MENTORS IN ORTHOPEDICS

RADIOLOGICAL MODES OF FIXATION OF A TAPERED, WEDGED PROXIMALLY COATED FEMORAL STEM

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SUMMARY

Background: Tapered wedge femoral stems are designed to achieve proximal metaphyseal fixation, theoretically reducing stress shielding and thigh pain. However, variations in femoral morphology and surgical technique may result in alternative patterns of implant-bone contact, the clinical significance of which remains poorly defined for hydroxyapatite-coated beta-titanium alloy stems.

Objective: This study aimed to classify the radiological fixation modes of a proximally hydroxyapatite-coated tapered stem and evaluate their correlation with clinical outcomes and femoral morphology.

Key Points: A retrospective analysis was conducted on 106 primary total hip arthroplasties with a minimum two-year follow-up. Radiological fit was categorized into five patterns: proximal, distal, combined, three-point, and no-fit. Proximal wedging occurred in only 35% of cases and was significantly associated with Dorr type B femurs ($p=0.01$). Conversely, distal and combined fits were more prevalent in Dorr type A femurs ($p=0.001$ and $p=0.04$, respectively). While three-point fixation showed a trend toward association with thigh pain ($p=0.05$), overall clinical results, including Hospital for Special Surgery scores, were independent of the fixation mode or bone type. All stems achieved secondary osseointegration without evidence of subsidence or loosening. Severe thigh pain was specifically associated with stems in varus alignment or those where the distal tip contacted the cortex.

Conclusion: Although tapered stems are designed for proximal wedging, diverse fixation patterns occur due to metaphyseal-diaphyseal mismatch. These variations do not compromise short-term clinical outcomes or implant stability, suggesting the versatile fixation capabilities of this stem design.

KEYWORDS

Arthroplasty, Replacement, Hip; Femur; Hip Prosthesis; Osseointegration; Radiography

I. INTRODUCTION

Modes of fixation of cementless femoral stems have important clinical implications as they determine the initial fixation and subsequent bone ingrowth [1,2]. Tapered wedge femoral stems with proximal porous coating were introduced to reduce stress shielding of the proximal femur and reduce the incidence of thigh pain, and have shown excellent intermediate and long-term results [1, 3-15]. However, implant shapes and sizes do not always perfectly match the patient's femoral geometry and there is always a risk of intra-operative femur fracture with oversized components and the risk of subsidence and early mechanical failure with undersized components. Although these stems are designed to feature proximal, canal filling bone contact, it may not always be possible to get a proximal wedging of the stem due to variation in femoral geometry as well as the operative technique [16]. Thus an additional mode of 3 point fixation pattern has also been described for these implants [15]. However, we have observed other modes of radiological fixation without clinical or radiological failure. The aim of this study was to analyze the results of a tapered, proximally hydroxyapatite coated uncemented femoral stem (Accolade TMZF®, Stryker Orthopedics, Mahwah, NJ) and to describe the various modes of radiologic fixation attained in these implants. We also sought to correlate these radiological modes of stem fixation to the clinical outcome.

II. MATERIAL & METHOD

We retrospectively analyzed 106 primary cementless total hip arthroplasties in 100 patients with a minimum of two year follow-up. These study patients were a part of another ongoing study, where the first 53 consecutive patients operated by a junior surgeon (ASR) just out of his fellowship training were matched to 53 patients (out of 458) operated by his mentor and the senior surgeon (CSR) during April 2002 to November 2004 (unpublished data). The matching was based on age, gender, BMI, diagnosis, Charnley class [17], and pre-operative Hospital for Special Surgery hip score (HSS) [18]. Two patients were lost to follow-up and one had incomplete radiographic data. Thus 100 patients (50 pairs) with 106 THAs were included for analysis and their demographics are shown in Table 1.

No. of Hips (patients)	106 (100)
Age (years)	59 (range 45 to 77)
Body Mass Index	27.35 (range 20.25 to 42.77)
Sex M:F	63:37
Mean pre-op HSS score (range)	19.1 ± 5.8 (6-31)
Dorr classification	Type A: 42 Type B: 64
Diagnosis	Degenerative Joint Disease: 94 Avascular Necrosis: 8 Rheumatoid arthritis: 2 Fracture neck of femur: 2

Table 1. Demographic data on 100 patients (106 THAs)

II.1. Implant

The cementless femoral component implanted in this study was the Accolade TMZF (Stryker orthopedics, Mahwah, NJ) composed of a proprietary beta-titanium alloy comprised of titanium, molybdenum, zirconium, and ferrous. It is collarless, tapered and wedge-shaped with a circumferential plasma-spray coating on its proximal body. It yields a modulus closer to bone, for increased flexibility and the potential reduction of thigh pain, which is sometimes associated with stiffer materials. TMZF has 25% greater flexibility and 20% higher tensile strength [19]. It is also stronger under notched conditions. The improved mechanical properties of TMZF allow for design of thinner stems and minimize the likelihood of thigh pain [1]. A tapered titanium stem provides a progressive transition from the bulky and relatively inflexible proximal segment to the finer and more flexible distal section. The TMZF stem has a trapezoidal neck that allows for improved ROM and reduces the probability of instability. The implant is available in standard (132o) and extended (127o) offset options. The circumferential HA coating and the double-taper design contribute to better initial stability and fixation of the stem which relies on metaphyseal fixation with minimal reaming and broaching to minimize bone loss.

