Design Consideration for Modular Stems

by

Timothy McTighe, Dr. H.S. (hc) Executive Director

Joint Implant Surgery & Research Foundation

Chagrin Falls, Ohio

* Acknowledgement of support from many surgeons over the years that are part of JISRF and our on going clinical/ surgical research.

RLO*: Charleston

Joint Replacement Surgery 2010, *May 6-7, 2010*

Charleston Place Hotel Charleston, South Carolina

**** Real Life Orthopaedics***

Remember the Goals of THA

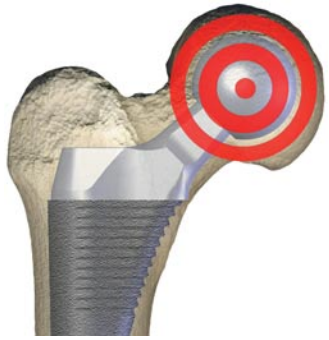
Eliminate Pain

- New Bearing Surface

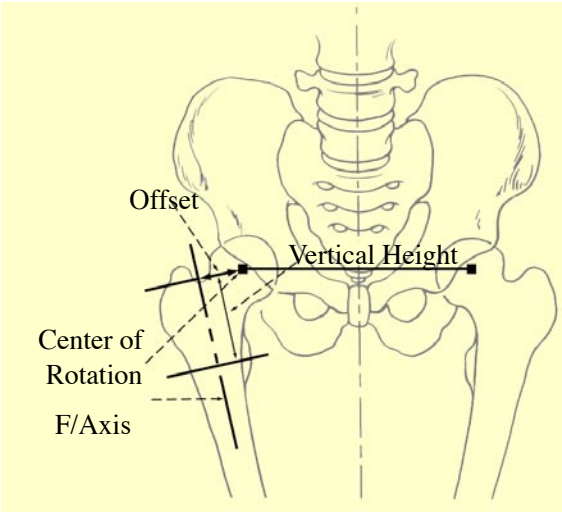
Restore Function

- Reproduce Hip Mechanics

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

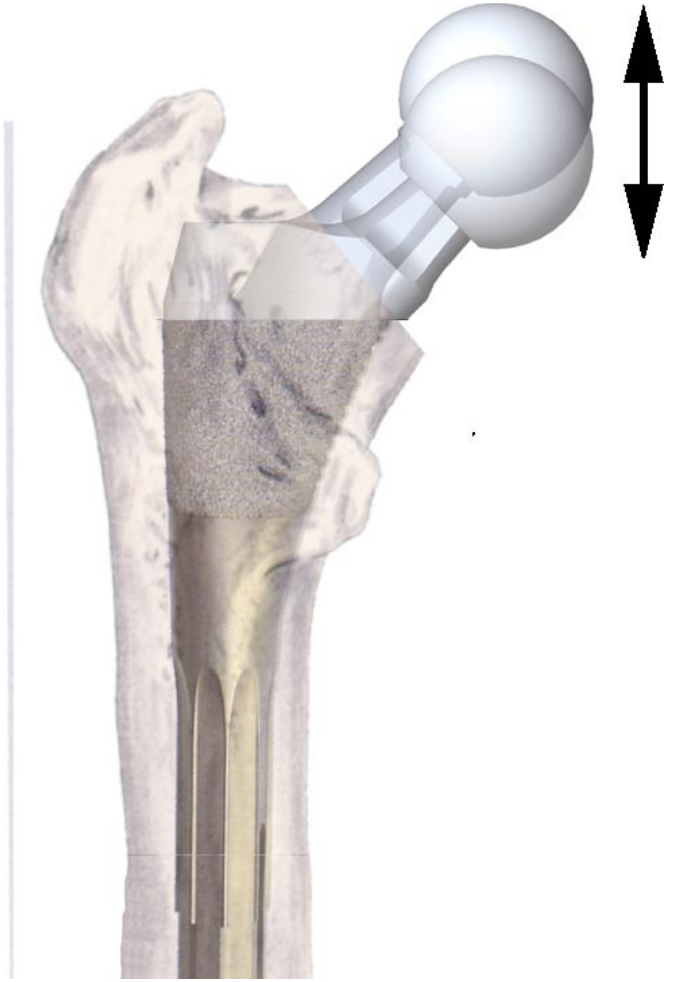


Difficult to adjust w/ monoblock stem



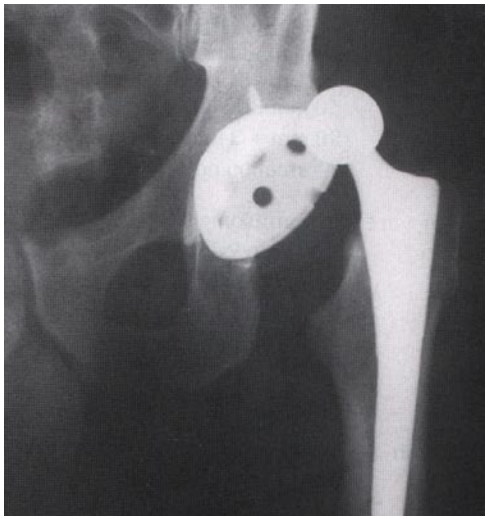
Challenge: Joint Stability takes precedent over desired leg length

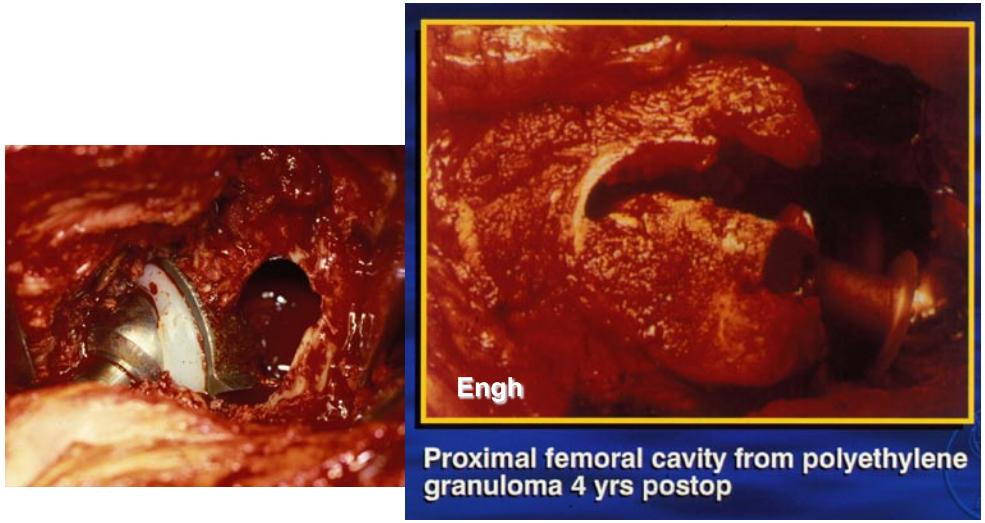
Single Biggest Legal Problem (Cameron)



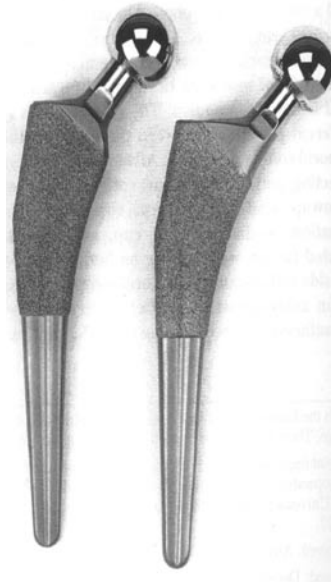
#1 Dislocation

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





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



Dr. Amstutz "Despite a number of improvements in femoral stem neck geometry and increasing femoral head sizes up to 36mm, 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"

