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Original Article

Multi–functional intramedullary self-locking ulna nailing system: Proximal oblique locking without the need of fluoroscopic guidance, and it's effects on olecranon joint surface

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Abstract

Aim: Due to the necessity of using the small diameter nails in the ulna, negative outcomes such as failure in the self-locking, long term exposure to radiation, and increased operation time are expected. Several clinical trials propose that an ideal nail system for unlar fixation challenge has not been developed yet.
Material and Methods: This study involved the use of a new multifunctional intramedullary self-locking ulna nailing system and 36 intact dry cadaveric ulna bones. The relationship between the oblique self-locking screw, which has made a crucial contribution to the nailing system, and the joint surface of olecranon was investigated because this screw does not necessitate the use of fluoroscopic guidance and is easy to apply.
Results: In our study, during anterior or medial or posterior oblique locking, no olecranon joint surface damage occurred on any bone with a locking rate of 100%.
Conclusion: The clinical trials demonstrated that the proximal oblique locking was achieved easily in a short period of time, indicating the device's immense value for the patient and the surgeon.

Keywords: Intramedullary nail; olecranon; self-locking screw

INTRODUCTION

In the treatment of long bone fractures, intramedullary nailing has a large number of advantages over numerous problems. Intramedullary nailing offers smaller scars, less blood loss, minimal surgical trauma and shorter operation duration, early fusion, decreased infection rate, no need for external fixation, and accelerated use and movement of extremities (1-4).

Particularly, in the fractures of the diaphyseal femur and its vicinity, intramedullary self-locking nails are among preferred fixation methods. Whereas it cannot be extensively used in ulna whose medullary structure is narrow and angular (5,6).

In recent years, the use of different intramedullary nails in ulna fractures has accelerated the search for an ideal nail system (1-3,7-9). Due to the necessity for using more small-diameter nails in the ulna, self locking failure, long-term radiation exposure, and longer operation times are among common problems.

Owing to the specific disadvantages of each one of the nails and nail systems used in the past, osteosynthesis using plates and screws are preferred in the ulna-related problems (10,11). In parallel to the technological developments and continuing research for an intramedullary fixation method for ulna problems, a large number of new intramedullary fixation systems have been developed (12-17). In addition to that several clinical trials proposed that an ideal nail system for the ulna fixation challenge has not been developed yet.

We hypothesize thatthe newly developed multifunctional intramedullary self-locking ulna nail system would allow proximal locking without a need for fluoroscopic guidance and minimizes the harm caused to the olecranon joint surface.

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In this study, the relationship between the oblique self-locking screw, which has been considered to make a crucial contribution to the nailing system, and the joint surface of olecranon was investigated because this screw does not necessitate the use of fluoroscopic guidance and is easy to apply.

MATERIAL and METHODS

This study involved the use of a new multifunctional intramedullary self-locking ulna nailing system (Figure 1) and 36 intact dry cadaveric ulna bones. The nail was made of titanium in five distinct diameters(3.5, 4, 4.5, 5,and 6 mm) and lengths (20, 22, 24, 26, 28, and 30 cm). The proximal section of the nail had different locking options. The slot was 4.5 mm in length and 6 mm in diameter.

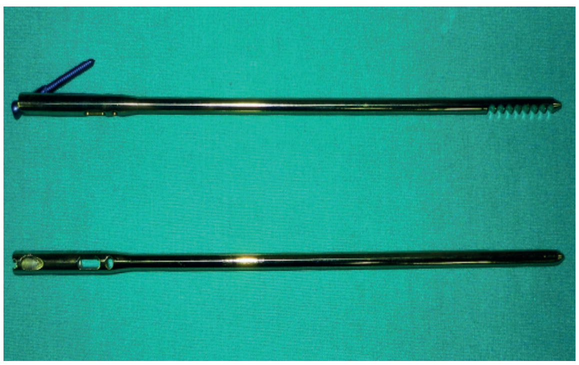

Figure 1. New multifunctional intramedullary self-locking ulna nailing system: proximally and distally located locking screw spaces and oblique locking screw

Proximal locking of the new nail system includes three slots. These are Oblique Slot (Static Locking), Oval-Oblong Slot (Dynamic Locking and Compression) and Circular Slot (Static Locking), which are described respectively in each paragraph below.

