PROFEMUR® Total Hip Modular Neck System

TECHNICAL MONOGRAPH

WRIGHT.

PROFEMUR®

total hip SYSTEM

MODULAR NECK

technical monograph

PROFEMUR®
modular neck

introduction

FIGURE 1| Head Centers Provided by Various PROFEMUR® Neck Configurations

The PROFEMUR® Hip Stems feature patented modular neck technology, which allows the surgeon to optimally restore normal hip biomechanics for each patient. Since 1985, surgeons have been utilizing the PROFEMUR® Modular Necks for:

- Minor variations in cup position or stem anteversion
- Impingement issues
- Anatomic variation in version neck orientation
- Avoiding the use of elevated liners & custom implants
- Independently adjust limb length and offset
- Additional neck length options for ceramic bearings

Additionally, surgeons who advocate small incisions have enjoyed the streamlined design of the PROFEMUR® Hip Stems. During implantation with a fixed neck hip stem, surgeons were having difficulty implanting the stem in the ideal orientation due to impingement of the fixed neck on the soft tissues during stem insertion. Since the PROFEMUR® Hip Stems have a modular neck, surgeons can easily achieve the optimal stem orientation during insertion with small incision.

Surgeons have chosen the PROFEMUR® Hip Stems for over 50,000 patients due to the modular necks and the surgeon ability to obtain a stable hip for each and every patient.

DESIGN HISTORY

The first PROFEMUR® modular neck prototypes were produced in 1985 by Wright Cremascoli Ortho (Milan, Italy). Following extensive finite element analysis and mechanical testing at the renowned Rizzoli Institute, various neck configurations (featuring an oval Morse taper) were finalized and commercialized (US patent 4,957,510) | **FIGURE 1**.

FIGURE 2 | PROFEMUR® R Hip System

CLINICAL HISTORY

Modular necks have been employed by Wright Cremascoli Ortho since 1985. Over 50,000 have been successfully implanted in both primary and revision hip procedures.

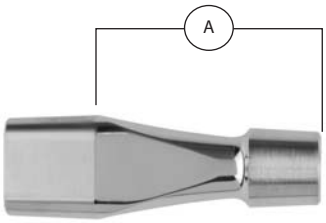
Kohler, Kostler, Willert[1] in 1997 shared their clinical experience with hip revision cases using multiple hip stems which included the PROFEMUR® Hip Implants. They revised 67 patients with 69 PROFEMUR® Hip Implants with a follow up period of 6 - 54 months | **FIGURE 2.** Of the stems revised to PROFEMUR® Hips, 31 were cemented and 38 were noncemented. Through use of the PROFEMUR® Hip for revision, the mean Harris Hip Scores improved from 44.6 to 75 points and radiographic examination showed good bone integration and formation. *No complications were reported due to the use of the modular necks.*

Masse *et al* [2] in 1996 related 2.5 year clinical results with 134 cases, using the PROFEMUR® Hip for revision. In these cases, the mean Harris hip scores improved an average of 34 points. *No complications related to the use of modular necks were reported.*

Toni *et al* [3] in 2001 published 3 to 5 year clinical results of 216 cementless hip arthroplasties using PROFEMUR® Modular Necks and ceramic bearings in 208 patients between 1995 and 1997 with Anca-Fit™ Stem. From radiographic analysis, 99.4% of the prostheses showed osseointegration. There was no evidence of periprosthetic osteolysis other than one patient who required a stem and cup revision after 2 years. *No failures were related to the neck modularity.*

Also in 2001, Toni *et al* [4] reported clinical experience with 347 modular neck cementless hip stem implantations between January 1996 and December 1998. Follow up of 12 to 45 months was obtained for 316 of the patients. There were four cases of dislocation (1.2%), two healed without surgical intervention. One was caused by undersizing of the stem. The fourth case was corrected surgically by replacing the long straight modular neck with a 15-degree retroverted long neck.

