Outcomes Following Early Weight Bearing in Syndesmotic Injuries: A Randomized Controlled Trial and Update

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INTRODUCTION:
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Background: Syndesmotic injuries occur in 10% of ankle fractures. Restoration and maintenance of the distal tibiofibular stability is crucial. The literature regarding time to weight bearing is scarce, with the majority recommending greater than 6 weeks of non-weight bearing. No studies examine the safety ofearly weight bearing in syndesmotic injuries, and current early weight bearing studies after ankle fractures typically exclude syndesmotic injuries. Dynamic stabilization of syndesmotic injuries using suture button constructs has been reported to have advantages compared to traditional syndesmosis screw fixation with respect to preventing malreduction, reducing the need for implant removal, and allowing for faster time to full weightbearing while resulting in similar clinical functional scores and safety profiles. However, clinical validation for the safety and efficacy of early weightbearing after dynamic stabilization has not been reported to the investigators' knowledge. As such, the primary arguments against the use of suture button fixation are centered on relative implant cost and validation of clinically significant benefits.
Purpose: The purpose of this randomized controlled trial is to measure differences between early weight bearing at 2 weeks and delayed weight bearing at 6 weeks in terms of outcomes, hardware failure, and loss of reduction at 1 year.
METHODS:
This study is an Institutional Review Board-approved prospective, randomized clinical trial. Adult patients with rotational ankle fractures were identified and screened for inclusion prior to consent. Randomization occurred after fixation and no fracture types (bimalleolar, trimalleolar, etc) were excluded. Post-operatively, patients requiring syndesmotic fixation were randomized one-to-one to an early weight-bearing (EWB) or delayed weight-bearing (DWB) group.
All patients followed up at 2 weeks, 6 weeks, 12 weeks, 6 months, and 1 year and filled out Patient-Reported Outcomes Measurement Information System (PROMIS), AAOS Foot and Ankle Score (AOFAS), surgical experience (SSQ-8), and work productivity and activity impairment (WPAI) forms at their visits.
Assessment of the injured and uninjured syndesmosis were made according to previously published protocols (See supplemental images 1-3). Maintenance of the syndesmotic reduction was determined by comparing the immediate post-op and 1-year CT scans. Radiographic parameters reported included: mean syndesmotic width, medial clear space, tibiofibular overlap, tibiofibular clear space, and inter-button distance.
RESULTS:
106 patients from September 2019 to September 2022 were enrolled, with 66 screen fails (did not require syndesmotic fixation). 40 patients were eligible for the study. 32 completed the study, 16 patients in the EWB and 23 in the DWB group. There were no differences in demographics including age, gender, race, or marital status nor statistical differences in laterality of ankle fracture. Nor was there any significant difference in type of ankle fracture sustained by participants in each group comparing bimalleolar, bimalleolar equivalent, bimalleolar fracture dislocation, trimalleolar, trimalleolar fracture dislocation, and isolated lateral malleolar fractures.
The EWB group had higher pain (VAS) scores at 2 weeks compared to the DWB (4.62 ± 2.84 vs 2.87 ± 2.31, p=0.039). Ankle dorsiflexion at 1 year post op was significantly increased in the EWB group compared to the DWB group with 14.2° ± 3.97° vs 7.71° ± 4.46°, (p-value=0.017) . The AAOS Foot and Ankle core standardized mean score was significantly higher for the EWB group compared to the DWB group at 2 weeks post op (p=0.012). There were no differences in the development of arthritis or pre-exisiting arthritis between the groups. On the 6-week SSQ-8 there was no significant difference in those satisfied and very satisfied vs unsatisfied and very unsatisfied (p=1.00). There was no significant difference in complications between the EWB and DWB groups before 1 year (p=0.37) and after 1 year (p=0.41).
There was no significant difference in the maintenance of syndesmotic reduction between the EWB and DWB groups at baseline and at 1 year post op. Baseline mean syndesmotic width was 1.03mm ± 2.15mm in the EWB group and 1.01mm ± 2.29mm in the DWB group (p=0.99),and 1-year post op mean syndesmotic width was 1.22mm ± 3.36mm in the EWB group and 1.27mm ± 1.48mm in the DWB group (p=0.89).
DISCUSSION AND CONCLUSION:
There has not been an established standard of care regarding return to weight bearing after operative fixation of the syndesmosis secondary to a lack of quality evidence. The results of this randomized controlled clinical trial support early weight bearing at 2 weeks when utilizing dynamic stabilization. No differences in complications, malreduction, or arthritis development were noted between the two groups. Patients allowed to bear weight earlier had almost 7 degrees of

improved ankle dorsiflexion at one year. This novel finding can help guide orthopaedic surgeons' decision-making regarding post operative management after repairing syndesmotic injuries with dynamic stabilization.

Conclusion

It is safe to allow early weight bearing (2 weeks) after dynamic suture button fixation of the syndesmosis yielding improved post-operative range of motion at 1 year, comparable rates of complications, and high satisfaction scores without increased risk of loss of syndesmotic reduction or ankle malreduction.