

# Extra-Osseous TaloTarsal Stabilization using **HyProCure**<sup>®</sup>: Preliminary Clinical Outcomes of a Prospective Case Series

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## Purpose

The purpose of this prospective, multicentered study was to evaluate subjective outcomes of the **HyProCure**<sup>®</sup> extra-osseous talotarsal stabilization (EOTTS) device as a standalone procedure in a randomized pediatric and 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. **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

- Thirty five patients (46 feet) treated for RTTD from March 2010 to November 2011 were identified and agreed to participate.
- The diagnosis, enrollment, and treatment were performed by 4 foot and ankle surgeons from 3 different facilities.
- The diagnosis of RTTD was determined through detailed clinical evaluation and confirmed by radiographic analysis.
- 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.
- Preoperative MFS scores were procured before the EOTTS surgery for each foot.
- The mean age at surgery was 41 (range 8 to 72) years.
- Postoperative MFS scores were obtained from the patients at 1, 2, and 3 weeks, 1, 2, 3, and 6 months, and 1 year postoperatively to determine the outcomes in regard to pain relief, functional activity, and the appearance of the operated foot.

## Results

- At the one year follow-up:
  - Foot pain decreased by 36.97%.
  - Foot functional activities improved by 14.39%.
  - Foot appearance improved by 29.49%.
- The greatest magnitude of improvement occurred 4 weeks postoperatively, with gradual improvement continuing through to the 1-year follow-up.
- Implants were removed from 2 patients (2 feet, 4.35%).
- No unresolved complications were observed.
- 21 patient (25 feet) experienced improvement in secondary conditions without undergoing additional procedures to correct those conditions.

**HyProCure**<sup>®</sup> produced positive subjective outcomes when used in the treatment of talotarsal dislocation (partial) as a stand-alone procedure.

## Clinical Significance & Conclusions

- Maryland Foot Scores at one year showed 70% in the 90-100 score range.
- No patients with low preoperative assessment scores showed a failure to improve in the subjective analysis.
- The implant removal rate was 4.35%, 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.

Additional Scientific Papers on **HyProCure**<sup>®</sup> are available. Visit the *Library* section on:

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