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Comparing the Long-Term Results of Two Uncemented Femoral Stems for Total Hip Arthroplasty

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ABSTRACT

327 proximal and 185 extensively coated femoral stems with mean 10-year follow-up were reviewed. Implant survivorship, clinical outcomes, and radiographic analyses were compared. Kaplan–Meier implant survivorship was 97.5% for the proximal, and 98.8% for the extensively coated stem for stem-only revisions at 10-years. The proximally coated stem outperformed on the PCS arm of the SF-12 ($P = 0.04$) and stiffness arm of the WOMAC ($P = 0.03$). Otherwise, all clinical outcomes were comparable. Thigh pain incidence was 12.5% and 5.3% for the extensive versus proximally coated groups, respectively ($P = 0.007$). Radiographic review identified more severe stress shielding ($P < 0.001$) in the extensively coated stems. This study supports the long-term clinical track record of total hip arthroplasty using two different cementless stem designs.

There have been several cementless femoral component designs that have been utilized in total hip arthroplasty. Two of the most popular press-fit cementless designs have been proximally coated, tapered stems and fully porous coated, cylindrical femoral stems [1]. The former achieves more proximal fixation, whereas the latter achieves more distal fixation [2]. Proximally coated stems were designed to reduce the incidence of thigh pain associated with early fully porous coated designs, as well as proximal bone loss associated with stress shielding [3]. Early biomechanical studies showed that proximally coated cementless stems exhibited tremendous fixation and high load to failure with axial loading [4]. However, there were concerns regarding lower loads to failure with regards to torsional loads in the proximal femur [5]. Thus, the distal fixation achieved with an extensively porous coated stem may provide greater resistance to torsional loads [3]. Larger and stiffer stems that fill the femoral canal are effective at relieving stress from the surrounding bone. This has been shown to contribute to stress shielding in the weaker, proximal femoral metaphysis [1].

The Synergy stem (Smith and Nephew, Memphis, TN) is an example of a proximally coated, tapered stem. Fabricated from titanium alloy, it utilizes three-point fixation for initial implant stability [6]. The Prodigy stem (DePuy, Warsaw, IN) is a second generation, fully porous coated stem made from cobalt chrome. It includes the option of a medial diaphyseal cutout in order to reduce stem rigidity [7,8]. Both the Synergy and Prodigy stems have demonstrated excellent survivorship and clinical outcomes at minimum 5-year review [6,7,9,10]. Mid-term survivorship was 99.5% for the Synergy stem, and 99–100% for the Prodigy stem for stem-specific revisions at 5-years [6,9,10]. More recently, Hennessy et al reported a survivorship of 100% for the Prodigy stem, with an average Harris Hip Score of 86 at minimum 10-year follow-up [7]. However, there have been no long-term comparisons of outcomes and survivorship for these two stem designs.

The purpose of this study was to 1) determine if there is a difference in survivorship across two different cementless femoral stems, and 2) are clinical and radiographic outcomes similar at long-term follow-up.

Materials and Methods

We retrospectively reviewed all patients who had a total hip arthroplasty using either a proximally coated cementless stem (Synergy) or extensively coated cementless stem (Prodigy) at our institution between 1996 and 2002. Approval for the study was obtained from the institutional research board. Prospectively collected data were then pulled from our institutional arthroplasty database, as well as patient chart review. Only those stems with a minimum 10-year follow-up clinical and radiographic data were included in the study. Excluded cases included those stems that were cemented, and revisions for any reason prior to 10-year follow.

A total of 597 proximally coated 275 extensively coated stems were eligible for 10-year review. Demographic data including patient age, sex, body mass index (BMI), primary diagnosis, and time to latest clinical and radiographic follow-up were collected (Table 1). We also

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Table 1
Demographic Data.

	Synergy (n = 327)	Prodigy (n = 185)
Age (mean ± SD)	60.7 ± 13.4	61.3 ± 10.4
Gender	Female: 153 (46.7%)	Female: 74 (40.0%)
BMI (mean ± SD)	30.0 ± 7.1	29.9 ± 6.7
Primary diagnosis:		
Osteoarthritis	282 (86.2%)	164 (88.6%)
Osteonecrosis	20 (6.1%)	6 (3.2%)
Inflammatory arthritis	8 (2.4%)	6 (3.2%)
Post-traumatic arthritis	1 (0.3%)	4 (2.2%)
Childhood disease (SCFE, DDH)	16 (4.9%)	5 (2.7%)
Time to latest follow-up (years ± SD)	10.56 ± 2.37	10.94 ± 3.10

report data on acetabular and bearing components used for the index procedures (Table 2). Patient deaths occurring prior to long-term follow-up were noted. Twenty-one percent of the proximally coated stems were ineligible due to death (n = 77) or revision (n = 49) prior to 10-year review. Twenty percent of the extensively coated stems (23 deaths and 32 revisions) were ineligible. Of those eligible, 327 proximally coated stems and 185 extensively coated stems had complete clinical and radiographic data at a minimum of 10-years.

Implant survivorship was analyzed. Stem specific revisions of any etiology prior to 10-year follow-up were collected, including periprosthetic fracture, aseptic loosening, and fractured prosthesis. The date of revision and time elapsed since the index procedure were recorded. All-cause revisions included stem specific revisions, as well as acetabular reconstructions, polyethylene and femoral head exchanges, and staged procedures for deep infections.

