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

Design Rationale and Early Clinical / Surgical Observations with a Short Curved Tissue Sparing Hip Implant **"The Apex ARC™ Stem"**

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Abstract:

Architectural changes occurring in the proximal femur (resporption) after THA (due to stress shielding) continues to be a problem[1,2,3,4,5,12]. Proximal stress shielding occurs regardless of fixation method (cement, cementless). The resultant bone loss can lead to implant loosening and or breakage of the implant. We are seeing younger patients with higher levels of physical activity as compared to just a decade ago. This has brought back a renewed interest in hip resurfacing along with significant interest in minimally invasive surgical approaches and smaller profile implants.

Tissue sparing surgery in THA is credited to Prof. Pipino, from Monza, Italy who has been working on this concept for over 30 years[6].The Apex ARC™ Stem is built off the pioneering work of Pipino, Freeman, Townley and Whiteside with new novel design features. In this paper, we review design rationale, surgical technique, clinical impressions, learning curves and lessons learned to-date. In particular, our first 650 stems have been implanted, with 500 being reviewed by the posted surgical team over the past 16 months. *Key Words: Total Hip Arthroplasty, tissue sparing, neck preserving, neck stabilized*

Introduction:

Total hip arthroplasty is one of the most effective orthopaedic procedures with a very high success rate as measured by pain relief, improved function and patient satisfaction. However, over the past ten years there has been a significant level of interest in more conservative approaches to hip surgery. Resurfacing, minimal invasive surgical incisions and short stem implant designs.

Patients today demand more out of the hip reconstruction and their increase activity places a higher demand on the implant.

A number of femoral component failure patterns after conventional total hip replacement have been identified. One of the most common is downward migration and varus rotation tilting of the femoral component.

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There is a significant increase in the use of short cementless stems and a decrease in hospital stay for the index procedure[7]. The current trend of getting the patient up and out of the hospital and back to their busy life style does place additional biomechanical loads on the artificial device.

Some recent reviews report on primary total hip survival (Kaplan-Meier) on uncemented hips at ten years to be 72% to 86% in patients less than 60 years old and from 90% to 96% in older patients[8]. So we are seeing risk for revision surgery at 10 years to range from 5% to 20%. This is a significant concern.

A number of the current short stems introduced into the market are no more than standard stems cut short. There is concern with the increase in younger and more active patients that these modified short stems be adequate to resist the increased biomechanical loads placed on them?

Modern short stems come in a variety of shapes with varying design features. However, there does not exist a classification system for uncemented short stem implants that would allow comparisons of clinical and radiographic results[9].

The purpose of this paper is to review a new novel neck sparing total hip stem and the method by which this stem achieves implant/bone stability, surgical technique required, and observations as to early clinical outcomes.

Material & Methods:

A retrospective review of patients who underwent primary THA with a novel short curved neck sparing "ARC™" total hip stem. The inclusion period was between April 2010 and September 2011.

This is part of previous work by some of the same group presented at the Osteoarthritis Research Society International in San Diego, September 2011.

There has been 650 stems implanted with this novel neck sparing stem design since April 2010 with 500 from the surgical team (seven) posted for review. All surgeons are at different locations and all underwent specific training to familiarize themselves with the stem design and required surgical technique. All seven were part of the initial surgical team to aid in designing and fine tuning of surgical instruments.

Three surgeons utilized the single anterior approach, two utilized the posterior approach and two did some of each. No anterior lateral or direct lateral approaches were used. A variety of acetabular components were used as were a variety of bearing surfaces (MoM, MoP, CoP, and CoC). There were even a few dual mobile style cups used in small profile patients were a 32mm head diameter was not possible.

Dual-mobile style cup

This stem allows the surgeon to chose the best bearing surface indicated for the individual patient.

Out of the 500 patients 350 patients had greater than one year follow up. There has been an increased usage in the past six months with CoP and all surgeons in this review have moved away from MoM in their usage for THA. One surgeon in the group still performs Hip Resurfacing (HR) in males under the age of 65.

The current bearing selection by this group is one surgeon used CoC for young active patients, six utilize CoP in their younger patients. Six use MoP for their older patients and two are utilize dual mobile style bearings in the small female profile. No 28mm or smaller head diameters are recommended with the use of a neck retaining design.

Typical patient profile showed two-thirds being female with an age range overall between 17 to early 90s. Majority were treated for OA.

This stem has been used in all Dorr bone classifications (A,B,&C). The difficulty has been limited to small profile patients where the stem profile has been too large.

This review was limited to looking at stem revision rate for dislocation, aseptic and septic loosening.

Biomechanics:

Why save the femoral neck in THA?

That question was attempted to be answered by Mr. M.A.R. Freeman in his original article titled **"Why Resect The Neck?"** published in 1986 British Editorial Society of Bone and Joint Surgery[10].

