Can Electromagnetic Navigation for Distal Locking of Intramedullary Nail Reduce Procedure Time and Radiation Exposure?

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Background/Purpose: Distal locking screw insertion for intramedullary nails can lead to prolonged operation time, increased irradiation, and frustrations for those surgeons who treat tibial shaft fracture occasionally. Failure to insert distal locking screws can lead to malunion or nonunion. Electromagnetic navigation (E-navigation) was developed to provide surgeons with fast and easy technique for distal locking screw insertion. It provides 3-dimensional images and real time feedback of drill bit tip and locking holes location on the monitor without use of fluoroscopy. The purpose of this study was to compare the distal locking screw insertions using a conventional method (CM), and E-navigation. We hypothesized that the use of E-navigation would decrease the procedure time and fluoroscopy exposure time over all.

Methods: We conducted a multicenter randomized parallel group study at ten hospitals. Patients who underwent surgical fixation of tibia by intramedullary nail were recruited and randomized to one of two groups by method of distal locking: (1) CM such as free-hand technique or radiolucent drill technique and (2) E-navigation. The decision to use free-hand or radiolucent drill was according to surgeon's preference. Two distal locking screws insertion (SI) time starts at time of removing guide wire for nail and completion of two interlocking placement was recorded, and SI fluoroscopy time was also recorded. Statistical analysis was performed using the Tukey-Kramer method with significance set at a P value <0.05.

Results: From December 2011 to December 2014, 157 patients were recruited for the study. 79 patients were CM group (40 with free-hand technique, and 39 with radiolucent drill technique), and 78 were E-navigation group. SI time was 800 seconds in E-navigation, 1015.7 seconds in radiolucent drill, and 829.4 seconds in free-hand (Fig.1a). SI fluoroscopy time was 37.2 seconds in E-navigation, 289.2 seconds in radiolucent drill, and 173.5 seconds in free-hand (Fig.1b).

Discussion/Conclusion: There have been 5 publications about E-navigations used in distal locking procedure as far as we know. All but one concluded that use of E-navigations shortens the time of distal locking screw fixation time, but Maqungo et al reported that time to insert distal locking screws were not significant in both methods and concluded that the surgeons are well versed in the free-hand technique, that E-navigation was equivalent in speed. In our study SI time of E-navigation and free-hand also did not have significant difference. It might not be necessary to use E-navigation for experienced surgeons concerning speed,

See pages 47 - 108 for financial disclosure information.

but all five articles and our study showed significant reduction in the radiation exposure. In our study, we were able to reduce about 80% of fluoroscopy time. That is a great advantage since radiolucent drill technique is the major technique used in our country. We believe E-navigation is a great option for quicker distal locking, and more in reducing the radiation exposure to patient and surgeons.



The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.