

Joint Implant Surgery & Research Foundation Chagrin Falls, Ohio, USA

FEA Analysis of Neck Sparing Versus Conventional Cementless Stem

Declan Brazil, PhD1; & Timothy McTighe, Dr. H.S. (hc)1,

Acknowledgement: Kevin Ong, PhD, Exponent, Inc., Philadelphia, PA, USA (FEA Bone Response)

Professor Ian Woodgate*, MD, N.S.W., Australia (x-ray review); Adrian van der Rijt*, MD, Wagga Wagga, Australia (x-ray review); John Keggi*, MD, Watertown, CT, USA (x-ray review); Louis Keppler*, MD, Cleveland, OH, USA (x-ray review);

Abstract:

Finite element analysis is a valuable tool in prosthetic design and helps predict specific mechanical behaviors between mechanical testing and clinical observations¹. We have studied the effect of tensile stresses of both conventional length stems with conventional neck resections and compared them to a novel short curved neck sparing tissue

Introduction:

Finite element analysis is a valuable tool in prosthetic design and helps predict specific mechanical behaviors¹. We have seen an influx of short stem designs for routine use in total hip arthroplasty in the past 5-10 years^{2,3}. Along with the influx of short stems there has also been increased interest in short curved neck sparing stem designs. These neck sparing stems are both bone and soft tissue conserving and are an alternative to both hip resurfacing and conventional cementless stems^{4,5}. With the current MoM concerns we can speculate the market will be looking for an alternative to hip resurfacing^{8,9,10}.

There has been a long history of neck sparing stems particularly in the area of conventional length cemented and cementless stem designs^{2,6,7}. The early pioneers of conventional style stems have been M.A.R. Freeman, C. Townley, and L. Whiteside. preserving stem design and have found correlation between FEA modeling and plain radiographics. Neck sparing stem with a novel conical flair does improve bio-mechanical conditions in THA as compared to conventional length cementless stems.

Key words: Total Hip Arthroplasty, neck sparing, conventional, bone remodeling, stress shielding, finite element analysis

The Godfather of the short curved neck sparing stem has been Professor F. Pipino who's experience dates back thirty years⁴.

To-date, most if not all, neck-sparing stems have been somewhat disappointing in their long-term ability to stimulate and maintain the medial calcar². Partially for that reason a new design approach was undertaken to improve proximal load transfer and to create a bone and soft tissue sparing stem that would be simple in design, amenable to reproducible technique, have contemporary features like modular necks and be cost effective in today's health care climate.

From the:

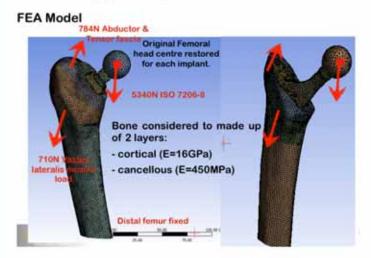
¹Joint Implant Surgery & Research Foundation 46 Chagrin Plaza #118, Chagrin Falls, OH 44022 Non-Profit Founded in 1971 www.jisrf.org

^{*}Tissue Sparing Implant Study Group Joint Implant Surgery & Research Foundation

Materials and Methods:

A finite element model was generated to compare stresses generated in conventional cementless stem compared to a short curved neck sparing stabilized stem when restoring the same head center. Comparisons were also done looking at the strain in the bone, consideration of the effects of varus / valgus tilting, consider the bio-mechanical benefit of "Neck Sparing" stem and the bone remodeling of neck sparing with a novel conical flair design to a conventional tapered style cementless stem.

Model Setup (First test)



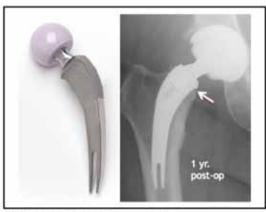
Components used to restore head center were:

TSI[™] implant size 1 (range supplied 1 through 5), 22 mm modular neck with + 8 mm head.

Taperloc Stem size 3, high offset with +8 mm head.

Both stems have proximal coated plasma bodies and distal stems uncoated. Both stems were bonded to the bone in coated region and frictionless conditions of remaining part of the stem.

