Characterization of patient specific contact pressures within the talar footprint of retrieved Agility total ankle arthroplasty tibial components

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My disclosure is in the Final AOFAS Program Book.

I have no potential conflicts with this presentation.
Background

- DePuy Agility Total Ankle
  - Fixed bearing, semiconstrained
  - Oversized polyethylene articulation
  - Requires syndesmotic fusion

- Initial results promising\(^1\)

- Midterm results\(^2\)
  - Osteolysis and loosening

- Vaupel et al analyzed retrieved implants\(^4\)
  - Abrasion, pitting, dishing were identified as damage modes
Background

• “Talar Footprint” identified
  – Primary articulation of talar component
  – Most wear occurred at the edges of the “footprint”

• Previous studies analyzed pressure measurements with talar component allowed to freely articulate\(^3\)
Hypothesis

- Increased constraint of the unintentional ‘talar footprint’ leads to increased contact pressures, and therefore increased edge loading

- Edge loading at perimeter of ‘talar footprint’ defect accelerates polyethylene wear resulting in early failures of the Agility design

- In effect, the talar footprint induces a constrained articulation and increased contact pressures, which may lead to early device failure
Materials and Methods

- Testing was performed using 6 retrieved implants all demonstrating a talar footprint within the polyethylene insert
  - 1\textsuperscript{st} generation (n=2); 2\textsuperscript{nd} generation (n=2); 3\textsuperscript{rd} generation (n=2)

- Talar and insert components were mounted to a custom-built testing fixture
  - Loading profiles were controlled by MTS software for an 858 Mini Bionix II materials testing machine

- Tekscan\textsuperscript{®} ankle pressure sensor (model #5033) was positioned within the tibio-talar articulation footprint for data collection
Methods and Materials

- Axial loads applied in stepwise increments from one to six times actual patient body weight (collected from medical record review)
- Pressures recorded, mapped, and graphed at each body weight
Results

Representative contact pressure maps from mechanical testing, showing 1st, 2nd and 3rd generation Agility designs (L to R).

- Peak pressures averaged 2.02 to 10.70 MPa
- Contact pressures increased with increasing body weight
- Peak contact pressures occur along the perimeter of the device articulation in the footprint, most notably in the 2nd generation design (wedge-shaped talar component)
Results

Average Peak Pressures Per Body Weight Multiplier

- 1st Gen. BW 104 kg
- 1st Gen. BW 97.52 kg
- 2nd Gen. BW 90.72 kg
- 2nd Gen. BW 90.72 kg
- 3rd Gen. BW 62.2 kg
- 3rd Gen. BW 104.3 kg

Peak Pressure (MPa)

Body Weight Multiplier

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Discussion

• Operative notes from each retrieved implant described loose components with osteolysis

• Measured peak forces illustrate the quantitative effects of the constrained articulation within the “talar footprint”

• Constrained articulation in vivo was unexpected, and these experiments seek to understand pathway to implant failure after “talar footprint” was established

• Measured peak pressures were near or greater than 10 MPa in multiple implants which is the industry limit for polyethylene

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Conclusion

- Increased articulation constraint leads to increased contact pressures
- Increased contact pressures lead to increased wear and wear debris
- Increased wear and debris may ultimately lead to the early failure and osteolysis seen with the Agility total ankle system, especially in the anatomic locations described in literature$^4$