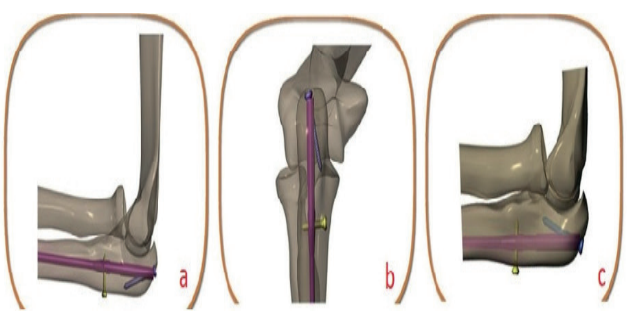

Figure 2. It shows every hole of the nail from different angles. a) sagittal view with proximal oblique locking to the posterior endb)coronal view c)sagittal view with proximal oblique locking to the anterior end

The nail was placed at a 20-degree angle versus the longitudinal axis from its proximal head. A single self-locking could be made to the medial, anterior, and posterior cortices through rotations of the nail (in all directions except the proximal radioulnar joint zone). The use of fluoroscopic guidance was not required.It prevented rotational forces exerting pressure on the nail and causing proximal-distal migrations.

The nail could perform dynamic transverse, lateromedial, and posteroanterior self-locking, allowing a 7-mm compression 30 mm distal from the proximal end of the nail.Toachieve an oblique slot locking and compression in the oval slot, the same special self-locking screwwith dimensions of 4×3×35 mm^3 was used.It prevented rotational forces to exert pressure on the nail, thus avoiding proximal–distal migrations and proximal fragmentation while allowing primary compression and dynamization (Figure 2).

Transverse, latero-medial andpostero-anterior static interlocking is performed 45 mm distally from the proximal end of the nail. The self-locking screws for the oblique and circular slots were 3 mm in diameter and of 7 different lengths 12, 14, 16, 18, 20, 22, and 24 mm. The same screws were used for the distal locking. It also minimized the rotational forces and proximal–distal migrations.

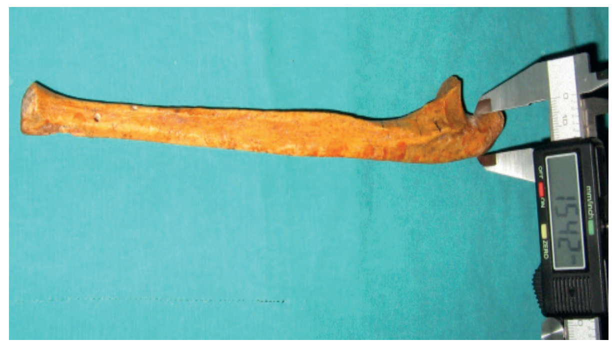

Figure 3. Olecranon thickness (h): distance from the deepest spot of trochlear notchto the posterior cortex measured using a digital display caliber (Vernier caliber)

The method described below was used for measurement in all bones.

Olecranon thickness (h): The distance between the deepest point of the trochlear notch and the posterior cortex was measured using a digital display caliber (Vernier caliper) and recoded (Figure 3).

The distance (d) between the proximal entry point and the deepest point of incisura oleocraniwas measured using a digital display caliber (Vernier caliper) and recorded (Figure 4).

Figure 4. Taking a measurement of the distance (d) between the proximal entry point and the deepest point of incisura oleocrani using a digital display caliber (Vernier caliber)

Using a 2-mm K wire, the medullary cavity of the ulna was reached from 3 mm lateral and 6.5 mm proximal of the most extended point of the olecranon peak. The wire was advanced 5 cm using a 6-mm drill bit. For every ulna bone, a nail with 4 mm diameter and 20 cm length, which was previously prepared so that its' grooves and guide grooves faced each other, was moved with partial rotations toward the distal end. Meanwhile, the distal grooves were directed toward the radial bone. (If desired, the direction and zone of the grooves were tracked with the external guide in the nailing system. This way, the direction of oblique slot locking placed in the opposite direction on the nail, and the proximal radioulnar joint was kept away from the joint). Following the insertion of the nail, the nail driver was removed. Using a threaded sleeve through the oblique screw slot (directed toward anterior, medial, and posterior), the ulna was drilled full-thickness with a 2.5-mm drill bit from the proximal end. Then, using the special self-locking proximal screw (4×3×35 mm^3), locking was achieved. In all three locations, visual inspection was performed to see whether the self-locking screw protruded from the joint surface of the olecranon (Figure 5).

The time elapsed from the opening of the nail inlet port until the completion of the proximal oblique locking was recorded.

Complication-free oblique locking rate was recorded.