II.2. Surgery

All surgeries were done with a posterolateral approach. After a starter reamer, a Midas Rex burr was used to take out remnant superolateral neck. This ensured appropriate seating of the broach and also avoided the varus positioning. No endosteal reaming was used and the canal was successively broached using the maximum permissible broach size to ensure cortical contact of the stem at the metaphysio-diaphyseal junction. The judgment for final size of the prosthesis was made by auditory and tactile feedback obtained during broaching to achieve final seating of the broach without further subsidence. In spite of the variation in bone stock, excellent intraoperative stability of the implant could be achieved in every patient. Line to line reaming of the acetabulum was performed and the cup (PSL®: Stryker Orthopaedics, Mahwah, NJ, USA) was press-fit in place. The choice of liner was at the discretion of the surgeon depending on age, activity levels and demands of the patients and consisted of either cobalt chrome or ceramic-on-polyethylene (Cross-Fire®, Stryker Orthopaedics, Mahwah, NJ, USA), or ceramic on ceramic (alumina V40 femoral head and Trident alumina insert, Stryker Orthopaedics, Mahwah, NJ). Post operatively, immediate weight bearing as tolerated was allowed with a walking aid. The patients were instructed to increase their walking distance each day with a goal of one mile.

II.3. Clinical evaluation

Postoperatively the patients were evaluated at 6 weeks, 3 months, one year and two years. A standardized self administered questionnaire, including a HSS score was administered at each visit [18]. The occurrence of thigh pain was especially assessed and graded as no pain, mild pain or pain that limited activity [20].

II.4. Radiologic evaluation

Immediate postoperative AP pelvis, 6 weeks and 2 years postoperative AP and lateral radiographs were used for analysis. The technique was standardized and the radiographs were obtained by the same group of experienced technicians. The radiological examinations were performed by two independent authors (RM and AVM). Diameter of head was preferably measured on each film for correction of magnification. Dorr femur type [21] was assessed preoperatively on each patient. Femoral alignment was considered to be in neutral if the long axis of the component and the femur were within 3 degrees of each other; otherwise the component was designated to be either in varus or valgus alignment [22]. Stability of the implant was assessed by the criteria of Engh et al [23]. In addition, the femoral implant-bone interface was divided into two zones – Zone I was the area around the porous surface of the component and zone II was the area around the smooth distal part of the stem. [22] A component was defined as stable when there was no subsidence and no demarcation (reactive) line in Zone 1. A zone of demarcation encompassing more than 50 % of the zone 1 interface was considered a sign of probable failure of bone ingrowth. A vertical migration of ≥3mm from the easily identified shoulder of the implant to the tip of the greater trochanter was considered to indicate definite subsidence [24]. Also, the prosthesis was classified as unstable if the alignment of the femoral component had changed since the operation. In addition, recorded signs of remodeling were allocated to Gruen zones 1–14 [25] and included endosteal bone bridging to the implant (spot welds), demarcation lines, distal cortical hypertrophy (recorded when there was an increase in the outside diameter of the cortex at the maximal point of hypertrophy), partial or complete pedestal formation at the tip, osteolysis (defined as signs of a radiolucent cavity in the periprosthetic bone), and calcar changes (atrophy or hypertrophy). Heterotopic ossification was recorded using the Brooker et al. grading system [26].

The primary radiologic fit of the femoral stem was classified to be either proximal, distal, a combination, a three point or none (undersized). Proximal fit was defined when the flare of the implant (In Zone 1) wedged or was within 1 mm of the flare of the meta-diaphyseal junction of the bone. Distal fit was defined when there was no radiologic gap between the bone cortices at the diaphysis and the distal half to third of the implant (Zone 2). A three point fit was defined when the implant was fixed via a three point contact with the bone cortices (both Zones 1 and 2). This was more commonly evident on the lateral view. A combination fit was a combination of the above and was either proximal-distal fit or a three-point with proximal wedge. A no-fit was described for those implants which could not be asserted to be wedged in the above modes. The intraobserver agreement (RM) for this new classification was 95.8% with a kappa value of 0.952 and was statistically significantly different from 0 (p=0.001). The inter observer agreement (RM and AVM) was 95.5% with a kappa value of 0.939 and was statistically significantly different from 0 (p=0.001). A value of 1 means that both observers agree on every single case and a value of 0 means that any agreement has been by chance only. Thus these values suggest the reproducibility of this classification system with good inter and intra observer agreement [27].

