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Review Article

Distal Locking of Intramedullary Nailing: Current Technology to Improve Accuracy, Radiation Exposure, and Operative Time

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Abstract

Distal locking during intramedullary nailing of long bone fractures remains a challenging part of this procedure, especially for novice surgeons. The conventional freehand method has been the mainstay for the placement of distal locking screws. However, the conventional freehand method possesses the disadvantages of additional radiation exposure as well as increased operative time and inaccuracy for the inexperienced surgeon. Numerous technology adjuncts have been developed to improve upon the distal locking technique during the intramedullary nailing of long bone fractures. In this review, we discuss the common technology that has been designed to facilitate the placement of distal locking screws, which include electromagnetic navigation systems, computer-assisted/robotic systems, laser guiding systems, the flag and grid technique, proximally mounted targeting devices, and self-locking nailing systems.

Keywords: Intramedullary Nailing; Distal Locking Screws; Accuracy; Radiation Exposure; Operative Time

Abbreviations

IMN: Intramedullary Nailing; FH: Freehand; SIGN: Surgical Implant Generation Network

Introduction

Intramedullary nailing (IMN) represents one of the mainstay treatments for diaphyseal long bone fractures as it provides adequate fracture stabilization. With IMN, early mobilization and return to function of the injured limb are achieved, and the procedure can be performed in a minimally invasive manner. However, placing the distal locking screws still remains one of the most significant challenges of the IMN procedure, especially for novice surgeons [1]. Various problems can be encountered during distal locking fixation, such as the prolongation of the operative time, the formation of stress points in the bone cortex due to repeated drill hole attempts, the distal locking screw missing the nail, and the accumulating radiation exposure due to recurrent fluoroscopy use.

This review will discuss the technology designed to facilitate the placement of distal locking screws during IMN, which in turn aims to improve accuracy, reduce radiation exposure, and reduce operative time. Electromagnetic navigation systems, computer-assisted/robotic systems, laser guiding systems, the flag and grid technique, proximally mounted targeting devices, and self-locking nailing systems are all represent established technologic aids to achieve distal locking with IMN.

Electromagnetic navigation system

The electromagnetic navigation system, popularized by the Smith and Nephew product, the Sureshot Distal Targeting System (Sure shot), consists of three main parts: a computerized control unit, a handheld targeter that produces an electromagnetic field, and a sensor probe. The sensor probe is inserted into the nail and with the targeter provides real-time electromagnetic tracking data where one can visualize the IMN's distal screw slot on a computer monitor. The system provides a green circle for the ideal location of the interlocking screw, as well as a red circle for the drill tip's position in space. When these two circles overlap, a surgeon can place the distal locking screws in their proper location [2]. Much research has been conducted comparing the electromagnetic navigation system Sureshot to the conventional freehand method for IMN, which we will discuss here.

Wang., *et al.* performed a randomized control trial on 89 patients with tibial diaphyseal fractures treated with IMN comparing the Sureshot Distal Targeting System to the conventional freehand method. The Sureshot Distal Targeting System group consisted of 54 patients, while the freehand method consisted of 35 patients. All of the distal locking in both groups was performed by the same surgeon. In their study, the authors found the mean time to distal locking in the electromagnetic navigation system group was significantly less than in the freehand group (5.89 ± 2.02 minutes vs. 12.26 ± 4.40 minutes, $p < 0.05$). The radiation exposure time was also significantly less in the navigation group (2.13 ± 0.73 seconds vs. 19.09 ± 10.41 seconds, $p < 0.05$). Finally, the one-time success rate of distal locking in the navigation group was 100% compared to the freehand group rate of 34.3%, which was statistically significant ($p < 0.05$). Wang., *et al.* concluded that the electromagnetic navigation system offers the advantages of shorter locking time without radiation for tibial IMNs [2].

