Body mass index is not a clinically meaningful predictor of patient reported outcomes of primary hip replacement surgery: prospective cohort study

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SUMMARY

Objectives: To describe whether body mass index (BMI) is a clinically meaningful predictor of patient reported outcomes following primary total hip replacement (THR) surgery.

Design: Combined data from prospective cohort studies. We obtained information from four cohorts of patients receiving primary THR for osteoarthritis: Exeter Primary Outcomes Study (EPOS) (n = 1431); EUROHIP (n = 1327); Elective Orthopaedic Centre (n = 2832); and St. Helier (n = 878). The exposure of interest was pre-operative BMI. Confounding variables included: age, sex, SF-36 mental health, comorbidities, fixed flexion, analgesic use, college education, OA in other joints, expectation of less pain, radiographic K&L grade, ASA grade, years of hip pain. The primary outcome was the Oxford Hip Score (OHS). Regression models describe the association of BMI on outcome adjusting for all confounders.

Results: For a 5-unit increase in BMI, the attained 12-month OHS decreases by 0.78 points 95%CI (0.27–1.28), P-value 0.001. Compared to people of normal BMI (20–25), those in the obese class II (BMI 35–40) would have a 12-month OHS that is 2.34 points lower. Although statistically significant this effect is small and not clinically meaningful in contrast to the substantial change in OHS seen across all BMI groupings. In obese class II patients achieved a 22.2 point change in OHS following surgery.

Conclusions: Patients achieved substantial change in OHS after THR across all BMI categories, which greatly outweighs the small difference in attained post-operative score. The findings suggest BMI should not present a barrier to access THR in terms of PROMs.

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Introduction

Total hip replacement surgery (THR) is a commonly performed and successful surgical intervention, providing substantial relief from pain and improvement in functional disability in patients with hip arthritis. The lifetime risk for undergoing a hip replacement in the UK is estimated to be 11.6% for women and 7.1% for men. Recent studies have reported that around 10% of patients are not satisfied with their hip replacement within a year following surgery. It is generally acknowledged that the key indications for surgery include joint pain, functional limitation and radiographic evidence of arthritis. There is no consensus as to the severity of
symptoms that indicate surgery is required\textsuperscript{10}, and no universally accepted criteria to determine the indications for surgery\textsuperscript{7}.

Obesity is a known risk factor for the development of hip osteoarthritis\textsuperscript{1}, and it has been shown that obese patients have a greater clinical need for surgery\textsuperscript{12}. Data from the UK National Joint Registry\textsuperscript{13} show that the average body mass index (BMI) of patients receiving hip replacement has been increasing steadily over time. Contrary to this, there is growing evidence in the UK that commissioners are restricting access to hip replacement for obese patients stating that obesity increases the risk of complications following surgery\textsuperscript{14–25}. Accordingly NICE clinical guidelines have stated that restriction of referral for surgery based on health issues such as BMI has no basis in evidence and that whilst the risks of complications may be slightly higher there is no evidence supporting this as a reason to deny treatment\textsuperscript{26}. Regarding patient reported outcomes, literature on the effect of BMI is conflicting.

Some authors conclude that obesity is associated with worse pain and functional outcomes\textsuperscript{27–29}, whilst others have found no association\textsuperscript{30–33}. Literature reviews conclude that observed differences in risk for obese patients are small, and they can still expect large symptomatic improvement following surgery\textsuperscript{34}. There are several limitations within the existing literature: the sample sizes of some of the London boroughs are small with few patients and in the morbidly obese groups; statistical methods used are weak, such as categorising BMI reducing statistical power and selection bias due to missing data; and most importantly limited adjustment for confounding.

To our knowledge, data from a single cohort study does not exist containing the required information to adjust for all important confounding variables, and multiple data sources are therefore necessary. Within the recent literature methodology has been developed in order to combine data from multiple sources in order to adjust for a wider range of confounding factors\textsuperscript{36} or allow a wider range of variables to be included in a model\textsuperscript{37}.

Set against the conflicting literature regarding the influence of obesity on patient reported outcomes following hip replacement, and concerns that access to surgery is being restricted for obese patients, as part of the Clinical Outcomes in Arthroplasty Study (COAST) the aim of this paper was to provide a comprehensive assessment of the effect of obesity on patient reported outcomes of hip replacement, through combining data from large prospective cohort studies allowing us to take account of a wide and comprehensive range of important confounding factors.

