



Design Rationale MSA™ Total Hip Stem Design (Muscle Sparing Approach)

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Background

Total Hip Arthroplasty (THA) has been and continues to be an excellent surgical treatment for diseases of the hip joint. Cementless designs appear to be growing in market acceptance and current clinical results demonstrate 97% good to excellent results at 15-17 years post-op. In spite of these encouraging results there is growing demand for more conservative surgical approaches to hip disease and surgical intervention.

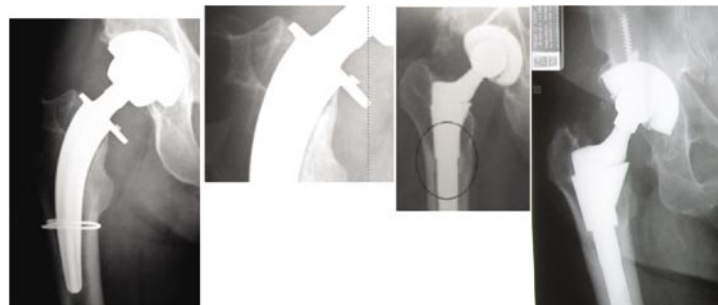


AML® Stem

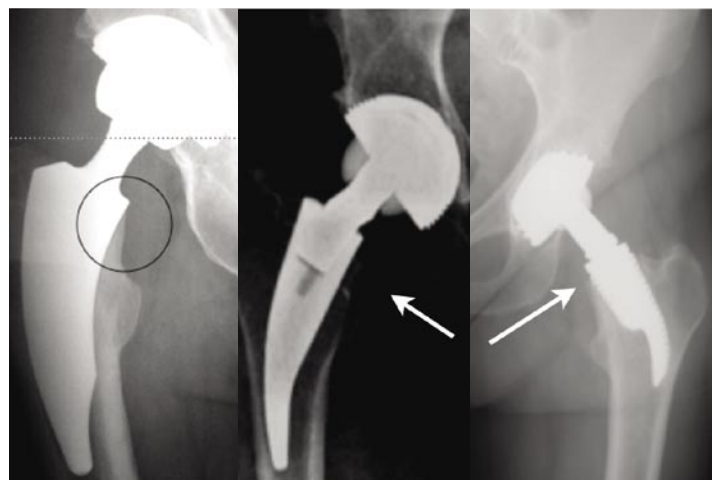
Taper-Lock™ Stem

Huggler Hip

However, bony structural changes do occur after stemmed total hip arthroplasty (THA).

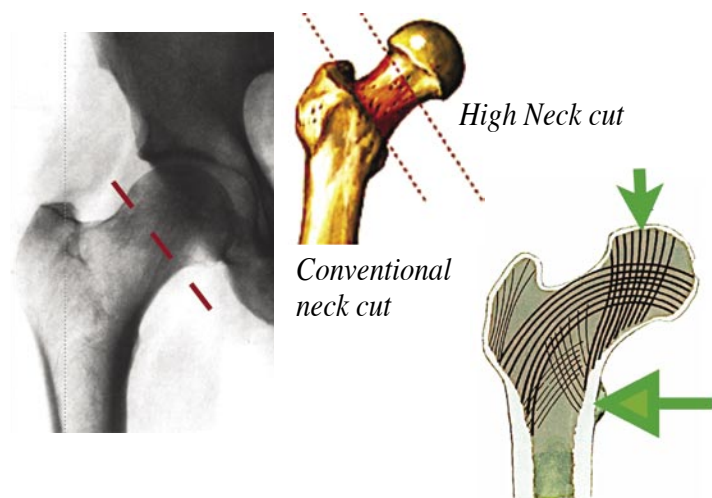


Examples of stress shielding, occurs with most stemmed devices.