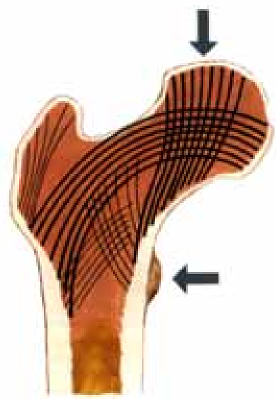
In this paper Freeman points out that there were three probable reasons for resection of the femoral neck: 1. Surgical convenience, 2. the fear of mechanical impingement, and 3. the danger of resorption of calcar. He gives a nice historical review of the Moore and Thompson stems and how neck resection evolved into a standard approach.

Impingement has largely been addressed by newer acetabular component designs and the use of 32mm and larger head diameters to increase functional ROM. However, careful cup positioning, removal of osteophytes and extensive trial range of motion must be carried out to reduce any chance of mechanical impingement. Also the advent of the modular neck junctions allows fine tuning of joint mechanics and has become a valuable tool in avoiding impingement issues.

As for calcar resorption we know either too much or too little stress can result in bone resorption.

Wolff's Law:

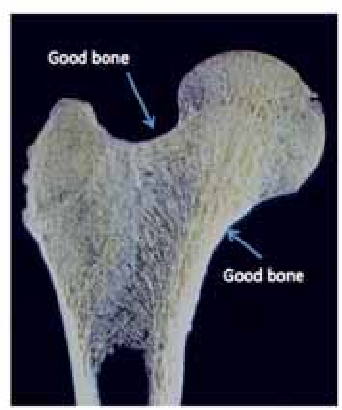
"Accordance to these forces, the natural trabecular pattern of the bone and the trabecular orientation provide support against the natural functional loading, thus creating the necessary functional stability of the individual bone areas."

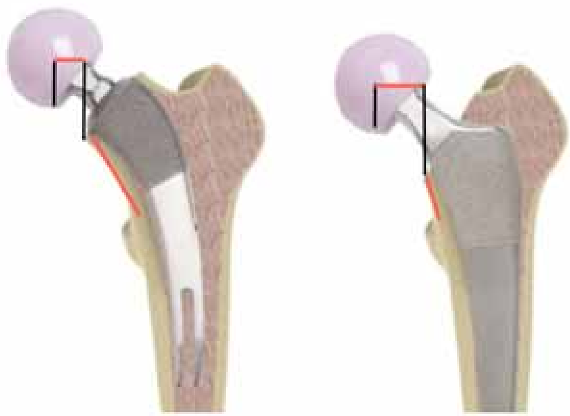


In the proximal femur, the femoral neck and the adjoining medial aspect of the femur in the calcar region show the strongest bone structure with a high load capacity to support the stem.

Femoral neck retention reduces both torsional and bending moments (forces) at the stem / bone interface.

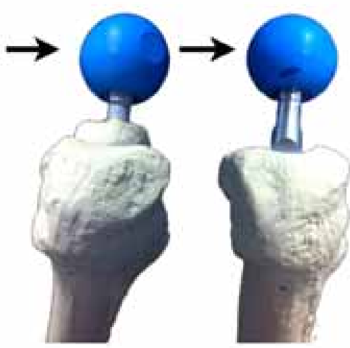
"Remember in accordance with Wolff's Law, the reduction of stresses relative to the natural situation would cause bone to adapt itself by reducing its mass, either by becoming more porous (internal remodeling) or by getting thinner (external remodeling).





Illustrations comparing neck retention to conventional neck resection.

The neck on the right has been resected at the conventional level; in the one on the left the neck has been retained. Because the difference in the height of resection the length of the moment arms, the varus-turning moment increases by a factor of four when the neck is resected[10]. At the same time the area of bone available for supporting the vertical component of the resultant of the forces acting on the implant is almost tripled



The anterior-posterior directed component of the resultant force is represented by an arrow. Neck resection generates a significant torsional moment.

In-Vivo Bone Response

This one year radiographic view clearly demonstrates that the initial gap below the medial conical flair has filled in with bone. The rest of the stem is by all appearance benign. No reactive lines, no distal pedestals and no subsidence.

Design:

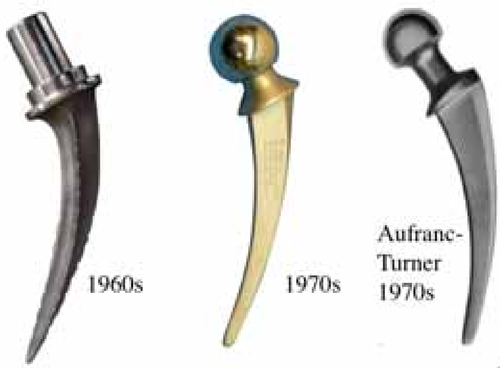
The ARC™ Stem is a simple short curved trapezoidal neck sparing design that is tissue conservative (hard & soft) and features a number of unique and novel elements to improve upon short and long-term survivorship[11].

The basic curvature of the stem comes from the historical work of Thompson and Mueller.

Mueller Rasp / ARC™ Stem

Historically there has been a number of curved stems. The application of the stem and how it was used often left a lot to be desired, however the curve was on target. If porous coating had been around a number of these designs would have functioned very well. Many were designed as press fit and then later used with bone cement. The curve was a good idea, the Thompson is still in use in parts of the world today.