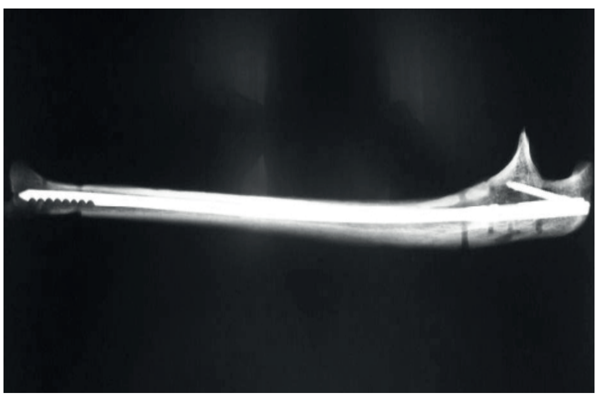

Figure 5. Proximal oblique locking to the anterior end in the cadaver bone

RESULTS

The lowest thickness of the olecranon was 15.5 mm and the highest 18 mm; the average was found to be 16.6 mm (Table 1). On top of that the distance between the entry spot of the olecranon and its deepest location was 10 mm (lowest) and 15 mm (highest), and the average was found to be 12.8 mm (Table 1).

As a requirement of the nailing system design, the oblique self-locking screw started protruding in its full thickness at a 15 mm distance from the proximal tip of the nail (Figure 4). And when the proximal end of the nail was placed so as not to expose the olecranon tip, the oblique locking was easily accomplished at the rate of 100% in all dry cadaver ulna bones included in the study (Table 1).

The time elapsed from the opening of the nail inlet port until the completion of the proximal oblique lockingwasrecorded. Thelowest time measuredwas 4 min, thehighestbeing 9 min, and average application time was 6.3 min (Table 1). Olecranon joint surface damage was not observed during any of the anterior, medial or posterior oblique locking processes.

DISCUSSION

Intramedullary fixation is extensively applied in the long (cylindrical) bones due to its numerous advantages, such as early fusion, decreased infection rate, tiny scars, less blood loss, minimal surgical trauma and shorter operation time, and earlier functional recovery in the extremities.

The most appropriate intramedullary fixation system for ulna should allow to be nailed down along the medullar canal, should not lead to deformation on the joint surfaces, should not restrict joint movement, should allow driving the thickest nail having maximum cortical contact to fill the medullar diameter, should be easy to drive and remove in shortest period of time using few instruments, should not necessitate the use of fluoroscopic guidance and/or guide for distal and proximal self-locking or minimize the requirement thereof, should not allow distal or proximal migration, and should ensure early functional recovery (12,13,16).

Primarily in ulnar fractures, which occur under the impact of rotational forces and whose medullar structure is short and angular, many intramedullary fixation methods have been employed up to date. Nevertheless, an ideal system has not yet been attained (12-14).

In proximal fractures of ulna, plate-screw stabilization, might lead to periostal dethacment. This increases infection rate and delays fusion (18). Other disadvantages include visible scar tissue and recurring fracture after plate removal (19). In addition to deeming periodic peeling redundant, intramedullary nails also minimizes skin incisions while conserving blood circulation and helping fusion (20).

Schone have used silver rods in radius and ulna fractures in 1913 (21). In later years, Kirschner wires (k-wires) and Steinmann nails were introduced (22,23). However these implants were leading to non-fusion complications at a high rate. Bohler started to use Giant Kuntscher nails and observed a high rate of implant breakage. Later on Rush Pins came into use and this nail also had a 10% rate of non-fusion. Street developed a square nail providing rotational control and lowering non-fusion rates (24,25).

After then, Sage Nails provided good rotational control with its sharp edges, although they had lower durability (26). As a result, intramedullary non-lockable rods can not ensure rotational control especially in segmental fractures (27).

Pedro identified a need for intra-operative fluoroscopy, post operative bracing and implant removal in some patients. Our nail does not only resolve the need for

Table 1. The table of the bones shows the distance from and between the dippiest spot of incisuraoleocrani posterior cortex; Anterior Locking and Joint Damage