Patients had routine post-operative follow-up at 6 weeks, 3 months, 1 year, and then annually or bi-annually. Harris Hip Score [11], WOMAC [12], and SF-12 [13] scores were collected at each follow up visit. The pre-operative and most recent post-operative scores were recorded to allow for calculation of the change score at long-term follow-up. Patients were also asked about the incidence of anterior thigh pain with activity at each visit.

Plain radiographs were taken at routine follow-up visits. Views included an anterior-posterior (AP) pelvis, as well as an AP and lateral view of the involved hip. Images were reviewed via a Web-based image viewer Centricity Enterprise Web (GE Medical Systems, 2006) under 2× magnification. Radiographic interpretation was performed by the primary author as well as a fellowship trained arthroplasty surgeon who did not operate on any of the involved subjects.

Radiographic analysis included identification of spot welding, a sign of osseointegration [14]. This was recorded in each corresponding Gruen zone if present [15]. Stress shielding was interpreted using the concepts documented previously by Engh [16,17]. Mild stress shielding was radiographic bony resorption in Gruen zones 1, 7, 8, and 14. Moderate stress shielding was bony resorption in the aforementioned Gruen zones, and extending into zones 2, 6, 9, and 13. Finally, severe stress shielding included resorption extending into any of the remaining Gruen zones. Pedestal formation, or a radiosclerotic density distal to the tip of the femoral component, was also recorded. Heterotopic bone formation was classified according to Brooker [18].

Demographic variables were assessed with descriptive statistics. The association between group and categorical data was evaluated by means of Pearson chi squared or Fisher exact test depending on which was most suitable. All of our outcome measures (WOMAC, SF-12 and HHS) were evaluated preoperatively and postoperatively by an independents groups t-test. A two sided P value of <0.05 indicated statistical significance. Kaplan–Meier analysis was used to generate survivorship curves with 95% confidence intervals and to determine predicted cumulative survivorship at 10 years. This was employed using stem only revisions as the primary endpoint. We used SPSS v.20 (SPSS Inc., Chicago, IL, USA) for all analyses.

Results

Implant survivorship was comparable between both stems when considering the primary endpoint of stem-only revisions. Fifteen proximally coated stems and 4 extensively coated stems were revised at 10-years, translating into survivorship of 97.5% (95% CI 96.8–98.2%) and 98.8% (95% CI 98.1–99.5%) respectively at 10-year follow-up (Fig. 1, Table 3). Implant survivorship for all-cause revisions was 94.0% (95% CI 93.0–95.0%) for the proximally coated cohort, and 92.7% (95% CI 91.1–94.3%) for the extensively coated cohort at 10-years (Table 4). There were more revisions for periprosthetic fractures and aseptic loosening in the proximally coated group, however, these findings did not reach statistical significance. It is interesting to note that the 2 fractured extensively coated implants were both 10.5 mm diameter stems, the smallest diameter used in the Prodigy stem system. A total of 19 of the 10.5 mm diameter stems were used in the extensively coated cohort.

The only change score to reach statistical significance was the Physical Composite Score (PCS) component of the SF-12 questionnaire ($P = 0.002$, Table 5). The mean post-operative scores for the PCS component of the SF-12 ($P = 0.04$) and stiffness arm of the WOMAC were statistically significant ($P = 0.03$, Figs. 2, 3). The post-operative Harris Hip Scores for the proximally coated and extensively coated stems were 91.41 and 89.64 respectively ($P = 0.16$, Fig. 4). Thigh pain was reported in 12.5% of patients in the extensively coated group and 5.3% of patients in the proximally coated group at 10-year review ($P = 0.007$).

Long-term radiographic interpretation (Table 6) revealed mild stress shielding in 54.7%, moderate stress shielding in 39.1%, and severe stress shielding in 6.2% of proximally coated stems. In the extensively coated group, 44.6% demonstrated mild stress shielding, 37.6% had moderate stress shielding, and 17.7% had severe stress shielding. Statistical significance was reached for the severe stress

Table 2
Acetabular and Bearing Implants.

	Synergy (n = 327)	Prodigy (n = 185)
Acetabular component	Reflection Spiked (Smith and Nephew, Memphis, TN): 195 Reflection Interfit (Smith and Nephew, Memphis, TN): 116 Duraloc 300 Series (DePuy, Warsaw, IN): 12 Duraloc 1200 Series (DePuy, Warsaw, IN): 2 Duraloc Sector (DePuy, Warsaw, IN): 2	Duraloc 300 Series (DePuy, Warsaw, IN): 177 Duraloc 1200 Series (DePuy, Warsaw, IN): 4 Duraloc Sector (DePuy, Warsaw, IN): 4
Femoral head component	Cobalt Chrome Femoral Head (Smith and Nephew, Memphis, TN): 294 Zirconia Femoral Head (Smith and Nephew, Memphis, TN): 28 Articuleze Cobalt Chrome (DePuy, Warsaw, IN): 4 Biolox forte Ceramic Head (CeramTec, Plochingen, Germany): 1	Articuleze Cobalt Chrome (DePuy, Warsaw, IN): 179 Biolox forte Ceramic Head (CeramTec, Plochingen, Germany): 6
Bearing articulation	Reflection Polyethylene Liner (Smith and Nephew, Memphis, TN): 305 Enduron Polyethylene Liner (DePuy, Warsaw, IN): 16 Reflection Ceramic Liner (Smith and Nephew, Memphis, TN): 6	Enduron Polyethylene Liner (DePuy, Warsaw, IN): 177 Marathon Polyethylene Liner (DePuy, Warsaw, IN): 8