Dr. Joao de Azevedo Lage, Brazil implanted thousands of his novel curved stem.



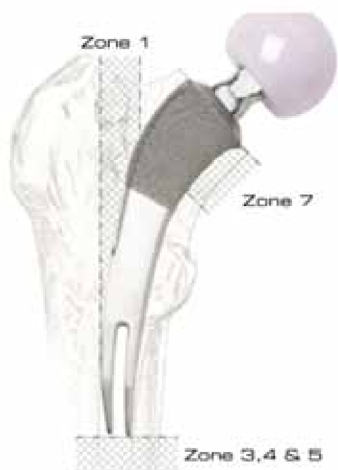
Aufranc-Turner 1970s

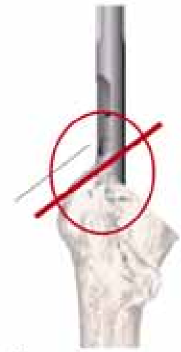
Pipino's Biodynamic stem 70s & 80s

Thompson still used in parts of the world

This simple yet novel stem design allows for considerable tissue conservation of both hard and soft tissue. As you can see here in this illustration bone is preserved in Gruen zones [7, 3,4,5] and zone [1].

The curve reduces the need to go lateral where you can risk damage to the musculature and increased bleeding by removal of cancellous bone in the greater trochanter. You are also not forcing blood and fat down the canal as one does with conventional length stems.





No need to go lateral into zone I

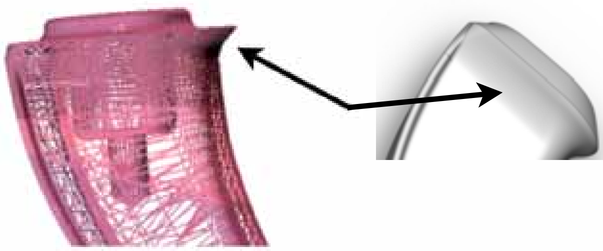
The stem shape is that of a curved trapezoidal design that is intrinsically stable. The torsional stability is enhanced by the lateral T-Back feature.

This however has proven to be too aggressive in the small female profile and has been removed on the size 0 stem.

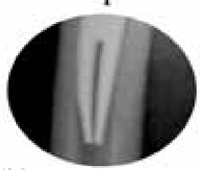
The proximal porous coating is applied circumferentially to the upper third of the stem and is a combination of commercially pure titanium applied first using a plasma spray process after which a thin layer of hydroxyapatite (HA) is also applied using a plasma spray process.

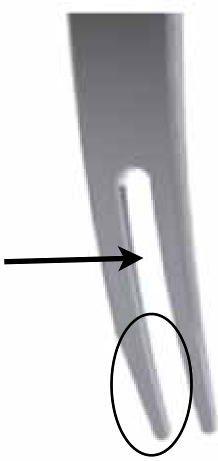
The proximal portion of the stem has a patent pending novel conical flair element that is designed to off load compressive loads to the medial calcar.

This very unique feature has demonstrated positive stress transfer in both FEA modeling and now clinical observations.



Lateral distal relief of 11° reduces any distal tip contact if the stem is in slight varus position. The sagittal slot reduces distal stiffness reducing the potential of distal load transfer and reduces hoop tension in type A bone by allowing stem to pinch in.





Sagittal slot

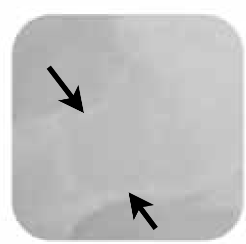
Lateral relief 11° angle

Why a Modular neck?

Restoration for THA is a challenge with monoblock stem designs. Over lengthening the hip center to achieve joint stability is a significant problem and can lead to both mechanical and legal problems.

Mechanical impingement of the cup and stem or of bone-on-bone is a concern with neck sparing stem designs. Accuracy of femoral stem anteversion and acetabular cup anteversion would ensure mating of the femoral head in the cup without mechanical impingement. This requires both design and technique to repeatedly create this combined anteversion.

Combined anteversion has become more relevant with the use of non-cemented implants especially neck sparing designs. The non-cemented femoral stem must have a stable press fit to obtain bone fixation. A stable press fit means the stem must adapt to the femoral bone geometry which is highly variable; accordingly, there is often less ability to adjust the stem anteversion in uncemented compared to cemented stems. Cemented stems can be rotated within the femoral bone to provide 10° to 20° anteversion. Cementless stems of any geometry are limited by the anteversion of the bone, the anteroposterior isthmus at the level of the lesser trochanter, and the posterior fin of bone in Dorr type A and B bone. Neck sparing stems are limited by the internal cortical dimensions of the anteroposterior isthmus of the femoral neck.



