Joint Implant Surgery
& Research Foundation
APRIL, 2002

JISRF Update

Cementless Modular Stems

By Timothy McTighe, Editor

Introduction

Our past November 2001 feature article reviewed and highlighted a specific modular design for use in a cemented total hip stem. This article will look at modular cementless stems. Both of these publications are dealing with the restoration of the joint mechanics. The goal of biomechanical restoration of the hip is the same regardless of the type of stem fixation used. However, due to the inherent properties of materials, limitations can and do occur for specific design features. Example: specific designs that are acceptable and reliable for cobalt chrome alloy might be unacceptable for titanium alloy designs.

The early nineties saw a number of first and second-generation modular stems come and go.

It is important to understand the specific design features and goals of Modular Total Hip Stems and not to lump all designs into one simple category " Modular Stems". In fact, modular sites, designs, features, material and quality can be quite different in nature and sophistication.

Modularity Classification

- Proximal
- Mid-stem
- Distal

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Joint Implant Surgery and Research Foundation is a non-profit scientific and educational organization founded in 1971 by professor Charles O. Bechtol, M.D.

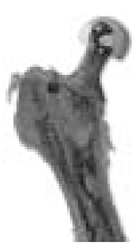
The foundation over its past 30 years has conducted CME activities for both surgeons and nurses while sponsoring clinical / surgical study groups, including basic science projects that have led to the development and marketing of significant Total Joint Replacement Implants.

Product Review

Proximal

Head/Neck

AML® is now considered both state-of-the-art in head/neck design and gold standard as cementless stem.

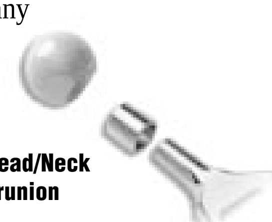


Retrieved ingrowth sample (Collier)

Example head/neck taper

Neck Extensions

Trunion sleeves offer increased neck length adjustments, however, tend to reduce range of motion. Many designs have discontinued offering this feature.



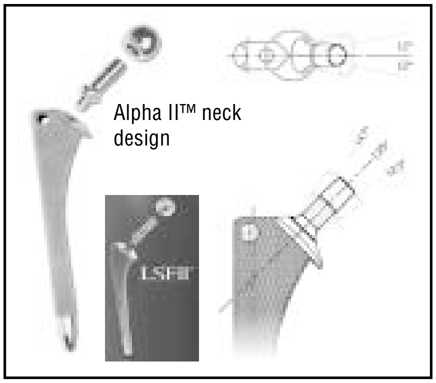
Head/Neck Trunion

Product Review *(continued)*

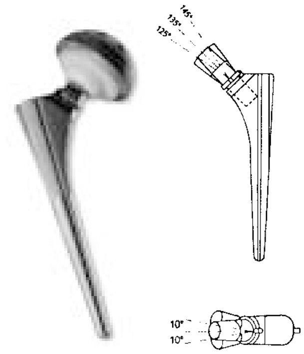
Modular Necks

These designs allow for adjustment of hip mechanics in a mono-block stem. In addition, they provide the option for stem insertion prior to cup preparation, thus reducing operative blood loss. The OTI design is the only c.c. modular neck design of which we are aware.

OTI



Cremascoli neck designs



Lima F2L™ Multineck design

Anterior / Posterior Pads

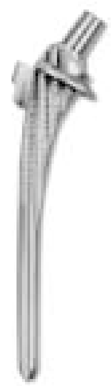
This design allowed for adjustment of fit & fill in the A-P width of the implant. It was criticized for not having circumferential porous proximal coating. While the design allowed for adjustment or fine tuning of joint mechanics, it was discontinued.

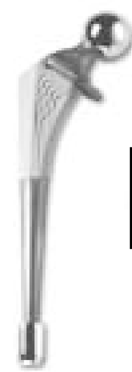
Richards Modular Stem

Modular Collars

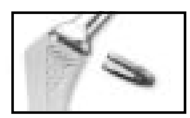
These designs increase collar/calcar contact. Omni-Flex porous was criticized like the RMS for not having circumferential coating and was discontinued, however the HA version is still in limited use. There have been no reported fractures of their collars.

Link®





OmniFlex™

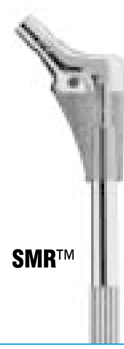


Proximal Shoulders (bodies)

This area of modularity encounters the largest differential in design styles. Some devices like Apex and Margron are more than just a neck, but less than a metaphyseal body. They have the design option of increasing their proximal body height to compensate for bone loss. Some of these designs, like Apex and Margron, also allow for variable anteversion.

These designs all feature different locking mechanisms for the modular components.

Apex Modular™



SMR™

Margron™

Infinity™

Product Review *(continued)*

Stem Sleeves

Stem sleeves offer the advantage of fit & fill with adjustment of hip mechanics. Some designs like the S-Rom™ require removal of the stem to correct offset or version, while newer designs allow for correction with the stem *insitu*. All of these designs feature a modular site located within the femoral bony cavity. This has a higher concern of fretting wear debris being delivered directly to the implant/bone interface versus designs with modular sites located out of the femoral cavity.