Methods

As part of the COAST study access was available to data from four large prospective cohorts of patients receiving primary hip replacement (THR) for osteoarthritis. The datasets have previously been reported elsewhere and are described in brief as follows: (1) The European collaborative database of cost and practice patterns of THR (EUROHIP) contains information on 1327 patients receiving primary THR across 20 European orthopaedic centres in 12 countries in 2002\textsuperscript{38}; (2) Exeter Primary Outcomes Study (EPOS) is a prospective study of 1431 patients with a primary diagnosis of OA who had THR between 1999 and 2002\textsuperscript{39}; (3) Elective Orthopaedic Centre database (EOC) – a purpose built Orthopaedic treatment centre opened in 2004 performing THR for four acute NHS Trusts in South West London, UK. The EOC database includes 2832 patients receiving primary THR for OA between 2005 and 2008\textsuperscript{40}; (4) St. Helen Hospital outcome programme – a district general hospital serving the London Boroughs of Sutton and Merton\textsuperscript{7}. The dataset contains 787 patients with OA receiving primary THR whose operations were undertaken from 1995 to 2007.

The primary outcome of interest is the Oxford Hip Score (OHS)\textsuperscript{41}, consisting of 12 questions asking patients to describe their hip pain and function during the past 4 weeks. Each question is on a Likert scale taking values from 0 to 4. The total score is created by summing the responses to each of the 12 questions, ranging from 0 to 48, where 0 is the worst possible score (most severe symptoms) and 48 the best score (least symptoms). Follow up OHS questionnaires were collected at 12-months in all four studies. However, in the EOC and EUROHIP cohorts the 12-month OHS was only collected for a minority of patients. The predominant follow up for EOC was the 6-month OHS, and for the EUROHIP study the 12-month WOMAC score. We therefore derived a 12-month OHS for both of these studies in the following way: (1) EOC = 250 patients in the EOC and St. Helier datasets completed both 6 and 12-month OHS scores. Using truncated regression modelling we derived an equation to predict the 12-month OHS from the 6-month OHS (R\textsuperscript{2} 50.8%); (2) EUROHIP = 110 patients completed both the OHS and WOMAC scores at baseline and 12-months follow up. Truncated regression models were used to predict the OHS from the WOMAC score at baseline (R\textsuperscript{2} 75.5%) and 12-month follow up (R\textsuperscript{2} 63.4%).

The main predictor of interest is pre-operative BMI treated as a continuous variable. Across the cohorts data was available on a wide range of patient and surgical variables. A-priori a list of these variables was circulated to co-authors and consensus obtained on the following extensive list of potential confounders: age, sex, SF-36 mental health score, comorbidities (deep venous thrombosis, pulmonary embolism, urinary tract infection, other musculoskeletal disease, neurological, respiratory, cardiovascular, renal, hepatic disease or treatment for other medical conditions), fixed flexion range of motion (degrees), analgesic use, college education, OA in other joints, expectation of less pain, radiographic Kelgren & Lawrence (K&L) grade, American Society of Anesthesiologists (ASA) status, years of hip pain, surgical approach (anterolateral or posterior) and femoral component offset size (millimetres offset). Each study collected data on age, sex, BMI and Quality of Life, however there were differences in the other confounders recorded (Table I).

Statistical methods

In accordance with Katz et al.\textsuperscript{42} we fitted two models to describe the association with BMI on: (1) the 12-month OHS as a measure of the level of post-operative pain and functional status achieved by 12-months (the destination). Linear regression modelling is used adjusting for the baseline OHS and confounding factors; (2) change in OHS between baseline and 12-months (the journey). A repeated measures linear regression model is fitted, where the outcome is the pre- and post-operative OHS, and an interaction term fitted between BMI and time, to describe the change in OHS over time within BMI categories, adjusting for confounding factors.

Primary analysis

Each of the four cohort studies was analysed separately to describe the association of BMI on outcome. Models are adjusted only for confounders of age and sex in order to construct related hypotheses in each study. Fixed-effects meta-analysis using inverse variance weights is used to combine results and estimate a common effect size of BMI on outcome. We tested for evidence of heterogeneity across studies.

