Electromagnetic distal targeting system does not reduce the overall operative time of the intramedullary nailing for humeral shaft fractures

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ABSTRACT

Introduction: We aimed to evaluate the efficacy of the use of the electromagnetic distal targeting system in treating humeral shaft fracture.

Methods: Patients were divided in: Group 1) patients that received a distal locking screw placement following the free-hand technique; Group 2) patients in which the distal locking screw was performed using the SURESHOT device.

Results: No differences were noted comparing Group 1 (freehand) [71,9 range 40–135 min] to Group 2 (SURESHOT) [70, range 25–125 min].

Conclusion: The use of the EM distal targeting system doesn't reduce the overall operative time of the humeral shaft fracture fixation using IMN.

1. Introduction

Fractures of the humeral shaft are relatively frequent accounting for 20% of humeral fractures and approximately 3–5% of all fractures.^{1,2} The management of these fractures remains challenging and often controversial. Open reduction and internal fixation (ORIF) with plate and screw has traditionally been the preferred method to surgically treat humeral shaft fractures. However, plate osteosynthesis is associated with negative features, such as direct exposure of the fracture site, disruption of the periosteal blood supply, risk of radial nerve injury, increased blood loss and difficulty with complex fracture patterns.^{3,4} Because of a high rate of surgical complications, intramedullary nailing (IMN) gained popularity and different authors recommend it as a standard approach for the treatment of humeral shaft fracture.^{5,6} The main advantage of IMN is represented by a less invasive procedure and a high fixation stability that contribute to a high healing rate. A further advantage is the reduction of complications observed using plate and screws, such as iatrogenic radial nerve injury and increased blood loss.^{7,8} On the contrary, the most important disadvantage of the use of IMN is represented by the difficulty of distal screw placement. Even if different systems of distal locking have been developed, the freehand screw placement (FH) represents the most used method for interlocking IMN and requires some level of surgical expertise.

However, distal screw placement can vary significantly in terms of time to perform the procedure. In fact, this technique has been reported to delay the overall operative time, leading to an increased radiation exposure to the patient and surgical personnel.^{9,10}

Recently, a new distal targeting system was commercially introduced (SURESHOT TM, Smith & Nephew, Inc., Memphis, TN, USA) that utilises a computerised electromagnetic field tracking technology to place screws during distal locking (EM technique). This system consists in a radiation-free technology that provides a 3D real-time feedback of location and orientation of the drill, relative to the nail interlocking hole. The reported merits of this new technology consist in a reduction of the operative time and a reduction of the radiation exposure.^{11,12} Even if different authors have evaluated the application of this technology for femur and tibia fractures, poor data are present concerning its use for humeral shaft fracture.^{11–14} For this reason, it is not clear if EM technology could effectively help surgeons in reducing the operative time during humeral IMN.

The purpose of the present study is to evaluate the efficacy of the use of the electromagnetic distal targeting system in treating humeral shaft fractures. The authors hypothesised that distal targeting system could reduce the overall surgical time for interlocking IMN compared to the standard fluoroscopic freehand technique.

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2. Materials and methods

We performed a retrospective study of all patients who underwent operative fixation of humeral shaft fractures from January 2010 to December 2016 at two major Traumatology Units of Palermo (AOU “Paolo Giaccone” - ARNAS Ospedale Civico). Only patients that required antegrade IMN were included. Inclusion criteria were humeral shaft fracture treated with IMN requiring an IMN distal locking with at least one screw. The exclusion criteria for the study were open fractures, polytrauma, associated fractures that required ORIF in the same surgery, pathological fractures, fractures older than 2 weeks, neurovascular injury, and a history of previous humeral fractures. All patients that were treated using inflatable intramedullary nails, self-locking nails or that required two distal locking screws placement were excluded from the study.

Two independent reviewers (S. Z. and (M. B.) that were blinded to the subject and purpose of the study extracted and recorded relevant data from each medical record.

Specifically, for each patient, the following information was recorded: gender, age, accident type, localization of the fracture, concomitant injuries, intra and postoperative complications including nerve injury. X-ray images were independently reviewed and all fractures were classified according to the AO classification. In cases of disagreement in coding among fractures, a consensus was reached through discussion. Further, if an agreement was not achieved, the senior author (L.C.) was consulted for the final decision.