Dr. Sivash is credited with creating the first stem/sleeve cementless total hip stem introduced in the United States by the U.S. Surgical Corporation.

The Sivash total hip system never received major clinical or market success, partially due to the difficulty of the surgical technique, and the positioning of this constrained device. We must, however, not overlook its major areas of contribution.

- Titanium alloy for femoral stem and chrome cobalt for head articulation
- Cementless (threaded) petalled acetabular component
- Titanium alloy proximal sleeves for enhanced collar calcar contact
- Constrained articulation (metal on metal)

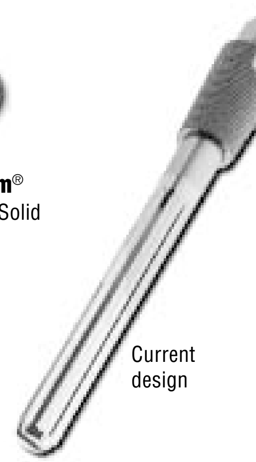
In 1975 Noiles and Russin redesigned the Sivash stem to improve its function in cementless THA. Adding eight longitudal flutes similar to that of the Samson intramedullary rod reduced torsional forces on the implant interface.

Dr. Hugh Cameron started his clinical use of threaded sleeves and the S-Rom stem in July, 1984. Due to demanding surgical technique, an array of press-fit taper-lock sleeves was developed. This evolved into the current stem sleeve combination and is now considered the gold standard for modular cementless stems.

Sivash

SRN™

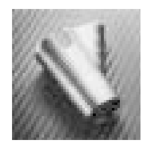
S-Rom®
1984 Solid Fluted Stem



Current design

SRN™ (1975)

S-Rom (1983)



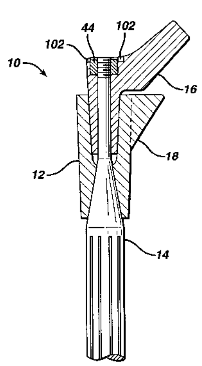
SPT™ (1984)

SPA™ (1984)

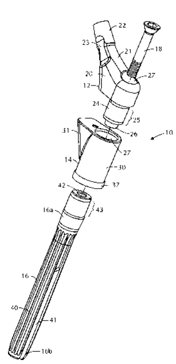
AcuMatch™

UniSyn™

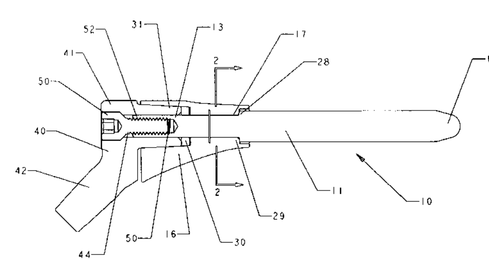
Recently Issued Stem Sleeve Patents



Noiles, et al
2001



Fernandez, et al
2001



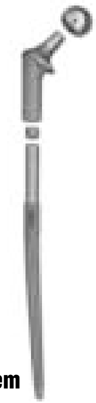
Doubler, et al
2001

Product Review *(continued)*

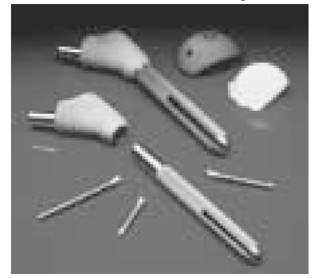
Mid-Stem

These designs offer versatility in correction of sizing mismatch between proximal and distal femoral anatomy. This feature has been very helpful in complex revision cases.

Cremacoli



Link™ MP Stem



Impact™

Mallory/ Head™

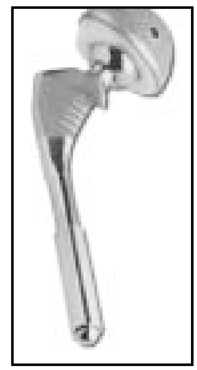
Distal Sleeves

These designs allow for distal stem fit with different distal style options (smooth, fluted, or porous). One of the more interesting concepts is the Omniflex™ stem from Osteonics. This stem features a polished distal stem tip. The design goal was to improve load transfer and minimize the thigh pain associated with a poor fitting or toggling distal stem.

Devices like the APR II and RMS had other under-designed features including the lack of circumferential coatings, poor locking designs on modular cups, and, in the case of the APR II titanium femoral heads, significant bone lysis. The combination of problems certainly affected the acceptance of distal sleeve designs. Possibly, with current technology, distal sleeves could be designed with minimal abrasion wear problems. However, I believe distal sleeves would have great difficulty gaining acceptance in the marketplace.

Of these devices, I believe only the Omniflex HA stem is still available.

Richard's Matrix™



APR II™

HA OmniFlex™

Precision Osteolock™

Multi-Modularity

The RMS is the best example of excess modular sites for a cementless hip stem.

In addition to the modular sites for its cementless porous cup and optional screws, you could end up with over six interface sites. From a fit & fill point of view this system was a very novel approach that offered significant versatility in addressing surgical and anatomical situations. However, it faced too many problems in the market and has been discontinued.

