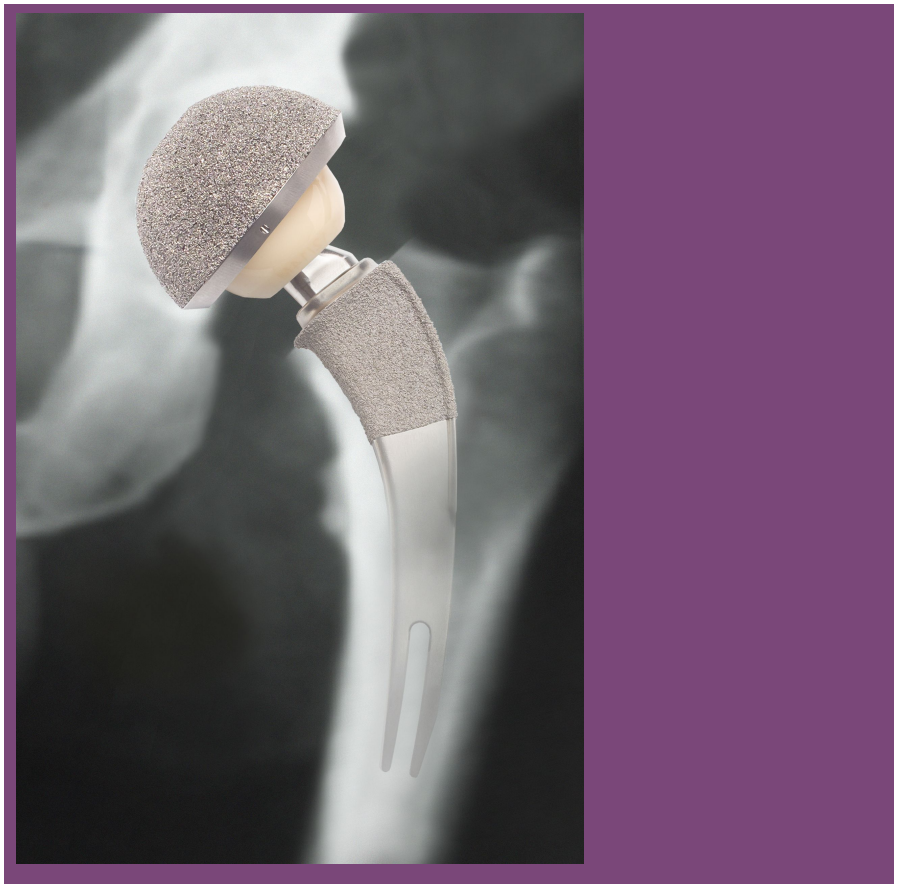
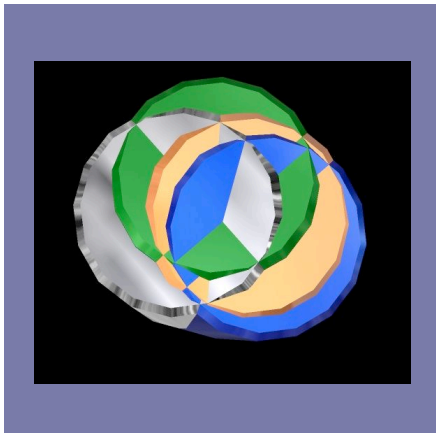
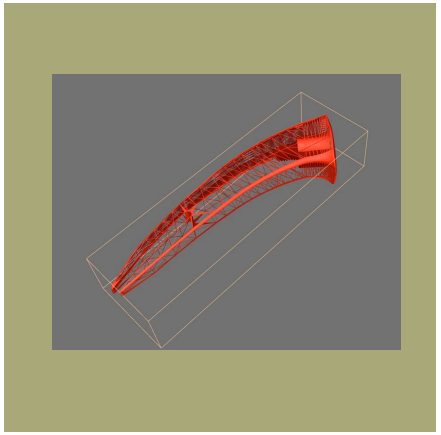
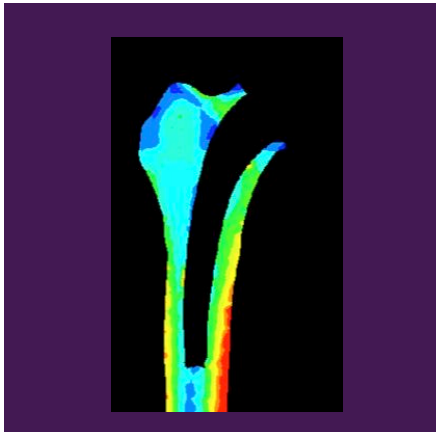








The Design Rationale of the ARC™ Stem

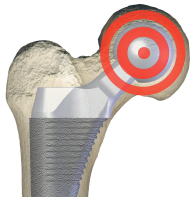
Louis Keppler, MD, Co-Director
Spine & Orthopaedic Institute, Cleveland, OH
Clinical Surgical Research Advisor, JISRF
&
Timothy McTighe, Dr. H.S. (hc)
Executive Director, JISRF, Chagrin Falls, OH

Apex ARC™
Tissue Sparing Femoral Stem
July 10, 2010, Tampa, FL

Sponsored by OMNIlife science

Disclosure

- In accordance with Professional guidelines the authors acknowledge there is a financial relationship with the content of this paper
- Presenting Author: Consulting Surgeon to Omnilife science, Member of CDD,LLC
- Co-Author: Consultant to Omnilife science, Member of CDD,LLC



Goals of THA

Eliminate Pain

- New Bearing Surface

Restore Function

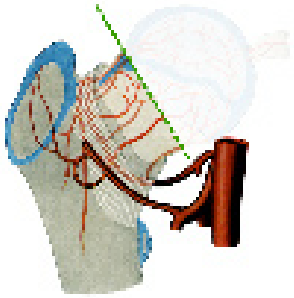
- Reproduce Hip Mechanics

1. Femoral Offset
2. Neck Length
3. Combined Version Angle
4. **Reduce Tissue Damage (is becoming a priority)**

THA , TKA, and Uni Knees are now being preformed as out patient surgery in select patients and select hospitals around the country. This trend will more than likely continue.

