Proximal Modular Stem Design “Dual Press™” With a Dual-Tapered “K2™” Trapezoid Stems

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Abstract: Fat tapered wedge style stems in THA have a long history dating back to Maurice Muller in the 1960’s and Karl Zweymuller in the 1970’s. The profile of this design allows for: simple surgical technique; sequential broaching; no reaming; wedge fit providing immediate implant to bone stability. Tapered cementless stems were introduced in the United States with the Tri-Lock™ in 1981 in c.c. (2001 Ti) and Taperloc™ in 1982. Since then there has been a number of monoblock tapered stem designs (Corail, Accolaid, CLS) introduced into the world market. One problem associated with monoblock tapered stems has been leg length discrepancy. Proximal modularity increases the number of implant parameter variables, allowing semi-custom or fine tuning of joint mechanics. This paper will review 550 K2™ proximal modular stems implanted since 2005 with a novel “Dual Press” Modular junction. We have found this design to increase accuracy of restoring joint mechanics and reducing hip dislocations. Key Words: Dual Press, tapered, joint mechanics, proximal modular. March, 2009 Published by JISRF.

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. 1 Over the past ten years cementless THA has become the gold standard in the United States for THA. 2,3,4,5 Tapered stem designs have grown in acceptance and usage since their introduction in Europe in the 1960’s. 6

Modern stems come in a vast array of designs, but virtually all have a modular head neck junction. 5,7 The increased trend of using tapered stem designs places more of a burden on correct restoration of hip mechanics due to the variability of mid-stem contact point during stem insertion. The importance of restoration of femoral offset is well published. 8,9 However, many modern stems offer limited offsets.

Unlike traditional dual-tapered stem designs, the K2™ proximal modular stem allows intra-operative versatility with the ability to independently select the correct stem, neck and head configuration based on individual patient anatomy.

Material & Methods:

A retrospective analysis of patients who underwent primary THA with a proximal modular “Dual Press K2™ Stem” was undertaken. The inclusion period was between January 2005 and March 2009.

This is a continuation of previous work by the same group that presented data at the 2007 Australian Orthopaedic Association on restoration of head center data with this stem.

There has been 550 stems implanted with this novel proximal modular stem design by three separate groups. Two used a small posterior incision, and one group used the anterior single and dual incision. A variety of acetabular components were used with two of the groups primary bearing being large MOM, while the anterior group used predominately COC.

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The COC were 32 mm head diameter and the MOM were large heads greater than 36 mm. There has been an increased usage in the past year of ceramic on cross linked poly by the MOM users as a result of increased concern over published reports. These reports indicate high metal ions, metal sensitivity, and some minor short term acetabular component aseptic loosening problems.

Out of the original 550 patients 390 had greater than two year follow up. Typical patient profile showed two-thirds being female with an age range from mid 20s to late 80s. Majority were treated for OA.

Stem has been used in all Dorr bone classifications (A, B & C). Although two of the groups preferred using a modular straight stem design to provide proximal-distal mismatch (Apex™ Modular Straight stem) resulting in less distal bone removal in type A bone.

This review was limited to looking at revision rate for dislocation, aseptic and septic loosening. Since most patients underwent hard on hard bearings wear evaluation, at this point, was not a concern.

**Biomechanics**

Why should we restore joint biomechanics?

- Improved abductor function
  - Less fatigue
  - More comfort for patient
- Leg length
  - Annoying / Debilitating
  - Back pain
  - Litigation

Over lengthening to achieve joint stability is a significant problem in THA. Leg length inequality is the number one cause of litigation in THA.

Dr. Amstutz has stated: “Despite a number of improvements in femoral stem neck geometry and increasing femoral head sizes up to 36 mm, dislocation continues to be a significant problem after THA”. Reduction of mechanical impingement can be helped with larger head technology but do not confuse mechanical impingement with intrinsic instability. Muscle laxity is rarely improved with the use of just large heads.

The acetabulum is generally spherical in shape and its opening is oriented closer to 55° than 45°, downward in the coronal and sagittal plane, and anteverted approximately 15° to 20° in the midsagittal plane.

Initial acetabular component stability is affected by the cup’s ability to engage with the host bone. This is a function of cup design, size, and surgical technique. Cups of a true hemispherical design are more stable than low-profile designs.

Large heads can increase jump distance if positioned at 35°- 40° of abduction. Too vertical can increase edge loading and run away wear in MOM and in poly can increase stress resulting in increased wear and deformation and breakage of lipped liners.