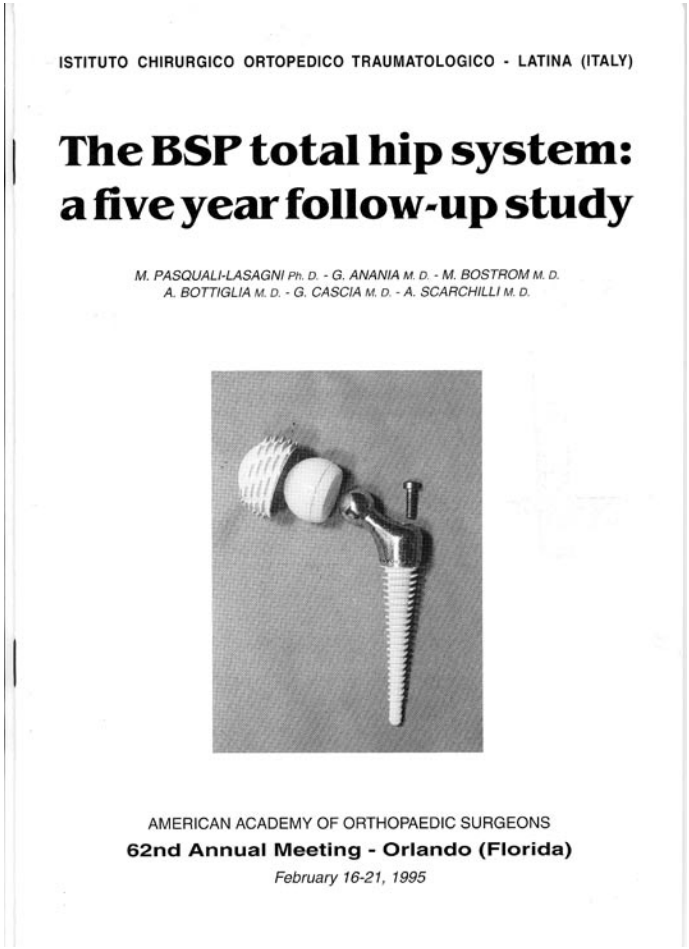
Modularity of Femoral Components

- Modularity or multi-piece stems are becoming commonplace in THA with virtually all implant companies offering one version or another.

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

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

[56] **References Cited**

U.S. PATENT DOCUMENTS

Re. 28,895	7/1976	Noiles .	
D. 339,634	9/1993	Hori et al. .	

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0050533	4/1982	European Pat. Off.	623/23
0543099	5/1993	European Pat. Off.	623/23
2580171	10/1986	France	623/23
2689001	10/1993	France	623/23
2558446	7/1976	Germany	623/23
3535158	4/1987	Germany	623/18
4320086	12/1994	Germany	623/23
2159416	3/1985	United Kingdom .	

OTHER PUBLICATIONS

Joint Implant Surgery and Research Foundation Update, *JISRF*, Apr. 1992.

Particulate Debris in Total Hip Arthroplasty: Problems and Solutions, a Scientific Exhibit at the 1993 AAOS Meeting, San Francisco, CA.

Cook et al., Journal of Biomedical Materials Research, 18, 497–512, (1984).

Yue et al., Journal of Biomedical Materials Research, 18, 1043–1058, (1984).

Zimmer "Implant Metals" product catalog Rev.2A, (Sep. 1974).

"The Freeman Total Hip Systems," Corin Medical Limited, Gloucestershire, England, 1985.

Freeman, M.A.R., "Why Resect the Neck?", The Journal of Bone and Joint Surgery, vol. 68–B, No. 3, May 1986, pp. 346–349.

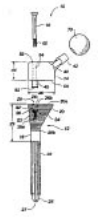
Freeman, et al., in The Young Patient with Degenerative Hip Disease, Sevastik J. Goldie I (ed.), Stockholm, Sweden, 1986, pp. 281–292.

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

[57] **ABSTRACT**

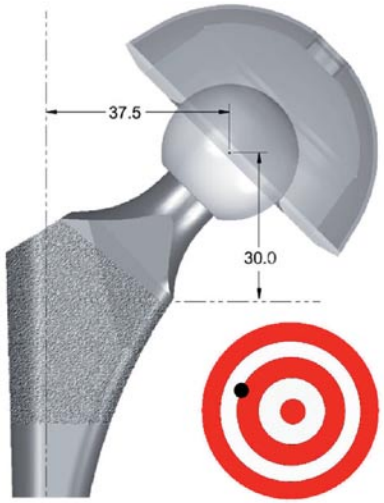
A modular hip stem prosthesis including a separate and interchangeable stem piece and proximal shoulder piece. Coronal and sagittal slots are formed in a rounded distal end of the stem in a substantially right-angle orientation. A neck member extends angularly outward from the shoulder piece and is configured 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

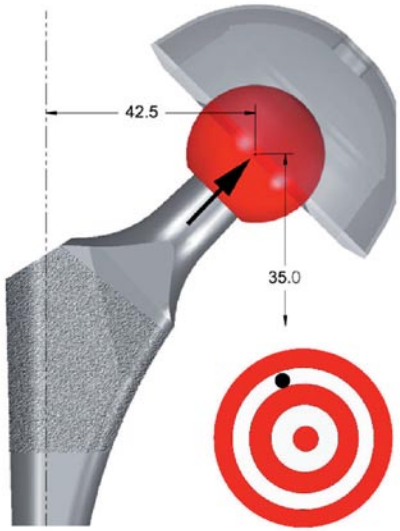


AAOS 2006 Scientific Exhibit
Target Restoration

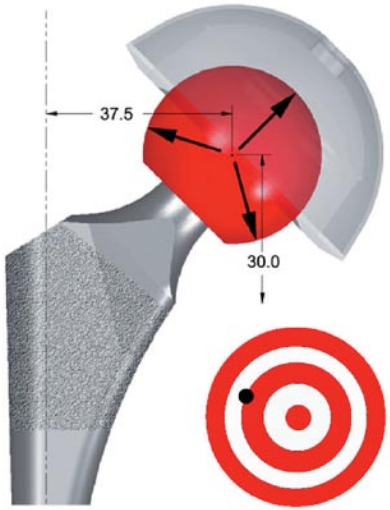
By: Tom Tkach, MD; Warren Low, MD; George B. Cipolletti, MS;
Timothy McTighe, Dr. H.S. (hc)



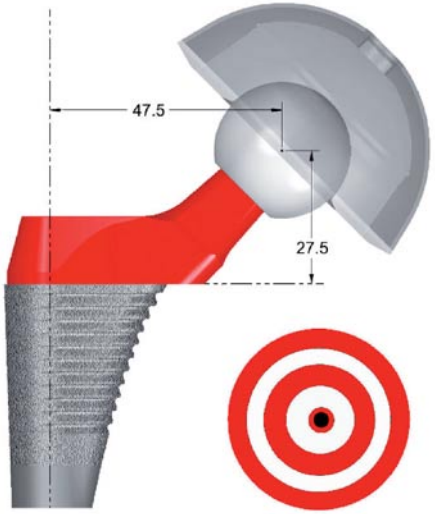
Instability - What should be done? Trail reduction demonstrates joint instability with slight increased leg length.