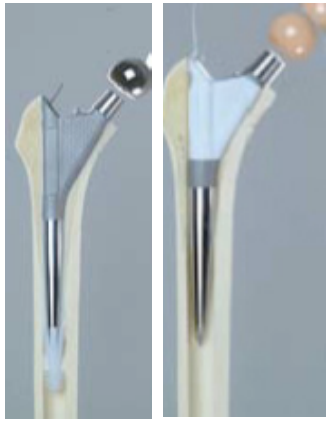
There is a historical reference to neck sparing THA

- Freeman, made the argument back in 1986 that modern hip stems should retain the femoral neck
- Studies showed that 70% of the blood flow to the femoral neck is retained after THA and the vitality of the bone is good



Freeman is acknowledged to be the "Godfather of the modern neck sparing concept"

- Freeman went on to design both cemented and cementless stems and these are still used in the international market



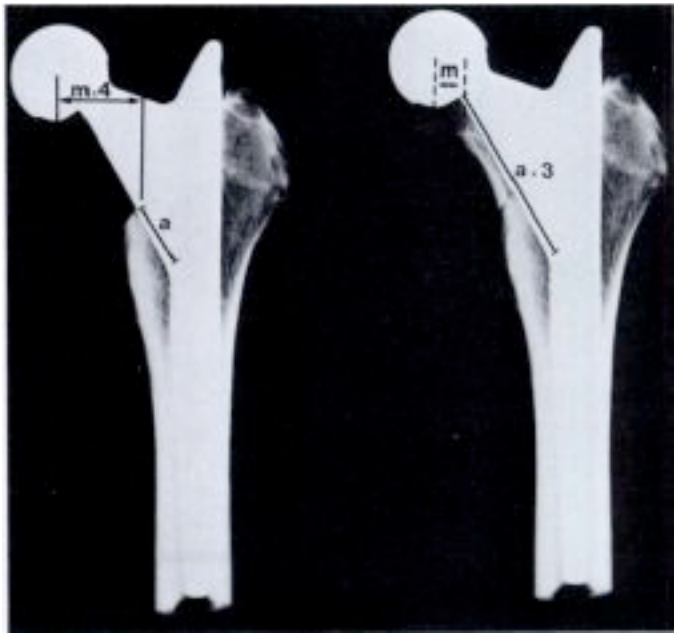
- He was at that time more concerned with aseptic loosening and the torsional loads that he and many believe to be the principal cause of failure
- Freeman advocated a straight stem and it required significant lateral effort!

Topic For Debate

Why Resect The Neck?

M.A. R. Freeman JBJS 1984

- The varus-turning moment increases by a factor of 4 when the neck is resected
- Increase of femoral offset also increase torsional loads on the implant interface



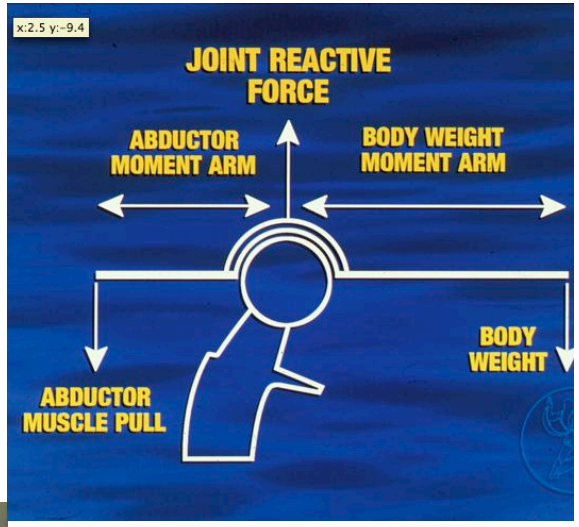
The bending moment is also reduced by saving the neck

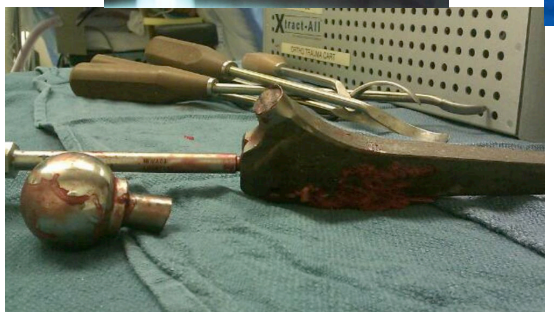
"the neck of the femur is not obviously reduced in strength in the osteoarthritic hip and is no more weaker than the rest of the femur in the inflammatory arthropathies."

Femoral Offset

(fatigue concern - all devices are subject to failure)

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

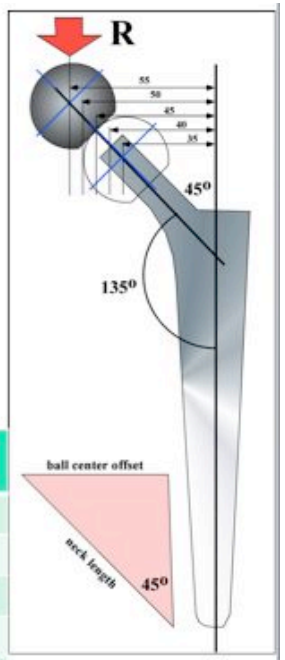




- Neck retention reduces bending moment & torsional loads

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

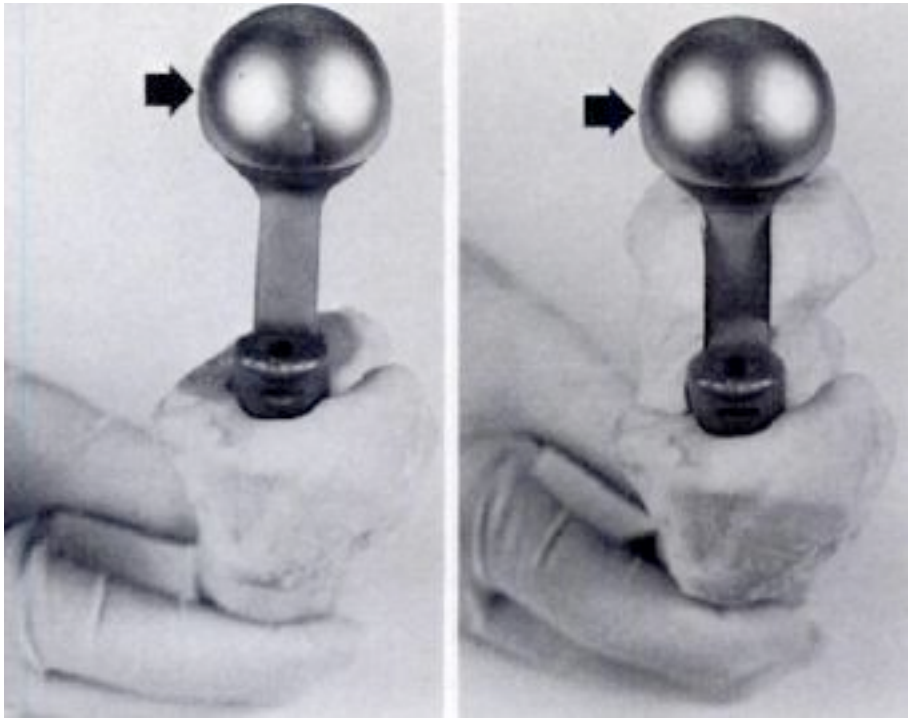
offset	Neck-length	Nm
35 mm	49.50	84
40 mm	56.58	96
45 mm	63.65	108
50 mm	70.72	120
55	77.79	132



