RESEARCH ARTICLE

A Single Femoral Component for All Total Hip Replacements Performed by a Trust? Does This Affect Early Clinical and Radiological Outcomes?

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Abstract

Background: Hospitals may be under pressure to implement cost saving strategies regarding prosthesis choice. This may involve the use of components which are not the first preference of individual surgeons, or those they have little experience with. We aim to examine the effect of standardizing the type of femoral stem used in a single trust, and determine whether this is safe practice, particularly in those who have never used this particular stem before.

Methods: We report results at 2 years of 151 primary total hip arthroplasties performed using a single femoral stem. Data was split into 2 groups: those in which the operating surgeon was previously using this femoral stem, and those who were not. Radiographic outcomes measured were leg length discrepancy, cement mantle grade, and femoral stem alignment. We also report on clinical outcomes, complications, and construct survivability.

Results: No significant differences in clinical outcomes were observed. Cement quality was generally worse in those with no prior use of this stem. Leg length inequality was greater in those previously using the stem (+1.57mm vs 3.83mm), however this did not correlate to clinical outcomes. Alignment was similar between the groups (*P=0.464*).

Conclusion: Our findings suggest that although clinical outcomes are similar at 2 years, radiological differences can be observed even at this early stage in follow up. Choice of components for arthroplasty should remain surgeon led until long term follow up studies can prove otherwise.

level of evidence: III

Keywords: Arthroplasty, Femoral stem, Radiographic results

Introduction

The sub-specialty of total hip arthroplasty (THA) is a rapidly growing field with nearly 80,000 operations now performed in the United Kingdom annually (1). By 2030 this number is expected to rise by 174% (2). Over the last 50 years this procedure has developed into an extremely safe and effective one, and with this success has even been hailed as one of the most significant achievements in modern surgery (3). However, with new technological advances come increasing costs, and the price of implants has grown faster than any other component part of this procedure (4, 5). Efforts therefore need to be made to implement cost saving strategies, which may involve the use of lower priced stems or through volume discounting (6, 7). Surgeons may feel pressure by local trusts or hospitals to choose particular implants based on cost, and there is a danger of loosing control over implant selection in the future. Evidently this should not come at the expense of patient safety, however the effect of changing implants has not been well evaluated (8). In addition new, or cheaper, prosthesis are often less well

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evidenced. As complications such as dislocations or future revision surgery are often not initially apparent, the cost-benefit analysis becomes complicated and decisions to change prosthesis but be made with this in mind (9).

Most research to date in arthroplasty has focused on the clinical outcomes of individual or grouped component parts. The effect of introducing new prostheses on individual surgeon's outcomes or those of surgeons in a unit however, has not been well studied. The operation itself is technically challenging with a component dependent learning curve, and one must be cautious when introducing new implants or applying a new technique (10, 11). Recently Peltola et al (2012) showed a higher risk of early revision when introducing a new type of endoprosthesis for total knee arthroplasty (TKA) into a hospital (12). High risk of early revision surgery in THA has also been shown to be greater in the first 15 operations with a new stem or cup in a nationwide study of 39,125 operations (13). This risk was shown to be significant (HR 1.3, CI 1.1-1.5) and a learning curve was observed with some stems being easier to implement than others. Whilst surgeon related factors undoubtedly play a role Ramdas et al (2012) found that a single prior use of certain stem components reduced the duration of THA by 25% (14-16).

To the authors' knowledge no paper to date has looked at the effect of standardizing the prosthesis used within a unit for all THA procedures performed there. Certainly the existing evidence would suggest that prior experience of a component does matter, and introducing new prostheses is not without its risks. We aim to compare the outcomes between groups of surgeons who have prior experience using a particular femoral stem and in those who are naïve to this and for whom this is not their preferred choice. We hypothesize that those who have used this prosthesis before will perform better. From the existing literature on learning curves in arthroplasty, we expect differences if any, to be most apparent in the short-term. In the current climate of cost-awareness and cost-reduction, surgeons' autonomous control of implant selection may be at risk, and we aim to evaluate the effect of this.

