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Original Research

Early Radiographic Fit and Fill Analysis of a New Metaphyseal-Filling Triple Taper Stem Designed Using a Large Computed Tomography Scan Database

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ABSTRACT

Background: Numerous cementless stems are available to maximize implant stability, fit, and survivorship in total hip arthroplasty. Recently, a new metaphyseal-filling triple-taper collared stem was designed using femoral morphology data obtained from over 1300 computed tomography scans. The purpose of this study was to evaluate the radiographic fit and fill of this new stem in the coronal and sagittal dimensions.

Methods: In this retrospective review, postoperative radiographs of patients receiving this new stem were analyzed in accordance with previously published fit and fill analyses. All radiographs were taken 6 weeks postoperatively. Means and standard deviations were reported for all fit and fill parameters.

Results: Fifty-nine hips were analyzed from 55 patients undergoing total hip arthroplasty. The coronal proximal fill was 85.02 ± 8.06%, and coronal distal fill was 75.21 ± 9.71%. The sagittal proximal fill was 86.51 ± 8.77%, and sagittal distal fill was 59.17 ± 8.66%. Mean calcar collar coverage was 80.64 ± 19.6% and all patients had full seating of the collar. Six cases (10.2%) had a collar length greater than the calcar length, with a mean collar overhang of 0.7 ± 0.4 mm.

Conclusions: This new stem demonstrated significant proximal fill in both the coronal and sagittal planes and validates the design intent of this implant. This is the first study to evaluate sagittal fit and fill of a femoral stem. Long-term follow-up is required to understand the clinical impact these fit and fill characteristics may have on patients' long-term outcomes.

Introduction

Cementless total hip arthroplasty (THA) has been performed since the late 1950s, and its implementation is credited to McKee and Watson-Farrar. [1] Since its initial conception, numerous cementless stem designs have been developed to maximize implant stability, fit, and overall survivorship. [2–11] The clinical performance data on a multitude of available stems has shown acceptable survivorship. [12–19] Given the lack of consensus on an ideal prosthesis, an ideal stem fit and fill within the femoral canal have been investigated. Percent fill influences bony fixation through load transfer to the proximal femur. [20] Metaphyseal stem fill has been demonstrated to reduce initial torsional motion and improve bony fixation in several biomechanical studies. [21–23] Additionally, optimized stem fit and fill improve initial stability and decrease the amount of subsidence in long-term follow-up. [24–26] There is also a significant correlation between poor stem congruity within the femoral canal and an increased incidence of thigh pain and aseptic loosening. [27]

Stem fit within femurs of multiple morphologies is an important factor for improving longevity. [27] Although preoperative templating can be helpful in assessing the anticipated surgical results, postoperative stem fit can be unpredictable. Postoperative

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radiographs are a valuable tool in assessing the congruity of particular stems after their insertion. Multiple classification systems exist in an attempt to quantify the fit and fill parameters of stems within the femoral canal. These characteristics have been broadly classified into one of 3 categories based on the proximal and distal engagement of a particular stem. [28] Type I stems demonstrate both proximal and distal engagement; type II stems have only proximal engagement; and type III stems have only distal engagement.

Type I stems have the most overall stability, given their proximal and distal engagements, while type III stems have the least, given their sole engagement distally within the femoral canal ref. Particular attention should be paid to stems with type III femoral canal fill given the concern for distal stem potting, which has been associated with stem subsidence, pain, and aseptic failure. [29] Additionally, quantitative measurements of proximal and distal fit have been published and allow for a standard method of assessing postoperative results. [28] With this framework in mind, systematic radiographic analysis can be performed to compare the fit and fill characteristics of multiple stems.

In recent decades, special attention has been paid to developing stems with a highly congruent fit. [30] Three-dimensional computed tomography (CT)-based stems have been designed using morphologic data of patients' femurs with the goal of enhancing implant fit and overall stability. [30] In recent years, a new metaphyseal-filling triple taper collared stem was designed using femoral morphology data obtained from a large database of high-resolution CT scans. [31] The stem was designed for optimized sagittal and coronal femoral fit across broad patient femoral morphologies and is accompanied by a size-specific collar. [31]

The purpose of this study was to assess the radiographic fit and fill characteristics in both the coronal and sagittal dimensions using postoperative anterior-to-posterior (AP) and lateral radiographs of a new metaphyseal-filling stem. Additionally, this stem's size-specific collar was evaluated for overall fit on the calcar and its ability to minimize collar overhang across various femoral morphologies. We hypothesized that this new stem would demonstrate excellent fit and fill characteristics in the coronal and sagittal planes with minimal collar overhang.