In summary, the clinical effectiveness and dependability of the modular necks has been consistently demonstrated throughout the PROFEMUR® Hip clinical history. *Utilized in both primary and revision applications, the current neck design has been successfully employed to improve surgical outcomes with no reported failures.*



FEMORAL NECKS

TYPE	A
Straight (Neutral)	
Short	28
Long	38.5
Varus/Valgus 8 Degree	
Short	27
Long	38
Ante/Retro 8 Degree	
Short	28
Long	38.5
Ante/Retro 15 Degree	
Short	28
Long	38.5
4 Degree Ante/Retro - 6 Degree Varus/Valgus 1	
Short	28
Long	38.5
4 Degree Ante/Retro - 6 Degree Varus/Valgus 2	
Short	28
Long	38.5

FIGURE 3 |PROFEMUR® Neck Geometries

FIGURE 4 |Reduced Profile of PROFEMUR® Necks Compared to Standard Fixed Necks

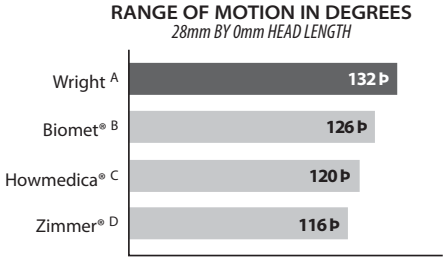
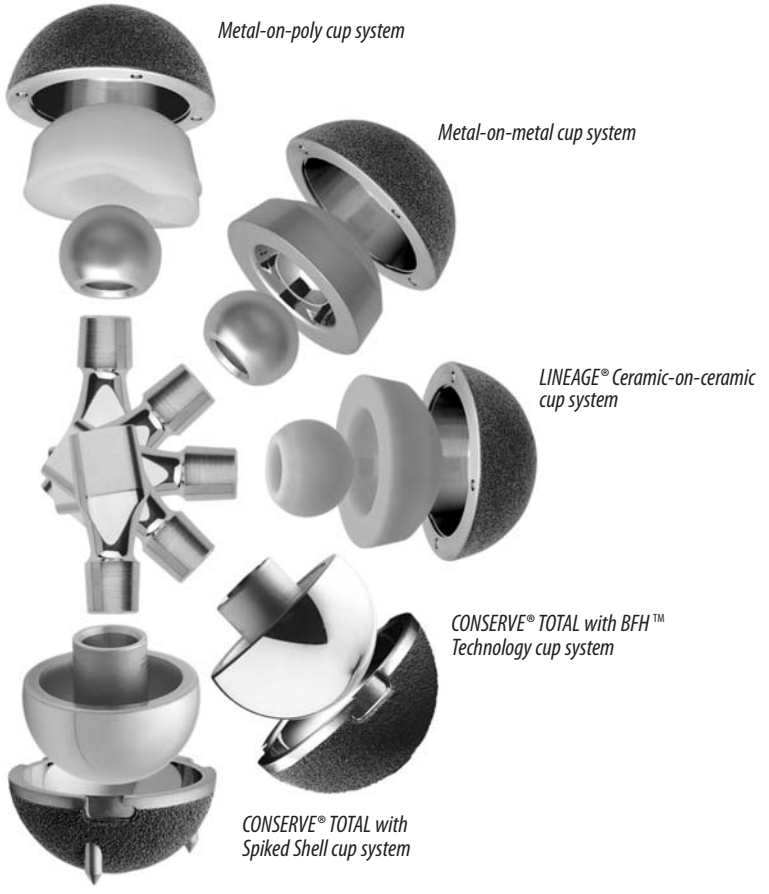


FIGURE 5 | Range of Motion in Degrees

Ref. A Data on file at Wright Medical Technology, Inc.
Ref. B www.biomet.com, 2001
Ref. C www.ceramic-hip.com, 2001
Ref. D VerSys™ Design Rationale. 1996 Zimmer, Inc. publication

MODULAR NECK DESIGN FEATURES

As indicated in the results of Toni *et al* [4], one of the greatest benefits of the PROFEMUR® Modular Necks is that they allow surgeons to correct leg length and offset intraoperatively. The surgeon may choose between six interchangeable neck geometries; available in two lengths. **| FIGURE 3** The varied configurations give surgeons the ability to address impingement and dislocation issues intraoperatively; thus allowing greater ability to balance the hip and restore normal motion. Furthermore, the necks were designed with a reduced profile between the tapers to optimize range of motion **| FIGURES 4 & 5**. Further adjustments may be made by varying femoral head neck length (available in -3.5, 0, +3.5, +7, and +10.5 mm). The neck and head are connected via a standard 12/14 Morse taper. In addition, the necks are composed of a titanium alloy (Ti6Al4V) which is proven to afford suitable mechanical properties, ideal biocompatibility, and excellent resistance to corrosion.



