FEATURE ARTICLE

New Proximal "Dual Press™" Modular Stem Design

By *JISRF/Apex Study Group Members

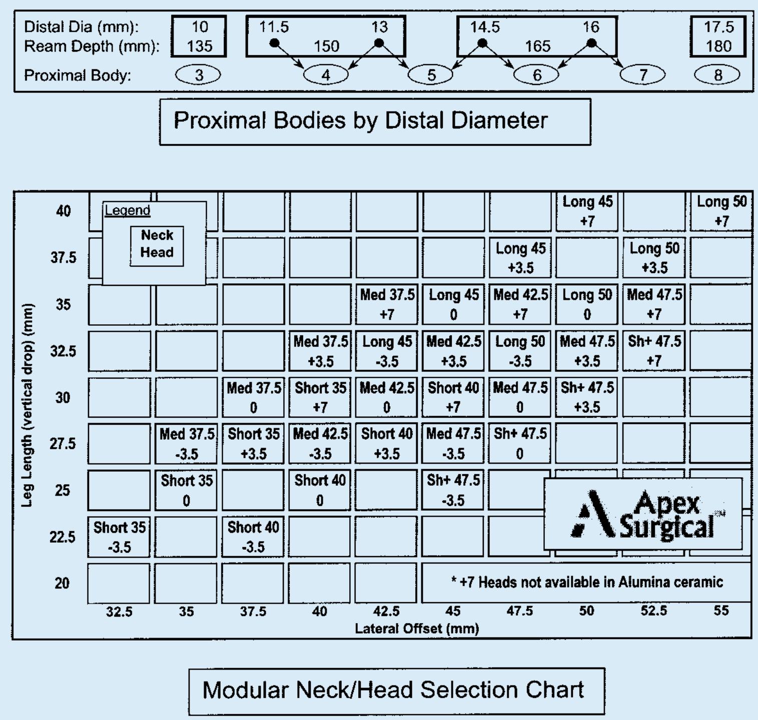
The clinical success of the S-Rom cementless stem not only comes from its modular feature improving on fit & fill but primarily from its stable intrinsic design features: proximal cone; medial triangle; distal straight stem with torsional flutes and a coronal slot.

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



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

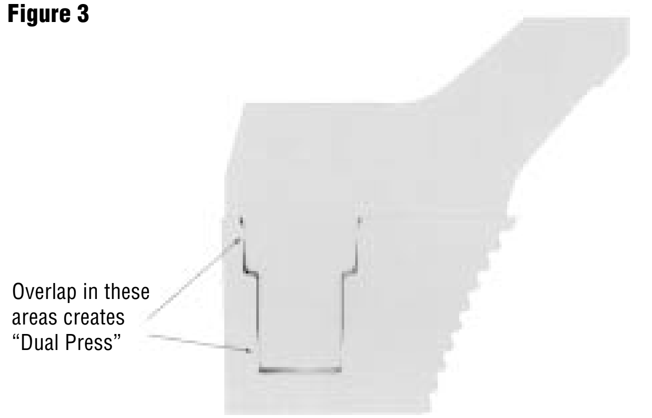
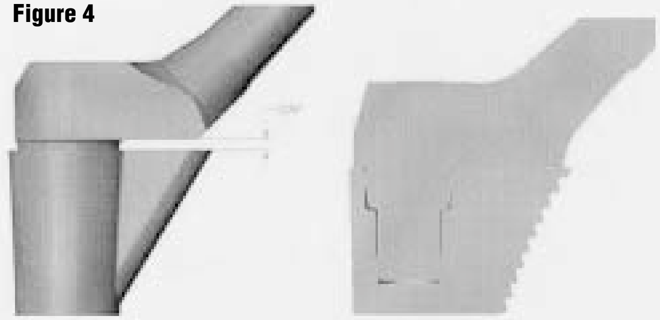


Figure 4



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).

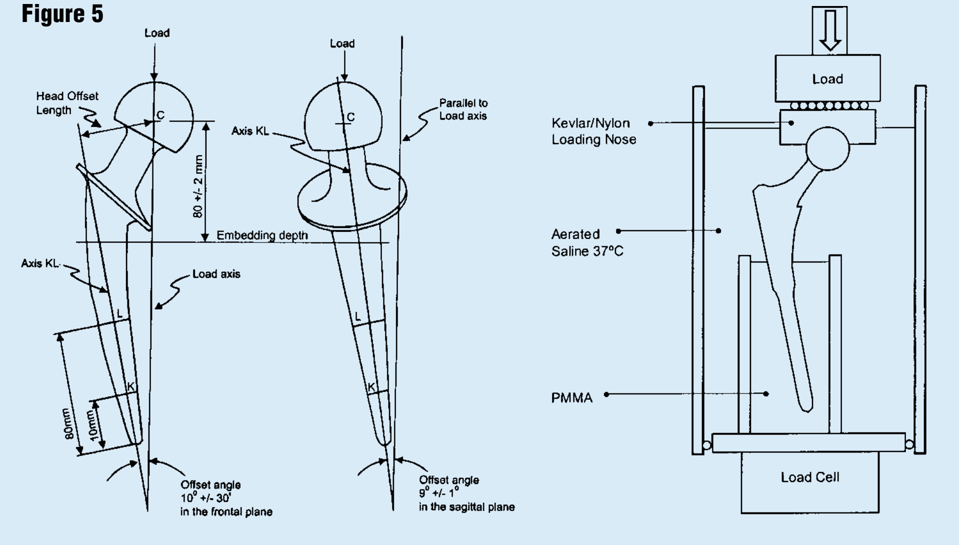
Finally, the three disassembled components were examined under a stereomicroscope for evidence of fretting and corrosion between the mating parts. Fortunately, the worst damage (type "C") on the fatigue-tested Apex Modular femoral stems was found on a location that is unlikely to fracture. The location 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 5×10^6 cycles without failure, as required by ISO 7206-8 and the FDA guidance document for femoral stem prostheses.

