Design Considerations for Modular Stems

By
Timothy McTighe, Dr. H.S. (hc)

Acknowledge: H.U. Cameron, D. Brazil, T. Donaldson, L. Keppler J. Keggi, E. McPherson, A. Turnbull, B. Vaughn and all the surgeons that have encourage and participated in clinical/surgical research with me since 1984

DARF, 12th Annual Meeting
October 6-8, 2010 *Palm Springs, CA*

Disclosure

In accordance with ACCM guidelines
I acknowledge that there is a financial relationship (non-exclusive) between JISRF and orthopaedic industry and that I also have a financial relationship (non-exclusive) with a number of orthopaedic companies including .

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Joint Implant Surgery & Research Foundation

Founded in 1971
by

Prof. Charles O. Bechtol, M.D.
I attending my first hip course In Chicago in 1973 sponsored by JISRF

Remember the Goals of THA

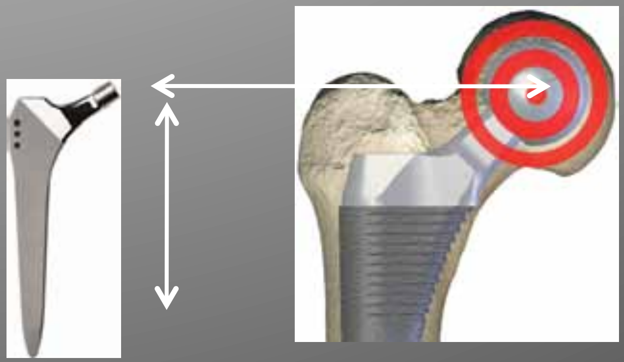
Eliminate Pain

- New Bearing Surface

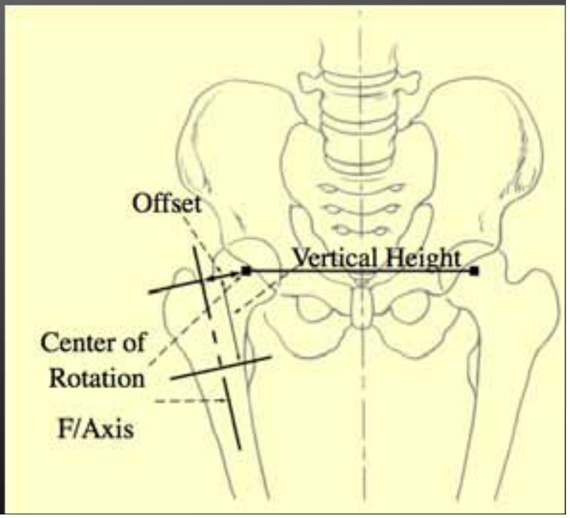
Restore Function

- Reproduce Hip Mechanics

1. Femoral Offset
2. Neck Length
3. Combined Version Angle



Difficult to adjust with/ monoblock stem



Challenge: Joint Stability takes precedent over desired leg length

Single biggest medical/legal problem in THA is leg length Cameron

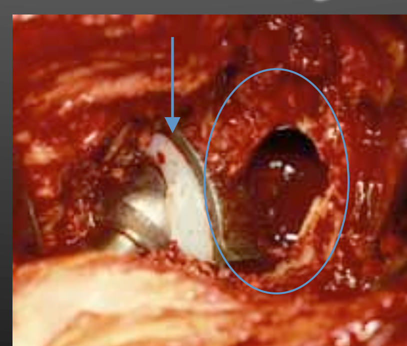
- Offset is limited with monoblock designs
- Modularity means versatility

Two Remaining Significant Problems in THA

#1 Dislocation

- Reports from 1-8%
- Higher in Posterior Approach
- Higher in Sm. Dia. Heads 22mm
- Higher in Revisions >20%

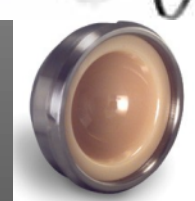
#2 Wear Debris/Lysis

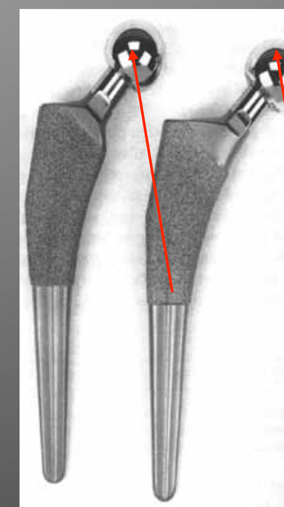


Proximal femoral cavity from polyethylene granuloma 4 yrs postop

Current Trends:

- Big Heads
- Navigation
- Constrained Sockets
- Increased Offset stems
- Hard on Hard Bearings





Dr. Amstutz
“ Despite a number of improvements in femoral Neck geometry and increasing femoral head sizes up to 36 mm, dislocation continues to be a significant problem after THA”

CURRENT DISLOCATION COSTS

Estimating a conservative 2% dislocation rate, there would be a corresponding 6,000 dislocated hips each year.

· Non-operatively treated - 4,500 (75%) - $6,000
Cost: relocation, brace, x-rays, rehabilitation

· Operatively treated - 1,500 (25%) - $25,000
Cost: operation, brace, and rehabilitation

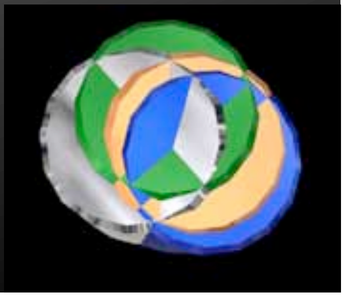
$6,000 x 4,500 = $27 million
$25,000 x 1,500 = $37.5 million

Total cost of dislocations per year in the United States. $64.5 million

"Wright Medical Web Site"

Modularity of Femoral Components

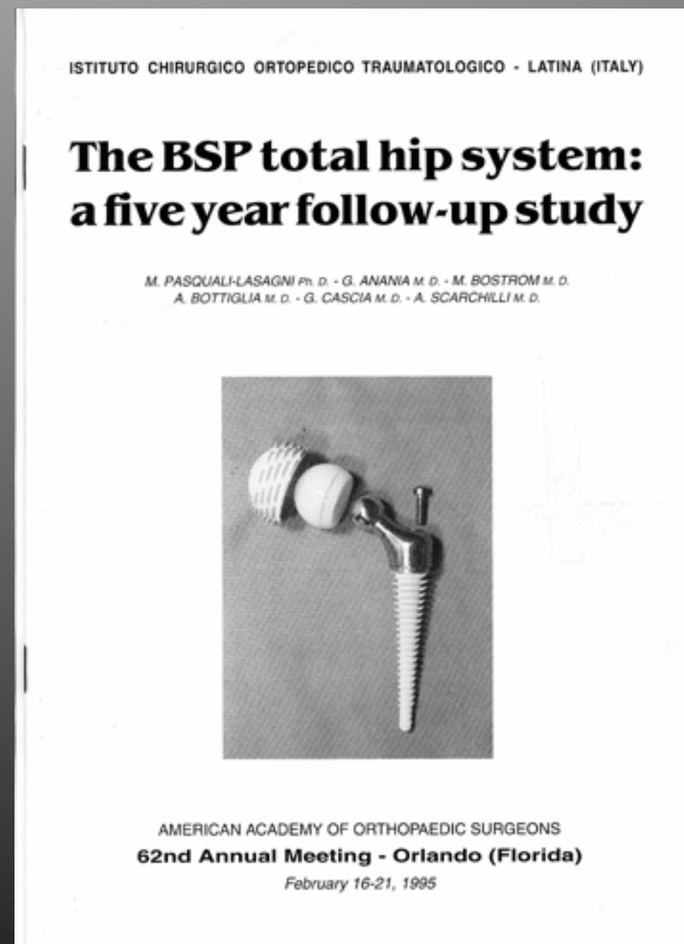
- Modularity or multi-piece stems are becoming commonplace in THA with virtually all implant companies offering one version or another.
- A sift from fit & fill to restoration of biomechanics



Modularity is not new

Proximal Modularity

Designed in the 1970's by Bousquet et al.
First reference:
39 Annual meeting of the CAOA 1983
Vol. 1, n 2 (15-28) 1985 Journal of
Orthopaedic Surgical Techniques



ISTITUTO CHIRURGICO ORTOPEDICO TRAUMATOLOGICO - LATINA (ITALY)

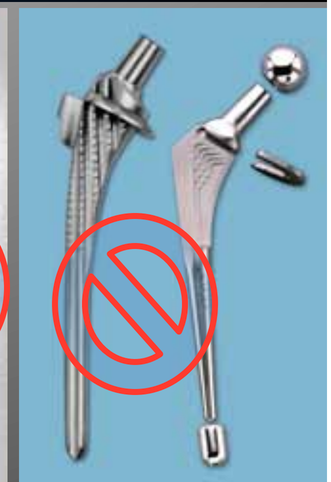
The BSP total hip system: a five year follow-up study

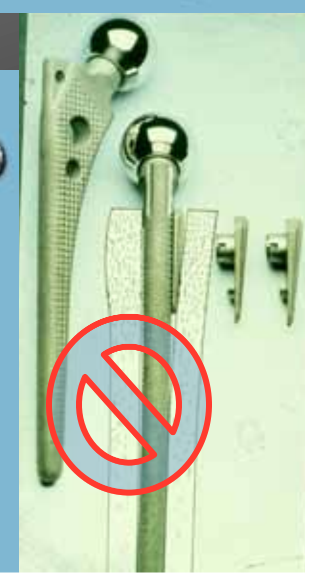
M. PASQUALI-LASAGNI Ph. D. - G. ANANIA M. D. - M. BOSTROM M. D.
A. BOTTIGLIA M. D. - G. CASCIA M. D. - A. SCARCHILLI M. D.

