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# How Does Femoral Component Design Influence Proximal Femoral Bone Mass After Total Hip Replacement? A Randomized Controlled Trial

\*Pablo A. Slullitel, MD<sup>1</sup>

\*Mohit M. Mahatma, MRes<sup>2</sup>

Mohsen Farzi, PhD<sup>3</sup>

George Grammatopoulos, BSc (Hons), MBBS (Hons), DPhil (Oxon), MRCS (Eng), FRCS  
(Tr & Orth)<sup>1</sup>

\*J Mark Wilkinson, PhD, FRCS (Tr&Orth)<sup>2</sup>

\*PE Beaulé, MD, FRCSC<sup>1</sup>

<sup>1</sup>Division of Orthopaedic Surgery, The Ottawa Hospital, Ottawa, Canada, <sup>2</sup>Department of Oncology and Metabolism, University of Sheffield, Sheffield, UK, <sup>3</sup>Centre for Computational Imaging and Simulation Technologies in Bioscience, University of Leeds, Leeds, UK

\*Equal contribution

## Correspondence to:

P Beaulé, Division of Orthopaedic Surgery, The Ottawa Hospital - General Campus, 501 Smyth Road, CCW 1640, Ottawa, Ontario, Canada K1H 8L6. Email: [pbeaule@toh.ca](mailto:pbeaule@toh.ca)

JM Wilkinson, Department of Oncology and Metabolism, The Medical School, Beech Hill Road, Sheffield, S102TN, United Kingdom. Email: [j.m.wilkinson@sheffield.ac.uk](mailto:j.m.wilkinson@sheffield.ac.uk)

## Author contributions

PA Slullitel: Conducted data analysis, Wrote the manuscript

MM Mahatma: Conducted data analysis, Wrote the manuscript

M Farzi: Assisted with data analysis, Edited the manuscript

G Grammatopoulos: Assisted with data analysis, Edited the manuscript

JM Wilkinson: Co-designed the study, Led data analysis, Wrote the manuscript

PE Beaulé: Led and co-designed the study, Led patient recruitment, Edited the manuscript

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**Ethical review statement**

The trial was approved by Ottawa Hospital Institutional Review Board (OHSN-REB 2010913-01H) and registered with [clinicaltrials.gov](https://clinicaltrials.gov) (NCT01558752).

3 **Abstract**

4 **Aims**

5 In this randomized **controlled** trial (**RCT**), we aimed to compare post-operative bone  
6 remodeling and bone turnover over 2 years following total hip arthroplasty using the short,  
7 proximally-coated Tri-Lock ‘Bone-Preserving Stem’ versus a conventional, fully-coated  
8 Corail prosthesis.

9 **Methods**

10 Forty-six participants received the Tri-Lock prosthesis and 40 received the Corail. At  
11 baseline, both groups had similar demographics, proximal femoral bone mineral density  
12 (BMD), bone turnover markers, radiographic canal flare index, and patient-reported  
13 outcome measure scores. Outcomes were **measured** at week 26, 52, and 104.

14 **Results**

15 Loss in periprosthetic bone, measured by high sensitivity Dual-energy X-ray  
16 Absorptiometry Region Free Analysis (DXA-RFA) was identified at the calcar and  
17 proximal lateral femur in both prosthesis groups ( $p < 0.05$ ). However, the conventional  
18 prosthesis demonstrated a smaller reduction in BMD versus the bone-preserving prosthesis  
19 ( $p < 0.001$ ). This effect was most prominent in the region of the femoral calcar **and greater**  
20 **trochanter**. A small gain in BMD was also identified in some areas **that was greater** with  
21 the **conventional versus the bone-preserving prosthesis** ( $p < 0.001$ ). Both groups  
22 experienced similar changes in bone turnover markers and improvement in PROMs scores  
23 over the study period ( $p > 0.05$ ). **The** adverse event rate was **also** similar between groups  
24 ( **$p > 0.05$** ).

25 **Conclusions**

26 This **RCT** shows that prostheses intended to preserve proximal femoral bone do not  
27 necessarily perform better in this regard than conventional cementless designs. DXA-RFA  
28 is a sensitive tool for detecting spatially-complex patterns of periprosthetic bone  
29 remodeling.

30 **Level of Evidence:**

31 **Therapeutic** Level 1

## 32 **Introduction**

33 Although pooled data from THA case-series and joint registries shows a 25-year  
34 prosthesis survivorship of between 58%-78%<sup>1</sup>, the burden of periprosthetic femoral fracture  
35 after total hip arthroplasty (THA) continues to increase<sup>2</sup>. This observation has prompted the  
36 emergence of shorter-stemmed, ‘bone-preserving’ femoral prostheses intended to mitigate  
37 the periprosthetic fracture risk and simplify revision surgery. Those advocating for shorter  
38 stems argue for reduced femoral bone removal at surgery, reduced strain-adaptive  
39 remodeling (stress shielding) within the proximal femur, and tissue-sparing approaches  
40 during femoral canal preparation and prosthesis insertion<sup>3,4</sup>.