Materials and Methods

Data was collected retrospectively over a 1 year period, which immediately followed a change in departmental femoral prosthesis use, and included all THA procedures performed during the follow up period. Before this point consultants were able to choose their preferred femoral stem, however the new constraints restricted them to the cemented, DePuy synthes C-Stem AMT (DePuy Int, Leeds UK). We identified 151 patients who underwent elective, primary THA for osteoarthritis of the hip using this stem. We excluded traumatic indications for hip surgery, revision surgery, and patients undergoing bilateral THA. 36 patients (24%) had a pre-existing contralateral prosthesis in situ, however none had previously undergone surgery to the ipsilateral hip. Surgery was performed across 2 sites (one hospital trust) by 6 experienced lower limb consultants. Two of these had more than 1 years experience using this prosthesis as their preferred stem before the departmental change. The others had previously used a mix of cemented and un-cemented femoral stems prior to the start period of this study. Post-operative outcomes were then analysed between these groups. The choice of femoral head and acetabular components used was based on individual preference of the performing surgeon and case suitability. The femoral component was implanted with a marathon XLPE cemented cup (DePuy) in 75% of cases, Elite plus Ogee cup (DePuy) in 5%, and a Pinnacle duofix cup (Corail) in 12% of cases. Cup type was not recorded in 8% of cases.

Patients' demographic and clinical data was retrieved from MEDITECH and Medicorr, computerized database systems. Radiological evaluation was performed on the Patient Archive and Communication System (PACS) and measurements were taken using the integrated measuring tools. Radiographic analysis was performed by the lead author in all cases. Pre and post-operative films were reviewed for leg length discrepancy, cement mantle quality and femoral stem alignment.

Leg length was measured as has been described in other studies (17-20). Reference points used were the inferior margin of the acetabular teardrop and a perpendicular line drawn between the most prominent point of the lesser trochanter. The distance between these measured to the nearest millimeter. This was considered clinically significant when measurable leg length was lengthened by greater than 6mm, or shortened by greater than 10mm. Although a controversial subject, this has been shown to be universally perceived beyond these ranges (21). Cement mantle quality was measured using the Barrack grading scale as originally described (22). This is shown in Figure 1. Finally femoral

Grading	Radiographic characteristics
A	Complete filling of the medullary canal without radiolucent lines between cement and bone (white-out)
B	Radiolucent line covering up to 50% of the cement-bone interface
C	Radiolucent line covering between 50 and 99% of the cement-bone interface, or incomplete cement mantle
D	Complete radiolucent line (100%) at the cement-bone interface and/or absence of cement distally to the end of the stem

Figure 1. Barrack grading system of cement mantle quality.

stem alignment was measured. This was considered to be in excessive valgus/varus alignment at greater than 5° (4, 23).

Analysis was then performed between the two groups, one in which the operating surgeon had >1 years experience using this prosthesis, and the other group of surgeons who had no prior use of this prosthesis. Unpaired (Student's) t-tests were used on all continuous outcome variables, and the two-tail Fisher's exact test was used for nominal variables. The Kruskal-Wallis H test (an extension of the Mann-Whitney U test) was used for ordinal data. A value of $P<0.05$ was considered statistically significant.

Results

Over the study period 70 cases were performed by surgeons who had not previously used this stem, and 81 by those experienced with this component. The consultant was recorded as the operating surgeon in all cases. A descriptive overview of the study population can be seen in Table 1. No significant differences were observed with morbidity, as measured by the American Society of Anesthesiologists (ASA) grade ($P=0.216$). Average post-operative length of stay was 4.7 days, and this was greater in the group previously using this prosthesis (mean 3.61 (SD 2.68) vs 5.63 (SD 5.97), $P=0.01$).

At an average follow up period of 23 months (range 386-1108 days) no dislocations were observed. There were 3 mortalities, all within 6 months from surgery. The cause of one was not documented, however the other 2 patients died from unrelated, previously undiagnosed carcinomas. One surgeon who has not previously used this component experienced failure of the cement gun during surgery. This caused a small distal perforation, which was managed with partial weight bearing for 6 weeks with no further complications. Other complications can be seen in Table 2, no significant differences were observed between groups.

Assessment of cement mantle quality on post-operative radiographs was performed on all patients using the Barrack grading system as shown in Table 3. Cement quality was generally poorer in those whom were not previously using this prosthesis. Although this data did not lend itself to statistical analysis, Figure 2 shows a trend towards better cement quality (A and B grades) after 40 cumulative cases performed in those who had not previous used this femoral stem.

