Poster 301
2011 World Congress on Osteoarthritis
September 15-18, 2011 in San Diego, California

"Early Learning Experience with a Neck Stabilized THA Stem for Treating Osteoarthritis"

By: T. McTighe[1], C. Bryant[1*], D. Brazil[1*], J. Keggi[1*], L. Keppler[1*]

Purpose:

Total hip arthroplasty is one of the most effective orthopaedic procedures with a very high success rate as measured by pain relief, improved function and patient satisfaction. However, since the introduction of total hip arthroplasty in the 1940s, a range of design philosophies for femoral components have demonstrated variable clinical results. Aseptic loosening, joint dislocation, thigh pain, bone resorption and femoral component failure have been some of the complications that plague this procedure.[1,2] The past few years has seen an influx of so-called short stems with very little clarification as to design features, required surgical technique and long-term clinical outcomes. Most devices, meet with some level of learning curve and most systems do little in the way of warning new surgeons as to the perils and pitfalls during the initial surgical phase. This paper is designed to review the lessons learned during the first year of surgical experience with a new neck stabilized implant stem.[1,2,3,4]

Why the need for a new design concept?

- **Concerns with survivorship of young active patients**

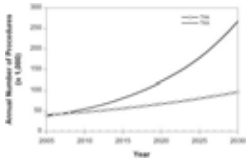
  (Kaplan-Meier 72% to 86% in patients <60 yrs. old)[5]

  Hips fail for a number of reasons:[6,7,8,9]
  - Loosening of the hip replacement
  - Infection of the hip replacement
  - Dislocation of the hip
  - Breakage or wearing out of the implant
  - Damage to the surrounding bone (periprosthetic fracture)

Examples of failures of conventional THA

- **Concerns with Hip Resurfacing** [10,11] **(Decreasing indications)**
  - Broader indications
  - Broader selection of bearing material (MoM biological concerns: **ALVAL** **A**septic, **L**ymphocytic **V**asculitis and **A**ssociated **L**esions)
  - More conservative approach (Tissue sparing both hard and soft tissue)

- **Concerns with Rising Health Care Cost**
  - Hip replacements are expected to increase 174% in the next 20 years[12]
  - The number of patients waiting more than nine months for hip and knee replacements in North Wales has increased by 11,700%.
  - Less inventory requirements
  - Less instruments



- **Concerns with Retrievability and Conversion for Revisions**
  - More hard & soft tissue to work with for revision surgery

1 **Timothy McTighe, Dr. H.S. (hc)**
Executive Director
Joint Implant Surgery & Research Foundation
www.jisrf.org

1* **JISRF Study Group Members**
Tissue Sparing Implant™ (TSI™) Total Hip Stem Designs

Declan Brazil, PhD, NSW, Au
Charles Bryant, MD, Oklahoma City, OK, USA
John Keggi, MD, Waterbury, CT, USA
Louis Keppler, MD, Cleveland, OH, USA