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

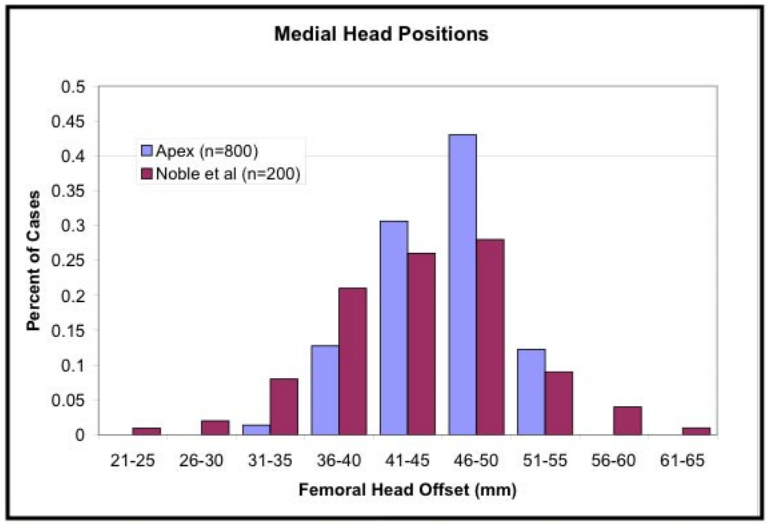
AAOS 2006 Scientific Exhibit

957 THA's Performed (2001-2005)

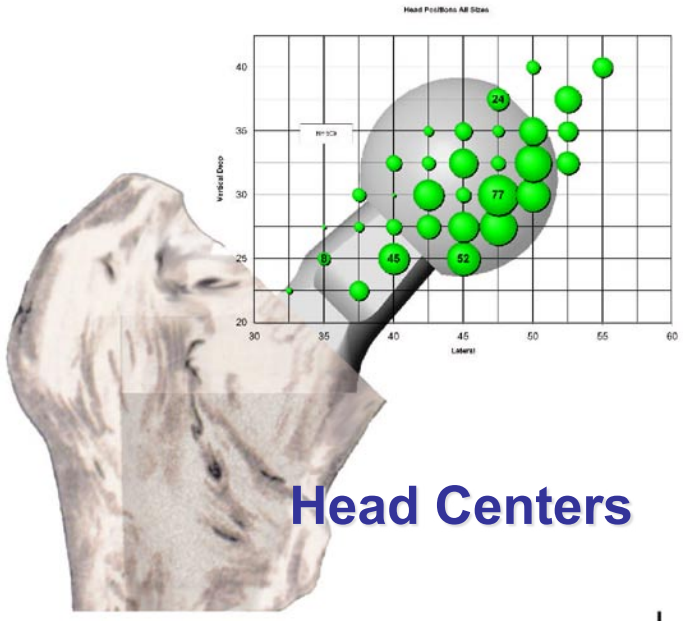
842 Primary/115 Revisions

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.



Head Centers

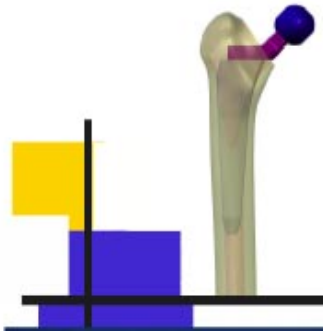
Version Position

Typical 15 - 40° more ROM with neck anteverted.

Neutral neck position.

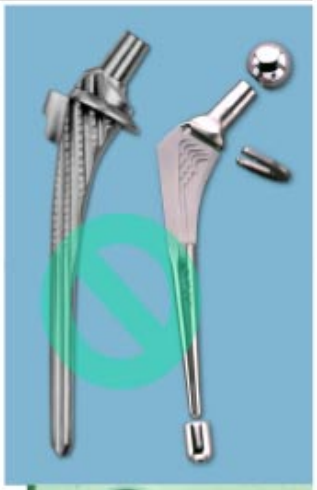
15° anteversion.

Aneterved neck used 18 times in the first 200 cases.



Modular junctions are not equal in design, function and technique

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



Concern

- Patient Related Activities and Biomechanical loads!

Torsional Loads

12-23 Nm max.

30-40Nm

30 Nm of torque needed to loosen an implant

- Femoral Component Failure is a Concern
- Both clinical and Medical/Legal

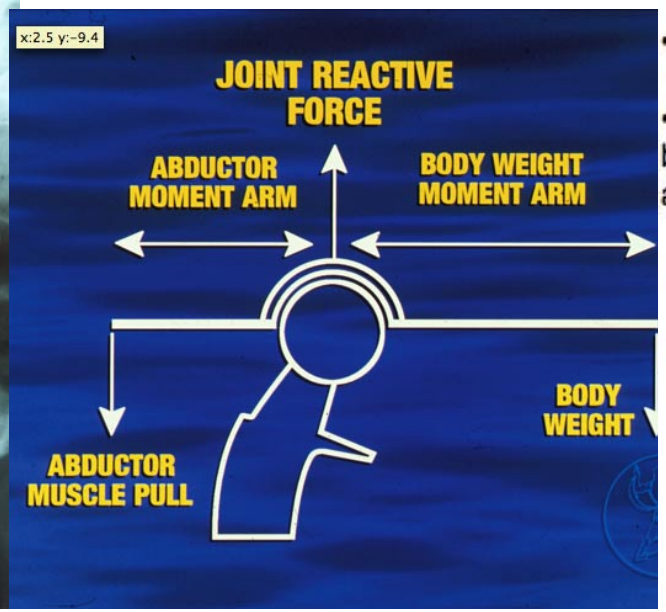
- The more modular sites the more possible problems

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

Femoral Offset

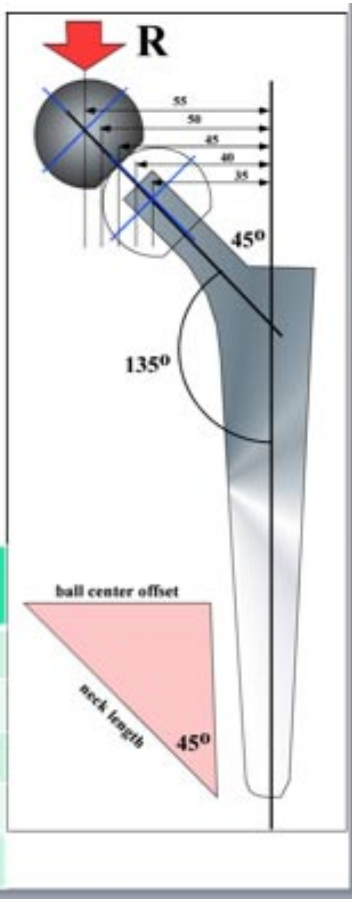
(fatigue concern - all devices are subject to failure)

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



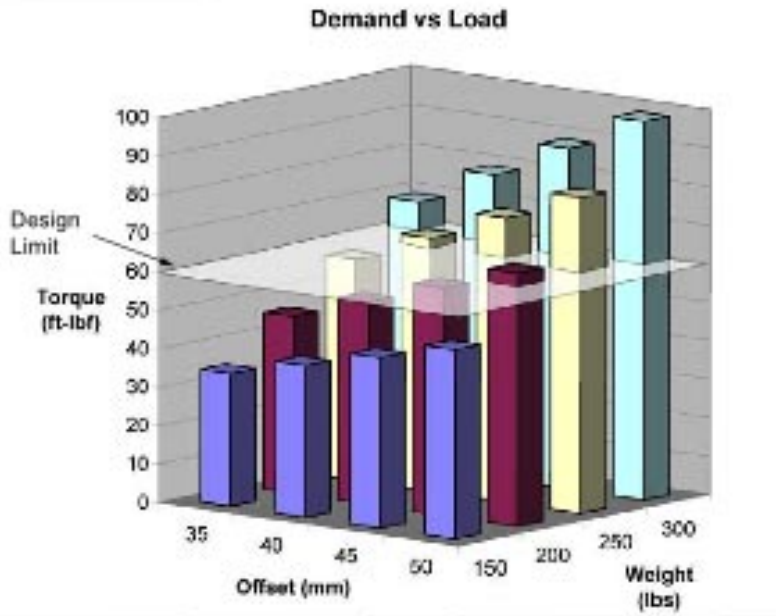
•8% per 1mm increase in true lateral ball-center offset
•6% per 1mm increase with the ball's neck-length size adjustment.