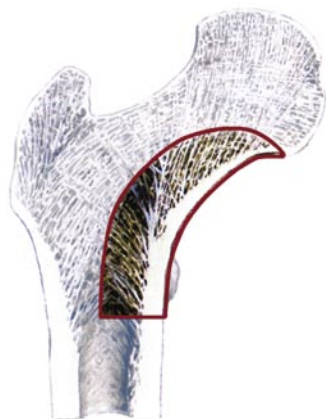
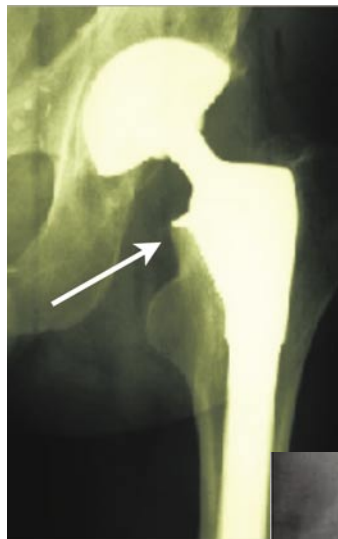
Even in short stems

We can do better in both bone remodeling and in surgical approach.

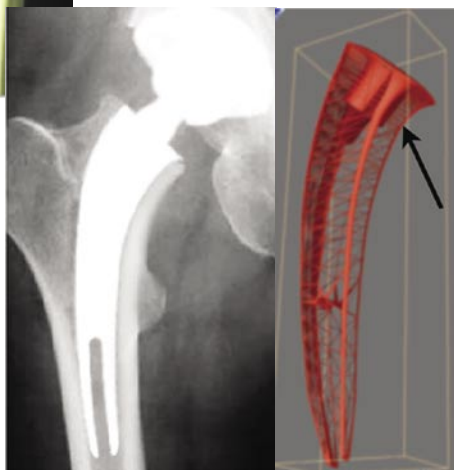


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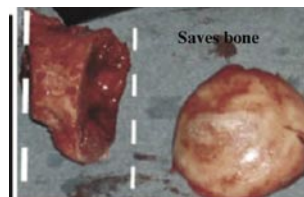
Reprint request: Timothy McTighe, Dr. H.S. (hc), Executive Director,



Proper loading can stimulate bone as seen in this conical collared stem design. Conical collar on the left and internal conical flare are design to off load compressive forces at the medial neck.

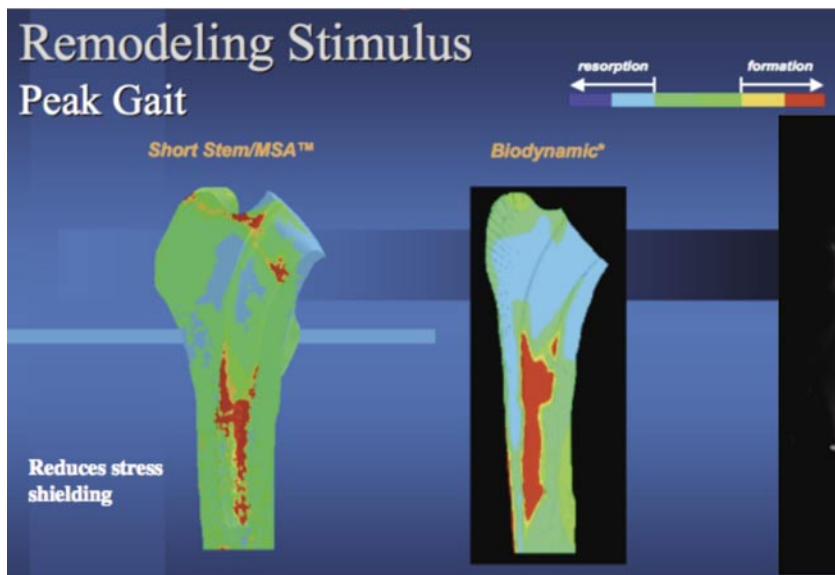


Design and Technique provides for conservative approaches to THA.



