- Memorandum - Modular Necks

To: TSI™ Study Group Members
From: Timothy McTighe Dr. HS (hc) & Declan Brazil, PhD
July 17, 2012

Coming off the recent problems with MoM bearings we are now seeing some concerns with modular necks. This should not be a surprise for some of us have been concerned with certain designs and materials used in modular junctions for some time now. However, with that said we have not faced the same level of media coverage in the past that we have seen with the MoM issue. This in our opinion will have an impact on all modular style implants. We intend to keep all our members informed to the best of our ability as to the modular neck junction used in the TSI™ modular neck technology as commercialized by Omnilife Science (The ARC™ Stem) in the US and Global Orthopaedics (The MSA™ Stem) in Australia.

Posted on our web site: www.jisrf.org under the TSI™ Study Group we have over 30 references on presentations at CME activities from around the world. Updates, papers and case reports will also be highlighted in our next Reconstructive Review scheduled to be published in the next couple of weeks.

Our first patients were treated in December of 2007 over four and one half years ago. In Australia we have had one report of a revision case that met with some subsidence do to an intraoperative crack that was not recognized at the time of surgery. The surgeon involved felt it was an early learning curve situation and has not come across any more problems with the stem. There have been no reports of pseudo tumors or any reported concerns of modular junction problems with the MSA device.

The US experience with the ARC™ Neck Sparing Stem began in April 2010. So we are out over two years. We have report on over 1,200 stems implanted in the US at this years April 2012 World Congress on Osteoarthritis in Barcelona, Spain. In that series we reported on five (5) explanted stems. Details can be viewed on web site: www.jisrf.org TSI study group page. None of those cases had a problem with the modular junction except one case that had a head/neck disassociation do to a mismatch of components. This has been published in a number of our papers and lectures. There have been no clinical signs of pseudo tumors, fretting, corrosion or ongoing hip pain.

Here is some basic information as to modular necks in THA. Modular necks have a long history in the international market. Some designs have met with problems over the years and have been redesigned and improved. I have seen concerns with the Cremascoli titanium modular necks as far back as 1993.

The recent concern is about the Stryker ABG II and Rejuvenate Stems. These are both stems designs that have a track record with Stryker and a chrome cobalt modular neck has been added to their designs. Both of these are conventional cementless style stems with a traditional neck resection.

Retrieved Rejuvenate Neck & Dual Mobility Cup

June 2008 - The FDA approves the Rejuvenate Modular Hip System based on the design's similarity to an already approved product: Wright Medical Technology's Pro-Femur Total Hip Modular Neck System. The Pro-Femur has had serious issues with corrosion at the modular sites resulting in a host of problems, including fractures and adverse tissue response.

April 2012 - Stryker Orthopaedics issues an urgent Safety Alert for its Rejuvenate Modular Stems and Necks.

The Safety Alert defines the potential hazards as follow: "Excessive metal debris and/or ion generation. Fretting and/or corrosion at or about the modular neck junction may lead to increased metal ion generation in the surrounding joint space. Contact between metal ions and tissues and structures during an implant's service life may result in an Adverse Local Tissue Reaction (ALTR), the inflammation of associated tissues experiencing immunological response (metallosis, necrosis, and/or pain). An ALTR may result in the need for revision surgery. Excessive fretting debris. Fretting may lead to increased metal debris in the joint space (concentration of debris exceeds individual patient threshold) resulting in osteolysis [bone dissolution]. Osteolysis may be asymptomatic and may result in the need for revision surgery.)"

We have seen other modular necks meet with fatigue problems like the OTI/Encore chrome cobalt design.

OTI old style

Encore Redesign

Both the diameter and the taper length were increased by a significant percentage. Since the redesign to my knowledge there have been no more fatigue failures of the neck.

Here you can see in this Cremascoli style taper the percentage of the overall length of the modular neck that engages with the taper is less than 1/3 of the neck length.

Taper stability is a function of surface contact area. The more surface the better the stability.

Neck Sparing stems have less risk because there is a reduced bending and torsional moment.

Here is the MSA™ Neck Sparing Modular Neck in a short neutral style. As you can see more than 50% of the overall modular neck engages with the taper.

In the ARC™ Neck Sparing Stem we see similar percentages of taper engagement approximately 50%.

As a general rule most conventional style stems with a traditional neck resection have between 15-20% taper engagement. The TSI™ Neck Sparing Technology with both the MSA and

ARC style necks have approximately 50% taper engagement. Dependent on what length of neck used. Even the longest TSI neck sparing design has more engagement than the shortest conventional style stem with a traditional neck resection.