The benefits of these necks are further complemented by Wright's alternative hard bearings options illustrated above. These advanced materials are less forgiving to impingement and require optimal head position for ideal longevity, a fundamental feature of the modular neck.

TESTING

Modular neck clinical experience and extensive laboratory tests have proven the coupling between the modular neck and femoral implant provides:

- Structural reliability
- Absence of significant micromovement
- Absence of fretting corrosion

These excellent characteristics are obtained due to the patented geometry of the coupling. The neck taper and the femoral implant neck housing feature have an oblong, conical profile which provides excellent stability under stress and prevents significant movement. The surface of the modular neck taper is finely machined to create spiral grooving. When the neck is inserted into the neck housing the crests of these grooves deform; ensuring intimate contact and reduction of micromotion. The necks are made from titanium alloy (Ti6Al4V) which is proven to afford suitable mechanical properties, ideal biocompatibility, and excellent resistance to corrosion.

PROFEMUR® R Revision System - Neck/Body Taper Assembly and Distraction[5]

Six neck/proximal body couplings were tested using the PROFEMUR® R revision hip in 2000 | **FIGURE 6**. Assembly for four of the couplings occurred by three firm surgical mallet blows of the components on a wooden table-top. Assembly of the two remaining couplings occurred in a fresh cadaver femur. The average assembly force was 11668 N for the table assembly and 10568 N for the femoral assembly. The average distraction force was 3970 N for the table-assembled couplings and 3328 N for the couples assembled in the femur (both are nearly 3 times of a 250 lb. body weight, or 1112 N) | **FIGURE 7**. This test was a static test since the implants were assembled then immediately distracted. *It can be assumed that the distraction values would be higher once the implant is subjected to axial, cyclic loading, i.e. walking.*

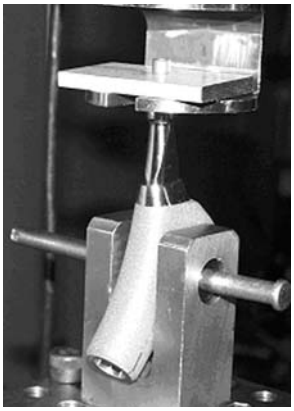


FIGURE 6 | Distraction Testing

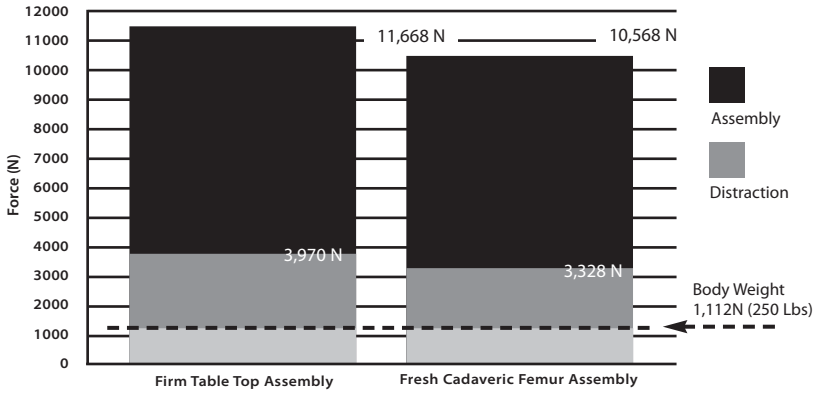
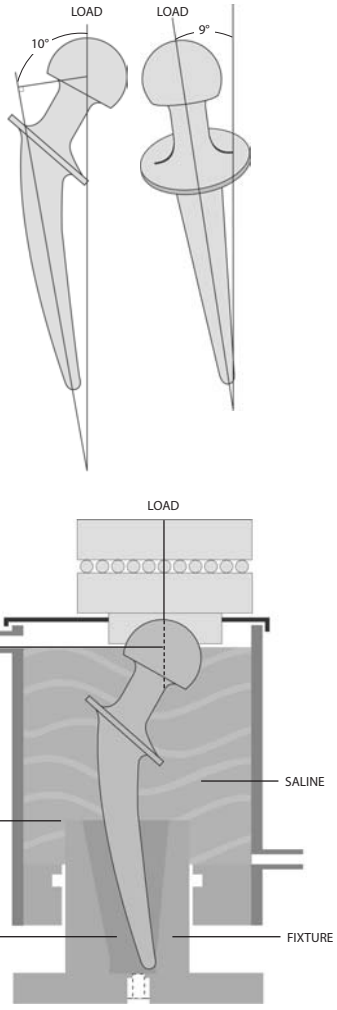


