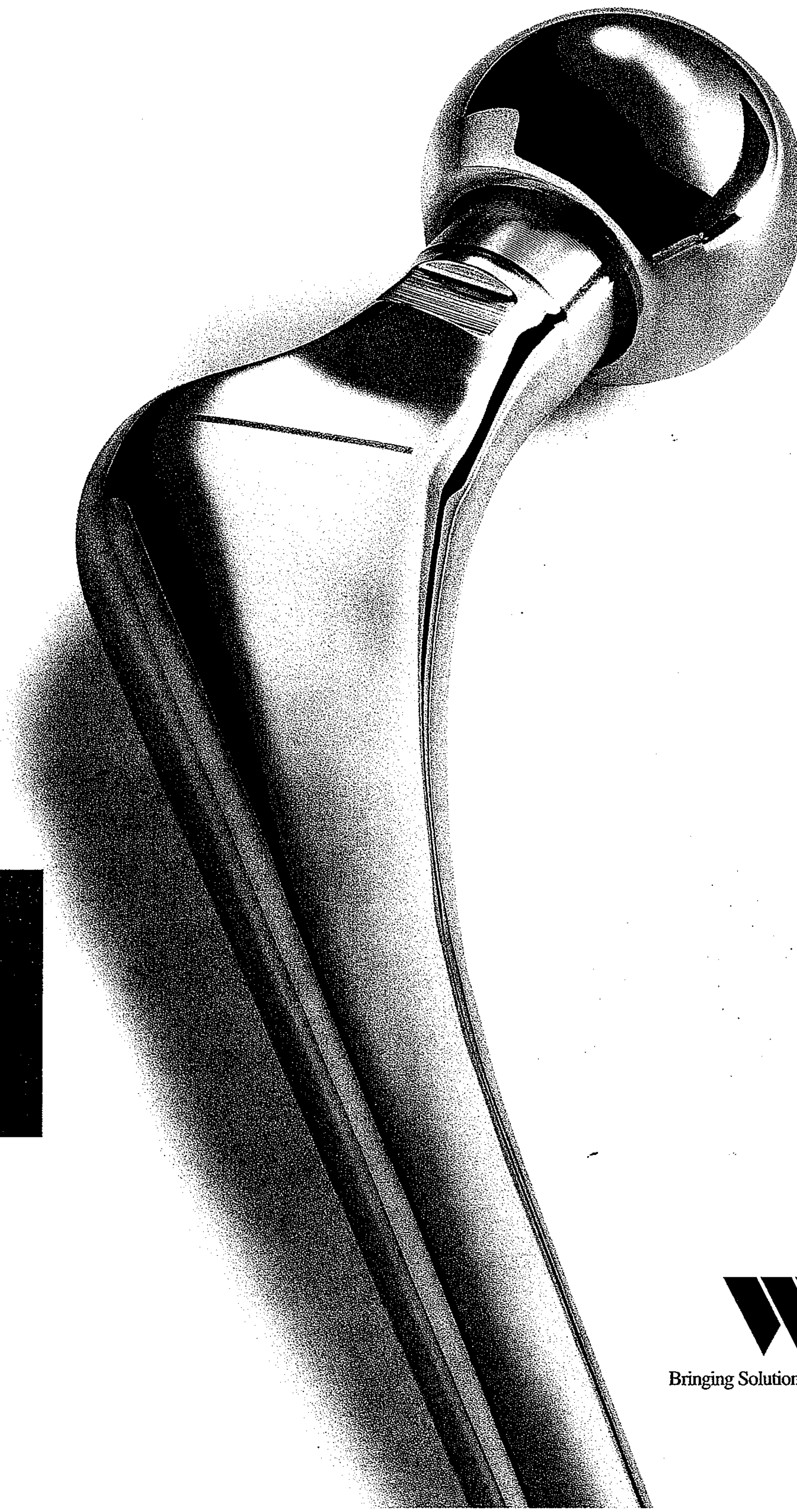
PERFECTA® Ra

FEMORAL STEMS



Bringing Solutions to the Table™

INTRODUCING

PERFECTA® Ra

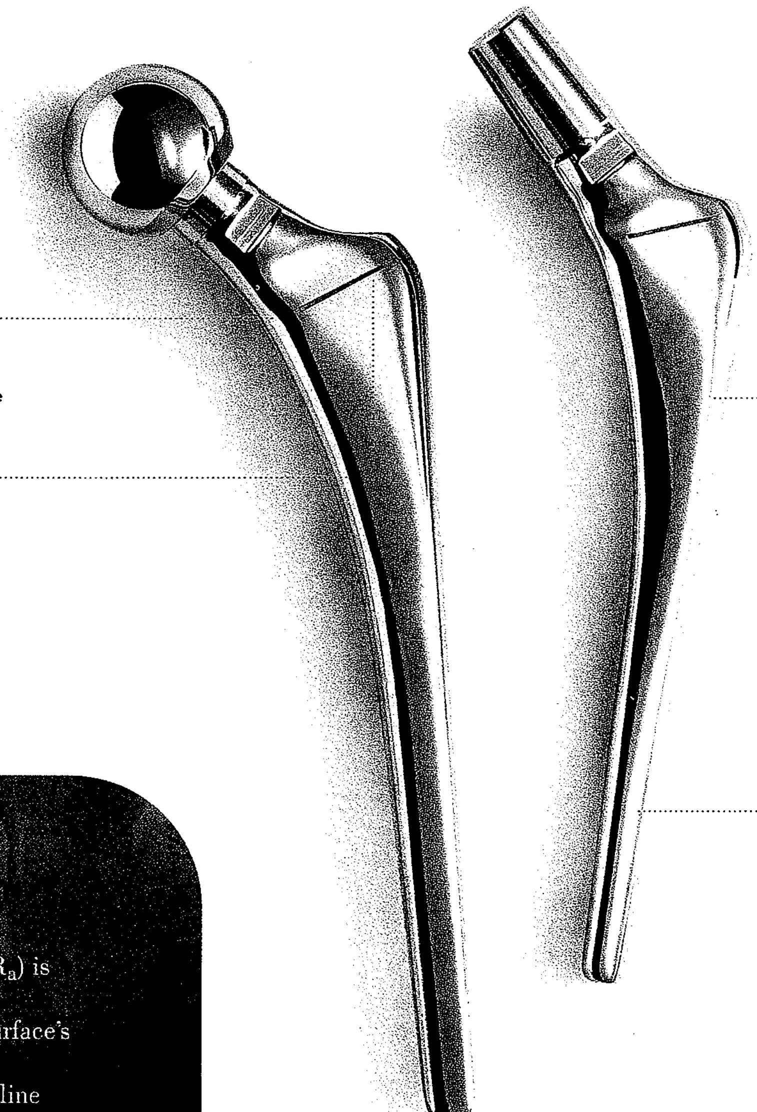
FEMORAL STEMS

Highly Polished Surface
reduces stem-cement friction and potential debris generation

allows "interactive" cement engagement with minimal abrasion

Collarless Design
encourages radial load transmission through the cement mantle to the host bone

Laser Etching
denotes the appropriate level of insertion following femoral preparation



Forged CoCr
the material of choice for durability, wear resistance and cement mantle protection

Tri/Planar Wedge
tapered wedge optimizes fit while promoting compressive loading

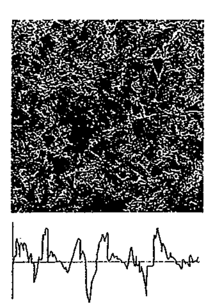
enhances stem-cement stability as the tapered wedge continuously engages within the cement mantle

Anatomic 3° Distal Taper
matches patient anatomy while minimizing cement stress distal to the implant

What is Ra?

Average Surface Roughness (R_a) is the average distance from a surface's peaks and valleys to its mean line (or centerline). The lower the Ra, the smoother the surface. The smooth, low-friction surfaces and unique design of the PERFECTA® Ra stems offer distinct advantages to patients requiring cemented total hip arthroplasty.

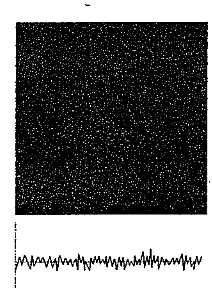
High Ra



125X SEM photos comparing two surfaces.

Surface profiles shown below.

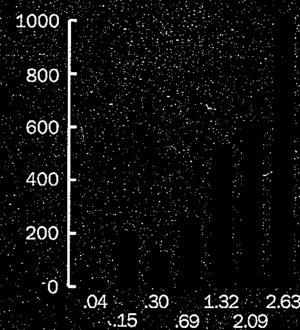
Low Ra



