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Understanding the uptake of new hip replacement implants in the UK: Analysis of data from the National Joint Registry for England and Wales

Journal:	BMJ Open
Manuscript ID	bmjopen-2019-029572
Article Type:	Research
Date Submitted by the Author:	31-Jan-2019
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Keywords:	Orthopaedic & trauma surgery < SURGERY, Joint replacement, Implant Patient, Surgeon, National Joint Registry

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Understanding the uptake of new hip replacement implants in the UK: Analysis of data from the National Joint Registry for England and Wales

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Keywords

Orthopaedics, joint replacement, implant, patient, surgeon, national joint registry

Data sharing statement

Access to the data analysed in this study required permission from the National Joint Registry for England, Wales and Northern Ireland Research Sub-committee. http://www.njrcentre.org.uk/njrcentre/Research/Researchrequests/tabid/305/Default.aspx contains information on research data access request to the National Joint Registry.

Acknowledgements

We thank the patients and staff of all the hospitals who have contributed data to the National Joint Registry. We are grateful to the Healthcare Quality Improvement Partnership, the National Joint Registry Steering Committee, and staff at the National Joint Registry for facilitating this work.

Disclaimer

The views expressed represent those of the authors and do not necessarily reflect those of the National Joint Registry Steering Committee or Healthcare Quality Improvement Partnership, who do not vouch for how the information is presented. The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

Ethics approval

Patient consent was obtained for data collection by the National Joint Registry. According to the specifications of the NHS Health Research Authority, separate informed consent and ethical approval were not required for the present study.

Author Contributions

CP, AB, AJ and MW designed the study. CP, AB, AS, JMW, LH, AJ and MW reviewed the published work. CP conducted the statistical analysis and wrote the report. CP had full access to all the data and AB is the guarantor.

Conflicts of Interest

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work. AB and MW are involved in a separate grant to the University of Bristol funded by Stryker. All other authors declare no financial relationships with any organisations that might have an interest in the submitted work in the previous three years. All authors declare no other relationships or activities that could appear to have influenced the submitted work.

Funding

This study was funded by the NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care. Adrian Sayers was supported by a MRC fellowship MR/L01226X/1.

Word count 3213 words

Abstract

Objectives

Primary: to describe the uptake of new implant components (femoral stem or acetabular cup/shell) for total hip replacements (THRs) in the National Joint Registry for England and Wales (NJR). Secondary: to compare the characteristics of: a) surgeons and b) patients who used/received new rather than established components.

Design

A cohort of 618,393 primary THRs performed for osteoarthritis (±other indications) by 4,979 surgeons between 2008-2017 in England and Wales from the NJR. We described the uptake of new (first recorded in NJR >2008) stems/cups, and variation in uptake by operating surgeons (primary objectives). We explored surgeon-level and patient-level factors associated with use/receipt of new components with logistic regression models (secondary objectives).

Outcomes

Primary outcomes: total number of new cups/stems, and proportion of operations using new versus established components. Secondary outcomes: odds of: a) a surgeon using a new cup/stem in a calendar-year, b) a patient receiving a new rather than established cup/stem.

Results

Sixty-eight new cups and 72 new stems were used in 72,349 primary THRs (11.7%) by 2,423 surgeons (48.7%) 2008-2017. Surgeons used a median of one new stem and cup (IQR=1-2 both, max=11 cups, max=9 stems). Surgeons performed a median of 22 THRs (IQR 5-124, range 1-3,938), a median of 5.0% (IQR 1.3-16.1%) and 9.4% (IQR 2.8-26.7%) used new stems and cups respectively. Patients aged <55 years old versus those 55-80 had higher odds of receiving a new rather than established stem (OR=2.13, 95%CI 2.04-2.23) and cup (OR=1.40, 95%CI 1.34-1.45). Women had lower odds of receiving a new stem (OR=0.81, 95%CI 0.78-0.84), higher odds of receiving a new cup (OR=1.11, 95%CI 1.08-1.14).

Conclusions

Large numbers of new THR components have been introduced in the NJR since 2008. Half of surgeons have tried new components, with wide variation in how many types and how often they have been used.

Article Summary

Strengths and limitations of this study

- This study provides a nationally representative description of the uptake of new implant components for total hip replacements in England and Wales.
- This is the first study to describe the variation in uptake of new components by surgeons, and surgeon characteristics which may be associated with the use of new components.
- Although implant component brand names were checked by the authors, some components may have been reclassified or we may still have misclassified some components as either new or established, but the introduction of unique device identifiers should remove this problem in future.
- The surgeon assigned as lead operating surgeon in the NJR may not be correct, although consistency between our sensitivity and primary analyses indicate that this is unlikely to have substantially affected our findings.
- Hospital-level or regional variation in suppliers may be important factors affecting implant uptake, but these were beyond the scope of this study.

Background

Total hip replacements (THRs) are mainly performed to treat pain and functional limitation due to osteoarthritis (OA).[1] It is a highly successful surgical procedure with typical 10-year revision rates <5%,[2] the current NICE benchmark.[3] However, younger patients are more likely to require revision surgery; the lifetime revision risk for men having a THR in their 50s is ~35% compared with 5% in their 70s.[4] Such patients may benefit the most from developments in THR that lead to reduced revision rates or improved outcomes.

Some new implant designs intended to benefit these more active and/or younger patients have been high-profile failures, for example metal-on-metal THRs [5] including the Articular Surface Replacement (ASR) prostheses in particular.[6] Many new implants, the ASR included,[7] were introduced with minimal supporting evidence of their effectiveness [8] and may offer at best no improvement over pre-existing components.[9] An influential agenda for surgery research (IDEAL) was developed, providing a framework for future investigations into surgical innovations, which recommended the phased introduction of new medical devices.[10] The rapid uptake of metal-on-metal THRs was found to be inconsistent with this, it is not clear whether the introduction of newer implants since has followed the framework.

There is wide variation between and within regions of common surgical procedures.[11] The large number of different components used in primary THRs (127 femoral stems and 105 acetabular cups recorded in the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) in 2016) [12] may be an important source of variation. Many registries describe the volume of different implant components used annually but not the variation in uptake of new implants between surgeons or which patients receive them. More research is needed to understand and reduce avoidable variation in outcomes created by differences in surgical activity.

We aimed to:

- 1. Describe the uptake of new implants for THRs in the NJR
- 2. Describe how this uptake varies by surgeons
- 3. Compare surgeons who use new compared with established components
- 4. Compare patients who receive new compared with established components

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Methods

Data Source

The NJR was established in 2003.[2] Data entry for Northern Ireland and the Isle of Man did not commence until 2013 and 2015, respectively therefore they are excluded from this analysis.

Study sample

We included the cohort of patients who received a primary THR for OA (± other indications) between 1st January 2008 and 26th February 2017. We used NJR data from 2003 onwards to calculate the date each implant component was first used and the total number of implantations. We excluded people who had not given consent for recording of personal details, those who received a resurfacing rather than stemmed THR, and where the brand of their acetabular or femoral components was uncertain.

Patient involvement

This study was designed and undertaken without patient involvement.

Definition of new and established implant components

We identified the implant component brand from component labels recorded in the NJR and categorised all femoral (stem) or acetabular (cup or shell) components with a first recorded use by any surgeon in the NJR on or after 1st January 2008 as 'new'. Components with a first recorded use before 2008 were categorised as 'established'.

Surgeon uptake of new implant components

All surgeons with operations recorded in the NJR are assigned an anonymised identifier and their role in the operation ("consultant in charge" or "operating") is recorded. We summarised each operating surgeon's activity across each calendar-year in which they performed \geq 1 THR. We considered five potential surgeon-level factors which may be associated with use of a new component in a calendaryear: total volume of THRs performed in that year, proportion of those THRs performed on patients <55 years old (<10% and \geq 10%), source of funding for THRs ('100% NHS funded' or 'some or all privately funded'), proportion of THRs performed on patients with an American Society of Anaesthesiologists (ASA) grade III-V (<25% and \geq 25%), and the range of stem-cup combinations used in that calendar-year (' \leq 3', '4-6', '7-10' and '>10').

Patients receiving new implant components

We used date of surgery to order patients within implant components and within surgeons. We categorised patients according to whether the component they received was new or established. We considered five potential patient-level factors which may be associated with their receipt of new components: age at the time of THR (<55, 55-80, and 80+ years), gender, body mass index (BMI), ASA grade, and NHS or private funding.