41 At prosthesis design, computational modeling techniques such as finite element  
42 analysis (FEA) are commonly used to predict and optimize prosthesis-bone construct  
43 stability and load transfer characteristics<sup>5,6</sup>. In order to validate FEA findings in patients, a  
44 clinical measure of bone strain-adaptive remodeling is required, and Dual-energy X-ray  
45 Absorptiometry (DXA) is typically used for this purpose<sup>7-9</sup>. However, DXA analysis using  
46 the conventional Gruen zone region of interest (ROI) approach has limited ability to resolve  
47 spatially-complex patterns of bone remodeling around prostheses<sup>10</sup>. **To address this, DXA-**  
48 **Region Free Analysis (DXA-RFA) was developed, allowing resolution of bone mineral**  
49 **density (BMD) at the individual pixel level<sup>11-14</sup> and because it does not average the**  
50 **pixel-level data into ROIs, there is no loss of resolution and interpretation variations**  
51 **associated with conventional DXA studies<sup>15</sup>.**

52 The primary aim of this randomized **controlled** trial (**RCT**) was to determine  
53 whether periprosthetic bone loss measured by DXA-RFA over 2-years after THA using the  
54 proximally porous-coated and shorter stemmed Tri-Lock “Bone-Preserving Stem” (BPS®)

55 femoral prosthesis (DePuy Synthes, Warsaw, USA) is lower than that occurring around the  
56 conventional collarless Corail® prosthesis (DePuy Synthes). We also compared  
57 biochemical markers of bone turnover, patient-reported outcome measures (PROMs) and  
58 adverse events (AEs) between groups.

59

## 60 **Materials and Methods**

61 Between May 2013 and May 2017, 2485 patients underwent THA at The Ottawa Hospital  
62 **amongst six surgeons. Initial screening eliminated 1927 patients for the following two**  
63 **reasons: two surgeons were not participating in the study (n=689); and initial chart**  
64 **reviewed by the research team met the exclusion criteria (n=1238). A consecutive**  
65 **group of 558** patients were **further interviewed** for eligibility out of which 88 patients  
66 with idiopathic osteoarthritis of the hip were recruited to the trial (Figure 1). The trial was  
67 IRB-approved, registered with clinicaltrials.gov (NCT01558752), and conducted in  
68 accordance with the Declaration of Helsinki. Patients with prior hip surgery, severe femoral  
69 bone deficiency, femoral neck fracture, known secondary causes of arthritis, **known**  
70 metabolic bone disease and past or present use of drugs known to affect bone metabolism,  
71 and patients anticipated to receive contralateral hip surgery within **1-year**, were excluded  
72 from the study. Using computer-generated, varied block randomization with allocation  
73 concealment, patients were randomized during the preoperative outpatient visit. Treatment  
74 allocation was made on a 1:1 basis to receive either the Tri-Lock BPS with a modular  
75 cementless porous-coated acetabular component (Pinnacle®, Depuy Synthes) using a  
76 metal-on-polyethylene bearing surface, or the Corail® prosthesis with a titanium porous-  
77 coated monoblock shell (DeltaMotion®, Depuy Synthes) using a ceramic-on-ceramic

78 bearing surface. **The Tri-Lock “Bone-Preserving Stem” (BPS®) femoral prosthesis**  
79 **(DePuy Synthes, Warsaw, USA) is a commonly used example of this philosophy.**  
80 **Manufactured in TiAl6V4 alloy with a stem length of 95 to 119mm, the Tri-Lock**  
81 **prosthesis has a thin tapered-wedge geometry with a reduced lateral shoulder and**  
82 **GRIPTION® porous titanium coating in its proximal (metaphyseal) section (pore size**  
83 **300 microns, volume porosity 80%) that is designed to closely fit the proximal**  
84 **femoral metaphysis and promote osseointegration. The prosthesis is inserted with a**  
85 **bone-cutting broach. The Corail is also a tapered-wedge stem composed of the same**  
86 **TiAl6V4 alloy, but with a more conventional geometry and is fully hydroxyapatite-**  
87 **coated (HA thickness 155 microns, pore size 250 microns, volume porosity 75%). The**  
88 **Corail is inserted using a compaction broach.** After randomization, two patients  
89 allocated to the Corail group received an alternate implant as the femoral canal was deemed  
90 by the surgeon to be not suitable for the Corail prosthesis and were excluded from further  
91 study. The participant and allied health providers remained blinded to treatment group  
92 allocation until after the final study visit (2-years).

93 **Surgical technique.** In all, 46 patients received the Tri-Lock prosthesis and 40 received the  
94 Corail. Each prosthesis was inserted according to its specific manufacturer’s instructions  
95 and design philosophy. Four surgeons performed the procedures, each using their preferred  
96 surgical approach. In the Tri-Lock group 33 were performed using the anterior approach, 6  
97 lateral, 1 posterior, and 6 posterolateral; and for the Corail 26 were anterior, 8 lateral, 1  
98 posterior, and 5 posterolateral (chi-squared = 0.792, p=0.851). Postoperatively, immediate  
99 full weight-bearing was allowed using crutches. Routine postoperative thromboembolic

100 prophylaxis consisted of 5 days of 10mg rivaroxaban daily, followed by 25 days of 81mg  
101 aspirin daily.