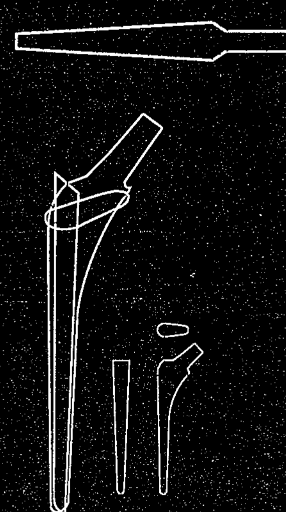
Polished Approach
Cement Protection

The key to clinical success in cemented hip arthroplasty is to avoid loosening of the stem within the cement mantle. Recent studies suggest that a frequent cause of loosening is degradation of the stem-cement interface.[1,2] Choosing a stem designed to address the dynamic effects within the cement mantle may be a critical factor toward achieving long term clinical results.

Studies suggest that stems that have become loose within the cement mantle will inevitably experience micromotion.[3] The abrasive effect of roughened stems moving against the cement can lead to excessive debris and further loosening.[3,4] The highly polished surfaces of the PERFECTA® Ra stem decrease the probability of mechanical failure by reducing stem-cement friction and localized stresses that can lead to cement abrasion and debris.[3,5,6]

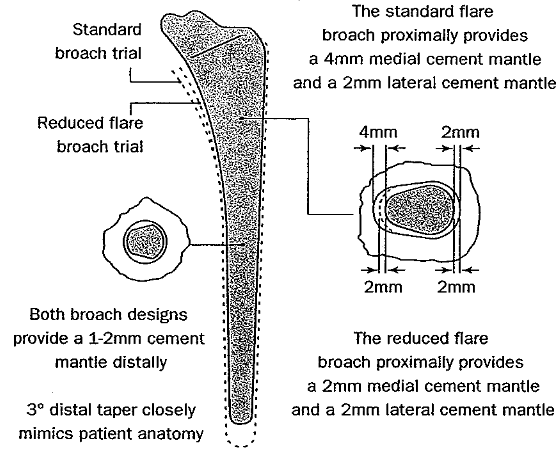


To reduce the incidence of loosening and promote cement mantle protection, the PERFECTA® Ra stems utilize the same Tri/Planar Wedge design incorporated throughout the PERFECTA® Hip System. In conjunction with the stem's collarless design, a wedge shape in the transverse, coronal, and sagittal planes ensures compressive radial loading, placing the cement in compression while minimizing shear and tensile forces at the stem-cement interface.[7] The result is a synergistic and cooperative stem-cement relationship.