Statistical analyses

We described the use of unique stems and cups in primary THRs performed since January 1st 2008, the cumulative use of new components in patients, and the count of surgeons who used new components. We also described the total number of all and new cups, stems, and combinations.

Surgeon-level factors

In analyses of surgeon-level and patient-level factors associated with use of or receipt of new implants we included only those people with complete exposure and outcome data for the surgeon-level and patient-level analysis models (i.e. complete case analysis). We assumed that data were missing at random but did not use multiple imputation to account for these missing data since there were no variables in the NJR dataset which were not already in our regression models and which may have carried information about the missing data (particularly BMI).

Our outcome was whether a surgeon used a new component at least once for a THR in a calendar-year (stems and cups analysed separately), unit of analysis was surgeon calendar-years and exposure variables were those surgeon-level factors defined previously. We used multivariable adjusted logistic regression models, accounting for the clustering of calendar-years within surgeons.

Patient-level factors

Our outcome was whether a patient received a new rather than established component (stems and cups analysed separately), unit of analysis was patients and exposure variables were those patient-level factors defined previously. Patient-level factors were included in multivariable adjusted mixed-effects logistic regression models, with patients nested within surgeons.

Sensitivity analyses

We conducted two sensitivity analyses. To determine whether the lack of variability in patients operated on by low volume surgeons affected our results we repeated our surgeon-level analysis excluding calendar-years for surgeons in which they performed <10 THRs. We also considered that the choice of

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component was made by the consultant in-charge rather than the operating surgeon (the consultant incharge was not the operating surgeon for ~16% of THRs). We repeated our surgeon-level analysis by consultant in-charge and repeated our patient-level analysis with patients clustered within consultant in-charge.

All analyses were performed using Stata v15 (StataCorp).

Results

Overall use of implant components

Between 1st January 2008 and 26th February 2017, 618,393 primary THRs were performed for OA in England and Wales and recorded in the NJR. The mean age of the patients was 68.5 years (SD=11.1 years), 60.7% were female, their ASA grades were I:14.2%, II:69.9%, III:15.5% and IV/V:0.5%. Twenty-three percent had a normal/underweight BMI, 39.6% were overweight and 37.6% obese. THRs were performed by 4,979 surgeons using 189 different stems, 187 cups and 2,026 stem-cup combinations. Surgeons used a median of three different stems (IQR=2-5, max=21), four cups (IQR=2-7, max=27) and five combinations (IQR=2-9, max=60), and performed a median of 22 THRs over the period (IQR 5-124, range 1-3,938).

Use of new implant components

During this period 68 new cups (47 uncemented, Table S1) and 72 new stems (51 uncemented, Table S2) were first used. The rate of introduction of new cups and stems remained stable (~16 new components/year, Figure S1). Twelve percent (n=72,349) of THRs performed used a new stem, cup, or combination. In 2016, 14.9% of THRs used a new cup (n=12,768/85,835) and nine percent a new stem (n=7,744, Figure 1). Forty eight percent (n=2,423) of surgeons who performed a THR in this period used at least one new implant component.

New cups were used in 9.0% (n=55,360) THRs performed by 41.5% (n=2,066) surgeons (Table S1), new stems in 4.7% (n=28,924) THRs by 26.4% (n=1,313) surgeons (Table S2) and new combinations in 1.9% (n=11,935) THRs by 12.5% (n=624) surgeons. Most new cups (n=31,448, 56.8%) and almost all new stems (n=25,684, 88.8%) were uncemented. The median number of new stems, cups and combinations used by surgeons was one (IQR=1-2, cups max=11, stems max=9 and combinations max=13; Tables S3-S5). The median THRs performed using new stems was three (IQR 1-12, max=769) and new cups was

four (IQR 1-17, max=1,211). The median proportion of a surgeon's THRs performed using new stems was 5.0% (IQR 1.3-16.1%), new cups 9.4% (IQR 2.8-26.7%) and new combinations 3.6% (IQR 0.9-13.3%).

The five most frequently implanted new stems were used in 18,528 THRs (63.1% of THRs using a new stem, Table S2). The five most frequently implanted new cups were used in 44,633 THRs (80.6% of THRs using a new cup, Table S1). Uptake of the two most popular new cups was rapid (5,000 uses of Exeter X3 Rimfit <1,000 days, 5,000 uses of Trinity ~1,500 days after first use, Figure 2) but was slower for new stems (5,000 uses of Polarstem Cementless ~2,800 days, Figure 2). Conversely, a third of the new stems and cups (n=24/72 new stems, n=24/69 new cups) have been used in \leq 10 THRs.

Surgeon-level and patient-level factors associated with new implant components

Our complete case analysis included 431,955 out of a possible 618,393 THRs (69.8%) and 19,810 surgeon calendar-years (Figure S2). We were missing data for BMI (n=186,308, 30.1%) and source of funding (n=1,514, 0.2%).

Characteristics of surgeons using new implant components

Multivariable adjusted associations between surgeon-level factors and their use of new components in a calendar-year were consistent between stems and cups (Table 1, unadjusted Table S6). Surgeons who treated more younger patients had 51% higher odds of using a new stem (OR=1.51, 95%CI 1.34-1.69, p<0.001) and 45% higher odds of using a new cup (OR=1.45, 95%CI 1.32-1.59, p<0.001) in a calendar-year. Those who performed more THRs/year had 2% and 8% higher odds of using new stems (OR=1.02, 95%CI 1.00-1.05, p=0.03) and cups respectively (OR=1.08, 95%CI 1.05-1.10, p<0.001). Private funding was associated with 23% increased odds of using new stems (OR=1.23, 95%CI 1.06-1.42, p=0.006) and weakly associated with 11% increased odds of using new cups (OR=1.11, 95%CI 0.98-1.25, p=0.10). Use of more stem-cup combinations was strongly associated with increased use of new components (ORs for '>10' vs. ' \leq 3' combinations: 23.3 and 13.9 for stems and cups respectively, p values <0.001). Proportion of patients with ASA grades III-IV was associated with 23% higher odds of using new cups (OR=1.23, 95%CI 0.96-1.22, p=0.18).

Characteristics of patients receiving new implant components

A higher proportion of recipients of new compared with established implant components were aged <55 years old (10.2% established vs. 21.1% new stems; 10.4% established vs. 14.6% new cups; Table 2), although the main recipients of all components were aged 55-80 years. Fifteen percent of recipients of established stems (15.2%) were \geq 80 years old compared with 7.6% of recipients of new stems, but there

was little difference in the proportion of older recipients of established (14.9%) and new (13.5%) cups. Across all components and component age, women were the main recipients of THRs. There was no difference in BMI between recipients of established and new stems or cups. A higher proportion of recipients of new components had ASA grade I (20.1% new vs. 14.2% established stems; 16.5% new vs. 14.3% established cups). A higher proportion of people with privately funded THRs had new components (stems: 18.4% new vs. 12.8% established; cups: 18.6% new vs. 12.5% established).

Multivariable adjusted mixed effects logistic regression models (Table 2, unadjusted Table S7) found that patients <55 years old, compared with those 55-80, had 113% and 40% higher odds of receiving a new rather than established stem (OR=2.13, 95%CI 2.04-2.23, p<0.001) and cup (OR=1.40, 95%CI 1.34-1.45, p<0.001). Women had 19% lower odds than men of receiving a new stem (OR=0.81, 95%CI 0.78-0.84, p<0.001), but 11% higher odds of receiving a new cup (OR=1.11, 95%CI 1.08-1.14, p<0.001). There was weak evidence that people with higher BMI had 14% higher odds of receiving a new stem (OR for underweight/normal vs. Class II Obese=1.14, 95%CI 1.07-1.22, p<0.001) but BMI was not associated with receiving a new cup (e.g. OR for underweight/normal vs. Class II Obese=0.97, 95%CI 0.93-1.02, p=0.29). Higher ASA grade was associated with 40% lower odds of receiving new stems (OR for ASA grades 'IV + V' versus 'I' = 0.60, 95%CI 0.45-0.80, p<0.001), but associated with 26% higher odds of new cups (OR for ASA grades 'IV + V' versus 'I' = 1.26, 95%CI 1.06-1.51, p=0.01). Patients with private versus NHS funding had six percent lower odds of receiving new stems (OR=0.94, 95%CI 0.89-0.99, p=0.02), but 13% higher odds of receiving new cups (OR=1.13, 95%CI 1.08-1.18, p<0.001).

