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The Utilization of Electromagnetic Tracking to Facilitate Distal Targeting During Intramedullary Nailing

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Summary

Locked intramedullary (IM) nailing may be considered the standard treatment for long-bone shaft fractures. While this technique has been shown to reduce malunion and limb shortening risk, locking the nail into place is a very challenging step of the procedure. Several technologies have been introduced to help facilitate accurate screw insertion and locking. However, electromagnetic (EM) tracking has emerged as perhaps the most promising alternative. The SURESHOT° Distal Targeting System (Smith & Nephew, Inc., Memphis, TN, USA) represents an innovative application of EM technology. Utilizing an ionizing radiation free EM field, this system is capable of accurately mapping the position and orientation of a sensor that is positioned within the IM nail. Data obtained from this sensor enables the system to display a virtual representation of the nail and screw insertion path. Using real-time virtual feedback, the surgeon simply achieves the desired alignment and completes distal targeting and locking. SURESHOT may support improved outcomes in fracture patients by significantly improving drilling accuracy, reducing locking time and minimizing requisite radiation exposure in the operating room. Research is currently underway to further explore the clinical efficacy of this system.

Introduction

Intramedullary (IM) nailing and fixation has emerged as a standard treatment for frequently encountered long-bone shaft fractures [1, 2]. As with most orthopaedic procedures, an evolving surgical technique has helped to greatly improve clinical outcomes in fracture patients. A key development in IM nailing was the inclusion of locking screws in the proximal and distal portions of the nail. Locking the nail into place helps to control limb length, rotation, and angulation, which reduces malunion and shortening risk [1]. This technique also enables the treatment of difficult proximal, distal, and unstable shaft fractures [3]. While the benefits of IM nail locking are not in question, there remains one key consideration. Locking may be considered the most difficult step of this procedure [2].

Before the IM nail can be locked into position, the screw entry point and insertion path must be accurately determined [2].

Traditionally, this step has required the use of intraoperative x-ray. A C-Arm fluoroscopy unit allows the surgeon to obtain a radiographic image of the nail in vivo. Insertion of the screw is then attempted utilizing a freehand drilling technique. While common, this approach is technically demanding and requires considerable experience to effectively be executed [2]. Furthermore, the need to repeatedly adjust C-Arm orientation and the screw insertion path can extend operative time and increase the duration of x-ray exposure for both the patient and operating room staff [4, 5]. With just one additional minute of C-Arm use, radiation exposure can increase by approximately 0.4-4.0 rad [6, 7]. Therefore, improving first-time drilling and targeting accuracy during locking is critical.

Alternative targeting technologies have been introduced to improve the accuracy and ease of IM nail locking. Mechanical and robotic guidance have both been utilized with some success [2, 8-10]. Here, radiographic imaging and opaque markers allow the surgical space to be effectively mapped. Once nail position and orientation are determined, the screw insertion path is mechanically maintained by an encompassing structure until locking is complete. However, there are two key limitations with this approach. First, nail geometry commonly changes during insertion, creating the risk of positioning error [11]. Second, a fixed mechanical path and enclosed surgical space may be considered cumbersome and obtrusive to the surgeon [2]. A more ideal system would provide accurate guidance, while preserving operative freedom of movement and patient access during the duration of the procedure.

Computerized optical tracking systems have been successfully utilized in the clinical environment due to their high degree of accuracy [12-15]. Once the coordinates of the surgical space, patient, and instrumentation are all established, a camera and computer interface can be used to provide real-time virtual feedback to the surgeon [2, 13]. While this system would indeed seem far more ideal, the technology is critically limited during IM nailing. All optical systems require a direct line of sight between the camera and light-emitting sensor [13, 15]. This is simply not possible when the surgical target is embedded within the patient's body [13, 15]. Fortunately, an alternative computerized tracking technology does appear to be particularly well suited for this application. Specifically, electromagnetic tracking systems (EMS) appear to support accurate, rapid, and reliable locking results during IM fracture fixation.