A short curved stem saves both soft tissue and hard tissue damage that is required for straighter stem designs.

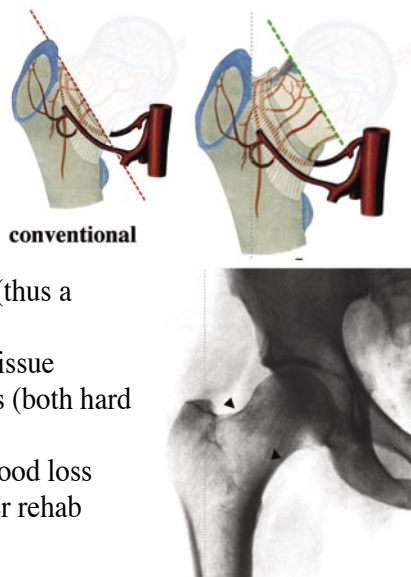
FEA Modeling has demonstrated positive remodeling confirmed by radiographic findings.



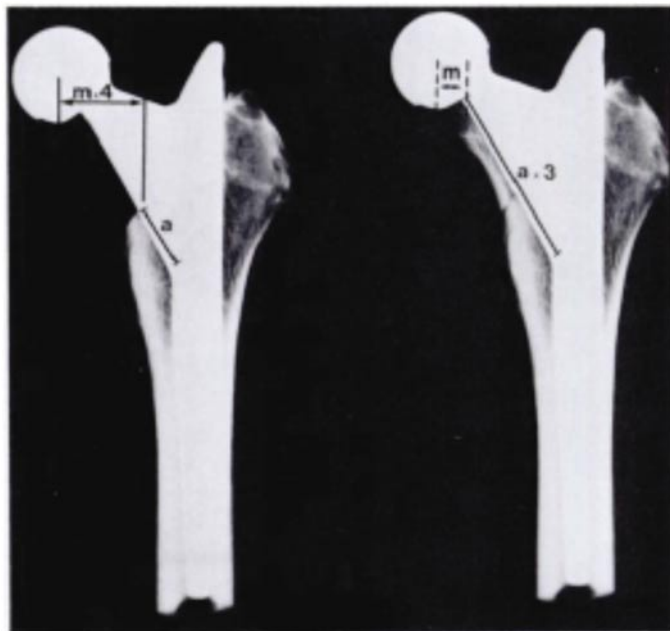
FEA Modeling demonstrates better proximal remodeling for the Tissue Sparing Implant (MSA™ Stem) design as compared to the short Biodynamic™ stem from Pipino earlier work.

Neck Retention

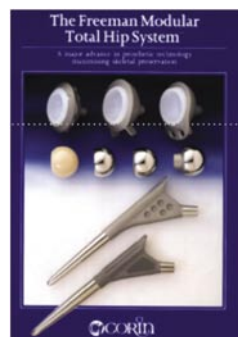
- Provides better blood flow vs. hip resurfacing
- Provides better axial and torsional stability vs. conventional THA (thus a shorter stem)
- Provides for more tissue sparing approaches (both hard and soft tissue)
- Potential for less blood loss
- Potential for quicker rehab



Freeman is credited with the Concept of Neck Retention.



Surgeon designers have advocated neck sparing design however have experienced variable results.



Freeman



Whiteside



Townley

Pipino

Corin Minihip

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.

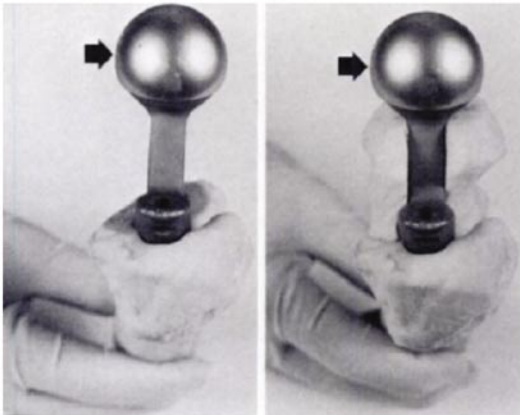
The varus-turning moment increases by a factor of 4 when the neck is resected

There is a trend for short stems but not all short stems are neck sparing designs.