FIGURE 7 | Neck/Body Taper Assembly and Distraction Loads



FIGURES 8 & 9 | ISO Specification 7206/4

FIGURE 10 |Typical 10/9 Fatigue Testing Set-up with Environmental Chamber.

10/9 Fatigue Testing PROFEMUR® R, PROFEMUR® Z, and PROFEMUR® E Hips With and Without Plasma Spray Coating[6,7,8,9,10]

Fatigue testing was performed at the WMT testing facility per ISO 7206/4 and 7206/8, on "worst-case" component combinations for each system **| FIGURES 8 & 9**. Using the ISO guidelines, the assembled components were fixtured in an acrylic potting media oriented at 10 degrees adduction and 9 degrees of flexion within an environmental chamber containing saline solution **| FIGURE 10.** This orientation represents the heel-strike phase of the gait cycle. In testing of each PROFEMUR® Hip System, all six samples passed the testing requirements with no failures after 5 million cycles at a maximum load of 2300 N. *After completion of the fatigue testing, the assembled components were checked and no visible signs of taper fretting were found around any of the modular connections or within the environmental chamber.*

PROFEMUR® E **PROFEMUR® Z**

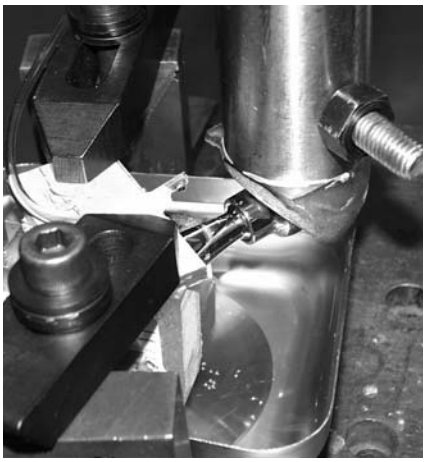


FIGURE 11 |Deep Flexion Testing Set-up with Saline Drip Over Neck Taper.

Deep Flexion Fatigue Testing[11, 12]

This test was performed on two occasions, once with the PROFEMUR® R Hip System and once with the PROFEMUR® Z Hip System. Twelve samples were tested to examine the structural integrity of the modular neck taper in the "worst case" orientation of a person rising from deep flexion, i.e. rising from a chair. The long varus/valgus neck and 10.5 mm long 28mm femoral head implant combination allowed the largest bending moment, as well as torsion, and represented the "worst-case" scenario for implant selection. The assembled implants were fixtured within the testing frame such that the orientation mimicked that of a sitting person's proximal femur. A maximum load of 2300 N was applied at a ninety degree angle (with respect to the floor) at 2 Hz for one million cycles | **FIGURE 11**. One million cycles is equivalent to rising from a chair fifty times a day for over fifty-four years. *None of the twelve specimens failed, and the neck remained fixed within the proximal body taper housing.*

Fretting Analysis of the Neck Taper – Weight Loss[14]

A cyclic loading test was performed on two types of hip implants. One set of implants tested featured the same modular necks as the PROFEMUR® Hip System. The other implants tested were prototypes which featured a smaller neck taper. The tests were conducted in three different environments: FeCl3, buffered Ringer's solution, and air. Load was applied at 2 Hz ranging from 200 to 2100 N (3x 160 lbs. body weight) for one million cycles; which approximates a yearly loading cycle. Both taper sizes were found to be corrosion resistant, however there were signs of mechanical wear which differed widely between the two sizes. The prototype necks in the acidic FeCl3 lost an amount of material in the range of 100 to 200 mg. The necks identical to those of the PROFEMUR® Hip System showed a material loss in the range of 0 – 1mg. *This test demonstrated sound taper design is essential in minimizing both corrosion and mechanical wear.*

