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Original article

InSafeLock humeral nail provides a safe application for proximal and distal locking screws with distal endopin – An anatomical study

Murat Tasci [a,*], İsmail Turkmen [a], Haluk Celik [a], Mehmet Akif Akcal [b], Rahime Şekerci [c], Nigar Keles [c], Necdet Saglam [a], Fuat Akpinar [a]

[a] *Umraniye Training and Research Hospital, Orthopaedics and Traumatology, Istanbul, Turkey*
[b] *Antalya Ataturk State Hospital, Orthopaedics and Traumatology, Antalya, Turkey*
[c] *Akdeniz University, Anatomy, Antalya, Turkey*

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ABSTRACT

Introduction: Efforts to prevent iatrogenic neurovascular injuries with humeral intramedullary nailing lead to design new implants and inside to out distal locking technique using an endopin aims to provide a safer screw application. InSafeLock (TST, Istanbul, Turkey) humeral nail have been recently developed to minimize the possible screw related complications. The anatomical relationship between locking screws and neurovascular structures with the application time were compared between Trigen Humeral Nail (Smith and Nephew, Memphis, USA) and InSafeLock Humeral Nail.
Hypothesis: InSafeLock humeral nail would be safer than Trigen Humeral nail in terms of neurovascular injury.
Materials and methods: Seven cadavers were used with both shoulders and surgical application of two nails was performed as the manufacturer guide. An Insafelock humeral nail was used for each right humerus and a Trigen humeral nail was used for each left humerus. Once the nails were placed, proximal and distal region of the nails were dissected to evaluate the relationship between screws and adjacent anatomical structures. The duration of the each screw was assessed via a stopwatch.
Results: No significant finding was noted for the relationship between the neurovascular structures and proximal screws in two groups ($p < 0.05$). The distal locking of the InSafeLock humerus nail had a shorter application time and no neurovascular damage was recorded.
Discussion: The newly developed Insafelock humerus nails are at least as safe and effective as current humeral nails available on the market. Additional benefits include the preservation of neurovascular structures, as the Insafelock humerus nail does not require the use of an extra incision. Furthermore, surgical time is significantly shorter with using distal endopin.
Level of study: III, controlled laboratory study.

1. Introduction

Fractures of the shaft of humerus are relatively common with an incidence of 1–3% of all fractures [1,2]. Humeral shaft fractures are usually treated with non-operative treatment, however in case of polytrauma, open fractures, pathological fractures, humeral head split fractures, fractures associated with neurovascular injuries, nonunion and not toleration to bracing may require surgical intervention [3]. Surgical fixation options include plating, intramedullary nails, and external fixators [3–5]. Studies have reported good results with both plate and nail fixation for the treatment of humeral shaft fractures [6,7]. One of the advantage of the humeral nails is to be applied with minimal soft tissue dissection however iatrogenic neurovascular injuries may be encountered due to blind dissection for locking screws. In an anatomical study, Trigen Humeral Nail (Smith and Nephew, Memphis, USA) was concluded the safest nail design in terms of proximal locking screw application and proximity to the neurovascular structures among six different humeral nails in the market however distal region has not been assessed yet [7].

Efforts to prevent iatrogenic injuries lead to design new implants and inside to out distal locking technique using an endopin aims to provide a safer screw application. InSafeLock (TST,

* Corresponding author. Atatürk mah. Guner sokak, Metropark Sitesi A2 Blok D10, Kuçukçekmece, Istanbul, Turkey.
E-mail address: murat_tasci26@hotmail.com (M. Tasci).

