

Clinical Results of a Modular Neck Hip System: Hitting the “Bull’s-Eye” More Accurately

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Abstract

In this article, we present 2-year clinical results of a modular neck tapered hip stem, based on 634 patients from a 2-center study. Nearly half of the patients in this series required use of a head center location offered by the modular neck stem but not available in a nonmodular stem with an identical body. The modular neck enabled femoral-first preparation, which facilitates establishing the desired total version of the reconstruction. No fractures of a stem or modular neck occurred, and there were no dissociations of the head-neck junction. There were no complications or revisions related to the femoral implant.

Optimal leg length, femoral offset, and total version are goals in total hip arthroplasty. Neck modularity improves the ability to re-create the head center to achieve these goals and to hit the “bull’s-eye” in total hip arthroplasty.

In this article, we report preliminary clinical results of a modular neck hip stem (Figure 1) used in primary total hip arthroplasty (THA). The modular neck total hip stem offers more options in improving head center. Joint stability and range of motion (ROM) are critical for long-term success in THA. Multiple studies have shown the importance of component position on the acetabular and femoral sides. Accurate component position is critical in avoiding impingement, which leads to dislocation and early liner wear. Re-creating the hip center or “bull’s-eye” requires re-creating correct offset, version, and leg length (Figure 2). Neck modularity allows preoperative planning

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and intraoperative adjustment for offset, version, and leg length, independently of one another—a significant advantage in re-creating the head center. Most nonmodular stems have only 10 options; the modular neck stem has 60 options. Although there is not as much clinical experience with modular neck implants as with traditional implants, clinicians have advocated the benefits of modular neck implants: their ability to restore normal hip biomechanics and optimize joint stability.¹⁻⁵

RATIONALE AND BIOMECHANICAL TESTING: STEM DESIGN

The Zimmer® M/L Taper Hip Prosthesis with Kinectiv® Technology (Zimmer, Warsaw, Ind) was chosen because it is a broach-only stem that facilitates small-incision surgery and incorporates the design philosophy of a system with successful 20-year follow-up.⁶ The stem and neck are manufactured from titanium alloy (Ti6Al4V). Thirteen



Figure 1. Modular stem with independent offset, version, and leg length using Kinectiv® (Zimmer, Warsaw, Ind) modular neck.



Figure 2. Hitting the bull’s-eye refers to accurate re-creation of normal hip center of rotation, including 3-dimensional plane of version, offset, and leg length.

Table I. Clinical Material

Age, mean years (range)	63 (21-97)
Body mass index, mean (range)	28 (16-52)
Sex, male/female	51% / 49%
Hip side, left/right	45% / 55%
Acetabular configuration, metal-on-polyethylene/metal-on-metal	57% / 43%
Stem configuration, standard/outlier	56% / 44%
Preoperative diagnosis	
Osteoarthritis	93%
Developmental hip dysplasia	3%
Avascular necrosis	3%
Inflammatory arthritis	1%

Table II. Complications

	Patients, n (revisions)	Events, n	Patients, %
General complications			
Death	5	5	0.8
Anemia	1	1	0.2
Congestive heart failure	1	1	0.2
Pulmonary embolism	1	1	0.2
Other	4	6	0.6
Hip-related complications			
Acetabular implant failure	15 (14)	15	2.4
Dislocation	4 (2)	6	0.6
Deep vein thrombosis	8	8	1.3
Fracture	4 (1)	4	0.6
Deep infection	2 (2)	2	0.3
Wound drainage	2 (1)	2	0.3
Other	2	2	0.3

stem sizes and 32 neck implants can accommodate a range of leg-length, femoral offset, and femoral version adjustments. The stem's modular female taper accepts the 32 different neck implants and therefore allows 60 different head center locations. As each neck is designed to mate only with a +0-mm (zero) femoral head, it can be designed for optimal ROM and strength. When another junction is introduced, strength and fretting/corrosion must be addressed. Research has shown strength performance and fretting/corrosion to be multifactorial in modular implants.^{7,8} Investigators who tested fatigue, fretting/corrosion, and junction stability on this neck junction design considered load, orientation, temperature, pressure, and acidity (pH) of the environment.⁹ As with all femoral implants, fatigue strength performance is influenced by amount of offset, amount of version, and, in the case of modular neck implants, taper design geometry. This design offers enough flexibility in these parameters to address a range of patient morphologies while meeting strength requirements that surpass ASTM (American Society for Testing and Materials) and ISO (International Organization for Standardization) standards.

