THE VIABILITY OF SHORT STEMS IN TOTAL HIP ARTHROPLASTY

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Synopsis

Title	The Viability of Short Stems in Total Hip Arthroplasty
Short Title	Short Stems Study
Protocol Date	05/11/2015
Study Duration	3-3.5 years
Study Center(s)	Northwestern Memorial Hospital (NMH), Northwestern Memorial Faculty Foundation (NMFF)
Objectives	To determine the viability of short stems in THA
Number of Subjects	75
Diagnosis and Main Inclusion Criteria	Patients requiring total hip arthroplasty

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1.0 INTRODUCTION - BACKGROUND AND RATIONALE

Porous-coated cementless stems were introduced in the late 1970s, in response to the high incidence of aseptic loosening associated with cemented stems (Judet et al 1978, Kavanagh et al 1989, Lord 1982, Stauffer 1982). The stem's porous surface achieves fixation via bony ingrowth at the endosteum (Engh et al 1987). In an effort to mimic the femur's natural stress distribution, many designs preferentially load the metaphysis (Joshi et al 2000). One such design is the proximally coated titanium tapered wedge, which is widely used today (Pitto et al 2010). Because loading is primarily dictated by bony ingrowth, the proximal porous coating avoids fixation at the diaphysis. The flat, tapered geometry reduces stiffness compared to cylindrical stems, thereby propagating stress to the proximal femur, rather than down the stem's axis (Engh et al 1987, Harvey et al 1999), (Boehm 1998). Further contributing to decreased stiffness is titanium's low elastic modulus, relative to that of cobalt-chromium (Harvey et al 1999, Mulliken et al 1996). Some contend the need for distal fixation in Dorr type C hips due to thin cortical bone at the metaphysis; however, proximally engaging stems have been shown to perform well in these patients (Kelly et al 2007, Reitman et al 2003).

If a stem's objective is to load proximally, then perhaps it need not extend into the diaphyseal canal. The emergence of short stems has initiated an alternative means of proximal loading, without the disruption of diaphyseal bone stock. The smaller incisions involved with short stem total hip arthroplasty (THA) reduce damage to muscle and soft tissue (Molli et al 2012). This enables a faster, more complete recovery for the patient, as well as a cosmetically superior result (Sherry et al 2003). Additionally, the preservation of bioavailable bone can be advantageous if a revision surgery is required (Toth et al 2010). Because short stems do not extend into the diaphysis, issues regarding proximal-distal mismatch of the femur are avoided (Patel et al 2013). This eases implantation and reduces the risk of intraoperative fracture (Azzam et al 2010, Cooper & Rodriguez 2010). The risk of intraoperative fracture is further mitigated because short stem THA does not require the use of reamers (Molli et al 2012, Scott et al 1975, Taylor et al 1978).

Although the standard-length proximally coated titanium tapered wedge has a successful long-term track record, its design leaves room for improvement (Mallory et al 2001, Marshall et al 2004). Standard length stems cause stress-shielding in Gruen zones 1 and 7, suggesting that the diaphyseal portion of a stem may interfere with proximal loading (Gibbons et al 2001, Schmidt et al 2004). Even proximally coated flat tapered stems are subject to diaphyseal loading (Cooper et al 2011). The Accolade stem has been associated with significant early subsidence, especially in males with Dorr type A hips (Jacobs & Christensen 2009). This suggests that the stem may wedge distally, thereby interfering with osseointegration (White et al 2012). By achieving a purely metaphyseal fit, short stems can prevent excessive bone loss secondary to stress shielding (Gustke 2012). We believe short stems are an equally effective alternative to traditional tapered stems in THA; however, long-term studies are essential to proving their efficacy.