The acetabular cup position has traditionally been anteverted with the assumption the femoral component would be a mean 15° anteverted. The arthritic acetabulum has a mean 12° anteversion and non-arthritic acetabula have mean anteversion of

19.9° ± 6.6° with the mean in women being 21.3° and men 18.5°. Therefore, the traditional safe zone for cup placement has been 15° ± 10° or 20° ± 10°. If the stem has only 5° of anteversion, especially in a woman, the acetabular safe zone of 15° to 20° does not give an acceptable combined anteversion. This risk is compounded in 10% of hips in which the pelvis is tilted 10° or more from neutral and the surgeon's estimate of anteversion can be wrong by 10°. In clinical studies, cup anteversion is not within the desired safe zone as often as 55% to 78% of the time[16].

The only sure way to determine proper orientation of combined version angles is by use of implant trials and conducting a range of motion. The use of modular necks with varying angles provides the best options to the surgeon in real time to fine tune the patient's joint mechanics.

Neck retaining stems like the ARC™ Stem that fits and fills the retained femoral neck are inflexible to alteration of stem version angle. Thus the need for modular necks in a variety of angles: Neutral, Varus, Valgus, Anteverted & Retroverted.

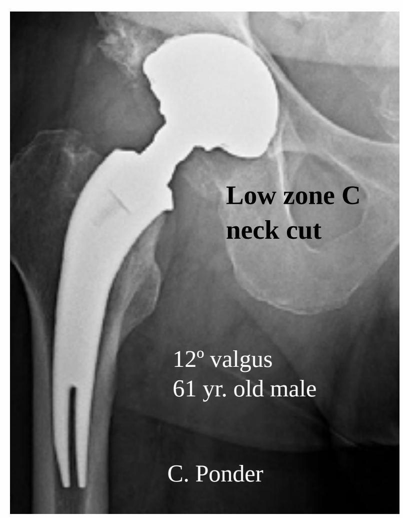
A modular neck also allows for femur first technique since the stem can be implanted and retracted out of the way without the neck interfering with acetabular exposure. It also helps providing another physical landmark for cup orientation.

Neck trials can be used on trial stem or definitive stem.

Trial neck in place with definitive cup and stem. The opportunity is still there for fine tuning of joint mechanics.

A modular neck separates the vertical height from the version and femoral offset angles. Providing the ability to intra-operatively restore joint mechanics without disruption of the implant / bone interface. It also provides an opportunity to retain a well fixed femoral stem in an acetabular revision.

There is a tapped threaded hole for extraction and is the same size tapped hole in the stem for extraction.

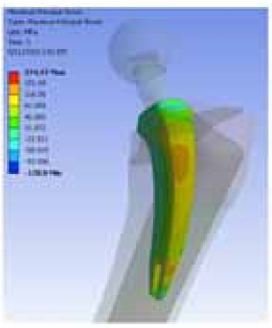


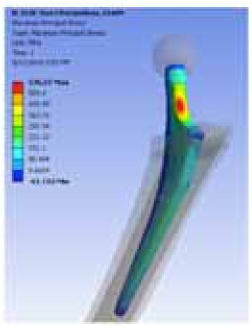
Example of using modular valgus neck shaft angle to help make up some vertical height.

Fatigue Concerns with modular sites:

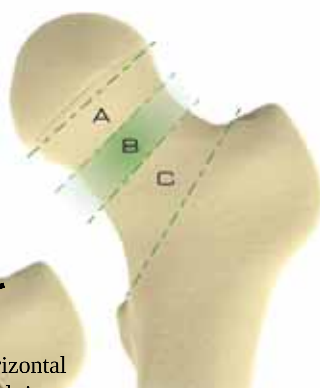
We have reported on modular junction failures in the past and have seen must modular junctions have problems from time to time. However, we have also reported on monoblock stem design failures in cemented, cementless titanium and chrome cobalt designs. The basic conclusion has been unsupported stems are at increased risk of mechanical failure[13,14,15].

Contemporary neck sparing stem designs with modular c.c. junctions can be and have been designed to be stronger than many monoblock titanium stems and many titanium modular neck conventional cementless stems.



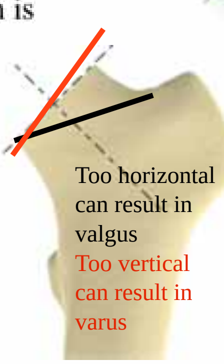


35% less tensile stress in neck stabilized stem vs. monoblock



Surgical Technique:

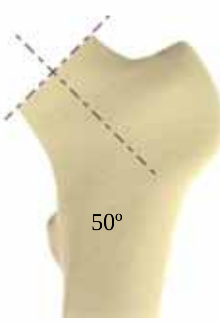
The neck resection is conservative but allows some flexibility to both adapted to both patient anatomy and surgical preference.



