Proximally Versus Fully Porous-coated Femoral Stems

A Multicenter Randomized Trial

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Abstract There are two broad-based categories of cementless femoral component designs: proximally porous-coated and fully porous-coated. While both have been widely used, there remains debate regarding differences in clinical outcome scores, relative incidence of thigh pain, and development of stress shielding. We investigated these variables in a multicenter prospective randomized blinded clinical trial of 388 patients from three centers: 198

patients had a proximally porous-coated tapered cementless femoral component and 190 patients had a fully porous-coated cementless femoral component. A minimum followup of 2 years (mean, 6.7 years; range, 2.0–8.65 years) was available in 367 of the 388 patients (95%). We observed no differences in age at surgery, body mass index, or preoperative clinical outcome scores (WOMAC, SF-12, Harris hip score, UCLA activity, thigh pain) with the two groups. We determined serial bone density changes in a subcohort of 72 patients from two of the three centers. The postoperative clinical outcome scores were similar at all followup intervals, and we observed no differences in the incidence of thigh pain at any time. Bone density reduction in Gruen Zone 7 was greater with the fully coated stem than the proximally coated stem (24% versus 15% reduction, respectively). Both fully and proximally coated stems performed well, with no clinical differences at 2 years' followup, except in bone mineral density evaluations.

Level of Evidence: Level I, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution has approved the human protocol for this investigation that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

This work was performed at London Health Sciences Centre, Tulane University Medical Center, University of Alabama at Birmingham Orthopaedics, and University of Manitoba Joint Replacement Group.

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Introduction

There are a large number of cementless implants on the global market from multiple implant manufacturers. In general, the press-fit designs fall into two categories: fully porous-coated cylindrical stems that achieve primarily distal fixation and proximally porous-coated tapered stems that achieve primarily proximal fixation. Both designs have multiple publications supporting excellent clinical results with reproducible mid- to long-term followup. While the clinical track records of both stem designs appear

equivalent to date, proponents of proximally coated stems argue fully coated stems have a greater incidence of thigh pain and femoral stress shielding.

The reported incidence of thigh pain after THA with a fully coated femoral component varies between 3% and 20% [7, 13, 27]. While many surgeons presume proximally coated stems, or cemented stems, have a lower incidence of thigh pain than fully coated stems, this remains controversial [1, 2, 17, 25, 28, 30, 38]. Most authors recognize the reported incidence of thigh pain will be influenced by the way a patient is asked about its presence, a point best controlled with a prospective randomized blinded clinical trial.

Femoral bone loss or resorption, so-called stress shielding, around well-fixed femoral components is thought to occur around most, if not all, stem designs [12, 32, 34, 38]. This phenomenon is reportedly exacerbated with fully coated stems [12, 15, 18]. While stress shielding is seen radiographically, its clinical relevance remains to be determined [6, 16, 22]. Engh et al. [16] have demonstrated, while stress shielding did occur in a cohort of the fully porous-coated stems they evaluated, this did not result in specific clinical complications. At the same time, theoretically this bone loss could make a future revision more challenging, although that has not been demonstrated in the literature. Potential complications have also included greater and lesser trochanteric avulsion fractures [33]. Multiple factors have been implicated in the potential to develop stress shielding, including implant design variables, extent of porous coating, stem material, stem stiffness, stem geometry, and method of component fixation.

In a prospective randomized blinded clinical trial, we therefore compared a fully porous-coated femoral component to a proximally porous-coated component to examine differences in (1) clinical scores (WOMAC, SF-12, Harris hip score [HHS], UCLA activity), (2) incidence of thigh pain, and (3) development of stress shielding (as determined by dual-energy xray absorptiometry [DEXA]).

Patients and Methods

Between January 2000 and December 2003, we enrolled 388 patients in this randomized, controlled trial at three institutions: 194 patients at the London Health Sciences Centre (London, Ontario, Canada), 119 patients at Tulane University Medical Center (New Orleans, LA), and 75 patients at the Concordia Hospital (Winnipeg, Manitoba, Canada). We included patients with degenerative disease of the hip undergoing primary THA with either Charnley A or B classification, Dorr A or B femoral morphology as determined by the enrolling surgeon, and between 40 and 75 years of age. We excluded patients with preexisting

bone disease including rheumatoid arthritis and avascular necrosis, systemic conditions affecting bone density, and/or a contralateral revision or poorly functioning THA.