102 **Outcome measures and monitoring.** All DXA scan acquisitions were made using the  
103 same GE Lunar iDXA densitometer (GE Healthcare Lunar, Madison, WI) in ‘orthopaedic’  
104 scan mode and using a standard acquisition protocol<sup>16</sup>. Scans were made at post-operative  
105 baseline (within 2-weeks of surgery), and at weeks 26, 52 and 104 postoperatively.  
106 Analysis of the acquired pixel-level bone maps was made using the ‘Encore’ windows-  
107 based user interface (GE Healthcare) and implemented in Matlab v9.5 R2018b (Mathworks  
108 Inc, Cambridge, MA). Each image was composed of approximately 10,000 pixels (each  
109 0.60mmx0.60mm in size), and analyzed according to a previously described protocol<sup>13</sup>. A

110 **post-operative baseline conventional BMD measurement of the contralateral native**  
111 **hip (without THA) was also made to assess for evidence of pre-existing osteoporosis.**

112 Biochemical markers of bone turnover were measured from morning-fasting serum samples  
113 taken at pre-operative baseline and at weeks 12, 26, 52 and 104. Carboxy-terminal  
114 telopeptide of type I collagen (CTX), a marker of type-I collagen resorption, was measured  
115 by electrochemiluminescent assay ( $\beta$ -CrossLaps, Elecsys, Roche Diagnostics,  
116 Indianapolis, USA). Intact amino-terminal propeptide of type I procollagen (PINP), a  
117 marker of type-I collagen formation, was also measured using the Elecsys system.

118 Plain radiographic assessments using anteroposterior pelvic and lateral radiographs,  
119 were made post-operatively and at weeks 12, 26, 52, and 104. Differences between  
120 preoperative and postoperative global offset, as well as leg length discrepancy, were  
121 measured by an arthroplasty surgeon, following previously described methods<sup>7</sup>. The canal  
122 flare index was measured as per Boyle et al.<sup>17</sup> (stovepipe<3, normal 3-4.7, champagne flute

123 >4.7-6.5). Stem alignment was measured and grouped in varus ( $\geq +1^\circ$ ), neutral  
124 ( $< +1^\circ / > -1^\circ$ ) and valgus position ( $\leq -1^\circ$ ). Characterization of lucencies and bone  
125 resorption was based on the zones described by Gruen with a slight modification for the  
126 short stem<sup>18</sup>. Non-progressive periprosthetic lucencies of <2mm, outlined by a thin sclerotic  
127 line, were considered as normal<sup>8</sup>.

128 PROMs assessments and recording of AEs were made on the same day as the  
129 radiological assessments. PROMs included the modified Harris Hip Score (mHHS)<sup>19</sup>, the  
130 Western Ontario and McMaster University Osteoarthritis Index (WOMAC)<sup>20</sup> score and the  
131 University of California, Los Angeles (UCLA) activity scale<sup>21</sup>.

132

133 **Statistical analysis.** All analyses were made ‘per-protocol’ using two-tailed testing and a  
134 critical p-value of 0.05. Categorical data was analyzed using the **chi-squared** test.  
135 Continuous data were analyzed parametric and non-parametric tests, as appropriate to each  
136 dataset distribution. **Longitudinal continuous data was analyzed by repeated-measures**  
137 **ANOVA. For DXA-RFA, these analyses were made after** correction for multiple testing  
138 by False Discovery Rate (FDR)<sup>14</sup>, **and** denoted as q-values (**with**  $q \leq 0.05$  considered  
139 statistically significant). The power calculation was based upon data for cementless femoral  
140 prostheses assuming a between-group difference in Gruen zone 7 of 0.14g/cm<sup>2</sup> (10%,  
141 standard deviation 0.23) by conventional DXA analysis, giving a sample size of 43  
142 participants per group for 80% power at the 5% significance level.

143

#### 144 **Source of Funding**

145 The project was funded by Johnson & Johnson Medical Products and Synthes  
146 Canada Ltd. (d.b.a. DuPuy Synthes). The funder manufactures all prostheses studied in this

147 work, took no part in the design or conduct of the trial, analysis or interpretation of the  
148 results or preparation of the manuscript.

149

## 150 **Results**

151 A total of 47 females and 39 males with a mean age of  $59.4 \pm 10.6$  years old  
152 completed follow-up (98% of subjects randomized) and were included in the analysis.  
153 Patients in the Tri-Lock group (n=46) were of similar age, sex, body mass index (BMI) as  
154 those on the Corail group (n=40, Table 1,  $p > 0.05$  all comparisons). **BMD of the**  
155 **contralateral native proximal femur was also similar between groups and within the**  
156 **normal expected reference ranges (BMD, t- and z-scores  $p > 0.05$  all comparisons).**  
157 There were more patients in American Society of Anaesthesia (ASA) class III in the Tri-  
158 Lock versus the Corail group ( $p = 0.049$ ).