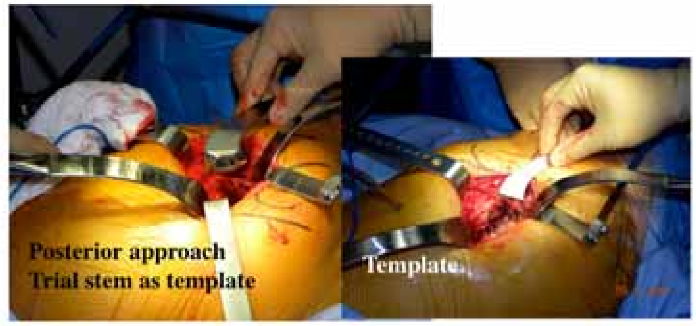
Zone A: 0-5 mm

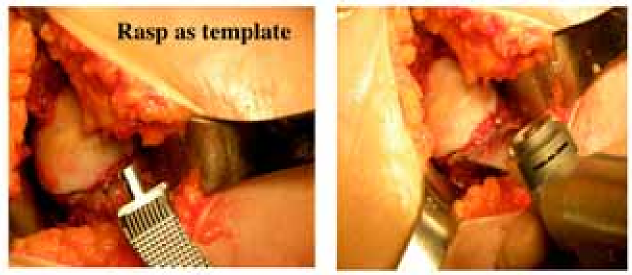
Zone B: 5-10 mm

Zone C: > 10 mm

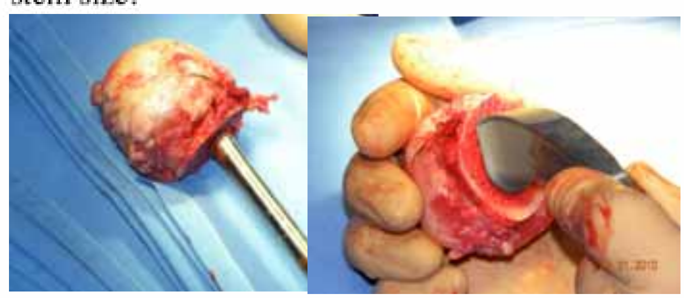


Neck angle is somewhat flexible but a recommendation is to use the resection guide or trial stem or rasp for orientation provides for optimal conical flair / bone contact.

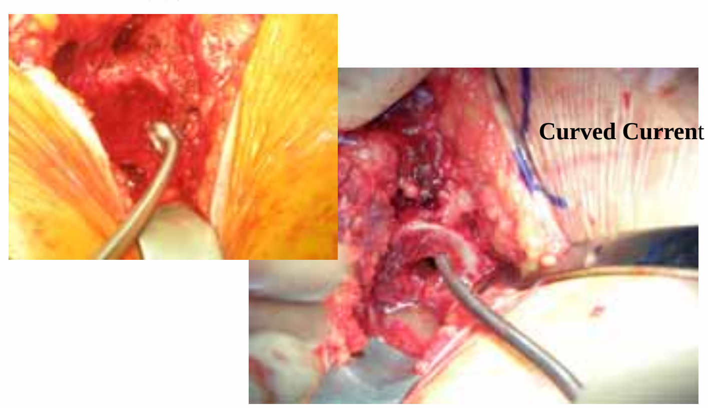




After head resection a good technique is to take the head and trial stem and use the trial stem as a template. It provides a rough estimate as to the final stem size.

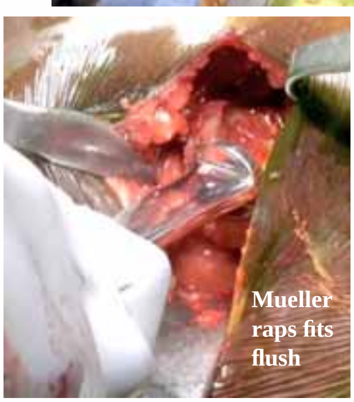


Opening the Femoral Canal can be accomplished by a number of ways and is up to surgeon's preference. A curved current, a curved metal sucker, a trocar drill or a starting AWL can be used to enter the canal.

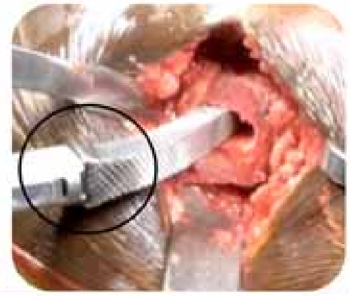


Care should be used with the AWL in softer bone.

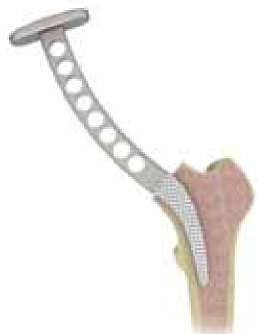
Proximal Canal Preparation is carried out with the use of a rat tail rasp and starter rasp before selection of definitive stem rasps.



Some surgeons prefer using a Mueller style rasp as their starter before going to their **definitive rasp** that shapes the conical flair.