Sensitivity analyses

Results of our first sensitivity analyses (excluding calendar-years for surgeons with <10 THRs) differed only minimally from our primary analyses (Table S8), indicating that our results were not biased by lowvolume surgeons. Results of our second sensitivity analyses ('consultant in-charge' as the clustering variable) also differed only minimally from our primary analyses (Tables S9-S10).

Discussion

Sixty-eight new cups and 72 new stems were first used in THRs in the NJR for OA between 2008 and 2017. Most THRs used components introduced before 2008 but 12% used a new stem or cup. Uptake of some new implant components was very rapid. Conversely, uptake of a third of new components has been slow. Most surgeons used a maximum total of seven different cups or stems, of which one or two

were new components. A small number of surgeons used a wide variety of different components, including new stems, cups and combinations.

Strengths of our study include the use of the NJR dataset, the largest arthroplasty register with comprehensive data capture (>95% in the period studied). This is the first to describe the variation in factors associated with uptake of new implant components by surgeons and receipt of new components by patients. Our study has several weaknesses. We classified a component as new based on the first record of a brand name in the NJR, but this does not exclude the possibility that a component was introduced earlier to other markets outside the UK. Furthermore, new components may constitute procedures not uploaded to the NJR (missing primary THRs estimated <5%). Also, some of these components may be minor modifications or a rebadged/renamed version of an existing component and some may also cover successive versions of a component. The correct operating surgeon may not be assigned to every operation. The extent to which this applies is unknown but may result in inaccurate estimates of surgeon-level associations, although our sensitivity analyses indicate that this is unlikely. The associations we have reported may be confounded by unmeasured factors (residual confounding) and in the absence of pre-existing literature on the uptake of new implants the findings from the regression models should be considered exploratory. We were missing BMI data for some people and elected not to use multiple imputation to account for these missing data. Finally, we did not have data on hospital-level factors or regional variation in suppliers in our analyses, which may be drivers of selection.[13]

Approximately 16 new implant components/year (stems and cups) were introduced in the NJR between 2008-2017. Comparisons with Australia (34 implant components/year 2003-2008) [14] and Finland (2-4 components/year 1980-2013) [15] suggest that this rate is not unusual, but that there is large variation internationally. The rapid uptake of some new components indicates that phased introduction, as recommended in the IDEAL Framework and others,[16] are unlikely to be happening. Conversely, a third of new implant components have not yet accrued more than ten uses. Postmarket surveillance of THRs, due to their longevity, performs a safety monitoring role which cannot easily be replaced by pre-approval clinical data. Since the statistical methods are not applicable to components used in small numbers collaboration between international arthroplasty registries may allow more effective monitoring for low-volume components.

Over half of surgeons in our study used ≤5 different stems, cups, or combinations, similar to a median of two different implant brands reported by surgeons in the USA in 1997.[17] The volume of THRs

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performed by surgeons using new components was often low (median \leq 4 THRs with new components varied versus median 22 THRs in total), but the proportion of their THRs using any new components varied from one percent (lower quartile) to 27% (upper quartile). Surgeons who use a wider range of prosthesis combinations in THRs may have higher revision rates [18] and early THRs performed after switching implants may have a higher revision risk (a.k.a. 'learning-curve').[19] While this suggests that surgeons should rely on a narrow range of implant components and rarely switch, a phased introduction of new implant designs, as is done in Sweden, may mitigate the learning-curve effect.[20] Since there are no contemporary comparisons of the range of implant components surgeons use and their relative volumes, it is unclear whether the between-surgeon variation we have reported may be associated with worse implant survival and warrants further research.

We found that newer components were being used in patients likely to be more active (i.e. younger and/or male patients). There has been increasing evidence that uncemented implants, particularly stems, should not be used in older patients, but some uncertainty remains about their use in young patients (especially uncemented cups).[21–23] Since the majority of new cups and stems are uncemented, the decision to use these implant components in younger patients may increase the already high lifetime risk of revision surgery for these patients. Associations between BMI or ASA grade and receipt or use of new components were inconsistent between stems and cups and did not provide clear support for the use of new implant components in patients likely to be more active (i.e. lower BMI and ASA grades). It may be of interest to further investigate the implant component choices made for patients with higher BMI or ASA grades.

The most comparable previous work used NJR data to explore patient-level and hospital-level determinants that patients receive uncemented versus cemented implants.[13] Uncemented components were less likely to be used in women and older patients, and hospitals treating older patients were less likely to use them. Our results indicate that surgeons who treat a higher proportion of younger patients are more likely to use newer components. Our most marked finding, that surgeons who used a wide variety of stem-cup combinations (either established or new) were much more likely to try a new component, may be somewhat self-evident but suggests that there may be a subset of surgeons who change components more quickly than their peers. Whether this behaviour, alongside the previously discussed learning-curve, is related to outcomes of THRs is currently unclear.

Conclusions

A large number of new THR implant components have been introduced into use in the NJR since 2008. The majority of THRs performed since 2008 used components which have been in use for a long time, but a large number of surgeons have tried new components, with wide variation in how many types and how often they have been used. The impact of this variation on patient outcomes is currently unclear. New rather than established implant components are more likely to be used in patients who are younger and/or male, although whether this will reduce the high lifetime risk of revision for this population is unclear.

References

- 1 Dreinhöfer KE, Dieppe P, Stürmer T, *et al.* Indications for total hip replacement: Comparison of assessments of orthopaedic surgeons and referring physicians. *Annals of the Rheumatic Diseases* 2006;**65**:1346–50. doi:10.1136/ard.2005.047811
- 2 National Joint Registry for England, Wales and Northern Ireland. 14th Annual Report 2017. 2017.
- 3 National Institute for Health and Care Excellence. Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip. NICE 2018.
- 4 Bayliss LE, Culliford D, Monk AP, *et al.* The effect of patient age at intervention on risk of implant revision after total replacement of the hip or knee: a population-based cohort study. *The Lancet* 2017;**389**:1424–30. doi:10.1016/S0140-6736(17)30059-4
- 5 Smith AJ, Dieppe P, Vernon K, *et al.* Failure rates of stemmed metal-on-metal hip replacements: Analysis of data from the National Joint Registry of England and Wales. *The Lancet* 2012;**379**:1199–204. doi:10.1016/S0140-6736(12)60353-5
- de Steiger RN, Hang JR, Miller LN, *et al.* Five-Year Results of the ASR XL Acetabular System and the ASR Hip Resurfacing System. *The Journal of Bone and Joint Surgery-American Volume* 2011;**93**:2287–93. doi:10.2106/JBJS.J.01727
- 7 Reito A, Lehtovirta L, Lainiala O, *et al.* Lack of evidence—the anti-stepwise introduction of metal-onmetal hip replacements. *Acta Orthopaedica* 2017;**88**:478–83. doi:10.1080/17453674.2017.1353794
- 8 Kynaston-Pearson F, Ashmore AM, Malak TT, *et al.* Primary hip replacement prostheses and their evidence base: systematic review of literature. *BMJ* 2013;**347**:f6956. doi:10.1136/bmj.f6956
- 9 López-López JA, Humphriss RL, Beswick AD, et al. Choice of implant combinations in total hip replacement: systematic review and network meta-analysis. BMJ (Clinical research ed) 2017;**359**:j4651. doi:10.1136/bmj.j4651