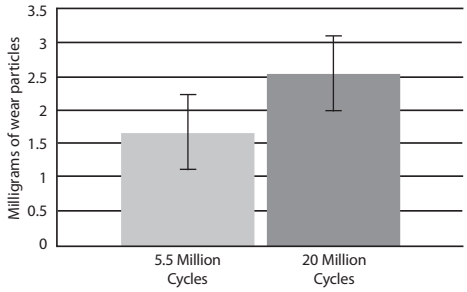


FIGURE 13 |Fatigue Generated Titanium Production By Weight PROFEMUR® Modular Neck Loaded to 3300N

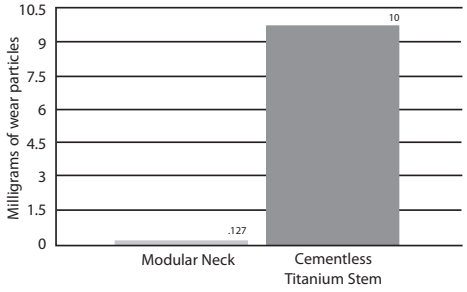


FIGURE 14 |One Year Weight Loss (1 Million Cycles)

Fretting Analysis of the Neck Taper – Weight Loss[15]

This study involved an accelerated cyclic loading test (10 Hz) in Ringer's solution with increasing loading regimes, which compared various implant body sizes to the weight loss of their modular necks. The implant tested had the same modular neck taper housing as the PROFEMUR® Hip System. Testing was performed for 5.5 million cycles to approximate the first 5 years post-implantation. The testing on the larger stems was continued to 20 million cycles **| FIGURE 13.** Fretting wear was characterized by the post-test weight lost by the neck after separation from the neck taper housing and removal of the femoral head. The weight loss due the head and neck taper could not be separated from the weight loss of the neck and body taper. The weight loss measurement was therefore entirely attributed to the neck and body taper. The larger stems exhibited the greater neck weight loss. It was noted that some weight loss came from separating the neck/body taper, and the material lost probably would never have spread out of the taper area. Estimated weight loss in the worst case modular neck junction (largest stem) was 0.6 mg/year for the first 5 years and 0.1 mg/year for the next 15 years.

A normal and stable cementless hip implant is likely to produce less than 10 mg/year of metal debris.[15] *The amount of weight loss from the modular neck should therefore not have any significant effect; such as causing osteolysis.*

NOTE | Dividing the 2.54mg total weight loss by 20 yields the amount of weight loss per 1 million cycles **| FIGURE 14** . Considering 1 million cycles to be equivalent to the number of cycles in 1 year allows direct comparison of weight loss per year to the 10mg weight loss from a cementless titanium stem rubbing against bone cited in this reference.

19kN (4300 lbs.) - PROFEMUR® System

20kN (4500 lbs.) - AML®

FIGURE 15 |PROFEMUR® Modular Neck and AML® Neck Yield Strength Test

Modular Neck Yield Strength Compared to DePuy AML®[16]

This evaluation was performed to show the strength of the PROFEMUR® Hip System modular neck compared to the "gold standard" of primary cementless THA. The assembled PROFEMUR® Hip System components (10.5 mm long head, long straight neck, and small proximal body) were chosen to match the neck length and offset of the 12mm DePuy AML® femoral implant with a 10.5mm long 28mm femoral head. The PROFEMUR® Hip and AML® specimens were fixed in acrylic and mounted within the testing frame at the 10 degree adduction / 0 degree flexion orientation specified in ISO 7206-6. The loading member of the test frame moved down onto the head of each specimen at a rate of 25 mm/minute. The peak load recorded signified the yield of the neck. *The load values shown to the left indicate the PROFEMUR® Hip System modular neck has comparable strength to the AML® femoral implant neck* | **FIGURE 15.**

As evidenced in this technical monograph, laboratory testing and clinical history has consistently demonstrated the strength and durability of the PROFEMUR® Modular Necks. It is hoped that familiarity with this work may instill confidence in the longevity and effectiveness of these innovative implants. Also, the benefits of modular necks are reaffirmed with every surgical use. The multiple neck options ensure outstanding clinical results by empowering surgeons with the ability to ideally fine-tune length and femoral head position for every patient.

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