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
62nd Annual Meeting - Orlando (Florida)
February 16-21, 1995

Modular junctions are not equal in design, function or technique

- Many modular designs have come and gone
- Will clinical outcomes justify the cost





Examples
of modular junction failures

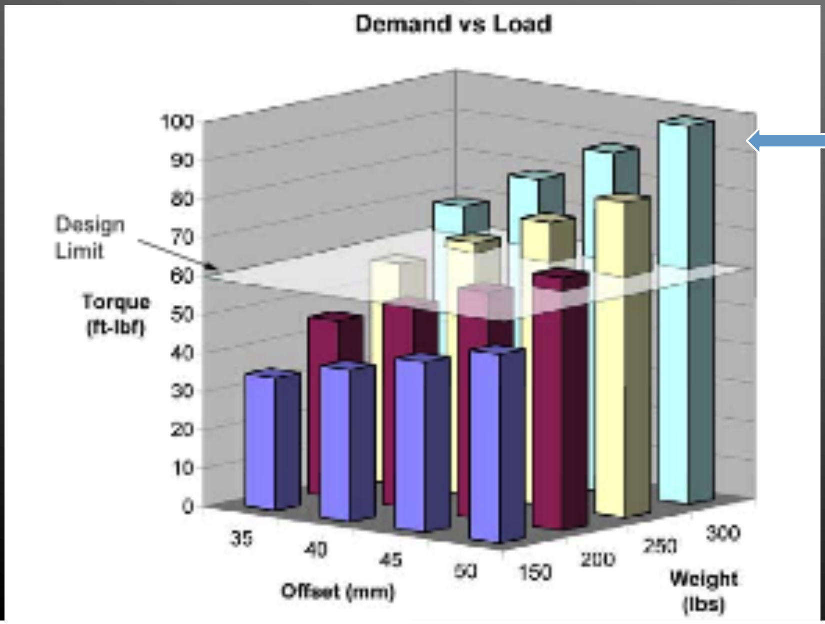
Being Fair
Monoblock stems also fail

All devices are subject to failure!

Modular junctions are not equal

Historical Torsional Loads have been underestimated

Intrinsic stability of tapers



95 ft-lbs/128.8 Nm

Old design

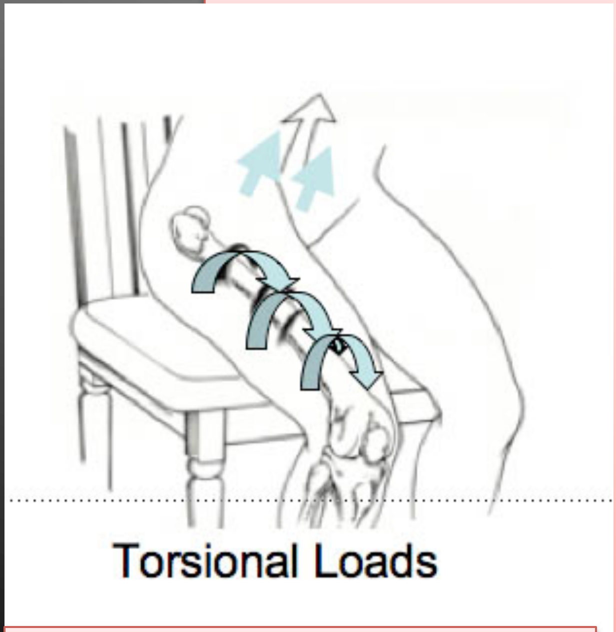
1984

Reported stem/ sleeve Slippage in undersized stems

Extrinsic stability of composite design

Concern

- Patient Related Activities and Biomechanical loads!

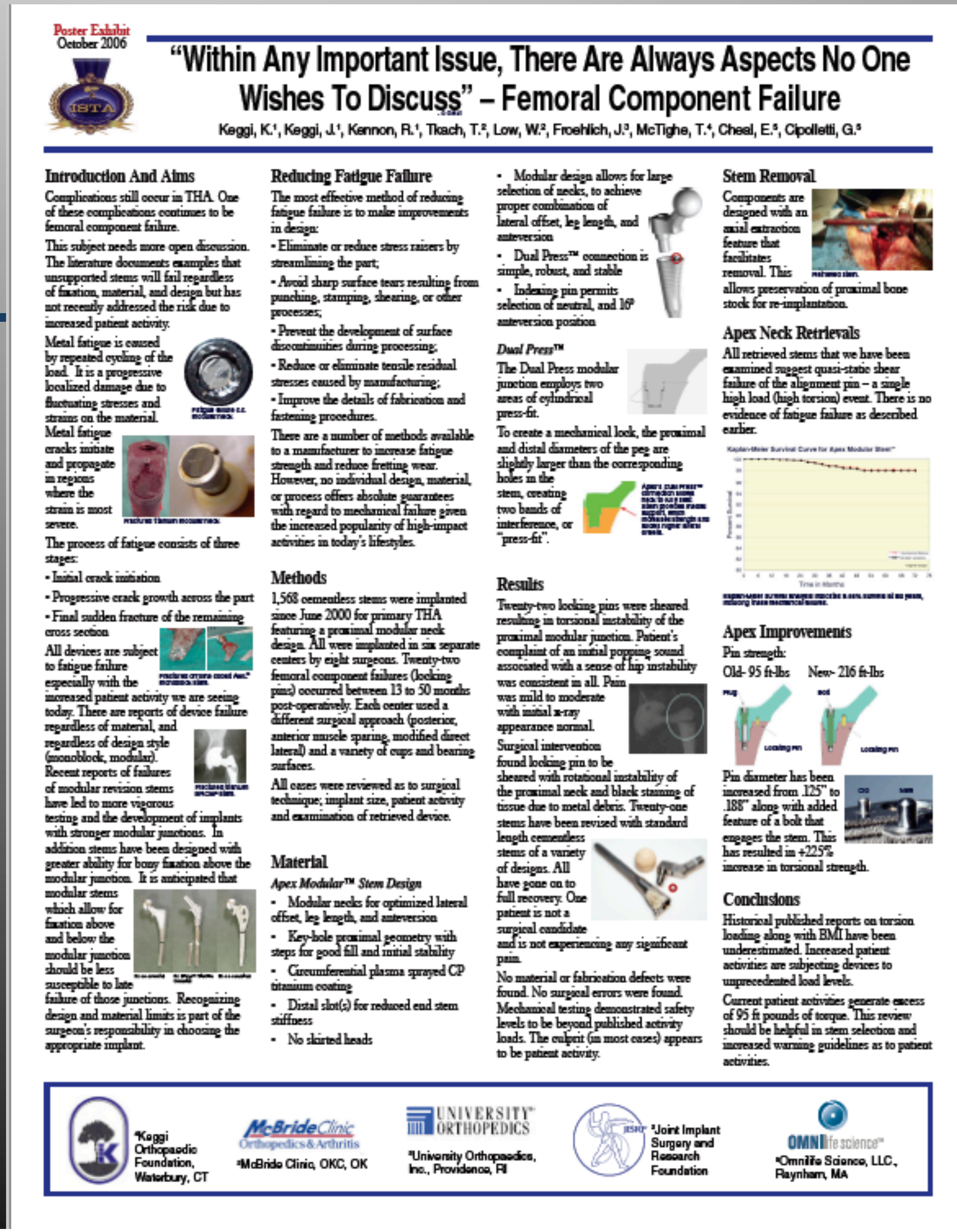


30-40Nm

12-23 Nm max.

30 Nm of torque needed to loosen an implant

- Femoral Component Failure is a concern both clinically and legally
- The more modular sites the more possible problems



Poster Exhibit
October 2006

"Within Any Important Issue, There Are Always Aspects No One Wishes To Discuss" – Femoral Component Failure

Keggi, K.[1], Keggi, J.[1], Kennon, R.[1], Tkach, T.[2], Low, W.[2], Froehlich, J.[3], McTighe, T.[4], Cheal, E.[5], Cipolletti, G.[5]

Introduction And Aims

Complications still occur in THA. One of these complications continues to be femoral component failure.

