Impact of change of knee prosthesis on early clinical outcomes in a large volume arthroplasty centre

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ABSTRACT

INTRODUCTION The aim of our study was to investigate the effect of changing the default knee prosthesis in a high volume dedicated arthroplasty unit from DePuy's PFC® Sigma® to Smith & Nephew's Genesis™ II.

METHODS A retrospective analysis was performed of prospective data on primary total knee replacements (TKRs) from January 2009 until December 2011. This provided information on the operative time, length of stay, pain at mobilisation, radiography analysis, any complications, and readmission at 30 and 60 days.

RESULTS The total numbers of primary TKRs using the PFC® and Genesis™ II prostheses were 1,061 and 1,268 respectively. The results showed a slight increase (maximum of five minutes) in the operative time for all the surgeons except one surgeon, whose operative time reduced by an average of seven minutes. There was no significant adverse outcome after the change in the knee implant. There was no clinically significant increase in the length of stay, pain at mobilisation or complication rates. There was a twofold increase in the wastage of the implant in the Genesis™ II group in the initial learning period.

CONCLUSIONS Through a competitive process of implant tendering, we have successfully introduced a new implant into a large elective orthopaedic unit. This has resulted in significant financial savings without adversely affecting our clinical practice or patient outcome.

KEYWORDS

Recession – Cost effectiveness – Implants – Joint replacement

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In orthopaedic surgery, hip and knee implants form a significant part of the department's cost. One of the ways in which savings can be achieved is through a tendering process for the procurement of implants. Moreover, by choosing a single hip and knee implant, further savings could be achieved. As a result of this process, an unfamiliar implant may be introduced into the department, which can lead to concerns from surgical staff due to unfamiliarity with the implants and instruments, the learning curve involved and the resulting potential complications. There are no published studies in the literature investigating the effect of these changes on clinical practice and patient outcomes.

The aim of our study was to investigate the effect of changing the default knee prosthesis in a high volume dedicated arthroplasty unit. We also looked at the economic impact of this change on our department.

Methods

The Royal Bournemouth Hospital is a National Health Service district general hospital performing high numbers of hip and knee replacements each year, mostly in a specialised arthroplasty unit. The unit has a standardised multidisciplinary pathway for primary hip and knee replacements with the aim of reducing length of hospital stay (LOS) and improving the quality of care provided to patients.

The primary implant for total knee replacements (TKRs) at our elective orthopaedic centre was changed from PFC® Sigma® (DePuy, Warsaw, IN, US) to Genesis™ II (Smith & Nephew, Memphis, TN, US) in October 2010, following a comprehensive tendering process. The Genesis™ II implant was chosen because of good long-term clinical outcome,¹ easy instrumentation and the cost of the implant.

Figure 1 Operative times for the PFC® and Genesis™ II prosthesis groups for the seven surgeons (with standard error of the mean)

Figure 2 The operative times for PFC® and Genesis™ II procedures at three-monthly intervals for Surgeon C (with standard error of the mean)

Prospective data from January 2009 until December 2011 on all primary TKRs were assessed retrospectively. This provided information on the operation date, age at surgery, primary surgeon, assistant, operative time, any complications, and readmission at 30 and 60 days. Another database, which had been maintained by the physiotherapy team since the inception of our elective centre in 2007, was also analysed. The data from this database included LOS, pain at first time mobilisation (from a scale of 0 to 10) and range of movement at discharge from hospital. The data for total hip replacements were analysed as a control to verify both the databases.

The two databases were integrated and further analysis was carried out in Access® and Excel® software (Microsoft, Redmond, WA, US). Initial analysis included operative time, LOS and pain at mobilisation. Further subanalysis was performed for individual surgeons for these criteria. Radiography was also analysed for a three-month period immediately before and after the change of TKR implant. The parameters analysed were femoral and tibial alignment in coronal and sagittal alignment, and anterior notching.

The data were analysed statistically by comparing the group means of dependent variables using Student's t-tests. Statistical significance was set at $p < 0.05$. All analysis was performed in Prism® software (GraphPad Software, La Jolla, CA, US).

Results

Over the 3-year study period, primary TKRs using the PFC® prosthesis were performed on 1,061 knees while the number of cases using the Genesis™ II prosthesis was 1,268. The mean operative time for PFC® and Genesis™ II procedures was 69 minutes (range: 38–157 minutes) and 72.4 minutes (range: 38–203 minutes) respectively ($p < 0.05$). There were 35 surgeons who performed PFC® TKRs while 31 surgeons performed the procedure with Genesis™ II. To reduce the surgeon bias, the operative time of the seven surgeons who performed TKRs with both implants were further analysed. The operative time for this subgroup was 62.6 minutes for PFC® and 64.5 minutes for Genesis™ II ($p = 0.0175$).

The operative times for individual surgeons were also compared (Fig 1). The results showed a slight increase (maximum of five minutes) in the operative time for all the surgeons except one (Surgeon C), whose operative time reduced by an average of seven minutes. His operative time was further analysed for PFC® and Genesis™ II TKRs. Figure 2 shows his PFC® and Genesis™ II operative times at three-monthly intervals.