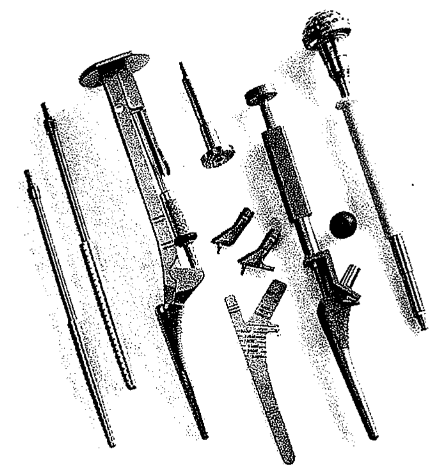
Cement Mantle Thickness, The Option is Yours

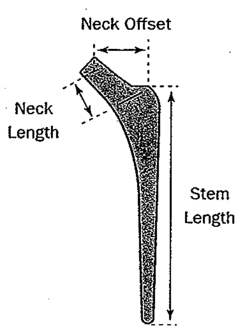
Studies have shown the optimum thickness of the medial cement mantle proximally is 2 to 5mm thick.[9] The PERFECTA® Ra provides two medial flare broaching options within this range while offering anthropometric implant sizing. Distal centralizers are available to ensure uniform cement mantle thickness distally.



Smart Technique Deserves Smart Instrumentation

To minimize cement stresses, a stem must offer more than a highly polished finish. Stem shape, cementing technique and effective instrumentation further contribute to a cemented implant's longevity. The PERFECTA® Ra stems utilize the straightforward, universal instruments of the PERFECTA® Hip System. These simplified instruments minimize inventory requirements and surgical staff training.





PERFECTA® Ra Hip Stem Dimensions (mm)

Size	Stem Length	Base Neck Length	Offset for 28mm SLT Taper Head -3.5	+0	+3.5	+7.0	+10.5
10.5	120	32	33	36	38	41	43
12.0	130	37	37	39	42	45	47
13.5	145	37	37	40	42	45	47
15.0	155	42	41	44	46	49	52
16.5	165	42	41	44	47	49	52
18.0	175	42	42	44	47	50	52

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TECHNICAL MONOGRAPH

DESIGN CHARACTERISTICS OF THE

PERFECTA® Ra POLISHED HIP STEM

Introduction

Cemented fixation in total hip arthroplasty continues to be the gold standard in the orthopaedic community. It is undisputed that a significant cause of clinical failure is implant loosening due to the degradation of the cement-stem interface.[1] Surface treatments designed to improve this interface have included enhanced macrotextures, roughened surface finishes, and precoating acrylic cement to the stem during the manufacturing process. However, the long-term clinical success with the original Charnley stem, a smooth-surfaced implant, has been impressive. Clinical review of implant databases such as the Swedish National Register has renewed interest in polished surface stems.

Highly polished implant surfaces were introduced with the original Charnley stem in the 1960s. By the 1970s, Sir John Charnley reported good results with what has become known as "low friction arthroplasty."[2] The success of the original polished Charnley prosthesis is well reported in the literature.[3,4,5,6,7] The original Charnley prosthesis, a stainless steel implant with a flat back, was implanted with finger-packed cement that served as a grout rather than as an adhesive.

In 1970, Robin Ling introduced the Exeter Hip Stem, a polished, tapered wedge prosthesis designed to subside within the cement mantle. Ling's philosophy was based on the plastic deformation of cement over time. The Exeter Stem design accepts creep within the cement mantle, allowing the stem to seek equilibrium within the cement rather than propagate cracks. While popular in Europe, this view did not garner wide attention in the US until nearly 25 years later.

By the mid 1970s, stems were frequently no longer polished and had a variety of surface finishes. Few surgeons other than Ling, Dall, Rockburn, and Olsson have stressed the importance of a polished stem.[8] The subtle transformation from polished surfaces to more roughened surfaces occurred without sufficient clinical or laboratory studies from either designers or manufacturers of prostheses.[8] Fowler, reporting Ling's results, first recognized that there was a difference in clinical performance between prostheses featuring smooth finishes and those with more roughened surfaces, observing a marked increase in loosening and lysis of the Exeter prosthesis after it inadvertently was changed from a polished to a roughened surface.[8]

The movement toward macrotexturing and rougher surface finishes was intended to improve upon the fixation of the implant at the cement-implant interface. Loudon and Charnley published results of the original Charnley polished flat-back design in 1980, reporting subsidence of over 1.6mm in 43% of the cases, with 26% showing transverse fractures of the distal cement.[9] These findings indicated that the polished and tapered stem had moved distally within the proximal cement and that the tip had "bottomed out" to end-load on the distal cement. Despite some downward movement, the prostheses seemed to assume new and stable positions and produce only minimal symptoms.[10]

At that time, the radiographic evidence of subsidence was perceived to be a problem, and a satin finish and dorsal "cobra flanges" were added to the third generation Charnley stem. This apparently minor change altered the behavior of the stem and also may have altered the long-term clinical results. In 1993, Dall reported 4- to 17- year results with later generations of the Charnley stem that did not compare favorably with those of the original Charnley stem and considered surface roughness as a possible cause.[5]

In the 1980s, the desire to achieve rigid mechanical interlock between the stem and the cement mantle encouraged the addition of polymethylmethacrylate precoating to the prosthesis, as cement bonds best to itself. Early aseptic loosening of the most widely used precoated design caused the paradigm to shift rapidly away from this concept.