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42 43 44 45 46		2
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56 57 58 59		
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- 10 McCulloch P, Altman DG, Campbell WB, *et al.* No surgical innovation without evaluation: the IDEAL recommendations. *The Lancet* 2009;**374**:1105–12. doi:10.1016/S0140-6736(09)61116-8
- 11 Birkmeyer JD, Reames BN, McCulloch P, *et al.* Understanding of regional variation in the use of surgery. *The Lancet* 2013;**382**:1121–9. doi:10.1016/S0140-6736(13)61215-5
- 12 National Joint Registry for England W and NI. Prostheses used in hip, knee, ankle, elbow and shoulder replacement procedures 2016. 2017.
- 13 Davies C. An analysis of choice: a case study on hip prostheses. 2011.
- 14 Anand R, Graves SE, de Steiger RN, *et al.* What Is the Benefit of Introducing New Hip and Knee Prostheses? *The Journal of Bone and Joint Surgery-American Volume* 2011;**93**:51–4. doi:10.2106/JBJS.K.00867
- 15 Peltola M. Impact of technological change on quality of care: Studies on total hip and knee replacement. 2016.
- 16 Zywiel MG, Johnson AJ, Mont MA. Graduated Introduction of Orthopaedic Implants. *The Journal of Bone & Joint Surgery* 2012;**94**:e158. doi:10.2106/JBJS.K.01675
- 17 Sharkey PF, Sethuraman V, Hozack WJ, *et al.* Factors influencing choice of implants in total hip arthroplasty and total knee arthroplasty: Perspectives of surgeons and patients. *Journal of Arthroplasty* 1999;**14**:281–7. doi:10.1016/S0883-5403(99)90052-9
- 18 Australian Orthopaedic Association. Hip, Knee & Shoulder Arthroplasty: Annual Report 2017. Australian Orthopaedic Association 2017. https://aoanjrr.sahmri.com/documents/10180/397736/Hip%2C%20Knee%20%26%20Shoulder%20 Arthroplasty
- 19 Peltola M, Malmivaara A, Paavola M. Hip prosthesis introduction and early revision risk. *Acta Orthopaedica* 2013;**84**:25–31. doi:10.3109/17453674.2013.771299
- 20 Mohaddes M, Björk M, Nemes S, *et al.* No increased risk of early revision during the implementation phase of new cup designs: Analysis of 52,903 hip arthroplasties reported to the Swedish Hip Arthroplasty Register. *Acta Orthopaedica* 2016;**87**:31–6. doi:10.1080/17453674.2016.1181818
- 21 Mäkelä KT, Matilainen M, Pulkkinen P, et al. Failure rate of cemented and uncemented total hip replacements: Register study of combined Nordic database of four nations. BMJ (Online) 2014;**348**:1–10. doi:10.1136/bmj.f7592
- 22 Stea S, Comfort T, Sedrakyan A, *et al.* Multinational comprehensive evaluation of the fixation method used in hip replacement: Interaction with age in context. *Journal of Bone and Joint Surgery American Volume* 2014;**96**:42–51. doi:10.2106/JBJS.N.00463
- 23 Hailer NP, Garellick G, Kärrholm J. Uncemented and cemented primary total hip arthroplasty in the Swedish Hip Arthroplasty Register: Evaluation of 170,413 operations. *Acta Orthopaedica* 2010;**81**:34–41. doi:10.3109/17453671003685400

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Table 1 Results from multivariable adjusted logistic regression models showing the association between surgeon-level factors and use of new stems and cups

			Stems		Cups					
Exposure	Established (n=17,753) ³	New (n=2,657) ³	OR ¹	(95% CI)	p1	Established (n=15,891) ³	New (n=4,519) ³	OR ¹	(95% CI)	p1
Proportion of THRs performed on										
patients <55 years old										
<10% (ref.)	12,734 (71.7%)	1,294 (48.7%)	1	-	-	11,629 (73.2%)	2,399 (53.1%)	1	-	-
≥10%	5,019 (28.3%)	1,363 (51.3%)	1.51	(1.34 to 1.69)	<0.001	4,262 (26.8%)	2,120 (46.9%)	1.45	(1.32 to 1.59)	<0.001
Number of THRs performed in calendar year ²			1.02	(1.00 to 1.05)	0.03			1.08	(1.05 to 1.10)	<0.001
(per 10 additional cases)	7.0 (2.0, 23.0)	28.0 (9.0, 58.0)		To.		6.0 (2.0, 20.0)	24.0 (8.0, 54.0)			
Proportion of THRs funded privately										
100% NHS funded (ref.)	12,551 (70.7%)	1,337 (50.3%)	1	-	(A)	11,420 (71.9%)	2,468 (54.6%)	1	-	-
Some or all funded privately	5,202 (29.3%)	1,320 (49.7%)	1.23	(1.06 to 1.42)	0.006	4,471 (28.1%)	2,051 (45.4%)	1.11	(0.98 to 1.25)	0.10
Number of stem- cup combinations used in calendar							L			
year ≤3 (ref.)	13,915 (78.4%)	933 (35.1%)	1	-	-	12,922 (81.3%)	1,926 (42.6%)	1	-	-
4-6	3,184 (17.9%)	1,032 (38.8%)	3.97	(3.51 to 4.50)	<0.001	2,514 (15.8%)	1,702 (37.7%)	3.47	(3.12 to 3.85)	<0.002
7-10	595 (3.4%)	548 (20.6%)	9.84	(8.11 to 12.0)	<0.001	416 (2.6%)	727 (16.1%)	7.12	(5.90 to 8.61)	<0.001
>10	59 (0.3%)	144 (5.4%)	23.3	(15.3 to 35.6)	<0.001	39 (0.2%)	164 (3.6%)	13.9	(9.00 to 21.5)	<0.001

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Proportion of THRs performed on patients with ASA grade III-V										
<25% (ref.)	12,779 (72.0%)	2,019 (76.0%)	1	-	-	11,464 (72.1%)	3,334 (73.8%)	1	-	-
≥25%	4974 (28.0%)	638 (24.0%)	1.09	(0.97 to 1.23)	0.16	4,427 (27.9%)	1,185 (26.2%)	1.23	(1.12 to 1.35)	<0.001

1 – odds ratios, 95% confidence intervals and p-values are from logistic regression models adjusted for all exposure variables, 2 - median (lower to upper quartile), 3 - proportions displayed are based on surgeon-calendar years

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T	ble 2 Results from multivariable adjusted mixed-effects regression models (patients nested within surgeons) of age, gender, categorised BMI, ASA grade and source of
fu	nding on stem age and cup age, with category proportions

	Stems				Cups					
	Established	New	OR ¹	(95% CI)	р	Established	New	OR ¹	(95% CI)	р
	(n=410,613)	(n=21,342)		. ,	•	(n=391,369)	(n=40,586)		. ,	•
Age										
<55 years old	42,078	4,495	2.13	(2.04 to 2.23)	<0.001	40,637	5,936	1.40	(1.34 to 1.45)	< 0.001
,	(10.2%)	(21.1%)		(/		(10.4%)	(14.6%)	_	(/	
55 to 80 (ref.)	306,218	15,233	1	-	-	292,278	29,173	1	-	-
	(74.6%)	(71.4%)				(74.7%)	(71.9%)			
≥ 80 years old	62,317	1,614	0.49	(0.46 to 0.52)	< 0.001	58,454	5,477	0.90	(0.87 to 0.94)	< 0.001
,	(15.2%)	(7.6%)		((14.9%)	(13.5%)		(
Gender										
Male (ref.)	161,920	9,455	1	-	-	155,709	15,666	1	-	-
	(39.4%)	(44.3%)				(39.8%)	(38.6%)			
Female	248,693	11,887	0.81	(0.78 to 0.84)	<0.001	235,660	24,920	1.11	(1.08 to 1.14)	< 0.001
	(60.6%)	(55.7%)				(60.2%)	(61.4%)		, , , , , , , , , , , , , , , , , , ,	
BMI										
Underweight and	93,578	4,639	1	-	-	88,450	9,767	1	-	-
normal (ref.)	(22.8%)	(21.7%)				(22.6%)	(24.1%)			
Overweight	162,562	8,425	1.04	(1.00 to 1.09)	0.06	155,070	15,917	0.97	(0.94 to 1.01)	0.11
	(39.6%)	(39.5%)		(/		(39.6%)	(39.2%)			
Class I Obese	103,566	5,495	1.07	(1.02 to 1.12)	0.006	99,110	9,951	0.97	(0.93 to 1.00)	0.07
	(25.2%)	(25.7%)		()		(25.3%)	(24.5%)		()	
Class II Obese	38,175	2,096	1.14	(1.07 to 1.22)	<0.001	36,611	3,660	0.97	(0.93 to 1.02)	0.29
	(9.3%)	(9.8%)				(9.4%)	(9.0%)		(
Class III Obese	12,732	687	1.07	(0.97 to 1.19)	0.17	12,128	1,291	1.01	(0.94 to 1.09)	0.70
	(3.1%)	(3.2%)		ΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥΥ		(3.1%)	(3.2%)		· · · ·	
ASA grade										
l (ref.)	58,391	4,292	1	-	-	55,989	6,694	1	-	-
. (,	(14.2%)	(20.1%)				(14.3%)	(16.5%)			
	287,661	14,421	0.79	(0.75 to 0.82)	< 0.001	274,383	27,699	1.03	(0.99 to 1.06)	0.16
	(70.1%)	(67.6%)		()		(70.1%)	(68.2%)		(
	62,821	2,565	0.64	(0.60 to 0.69)	< 0.001	59,394	5,992	1.08	(1.02 to 1.13)	0.003
	(15.3%)	(12.0%)		((15.2%)	(14.8%)		(
IV + V	1,740	64	0.60	(0.45 to 0.80)	0.001	1,603	201	1.26	(1.06 to 1.51)	0.01
•• * •	(0.4%)	(0.3%)		((0.4%)	(0.5%)		(