159 At immediate post-operative baseline, the distribution of periprosthetic BMD was  
160 similar between groups (Figure 2). **Subsequent bone loss around both prostheses was**  
161 **observed in the area of the calcar and in a cancellous area of the distal greater trochanter**  
162 **(Figure 3). Bone loss was significantly greater in the Tri-Lock group versus the Corail**  
163 **over the 2-year study period and observed at all interval timepoints (ANOVA**  
164  **$p < 0.0001$ , Table 2). Small areas of significant bone gain were also observed over the**  
165 **follow up period that was broadly but sparsely distributed for both prosthesis types**  
166 **(Figure 3). This gain was initially more apparent in the inferior lesser trochanter in**  
167 **the Tri-Lock group ( $p < 0.001$ ), but over the full study period was greater in the Corail**  
168 **group (Table 2 ANOVA  $p < 0.001$ ).**

169 At pre-operative baseline, serum values for the bone resorption marker CTX and the  
170 bone formation marker PINP were similar ( $P > 0.05$  both comparisons, Table 1). Post-

171 operatively both bone turnover markers underwent a transient increase, peaking at week 26,  
172 before returning to baseline by week 52 (Figure 4). No between-group differences in bone  
173 turnover markers were identified (ANOVA,  $p>0.05$  both comparisons).

174 At preoperative radiological assessment, the mean canal flare index was  $3.92\pm 0.6$ ,  
175 and was similar between groups ( $p=0.549$ ). On immediate post-operative radiographs, the  
176 prosthesis was positioned in greater varus in the Corail versus the Tri-Lock group (mean  
177  $2.07^\circ$  versus  $0.78^\circ$   $p=0.001$  Table 3). Other radiographic parameters were similar between  
178 groups. Non-progressive,  $<2\text{mm}$  lucent lines were detected in zones 1 and 7 of one Tri-  
179 Lock stem and in the same zones of three Corail stems. No cases had evidence of femoral  
180 component loosening.

181 Patients in both treatment groups had similar mHHS, WOMAC and ULCA scores  
182 at pre-operative baseline ( $p>0.05$  all comparisons, Table 4). Both groups experienced  
183 similar improvements in all PROM scores at week 104, with no difference in the change  
184 scores between groups. There were 8 AEs in the Tri-Lock group and 5 in the Corail group  
185 ( $p=0.741$ ). **This included 3 (7.5%) calcar cracks in the Corail group and 1 (2.17%) in**  
186 **the Tri-Lock group; 1 (2.5%) deep infection in the Corail group; 1 (2.2%) femoral**  
187 **nerve palsy in the Tri-Lock group; and 6 episodes of postoperative thigh pain at the**  
188 **latest follow-up (5 [10.9%] in the Tri-Lock group and 1 [2.5%] in the Corail).** One  
189 case (2.2%) in the Tri-Lock group developed aseptic loosening and underwent revision  
190 surgery with a non-modular, distally-fixed, conical stem at week 96.

191 We used linear regression analysis to explore the relationships between the area of  
192 greatest bone loss within the proximal medial femur and possible predictive factors,  
193 including age, sex, radiographic and PROMs variables. Although a correlation matrix  
194 suggested a relation between prosthesis alignment and BMD change at week 104 (Pearson

195  $r= 0.386$ ,  $p<0.001$ ), this was entirely accounted for by prosthesis group. In the final  
196 regression model, only prosthesis group remained a significant predictor of bone loss in the  
197 proximal medial femur (adjusted  $r^2= 0.063$ ,  $\text{Beta}=7.591$  (standard error= $2.996$ );  $p=0.013$ ),  
198 with greater loss for the Tri-Lock prosthesis.

199

## 200 **Discussion**

201 The goal of modern joint arthroplasty is to create a prosthesis-host construct that  
202 provides predictable pain relief and restores function, whilst causing the minimal possible  
203 disruption to the local biological environment<sup>18</sup>. The emergence of shorter “bone-  
204 preserving” femoral prostheses **follows** that philosophy, but the effect **of these prostheses**  
205 on the local bone environment in the patient remains unclear<sup>22</sup> **and is mainly based on**  
206 **FEA modeling**<sup>17, 23-26</sup>. In this 2-year RCT, **both the Tri-Lock BPS and CORAIL** designs  
207 resulted in only a modest disturbance of the natural patterns of strain-adaptive remodeling  
208 of the proximal femur, and both performed similarly in terms of plain radiographic  
209 **outcomes, PROMs and AE rates. Both designs are tapered wedges made from the**  
210 **same titanium alloy, but differ in stem length, geometry, extent and type of surface**  
211 **coating, and fixation philosophy (3-point fixation versus conventional taper)**. However,  
212 contrary to our anticipated results, we found better bone conservation around the  
213 conventional prosthesis than the proposed bone-preserving one.