At the same time, the long-term outcomes provided by the Swedish Hip Register permitted a retrospective clinical analysis of various implant designs. The original Charnley and Exeter polished stems have shown superb results[11], prompting a closer look at surface finish as a determinant of clinical outcomes.

Differences in Philosophy on Bone Cement - *Low Friction or Rigid Fixation?*

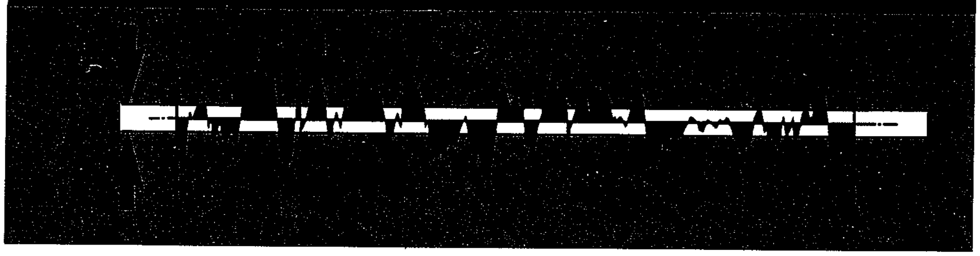
The popular view of cemented hip arthroplasty in the United States is to achieve immediate, rigid fixation through mechanical interlock at the cement-implant interface. This perspective acknowledges that the failure mechanism frequently is loosening at the implant-cement interface. This philosophy considers bone cement to act as a solid compound, forming a vise-like grip around the implant within the medullary canal. In order to achieve this rigidity, macrotexture is desirable, as the texturing enables cement interdigitation with the prosthesis. Compressive collars on the anterior and posterior aspects of the implant convert some of the shear forces to compressive forces, strengthening the mechanical bond between implant and cement. Consequently, many of the best-selling implants incorporate these design features.

However, this philosophy of rigid fixation contradicts the success demonstrated by the original Charnley and Exeter stems. A retrospective look at the clinical outcomes of polished cemented implants allows for in-depth analysis of the causes for this success. One idea central to the design philosophy of polished implants is that of "low friction arthroplasty". Just as Charnley intended to reduce the articulating friction between the femoral head and the socket, a smooth surfaced implant reduces friction between the cement and the implant. This design is effective with stem features that enhance this low friction concept: no macrotexture to grab the cement, no collar to hinder stem-cement equilibrium, and a tapered wedge shape to stabilize the stem within the bone-filling grout of cement. With polished implants, the focus shifts from the cement-implant interface to the cement-bone interface. The stem is intended to remain debonded from the cement mantle, with the highly polished surface minimizing cement debris generation that acts as third party wear leading to osteolysis. The **PERFECTA®** **Ra** is a collarless, polished, tapered implant designed to meet the goals of low friction arthroplasty.

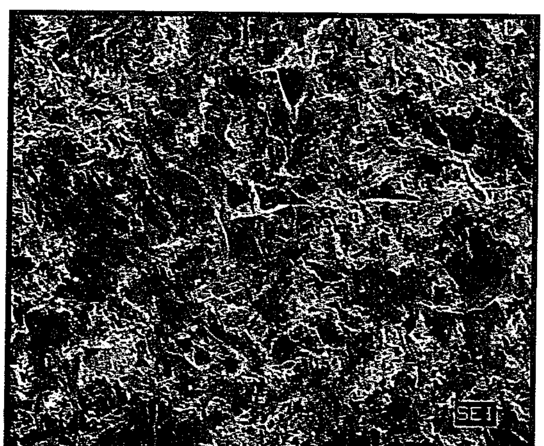
Differences in Surface Finish - *What is Ra?*

Average surface roughness (Ra) is the average distance from a surface's peaks and valleys to its mean line (or centerline). The lower the Ra, the smoother the surface. The higher the Ra, the greater the surface area for cement interdigitation. Appropriate surface finish is determined based on the desired cement-implant interface. Smoother implant surfaces have lower cement-implant interfacial fixation strength, whereas rougher surfaces have greater fixation strength.[12] At the same time, an inappropriate surface finish can lead to an ineffective interface, which may result in implant loosening. With interface motion, the smoother surfaces are less abrasive of bone cement, whereas rougher implant surfaces are more abrasive. Because of enhanced bone cement attachment, rougher implant surfaces may have a lower probability of interface motion, while at the same time, a higher debris generation consequence if motion occurs. In contrast, smoother implant surfaces may have a higher probability of interface motion with a lower debris generating consequence of that motion.[12]

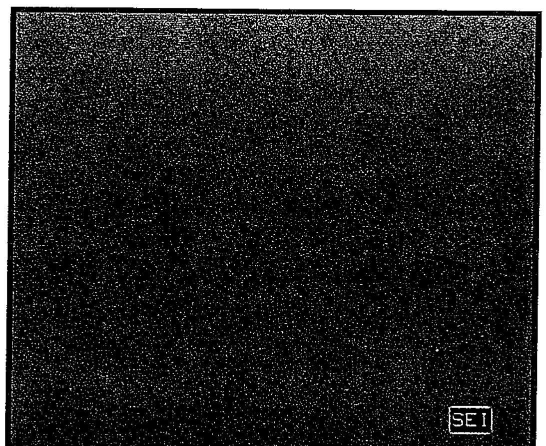
Graphical depiction of the derivation of Ra.



SEM photographs, at 125X magnification, of a grit-blasted surface and a polished surface.

