Fixation using Alternative Implants for the Treatment of Hip Fractures (FAITH): A Multi-Centre Randomized Trial Comparing Sliding Hip Screws and Cancellous Screws on Revision Surgery Rates of Femoral Neck Fractures

SUMMARY OF RESEARCH PROPOSAL

Rationale
Hip fractures occur in 280,000 Americans (over 5,000 per week) and 36,000 (over 690 per week) Canadians annually. The number of hip fractures is likely to exceed 500,000 annually in the United States and 88,000 in Canada. The estimated annual health care costs will reach a staggering $9.8 billion in the United States and $650 million in Canada. Hip fractures are associated with a 30% mortality rate and profound temporary and sometimes permanent impairment of independence and quality of life. Worldwide, 4.5 million persons are disabled from hip fractures yearly with an expected increase to 21 million persons living with disability in the next 40 years. Experimental data suggest that cancellous screws offer greater preservation of blood supply, while sliding hip screws provide greater biomechanical stability to bending stresses. While both arguments are persuasive, the impacts of these biologic alterations on outcomes that are important to patients offer more compelling guidance for clinical practice.

Need for a Definitive Randomized Controlled Trial
We summarize the rationale for the trial below. First, although current opinion among orthopaedic surgeons favours the use of cancellous screws over sliding hip screws, there remains sufficient divergence in perceptions and sufficient interest to resolve this issue to warrant a large randomized controlled trial. Second, despite the popularity of cancellous screw fixation, there is a strong biologic rationale supporting the sliding hip screws, a more biomechanically stable construct, in older patients with osteopenia or osteoporosis. Third, while our meta-analysis provides indirect and direct evidence that a sliding hip screw may reduce revision surgery rates, the evidence remains far from definitive. The current best estimate of treatment effect with sliding hip screws is based upon small trials with methodological limitations including unconcealed randomization and lack of blinding. The resulting estimates include wide confidence intervals (i.e., displaced fractures: RRR=27%, 95%CI: 48%,-4%, P=0.08). Whatever approach to internal fixation proves best, a large proportion of patients will continue to need revision surgery that is associated with high morbidity and appreciable mortality.

Objective
Our primary objective is to assess the impact of sliding hip screws versus cancellous screw fixation on rates of revision surgery at 2 years in individuals with femoral neck fractures.

Hypothesis
We hypothesize that sliding hip screws will have lower rates of revision surgery at 24 months compared with cancellous screws.

Study Design
We propose a multi-centre, concealed randomized trial design using minimization to determine patient allocation. Surgeons across North America, South America, Europe, Australia, Asia, and Africa will participate. Surgeons will use one of two surgical strategies in 1,500 patients who have sustained a femoral neck fracture. The first strategy involves fixation of the fracture with multiple small diameter cancellous screws (i.e., cancellous screws group). The second treatment strategy involves fixation of the fracture with a single larger diameter screw with a sideplate (i.e., sliding hip screw group). Study personnel will monitor critical aspects of peri-operative care and rehabilitation for protocol deviations. We will assess patients at hospital admission (baseline), 1 week, 10 weeks, 6 months, 9 months, 12 months, 18 months, and 24 months after surgery. The primary outcome is revision surgery within 2 years of the initial surgery. We will independently adjudicate revision surgery rates at regular intervals up to 2 years.

Potential Impact of Study
This trial will not only change current orthopaedic practice, but will set a benchmark for the conduct of future orthopaedic trials.