Implant materials: TSI stem is Titanium Alloy with a CoCr modular neck. Taperlock is a monoblock Titanium Alloy both have commercially pure titanium plasma porous surface.



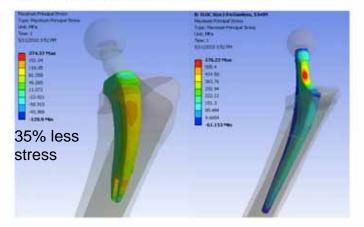
TSI™ Neck Sparing Stem typical view



TaperlocTM Conventional stem typical view

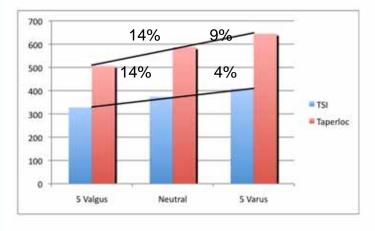
Results:

The maximum principal tensile stress in the neck sparing stem was 35% less than that of the conventional monoblock design.





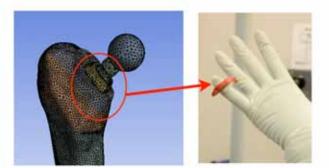
The effect of varus tilting stem was much less for the neck sparing TSI stem compared to the monoblock Taperloc stem.





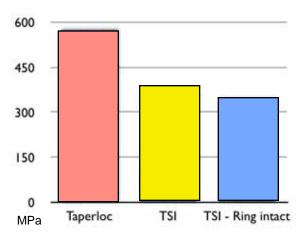
Neck Sparing Advantage

The ring of cortical bone saved in the neck sparing stem has significant bio-mechanical advantage. Pipino refers to this as a tension band. So it benefits us to reduce the chip fractures and not disrupt this band of bone.

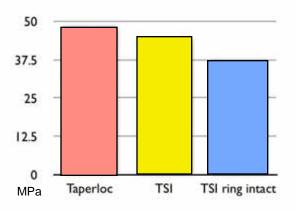


Stress in the Femoral Component

The principal stress in the femoral component was lowest for model with cortical neck ring intact compared to the monoblock conventional cementless stem.



The stress in the distal femur reduces with the TSI neck sparing stem and reduces even more if the cortical rim remains intact.





Small chip fractures reduce the optimal biomechanical benefit of the conical flair.

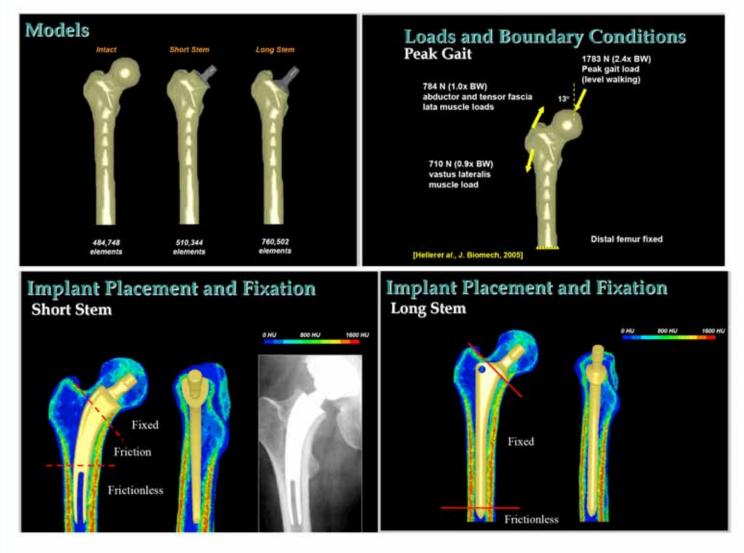
Model Setup (Second test Bone Response) 2,11

A J J. V V V

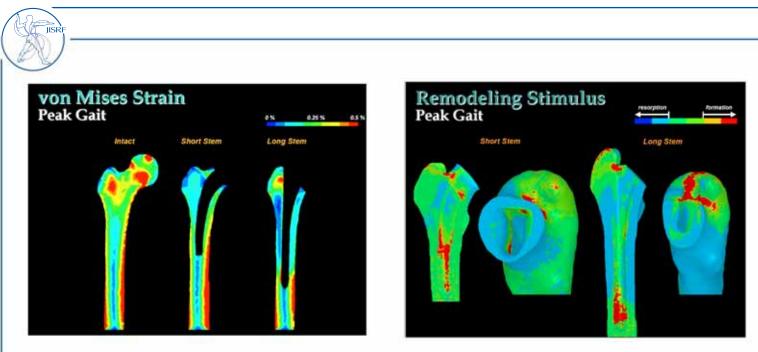
United States National Library of Medicine