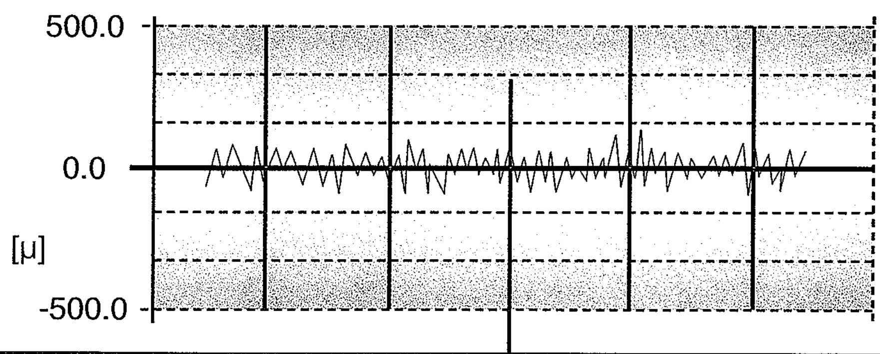


Grit-blasted surface (High Ra)

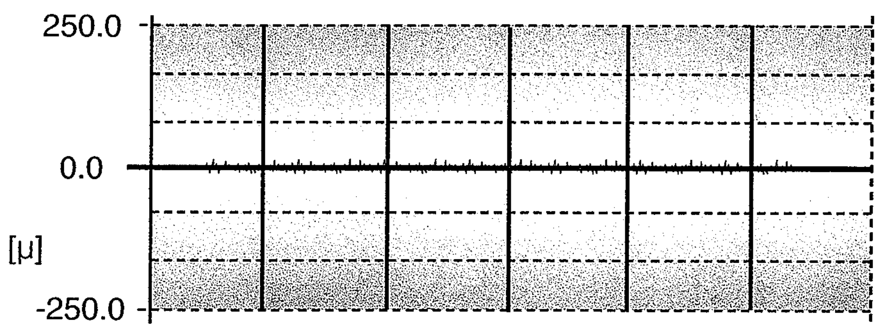


Polished surface (Low Ra)

Graphical depiction of high and low Ra, measured by a Hommel America surface roughness analyzer.



Surface profile of high Ra



Surface profile of low Ra

Differences in Philosophy - *Adhesion vs Abrasion?*

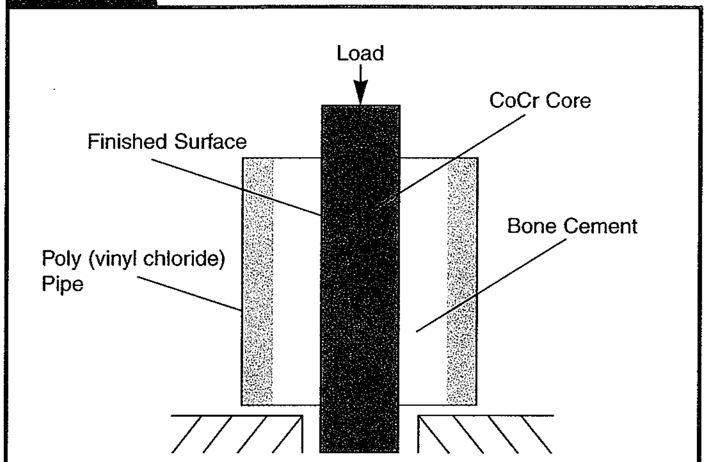
The prolonged use of cemented total hip replacement may be approached by either extending the duration of implant function after cement-implant interface loosening with smooth surfaced implants or, in contrast, by extending the duration of cement-implant interface adhesion with rougher surfaced implants. Adhesion and abrasion are the two contrasting mechanisms that may impact the longevity of an implant's success.[12]

Push Out Testing

The adhesion strength of the cement-implant bond was measured by Crowninshield, et al, using destructive push out tests of cylindrical shear specimens (Fig 1, Table 1)[12]. These types of push out specimens have been used widely in interfacial shear studies. Care was taken to hold geometry and loading conditions constant so that the effects of surface finish alone could be observed.

Push Out Testing (Cont.)

Figure 1



Push out test method used in cement to metal adhesion measurement

TABLE 1

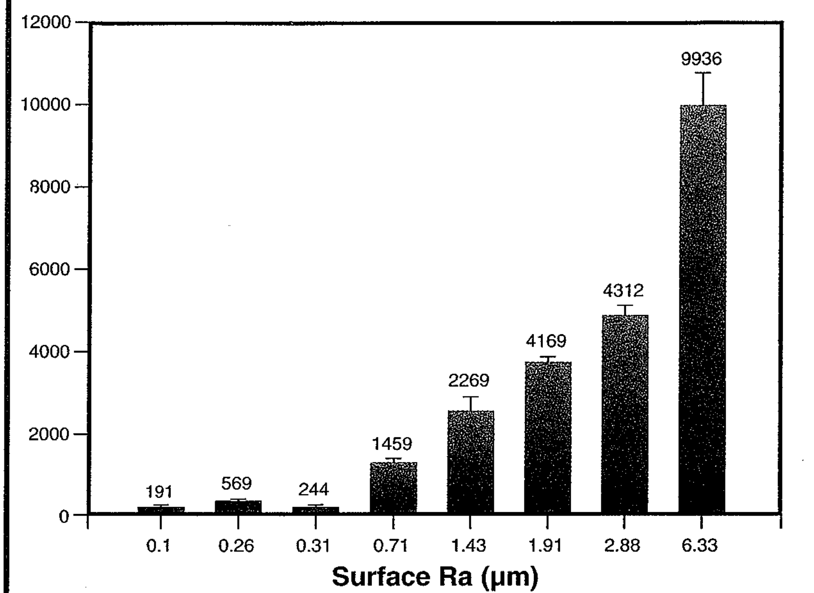
Surface Roughness Data for the Push Out Rods Used in Cement to Metal Adhesion Testing