Secondary analysis

As each study collected data on a different set of confounders, combining studies together results in a high proportion of missing data (Table I). Within the literature methodology has been developed to combine data from multiple data sources to adjust for a wider range of variables\textsuperscript{36,37}. We use the method of Multivariate
Imputation by Chained Equations (MICE) to combine the data\textsuperscript{43,44} (full details of the methods are provided in a supplementary file). We included all of the covariates (as listed earlier) together with the outcome variable in the imputation model as this carries information about the missing values of predictors. Regression models were then fitted to the combined dataset to describe the association of BMI on outcome adjusting for the full range of confounding factors.

Results

Prior to surgery baseline data was available on 6377 patients receiving primary THR for OA, of whom 4413 (69.2\%) completed both baseline and 12-month follow up OHS and were included in the analysis. Table IIdescribes the characteristics of patients in each of the four studies. There were small differences between patients that did, and did not, complete the follow up questionnaire. Those that completed the follow up had better pre-operative OHS in two of the studies (EUROHIP and EOC), and in the EPOS cohort those responding to the questionnaire were younger. Importantly, BMI was similar in both completers and non-completers across all four studies. For those included in the analysis, patients in the EOC cohort had better pre-operative pain and function (as measured by the OHS), whilst those in EUROHIP had more severe pre-operative symptoms. Patients in the EUROHIP and St. Helier cohorts were slightly younger than those in the other cohorts. There were a higher proportion of men in the EUROHIP study. The distribution of BMI was similar across all four studies (Table III) with a median of 26.8, Inter-quartile range (24.3, 30.1) and a range from 14.6 to 54.3. Separating the distribution of BMI into WHO categories\textsuperscript{45} 24 (0.9\%) of patients were underweight (BMI <18.5), 864 (31.7\%) normal (BMI 18.5–25), 1139 (41.8\%) overweight (BMI 25–30), 502 (18.4\%) obese class I (BMI 30–35), 150 (5.5\%) obese class II (BMI 35–40), and 47 (1.7\%) obese class III (BMI 40+).

Primary analysis

The results of the analyses of each individual study are displayed as a forest plot in Fig. 1. For the analysis of the effect of BMI on attained post-operative pain and function, each of the studies showed a small negative effect of BMI on outcome, but this did not reach statistical significance in all studies. The overall summary estimate from the meta-analysis was statistically significant suggesting that after adjusting for age and sex, for a 5-unit increase in BMI, the 12-month OHS decreases by 0.84 95%CI (0.59–1.08) points.

Secondary analysis

For the combined dataset, in the analysis of the effect of BMI on attained post-operative pain and function, adjusting for age and sex...
only, for a 5-unit increase in BMI, the 12-month OHS decreases by 0.96 units (95% CI (0.57 to 1.35), P-value < 0.001. Adjusting for all potential confounding factors, the effect is attenuated to 0.78 units (95% CI (0.27 to 1.28), P-value 0.003. Although the effect size is small, it is important to note that there is a cumulative linear effect where the difference in post-op OHS becomes larger with increasing BMI. For example, compared to people with a normal BMI (20 to 25), those in obese class II (BMI 35 to 40) would have a post-operative OHS that is 2.34 units lower, and those in obese class III (BMI 40+) 2.12 units lower. There was no evidence of an interaction between BMI and the pre-operative OHS.

Repeated measures analysis exploring the change in OHS between baseline and 12-months, suggests that patients achieved substantial improvement (change) in OHS, regardless of their pre-operative level of BMI (Table IV). After adjusting for all confounders, patients in the normal group (BMI 18.5 to 25) had a 23.0 point change in OHS between the pre- and 12-month post-operative assessment, those in the overweight group (BMI 25 to 30) a 22.4 point change, the obese class I group (BMI 30 to 35) 22.7 points, obese class II (BMI 35 to 40) 22.2 points, and obese class III (BMI 40+) 24.2 points. Hence, there is a substantial improvement in OHS after THR across all BMI categories, which greatly outweighs the small difference in attained post-operative OHS (Fig. 2).