Right hip 39 year old male 5' 11," 199 lbs

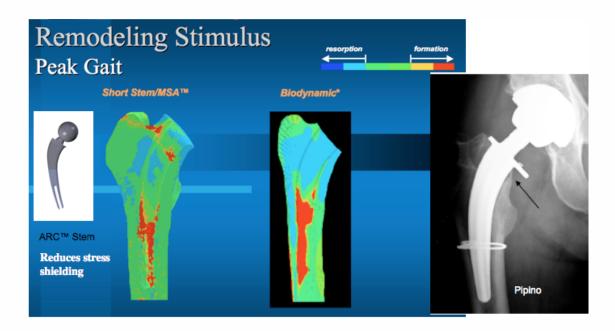
Visible Human Project: Digital image data set of complete human male and female cadavers in MRI, CT and anatomical modes.



The short stem is the TSI[™] Neck Sparing Design and the long stem is a AML® fully porous coated conventional cementless style stem.

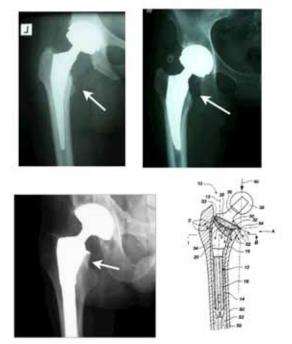


Bone remodeling strains clearly demonstrated better loading conditions with the TSI short stem compared to a AML fully porous coated style stem. This FEA model compares nicely to published clinical bone remodeling response for the AML stem.



The short TSITM stem marked (MSATM) demonstrates better loading patterns as compared to Pipino's first stem the Biodynamic which was made of c.c. material. The x-ray on the right is his current stem CFP which still has had some medial calcar bone resporption issues. This in our opinion is an example that his flat angled collar does not transfer load as he might have expected. He has had excellent clinical results as related to aseptic loosening and functional range of motion⁴. The medial calcar stress shielding in his current design has not presented any clinical problems to-date.

Some designs, long stem or short, do not load the medial calcar and the neck resorbs.



Previous work McTighe et. al. 1995 U.S. Patent 5,725,594

A monoblock style fit and fill stem with a conical collar did load and maintain the medial calcar. The TSITM conical flair came from that experience.

Radiographic Examples of the TSI[™] Stem

The TSI advanced hip technology (patents pending) has been licensed and there are two commercial version currently in the market place. The ARCTM Stem is produced by Omnilife scienceTM, E. Taunton, MA, USA and the MSATM Stem is produced by Global Orthopaedic Technology, NSW, Australia. The major design features are the same with some minor differences in level of porous coating and stem sizing. Both are demonstrating equivalent clinical and radiographic results.

ARCTM Stem MSATM Stem

Our first case was performed in December 2007 in NSW, Australia by Professor Ian Woodgate. Five initial cases were performed under tight clinical controls to validate our design concept. First generation prototype instruments were utilized and implanted with a large head metal-on-metal bearing. All five cases from a surgical technique point of view were successful. All of these patients have continued to do very well from a clinical review perspective. The following is one example at 2 1/2 year follow up from that first series. This patient is now out almost four years and doing very well.