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Source of funding										
	358,057	17,424	1	-	-	342,458	33,023	1	-	-
NHS	(87.2%)	(81.6%)				(87.5%)	(81.4%)			
	52,556	3,918	0.94	(0.89 to 0.99)	0.02	48,911	7,563	1.13	(1.08 to 1.18)	< 0.001
Private	(12.8%)	(18.4%)		. ,		(12.5%)	(18.6%)		. ,	

1 – odds ratios, 95% confidence intervals and p-values are from mixed-effects logistic regression models adjusted for all exposure variables

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Figure 1 Proportion of total hip replacements between January 2008 and February 2017 using stem or cups/shells introduced in different time periods (before 2004, 2004-2006, 2006-2008, 2008 onwards)

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Figure 2 Cumulative total use of the top 5 new stems and cups/shells by days since they were introduced

.ups/shells by days since they were introdu

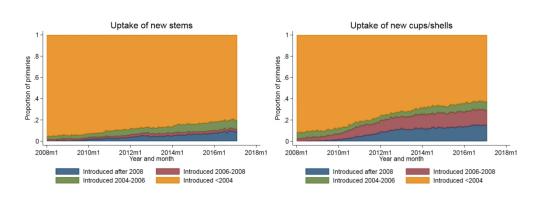
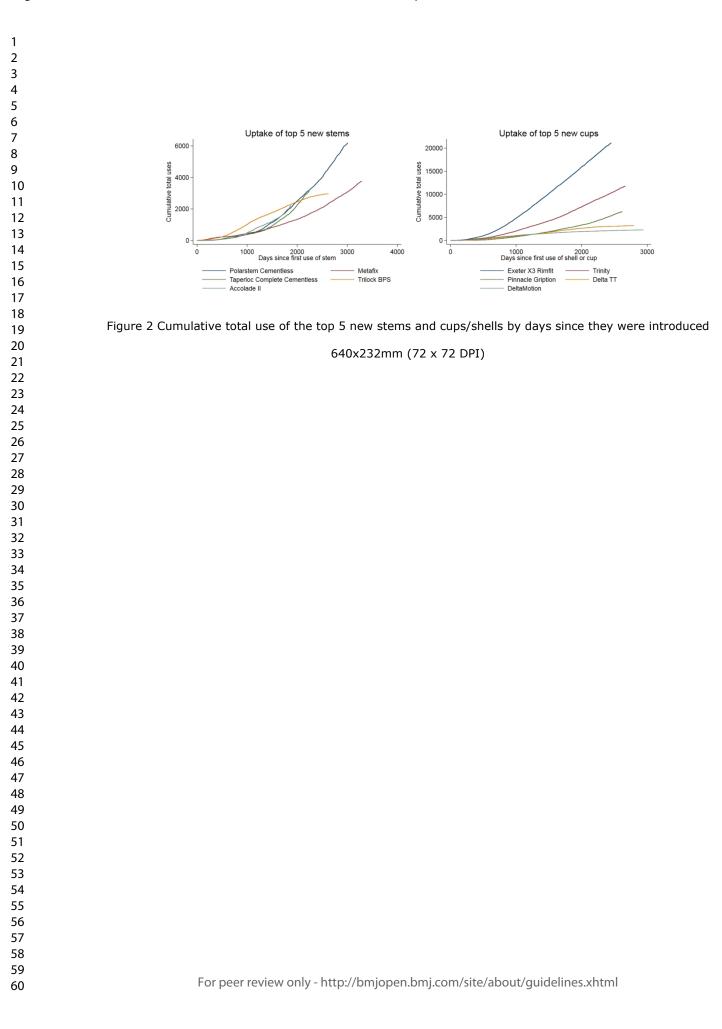


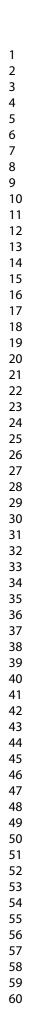
Figure 1 Proportion of total hip replacements between January 2008 and February 2017 using stem or cups/shells introduced in different time periods (before 2004, 2004-2006, 2006-2008, 2008 onwards)

640x232mm (72 x 72 DPI)

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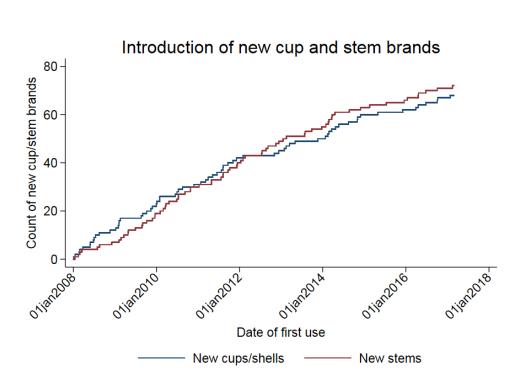
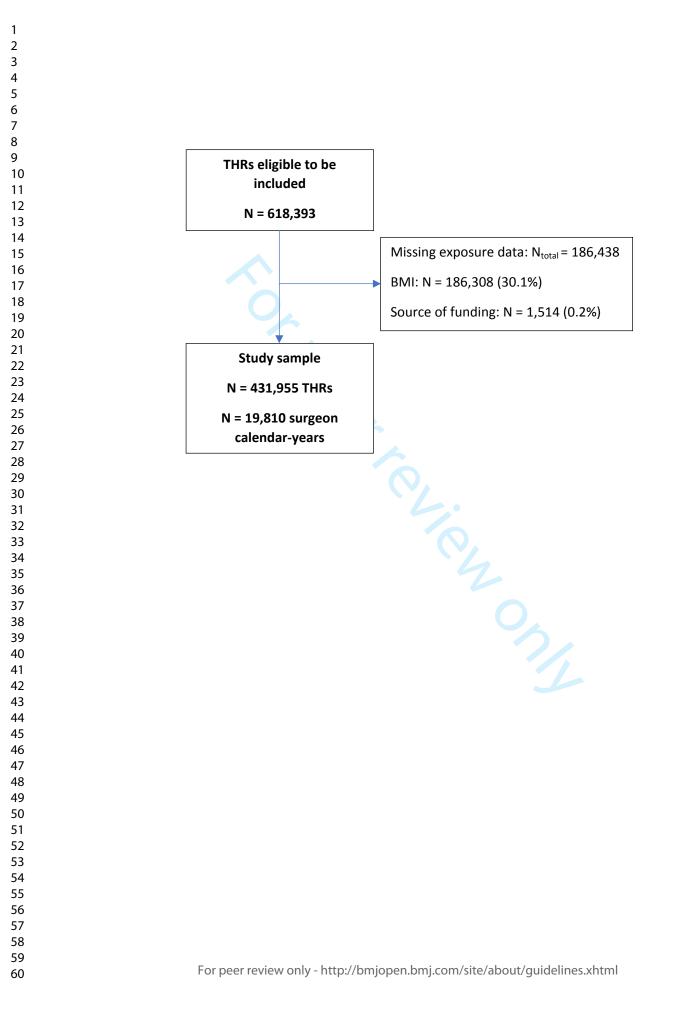


Figure S1 The cumulative introduction of new brands of cup and stem components for THRs, between January 1st 2008 and 26th February 2017

319x232mm (72 x 72 DPI)



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Supplementary material

Table S1 Uptake of new cups first used between January 1st 2008 and 26th February 2017