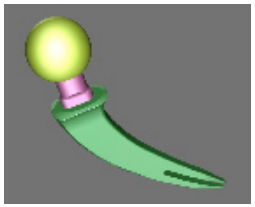
- We know the hip sees over 92 Nm

Torsional Resistance

A/P directed resultant force



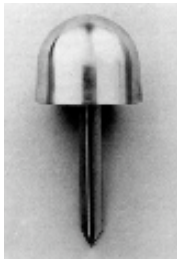
With the neck resected this force generates significant torsional moment on the device which is resisted by shear at the stem/bone interface. Freeman



Interesting history on conservative devices

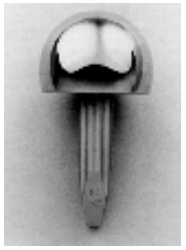
Bohlman 1939

Bohlman 1940



Judet 1950

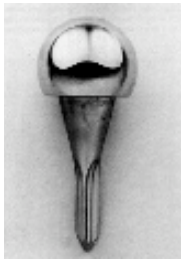
Vitallium Judet 1951



Judet grooved 1952

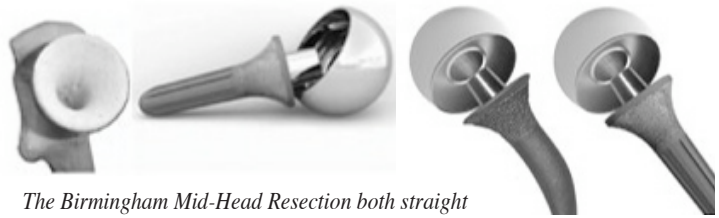
Ferciot 1953

J.E.M. Thompson 1950



Vitallium Thompson 1951

A modern movement



The Birmingham Mid-Head Resection both straight and curved stem designs

Some recent short stems

Platform stem
DePuy

Townley and Whiteside followed with their own straight stem designs

- Whiteside developed a couple of different stems the first with Biomet and more recently with his own company

Biomet Whiteside Modular
Was a S-rom style with neck sparing feature

Current style is more rectangular with a flatter A/P profile

In personal communications McTighe he has stated that both of his neck-sparing stems do encounter a level of bone resorption 12-14 months post-op, and then stabilize. He feels there is a significant mechanical advantage to saving the neck in the early stages of bone remodeling, in that the neck does provide resistance to torsional loads and allows the stem to reach a steady "interface" state with the bone.

Professor Pipino

- Is the Acknowledged Leader in advocating short curved neck-sparing THA
- He has argued for tissue sparing both hard and soft tissue
- His original work dates back to 1979 and

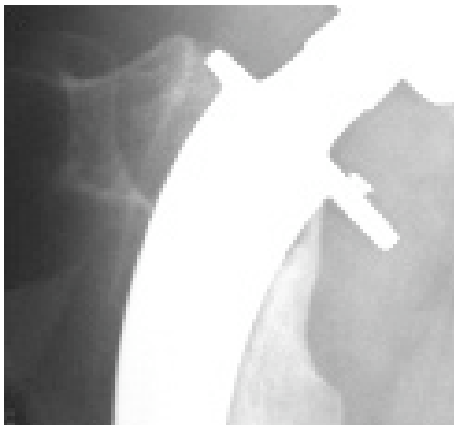
started implanting his first stem "Biodynamic"

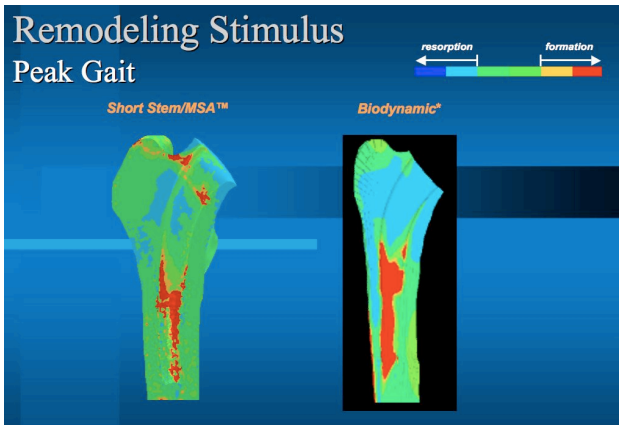
from 1983-1996

- This early design featured c.c. material, collar porous sintered beads on 2/3 of the stem, distal polished tip, 4 stem sizes 1 curve and 135° neck/shaft angle.
- He had encouraging results but was disappointed with bone remodeling

Pipino current stem design CFP™

- He has experienced improved results over the c.c. material, but still encounters some stress shielding



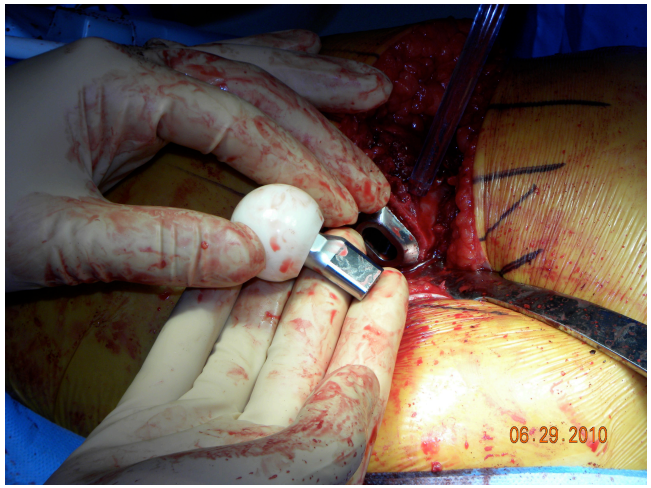


- FEA modeling of the MSA/ARC stem has demonstrated better bone loading patters compared to the Biodynamic™ design
- The CFP stem is the current bench mark in clinical/surgical results for short curved neck-sparing stems

Short Curved Tissue Sparing stems the next logical step

- We are starting to see more designs being introduced that feature curved short stems, some are neck sparing and some are not.
- Most are monoblock in neck features

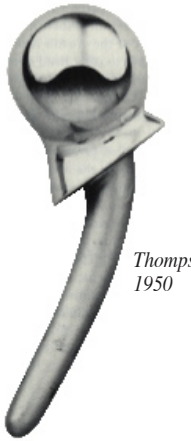
Corin



•Modular necks provide for fine-tuning joint mechanics without disruption of implant bone interface

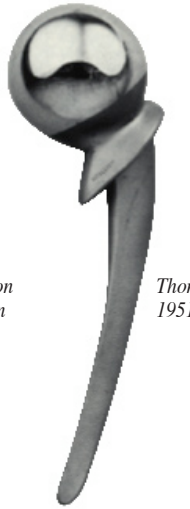
The History of curved stems
"The curve was right"
The application was wrong!