Ulna No:	"h" Distance mm	"d" Distance mm	AL/JD	PL/JD	PL/JD
1	16.7	11.5	+ / -	+ / -	+ / -
2	16.4	14.2	+ / -	+ / -	+ / -
3	16.0	12.3	+ / -	+ / -	+ / -
4	15.5	14.7	+ / -	+ / -	+ / -
5	15.9	13.8	+ / -	+ / -	+ / -
6	18.0	15.0	+ / -	+ / -	+ / -
7	17.1	14.0	+ / -	+ / -	+ / -
8	17.4	12.7	+ / -	+ / -	+ / -
9	18.0	13.8	+ / -	+ / -	+ / -
10	18.0	15.0	+ / -	+ / -	+ / -
11	16.0	12.0	+ / -	+ / -	+ / -
12	15.7	10.9	+ / -	+ / -	+ / -
13	17.2	14.4	+ / -	+ / -	+ / -
14	17.5	13.6	+ / -	+ / -	+ / -
15	16.3	13.2	+ / -	+ / -	+ / -
16	16.8	12.7	+ / -	+ / -	+ / -
17	17.0	14.9	+ / -	+ / -	+ / -
18	16.5	13.1	+ / -	+ / -	+ / -
19	16.5	13.0	+ / -	+ / -	+ / -
20	15.8	11.0	+ / -	+ / -	+ / -
21	17.1	13.9	+ / -	+ / -	+ / -
22	18.0	14.9	+ / -	+ / -	+ / -
23	16.0	11.0	+ / -	+ / -	+ / -
24	16.6	12.4	+ / -	+ / -	+ / -
25	16.9	12.8	+ / -	+ / -	+ / -
26	15.7	11.6	+ / -	+ / -	+ / -
27	15.9	10.5	+ / -	+ / -	+ / -
28	17.8	14.0	+ / -	+ / -	+ / -
29	16.0	11.3	+ / -	+ / -	+ / -
30	16.0	10.9	+ / -	+ / -	+ / -
31	15.9	10.4	+ / -	+ / -	+ / -
32	15.6	12.8	+ / -	+ / -	+ / -
33	16.3	13.0	+ / -	+ / -	+ / -
34	17.1	13.5	+ / -	+ / -	+ / -
35	16.8	12.7	+ / -	+ / -	+ / -
36	15.7	10.3	+ / -	+ / -	+ / -
	Ave.:16.6 Min:15.5 Max:18.0	Ave.: 12.8 Min. : 10.3 Max.: 15.0	AL: 36 / JD: 0	ML: 36 /JD: 0	PL: 36 / JD:0

"h" : Olecranon Thickness: Distance from dippiest spot of incisuraoleocrani posterior cortex (Picture -)
"d" : Distance between entry point of olecranon dippiest spot of incisuraoleocrani (Picture -)
AL/JD : Anterior Locking (+/-) / Joint Damage (+ /-)
ML/JD : Medial Locking (+/-) / Joint Damage (+ /-)
PL/JD : Posterior Locking (+/-) / Joint Damage (+ /-)

fluoroscopy, it also does not require post operative bracing and we predict that its contemporary medullary design will minimize implant removal (13). Hong et al. in a study where they shared their experience with lockable intramedullary nails in 2005, defined 12.5% infection rate (14). The design of the new nail system allows the applicability of a dynamic and static interlocking and achievement ofrequired compression. Also, it does not require the use of fluoroscopic guidance for oblique locking, thanks to its oblique slot. Which we believe is a feature that will shorten surgery time and thereby minimize infection risk.

The studies performed on the proximal ulnar anatomy have contributed to the development of the intramedullary fixation systems (5,6,28,29). The entry point for the nail on the olecranon was chosen for the present studybecause it is through this point a nail with a maximumthicknessinserted into the medullary groove could reach the most distal site (5).

In 2013, a team, including some of the authors of this study, published the clinical study of this nail (30). Present work was intended to verify the feasibility of the centromedullary nail without using fluoroscopy.

A locking achieved through the oblique slot contained in the design of the new nail was highly advantageousin the system, particularly for determining the relationship of the self-locking screw with the trochlear notch. Therefore, measurements of "h" and "d" distances were taken: (h) represents the lowest thickness of the olecranon as 15.5 mm; the highest was 18mm, and the average16.6 mm. The lowest distance from thedeepest point of the entry of the olecranon (d) was 10.3 mm, the highest 15mm, and the average12.8 mm.

Once the oblique locking was achieved with the new nail inserted from a suitable entry point, considering the outcomes, a joint surface injury did not occur at the trochlear notch zone. Because, the oblique locking screw leaves at 15 mm from the top of nail in full thickness, while the total thickness of the nail and the screw is 9 mm. Once "h" distance (16.6 mm in average) of olecranon was considered, it would be theoretically understood that the screw stands at approximately 4 mm away from the joint surface.

In the present study, during anterior or medial or posterior oblique locking, no olecranon joint surface damage was observed on any bones, and locking was accomplished at the rate of 100%.

The opening of the nail entry point, nail insertion, and proximal oblique locking in dry cadaver ulna bones overall took 4 min (lowest), 9 min (highest), and 6.3 min (average).

The clinical trials demonstrated that the proximal oblique locking in the system was achieved easily in a short period of time, indicating its immense value for the patient and the surgeon.

CONCLUSION

The newly developed multifunctional intramedullary self-locking ulna nail system would allow proximal locking without a need for fluoroscopic guidance and minimizes the harm caused to the olecranon joint surface.

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Ethical approval: This article is a mechanical study. There is no ethics committee approval.

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