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



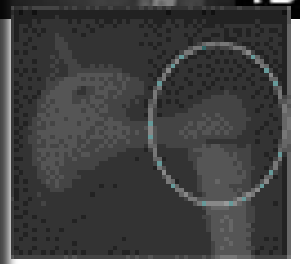
Modular junctions are not equal

Intrinsic stability of tapers

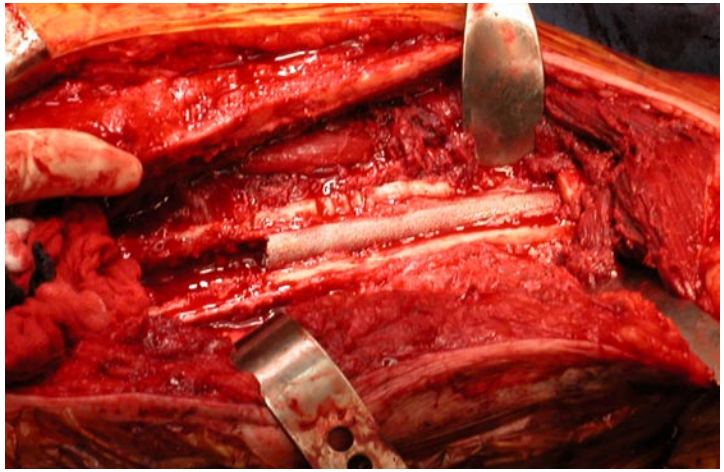


Extrinsic stability of composite design

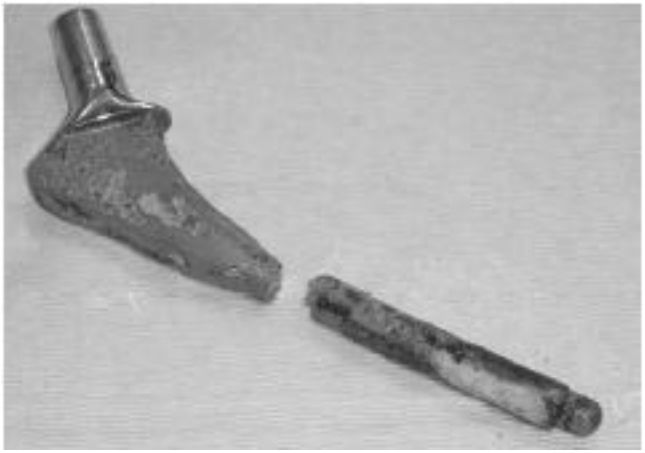
Examples
of modular junction failures



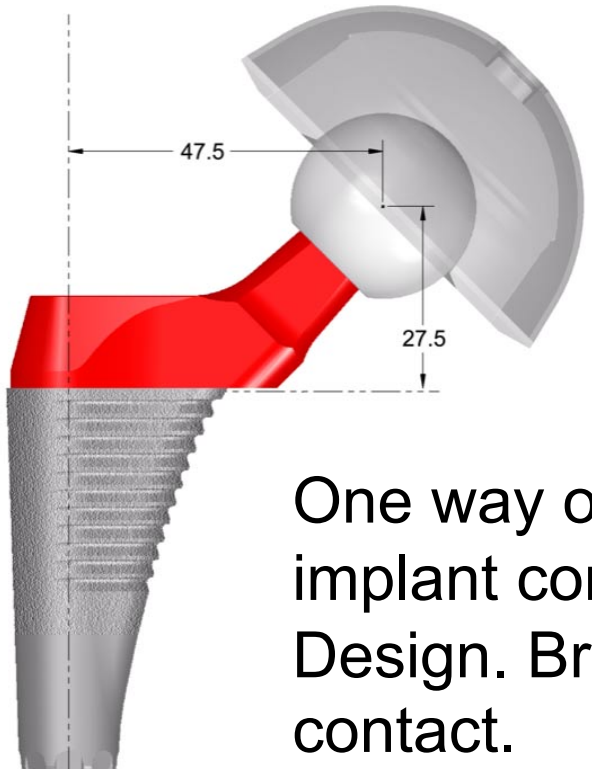
Being Fair
Monoblock stems also fail



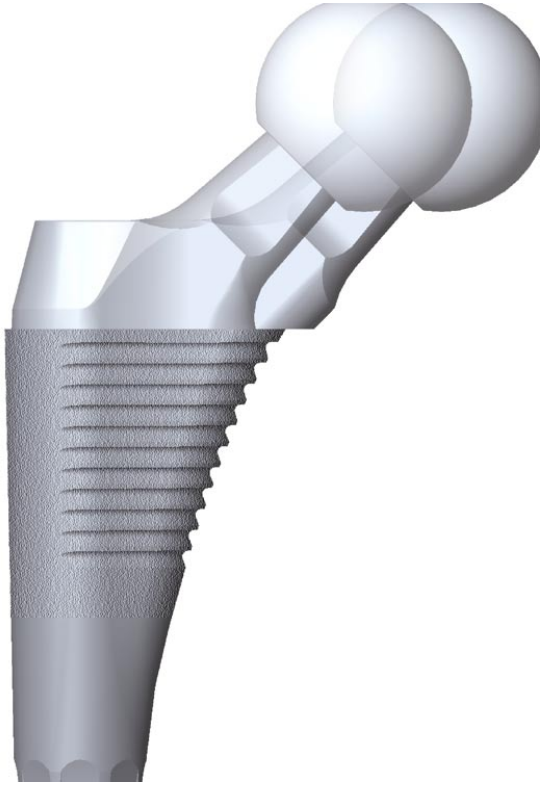
All devices are subject to failure!



Femoral Offset Concerns

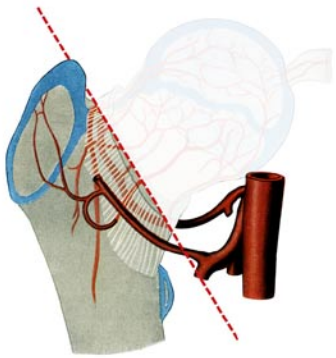


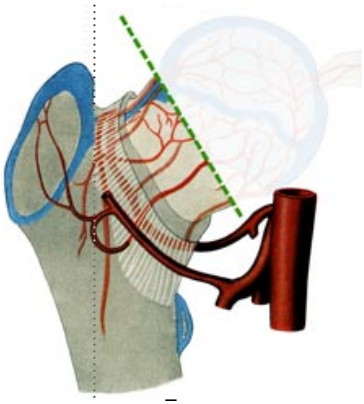
One way of reducing implant concerns is by Design. Broad surface contact.