No significant difference in femoral alignment was observed between the two groups. 4 stems were inserted in excessive varus, and 1 in varus in the group experienced with this stem. 1 stem was inserted in varus

Table 1. Study demographics

Demographic	No previous experience (n = 70)	> 1 years experience (n = 81)	*P*
Mean age	67 (range 42-85)	73 (range 48-87)	0.072
M:F	33:37	24:57	0.193
Mean ASA grade	2	2	0.216
1	12 (17%)	6 (7%)	-
2	46 (66%)	60 (74%)	-
3	12 (17%)	14 (17%)	-
4	0	1 (1%)	-
% Performed by consultant	100%	100%	-
Number of surgeons performing (number of cases)	4 (13,16,20,21)	2 (36,45)	-
Right:Left	37:33	52:29	0.1857
Contralateral prosthesis in situ?	19 (27%)	17 (21%)	0.4449

Table 2. Post-operative complications observed in the first 12 months following surgery

Post operative complaint	No previous experience (n = 70)	> 1 years experience (n = 81)	*P*
Pain	3 (4.3%)	3 (3.8%)	1
Trochanteric bursitis	2 (2.9%)	0	0.213
Suture abscess	1 (1.4%)	0	0.464
Leg length discrepancy	2 (2.9%)	2 (2.5%)	0.633
Superficial wound infection	1 (1.4%)	1 (1.2%)	0.714
Back pain	0	1 (1.2%)	1

Table 3. Barrack grading of cement quality on post-operative radiographs

Barrack grading	Group with no previous experience, n	Group with > 1 years prior experience
A	30 (42.9%)	39 (48.1%)
B	31 (44.3%)	34 (42.0%)
C	8 (11.4%)	7 (8.6%)
D	1 (1.4%)	1 (1.2%)

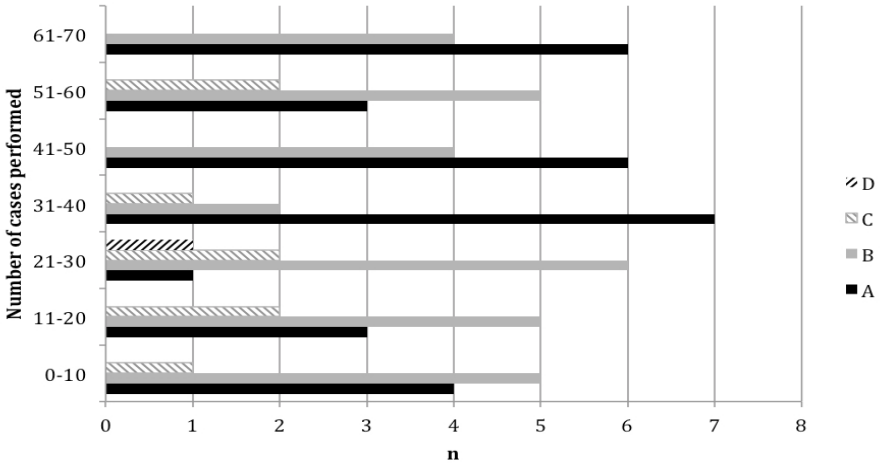

Figure 2. Change in Barrack grade per number of cases performed in the group not previously using this femoral stem.

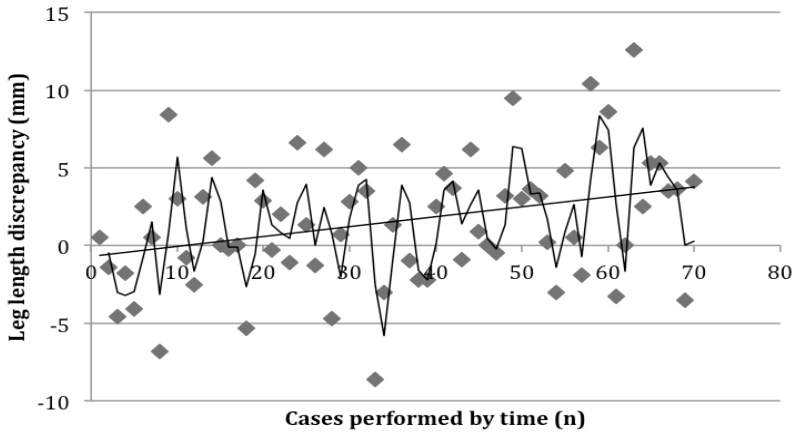

Figure 3. Leg length discrepancy per cases performed in the group not previously using this femoral stem

and 2 in valgus in the group not previously using this component (*P=0.464*). The incidence of this was uniform over the number of cases performed in both groups and showed no variation with time.

