

The Radiographic Targeting Attachment-A New Freehand Targeting Device for Distal Locking of Intramedullary Nails

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Abstract

The radiographic targeting attachment (RTA) being developed by Eclipse Orthopaedics offers a new way to perform the distal locking portion of intramedullary nailing procedures by combining the modalities of fluoroscopy and drilling into a single device. With the RTA device, an orthopedic surgeon possesses a drill that can take its own fluoroscopic images; thus, providing a way to improve radiation exposure, operative time, and ease of use. In preliminary cadaveric studies, the RTA device lowered the radiation exposure by 50%, reduced the operative time for distal locking by 30%, and was subjectively easier to use via orthopedic surgeon feedback. The RTA device has demonstrated initial success in pre-clinical studies and Eclipse Orthopaedics is currently seeking larger preclinical studies to demonstrate the RTA device's efficacy for eventual clinical use [1].

Keywords: Radiographic Targeting Attachment; Distal Locking; Radiation Exposure; Intramedullary Nailing

Abbreviations

RTA: Radiographic Targeting Attachment; IMN: Intramedullary Nailing; NIH: National Institutes of Health; SBIR: Small Business Innovation Research

Introduction

The radiographic targeting attachment (RTA) device being developed by Eclipse Orthopaedics provides a solution for the challenging distal locking portion of intramedullary nailing (IMN) for long bone fractures [1]. The conventional freehand method with C-arm fluoroscopy guidance has been the standard technique for the placement of distal locking screws. However, this freehand method relies on a surgeon performing 'perfect circles' for screw placement, which can be difficult and result in excessive radiation exposure, increased operative time, repeated drill hole attempts leading to the formation of stress points in the bone cortex, and even the distal locking screw missing the nail in its entirety. While trauma fellowship-trained orthopedic surgeons seldom struggle with perfect circles and distal locking, the orthopedic surgeon in the community setting may experience difficulty due to the lower IMN case volume and time gap between IMN cases [2]. Thus, a safer, easier, and faster way to perform distal locking in IMNs is needed, especially in the community setting and for novice orthopedic surgeons, and the RTA device addresses this problem.

The RTA device was developed with several goals, such as to be accurate, to reduce radiation exposure, to reduce operative time, to work within existing surgical techniques, to work with any nail system and/or drill, and to be easy to learn. From a clinical perspective, the RTA device was developed for IMN procedures, including hip fractures, femoral shaft fractures, tibial shaft fractures, or any other procedure where IMN is indicated. In this review, we discuss the RTA device and its applicability to the orthopedic field.

What is the RTA?

The RTA device combines the modalities of fluoroscopy and drilling into a single device (Figure 1). More specifically, the RTA device has the capability of shooting its own fluoroscopic image, while also being able to clip on to commercial orthopedic drills used in IMN cases. Thus, once the RTA device is attached to the drill, a surgeon immediately possesses a single device to both shoot fluoroscopic images and drill with one's own hand dexterity. With the ability to shoot one's own fluoroscopy, the need for a C-arm and radiology technician at this stage of the IMN procedure becomes obsolete. Moreover, there is no longer a potential obstruction of the C-arm blocking the drill's pathway. The RTA device's components consist of a 1) drill attachment, 2) removable x-ray module, 3) x-ray imager, 4) drill bits with radiolucent shanks, and 5) a tablet computer to display to fluoroscopic image (Figure 2).

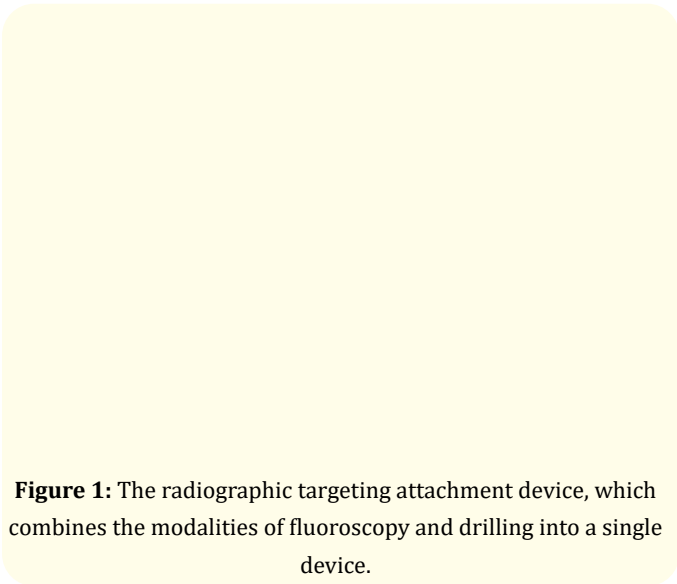


Figure 1: The radiographic targeting attachment device, which combines the modalities of fluoroscopy and drilling into a single device.