Material and methods

After institutional review board approval, a retrospective review was performed of all patients that underwent THA with a new metaphyseal-filling with triple-taper collared stem between December 2021 and May 2022. All procedures were performed by a single fellowship-trained adult reconstruction surgeon through a modified Smith-Petersen approach at a single academic institution. Patients were encouraged to be weight-bearing as tolerated and to ambulate on postoperative day zero. Patients received Insignia femoral and Trident II acetabular components (Stryker Orthopaedics, Mahwah, NJ). All acetabular components were implanted using a press-fit technique with or without screws.

Patients were included in the final cohort if they had standing AP and lateral radiographs preoperatively and at 6 weeks postoperatively. Standing hip radiographs were obtained per our standard protocol with patients' feet internally rotated approximately 15 degrees. Magnification of all radiographs were calibrated according to the known size of the patients' implanted ceramic heads (36 mm), which was confirmed with implant records from operative reports. We identified and analyzed 59 THAs performed in 55 patients during this time period who met the above criteria. Radiographic fit and fill parameters were measured by 2 independent reviewers.

Medial-to-lateral (ML) fit and fill parameters were measured as previously described by Issa et al. [28] AP fill measurements were obtained as well, similar to the described ML fill measurements. Proximal stem fill (ML and AP) was calculated at a plane 10 mm above the lesser trochanter (LT), and distal stem fill (ML and AP) was calculated at a plane 60 mm below the LT. The proximal portion of the stem was defined as the area below the femoral neck cut and contained within the metaphyseal coating of the proximal stem. The proximal gap (Pg) was measured as the gap between the proximal region of the stem to medial cortical bone at 10 mm above the LT. The medial and lateral distal gaps were subsequently measured at 60 mm below the LT and denoted as Dg1 and Dg2, respectively. Additionally, the minimum and maximum gaps of the stem to cortical bone were measured in the medial proximal region (Pmin and Pmax), along with distal medial region (DMmax and DMmin), and distal lateral region (DLmax and DLmin). The proximal and distal percent fills were defined as the ratio of the stem width to the canal width at a plane 10 mm above the LT and 60 mm distal to LT, respectively. This same radiographic evaluation process was performed on lateral films to determine the sagittal fit and fill of the implanted stems. Notably, the anterior and posterior distal gaps measured at 60 mm below the LT were denoted as Dg3 and Dg4, respectively (Figs. 1 and 2).

The percent fill was measured for both the coronal and sagittal planes. The percent of collar coverage of the calcar and any collar overhang were measured. Seating of the collars was also assessed, and any gap between calcar and collar was noted. All stems were assessed for signs of distal potting, which was defined as complete diaphyseal distal fill without complete metaphyseal proximal fill. All data was recorded using a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, WA). All statistical analysis was performed using Microsoft Excel as well. Means and standard deviations were reported for the aforementioned fit and fill parameters.

Results

Of the 59 hips reviewed, 25 (42.37%) and 34 (57.63%) were classified as Dorr A and Dorr B, respectively. On AP radiographs for all hips, the ML proximal fill was 85.02 ± 8.06% and the ML distal fill

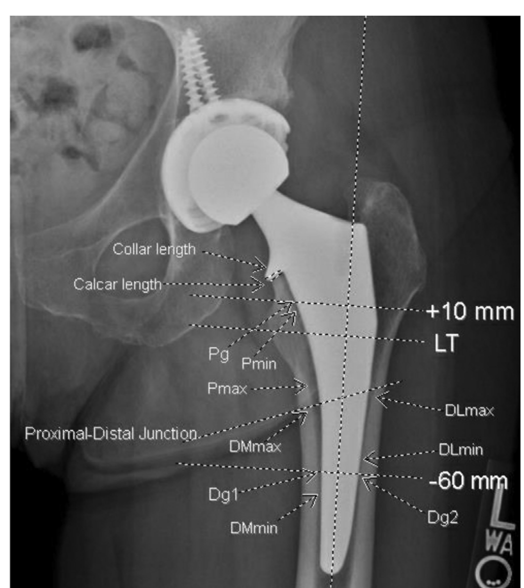

Figure 1. AP radiographic proximal and distal fit and fill measurements.

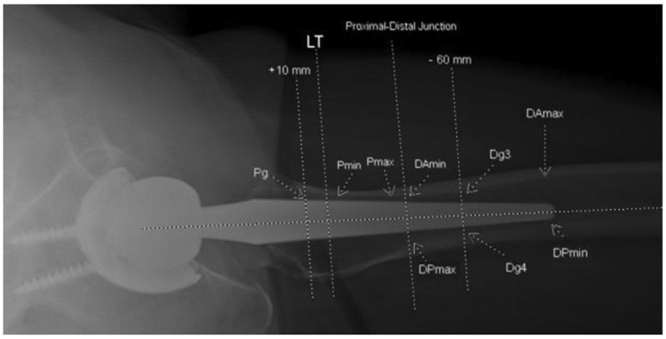

Figure 2. Lateral radiographic proximal and distal fit and fill measurements.