We performed a sample size calculation based on detecting a difference in the incidences of postoperative thigh pain between the two study groups, assuming an overall alpha error (two-sided) of 5% with a statistical power of 80% (beta error = 0.20). We assumed the incidence of thigh pain in the ProdigyTM group would be 25% compared to 10% in the SynergyTM group at 2 years' followup. With these assumptions, approximately 97 patients per study group were needed. Allowing for errors in the thigh pain incidence predictions and for withdrawals and losses to followup, we assumed at least 130 patients were needed in each study group. After agreeing to be enrolled in this study, patients were randomly assigned to receive either a proximally porous-coated femoral implant (n = 198) or a fully porous-coated femoral implant (n = 190). There were no differences in the patient demographic parameters between groups (Table 1). At a minimum 2 years' followup (mean, 6.7 years; range, 2.0–8.65 years), 367 of the 388 patients (95%) were available for review; three were lost to followup, two refused to participate in followup visits, five died due to issues unrelated to the surgery, three revisions had occurred before 2 years (two for stem loosening [one ProdigyTM and one SynergyTM stem] and one for chronic instability), and eight patients either geographically relocated or were moved to nursing homes and were unable to continue with their 2-year appointments. All three institutions' hospital ethics boards had approved the study before the enrollment of patients.

The femoral implants used were a tapered, titanium, proximally porous-coated (titanium bead) stem (SynergyTM; Smith and Nephew Inc, Memphis, TN) or a cylindrical, cobalt-chrome, fully porous-coated (cobalt-chrome-molybdenum alloy bead) stem (ProdigyTM; DePuy Inc, Warsaw, IN). The acetabular component implanted was at the discretion of the surgeon but almost exclusively followed along the lines of the stem manufacturer. In other

Table 1. Patient demographics at time of enrollment in the two femoral stem groups

Parameter	Femoral stem		p Value
	Synergy TM	Prodigy TM	
Number	198	190	
Gender (female:male)	46%:54%	41%:59%	0.161
Age at surgery (years)	61	60	0.410
Height (cm)	169	171	0.151
Weight (kg)	87.7	88.0	0.882
Body mass index	30.5	31.2	0.570

words, those patients receiving a Synergy™ stem received a Reflection™ shell with a modular polyethylene insert (Smith and Nephew Inc). Similarly, those patients receiving a Prodigy™ stem received a Duraloc™ series acetabular component with modular polyethylene liner (DePuy Inc). All patients received a 28-mm cobalt-chrome head. With the exception of the femoral stem and acetabular component implanted, all patients received identical care in every other aspect, including postoperative weightbearing of 50% for both groups.

Patients and the research personnel including the clinical study nurse at each site that oversaw enrollment into the study and all subsequent clinic visits, including the collection of clinical data, were blinded as to component type. All patients were seen and evaluated preoperatively and at 6 weeks, 3 months, 6 months, 1 year, and 2 years postoperatively. Preoperatively and at every postoperative visit, the HHS [19], WOMAC score [3, 4], SF-12 score [37], and UCLA activity ratings score [39] were obtained. To examine the potential differences in thigh pain between stems, a protocol was developed to create a standardized method of assessing the site, frequency, and severity of thigh pain in each patient. This was performed at each followup visit in which the patients completed a brief, self-administered questionnaire that included specific questions regarding the frequency of thigh pain (daily, weekly, monthly, less frequent), a diagram to document its proximal location, and a 100-mm visual analog scale (from 0–100) for the assessment of its severity.