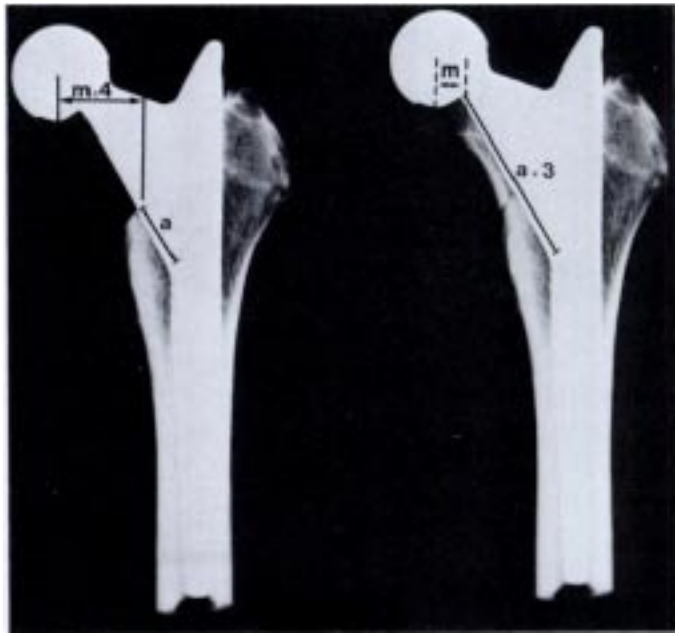


Another way is by design
Save the neck

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

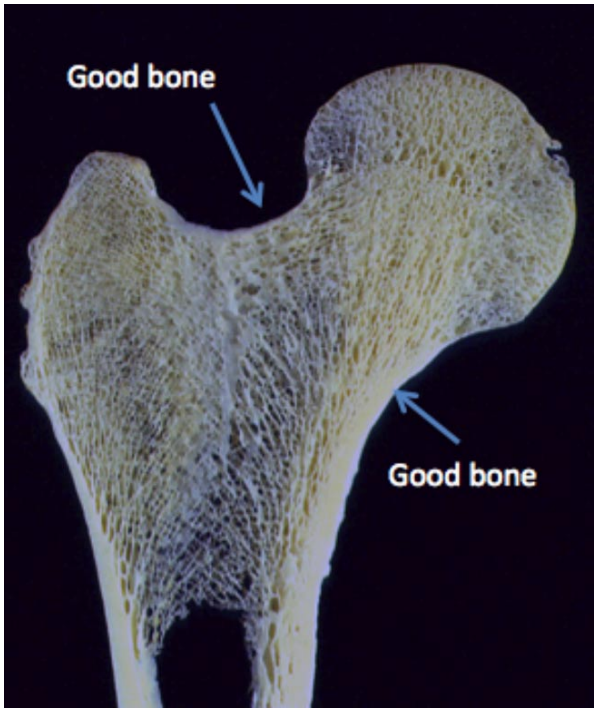


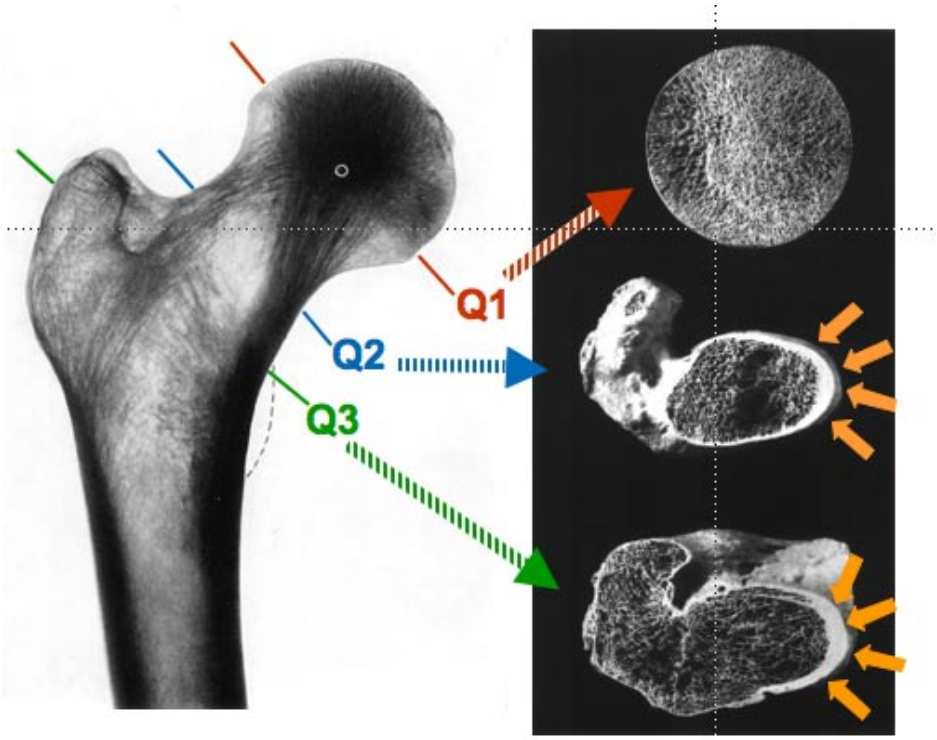




Topic For Debate
Why Resect The Neck?
M.A. R. Freeman JBJS 1984

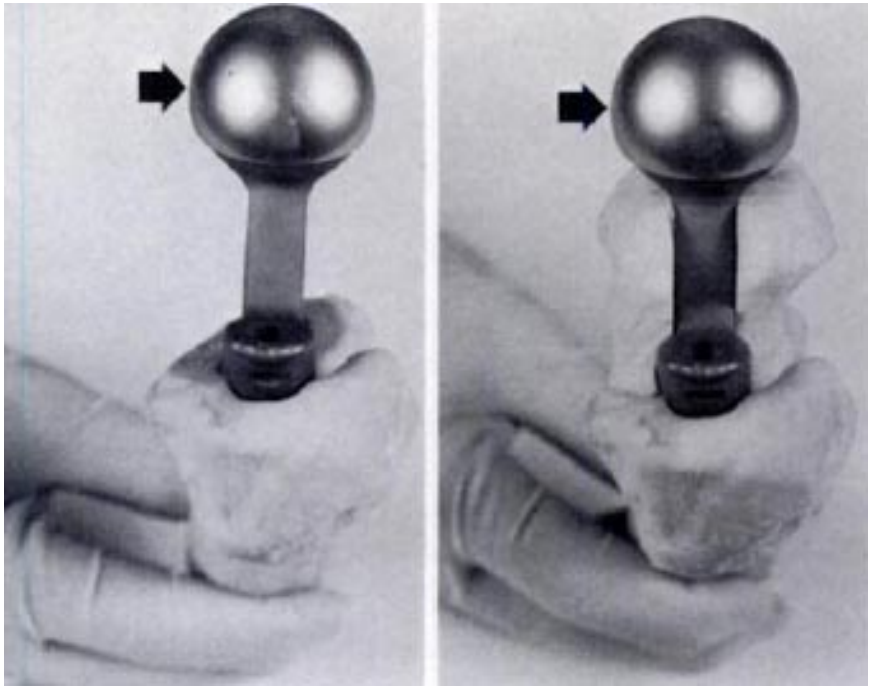
Save the Architecture





Torsional Resistance

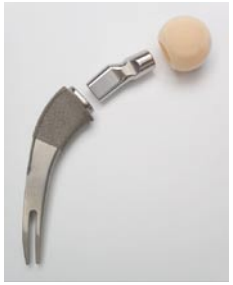
A/P directed resultant force

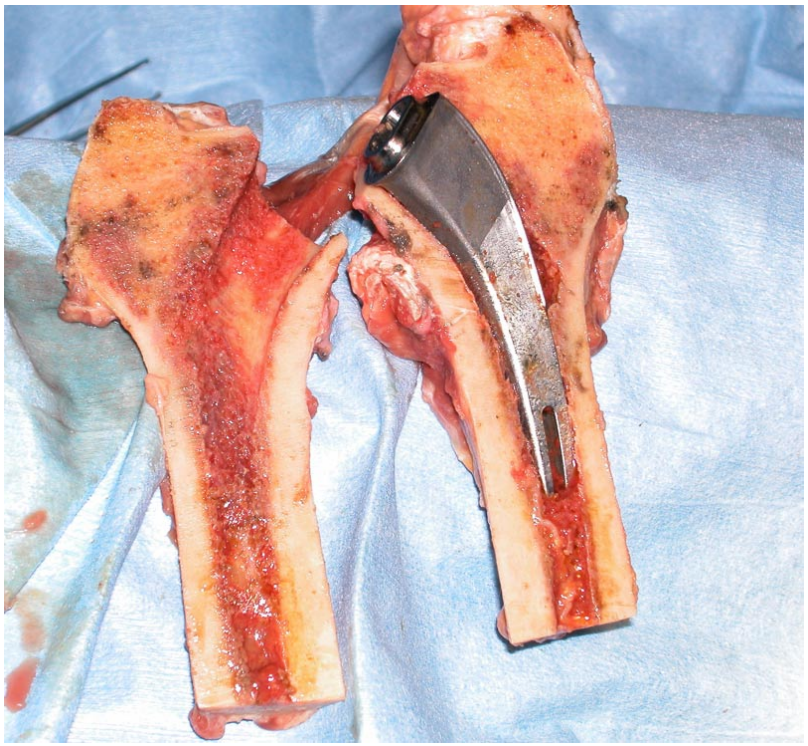


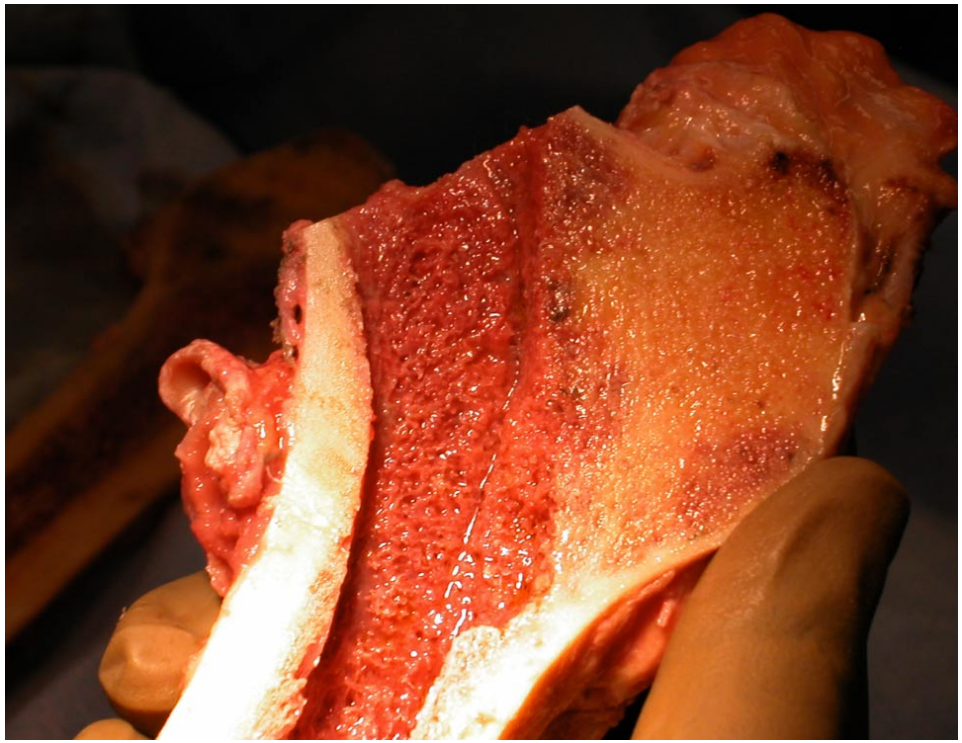
With the neck resected this force generates significant torsional moment on the device which is resisted by shear at the stem/bone interface.

