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Original research

Midterm analysis of the seleXys cup with ceramic inlay

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ABSTRACT

Background: Ceramic-on-ceramic (CoC) articulations in total hip replacement (THR) has been accepted as giving reliable mid-term results; however recent studies have reported higher revision rates of some implants. This study analyses the nationwide results of the seleXys TPS cup and the Bionit2 liner (Mathys, Bettlach, Switzerland) with respect to implant survival, cause for revision and mortality rates compared to other CoC articulations using the same stem.

Methods: Utilising the New Zealand Joint Registry, we compared the seleXys TPS cup with Bionit2 liner used with an uncemented Twinsys femoral stem to every other uncemented CoC THR using the same stem. Multivariate analysis was used to determine the effects of patient age, gender, ASA score and implant head size on these rates.

Results: Between 2006 and 2013 a total of 1035 seleXys THRs were performed on 862 patients. The comparison group had 375 THRs on 280 patients. There were 77 revisions (1.4/100 component years) in the study group and two in the comparison group (0.12/100 component years). Overall hazards ratio for revision was 12.22 times higher and female gender was associated with an increased risk (hazards ratio 1.77). Causes for revision were disturbing noises (23.4%), acetabular loosening (20.8%), and fracture of the liner (18.2%). Mortality rates were not significantly different ($P = .567$).

Conclusions: The seleXys TPS cup with the Bionit2 ceramic inlay coupling has an unacceptably high failure rate. We recommend avoiding this implant coupling and would advise that patients treated with this implant need close clinical and radiological follow-up.

Introduction

Total hip joint replacement (THR) is a common procedure, reliably improving pain, function and mobility [1,2]. However, this procedure continues to be refined to further improve outcomes, with implant design, materials and couplings being the focus of recent advances [3-5].

Modular spherical pressfit acetabular components are commonly used for cementless cup fixation in THRs with the potential for an improved long-term bond between the prostheses and acetabulum if reliable bone ingrowth or ongrowth occurs [6,7].

The seleXys cup (Mathys, Bettlach, Switzerland) is one such system which has been used extensively over the last decade [8-12]. The elliptical design and the slightly flattened pole of the cups allows secure placement within the acetabulum, achieving reliable primary stability. This system is comprised of three different cup types (TPS, titanium plasma sprayed; TH+, tetrahedron+; PC, porous coated), for which five different liners are available; two ceramic (Ceramys and Bionit2), two polyethylene (Standard and Vitamys—vitamin-E-stabilised HXLPE) and one metal (Fig. 1) [13].

The seleXys cup is the successor of the Unicup/Macrofit system, which was introduced in 1996 [14]. The seleXys system was first

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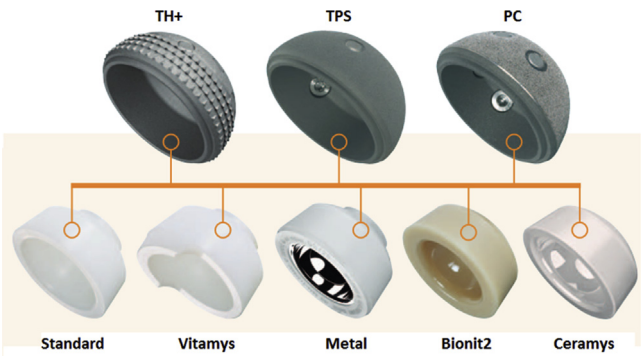

Figure 1. The seleXys family—cups and liners.

implanted in this country in 2005 and various types are still available, but its popularity has reduced since 2010 due to its poor short-term follow-up results with apparently higher revision rates [15-18].

The aim of this study was to analyse the revision rates of the seleXys cup with ceramic inlay to a comparable control group recorded within the New Zealand Joint Registry (NZJR).

Material and methods

The NZJR data was analysed as of 1 March 2016. This registry has national ethical approval and all patients registered gave consent for analysis of their outcome data. The registry data has been collected prospectively since 1999 and the audited capture rate of the NZJR is greater than 95% [12].

Since its introduction to the market in 2006, the seleXys cup with a ceramic liner had been used in 1234 cases. Within New Zealand, only the TPS acetabular component was used with different liners and eight different stem types.

The study group consisted of all THRs using the seleXys TPS cup with a Bionit2 liner and an uncemented Twinsys femoral component (Twinsys, Mathys) as this as the commonest stem used with this articulation (1035/1234 = 83.87%). We used every other THR using the same uncemented Twinsys stem and ceramic inlay recorded in the NZJR as the comparison group (375 cases).