Discussion

Main findings

This study provides a comprehensive assessment of the association of BMI on PROMs of THR. Its strength lies in utilising data from four large, representative, prospective cohort studies that allowed us to accurately assess the size of effect of BMI on PROMs and to adjust for a full range of potential confounders. Our findings confirm a small statistically significant difference in the effect of

Table II

<table>
<thead>
<tr>
<th>Study</th>
<th>Variables</th>
<th>Non-completers</th>
<th>Completers</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPOS</td>
<td>OHS pre-op</td>
<td>(n = 164)</td>
<td>(n = 1267)</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>Age at operation:</td>
<td>15.81 (8.15)</td>
<td>16.49 (7.77)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Sex:</td>
<td>72.64 (9.93)</td>
<td>68.80 (9.80)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>70 (43%)</td>
<td>462 (37%)</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>92 (57%)</td>
<td>800 (63%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI</td>
<td>26.30 (23.62, 29.76)</td>
<td>26.72 (24.39, 30.04)</td>
<td>0.21</td>
</tr>
<tr>
<td>EUROHIP</td>
<td>OHS pre-op</td>
<td>(n = 476)</td>
<td>(n = 851)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Age at operation:</td>
<td>13.26 (8.43)</td>
<td>15.67 (8.61)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sex:</td>
<td>65.68 (11.22)</td>
<td>65.70 (10.67)</td>
<td>0.98</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>199 (43%)</td>
<td>360 (45%)</td>
<td>0.68</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>260 (57%)</td>
<td>448 (55%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI</td>
<td>26.72 (24.02, 29.41)</td>
<td>26.94 (24.69, 30.12)</td>
<td>0.012</td>
</tr>
<tr>
<td>EOC</td>
<td>OHS pre-op</td>
<td>(n = 1234)</td>
<td>(n = 1598)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Age at operation:</td>
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<td>19.51 (8.77)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sex:</td>
<td>70.27 (11.30)</td>
<td>70.73 (10.35)</td>
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<tr>
<td></td>
<td>Male</td>
<td>428 (35%)</td>
<td>577 (36%)</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>801 (65%)</td>
<td>1018 (64%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI</td>
<td>27.34 (24.35, 30.98)</td>
<td>26.72 (23.89, 30.44)</td>
<td>0.032</td>
</tr>
<tr>
<td>ST HELIER</td>
<td>OHS pre-op</td>
<td>(n = 90)</td>
<td>(n = 697)</td>
<td>0.95</td>
</tr>
<tr>
<td></td>
<td>Age at operation:</td>
<td>17.47 (7.63)</td>
<td>17.52 (8.30)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sex:</td>
<td>66.30 (14.52)</td>
<td>66.54 (12.01)</td>
<td>0.88</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>37 (41%)</td>
<td>278 (40%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>53 (59%)</td>
<td>419 (60%)</td>
<td>0.82</td>
</tr>
<tr>
<td></td>
<td>BMI</td>
<td>27.00 (23.00, 30.00)</td>
<td>27.00 (24.00, 30.00)</td>
<td>0.34</td>
</tr>
</tbody>
</table>

* To compare characteristics of completers and non-completers, a chi-squared test is used for categorical variables, a two-sample t-test for normally distributed continuous variables, and Kruskal–Wallis test for non-normally distributed variables.

For normally distributed continuous variables numbers represent mean (standard deviation), for non-normally distributed the median (inter-quartile range).

Table III

<table>
<thead>
<tr>
<th>BMI categories</th>
<th>EPOS</th>
<th>EUROHIP</th>
<th>EOC</th>
<th>ST HELIER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight (&lt;18.5)</td>
<td>12 (1.0%)</td>
<td>0 (0.0%)</td>
<td>6 (1.8%)</td>
<td>6 (1.5%)</td>
</tr>
<tr>
<td>Normal (18.5–25)</td>
<td>370 (31.0%)</td>
<td>218 (27.8%)</td>
<td>116 (34.4%)</td>
<td>160 (38.8%)</td>
</tr>
<tr>
<td>Overweight (25–30)</td>
<td>509 (42.7%)</td>
<td>363 (46.3%)</td>
<td>123 (36.5%)</td>
<td>144 (35.0%)</td>
</tr>
<tr>
<td>Obese class I (30–35)</td>
<td>215 (18.0%)</td>
<td>147 (18.8%)</td>
<td>69 (20.5%)</td>
<td>71 (17.2%)</td>
</tr>
<tr>
<td>Obese class II (35–40)</td>
<td>70 (5.9%)</td>
<td>46 (5.9%)</td>
<td>12 (3.6%)</td>
<td>22 (5.3%)</td>
</tr>
<tr>
<td>Obese class III (40+)</td>
<td>17 (1.4%)</td>
<td>10 (1.3%)</td>
<td>11 (3.3%)</td>
<td>5 (2.2%)</td>
</tr>
</tbody>
</table>