RMS™
Modular Head
Modular neck trunion
Modular A/P Porous Pads
Modular distal Sleeves

Summary

These stems represent some of the current trends in both design and marketing efforts. This tendency is no doubt due to both the clinical and market success of the S-Rom and competition attempting to improve upon the S-Rom stem by offering different design features. These designs attempt to offer features for fit & fill of the implant to the bone and some adjustment of joint mechanics.

Certain modular designs' goals have changed over the past 15-17 years. In the early 1980s fit & fill were the principal objectives. Today aseptic loosing does not have the same concern. The reduction of particulate derbies and restoration of hip mechanics are the focal point.

The AML certainly has become the gold standard for cementless monoblock stems and the S-Rom stem is considered the gold standard for modular cementless stems. As with all advancements in design and technology, products that work well today would not necessarily be designed as is with our current knowledge base.

In 1995, along with coauthors Trick and Koenman, we wrote a chapter in the Encyclopedic Handbook of Biomaterials and Bioengineering, "Design Considerations For Cementless THA". In that chapter we reviewed the use of modularity and made some predictions as to product design features in the near future. The main focus of our design direction was for the stem to incorporate a proximal modular body that would allow for correction of version, offset and vertical height without disruption of the stem body from its bone interface. Proximal bodies of different sizes and shapes would be available that provide for versatility and retrievability with little or no bone destruction.

McTighe, et al "Intrinsic" Design

No one would argue that restoration of hip mechanics is critical to a long-term successful clinical outcome. Today designs exist that allow the correction, or fine-tuning, of the hip mechanics after the stem has been implanted. This issue will feature one specific design (Apex Modular Stem).

Surgeon Highlight

Dr. Tkach implanting new modular cementless stem.

Dr. Tom Tkach

Oklahoma City, Oklahoma

Education:

Premedical	B.S., Zoology, University of Oklahoma - 1985 M.D., University of Oklahoma - 1989
Intern	General Surgery, University of Oklahoma - 1989 to 1990
Residency	Orthopaedic Surgery and Rehabilitation, University of Oklahoma Health Sciences Center - 1990 to 1994
Fellowship	Total Joint Fellowship, University of Utah - 1994 to 1995

Honors & Awards:

The University of Oklahoma College of Medicine Admissions Committee - 1989

The University of Oklahoma Dean's List, Fall - 1983

Professional Organizations:

Oklahoma Medical Student Association
Oklahoma State Medical Association
Oklahoma County Medical Society
Oklahoma State Orthopaedic Society
American Academy of Orthopaedic Surgeons
American Medical Association
American Association of Hip and Knee Surgeons
Mid-America Orthopaedic Association

FEATURE ARTICLE

New Proximal "Dual Press™" Modular Stem Design

By *JISRF/Apex Study Group Members

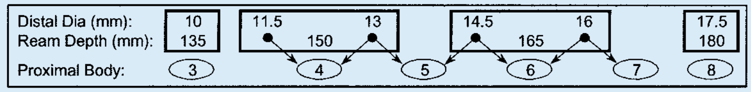
The clinical success of the S-Rom cementless stem not only comes from its modular feature improving on fit & fill but primarily from its stable intrinsic design features: proximal cone; medial triangle; distal straight stem with torsional flutes and a coronal slot.

Today there are a number of cementless stems, both monoblock and modular, that incorporate these same features. However, a number of concerns still remain: limitations for correction of joint mechanics (particularly after stem implantation); generation of particulate derbies; fatigue strength and retrievability.

Figure 1

Apex Modular femoral components

Figure 2



Proximal Bodies by Distal Diameter

Legend: Neck / Head

Leg Length (vertical drop) (mm)	32.5	35	37.5	40	42.5	45	47.5	50	52.5	55
40								Long 45 +7		Long 50 +7
37.5							Long 45 +3.5		Long 50 +3.5	
35					Med 37.5 +7	Long 45 0	Med 42.5 +7	Long 50 0	Med 47.5 +7	
32.5				Med 37.5 +3.5	Long 45 -3.5	Med 42.5 +3.5	Long 50 -3.5	Med 47.5 +3.5	Sh+ 47.5 +7	
30			Med 37.5 0	Short 35 +7	Med 42.5 0	Short 40 +7	Med 47.5 0	Sh+ 47.5 +3.5		
27.5		Med 37.5 -3.5	Short 35 +3.5	Med 42.5 -3.5	Short 40 +3.5	Med 47.5 -3.5	Sh+ 47.5 0			
25		Short 35 0		Short 40 0		Sh+ 47.5 -3.5				
22.5	Short 35 -3.5		Short 40 -3.5							
20										

Lateral Offset (mm)

* +7 Heads not available in Alumina ceramic

Modular Neck/Head Selection Chart

With these concerns in mind a design goal was established to provide for a new proximal modular cementless stem (Fig. 1) that would address the proven fit & fill features of today's contemporary cementless stems with updated modular features that provide for more intra-operative options (Fig. 2).

