INTRODUCTION:
The AGILITY™ (DePuy, Warsaw, IN) total ankle arthroplasty (TAA) system was introduced in response to the high failure rates associated with the first generation of total ankle arthroplasty. First generation failures were generally attributed to increased loads across cement-bone interface, increased bone resorption and poor surgical technique. Advancements in product design have increased the implantation life of the device; however, chronic loosening of the implant’s components is attributed as the primary clinical reason for failure of the AGILITY™ (DePuy, Warsaw, IN) system. Chronic loosening of components attributed to high contact stresses in the ankle and implantation technique.

This study connects clinical failure modes and radiographical analyses to macro and microscopic evaluation of each retrieved component (tibial, talar and polyethylene insert) of 10 AGILITY™ (DePuy, Warsaw, IN) TAA systems.

METHODS:
Ten AGILITY™ (DePuy, Warsaw, IN) TAA systems were retrieved through revision surgeries between 2002 and 2007. Devices were ultrasonically cleaned in a diluted solution of Micro 90 surfactant for five minutes. The process was repeated with a solution of 90% Ethanol. Devices were air dried and vacuum-sealed to prevent further oxidation.

Talar, tibial, and polyethylene components were analyzed for common damage modes using light microscopy (MZ-16 Zoom, Leica Inc.) and scanning electron microscopy (SEM, JEOL JSM 6400, JEOL LTD). Polyethylene inserts were sputtered with a 2.5mm thick Au-Pd coating to enhance contrast and provide further characterization with the SEM. Two observers evaluated damage modes of the devices. Observations were made on the following six different damage modes: embedding, dishing, grooving/scratching, pitting, burnishing and abrasion.

Clinical and radiographical analyses were completed for nine cases, whose medical records were available. Radiographical analysis included identification of radiolucent lines, ballooning lysis, medial malleolar line (MML), and angles of specific implant relationships according to the method described in Pyevich et al. on post-operative primary implantation versus pre-implant removal radiographs [1].

RESULTS:
Damage was observed on all three components, particularly on the polyethylene inserts of the tibial component. Polyethylene inserts exhibited burnishing in 100%, grooving/scratching in 100%, dishing in the form of a talar indentation in 100%, pitting in 87.5% and abrasion in 100% of the eight retrievals. Additional burnishing damage was observed in 100% of the titanium tibial components (n=9) and grooving/scratching damage on 60% of the talar components (n=10). SEM micrographs of surface damage can be seen in Figure 1.

Figure 1: SEM micrographs of surface damage. Abrasion (a), embedded titanium (b) on polyethylene inserts. Grooving/scratching on Titanium tibial component (c), fretting on cobalt-chrome talar component (d).

Radiographs illustrated ballooning osteolysis or radiolucent lines in 89% (n=9) of the pre-implant removal radiographs examined as shown in Figure 2.

DISCUSSION:
The intended mismatch in shape and size between the talar and tibial components allows the talar component to seek its own position across the entire surface of the insert, which provides increased freedom of movement and rotation. The observed indentation, or dishing, in the shape of the talar component on all of the polyethylene inserts may indicate that the talar component does not articulate across the entire surface, but instead stays in one position as loads are transferred across the surface.

Dishing, along with the high frequencies of abrasion and pitting, may explain the deformation of polyethylene and production of third body particles. This sequence of damage events may ultimately lead to osteolysis around the implant and component loosening, which has been thoroughly published in hip literature.

Although the analyzed devices were all retrieved during revision surgeries and failed and could not be compared to other devices that did not fail. It is important to consider that all devices showed extensive and similar damage to individual components.

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REFERENCES: