# THE IMPACT OF BODY MASS INDEX ON PATIENT REPORTED OUTCOME MEASURES (PROMs) AND COMPLICATIONS FOLLOWING PRIMARY HIP REPLACEMENT


## Abstract

*The influence of BMI upon patient-reported outcomes (OHS/EQ-5D index) and complications following THR was examined for a cohort of patients using linked national data. Outcomes were compared across BMI groups (19.0kg/m$^2$-29.9kg/m$^2$ [Reference], 30.0kg/m$^2$-34.9kg/m$^2$ [Obese class I], 35.0kg/m$^2$+ [Obese class II/III]), adjusted for case-mix differences. Obese class I patients had a significantly smaller improvement in OHS (18.9 versus 20.5, $p<0.001$) and a greater risk of wound complications (odds ratio [OR]=1.57, p=0.006). For obese class II/III patients, there were significantly smaller improvements in OHS ($p<0.001$) and EQ-5D index ($p<0.001$), and a greater risk of wound complications (p=0.006), readmission (p=0.001) and reoperation (p=0.003). Large improvements in OHS and EQ-5D index were seen irrespective of BMI, although improvements were marginally smaller and complication rates higher in obese patients.*

## Introduction

Body mass index (BMI) and rates of obesity within the population are increasing across the developed world (1), resulting in poorer general health and greater risk of lower limb osteoarthritis (OA) (2, 3). The National Joint Registry (NJR) in England and Wales has noted a year-on-year increase in total hip replacements (THRs) performed overall and in obese patients, with 38% having a BMI over 30kg/m$^2$ in 2011 compared with less than 30% in 2003 (4).

There is some evidence that lower limb arthroplasty in obese patients is more technically demanding (due to instrumentation issues), takes longer to perform (5), is associated with higher surgical and medical complications in the early post-operative period (6, 7), and outcomes such as function and implant longevity may be poorer (8-10). Thus, raised BMI might be used to ration primary THR in a public funded health service, in effect denying patients access to surgical intervention (11). Restrictions might apply to BMIs >35kg/m$^2$, although lower cut-off limits have been proposed (12). However, the evidence for denying access to a hip surgeon for patients with a high BMI is limited, and may be inappropriate (13, 14).

Patient reported outcome measures (PROMs) offer patient-centred evidence of the benefit of a procedure, and supplement clinical measures traditionally used to assess the success of joint replacement such as risk of revision (15). PROMs have been routinely collected by the Department of Health (DoH) for National Health Service (NHS) patients undergoing THR in England and Wales since 2008. PROMs include a joint specific score, a general health measure and self-reported complication data. These can now be linked to the NJR dataset in order to compare early outcomes for specific patient and implant groups at a national level.

This analysis explores the impact of BMI on PROMs and complications following primary THR.

## Methods

### *Design*

A retrospective cohort study was conducted using prospectively collected patient-level NJR and PROMs-linked data to compare general and joint specific outcome scores and self-reported complications at a minimum 6 months following primary THR in patients with varying BMI.

### *Data*

Data on hip replacement patients, their surgeons and implants used are collected by the NJR across England and Wales. The national PROMs study collects joint-specific and general health scores pre- and six months post-operatively. Self-reported post-operative complications are also available. By linking the two datasets at the level of the patient we were able to combine PROMs with the corresponding demographic and operative details held in the NJR. In order to link the two datasets a number of linkage criteria were used. Firstly, to ensure correct matching, two unique identifiers (NJR and procedure numbers) recorded in both datasets were used. Secondly, the operation date recorded by the patient in the PROMs data had to be within +/-30 days of the operation date recorded on the NJR record, to ensure the patient was scoring the same procedure.

We chose to perform the analysis using the single most commonly used brand of cemented and cementless THR, in order to control for any implant influences while providing widely applicable results for THRs performed in England and Wales. According to the NJR 8$^{th}$ Annual Report, the commonest cemented THR brand used since 2003 is the Exeter V40 hip and Contemporary socket (Stryker Orthopaedics, Mahwah, New Jersey, United States), accounting for 23.2% of all cemented THRs (37,995 of 163,981) (16). The Corail stem/Pinnacle cup (DePuy Ltd, Leeds, United Kingdom) is the most commonly used cementless THR (31.2% [40,879] of 130,920 cementless THRs).

There were a number of exclusion criteria. For the NJR data these were: all procedures with an indication other than OA, procedures with missing implant or patient data, and procedures with missing or outlying BMI (<19kg/m$^2$ or >65kg/m$^2$) data were excluded. Procedures with PROMs data that were missing, undated, dated more than 12 months prior to or following the operation, or non-identical duplicates were excluded; for identical duplicates the first record was retained for analysis. Where the presence of a co-morbidity or complication was sought in the questionnaire but left blank by the patient, it was assumed to be absent. The study population is summarised in Figure 1. The demographic, surgical and implant-related variables available for analysis are listed in Table 1.

The national PROMs project uses validated measures of hip-specific (Oxford hip score [OHS]) (17) and general health outcomes (EuroQol [EQ-5D-3L]) (18). For this analysis the outcomes of interest were improvements between the pre- and post-operative scores (the ‘change scores’) and self-reported post-operative complications (bleeding, wound problems, readmission and reoperation). Change scores, being approximately normally distributed, are analytically preferable to post-operative scores (19). The OHS (scored 0 lowest to 48 highest) has previously been shown to be a reliable, valid and responsive outcome measure and can be used for the clinical assessment of large hip arthroplasty databases in a cross-sectional population (20). The EQ-5D-3L consists of 2 parts - the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D descriptive system evaluates five different aspects of general health (mobility, self-care, usual activities, pain/ discomfort and anxiety/depression). Each dimension has 3 levels: no problems, some problems, extreme problems. The respondent indicates his/her health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the 5 dimensions. These scores are then combined using population weightings to produce a single index value (-0.59 to 1.00) for health status (18). The EQ VAS records the respondent's self-rated health on a visual analogue scale where the endpoints are 'best imaginable health state' and 'worst imaginable health state'. This information can be used as a quantitative measure of health outcome; variations over time can be used for clinical and economic appraisal. The EQ-5D-3L is commonly used throughout Europe for assessment in a variety of different clinical settings, including joint replacement, and was chosen by the Department of Health in the United Kingdom as the most suitable generic health measure for the PROMs project because reliable UK population weighting values were available (21) (For more information on EuroQol assessment visit http://www.euroqol.org). Patients are also asked about comorbidities, general health and self-reported disability as part of the pre-operative PROMs questionnaire. These can be used to understand and match the differences in health status between patient groups. Sample sizes for all the BMI groups were in excess of the minimum numbers identified in the PROMs feasibility pilot to identify meaningful differences (more than 150/group) (19).

***Statistical analysis***

The variables available for the analyses are shown in Appendix Table 1. To align with its clinical application, BMI was grouped into three categories: 19.0kg/m$^2$-29.9kg/m$^2$ (normal and overweight - reference group), 30.0kg/m$^2$-34.9kg/m$^2$ (Obese class I), 35.0kg/m$^2$+ (Obese class II and III). BMI was also assessed as a continuous variable to ensure BMI categorisation did not qualitatively alter the findings. Differences in baseline characteristics across the BMI groups were analysed using analysis of variance test (ANOVA, continuous data variables) or

Chi-square test (categorical data variables). Analyses of cemented and cementless procedures were performed independently as no attempt was made to adjust for baseline differences between types of implants.

Univariable analysis was performed initially to identify variables potentially influencing each outcome, based on statistical rejection criteria of $p>0.10$; these variables were then included in the multi-variable models. Analysis of covariance (ANCOVA) was used for testing differences in OHS and EQ5D index change scores across BMI groups. Multi-variable logistic regression was used to analyse differences in the risk of each of the complications across BMI groups. Time from implantation to questionnaire completion was included in models to evaluate whether differences in duration of follow-up influenced findings. Pre-operative scores were included within all models, as recommended by the Oxford group (20).

