

OsteoSinter® EVANS and COTTON wedges and related accessories

Early Clinical Outcomes

Introduction

Adult Acquired Flatfoot Deformity (AAFD) or Progressive Collapsing Flatfoot Deformity (PCFD), is a complex 3D deformity with varying degrees of hindfoot valgus, forefoot abduction through decreased talonavicular (TN) coverage, midfoot supination (collapse of the medial longitudinal arch) [1] and failure of the capsular and ligamentous structures of the foot [2].

OsteoSinter® EVANS and COTTON wedges are porous titanium implants used to correct adult-acquired flatfoot deformities, specifically for stage II posterior tibial tendon dysfunction. As the implant is highly porous, it induces the osteointegration of the surrounding bones through the interconnected porous parts, which allow the implant to be firmly affixed unless unexpected infection or bone damage occurs.



Methods

Clinical data from an observational investigation were collected from 20 patients. Follow-up results at 1 year have been obtained from 10 patients at date. Any adverse events including infection, revisions and evidence of immune response were to be noted.

Clinical outcome was assessed using AOFAS Ankle-Hindfoot Score and Short Form-36 (SF-36) health survey. These were collected pre-operatively and post-operatively at 6 months and one year.

The degree of correction achieved for each patient was evaluated using radiological controls: Talocalcaneal divergence angle, Talonavicular Uncoverage percentage and Meary's angle. These data were collected pre-operatively and post-operatively at 3 months, 6 months and one year.

CT scanning after 1 year was used to evidence osteointegration of the implant.



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The radiological analysis of the reference angles showed improvements after 1 year of implantation (Fig.1):

- Meary's Angle: $26^{\circ} \pm 16.8^{\circ}$.
- Talocalcaneal divergence angle: $18.1^{\circ} \pm 8.3^{\circ}$.
- Talonavicular Uncoverage percentage: $34.5\% \pm 13.1\%$.

No peri-implant radiolucencies were observed suggesting implant instability. The position of the implants has been maintained (Fig.2).

The AOFAS Ankle-Hindfoot score and SF-36 score showed a scoring mean value improvement of 51 and 22%, respectively. Differences between preoperative and post-operative scores at 1 year were statistically significant (Fig.3).



Fig. 1: Preoperative and postoperative Rx at 1 year.



Fig. 2: CT scan images show bone growth at the implant-bone interface and through the internal cavity of the wedge.

Conclusions

All patients present improvement in the reference angles between post-operative value compared with pre-operative. An improvement of the functional assessment and quality of life scales was registered for all patients. Moreover, the use of ancillary fixation (plate) was not required in any of the interventions.

Osseointegration of the implant (bone union) has been evidenced by means of CT-scan images.

No complications have been reported to date including osteolysis, graft site inflammation or immune response.

References

- [1] Abousayed, M. M. et al., Clin. Orthop. Relat. Res. (2016).
- [2] Vulcano E et al., Curr Rev Musculoskelet Med (2013).
- [3] p00100_4.1.25-1

No serious reportable adverse events have been notified after 1.100 surgeries performed with Osteo-Sinter® EVANS and COTTON wedges (April 2024).

Images courtesy of Dr. Poggio.

For further information please contact **AMES MEDICAL PROSTHETIC SOLUTIONS, S.A.U.**
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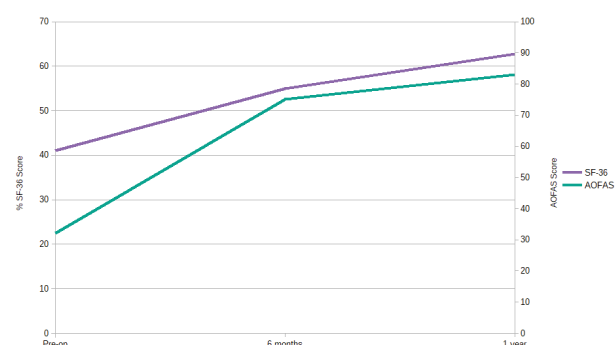


Fig. 3: AOFAS Ankle-Hindfoot and SF-36 scores.