Gosset Acrylic head curved stem 1948



Thompson 1950

Burns version of Thompson 1950



Thompson 1951

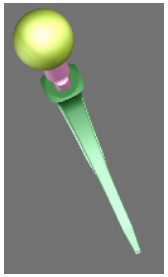
Thompson 1959 model 5

Bechtol 1956

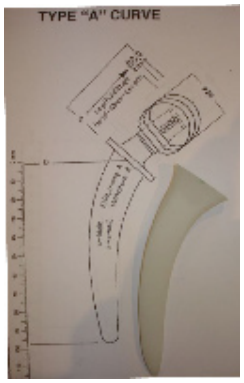
DePuy stem from 1960s

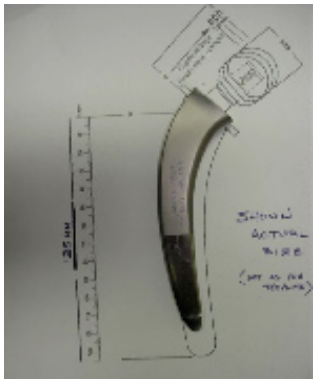
Muller Curved stem 1970

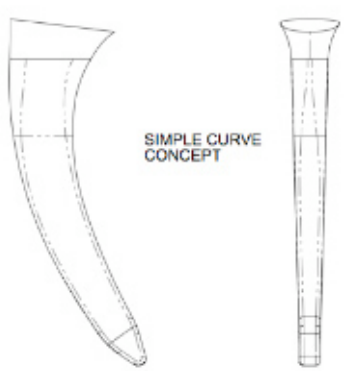
A modified shorten Muller Press fit stem function well for 15 years. K. Berend



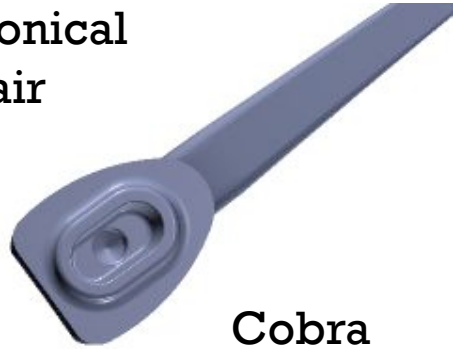
The design process was to address tissue sparing approaches with improved load transfer in a simple curved stem design. Reduced inventory (instruments & implants). We looked at a lot of different parameters. These are just a sample .patents pending