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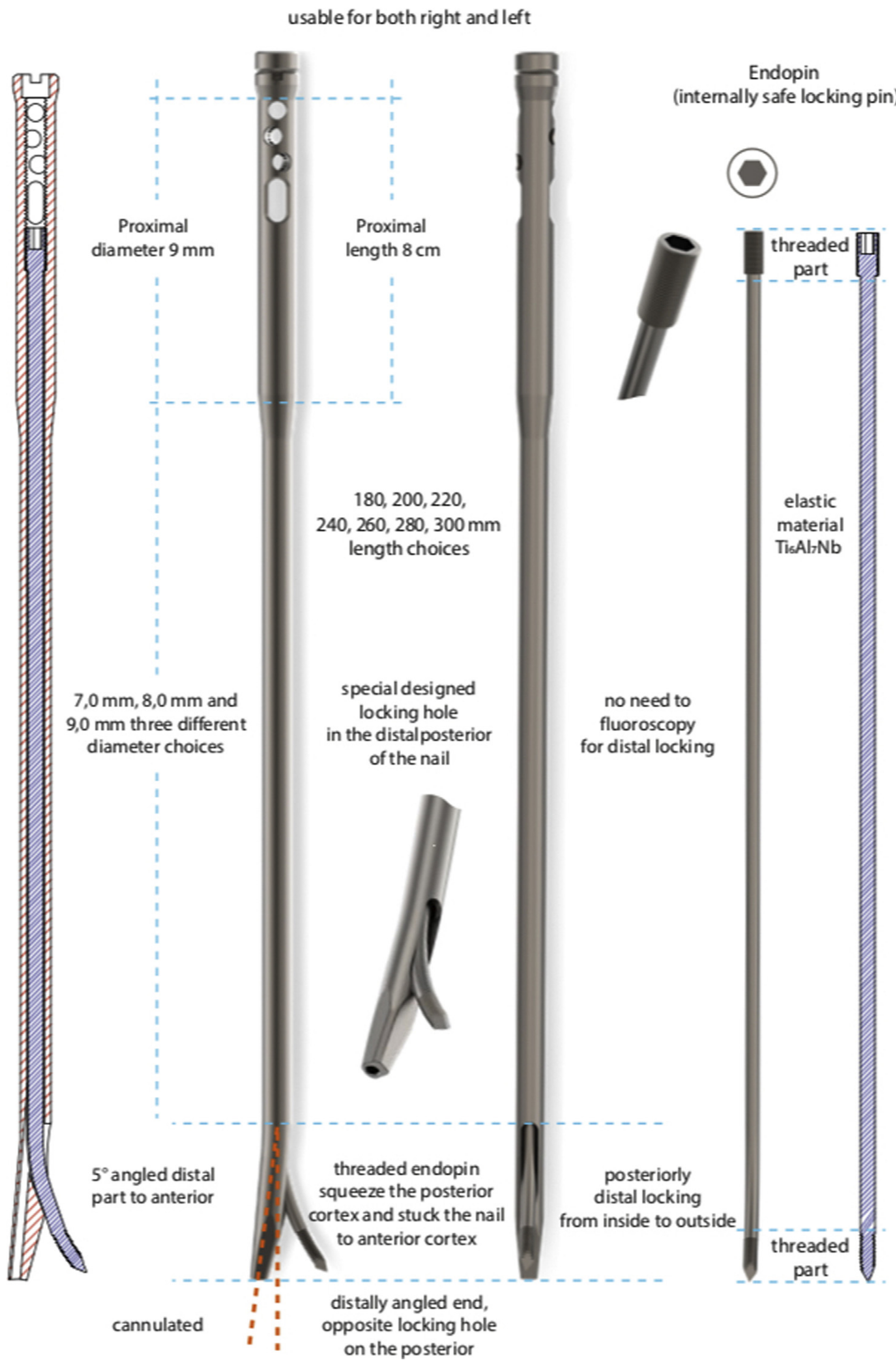

Fig. 1. The anatomical features of the InSafeLock Humeral Nail.

Istanbul, Turkey) humeral nail have been developed in this direction to minimize the possible screw related complications (Fig. 1).

In the present cadaveric study, the anatomical relationship between locking screws and neurovascular structures were assessed using Trigen Humeral Nail and InSafeLock Humeral Nail. The duration of application of the screws was also compared within two different design. Our hypothesis was InSafeLock humeral nail would be safer than Trigen Humeral nail in terms of neurovascular injury.

2. Materials and methods

Seven adult male and Caucasian cadavers with both intact upper extremities were involved the study. Mean age was 74 years (70 to 90) and no cadavers had a previous dissection. An Insafelock humeral nail was used for each right humerus and a Trigen humeral nail was used for each left humerus. Since aim of the study was to evaluate the anatomical relationship between distal locking and anatomical structures, no fractures were created. Once the nails