Electromagnetic Tracking

EMS systems are designed to determine the position and orientation of special sensors that have been positioned within surgical tools. Tracking begins with a computerized control unit that powers and controls an electromagnetic (EM) field generator. The generator projects a safe EM field across the operative site, which is free of potentially dangerous ionizing radiation [16]. It is this field that enables a highly precise map to be drawn of the surgical space. When the surgical tool containing the system sensor is placed into that mapped space, the sensor emits a small electric current. Once that current is converted to a digital signal, the control unit can identify the tool and plot its exact location. That data is then sent to a host computer which can display the tracking information via application software. Unlike optical tracking systems that are limited by line of sight, EM tracking can be accurately performed while the sensor is contained within the body.

There are several key features that make EMS particularly well suited for utilization during IM nailing [15]. First and foremost, EM tracking can precisely track surgical instruments, independent of line of sight [13, 15]. This is made possible by the EM field. Within the surgical space map, all coordinates can be measured around a directional Z-axis (Figure 1A). The key to tracking is that the system sensor positioned within the surgical tool is also oriented around its own Z-axis (Figure 1B). This is what allows the control unit to assess the sensors' relative position and orientation within the mapped space. A second key feature of EMS is the refresh rate. Sensor data must be obtained and processed by the control unit fast enough to ensure real-time virtual feedback to the surgeon. As compared to other tracking systems, EMS does support a refresh rate that is acceptable for surgical use [13, 15]. Finally, EMS is highly conducive to the trauma operating room environment. In contrast to mechanical and robotic guidance systems, EMS is very unobtrusive and does not restrict or alter surgeon access to the patient [2, 15]. Furthermore, EMS is not adversely affected by light and sound levels within the operating room, and is not overly susceptible to field deviation when exposed to conductive or ferromagnetic objects [13, 17]. Any potential for EM field interference is mitigated by the relatively small distance between the system sensor and the field generator [18]. Further, it is important to account for any metallic items that may still be in the field, including any instruments or metal structures that may be supporting the operative limb.

Figure 1: The coordinate system of the generated EM field (A), and the Z-axis orientation within the length of the sensor coil (B)

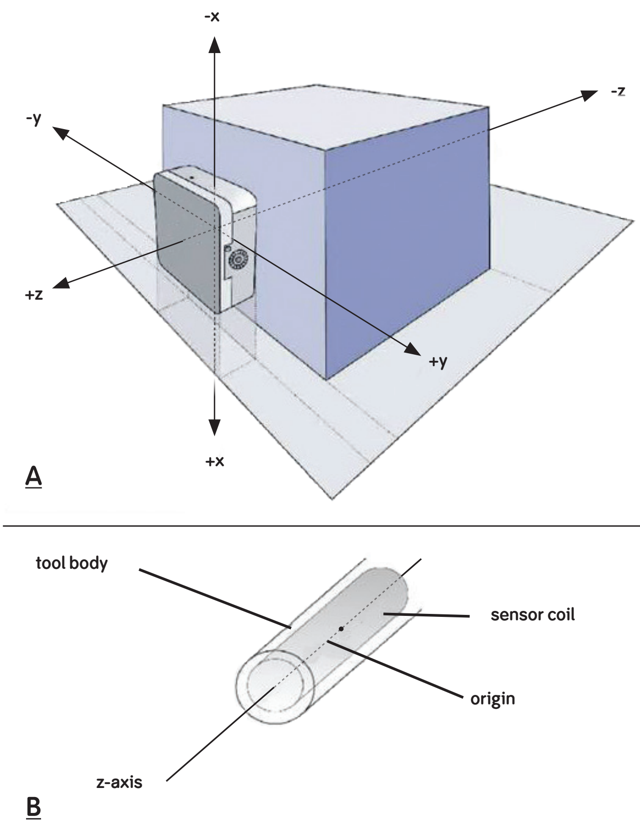
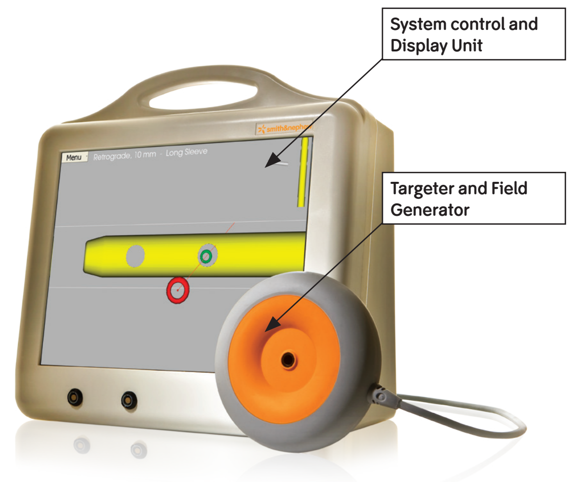