Torsional Resistance

*A/P directed
resultant force*



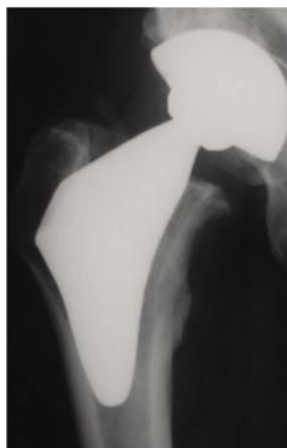
With the neck resected this force generates significant torsional moment on the device which is resisted by shear at the stem/bone interface.

Reviewing historical hip designs finds Michael Freeman advocating neck-sparing features in his early hip designs from the 1970's. He demonstrated, as has Leo Whiteside that there is mechanical advantage in retaining the femoral neck. Both torsional and axial loads are reduced along with bending moments on the femoral component. Charles Townley was another design-surgeon that advocated retaining the femoral neck. Freeman, Whiteside and Townley all advocated neck retention with conventional length total hip stems.

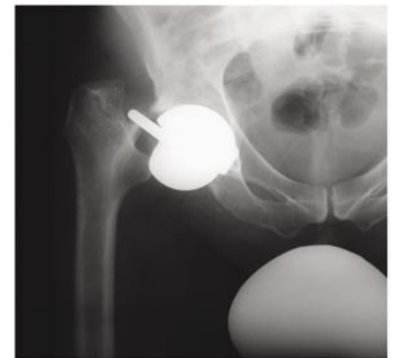
Professor Pipino from Milan, Italy has been promoting the use of neck retention short curved stems for the past 25 years. He has taken the conservative approach even further by advocating tissue-sparing (hard and soft) techniques for THA.

Some of the historical problems of the past deal with the architectural changes that occur in the proximal femur after stem implantation. The challenge has been to create design that loads the medial calcar in compression maintaining the integrity of that bony structure.

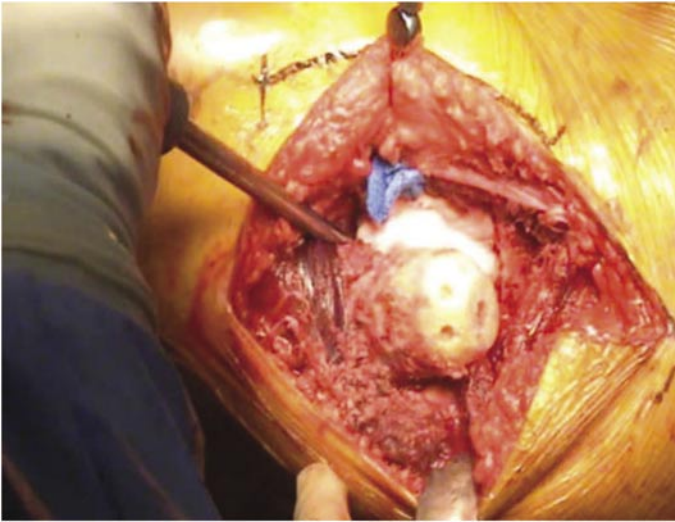
Some short stems require significant bone removal from the lateral side of the bone, risking fracture of the greater trochanter. These design also face considerable difficulty in removal.



Improved metal bearings have rekindled the interest in metal on metal Hip Resurfacing. However this procedure is hardly a tissue preserving surgical approach. Soft tissue exposure is more extensive than traditional THA and more bone is also removed on the acetabular side as compared to conventional THA.



