DESIGN FEATURES AND EARLY CLINICAL RESULTS WITH A MODULAR PROXIMALLY FIXED LOW BENDING STIFFNESS UNCEMENTED TOTAL HIP REPLACEMENT

By Hugh U. Cameron, Yung-Bok Jung, Douglas G. Noiles, and Timothy McTighe

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"S-ROMTM MODULAR STEM SYSTEM"

INTRODUCTION

For an uncemented femoral component in total hip replacement to be successful, it is universally agreed that initial stability is essential. In order to achieve stability, diaphyseal (distal) and metaphyseal (proximal) fill is required. "Fill" means that the implant approaches the endosteal cortex. The reason for this is that the strength of the intramedullary bone increases with the proximity to the endosteal cortex.

Distal stem diameter is determined by diaphyseal reaming. Modern techniques of in intramedullary nail insertion demands removal of a certain amount of endosteal cortex. It seems reasonable, therefore, to insert a hip stem in the same fashion. IM nails are all split to allow some closure thus reducing the risk of splitting the femur. As weight is applied to the femur, the femur tends to flex into the direction of the anterior bow. A stiff metal rod is unlikely to flex, therefore, relative movement between the stem tip and the bone occurs. This can produce so-called, "end-pain." If the stem tip is split in the coronal plane, the split decreases the bending stiffness of the tip of the femoral component. If the component is made of titanium rather than cobalt chrome, the bending stiffness can potentially approach that of the femur. If the strain rates are matched, differential movement should not occur, and there should be no end pain."

A short circular cross section stem has minimal resistance to rotation. As rotatory forces on the hip stem are quite high, it seems reasonable to add flutes to the distal stem to provide rotatory stability.

These facts, when combined, define distal stem geometry and insertion techniques. The stein is titanium, circular, fluted, and split in the coronal plane. It is inserted like an intramedullary nail requiring intramedullary reaming of the endosteal cortex and firm driving. A stem of this nature provides distal stability without distal fixation.

The metaphyseal geometry does not necessarily have any relationship to diaphyseal geometry. In order to fill the diaphysis and metaphysis without a custom prosthesis, a large number of implants with different geometries would be necessary for every stem size. In these days of fiscal constraint, this is not possible. The solution to this dilemma is to make the metaphyseal portion detachable or modular. By this means, a variety of different proximal geometries can be created for every stem size. This variety is provided by having a series of sleeves for the metaphyseal region which attach to the stein by means of a taper lock.

Taper locks or Morse cones, which attach modular heads, have been in use in orthopaedic surgery for a long time. When impacted, the lock achieved is very good, and failure by disassembly in service has yet to be described in the literature.

DESIGN CONSIDERATIONS

A 3' per side taper was chosen. The worst case hoop tension in the sleeve is about 32,000 psi. However, the hoop stress created by the heaviest load applied is never released because of the taper locks, and thus is not a cyclic stress. Therefore, the low fatigue strength of porous coated titanium alloy is not a limiting factor. The tensile strength of the porous coated titanium is over 400,000 psi., and no porous coated sleeve has failed in an extended series of fatigue tests where the stem was taken to failure'.

The initial sleeve used was a conical selftapping threaded sleeve. This proved technically difficult to insert and had a long "learning curve." In spite of this, the results have been very good, especially the virtual absence of thigh pain.

The second sleeve to be tested was the sleeve which roughly matched the geometry of the metaphyseal cancellous bone cavity. In order to insert this accurately, it was realized that hand broaching could not be used, therefore, a proximal conical reamer and calcar miller were developed. The canal is now totally prepared by reaming with no broaching at all.

The sleeves were designed with proximal steps or ridges in order to convert hoop stress in the proximal femur to compressive loads. A few of these have been implanted and have functioned very well. These were called the ZTTM.

It was recognized that this sleeve could be porous coated with titanium beads thus increasing interfacial fixation. The coating of the sleeve rather than the stein provided some spectacular potential Solutions to various problems associated with porous coatings.

When porous coating a super alloy, the necessary beat treatments frequently degrade the metallurgy of the substrate metal leading to serious weakening. Coating the sleeve, however, leaves the stem a "superalloy" which is unlikely to fail. Furthermore, as a fully impacted sleeve is subject to uniform noncyclic hoop stress, the chance of crack propagation in this sleeve is remote.