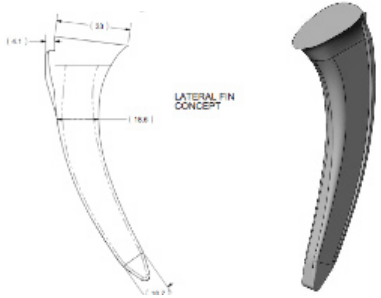


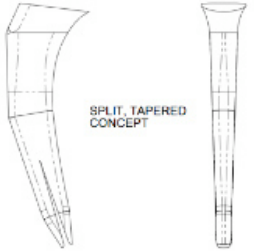


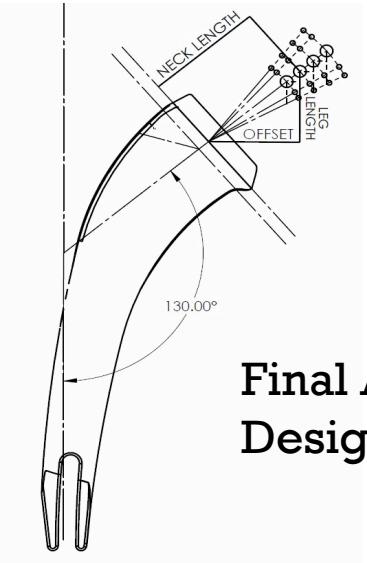
Conical flair



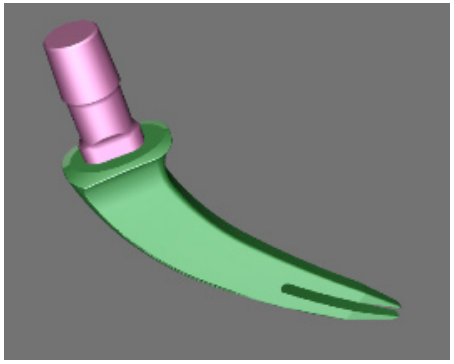
Cobra style

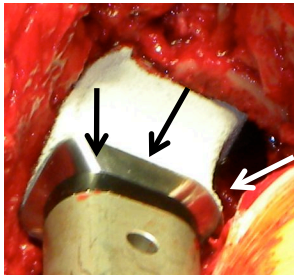




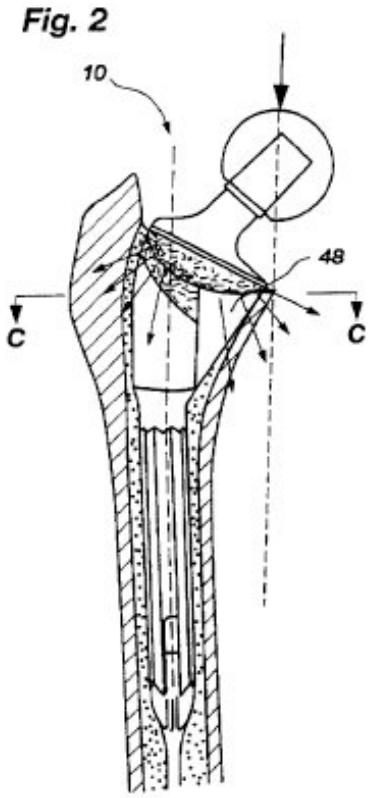


Final ARC™ Design

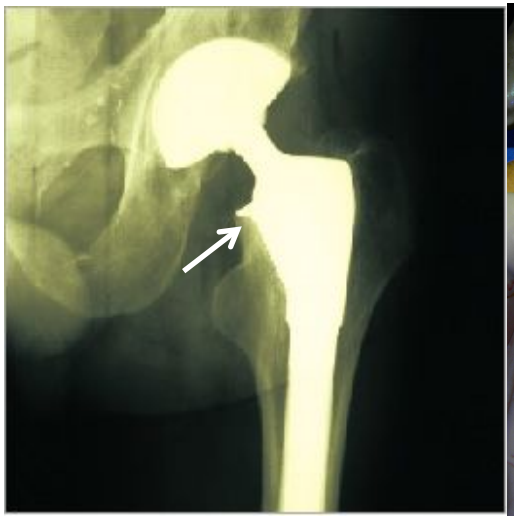




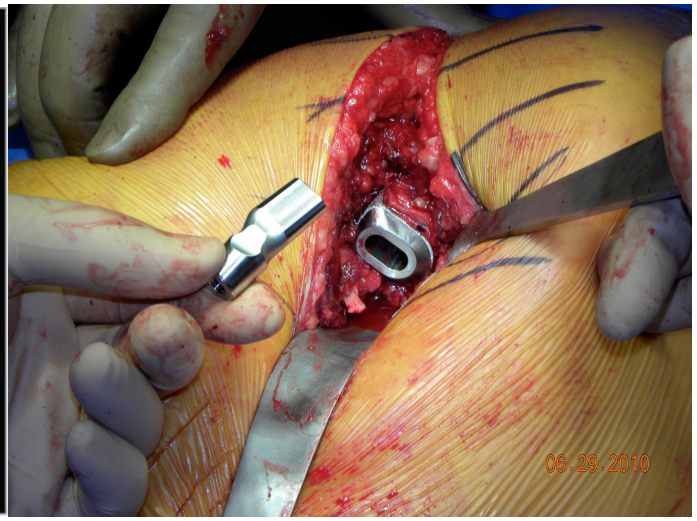
The conical flair was build off conical collar of 1993 stem design



McTighe et el patent

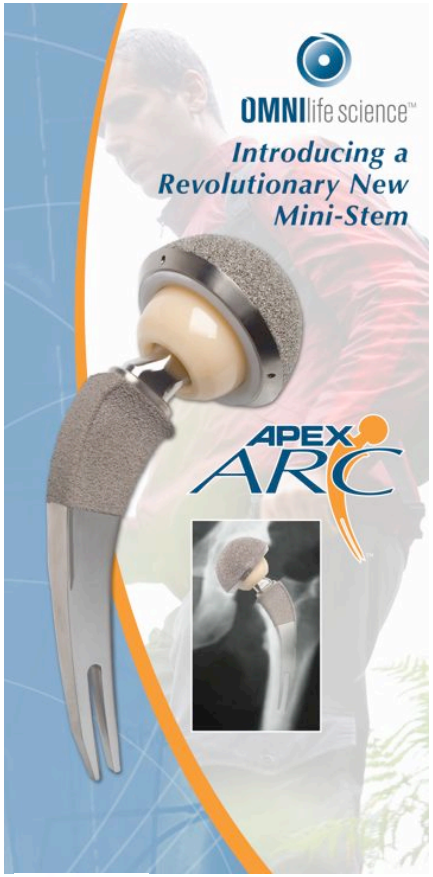


Good compressive load transfer

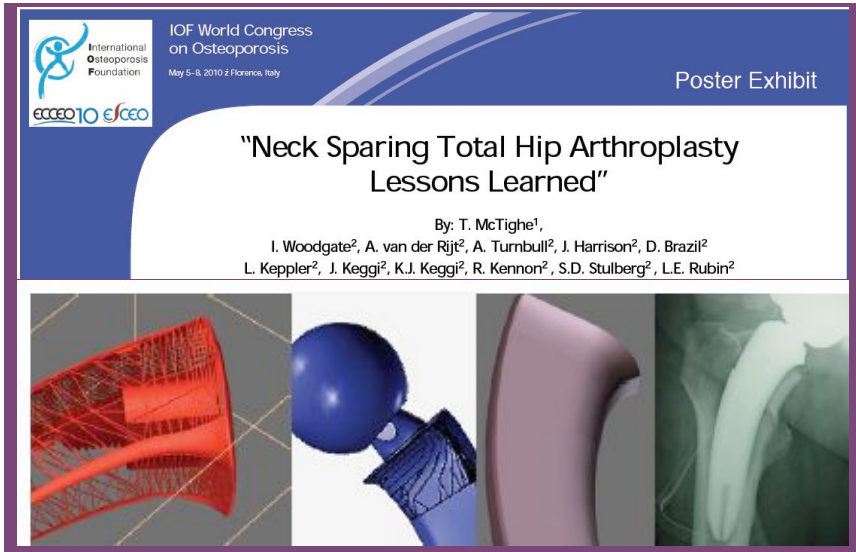


- Good fit of the conical flair
- No damage to lateral structures
- Adjustment by modular neck

The end result is the ARC™ tissue sparing total hip stem

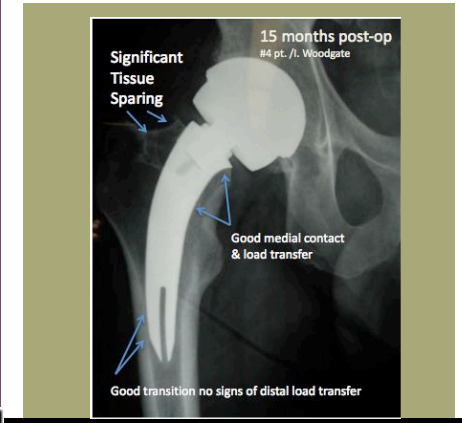


•Hundreds of x-rays templated for base line sizing in Australia and U.S.
•In depth review of the history on neck sparing total hip stems
•Attendance in Pipino's continuing educational course
•Cadaver workshops in Australia and U.S.
•Five custom cases to validate original concept out 2 1/2 years
•Over 20 intra-operative trials before implantation in two countries by over 12 surgeons
•100 cases in Australia
•50 cases in U.S.
•1 case of stem subsidence (1cm) in 80 year old male 6 months post-op no symptoms no plan on revision (was a crack not sure if intra-op or post-op)
• Over 28 reference (papers, abstracts, oral papers) presented on this concept in past 2 ½ years (posted on JISRF web site)
• International Study Group established on the concept of tissue sparing THA (JISRF)
•No stem revision to-date in Australia or U.S.
•All surgeons continue to use the stem, indications increasing (still very early but encouraging at this stage of development and clinical follow-up