Cells in the table represent the number (percentage) of patients in each BMI category.
BMI on post-operative pain and function (the destination), where compared to people of normal BMI (20–25), those in the obese class II group (BMI 35–40) would have an OHS that is 2.34 points lower. It has previously been suggested that the minimum clinically important difference (MCID) (the smallest amount of change in OHS that is likely to be clinically important) is around 5 points, based on observations that a half standard deviation in the change score has been shown to represent a meaningful difference, and that the MCID may be as low as 2 points such that even a small change may be clinically important. Hence, although statistically significant, differences in attained 12-month OHS across different categories of BMI only approach potential clinical relevance in obese classes II and III. Regardless, this effect is greatly outweighed by the substantial improvement (change) in OHS seen across all categories of BMI (the journey) following surgery where in the obese class II group (BMI 35–40), after adjusting for all confounders, patients achieved a 22.2 point change (improvement) in OHS over the year following surgery. The findings are consistent across studies and robust to adjustment for a wide range of confounding factors. The findings suggest that BMI should not present a barrier to access THR in terms of PROMs.

**Strengths and limitations**

The strengths of this study include the relatively large sample size using four separate cohorts with data collected prospectively with a good rate of follow up, the use of a reliable, valid and responsive instrument for assessing outcomes of THR, and the generalizability of the findings using data from the UK and Europe. A further strength is the comprehensive adjustment for confounding through combining data in a subset of the studies. A limitation of the study is that we have only evaluated short term outcomes at 12-months following surgery, and it is unclear what the effect will be in the long term. In addition, only 1.6% of patients within this study had a BMI of 40+, hence we did not have the power to evaluate the effect of this most severe category of obesity on outcomes, and further work is required to determine whether there is a threshold effect above which outcomes are worse. Across the four studies, patients were operated on during different periods of time and a limitation is that there are variations in the time spans of the various cohorts. The use of multiple imputation methods present potential limitations. They require us to make the assumption data are missing at random (MAR), which is plausible in the context of this study as the reason for missing data is due to variables not being collected in the study. Plausibility is further enhanced by inclusion of a wide range of covariates to ensure enough variables predictive of missing information are included. Further limitations are that in the EUROHIP study data on OHS was only collected in a minority of patients, the majority having a WOMAC score, hence we had to derive the OHS from the recorded WOMAC score. Inconsistency in the outcome measures collected across studies is not unexpected — this has lead to the development of a core set of outcomes being supported by the COMET initiative when collecting data for future studies. As highlighted in a recent systematic review in situations where different outcome measures have been collected it is not uncommon to map one outcome measure to another, as we have done in this study. Reassuringly, the results from the EUROHIP study were entirely consistent with those of the other three studies.

![Fig. 2. Change on OHS between baseline and 12-months follow up, stratified by BMI categories.](image-url)
What is already known