This subject needs more open discussion. The literature documents examples that unsupported stems will fail regardless of fixation, material, and design but has not recently addressed the risk due to increased patient activity.

Metal fatigue is caused by repeated cycling of the load. It is a progressive localized damage due to fluctuating stresses and strains on the material. Metal fatigue cracks initiate and propagate in regions where the strain is most severe.

The process of fatigue consists of three stages:
- Initial crack initiation
- Progressive crack growth across the part
- Final sudden fracture of the remaining cross section

All devices are subject to fatigue failure especially with the increased patient activity we are seeing today. There are reports of device failure regardless of material, and regardless of design style (monoblock, modular). Recent reports of failures of modular revision stems have led to more vigorous testing and the development of implants with stronger modular junctions. In addition stems have been designed with greater ability for bony fixation above the modular junction. It is anticipated that modular stems which allow for fixation above and below the modular junction should be less susceptible to late failure of those junctions. Recognizing design and material limits is part of the surgeon's responsibility in choosing the appropriate implant.

Reducing Fatigue Failure

The most effective method of reducing fatigue failure is to make improvements in design:
- Eliminate or reduce stress raisers by streamlining the part;
- Avoid sharp surface tears resulting from punching, stamping, shearing, or other processes;
- Prevent the development of surface discontinuities during processing;
- Reduce or eliminate tensile residual stresses caused by manufacturing;
- Improve the details of fabrication and fastening procedures.

There are a number of methods available to a manufacturer to increase fatigue strength and reduce fretting wear. However, no individual design, material, or process offers absolute guarantees with regard to mechanical failure given the increased popularity of high-impact activities in today's lifestyles.

Methods

1,568 cementless stems were implanted since June 2000 for primary THA featuring a proximal modular neck design. All were implanted in six separate centers by eight surgeons. Twenty-two femoral component failures (locking pins) occurred between 13 to 50 months post-operatively. Each center used a different surgical approach (posterior, anterior muscle sparing, modified direct lateral) and a variety of cups and bearing surfaces.

All cases were reviewed as to surgical technique; implant size, patient activity and examination of retrieved device.

Material

Apex Modular™ Stem Design
- Modular necks for optimized lateral offset, leg length, and anteversion
- Key-hole proximal geometry with steps for good fill and initial stability
- Circumferential plasma sprayed CP titanium coating
- Distal slot(s) for reduced end stem stiffness
- No skirted heads
- Modular design allows for large selection of necks, to achieve proper combination of lateral offset, leg length, and anteversion
- Dual Press™ connection is simple, robust, and stable
- Indexing pin permits selection of neutral, and 16° anteversion position

Dual Press™

The Dual Press modular junction employs two areas of cylindrical press-fit.

To create a mechanical lock, the proximal and distal diameters of the peg are slightly larger than the corresponding holes in the stem, creating two bands of interference, or "press-fit".

Results

Twenty-two locking pins were sheared resulting in torsional instability of the proximal modular junction. Patient's complaint of an initial popping sound associated with a sense of hip instability was consistent in all. Pain was mild to moderate with initial x-ray appearance normal.

Surgical intervention found locking pin to be sheared with rotational instability of the proximal neck and black staining of tissue due to metal debris. Twenty-one stems have been revised with standard length cementless stems of a variety of designs. All have gone on to full recovery. One patient is not a surgical candidate and is not experiencing any significant pain.

No material or fabrication defects were found. No surgical errors were found. Mechanical testing demonstrated safety levels to be beyond published activity loads. The culprit (in most cases) appears to be patient activity.

Stem Removal

Components are designed with an axial extraction feature that facilitates removal. This allows preservation of proximal bone stock for re-implantation.

Apex Neck Retrievals

All retrieved stems that we have been examined suggest quasi-static shear failure of the alignment pin – a single high load (high torsion) event. There is no evidence of fatigue failure as described earlier.

Apex Improvements

Pin strength:
Old- 95 ft-lbs New- 216 ft-lbs

Pin diameter has been increased from .125" to .188" along with added feature of a bolt that engages the stem. This has resulted in +225% increase in torsional strength.

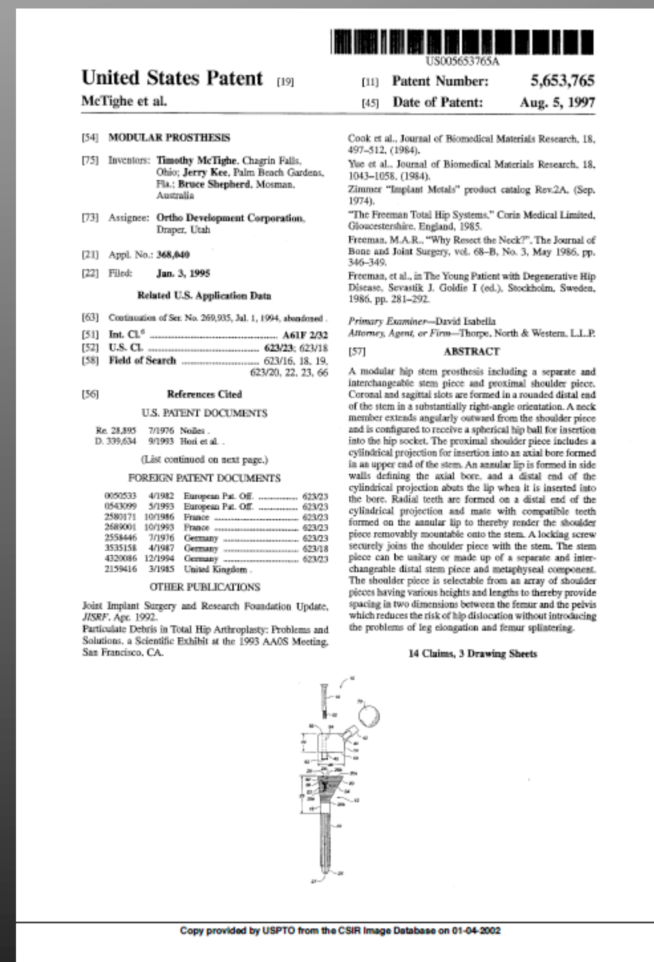
Conclusions

Historical published reports on torsion loading along with BMI have been underestimated. Increased patient activities are subjecting devices to unprecedented load levels.

Current patient activities generate excess of 95 ft pounds of torque. This review should be helpful in stem selection and increased warning guidelines as to patient activities.

[1]Keggi Orthopaedic Foundation, Waterbury, CT
[2]McBride Clinic, OKC, OK
[3]University Orthopaedics, Inc., Providence, RI
[4]Joint Implant Surgery and Research Foundation
[5]Omnilife Science, LLC., Raynham, MA

The Stability™ & Intrinsic™ designs were influenced by European Concepts



US005653765A

United States Patent [19]

McTighe et al.

[11] **Patent Number: 5,653,765**

[45] **Date of Patent: Aug. 5, 1997**

[54] **MODULAR PROSTHESIS**

[75] Inventors: **Timothy McTighe**, Chagrin Falls, Ohio; **Jerry Kee**, Palm Beach Gardens, Fla.; **Bruce Shepherd**, Mosman, Australia

[73] Assignee: **Ortho Development Corporation**, Draper, Utah

[21] Appl. No.: **368,040**

[22] Filed: **Jan. 3, 1995**

Related U.S. Application Data

[63] Continuation of Ser. No. 269,935, Jul. 1, 1994, abandoned.

[51] **Int. Cl.**^{6} **A61F 2/32**

[52] **U.S. Cl.** **623/23**; 623/18

[58] **Field of Search** 623/16, 18, 19, 623/20, 22, 23, 66

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Primary Examiner—David Isabella
Attorney, Agent, or Firm—Thorpe, North & Western, L.L.P.

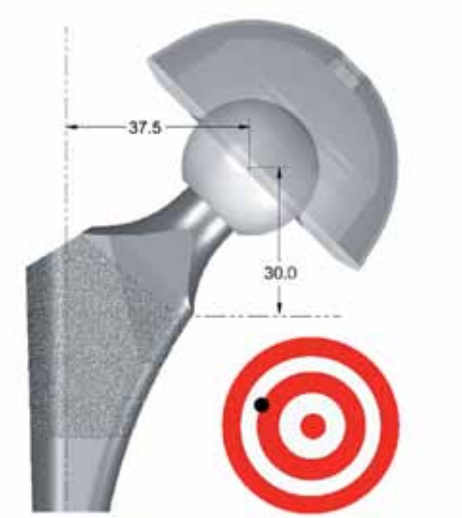
[57] **ABSTRACT**

A modular hip stem prosthesis including a separate and interchangeable stem piece and proximal shoulder piece. Coronal and sagittal slots are formed in a rounded distal end of the stem in a substantially right-angle orientation. A neck member extends angularly outward from the shoulder piece and is configured to receive a spherical hip ball for insertion into the hip socket. The proximal shoulder piece includes a cylindrical projection for insertion into an axial bore formed in an upper end of the stem. An annular lip is formed in side walls defining the axial bore, and a distal end of the cylindrical projection abuts the lip when it is inserted into the bore. Radial teeth are formed on a distal end of the cylindrical projection and mate with compatible teeth formed on the annular lip to thereby render the shoulder piece removably mountable onto the stem. A locking screw securely joins the shoulder piece with the stem. The stem piece can be unitary or made up of a separate and interchangeable distal stem piece and metaphyseal component. The shoulder piece is selectable from an array of shoulder pieces having various heights and lengths to thereby provide spacing in two dimensions between the femur and the pelvis which reduces the risk of hip dislocation without introducing the problems of leg elongation and femur splintering.