Han., *et al.* also evaluated the Sureshot Distal Targeting System with a randomized control trial, but unlike Wang., *et al*. these authors evaluated the electromagnetic navigation system for femoral fractures requiring IMN treatment. In their study, 29 patients received the Sureshot and 26 patients underwent the conventional freehand method. The same surgeon inserted the distal locking screws for both groups. The authors found the mean time to distal locking was significantly less in the navigation group compared to the freehand group (6.1 ± 1.4 minutes vs. 19.5 ± 6 minutes, $P < 0.05$). The radiation exposure time was also significantly less in the navigation group (2.2 ± 1.1 seconds vs. 26.8 ± 13.3 seconds, $p < 0.05$). From these results, Han., *et al.* concluded the electromagnetic navigation system allows distal locking to be achieved in a quicker amount of time and with less radiation [1].

Grimwood., *et al*. also studied electromagnetic navigation system for distal locking in IMN and compared it to the freehand method. Their study included both tibial and femoral fractures and had 19 patients in the electromagnetic navigation group and 10 patients in the freehand group. The patients were divided into tibial and femoral subcategories. The authors found the electromagnetic navigation system significantly reduced fluoroscopy time by 49 seconds for tibial IMN and by 28 seconds for femoral IMN. The radiation dose was also significantly reduced in the electromagnetic navigation group by 18 cGy/cm^2 for tibial IMN and by 181 cGy/cm^2 for the femoral IMN. The authors concluded that the electromagnetic navigation system can decrease both fluoroscopic time and radiation dose [3].

Zhu., *et al.* conducted a meta-analysis to compare the electromagnetic navigation technique versus the freehand method with respect to accuracy and effectiveness. Their literature search yielded 8 studies with a total of 611 patients involving 305 in the electromagnetic group and 306 in the freehand group. Zhu., *et al*.'s analysis revealed that the electromagnetic group reduced the distal locking time by 4.1 minutes as well as reduced the fluoroscopic time by 25.3 seconds. The analysis did not find any significance regarding the accuracy of distal screw placement nor in the total operative time. The authors concluded that electromagnetic navigation can aid in the treatment of diaphyseal fractures in the lower extremities [4].

Allard., *et al*. studied the electromagnetic navigation system in specifically humeral diaphyseal fractures as the majority of previous work has just tested the device in IMNs for femoral and/or tibial fractures. For their study, they evaluated the use of the Sureshot Distal Targeting System (Smith and Nephew) with the Trigen humeral IMN (Smith and Nephew) and involved 51 cases where distal interlocking screws were attempted to be installed. Of these 51 cases, they found the screws were locked successfully in 40 cases (78.4%), while there were 11 failures (21.6%). There were 10 cases (19.6%) of drilling pilot holes without using the corresponding interlocking screw and 1 case (1.9%) where the screw was placed outside the interlocking hole. The authors had fluoroscopic operative data available for 21 patient cases and found that the average amount of fluoroscopic images taken was 29 ± 22.1 (range, 7-88 images), the average fluoroscopic time was 42 ± 28 seconds (range, 8-114 seconds), and the cumulative radiation exposure was 39.90 ± 35.55 $cGcm^2$ (range, 3.76-128.96 $cGcm^2$). Allard., *et al.* concluded that the Sureshot had a lower success rate for the IMN of diaphyseal humerus fractures than the rates previously reported femoral or tibial fractures [5].