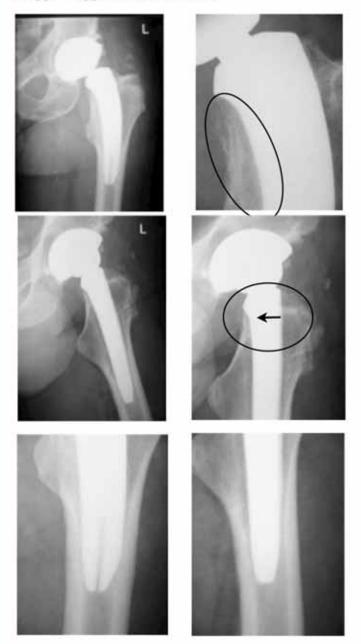
As you can see in this 2 1/2 year follow up, the stem is stable, no subsidence, good medial curve contact slight rounding of medial neck with the appearance of bone filling in the small gap at the conical flair. No distal reactive lines and no sign of distal load transfer. The entire stem below the conical flair appears to be in a bone benign state. This is fairly typical of what we are seeing when some portion of the conical flair engages bone. The flair can be above the resection line but should bottom out somewhere within the conical flair zone.





X-Ray review 18 months post-op on the TSI[™] Neck Sparing Stem

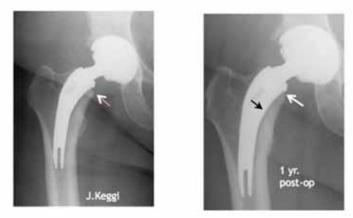
(MSA[™] Stem) Surgeon: Dr. Adrian van der Rijt, Wagga Wagga, NSW, Australia



Maintenance of medial curve contact, no reactive lines, no distal pedestals, no distal hypertrophy. Proximal lateral shows positive bone reaction with streaming of bone to the implant. Extremely encouraging X-rays.

X-Ray 12 month post-op Review (ARC[™] Stem)

Surgeon: John Keggi, MD, Watertown, CT, USA



This x-ray correlates nicely with what we have seen in Australia. The one year post-op appears to be a stable stem with no subsidence and the appearance of the small gap at the medial conical flair has filled in. The rest of the stem shows good maintenance of initial bone contact with some appearance of smoothing of medical curve cortical interface. No distal reactive lines or pedestals.

THA has been one of the most significant surgical procedures ever created and the technology and surgical techniques keep evolving. However specific design features and their potential benefits are only reached if one understands the features and can try to maximize those features. Trying to validate basic science, like finite element analysis, is done by clinical evaluation and review. We believe we have seen some excellent clinical examples that support our design concept of the conical flair in stimulating the bone of the medial calcar.

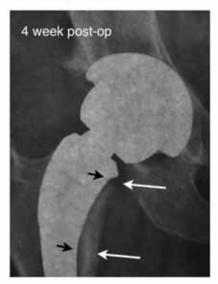


Example of good medial curve contact in a valgus neck shaft angle and was addressed with a valgus modular neck.

X-Ray Review 1 year post-op

Surgeon: William Vincent Burke, MD, Fort Lauderdale, FL, USA

The following is also an example that clearly demonstrates that if the design feature (conical flair) is not used there will not be benefit from that individual feature.



The 4 week post-op clearly shows that the conical flair is well above the resection line. There also appears to be a slight gap in the metaphyseal medial curve region. This likely could have been a result of the rasping preparation for the stem. With thew this view it is difficult to determine leg length or femoral offset.



One year post-op observations: Leg length might be slightly long however, Shenton's line appears to be continuous and smooth. If the vertical height



was reduced more femoral offset might be called for.

Stem appears to be stable with no signs of subsidence. Since the conical flair was above the resection line the medial calcar has not benefited from the potential compressive loads from the flair to the medial femoral neck.

The gap from the original resection point to the proximal tip of the conical flair appears to have lengthen with slight rounding of the medial neck. This appearance would suggest mild stress bone resporption "stress shielding" has occurred. This would be a typical bone reaction seen in most total hip stems and seem to be a very logical reaction in this case.

Of interest is the gap in the metaphyseal medial curve region has disappeared suggesting that the bone has remodeled and filled in that space. This would suggest a stable implant / bone interface with good load transfer. There appears to be a hint of distal hypertrophy just behind the lateral flange of the sagittal slot. When load is transferred distal it is a sign some load is bypassing the proximal geometry.

Generally, proximal stress shielding is not progressing after the first year and this patient appears to have a well fixed stable stem. The issue of slight increase in leg length, slight medial bone resporption and the hint of distal hypertrophy should present no clinical symptoms. It is of interest from a biomechanical observation on bone loading¹².

