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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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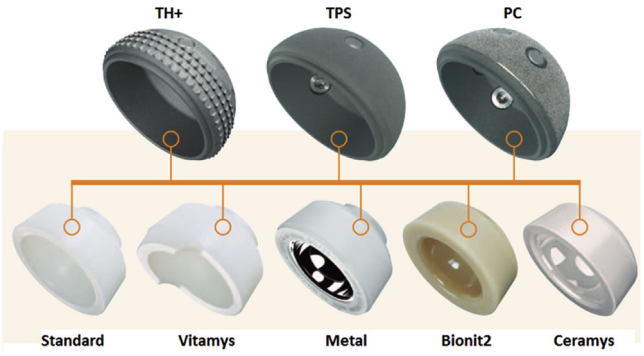

Figure 1. The seleXys family—cups and liners.

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.

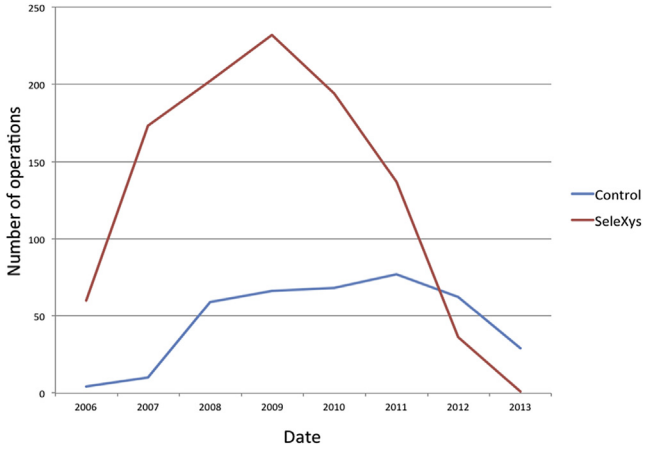

Figure 2. Number of operations performed during the study period.

Table 1
Revision rates between the groups ($P < .001$).

Prosthesis	Procedures	Component years	Revised	Rate/100 component years	Lower 95% CI	Upper 95% CI
Non-seleXys	375.00	1610.7	2	0.12	0.01	0.40
SeleXys	1035.00	5517.8	77	1.40	1.09	1.73
Total	1410.00	7128.6	79	1.11	0.87	1.37

Table 2
Mortality rates between the groups ($P = .567$).

Prosthesis	Patients	Person years	Deceased	Rate/100 person years	Lower 95% CI	Upper 95% CI
Non-seleXys	280.00	1237.73	6	0.48	0.18	1.06
SeleXys	862.00	4820.34	34	0.71	0.49	0.99
Total	1142.00	6058.07	40	0.66	0.47	0.90

Table 3
Gender distribution between the groups ($P < .001$).

Gender	Non-seleXys	SeleXys	Total
Female	58.9%	44.6%	48.4%
Male	41.1%	55.4%	51.6%

Table 4
Age distribution between the groups ($P < .001$).

Age (y)	Non-seleXys	SeleXys	Total
<55	26.4%	37.4%	34.5%
55-64	32.8%	40.8%	38.7%
65-74	37.1%	20.1%	24.6%
≥75	3.7%	1.7%	2.3%

Table 5
ASA distribution between the groups ($P = .116$).

ASA	Non-seleXys	SeleXys	Total
1	36.8%	30.9%	32.5%
2	54.9%	58.4%	57.5%
3	8.3%	10.4%	9.8%
4	0.0%	0.3%	0.2%

Table 6
Head size distribution between the groups ($P < .001$).

Head size (mm)	Non-seleXys	SeleXys	Total
≤28	0.0%	6.6%	4.8%
32	45.9%	31.1%	35.0%
36	54.1%	62.3%	60.1%

Table 7
Gender as a predictor of revision ($P = .037$).

Gender	Not revised	Revised	Total
Female	47.8%	59.5%	48.4%
Male	52.2%	40.5%	51.6%

Table 8
Age as a predictor for revision ($P = .065$).

Age (y)	Not revised	Revised	Total
<55	33.7%	48.1%	34.5%
55-64	39.1%	30.4%	38.7%
65-74	24.8%	21.5%	24.6%
≥75	2.4%	0.0%	2.3%

Table 9
ASA score as a predictor for revision ($P = .444$).

