

AT 5 YEARS HIGHLY-POROUS-METAL TIBIAL COMPONENTS WERE DURABLE AND RELIABLE: A RANDOMIZED CLINICAL TRIAL OF 389 PATIENTS

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INTRODUCTION

Highly-porous-metals (HPM) have demonstrated excellent bone ingrowth properties and are an intriguing option for uncemented fixation in TKA. We performed a randomized clinical trial (RCT) to assess the durability and reliability of a highly porous metal tibia compared to a traditional cemented tibia.

METHODS

From 2003 to 2006, 389 patients (age 67.8 ± 8.7 years; 54% female) were randomized to three groups; (1) Uncemented highly porous tibia (2) Cemented highly porous tibia (as per original FDA approval); (3) Traditional cemented tibia. Advanced computerized randomization was done dynamically based on age, sex and BMI. The same cemented posterior-stabilized femoral component was used in every case. Durability was judged by survivorship analysis at 5 years. Reliability was judged clinically: Knee Society scores, range of motion, and complications. Radiographic assessment included alignment, radiolucency, implant migration / loosening. Patients were followed until death, revision or for a minimum of 2 years (mean followup of 5.2 years (range 2–8.9 years)). Four patients were lost prior to 2 years.

RESULTS

Highly porous tibias (both uncemented and cemented) were as durable as a traditional cemented tibial modular tibial component, judged by survivorship at 5 years using a contemporary intention-to-treat analysis (96.8 % (1); 97.6 % (2); 96.7 % (3); NS $p = 0.59$). Per-protocol analysis revealed that no highly porous metal tibia in this study was revised for aseptic loosening. The cumulative risk of revision at 5 years was 0.08 % for tibia aseptic loosening and 2.8 % for all causes. There was no difference in clinical or radiographic outcomes among the three groups except that non-progressive radiolucent lines were more common in the cemented groups.

CONCLUSIONS

In this large RCT, highly porous metal tibias provided durable fixation at 5 years, reliable clinical outcomes and no highly porous metal tibia was revised for aseptic loosening.