Reflecting analysis of a large dataset, statistical models for the change scores were evaluated with the margins function in STATA in order to provide predicted values (including 99% confidence intervals) for each of the BMI categories. P-values are provided as statistical tests of the differences between the reference and other BMI categories. For complication risks, results are presented as odds ratios (ORs) with 99% CIs: ratios greater than one indicate that risk is higher when compared with the reference BMI category. Due to the statistical methods employed, and the large population size, only covariates fitting models with $p<0.01$ were considered significant influences, to reduce the risk of Type 1 error. All models were fitted using STATA 12 (StataCorp LP, Texas, USA).

In order to provide 'real-world' clinical scenarios, predicted changes in OHS were produced for the cemented model using the margins function in STATA. This demonstrated the differences in hip specific improvement when sex, differences in pre-existing health status and disability, and level of pre-operative OHS were specified within the model, in addition to BMI.

## Results

There were 8547 NJR-PROMs linked primary procedures, of which 65% had BMI data. Of the remaining 5535, 2656 were cemented Exeter Contemporary and 2879 were cementless Corail Pinnacle.

***Cemented hip replacement baseline characteristics***

There were 1640 patients (61.7%) with a BMI of 19 to 29.9kg/m$^2$, 695 (26.2%) 30 to 34.9kg/m$^2$ and 321 (12.1%) 35kg/m$^2$ and over (Table 1). Obese patients were more likely to be younger ($p<0.001$), female ($p=0.002$) and have a higher ASA grade ($p<0.001$). Similarly, diabetes ($p<0.001$) and hypertension ($p<0.001$) were more prevalent in patients with higher BMI, but proportions of other comorbidities were not significantly different. Pre-operative general health ($p<0.001$) was poorer and self-reported disability ($p<0.001$) more common in obese patients.

Pre-operative scores were significantly lower in obese patients (OHS: $p<0.001$, EuroQol VAS: $p<0.001$, EQ5D index: $p<0.001$); time from operation to post-operative questionnaire completion was similar across groups (209.0 to 209.6 days, $p=0.636$) (Table 1).

***Cementless hip replacement baseline characteristics***

There were 1738 patients (60.4%) with a BMI of 19 to 29.9kg/m$^2$, 713 (24.8%) 30 to 34.9kg/m$^2$ and 428 (14.9%) 35kg/m$^2$ and over (Table 2). Similarly to the cemented group, obese patients were more likely to be younger ($p<0.001$) and have a higher ASA grade ($p<0.001$), but there were no differences in proportions of females. Diabetes ($p<0.001$), hypertension ($p<0.001$) and depression ($p=0.006$) were more prevalent in patients with higher BMI, but proportions of other comorbidities were not significantly different. Pre-operative general health (p<0.001) was poorer and self-reported disability (p<0.001) more common in obese patients.

Pre-operative scores were significantly lower in obese patients (OHS: p<0.001, EuroQol VAS: p<0.001, EQ5D index: p<0.001); time from operation to post-operative questionnaire completion was similar across groups (207.6 to 210.0 days, p=0.985) (Table 2).

***Surgical factors***

The majority of operations were performed through the posterior approach (cemented: 55.4% [1471]; cementless: 63.6% [1830]), with the patient in a lateral position (79.1% [2102]; 78.4% [2256]), by a consultant (64.0% [1700]; 77.0% [2216]), and using regional anaesthesia (78.8% [1792]; 80.4% [1923]). Low molecular weight Heparin (53.6% [1218]; 66.2% [1593]) and mechanical methods (80.3% [2133]; 89.9% [2636]) were used as venous thromboembolic prophylaxis in the majority of cases (Table 3).

***Oxford Hip Score improvement***

For the cemented procedure, univariable analysis showed no differences in OHS improvement across the BMI groups. However, after adjusting for other influential variables, when compared with the reference BMI group (20.5, 99% CI 20.0 to 21.1), both obese class I (18.9, 99% CI 18.1 to 19.8, p<0.001) and class II/III patients (18.7, 99% CI 17.5 to 19.9, p<0.001) had a significantly lower improvement in OHS (Table 4).

For cementless procedure, there was no difference in OHS improvement between BMI groups in univariable analysis. After risk adjusting, when compared with the reference BMI group (21.5, 99% CI 21.1 to 22.1), obese class II/III patients (20.0, 99% CI 18.9 to 21.0, p<0.001) had a significantly lower improvement in OHS (Table 5).

In the ‘real-world’ scenarios, when a male patient with a BMI between 19 and 29.9kg/m$^2$ reporting a pre-operative OHS of 10, no disability, very good preoperative health and minimal comorbidities undergoes a cemented THR, they should expect an improvement in OHS of 32. A female patient with a BMI of 35kg/m$^2$+, self-reported fair health, presence of disability and co-morbidities and a pre-operative OHS of 25, an improvement in OHS of only 9 was predicted. Self reported disability, pre-operative function and health scores, and comorbidities were greater influences on OHS change than BMI. A lower pre-operative OHS predicts a greater improvement, whilst presence of a disability and comorbidities, poorer health and higher BMI predicts lower improvements in OHS (Table 6).

***EQ5D index improvement***

For the cemented procedure, there were no differences in EQ5D index improvement between BMI groups in univariable analysis. After risk adjusting, both obese class I (0.394, 99% CI 0.372 to 0.416, p=0.036) and class II/III patients (0.387, 99% CI 0.353 to 0.420, p=0.043) had lower improvement in EQ5D index when compared with the reference BMI group (0.416, 99% CI 0.401 to 0.431), but neither was significant at the threshold value (Table 4).

For the cementless procedure and univariable analysis, the EQ5D index improvement was actually higher in obese class II/III patients (0.453, 99% CI 0.410 to 0.497, p=0.016) when compared with the reference group (0.408, 99% CI 0.386 to 0.429), but this failed to reach the significance threshold specified. However, after risk adjustment obese class II/III patients

(0.371, 99% CI 0.341 to 0.401, p<0.001) had a significantly lower improvement in EQ5D index compared with the reference BMI group (0.425, 99% CI 0.410 to 0.441) (Table 5).

***Risk of complications***

In the cemented group there was a significantly increased risk of complications in obese class II/III patients compared to the reference group, adjusted for other variables: wound complications, OR=2.06, 99% CI 1.25 to 3.40, p<0.001; readmission, OR=1.99, 99% CI 1.17 to 3.39, p=0.001; and, reoperation, (OR=2.73, 99% CI 1.14 to 6.53, p=0.003). Complications were less pronounced in obese class I patients with only wound complications being significant at the 1% level (p<0.01), OR=1.57, 99% CI 1.03 to 2.38, p=0.006. Bleeding risk was similar across all groups (Table 7).

For the cementless group, wound complications were significantly higher in obese class II/III patients (OR=2.39, 99% CI 1.52 to 3.75, p<0.001) when compared to the reference group, after risk adjusting. Complication risk between the reference and other BMI groups for bleeding, readmission and reoperation were similar (Table 8).

## Discussion

This retrospective cohort study using NJR-PROMs linked data provides evidence of large improvements in OHS and EQ5D index at 6 months following surgery irrespective of BMI, although improvements were marginally smaller and complication rates higher in obese patients, after adjusting for other influences. Our key finding was that joint specific and general health gains were lower and the complication risks higher as BMI increased from obesity class I to II/III. These findings were similar for both cemented and cementless implants. We also found that a number of other variables influence outcome scores in addition to BMI including self reported disability, pre-operative function and health scores, and comorbidities. This finding is clinically important as it can be used to describe the potential benefit in function, together with the risks of complications, to individual patients. It also provides evidence that BMI in isolation should not be the sole determinant of restrictions in referral to orthopaedic services.

Whilst this is the largest study to date to report the affect of BMI on functional outcome within single THR brands, there are some potential limitations for the findings. The study design is observational and thus vulnerable to omitted variables, which may have confounded our findings. Some data were unavailable for analysis; for example, radiological data on cup positioning (which may be more difficult in patients with higher BMI). Moreover, there were large numbers of procedures that could not be analysed, either because of dataset linkage issues, missing NJR or PROMs data fields or absent BMI data (35% of the linked NJR-PROMs data). Despite these limitations, the data available for analysis were extensive and adjustments for differences in the baseline characteristics of BMI groups (where available) were performed. In addition, similarities between the unadjusted and adjusted models, and robustness under different model fitting assumptions support the stability of estimates.

It could be argued that all THR brands should be examined to increase numbers for analysis and broaden the scope of findings of the study. By restricting the implants to only the most commonly used from each group we were able to remove difficulties adjusting for the performance of different brands, which may be used in far smaller numbers and propensity in different sub-groups of patients.  The two implants analysed represent 29% (100,803) of all cemented and cementless implants (344,185) used in England and Wales since 2003.  The remaining 71% are made up of 140 femoral stem brands and 117 acetabular components (4). Despite the exclusion of other brands, the study cohort provided adequate numbers of procedures for analysis according to recommendations for sample size arising from the PROMs feasibility study (19) and by the Oxford score design group (20). Additionally, our sensitivity analyses, based on commonly used component sets in each type of hip, provided similar results, suggesting our findings may generalize across different bearings, head sizes and fixation methods.

Pre-operative health scores were included in our multi-variable analyses; it might be argued that these should not be included since patients with higher BMI are likely to have poorer function, potentially creating a flaw in the study findings, as multi-variable testing adjusts for the effect of pre-operative function. However, demographic data supports this; whilst different BMI groups were not exactly matched in terms of pre-operative scores, the differences were clinically small. Moreover, by providing predicted OHS improvements for different clinical situations, this study has confirmed that BMI is only one of several important variables influencing outcome, and its (independent) influence on change score is small. Interestingly, the differences in OHS improvement across groups is less than the threshold of 3 points suggested by the OHS designers to demonstrate a clinical important difference (20).

Previous work has demonstrated that risk of revision is significantly (1.5 times) higher in patients with a BMI >30kg/m$^2$ following cementless hip replacement with a Corail/Pinnacle (10), although BMI was not found to influence implant survival in analyses of the cemented Exeter Contemporary (22). This could be a result of greater subsidence risk with cementless implants in patients with a higher BMI, or may be an erroneous finding, as previously published work has proposed that weight rather than BMI directly influences implant survival (23).

Other studies of suggest that arthroplasty patients with a high BMI may have more complications (7), including a greater risk of infection (24) and dislocation (9, 25), slower recovery (26), and poorer function (9) after THR. However, several studies have found consistently good improvement irrespective of BMI with comparable satisfaction and implant survival (27-29). A study of 3290 THR patients found that morbidly obese (BMI>40kg/m$^2$) patients had a similar change in outcome scores postoperatively to those with lower BMIs. Although final outcome scores were found to be lower (as in this current study) and complications higher, the authors concluded that morbidly obese patients may have as much to gain from THR as patients with a lower BMI (13). This view was supported by an analysis of 1421 THRs by Andrew et al, in which no difference in OHS was found at 5 years between BMI groups (14). In addition, they found little difference in change of OHS between 3 months and 5 years following replacement, suggesting that the results at 6 to 12 months post-operatively in our current study are a reliable indication of longer-term outcome. Interestingly, a similar study on TKR patients (without separate brand analysis) found no difference in change scores across different BMIs in 13,673 procedures (30).

In summary, patients experience a good improvement in outcome following THR irrespective of BMI. However, improvements were slightly smaller and complication rates higher in obese patients, after adjusting for other influences. A number of other patient variables also influence outcome scores in addition to BMI. In terms of improvement in health and function, a high BMI in isolation should not be a justifiable reason for denying surgery within a public funded health service. This sub-group of patients should be counselled that improvement following hip replacement is likely to be less than that for an equivalent normal weight individual. Strategies to lower BMI, such as pre-operative weight loss programmes (including bariatric intervention (31)), should be considered.

Word count: 3257

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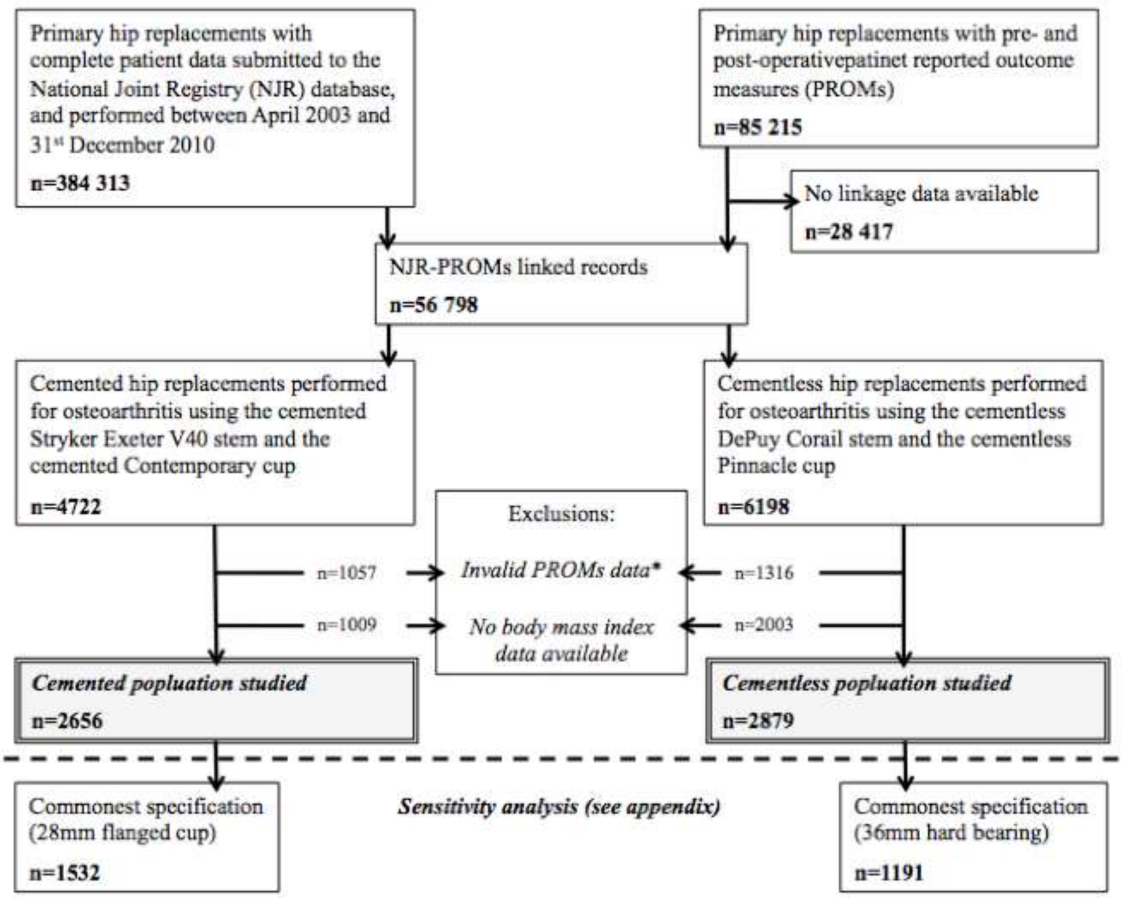
**Figure 1.** Flowchart describing study cohort




*Invalid PROMs data includes records with missing outcome score records, pre-operative scores dated more than 12 months prior to the operation, post-operative records without a date or dated <6 months or >12 months following the primary hip replacement, non-identical duplicates (all excluded) and identical duplicates (only one record retained)

**Table 1.** Patient demographics and PROMs data for cemented Stryker Exeter V40 Contemporary hip replacement, by body mass index

| | All patients | Body mass index | | | *Differences between BMI groups** |
|---|---|---|---|---|---|
| | | *19 to 29.9kg/m²* *(Reference group)* | *30 to 34.9kg/m²* *(Obese class I)* | *35kg/m² +* *(Obese class II/III)* | |
| Number (%) | 2656 | 1640 (61.7) | 695 (26.2) | 321 (12.1) | |
| ***Patient factors*** | | | | | |
| Age, mean years (standard deviation [sd], range) | 73.3 (7.7, 36.7 to 93.7) | 74.3 (7.6, 36.7 to 93.7) | 72.3 (7.4, 45.1 to 92.9) | 70.7 (7.4, 46.4 to 92.1) | p<0.001 |
| Females | 1687 (63.5) | 1025 (62.5) | 430 (61.9) | 232 (72.3) | p=0.002 |
| ASA | | | | | |
| *1* | 274 (10.3) | 195 (11.9) | 67 (9.6) | 12 (3.7) | p<0.001 |
| *2* | 1912 (72.0) | 1186 (72.3) | 500 (71.9) | 226 (70.4) | |
| *3+* | 470 (17.7) | 259 (15.8) | 128 (18.4) | 83 (25.9) | |
| Co-morbidities | | | | | |
| *Heart disease* | 268 (10.1) | 149 (9.1) | 83 (11.9) | 36 (11.2) | p=0.086 |
| *Stroke* | 32 (1.2) | 16 (1.0) | 12 (1.7) | 4 (1.3) | p=0.314 |
| *Diabetes* | 270 (10.2) | 120 (7.3) | 102 (14.7) | 48 (15.0) | p<0.001 |
| *Hypertension* | 1219 (45.9) | 682 (41.6) | 360 (51.8) | 177 (55.1) | p<0.001 |
| *Circulation* | 220 (8.3) | 117 (7.1) | 68 (9.8) | 35 (10.9) | p=0.020 |
| *Lung* | 187 (7.0) | 119 (7.3) | 40 (5.8) | 28 (8.7) | p=0.196 |
| *Depression* | 132 (5.0) | 71 (4.3) | 41 (5.9) | 20 (6.2) | p=0.151 |
| Preoperative general health | | | | | |
| *Excellent* | 94 (3.6) | 65 (4.0) | 23 (3.4) | 6 (1.9) | p<0.001 |
| *Very good* | 767 (29.4) | 517 (32.1) | 184 (26.9) | 66 (20.9) | |
| *Good* | 1207 (46.3) | 727 (45.2) | 328 (47.9) | 152 (48.1) | |
| *Fair* | 470 (18.0) | 259 (16.1) | 126 (18.4) | 85 (26.9) | |
| *Poor* | 72 (2.8) | 41 (2.6) | 24 (3.5) | 7 (2.2) | |
| Preoperative disability | 1548 (58.3) | 901 (58.9) | 425 (66.4) | 222 (75.3) | p<0.001 |
| ***Patient reported outcome scores*** | | | | | |
| Oxford Hip scores | | | | | |
| *Pre-operative, mean (sd, range)* | 18.2 (8.1, 0 to 48) | 19.2 (8.1, 0 to 44) | 17.4 (7.9, 0 to 48) | 15.3 (7.4, 1 to 40) | p<0.001 |
| *Post-operative, mean (sd, range)* | 38.3 (8.9, 2 to 48) | 39.4 (8.3, 6 to 48) | 36.8 (9.4, 2 to 48) | 35.7 (9.6, 4 to 48) | p<0.001 |
| EQ5D visual analogue score | | | | | |
| *Pre-operative, mean (sd, range)* | 67.1 (19.8, 0 to 100) | 68.3 (19.2, 0 to 100) | 67.2 (20.4, 0 to 100) | 60.8 (20.7, 4 to 100) | p<0.001 |
| *Post-operative, mean (sd, range)* | 75.2 (17.8, 0 to 100) | 76.6 (17.4, 0 to 100) | 74.0 (18.1, 0 to 100) | 70.7 (18.6, 0 to 100) | p<0.001 |
| EQ5D index | | | | | |
| *Pre-operative, mean (sd, range)* | 0.368 (0.313, -0.484 to 1) | 0.392 (0.307, -0.429 to 1) | 0.345 (0.322, -0.484 to 1) | 0.305 (0.315, -0.349 to 0.796) | p<0.001 |
| *Post-operative, mean (sd, range)* | 0.779 (0.225, -0.239 to 1) | 0.799 (0.217, -0.239 to 1) | 0.756 (0.232, -0.239 to 1) | 0.728 (0.235, -0.074 to 1) | p<0.001 |
| Time from operation to PROMs completion, mean days (sd, range) | 209.2 (29.1, 183 to 358) | 209.1 (29.0, 183 to 358) | 209.6 (29.4, 183 to 358) | 209.0 (29.3, 184 to 337) | p=0.636 |

ASA – American Society of Anaesthesiologists score, PROMs – Patient reported outcomes measures
* - analysis of variance test (continuous data variables) or Chi squared (categorical data variables)

**Table 2.** Patient demographics and PROMs data for cementless DePuy Corail Pinnacle hip replacement, by body mass index

| | All patients | Body mass index | | | Differences between BMI groups* |
|---|---|---|---|---|---|
| | | *19 to 29.9kg/m$^2$ (Reference group)* | *30 to 34.9kg/m$^2$ (Obese class I)* | *35kg/m$^2$ + (Obese class II/III)* | |
| Number (%) | 2879 | 1738 (60.4) | 713 (24.8) | 428 (14.9) | |
| ***Patient factors*** | | | | | |
| Age, mean years (standard deviation [sd], range) | 65.8 (9.5, 25.2 to 94.0) | 66.7 (9.6, 26.2 to 94.0) | 65.3 (9.2, 25.2 to 90.2) | 62.9 (9.1, 28.7 to 88.2) | p<0.001 |
| Females | 1602 (55.6) | 979 (56.3) | 374 (52.5) | 249 (58.2) | p=0.112 |
| ASA | | | | | |
| *1* | 554 (19.2) | 417 (24.0) | 106 (14.9) | 31 (7.2) | p<0.001 |
| *2* | 2057 (71.5) | 1202 (69.2) | 541 (75.9) | 226 (73.4) | |
| *3+* | 268 (9.3) | 119 (6.9) | 66 (9.3) | 83 (19.4) | |
| Co-morbidities | | | | | |
| *Heart disease* | 226 (7.8) | 130 (7.5) | 51 (7.2) | 45 (10.5) | p=0.082 |
| *Stroke* | 35 (1.2) | 22 (1.3) | 8 (1.1) | 5 (1.2) | p=0.953 |
| *Diabetes* | 219 (7.6) | 81 (4.7) | 76 (10.7) | 62 (14.5) | p<0.001 |
| *Hypertension* | 1123 (39.0) | 582 (33.5) | 300 (42.1) | 241 (56.3) | p<0.001 |
| *Circulation* | 136 (4.7) | 74 (4.3) | 34 (4.8) | 28 (6.5) | p=0.136 |
| *Lung* | 158 (5.5) | 88 (5.1) | 36 (5.0) | 34 (7.4) | p=0.054 |
| *Depression* | 172 (6.0) | 96 (5.5) | 36 (5.0) | 40 (9.3) | p=0.006 |
| Preoperative general health | | | | | |
| *Excellent* | 150 (5.4) | 110 (6.6) | 26 (3.8) | 14 (3.4) | p<0.001 |
| *Very good* | 870 (31.5) | 582 (35.0) | 206 (30.0) | 82 (19.8) | |
| *Good* | 1210 (43.8) | 698 (42.0) | 321 (46.7) | 191 (46.1) | |
| *Fair* | 473 (17.1) | 241 (14.5) | 121 (17.6) | 111 (26.8) | |
| *Poor* | 61 (2.2) | 31 (1.9) | 14 (2.0) | 16 (3.7) | |
| Preoperative disability | 1405 (53.9) | 783 (50.1) | 350 (53.9) | 272 (68.9) | p<0.001 |
| ***Patient reported outcome scores*** | | | | | |
| Oxford Hip scores | | | | | |
| *Pre-operative, mean (sd, range)* | 18.8 (8.1, 1 to 43) | 19.9 (8.1, 2 to 43) | 18.5 (7.8, 2 to 43) | 15.1 (7.3, 1 to 39) | p<0.001 |
| *Post-operative, mean (sd, range)* | 40.1 (8.6, 0 to 48) | 40.8 (8.1, 6 to 48) | 40.0 (8.3, 8 to 48) | 37.0 (10.1, 1 to 48) | p<0.001 |
| EQ5D visual analogue score | | | | | |
| *Pre-operative, mean (sd, range)* | 66.7 (20.9, 0 to 100) | 68.5 (20.1, 0 to 100) | 66.5 (21.0, 0 to 100) | 60.1 (22.7, 4 to 100) | p<0.001 |
| *Post-operative, mean (sd, range)* | 77.1 (18.4, 0 to 100) | 78.6 (17.3, 0 to 100) | 77.3 (17.3, 0 to 100) | 70.9 (20.6, 0 to 100) | p<0.001 |
| EQ5D index | | | | | |
| *Pre-operative, mean (sd, range)* | 0.381 (0.313, -0.349 to 1) | 0.414 (0.306, -0.349 to 1) | 0.379 (0.310, -0.239 to 1) | 0.253 (0.316, -0.349 to 0.796) | p<0.001 |
| *Post-operative, mean (sd, range)* | 0.799 (0.246, -0.594 to 1) | 0.823 (0.228, -0.594 to 1) | 0.800 (0.231, -0.074 to 1) | 0.705 (0.306, -0.319 to 1) | p<0.001 |
| Time from operation to PROMs completion, mean days (sd, range) | 208.5 (27.8, 183 to 363) | 208.5 (27.8, 183 to 363) | 207.6 (27.1, 183 to 363) | 2010.0 (28.6, 183 to 362) | p=0.985 |

ASA – American Society of Anaesthesiologists score, PROMs – Patient reported outcomes measures
* - analysis of variance test (continuous data variables) or Chi squared (categorical data variables)

**Table 3.** Surgical factors for populations studied

| | Cemented (Exeter Contemporary) | Cementless (Corail Pinnacle) |
|---|---|---|
| Number | 2656 | 2879 |
| Approach | | |
| *Posterior* | 1471 (55.4) | 1830 (63.6) |
| *Direct lateral* | 1117 (42.1) | 888 (30.8) |
| *Other* | 68 (2.6) | 161 (5.6) |
| Chemical VTE prophylaxis | | |
| *LMWH only* | 1218 (53.6) | 1593 (66.2) |
| *Aspirin only* | 233 (10.2) | 208 (8.7) |
| *Other* | 701 (30.8) | 379 (15.8) |
| *None* | 122 (5.4) | 225 (9.4) |
| Mechanical VTE prophylaxis | | |
| *GCS* | 747 (28.1) | 912 (37.9) |
| *GCS/mechanical pump combination* | 663 (25.0) | 662 (27.5) |
| *Foot pump only* | 413 (15.6) | 221 (9.2) |
| *Mechanical calf pump only* | 280 (10.5) | 350 (14.6) |
| *Other* | 30 (1.1) | 17 (0.7) |
| *None* | 523 (19.7) | 243 (10.1) |
| Anaesthesia | | |
| *Regional* | 1085 (47.7) | 1369 (57.2) |
| *General* | 481 (21.2) | 470 (19.6) |
| *Regional and general* | 708 (31.1) | 554 (23.2) |
| Grade | | |
| *Consultant* | 1700 (64.0) | 2216 (77.0) |
| *Other* | 956 (36.0) | 663 (23.0) |
| Position | | |
| *Lateral* | 2102 (79.1) | 2256 (78.4) |
| *Supine* | 172 (6.5) | 149 (5.2) |
| *Unknown* | 382 (14.4) | 474 (16.5) |

VTE – Venous thromboemolism, LMWH – Low molecular weight Heparin, GCS – Graduated compression stockings

**Table 4.** Patient reported outcome scores following primary cemented Stryker Exeter V40 Contemporary hip replacement, by body mass index (simple and multivariable analyses)

| | Simple | | | Multivariable | | |
|---|---|---|---|---|---|---|
| | **Value** | **99% CI** | **P value** | **Value** | **99% CI** | **P value** |
| **Change in OHS** | | | | | | |
| *BMI 19 to 29.9kg/$m^2$ (n=1640)* | 20.2 | 19.5 to 20.8 | Reference | 20.5 | 20.0 to 21.1 | Reference |
| *BMI 30 to 34.9kg/$m^2$ (n=695)* | 19.5 | 18.5 to 20.4 | 0.116 | 18.9 | 18.1 to 19.8 | <0.001 |
| *BMI 35kg/$m^2$ + (n=321)* | 20.4 | 19.0 to 21.8 | 0.708 | 18.7 | 17.5 to 19.9 | <0.001 |
| **Change EQ5D index** | | | | | | |
| *BMI 19 to 29.9kg/$m^2$ (n=1640)* | 0.408 | 0.386 to 0.431 | Reference | 0.416 | 0.401 to 0.431 | Reference |
| *BMI 30 to 34.9kg/$m^2$ (n=695)* | 0.410 | 0.376 to 0.444 | 0.928 | 0.394 | 0.372 to 0.416 | 0.036 |
| *BMI 35kg/$m^2$ + (n=321)* | 0.418 | 0.367 to 0.468 | 0.669 | 0.387 | 0.353 to 0.420 | 0.043 |

*OHS – Oxford Hip Score, BMI – Body mass index*

**Table 5.** Patient reported outcome scores following primary cementless DePuy Corail Pinnacle hip replacement, by body mass index (simple and multivariable analyses)

| | Simple | | | Multivariable | | |
|---|---|---|---|---|---|---|
| | **Value** | **99% CI** | **P value** | **Value** | **99% CI** | **P value** |
| **Change in OHS** | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=1738)* | 20.9 | 20.3 to 21.5 | Reference | 21.5 | 21.1 to 22.1 | Reference |
| *BMI 30 to 34.9kg/m$^2$ (n=713)* | 21.5 | 20.5 to 22.4 | 0.188 | 21.3 | 20.5 to 22.1 | 0.532 |
| *BMI 35kg/m$^2$ + (n=428)* | 21.9 | 20.7 to 23.1 | 0.065 | 20.0 | 18.9 to 21.0 | <0.001 |
| **Change EQ5D index** | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=1738)* | 0.408 | 0.386 to 0.429 | Reference | 0.425 | 0.410 to 0.441 | Reference |
| *BMI 30 to 34.9kg/m$^2$ (n=713)* | 0.420 | 0.386 to 0.454 | 0.422 | 0.419 | 0.395 to 0.442 | 0.527 |
| *BMI 35kg/m$^2$ + (n=428)* | 0.453 | 0.410 to 0.497 | 0.016 | 0.371 | 0.341 to 0.401 | <0.001 |

*OHS – Oxford Hip Score, BMI – Body mass index*

**Table 6.** Predicted OHS improvement for specific self-reported patient factors, based on cemented hip replacement model

| | **Preoperative very good health** | | | | **Preoperative fair health** | | | |
|---|---|---|---|---|---|---|---|---|
| | **No disability** | | **Disability** | | **No disability** | | **Disability** | |
| | Minimal co-morbidity* | Co-morbidity present ϕ | Minimal co-morbidity | Co-morbidity present | Minimal co-morbidity | Co-morbidity present | Minimal co-morbidity | Co-morbidity present |
| **Females** | | | | | | | | |
| ***BMI 19 to 29.9kg/m²*** | | | | | | | | |
| *Pre-op OHS 10* | 30.4 | 26.0 | 28.4 | 23.9 | 29.6 | 25.1 | 26.2 | 23.1 |
| *Pre-op OHS 15* | 26.4 | 21.9 | 24.3 | 19.9 | 25.5 | 21.1 | 22.1 | 19.1 |
| *Pre-op OHS 20* | 22.4 | 17.9 | 20.3 | 15.9 | 21.5 | 17.1 | 18.1 | 15.0 |
| *Pre-op OHS 25* | 18.3 | 13.9 | 16.3 | 11.9 | 17.5 | 13.1 | 14.1 | 11.0 |
| ***BMI 30 to 34.9kg/m²*** | | | | | | | | |
| *Pre-op OHS 10* | 28.9 | 24.5 | 26.9 | 22.4 | 28.1 | 23.6 | 24.7 | 21.6 |
| *Pre-op OHS 15* | 24.9 | 20.4 | 22.8 | 18.4 | 24.1 | 19.6 | 20.6 | 17.6 |
| *Pre-op OHS 20* | 20.9 | 16.4 | 18.8 | 14.4 | 20.0 | 15.6 | 16.6 | 13.5 |
| *Pre-op OHS 25* | 16.9 | 12.4 | 14.8 | 10.4 | 16.0 | 11.6 | 12.6 | 9.5 |
| ***BMI 35kg/m² +*** | | | | | | | | |
| *Pre-op OHS 10* | 28.8 | 24.4 | 26.8 | 22.3 | 28.0 | 23.5 | 24.6 | 21.5 |
| *Pre-op OHS 15* | 24.8 | 20.4 | 22.8 | 18.3 | 24.0 | 19.5 | 20.6 | 17.5 |
| *Pre-op OHS 20* | 20.8 | 16.3 | 18.7 | 14.3 | 19.9 | 15.5 | 16.5 | 13.5 |
| *Pre-op OHS 25* | 16.8 | 12.3 | 14.7 | 10.3 | 15.9 | 11.5 | 12.5 | 9.4 |
| **Males** | | | | | | | | |
| ***BMI 19 to 29.9kg/m²*** | | | | | | | | |
| *Pre-op OHS 10* | 32.2 | 27.8 | 30.2 | 25.7 | 31.4 | 26.9 | 28.0 | 24.9 |
| *Pre-op OHS 15* | 28.2 | 23.8 | 26.2 | 21.7 | 27.4 | 22.9 | 24.0 | 20.9 |
| *Pre-op OHS 20* | 24.2 | 19.8 | 22.1 | 17.7 | 23.4 | 18.9 | 19.9 | 16.9 |
| *Pre-op OHS 25* | 20.2 | 15.7 | 18.1 | 13.7 | 19.3 | 14.9 | 15.9 | 12.8 |
| ***BMI 30 to 34.9kg/m²*** | | | | | | | | |
| *Pre-op OHS 10* | 30.7 | 26.3 | 28.7 | 24.2 | 29.9 | 25.5 | 26.5 | 23.4 |
| *Pre-op OHS 15* | 26.7 | 22.3 | 24.7 | 20.2 | 25.9 | 21.4 | 22.5 | 19.4 |
| *Pre-op OHS 20* | 22.7 | 18.3 | 20.7 | 16.2 | 21.9 | 17.4 | 18.5 | 15.4 |
| *Pre-op OHS 25* | 18.7 | 14.2 | 16.6 | 12.2 | 17.8 | 13.4 | 14.4 | 11.4 |
| ***BMI 35kg/m² +*** | | | | | | | | |
| *Pre-op OHS 10* | 30.7 | 26.2 | 28.6 | 24.2 | 29.8 | 25.4 | 26.4 | 23.3 |
| *Pre-op OHS 15* | 26.6 | 22.2 | 24.6 | 20.1 | 25.8 | 21.4 | 22.4 | 19.3 |
| *Pre-op OHS 20* | 22.6 | 18.2 | 20.6 | 16.1 | 21.8 | 17.3 | 18.4 | 15.3 |
| *Pre-op OHS 25* | 18.6 | 14.2 | 16.6 | 12.1 | 17.8 | 13.3 | 14.4 | 11.3 |

** Minimal co-morbidity – ASA 2, no depression, no circulatory problems*

*ϕ Co-morbidity present – ASA 3, depression, circulatory problems*

*BMI – Body mass index, ASA – American Society of Anaesthesiologists, Regional anaesthesia and posterior approach used in model.*

**Table 7.** Patient reported complications following primary cemented Stryker Exeter V40 Contemporary hip replacement, by body mass index (simple and multivariable analyses)

| | % | n | Simple | | | Multivariable | | |
|---|---|---|---|---|---|---|---|---|
| | | | OR | 99% CI | P value | OR | 99% CI | P value |
| **Bleeding complications** | | | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=1640)* | 3.7 | (61) | 1 | | | 1 | | |
| *BMI 30 to 34.9kg/m$^2$ (n=695)* | 5.3 | (37) | 1.46 | 0.84 to 2.52 | 0.079 | 1.47 | 0.83 to 2.60 | 0.083 |
| *BMI 35kg/m$^2$ + (n=321)* | 4.4 | (14) | 1.18 | 0.54 to 2.58 | 0.584 | 1.16 | 0.52 to 2.57 | 0.633 |
| **Wound complications** | | | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=1640)* | 7.2 | (118) | 1 | | | 1 | | |
| *BMI 30 to 34.9kg/m$^2$ (n=695)* | 10.8 | (75) | 1.56 | 1.04 to 2.33 | 0.004 | 1.57 | 1.03 to 2.38 | 0.006 |
| *BMI 35kg/m$^2$ + (n=321)* | 15.0 | (48) | 2.27 | 1.41 to 3.64 | <0.001 | 2.06 | 1.25 to 3.40 | <0.001 |
| **Readmission** | | | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=1640)* | 6.2 | (102) | 1 | | | 1 | | |
| *BMI 30 to 34.9kg/m$^2$ (n=695)* | 8.8 | (61) | 1.45 | 0.94 to 2.24 | 0.027 | 1.45 | 0.94 to 2.24 | 0.028 |
| *BMI 35kg/m$^2$ + (n=321)* | 11.2 | (36) | 1.90 | 1.13 to 3.22 | 0.002 | 1.99 | 1.17 to 3.39 | 0.001 |
| **Reoperation** | | | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=1640)* | 1.6 | (26) | 1 | | | 1 | | |
| *BMI 30 to 34.9kg/m$^2$ (n=695)* | 2.7 | (19) | 1.74 | 0.79 to 3.83 | 0.068 | 1.67 | 0.76 to 3.68 | 0.095 |
| *BMI 35kg/m$^2$ + (n=321)* | 4.4 | (14) | 2.83 | 1.19 to 6.75 | 0.002 | 2.73 | 1.14 to 6.53 | 0.003 |

*OR – Odds ratio, BMI – Body mass index*

**Table 8.** Patient reported complications following primary cementless DePuy Corail Pinnacle hip replacement, by body mass index (simple and multivariable analyses)

| | % | n | Simple | | | Multivariable | | |
|---|---|---|---|---|---|---|---|---|
| | | | OR | 99% CI | P value | OR | 99% CI | P value |
| **Bleeding complications** | | | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=1738)* | 5.1 | (89) | 1 | | | 1 | | |
| *BMI 30 to 34.9kg/m$^2$ (n=713)* | 6.3 | (45) | 1.25 | 0.77 to 2.03 | 0.240 | 1.10 | 0.64 to 1.90 | 0.647 |
| *BMI 35kg/m$^2$ + (n=428)* | 5.8 | (25) | 1.15 | 0.63 to 2.10 | 0.550 | 1.15 | 0.59 to 2.25 | 0.595 |
| **Wound complications** | | | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=1738)* | 6.6 | (115) | 1 | | | 1 | | |
| *BMI 30 to 34.9kg/m$^2$ (n=713)* | 9.5 | (68) | 1.49 | 0.99 to 2.25 | 0.013 | 1.43 | 0.93 to 2.21 | 0.032 |
| *BMI 35kg/m$^2$ + (n=428)* | 14.5 | (62) | 2.39 | 1.55 to 3.68 | <0.001 | 2.39 | 1.52 to 3.75 | <0.001 |
| **Readmission** | | | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=1738)* | 6.3 | (110) | 1 | | | 1 | | |
| *BMI 30 to 34.9kg/m$^2$ (n=713)* | 5.5 | (39) | 0.86 | 0.52 to 1.40 | 0.419 | 0.87 | 0.50 to 1.50 | 0.503 |
| *BMI 35kg/m$^2$ + (n=428)* | 7.0 | (30) | 1.12 | 0.64 to 1.93 | 0.608 | 1.32 | 0.72 to 2.41 | 0.233 |
| **Reoperation** | | | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=1738)* | 2.0 | (35) | 1 | | | 1 | | |
| *BMI 30 to 34.9kg/m$^2$ (n=713)* | 1.4 | (10) | 0.69 | 0.27 to 1.76 | 0.309 | 0.69 | 0.27 to 1.76 | 0.309 |
| *BMI 35kg/m$^2$ + (n=428)* | 2.3 | (10) | 1.16 | 0.46 to 2.96 | 0.675 | 1.16 | 0.46 to 2.96 | 0.675 |

*OR – Odds ratio, BMI – Body mass index*

**Supplementary material**

The reliability of the multi-variable statistical models was explored in a number of ways: covariates found not to be statistically significant were excluded from the model, based on statistical entry ($p<0.05$) criteria; the same covariates were fitted forward and reverse stepwise manually to ensure findings were not qualitatively affected in the final model, with any inconsistency reported; the final models were re-evaluated as a directly entered model (non-stepwise), and were assessed by exploring 2-way interactions between covariates.

The purpose of the analysis was hypothesis generating rather than hypothesis testing, consequently there is no adjustment for multiple testing and the choice of level of statistical significance is somewhat arbitrary.

To test the models generated, a sensitivity analysis was performed using only the most commonly implanted component sets within the cemented (28mm flanged cup, representing 70% of all Exeter V40-Contemporary THRs implanted in 2010) and cementless groups (36mm hard bearing, representing 51% of all Corail Pinnacle THRs implanted in 2010).

Tests for interaction (multiplicative) between covariates were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final models. Sensitivity analysis of the commonest component sets within cemented and cementless groups showed similar results for OHS and EQ5D index change, indicating that the findings of the entire cohort are applicable to a range of component choices within brands (Appendix Tables 3 and 4). Treating BMI as a continuous or categorical variable did not qualitatively affect the model.

**Appendix Table 1.** Summary of demographic and surgical variables available for analysis (those found to have a significant influence on specific statistical models and therefore included in final models are shown)

| | Source | Description | Included in final models* |
|---|---|---|---|
| ***Patient factors*** | | | |
| Age (years) | NJR/PROMs | | 7 |
| Sex | NJR/PROMs | | A,E,1,3 |
| American Society of Anaesthesiology grade | NJR | Grades 1 to 4 | E |
| Body mass index (BMI) (kg/m$^2$) | NJR | Only BMI within 15 kg/m$^2$ to 65 kg/m$^2$ included | All |
| Comorbidities | PROMs | Recorded by patients as part of the pre-operative PROMs questionnaire. Ten co-morbidities: i) ischaemic heart disease, ii) respiratory disease, iii) diabetes, iv) hypertension, v) kidney disease, vi) liver disease, vii) circulatory problems, viii) cancer, ix) depression, x) stroke | A (vii), B (vii,ix), C (vii,ix), D (vii, ix, x), E (vii,ix), F (i,vii,ix) G (vii,ix,x), H (vii, ix, x), 6 (iii), 4(v) |
| Pre-operative general health | PROMs | Indicates the patient's perception of their own general health with five options: i) excellent, ii) very good, iii) good, iv) fair, v) poor | A,B,C,D,E,F, G,H |
| Pre-operative disability | PROMs | Indicates whether the patient considers themselves to have a disability | A,B,C,D,E,F, G,H, 1 |
| Pre-operative Oxford Hip Score | PROMs | Derived from adding the points (0 to 4) together from the response to hip symptom-specific questions on a scale of 0 to 48 (0 worst, 48 best) | A,C,E,F,G |
| Pre-operative EQ5D Visual Analogue Score | PROMs | Indicates how well the patient feels on the day of completing the questionnaire on a scale of 0-100 (0 worst, 100 best) | 2 |
| Pre-operative EQ5D index | PROMs | Single summary score derived from EQ5D profile (based on response to 5 questions) by applying a formula with appropriate operation specific weightings (0 to 1) | B,D,F,H |
| ***Surgical factors*** | | | |
| Lead surgeon grade | NJR | Consultant or other | No |
| Hospital funding | NJR | NHS or other | |
| Approach | NJR | Posterior or direct lateral | A,B,C,D,E,F, G,H, 1,5 |
| Patient position | NJR | Lateral or supine | No |
| Anaesthesia | NJR | i) Regional only, ii) general only, iii) general and regional | E |
| Chemical venous thromboembolism prophylaxis | NJR | Intended prophylaxis as recorded at time of operation: i) aspirin only, ii) LMWH only, iii) other, iv) none | 7 |
| Mechanical venous thromboembolism prophylaxis | NJR | Intended prophylaxis as recorded at time of operation: i) TEDS only, ii) combination TEDS/mechanical pump, iii) foot pump only, iv) intermittent calf pump only, v) other, and vi) none | 6 |
| Time from operation to post-operative PROMs completion | PROMs | Calculated from the date of operation as recorded on the NJR database to the date of post-operative PROMs as recorded on the questionnaire | No |

*PROMS outcome scores for:*
commonest cemented implants: A. OHS change, B. EQ5D index change
commonest cementless implants: C. OHS change, D. EQ5D index change
all cemented implants: E. OHS change, F. EQ5D index change
all cementless implants: G. OHS change, H. EQ5D index change
*PROMS patient reported complications for:*
cemented implants: 1. wound, 2. bleeding, 3. readmission, 4. further surgery
cementless implants: 5. wound, 6. bleeding, 7. readmission, 8. further surgery