Cup/shell brand	1 1	Patients	Percent	Surgeons	Month first used	Month last used
Exeter X3 Rimfit		21,116	38.1%	975	Jun 2010	Feb 2017
Trinity	1	11,752	21.2%	310	Nov 2009	Feb 2017
Pinnacle Gription	1	6,250	11.3%	599	Dec 2009	Feb 2017
Delta TT	1	3,215	5.8%	193	Jun 2009	Feb 2017
DeltaMotion	1	2,300	4.2%	172	Feb 2009	Feb 2017
Versafit CC Trio	1	1,713	3.1%	50	Mar 2011	Feb 2017
RM Pressfit Vitamys	1	872	1.6%	37	Aug 2011	Feb 2017
Exceed ABT Cemented		865	1.6%	67	Jun 2011	Feb 2017
RM Pressfit	1	686	1.2%	50	May 2008	Feb 2017
G7 Cementless Acetabular Component	3	621	1.1%	36	Aug 2014	Feb 2017
AEON Cemented Acetabular Cup		614	1.1%	46	Sep 2011	Feb 2017
Plasmafit Cementless Cup	1	546	1.0%	50	Nov 2012	Feb 2017
Allofit IT	1	491	0.9%	21	Jan 2010	Jan 2017
Duracel		465	0.8%	45	Mar 2013	Feb 2017
ADES Cemented		342	0.6%	72	Feb 2014	Feb 2017
Regenerex Ringloc+	1	323	0.6%	70	Feb 2009	Feb 2017
XLFit Acetabular Cup	1	293	0.5%	56	Apr 2015	Feb 2017
April - Polyethylene	1	220	0.4%	33	Jan 2012	Feb 2017
ADES	1	205	0.4%	39	May 2014	Feb 2017
Delta One TT	1	202	0.4%	82	Jun 2010	Feb 2017
Trident Constrained Cup		199	0.4%	84	Jan 2008	Feb 2017
Delta PF	1	198	0.4%	9	Mar 2011	Nov 2014
MIHR Cup	1	197	0.4%	12	Mar 2008	Aug 2011
Tribofit	1	184	0.3%	10	Jul 2010	Nov 2016
seleXys TH+	1	174	0.3%	13	Nov 2008	Apr 2011
OptiCup CEP		147	0.3%	18	Nov 2014	Feb 2017
Restoration ADM Cup	1	140	0.3%	32	May 2011	Feb 2017
Gyros	1	129	0.2%	28	Jan 2010	Dec 2013
Allofit-S IT	1	126	0.2%	22	Aug 2010	Jun 2016
EcoFit Cementless Cup	1	102	0.2%	5	Feb 2013	Mar 2015
Novation	1	93	0.2%	10	Nov 2009	Aug 2014
M2A Magnum	1	79	0.1%	30	Feb 2008	Jun 2010
Captiv DM	1	78	0.1%	9	Aug 2011	Feb 2017
Freedom		78	0.1%	17	May 2008	Nov 2014
seleXys DS Cementless	1	56	0.1%	16	Mar 2014	Dec 2016

		55,360				
Capitole T	1	1	0.0%	1	Nov 2014	Nov 20
Mitre Cup		1	0.0%	1	Nov 2013	Nov 20
Ringloc	1	1	0.0%	1	Jan 2011	Jan 20
Charnley KS		1	0.0%	1	Jul 2011	Jul 20
Endurance Cemented Cup		1	0.0%	1	Oct 2016	Oct 20
FIXA Duplex Cemented		1	0.0%	1	Jan 2017	Jan 20
Arden		1	0.0%	1	Feb 2008	Feb 2
Versacem		1	0.0%	1	Oct 2009	Oct 2
Polymax	1	1	0.0%	1	Oct 2016	Oct 2
Versafit DM	1	2	0.0%	2	May 2008	Feb 2
Evidence		2	0.0%	1	Oct 2014	Mar2
J-Loc	1	2	0.0%	2	Mar 2013	Aug 2
Solution Cemented Cup		2	0.0%	1	Dec 2015	Feb 2
XPE Cup		2	0.0%	1	Jun 2016	Oct 2
Sirius Cementless Cup		3	0.0%	2	Aug 2011	Nov 2
Capitole C		3	0.0%	3	Jan 2013	Jul 20
2M Dual Mobility	1	3	0.0%	2	Nov 2012	Sep 2
Horizon	~	3	0.0%	2	Jul 2008	Jul 20
Par-5	1	3	0.0%	3	Jan 2008	Mar 2
Regenerex Revision	1	4	0.0%	3	Jan 2009	Jan 2
Zimmer Cemented Cup		6	0.0%	4	May 2013	Sep 2
U-Motion II	1	8	0.0%	4	Apr 2016	Feb 2
Equateur	1	9	0.0%	5	Jul 2008	Nov 2
A Class		9	0.0%	4	Feb 2009	Feb 2
Delta Revision TT	1	12	0.0%	8	Nov 2010	Aug 2
Cormet Prime	1	12	0.0%	5	Jan 2010	Sep 2
Fixa Duplex	1	17	0.0%	1	Mar 2016	Feb 2
Fixa Ti-Por	1	20	0.0%	4	Apr 2014	Oct 2
seleXys DS Cemented		20	0.0%	12	Feb 2014	Apr 2
MPACT	1	30	0.1%	9	Dec 2011	Feb 2
ASR 300 Cup	1	36	0.1%	1	Jan 2009	Jan 20
MMC Resurfacing	1	36	0.1%	10	Aug 2009	Jan 20
Restoration Gap2		36	0.1%	24	Mar 2008	Dec 2

1 – Uncemented fixation, Rows in **bold** = five most commonly used new cups

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Stem brand	UC ¹	Patients	Percent	Surgeons	Month first used	Month last used
Polarstem Cementless	1	6,191	21.4%	196	Dec 2008	Feb 2017
Metafix Stem		3,766	13.0%	166	Feb 2008	Feb 2017
Taperloc Complete Cementless		3,120		151	Jan 2011	Feb 2017
Stem		_, _	10.8%	_		
Trilock BPS	1	2,966	10.3%	142	Dec 2009	Feb 2017
Accolade II	1	2,215	7.7%	180	Jan 2012	Feb 2017
miniHip	1	1,860	6.4%	101	Mar 2009	Feb 2017
AMIStem-H	1	1,223	4.2%	38	Aug 2009	Jan 2017
Exeter No.1 125mm stem Line		836		211	Aug 2014	Feb 2017
Extension			2.9%		_	
Aeon Cemented Stem		724	2.5%	54	Sep 2011	Feb 2017
TriFit TS hip stem	1	684	2.4%	44	Sep 2012	Feb 2017
SPS Evolution		670	2.3%	48	Jan 2012	Feb 2017
Corail Cemented		531	1.8%	52	Apr 2009	Feb 2017
C-Stem AMT Line Extension		428	1.5%	127	Jul 2013	Feb 2017
H-Max S Monoblock Stem		419	1.4%	36	May 2010	Dec 2016
EcoFit Cementless Stem		319	1.1%	15	Sep 2010	Jan 2017
H-Max M Modular Stem	1	316	1.1%	20	Mar 2010	Aug 2014
Finsbury Type C	1	302	1.0%	39	Aug 2008	Sep 2010
Silent	1	218	0.8%	21	Feb 2008	Feb 2014
Metha Monoblock Stem	1	212	0.7%	26	Aug 2011	Feb 2017
Trilliance		178	0.6%	11	Jul 2011	Jan 2017
OptiStem		165	0.6%	22	Nov 2014	Feb 2017
Sirius stem		138	0.5%	10	Apr 2014	Feb 2017
Corail Revision Stem		133	0.5%	89	Jul 2010	Feb 2017
Profemur L Classic		132	0.5%	17	Mar 2014	Feb 2017
Profemur TL		121	0.4%	23	Jan 2008	Jul 2014
AMIStem-C		110	0.4%	3	Jul 2012	Feb 2017
Master SL		102	0.4%	8	Jul 2013	Feb 2017
Novation Element Stem	1	90	0.3%	9	Nov 2009	Jul 2014
CBC Evolution	1	83	0.3%	8	Jan 2013	Feb 2016
Nanos	1	78	0.3%	5	Dec 2011	Nov 2016
Amoda	1	67	0.2%	1	Apr 2010	Aug 2011
Harmony Modular	1	65	0.2%	6	Mar 2010	Mar 2015
ABG II Cementless Stem (modular)	1	52	0.2%	9	Apr 2009	Sep 2012
SL ()	1	51	0.2%	5	Sep 2009	May 2011
XActa		47	0.2%	5	Jan 2014	, Nov 2016
Avenir Muller Cementless	1	33	0.1%	6	Jun 2016	Feb 2017
Harmony Cemented		25	0.1%	8	Feb 2014	May 2015

