Clinical and Radiographic Outcomes of Headless Screws in Traumatic and Reconstructive Hindfoot Applications

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Introduction: A new cannulated compression headless screw has been FDA cleared with Medical Device Directive (MDD) CE marking for use in various trauma applications including osteotomy, joint fusion, fracture repair and bone reconstruction. Prominently, headless screws have been shown to provide stable fixation with minimal soft tissue irritation, which is particularly beneficial in the complex anatomy of the hindfoot.[1,2] The purpose of this research was to evaluate the clinical and radiographic outcomes and device-related adverse events of patients treated with headless trauma screws in traumatic and reconstructive hindfoot applications in support of the growing demands of European medical device regulations.

Methods: Institutional Review Board (IRB) approval was obtained to perform a retrospective and prospective registry evaluating patients who underwent trauma and bone reconstructive procedures in hindfoot applications with headless trauma screws manufactured from titanium alloy. Patients were evaluated for clinical and radiographic healing, device-related adverse events, and functional recovery using Visual Analog Scale (VAS) pain scores and the 36-Item Short Form Survey (SF-36). Statistical significance was calculated between pre-operative and final post-operative measurements using a two-tailed, paired T-test with significance set at $p<0.05$.

Results Section: Included in the study were 75 patients who underwent traumatic and reconstructive hindfoot procedures. A total of 18 patients were treated for osteotomy of the calcaneus, 37 patients were treated for joint arthrodesis (of the talus and calcaneus (n=22), talus, calcaneus and navicular (n=14), or talus and navicular (n=1)), and 20 patients were treated for fracture repair (of the calcaneus (n=14), talus (n=3), navicular (n=1), calcaneus and talus (n=1), or calcaneus and navicular (n=1)). Of the 75 patients treated, 66 patients had comorbidities or patient risk factors commonly associated with impaired bone healing including obesity, smoking, diabetes, advanced age (≥65 years old), and hypertension. Several patients underwent concurrent procedures including, but not limited to, gastrocnemius recession, arthrodesis, fracture repair, and osteotomy with use of other hardware as needed. Time to radiographic healing was similar amongst the various treatments despite the different bones treated and procedures performed. Time to radiographic healing for patients treated for osteotomy was 5.78±3.63 months, for patients treated for joint arthrodesis was 5.56±2.82 months, and for patients treated for fracture repair was 6.10±3.18 months. Overall, the time to radiographic healing for patients treated for all hindfoot applications combined was 5.76±3.11 months. The overall radiographic success rate was 92% (69/75). Six comorbid patients with risk factors including, but not limited to, obesity, hypertension, and advanced age, developed pseudarthrosis/nonunion.

A subset of patients treated completed Patient Reported Outcome Measurements (PROMs) at pre-operative and final clinic visits. Subjects demonstrated significant ($p<0.05$) improvement in VAS pain scores, and functional outcomes as determined by the SF-36 (Table 1).

Table 1: Pre-Operative and Final Post-Operative Patient Reported Outcome Measurements

	Pre-Operative Average	Final Follow-up Average	P-Value
VAS Pain Scores (n=25)	51.24 ± 30.12	12.84 ± 20.07	P= 0.00003
SF-36: Physical Functioning (n=20)	32.5 ± 28.58	59.5 ± 30.03	P= 0.0004
SF-36: Role Limitations to Physical Functioning (n=20)	30.63 ± 24.49	50.63 ± 39.63	P= 0.057
SF-36: Pain (n=20)	37 ± 19.39	62.5 ± 19.53	P= 0.0002

Discussion: This research confirms functional recovery and radiographic healing in patients treated for hindfoot applications with headless trauma screws. Despite the high number of patients with comorbidities and risk factors to impaired bone healing treated for hindfoot procedures, high healing rates were achieved. Additionally, patients reported restoration of functionality and alleviation of pain following treatment. While additional research is required to fully evaluate headless screws for all foot applications, early evidence supports the ability of these devices to obtain successful healing outcomes in the hindfoot.

Significance/Clinical Relevance: To our knowledge, this study was the first to demonstrate improved patient reported outcomes, including restoration of functionality and alleviation of pain, following treatment with headless trauma screws for hindfoot applications. Additionally, study results demonstrated the ability of headless trauma screws to provide early structural support in the healing process that ultimately lead patients to obtain solid boney fusion with both radiographic and clinical success.

References:

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