ASA	Not revised	Revised	Total
1	32.8%	30.4%	32.7%
2	56.9%	64.6%	57.3%
3	10.1%	5.1%	9.8%
4	0.2%	0%	0.2%

Table 10
Head size as a predictor for revision ($P = .028$).

Head size	Not revised	Revised	Total
≤28	4.5%	10.1%	4.8%
32	34.9%	38.0%	35.0%
36	60.6%	51.9%	60.1%

Table 11
Univariate hazards ratio analysis of the seleXys cup.

	P-value	Hazards ratio	95% confidence interval	
			Lower	Upper
SeleXys	.001	11.49	2.82	46.82

Table 12
Multivariate analysis of the variables predicting revision—gender and head size.

	P-value	Hazards ratio	95% confidence interval	
			Lower	Upper
Gender (female)	.016	1.77	1.11	2.82
Size (≤28)	.475	0.76	0.35	1.62
SeleXys	.001	12.22	2.98	50.01

Table 13
Multivariate analysis of the variables predicting revision—age, gender and head size.

	P-value	Hazards ratio	95% confidence interval	
			Lower	Upper
Gender (female)	.019	1.75	1.10	2.79
Size (≤28)	.469	1.32	0.62	2.83
SeleXys	.001	11.53	2.81	47.29
Age group	.173	0.82	0.61	1.09

Table 14
Correlation between head size and gender.

Implant head size	Female gender	Male gender
28 or smaller	95.4%	4.6%
32	81.5%	18.5%
36	23.3%	76.7%

Discussion

New Zealand has a population of 4.6 million people [19]. Between January 1999 and March 2016 more than 100,000 primary THRs had been recorded on the NZJR. There are over 1000 THR combinations recorded but only 202 of which have had more than 50 implants inserted. Since 2005 the seleXys cup with a ceramic liner was used in New Zealand in 1234 cases and was one of the top 10 acetabular components used between 2008 and 2010 [8-10]. However, our results show an unacceptably high revision rate of 1.4/100 component years for this implant in contrast to a revision rate of 0.12/100 component years of every other ceramic on ceramic THR using the same uncemented Twinsys stem. Multivariate analysis would suggest that when compared with other CoC articulations that this result is likely to be implant specific.

The patients in the study and comparison groups were not randomised, and there was a significant difference in relation to gender, age and prosthesis head size (Tables 3-6). We have purposely used a comparison group which was based on the femoral stem in order to try and isolate failure secondary to the acetabulum and articulation surfaces alone and therefore there was no attempt to match the two groups. We realised that it could be a serious bias in our study so we also examined how these differences can influence our results. Tables 7-10 show that examining all 1410 cases only gender and femoral head size are significant predictors of revision, age and ASA score of the patient are not. Female gender and small head size were associated with a higher revision rate in the univariate analysis, however on multivariate analysis the effect of head size was found to be related to female gender, rather than an independent risk factor for revision. Furthermore, on multivariate analysis accounting for the gender and head size differences between the groups a hazards ratio of 12.22 was found for the study group.

This is consistent with other studies published over the last few years [16-18,20]. Ilchmann and colleagues (2010) reported on their first 115 seleXys TH+ cups combined with a Ceramys liner, and showed that 5.3% of their implants had aseptic acetabular loosening within 20 months [20]. This was later supported by Haverkamp and colleagues (2013), who experienced an unacceptable high revision rate of 7.4% in their 257 elective THRs using the seleXys TH+ acetabular component combined with a Ceramys liner during a short 3-21 months follow-up period [18]. More recently Brodt and colleagues (2015) presented their results of 280 seleXys TH+ acetabular components and found a similar revision rate of 10% within 48 months [16].

A recent analysis of the Australian Orthopaedic Association's National Joint Replacement Registry (AOAJNRR) indicated that the revision rates for the seleXys TH+ and TPS acetabular shells were higher than expected. The individual revision rates are 4.28/100 component years for seleXys TH+ acetabular shells and 1.79/100 component years for seleXys TPS shells. The revision rate for all other THRs on the registry is 0.68/100 component years. These high revision rates resulted in Mathys Orthopaedics ceasing its supply of seleXys TH+ acetabular shells in April 2013 and seleXys TPS shells in June 2014, with a hazard alert for the seleXys TH+ and TPS acetabular shells being released in September 2015 [21]. Both implants have subsequently been cancelled from the Australian Register of Therapeutic Goods [22].

