# APEX 3D Total Ankle Replacement System: An Ambispective Early Outcomes Study

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# Purpose

To assess the safety, clinical/radiographic outcomes, and benefits of this index device.

- Total ankle arthroplasty (TAA) continues to be a growing procedure for its indicated patient population
- Currently, no literature exists reporting on the clinical performance of the APEX 3D Total Ankle Replacement (TAR) System (Paragon 28®).
- Longevity and efficacy of TAR systems are not well reported.

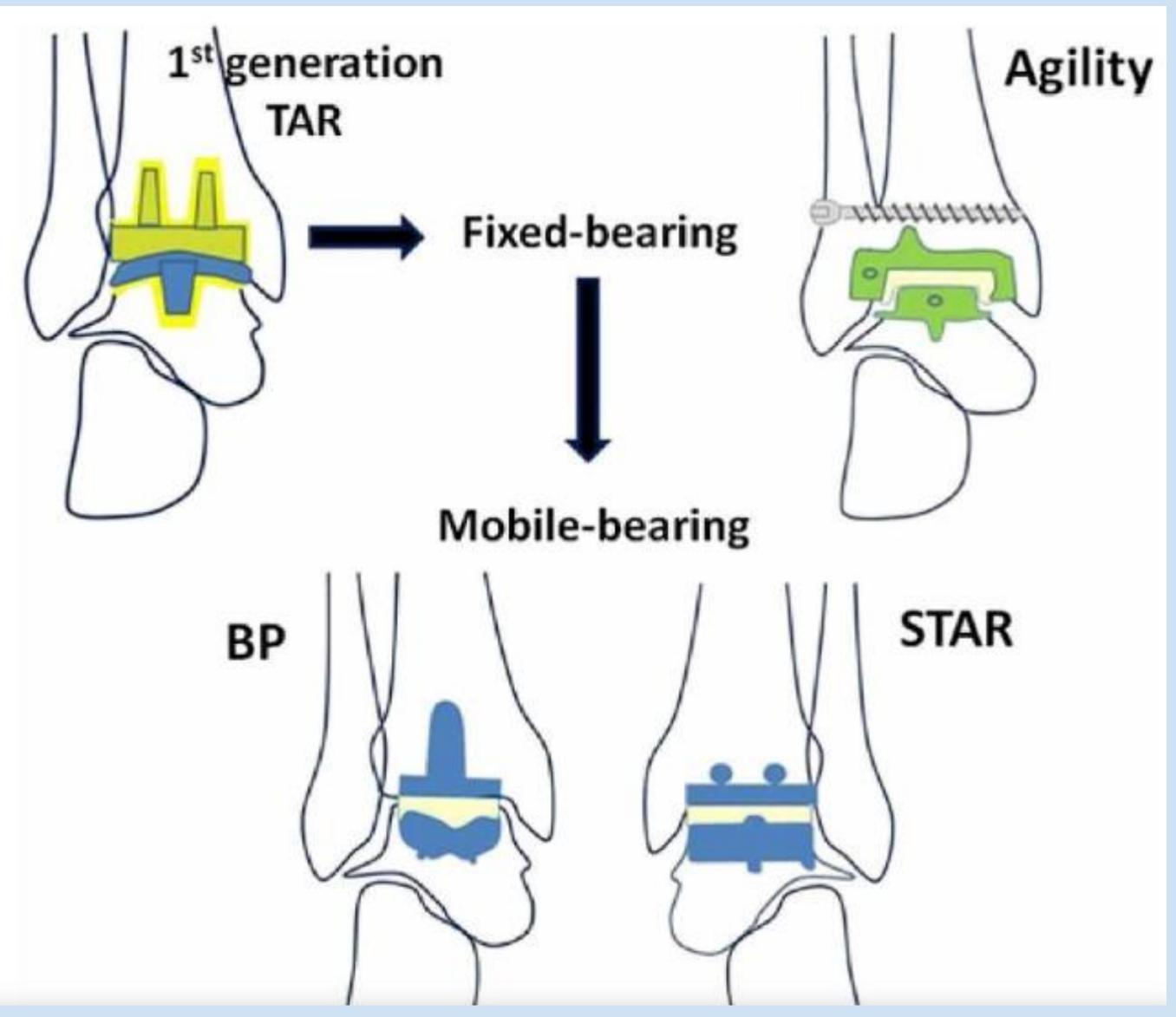


Figure 2. Evolution of first-generation total ankle replacement systems into second-generation designs. Focus on multi-axial articulation and improved osteoincorporation observed prolonged survival rates. These design improvements reduce the shear forces that previous iterations combated because of single point of articulation existing in the prosthetic joint replacement.