MATERIALS AND METHODS

We have preliminary results of using the modular neck THA Kinectiv hip stem in 634 patients. These patients underwent a minimally invasive primary THA through a posterior approach (described in multiple studies¹⁰⁻¹⁴) between April 1, 2007, and November 1, 2008, at Providence St. Vincent Medical Center in Portland, Oregon

(n = 331) or Hackensack University Medical Center in Hackensack, New Jersey (n = 303). Both centers obtained institutional review board approval for this study.

CLINICAL MATERIAL

Mean patient age was 63 years (Table I). There was a near equal distribution of women (49%) and men (51%). Preoperative diagnoses were osteoarthritis (93%), inflammatory arthritis (1%), avascular necrosis (3%) and developmental hip dysplasia (3%). Mean body mass index was 28 (range, 16-52).

Outliers

The Kinectiv neck stem provides 60 different head center options allowing for independent offset, length, and ver-

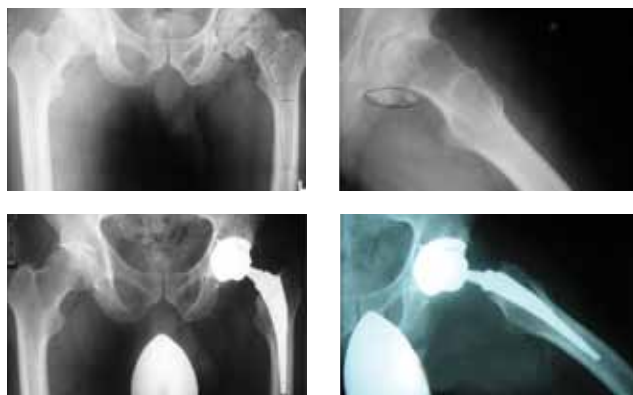


Figure 3. Case example: varus extra-extended dysplastic hip before surgery (top) and after surgery (bottom).

Table III. Quality-of-Life Measures, Preoperative and for Postoperative Matched Samples

Measure	N	Preoperative		Postoperative Samples			
		Mean	SD	1 Year		2 Years	
				Mean	SD	Mean	SD
Harris Hip Score	616	50	14				
SF-12 Physical Health	616	32	8				
SF-12 Mental Health	615	54	11				
Harris Hip Score	431	50	14	91	11		
SF-12 Physical Health	433	33	8	49	10		
SF-12 Mental Health	435	54	10	55	7		
Harris Hip Score	162	51	14	92	10	91	12
SF-12 Physical Health	160	33	8	50	9	50	10
SF-12 Mental Health	163	54	10	56	7	55	8

sion. Patients were presented as traditional hip patients or as outliers. Outliers were patients who required an anteverted or retroverted neck or an offset neck resulting in a head center not offered by a nonmodular stem with identical body. Figure 3 presents an example of an outlier in whom a typical stem would most likely result in leg-length discrepancy or inappropriate offset.

Statistical Methods

Continuous variables are presented as means (ranges), and categorical variables as percentages. Quality-of-life measures are summarized as means and standard deviations. Follow-up was calculated as time between surgery and most recent follow-up. Date of most recent follow-up was latest date of patient contact or examination or death date. Statistical analysis was performed with PASW Statistics 17 (SPSS, Chicago, Ill) and R 2.9 (<http://www.R-project.org>).

CLINICAL RESULTS

Patients (n = 634) were observed for a total of 752 patient-years (mean, 1.2 years; maximum, 2.6 years); 457 patients (72%) were examined at 1 year, and 211 patients (33%) at 2 years. Six patients (1%) were reported as being lost to follow-up, and 7 patients (1%) withdrew from the study.

