

# Extra-Osseous Talotarsal Stabilization using *HyProCure*<sup>®</sup> in Adults: A 5-Year Retrospective Follow-up

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## Purpose

The purpose of this clinical investigation was to evaluate postoperative subjective outcome measures of the *HyProCure*<sup>®</sup> extra-osseous talotarsal stabilization (EOTTS) device as a standalone procedure in a randomized adult population treated for symptoms associated with recurrent and flexible talotarsal joint dislocation.

## Background

The stability of the talotarsal joint is crucial to maintain proper balance, uniform weight distribution, normal gait pattern, and biomechanical function, not only for the foot and ankle but also for the proximal musculoskeletal structures (knee, pelvis, and spine). Abnormal forces within the talotarsal joint lead to excessive hindfoot motion, which results in a prolonged period and excessive amount of pronation during static and dynamic weight-bearing activities. It has been recommended that interventions that reduce or eliminate excessive pronation should be considered. Subtalar arthroereisis, a surgical procedure that lifts the talus and blocks the anterior lateral process, has been used to treat this condition since the 1960s. However, clinical outcomes of this procedure have historically been less-than-optimal, with reported removal rates of around 40%. *HyProCure*<sup>®</sup> is designed to restore, as close as possible, the normal articular relationships of the talotarsal joint without compromising the normal range of hindfoot motion and provides correction in all three cardinal planes of foot motion.

## Methods

- Eighty-three adult patients (minimum age of 18 years at the time of surgery) on whom the *HyProCure*<sup>®</sup> procedure was performed between October 2004 and December 2006 participated in this study (117 feet).
- Exclusion criteria for the study included patients who had received *HyProCure*<sup>®</sup> in conjunction with hindfoot/midfoot osseous procedures or soft tissue procedures that may aid in the correction of talotarsal instability. 68% of patients had no other procedures performed.

- The mean age at the time of surgery was 58 (range 22 to 85) years.
- The average follow-up was 51 months post-operative.
- Patients were asked to provide honest responses to the Maryland Foot Score Questionnaire. The assessment asked patients to evaluate outcomes in three key areas – pain, foot function and foot appearance.

*HyProCure*<sup>®</sup> has a less than 6% removal rate and is highly effective in the treatment of talotarsal dislocation (partial) as a stand-alone procedure.

## Clinical Significance & Conclusions

- Patient satisfaction scores showed excellent long-term results, with a high level of tolerability and overall improvement in the quality of life of the patients. The average total score was 88 out of 100.
- In each category, the majority of patients chose the highest possible satisfaction rating; 52% reported complete alleviation of foot pain, 69% had no limitations on their foot's functional abilities and 80% reported complete satisfaction with the appearance of their foot.
- The implant removal rate was less than 6% (5.94), which is significantly lower than reported rates of arthroereisis devices (average 40% removal rate). The low removal rate and minimal postoperative complications are attributed to the unique design and insertion properties of *HyProCure*<sup>®</sup>.
- This study shows the use of the *HyProCure*<sup>®</sup> EOTTS device is tolerated with minimal risk and high patient satisfaction and a significantly lower removal rate than arthroereisis devices.

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