From Yu JJ, Sheskier S. "Total ankle replacement--evolution of the technology and future applications". Bull Hosp Jt Dis



Figure 1. Paragon 28® APEX 3D Total Ankle Replacement System. A three-component system that utilizes multi-axial articulation to best mimic the native anatomy of the tibiotalar joint. With options of computer tomography (CT) guided preoperative planning models and evolution of the vitamin e cross-linked polyethylene insert aim to improve surgical accuracy and implant retention without migration or subsident changes within the adjacent bone surface.

# Background

- Historically, arthrodesis was the standard for significant end-stage osteoarthritis due to low survivorship rates of first-generation total ankle arthroplasty systems.
- With device evolution and heightened awareness of patient selection criteria, positive outcomes were reported for the long-term viability of TAA.
- Second-generation designs included the Scandinavian Total Ankle Replacement (STAR) and the Beuchel-Pappas (BP) prostheses, reporting 10+ year survival rate at 90% and 95.4% respectively.
- A recent meta-analysis on third-generation devices' 5-year survivorship averaged 90.6%.
- Fourth-generation TAA compounds this evolution of TAA systems by minimizing bone resection while implementing preoperative planning systems.

### Methods

- This is an IRB-approved, ambispective, single-arm, multi-surgeon, non-randomized, multi-site, consecutive case series.
- Patients who received an APEX 3D TAR and who had adequate radiographs were included in the retrospective portion of the study.
- After informed consent, patients were included in the prospective portion of the study.
- Indications for TAA included post-traumatic, severe rheumatoid, and degenerative osteoarthritis.
- The device was assessed through radiographic assessment, clinical examination, duration of implant retention, and patient reported outcome scores (American Orthopaedic Foot & Ankle Society (AOFAS), Buechel-Pappas, 36-Item Short Form Survey (SF-36), Pain Score).
- Incidence of secondary related procedures and adverse events related to the index device were recorded. Two-tailed paired t-tests were utilized to compare significance of pre- vs postoperative reported outcomes.

### Results

A final cohort included 89 patients with average follow-up of 14.9 months (range 10.0-30.3). Mean age was 67.1 (range 37-94), BMI of 30.9 (range 18-54), and male/female distribution was 41/48 respectively.

- All-cause metal component survivorship rate at one year was 96.6% (86/89).
- Incidence of radiolucency was 15.7% (14/89), heterotrophic ossification was 3.4% (3/89), and subsidence was 3.4% (3/89).
- Coronal alignment was significantly improved postoperatively (p<0.0001).
- No significant differences were observed in coronal or sagittal alignment of the tibial and talar components relative to the 6-month post-operative baseline assessment at 12 or 24-months postoperatively.
- Significant improvement was observed in mean AOFAS (+29.2, P=0.002), BP (+15.2, P=0.009), SF-36 Physical Function (+26.9, P=0.011), and Pain Scores (-2.5, P<0.001) at 12-months postoperatively. Patient postoperative satisfaction was reported at 95.0%.



**Figure 3.** Early iteration of first-generation total ankle replacement in the 1970's by Lord and Marotte (A) that took inspiration from total hip arthroplasty "ball and socket" design but saw high loosening rates, mechanical failure, and osteolysis. The "gold standard" treatment for addressing tibiotalar osteoarthritis was ankle arthrodesis (B) that fused that joint resolving arthritis pain but limited range of motion significantly.

From Overley BD Jr. Total ankle replacement: a historical perspective. Clin Podiatr Med Surg. 2012 Oct;29(4):547-70. doi: 10.1016/j.cpm.2012.07.003. Erratum in: Clin Podiatr Med Surg. 2013 Oct;30(4):607. PMID: 23044062.



Figure 4. Pre- and postoperative implementation of the APEX 3D Total Ankle Replacement System with flat talar component. With careful preoperative planning, surgeons can perform biplanar corrections for anatomic varus/valgus alignment and reestablish native jointline and spacing from reduced tibiotalar angle as a result of progressive degenerative joint collapse. Opportunity for CT preoperative mapping ensures providers with proper anterior to posterior orientation and fixation.

# Analysis and Discussion

As the first study reporting on short-term clinical and radiographic outcomes, the APEX 3D Total Ankle Replacement System has produced promising results supporting the procedural efficacy and safety of index

- Survivorship and component retention offering effective short-term viability
  - Significant improvement in:
  - Patient reported outcomes
  - Radiographic assessment
    - Pain scores

Deciding on treatment for end-stage osteoarthritis should be patient-specific and comorbid-dependent to optimize postoperative success. Extended prospective follow-up will support the definitiveness of long-term device performance.

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#### **Financial Disclosures:**

- PMC serves as a consultant for Paragon 28® and Arthrex • DKB serves as a consultant for Paragon 28<sup>®</sup> and holds intellectual property rights in Stryker
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