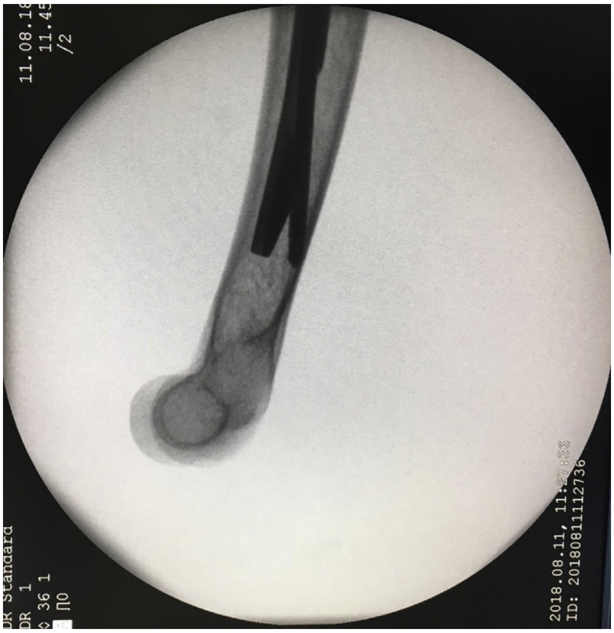

Fig. 2. Fluoroscopic view after the application of the endopin.

were placed, proximal and distal region of the nails were dissected to evaluate the relationship between screws and adjacent anatomical structures. All surgeries were performed by one orthopedic surgeon.

2.1. Surgical technique and measurements

The cadavers were placed in the supine position and 2 cm longitudinal incision was made in both shoulders from the anterolateral corner of the acromion. The deltoid muscle was then separated along the muscle fibers and subacromial bursa was removed. Prior to any intervention, nail length was determined based on measurements of each cadaver. Care was taken to leave the distal part of the nail 2–2.5 cm proximal to the olecranon fossa, and the proximal nail length was selected so that final placement would not disturb the articular surface beneath the cartilaginous border. A 7 mm nail diameter was selected to minimize any damage to the bone. Supraspinatus tendon was passed with a split incision and the K wire was inserted posterolateral to the biceps tendon in the medial position between the greater tubercle and the humeral head. The selected nails were then inserted over the guidewire into the intramedullary space of the proximal humerus. In Insafelock nail group, distal insertion was conducted via K wire insertion and internal locking of the screw was conducted with an endopin. A single fluoroscopic shoot was used for the assessment of the endopin (Fig. 2). In Trigen group a mini-incision with blind dissection was made at the level of distal hole. Drilling and screw locking were performed using a soft tissue protector. Two screws were used for distal locking in Trigen group under the fluoroscopy. Proximal screw locking was applied in a similar fashion for both the Insafelock and Trigen humerus locking nails using screw guides (Fig. 3). Three proximal screws were used in each group. Screws were named with numbers from proximal to distal.

Once the screws were placed, carefully dissection was made along the proximal and distal regions of the nail. The distances to proximal screws were assessed for axillary nerve, circumflex arteries, and biceps tendon, respectively. Besides, the distance between distal locking screw and radial nerve was also measured. Iatrogenic injuries were noted if any damage occurred. Duration of the

Fig. 3. Anteroposterior radiographic view of the InSafeLock Humeral Nail.

application of the distal screws and endopin were measured with a stopwatch.

2.2. Statistical analyses

Normal distribution of the parameters was evaluated using the Shapiro–Wilk normality test. The Mann–Whitney U test was used to compare descriptive statistics (mean, standard deviation, median), which implements two-tailed analyses and accounts for the differences in variance between right- and left-sided data. The Wilcoxon signed-rank test was used to separately compare the right and left non-parametric parameters. p-value was set at 0.05. Analyses were performed using IBM SPSS Statistics 22 software (SPSS IBM; Istanbul, Turkey).

3. Results

The average values of distances between screws and anatomical structures with application time of the screws have been displayed in Table 1.

There were no significant differences in terms of the distance to the neurovascular structures in proximal screw-1 between the Trigen and Insafelock humeral nails. The distance of proximal screw-2 to the posterior circumflex artery was significantly farther with Insafelock nails compared to Trigen nails ($p < 0.05$) (Table 2). In the Insafelock group, the average distance from the axillary nerve to the proximal screw-3 was 1.5 mm. In the Trigen humeral nail group, proximal screw-3 which placed along the anterior–posterior axis

Table 1
Evaluation of separate working parameters on right and left sides.