Which do you think has better torsional stability?

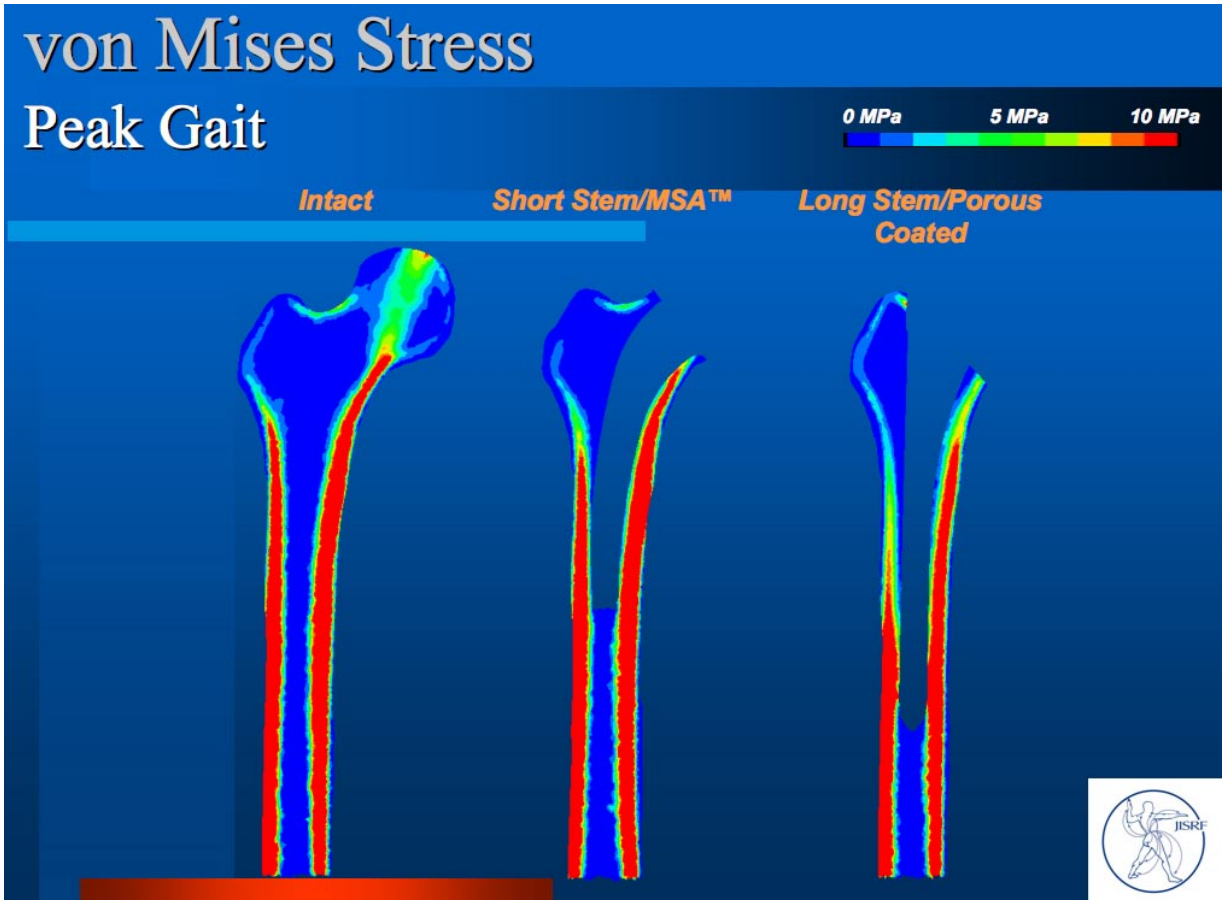
Persevering what we can by design & technique







FEA Modeling



International Osteoporosis Foundation

IOF World Congress on Osteoporosis

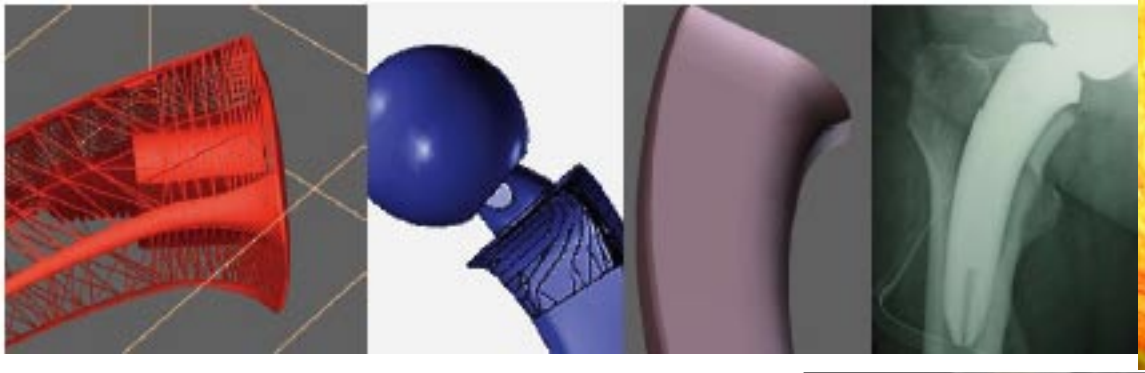
May 5-8, 2010 ź Florence, Italy

Poster Exhibit

"Neck Sparing Total Hip Arthroplasty Lessons Learned"

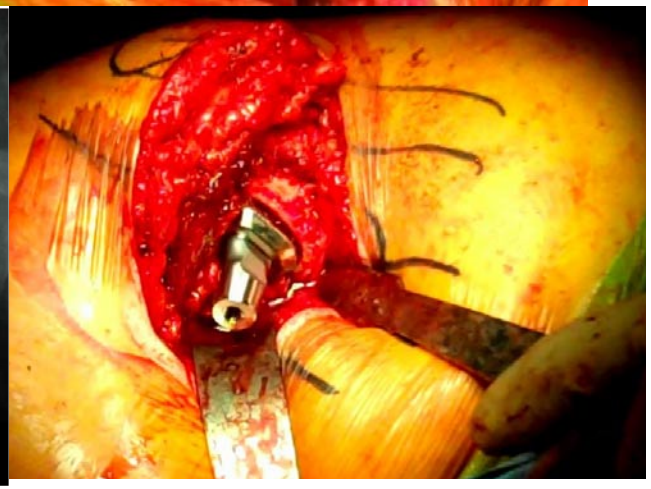
By: T. McTighe[1],
I. Woodgate[2], A. van der Rijt[2], A. Turnbull[2], J. Harrison[2], D. Brazil[2]
L. Keppler[2], J. Keggi[2], K.J. Keggi[2], R. Kennon[2], S.D. Stulberg[2], L.E. Rubin[2]