In a shear load mode, bead separation is a potential problem. The static shear strength of

most beaded systems is about 30 MPa. Therefore, dynamic shear leads over 10 MPa are likely in the long run to cause failure at the bead substrate metal interface. The simplest form of protection is to convert shear loads to compressive loads by means of steps.

Lastly, one of the major problems with ingrowth implants - retrieval - was solved. Should the hip require removal, the stern can be backed out of the sleeve and the fixation attacked from above and below. If all else fails, the sleeve can readily be cut up in situ with a powerful high speed burr.

A further advantage of this sleeve was noted when doing CDH cases. The femoral neck is frequently anteverted. If the hip is inserted for maximum metaphyseal coverage, it ends up too anteverted and dislocation can ensue. With detachable sleeve, however, the sleeve can be inserted for maximum bony contact and the version of the femoral component can be oriented for optimal function and locked in position by the Morse taper and distal flutes.

HISTORY

Threaded femoral components for intramedullary fixation were first used by McBride² in 1948, and more recently by Bousquet³ and Bornand in Europe. The current S-ROM[™] System represents the fourth generation in the evolution of the Sivash Total Hip System since it was introduced in the United States in 1972.

Sivash⁴ began development of a total hip prothesis in 1956 at the Central Institute for Orthopaedics and Traumatology, Moscow, Russia. By 1967, Sivash had selected titanium alloy material for the femoral stem and proximal sleeve and chrome cobalt alloy for his acetabular component, socket-bearing and femoral head. His major focus included the design of a constrained socket. The Sivash System, introduced in the United States by the U.S. Surgical Corporation, never received major clinical or market success, partially due to the difficulty of the surgical technique, and the positioning of this constrained device. However, one must not overlook three major areas of contribution made by Sivash:

1. Titanium alloy for femoral stem and chrome cobalt for head articulation.

- 2. Cementless (threaded) petalled acetabular component.
- 3. Titanium alloy proximal sleeves for enhanced collar calcar contact.

Sivash's work in the area of titanium and chrome cobalt predates the earliest publication of the acceptable combined use of these two materials, by Bultitude and Morris of the British Atomic Weapon Research Establishment in 1969.



Early clinical experience in the United States with the Sivash prosthesis was mixed. The prosthesis was developed and intended for non-cemented use, therefore, the technique was quite demanding. In 1972, the FDA approved the use of bone cement, which resulted in diminishing interest in cementless devices. Further, the original femoral stem was a round tapered peg, which led to a number of noncemented failures due to rotation of the stem in the femur. A number of these prostheses were cemented. Another design feature of this prosthesis was two medial to lateral fenestrations in the distal stem. These fenestrations caused stress concentration in the distal stem when cement in the femur failed proximally, resulting in stern failures.

In 1975, Noiles, working with Russin, redesigned the stem of the Sivash prosthesis to improve its function in cementless arthroplasty by adding features which would prevent failure by rotation of the stein in the femoral canal. The resulting stern, the SRNTM,

incorporated eight longitudinal flutes similar to that of the Samson intramedullary rod. Since the stein was intended for cementless use, a multiplicity of macro cross-slots or crenelations were incorporated in the anterior and posterior aspects of the stem. In addition, after some additional laboratory research, a design modification was made to avoid the potential risk of splitting the femur by adding a distal coronal slot, like that of a clothespin.



This modification reduces the bending stiffness by design, insuring minimal distal-load transfer. In addition, Noiles redesigned the circular proximal sleeve to a more acceptable eccentric design. These modifications created what is known today as the SRN Total Hip System.



Dr. Benjamin Meyer⁵ (now deceased) of Birmingham, Alabama, used a self-tapping threaded proximal sleeve in conjunction with the SRNTM Total Hip Stem. A final redesign variant produced a stem with distal flutes and



slot, but without the cross notches or crenelations of the SRN. This stem series, designated S-ROM, is used with a large array of proximal taper-lock sleeves, all of which are designed to optimize proximal fixation in the femur. This stem when used with the S-ROM acetabular series provides stability with enhanced range of motion.

