AN INTERNATIONAL MULTI-CENTER STUDY ON THIGH PAIN IN TOTAL HIP REPLACEMENTS

by

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INTRODUCTION

Thigh pain has not been a clinical problem with cemented femoral components. However, with the increase in femoral cementless surgery over the past 6-10 years, thigh pain has become an increasingly encountered clinical problem. Incidences of 10-30% have been reported with most cementless devices.

At the recent December, 1989, Current Concepts Meeting in Orlando, Florida, Dr. Charles James reported on the following statistics concerning thigh pain:[6]

James - AML™
- 12% proximal 1/3 coating
- 6% 5/8 coating

Engh - AML
- 15% proximal 1/3 coating
- 5% 5/8 coating

Dorr - APR™ (Type C-bone)
- 62% at 6 months
- 23% at 1 year
- 16% at 2 years

Galante - HG™ Stem (Average follow-up 44 months)
- 76.5% no pain
- 19.3% slight pain
- 1.5% mild pain
- 0.7% moderate pain
- 0.0% severe pain

The purpose of this exhibit is to review different implant designs and materials relative to post-operative thigh pain.

Thigh pain can be a multi-factorial problem.

1. Loose implant
2. Modulus mismatch
3. Infection
4. Spine etiology

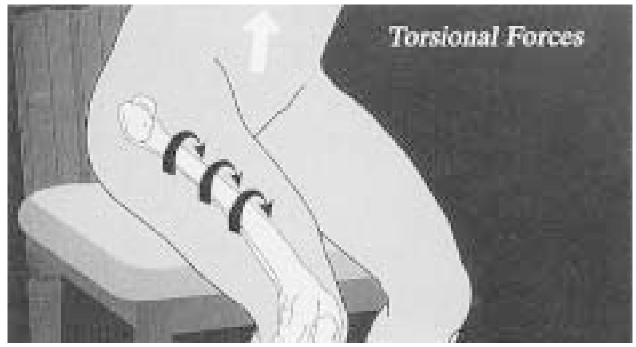
However, we will show that two specific scenarios exist for most post-operative thigh pain. The first is implant instability (torsional and /or axial) and the second is modulus mismatch between the implant and the bone at the distal tip of the implant.

This exhibit clearly demonstrates how certain designs affect post-operative thigh pain.

It is generally agreed that fit and fill are necessary to achieve immediate implant stability for cementless devices. Current cementless press fit designs and techniques can achieve excellent stability against axial loading, however, many daily activities produce high torsional loads in the femur which can cause loosening of the femoral component. [3,4,7]

Achieving a tight proximal fit is difficult due to the varying geometry of the proximal femur. Noble et a], reported that a constant proportional relation-hip is not present between the shape and size of the metaphysis and diaphysis of the femur.[8]

If torsional and/or axial instability is a major cause for femoral component loosening and thigh pain, then designs and techniques must be developed to achieve a tight proximal and tight distal fit. Whiteside has shown that a tight fit in the metaphysis and diaphysis can be obtained with significant improvement in resistance to torsional loading. This may have a positive effect on clinical results.[9]



Torsional forces

MATERIALS AND METHODS

A total of 1055 patients have been evaluated for thigh pain after receiving a primary total hip replacement. An array of different designs and materials has been used. The selections include 6 different designs utilizing 4 different materials with only 1 design utilizing acrylic cement for fixation.

STEM DESIGN	MATERIAL	FIXATION
1. PCA™	Chrome-cobalt	Porous press fit
2. Harris /Galante™	Titanium alloy	Titanium fiber pads, press fit
3. Isoelastic™	Polyacetal	Press fit
4. Porous Polysulfone™	Composite titanium alloy and polysulfone	Porous polysulfone press fit
5. S-ROM™	Titanium alloy	Porous titanium press fit
6. International™	Titanium alloy	Cemented

PCA

PCA is made of chrome cob, available in a variety of right and left femoral stem sizes which are proportional to the physiological shape of the femur to improve initial fixation stability and stress distribution at fixation interfaces.

Varying neck lengths are achieved through a choice of three interchangeable femoral head components which lock onto the femoral stem by a modular taper neck design.

Ingrown - thigh pain associated with strenuous activity

A variety of long stems are available for revision situations.

HARRIS/GALANTE

The HGP™ Stem is a straight stem design manufactured of titanium alloy. It is designed with a Morse taper neck and will accept a variety of head sizes and lengths. The stem is designed with rounded corners, its proximal cross-section is trapezoidal. It has a high rounded shoulder with a straight lateral margin to the tip of the prosthesis. The distal stem is a rounded configuration with four grooves. Flat pads are commercially pure titanium mesh which has been applied in recesses on three sides (anterior, posterior and medial) of the proximal third of the stem. The pads are diffusion bonded to the implant substrate.