Long-term studies of short stems are lacking in current literature. With respect to initial stability and bony ingrowth, short-term data is promising; however, there is still potential

for late aseptic failure (Capello et al 2009, Kroell et al 2009, Morales de Cano et al 2013, Schmidutz et al 2012). By conducting a single blinded, prospective, randomized investigation of two stems of varying length with equal metallurgy, coating, and proximal geometry, we can identify the effects of stem length on long-term outcomes.

2.0 OBJECTIVES

The goal of this study is to determine the viability of short femoral stems as an alternative to standard-length stems in total hip arthroplasty.

3.0 SELECTION OF SUBJECTS

3.1 INCLUSION CRITERIA

- Must require a total hip arthroplasty.
- Ages 18-85 years, regardless of gender, ethnicity, or pathology

3.2 EXCLUSION CRITERIA

- This study excludes any populations at risk.
- Minors, as well as any persons unable to consent, will not be eligible.

4.0 SUBJECT REGISTRATION

The subjects will be recruited by the PI and co-investigator at the orthopaedic surgery clinic in 675 N. St. Clair, Galter 17-100. The study will be reviewed with the subjects and they will be consented by the PI, co-investigator, or other authorized study staff.

5.0 STUDY DESIGN & METHODS

50 patients will be recruited over 12-18 months. Half of the patients will receive the Taperloc Microplasty short femoral stem, while the other half will receive the standard-length Taperloc stem. Patients will be randomized in the operating room through the opening of opaque, study-numbered envelopes during preparation of the femur. Immediate weight bearing will be allowed post-operatively. Patient-reported outcomes, as well as x-ray analysis, will be administered immediately post-operatively, 6 weeks post-operatively, 3 months post-operatively, 6 months post-operatively, 12 months post-operatively, and 2 years post-operatively. X-ray analysis includes antero-posterior pelvis, and lateral hip radiographs. The X-rays will be sent to Dr. Rainer Biedermann at the University of Innbruck, Austria for analyses using the EBRA-FCA software. Patient-reported outcomes will be measured using the Harris Hip and SF-36 questionnaires.

Procedures such as X-rays will be used during this research study to see how the patient is doing. The cumulative radiation exposure from these tests is considered small and is not likely to adversely affect the patient or their disease. However, the effects of radiation add up over a lifetime. It is possible that having several of these tests may add to the patient's risk of injury or disease. When deciding to enter this study, the patient should about your past and future contact with radiation. Examples of contact with radiation include x-rays taken for any reason or radiation therapy for cancer treatment.

There are no other known risks involved in this study, aside from the minor inconvenience of completing questionnaires. One possible risk related with the patient's

participation in this study is the loss of privacy. To reduce these risks, all of the information collected will be de-identified (the patient will be assigned a study number and all data will be linked to that number and not the patient's name) and stored in a password protected file on a password protected computer. Some of the questions asked may be upsetting, or the patient may feel uncomfortable answering them. If the patient does not wish to answer a question, they may skip it and go to the next question.

Additionally, both stems used in this study are standard surgical stems used by orthopaedic surgeons. Therefore, there are no additional risks involved in the use of these stems for this study.

6.0 STATISTICAL PLAN

This sample size is small enough to feasibly recruit over the given time period, yet large enough to correlate differences between the two groups. Antero-posterior pelvis and lateral hip radiographs will show patterns of stress-shielding, and the EBRA-FCA method provides a non-invasive means of measuring the extent of implant migration (if any). Patient-reported outcomes will be used to determine the effect of each implant on the patients' daily lives. Routine follow-up over 2 years is necessary to determine the long-term impact of each implant.

7.0 DATA COLLECTION & RECORD KEEPING

All information regarding the nature of the proposed investigation provided to the investigator (with the exception of information required by law or regulations to be disclosed to the IRB, the subject, or the appropriate regulatory authority) will be kept in confidence by the principal investigator. All personal information will be treated as strictly confidential and not made publicly available. All records are stored in a locked filling cabinet and password protected computers which are accessed only by the Principal Investigator and Study Coordinators. All identifiable data will be destroyed a year after the study is complete.

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