Hip Resurfacing (HR) has demonstrated a significant longer learning curve than traditional THA and results at eight years are closer to 95% survivorship. At first glance, one would think these results were comparable. However, we must remember that indications for Hip Resurfacing (HR) are at most 10-15% of THA.



Example of John Keggi doing a Birmingham Hip Resurfacing vs. a MSA™ Neck Sparing Stem



Note: Incision and additional bone removal on socket side is more than current small anterior conventional THA or anterior Neck Sparing Stem approach. No special instruments other than a bone hook for elevation of the femur is needed.

Does hip resurfacing really address conservative principles?

- Hip resurfacing requires a larger soft tissue approach vs. small or MIS conventional surgical incisions
- Most hip resurfacing is done by the posterior approach, which has been shown to significantly affect blood flow to the femoral head
- Currently only Metal on Metal (MOM) and Metal on Polyethylene (Poly) are available for resurfacing and Metal on Polyethylene in the past has demonstrated drastic clinical results

- Most surgeons do not recommend MOM for woman of childbearing age
- MOM has been shown to be contra-indicated in postmenopausal women
- Current resurfacing has a high demand learning curve
- Hip resurfacing is not bone conserving on the socket side
- Hip resurfacing does not allow for adjusting or fine tuning femoral offset, neck length or version angle
- There is concern as to long-term systemic reaction to metal ions

So what is the answer for this increasing demand for a more conservative surgical intervention? We believe one very viable option is the Tissue Sparing Implant™ Designs or the Muscle Sparing Approach “MSA™ Stem.

The MSA™ Hip Stem features novel design structures that provide for simple reproducible surgical technique, improved biomechanical loads and true tissue sparing techniques for both hard and soft tissue.

MSA design objectives

The design approach was undertaken to improve proximal load transfer while creating a bone or tissue sparing stem that would be simple in design, amenable to reproducible technique, provide for fine tuning joint mechanics while stimulating and maintaining compressive loads to the medial calcar.



In theory neck retaining devices provide for:

- Bone and/or Tissue conservation
- Restoration of joint mechanics
- Minimal blood loss
- Potential reduction in rehabilitation
- Convertible to standard THA in case of revision
- Simple reproducible surgical techniques
- Opportunity to pick Modular options in appropriate bearing surface
- Opportunity to select optimum femoral head diameter
- The selection of any standard surgical approach to the hip

There are a number of trends occurring in THA that are worth noting that can be selectively addressed with the MSA1 Stem System.

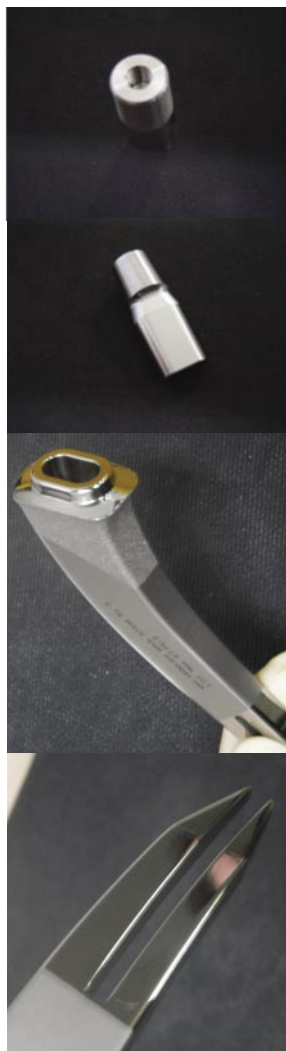
- Hip resurfacing is getting more attention with Metal on Metal bearings and the demand from patients requesting a device that allows them an opportunity to get back to their active lifestyles.
- Large head diameters provide a sense of hip stability and appear to be reducing short-term dislocation. DARIF M-O-M Hip Replacement Surgery Update on Current Successes and Controversies Meeting May 2-3, 2007, San Bernardino, CA
- There is more awareness to restoring joint mechanics providing for better long-term results.