Surface Finish	Ra *Average* *(μm)*	Ra *Standard Deviation* *(μm)*
Finish 1: mirrorlike polish	0.10	0.01
Finish 2: mass tumble	0.31	0.07
Finish 3: glass bead blast	0.26	0.02
Finish 4: 400-grit belt polish	0.71	0.06
Finish 5: 60-grit alumina + glass bead blast	1.43	0.31
Finish 6: 60-grit alumina blast	1.91	0.32
Finish 7: 24-grit alumina blast	2.88	0.28
Finish 8: 16-grit alumina blast	6.33	0.74

The force required to push eight groups of different surface finish metal pins out of cement preparations is shown in Figure 2[12]. As expected, the test results show increased cement adhesion strength with increased metal surface roughness. These data suggest that the adhesion strength of the cement-implant interface is dominated by the mechanical interlock of bone cement into the surface roughness. The **PERFECTA® Ra**, with a maximum surface roughness (Ra) of 0.16μm (4μinch), has low adhesion, in keeping with the low-friction philosophy of smooth stems.

Push Out Testing (Cont.)

Figure 2

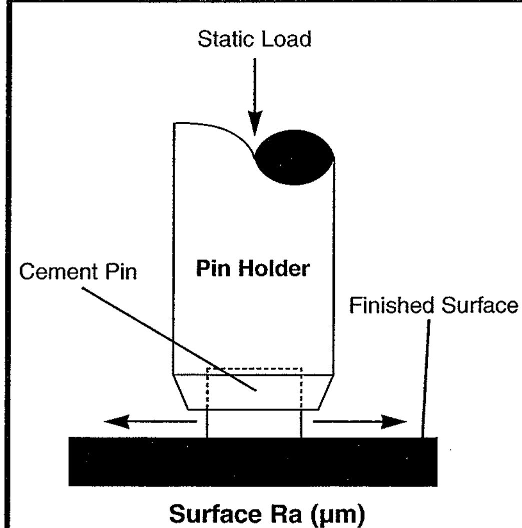


Average Push Out Force Measured For Various Metal Surface Roughnesses

Abrasion Testing

The rate of abrasion of bone cement against metals of varying surface finish was also measured by Crowninshield, et al, using pin on flat wear tests (Fig 3, Table 3)[12]. The cement pin was pressed against CoCrMo alloy disks of varying surface finish. The pin on flat test method represents a simplification of the cement abrasion that may occur in the scenario of a loose femoral component experiencing cyclic displacement with respect to the surrounding cement mantle. The load and displacement of the cement pin and flat metal surface was well controlled and the material loss through abrasion was measured by changes in cement pin height.

Figure 3



Pin On Flat Test Method Used In Cement To Metal Abrasion Measurement

Abrasion Testing (Cont.)

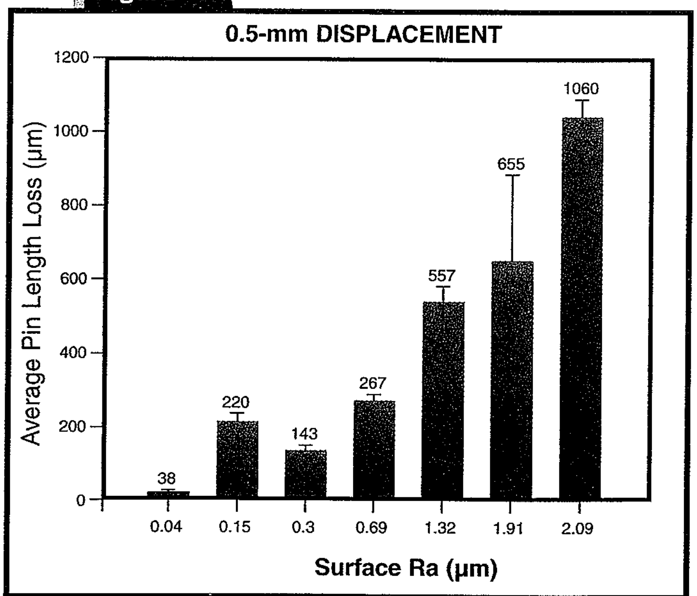
TABLE 3

Surface Roughness Data for the Pin on Flat Disks Used in Cement on Metal Abrasion Testing

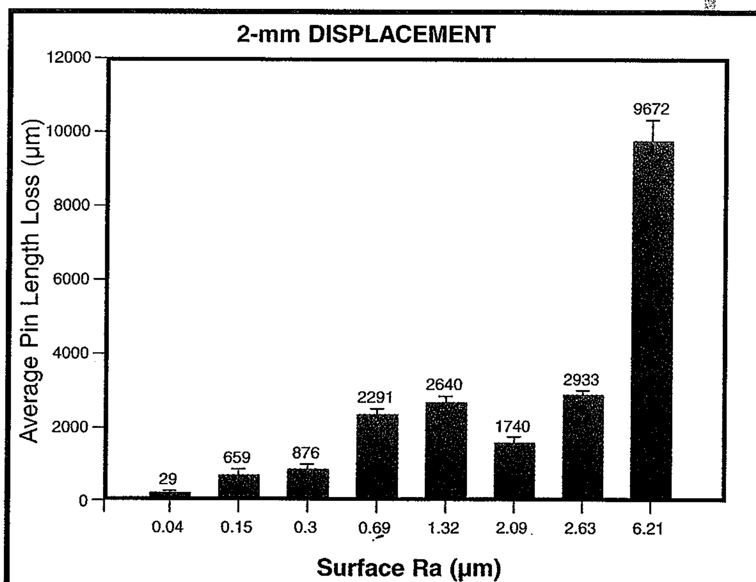
Surface Finish	Ra Average (μm)	Ra Standard Deviation (μm)
Finish 1: mirrorlike polish	0.04	0.00
Finish 2: mass tumble	0.15	0.00
Finish 3: glass bead blast	0.30	0.00
Finish 4: 400-grit belt polish	0.69	0.06
Finish 5: 60-grit alumina + glass bead blast	1.32	0.21
Finish 6: 60-grit alumina blast	2.09	0.10
Finish 7: 24-grit alumina blast	2.63	0.11
Finish 8: 16-grit alumina blast	6.21	0.85