214 **In a post-mortem study**, Engh<sup>27</sup>, demonstrated the effect of prosthesis stiffness on  
215 the local bone environment **and whereby short stems would load the proximal femur in**  
216 **a more physiological way, therefore preventing future stress shielding. Several**  
217 **authors have studied this looking at a variety of stem designs with mixed results**  
218 **(Table 5)**<sup>28-32</sup>. However, given the diversity of conventional and short stems available

219 **in the market and each with different load-sharing philosophies<sup>22</sup>, our results cannot**  
220 **be extrapolated to other designs that were not subjected to a similar high-resolution**  
221 **DXA-RFA analysis. Similarly, canal preparation technique may also affect**  
222 **periprosthetic bone remodeling. In the non-destructive clinical setting, Hjorth et al**  
223 **compared** compaction versus standard broaching when implanting the same Bi-Metric  
224 stem, **and** found only minor BMD differences in favor of compaction at 1- and 5-years<sup>33</sup>.  
225 **Their study used conventional DXA analysis that was not able to resolve the implant-**  
226 **bone interface. Using DXA-RFA we resolved events at pixel level at this interface and**  
227 **found no substantial difference between the implant groups to suggest a meaningful**  
228 **effect of broaching technique on the initial periprosthetic interface BMD. Further,**  
229 **given that the post-operative changes in BMD between the groups were not**  
230 **differentially located at the implant-bone interface, we conclude that the differences in**  
231 **broaching technique between the groups was not a significant contributor to the**  
232 **observed BMD outcomes.**

233 Modern imaging approaches, such as computational tomography and magnetic  
234 resonance imaging, also provide cross-sectional detail at high-resolution. However, despite  
235 advances in metal-reduction sequences, **challenges due to beam hardening, metal**  
236 **susceptibility artifacts and other issues remain that limit their application when**  
237 **studying events at or near the implant-bone interface<sup>34-36</sup>. DXA-RFA applied here,**  
238 **apart from not suffering artifact limitations to the same extent, uses advanced**  
239 computer vision algorithms to resolve bone architecture including events at the implant-  
240 bone interface<sup>15</sup>, and allows study of any prosthesis geometry without the resolution and  
241 sampling limitations of ROI-based analysis<sup>37, 38</sup>. **However, as each prosthesis and its**  
242 **canal preparation technique (i.e. different broach designs) are not separable, we were**

243 **unable to comment directly on the independence of each element on the overall**  
244 **observed bone remodeling effects.**

245 Our study also has limitations. **The inclusion of different bearing surface couple**  
246 **for each femoral prosthesis may be considered as a potential confounding factor in**  
247 **respect of axial load transferred to the proximal femur. However, in the design of this**  
248 **study we did not consider this to be a material issue, based upon previous literature**  
249 **addressing this question. In 2007, Kim et al reported the results of an RCT in which**  
250 **50 subjects undergoing simultaneous, bilateral, cementless THA received an alumina-**  
251 **on-alumina bearing in one hip and an alumina-on-polyethylene in the other, finding**  
252 **no differences in proximal femoral periprosthetic BMD between the bearing couples**  
253 **over 5 years<sup>39</sup>.**

254 The 2-year timeframe does not reflect the service life of the prosthesis. However,  
255 this study was constructed to quantitate the effect of each prosthesis philosophy on bone  
256 remodeling **over the period when these changes are most dynamic.** Our biochemical  
257 marker data confirmed that **the major phase of prosthesis-related** bone remodeling is  
258 complete within the **2-year** timeframe used in this study (return of markers to baseline  
259 **bone turnover rates**), and are consistent with previous studies of femoral **strain-adaptive**  
260 bone remodeling after THA<sup>40, 41</sup>. Our biomarker data did not differentiate the prosthesis  
261 brands. Serum biomarker data reflect bone turnover events throughout the body. Whilst the  
262 observed biomarker changes reflected the surgical event, it is perhaps not surprising that  
263 they were insufficiently sensitive to resolve the subtle differences in local bone remodeling  
264 observed between the prostheses. DXA-RFA, like all DXA analyses, provides a 2-  
265 dimensional composite of 3-dimensional events. However, this is a limitation of DXA itself

266 rather than the RFA-analysis technology that can also be applied to cross-sectional image  
267 data.

268           Although modestly different in their bone remodeling characteristics, this trial  
269 shows that the Corail prosthesis has more favorable bone remodeling characteristics than  
270 the Tri-Lock BPS. However, large-scale clinical data also shows us that design features  
271 which facilitate proximal load transfer and reduce early periprosthetic fracture rates do not  
272 necessarily perform in the same way later in the prosthesis' service life<sup>42</sup>. Ultimately, long-  
273 term periprosthetic fracture and loosening-free prosthesis survival in large clinical series  
274 will **determine the clinical significance of more physiological loading of the femur in**  
275 **regards to a cementless prosthesis design's overall performance**<sup>43, 44</sup>.

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423

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431 **Legend to figures**

432

433 Figure 1. Consort diagram showing patient selection, treatment allocation and analysis  
434 between the prosthesis groups.