References:
1. McTighe, T., et. al. **"Design Considerations for Cementless THA"** Encyclopedic Handbook of Biomaterials & Bioengineering, Part B, Applications Vol1, Marcel Dekker, Inc. 1995 pp. 587-609
2. McTighe, T., et. al., **"A New Approach to Neck Sparing THA Stem"** AAOS Poster 32- March 2008, San Francisco, CA
3. McTighe, T., et. al. **"Neck Sparing Total Hip Arthroplasty-Lessons Learned"** International Osteoporosis Foundation, May 2010, Florence Italy, Poster Exhibit
4. McTighe, T., Stulberg, S.D., **"Lessons Learned: Tissue Sparing THA"** Mini-Symposium held prior to AAHKS 20th Annual Meeting, November 5, 2010, Dallas, TX.
5. Corbett, KL, Losine, E., et. al., **(2010) "Population-Based Rates of Revision of Primary THA: A Systematic Review"** www.plosone.org/article
6. Bechtol, C.O., **"Failure of Femoral Implant Components In Total Hip Replacement Operations"** Ortho Rev. Vol. IV, No. XI, Nov. 1975
7. Bechtol, C.O., **"The many Faces of Total Hip Replacement"** Ortho, Rev. Vol. III, No. 4, 1974
8. Freeman, M.A.R., et. al., **"Cementless Fixation of Prosthetic Components in Total Hip Arthroplasty in The Young Patient with Degenerative Hip Disease"**
9. McTighe, T., **"Reference Book on Total Hip Modularity"** third edition, JISRF pub. Jan. 2009 www.jisrf.org
10. **"Metal on Metal Bearings in THA-Surgeon Interview"**, May 2010 www.jisrf.org/activities/052010.htm
11. **"British Orthopaedic Association: Advise to Patients with Metal On Metal Hips"** www.jisrf.org/activities/052010.htm
12. Kutz, S., et.al., **"Projections of Primary and Revision Hip and Knee Arthroplasty in the United Staes from 2005 to 2030"** The Journal of Bone & Joint Surgery, Vol. 89, Issue 4, April 1, 2007.
13. Brazil, D., McTighe T., **"FEA Analysis of the TSI™ Neck Stabilized Stem"** Oral Paper Mini Symposium Held prior to AAHKS 20th Annual Meeting, November 5, 2010 jisrf.org/joint_replacement_video_publications.htm

Methods:

One year follow up on 200 cases by three surgeons at different centers. A novel tissue sparing neck stabilized stem design (ARC™ Neck Sparing) was used in all cases.

Two surgeons used the anterior single incision and one surgeon used a small posterior surgical approach.

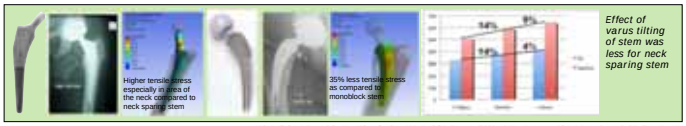
Example: anterior approach for HR vs. single incision anterior approach for neck sparing stem. Posterior approach for neck sparing good exposure on socket with retention of femoral neck.

All were implanted with cementless acetabular components of four different designs and three different bearing surfaces. Intraoperative x-rays were taken on all patients undergoing the posterior approach and half of all anterior approach patients had intraoperative fluoroscopy or plain x-rays taken.

FEA studies were evaluated to determine best stem orientation and instrumentation designed and developed for surgical preparation of femoral stem.

Results:

FEA Analysis of Neck Stabilized Stem vs. Conventional Cementless Taper Total Hip Stem[13]



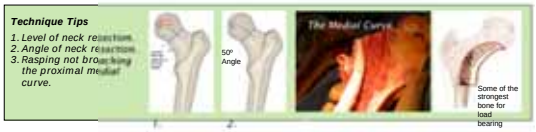
One stem has been revised due to sepsis and was eventually converted to a primary cementless stem. No stems have been revised due to aseptic loosening. Two modular necks were explanted for exposure to the acetabular component due to dislocations, providing better exposure to the socket while leaving the femoral stem in place.

Two stems were removed one for dislocation and one for pain due to heterotopic bone formation. Both revised to conventional cementless primary stems.

Surgical evaluation clearly demonstrates there is no difficulty for access to the socket or proximal femur when using a neck sparing stem design.

Intraoperative evaluation demonstrated the need for a smaller stem size in small female patients.

Surgical technique demonstrated three unique learning aspects of utilization of a curved small neck stabilized stem design.



Observations:

The initial year (April 2010 to April 2011) results of a novel modular neck stabilized curved stem design clearly demonstrates that this approach can be used as a main stream treatment for the osteoarthritic patient.

The advantage of neck sparing stabilized stems saves tissue, both hard (bone) and soft tissue as compared to conventional cementless total hip stem designs. This new approach has the potential benefit of less blood loss, quicker rehabilitation and if necessary easier removal and conversional of revision surgery. We are encouraged with our initial clinical / surgical impression and believe the potential advantages warrant further evaluation of this new approach to THA.

Bone remodeling clearly demonstrates advantages to this novel design as compared to conventional cementless THA.

Long term clinical follow up with validate this design concept.