14 Claims, 3 Drawing Sheets

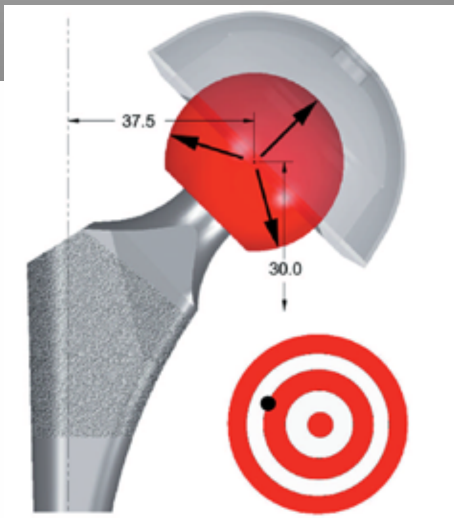
AAOS 2006 Scientific Exhibit
Target Restoration

By: Tom Tkach, MD; Warren Low, MD; George B. Cipolletti, MS;
Timothy McTighe, Dr. H.S. (hc)

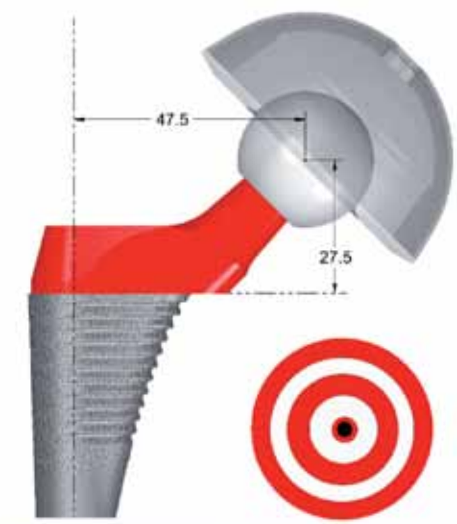


Instability - What should be done? Trail reduction demonstrates joint instability with slight increased leg length.

Modular Heads allow length adjustment, unfortunately increase head length increases leg length.



Big Heads! Theoretically, a bigger head is more stable... At the extremes of motion when the neck impinges In this case, intrinisic stability is unchanged (Head center stays the same).



Biomechanical Solution Modular Neck! Add offset for joint stability reduce length for proper gait.

- **This proximal modular design permits the independent selection of offset, version and leg length.**

Head Center Data

2,000 Proximal modular stems implanted 2001-2005

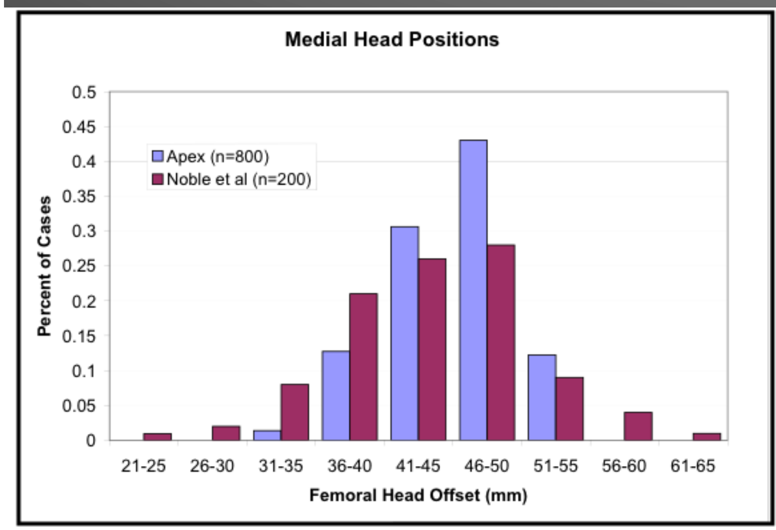
AAOS 2006 Scientific Exhibit

957 THA's Performed (2001-2005)

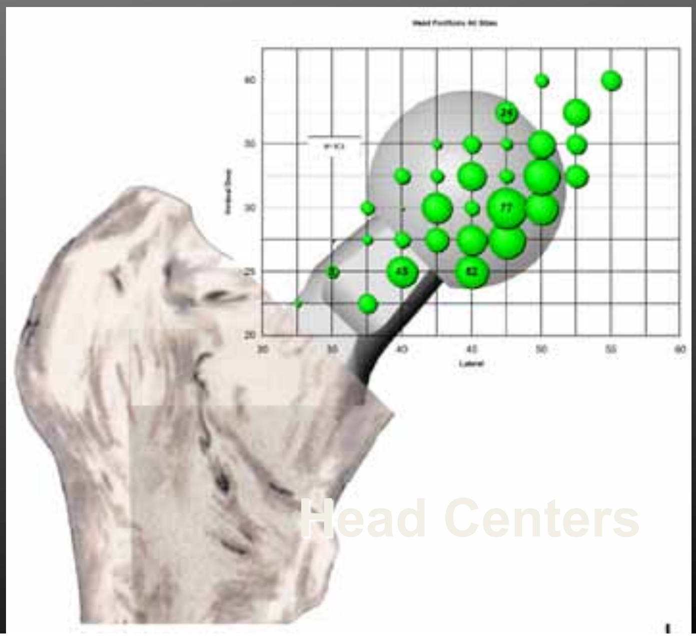
842 Primary/115 Revisions

Data collected on 800

- Center of bubble /head location
- Dia. Indication of frequency
- Several values are listed



1 Noble, Philip C., M.S., Alexander, Jerry W. B.S. et al, "The Anatomic Basis of Femoral Component Design", Clinical Orthopedics and Related Research, Number 235, October, 1988.



Version Position
Combined Version should be the focus

Typical 15 - 40° more ROM with neck anteverted.

Neutral neck position.

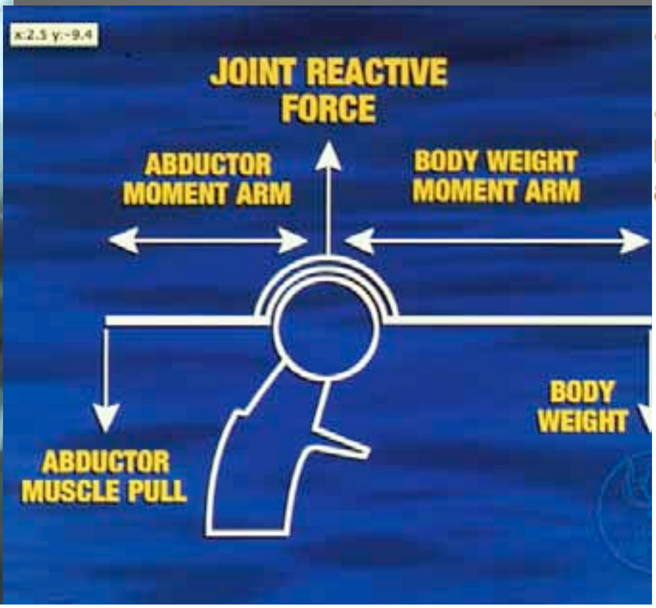
15° anteversion.

Aneterved neck used 18 times in the first 200 cases.