Numerous authors have commented on the need for, and the value of, a more accurate measure of periprosthetic bone density (PBD) [5, 14, 29, 31]. At the time of the study's inception, the use of DEXA scans to evaluate PBD was a relatively recent application allowing for more accurate and precise measurements of PBD [13, 20, 24, 35, 36]. To observe the potential differences in changes with PBD between stems, we performed DEXA scanning in a subcohort of 72 of the 367 patients (20%) at two of the three sites (London and Winnipeg). Scans were obtained preoperatively for both hips and the spine and for the operated hip and spine at 6, 12, and 24 months postoperatively. In addition, a DEXA scan was performed of the operated hip at 2 weeks to serve as the early postoperative baseline measure. Density changes on the operative limb were interpreted in terms of immediate changes, changes seen over time within a femoral component type, and changes seen between femoral components at any given time interval. One surgeon performed a posterolateral approach and all others performed an anterolateral approach. While the femoral preparation itself between the two stem types is obviously different, it was performed in a standardized fashion by all sites and surgeons. The Synergy™ stem is a taper design and is prepared with

proximal reaming and rasping, but no distal reaming. The Prodigy™ stem preparation includes distal cylindrical reaming, as well as proximal rasping. The bone density changes replicated these preparation differences. The two centers that took part in the DEXA analysis utilized different equipment (Hologic™ QDR4500 [Hologic, Inc, Bedford, MA] and GE Lunar Prodigy [GE Corp, Fairfield, CN]); however, the majority of the DEXA analysis, 61 of the 72 cases, was performed on the Hologic™ system. This technique was chosen based on the fact that bone density cannot be accurately derived from standard radiographs due to variability in multiple factors (eg, target distance, film lot exposure) [26]. Briefly, the device uses a narrowly collimated xray beam filtered to allow the emission of two energies (38 and 70 keV). These two energies attenuate differentially in soft tissue and bone, allowing for the calculation of bone mineral density in both grams and grams per square centimeter, with only a small radiation dose to the patient (< 5 mrem/scan). PBDs were calculated using commercial software from standardized anteroposterior DEXA scans at the appropriate intervals. Preoperatively, the PBDs were measured on one standard area from both hips and the spine for each patient. In the hip region, this area was defined as an area of 17.7×5 pixels (equivalent to 21×6 mm on the patient), with the distal end of the sample area being at the margin of the lesser trochanter, proceeding proximally. The lower lumbar spine was measured with DEXA to allow a measurement of normal bone loss occurring in each patient. PBD was calculated at each time for each Gruen zone based on the anteroposterior DEXA scans. Sample size calculation was performed to determine the number of patients that would require DEXA analysis. Once again, an overall alpha error (two-sided) of 5% and an 80% power (beta error = 0.20) was used. By assuming a coefficient of a variation in the cobalt stem of 25% and the titanium stem would demonstrate a 17% higher bone mineral density, a sample size of 34 patients per group was calculated to detect a 17% difference in PBD between the two stems. A total of 72 patients had DEXA analysis performed: 61 patients in London and 11 patients in Winnipeg. The lumbar spine DEXA evaluations were performed to act as a control and document any systematic changes over time of bone mineral density. No changes over time in either treatment group were observed (Table 2). Patients over the 2-year interval maintained their bone mass. Therefore, specific changes seen after component placement were assumed to be secondary to the surgery rather than due to any generalized bone loss. The contralateral femur was also evaluated at each of the time intervals to demonstrate any effect on lower extremity bone mass changes that may have occurred secondary to patients having undergone a THA procedure; similar to the findings in the lumbar spine,

Table 2. Average bone densities of the lumbar spine and contralateral hip in the two femoral stem groups

Location	Time	Bone density (g/cm ²)		p Value
		Synergy TM	Prodigy TM	
Spine	Preoperative	1.17	1.15	0.689
	6 months	1.18	1.14	0.411
	1 year	1.16	1.13	0.626
	2 years	1.18	1.15	0.557
Contralateral hip	Preoperative	0.98	1.02	0.507
	6 months	1.03	1.03	0.927
	1 year	1.04	1.03	0.660
	2 years	1.03	1.03	0.939

patients over this time interval had similar bone mineral density values preoperatively and at the last postoperative evaluation (Table 2). The baseline bone density evaluation at 2 weeks was compared with each subsequent time interval, in each of the Gruen zones, for both stem types to evaluate for progressive bone loss, or stress shielding. Absolute bone density differences between the two stem designs, in each of the Gruen zones, at each time interval, were also evaluated. It is important to understand this does not take into account the differing baseline values demonstrated at the 2-week baseline evaluation. An alternate, and perhaps more clinically relevant, way to evaluate the bone density changes between implants is to assess the percentage of bone loss seen in each of the Gruen zones between the immediate postoperative and 2-year postoperative assessments and this was evaluated. Additionally, the relative effect of baseline bone mineral density on subsequent risk for stress shielding was assessed. Patients were divided into three groups based on baseline DEXA values: Group 1 representing 20th percentile or lower, Group 2 representing 20th to 80th percentile, and Group 3 representing 80th percentile or higher. Lastly, the relative effect of stem size and bone loss was evaluated. Both the SynergyTM and ProdigyTM stem lines were divided into smallest, middle, and largest stems to evaluate for patterns of bone loss related to stem size.