The trend of navigation, large MOM bearings and increased use of constrained sockets clearly demonstrates that joint stability is a real problem especially in light of the increased patient related activities in todays life-styles.
Two previous papers have clearly demonstrated improved outcomes with this style proximal modular Dual Press junction. “Target Restoration of Hip Mechanics in THA” AAOS exhibit 2006 and 2007 AOA exhibit “Restoration of Femoral Offset Using a Dual-Tapered Trapezoid Stem.”

Distal and mid-stem fixation point in tapered stems affect biomechanical position of the reconstruction.

Monoblock designs make restoration of joint mechanics difficult! Stem fit needs to be separated from joint mechanics.

Only the independent selection of offset, version and leg-length provides for optimal intrinsic stability and restoration of joint mechanics.

The incidence of dislocation of primary hip replacement is quite variable but remains a significant problem.

A number of factors have resulted in decreased risk of dislocation. These factors include smaller and improved neck designs, greater head to neck ratio, more surgical options for length and offset, and soft tissue solutions such as the “Mayo” repair.
Design

The K2 Dual-Tapered Trapezoid Stem is built off the design and clinical experience of our senior author’s experience in using the Zweymuller stem.

The stem profile provides excellent torsional stability but can be difficult with the large lateral shoulder during stem insertion in smaller muscle sparing approaches.

The K2 features the flat stem profile of the Zweymuller with reduced lateral shoulder profile and proximal porous coating for enhanced long-term fixation.

The proximal shoulder features the novel “Dual-Press™” modular junction which provides for fine-tuning joint mechanics without disruption of implant-bone-interfaces.16

The patented Dual Press™ modular connection mechanism allows the neck to fully seat against the proximal surface of the stem utilizing a simple assembly device. Unlike traditional taper-style modular junctions, this eliminates gapping and evenly distributes forces throughout the entire shoulder of the stem.

Surgical Technique

Femoral Head Resection

Measure proximally from the lesser trochanter and mark the distance which corresponds to the proper resection level from preoperative planning. Resect the neck. The resection should be directed obliquely and medially from the level marked above the trochanteric fossa.17

Technique Tip: A conservative cut is recommended here. Fine tuning may be accomplished later in the procedure.

Intramedullary Access

This is one of the most important steps. A box chisel is used making sure you are lateral and in straight axial alignment with the canal of the femur.

A tapered reamer is then used to aid in opening the femoral canal and ease of broaching.

Sequential broaching is then carried out to ensure the proper size can be inserted.
**Trial Reduction**

The modular neck trials slide onto the stud on the proximal end of the broach. Select the neck trial based on preoperative planning and on the previous intraoperative assessments. Slide the neck trial onto the broach, taking care to establish the proper version (0 or ±13 degrees anteversion). Affix a modular head trial onto the neck trial and reduce the hip. Assess leg length, range of motion, and stability. Adjust as necessary by choosing a different neck / head combination, or by anteverting, or both.

**Note:** Trial head / neck can be done both on the broach and on the final implanted stem. This ensures that you can fine tune joint mechanics without disruption of bone-implant-interface.

Leg length and offset may be fine tuned by changing the neck and/or head. Often stability can be enhanced by choosing an anteverted neck (±13°).

**Implant Assembly**

Device may be assembled on the back table or in situ depending on surgeon preference or surgical indication. The important feature to remember is that the surgeon has last minute opportunity to fine-tune joint mechanics without disruption of implant-bone-interface.

If assembled on the back table selection of appropriate proximal shoulder / neck (neutral or version 13°) is then assembled and inserted on the stem as a monoblock stem would be. If necessary proximal modular neck can be removed and any adjustments made prior to closure.

**Important:** Care must be taken to ensure that the mating surfaces of the stem and neck are clean prior to and during assembly. Entrapped bone or soft tissue may result in incomplete seating of the neck.

The use of modular stems regardless of surgical approach allows for reduced tissue trauma during stem preparation and insertion.
Results

550 K2™ stems have been implanted since 2005. 410 with the anterior approach approximately half with a single incision and half done with a dual incision.

210 patients are past two year follow-up.

Anterior Approach

Dislocations = 0
Stem Revisions = 3
Aseptic loosening = 0
Septic loosening = 1
Leg/length discrepancy +/- 5 mm = 0
Thigh Pain = 0

0 mechanical failure of modular junction

The three stems revisions were for one septic loosening and two post-operative peri-prosthetic fractures in women (type C bone). The two peri-prosthetic fractures were treated with long stem cementless Zweymuller stems and both healed uneventfully.