Computer-assisted/robotic systems

Yaniv., *et al.* developed a novel robot-based system for distal locking in IMN that provides a virtual reality view of the bone and instrument positions updated in real time. Once the fracture has been reduced, the robot is mounted to the IMN head or the distal bone. When the robot is mounted to the IMN nail, the drill guide is attached to it and this provides precise guidance for freehand drilling of the distal locking screws. An image calibration ring is also attached to the C-arm intensifier. The C-arm is then adjusted under software guidance and the robot positions so that the drill guide and the IMN distal locking holes are in parallel and coincide with a single fluoroscopic image. Once the robot determines the correct position, the surgeon can drill the pilot holes and proceed to place the distal locking screws. Previous computer-assisted systems have provided a virtual view for the surgeon to use as a guide. However, Yaniv., *et al.* design provides a virtual view in addition to providing a mechanical guide for the surgeon to use during drilling. This eliminates the issue of freehand slipping or deviation during drilling that sometimes occurs with previous computer-assisted systems without the drill guide. Yaniv., *et al*. also claim their design is unobstructive, less expensive, and does not require leg immobilization as advantages compared to other computer systems [6].

Yaniv., *et al.* studied their system *in vitro* and found that their system only had an angular error of 1.3° ± 0.4° between the computed drill guide axes and the real locking hole axes. Moreover, there was a 3.0 ± 1.1mm error in the entry and exit drill point. The authors concluded that these parameters are adequate for successful IMN distal locking [6].

Laser Guided Navigation Device

Gao., *et al*. designed a laser-guided navigation device, which can aid in distal locking screw placement of an IMN. The technique is based on a G-arm and a matching positioning technique that can be accountable due to the accuracy and stability of a laser beam. The device consists of a horizontal green laser pointer, a coronal red laser pointer, and round straps that attach to the G-arm image intensifier and hold the two laser pointers with pedestals. Prior to the operation, the straps were positioned on the G-arm in such a way that the two lasers, the x-ray fluoroscopy center, and display screen center all completely overlapped. Then for the distal locking portion of the operation, the distal nail hole of the IMN was adjusted in the G-arm image until it was a perfect circle that was on the center of the display screen. In this way, one can conclude that the intersection of the two laser lines was the center of the IMN distal locking hole. In essence, one is using lasers as an adjunct to locate the IMN distal hole as opposed to using repeated fluoroscopic images [7].

Gao., *et al*. tested their device against the conventional freehand (FH) method for the distal locking of femoral IMNs with each group having 40 times of distal locking. Compared with the FH technique, the laser guided navigation device had the advantages of shorter operative time, less radiation exposure, and a higher first success rate. More specifically, the laser group only took 212 ± 105 seconds to complete the distal locking screw, compared to the freehand group that took 345 ± 165 seconds ($p < 0.001$). The laser group had only 41 ± 15 seconds of radiation exposure compared to 164 ± 57 seconds in the freehand group ($p < 0.001$). The laser group also had a higher first success rate of 93.75% compared to the freehand group with a rate of 62.5% ($\chi^2 = 21.36$, $p < 0.001$). Moreover, the actual trajectory of the wire in laser group was closer to the ideal trajectory in the coronal and horizontal planes. And the learning curve time to efficiently place a distal locking screw was shorter in the laser group. With these results, Gao., *et al.* concluded that their laser guided navigation device can improve the efficiency of IMN distal locking [7].

Flag and grid technique

Yiannakopoulos., *et al.* published a modification to the 'perfect circles' freehand technique in which they attached a temporary metallic grid to the patient's skin to act as a fixed navigational aid. With this metallic grid, the location of the distal IMN screws slots in relation to the grid can be ascertained with limited fluoroscopy. Under fluoroscopy, a Steinmann pin with a metallic handle attached to its blunt end (what Yiannakopoulos., *et al.* refer to as the "flag") is then used to target and create the screw holes.

Yiannakopoulos., *et al.* tested their 'flag and grid technique' in a prospective nonrandomized trial in which Group A consisted of 62 patients (24 femoral IMNs, 39 tibial IMNs) and received the flag and grid technique, whereas Group B consisted of 44 patients (15 femoral IMNs, 31 tibial IMNs) and received the conventional freehand method. The authors found that the distal locking time was 5.1 ± 2.7 minutes in Group A compared to 19.0 ± 7.1 minutes in Group B ($p < 0.001$). The mean number of fluoroscopic images was 6.2 images (range, 5-9 images) in Group A compared to a mean 28.4 images (range, 17-52 images) in Group B ($p < 0.001$). The mean radiation time in Group A was 0.062 minutes (range, 0.05-0.09 minutes) compared to 0.284 minutes (range, 0.17-0.52 minutes) in Group B ($p < 0.001$). Yiannakopoulos., *et al.* concluded that this technique is reproducible, inexpensive, and easy to learn, while reducing the radiation exposure and distal locking operative time [8].

