single cortex defect to occur; thus, the failure force was significantly higher in group 2.

Biomechanically, using armrests, the maximum load delivered to the arm does not exceed 50% of the body weight.¹⁹ In addition, when lower extremity bones, such as the femur and tibia, are exposed to a high axial load and low rotational forces, the humerus is subjected to high torsional forces and a low axial load.³ These results suggest that the axial failure forces of the two nails are much higher than the physiological forces (>260 kg).

The proximal humerus is subjected to internal rotation by the subscapularis, pectoralis major and latissimus dorsi muscles, while the distal humerus is subjected to external rotation forces by the

forearm and hand.^{20,21} The rotational stability of humeral shaft fractures is very important due to these high rotational forces. Biomechanical studies have shown that the intact humerus has an average torsional strength of 53 Nm and a torsional stiffness of 2800 Nmm/deg.²² However, the situation is different in defective bones. In a biomechanical study conducted by Schopfer et al. involving defective bones, the mean failure torque was 10400 Nmm using the Russell Taylor (RT) nail.²³ Similarly, Blum et al. performed a retrograde humeral nail study investigating the defective cadaveric humerus using an RT nail, and the average stiffness with 6 Nm of torque was 130 Nmm/deg, while the mean failure torque value was 13.8 Nm.⁸ Dalton et al. compared RT and Seidel nails, and the mean torsional stiffness values were 44.67 and 54.41 Nmm/deg, respectively.²⁴ We found that the initial and final stiffness values of the Expert humeral nail after rotational loads were significantly

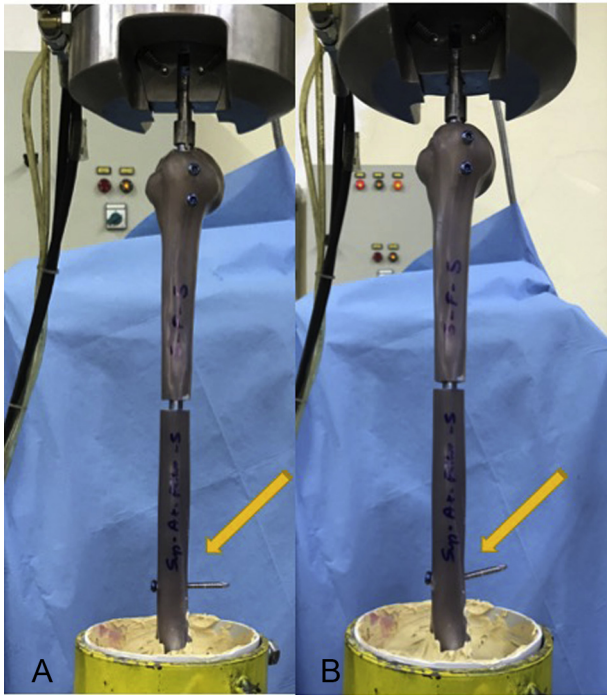


Fig. 6. Failure caused by plastic deformation in the distal screw after axial loading in group 2.

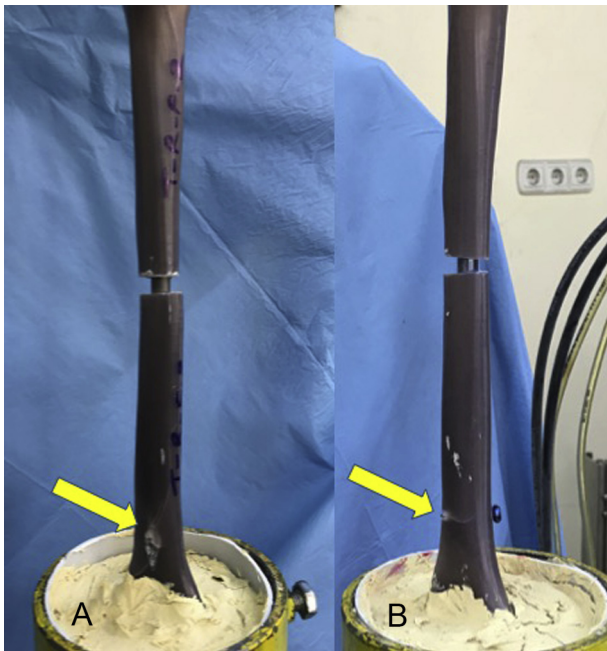


Fig. 7. A: In group 1, rotational failure was caused by a spiral fracture in the distal humerus. B: In group 2, rotational failure was caused by a transverse fracture in the distal humerus.

higher (initial stiffness 671.6 ± 78.3 Nmm/deg and 996.5 ± 88.6 Nmm/deg, $p = 0.004$; final stiffness 770.8 ± 55.2 Nmm/deg and 1123.3 ± 60.4 Nmm/deg, $p = 0.004$). The difference between the initial and final torsional stiffness can be explained by the double cortex involvement in group 2, but the torsional stiffness values in both groups are similar to those reported in biomechanical studies in the literature.^{7,11,25–27}

We believe that this torsional stiffness difference is due to the design of the InSafeLOCK humeral nail and that the stiffness is lower due to the minimal movement of the nail around the endopin. However, no significant difference was found in the torsional failure values between the two nails ($p = 0.055$). However, the difference observed in the torsional failure patterns is notable. In group 1, the rotational force from the single posterior cortex leads to the formation of spiral fractures, but in group 2, the rotational forces combine the anterior-posterior screw holes to cause transverse fracture.

This experimental study shows that adequate fixation is provided by both nails. However, the main difference between the two nails is the distal locking mechanism. The Expert humeral nail is a proven, reliable, widely used tool in surgical practice. This nail can be used to perform proximal locking or fixing with one static and one dynamic screw or spiral blade and one static screw. Distal locking can be achieved with 3 screws (anterior-posterior, lateral-medial and oblique screws applied in different directions). However, the proper position and fluoroscopy control are necessary for distal locking. The most important problem with nails is the risk of neurovascular injury, especially radial nerve injury at the distal side. Neurovascular exploration is needed to avoid this complication. In a study conducted by Rommens et al., a 3% rate of radial nerve damage was observed in patients treated with humeral nails.²⁸ A study conducted by Baltov et al. involving patients with a nailed humerus shaft fracture found a 0.9% rate of radial nerve damage and a 1.8% rate of lateral antebrachial cutaneous nerve injury due to distal locking A-P screws.²⁹ The main difference in the InSafeLOCK nail is the distal locking system. Distal locking can be performed without additional incisions and X-ray visualization.

The limitations of our study include the experimental study design and the use of a sawbone instead of a cadaver. The biological response after fixation and the change in the relationship between the nail and endopin over time are unknown. We evaluated both humeral nail systems only for the transverse humeral fracture model and different fracture types might significantly affect the performance of the nails. Although this study evaluated only the 9 mm diameter medium size, which is often used in our country, varying nail diameters would have different biomechanical qualities. Additionally, we did not compare other types of commercially available intramedullary nails, and applying cyclic loading tests and load to failure tests in anterior-posterior and varus-valgus loading could improve the quality of the study.

Conclusions

These results provided a biomechanical demonstration of the adequate stability of both nails after axial and rotational loading. In contrast to the experimental process, nails in the humerus can be exposed to multidirectional forces in the human body that are difficult to imitate. Therefore, the reliability of this newly designed humeral nail needs to be supported by randomized controlled trials in the future.

Conflict of interest

The authors declare that they have no conflict of interest.

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