4 year Post Op. - Pain free

The stem incorporates a thin medial collar which is designed to contact the calcar, after precision rasping. The overall geometry and neck and stem lengths are virtually identical to the Harris Precoat™ stem.

POROUS POLYSULFONE

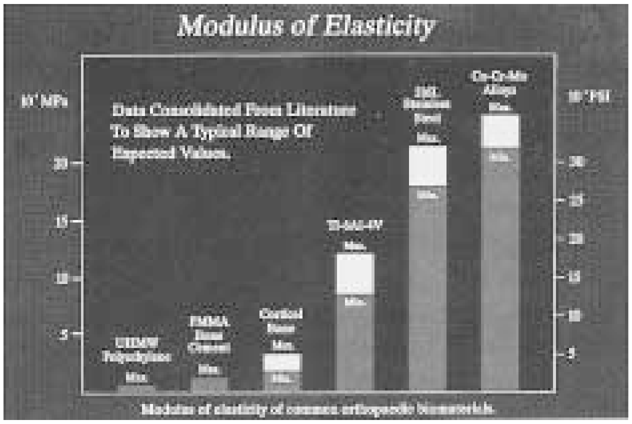
Description

The femoral component is made of titanium alloy with a collarless design with porous polysulfone over 5/8 of the device. The stem is available in six sizes and lengths are proportionate to the size. The design features a modular taper neck that will accept either ceramic or chrome cobalt heads. The physical characteristics of the coating are: 33%, porosity, 250 micron-pore size, low modulus 0 /7 that of chrome cobalt).

Theoretical Advantages

Utilization of a high-strength, porous plastic coating can produce more flexible stems (by reducing metal cross section), thus reducing the modulus mismatch between implant and bone.

15 month Post Op. - Painful when ambulates without aid



Modulus of elasticity

S-ROM

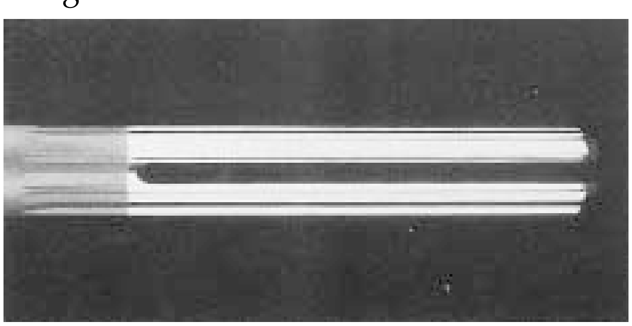
Description

The S-ROM stem has three distinguishing dimensions:

1. Stem Diameter (proximal and distal)
2. Stem Length
3. Neck Length

These stems have a proximal taper, a fluted 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.[2]

The fluted distal stem design has a minor and a major stem diameter. The flute depth is approximately 0.5 mm. There are presently six stem diameters available. Stem lengths are available in standard long, extra long, and extra-extra long lengths. All stems have a coronal distal slot (clothespin). Long, extra longarld extra-extra long stems are available in either neutral or bowed left or right.


S-ROM coronal split

The ZTT™ proximal sleeves have two distinct dimensions. First is a conical body that is available in three sizes at 2 mm increments for each stem size. The second dimension is the triangle portion which is available in two sizes on the smaller cones and three sizes on the largest cone.

The array of styles and sizes of the S-ROM proximal sleeves allows the surgeon to build a custom-type fit at the time of surgery for each patient while using standard stock items. This gives the advantage of adapting the prosthesis to the geometry of the patient.

ISOELASTIC

Description

The prosthesis is made of acetalcopolymer. Polyacetal resin has art elastic modulus approaching that of bone. It is highly durable with excellent biocompatible properties. The surface of the proximal part of the stem has 2 turn notches with small connections where bone growth can interlock. The distal part of the stem has a grooved surface. To achieve structural strength in the neck, the component is reinforced by a metallic core that is tapered towards the distal tip. Additional fixation is accomplished by use of two proximal cancellous bone screws.

The prosthesis is available in six diameter and is 150 mm in length. Longer stems (180 turn and 240 mm) are available for revisions.


4 year Post Op. - Painful - Revised to S-ROM

CEMENTED STEMS

INTERNATIONAL

Well-fixed, cemented stems do not have thigh pain because of two significant factors. First, the acrylic cement prevents significant micromotion that would result in axial or torsional instability. Second, modern cementing technique involves plugging the femoral canal approximately I to 2 cm below the distal stem. The cement decreases the differential movement between the bone and the implant thus reducing likelihood of the femur engaging the stiff distal stem.

Over the past four years the senior author has implanted over 300 cemented stems for primary total hip replacement. There has not been a single case of end stem thigh pain encountered. However, radiographic evidence of loosening in other cemented devices does correspond with clinical symptoms of thigh and/or hip pain.