In the current study, the most common reasons for revision were disturbing noises, loosening of the acetabular component, pain and fracture of the ceramic liner. These findings are consistent with the results of the prospective cohort study of 181 cups published by Ilchmann and colleagues (2014) as well as the AOAJNRR [17].

Squeaking and disturbing noises in ceramic-on-ceramic THRs are well recognised [3,23-25]. The exact aetiology is unknown, but is likely multifactorial, including component design, patient weight, cup malposition, abnormal wear patterns and soft tissue crepitus. However revision due to abnormal noise or ceramic liner fracture is uncommon with the NZJR recording a 8.2% and 7.8% incidence respectively across all CoC articulations over 16 years. The 23.4% and 18.2% incidence in this study group is alarming. Again, this is a recognised complication of THR and may relate to implant malposition [26-28]. Unfortunately, NZJR data fails to assess implant position and therefore limits our study's ability to discern the cause of ceramic liner fracture. The controversy between utilisation of a larger femoral head for stability, at the sacrifice of a thinner liner, which may predispose to fracture is not answered by this study [27,29-31].

Aseptic loosening of the acetabular component is also a recognised complication of uncemented THR [17,26] and occurred in 20.8% of the study patients. This rate is higher than expected for implants with a medium term follow up and may be related to cup design or debris secondary to excessive ceramic wear. The high incidence of noise and ceramic fracture suggests that the problem may reside with the ceramic articulation.

Patient mortality was not significantly different between our two study groups. Although our study is limited by defining mortality as time from the initial THR, as in bilateral cases, there was no evidence to suggest that the seleXys cup increases the risk of patient mortality.

Conclusions

This study shows that the seleXys TPS cup with the Bionit2 ceramic liner has an unacceptably high revision rate of 1.4/100 component years. Disturbing noises, acetabular component loosening, and fracture of the ceramic liner are the main causes for revision. Due to our findings we recommend against using this combination and suggest patients treated with this implant should undergo close clinical and radiological follow-up.

References

[1] Gaffey JL, Callaghan JJ, Pedersen DR, et al. Cementless acetabular fixation at fifteen years. A comparison with the same surgeon's results following acetabular fixation with cement. J Bone Joint Surg Am 2004;86-A(2):257.
[2] Stefl MD, Callaghan JJ, Liu SS, et al. Primary cementless acetabular fixation at a minimum of twenty years of follow-up: a concise update of a previous report. J Bone Joint Surg Am 2012;94(3):234.
[3] Restrepo C, Parvizi J, Kurtz SM, et al. The noisy ceramic hip: is component malpositioning the cause? J Arthroplasty 2008;23(5):643.
[4] Mäkelä KT, Eskelinen A, Pulkkinen P, Paavolainen P, Remes V. Total hip arthroplasty for primary osteoarthritis in patients fifty-five years of age or older. An analysis of the Finnish arthroplasty registry. J Bone Joint Surg Am 2008;90(10):2160.
[5] Mäkelä KT, Eskelinen A, Pulkkinen P, Paavolainen P, Remes V. Results of 3,668 primary total hip replacements for primary osteoarthritis in patients under the age of 55 years. Acta Orthop 2011;82(5):521.
[6] Tice A, Kim P, Dinh L, Ryu JJ, Beaulé PE. A randomised controlled trial of cemented and cementless femoral components for metal-on-metal hip resurfacing: a bone mineral density study. Bone Joint J 2015;97-B(12):1608.
[7] Kim YH, Park JW, Kim JS, Kim IW. Twenty-five- to twenty-seven-year results of a cemented vs a cementless stem in the same patients younger than 50 years of age. J Arthroplasty 2016;31(3):662.
[8] Hobbs T, Rothwell A, Henwood A. New Zealand Orthopaedic Association The New Zealand Joint Registry ten year report January 1999 to December 2008. New Zealand: New Zealand Orthopaedic Association; 2008.
[9] Hobbs T, Rothwell A, Henwood A. New Zealand Orthopaedic Association The New Zealand Joint Registry 11 year report January 1999 to December 2009. New Zealand: New Zealand Orthopaedic Association; 2009.
[10] Rothwell A, Henwood A, Hobbs T. New Zealand Orthopaedic Association the New Zealand Joint Registry twelve year report January 1999 to December 2010. New Zealand: New Zealand Orthopaedic Association; 2010.
[11] Rothwell A, Larmer P, Hobbs T, Rothwell A. The New Zealand Joint Registry Annual Report Editorial Committee. New Zealand: New Zealand Orthopaedic Association; 2014.
[12] Rothwell A, Larmer P, Hobbs T, Rothwell A. The New Zealand Joint Registry annual report 2015. New Zealand: New Zealand Orthopaedic Association; 2015.