The abrasion of bone cement loaded and cyclically displaced on eight different metal surface finishes is presented in Figures 4 and 5[12]. As expected, the test results show a direct relationship between increased cement abrasion rate and increased surface roughness. The smooth surface of the **PERFECTA® Ra** stem minimizes cement abrasion during its migration to its optimal fit.

Figure 4



Average Cement Abrasion After 250,000 Cycles for 0.5mm Cement-Metal Displacement For Various Surface Roughnesses



Average Cement Abrasion After 250,000 Cycles for 2mm Cement-Metal Displacement For Various Surface Roughnesses

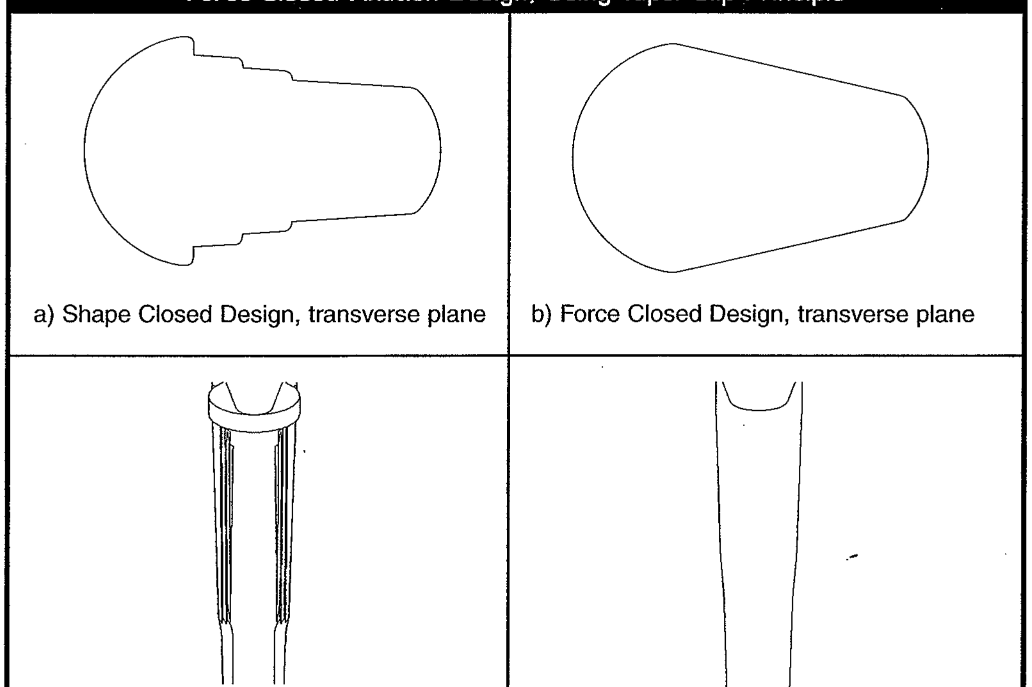
Stem Shape

The interdependence between stem shape, desired surface finish, and migration must be appreciated. A SHAPE CLOSED fixation design implies the objective of providing immediate stability by a match of shapes (Figure 6a, c, e). An example of this composite beam principle is a prosthesis with a wide collar, to be positioned on the calcar. Such a design is not supposed to subside postoperatively.[13] In this instance, it is beneficial to incorporate macrotextures such as intramedullary flanges or collars to increase the surface area of the stem while increasing compressive load of the bone cement. The strain in the stem and the cement is identical at the interface at all times and stress in the cement can only be relieved when the interface ruptures. The development of radiolucency is presumed to indicate that this interface is damaged and that the construct is then at risk of failure.[14]

A FORCE CLOSED fixation design, conversely, is meant to obtain its stability by the action of forces (Figure 6b, d, f). This taper-slip principle is familiar from the press fit cone fixation of a modular head on a Morse tapered femoral neck. A straight tapered, polished stem can be seen as a force closed fixation design.[13] This design should not incorporate any surface details such as flanges or collars that would impede with the taper-wedge fit of the polished implant within the cement mantle. The stem-cement composite is held together by the force pressing the stem downward into the cement. The greater the load, the tighter is the fit of the taper. As the taper interacts with the cement mantle, radial compressive forces are created in the adjacent cement and transferred to bone as hoop stress.[14]

Figure 6

Shape Closed Fixation Design, Using Composite Beam Principle and Force Closed Fixation Design, Using Taper-Slip Principle



a) Shape Closed Design, transverse plane

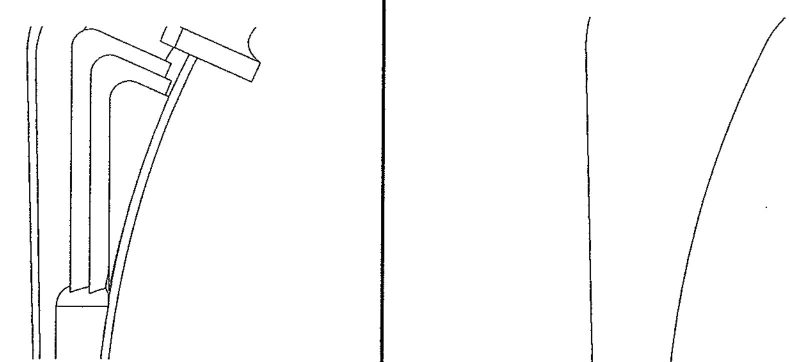
b) Force Closed Design, transverse plane

c) Shape Closed Design, sagittal plane

d) Force Closed Design, sagittal plane

Stem Shape (Cont.)