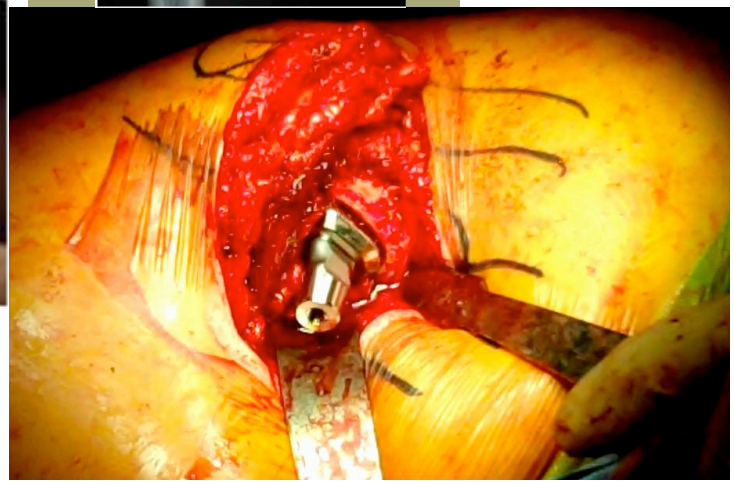


Prof. K. Keggi, MD
Presented in
Florence, Italy
May 2010

Novel: proximal conical flair loads the medial neck



Posterior approach **Anterior approach**






Design Considerations for Modular Stems

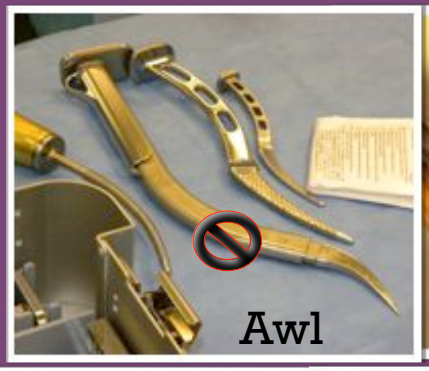
Timothy McTighe, Dr. H.S. (hc)
Executive Director
Joint Implant Surgery & Research Foundation Chagrin Falls, Ohio

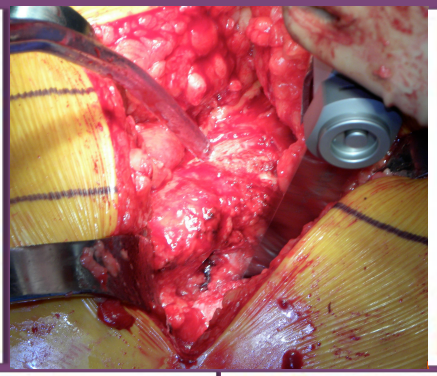
* Acknowledgement of support from many surgeons over the years that are part of JISRF and our on going clinical/surgical research

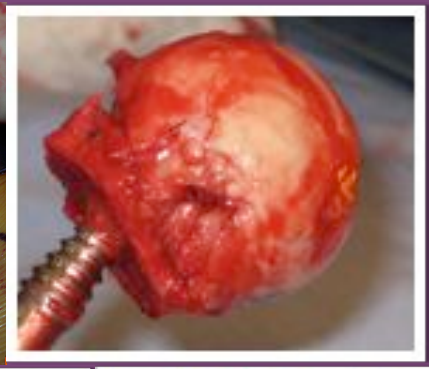
RLO*
Joint Replacement Surgery
May 6-7, 2010
Charleston Place Hotel Charleston, S. C.
•Real Life Orthopaedics
•H. Del Schutte, MD Course Director

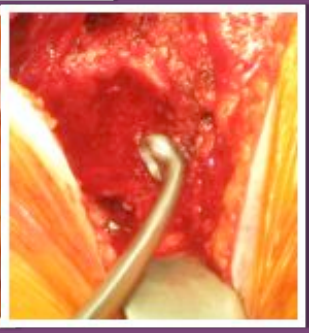
Surgical Technique
Posterior Approach Keppler

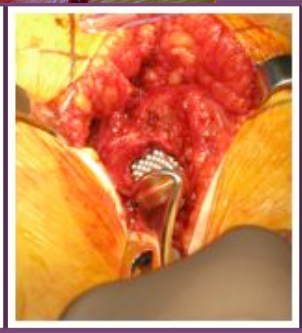
Femoral head is dislocated then the small femoral trial is superimposed over as a marking template for level of femoral head resection 5-8 mm sub cap at about 50°. Now finishing the stem first.