MSA features

The Muscle Sparing Approach™ Stem System provides for:

- A simple reproducible surgical approach
- A conservative approach to soft tissue dissection with reduced blood loss
- A conservative approach to bone socket preparation
- A more conservative femoral approach vs. conventional THA
- Selection of optimum head diameter
- Surgeon selection of bearing surfaces (MOM, COC, COP, MOP, COM)
- Reduced Rehabilitation time
- Conversion to a conventional THA if revision is necessary

The MSA™ Stem is a combination of a simple curved stem with a unique lateral T-back the design of which provides ease of preparation, insertion and enhanced torsional stability (the unique combination of stem curve and flat Anterior/Posterior profile provides resistance to torsional forces). The proximal design has a novel terminal conical design shape to stimulate and transfer compressive forces to the medial calcar. A



modular neck provides for fine-tuning joint mechanics without disruptions of implant bone interfaces (aids in restoring joint anatomy). A distal sagittal slot reduces the distal stiffness of the stem reducing chances of lateral cortex perforation. In the rare case of stem removal being required, a threaded hole is provided for a solid locking feature with instruments for retrievability.

The MSA has a novel approach combining the old and new to create a simple reproducible approach to THA that provides for a larger indication than hip resurfacing and a more conservative operative approach compared to conventional THA.

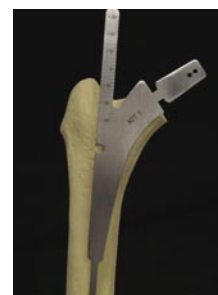
Posterior Surgical Technique

As with Dorr's technique, the patient is positioned in the lateral decubitus position. The skin incision is a short oblique incision centered over the posterior aspect of the greater trochanter. The fascia is divided in line with the fibers of the gluteus maximus. The gluteus maximus muscle is split for about 10 cm. At this point a Charnley self-retaining retractor may then be placed. The abductor musculature is protected and the piriformis tendon is released. The remaining short external rotators and gluteus maximus tendon insertion are not disturbed. The posterior capsule is incised at the base of the neck superiorly, posteriorly and inferiorly and "T" posteriorly. The acetabular insertion of the capsule is preserved. Incising the anterior capsule superiorly is often performed to release contractures.



Osteotomy guide

There is a cutting template that is aligned with the center of the femoral head and provides for visual alignment for our neck osteotomy.

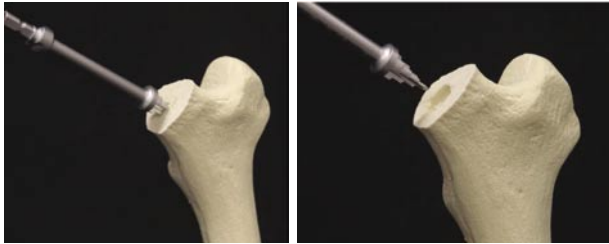


The subcapital high neck resection in no way restricts acetabular exposure.

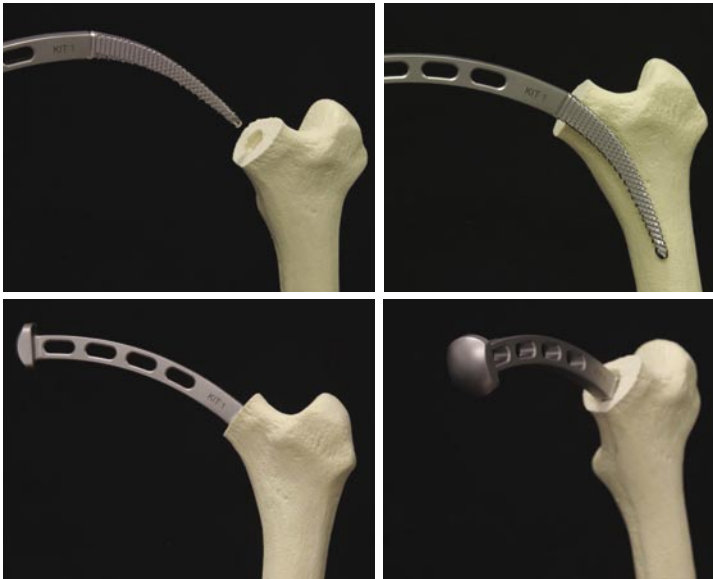
Head resection is approximately 8 mm below the subcap region of the head/neck.