Side	*n*	Min–Max	Average ± SD (median)
Right (Insafelock)			
Proximal screw 1			
Axillary nerve (mm)	7	2–33	17.43 ± 9.61 (16)
A.c.post (mm)	7	11–30	21 ± 7.21 (22)
A.c.ant (mm)	3	20–25	23.33 ± 2.89 (25)
Proximal screw 2			
Axillary nerve (mm)	7	13–43	26.71 ± 9.48 (27)
A.c.post (mm)	7	21–38	28.29 ± 7.39 (27)
A.c.ant (mm)	2	33–38	35.5 ± 3.54 (35.5)
Proximal screw 3			
Axillary nerve (mm)	6	0–15	4 ± 5.9 (1.5)
A.c.post (mm)	6	2–14	8.17 ± 4.26 (7)
A.c.ant (mm)	3	10–33	20 ± 11.79 (17)
Left (Trigen)			
Distal screw 1			
Time (min)	7	1.83–2.83	2.37 ± 0.5 (2.7)
Proximal screw 1			
Axillary nerve (mm)	7	11–36	21.43 ± 8.42 (22)
A.c.post (mm)	7	4–35	23.43 ± 9.64 (26)
Proximal screw 2			
Axillary nerve (mm)	7	11–32	20 ± 6.61 (20)
A.c.post (mm)	7	6–27	15.29 ± 8.24 (15)
Proximal screw 3			
Biceps tendon (mm)	7	1–21	5.67 ± 7.79 (2.5)
Distal screw 1			
Time (min)	7	4.17–11.33	8.27 ± 2.85 (8.7)
Radial nerve (mm)	7	7–15	12 ± 2.58 (12)
Distal screw 2			
Time (min)	7	3.08–10.08	7.25 ± 2.85 (8.3)
Radial nerve (mm)	7	2–12	8.43 ± 3.31 (9)

a.c.ant: arteria circumflexia anterior; a.c.post: arteria circumflexia posterior.

Table 2
Evaluation of time, axillary nerve, a.c.post and a.c.ant parameters of the proximal screw 1, proximal screw 2, proximal screw 3 and distal screw 1 levels between Trigen and Insafelock nails.

	Right (InSafeLOCK)	Left (Trigen)	*p*
	Avr ± SD (median)	Avr ± SD (median)	
Proximal screw 1			
Axillary nerve (mm)	17.43 ± 9.61 (16)	21.43 ± 8.42 (22)	0.482
A.c.post (mm)	21 ± 7.21 (22)	23.43 ± 9.64 (26)	0.482
Proximal screw 2			
Axillary nerve (mm)	26.71 ± 9.48 (27)	20 ± 6.61 (20)	0.109
A.c.post (mm)	28.29 ± 7.39 (27)	15.29 ± 8.24 (15)	0.020*
Distal screw 1			
Time (min)	2.37 ± 0.5 (2.7)	8.27 ± 2.85 (8.7)	0.002*

a.c.ant: arteria circumflexia anterior; a.c.post: arteria circumflexia posterior.
* $p < 0.05$ Mann–Whitney U Test.

was detected approximately 1 mm to the biceps tendon in three cadavers.

Among the Insafelock nails, proximal screw-1 was significantly closer to the axillary nerve than proximal screw 2 ($p < 0.05$). Proximal screw-3 was significantly closer to the axillary nerve compared to both proximal screw-1 and proximal screw-2 ($p < 0.05$) (Table 3). Proximal screws 1 and 2 revealed a higher safety profile than proximal screw-3 with respect to proximity to the posterior circumflex artery ($p < 0.05$) (Table 3) (Fig. 4). No significant finding was noted for the relationship between the anterior circumflex artery and proximal screws. There were no significant differences in terms of the distances between the proximal locking screws of the Trigen humeral nails and adjacent neurovascular structures. Proximal screw-1 was more posterior to the axillary nerve and posterior circumflex artery compared to proximal screw 2, although this finding was not statistically significant.

There was no evidence of safety risks with insertion of the Insafelock nails (distal screws) into nearby neurovascular structures (Table 4). Although the mean distance from distal screw 2 to the radial nerve in the Trigen humeral nail was 9 mm, in one cadaver 2 mm proximity was detected (Fig. 5).

The application time of distal screw-1 was significantly shorter with Insafelock nails compared to Trigen nails ($p < 0.05$) (Table 2).

The application time for distal screw-1 was significantly longer compared to distal screw-2 ($p < 0.05$) in the Trigen nail group. In addition, the distal screw 1 was located significantly farther from the radial nerve than distal screw-2 ($p < 0.05$).