The Apex Modular hip stem employs a modular junction between the titanium alloy stem and neck that is simple, robust, and very stable. This patent pending modular design allows for a large selection of necks to enable the proper combination of anteversion angle, lateral offset, and neck length/leg length, for the restoration of proper soft tissue tension and joint biomechanics.

The neck is connected to the stem with a Dual Press junction (Fig. 3). This modular attachment mechanism is new to orthopaedic implants, but the concept was derived from conventional mechanical tool design. The main distinguishing feature is that the hole in the stem and the mating peg on the neck are cylindrical rather than conical or tapered. To create a mechanical lock, the proximal and distal diameters of the peg are slightly larger than the corresponding holes in the stem, creating two bands of interference, or "press fit".

This design eliminates the need for locking tapers, which can be difficult to manufacture and prone to disassociation, and avoids the use of screws, which can loosen and disassemble. For all practical purposes, the stem performs as a one-piece stem (with a conventional modular head) after attachment of the neck.

The proximal end of each stem includes an alignment pin that engages with a mating hole on the distal surface of each

Figure 3

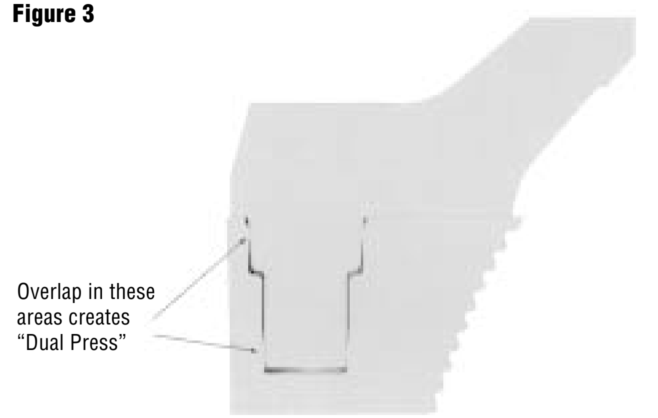
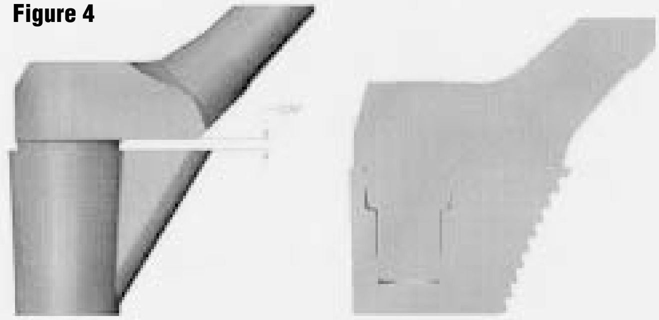


Figure 4



Schematic of S-ROM ® (taper-fit) Schematic of Apex (Dual Press)

modular neck. Each neck has three holes, corresponding to zero, plus 15, and minus 15 degrees of version. This ability to adjust neck orientation eliminates the need for separate left and right stems, thus reducing inventory requirements, while enabling better restoration of joint biomechanics. The pin and hole also provide additional torsional stability, as well as control of the version angle.

The problem with a taper connection is that the axial position of the two parts after assembly cannot be controlled exactly, due to the required manufacturing dimensional tolerances. For example, notice the large axial gap (intentional) between the taper-fit S-ROM® stem and sleeve (Fig. 4). In such a design, all of the load applied to the femoral head must pass through the tapered portion, and there will always be variability (due to manufacturing tolerances and force of assembly) of the final axial position (i.e. leg length).

In contrast, the advantage of a press-fit connection (used in the stem-neck junction of the Apex Modular hip) is that the two parts can be designed and manufactured to fully seat upon assembly.

What does this mean for the Apex Modular stem? This press-fit design provides two important advantages (see Figures 3 and 4):

1) the neck can be fully seated against the top surface of the stem, so leg length is predictable; and,

2) the neck strength is increased by the direct support of the stem (versus having all of the load transmitted through the peg), so offsets can be greater.

Narrative Summary of Testing To Date†

The Apex Modular™ Hip Stem includes two modular connections: the industry standard taper connection between the modular head and the modular neck, and the Dual Press™ connection between the modular neck and the modular stem. Testing of these modular components included: forces required for assembly of the neck onto the stem; fatigue strength of the construct; post-fatigue disassembly strength of the neck from the stem; and fretting of the fatigue-tested components. Prior to fatigue testing, three of the modular femoral stems and necks were assembled using an instrumented mallet to measure the required assembly forces, at the Orthopaedic Bioengineering Laboratory, UCSF. For each impact applied to the neck, the force profile and instantaneous peak force were recorded. The maximum peak force required for assembly of these components ranged from 801 to 944 lbf.