Well fixed cemented stem - no pain

Loose cemented stem - painful

SUMMARY OF RESULTS
Percentage of thigh pain

Description	1yr*	2yr	3yr	4yr	5yr
International (cemented)	-0-	-0-	-0		
S-ROM	2.3%	0.4%	-0-	-0-	-0-
S-ROM/solid	33.3%	33.3%			
H/G	5.2%	0.1%	2.7%	-0	
Isoelastic	9.0%	7.2%	7.2%	14.8%	
PCA	30.0%	35.0%	34.0%	37.5%	45.8%
PPS	47.0%	52.0%	58.0%		

*Statistical data:
International significantly lower than others (Chi-square, P< .05).
S-ROM significantly lower than S-ROM Solid (Chi-square, P<.05).
S-ROM and H/G are not significantly different (Chi-square, P< .05).

S-ROM w/ coronal split
(Bone Type A, B, C)

Description	1yr	2yr	3 yr	4yr	5yr
None	295	222	200	150	50
Slight	7	1	-0-	-0-	-0
Moderate	-0-		-0-	-0-	-0
Severe	-0-	-0-		-0-	-0
Revised	-0-	-0-	-0-	-0-	-0
Total Follow Up	302	223	200	150	50
% Encountering Pain	2.3%	0.4%	0.0%	0.0%	0.0%

S-ROM Solid

Painful (6 months) - Pain subsided by 12 months

S-ROM Modified

Shortened coronal stem - Pain free

S-ROM w/Coronal Split

Pinched closed - Painful (6 months) - Pain subsided by 12 months

Open - Pain free

S-ROM Solid
(Bone Type B, C)

Description	6mo	1yr	2yr
None	1	4	4
Slight	5	2	2
Moderate	-0-	-0-	-0
Severe		-0-	-0
Revised	-0-	-0-	-0
Total Follow Up	6	6	6
% Encountering Pain	83.3%	33.3%	33.3%

Harris/Galante
(Bone Type A, B)

Description	1yr	2yr	3yr	4yr
None	72	62	35	7
Slight	3	-0-	1	-0
Moderate	1	1		-0
Severe	-0-	-0-	-0-	-0
Revised	-0-	-0-	-0-	-0
Total Follow Up	76	63	36	7
% Encountering Pain	5.2%	0.1%	2.7%	0.0%

Isoelastic
(Bone Type A, B)

Descriptio	1yr	2yr	3yr	4yr
None	158	153	102	23
Slight	13	8	3	-0
Moderate	3	3	1	
Severe	-0-	1	4	-0
Revised	-0-	-0-	-0-	4
Total Follow Up	174	165	110	27
% Encountering Pain	9.0%	7.2%	7.2%	14.8%

PCA
(Bone Type A, B)
(High percentage of stems were undersized)

Descriptio	1yr	2yr	3yr	4yr	5yr
None	58	50	49	40	13
Slight	15	21	17	14	9
Moderate	7	4	7	7	1
Severe	3	2	2	3	1
Revised	-0-	1	1	-0-	1
Total Follow Up	83	77	75	64	24
% Encountering Pain	30%	35%	34%	37.5%	45.8%

PPS
(Bone Type A, B, C)

Description	1yr	2yr	3yr
None	60	42	13
Slight	37	35	11
Moderate	14	11	6
Severe	3	1	1
Revised	-0-	7	10
Total Follow Up	114	89	31
% Encountering Pain	47%	52%	58%

International (cemented)
(Bone Type A, B, C)

Description	1yr	2yr	3yr
None	300	275	200
Slight	-0-	-0-	-0
Moderate	-0-	-0-	-0
Severe	-0-	-0-	-0
Revised	-0-	-0-	-0
Total Follow Up	300	275	200
% Encountering Pain	0.0%	0.0%	0.0%

Definition of Pain Score

None	Self explanatory
Slight	No pain medicine and does not effect activity
Moderate	Analgesic and does effect activity if overdone
Severe	Analgesic and requires walking aid

SUMMARY

In reviewing two separate low modulus composite designs, there was an unacceptable high rate of pain due to aseptic loosening. The Isoelastic stem, however, was statistically better than the PPS. This might be due to the proximal geometry which offers more surface area resulting in increased stability. Both devices, however, have increasing thigh pain and revision rates suggesting implant instability.

In using low modulus material it is apparent that it is difficult to achieve the required proximal rigidity needed to achieve implant to bone stability.

Looking at one particular anatomical design we find a higher than average incidence of thigh pain, which progresses from 30 to 45.8% in five years. This would also indicate implant instability.