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

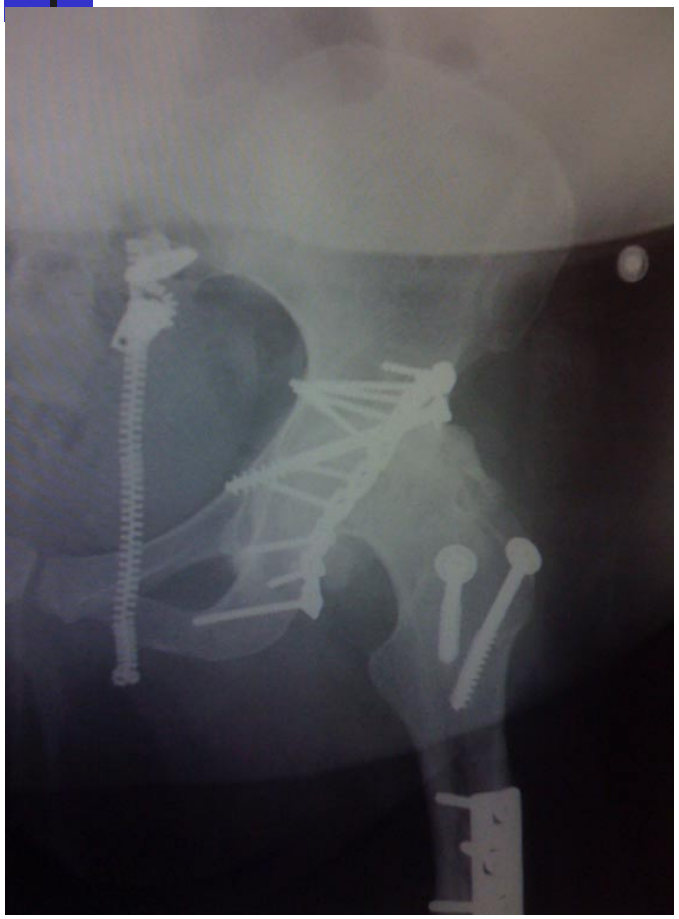


Novel: proximal conical flair loads the medial

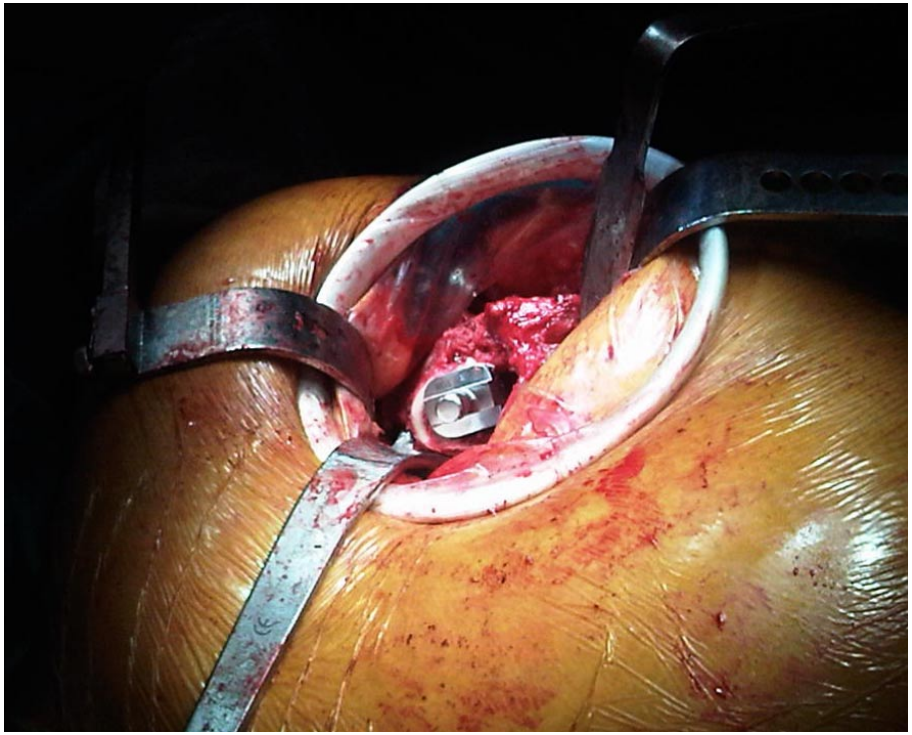
Posterior approach **Anterior approach**



38 yr old female
auto / injured at 16 in 1987
comminuted acetabular fx & femoral shaft fx.