Mean leg length discrepancy fell between accepted ranges in both those new to and those familiar with this femoral stem (+1.57mm (range -8.6 – 12.6, SD 4.10) and +3.83mm (range -2.8 – 13.2, SD 3.67) respectively). This was significant (*P<0.05*) and represented a mean 3.94mm and 8.53mm increase in leg length respectively when compared to pre-operative values. No cases were considered significantly shortened in either group. There was a noticeable trend towards lengthening over time in the group who had not used this stem before, see Figure 3.

It is possible that this represents a learning curve effect, however the reason for this is not clear. In this group 10 cases (14.3%) were considered to be significantly lengthened compared to 21 (26.0%) cases in those familiar with this femoral stem. The incidence of this was uniform over time in both groups and did not appear to be dependent on the number of cases performed over the first year of using this prosthesis. Regardless, there was no significant difference in patient reported leg length discrepancy between groups.

Discussion

This study is unique in that compares the early clinical and radiological outcomes between two populations of consultants who had differing experiences using a certain component. The early clinical results of our study are satisfactory, with no significant differences in patient reported outcomes observed at 2 years. Although this might be expected when comparing two experienced groups of surgeons, differences in radiological measurements of the femoral stem were certainly observed. Furthermore, the preservation of a low complication rate may also be due to surgeon-controlled choice of acetabular component and choice of femoral head. We acknowledge that the follow up period is short, and a longer follow up period is required to fully analyse these effects.

The number of surgeons in this study is representative of a standard sized orthopaedic unit. Component survivorship was 100% at one year, and clinical outcomes were comparable between those who were experienced with this stem, and those who had never used this before. Although the follow up period of this study was short, this reflects the findings of previous studies, which report 100% stem survivorship at 12 months, and 96.9% survivorship at 99 months (95% CI 84.2-100%) when using this stem (25, 26).

Perhaps the most significant finding was poorer cement quality in those with no prior use of this stem. Although this showed a trend towards improvement over time, technical difficulties with the gun supplied with the set were experienced in one case, requiring close post-operative follow up. Events such as these highlight the importance of familiarity with particular sets of equipment, which may be as important in determining outcomes as individual surgeon skill.

There is no doubt that early radiological findings and quality of fixation are good predictors of patient reported outcomes and overall construct survivability (27, 28). Individual components have been shown to have their own learning curve and in our study this femoral stem demonstrated an observable learning curve with respect to cement grading (6). Although we did not comment on specific outcomes for individual consultants the general learning curve appears to be short. Better outcomes were seen after 30 cumulative procedures, however it is unclear if this learning curve was complete after 70 cumulative cases. This is of a similar magnitude to that reported by other studies (11, 13).

Extreme leg length discrepancy was actually found to be less in the group new to the stem. This was unexpected as broaching and subsequently inserting the stem is considered the most technical part of this procedure (16). The authors were unable to explain this finding, and the mean leg length fell within acceptable limits for both groups. The perceived, or reported effect of this appears to be negligible in our study, however leg length discrepancy is a common complaint after THA and perceived in as many as 34% of cases (29, 30). Only 2% of patients complained of this in our series, and there were no differences in patient-reported outcomes or dislocations between groups. Again, a trend was observed in the group new to the prosthesis, which may represent surgeons becoming more familiar with this component over time. It is possible that with stem subsidence leg length discrepancy may become more noticeable over time.

We fully acknowledge the limitations of this study. Surgeon related factors are difficult to define, and do not lend themselves readily to research despite these being widely recognized as potential confounders in this field. We did not account for this potential source of bias although we believe the sample size and number of consultants represented represents an average sized orthopaedic unit, and thus the results can be further extrapolated. Fortunately our revision rate was nil, which is in contrast to that of Peltola et al who looked at the effect of introducing a new endoprosthesis on the outcomes of TKA (12). As has previously been suggested, introduction of a new endoprosthesis may carry different risks dependent on the procedure being performed (13). TKA depends heavily on the use of implant specific instrumentation. The role of this in THA is less, which may allow for easier transfer of skills between components and may account for our more positive results.

Overall we would strongly advocate for a cautious approach when implementing policies such as this even at a local scale. Ultimately the real outcome of THA is multifactorial and does not depend on just femoral stem choice. However we have observed several differences in outcomes at an early stage, the long-term effects of which are unclear. Anatomy and the general status of the patient are important considerations for implant choice. Serious consideration should be taken when threatening the surgeons' ability to make this choice. With new technological innovations and pressure to save costs, surgeons' autonomy over component choice may be threatened and this type of policy may become increasingly frequent. This is surely therefore an area that merits further research.

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