Femoral exposure is simplified without the need to dissect the soft tissue of the piriformis fossa, resect the lateral femoral neck or disturb the medial greater trochanter and abductor insertion.

A starter AWL is used by either power or hand and is about 2 cm in length. This should be positioned slightly inferior on the resected femoral neck.



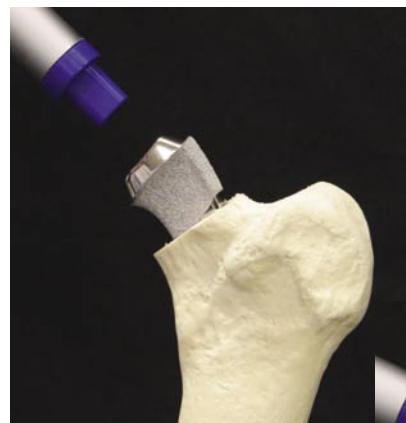
The femoral canal is entered with a small curved rasp. The curvature mimics that of the natural medial curvature of the femur and preserves the proximal lateral cortex of the neck. This is designed as a rasp to help shape the natural medial curvature of the femur.



Note:

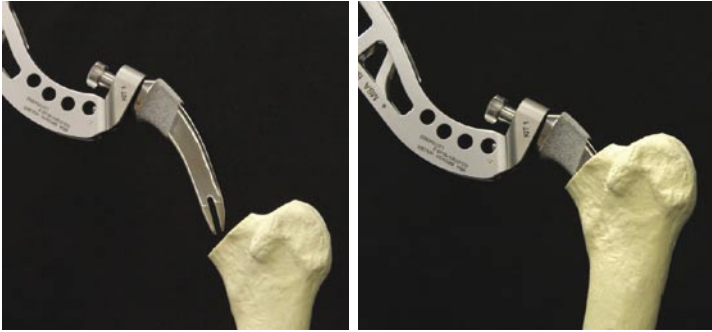
The internal conical flair allows for some variance in level of osteotomy. The higher the neck resection the smaller the size of the stem.

Once the femoral canal is opened with the curved handle starter rasp, progressive rasping is then followed by a size #1 rasp that has an optional pilot guide wire. This is a modular threaded guide pin and helps to ensure proper orientation of our size #1 rasp.



Hand driver



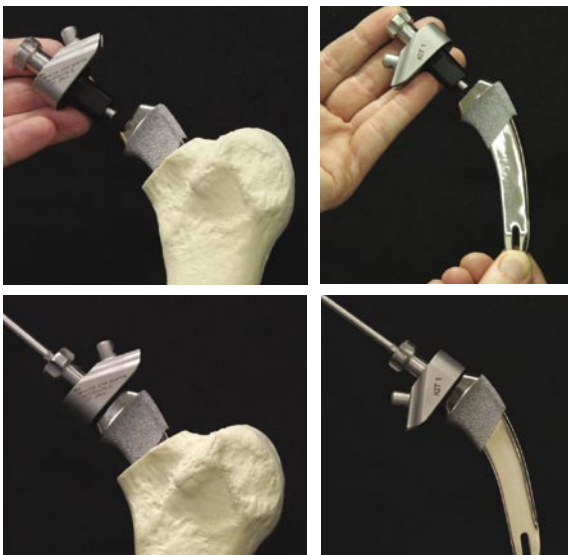


Rasps are used in proper sequence and come in sizes 1-5 incremental sizes. The common bell curve demonstrates sizes 2 & 3 to be more commonly used. Remember the higher the neck osteotomy the smaller the stem size. So in a small size if the number #1 rasp is too tight to properly fit you can resect additional neck (5-8 mm) to help open up to a larger stem size.



