A Randomized Clinical Trial to Compare the Safety and Efficacy of the Oxford® Cementless Partial Knee: Results of First Use in the United States

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INTRODUCTION:
Cementless implants have been developed for use in arthroplasty to improve long term bone fixation which is particularly salient in the context of unicompartmental knee arthroplasty (UKA). The purpose of this study was to report the results of the first randomized controlled trial of the Oxford cementless partial knee implant in the United States.
METHODS:
A single-blind, multicenter, randomized controlled trial to demonstrate non-inferiority of the cementless partial knee implant compared to the cemented variant. Patients seeking unilateral or bilateral UKA were allocated 2:1 to receive the cementless or cemented device between November 2013 and November 2018. Four primary endpoints were identified to demonstrate non-inferiority of the cementless device in terms of survivorship, radiographic results (no evidence of osteolysis, subsidence/migration, or component fracture), and function (Knee Society Scores).
RESULTS:
Three hundred seventy-eight patients were randomized: 241 received the cementless implant and 137 the cemented. Two-year implant survivorship was similar between the cementless (94.0%, 95%CI 89.9 – 96.8) and cemented cohort (97.5%, 95%CI 93.0 – 99.5, p=0.19); Kaplan-Meier analysis demonstrated this was maintained at five years (91.7%, 95%CI 86.4 – 95.0 vs. 95.6%, 95%CI 88.4 – 98.4, p=0.128). Examination of radiographic success revealed non-inferior performance of the cementless prosthesis (93.8% vs 97.4%, p=0.19). Mean Knee Society Function (89.9±13.0 vs. 89.8±14.0, p=0.95) and Knee Society Assessment (95.5±8.5 vs. 95.6±6.9, p=0.92) Scores were excellent with no differences between fixation approaches at two years.
DISCUSSION AND CONCLUSION:
The cementless variant of this partial knee implant demonstrated non-inferior survivorship, radiographic, and clinical outcomes in the first cohort of patients to receive the device in the United States. Cementless fixation may be an attractive option for patients with adequate bone quality.