Stastistical analysis was done using SPSS 16.0 software (SPSS Inc., Chicago, IL). The relation between the radiological fit and Dorr type femur, gender, thigh pain, subsidence and surgeon was assessed by a Fischer's Exact test. One way ANOVA test was performed for relation between the radiological fit and the clinical outcomes. A p value less than 0.05 was considered significant.

III. RESULTS

There was significant improvement in pain relief, function, and motion following the total hip arthroplasties with the mean HSS of 38.7 ± 2.5 (range, 30 to 40; p=0.001).

Forty two (39.6 %) hips had Dorr type A morphology and 64 (60.4 %) type-B. No patient in this series had type C bone. Significantly greater number of females had Dorr type B bone (25 of 36 hips) compared to males (38 of 70 hips) (p=0.02).

The type of radiological fit is shown in Table 2.

	Dorr type		
Wedging	A	B	Total
None	1(2.4%)	14 (21.9%)	15(14.2%)
Proximal	8(19.0%	28 (43.8%)	36(34.0%)
Distal	18 (42.9%)	6 (9.4%)	24(22.6%)
Proximal + Distal	10 (23.8%)	6 (9.4%)	16(15.1%)
3 Point	5(11.9%)	10 (15.6%)	15(14.2%)
Total	42	64	106

Table 2: Distribution of various radiological fits among the femoral orphological types

The proximal fit and no fit were significantly associated with Dorr type B bone (p=0.01 and p=0.004 respectively).The distal fit and the combined proximal and distal fit were significantly associated with Dorr type A (p=0.001 and p=0.04 respectively). Thus the classical proximal wedging desirable for taper wedge stem could be achieved more commonly in type B femurs. 3 point fixation was more commonly seen in Type B femurs although the difference was not statistically significant (p=0.4).

The clinical results were independent of bone type and the type of the radiological fit. There was no association between the types of radiological fit or Dorr type bone and thigh pain, although there was a trend for the association of 3-point fixation with pain (p=0.05). Similarly, there was no association between the fit with HSS hip scores (p=0.4).

Significantly more males had a distal fit (22 of 24 distal fits; p=0.003) and a combined proximal and distal fit (15 of 16; p=0.01). On the other hand, more females had 3 point fixation (10 of 15; p=0.001).

There was no significant difference between the surgeon and the type of fit achieved (p=0.17).

There was no evidence of osteolysis, subsidence, gross wear, and loosening of components. All implants stems were deemed bony stable. No stem showed subsidence more than 3 mm. No patient had calcar hypertrophy or atrophy, or the development of progressively widening lucencies in any zones. Incomplete pedestal distal to the stem tip was found in 15 cases; 5 in no fit, 3 in distal fit, 3 with combined fit, 4 with 3 point fixation. There was significant association of the pedestal formation with no fit ($p=0.037$) whereas there was no significant association of the pedestal formation with proximal, distal, combined or 3 point fixation ($p= 0.083$, 0.545, 0.598 and 0.358 respectively). Two of these hips had non-progressive demarcation line in Zone 2 (the smooth distal portion). One patient with proximal fit had demarcation around the stem tip without pedestal formation. Two patients had cortical hypertrophy. Both the patients had a distal fit (Fig. 2). Two hips had more than 30 of varus with the stem indenting the lateral cortex and both the patients complained of thigh pain. Osteolysis was not seen in any Gruen zones. 13 hips showed asymptomatic heterotopic ossification (11 Grade 1 and 2 Grade 2).

There were no intraoperative fractures. Seven patients had mild transient thigh pain during the first 3 – 6 months following surgery. Three additional patients had thigh pain interfering with daily activities. Pain subsided in 8 months in one patient but persisted in the other two. Out of these three patients with severe thigh pain, two patients had a varus stem with tip of the stem touching lateral cortex while in the third patient, the tip was touching the posterior cortex (Fig. 3).

IV. DISCUSSION

The fit of a cementless femoral component is important in deciding the initial stability, bony ingrowth, thigh pain, stress shielding and endosteal irritation. Dalton et al [2] found that hydroxyapatite- coated implants with an initial bone-prosthesis gap of <1 mm demonstrated significantly increased mechanical attachment strength and bone ingrowth. Whiteside described a relation between tight femoral canal fit, cortical hypertrophy, and the absence of pain, whereas a nontight fit did not cause cortical hypertrophy but was associated with pain [28]. Excellent early stability is associated with low incidence of thigh pain [22]. On the other hand, Gosens et al [16] did not find any correlation between the clinical parameters and femoral fit. We undertook this study to explore whether TMZF stem shows classical radiological fits described for tapered wedge stem namely, proximal wedging or the 3 point fixation or there are other pattern(s) of radiological fit and the relationship with the clinical results.