435

436 Figure 2. Heatmaps showing baseline pixel-level BMD distribution in each prosthesis  
437 group measured by DXA-RFA.

438

439 Figure 3. **Heatmaps showing pixel-level change in BMD over 104 weeks in each**  
440 **prosthesis group measured by DXA-RFA. Left 3 panels show percentage BMD change**  
441 **at each timepoint after FDR correction. Right 2 panels show within group areas of**  
442 **significant change (Q value). Between group analyses for areas of loss and gain are by**  
443 **repeated measures ANOVA over 104 weeks.**

444

445 Figure 4. Graphs showing changes in serum concentrations of A) Carboxy-terminal  
446 telopeptide of type I collagen (CTX), and B) Amino-terminal propeptide of type I  
447 procollagen (PINP) in each prosthesis group over 104 weeks. Analysis is between group by  
448 repeated-measures ANOVA **over 104 weeks.**

**Table 1. Baseline demographic characteristics of completing participants.** Values are mean  $\pm$  standard deviation. Analyses are between group by <sup>†</sup>Chi-squared test or <sup>‡</sup>t-test.

<b>Variable</b>	<b>Tri-Lock Prosthesis (n=46)</b>	<b>Corail prosthesis (n=40)</b>	<b>p-value</b>
<b>Gender</b>			
<b>Male</b>	22	17	0.621 <sup>†</sup>
<b>Female</b>	24	23	
<b>Age in years</b>	60.4 $\pm$ 10.1	58.6 $\pm$ 10.2	0.312 <sup>‡</sup>
<b>BMI</b>	27.4 $\pm$ 2.9	27.6 $\pm$ 2.5	0.859 <sup>‡</sup>
<b>ASA class (Count, %)</b>			0.049 <sup>†</sup>
<b>I</b>	1	3	
<b>II</b>	28	31	
<b>III</b>	17	6	
<b>IV</b>	0	0	
<b>Baseline CTX (ng/ml)</b>	0.425 $\pm$ 0.193	0.403 $\pm$ 0.186	0.609 <sup>‡</sup>
<b>Baseline PINP (ng/ml)</b>	54.47 $\pm$ 21.39	55.92 $\pm$ 10.82	0.753 <sup>‡</sup>
	<b>Contralateral native hip (n=36)</b>	<b>Contralateral native hip (n=33)</b>	
<b>Total hip BMD (g/cm<sup>2</sup>)</b>	1.01 $\pm$ 0.14	1.01 $\pm$ 0.148	0.966 <sup>‡</sup>
<b>t-score total hip</b>	-0.28 $\pm$ 1.07	-0.25 $\pm$ 0.99	0.889 <sup>‡</sup>
<b>z-score total hip</b>	0.40 $\pm$ 1.18	0.39 $\pm$ 0.90	0.953 <sup>‡</sup>

**Table 2. Pixel-level bone mineral density changes in the Tri-Lock versus Corail Prosthesis groups over 104 weeks.** Analysis is number of pixels with change/total number of pixels in Tri-Lock versus Corail group by Repeated Measures ANOVA after False Discovery Rate correction at 5%. †Indicates post-hoc p-value at interval timepoints.

<b>Mean ± SD number of pixels/total per femur with significant BMD decrease</b>			
<b>Time</b>	<b>Tri-Lock</b>	<b>Corail</b>	<b>p-value</b>
<b>26 weeks</b>	927/9460 (9.80%) ± 82	0/11115 (0.00%) ± 0	<0.001 <sup>†</sup>
<b>52 weeks</b>	661/9460 (6.99%) ± 67	504/11115 (4.53%) ± 76	<0.001 <sup>†</sup>
<b>104 weeks</b>	1295/9460 (13.69%) ± 73	1072/11115 (9.64%) ± 50	<0.001 <sup>†</sup>
<b>ANOVA</b>			<0.001
<b>Mean ± SD number of pixels/total per femur with significant BMD increase</b>			
<b>Time</b>	<b>Tri-Lock</b>	<b>Corail</b>	<b>p-value</b>
<b>26 weeks</b>	21/9460 (0.22%) ± 6	0/11115 (0.00%) ± 0	<0.001 <sup>†</sup>
<b>52 weeks</b>	61/9460 (0.64%) ± 7	67/11115 (0.60%) ± 6	0.002 <sup>†</sup>
<b>104 weeks</b>	122/9460 (1.29%) ± 11	374/11115 (3.36%) ± 40	<0.001 <sup>†</sup>
<b>ANOVA</b>			<0.001

**Table 3. Radiographic outcomes of both prostheses by week 104.** Values are mean  $\pm$  standard deviation. Analyses are between groups by t-test.

<b>Radiographic variable</b>	<b>Tri-Lock prosthesis (n=46)</b>	<b>Corail prosthesis (n=40)</b>	<b>p-value</b>
<b>Mean global offset difference (mm)</b>	0.02 $\pm$ 5.13	-1.57 $\pm$ 4.77	0.072
<b>Mean leg length discrepancy (mm)</b>	-0.09 $\pm$ 1.82	0.73 $\pm$ 1.86	0.028
<b>Mean stem alignment angle (degrees, varus +, valgus -)</b>	0.78 $\pm$ 1.52	2.07 $\pm$ 2.11	< 0.001
<b>Mean linear bone resorption at calcar (mm)</b>	0.78 $\pm$ 0.94	0.65 $\pm$ 0.92	0.451