According to inclusion and exclusion criteria, patients were divided into two groups: Group 1) patients that received an IMN fixation with a distal locking screw placed following the free-hand technique; Group 2) patients in which the distal locking screw was performed using the SURESHOT device (Smith & Nephew, Inc., Memphis, TN, USA). For all patients, the same surgical procedure was performed. The beach-chair position was used and an anterior approach with a small rotator cuff incision was performed to allow the access of the guide-wire. After closed fracture reduction and ball-tip guide-wire positioning, the medullary canal was reamed and an intramedullary nail with a correct size was inserted in the humerus. Following freehand technique (Group 1), the distal locking screw placement was obtained using an image intensifier positioned perpendicularly to the arm. The intensifier was then adjusted in the coronal plane to achieve a perfect circle, indicating coaxial alignment of the distal locking hole. At this point, a bone awl was then moved under fluoroscopy-based image guidance and placed in the centre of the circle. A drill was next placed into the hole and checked in coronal and transverse planes. Finally, a distal locking screw was placed under fluoroscopic guidance and checked in both planes. Following the SURESHOT technique (Group 2), the distal locking screw placement was performed using the electromagnetic field tracking technology. After nail insertion and drill guide probe placement, the SURESHOT Targeter was connected to the navigation screen. Once the image of the IM nail was available, the trajectory of the Targeter was adjusted until both the green and red circles were concentric. The alignment of the circles provided the ideal direction for bone drilling (Fig. 1). At this point, the bone was drilled through the far cortex and the length was measured using the calibrations (Fig. 2). Finally, the distal locking screw was placed and checked under fluoroscopy. For both groups, proximal locking screws were inserted using the corresponding mechanical guiding systems attached to the proximal part of the nail.

For each patient, the duration of the entire procedure (expressed in minutes) was recorded. Further, the success or failure of the targeting device, defined as the capacity of distal locking screw placement or the conversion to the freehand technique, were recorded.

2.1. Statistical analysis

Data was analysed with SPSS statistical software, version 18.0

Fig. 1. Navigation screen of the SURESHOT system.

Fig. 2. The SURESHOT Targeter used to correctly drill the bone.

(SPSS, Inc., Chicago, IL). The first 4 procedures of each surgeon were excluded from statistical analysis to avoid arousal responses associated with the learning curve of distal screw placement using SURESHOT technology. Descriptive statistics, including means and standard deviations, were performed for each studied group. Differences of surgical time between groups were analysed using a paired Student's test. Finally, p-values less than 0.05 were considered to be statistically significant. Further, the rate of the success or failure of the targeting device was calculated.

3. Results

We found 250 patients that presented a surgically treated humeral shaft fracture. Of these, 132 were treated using an antegrade locking nail and reached inclusion criteria of the study. After removal, the first 4 procedures of each surgeon, 100 fractures were finally included in the present study. 49 were male, while 51 were female. The main age at time of injury was 54.5 years (range, 15–89 years). According to AO classification, 67 fractures were A, 14 were B, and 19 were C (Table 1). The most common cause of injury was traffic accident in 83 patients, while 17 patients referred a fall. The mean length of hospitalisation was 4.3 days (range: 3–7 days). No significant differences were noted between age, causes of injury and fracture type. Eight surgeons were involved in the surgical care of patients included in the study. Concerning Group 1, in 25 patients the IMN fixation was obtained using the T2

Table 1

Type of humeral shaft fractures treated with antegrade IMN.

Fracture type (AO)	Patients (n = 100)		
A	A1	26	67
	A2	5	
	A3	36	
B	B1	3	14
	B2	10	
	B3	1	
C	C1	15	19
	C2	1	
	C3	3	

humeral nail (Stryker, Mahwah, NJ, USA)), while in 22 patients the Polarus humeral nail (Acumed, Beaverton, OR, USA) was used. In all patients of Group 2 (53 patients) a Trigen humeral intramedullary nail (Smith & Nephew, Inc., Memphis, TN, USA) was used. The distal locking was successful obtained in all patients of Group 2, while in two patients of Group 1 (Polarus Nail) a missing of distal locking screw placement was noted. The mean operative time was of 71,2 min $\pm$ 22 SD (range 25–135). Specifically, no significative differences were noted comparing Group 1 (71, 9 min $\pm$ 21,9 SD; range 40–135) to Group 2 (70 min $\pm$ 23 SD; range 25–125). Further, no surgical time difference was observed between groups when it was compared among surgeons of different Hospitals and different types of fractures. In addition, in both groups no complications correlated to the IMN were noted.

4. Discussion

The main result of the present study was that the use of the EM distal targeting system was not able to reduce significantly the overall operative time of the humeral shaft fracture fixation using IMN. However, a high efficiency of the SURESHOT was observed as any missing of distal locking screw placement was noted using the EM technology.