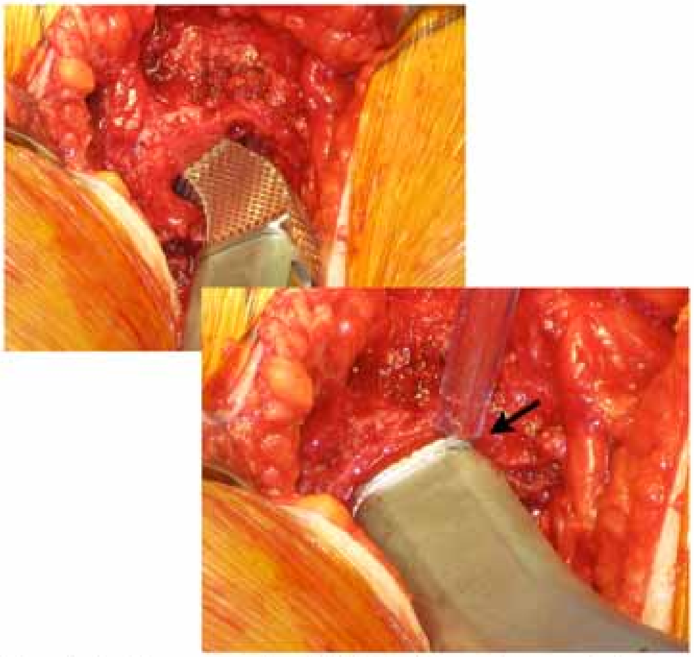
The medial curve needs to be worked, shaping the medial curve of the proximal femur.



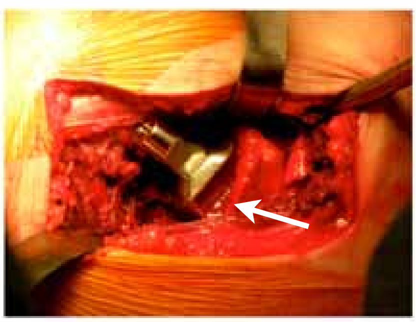
This should be done in a filing motion shaping the medial curve. The curvature of the stem eliminates the need of having to go lateral into the trochanteric bed.

This not only has the advantage of saving bone, but reducing bleeding and reducing potential injury to the abductor soft tissue.

Progressive rasping is carried out till a tight fit in the femoral neck. Remember you are fit and filling the femoral neck not the femoral canal.

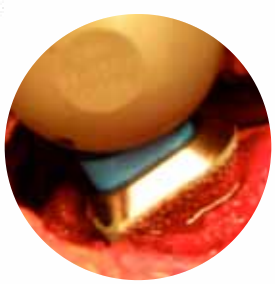


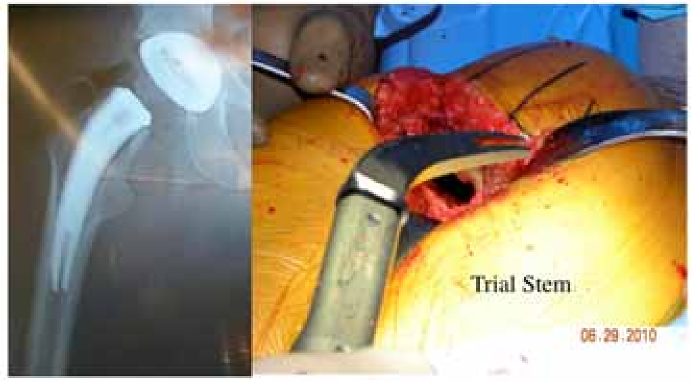
The definitive rasp should fit flush on the conical flair if your initial osteotomy was at the correct angle. If the conical flair is slightly above your resection line do not worry this will not compromise your initial stability.



If your initial neck resection is off you could have a gap around the conical flair of the stem.

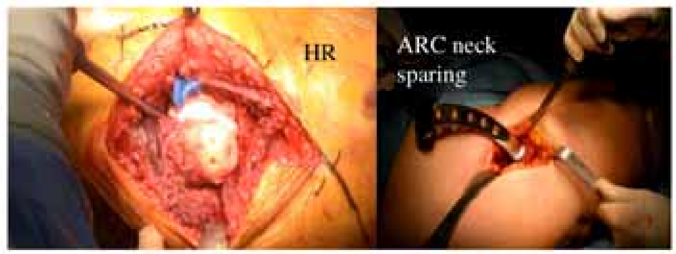
This does not present a problem with initial stability but will not take advantage of the biomechanical loading feature of the conical flair. Small gaps have been seen to fill in at approximately 8-12 months.



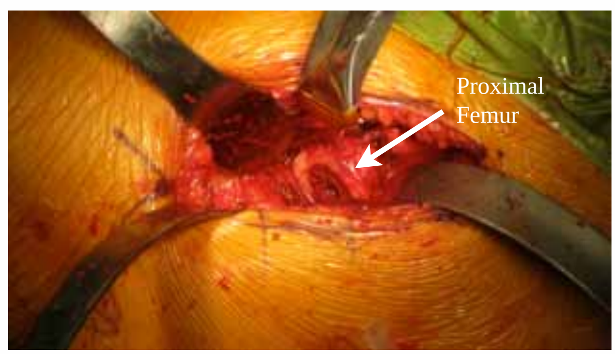


Trial stem in place with trial modular neck.

A short curved stem is easier to insert requiring less posterior capsule releases as compared to a straight stem or hip resurfacing.



Hip Resurfacing requires considerable soft tissue releases as compared to a small curved neck sparing stem.