Proximally mounted targeting devices/sign system for intramedullary nailing

Regarding proximally mounted targeting devices, Anastoupoulus., *et al.* reported on the Stryker S2 Tibial Intramedullary Nail (Stryker Trauma GmbH, Schönkirchen, Germany), which contains a targeting system with three elements: 1) a nail groove between the two distal locking holes, which facilitate pinpointing the exact location of the distal holes; 2) a beveled-tip probe to aid in correct positioning of the nail groove; and 3) a targeting device mounted proximally that allows proper positioning of the distal screws in accordance with the nail's length. The distal end of this targeting device includes a target clip with two locking holes that correspond to the nail's holes along with three central holes oriented on a perpendicular axis between them, which serve as a guide for the probe's insertion to localize the nail's groove [9].

The distal locking of the nail is achieved with minimal radiation with a combination of the IMN's design as well as surgical technique. First, the IMN is inserted 10mm more distal than its intended final position. Once the IMN is seated in this position, the target device is proximally mounted to the IMN. Then only a single fluoroscopic image is generally needed to assess for any nail deformation from the intramedullary canal insertion. Next, the central hole that best overlaps with the nail's shadow is selected of the three possible central holes to serve as the pilot hole to drill through the medial cortex. The targeting device is then removed, and the pilot hole is cleaned of debris. The probe is then inserted into the pilot hole and the nail's groove is identified with turning the probe until tightly contoured within the groove. Then the IMN is retracted 10mm with the probe in the nail groove until the probe falls directly into the distal locking hole. The inability to twist the IMN with the aiming arm can verify the probe's location in the distal locking hole. A sleeve is then introduced over the probe and then the targeting device is reattached incorporating the sleeve. Now the proximal hole can be localized using the targeting device as well, and the steps can proceed to place the distal locking screws with no fluoroscopy [9].

Anastoupoulus., *et al.* tested this Stryker S2 Tibial Intramedullary Nail (Stryker Trauma GmbH, Schönkirchen, Germany) in 63 tibial shaft fractures. They found an average total operative time of 47 ± 9.5 minutes (range, 35–68 minutes), and an average distal locking time of 6.5 ± 2.1 minutes (range, 4-15 minutes). The total radiation exposure for distal locking consisted of two fluoroscopic shots, with one shot being before targeting and another for confirmation regarding proper screw insertion. The average radiation time was 0.85 seconds (range, 0.4-1.2 seconds), and the average radiation exposure was 1.4 mGy (range, 0.8–1.9 mGy). Of note, the authors had two failures (3.1%) with the IMN due to failure to identify the nail's groove through the selected pilot hole. Overall, the authors conclude that the Stryker S2 Tibial Intramedullary Nail can offer the advantages of reduced operative time and radiation exposure after familiarity with the system [9].