In this patient population, the distribution of outliers versus standard head center options by sex (Figure 4)

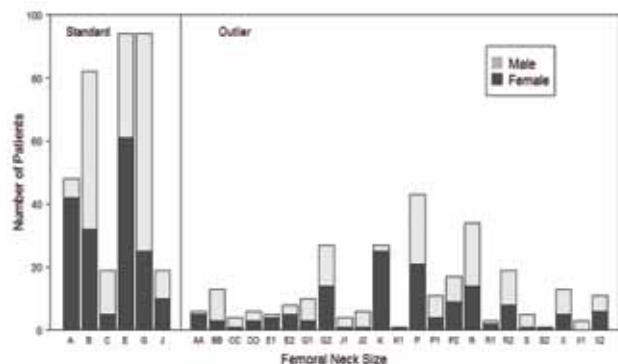


Figure 4. Distribution of neck sizes by sex.

shows significant variability in head center location with 29 of the 32 neck implants utilized. Aggregate distribution by investigator of standard and outlier head center location with differentiation of version and valgus/varus head centers is shown in Figure 5. The Portland neck distribution demonstrated 58% of the head centers in the outlier group—versus the 28% Hackensack distribution. A series of more than 25,000 consecutive cases based on implant manufacturer (Zimmer) sales data demonstrated a mix that falls in between these 2 cohorts: 52% outlier neck use (Figure 5).¹⁵ The Portland series also had 100% use of metal-on-polyethylene cups, compared with 11% in the Hackensack series.

Complications were listed as either general or hip related (Table II). There were 5 deaths, all unrelated to THA. There were no complications related to the femoral implant, no fractures of a stem or modular neck, and no dissociations of the head-neck junction.

Twenty devices were revised because of hip-related complications, including 14 acetabular implant failures, all metal-on-metal cups. Six dislocations occurred in 4 patients; 2 of the patients were treated by revising the cup to a position of less anteversion. There were 4 periprosthetic fractures: 1 femoral shaft fracture, which required revision secondary to a postoperative fall, and 3 intraoperative calcar fractures treated at time of surgery with cerclage wiring but no other postoperative



Figure 5. Distribution of outliers versus standard, by coinvestigators (left) and Zimmer sales data (right).



Figure 6. Insertion of modular femoral stem.

precautions. There were 2 deep infections. One occurred less than 6 weeks after surgery and was treated with exchange arthroplasty, and the other occurred more than 6 weeks after surgery and was treated with implant removal, with a temporary antibiotic spacer prosthesis implanted and a delayed exchange arthroplasty performed several months later. There were 2 wound drainage cases: a hematoma and a seroma. The hematoma was treated with irrigation and débridement and successful salvage of the implants. The seroma persisted and was treated with irrigation and débridement and then exchange arthroplasty. There was 1 case of a cellulitis, successfully treated with intravenous antibiotics.

Harris Hip Scores and Short Form 12 (SF-12) Physical Health scores increased dramatically from before surgery to 1 year after surgery and remained high 2 years after surgery (Table III).

DISCUSSION

In this article, we present the early clinical results of a modular neck total hip stem. In nearly half the cases, the head center used would not be available in a nonmodular system. This series is comparable to other THA series with respect to improvement in hip scores and complication rates. Results have been reported for several series of THAs using the posterior approach.^{10-14,16} There were no complications related to failure of the modular neck hip stem.

Mahfouz and colleagues¹⁷ have reported sex differences, including differences in offset, version, and head center height. Dorr and colleagues¹⁸ have reported on the importance of the total version, which is the combined femoral plus acetabular anteversion, and indicated that femoral anteversion is typically underestimated by the clinician. Multiple studies have demonstrated the importance of establishing accurate leg length for patient satisfaction.^{19,20} Proper leg length and offset restoration improve THA function and minimize risk for dislocation and limp.^{21,22}

The more accurately the head center is re-created in THA, the better the ROM and the lower the chance of impingement and dislocation.²³ Benefits of neck modularity in the Kinectiv design include ability to determine and adjust leg length, offset, and version independently.



Figure 7. Insertion of modular neck and femoral head for trial reduction.