Table 2
Lateral fit and fill parameters.

Lateral radiographic fit and fill parameter	Mean ± standard deviation
Pmin, anterior (mm)	0.88 ± 0.91
Pmax, anterior (mm)	4.66 ± 2.79
DAmax (mm)	5.64 ± 1.97
DAmin (mm)	1.53 ± 1.04
DPmax (mm)	6.56 ± 2.21
DPmin (mm)	1.71 ± 1.56
Pg, anterior (mm)	2.98 ± 2.36
Dg3, anterior (mm)	5.32 ± 1.57
Dg4, posterior (mm)	2.06 ± 1.65
Proximal fill (%)	86.51 ± 8.77
Distal fill (%)	59.17 ± 8.66

was 75.21 ± 9.71%, measured on the AP radiographs. (Table 1) On the lateral radiographs, the AP proximal fill was 86.51 ± 8.77% and the AP distal fill was 59.17 ± 8.66%. (Table 2) The maximum distance from the implant to cortical bone in the proximal medial stem had a mean distance of 3.48 ± 1.29 mm. Of the 25 Dorr A hips, the ML proximal fill was 83.16 ± 8.79%, the ML distal fill was 76.11 ± 9.42%, the AP proximal fill was 86.98 ± 8.56, and the AP distal fill was 63.64 ± 7.78%. Of the 34 Dorr B hips, the ML proximal fill was 86.32% ± 7.37%, the ML distal fill was 74.55 ± 9.70%, the AP proximal fill was 86.66 ± 8.81%, and the AP distal fill was 56.01 ± 7.49%. For all hips, the minimal distance between the stem and cortical bone was in the distal lateral portion of the stem had a mean distance of 0.46 ± 0.40 mm. The maximum distance from the implant to cortical bone was found to be at the distal and posterior aspect of the stem, with a mean distance of 6.56 ± 2.21 mm. The minimum distance between the stem and cortical bone in the AP dimension was noted to be along the anterior and proximal aspect of the stem, with a mean distance of 0.88 ± 0.91 mm. All AP and lateral fit and fill parameters are summarized in Tables 1 and 2.

Mean calcar collar coverage was 80.64 ± 19.6%, and all THAs had full seating of the collar (Table 3). Six cases (10.2%) had a collar length greater than the calcar length, with a mean collar overhang of 0.7 ± 0.4 mm. The maximum collar overhang was measured at 1.3 mm for a single THA. All of these instances of overhang were in small females with small proximal femoral anatomy. No stems showed evidence of distal potting.

Discussion

Cementless THA has been performed for over half a century, and many advancements have occurred since its initial debut. Registry data suggests that there is an increasing use of cementless THA worldwide, and the majority of all THAs performed in the United States rely on cementless fixation. [32–35] A multitude of stems are now available with the overall goal of providing optimal stability and bony fixation to achieve long-term survivorship. Metaphyseal-filling triple taper stems focus on optimizing fit and fill of the femoral canal to provide adequate cortical contact and initial stability to achieve bony fixation and long-term stability.

Historically, fit and fill stems required both reaming and broaching to prepare the femoral canal for implantation of the stem. However, modern broach-only triple taper stems are now available and have become popular as they do not require reaming. In principle, broach-only systems also promote bone conservation as metaphyseal bone is compacted during broaching and canal reaming is not inadvertently lost. There is also a special emphasis on anatomically fitting the stem within the proximal femur to provide maximum stability.

Morphometric stem designs have since been developed in attempt to provide an improved fit of the prosthesis within a patient's proximal femur. Prior designs were based on the Mueller stem (Zimmer, Winterthur, Switzerland), which was released in the 1970s. These tapered wedge stems had a constant medial curvature, and as this stem grew in size, it would also grow laterally. [36]

In 2012, the Accolade II (Stryker Orthopaedics, Mahwah, NJ) was released and became the first morphometric tapered wedge stem on the market. This stem possessed a size-specific medial curvature to better fit a broad range of femurs and was developed through the use of a large database of CT scans of patients' femurs. [30] Morphometric stems have been shown to have a four-times lower incidence of intraoperative femur fractures in comparison to standard taper wedged stems and have been hypothesized to improve patient outcomes. [37] The success of this particular stem has subsequently led to the creation of additional morphometric stems by multiple implant manufacturers.