**Appendix Table 2.** Demographics for sensitivity analysis

| | Cemented (Exeter Contemporary 28mm flanged polyethylene) | | Cementless (Corail Pinnacle 36mm hard bearing) | |
|---|---|---|---|---|
| Number | 1532 | | 1191 | |
| ***Patient factors*** | | | | |
| Age, mean years | 72.8 | | 63.0 | |
| (standard deviation [sd], range) | (7.7, 36.7 to 92.9) | | (9.7, 25.2 to 89.0) | |
| Females | 1036 | (67.6) | 540 | (45.3) |
| ASA | | | | |
| *1* | 165 | (10.8) | 282 | (23.7) |
| *2* | 1106 | (72.2) | 814 | (68.4) |
| *3* | 252 | (16.5) | 94 | (7.9) |
| *4/5* | 9 | (0.6) | 1 | (0.1) |
| Body mass index (kg/m$^2$) | | | | |
| *BMI 19 to 29.9* | 924 | (60.3) | 712 | (59.8) |
| *30 to 34.9* | 417 | (27.2) | 285 | (23.9) |
| *35+* | 191 | (12.5) | 194 | (16.3) |
| Co-morbidities | | | | |
| *Heart disease* | 137 | (8.9) | 95 | (8.0) |
| *Stroke* | 19 | (1.2) | 12 | (1.0) |
| *Diabetes* | 164 | (10.7) | 78 | (6.6) |
| *Hypertension* | 706 | (46.1) | 438 | (36.8) |
| *Circulation* | 122 | (8.0) | 37 | (4.0) |
| *Lung* | 112 | (7.3) | 69 | (5.8) |
| *Liver* | 6 | (0.4) | 5 | (0.4) |
| *Kidney* | 21 | (1.4) | 13 | (1.1) |
| *Nervous* | 13 | (0.9) | 7 | (0.6) |
| *Cancer* | 88 | (5.7) | 39 | (3.3) |
| *Depression* | 76 | (5.0) | 82 | (6.9) |
| Preoperative general health | | | | |
| *Excellent* | 57 | (3.8) | 62 | (5.3) |
| *Very good* | 467 | (31.0) | 375 | (32.3) |
| *Good* | 686 | (45.5) | 477 | (41.1) |
| *Fair* | 265 | (17.6) | 220 | (19.0) |
| *Poor* | 34 | (2.3) | 27 | (2.3) |
| Preoperative disability | 868 | (56.7) | 553 | (46.4) |
| Preoperative OHS, mean score | 18.4 | | 19.2 | |
| (sd, range) | (8.1, 0 to 44) | | (8.1, 2 to 42) | |
| Pre-opEQ5D VAS, mean score | 67.6 | | 66.2 | |
| (sd, range) | (19.7, 0 to 100) | | (20.6, 0 to 100) | |
| Pre-op EQ5D index, mean | 0.374 | | 0.387 | |
| (sd, range) | (0.311, -0.429 to 1) | | (0.317, -0.349 to 1) | |
| Time from operation to PROMs completion, mean days | 208.9 | | 209.6 | |
| (sd, range) | (29.1, 183 to 358) | | (29.0, 183 to 362) | |
| ***Surgical factors*** | | | | |
| Provider | | | | |
| *NHS* | 1313 | (85.7) | 1029 | (86.4) |
| *Other* | 3 | (0.2) | 4 | (0.3) |
| *Unknown* | 216 | (14.1) | 162 | (13.6) |
| Approach | | | | |
| *Posterior* | 866 | (56.5) | 765 | (64.2) |
| *Direct lateral* | 628 | (40.1) | 337 | (28.3) |
| *Other* | 38 | (2.5) | 89 | (7.5) |
| Chemical VTE prophylaxis | | | | |
| *LMWH only* | 623 | (47.3) | 625 | (60.5) |
| *Aspirin only* | 153 | (11.6) | 126 | (12.2) |
| *Other* | 438 | (33.3) | 193 | (18.7) |
| *None* | 102 | (7.8) | 89 | (8.6) |
| Mechanical VTE prophylaxis | | | | |
| *GCS* | 431 | (28.1) | 400 | (38.7) |

| | | | | |
|---|---|---|---|---|
| *GCS/mechanical pump combination* | 335 | (21.9) | 342 | (33.1) |
| *Foot pump only* | 253 | (16.5) | 64 | (6.2) |
| *Mechanical calf pump only* | 204 | (12.3) | 133 | (12.9) |
| *Other* | 23 | (1.5) | 12 | (1.2) |
| *None* | 286 | (18.7) | 82 | (7.9) |
| Anaesthesia | | | | |
| *Regional* | 708 | (53.8) | 562 | (54.5) |
| *General* | 238 | (18.1) | 229 | (22.2) |
| *Regional and general* | 370 | (28.1) | 241 | (23.4) |
| Grade | | | | |
| *Consultant* | 943 | (61.6) | 920 | (77.3) |
| *Other* | 589 | (38.5) | 271 | (22.8) |
| Position | | | | |
| *Lateral* | 1211 | (79.0) | 964 | (80.9) |
| *Supine* | 105 | (6.9) | 69 | (5.8) |
| *Unknown* | 216 | (14.1) | 158 | (13.3) |

OHS – Oxford hip score, VAS – Visual analogue score, NHS – National Health Service, VTE – Venous thromboemolism, LMWH – Low molecular weight Heparin, GCS – Graduated compression stockings

**Appendix Table 3.** Patient reported outcome scores following primary cemented Stryker Exeter V40 Contemporary hip replacement, by body mass index (simple and multivariable analyses)

| | Simple | | | Multivariable | | |
|---|---|---|---|---|---|---|
| | **Value** | **99% CI** | **P value** | **Value** | **99% CI** | **P value** |
| **Change in OHS (commonest implant specification*)** | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=924)* | 20.4 | 19.5 to 21.2 | Reference | 20.7 | 19.9 to 21.4 | Reference |
| *BMI 30 to 34.9kg/m$^2$ (n=417)* | 19.8 | 18.5 to 21.1 | 0.331 | 19.2 | 18.2 to 20.3 | 0.005 |
| *BMI 35kg/m$^2$ + (n=191)* | 20.0 | 18.1 to 21.9 | 0.643 | 18.6 | 17.0 to 20.1 | 0.002 |
| **Change EQ5D index (*)** | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=924)* | 0.406 | 0.376 to 0.436 | Reference | 0.410 | 0.390 to 0.431 | Reference |
| *BMI 30 to 34.9kg/m$^2$ (n=417)* | 0.414 | 0.370 to 0.457 | 0.722 | 0.392 | 0.363 to 0.422 | 0.190 |
| *BMI 35kg/m$^2$ + (n=191)* | 0.408 | 0.343 to 0.474 | 0.945 | 0.377 | 0.334 to 0.421 | 0.082 |

*Commonest implant specification: *Exeter V40 Contemporary flanged polyethylene cup (internal diameter 28mm)*
*OHS – Oxford Hip Score, BMI – Body mass index*

**Appendix Table 4.** Patient reported outcome scores following primary cementless DePuy Corail Pinnacle hip replacement, by body mass index (simple and multivariable analyses)

| | Simple | | | Multivariable | | |
|---|---|---|---|---|---|---|
| | **Value** | **99% CI** | **P value** | **Value** | **99% CI** | **P value** |
| **Change in OHS (commonest implant specification*)** | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=712)* | 21.2 | 20.3 to 22.2 | Reference | 21.7 | 20.9 to 22.6 | Reference |
| *BMI 30 to 34.9kg/m$^2$ (n=285)* | 20.7 | 19.2 to 22.3 | 0.481 | 21.0 | 19.7 to 22.3 | 0.218 |
| *BMI 35kg/m$^2$ + (n=194)* | 22.0 | 20.1 to 23.8 | 0.369 | 19.9 | 18.3 to 21.5 | 0.009 |
| **Change EQ5D index (*)** | | | | | | |
| *BMI 19 to 29.9kg/m$^2$ (n=712)* | 0.413 | 0.379 to 0.448 | Reference | 0.440 | 0.416 to 0.465 | Reference |
| *BMI 30 to 34.9kg/m$^2$ (n=285)* | 0.404 | 0.350 to 0.459 | 0.722 | 0.406 | 0.367 to 0.445 | 0.059 |
| *BMI 35kg/m$^2$ + (n=194)* | 0.449 | 0.383 to 0.515 | 0.217 | 0.358 | 0.312 to 0.405 | <0.001 |

*Commonest implant specification: *Corail Pinnacle ceramic-on-ceramic or metal-on-metal with 36mm head*
*OHS – Oxford Hip Score, BMI – Body mass index*