Cameron began his clinical use of the threaded proximal sleeve and the S-ROM Stem in July, 1984. While the threaded proximal sleeve has shown to give excellent short term clinical results, its surgical technique is quite



demanding. In an attempt to reduce the surgical demands, a large array of press-fit proximal taper-lock sleeves have been developed. All of which are designed to optimize proximal fixation in the femur. The designs of these proximal sleeves have progressed over the last several years to include press-fit and porous coated anatomical contours, press-fit and porous coated cones and self-tapping threaded cones. This system provides the first truly modular ability to treat the distal and proximal femoral areas separately to achieve a more custom-type fit.

Gorski⁶ has demonstrated the viability of this system in treating total hip replacement for congenital dislocations of the hip in a case report pending publication. Cameron⁷ has also shown the versatility of this system in treating fusion takedowns.

CLASSIFICATION OF PROXIMAL S-ROM[™] SLEEVES

SPT (SECURE PROXIMAL THREADED)



The SPTTM femoral sleeves have an exterior self-tapping conical bone screw thread for achieving immediate, secure, mechanical fixation in the proximal femur. The matching stems fit the inner locking taper of the sleeves.

S-ROM femoral stems are available in proximal diameters: 14,16,18,20, and 22mm. The corresponding SPT sleeves are identified by the appropriate proximal diameter, and for each proximal diameter size there are three sleeve sizes which graduate in size by major thread diameter. The sleeves in each proximal size have their major thread diameters designated by a letter code: C, D, and E. Thus, there are 15 SPT sizes.

SPA (SECURE PROXIMAL ARTHOPOR)



The SPA[™] sleeves are porous coated cones, and are available in A and B sizes for each of the five corresponding stems: 14, 16, 18, 20, and 22mm. These sleeves are indicated for both primary and revision surgery when one is dealing with little or no metaphyseal portion of the femur.

ZT B-CONE SERIES (ZERO SHEAR)



The ZTTM sleeve is an anatomical design with proximal steps or ridges. The function of the sleeve is to convert unnatural hoop stresses usually created by total hip replacement to compressive stresses, thus reducing the likelihood of resorbtive bone remodeling and latent aseptic femoral component loosening.

The modular aspect of the style and sizes of these sleeves allows the surgeon the ability to custom-fit both the proximal and distal portions of the femur, and to custom fit both the cone and the calcar region. For each stem size, the B-Cone series is available in five triangle sizes, ranging from A to E. These sleeves are available for the following femoral sizes: 16, 18, 20, and 22mm. Sleeves for each stem size have a constant cone dimension (B-Cone).

ZTT B-CONE SERIES (ZERO SHEAR TEXTURED)



The ZTTTM B-Cone Series is of identical geometry to the ZT B-Cone Series with the addition of one layer of commercially pure titanium beads sintered to the substrate. While this one layer does not detract from the basic geometry of the ZT, it does allow for enhanced implant interfacial strength. The ZTT B-Cone Series is available in the same size selection as the ZT B-Cone Series.



ZTT GRADUATED CONE SERIES



This series is the same design configuration as the ZTT B-Cone Series. It has been designed to include additional sizes which increase proportionately in both the cone arid triangle portions of the sleeve. This series offers three cone diameters with two triangle sizes each, for each corresponding stem size.

EXAMPLE: FOR 20mm STEM

CONE	TRIANGLE
	Sm. & Lg.
В	C&E
D	C&E
F	C&E

This results in six possible sizes for each stem.

SRN (ALLOGRAFT SLEEVE)



The SRNTM sleeve has been reborn with a new interest and indication as an allograft sleeve. This sleeve has an eccentric collar which allows

collar to calcar contact. It has proven helpful in grossly deficient femurs where bulk allograft is used. The proximal portion of the stein and sleeve are cemented into the allograft, preventing any possible micromotion of the stem and sleeve within the allograft. A step or oblique cut is made in the distal portion of the allograft and the proximal portion of the host femur. The two portions are married together with the distal fluted stem being inserted into the host femur cementless. The distal flutes on the S-ROM stem aid in rotational stability of the device while the SRN collar loads the allograft in compression.