The Accolade TMZF stem has a physiologically optimized design and self locking property. With its fit-without-fill design, the prosthesis fits tightly in the medial lateral dimension with no attempt being made to achieve anteroposterior fill. The unique taper wedge design feature allows the tapered prostheses to wedge into the metaphysis of proximal femur, providing excellent primary axial and rotational stability which ensures long term osseointegration and survivorship [1,22, 29, 30]. Proper preparation of the femur and selection of implant is mandatory to ensure proper fit of the prosthesis [11]. While using these stems, we try to match them with the proximal femoral morphology. The right fit results in the body of the stem fitting the metaphyseal cone while the stem sits snug into the femoral canal. Moreover, a 3-point fixation pattern [15] has also been described. But there are instances when the stem has a tendency to achieve a tight distal fit, which prevents the prosthesis from achieving a good metaphyseal fit [32].

The present study revealed that other modes of fixation are possible and the bony contact may vary between different patients. While the classical proximal metaphyseal wedging was achieved in a significantly greater number of patients with type B femur, they also showed a no radiological fit type of pattern frequently. Type A Dorr femur showed a distal alone or combined proximal and distal fit in a large number of patients (28 out of 42).

This metaphyseal-diaphyseal mismatch prevents the wedging of the prosthesis to provide the ideal desirable fit for the tapered prosthesis.

Good fit of the tapered stem requires a close match of the body of the stem to the prepared distal metaphysis of femur. In their clinical study of tapered stem design, Amstutz et al [33] stated that uniform stress transfer over the broadest area possible, together with the immediate stability provided by an exact fit, is the design goal. Fill is maximized in the metaphysis and proximal diaphysis. Kim [34] stated that while using tapered stems, close metaphyseal fit in coronal and sagittal planes without distal stem fixation provided an excellent mechanical fixation. That kind of fit could be achieved only in 35% cases (36 out of 100) in the present series.

Was there any correlation between radiological fit and thigh pain? None of the studies have evaluated this for TMZF stem until this date. Thigh pain is caused by a number of factors, including unstable fibrous fixation, a mismatch between the modulus of elasticity of the femoral component and bone, and endosteal irritation [35]. Hozack et al [22] reported 4% thigh pain using Prodigy stem and concluded that the stem stiffness and contact patterns likely play a role in the generation of stress shielding and thigh pain. Therefore, an implant with more distal fit and cortical contact pattern may cause relatively more stress to be delivered distally contributing to increased thigh pain and stress shielding while tapered stem allows for a more gradual transfer of stress and therefore a lower likelihood of thigh pain in well fixed components. Kim [33] also concluded that the cause of thigh pain may be a tight distal fill with a rigid stem. Herzwurm et al [36] noted a significant trend towards increased incidence of thigh pain in patients with excellent press fit (all-around cortical contact) versus those with good press fit. This cortical contact may predispose to distal fixation with stress transfer, especially in the presence of poor proximal fill. In our study, however, distal fit was not associated with thigh pain in any case even though cortical thickening of the midstem zones in patients with a tight femoral canal fit, suggesting stress transfer to these zones and unloading the more proximal zones [16] was seen in two patients.

This may be due to design as well as the material characteristics of the TMZF stem [1]. The other contributory factors could be excellent initial stability and hydroxyapatite coating, both of which have been associated with lower incidence of the thigh pain [22,38,39]. The only association seen was between the distal tip of the stem touching cortex on one of the views and the thigh pain.

One complication unique to uncemented arthroplasty is the reported high incidence (4%-28%) of associated femoral fractures [39-41]. This arises from the overzealous attempts by the surgeon to implant largest possible size to achieve immediate stability. The incidence of intra operative fractures with tapered stem, however, is very low and is reported to vary between no fractures [5], less than 1% [22] to 5% [10]. There was no intraoperative fracture in this series highlighting the fact that intraoperative good fit could be achieved in all cases without any iatrogenic fractures.

This is the first study to evaluate radiological fit of a TMZF stem in varying femoral bone morphology and its correlation with clinical results. Although no correlation could be seen between the type of radiological fit and the clinical results, the classical proximal wedging fit was seen only in 35% patients. Distal fit was the second commonest mode of radiological fit emphasizing the fact that metaphyseal – diaphyseal mismatch will have to be taken into account if taper wedge stems are to be designed with aim to achieve proximal wedging in larger proportion of patients.

This study has its limitations.The first limitation of this study was its retrospective nature, which may have some bias in data collection. The second limitation was a relatively small number of patients. Although this reduced the power of the study, certain trends were still appreciable. The third limitation was that this study may be specific for this particular stem design and may not be applicable for other cementless tapered stems.

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