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

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Introduction: A new cannulated compression headless screw has been FDA cleared and CE marked for use in various trauma applications including osteotomy, joint fusion, fracture repair and bone reconstruction. 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 forefoot traumatic and reconstructive 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 forefoot 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-op and final post-op measurements using a two-tailed, pared T-test with significance set at $p<0.05$.

Results Section: Included in the study were 45 patients who underwent forefoot trauma and reconstructive procedures. A total of 17 patients were treated for osteotomy, 2 patients were treated for osteotomy and joint arthrodesis, 23 patients were treated for joint arthrodesis, and 3 patients were treated for fracture repair. Of the 45 patients treated, 37 patients had comorbidities or patient factors commonly associated with impaired bone healing including obesity, smoking, diabetes, advanced age, and hypertension. Several patients underwent concurrent procedures including but not limited to capsulotomy, tenotomy, arthrodesis, and osteotomy with other hardware. Radiographic healing varied by the bone treated and procedure performed. Radiographic healing for patients treated for osteotomy healed in an average time of 25.41±16.97 weeks, patients treated for osteotomy and joint arthrodesis healed in an average time of 28.2±0 weeks, patients treated for joint arthrodesis healed in an average time of 22.74±13.04 weeks, and patients treated for fracture repair healed in an average time of 14.66±8.65 weeks. Overall, patients treated for all forefoot applications healed in an average time of 23.44±14.16 weeks. The overall radiographic success rate was 93.33% (42/45). Three comorbid patients with risk factors including, but not limited to, obesity, hypertension, and advanced age, developed pseudarthrosis by 26.08±13.03 weeks post-operative. One subject experienced delayed wound healing 1.5-months post-operative; the subject recovered without sequelae 2-months post-operative following prescription intervention.

A subset of patients treated, regardless of application, completed PROMs at pre-operative and final clinic visits. Subjects demonstrated significant ($p<0.05$) improvement in VAS pain scores, and physical functioning, role limitations for physical health and pain as determined by the SF-36 ($p<0.05$) (Table 1).

Table 1: Pre-Operative and Final Patient Reported Outcome Measurements (n=21)

	Pre-operative	Final Post-operative	P-value
VAS pain score [a]	36.88±29.29	5.16±12.42	P=0.0004
Physical functioning*, [a]	64.52±26.59	80.95±17.86	P=0.0020
Role limitations for physical health*, [a]	70.833±31.95	94.04±17.50	P=0.0125
Pain*, [a]	50.23±24.74	81.19±18.31	P<0.0001

[a] Subjects with no reported scores were excluded from analysis
* Determined by SF-36

Discussion: This research confirms functional recovery and radiographic healing in patients treated for forefoot applications with headless trauma screws. Despite the high number of patients treated for forefoot procedures with comorbid conditions, high healing rates were achieved. Additionally, patients obtained 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 forefoot.

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 manufactured from titanium alloy for forefoot applications. Additionally, study results demonstrated the ability of headless trauma screws to provide early structural support and ultimately obtain solid boney fusion resulting in both radiographic and clinical success.