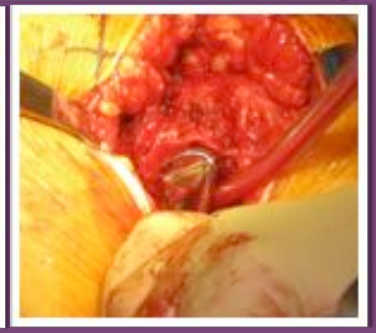


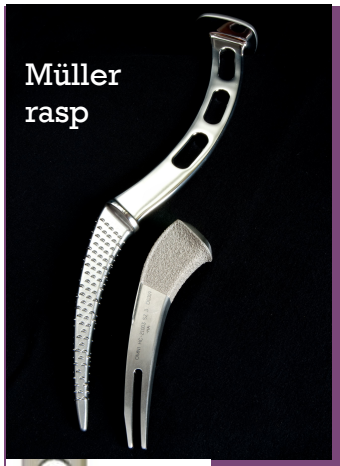


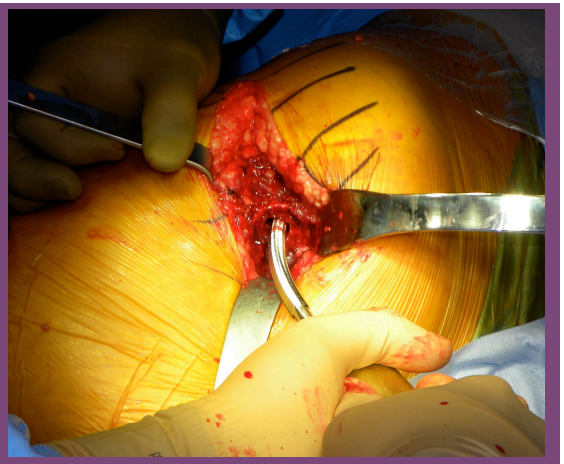


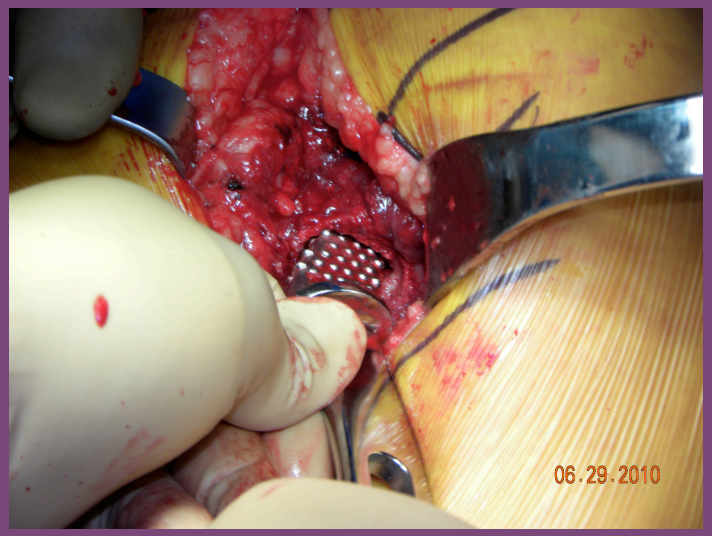


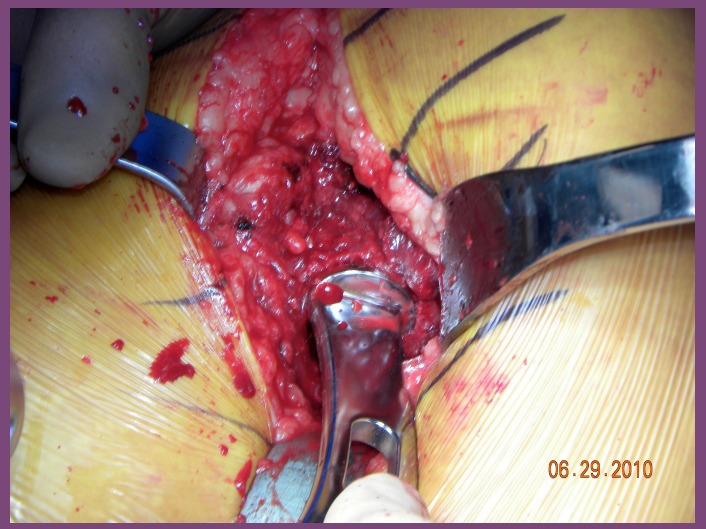








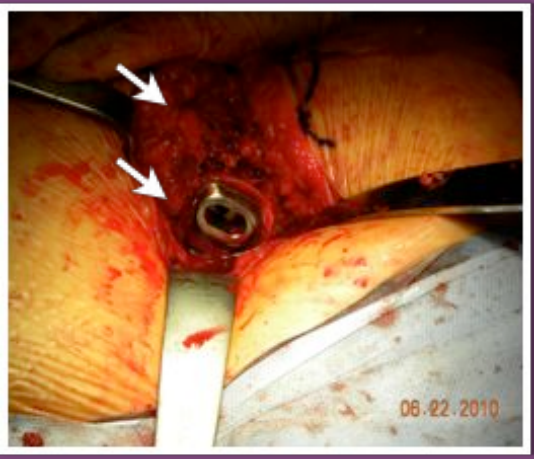




Rasp shape the bone do not broach

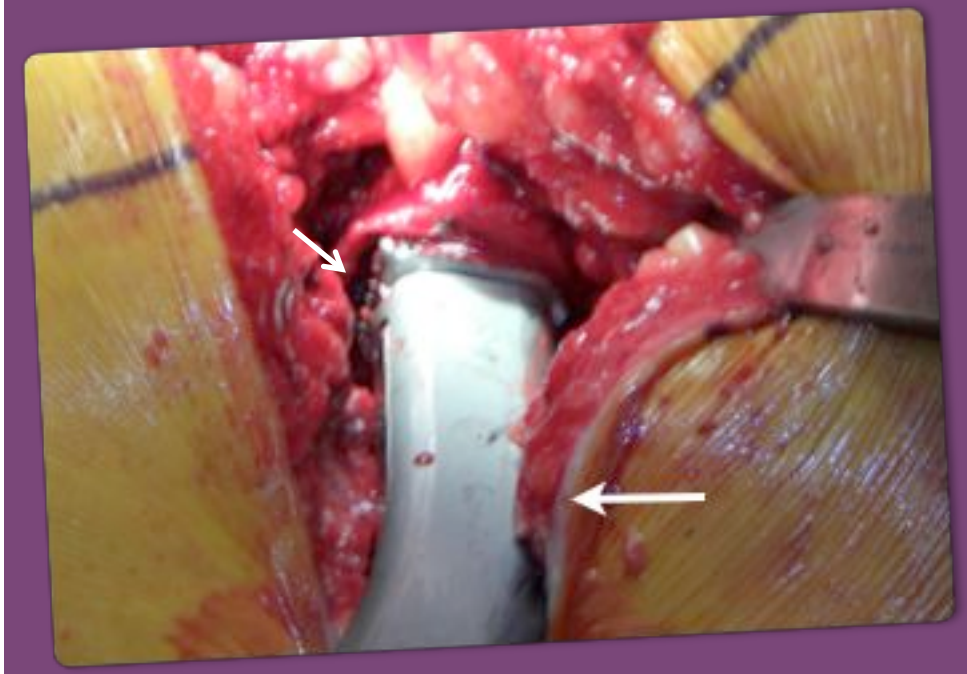
Intraoperative x-rays always taken

Adjustments made 80% of the time



Notice how none of the lateral structures were touched. Less tissue trauma!