The average LOS for the PFC® and Genesis™ II group was 4.58 days (range: 2–23 days) and 4 days (range: 2–20 days) respectively. There was no statistical difference in LOS between the two groups. There was also no statistical difference in LOS for the seven surgeons for the PFC® and Genesis™ II TKRs.

The average scores for pain at mobilisation for the PFC® and the Genesis™ II groups were 5.04 and 5.44 respectively ($p = 0.017$).

There was no increase in readmissions at 30 and 60 days postoperatively. There were two patients from the Genesis™ II group who developed pulmonary embolism and required anticoagulation. There was no statistical difference in the early revision rate between the two groups.

Radiography analysis showed equal distribution of outliers in both the implant groups with one case of periprosthetic fracture in each group. There was a statistically significant increase in the number of TKRs with anterior notching from 4.2% for the PFC® to 7.5% for the Genesis™ II group ($p < 0.05$). This was due to the difference in the referencing of the femoral condyle (moved from anterior reference to posterior reference system). However, this did not lead to an increase in the incidence of immediate periprosthetic fractures.

Implant wastage was calculated for the two groups. For the PFC® group, there were nine cases where the surgeon changed his mind regarding the tibial insert, two cases where an incorrect implant was opened and one case where the lip of the tibial insert was damaged during insertion. The total cost of this wastage was £1,959. For the Genesis™ II group, there were 18 cases where the tibial insert was changed because of damage during insertion, three cases of change in

the tibial component and three cases where an incorrect implant was opened. The total cost of this wastage was £3,821.

Discussion

Through a competitive tendering process for a single TKR implant, our department saved approximately 20% of our total prosthesis budget. This level of saving is aided by the fact that we are a large volume arthroplasty unit with approximately 1,100 primary TKRs and 1,000 primary total hip replacements per year.

In our hospital, we had been using the PFC® implant for the previous 20 years, and most of the surgeons in our department were trained and had used the same implant for most of their career. Consequently, there were understandable concerns when the primary knee prosthesis was changed. It was felt important to assess the impact of this significant change on our clinical practice. This study has shown that there was no significant adverse outcome after the change in knee implant. There was no clinically significant increase in operating time or LOS. Although the score for pain at mobilisation was statistically different for the two implant groups, the difference was less than half a point, which is probably not clinically significant. There was no increase in the early complication rates.

In a properly managed tendering process, each department should have the opportunity to test all the prospective implants. In our department, the senior authors had this opportunity. Despite this, there was a learning curve for the department as a whole. We noticed a very mild increase of less than two minutes in the operative time in the Genesis™ II group. Comparing the operative time of the seven surgeons, there was a general trend of minor increase in the operative time except for one surgeon (Surgeon C). Surgeon C has performed the highest number of TKRs in our centre with an average of 30 TKRs for every quarter. There was a slight increase in his operative time in the initial three-month period after the change of implant. The operative time reduced to the same as his PFC® operative time in the following quarter and with increasing experience the operative time reduced further.

Multiple studies have looked at the learning curve for navigated knee replacements.^{2–5} Jenny *et al* carried out a multicentre study on the learning curve in navigated knee replacements on 150 TKRs performed in experienced centres (control group) and 218 TKRs in beginner centres (study group).⁵ No difference was found between the groups except for operating time, which was significantly longer in the study group. However, this increase in operating time disappeared after 30 implantations in all beginner centres. Another study by Smith *et al* showed that the operating time levelled off after 20 cases.⁵

Our study demonstrates that after the introduction of a new implant, the operative time increases (but by less than an average of 5 minutes) and plateaus after 30 TKRs. Our unit has trained arthroplasty fellows for over 20 years, and we believe that appropriate and closely supervised training is fundamental in ensuring a smooth transition between implants.

It was anticipated that the change of implant may lead to pressure on theatre throughput. Careful planning and training of theatre personnel ensured that this effect was minimised. Although there was a slight increase in the operative time during the initial introduction of the new implant, the scale of this was not large enough to have a significant impact. It was therefore possible to maintain our productivity during the initial changeover phase.

In every orthopaedic department there is invariably a degree of implant wastage. We expected an increase in implant wastage during the initial period and this was indeed the case. The implant wastage rate was 0.7% in the PFC® group and 1.9% in the Genesis™ II group. This is still less than that noted by Zywiłł *et al*, who reported implant wastage of 2% in hip and knee replacements with the surgeon and operating room staff bearing primary responsibility in 75% of occurrences.⁶ The main wastage in our Genesis™ II group during the initial learning period was due to the different locking mechanism of the Genesis™ II insert. However, the financial size of this wastage was felt to be insignificant compared with the overall cost savings.

We accept that one weakness of this study is the lack of data comparing the functional outcome of the two groups. Nevertheless, both implants have excellent long-term outcomes.^{1,7–16} We are following up all of these patients for medium to long-term results and recommend that this forms part of the decision on implant change.

Conclusions

Through a competitive process of implant tendering, we have successfully introduced a new implant into a large elective orthopaedic unit that has resulted in significant financial savings without adversely affecting our clinical practice.

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