Figure 2: The radiographic targeting attachment's components both A) individually separated and B) assembled for distal locking of an intramedullary nail.

Preliminary data

Eclipse Orthopaedics performed preliminary cadaveric studies testing distal locking with the RTA device versus the conventional freehand method with 5 community setting orthopedic surgeons (Figure 3). In their study, they found the RTA device outperformed the conventional freehand method in all measured assessments. More specifically, compared to the conventional freehand method,

the RTA device lowered the radiation exposure by 50%, reduced the operative time for distal locking by 30%, and was subjectively easier to use via the orthopedic surgeon feedback [1].

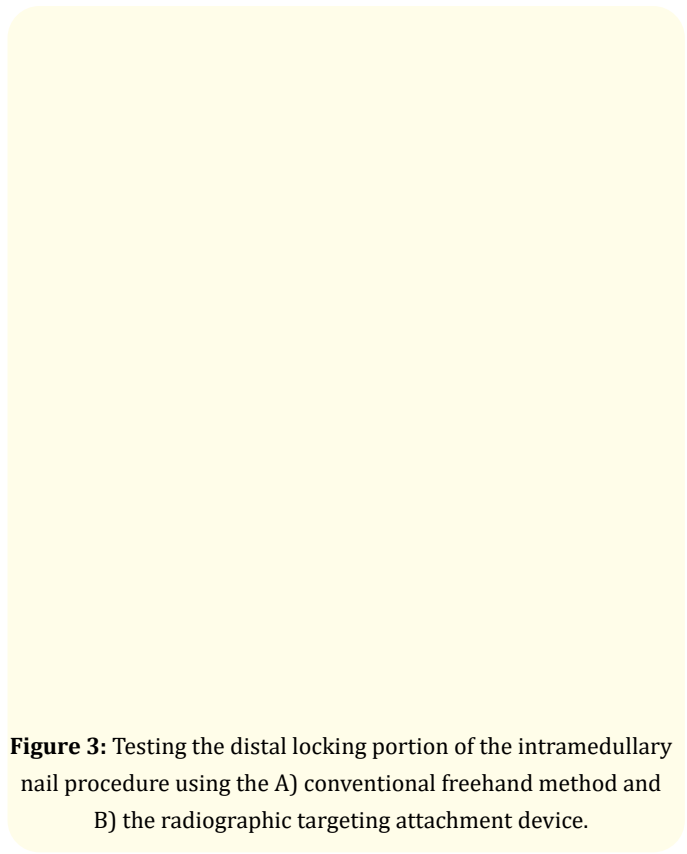


Figure 3: Testing the distal locking portion of the intramedullary nail procedure using the A) conventional freehand method and B) the radiographic targeting attachment device.

In addition to the improved radiation exposure, operative time, and ease of use, the RTA device also demonstrated operative feasibility in the cadaveric studies. The RTA device did not change the established surgical flow. As mentioned, the RTA device does not require a C-arm or a radiology technician, so the RTA device eliminated the step of aligning the C-arm to achieve perfect circles. Without the C-arm, the surgeon could approach the fixation aperture directly without the physical obstruction of the C-arm or concern for the radiation cone. Fluoroscopic images were obtained in real-time as drill placement and drill procedure occurred, and the images were displayed on a sterilely draped tablet that was placed anywhere outside the surgical field for surgeon convenience.

Future work

With the initial success and potential demonstrated by the preliminary cadaveric studies, Eclipse Orthopaedics is focused on conducting a larger scale study to further the RTA device's design and validate the RTA device's safety and efficacy in preparation for regulatory approval. Eclipse Orthopaedic is currently in the application process for the National Institutes of Health (NIH) Phase II Small Business Innovation Research (SBIR) grant.

Conclusion

The RTA device developed by Eclipse Orthopaedics offers a solution to the challenging distal locking portion of intramedullary nailing. In preliminary cadaveric studies, the RTA device lowered the radiation exposure by 50%, reduced the operative time for distal locking by 30%, and was subjectively easier to use via the orthopedic surgeon feedback. Eclipse Orthopaedics is currently seeking larger studies to demonstrate the RTA device's efficacy in preparation for clinical use.

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