Observations and Conclusions:

FEA modeling has demonstrated a significant biomechanical advantage with retention of the femoral neck as compared to conventional length and neck resection taper style stem. There is a 35% reduction in principle tensile stresses in the short curved TSI[™] neck sparing stem as compared to the conventional length Taperloc[™] style stem.

The effect of varus tilting of the head center of a monoblock conventional taper style stem has more than doubled the effect of stress on the femoral component.

Both the short curved neck sparing stem and conventional monoblock taper style stem have roughly the same overall bone / implant contact area and the distal stress in the femur is equivalent.

The FEA bone response also demonstrated better loading conditions for the short curved neck sparing TSI[™] stem than the AML® fully porous coated monoblock stem or the short curved neck sparing Biodynamic[™] stem. Both the AML and Biodynamic stems are made out of chrome cobalt material as compared to the TSI[™] stem being made of titanium alloy.

The X-rays presented are examples of more than 700 cases of the TSITM style stem (ARCTM & MSATM).

X-rays have demonstrated when the conical flair is engaged with the intact cortical rim we see a positive bone maintenance at the medial calcar region and, in some cases, an upward filling of small gaps at the medial conical flair zone. If the conical flair is above the neck resection line there is potential loss of the benefit of the offloading of compressive forces to the medial calcar. Even in the face of some minor medial calcar resporption when the conical flair is not engaged, there are no overt observations of distal load transfer.

The FEA modeling has demonstrated accurate predictions of actual clinical performance. A formal bone density study will help evaluate the bone response to this novel design feature.



All of these three different style stems work. One design saves more tissue (hard & soft), the TSI™ Stem.

"Remember in accordance with Wolff's Law, the reduction of stresses relative to the natural situation would cause bone to adapt itself by reducing its mass, either by becoming more porous (internal remodeling) or by getting thinner (external remodeling)"^{12, 13}

References:

- K.E. Tanner, A.L. Yettram, et al, "Is stem length important in uncemented endoprostheses?"; Med. Eng. Phys., 1995, Vol. 17, 291-296, June
- T. McTighe, I. Woodgate, A. Turnbull, et al, "A New Approach To Neck Sparing THA Stem"; AAOS Poster 32, March 2008, San Francisco
- A. Lombardi, K. Berend, V. NG, "Stubby Stems: Good Things Come in Small Packages" Orthopaedics Sept. 2011 / Vol. 34, Number 9
- F. Pipino, A. Keller, "Tissue-sparing surgery: 25 years experience with femoral neck preserving hip arthroplasty"; J Orthopaed Traumatol (2006) 7:36-41 DOI 10.1007/s10195-006-0120-2
- T. McTighe, C. Bryant, D. Brazil, J. Keggi, L. Keppler, "Early Learning Experience with a Neck Stabilized THA Stem for Treating Osteoarthritis"; Poster 301 / 2011 World Congress on Osteoarthritis, Sept. 15-18 San Diego, CA
- P. Braud, M.A.R. Freeman, "The Effect of Retention of the Femoral Neck and of Cement Upon the Stability of a Proximal Femoral Prosthesis" The Journal of Arthroplasty Vol. 5 Supplement Oct. 1990
- 7. M.A.R. Freeman, "Why Save The Neck?" J. Bone Joint Surg 68B: 346, 1986
- 8. BOA "Advise to Patients with Metal on Metal Hips"
- BOA "Metal on Metal Hip Replacement and Hip Resurfacing Arthroplasty: What does the MHRA Medical Device Alert mean?"
- BOA "<u>Medical Device Alert /All metal on metal hip replacements</u>" MDA/ 2010/033 22 April 2010
- K. Ong, T. McTighe "FEA of Bone Remodeling for Conventional AML® style stem versus Novel Short Curved Neck Sparing Total Hip Stem" Report on file 2007 JISRF.
- R. Huiskes, H. Weiner, et al, "The relationship Between Stress Shielding and Bone Resorption Around Total Hip Stems and the Effects of Flexible Materials" Clinical Orthopaedics & Related Research, Number 274, J. 1992
- C. Engh, A., Bobyn, and J.D. Glassman, "Porous coated hip replacement: The factors governing bone ingrowth, stress shielding, and clinical results" J. Bone Joint Surg. 69:45, 1987