Tests of fatigue strength, disassembly strength, and fretting of the Apex Modular femoral stem were performed by Paul Postak at the Orthopaedic Research Laboratories (under the direction of A. Seth Greenwald, D. Phil. (Oxon)). The smallest stem (size 2, 9 mm distal diameter) was tested with a medium 42.5 neck and a 28 mm head with a +7 mm offset. This combination results in a total lateral offset of 47.5 mm. The fatigue tests were performed with the load configuration as per ISO 7206-4 and load magnitude as per ISO 7206-8. In this configuration, the stem is tilted 9 degrees out-of-plane (in the anterior-posterior direction), which results in torsional loading of the stem and the neck-stem modular connection (Fig 5). Six devices reached $5x10^6$ cycles without failure, as required by ISO 7206-8 and the FDA guidance document for femoral stem prostheses.

The same six components were tested for static assembly strength (after fatigue). Each of the stem-neck assemblies was sequentially loaded to 60 ft-lbf of torsion, and then tension up to disassembly (or 1000 lbf, whichever came first). No disassemblies occurred during the torsional loading, with all stem-neck assemblies reaching the torque limit. The minimum tensile load required to disassemble the neck from the stem (after the fatigue and torsional loading) was 593 lbf (3 of the 6 stems reached the 1000 lbf limit).

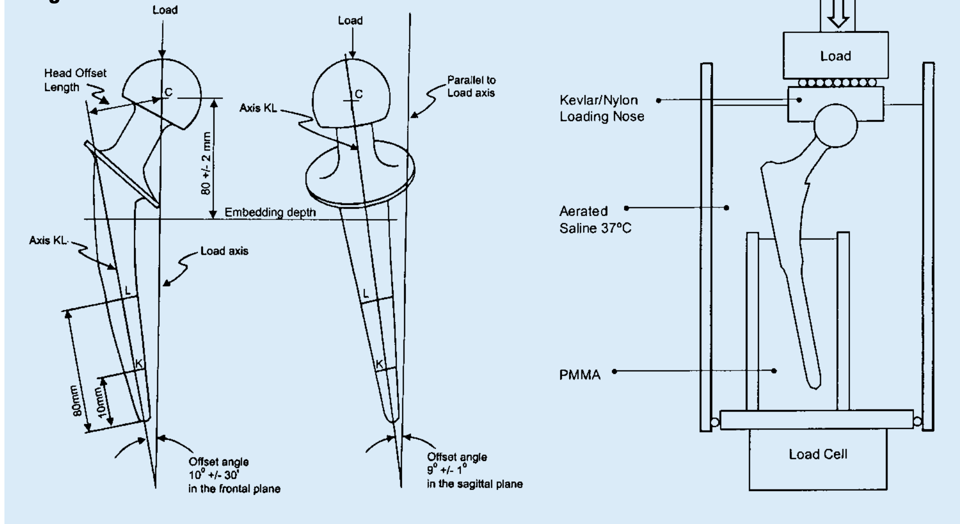
Finally, the three disassembled components were examined under a stereomicroscope for evidence of fretting and corrosion between the mating parts. Fortunately, the worst damage (type "C") on the fatigue-tested Apex Modular femoral stems was found on a location that is unlikely to fracture. The location and pattern of this damage corresponded to the outer edge of the proximal stem surface, where the neck was overhanging the stem. This overhang was relatively extreme in the tested components due to the combination of the smallest stem with a relatively high offset neck. There was no severe (type "C") damage at the critical neck-peg modular junction; the large majority of the damage at the press-fit surfaces was classified as slight (type "A"), with the remainder classified as mild (type "B").

In summary, the size 2, 9 mm stem with the medium 42.5 neck and +7 mm offset head (total lateral offset of 47.5 mm) successfully passed fatigue testing as per the relevant ISO standards and FDA guidance document. In addition, based on supplemental finite element studies (Fig. 6), the only stem-neck combinations that are worse case than the fatigue-tested combination are the size 2, 9 mm stem with the short 40, medium 47.5, or long 50 neck. These particular stem-neck combinations are contra-indicated due to the lack of corresponding fatigue tests. While one fracture occurred in the fluted region of an additional stem in the fatigue study, this fracture resulted from a failure of the embedding protocol, and the strength in the fluted region is equivalent to the strength of the fluted region of a similarly sized S-ROM stem.

Device Fatigue Testing

The fatigue tests were performed with the load configuration as per ISO 7206-4 and load magnitude as per ISO 7206-8. In this configuration, the stem is tilted 9 degrees out-of-plane (in the anterior-posterior direction), which results in torsional loading of the stem and the neck-stem modular connection (Fig. 5). The load was cycled at 10 Hz, sinusoidal loading, with minimum and maximum peaks of 300 N and 2300 N (compression), respectively. Six devices reached $5x10^6$ cycles without failure, as required by ISO 7206-8 and the FDA guidance document for femoral stem prostheses.

