“Historical Review of Stem Modularity”
by

Timothy McTighe, Dr. H.S. (hc), Hugh U. Cameron, M.B.C.H.B.S.**,
Louis Keppler, M.D❇., & Thomas Tkach, M.D.⁕
***Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio**
**Orthopaedic & Arthritic Institute, Toronto, Canada
❇ Orthopaedic Spine & Joint Institute, Cleveland, Ohio
⁕McBride Clinic, OKC, OK

Introduction

This review will look at modular stems designed for both cementless and cemented application. Both of these design applications are dealing with the restoration of the joint mechanics and aseptic loosening. 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

Design Review

➢**Proximal**

Head/Neck

Tapers are now considered state-of-the art for most total hip stems. The opportunity to correct for vertical height has provided significant advantages in achieving enhanced joint stability over monoblock head stem designs. However, this modular junction does not allow for independent adjustment of femoral offset from vertical height.

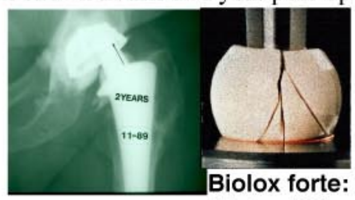
We now see Co-Cr-Mo alloy heads used on titanium alloy stems, Co-Cr-Mo alloy on Co-Cr- Mo alloy stems and Ceramic heads used on both titanium alloy and Co-Cr-Mo alloy stems. The use of Ti alloy as a bearing material for femoral heads has all but been discarded by the early 1990s as a result of increased wear.

The potential risk of fretting corrosion in the Morse taper region of modular junctions has been attributed to the presence of gaps between taper surfaces and differential metallic alloys. One way of reducing the potential fretting corrosion of tapers is the use of ceramic as the femoral bearing material.

Recent retrieval c.c. head on Ti stem with black staining on the trunion of the head taper. Keppler 10/08

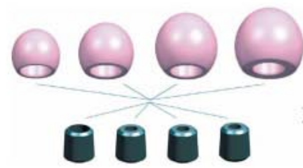
Ceramic heads have had some problems with fracture as shown in this two year post-op THA.

Improvement in material and fabrication has reduced this situation but demonstrates that there is concerns and considerations when selecting modular devices.



Biolox forte: 0.02% reported failure rate 2/10,000
Biolox delta: 2 in 100,000

Neck Extensions
Trunion sleeves offer increased neck length adjustments, however, tend to reduce range of motion.



➢**Helpful in revision situations**

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.

While modularity has its advantages especially in fine tuning joint mechanics, modular junctions can and do fail.

Examples of failed Ti modular necks

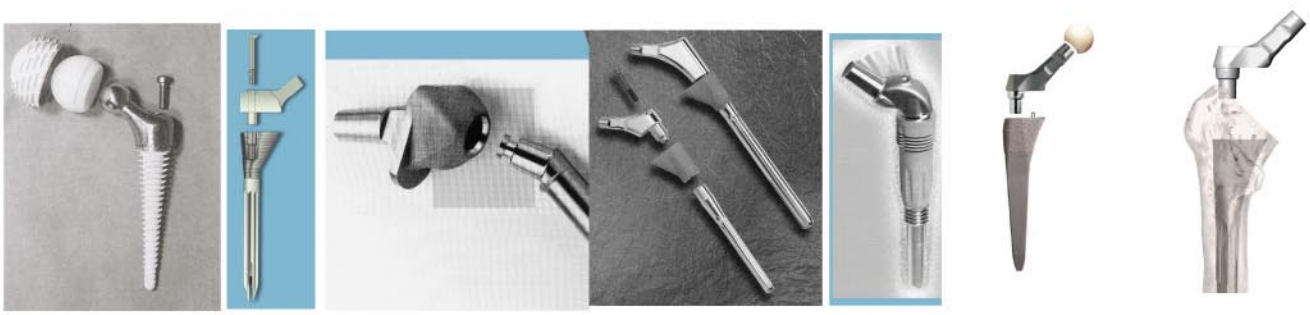
Examples of failed c.c. modular necks

Examples of varied modular necks

"Cutting-Edge Developments on Proximal Modularity in THA"
Mini-Symposium AAHKS, November 7, 2008 Dallas, TX

Modular Collars
These designs increase collar/calcar contact. Their clinical advantages has not been proven and usage has all but stopped.

Proximal Shoulders (bodies)
This area of modularity has the largest differential in design styles. Significant influence comes from European experience dating back to the 1970s. These devices 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, also allow for variable body height and version orientation.



Intra-operative fine tuning of joint mechanics (both version & offset can be a valuable tool with these design style proximal bodies.

It is however important to know the specific design features and required technique for these individual designs.