Femoral Offset

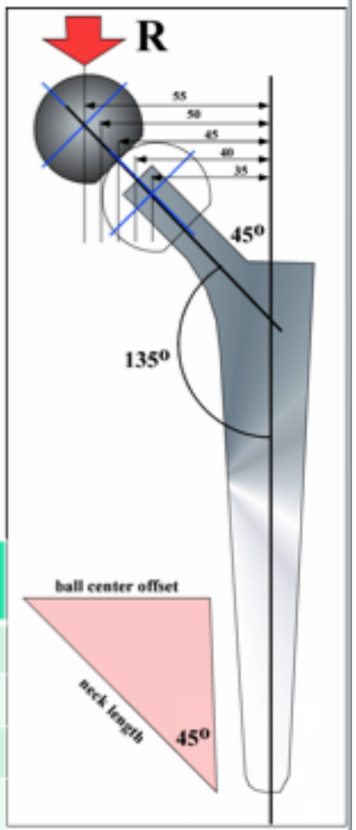
(fatigue concern - all devices are subject to failure)

- >Offset (reduces) hip reaction forces
- Increased offset increases torsional loads
- Increased offset increases bending moment of implants

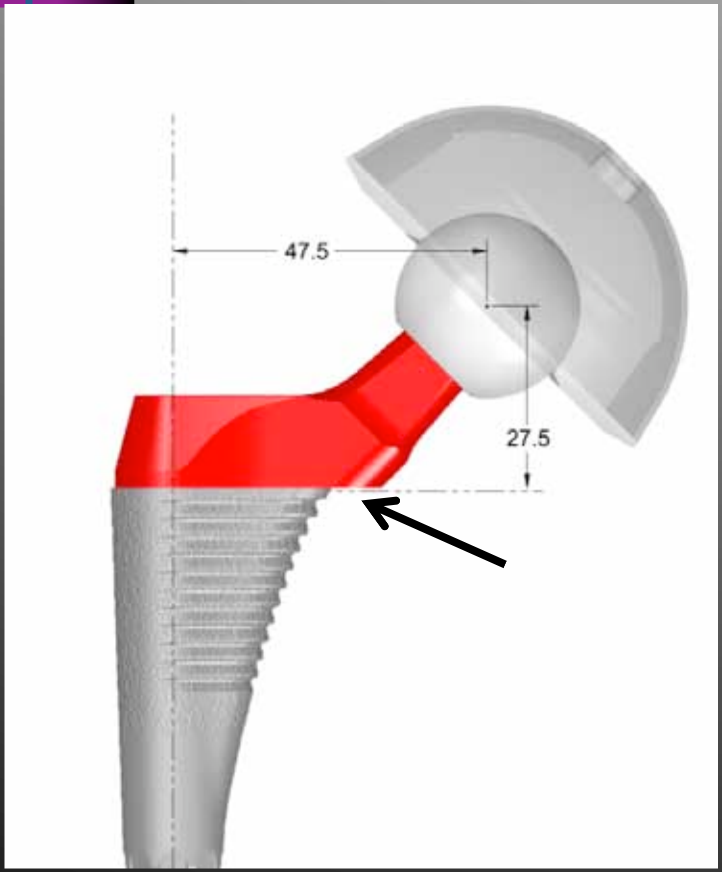


•8% per 1mm increase in true lateral ball-center offset
•6% per 1mm increase with the ball's neck-length size adjustment.

offset	Neck-length	Nm
35 mm	49.50	84
40 mm	56.58	96
45 mm	63.65	108
50 mm	70.72	120
55	77.79	132



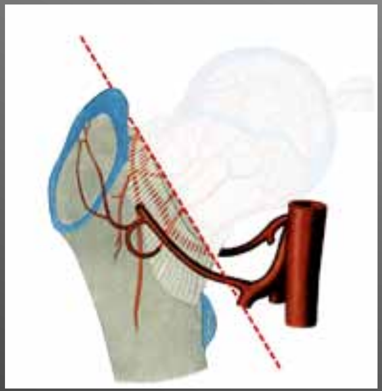
Femoral Offset Concerns

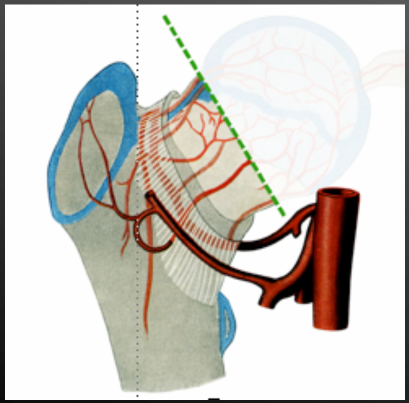


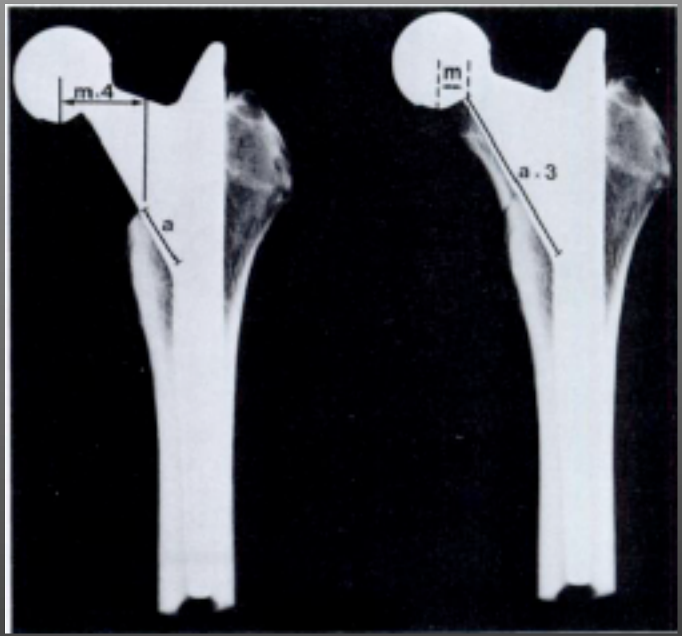
One way of reducing implant concerns is by Design. Broad surface contact.

