Analysis of Retrieved Salto Talaris Total Ankle Replacement Systems

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My disclosure is in the Final AOFAS Program Book.

I have a potential conflict with this presentation due to:

3C: Two co-authors are paid consultants for Tornier (PF, JCC)
Background

- Total ankle replacement (TAR) was introduced in the 1970s as an alternative to ankle fusion, though early implants suffered high rates of failure [1].

- The Tornier Salto Talaris
  - Approved for use in the United States in 2006, after use of its mobile-bearing counterpart in Europe starting in 1997 [2, 3]
  - Fixed bearing, anatomic design [3]

- No studies looking specifically at retrieved component damage of this implant; however, studies have investigated other designs of TARs [4]
Study Objective

• Correlate component damage with patient and surgical factors to elucidate trends in Salto Talaris TAR.
  • Record observed damage modes on four retrieved Salto Talaris TAR systems
  • Analyze severity of observed damage on components using
    – Light and Scanning Electron Microscopes (SEM)
    – Energy Dispersive X-ray Spectroscopy (EDX)
  • Collect pertinent patient and surgical data from medical records
Materials and Methods

- Four Salto Talaris TAR Systems
  - Retrieved at the time of revision surgery at 2 Institutions between 2010 and 2012
    - De-identified
    - Ultrasonically Cleaned
  - Components:
    - Cobalt chromium alloy* talar component (n=3)
    - Cobalt chromium alloy* tibial component (n=3)
    - Polyethylene insert (n=4)
  * Talar and tibial components also had titanium plasma spray applied to bone-contact surfaces
Materials and Methods

• Medical Record Review
  • Patient ages at implant and revision
  • Gender
  • Body Mass Index (BMI)
  • Implant Term of Implantation
  • Reason(s) for Revision

• Component Processing
  • Evaluated for the following damage modes:
    – Abrasion
    – Burnishing
    – Embedding
    – Pitting
    – Scratching
Results

• Patient Population
  • One male; Two females
  • Average Age at Implant and Revision
    – 68 years (range, 55-75) and 70 years (range, 58-76)
  • Average BMI
    – 31 (Range, 28-34)

• Device Population
  • 2 left; 2 right
  • Term of Implantation (averaged):
    – Talar and Tibial Components (metallic), 36 months (range, 29 - 44)
    – Insert (polyethylene), 27 months (range, 9 - 44)

• Reasons for revision:
  – Loosening (100%), pain (50%), subsidence (50%)
Results

Damage Mode Analysis:

- Damage was observed on all three components of the TAR (Figure 1)

- Burnishing on the talar components was located on the curved radii

- EDX spectra and particle morphology of embedded debris were consistent with cobalt chromium alloy as well as titanium (Figure 2B,C)

- Deformation/creep was also noted on the posterior rim of two inserts (Figure 2A)
Discussion and Conclusions

• Study limitations:
  • Small data set
  • Due to the retrieval nature of this study, no control has been established.

• Conclusions:
  • Results of this study serve as a basis for understanding areas of damage and wear on Salto Talaris TAR components as well as reasons for revision, which may serve to establish algorithms to determine devices at risk for failure.

• Future Work:
  • Radiographic analysis
  • Retrieved tissue analysis
  • Data set expansion
References