The Surgical Implant Generation Network (SIGN) IMN system was initially developed for 3rd world countries without fluoroscopy to stabilize tibial fractures and avoid delays in treating open tibia fractures notorious for adverse complications. The SIGN system does not rely on fluoroscopy at all for distal locking portion of the procedure and rather has an external jig target arm that is attached to locate the distal interlocking screw slots. To place a distal locking screw with the SIGN system, a cannula is first placed on the bone followed by a drill guide through the cannula. Then the surgeon can drill through the near cortex with this apparatus. The pilot hole made can then be enlarged with a hand step drill and can also be chamfered using the screw hole broach. The process of chamfering removes the ring of bone at the bottom of the hole in the near cortex and allows for a redirection of the opening. Then a solid slot finder is placed in the near cortex hole to locate the nail screw slot. Once the slot is located, the solid slot finder is replaced by a cannulated slot finder, which then allows a surgeon to subsequently drill into the far cortex. A depth gauge is used to measure the needed interlocking screw length and then the interlocking screw is placed. Of note, the SIGN system relies on the integrity of the IMN to find the distal slots. However, the IMN has the potential to undergo deformation with insertion into a long bone. This can present some challenges and requires improvisation and surgical skills to find the slot. Overall, without the need for fluoroscopy, the SIGN system eliminates radiation exposure and has its most utility in third-world countries where fluoroscopy is often not available [10].

Ikem., *et al*. treated 40 consecutive cases with diaphyseal fractures of the femur (65%), tibia (25%), or humerus (10%) and reported their descriptive results using the SIGN system. In their patient cases, the fracture patterns were comminuted (45%), transverse (40%), and oblique (15%). The authors found that the average time to union was 3 months and only observed 1 complication of screw loosening due to severe osteoporosis. Ikem., *et al*. concluded that the SIGN system offers high quality fracture care comparable to that received in any developed country and that the SIGN system can eliminate harmful radiation exposure to the patient and surgeon [11].

Self-locking nailing systems

Lepore., *et al.* studied the efficacy of the self-locking nail Fixion in the setting of closed femoral shaft fractures. The Fixion nailing system (Fixion; Disc-O-Tech, Tel Aviv, Israel) is a stainless steel cylindrical nail that achieves self-locking by becoming hydraulically inflated with normal saline, which expands and locks the Fixion nail within the intramedullary canal. The Fixion nail is inserted without the need for reaming and the infusion of normal saline can expand the nail by approximately 175%. After the saline infusion causes the Fixion nail to abut to the inner surface of the medullary canal along its entire length, the need for interlocking screws is unnecessary [12].

Lepore., *et al.* reported their results in 43 patients with femoral diaphyseal fractures receiving the Fixion nail compared to 43 patients with matched fracture patterns receiving a standard Stratec IMN. The average time to full weightbearing in the Fixion group was 3.8 months (range, 3-9 months) compared to 6.8 months (range, 3-11 months) in the Stratec group, which was significant ($p < 0.02$). The average time to radiographic healing in the Fixion group was 3.2 months (range, 3-9 months) compared to 7.5 months (range, 3-12 months) in the Stratec group, which was also significant ($p < 0.01$). All patients in both groups achieved union. Concerning return to work, 32/43 patients returned to work in the Fixion group, compared to 38/43 in the Stratec group, which was significant ($p < 0.05$). The authors concluded that the Fixion nail is an effective treatment for femoral diaphyseal fractures with the advantages of reduced operative time and reduced radiation exposure [12].

Conclusion

Numerous technologic devices and techniques have been described to aid in the distal locking of IMN. Each strategy aims to reduce radiation exposure and operative time, while also aiming to improve accuracy. Our review demonstrated that there is evidence for the use of these technologic devices. However, there are limitations to each of these techniques as well that must be considered. For instance, electromagnetic, computer, and robotic systems tend to be expensive, and a surgeon needs to weigh the cost-benefit analysis when deciding to employ these technologies. Laser systems can be dangerous to surgeon's eyes and require a meticulous set up. The flag and grid technique has been criticized as a method too difficult to be practical. Proximally mounted devices tend to experience difficulty when the IMN undergoes some deformation during insertion. Finally, some authors claim that the self-locking technologies do not offer the same torsional qualities as distally locked screws. Overall, technologic devices exist to improve accuracy, radiation exposure, and operative time during IMN distal locking. Our review discusses the most common adjuncts for IMN distal locking and provides a surgeon with possible options to tailor one's surgical technique.

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