**Table 4. Patient-reported outcome measures in the Tri-Lock versus Corail groups at pre-operative baseline and at week 104.** Values are mean  $\pm$  standard deviation. Analysis is:  $\dagger$  within group between baseline and week 104 by paired t-test, and  $\dagger\dagger$  between group improvement in PROM score by independent t-test

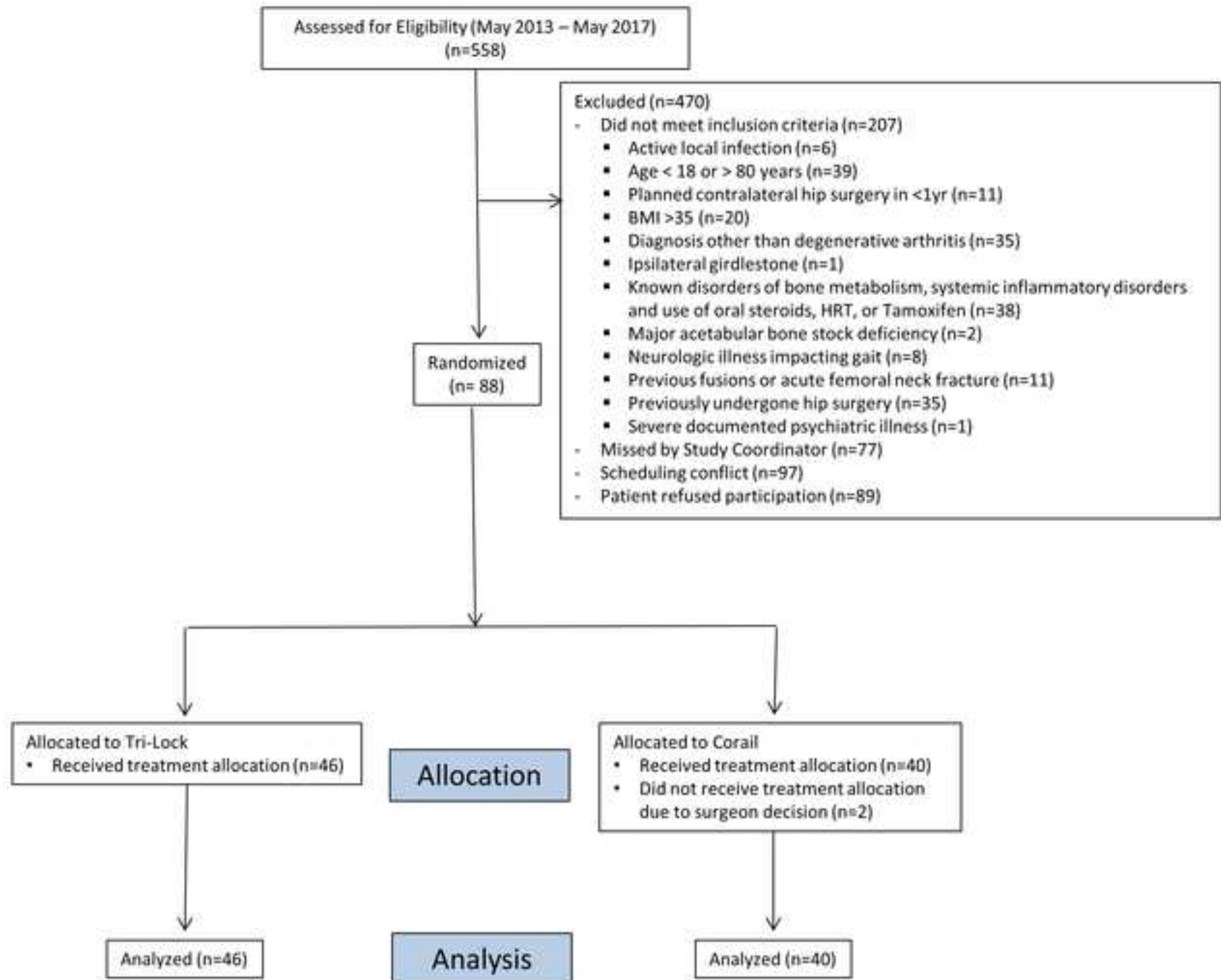
<b>PROMs (mean <math>\pm</math> SD)</b>	<b>Tri-Lock Prosthesis (n= 46)</b>	<b>Corail prosthesis (n= 40)</b>	<b>p- value</b>	<b><math>\dagger\dagger</math>p-value change scores between groups</b>
<b>Pre Harris Hip Score - Pain</b>	17.5 $\pm$ 7.19	19.2 $\pm$ 7.12	0.231	0.728
<b>Post Harris Hip Score - Pain</b>	35.6 $\pm$ 8.43	36.9 $\pm$ 8.96	0.342	
<b><math>\dagger</math>p-value</b>	<0.001	<0.001		
<b>Pre Harris Hip Score - Function</b>	27.7 $\pm$ 7.64	29.9 $\pm$ 6.83	0.167	0.132
<b>Post Harris Hip Score - Function</b>	42.0 $\pm$ 5.77	42.6 $\pm$ 7.40	0.275	
<b><math>\dagger</math>p-value</b>	<0.001	<0.001		
<b>Pre WOMAC - Pain</b>	47.3 $\pm$ 17.7	55.0 $\pm$ 14.9	0.054	0.362
<b>Post WOMAC - Pain</b>	87.2 $\pm$ 16.2	87.8 $\pm$ 16.8	0.661	
<b><math>\dagger</math>p-value</b>	<0.001	<0.001		
<b>Pre WOMAC - Stiffness</b>	43.8 $\pm$ 20.7	45.0 $\pm$ 19.2	0.518	0.890
<b>Post WOMAC - Stiffness</b>	78.5 $\pm$ 21.5	82.6 $\pm$ 22.0	0.284	
<b><math>\dagger</math>p-value</b>	<0.001	<0.001		
<b>Pre WOMAC - Function</b>	47.0 $\pm$ 17.1	58.4 $\pm$ 17.7	0.007	0.876
<b>Post WOMAC - Function</b>	87.2 $\pm$ 14.4	90.6 $\pm$ 15.8	0.150	
<b><math>\dagger</math>p-value</b>	<0.001	<0.001		
<b>Pre UCLA</b>	4.80 $\pm$ 1.78	5.23 $\pm$ 2.07	0.491	0.329
<b>Post UCLA</b>	6.26 $\pm$ 1.89	6.24 $\pm$ 2.16	0.654	