Was the proper size rasp is in place you can disengage the handle and the rasp will take trial necks for evaluation of neck length and femoral offset. Vertical length can be fine-tuned by either the modular neck and /or modular head.

If for any reason you need to removal the final neck implant there is a tapped hole that you can thread a slap hammer and retrograde the neck out of the stem.



Stem insertion can be done by inserting the stem by hand then impacting with a plastic tip stem impactor or by placing the stem onto a driving handle that provides for more control of the stem during insertion.

Handle locks onto stem for better control

Once the final stem is seated you can still fine-tune joint mechanics with the use of a modular neck. Their is an extraction hole in the trial neck to aid removal.

The definitive neck is then tapped into place.

The final head is selected and tap onto the neck of the stem. Note: The head/neck taper is a standard 12/14 Euro-Ceramtec taper.

If the final stem needs to be removed there is a stem removal collet that threads into the base of the femoral neck/stem that can be hooked to a slap hammer for retrograde removal of the stem.

We are excited about the potential this technique is going to provide not only to our younger more active patients but also our older patients that have reduced recuperative abilities. Tissue sparing approaches used with the posterior incision should provide for reduced postoperative pain, accelerated rehabilitation and if-and-when needed conversion to a standard conventional length THA with reduced risk associated with revision THA. The techniques are familiar to most orthopedic surgeons, do not require any special equipment, and should not present a steep learning curve.



MSA™ Stem early learning key points

Pre-operative x-rays

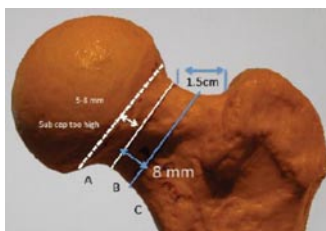
15-20° of internal rotation needed to determine proper femoral offset



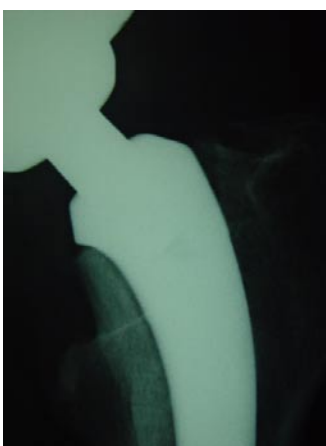
Sub cap too high, 5-8 mm below @ 55° is recommended, 20° IR



Lateral helps determine stem size



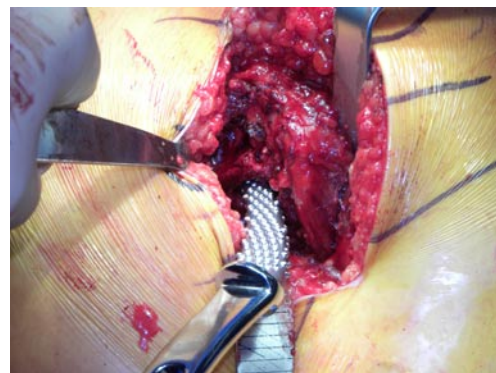
Neck Level Resection



Leg length and femoral offset can be measured intra-operatively by use of a hip calibration guide.



The original Mueller rasp is an excellent tool to work this medial curve.



- If leg length is too long with the shortest head/neck size then resect additional bone from the neck (3-5mm)
- Neck osteotomy angle is important but don't let it mislead you.
- Working the medial curve is a different technique (rasping not broaching)
- Intra-operative imaging is helpful during learning curve.
- Learning curve short (3-4 cases) but there is a learning process in using a curved neck sparing stem.



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