[13] Mathys. seleXys ® Modular cementless press-fit cup system - surgical technique. Switzerland: Mathys Ltd Bettlach; 2009.
[14] Jovanovic M, Russlies M, Hoffmann F. First five year results of the seleXys ® TPS Cup. Switzerland: Mathys Ltd Bettlach; 2005. p. 2–3.
[15] Thomas I, Milan J, Thomas-Peter R, et al. Preliminary results of a new nanocrystalline dispersion ceramic 'ceramys'. 2009. p. 1–4. Http://Www.Mathysmedical.Com/ [accessed 01.09.16].
[16] Brodt S, Matziolis G, Windisch C, et al. High failure rate of a new pressfit cup in mid-term follow-up. Int Orthop 2015;39(9):1813.
[17] Ilchmann T, Zwicky L, Gersbach S, Clauss M. Poor outcome of a spherical pressfit cup with a modern ceramic liner: a prospective cohort study of 181 cups. Hip Int 2014;24(4):333.
[18] Haverkamp D, Westerbos S, Campo MM, et al. Early loosening of a press-fit cup with ceramic-on-ceramic articulation: our early results. Arch Orthop Trauma Surg 2013;133(12):1757.
[19] Statistics NZ. 2013 Census. 2016 [Online], http://www.stats.govt.nz/Census/2013-census.aspx [accessed 01.09.16].
[20] Clauss M, Ilchmann T, Pannhorst S, Abächerli C. Early failure of a spherical pressfit cup. Swiss Med Wkly 2010;140(23-24):5S.
[21] Mathys Ltd. Bettlach. Urgent field safety notice. Switzerland: Mathys Ltd Bettlach; 2015.
[22] D. of H. | T. G. A. (TGA) Australian Government. SeleXys TH+ and TPS acetabular shells used in hip replacements. 2015 [Online], https://www.tga.gov.au/alert/selexys-th-and-tps-acetabular-shells-used-hip-replacements., https://www.tga.gov.au/alert/selexys-th-and-tps-acetabular-shells-used-hip-replacements [accessed 1.10.16].
[23] Wyatt MC, Jesani S, Frampton C, et al. Noise from total hip replacements a case-controlled study. Bone Joint Res 2014;33(6):183.
[24] Hoffmann F, Jovanovic M, Muschik M. Head size in relation to noise occurrence in ceramic-on-ceramic bearings. Tribol Total Hip Arthroplast 2011;28:91.
[25] Hothan A, Huber G, Weiss C, Hoffmann N, Morlock M. The influence of component design, bearing clearance and axial load on the squeaking characteristics of ceramic hip articulations. J Biomech 2011;44(5):837.
[26] Iamthanaporn K, Chareancholvanich K, Pornrattanamaneewong C. Revision primary total hip replacement: causes and risk factors. J Med Assoc Thai 2015;98(1):93.
[27] Lee YK, Ha YC, Koo KH. Comparison between 28 mm and 32 mm ceramic-on-ceramic bearings in total hip replacement. Bone Joint J 2014;96-B(11):1459.
[28] Traina F, De Fine M, Bordini B, Toni A. Risk factors for ceramic liner fracture after total hip arthroplasty. Hip Int 2012;22(6):607.
[29] Furnes O, Paxton E, Cafri G, et al. Distributed Analysis of Hip Implants Using Six National and Regional Registries: Comparing Metal-on-Metal with Metal-on-Highly Cross-Linked Polyethylene Bearings in Cementless Total Hip Arthroplasty in Young Patients. J Bone Joint Surg Am 2014;96 Suppl 1:25.
[30] Howie DW, Holubowycz OT, Middleton R. Large femoral heads decrease the incidence of dislocation after total hip arthroplasty: a randomized controlled trial. J Bone Joint Surg Am 2012;94(12):1095.
[31] Jameson SS, Lees D, James P, et al. Lower rates of dislocation with increased femoral head size after primary total hip replacement: a five-year analysis of NHS patients in England. J Bone Joint Surg Br 2011;93(7):876.