Another way by design
Save the neck

- The varus-turning moment increases by a factor of 4 when the neck is resected

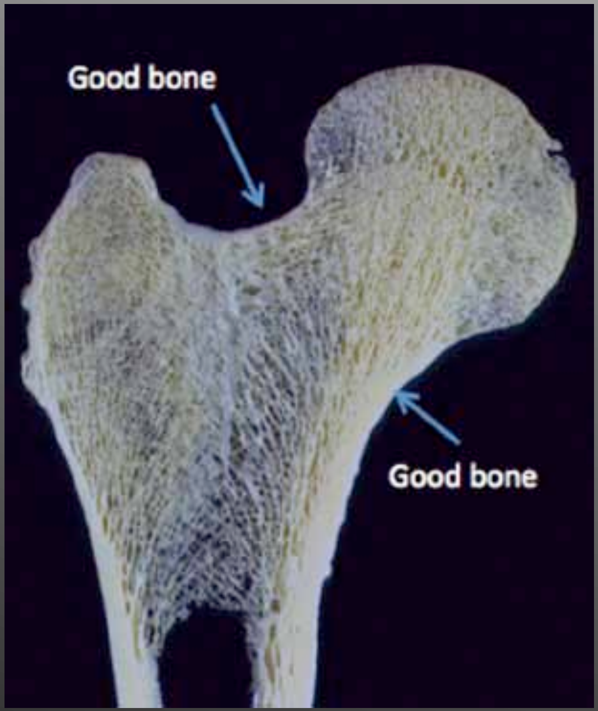


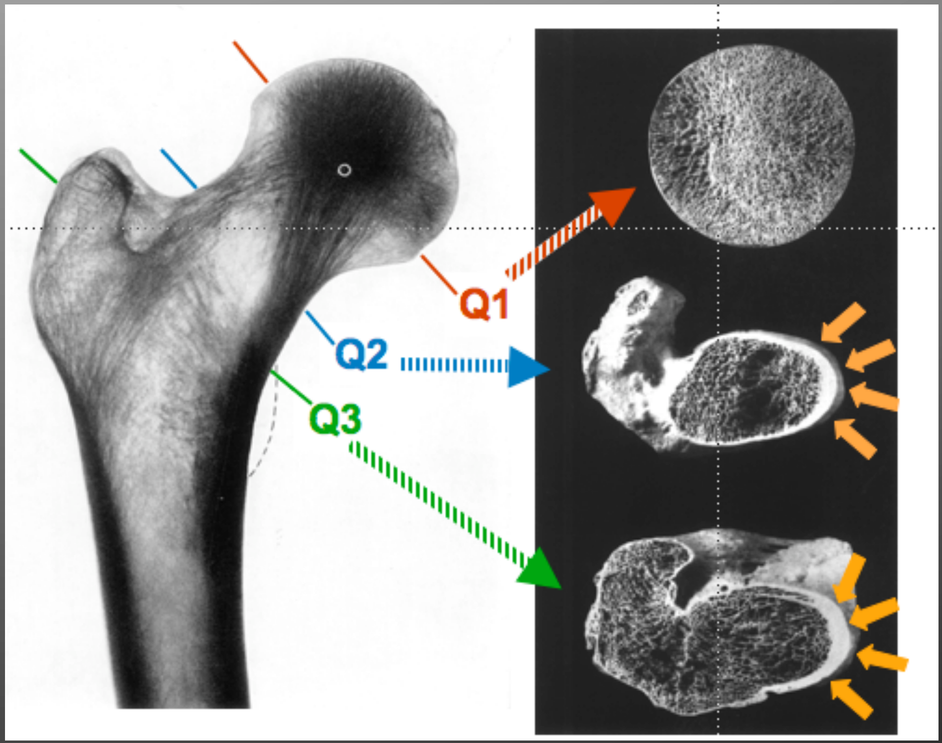




Topic For Debate
Why Resect The Neck?
M.A. R. Freeman JBJS 1984

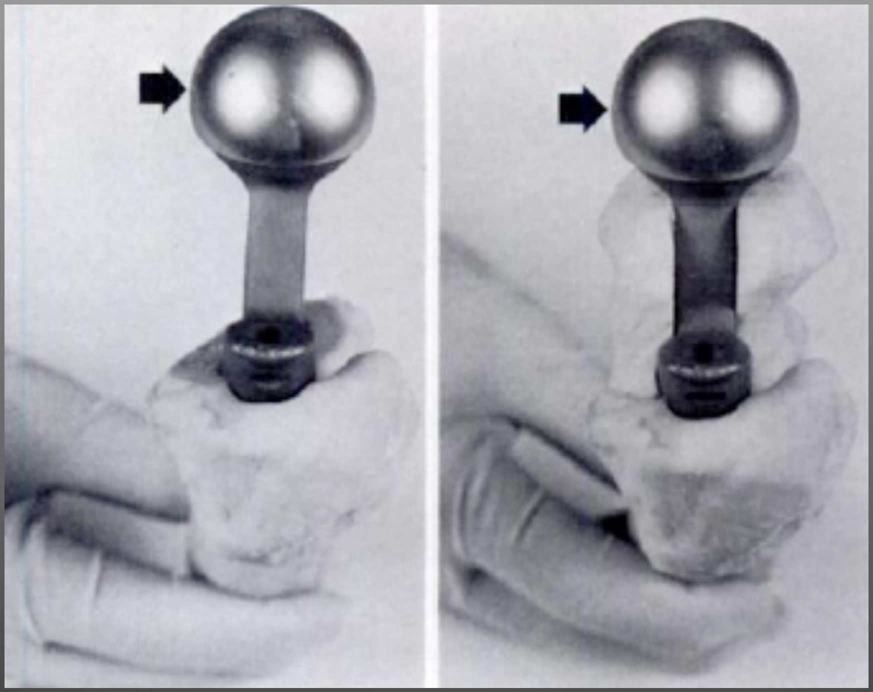
Save the Architecture





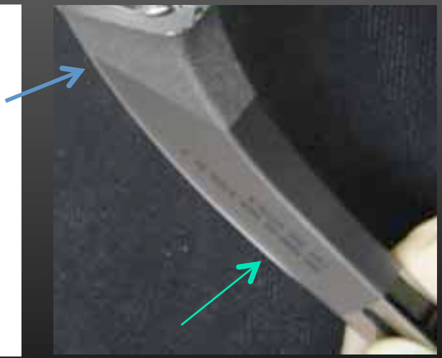
Torsional Resistance

A/P directed resultant force



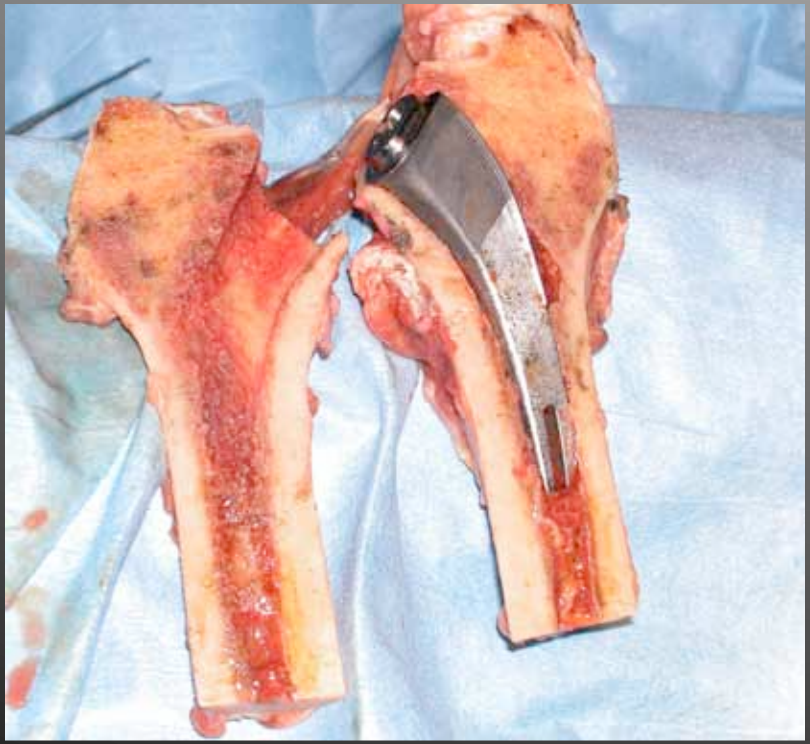
With the neck resected this force generates significant torsional moment on the device which is resisted by shear at the stem/bone interface.

Which do you think has better torsional stability?