Figure 6 (Cont.)



e) Shape Closed Design, coronal plane

f) Force Closed Design, coronal plane

Different philosophies require different stem design parameters. A shape closed design preferably should be rough or textured, because this enhances the bonding strength, and the stem is intended to remain in place. A force closed design should be polished, because this facilitates the implant's ability to seek its optimal taper fit within the cement mantle while minimizing cement debris.

The importance of separating the two philosophies is highlighted in Shen's review of Charnley and Exeter implants.[14] The excellent long-term results for the first-generation flat-back Charnley stems and the polished Exeter stems can be attributed to the taper-slip principle. The survival rates for dorsal "Cobra flanged" Charnley stems were lower, despite the use of modern cementing techniques, due to the change in stem function from taper-slip to composite beam. The introduction of the cobra flange prevented subsidence that leads to hoop stress generation, while the surface treatment of a matte finish was not strong enough to adequately engage mechanical interlock. It seems that a combination of the two design philosophies is likely to cause problems.

In a composite beam there must be secure bonding between metal and cement especially in relation to rotational forces. In a taper-slip system, employing a matte or satin finish can cause generation of excessive metallic and cement debris due to the subsidence that is critical to implant success. A distinction should be made between the requirements for the successful use of the two different engineering systems.[14]

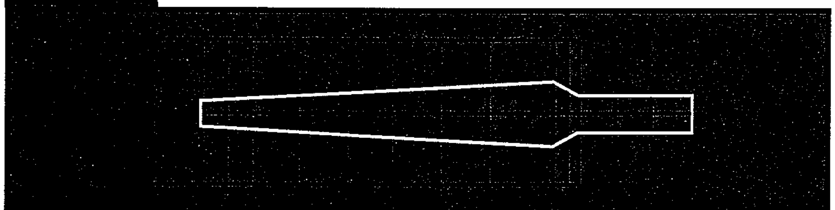
The radiographic interpretation of interfaces is also critical based on the engineering system used. A taper-slip system may appear to be on the verge of failure when assessed by the standards for a composite beam, but once it has subsided it can establish a new stable position. The criteria for radiographic failure of a composite beam cannot be applied to a loaded taper-slip system.[14]

A taper-slip system helps to maintain proximal bone through hoop stress developed during subsidence, and can maintain stability after subsidence. The system seems to be more forgiving, with less rigid requirements for a satisfactory cement mantle.

Stem Shape (Cont.)

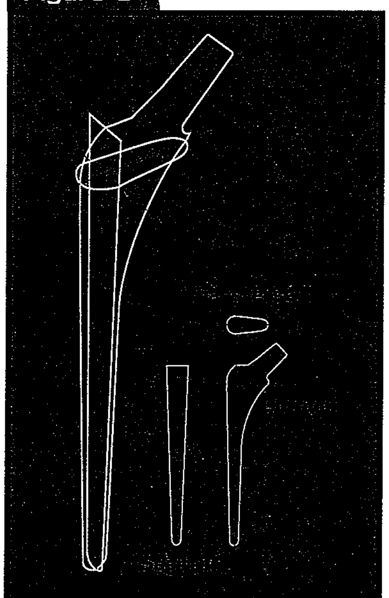
The optimal stem shape to minimize stress concentration in the cement layer was sought by Yoon, et al.[15] A gradient projection method of numerical optimization and a finite element method of stress analysis were employed. The optimal stem shape was found to be narrow in its distal end, close to the lower limit of 2mm. The width of the stem grew gradually wider toward the proximal region. At the most proximal section of the stem, the stem was tapered to reduce stresses in the cement mantle while maintaining the strength of the implant (Figure 8).[15]

Figure 8



The Optimal Shape of the Stem Profile

Figure 9



PERFECTA® Tri/Planar Wedge Shape

The **PERFECTA® Ra** is a tapered, wedge shape that activates the taper-slip principle during stem migration (Figure 9). The proximal taper design encourages radial compression through hoop stress, while the distal 3° taper minimizes cement strain distally. The proximal Tri/Planar wedge shape provides optimal fit and fill in the transverse, coronal, and sagittal planes.

SUMMARY

The **PERFECTA® Ra** Polished Stem provides a low friction alternative for cemented hip arthroplasty. The Tri/Planar wedge geometry of the stem offers a shape that is ideally suited for taper-slip stability. Design features that include the absence of a collar or macrotexture enable the stem to seat to its optimal fit. As the stem moves distally, the stability of the cement-stem interface increases. The low Ra, demonstrated by the smooth surface of the implant, facilitates the generation of hoop stresses that enhance cement compression without the creation of cement debris. The **PERFECTA® Ra** maintains the design features that made the original Charnley implant successful while incorporating aspects of contemporary cementing technique.

The **PERFECTA® Ra** is cleared by the FDA for use in the United States.

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