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The Role of Modularity in Primary THA - Is There One?

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Introduction

Modularity or multi-piece stems are becoming commonplace in hip revision surgery[6,13,15,17,19,21] with virtually all implant companies offering one version or another. The role of modularity would therefore seem to be firmly established for revision, but what of primary cases?[8,11]

This study is a follow-up to previous work with a further ten years of cases reviewed. The real question we face does the benefit of modularity pay higher dividends than the potential risk factors. We believe this review will provide guidance for others surgeons to aid in their decision making process.

For almost two decades the two senior authors have been using a proximally modular stem in primary cases. The S-Rom® stem has basically not changed since 1986.[4,12]

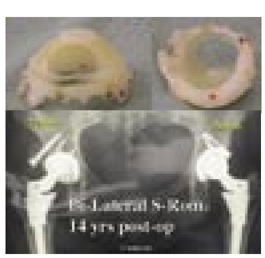
The stem design is a monoblock titanium alloy (maximum strength potential). The distal flutes historically were design off the Sampson™ IM Rod system. The Sharp flutes provide excellent distal torsional stability while reducing chances of distal fixation. It is the design intent of this device to provide proximal fixation and distal torsional stability. An additional feature of the stem is the distal coronal slot. This provides for dual benefits, the first is to reduce hoop tension during stem insertion thus reducing distal fractures of the femur. And second (found out only after the fact during clinical reviews) was the slot reduces distal bending stiffness hence end of stem pain has not been a problem (exception > 15mm dia. stems).[5]

Two Remaining Significant Problems in THA[10,12,15]

#1 Dislocation

- Reports from 2-8%
- Higher in Posterior Approach?
- Higher in Sm. Dia. Heads
- Higher in Revisions >20%

#2 Wear Debris/Lysis



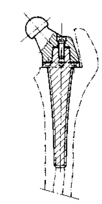
The Role of Modularity in THR

Modular means that the stem has 2 or more parts which can be joined. Does that means any stem with a modular head is a modular stem? Not in today's definition. This exhibit is limited to the femoral side and includes two or more modular parts.[7]

Modular Heads

Modular Stem History

Modular stems have a long history staring with McBride in 1948 that utilized a threaded femoral component publishing his first account in JBJS in 1952. This was followed in 1978 by Bousquet and Bornand with the development of a proximal modular stem that featured a proximal body that was attached to a stem via a conical mounting post, with 8 perforations that allowed for select angle orientation for biomechanical restoration. Their design also featured a screw-anchored intramedullary stem design that was coated with AL_2O_3. Their initial reports were presented in Basel in June 1982 at symposium on cementless hips and published in Morscher's 1984 book "The Cementless Fixation of Hip Endoprostheses". The BSP Modular stem followed in 1988 and featured a modular collar/neck assembly that was fixed to the stem with a morse taper joint, a swa-tooth macro interlock system (15º rotation per tooth), and a set screw.[3,18]