4. Discussion

Trigen humeral nails have a favor in terms of safety against the other nails in the market [7]. However, we found the application of the distal locking screws in the Trigen humeral nail with fluoroscopic guidewire and freehand technique with prolonged duration and similar safety design when compared with Insafelock nails.

In spite of the fact that our results showed a safe application of the screws of the Insafelock humeral nail, third screw revealed

Table 3
Evaluation of time, axillary nerve, a.c.post and a.c.ant parameters between proximal screw 1, proximal screw 2 and proximal screw 3 within the group.

Side	Proximal screw 1	Proximal screw 2	Proximal screw 3	Proximal screw 1 – Proximal screw 2 *p*	Proximal screw 1 – Proximal screw 3 *p*	Proximal screw 2 – Proximal screw 3 *p*
	Avr ± SD (median)	Avr ± SD (median)	Avr ± SD (median)			
Axillary nerve (mm)	17.43 ± 9.61 (16)	26.71 ± 9.48 (27)	4 ± 5.9 (1.5)	0.018*	0.028*	0.027*
A.c. Post (mm)	21 ± 7.21 (22)	28.29 ± 7.39 (27)	8.17 ± 4.26 (7)	0.018*	0.027*	0.028*
A.c. Ant (mm)	23.33 ± 2.89 (25)	35.5 ± 3.54 (35.5)	20 ± 11.79 (17)	0.157	0.593	0.180
Axillary nerve (mm)	21.43 ± 8.42 (22)	20 ± 6.61 (20)	–	0.674	–	–
A.c. Post (mm)	23.43 ± 9.64 (26)	15.29 ± 8.24 (15)	–	0.310	–	–

avr: average; a.c.ant: arteria circumflexia anterior; a.c.post: arteria circumflexia posterior.
* $p < 0.05$ Wilcoxon Sign Test.

Fig. 4. The distance between third screw and axillary nerve for InSafeLock Humeral Nail.

Fig. 5. The distance between distal screw and radial nerve for Trigen Humeral Nail.

a close proximity to the axillary nerve. From these findings, we believe that use of a locking screw for medial calcar of the humerus should not be used concurrently with the Insafelock humeral nail unless absolutely necessary for proximal fracture stabilization. In a cadaveric study, antegrade humeral nails were evaluated and axillary nerve iatrogenic damage was observed in three of 13 cadavers [8]. Nijs et al. concluded that oblique locking screws with bent nails can be a major risk factor in axillary nerve damage [7]. When examining the relationship between the biceps tendon and the proximal locking screw extending from the anterior posterior, tendon damage towards the tendon of the cadaveric biceps was not observed. It was observed in all but one cadaver, however, that the screw was often implanted just behind the tendon. Thus, the risk for tendon injury may increase if the proximal screw guide of the nail is placed incorrectly, or if the nail insertion is made more posteriorly.

Spiegelberg et al. showed that proximal screw locking in the antegrade humerus nail increases the risk for injury to the anterior branches of the axillary nerve, even when trocars and sleeves are used [8]. Our study illustrated that use of proximal screw 2 in Insafelock humerus nails was safer in the circumflex posterior area. Our study also evaluated the safety of the screws (proximal screw 2,

Table 4
Evaluation of time and radial nerve parameters between distal screw 1 and distal screw 2 in Trigen nails.

	Left side		*p*
	Distal screw 1	Distal screw 2	
	Avr ± SD (median)	Avr ± SD (median)	
Time (min)	8.27 ± 2.85 (8.7)	7.25 ± 2.85 (8.3)	0.018*
Radial nerve (mm)	12 ± 2.58 (12)	8.43 ± 3.31 (9)	0.017*

avr: average.
* $p < 0.05$ Wilcoxon Sign Test.

proximal screw 1, and proximal screw 3) toward the axillary nerve, circumflex posterior, and circumflex anterior. The results demonstrated that installing proximal screw 3 in the calcar should not be performed unless it is absolutely necessary to apply this nail to humerus fractures. If this approach is required, the risk of causing damage can be reduced by inserting mini-incisions and deltoid fibers using a clamp, reaching the bone, and drilling and screwing with trocars. When the axillary nerve and circumflex posterior were evaluated, it was found that Trigen humeral nails inserted into the proximal locking screws (proximal screw 1) provided superior security than proximal screw 2. While previous assessments have indicated that proximal screws of conventional humeral pose a risk to neurovascular structures, no comparison was made between the screws [7].