Upon completion of all 2-year patient followups, summary statistics were compiled. Stem group demographics were compared to ensure they were similar. Continuous demographic variables (age, height, weight, body mass index) were determined to be parametric with the Kolmogorov-Smirnov test and compared between the two stem groups using Student's *t* test. Differences in gender were determined using cross-tabulation with Fisher's exact test. Clinical outcome measures (WOMAC, SF-12, HHS, UCLA activity) and bone density were compared between stem groups with Student's *t* test after determining the data

were normally distributed with Kolmogorov-Smirnov test. The incidence and frequency of thigh pain were compared between study groups using cross-tabulation with the Mantel Haenzel summary chi square statistic. Severity of thigh pain was compared between study groups and time periods using repeated-measures analysis of variance. Changes in PBD between study groups and each Gruen zone were also evaluated using repeated-measures analysis of variance. All statistics were performed with SPSS[®] Version 16 (SPSS Inc, Chicago, IL).

Results

We observed no difference in the HHS, WOMAC, SF-12, or UCLA activity scores at the preoperative or 2-year postoperative visit between the implant groups (Table 3).

There was a high incidence of preoperative thigh pain related to the underlying diagnosis of osteoarthritis, but no differences between groups (71% in the SynergyTM group and 69% in the ProdigyTM group). At 6 months, 1 year (11% SynergyTM and 14% ProdigyTM), and 2 years (9% SynergyTM and 6% ProdigyTM), the incidence of thigh pain was similar in the two groups (Table 4). For those who reported thigh pain, the severity was similar in the two groups at all followup periods (Table 4). In patients who reported thigh pain, most reported experiencing pain daily rather than weekly, monthly, or less frequently; this finding was similar ($p > 0.102$) in the two cohorts.

The 2-week bone density changes reflected the differences in canal preparation for the ProdigyTM stem, with

Table 3. Clinical outcome measures in the two femoral stem groups

Outcome measure	Time	Femoral stem		p Value
		Synergy TM	Prodigy TM	
Harris hip score	Preoperative	43.2	43.1	0.953
	1 year	85.6	84.5	0.458
	2 years	86.4	86.7	0.832
WOMAC	Preoperative	47.1	49.1	0.342
	1 year	61.4	66.9	0.113
	2 years	65.9	67.2	0.717
SF-12 mental	Preoperative	51.3	51.8	0.613
	1 year	53.4	53.8	0.729
	2 years	53.2	53.4	0.939
SF-12 physical	Preoperative	29.5	30.6	0.185
	1 year	40.1	41.5	0.200
	2 years	42.0	42.0	0.999
UCLA activity score	Preoperative	3.9	3.9	0.715
	1 year	5.2	5.1	0.573
	2 years	5.3	5.4	0.661

Table 4. Incidence and severity of thigh pain in the two femoral stem groups

Time	Incidence			Severity*		
	Synergy™	Prodigy™	p Value	Synergy™	Prodigy™	p Value
Preoperative	71%	69%	0.75	80.74 ± 20.24	80.96 ± 20.70	0.84
6 months	11%	15%	0.254	38.67 ± 31.96	37.67 ± 23.01	0.94
1 year	11%	14%	0.512	42.82 ± 25.06	47.42 ± 27.99	0.683
2 years	9%	6%	0.527	42.25 ± 34.76	33 ± 20.05	0.661

* Values are expressed as mean ± SD on a 100-mm visual analog scale.