A screw-anchored intramedullary hip prosthesis

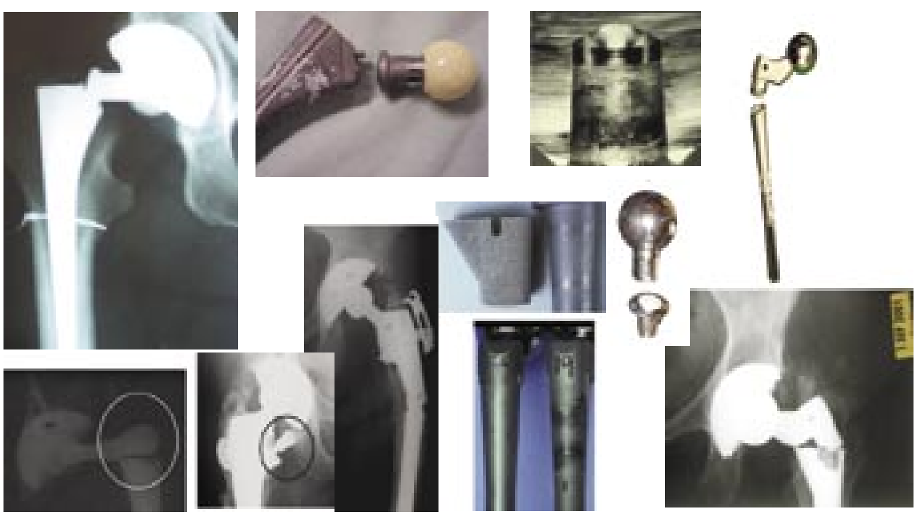
1988 proximal modular design

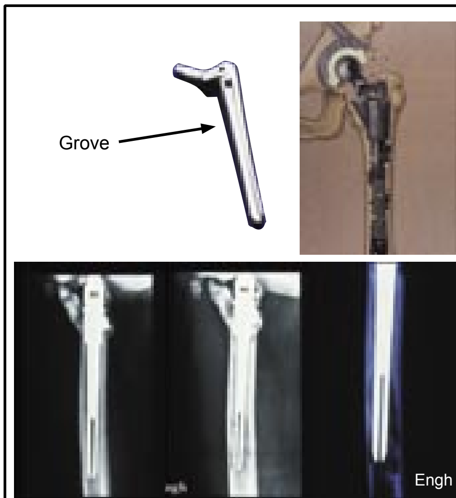
The current S-Rom® Stem System represents the fourth generation in the evolution of the Sivash Total Hip Stem since it was introduced in the United States in 1972.[16,22,23]

Sivash began development of his prosthesis in 1956 at the Central Institute for Orthopaedics and Traumatology, Moscow, Russia. By 1967 Sivash, had selected titanium alloy for the femoral stem and proximal sleeve and chrome cobalt alloy for his socket bearing and femoral head. A major focus was the design of a constrained socket. The Sivash Total Hip System, introduced by the U.S. Surgical Corporation, never received major clinical or market success, partially due to the difficulty of the surgical technique, and positioning of this constrained device.

Modular Designs That Have Come and Gone[14]

Modular Failures & Concerns - Increased Risk?





This is unique and has not been a significant problem

Unsupported Stems Will Fail Regardless of Fixation/Material/Design

(cement/cementless/monoblock/modular)

Bechtol described failure mode in 1970's[1]

Material

955 (S-Rom®) primary cases in a combined series performed by two surgeons at separate centers. 2-17 year follow-up (mean 11.5 yrs.)

HC: 517 cases (278 females/239 males) mean age 55; 162 CDH; Mod. Watson-Jones approach; 26 lost to follow-up; 28mm head (1986 stem design)

LK: 438 cases (237 females/201 males) mean age 68; 98 lost to follow-up (older pts./relocation of practice); 32mm head (1986 stem design); Posterior approach

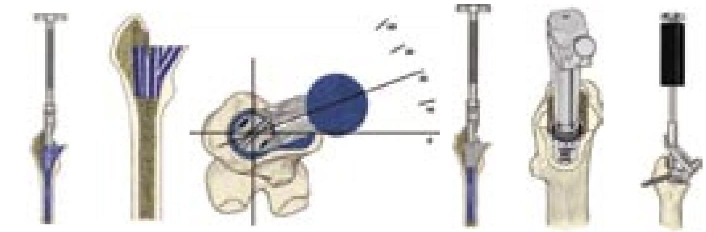
Note: variety of cups used

S-Rom® Evolution

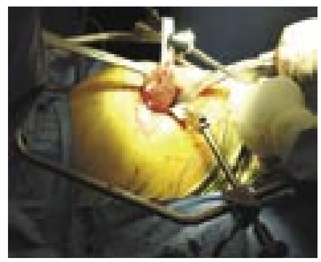
- Monoblock stem
- Stable Geometric Shape (Prox. Cone & medial triangle distal flutes)
- Variety of fit & Fill Sleeves
- Distal coronal slot
- Precise (modular) instrumentation

Surgical Technique

Neck resection · Pilot insertion · Distal ream · Conical ream · Miller placement Calcar mill · Trial sleeve insertion

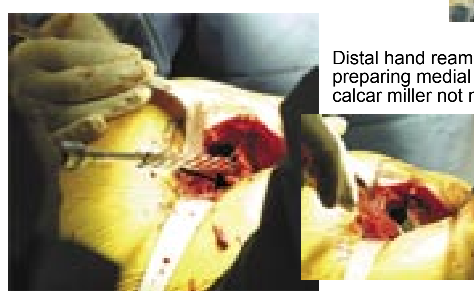


Trial sleeve in place · Trial stem · Final sleeve implanted · Stem insertion · Stem insertion tools



Metal bearing insertion.

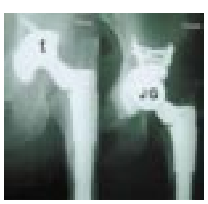
Hand ream / better feel.