<sup>†</sup> <b>p-value</b>	<0.001	<0.001		
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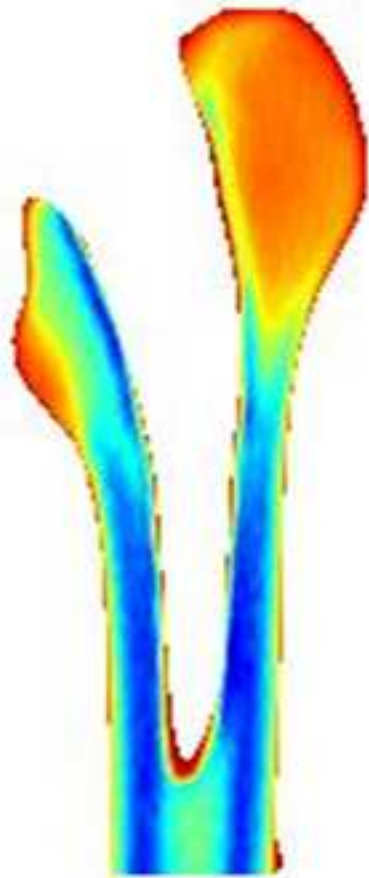
**Table 5: Previous randomized controlled trials (2015-onwards) reporting on bone mineral density results of a variety of stem designs.**

<b>Study</b>	<b>No. of hips (n)</b>	<b>Comparison groups</b>	<b>Mean Follow-up</b>	<b>Results</b>	<b>Limitations</b>
Schilcher et al (2017) <sup>28</sup>	60	Standard cementless femoral stem (Taperloc) vs. a 35-mm shorter version (Microplasty).	2-year	Greater bone loss around the shorter stem, although this was not statistically significant.	Underpowered to detect a significant difference in BMD between the prostheses.
Meyer et al (2019) <sup>29</sup>	140	Cementless bone preserving stem (Fitmore) vs. cementless straight stem (CLS Spotorno).	5-year	The bone-preserving Fitmore stem exhibited less proximal femoral bone loss than the CLS Spotorno conventional stem.	Different stem length of the 2 implants used with a modification to Gruen zones for better comparability.
Salemyr et al (2015) <sup>30</sup>	51	Ultra-short stem (Proxima) vs. conventional tapered stem (Bi-metric).	2-year	The conventional stem had greater bone loss (mainly in Gruen zones 1 and 7).	Lack of patient blinding. Possibly underpowered.
Freitag et al (2016) <sup>31</sup>	144	Cementless bone preserving stem (Fitmore) vs. cementless straight stem (CLS Spotorno).	1-year	Although both designs had implant-specific stress-shielding, the Fitmore stem had less proximal femoral bone loss than the CLS Spotorno stem (at ROI 6).	Short follow-up.
Kim et al (2016) <sup>32</sup>	400	Ultrashort anatomic	12-year	BMD was greater in the ultrashort stem group than in	Difficulty at evaluating

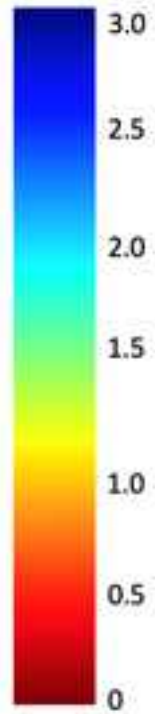
		cementless stem (Proxima) vs. conventional anatomic cementless stem (Profile)		the conventional stem group (mostly in zones 1 and 7).	longitudinal BMD changes using conventional DEXA of 2 different stem designs (e.g. slight changes in femoral rotation can affect precision of the measurement).
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**Tri-Lock**



BMD in  
grams/cm<sup>2</sup>



**Corail**