The use of distal locking screws carries the risk for damaging the radial nerve, median nerve, and brachial artery due to the axes of screw insertion [9]. Proximal locking screws in conventional humeral nails can be inserted using a guide, while distal locking screws are inserted using a freehand technique. The latter increases the overall duration of surgery and increases the total dose of fluoroscopy administered to the patient [10]. Furthermore, anatomical studies have demonstrated that blind percutaneous clamping of the lower extremity during distal screw insertion is unsafe for the humerus [11]. When distal locking screws were used, the time required for surgery and overall radiation dose received by the patient were both significantly increased [12–14]. In a separate study by Persiani et al., freehand distal locking nails were compared to humeral nails, which were locked with an electromagnetic guide. The freehand method was demonstrated to prolong the surgery and thereby, increased number of fluoroscopic shoots required [10]. In our work, screws applied at the distal end were shorter in the Insafelock nail. Distally applied screws on the Trigen humeral nails were applied freehand, which prolonged surgery and increased the number of fluoroscopies required.

The comparison of application time of the distal locking screws in the Trigen humerus nail demonstrated that distal screw 1 had a longer application time than distal screw 2. This difference was attributed to the ease of pre-determining the location of the second screw after applying the first screw to distal region. Although the application time of the second screw was shorter in the distal Trigen nails, this parameter was comparatively longer when using Insafelock nails. When locking the humeral nail freehandedly, the screw passage was narrow due to the concentration of major neurovascular structures concentrated in this region. It has been shown that among all screws implanted toward the distal end, the most distant screw passes closer to the radial nerve, which increases overall risk to the distal end. Studies have shown that there is a risk for damage to the radial nerve and lateral cutaneous nerve, particularly in the humeral nails containing distal locking screws on the anterior posterior and lateral medial sides [15,16].

Noger et al. looked at the proximity of the distal screws to the neurovascular structure and found that the most dangerous screw was the lateral to medial screw. In their study, 3 of the 10 cadavers showed direct contact with the radial nerve, with the mean radial nerve distance from the screw being $\sim$ 3.6 mm (0–8 mm). It was also found that the distal locking screws on the anterior posterior side were safer and distal locking screws on the lateral medial side were not recommended [16]. In our study, the mean distance from the distal locking screws to the radial nerve in the Trigen humeral nails was 9 mm. However, in a cadaver, second distal screw approached to radial nerve to 2 mm distance. Therefore, possible radial nerve iatrogenic injuries should be considered during the distal locking.

Distal locking screws on the lateral medial side are not the only a risk to the radial nerve, but also to the ulnar nerve, median nerve, and brachial artery [16]. The present study demonstrated that since a single cortex fixation, the Insafelock humeral nail could be applied safely for all neurovascular structures of the relevant region. The nail can be applied to the humerus without the need for an additional incision in the distal posterior aspect of the humerus.

In spite of the fact that Insafelock humeral nail reveals a safe and time saving application, biomechanical properties still need to be addressed. Siedel nail, a similar nail with endopin, was assessed and low rotational stability was observed on mechanical testing. However, authors stated that in vitro testing might not indicate successful fracture healing and good clinical outcome [17].

Our study had some limitations. First, the number of cadavers was relatively low, and most of them were not fresh frozen, which may have altered the physiologic properties of the tissues studied. One direct outcome of the latter was the increased difficulty of anatomical dissection. Second, the doses and number of fluoroscopy could not be quantified, as these parameters cannot be measured when connected to the device. However, the present study was the first anatomical study which compared the distal locking with inside to out technique and traditional locking with screws. Addressing these limitations, in future studies may yield more valuable data on the implementation of these surgical devices.

5. Conclusions

Our study demonstrated that the newly developed Insafelock humerus nails are at least as safe and effective as current humeral nails available on the market. Additional benefits include the preservation of neurovascular structures, as the Insafelock humerus nail does not require the use of an extra incision. Furthermore, surgical time is significantly shorter because of the method used to insert the distal screw through the nail. The overall safety profile is also satisfactory given that Insafelock humerus nails can be applied through the nail without the need for additional skin incision for distal locking.

Disclosure of interest

The authors declare that they have no competing interest.

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None.

Authors' contributions

MT: project development, data management, data analysis, manuscript writing and editing. IT: data collection, data analysis, statistical analysis, manuscript writing and editing. HÇ: data collection, data analysis, study supervision AA: data collection, data analysis NS: manuscript editing. FA: manuscript editing, study supervision.

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