Not a problem to shave
A little more neck

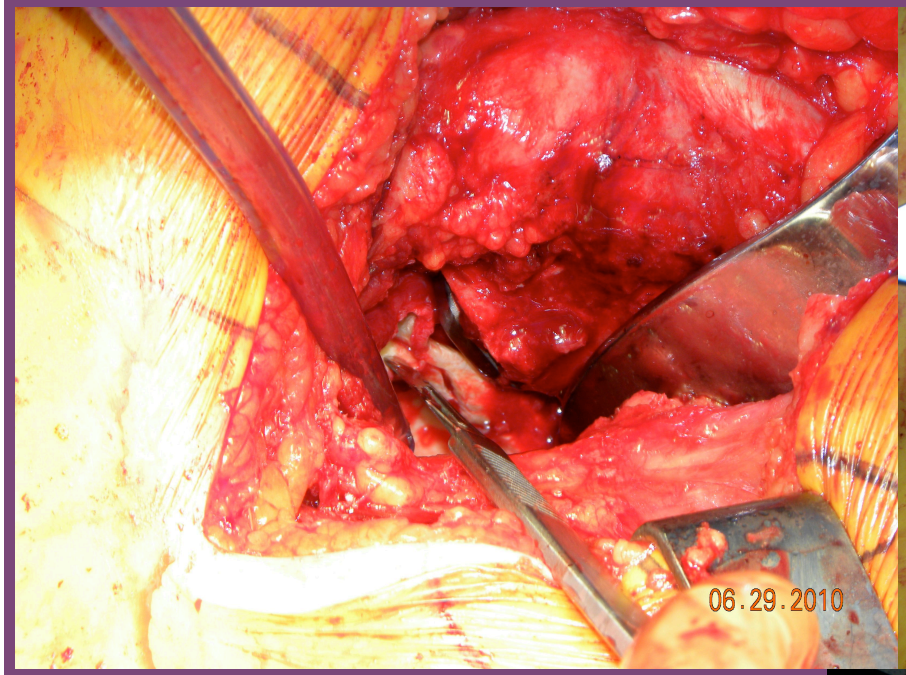


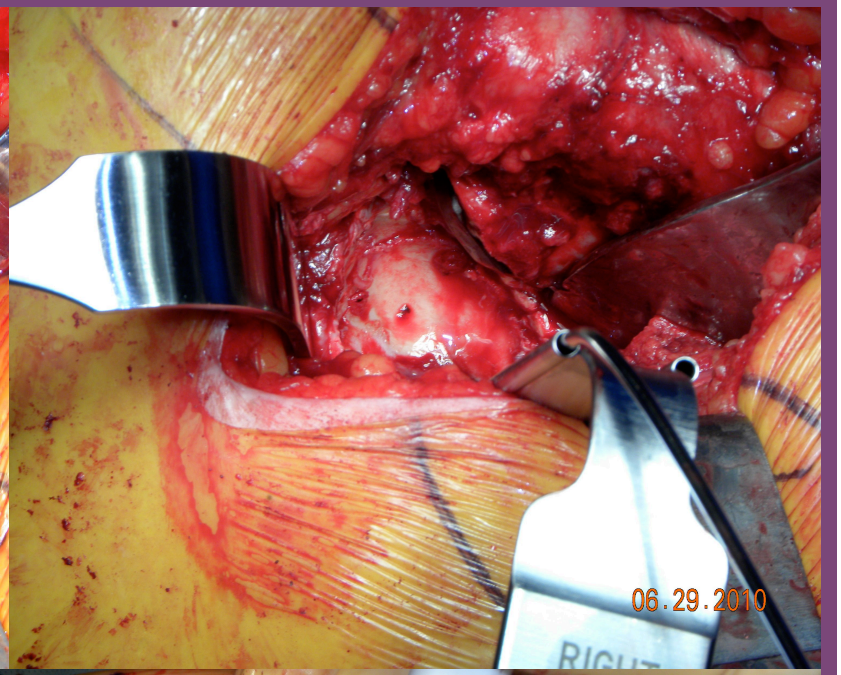
Curvature of rasp handle in large patients such as this can slightly misdirect the rasp by the medial soft tissue forcing lateral pressure on the direction of your rasp. This is not a difficult problem but one that should be recognized it can create a small opening gap between the bone and final implant at the proximal lateral implant interface.

- Fine tuning of joint mechanics is provided for by the modular neck and modular head without disruption of implant-bone interface
- Varus or valgus is used slightly more than neutral
- Version angle necks will be a nice addition to the system

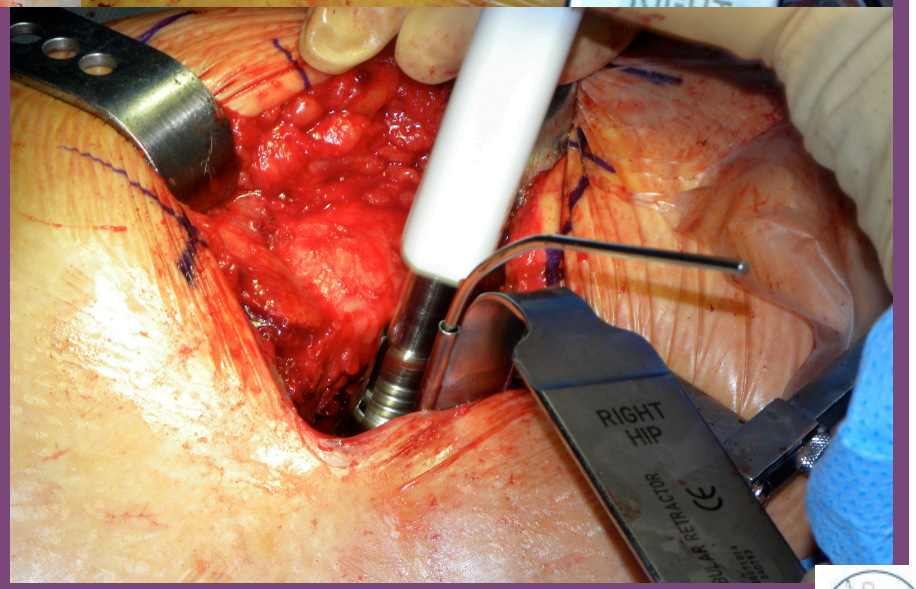
All positions are relative to neutral neck, neutral head center

Neck	Head	Offset	Leg Length	Neck Length
	-3.5	-2.7	-2.2	20.5
Neutral	0	0.0	0.0	24.0
	+3.5	2.6	2.2	27.5
	+7	5.4	4.5	31.0
	-3.5	-1.0	-4.6	20.5
8° Varus	0	2.0	-2.8	24.0
	+3.5	4.9	-0.9	27.5
	+7	7.9	1.0	31.0
	-3.5	-4.7	-2.1	20.5
8° Valgus	0	-2.3	2.4	24.0
	+3.5	0.0	5.0	27.5
	+7	2.3	7.6	31.0
	-3.5	-0.2	-5.8	20.5
12° Varus	0	2.8	-4.2	24.0
	+3.5	5.9	-2.5	27.5
	+7	9.0	-0.9	31.0
	-3.5	-5.8	0.7	20.5
12° Varus	0	-3.6	3.5	24.0
	+3.5	-1.5	6.2	27.5
	+7	0.7	9.0	31.0

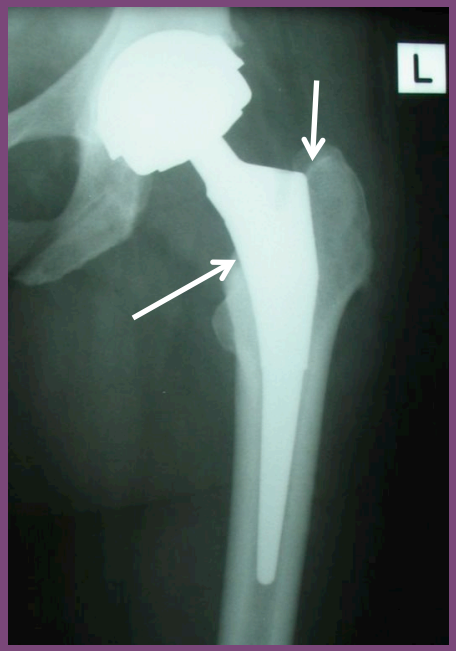




No difficulty with exposure with high neck cut or with doing femur first. Here we have the trial stem in place with no difficulty at all. Doing the femur first saves time and aids in cup orientation.



We are talking about a more conservative approach compared to conventional THA



The ARC™ Stem saves more hard and soft tissue, less trauma impression is less blood loss and has shorten surgery time for me 15-20 minutes. I am very encouraged at this stage of experience and believe I will be increasing indications as I continue to gain more experience. Revision if necessary should be easier. Keppler