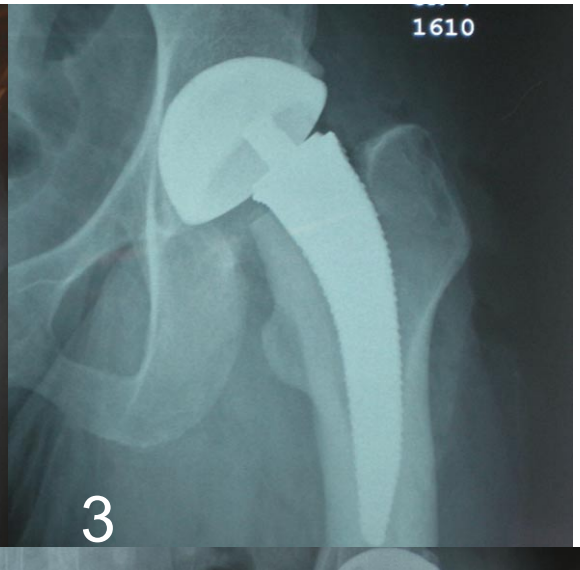


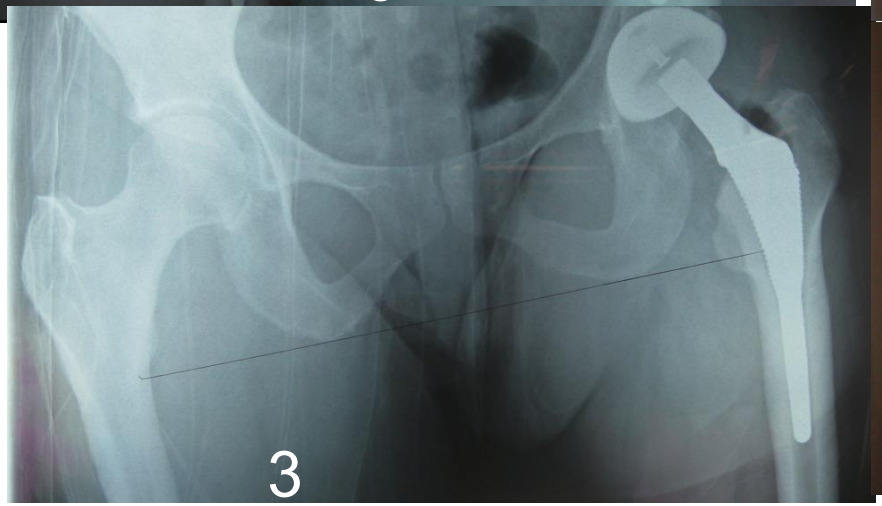
Dr. Charles Bryant trial rasp in place

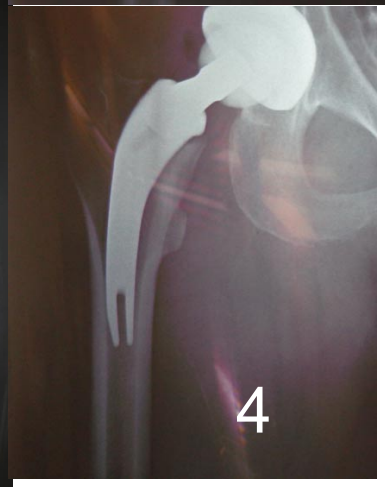


Anterior Approach

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

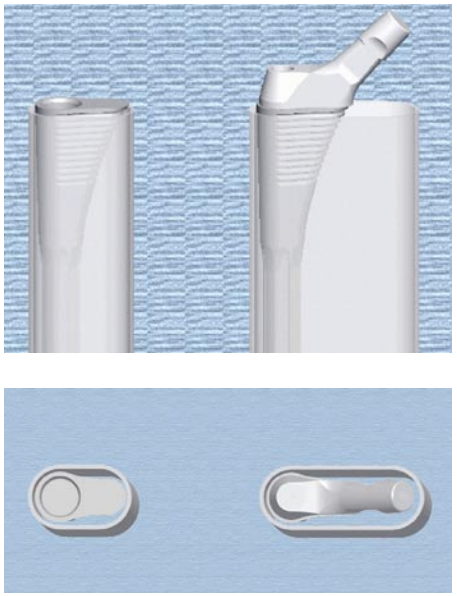






Modular Designs
Small Incisions

- 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

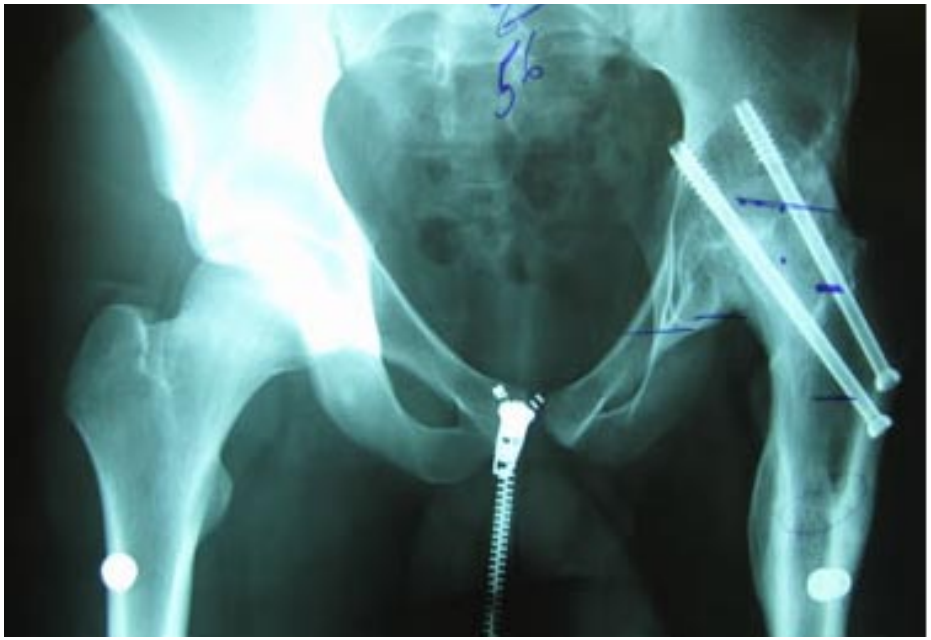
MoM cup removal

Dual Press™
Modular neck

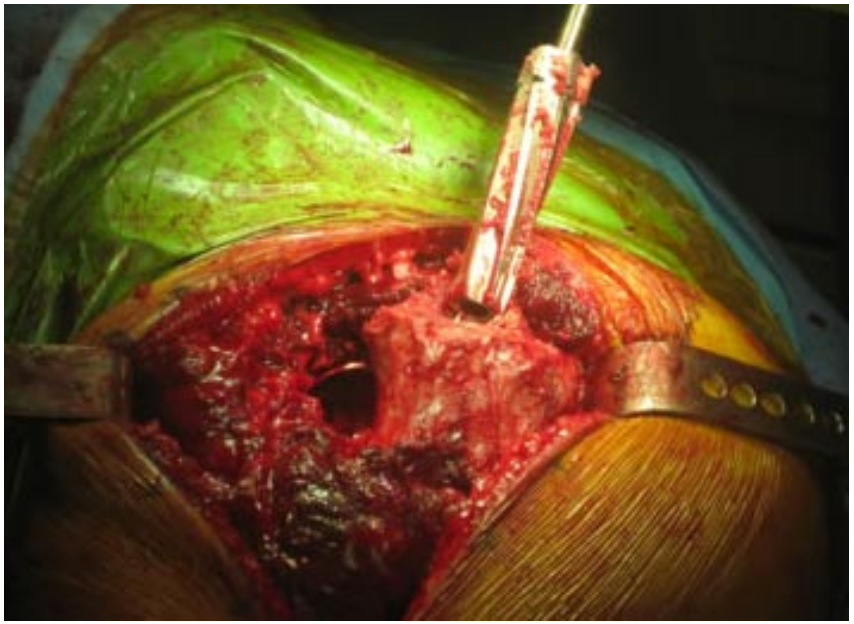
L. Keppler

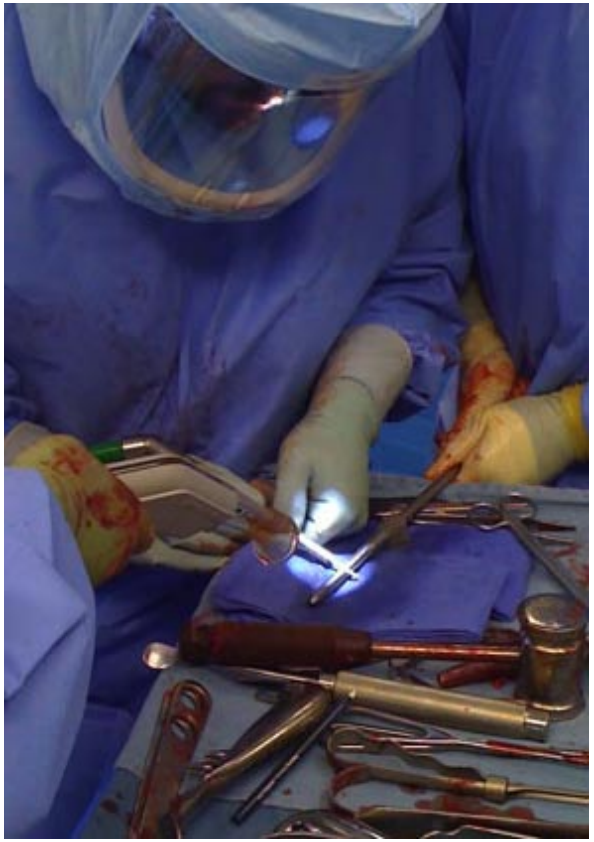
Was effective in all three cases!

18 yr old fusion takedown



Technique





Patient is happy
and doing well @ 6 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
Toronto, Ontario

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 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 Heads

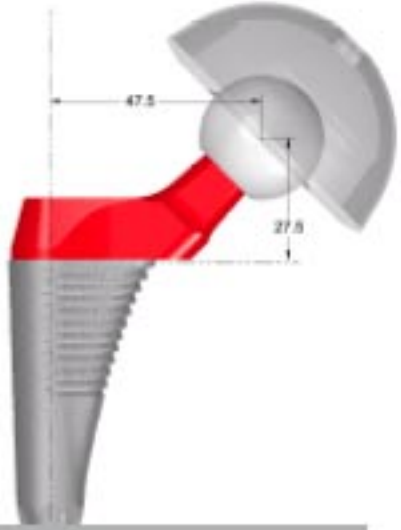
Modular Stem History

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?**

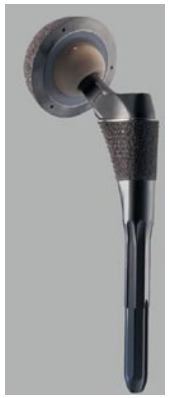
Second Generation "Dual press™" design 216 ft-lbs./292.8 Nm
Pin larger and stronger



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.