Retrieval Analysis of the Evolution of an Ankle Design

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INTRODUCTION: Total ankle arthroplasty (TAA) is a viable treatment for end-stage arthritis, but revision rates for ankle replacements are higher than in hip or knee replacements. As a relatively low-volume procedure, less is known about the impact of ankle design features on failure modes compared to other joints. To this end, we assessed a single manufacturer’s fixed-bearing designs for reason for retrieval (RFR) and other metrics. The first design (hereafter D1) was characterized by an intramedullary stem and a saddle-shaped bearing surface. The second design (D2) is an updated version of D1 but with the ability to accommodate a longer tibial stem, two pegs added to the talar components, and a sulcus-shaped bearing surface for greater stability. The third design (D3) features a low-profile tibial component with complete visualization of the implant-bone interface, and a sulcus-shaped talar component.

METHODS: An IRB-approved retrieval laboratory received retrieved components and surgeon-supplied RFR for 26 total ankles of 3 designs from a single manufacturer from 2010 to 2022. The polyethylene bearings of these retrievals were rated for clinical damage by three independent reviewers on a scale of 0 to 3. All designs were porous-coated and were rated for signs of bone ingrowth on a scale of 0 to 3. Polyethylene inserts received by the laboratory 6 months or less after retrieval (n = 15) were analyzed for oxidation using Fourier transform infrared spectroscopy.

RESULTS SECTION: Results in Figure 2 demonstrate the prominence of aseptic loosening as a failure mode among retrieved TAA components (35% overall). This is in line with failure modes expected for fixed-bearing ankle devices. This was especially evident for D2, for which 5 of 7 devices (71%) were retrieved for aseptic loosening. This may be a result of the design changes successfully eliminating other failures experienced in D1 (subsidence, etc.). Oxidation rates of these components is on par with values for other ankle polymeric components as reported by Currier et al., though the newer designs (D2, D3) have half the oxidation rates of the older design (D1) as indicated in Figure 3. Poly bearing damage and bone ingrowth scores were similar across all three designs.

DISCUSSION: Despite the small size of the retrieval record for TAA, these results indicate that evolved ankle designs offered by this single manufacturer appear to be related to the RFR, but they do not appear to greatly affect bone ingrowth or polymer damage. In addition, despite all bearings in this study being never irradiated, oxidation was found to occur in vivo. Lower oxidation in the newer designs suggests decreased stress and lower delivery of pro-oxidative species, likely related to the sulcus design. This work suggests several trends, and motivates the need for a systematic, multi-center collection of retrieved ankle components to increase failure mode assessment of TAA.

SIGNIFICANCE/CLINICAL RELEVANCE: Design changes within a single ankle family are reflected in reasons for revision. Incorporating a sulcus design lead to decreased chemical changes.


IMAGES AND TABLES:

Figure 1: Table showing demographic data for all designs. The in vivo duration of the newer devices (Designs 2 & 3) prior to failure is shorter than the older devices (Design 1), but this is expected as there has been more opportunity for long-term failure for the older devices.

<table>
<thead>
<tr>
<th></th>
<th>Design 1 (n=10)</th>
<th>Design 2 (n=7)</th>
<th>Design 3 (n=9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>64.8 (range, 37-81)</td>
<td>67.1 (range, 58-76)</td>
<td>62.3 (range, 48-75)</td>
</tr>
<tr>
<td>Sex</td>
<td>5 Female</td>
<td>2 Female</td>
<td>6 Female</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.9 (range, 18.0-47.4)</td>
<td>28.6 (range, 24.0-32.0)</td>
<td>30.3 (range, 22.1-41.9)</td>
</tr>
<tr>
<td>Duration (mos.)</td>
<td>72.6 (range, 22.7-144.8)</td>
<td>42.3 (range, 11.5-117.6)</td>
<td>45.3 (range, 6.9-79.4)</td>
</tr>
</tbody>
</table>

Figure 2: Reasons for retrieval separated by design (A-C) and reason for retrieval for all other ankles (D) in the entire retrieval collection (excludes ankles in panels A-C).

Figure 3: Oxidation rate calculated by taking the max ketone peak detected via FTIR divided by years in vivo.