We compared the overall risk of revision (implant longevity) and patient mortality between the two groups after the index procedure and then analysed the effect of gender, age, American Society of Anaesthesiologists (ASA) physical status score and the femoral component head size on these outcomes. Revision was defined as a repeat operation where at least one component was changed and was recorded as a rate/100 component years. The cause for revision was recorded and compared. Mortality was defined as death from the time of the first primary THR, thus in patients with bilateral THR, it was defined as the time from the initial THR.

Statistical analysis was performed using IBM SPSS Statistics 23 (IBM Corporation, Somers, New York). The chi-square test was used to compare the demographics between the two groups. Revision and mortality rates were compared by using the log-rank test. Cox proportional hazards regression was used to determine the independent effect of the prosthesis on the time to revision, allowing for differences in baseline demographics. The level of statistical significance was set at $P = .05$.

Results

The study group consisted of 1035 THRs (862 patients) and the comparison group consisted of 375 THRs (280 patients) implanted between 2006 and 2013, to give a three year minimum follow-up on the NZJR (Fig. 2).

During the study period there were 77 revisions performed on the study group (revision rate of 1.40/100 component years Table 1) and two in the comparison group (revision rate of 0.12/100 component years) which was statistically significant ($P < .001$).

The mortality rates of the two groups are shown in Table 2, where 34 of the 862 patients in the study group had died since their surgery (mortality rate of 0.71/100 person years) compared to, 6 of the 280 patients in the comparison group (mortality rate is 0.48/100 person years) which was not statistically significant ($P = .567$).

The distribution of age, gender, ASA and femoral component head size between the groups is shown in Tables 3-6. The study group had more males ($P < .001$), was younger ($P < .001$) and used larger femoral heads ($P < .028$) than the comparison group, but there was no significant difference in the ASA scores ($P = .116$).

Multivariate analysis was performed on all 1410 cases to find whether gender, age, ASA score and head size distribution are significant predictors of revision or not. The results are shown in Tables 7-10. Female patients ($P = .037$) and femoral head sizes 28 mm or smaller ($P = .028$) had a significantly higher revision rate. The age ($P = .065$) and the ASA score ($P = .444$) lacked statistical significance.

A univariate analysis showed that the study group had an 11.49 times higher risk for revision compared to the comparison group (Table 11). In the multivariate analysis, accounting for the effects of the gender and head size, the two significant predicting factors for revision, the hazards ratio was even greater at 12.22 (Table 12). In addition, the effect of age groups in this multivariate analysis, revealed it to not be a significant predictive factor, with the hazards ratio remaining significantly elevated at 11.525 with age difference accounted for (Table 13).

Our results also showed that examining all 1410 cases a smaller implant head size correlated with female gender, suggesting these are mutual risk factors (Table 14).

The most common reasons for revision of the study group which could be attributed solely to the articulation or acetabular component were disturbing noises (23.4%), loosening of the acetabular component (20.8%), and fracture of the ceramic liner (18.2%). Pain (19.5%) dislocation (14.3%), loosening of the femoral component (10.4%), deep infection (5.2%) and periprosthetic femoral fracture (3.9%) also contributed. Fifteen patients had two or more reasons for the revision.

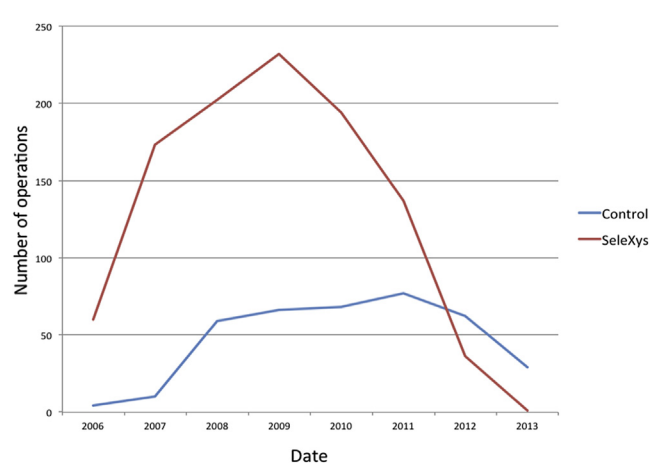

Figure 2. Number of operations performed during the study period.

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