Figure 5

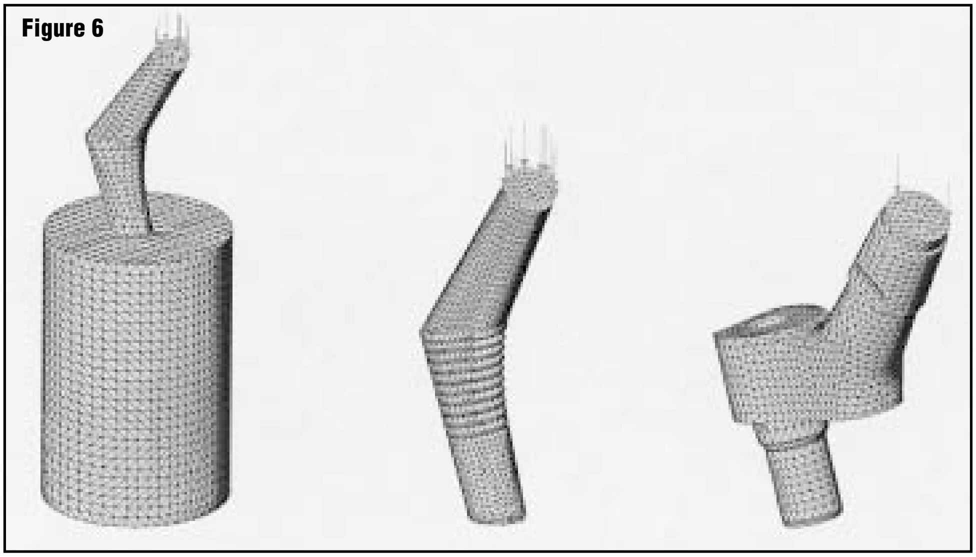


Specimen orientation and text schematic 3 as per ISO 7206-4.

Strength of Other Stem-Neck Combinations

A design analysis using finite element methods was performed to evaluate the strength of other stem and neck combinations relative to the combination that was fatigue tested (Fig. 6).

Figure 6



Example finite element meshes used to predict fatigue for the various stem-neck combinations.

The highest tensile stress, and thus the area at greatest risk of fracture initiation, was predicted to occur on the lateral surface of the stem. The maximum tensile and effective stresses in the neck were less than the maximum stresses in the stem, and thus the models predict that the neck is less likely to fracture than the stem.

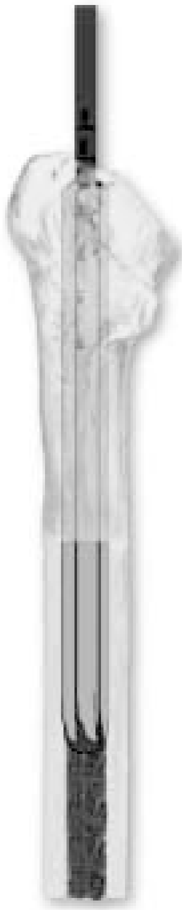
High Cycle Fatigue Testing of the Apex Modular™ Hip

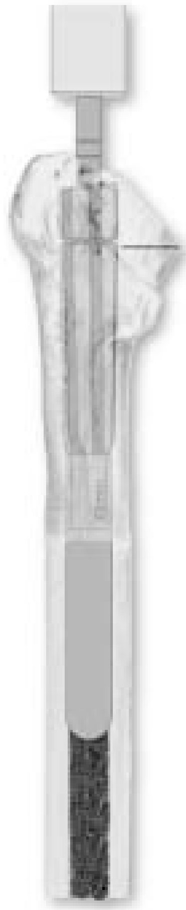
In addition to the previous study, size 6, 14.5 mm stem, and neck-head combination with 52.5 mm of lateral offset, survived 48.5 million cycles of fatigue loading with no failure. The increasing cyclic loads reached a maximum peak value of 6 times body weight for a 180 lb individual. The test was terminated at 48.5 million cycles due to failure of the cement used to embed the distal stem. The mating surfaces of the neck and the stem showed no signs of wear or fretting at the press-fit peg, and minimal fretting damage to the horizontal interface. The average amount of titanium debris generated over a 1 million cycle period, measure at 5, 10, 15 and 20 million cycles, was less than 0.004 mg. This equates to a volume of less than 0.001 mm^3 per 10^8 cycles. As a point of comparison, the reported volumetric wear of metal-on-metal total hip replacements is on the order of 1-6 mm^3 per year, or more than 1000 times higher than the titanium debris measured for the Apex Modular stem in the present study.

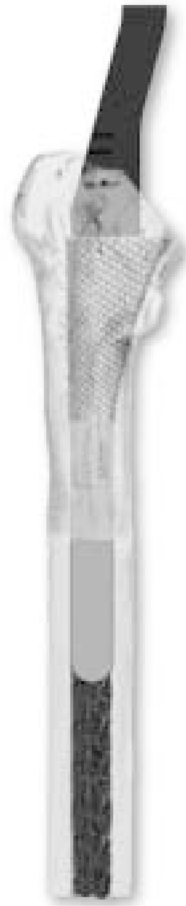
Surgical Procedure

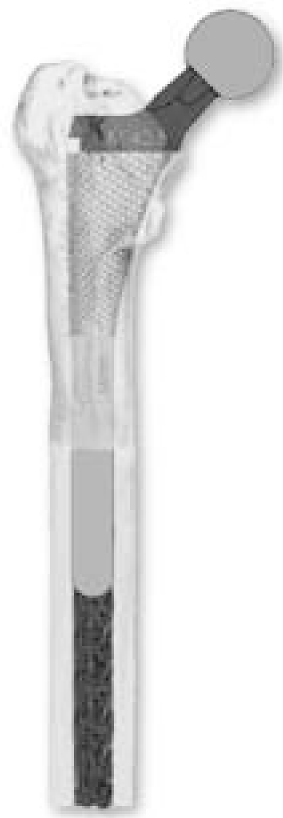
1. Femoral osteotomy
2. Open the medullary canal with an osteotome or reamer
3. Straight ream to correct size and depth
4. Conical ream to correct size and depth
5. Broach (medial calcar only)
6. Trial neck and head with broach
7. Assemble and implant stem and neck

