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ARE SHORT STEMS SAFE? A QUESTION OF STABILITY AND DESIGN

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SUMMARY
A shortened femoral component can be safe for implantation if and only if its proximal geometry is sufficient to provide stable initial fixation against proximal/distal, flexion/extension and rotational loads. This is an early, 2 year, retrospective review of the first 200 off-the -shelf lateral flare short stems implanted by three independent surgeons. There were no cases of subsidence or early aseptic mechanical failures. It demonstrates that previously published successful results achieved with a specific, non-cemented implant will not be compromised by shortening its stem to accomodate modern surgical approaches. This study concludes that shortening of a standard femoral component is safe provided it includes three specific proximal design features: a lateral flare, a flat posterior surface and a trapezoidal cross-section.

Keywords: femoral implant - non-cemented - stemm - femur - lateral flare

INTRODUCTION

Secure fixation to host bone is critically important for successful long-term survival of a femoral implant.

Non-cemented stemmed implants achieve fixation through a two step process. Initial fixation is achieved, at the time of implantation, by a combination of mechanical forces: friction and hoop stressing (circumferential displacement of the surrounding femoral bone), analogous to the fixation of a nail into a piece of wood, (fig. 1).

Like a nail, successful initial fixation of a traditional stemmed femoral implant is very much dependent the quality of the material into which it is implanted and maintenance of the integrity of the material into which it is being implanted.

Secondary, long-term fixation of a stemmed, non-cemented implant is achieved through osseous integration.

This is the intimate on-growth and in-growth of host bone onto and into the surface of the implant. Initial passive implant stability and intimate prosthesis-bone contact are absolutely necessary for this secondary, permanent osseous integration fixation to take place.

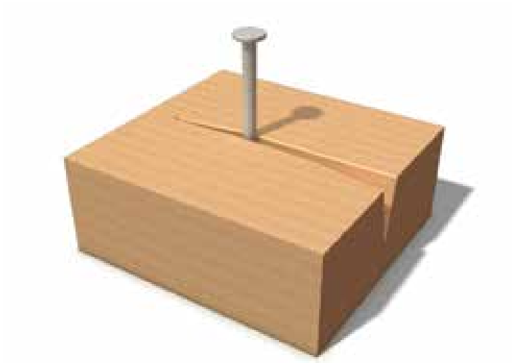


Fig. 1 - Initial Non-cemented Fixation. The analogy of non-cemented initial fixation to that of a nail in a piece of wood.

Micro motion in any plane, flexion/extension, varus/valgus, proximal/distal or rotational about the long axis of the femur, will compromise and prevent osseous integration from being achieved.

Recent trends toward smaller incisions and alternatives in surgical approaches have stimulated interest in reducing implant length. This reduction in stem length, and sometimes changes in component geometry to accommodate these approaches, has brought a myriad of "new" component designs into the marketplace (fig. 2). Although these new designs have been granted permission by the FDA to be implanted, there exists little standardized, regulatory methodology to test and validate how these changes in stem length or implant geometry will affect short stem safety and performance. It has been reported that simple reduction or removal of an implant's stem can significantly compromise achievement of initial stability[1,2].

The predicted consequences, early aseptic loosening and mechanical failure of these implants, has been reported[3].

Similarly, exclusive attention to specific design features, i.e. "bone conserving," to the exclusion of necessary geometric features has similarly led to an unacceptably high incidence of early aseptic failure with some of these "newer" design implants[4].

This paper will define a methodology for testing and determining the minimal design characteristics necessary for a short stem implant