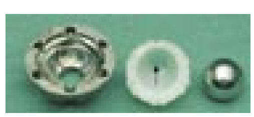


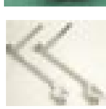
Distal hand reamer preparing medial triangle/ calcar miller not needed.

Examples of problems:

Poly Wear
If delay too long before revision poly wear through & cup damage







Helpful for cup revisions

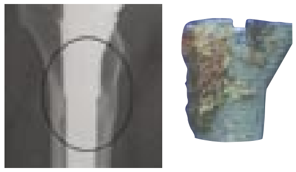
Fractured greater trochanter through osteolytic cyst
2 hook plate
1 wired
1 compression screws

Constrained liner - 28mm
Skirt on neck made it very vulnerable to mechanical failure.

Failure of bone in-growth so distal stem is part of the effective joint space. Osteolysis developed.

Osteolysis

HC: Distal to sleeve - 3; 2 primaries; 1 revision. LK: Distal to the sleeve - 0. Data suggests that the sleeve acts as a seal, reducing poly particles from passing distally. HA Sleeve: 114 currently being reviewed. Will this function as well? Note: the 2 primary cases of lysis one stem exchange with currette through sleeve and one stem/sleeve revision



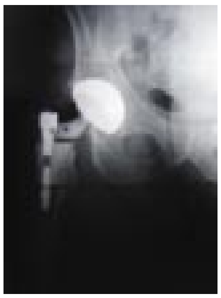
Sleeve acts as a seal

Dislocations

HC: 6 total; 3 closed reductions; 2 open reductions; 1 stem removed/ new stem inserted into sleeve (30-36mm neck). Note: Extensive trial reductions – does not take routine x-rays.

LK: 5 total; 2 closed reductions; 3 open reductions (constrained sockets).

Note: routinely takes intra-operative x-rays/ generally results in fine-tuning of fit.



Intra-op trial stem

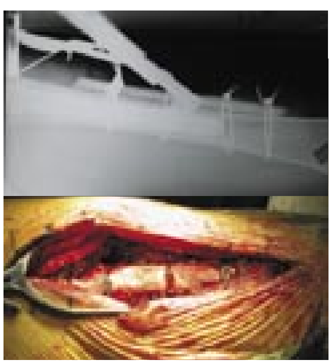
Trial ROM

Stem Revisions

HC: 5 total; 1 for aseptic loosening; 2 late sepsis; 2 early bone fractures.

LK: 4 total; 0 for aseptic loosening; 4 late sepsis.

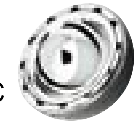
Note: 5 pts. Required onlay grafting for significant progressive end of stem pain (+15mm dia. stems)



Onlay strut graft

OmniTrack™ table mounted retractor system increases exposure particularly in revisions.

Lessons Learned



HC: Small dia. head greater wear problems; Routine now 32mm c.c. head; Large/active males metal-metal bearings; Neutral liner; Smaller incision; type C bone and elderly (cement stem).

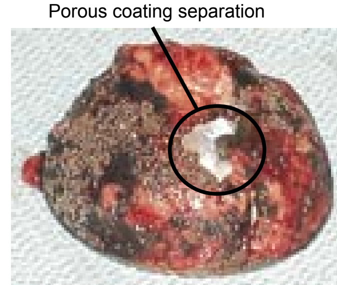
LK: 36mm ceramic head with cross-link poly; + 4mm lateral offset poly (for increased poly thickness & offset); Hand reaming (better feel for bone); Neutral liner; Routine posterior capsule closure (added security); Smaller incision (average 7cm); type C bone (does not use S-Rom, uses a taper cementless stem).

Small posterior incision

Since the advent of the S-Rom® (1984) prosthesis it has been clear that modular (stem/sleeve) approaches can be used to successfully address implant stability especially fit & fill problems.

Final Comments

Porous coating separation



Aseptic loose cup.

The long-term results for this series has demonstrated the S-Rom stem to be safe and effective for primary THA. Initial concerns over fretting and fatigue failure of the modular junction have not been observed.

The lack of aseptic loosening (1 stem) clearly demonstrates this design provides initial stability leading to long term fixation. Stem survivorship is 99.8% at 11.5 years (best case assuming none of the loss to follow-up were revised).

The main problem appears to be cup/liner related and the lack of distal lysis suggests that the stem/sleeve Morse taper interface does not act as a pathway for the migration of debris.

We continue to use and recommend this device.

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