The high difficulty to locking distally the humeral nail with screws makes this surgical step sometimes a frustrating part of IMN.¹⁵ Different factors have been described to interfere with a rapid and correct screw placement during surgery. At first, nails are subject to deformation after implantation into the medullary canal. Even rotational and bending forces are much more representative on femoral and tibial shaft fractures, in the humeral side this occurrence could be expected.^{15,16} Second, the distal humeral shaft presents a curved shape that makes difficult to point the drill for distal bone hole creation, as a drill slippage could frequently occur. Third, a non-fixed position of the upper limb extremity during surgery allows small rotational movements of both nail and distal humerus, increasing the risk of missing the distal nail hole. These aspects are responsible for the difficulty to place a distal locking screw following the freehand technique, and for the inadequate functioning of common mechanical guiding systems that are attached to the proximal part of the nail.¹⁵ Consequently, several attempts could be required for an accurate positioning of the screw, increasing the radiation exposure during fluoroscopy.

The introduction of EM targeting system has somewhat given significant help to surgeons, with the main merit of assuring a correct, radiation-free and speed screw positioning during nail locking. Following the SURESHOT technique, a flexible probe is inserted into the nail and placed just proximal to the interlocking hole. Therefore, the proximity of the probe to the locking holes compensates the possible implant deformation, which might occur during the nail insertion. Further, X-ray-radiation-free real-time navigation system allows a correct detection during drilling and screwing, preventing slippage and errors during hole creation.

In a recent prospective study on femur fractures, it was observed that in a high-volume institution (> 200 femoral nails per annum) the

EM was equivalent to FH technique in terms of accuracy and speed of distal screw placement, with the main benefit of significant reduction in radiation exposure.¹¹ Similarly, in a comparative study on 100 tibial fractures, Hoffmann et al. observed a high reliability of the EM guidance technique. Further, comparing to the standard free-hand fluoroscopic technique, the EM was associated with less complications, less surgical time, and no radiation exposure for the distal locking procedure.¹⁷ In a recent meta-analysis including studies on diaphysis fractures of lower limbs, it was demonstrated that the EM technique did outperform the FH method with reduced distal locking time and corresponding neglect fluoroscopy time and dose. Further, the incidence of misplaced screws and misorientation of drill bits did not increase.¹⁸ Specifically, it was observed that distal locking time was more reduced in the EM group than the FH group (7.0 min VS 11.1 min). Further, concerning data on fluoroscopy time, it was noted an increased duration in the FH than EM (30.7 s VS 5.4 s).¹⁸ Despite different studies on femur and tibial fractures, poor data still exist concerning the use of the EM technology for locking intramedullary nails in humeral shaft fractures. To our knowledge, only one study has described the use of the SURESHOT Targeter for locking IMN in humeral fractures.¹² In this study, it was noted a significant reduction of the exposure to ionizing radiation in the EM group (645.48 s, range 310–1110) than in the FH technique group (1023.57 s, range of seconds 510–1400). Further, they found a reduction of the surgical time for the correct positioning of the distal locking screws (EM: 4.35 s, range 2–8 Vs FH: 28.96 s, range 16–39). Even if these data are significant, small advantage in terms of time saved could be noted. Further, in the present study it is evident that the use of the SURESHOT technology did not improve the overall saved time, when it is used during humeral shaft fracture fixation. In fact, differences were not observed when the SURESHOT group was compared with the free-hand technique group. These data are surprisingly interesting, specifically based on what was reported in the literature concerning the use of EM technology. However, distal screw placement represents only a surgical step of the entire IMN procedure. Therefore, the overall surgical time could vary on the basis of difficulty that the surgeon may have during other surgical phases, such as guide-wire placement, nail insertion or proximal screw placement. On the other hand, any missing distal locking screw placement was observed in the EM group, demonstrating the high efficiency of the SURESHOT technology over conventional techniques. This data confirms previous results, concerning the efficiency and the safety of the EM technique for distal locking screw placement.

This study has several weaknesses. Major limitations are its retrospective nature and small size. However, our group of patients treated using the EM technique was larger in terms of size than other studies present in literature. Further, no radiation exposure during screw insertion was collected. This was secondary to the use of different types of image intensifiers that make intra-operative data difficult to compare. However, further studies are necessary to assess the effective merits of the electromagnetic navigation over the freehand technique, especially regarding cost-effective that could justify its routinely usage.

5. Conclusion

This study confirms the utility for electromagnetic distal targeting system for the correct placement of the distal locking screw during IMN humeral fixation. However, it was not able to reduce the overall operative time, when its usage was compared with the freehand technique.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jor.2018.08.028>.

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