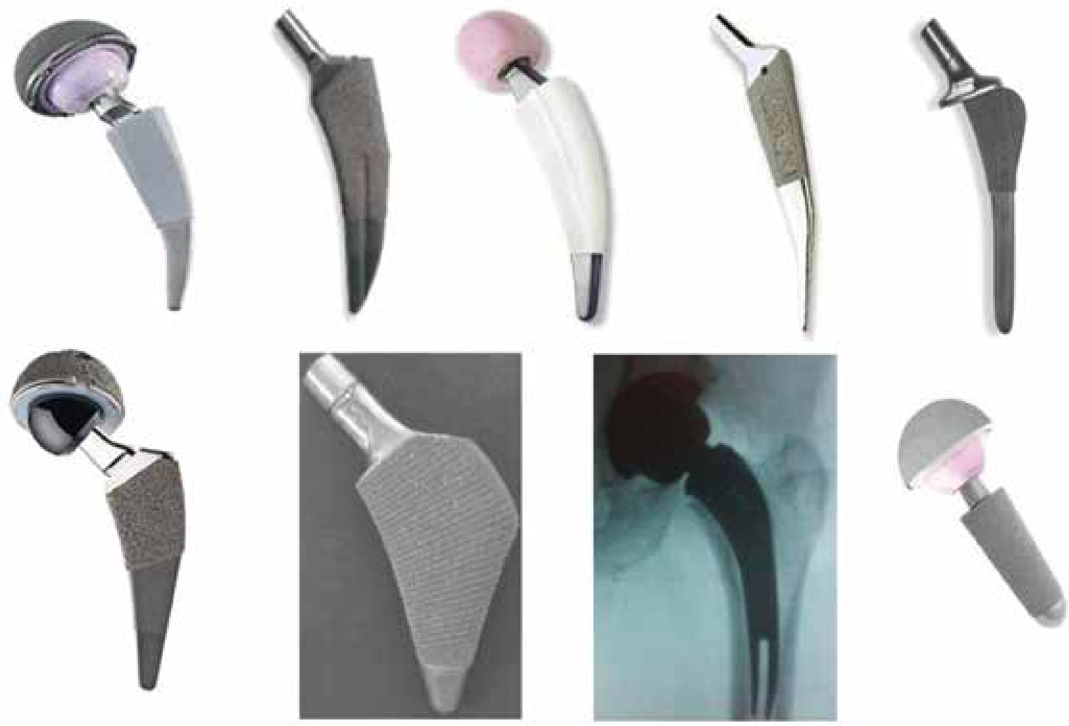


Fig. 2 - Various short and "new" geometry stems recently introduced into the marketplace.

to achieve sufficient and durable initial implant stability, regardless of bone quality and femoral geometry. It will also provide a report of the early clinical results of a specific short stem having these design characteristics.

MATERIALS AND METHOD

The short stem femoral implant (fig. 3 a, b, c) utilized in this study is predicated on a standard length implant (Fig. 4).
The standard length stem has been in clinical use for more than 15 years as an off the shelf product.
The "Lateral Flare" design has been in use as a custom product in both the standard and short lengths for 22 years.
Both off the shelf and custom versions have provided excellent clinical outcomes[5,6].
The standard length stem's distal two-thirds is tapered and polished to specifically discourage distal load transfer and osseous integration below Gruen zones 1 and 7. It also incorporates specific geometric features designed to stabilize the implant against flexion/extension (a flat posterior surface), varus/valgus and subsidence (a "lateral flare"), and rotation about the long axis of the femur (a proximal trapezoidal cross-section).
In vitro testing (fig. 5) was employed to evaluate the consequences of reduction of the standard stem length on the distribution of load within the femur[7].
Based on the similarity of in vitro loading characteristics of the shortened and standard non-cemented stem, a clinical evaluation of the short stem design was undertaken.
Three surgeons contributed the early follow up clinical evaluation data of their combined first 200 short stems implanted.
They implanted 78 (JF), 71 (SL) and 51 (ML) stems respectively.
The majority of cases were performed for primary OA (159); but they also included: RA (1), CDH (9), SCFE (2), AVN (9), post-traumatic etiologies[7], revisions of prior arthroplasties (12) and one revision of a prior arthrodesis of 25 years for secondary OA due to Legg-Calve-Perthes disease.
No patients were excluded for pre-existing osteoporosis.
All femoral geometries were included: 28 percent Type A, 50 percent Type B, and 22 percent Type C.


Fig. 3a - Short stem "lateral flare".


Fig. 3b - Short stem trapezoidal cross-section.