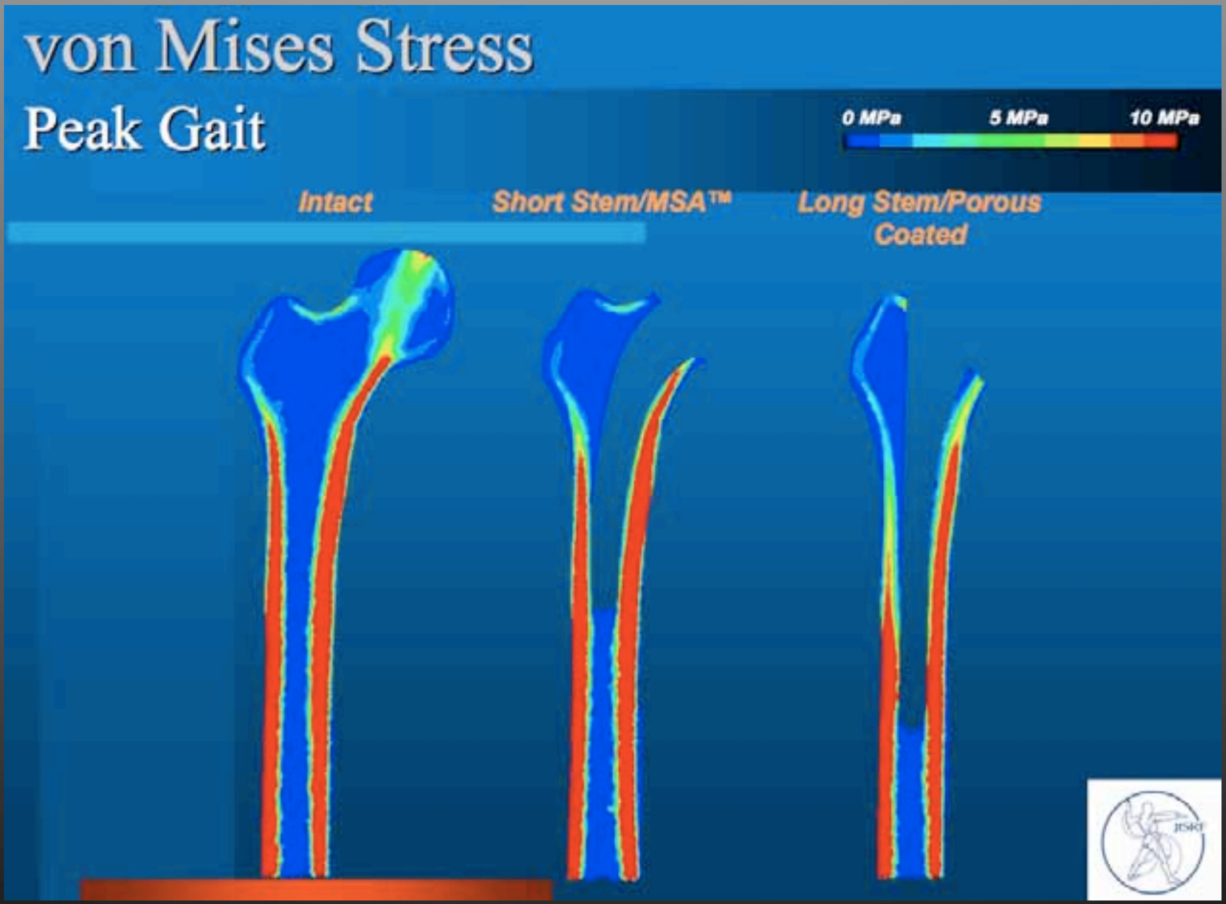


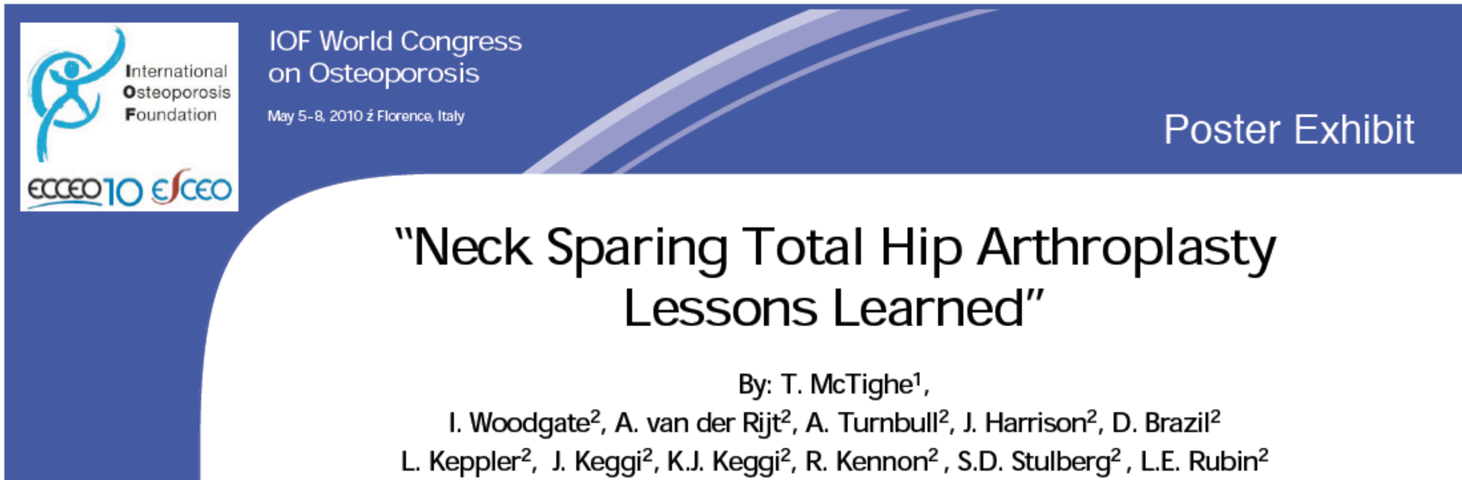
Curved trapezoid shape with/T back

Persevering what we can by design & technique

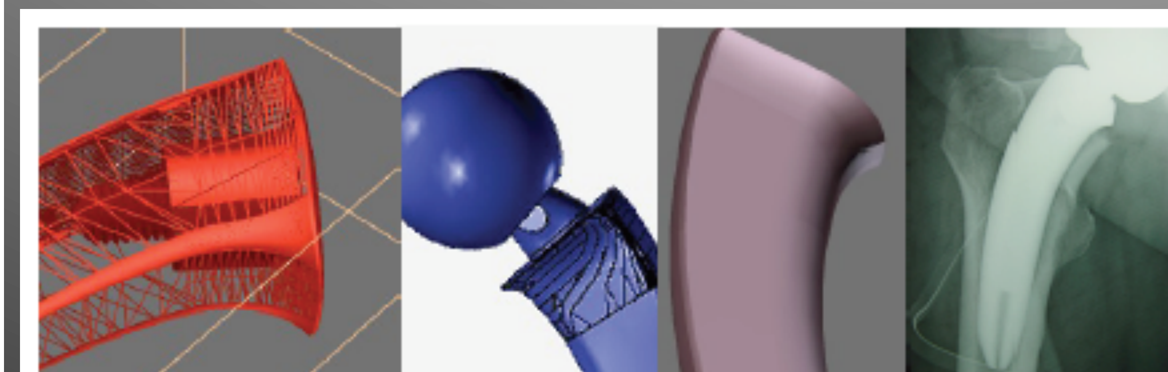


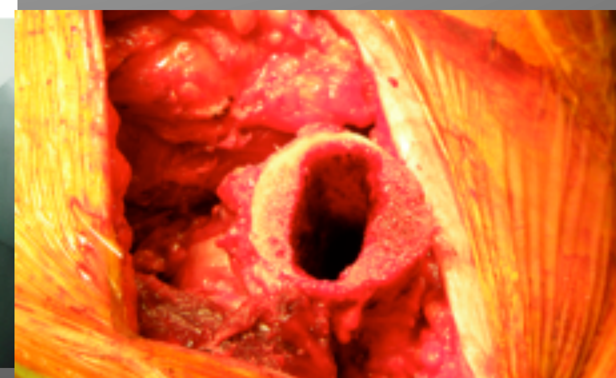
FEA Modeling





Prof. K. Keggi, MD
Presented in
Florence, Italy





Novel: proximal conical flair loads the medial

Posterior approach **Anterior approach**

38 yr old female

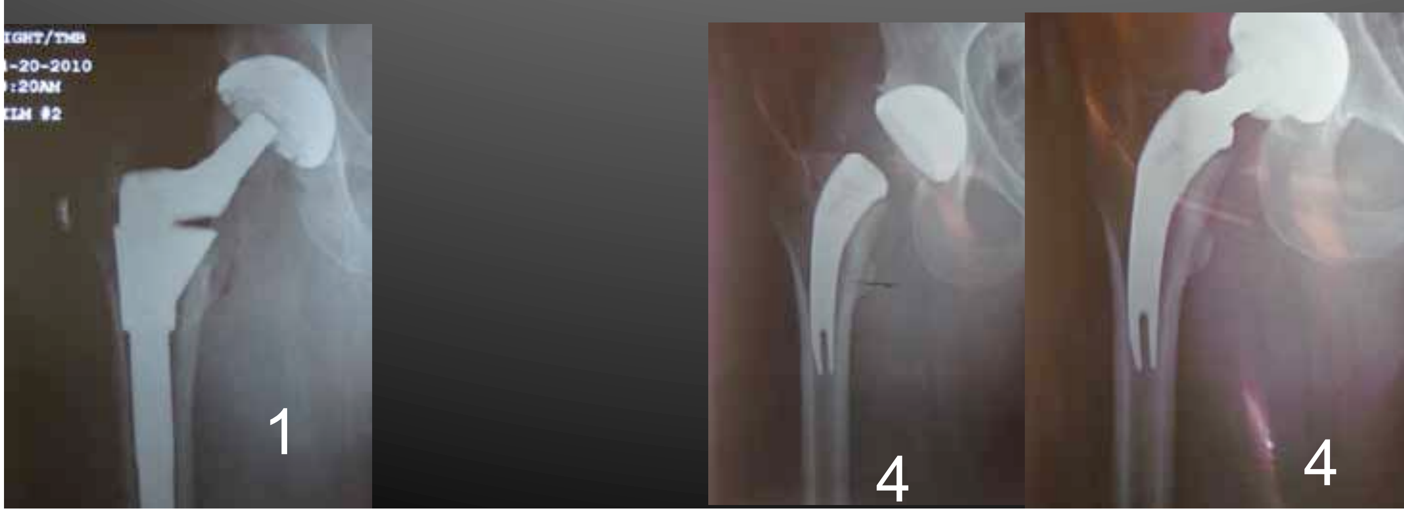
auto / injured at 16 in 1987

comminuted acetabular fx & femoral shaft fx.

Dr. Charles Bryant trial rasp in place

Anterior Approach

The need and use of modularity example of surgical day for Lou Keppler, MD, Cleveland, Ohio



Modular Designs Small Incisions

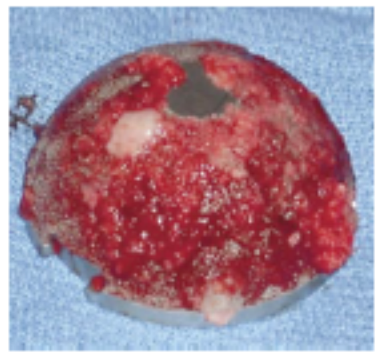
- Works for all incisions even small anterior "Keggi" approach

By L. Keppler, MD and T. McTighe, Dr. H.S. (hc)

