Comparison of Partially Threaded and Fully Threaded 4mm Cancellous Screws in Fixation of Medial Malleolar Fractures

Sayyed-Hadi Sayyed-Hosseinian, MD; Farshid Bagheri, MD; Mohammad-Hosien Ebrahimzadeh, MD; Ali Moradi, MD; Sogol Golshan, MD

Research performed at Shahid Kamyab Hospital, Mashhad University of Medical Sciences, Mashhad, Iran

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Abstract

Background: Several devices have been described for fixation of displaced medial malleolar fractures. Fully threaded cancellous screws engaging the bone may provide advantages compared to partially threaded screws. This study was designed to compare the clinical results of fully and partially threaded 4 millimeter cancellous screws in fixation of medial malleolar fractures.

Methods: In a randomized clinical trial study 44 patients with displaced closed medial malleolar fractures were randomly divided into two groups. Two fully threaded four millimeter cancellous screws were used for fracture stabilization (FT group) in the first group, while, the second group was operated by use of two partially threaded four millimeter cancellous screws (PT group). The clinical outcomes and complications were compared in two groups at one year follow up.

Results: Nineteen patients in FT group and 21 in PT group were present at final follow up. Nonunion was not developed in either group but two cases (9%) of delayed union occurred in PT group. The rate of postoperative infection and symptomatic hardware were not statistically different. Functional assessment using AOFAS, MOXFQ and VAS scores showed no significant difference between the two groups.

Conclusion: Both fully and partially threaded 4 mm cancellous screws can be considered as acceptable devices for the fixation of medial malleolar fractures with good and comparable clinical results.

Level of evidence: I

Keywords: Ankle fracture, Fracture fixation, Medial malleolus, Screw

Introduction

Displaced medial malleolar fractures typically require open reduction and internal fixation to achieve anatomic restoration of joint surface and initiation of early range of motion (1-3). The common advocated fixation method for these fractures as recommended by the AO foundation is to use two partially threaded 4mm cancellous screws (4). Because of the sparse cancellous bone of distal tibial metaphysis, application of screws in this region may be poor especially in bones suffering from osteoporosis.

Several factors can influence the performance of screws in fracture stabilization. Screw material, core diameter, thread depth, and number of threads engage the bone are important characteristics that affect the construct strength (5, 6). It has been shown that the length of thread engagement in the bone increases the
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pull out strength (7-10). Fully threaded screws with higher number of threads may have better purchase in the porous metaphyseal bone of distal tibia and increase the pullout strength thereby leading to better outcomes (9).

In a biomechanical study, Parker et al. showed that fully threaded 4 mm cancellous screws exert significantly higher compression at the fracture site compared to partially threaded isometric cancellous screws; however, to the best of our knowledge, clinical use of fully threaded 4 mm cancellous screws has not been reported in the English literature (11).

The goal of this study was to compare the clinical results of partially thread and fully threaded 4 mm cancellous screws for the fixation of the medial malleolar fractures.

and our null hypothesis was there was not any difference in clinical outcome of medial malleolar fractures treated with partially or fully threaded screws.

Materials and Methods
The ethical approval to conduct this study was provided by Mashhad University of Medical Sciences (IR.MUMS.REC.1394.255). Written informed consent was obtained from each patient. All three surgeons participated were experienced trauma surgeons.

Between January 2013 and January 2016, 44 patients with displaced medial malleolar fracture were enrolled in this clinical trial (IRCT2016062021482N3). Using computer generated allocation codes the patients were randomly divided into two groups. In the first group the fracture was stabilized by open reduction and internal fixation with two fully threaded 4-millimeter cancellous screws (FT group), while, two partially threaded 4-millimeter cancellous screws were used in the second group (PT group). The inclusion criteria were: displaced medial malleolar fracture with or without lateral malleolar fracture and age≥18 years old. Patients with tibial plafond fractures, open fractures, and pathologic fractures were excluded from the study. Rate of non- or delayed union as well as validated AOFAS and MOXFQ scores were used for primary outcomes (12-14). The secondary outcome measures included VAS scores, symptomatic hardware, and wound infection. [Figure 1].

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** Two of cases traveled to the other city far from of our region. One of them withdraws from the study, because of unknown reason.

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Figure 1. CONSORT 2010 Flow Diagram.
Surgical technique
Patients were positioned supine under general or spinal anesthesia, and a thigh tourniquet was used in all patients. In cases with concomitant lateral and/or posterior malleolus fractures, open reduction and internal fixation was performed using AO implants and techniques according to the AO recommendations (4). Cases of syndesmotic instability were addressed by transfixation using an either 3.5 or 4.5 mm quadricortical screw.