The two titanium straight stems did considerably better than the curved or low modulus devices. In addition the early thigh pain encountered subsided with time. This pain subsidence was due to bony distal changes which reduce the modulus mismatch between the bone and stiff implant. The clinical scores would also indicate that Noble is indeed correct on his work showing stability of straight stems to be superior to anatomical stems.[8]

Implant to bone stability must be the first priority in utilizing cementless devices. A reduction of the modulus of the distal stem is necessary to reduce modulus mismatch. However, in using composite materials with a low modulus it is difficult to maintain proximal rigidity.

No stems were revised due to thigh pain brought on by modulus mismatch. All stems which were revised had progressive thigh pain indicating implant instability.

Thigh pain (distal modulus mismatch) is a clinical symptom that is not progressive and tends to diminish as the distal host bone remodels due to distal stress transfer. One can predict the patient profile for thigh pain due to modulus mismatch.

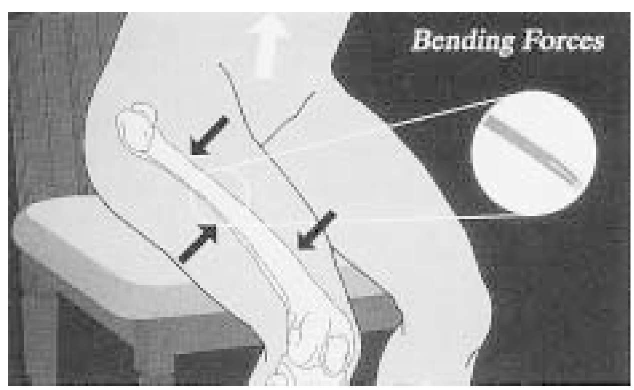
1. Type C bone
2. Acute anterior - bow
3. Activity level of patient
   (moderate to high)
4. Large distal diameter device

One can effectively reduce thigh pain by:

1. Fit and fill for torsional stability
2. Onlay cortical grafts
   (increase modulus of bone)
3. Reduce bending stiffness of distal stem
   (coronal split)

Ways to reduce bending stiffness of stem:

ActionApprox. Reduction (change from CC)	
1. C. C. to Ti Alloy	50%
2. 20% reduction of stem diameter	50%
3. Ti Alloy w/coronal split	80%
4. Ti Alloy hollow stem[1] (theoretical)	70%



Bending forces

In comparing the two S-ROM stems (one solid, the other split in the coronal plane), we find a higher percentage of thigh pain in the solid stem. This would indicate that greater than 50% reduction of distal bending stiffness is needed to effectively reduce thigh pain due to modulus mismatch.

The S-ROM an d H / G showed far better results concerning thigh pain. We think this is generally due to the effectiveness of straight titanium stem design.

The S-ROM with a coronal split showed best overall results. Initial stability is achieved by fitting and filling the proximal femur with a sleeve similar in concept to fitting and filling with bone cement. Distal torsional stability is achieved by eight flutes which engage the cortical bone. Distal modulus mismatch is reduced approximately 80% by splitting the distal stem in the same bending plane of the femur; then as the femur bends or bows, the implant bends reducing point contact and pressure.

This has also been done in Dr. Dorr's new revision stem design that also incorporates a coronal split.[5] His early clinical results are similar to those for the S-ROM presented here.

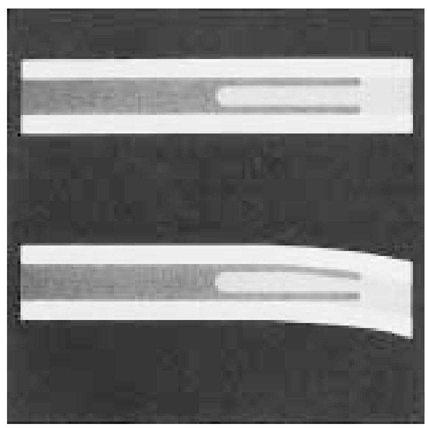
DISCUSSION AND CONCLUSION

There are considerable theoretical advantages of cementless devices versus cemented devices. However, cementless devices must achieve the initial short-term clinical results that can be accomplished by utilizing cement.

Fit and fill are necessary to achieve axial and torsional stability. This does not necessarily mean a reduction in end stem pain due to distal modulus mismatch.

Pain caused by distal modulus mismatch tends to subside as distal bone remodeling occurs.

Reducing the distal bending stiffness by a coronal slot design effectively reduces end stem pain. This suggests that distal modulus mismatch is one of the causes of end stem pain.



At Rest

Corona] Split (Clothespin) design reduces modulus mismatch, decreasing the bending stiffness of the component.

Isoelastic and *International* – These devices not available for distribution in U.S.
PPS – This device is limited by U.S. Federal law to investigational use.
S-ROM, PCA and *H/G* – Cementless application of these porous coated devices are limited by U.S. Federal law to investigational use.

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