this group demonstrating decreased bone density in Gruen Zone 3 (Synergy™, 1.95 g/cm²; Prodigy™, 1.53 g/cm²; $p < 0.001$) and Gruen Zone 5 (Synergy™, 2.05 g/cm²; Prodigy™, 1.76 g/cm²). All other Gruen zones showed no differences in bone density at the 2-week interval (Table 5, Columns c, e, and g). At 2 years' followup, the Synergy™ stem demonstrated substantial bone loss in Gruen Zones 1, 6, and 7 (Table 5, Columns c and d), while the Prodigy™ stem demonstrated an almost identical pattern, with substantial bone loss in Gruen Zones 1, 2, 6, and 7 (Table 5, Columns e and f). Various Gruen zones and time intervals showed a decreased bone density for the Prodigy™ stem cohort when compared to the Synergy™ stem cohort while other Gruen zones did not demonstrate that pattern (Table 5, Columns c, e, and g). Only in Gruen Zone 7 did the Prodigy™ stem demonstrate a greater ($p < 0.001$) percentage of bone loss at 2 years compared to postoperatively than the Synergy™ stem (23.7% versus 15.3%) (Table 6). In terms of the relative effect of baseline bone mineral density on subsequent risk for stress shielding, the same pattern was seen with both stem types in Gruen Zones 1 and 3: patients with greater baseline bone mineral density (Group 3 representing 80th percentile or higher) were at a greater risk of having a greater percentage of bone loss over time for both the Synergy™ stem cohort (Table 7) and the Prodigy™ stem cohort (Table 8). The Prodigy™ stem showed no differences in percentage of bone loss over time with different stem sizes (Table 9); however, the Synergy™ stem demonstrated a greater percentage ($p = 0.042$) of bone loss over time in Gruen Zone 7 with the larger stem diameters (Table 10).

Discussion

We performed a multicenter prospective randomized clinical trial comparing two distinct femoral component designs: a fully porous-coated cobalt-chrome stem and a proximally porous-coated titanium stem. While both stems have had excellent clinical track records, questions remain regarding each stem design and the relative incidence of thigh pain and postoperative bone density changes. We

therefore evaluated multiple validated outcome measures (WOMAC, SF-12, HHS, UCLA activity scores), the incidence and severity of thigh pain, and the postoperative DEXA scan changes to find any differences between stem designs.

There are several limitations to this prospective randomized clinical trial. First, the followup period at 2 years is clearly an early postoperative period and demonstrates early trends that will not necessarily be seen with longer-term evaluation. Second, the DEXA scans were only performed in a subcohort of 72 patients and are only adequately powered to demonstrate a 17% difference in bone density between stem designs. Clinically relevant bone density changes have not been clearly established in the literature; however, certainly one could argue a larger sample size would have demonstrated more significant changes between the stems if the trends remained the same. Additionally, because of the smaller sample size in the DEXA cohort, subgroup analysis of the effects of stem size and preoperative bone density to subsequent postoperative changes is underpowered to demonstrate significant differences. While the DEXA scans provided objective data that allowed comparison between two femoral components, these scans are a challenge to perform as part of a routine followup evaluation. Patients require additional imaging over plain radiographs, which increases time and costs of followup. Patients require a baseline DEXA evaluation early in their postoperative course to allow comparison to late imaging and DEXA is not routinely available in all radiology departments. Unfortunately, therefore, DEXA scans cannot be used as a practical routine postoperative evaluative tool. Third, while the majority of DEXA scans were performed at one center with one type of DEXA scanner (Hologic™ QDR4500), the second site employed a different type of scanner (GE Lunar Prodigy), which can introduce a potential evaluation error [21, 23]. However, we evaluated changes in bone density from baseline and each patient served as his/her own control in this study design. The results discussed are patterns of change from a baseline, rather than attempting to discuss absolute density values, which would be challenging with two types of DEXA scanners used in this trial.