Table S2 Uptake of new stems first used between January 1st 2008 and 26th February 2017

Total		28,924				
C2 Stem		1	0.0%	1	Feb 2015	Feb 201
Furlong HAC Hemiarthroplasty		1	0.0%	1	Oct 2010	Oct 201
Endurance Cemented Stem	-	1	0.0%	1	Sep 2013	Sep 201
Arcad Cemented		1	0.0%	1	Feb 2009	Feb 200
Regulus Cemented Stem		1	0.0%	1	Oct 2016	Oct 202
Friendly		1	0.0%	1	Jul 2012	Aug 20:
CDH Stem		1	0.0%	1	Nov 2012	Nov 20
Prodigy		1	0.0%	1	Jul 2010	Jul 20
optimys		1	0.0%	1	Feb 2017	Feb 20
Integrale		1	0.0%	1	Jun 2009	Jun 20
Wagner Revision Stem	1	1	0.0%	1	Apr 2016	Apr 20
Initiale Cemented Stem		1	0.0%	1	Jul 2008	Jul 20
Restoration Cemented Stem		1	0.0%	1	Feb 2014	Feb 20
Atlantis		3	0.0%	3	Dec 2011	Apr 20
Euros Cementless	1	3	0.0%	2	Aug 2011	Nov 20
Profemur Gladiator		4	0.0%	3	Mar 2010	Jul 20
G2 Cementless Stem		5	0.0%	5	Dec 2013	Nov 20
Securus		5	0.0%	5	Dec 2009	Mar 20
METS Cementless		5	0.0%	5	Feb 2013	Feb 20
Novation Stem		5	0.0%	2	Mar 2014	Mar 20
Quadra-C		6	0.0%	2	Oct 2009	Feb 20
Exception Cementless		6	0.0%	3	Feb 2010	Mar 20
UCP Stem		10	0.0%	5	Apr 2016	Feb 20
Harmony Cementless		10	0.0%	4	Apr 2011	Apr 20
GMRS		11	0.0%	9	Aug 2012	Sep 20
METS Cemented		12	0.0%	10	Dec 2012	Oct 20
AMIStem HP	1	12	0.0%	1	Dec 2015	May 20
Profemur Preserve	1	12	0.0%	5	Feb 2012	Jun 20
Echelon Cemented Stem		13	0.0%	9	Mar 2008	Dec 20
SMF		17	0.1%	1	Oct 2011	May 20
Arcad Cementless	1	17	0.1%	12	Sep 2010	Feb 20
Profemur TL Classic	1	19	0.1%	5	Jan 2016	Feb 20
FTS	1	20	0.1%	5	Feb 2009	Mar 20
SMS		22	0.1%	2	Jul 2015	Oct 20
miniMax		24	0.1%	2	Apr 2011	Sep 20

1 – Uncemented fixation, Rows in **bold** = five most commonly used new stems

Table S3 Number of different post-2008 shells/cups used by surgeon	S
--------------------------------------------------------------------	---

Number of new cups used	Number of surgeons	Percent	Cumulative percent
1	1,280	61.9%	61.9%
2	457	22.1%	84.0%
3	189	9.1%	93.1%
4	84	4.1%	97.2%
5	31	1.5%	98.7%
6	16	0.8%	99.4%
7	7	0.3%	99.8%
8	4	0.2%	100.0%
11	1	0.1%	100.0%
Total	2,069		

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1 888 67.6% 67.6% 2 260 19.8% 87.4% 3 97 7.4% 94.8% 4 38 2.9% 97.7% 5 15 1.1% 98.9% 6 9 0.7% 99.5% 7 4 0.3% 99.9% 8 1 0.1% 99.9% 9 1 0.1% 100.0% Total 1,313	2 3 4		Percent	Cumulative percent
3 97 7.4% 94.8% 4 38 2.9% 97.7% 5 15 1.1% 98.9% 6 9 0.7% 99.5% 7 4 0.3% 99.9% 8 1 0.1% 99.9% 9 1 0.1% 100.0%	3	888	67.6%	67.6%
4 38 2.9% 97.7% 5 15 1.1% 98.9% 6 9 0.7% 99.5% 7 4 0.3% 99.9% 8 1 0.1% 99.9% 9 1 0.1% 100.0% Total 1,313	4	260	19.8%	87.4%
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7 4 0.3% 99.9% 8 1 0.1% 99.9% 9 1 0.1% 100.0%	J	15	1.1%	98.9%
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9 1 0.1% 100.0% Total 1,313	7	4	0.3%	99.9%
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beet eview only	Total	1,313		

Table CT	The number of	funiaua nau	, stopp our	combinations	used simultaneous	hu hu curacenc
TUDIE 35	The number of	i unique nev	/ stem-сир	compinations	used simultaneous	y by surgeons

Stem-cup combinations	Number of surgeons	Percent	Cumulative percent
1	437	70.0%	70.0%
2	113	18.1%	88.1%
3	41	6.6%	94.7%
4	17	2.7%	97.4%
5	6	1.0%	98.4%
6	2	0.3%	98.7%
7	2	0.3%	99.0%
8	3	0.5%	99.5%
9	2	0.3%	99.8%
13	1	0.2%	100.%
Total	624	100%	

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		Stems			Cups	
	OR ¹	(95% CI)	р	OR ¹	(95% CI)	р
Exposure						
Proportion of THRs performed on patients <55 years old						
<10% (ref.)	1		-	1		-
≥10%	2.67	(2.39 to 2.98)	<0.001	2.41	(2.20 to 2.64)	<0.001
Number of THRs performed in	1.19	(1.16 to 1.22)	<0.001	1.23	(1.20 to 1.26)	<0.001
calendar year ²						
(per 10 additional cases)						
Proportion of THRs funded						
privately			2			
100% NHS funded (ref.)	1		-	1		-
Some or all funded privately	2.38	(2.09 to 2.71)	<0.001	2.12	(1.91 to 2.36)	<0.001
Number of stem-cup combinations						
used in calendar year						
≤3 (ref.)	1		-	1		-
4-6	4.83	(4.31 to 5.42)	<0.001	4.54	(4.13 to 5.00)	<0.001
7-10	13.7	(11.6 to 16.3)	<0.001	11.7	(9.91 to 13.9)	<0.001
>10	36.4	(24.4 to 54.4)	<0.001	28.2	(18.4 to 43.3)	<0.001
Proportion of THRs performed on						
patients with ASA grade III-V						
<25% (ref.)	1		-	1		
≥25%	0.81	(0.72 to 0.91)	0.001	0.92	(0.84 to 1.01)	0.08

Table S6 Results from unadjusted logistic regression models showing the association between surgeon-level factors and use of new versus old stems and cups

1 – odds ratios, 95% confidence intervals and p-values are from unadjusted logistic regression models

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Table S7 Results from unadjusted mixed-effects regression models (patients nested within surgeons) of age, gender, categorised BMI, ASA grade, and source of funding on stem and cup age

	Stems	6		Cups		
	OR ¹	(95% CI)	р	OR ¹	(95% CI)	р
Age (years)			-			-
<55 years old	2.31	(2.21 to 2.42)	<0.001	1.37	(1.32 to 1.42)	<0.001
55 to 80 (ref.)	1	-	-	1	-	-
≥ 80 years old	0.45	(0.42 to 0.48)	<0.001	0.92	(0.89 to 0.96)	<0.001
Gender						
Male (ref.)	1	- 04	-	1	-	-
Female	0.77	(0.75 to 0.80)	<0.001	1.10	(1.07 to 1.13)	<0.001
BMI						
Underweight and		-	- 2		-	-
normal (ref.)	1			1		
Overweight	1.11	(1.06 to 1.16)	<0.001	0.96	(0.93 to 0.99)	0.01
Class I Obese	1.16	(1.11 to 1.22)	<0.001	0.96	(0.93 to 1.00)	0.04
Class II Obese	1.25	(1.18 to 1.33)	<0.001	1.00	(0.95 to 1.05)	0.90
Class III Obese	1.18	(1.07 to 1.30)	0.001	1.07	(1.00 to 1.15)	0.07
ASA grade						
l (ref.)	1	-	-	1	-	
II	0.64	(0.61 to 0.67)	<0.001	0.95	(0.92 to 0.99)	0.007
III	0.47	(0.44 to 0.50)	<0.001	0.96	(0.92 to 1.01)	0.13
IV + V	0.40	(0.30 to 0.53)	<0.001	1.10	(0.93 to 1.33)	0.24
Source of funding						
NHS	1	-	-	1	-	-
Private	0.93	(0.88 to 0.98)	0.005	1.11	(1.06 to 1.16)	<0.001