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

Anterior / Posterior Pads
This design allowed for adjustment of fit & fill in the A/P dimension of the implant. They were criticized for not having circumferential porous proximal coating. While the design allowed for adjustment of fit & fill gaps allowed for migration of particulate debris resulting in bone lysis.

Stem Sleeves

Note: ACCME guidelines are to be neutral as possible in acknowledgment of trade names and commercialism.

However, one cannot describe this section of modularity without recognizing the significant contribution of the S-Rom™ modular stem design. This is not done out of any sense other than pure historical contribution that this design has made to the overall outcomes of THA. This has been recognized by all of industry as has the Charnley stem design for cemented arthroplasty.

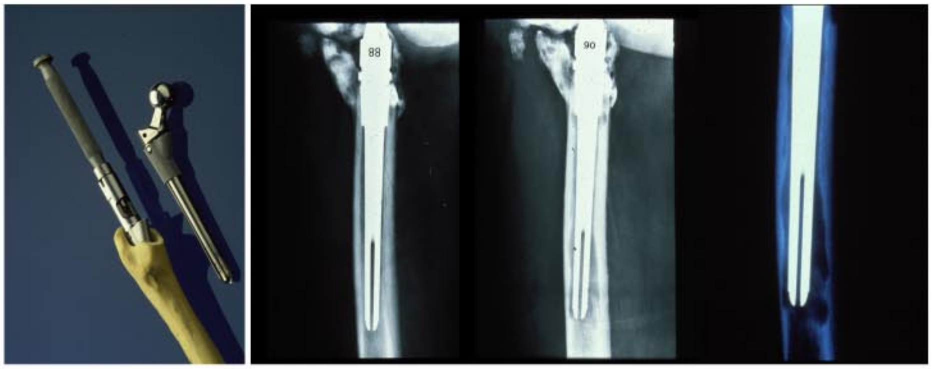
Stem sleeves offer the advantage of fit & fill with adjustment of hip mechanics. Some designs like the S-Rom ™ require removal of the stem to correct offset or version, while newer designs allow for correction with the stem *insitu*. All of these designs feature a modular site located within the femoral 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 longitudinal flutes similar to that of the Samson intramedullary rod reduced torsional forces on the implant/ bone 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 porous taper-lock sleeves were developed. This evolved into the current stem sleeve combination and is now considered the gold standard for modular cementless stems.

Evolution from the 1960s Sivash to the 1970s SRN, to the 1980s first generation S-Rom™ to its current design and the varied style sleeves along the way.

Design changes were made as a result of clinical / surgical concerns.



Groove acted as a gutter providing direct path of poly debris resulting in progressive lysis. Engh

The ultimate compliment is that of copying. Many of todays devices both modular and monoblock have copied the geometric shape of this cementless stem design.

Revision (stem-sleeve) & other modular junctions designs

Allow for significant bone loss and different designs feature different style modular junctions.

➢Mid-Stem Modularity

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.

Mid-stem modularity has a potential for more mechanical failures in part to the complex nature of revision surgery and often lack of proximal bone support. Not all mid-stem modular junctions are equal in mechanical features (fatigue properties). Generally, larger and longer taper junctions are stronger.

➢Distal Modularity

These designs allow for distal stem fit with different distal style options (smooth, fluted, or porous). One of the more interesting designs is the distal bullet design. 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. Some devices that featured distal sleeves had other under-designed features including the lack of circumferential coatings, poor locking designs on modular cups, and titanium femoral heads, resulting in increased particulate debris (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, we believe distal sleeves would have great difficulty gaining acceptance in the marketplace.

➢**Multi-Modularity**

Excess modularity on the stem in addition, to the modular sites for its cementless porous cup and optional screws, could end up with over six 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.

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 proximal modular stem-sleeve design of the 1980s and competition attempting to improve upon that 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 20+ years. In the early 1980s fit & fill was 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.

In 1995, a chapter in the Encyclopedic Handbook of Biomaterials and Bioengineering, "Design Considerations For Cementless THA" **McTighe, Trick & Koenman**. That chapter reviewed the use of modularity and made some predictions as to product design features in-the-near future. The main focus of future 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-implant interface. Proximal bodies of different sizes and shapes would be available that provide for versatility and retrievability with little or no bone destruction.

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.

Standard cementless modular stem designs offer significant value and we believe improve outcomes, however technology (material, design & surgical techniques) does evolve and the future holds as reflected by the past significant opportunity for advancement and improvement in clinical outcomes.

The future will continue to be focused on modularity. There will however be a new focus with tissue sparing designs that save both hard and soft tissue. Example this neck sparing stem with a modular head and neck. Also, this novel bearing material Polycarbonate-urethane (PCU) which reduces wear debris. **Modularity** is hear to stay!