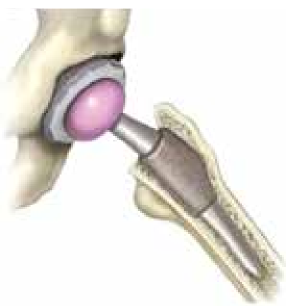


Fig. 3c - Short stem flat posterior surface.


Fig. 3d - Top view surgical technique.

Fig. 3e - MicroMax Anterior and lateral view.

There were 80 males and 120 females.
They ranged in age from 36-90 years.
The prostheses ranged in size from 8 to 16.5. Acetabular shells ranged from sizes 44-62mm. Modular acetabular inserts included highly cross-linked polyethylene or metal articulating surfaces.

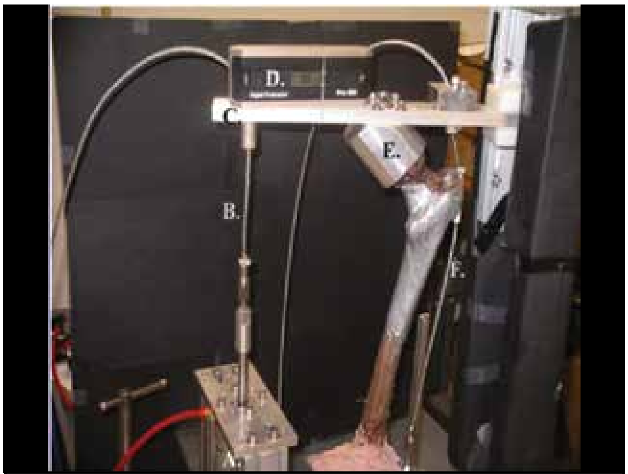
Bone Preservation: (DEXA Scanning) in Gruen zones 1 and 7; bone preservation at 12 months, no bone loss or stress shielding noted.

Average HHS scores: Preoperative: 61
At latest follow-up: 99

Subsidence (stability)[5]
0.32 +/- 0.24 mm @ 2years 0.51 +/- 0.31 mm @ 3 years
(less than 0.5 mm @ 2 years and less than 1 mm @ 4 years.

Fig. 4 - Standard length stem. This design utilizes LFIC (Lateral Flare Internal Collar) Technology.

Femoral heads ranged from sizes 28-44 mm, Co-Cr or ceramic, for THR.
There were 7 bipolar hemiarthroplasties performed for femoral neck fracture.
Surgical approaches included posterior with capsular repair, antero-lateral and anterior approach.
Patient assessments were conducted pre-operatively and post-operatively at 3 weeks, 6 weeks, 12 weeks, 6 months, 12 months and annually thereafter.
These included demographic data, standardized scoring (i.e. HHS) and radiographic evaluation at 3, 6, 12 and 24 months, performed by the operating surgeon. Radiologic evaluations included changes in femoral morphology (medullary densification as evidence of bony integration, diaphyseal hypertrophy, stress shielding), fracture, implant orientation, implant migration/subsidence.



The Dynamic Model
Figure:
A. Pneumatic Pressure Cylinder
B. Body Weight Force
C. Aluminium Plate for visual indication of pelvis
D. Digital protractor
E. Artificial Acetabulum
F. Iliotibial band/ abductor muscles (3/16″ steelcable).

Fig. 5 - In vitro testing apparatus for examining the distribution of loads within a native femur.

RESULTS

As reported by Arno et al.[7], shortening of the standard stem length "lateral flare" femoral component did not compromise initial implant stability.

They further demonstrated that a "stemless" implant most closely reproduced the distribution of loads seen in an intact femur.

With confidence that shortening of the standard design posed no mechanical risk to patients, a prospective study of short stems implanted in 200 consecutive patients was undertaken by three independent surgeons.

There was no pre-selection of patients.

Post-operatively, all patients were significantly improved in pain relief, increased function, increased range of movement in the affected hip and independence in activities of daily living, as measured by HHS.

There were two intra-operative, non-displaced fractures. One occurred in each of two surgeons' early cases. These represented a "learning curve" of the difference in surgical technique between traditional "press fit" impaction of a non-cemented implant and the less aggressive "rest fit" technique of seating the "Lateral Flare" design component. Both fractures did not require fixation. They were treated with limited weight bearing for 6 weeks and healed without consequence. There has been no evidence of femoral component subsidence, in spite of immediate full weight bearing in all other patients, regardless of bone quality or femoral geometry.

