A Randomised Controlled Trial Comparing the Thompsons Versus the Exeter® Polished Taper Stem and Unitrax® Head in the Treatment of Displaced Intracapsular Fractures of the Hip: The WHiTE 3: HEMI Trial

Alex L. Sims; Nick Parsons; Juul Achten; Xavier L. Griffin; Matthew L. Costa, PhD¹; Mike Reed ¹University of Oxford, Oxford, Oxfordshire, UNITED KINGDOM

Purpose: Our objective was to compare the change in health-related quality of life of patients receiving a traditional cemented monoblock Thompson hemiarthroplasty versus a modern cemented modular polished taper stem hemiarthroplasty for displaced intracapsular fractures of the hip.

Methods: This was a pragmatic, multicenter, multisurgeon, 2-arm, parallel group, randomized standard-of-care controlled trial. It was embedded within the WHiTE (World Hip Trauma Evaluation) Comprehensive Cohort Study. The trial was conducted on an intention-to-treat (ITT) basis. Five NHS trauma centers in England, UK undertook patient recruitment. The sample size was 964 patients. Hip fracture patients presenting to participating trusts between February 2015 and March 2016, over 60 years of age, and requiring hemiarthroplasty of the hip were eligible for recruitment. The main outcome measure was the EQ-5D-5L questionnaire, carried out on admission and at 4 months postoperation.

Results: The adjusted EQ-5D-5L at 4 months excluding mortality is 0.045 (95% confidence interval [CI] -0.007 to 0.098); P = 0.09. This decreases to 0.037 (95% CI -0.014 to 0.087; P = 0.156) when mortality is included. The minimum clinically important difference for EQ-5D-5L used in this study is 0.08; therefore any benefit between implants is unlikely to be noticeable by the patient. There is no difference in mortality or mobilization at this time point. There is a small benefit in length of stay in favur of the Exeter stem with a Unitrax head during the initial hospital admission.

Conclusion: Contrary to the current NICE (National Institute for Health and Clinical Excellence) Hip Fracture Guidelines, the use of the traditional Thompson hemiarthroplasty in the treatment of the displaced intracapsular hip fracture shows no difference in comparison to the recommended modern cemented hemiarthroplasty.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.