A 4-5 cm curvilinear incision was then made on the medial malleolus region. The dissection was continued down to the fracture, where the periosteum was reflected as necessary. Hematoma evacuation was followed by reduction of the medial malleolus. The fracture was then provisionally fixed with two 2 mm Kirschner wires. If the reduction was satisfactory under fluoroscopic view, one of the wires was removed and the screw path predrilled using a 2.7 mm bit.

The compression in FT group was applied with a reduction clamp and the fragment was fixed with two 4 mm fully threaded screws, while, two 4 mm partially threaded screws were used for fixation in PT group and the compression was automatically applied through the design of the screws [Figures 2; 3]. The screw lengths in both groups were 40-45 mm.

Postoperative care and rehabilitation
Postoperative care consisted of using a splint for 2-3 weeks, after which, the sutures were removed and touch-down weight bearing exercise was started. Patients were examined clinically and radiographically after 6 weeks and full weight bearing was allowed if union was obtained. Follow-up examinations with patients were performed at 3, 6, and 12 months intervals. The complications were categorized as wound dehiscence and infection, delayed union, and nonunion. Functional assessment of the patients was performed at 12 months postoperatively using American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot score, Manchester Oxford Foot Questionnaire (MOXFQ), and Visual Analogue Scale (VAS) score.

Statistical analysis
Due to the lack of any similar previous clinical study, this study was designed as a pilot. We enrolled consecutive patients fulfilling the inclusion criteria during the study period.

Chi Square, Mann-Whitney and T-test were used for statistical analysis. For all tests P<0.05 was considered as significant. All statistical analyses were performed using SPSS v.21.0 (IBM Corp., Armonk, NY, USA)

Results
The patients’ demographic data are summarized in Table 1. Among 44 patients included in the study, one patient from the PT group and three patients from the FT group were lost to follow-up. The remaining 19 patients were treated with FT screws and 21 patients treated with PT screws. The mean age and gender were similar between two groups. The two groups were also
comparable with regard to AO/OTA classification. Nonunion did not develop in any patient of either group; however, two patients in the PT group, both over 60 years and one of whom with diabetes, did not obtain union for 12 weeks [Table 2]. Two patients in the PT group and one in the FT group required second surgery for removal of symptomatic hardware. Superficial infection in two patients (one in each group) was successfully treated with oral antibiotics. Additional surgery was necessary for one patient from the PT group due to deep infection. No significant differences were seen in AOFAS, MOXFQ, and VAS scores between the two groups [Table 2].

Discussion

Treatment for a displaced medial malleolar fracture commonly involves the use of partially threaded cancellous lag screws (15). Lack of secure fixation in the sparse cancellous distal tibial metaphysis is a concern (16, 17). Biomechanical studies have confirmed higher pull out strength and greater compression at the fracture site for fully threaded screws (7, 8, 11, 18). The use of fully threaded bicortical 3.5mm screws for fixation of medial malleolar fractures has been reported with good results and less complication rates (19).

Although the overall union rate in this study was similar in both groups, two patients (9%, $P=0.6$) in the PT group had delayed union until 12 weeks. Both of these delayed unions occurred in elder patients (>60 years) while one of them had diabetes mellitus. Although uncontrolled diabetes mellitus is a risk factor for nonunion and delayed union, associated comorbidities were almost similar in both groups. This indicates that partially threaded screws may not be the optimal internal fixation device for use in elder patients with complications as has been reported in the literature.

Ricci et al. have reported a significantly higher rate of screw loosening (up to 11 times more) with the use of partially threaded screws for fixation of medial malleolar fractures (20). Barnes et al reported less pain and hardware prominence with headless compression screws. Although reoperation for symptomatic hardware in our study was higher in the PT group, the difference was not statistically significant ($2$ vs $1$; $P=0.6$).

Functional outcomes of the patients (AOFAS, MOXFQ, and VAS score) showed no significant differences between the two groups in the follow up period.

This study had a number of limitations. First, the number of enrolled patients was low and second, many of the patients were young (mean age: 30.5) making it unlikely that difficulty in achieving union would occur.
In an older group of patients, different results may be obtained.
In conclusion, the authors believe that both fully and partially threaded 4 mm cancellous screws can be considered as acceptable fixation devices for the fixation of medial malleolar fractures.

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References