There have been no reports of post-operative dislocations or thigh pain.

Prospective monitoring for changes in bone morphology and quality, as reported by Leali[5,6], is on-going.

To date, no adverse

Fig. 6 - Wolff's Law in action: post-operative changes in femoral bone morphology and quantity.

morphologic changes, i.e. proximal stress-shielding (Gruen zones 1 and 7) or diaphyseal hypertrophy (Gruen zones 2,3,5,6) have been observed.

DISCUSSION

In the 19th century, Julius Wolff described the dynamic response of connective tissues to their environment.
The term "Wolff's Law" was coined to explain these responses of connective tissue to mechanical stresses: hypertrophy with use, atrophy with disuse.
The changes in proximal femoral morphology following replacement of a damaged femoral head with a modern stemmed component follow this empirical law.
They have been well described by Prichett[8], Engh[9], Gibbons[10], Bobyn[11] and others.
It would appear that an ideal replacement component would be one that is both mechanically and biologically "invisible" to the host bone.
It should not stimulate or cause any deleterious changes in the distribution or quality of femoral bone, while remaining stable and well fixed. Traditional stemmed, non-cemented implants attempt to achieve this goal by means analogous to that of a nail inserted into a piece of wood. However, this "press fit" technique has been shown to be less than "invisible".
As it is frequently associated with loss of proximal bone stock in Gruen zones 1 and 7 (stress shielding), diaphyseal hypertrophy (distal load transfer), thigh pain (non-physiologic loading of the femur) and sometimes fracture on insertion (fig. 6).
Traditional press fit components are also unable to accommodate "Type C stove pipe" femoral geometry and poor bone quality.
An alternative concept of femoral loading, as described by Fetto[12], and later supported by other authors[13,14], suggests that the lateral femoral cortex may, during some phases of unilateral support during gait, experience compressive loading.
As such, it becomes possible to prioritize loading to Gruen zones 1 and 7 by use of a "lateral flare", which will engage the lateral femur as an additional base of implant support. In this way a femoral component can achieve a "rest fit" on top of the proximal femur, rather than "press fitting" it into the femoral canal (fig. 7).
This enhanced proximal geometry will prevent subsidence of the component under vertical loads regardless of bone quality or femoral canal geometry.
By incorporating a flat posterior surface design feature, a short stem femoral component can be firmly supported against the posterior cortex of the femur in order to maximally resist displacement by flexion/extension forces.
Further, effects of rotational forces about the long axis of the femur during activities such as stair climbing can be minimized by adopting a trapezoidal cross-sectional geometry to the shortened femoral component.
Combining these three design features, a "lateral flare", a flat posterior surface and a trapezoidal cross-section, will provide initial implant stability in three dimensions without reliance upon a stem.
Such a comprehensive design will create a "mechanically" invisible construct which permits a reduction in implant length compatible with "modern" surgical approaches while not compromising initial implant stability critical for osseous integration to take place.
These design features also produce an implant which most closely reproduces the distribution of stresses observed within the native femur.
They serve to create a "biologically inert" implant that preserves bone stock and morphology, while avoiding diaphyseal loading, hypertrophy and thigh pain.

CONCLUSIONS

Interest in "modern" surgical approaches has spawned an interest in the reduction of femoral component length and changes in component geometry.

Unfortunately, in the case of most of these newer non-cemented femoral implants, these design changes have proven unsuccessful.

They have been unable to accommodate poor bone quality, wide canal indices and more importantly have been unable to reliably provide the initial implant stability required to achieve long term osseous integration critical for implant longevity.

This study has demonstrated, however, that it is possible to produce a stable short implant compatible with "modern" surgical techniques, by the incorporation of specific design criteria: a "lateral flare", a flat posterior surface, and a proximal trapezoidal cross-section.

Such a combination of features will also provide an implant which most closely reproduces femoral loading seen in the native femur. ✦

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