Table 5. Bone densities in each Gruen zone in the two femoral stem groups

(a) Gruen zone	(b) Followup time	Synergy TM		Prodigy TM		(g) p Value (Synergy TM vs Prodigy TM)
		(c) Bone density (g/cm ²)	(d) p Value (2-week baseline vs each time interval)	(e) Bone density (g/cm ²)	(f) p Value (2-week baseline vs each time interval)	
1	2 weeks	0.83		0.77		0.821
	6 months	0.79	0.277	0.72	0.008	0.156
	1 year	0.75	0.006	0.72	0.007	0.135
	2 years	0.76	0.025	0.72	0.014	0.365
2	2 weeks	1.71		1.58		0.111
	6 months	1.67	0.435	1.48	0.001	0.006
	1 year	1.64	0.149	1.47	0.005	0.019
	2 years	1.64	0.285	1.51	0.026	0.047
3	2 weeks	1.95		1.53		< 0.001
	6 months	1.92	0.143	1.5	0.202	< 0.001
	1 year	1.89	0.019	1.51	0.487	< 0.001
	2 years	1.86	0.129	1.54	0.689	< 0.001
4	2 weeks	1.84		1.75		0.076
	6 months	1.84	0.274	1.73	0.282	0.035
	1 year	1.82	0.912	1.73	0.128	0.118
	2 years	1.84	0.699	1.76	0.778	0.151
5	2 weeks	2.05		1.76		0.002
	6 months	1.97	0.003	1.74	0.313	0.001
	1 year	1.99	0.04	1.71	0.13	0.001
	2 years	1.95	0.114	1.76	0.671	0.016
6	2 weeks	1.65		1.53		0.079
	6 months	1.6	0.018	1.45	< 0.001	0.027
	1 year	1.57	0.007	1.45	< 0.001	0.068
	2 years	1.57	0.022	1.42	< 0.001	0.
7	2 weeks	1.23		1.28		0.392
	6 months	1.08	< 0.001	1.01	< 0.001	0.344
	1 year	1.06	< 0.001	1.01	< 0.001	0.526
	2 years	1.04	< 0.001	0.97	< 0.001	0.278
Net average	2 weeks	1.56		1.38		0.002
	6 months	1.5	< 0.001	1.3	< 0.001	< 0.001
	1 year	1.48	< 0.001	1.31	< 0.001	0.002
	2 years	1.48	0.013	1.31	< 0.001	0.002

Both femoral components provided reproducible results in terms of clinical outcome scores. We observed no differences in WOMAC, SF-12, HHS, or UCLA scores at any time interval between the cohorts. This finding was expected, as both stems have been used widely in clinical practice with good clinical track records [7–10].

The overall incidence of thigh pain at 2 years was 9% for the SynergyTM stem and 6% for the ProdigyTM stem. While this may be considered higher than previously reported [7, 9] for these stems (Table 11), it must be emphasized, in this study, the data were prospectively

collected and patients were asked repeatedly and directly about the presence of thigh pain.

The DEXA scan evaluations demonstrated two distinct patterns of bone mineral density changes: immediate and progressive. The immediate 2-week postoperative scans demonstrated substantial differences between the stems that we believe represent changes secondary to different surgical femoral preparation techniques and have not been discussed previously in the literature. Preparation of the femur to accept the ProdigyTM stem includes distal cylindrical reaming and proximal rasping. To place the

Table 6. Two-week to 2-year percentage decrease in bone density by Gruen zone in the two femoral stem groups

Gruen zone	Percentage decrease		p Value
	Synergy™	Prodigy™	
1	6.21	6.44	0.946
2	−0.67	5.01	0.217
3	2.42	−1.17	0.235
4	−0.74	0.03	0.505
5	3.38	0.42	0.294
6	3.55	7.56	0.099
7	15.29	23.74	0.011
Net average	3.66	4.86	0.517

Synergy™ stem, no distal reaming is performed, only proximal reaming and rasping. This preparation difference was demonstrated in the DEXA scans, with patients having more bone loss in Gruen Zones 3 and 5 in the Prodigy™ cohort at 2 weeks. Progressive decrease in bone mineral

density comparing the 2-week results to those seen at 6 months, 1 year, and 2 years was thought to represent the presence of stress shielding. Both stems demonstrated this phenomenon. Only in Gruen Zone 7 could a difference be seen between the stems in terms of percentage of bone loss over time: 23.7% with the Prodigy™ stem and 15.3% with the Synergy™ stem. Further differences between bone mineral densities at different time intervals could be seen between stem designs, but only if the baseline values were not taken into account.

In this prospective randomized multicenter blinded clinical trial comparing a proximally porous-coated titanium taper stem design to a fully porous-coated cobalt-chrome stem design, we observed no differences in clinical outcome scores and incidence of thigh pain. Progressive femoral bone loss was seen with both component designs. Perhaps, over a longer followup period, the progression of stress shielding will vary with stem type, but that remains to be proven and would not follow previously published reports [11, 12] showing most changes occur within 2 years.