Femoral Instrumentation


Distal Ream


Proximal Ream


Broach


Trial

Clinical Summary to Date

- 380 total implanted (as of 1-Mar-02)
- 25 different surgeons
- 2 dislocation*
- No infections
- No revisions
- No significant leg length inequalities
- Approx. 10% anteverted
- No significant pain at 3 months

*The first patient had postop dislocation occurred while rising from a low seated position (lawn chair), closed reduction treated with a brace, no further incidence. The second patient encountered two dislocations due to medialization of acetabular component not recognized at time of surgery corrected by exchanging modular head to increased height. Patient now stable with no further complications.

Early impressions as a group

We are better able to address restoration of hip mechanics with this device as compared to prior experience with other cementless implants. However, only long-term outcome data will provide and demonstrate whether this device will improve clinical scores and survivorship. We are extremely encouraged at this point.

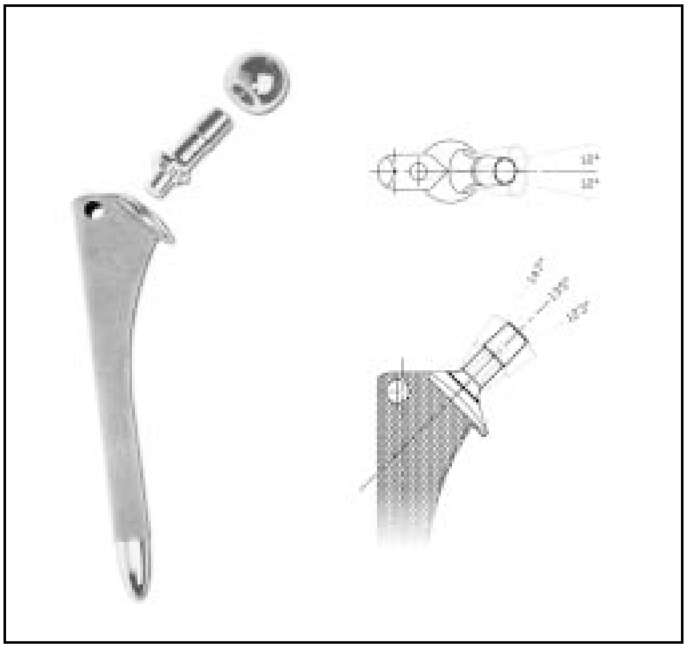
***Members**

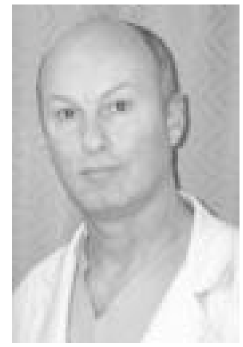
Warren Low, M.D., Oklahoma City, OK
Tom Tkack, M.D., Oklahoma City, OK
Joseph Chenger, M.D., Nashville, TN
Timothy McTighe, Chagrin Falls, OH
Edward J. Cheal, Ph.D., Lakeville, MA
George Cipolletti, M.S., Lakeville, MA
Dave LaSalle, M.B.A., Lakeville, MA
Jim Henry, B.A., Oklahoma City, OK
John Froehlich, M.D., Providence, RI
Lowell Niebaum, M.D., Las Vegas, NV
Del Schutte, M.D., Charleston, S.C.
Joseph McCarthy, M.D., Boston, MA

† Full technical monographs available upon request.

Early Impressions of a Modular Neck Cementless Total Hip Stem

By Milton John Smit, M.D., F.A.C.S.