Posterior Approach

Dislocations = 1
Stem Revisions = 0
Aseptic loosening = 0
Septic loosening = 0
Leg/length discrepancy +/- 5 mm = 0
Thigh pain = 1

0 mechanical failure of modular junction

Note: One female patient in the posterior group has recently been seen at first post-op visit (7 weeks), presenting with anterior thigh pain. Bone quality is Dorr B type. Stem is in a neutral position and appears to be well sized. This is a concern and patient will be followed-up in six weeks.

Two patients in the posterior group with MOM bearings have had cup revision due to cup spin out. One patient was one (1) year out with an ASR metal acetabular component. Patient presented with increasing groin and buttock pain. X-rays demonstrated that original cup position had changed and did not appear to be ingrown. The proximal modular junction of the K2 stem was disengaged allowing access to the socket.

K2 removal instruments provide ease of removal of proximal modular body making cup revision significantly easier with less bone destruction.

The Explant cup removal system (Zimmer) was used making removal with minimal bone loss possible.

A cementless porous component with adjunct screw and poly bearing was then inserted.

Second patient was female that presented a spun out MOM (Wright Medical) acetabular bearing component at her first post-op visit at seven (7) weeks.

Since intra-operative x-rays are taken on all patients it is assumed that cup slippage accrued during the early post-op period and then stabilized. Again the proximal modular junction was disengaged and cup removed with Explant system.

A new proximal modular neck and head were implanted with a cementless porous cup with one (1) screw for adjunct fixation.

One patient in the posterior group had multiple dislocations and was revised by disengagement of the proximal modular junction and exchanged with an increased femoral offset and anterverted modular neck.
**Discussion**

Modern day designs in implants and instrumentation have made THA more reproducible and in case of revision provide design features and benefits that reduce operative time, and complications as a result offer significant cost savings in revision scenario as compared to traditional monoblock stem designs.

The use of proximal modular stems has in our clinical practice reduced stem revisions and dislocations as compared to monoblock stems. In the rare occasion on cup revisions its use has allowed us to disengage the proximal modular junction for improved access to the acetabular component.

The K2™ Dual-Tapered Trapezoid Stem has proven to be safe and effective in both the anterior and posterior approaches and we remain very optimistic about its potential for long-term improvement in clinical outcomes.

Kristaps Keggi, M.D. says “The K-2 has made the anterior approach even more tissue sparing, and because of the restoration of the patient’s individually unique bony and soft tissue anatomy, that much more conducive to better function with even less chance of dislocations. It has been our hope that the K-2 modularity would also make the anterior approach easier to teach and learn for surgeons, while making life better for patients. The Keggi group feels this style modularity does indeed offer a renewed opportunity for the anterior approach to be adopted by more surgeons.”

One of our surgeons is in the process of reviewing data as to energy expenditure as a measure of improved performance by use of a mobile gait analysis device which should provide additional data in comparing monoblock and modular designs.

**Conclusion**

Proximal modularity of the femoral neck stem junction is an attractive option allowing fine-tuning of the mechanics of a hip replacement during the procedure, particularly with cementless fixation where the surgeon may have little control of the position of the implant within the bone. This is especially true where there are variations of the femoral anatomy.

We have found in both the anterior and posterior small incision approaches that in-situ assembly of the proximal modular “Dual Press™” design greatly facilitates minimally invasive surgery compared to insertion of a monoblock stem.

Modular designs also allow for many variations and combinations while keeping inventory levels down. While modularity has these advantages, it does come with its own problems. Modular junctions can fail, fretting at modular sites can occur and component failures have been seen. However, newer design features, like the current “Dual Press™” design, have demonstrated no mechanical failure since the introduction of this Dual-Tapered Trapezoid Stem in 2005.

Our multi-group experience has demonstrated this device to be safe, and effective. It has all but eliminated our dislocation rate and in the one case that did dislocate the design allowed for ease of revision by exchanging only the proximal modular neck body.

We have also seen advantage in the proximal body design allowing removal of this proximal junction for improved exposure in the case of two MOM cup spin outs.

We remain very encouraged by the performance of this device and are continuing to use this on a routine basis. Ongoing studies looking at gait analysis and other outcome measures will be provided in the future.
References