Patient Reported Outcome Measures (PROMs) are now the favoured measure of outcome used to see whether surgery has been successful from the patient's perspective. The PROMS most often used to assess the effects of THR include well-validated self-assessment measures of OA severity such as the OHS or Western Ontario and McMaster Universities (WOMAC) OA index, which assess pain, stiffness and function and 12-months is a commonly used and appropriate time at which to consider whether surgery has been successful. There is growing evidence in the UK that commissioners are requiring access to hip replacement for obese patients, stating that increasing levels of obesity increases the risk of complications following surgery. Within the literature there is some evidence to support this view that obesity increases the risk of complications, although such risks are most consistently observed amongst the morbidly obese. There is evidence of an increased risk of infection amongst obese patients, but the absolute risk is small, and this is in keeping with existing literature across other types of surgery. An increased risk of thrombo-embolic events has recently been observed, again consistent with other areas of surgery. Although the risks of complications may be slightly higher in these patients, in accordance with NICE guidelines, there is no evidence to support these as reasons to deny treatment. Of the studies that have explored the effect of obesity on prognosis survival, most have focused on the mid term outcomes and found no difference in survival rates. A recent large study of longer term outcomes over 20-years following THR found a small, but significant, effect of BMI with an increased risk of revision, particularly in the morbidly obese (BMI 40+) group, although the absolute numbers of revisions were small.

Regarding patient reported outcomes of hip replacement surgery, evidence from the literature on the effect of BMI is conflicting. Some authors conclude that increasing levels of obesity are associated with worse pain and functional outcomes, whilst others have found no evidence of an association. The general consensus being that any observed differences in risk for obese patients are small and they can still expect large symptomatic improvement following hip replacement, even though the may not attain the same level of post-operative pain and function. The main limitation of existing studies is the possibility of residual or unmeasured confounding. Given current attempts made by commissioners to ration access to hip replacement on the basis of BMI, and the conflicting results of existing studies, it is important to address this and other limitations in order to strengthen the evidence of whether or not a true association exists. Our findings confirm that whilst there are statistically significant differences in the attained level of post-operative pain and function, these differences are not clinically relevant, and are greatly outweighed by the substantial improvements (change) in pain and function seen across all pre-operative categories of BMI following surgery. These findings are robust to adjustment for an extensive range of confounding factors. The findings suggest that BMI should not present a barrier to access THR in terms of PROMs.

What this study adds

This study demonstrates that pre-operative levels of BMI should not present a contra-indication for hip replacement surgery on the basis of expected improvement in patients report pain and functional outcomes. Regardless of differences in pre-operative BMI these patients can expect to achieve substantial symptomatic improvement following surgery. Although there are small significant differences in attained post-operative scores, these differences are small and not clinically important.

Ethics

For the EPOS study ethical approval was obtained from the Salford and Trafford Research Ethics Committee (Project No: 98105 – MREC 98/8/20 UK Multicentre Exeter Primary Outcome Study). Informed written consent was obtained from all participants. For the EOC and St. Helier studies ethical approval was not required under NHS research governance arrangements. In the EUROHIP study each centre was responsible for local ethical approval if required, and this was duly obtained.

Author contributions

All authors were involved in the conception and design of the study, or acquisition of data, or analysis and interpretation of data, drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Prof Nigel Arden is the guarantor.

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Competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that: RNB, GT and PAD have no conflicts of interest; AJ has received honorariums, held advisory board positions (which involved receipt of fees), and received consortium research grants, respectively, from ROCHE, Anthera and Servier. MKJ, NKA, and CC have received honorariums, held advisory board positions (which involved receipt of fees), and received consortium research grants, respectively, from: Novartis and Alliance for Better Health and Lilly; Merck, Merck Sharp and Dohme, Roche, Novartis, Smith and Nephew, Q-MED, Nicos, Servier, GlaxoSmithKline, Schering-Plough, Pfizer, and Rottpharm; and Alliance for Better Bone Health, Amgen, Novartis, Merck Sharp and Dohme, Servier, Eli Lilly, and GlaxoSmithKline; DB has held an independent consultancy with ICNet and Stryker, and has been a grant holder on a Genzyme-funded study; DM has received royalties from Biomet and Wright Medical Technology, Inc, and receives research support from Depuy, A Johnson & Johnson Company, Stryker, Zimmer and Wright Medical Technology, Inc; they have no other relationships or activities that could appear to have influenced the submitted work. KP-G is a board member for DGOOC, EFORT, EPOS, AE, has received payment for lectures given to Waldemar LINK GmbH, Aesculap AG, Zimmer GmbH Germany and has received royalties from Zimmer Inc., Warsaw, USA; KD has held consultancy with Bioiberica and Amgen; RF has held independent consultancy with Stryker, Medacta, Smith & Nephew and is Director of Research at South West London Elective Orthopaedic Centre.
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