No special instruments or table is necessary for exposure or elevation of the femur

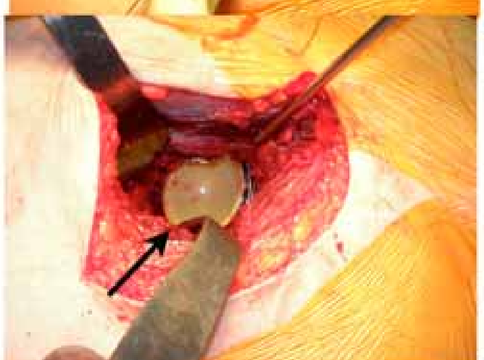
Stem insertion

Stem Seated

Acetabular Exposure:

There is no difficulty with a high neck cut in achieving exposure for either the anterior or posterior approach.

Posterior incision with the trial stem in place *Keppler*



Anterior incision: Stem implanted behind retractor there is no difficulty with exposure for acetabular reaming or insertion of acetabular component. No special instruments or tables are necessary to do a anterior single incision neck sparing short curved stem.

J. Keggi

Ceramic / Ceramic ARC™ Stem with Anterior Single Incision

Results:

650 ARC stems have been implanted since April 2010, 500 by the seven clinical / surgical advisory group, 270 were performed with the single anterior surgical approach and 230 were performed using the posterior approach.

Three surgeons used the anterior approach, three use the posterior approach and one surgeon does some selective cases with the anterior approach approximately 10% of the time.

Anterior Approach

Dislocations = 2

Stem Revisions = 3

Aseptic Loosening = 1

Superficial Infection = 2

Septic Loosening = 0

Leg / Length Discrepancy +/- 7 mm = 9 / 0.3%

Occult fracture distal end of stem = 1

Calcar Fractures wired = 2

Calcar Fractures not wired = 3

Hip pain = 1

Subsidence > 5mm = 3

Intra-op femoral perforation = 3

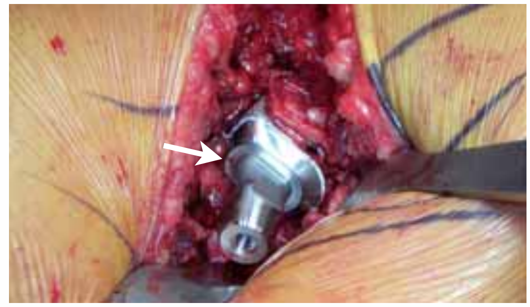
Intra-op calcar fractures resulting in stem bailout = 0

The aseptic loosening case was an intraoperative fracture not recognized at surgery. Patient came in two weeks post-op and had subsided about 5-6 mm and the fracture could be seen at the distal medial calcar. The stem stabilized but never healed and pain was persistent. Revision at five months to a primary cementless KII stem. There was no evidence of bone attachment. Stem was easily extracted and converted to a new primary stem. Patient is doing well. If fracture was recognized a simple wire would have prevented the revision surgery.

Aseptic loosening converted to a K2 primary stem. Pt doing well functioning like a primary patient.

Second female patient with an unrecognized calcar fracture subsided approximately 1 cm. Stem has settled and fracture healed. Patient is pain free and full weight bearing but has a trendelenburg sign due to shortening of the abductors.

Plan is to go in a replace current modular neck with a longer vertical height. This should resolve her gait problem.



Small chip fractures around the proximal cortical rim do not seem to make a difference at least in short-term stability.

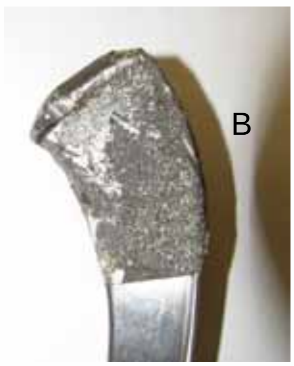
Two intra-operative perforations occurred during stem preparation by two different surgeons both in the single anterior incision approach and both were early in learning curve of the approach and of the stem. Perforation was recognized during trial stem insertion and was picked up on fluoroscopy and both cases the trial was removed and the final stem inserted by passing the perforation. No special precautions were given both patients went on uneventful and are doing well.

Trying to adapt to too many changes at once can be challenging.

Trial stem perforation (anterior-medial) caught and corrected with final stem. Patient had uneventful rehab and went on to a good recovery.

The two minor subsidence have stabilized and are functioning well. The curvature and conical proximal flair provide a shape that allows some minor settling to ensure a long-term bone / implant stable interface. Previous external collars have prevented stems from settling into a position of stability.

The two stem revisions were done outside the core group one for dislocation due to joint laxity (not due to any mechanical impingement issues) and one for hip pain due to heterotopic ossification. Both stems were revised to cementless primary stems.



Retrieved stem A had solid bone attachment at 8 months. Stem B was well fixed at 4 months no signs of loosening had the beginnings of bone attachment.

Well thought out retrieval instruments provided for ease of explantation with little bone destruction and left behind enough bone to convert to primary cementless stem length for both cases.

The single anterior approach by our group does not use a table at times a couple of our surgeons have used the Omni-track table mounted hook.