Table 7. Relative effect of baseline bone mineral density on subsequent risk of bone loss: Synergy™

Gruen zone	% Decrease			p Value	Post hoc analysis
	Group 1 (n = 7)	Group 2 (n = 19)	Group 3 (n = 7)		
1	7.54	1.75	16.98	0.038	Group 2 vs Group 3 (p = 0.031)
2	−16.02	−0.02	11.29	0.065	No differences
3	0.02	−0.36	12.39	0.024	Group 2 vs Group 3 (p = 0.022)
4	0.41	−1.63	0.51	0.645	No differences
5	−0.53	2.33	10.56	0.275	No differences
6	8.51	0.53	6.81	0.116	No differences
7	18.69	16.34	9.03	0.408	No differences
Net average	4.91	1.37	8.60	0.124	No differences

Group 1 represents 20th percentile or lower, Group 2 represents 20th to 80th percentile, and Group 3 represents 80th percentile or higher, separately for each zone of the 2-week bone density for the Synergy™ stem.

Table 8. Relative effect of baseline bone mineral density on subsequent risk of bone loss: Prodigy™

Gruen zone	Percent decrease			p Value	Post hoc analysis
	Group 1 (n = 6)	Group 2 (n = 18)	Group 3 (n = 6)		
1	0.17	5.80	14.64	0.152	No differences
2	−2.96	5.51	14.41	0.010	Group 1 vs Group 3 (p = 0.007)
3	−7.93	−1.15	8.19	0.088	No differences
4	−4.57	−0.12	4.76	0.017	Group 1 vs Group 3 (p = 0.014)
5	−5.37	1.72	3.47	0.032	Group 1 vs Group 3 (p = 0.049)
6	1.80	8.34	12.08	0.102	No differences
7	23.07	22.71	27.47	0.657	No differences
Net average	−0.38	4.66	10.71	0.004	Group 1 vs Group 3 (p = 0.003)

Group 1 represents 20th percentile or lower, Group 2 represents 20th to 80th percentile, and Group 3 represents 80th percentile or higher, separately for each zone of the 2-week bone density for the Prodigy™ stem.

Table 9. Relative effect of stem size and bone loss: Prodigy™

Gruen zone	% Decrease			p Value	Post hoc analysis
	Group 1 (n = 6)	Group 2 (n = 8)	Group 3 (n = 11)		
1	9.70	5.14	3.39	0.680	No differences
2	2.36	1.35	4.96	0.724	No differences
3	-3.36	2.88	-3.01	0.468	No differences
4	-0.42	-3.50	1.13	0.184	No differences
5	-0.72	-1.89	1.67	0.503	No differences
6	4.64	3.55	9.12	0.349	No differences
7	23.31	24.82	26.81	0.813	No differences
Net average	4.56	2.73	4.84	0.716	No differences

Group 1 represents stem sizes 10.5 and 12, Group 2 represents stem size 13.5, and Group 3 represents stem sizes 15, 16.5, and 18 for the Prodigy™ stem.

Table 10. Relative effect of stem size and bone loss: Synergy™

Gruen zone	% Decrease			p Value	Post hoc analysis
	Group 1 (n = 16)	Group 2 (n = 10)	Group 3 (n = 6)		
1	3.22	4.84	15.45	0.184	No differences
2	0.061	4.75	-14.61	0.260	No differences
3	5.97	-0.18	-3.12	0.175	No differences
4	-0.18	-1.95	-1.52	0.761	No differences
5	4.57	4.35	-2.31	0.578	No differences
6	1.40	5.35	5.41	0.547	No differences
7	11.93	15.53	28.07	0.042	Group 1 vs Group 3 (p = 0.033)
Net average	4.24	2.53	3.66	0.885	No differences

Group 1 represents stem sizes 9 to 12, Group 2 represents stem sizes 13 to 14, and Group 3 represents stem sizes 15 to 17 for the Synergy™ stem.

Table 11. Incidence of thigh pain in our study compared to other published studies

Study	Synergy™	Prodigy™
Callaghan et al. [7]	NA	3%
Danesh-Clough et al. [9]	3.00%	NA
MacDonald et al. [current study]	9%	6%

NA = not applicable.

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