- 3 **Case Report on Proximal Modularity**

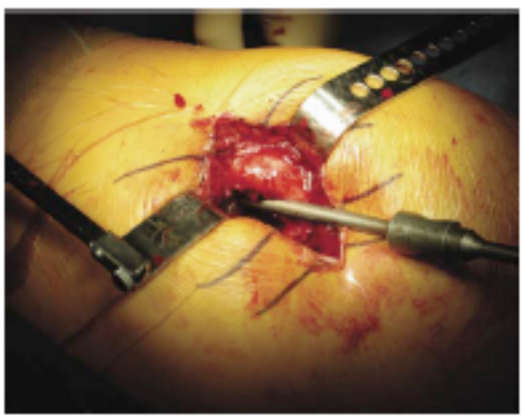
MoM Cup Spinout

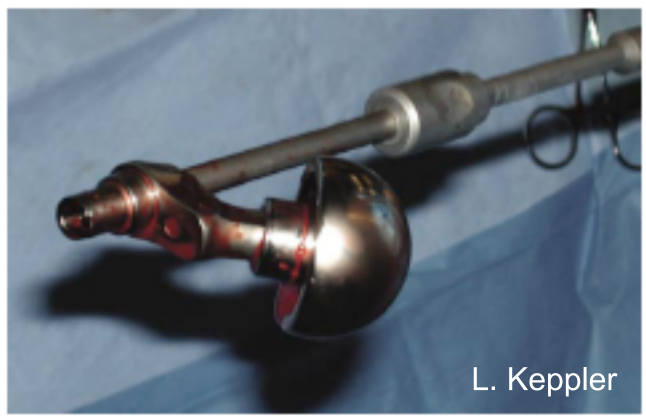
Explant™ Tool



MoM cup removal

Dual Press™ Modular neck

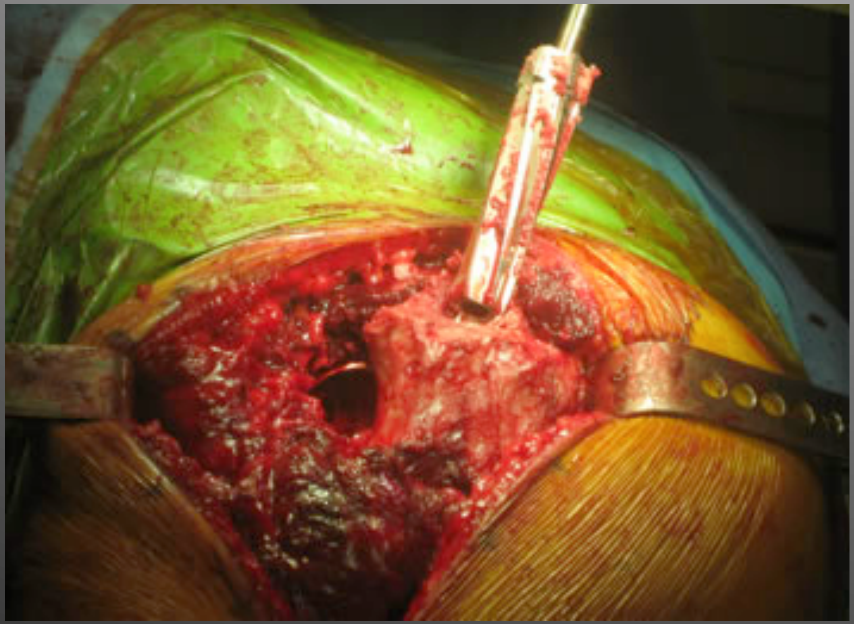




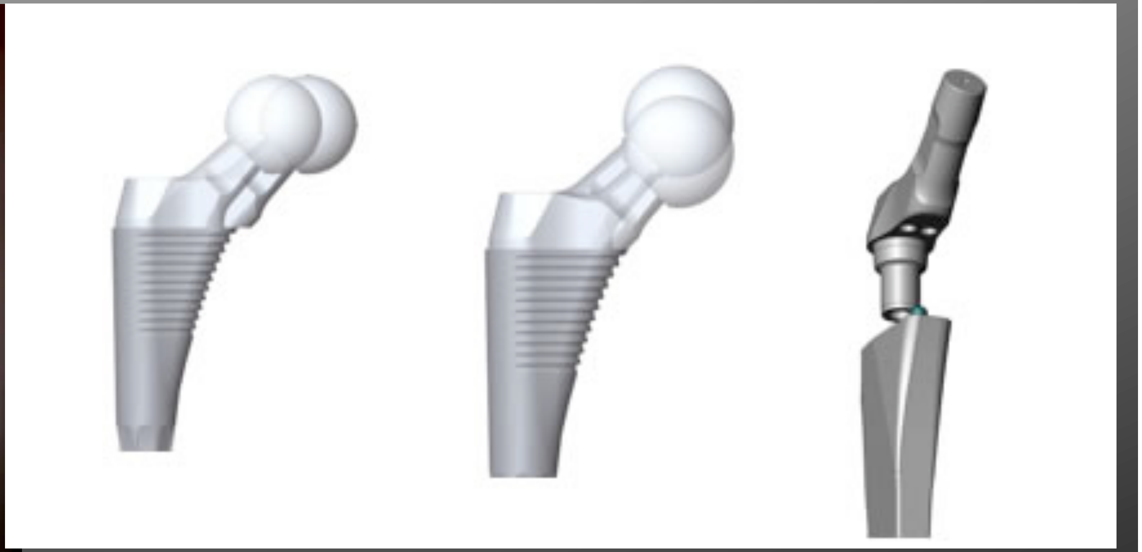
Was effective in all three cases!

Dr. Russ Nevins
18 yr old fusion takedown

Technique



Patient is happy and doing well @ 12 months



There is a role for modularity!

AAOS Scientific Exhibit 2006 • Chicago, IL

The Role of Modularity in Primary THA - Is There One?

By Louis Keppler, M.D.*, Hugh U. Cameron, MB, ChB, FRCS§, Timothy McTighe, Ph.D. (hc)Δ

* Horizon Orthopedic, Cleveland, OH

§ Sunnybrook & Women's Orthopaedic & Arthritis Institute, Toronto, Ontario

Δ Joint Implant Surgery and Research Foundation, 17321 Buckthorne Drive, Chagrin Falls, OH 44023, 440-543-0347 • www.jisrf.org

Introduction

Modularity or multi-piece stems are becoming commonplace in hip revision surgery[6,13,15,17,19,21] with virtually all implant companies offering one version or another. The role of modularity would therefore seem to be firmly established for revision, but what of primary cases?[8,11]

This study is a follow-up to previous work with a further ten years of cases reviewed. The real question we face does the benefit of modularity pay higher dividends than the potential risk factors. We believe this review will provide guidance for others surgeons to aid in their decision making process.

For almost two decades the two senior authors have been using a proximally modular stem in primary cases. The S-Rom® stem has

The Role of Modularity in THR

Modular Heads

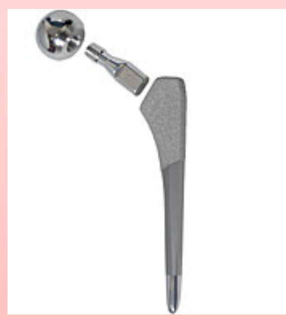
Modular means that the stem has 2 or more parts which can be joined. Does that means any stem with a modular head is a modular stem? Not in today's definition. This exhibit is limited to the femoral side and includes two or more modular parts.[7]

Modular Stem History

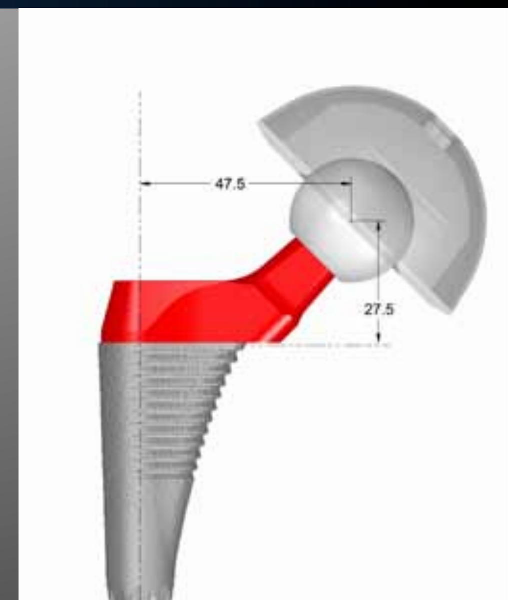
Modular stems have a long history staring with McBride in 1948 that utilized a threaded femoral component publishing his first account in JBJS in 1952. This was followed in 1978 by Bousquet and Bornand with the development of a proximal modular stem that featured a proximal body that

Modularity offers significant benefits but you need to know its limits!

- **Improved modular designs appears to have addressed many of these concerns but do we know its limits?**



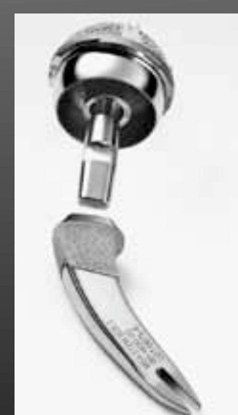
Second Generation “Dual press™” design 216 ft-lbs./292.8 Nm
Pin larger and stronger



Discussion

- Restoration of normal joint mechanics on a consistent basis is improved with modular designs.
- Provides for intra-operative fine tuning of biomechanics without disruption of implant bone interface.
- Provides for increased exposure to socket in revisions.
- Provides intra-operative options in case of dislocations.
- Significant number of small (10mm/11.5mm) stems required > 45mm offsets.




Conclusion

- The head center data suggest reconstruction benefits from the availability of many head centers for each stem size.
- Proximal modular design allows for restoration of proper soft tissue tension and joint biomechanics without disruption of implant interfaces
- New tissue sparing implant designs are emerging and hold significant promise

We are encouraged and remain enthusiastic about the features and benefits of proximal modularity.