Posterior Approach

Dislocations = 2

Stem Revisions = 1

Aseptic Loosening = 0

Septic Loosening = 1

Superficial Infection = 0

Leg / length Discrepancy +/- 7 mm = 3 / .013%

Fractures distal = 0

Calcar Cracks wired = 0

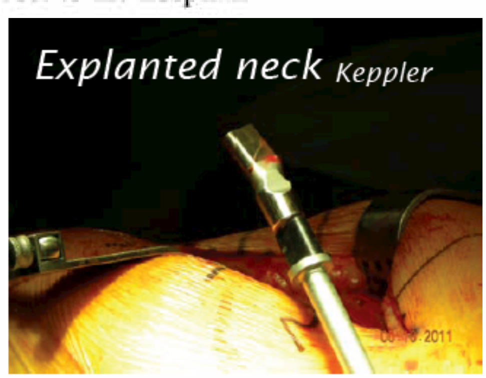
Calcar Cracks not wired = 1

Hip pain = 1 (process of being worked up/ potential spine problem)

Subsidence > 5mm = 0

Intra-op calcar fractures resulting in stem bailout = 2

The two dislocations were treated by explanting the femoral neck for exposure to the acetabular components providing better exposure while leaving the stem in place. One cup had spun out and was replaced with adjunct screw fixation and the second had a poly liner exchange to a hooded offset and increased femoral offset used on the modular neck (12° varus). Both cases were made considerably easier as a result of the modular neck design reducing surgical trauma to the patient and reducing overall cost to the hospital.



Complications outside the 500 case review:

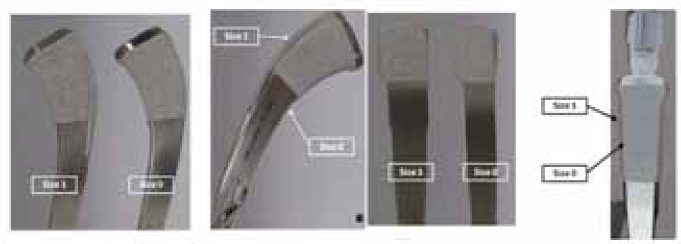
One neck stem disassociation. A MoM head cup combination was used and, even though the neck trunions were compatible, the design on the metal head had a truncated shape that prevented the neck from fully seating into the stem. As the disassociation occurred the medial calcar fractured.

Which was successfully converted to a cementless primary stem. Lesson learned.

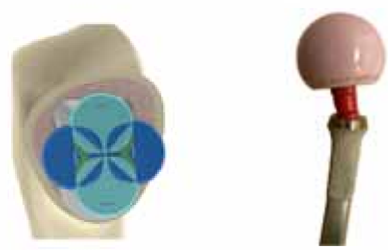
One patient had a fall resulting in a periprosthetic fracture requiring significant revision of total hip stem and previous trauma implants.

Observations:

The initial experience with this short curved novel neck sparing stem design has demonstrated that the stem and instruments needed some minor changes and additions. The five sizes covered about 90% of primary total hip indications. A small stem was needed for the small female profile. This has been done by eliminating the T-back and reducing the proximal geometry in this size. In addition, the size 1 and size 2 stems the T-Back profile has been reduced allowing better seating and elimination of lateral chip fractures to the cortical rim.



Anterverted / Retroverted neck have been added to aid in addressing combined version angles (12°) and reducing potential mechanical impingement issues.



The use of modular necks have provided increased opportunity to fine-tune joint mechanics without disruption of the implant / bone interface. It has also proven useful for increased exposure to the acetablum in case of revision surgery. It has provided a one stem approach regardless of surgical incision.

In the anterior single incision approach it has reduced the incidence in having to do extensive posterior capsular releases. In the posterior approach it has provided the opportunity to do a femur first approach.

When the conical flair is engaged with the cortical rim increased bone density occurs.

Four of our surgeon group now use this as their main stream hip implant and our three other surgeons are expanding their indications.

This stem design saves tissue, both hard (bone) and soft tissue as compared to conventional length, short metaphyseal cementless stems, and to hip resurfacing.

This new design approach has the potential benefit for less blood loss, quicker rehabilitation and, if necessary, easier removal and conversion to revision surgery.

Summary

There is a short learning curve for the surgeon (2-3 cases) and an easy transition for the O.R. surgical team with only one pan of instruments.

Six of the seven surgeons feel that these patients with this short curved neck sparing stem have gotten back to full weight bearing and a full active life style quicker than their conventional cementless THA. One surgeons gauges them as equivalent to his conventional stems. All feel that there is less blood loss and operative times have been reduced.

The few explants have proven to be easily converted to a primary stem for revisions. Two intraoperative calcar fractures resulted in a bail out to a conventional primary cementless stem. The modular neck has proven to be beneficial in a couple of cases for access to the socket in revision situations. The modularity of the neck also helps reducing risk of mechanical impingement.

There have been minor incidence of over lengthening the leg (11) greater than 7 mm however, none have had to be revised.

We are encouraged with our initial clinical / surgical observations (patients are happy) and believe the potential and real benefits warrant not only further evaluation but expanded evaluation of this tissue conserving approach to THA.

Example of bilateral hip with S-Rom® & ARC™ and 1 year follow up showing positive bone remodeling

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