Figure 5

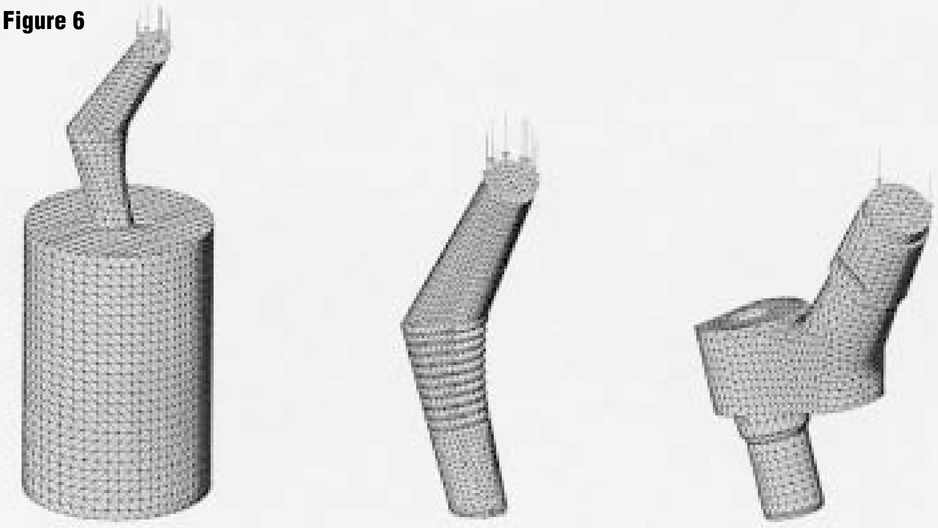


Specimen orientation and text schematic 3 as per ISO 7206-4.

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.

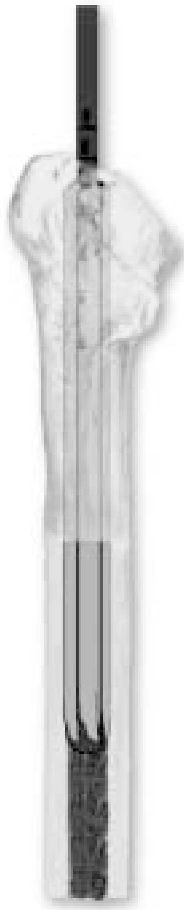
High Cycle Fatigue Testing of the Apex Modular™ Hip

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.

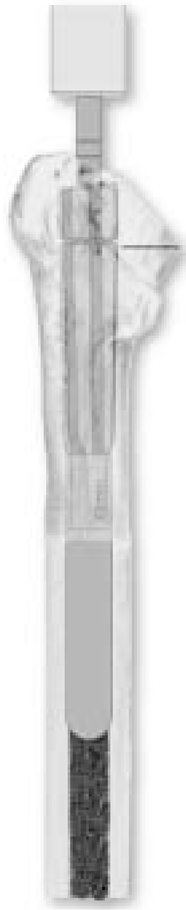
Surgical Procedure

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

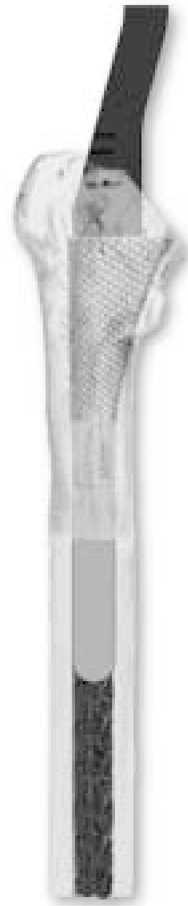
Femoral Instrumentation



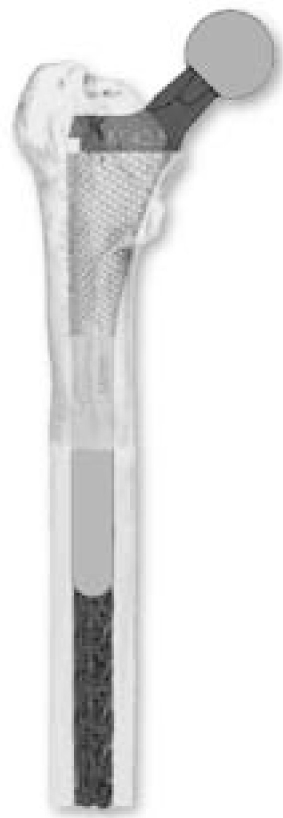
Distal Ream



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.

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† Full technical monographs available upon request.