The Insignia Hip Stem, a new metaphyseal-filling triple-taper collared stem system, was designed utilizing Stryker's proprietary Orthopaedics Modeling and Analytics database. [31] This database contains femoral morphologies obtained from a multitude of patients, and these CT scans were utilized to develop this particular stem. The Insignia Hip Stem has several unique features derived from the bone database. It has a unique sagittal fit, which prioritizes coronal fill before sagittal fill in attempts to preserve bone stock. [31] Additionally, it has a size-specific medial curvature to support calcar engagement and provides a size-specific collar to maximize calcar coverage while reducing overhang in smaller sizes. [31] The

Table 1
AP fit and fill parameters.

AP radiographic fit and fill parameter	Mean ± standard deviation
Pmin, medial (mm)	1.45 ± 1.02
Pmax, medial (mm)	3.48 ± 1.29
DMmax (mm)	3.44 ± 1.04
DMmin (mm)	1.63 ± 0.95
DLmax (mm)	2.03 ± 1.25
DLmin (mm)	0.46 ± 0.40
Pg, medial (mm)	2.22 ± 1.05
Dg1, medial (mm)	2.14 ± 1.12
Dg2, lateral (mm)	1.03 ± 0.66
Proximal fill (%)	85.02 ± 8.06
Distal fill (%)	75.21 ± 9.71

Table 3
Radiographic measurements of collars.

Radiographic evaluation of collars	Mean ± standard deviation
Length of collar (mm)	5.83 ± 0.34
Length of calcar (mm)	7.60 ± 1.66
Collar on calcar (%)	80.64 ± 19.43

distal aspect of this stem also contains a slim profile to accommodate less capacious canals. All stems also have a high offset option, which provide a direct lateral offset of 5 mm without influencing limb length. This system also has a unique Tri-Stage broach which has coronal extraction teeth to facilitate cancellous bone removal for enhanced cortical fit. However, the broach also possesses sagittal compaction teeth to preserve bone in the sagittal profile and enable initial stability. The broach contains distal diamond-cutting teeth to help remove diaphyseal bone and promote proximal fit. These features were designed to help stem fit and fill with the overall goal of increasing stability and function.

Metaphyseal fill has been correlated with improved vertical and rotational stability of femoral stems, which is a critical precursor to bony fixation and long-term stability. [18] This new metaphyseal-filling triple taper stem was designed to optimize cortical engagement and proximal fill in various femoral morphologies. The senior author now has extensive experience using this stem and has used it successfully in Dorr A, B, and C morphologies. However, as can be seen by this early series where only Dorr A and B femurs were implanted with this cementless stem, it is the senior author's preference to use cemented stem fixation in most Dorr C femur cases.

Overall, this stem demonstrated excellent results with an average of 85% fill in both the coronal and sagittal planes. This radiographic study was also the first to evaluate the fit and fill results of any stem in the sagittal (AP) dimension, as prior studies have only analyzed the coronal (ML) dimension. Overall, we believe this amount of fit to be adequate as cancellous bone is still present. We hypothesize that 100% fill may increase the risk of periprosthetic fracture. However, there is currently a lack of literature analyzing the risk of periprosthetic fracture with near 100% stem fill, which remains an opportunity for further investigation.

In regard to stem adjuncts, the use of a femoral collar is a potential tool to help provide additional initial stability in THA. The use of a collar allows load transfer to the resected calcar and may prevent implant subsidence within the femoral metaphysis. [38–40] Subsidence is a known complication of cementless THA, and early migration has been shown to be a predictor of aseptic loosening as well as poor clinical outcomes. [41,42] The use of collared femoral stems has remained controversial, as several studies have demonstrated small to nonexistent differences in outcomes with the use of collared stems in comparison to collarless stems. [43–45] Conversely, a number of clinical studies have demonstrated that collar-calcar coverage may prevent stem subsidence and malrotation within the first weeks following uncemented THA. [38-40] In order for a femoral collar to be used effectively, it must provide adequate coverage to the femoral calcar. [45] An undersized femoral collar may not be able to prevent stem subsidence or malrotation, and an oversized femoral collar may lead to iliopsoas or other soft tissue impingement. [46]

This fit and fill analysis does possess limitations. First, radiographs were obtained at 6 weeks postoperatively, and further analyses will need to be performed to assess fit and fill characteristics in the long-term. Additionally, all surgeries were performed by a single surgeon who was part of the design team for this stem. Although this surgeon was not involved in the fit and fill analysis or with obtaining data, the single surgeon nature of this study limits generalizability. Future investigations will include obtaining long-term data in addition to data from additional surgeons using this hip stem.

Conclusions

A CT-based stem design, implanted using a coronal extraction and sagittal compaction broaching system, afforded adequate proximal fill in both the coronal and sagittal planes. Additionally, the size-specific collar showed good calcar coverage with little collar overhang. This early fit and fill data validates the design intent of this new stem. While no adverse events were noted in this cohort, longer-term follow-up is required to understand the potential clinical implications of these findings.

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Conflicts of interest

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