Figure 2: The SURESHOT Distal Targeting System (Smith & Nephew, Inc., Memphis, TN, USA)



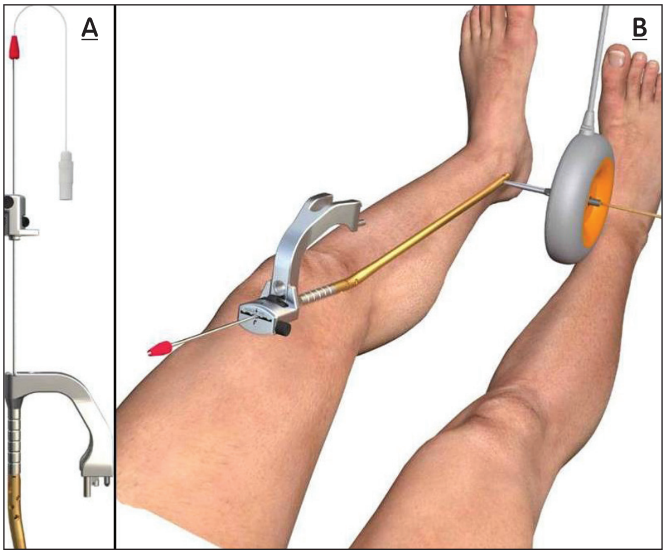
The Application of EMS during Distal Locking

The SURESHOT◊ Distal Targeting System (Smith & Nephew, Inc., Memphis, TN, USA) represents an innovative application of EMS technology. All of the essential tracking elements are contained within this system. However, the design of SURESHOT has been adapted specifically to facilitate distal locking during IM nailing. The computerized control unit is contained within the SURESHOT display and interface unit, while the EM field generator is actually located within the hand-held targeting device (Figure 2). The targeter is capable of projecting a focused EM field across the surgical site, similar to the illumination from a flashlight. Furthermore, the targeter is designed to be held securely and comfortably by the surgeon while distal targeting and locking is completed.

As discussed previously, EMS tracking is made possible by sensor interaction with the projected EM field. With SURESHOT, the sensor and accompanying hardware are designed to perfectly accommodate the TRIGEN◊ Intramedullary Nail (Smith & Nephew, Inc., Memphis, TN, USA; Figure 3). Once the TRIGEN nail is inserted into the patient, the system is able to reproduce an accurate virtual representation of the nail on the SURESHOT display unit. With the drill bit inserted through the targeter, the surgeon simply aligns the target with the real-time insertion path (the red and green circles illustrated in Figure 2), completes drilling, and then simply inserts the locking screw.

Tornetta et al [19] have verified the accuracy of SURESHOT in the clinical setting. The authors reported first-time locking accuracy for 24 tibial and femoral shaft fracture cases. Drilling accuracy of 100% and 96% was observed for each fracture type, respectively. Moreover, when compared to the standard freehand and guidance free technique, SURESHOT was found to reduce locking time by 32-48%. The authors note that these savings could reduce the time of C-Arm use by approximately 36-49 seconds, which is equivalent to approximately 0.785-2.362 rad of radiation emission [19]. While these results are both impressive and encouraging, it is not yet clear how this improved locking precision affects the clinical outcome of

Figure 3: System sensor inserted into TRIGEN◊ Intramedullary Nail (Smith & Nephew, Inc., Memphis, TN, USA; A), and the clinical application of SURESHOT during distal locking (B)



fracture patients. Furthermore, these reductions in radiation exposure have yet to be directly quantified. Smith & Nephew is therefore conducting a prospective, multicenter study to fully assess the clinical efficacy of the SURESHOT system (ClinicalTrials.gov Identifier: NCT01327508).

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