Exclusive use of +0-mm femoral heads eliminates skirted femoral heads to enhance ROM and makes the system inherently simple. The broad range of head center options addresses the disparate bone anatomy among patients. The broad head center opportunities allow preoperative planning to fit the stem in the femoral anatomy. This reduces the need to make significant adjustments to stem size to fit the patient to the implant. Preoperative planning for version is difficult, and femoral version is not fully appreciated until the femoral osteotomy is performed. The neck modularity in this uncemented tapered design allows for fitting the femoral anatomy without making significant adjustments to stem version, which have the potential to increase the risk for femoral fracture. Surgical techniques that have evolved with this stem include ability to prepare the femur first. Determination of femoral version allows for better determination of cup placement. Insertion of the stem first allows the stem to be inserted before preparation of the acetabulum, as there is no neck to interfere with cup insertion (Figure 6). This decreases blood loss because the stem is inserted immediately after broaching and before cup insertion. Stem insertion allows the trial reduction to be performed off the real femoral implant (Figure 7). We prefer to maximize anteversion on the femoral side to avoid excessive anteversion on the acetabular side, which can increase polyethylene wear and predispose to an anterior hip dislocation.

The modular neck stem facilitates surgical exposure in the minimally invasive posterior approach because the neck is not inserted until the trial reduction. Once the stem and cup are inserted, leg length is determined. Anteversion is determined by the Ranawat test to be between 35° and 50°. We then prefer to perform an “abduction shuck test” to determine proper offset. If this is sloppy, then offset is increased without sacrificing leg length. The capsule is also checked to see whether it can be repaired easily to the insertion site on the greater trochanter so that offset is not excessive. If the capsule is too tight, the surgeon can back down on the offset length without making the leg shorter and still be able to close the capsule, ensuring excellent hip stability.

Modular neck systems have become increasingly

popular, as they have the potential to address a wider range of patient anatomies and offer increased intraoperative flexibility. Potential concerns with the additional modular junction include fretting/corrosion and failure at the neck-stem junction. Three recent case reports of a failure of a modular neck hip stem (Profemur Z; Wright Medical Technology, Arlington, Tenn) have increased the attention being given to this potential complication.²⁴⁻²⁶ It should be noted that 2 of these cases involved fairly large patients and traumatic falls, and the third involved failure of a neck replaced during a revision surgery. A commonality in these cases is use of long necks, which all the authors postulated as a contributing factor. As noted earlier, fatigue strength performance is influenced by amount of offset, amount of version, and, in the case of modular neck implants, taper design geometry. The Kinectiv system does not offer as much offset or version, and the neck junction is appreciably longer than that of the implants in the case reports. Although our series is preliminary, there were no cases of stem or neck failure caused by the modular design. So far, more than 25,000 THAs have been performed with this modular stem, and there have been no reported implant failures of the neck-shaft junction.¹⁵ Historically, modularity has been a well-accepted advancement in prosthetic design, as evidenced in the early 1980 introduction of modular heads. The versatility added to the surgical procedure facilitated more accurate and stable biomechanical reconstruction. Initial concerns about strength and particulate debris eventually abated, and the modular head stem prosthetic design has become the standard. Although modular neck implants have been implanted for almost a decade, longer-term follow-up is needed to monitor the clinical effectiveness and performance of these designs.

This series illustrates the surgical advantages that have arisen from this technology. Increased preoperative and intraoperative flexibility of independent offset, version, and leg length provides more freedom to hit the “bull’s-eye” in terms of head center. The distribution of head center use in this cohort shows that most modular necks implanted in the Portland series were used to achieve head center locations that would not be available in the nonmodular design with identical body. This trend is corroborated by the larger distribution. Therefore, *outlier* appears to be a misnomer. The potential weakness of this interim analysis is the relatively modest clinical follow-up. We are continuing to follow this cohort, and long-term results will be reported to determine the safety and longevity of modular neck implants.

AUTHORS’ DISCLOSURE STATEMENT

Dr. Duwelius wishes to note that he is a paid consultant to Zimmer, Inc., and holds patents and is a Developing Surgeon and Consultant on Zimmer’s Kinectiv Stem. Dr. Hartzband wishes to note that he is a paid consultant to Zimmer, Inc. The other authors report no actual or potential conflict of interest in relation to this article.

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