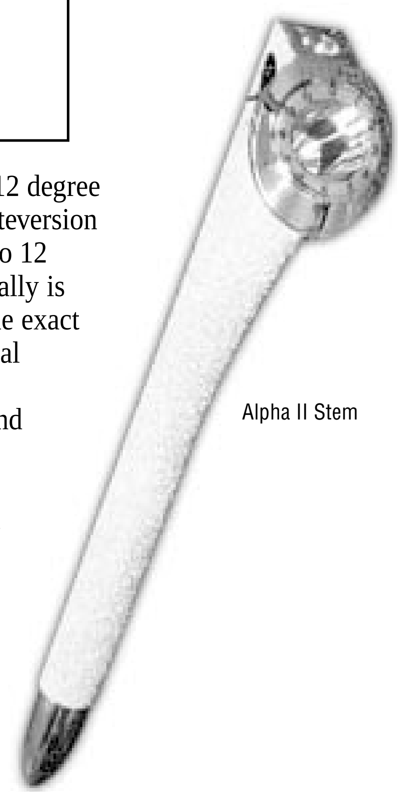
Dr. Milton Smit

For many years I have been satisfied with the solid fixation of the AML-type, fully porous-coated mono block stem. But I, as other clinicians, have noticed there is need for some proximal variability in design to help accommodate the various clinical conditions. Modular femoral stems have been designed to accommodate changes, such as difference in size between the stem and the hip as well as changes in rotation and neck shaft angle. I have recently come into contact with a new design modular neck (ALFA II hip). I have been using the fully porous-coated stem, the ALFA I, since 1996 and have implanted over 314 stems with no revisions. However, I did feel the need on several occasions to be able to adjust the neck for both varus hips and hips where the size of the femoral canal is disproportionate to the size of the hip joint. The ALFA II is designed to accommodate modularity specifically by being able to change the neck. It has the standard proximal Morse taper for articulation with the head but has a unique, distal double Morse taper at the distal end of the neck at the junction with the stem. This has mechanical indexing to allow for changing the rotation of the neck as well as the length of the neck separate from the stem. This has several theoretical advantages.

Since the design is a dual Morse taper, there is minimal risk for micro-motion or fretting.

Because a modular site is at the neck, it is easily accessible at the time of surgery being outside the bone. Since the neck is outside the bone, this can be modulated after fitting the femoral stem, which has two advantages, that is, the trial can be done after full stem implantation as a separate part of the procedure, and also allows for insertion of the stem prior to doing the acetabular component. This may, in theory, decrease blood loss at the time of surgery.

The mechanical indexing available at the distal double Morse taper lock allows for rotation along twelve separate points. By rotating the position, it can adjust the neck shaft angle from approximately 125 degrees to 147 degrees; and with the 8 degree and 12 degree available necks, the anteversion can be rotated from 0 to 12 degrees. This theoretically is helpful in correcting the exact anatomy of the proximal femur and aligning the direction of the head and neck directly into the acetabulum as desired. Clinically, of course, it would help correct lateral offset of the proximal femur to allow for adequate balancing the muscles without excessively lengthening the leg. In addition, the modular necks are available in three different lengths so whereas they can be indexed in different positions, they can also be chosen independently of the size and length of the stem. This theoretical advantage can be useful in adjusting differences in the neck and stem size. For instance, an elderly woman with a large femoral canal due to osteoporosis can be fitted with a large, well-fitted porous-coated stem and still use a



Alpha II Stem

short neck at an appropriate angle and rotation to correct the anatomy. Whereas, a large man who might have a very small canal due to strong cortical bone might use a smaller stem size and still require a longer neck, which can accommodate the patient's anatomy without using a head segment that does not have a collar. This might help correct the anatomy without adding impingement. In summary, being able to change all of these factors - rotation, neck shaft angle and length - the anatomy can be accommodated precisely to allow for excellent lateral offsets as well as correct leg lengths and version angles. Better control of these factors is necessary not only to prevent dislocations but, theoretically, to reduce polyethylene wear.

Finally, if a hip of this type were to show polyethylene wear, acetabular revision surgery would simplified since both the femoral head and neck can be completely removed. If the stem is stable, correction of neck shaft angle, version and leg length are relatively simple.

Early impressions to date are that this modular indexable neck design is no more difficult to use that the standard monoblock stem which is available in standard size necks at 8° of anteversion and 135° neck shaft angle. Although my use of this design is limited (16 cases to date), as with the earlier modular heads the more experience one gets the more

Version Angles

versatility one sees in this new modular junction.

Only long-term follow up will clearly demonstrate the viability of this design, but it appears to be a promising new alternative for restoration of joint mechanics for Total Hip Replacement. I would also note that additional studies are ongoing in other medical centers regarding the use of this same modular neck design in the cemented R-120™ Stem.

Commentary

In our feature article, laboratory testing has demonstrated improvements in the mechanical modular interface "Dual Press" while providing benefits to fatigue strength levels of the constructed stem. The sizing matrix offers an impressive array of options in adjustment of offset and leg lengths.

The system appears at this stage of development to have some limitations by design in the ability of positioning version angles. This should not and has not been a problem in treating primary or stage I revisions. However, it might be limited in this feature in treating complex revision cases. I am sure this will be addressed as the system grows to its next developmental stage.

The Alpha II modular neck stem offers a c.c. fully porous coated design similar to the market leader "AML™". This design offers the surgeon the opportunity for last minute adjustments or fine-tuning the joint mechanics without removing the femoral stem. A mono-block stem design does not offer the versatility of other modular stems for fit & fill features but has an advantage that the modular site is outside the bony cavity.

In addition, with the current trend of small "mini" incisions, proximal modular stem designs that allow for stem insertion and in-situ assembly provide a more reproducible technique and opportunity for last minute correction of joint mechanics. These examples of current stem designs demonstrate that the market place is offering various designs and features to better aid the operating surgeon to provide the best device indicated for his patient.

Remember, it is important to understand and appreciate the specific design features and required techniques for that design and not to lump all modular designs into one simple category of "Modular Stems."

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