The SRN sleeve is available in one size only for each of the following stem sizes: 16, 18, and 20mm.

The array of styles arid sizes of the S-ROM proximal sleeves allow the surgeon to build a custom-type fit at the time of surgery for each patient while using standard stock items. This not only reduces inventory requirements, but also gives the advantage of adapting the prosthesis to the geometry of the patient resulting in a more consistent clinical result.

S-ROMTM STEM DESIGN

The S-ROM Stem has four distinguishing dimensions:

- 1. Stem Diameter (Proximal & Distal)
 - 2. Stem Length
 - 3. Neck Length
- 4. Head Diameter

All of these steins have a proximal taper, a straight distal diameter, and a taper lock head fitting. A proximal taper permits the use of a variety of self-locking proximal sleeves to provide optimum load transfer to the proximal femur. The tapered head fitting permits a variation in neck lengths and head diameters.

STEM DIAMETER IS SPECIFIED BOTH PROXIMALLY AND DISTALLY

The first two numbers of the stem size designate these diameters. Example: 18 x 13 x 160mm stem, has an 18mm proximal diameter and a 13mm root distal diameter. The flute depth is approximately 0.5mm. There are presently five proximal diameters: 14,16, 18, 20, and 22mm.



STEM LENGTH IS MEASURED FROM THE DISTAL SHOULDER SURFACE TO THE EFFECTIVE DISTAL END OF THE STEM

The third number of the stem size designates this length. Example: $18 \times 13 \times 160$ mm stem as mentioned above has a 160mm stem length.

The S-ROM stems are available in standard, long, extra-long, and extra-extra long lengths. All stems have a fluted distal circular cross section and also have a coronal distal slot (clothespin). The long, extra-long, and extraextra long stems are available in either neutral or bowed, left or right.

The femoral head selection determines both the head diameter and the neck length. Femoral beads are available in 22, 28, and 32mm outside diameters. The 22mm head is available in one standard neck length, while the 28 and 32mm heads are presently available in the +0, +6, and +12 neck lengths. Femoral heads are made of forged chrome cobalt alloy, which allows a fine finish resulting in minimal wear debris.

RESULTS FOR S-ROM™ STEMS WITH SPT SLEEVES

CLINICAL RESULTS: SPT SLEEVE (Threaded)

48 Patients I - 3 year follow-up

29 Males / 19 Females

Age: 20 - 87 (average 55)

DISEASE:

Primary Disease

Osteoarthritis	34
Rheumatoid Arthritis	8
Avascular Necrosis	6
Acetabular Dysplasia	12

TYPE:

Primary	26
Revision	15
Girdlestone	7

HARRIS RATING:

94%	Excellent
2%	Good
4%	Poor

TRENDELENBERG:

At Six Months	89%
At Twelve Months	4%
At Twenty-Four Months	4%

TECHNICAL ERRORS AT INSERTION:

Varus Position	6 cases
Undersizing	4 cases
Calcar Split	6 cases

TWO PATIENTS (4% have pain)

Both revisions were inappropriate for primary stem

RADIOLUCENCY:

ZONE:	1 - 7	5 - 1
	2 - 9	6 - 5
	3 - 5	7 - 5
	4 - 1	

TWO PATIENTS HAVE COMPLETE RADIOLUCENCY, THIGH TIREDNESS AFTER EXERTION.

BOTH VERY UNDERSIZED.



Failed Surface Replacement

Post-Op: S-ROM Stem with SPT Sleeve



Pre-Op: Osteoarthritic Left Hip

Post-Op: S-ROM Stem with ZT Sleeve

Post-Op: Distal Lateral View (Clothespin)





PRELIMINARY RESULTS OF THE S-ROMTM STEM WITH THE ZTTTM SLEEVE

Fifty such cases have been done with a followup of 3 - 15 months. Obviously it is too early to give realistic results, but no problems have been encountered. Canal preparation by reaming rather than broaching has made this simple and easy and <u>no calcar splits</u> have been encountered.



In the initial ZTT sleeve, the cone part was the same for all five triangle sizes for each stem size. While this has worked well, experience suggested that, as well as offering a variable triangle size, the cone size should also vary. Experience with this is limited, but it does seem to provide enhanced endosteal contact.

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