FEA testing published comparing neck sparing to conventional stems looking at stress in the femoral neck. The principal tensile stress in the neck sparing stem was 35% less than that of a conventional monoblock design.

Does this mean that we will not have any problems in the future? No, you can never say never but we do feel we have designed a device that has considered more than other designs.

The TSI™ Design technology is out more than four (4) years in Australia with the MSA™ Stem and more than two (2) years in the US with the ARC™ Stem. There have been no reports of taper failure or any signs of fretting corrosion, pseudo tumors on unexplained hip pain.

We believe that modularity at the neck stem junction provides enhanced opportunity to fine tune joint mechanics and reduce risk to mechanical impingement.

Why the need for modular necks? All you have to do is see the current usage rate to validate the need.

- Neutral neck: 33%
- Neutral Long (3.5mm): 6% new size
- 8° varus/valgus neck: 16%
- 8° varus/valgus long (3.5mm): 5% long new size
- 12° varus/valgus neck: 16%
- 12° antverted/retroverted neck: 23%
- So as a combination of angled necks selected = 66%

Some would think that with a neck sparing stem you would just follow the natural anteversion of the femur and use a neutral neck. Just the opposite. You do not have the versatility to position your stem within the femoral neck to adjust for version. To achieve combined version angles between the femur and the acetabulum the intraoperative adjustability helps to achieve head center restoration.

Besides the independent review of the TSI™ Study Group there are two commercial entities Global Orthopaedic Technology and Omnilife Science following their cases.

At this early stage of clinical surgical observation all parties are cautiously optimistic.

Suggest References:

1. Reference Book on Total Hip Modularity, Third Edition Jan. 2009, JISRF pub www.jisrf.org
2. Declan Brazil, PhD; & Timothy McTighe, Dr. HS (hc); FEA Analysis of Neck Sparing Versus Conventional Cementless Stem, JISRF pub. Reconstructive Review Vol.1, Number.1 Oct. 2011
3. T. McTighe, I. Woodgate, A. van der Rijt, A. Turnbull, J. Harrison, D. Brazil L. Keppler, J. Keggi2 K.J. Keggi, R. Kennon2, S.D. Stulberg, L.E. Rubin; "Neck Sparing Total Hip Arthroplasty Lessons Learned"; Poster Exhibit IOF world Congress on Osteoporosis, May 2010, Florence Italy
4. T. McTighe, D. Brazil, Design Rationale and Early Clinical / Surgical Observations with a Short Curved Tissue Sparing Hip Implant -The Apex ARC™ Stem-; Jisrf pub. Reconstructive Review Vol1., Number 1Oct. 2012
5. T. McTighe, C. Bryant, D. Brazil, J.Keggi, L. Keppler; "Earl learning Experience with a Neck Stabilized THA for Treating Osteoarthritis" Poster 301 2011 World Congress on Osteoarthritis Sept. 2011 san Diego, CA
6. T. McTighe, D. Brazil, L.Keppler, J. Keggi, et al; "The first 1,225 Short Curved Neck Sparing Stems -Clinical Surgical Observations; Poster 68 ICJR CME meeting April 2012, Coronado, CA

CALL FOR ABSTRACTS!

Deadline September 6, 2012

13TH ANNUAL INSALL SCOTT KELLY INSTITUTE

SPORTS MEDICINE AND TOTAL KNEE & HIP COURSE

OCT 19 - 21, 2012 | NEW YORK, NY

SHERATON NEW YORK HOTEL AND TOWERS

International Congress for Joint Reconstruction(ICJR) and European Knee Associates(EKA) are combining forces to bring you the 13th Annual Insall Scott Kelly Institute Sports Medicine and Total Knee & Hip Course.

- Three days of cutting-edge technology and the latest surgical techniques in sports medicine and total knee and hip arthroplasty
- An international panel of today's orthopaedic experts
- Didactic lectures, interactive panel discussions and debates and case-based presentations
- Scientific poster and podium presentations

COURSE CHAIRMEN:

Jean-Noël A. Argenson MD
Aix-Marseille University, Hospital Sainte-Marguerite Marseille, France

Giles R. Scuderi, MD
Insall Scott Kelly Institute
New York, NY

W. Norman Scott, MD, FACS
Insall Scott Kelly Institute
New York, NY

For more information and to register visit www.icjr.net/2012newyork or contact info@icjr.net or 760-942-7859.