-

1 – odds ratios, 95% confidence intervals and p-values are from unadjusted mixed-effects logistic regression models

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Table S8 Sensitivity analysis 1: Results from multivariable adjusted logistic regression models showing the association between surgeon-level factors and use of new versus old stems and cups, excluding surgeon calendar-years with <10 THRs

		Stems			Cups	
Exposure	OR ¹	(95% CI)	р	OR ¹	(95% CI)	р
Proportion of THRs performed on patients <55 years old						
<10% (ref.)	1	-	-	1	-	-
≥10%	1.30	(1.14 to 1.50)	< 0.001	1.42	(1.26 to 1.59)	<0.002
Number of THRs performed in calendar year ²	1.02	(1.00 to 1.05)	0.04	1.05	(1.03 to 1.08)	<0.002
(per 10 additional cases) Proportion of THRs funded						
privately						
100% NHS funded (ref.)	1	- (<u>-</u>	1	-	-
Some or all funded privately	1.27	(1.08 to 1.49)	0.004	1.09	(0.95 to 1.25)	0.22
Number of stem-cup combinations used in calendar year			.6			
≤3 (ref.)	1	-	-	1	-	-
4-6	3.57	(3.04 to 4.18)	<0.001	3.05	(2.69 to 3.46)	<0.00
7-10	9.24	(7.47 to 11.4)	<0.001	6.45	(5.30 to 7.86)	<0.00
>10	22.1	(14.4 to 33.8)	<0.001	13.1	(8.48 to 20.4)	<0.00
Proportion of THRs performed on patients with ASA grade III-V						
<pre></pre>	1	-	-	1	-	
≥25%	1.20	(1.03 to 1.41)	0.02	1.32	(1.16 to 1.50)	<0.00

1 – odds ratios, 95% confidence intervals and p-values are from logistic regression models adjusted for all exposure variables

Table S9 Sensitivity analysis 2a: Results from multivariable adjusted logistic regression models showing the association between surgeon-level factors (consultant in-charge) and use of new versus old stems and cups

		Stems			Cups	
	OR ¹	(95% CI)	р	OR ¹	(95% CI)	р
Exposure						
Proportion of THRs performed on						
patients <55 years old						
<10% (ref.)	1	-	-	1	-	-
≥10%	1.49	(1.31 to 1.70)	<0.001	1.57	(1.41 to 1.75)	< 0.001
Number of THRs performed in	1.03	(1.01 to 1.04)	0.003	1.07	(1.05 to 1.09)	< 0.001
calendar year ²						
(per 10 additional cases)		No				
Proportion of THRs funded						
privately			h			
100% NHS funded (ref.)	1	-		1	-	-
Some or all funded privately	1.27	(1.09 to 1.49)	0.002	1.17	(1.02 to 1.33)	0.02
Number of stem-cup combinations						
used in calendar year						
≤3 (ref.)	1	-	-	1	-	-
4-6	3.69	(3.19 to 4.27)	<0.001	3.11	(2.76 to 3.53)	<0.001
7-10	8.78	(7.9 to 10.9)	<0.001	5.61	(4.58 to 6.88)	<0.001
>10	22.9	(15.2 to 34.6)	< 0.001	11.4	(7.46 to 17.3)	< 0.001
Proportion of THRs performed on						
patients with ASA grade III-V						
<25% (ref.)	1	-	-	1	-	_
≥25%	1.22	(1.06 to 1.42)	0.007	1.25	(1.11 to 1.41)	<0.001

 1 – odds ratios, 95% confidence intervals and p-values are from logistic regression models adjusted for all exposure variables

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Table S10 Sensitivity analysis 2b: Results from multivariable adjusted mixed-effects regression models (patients nested within 'consultant in-charge') of age, gender, categorised
BMI, ASA grade, and source of funding on stem and cup age

	Stems			Cups	Cups		
	OR ¹	(95% CI)	р	OR ¹	(95% CI)	р	
Age (years)							
<55 years old	2.20	(2.10 to 2.30)	< 0.001	1.40	(1.35 to 1.46)	<0.001	
55 to 80 (ref.)	1	-	-	1	-	-	
≥ 80 years old	0.48	(0.45 to 0.51)	< 0.001	0.91	(0.88 to 0.95)	<0.001	
Gender							
Male (ref.)	1	- 04	_	1	-	-	
Female	0.81	(0.78 to 0.84)	<0.001	1.11	(1.08 to 1.14)	< 0.001	
BMI							
Underweight and		-	- (-	-	
normal (ref.)	1			1			
Overweight	1.03	(0.99 to 1.08)	0.18	0.97	(0.94 to 1.00)	0.08	
Class I Obese	1.05	(1.00 to 1.11)	0.03	0.96	(0.92 to 0.99)	0.02	
Class II Obese	1.12	(1.05 to 1.20)	0.001	0.98	(0.93 to 1.03)	0.37	
Class III Obese	1.07	(0.96 to 1.18)	0.21	1.02	(0.95 to 1.10)	0.53	
ASA grade) ,	
l (ref.)	1	-	-	1	-		
II	0.77	(0.74 to 0.81)	< 0.001	1.02	(0.98 to 1.05)	0.41	
III	0.62	(0.58 to 0.67)	<0.001	1.05	(1.00 to 1.10)	0.04	
IV + V	0.59	(0.44 to 0.79)	< 0.001	1.20	(1.00 to 1.43)	0.05	
Source of funding							
NHS	1	-	-	1	-	-	
Private	1.05	(1.00 to 1.11)	0.06	1.16	(1.12 to 1.21)	<0.001	

1 – odds ratios, 95% confidence intervals and p-values are from mixed-effects logistic regression models adjusted for all exposure variables

Figure S1 The cumulative introduction of new brands of cup and stem components for THRs, between January 1st 2008 and 26th February 2017

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Figure S2 STROBE Flow diagram

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Reporting checklist for cohort study.

Based on the STROBE cohort guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cohort reporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

9 0				Page
1 2			Reporting Item	Number
3 4 5 6 7	Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	4
7 8 9 0	Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	4
1 2 3 4	Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	6
	Objectives	#3	State specific objectives, including any prespecified hypotheses	6
5 6 7 8	Study design	#4	Present key elements of study design early in the paper	7
9 0 1 2	Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
2 3 4 5 6	Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up.	7
7 8		#6b	For matched studies, give matching criteria and number of exposed and	See note
9 0		For	peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

Page 43 of 45			BMJ Open	
1			unexposed	1
2 3 4 5 6 7 8 9 10 11 12 13 14	Variables	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-8
	Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	7-8
	Bias	#9	Describe any efforts to address potential sources of bias	8-9
15 16 17 18	Study size	#10	Explain how the study size was arrived at	See note 2
19 20 21 22	Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	8-9
23 24 25 26	Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	8-9
26 27 28 29 30 31 32 33 34		#12b	Describe any methods used to examine subgroups and interactions	8-9
		#12c	Explain how missing data were addressed	8
		#12d	If applicable, explain how loss to follow-up was addressed	See note 3
35 36		#12e	Describe any sensitivity analyses	8-9
37 38 39 40 41 42 43 44 45	Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	9-10
46 47		#13b	Give reasons for non-participation at each stage	9-10
48 49 50 51 52 53 54 55 56		#13c	Consider use of a flow diagram	Figure S2
	Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	9-10
57 58		#14b	Indicate number of participants with missing data for each variable of	See note
59 60		For	peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

			·	5					
1			interest	4					
2 3 4 5		#14c	Summarise follow-up time (eg, average and total amount)	See note 5					
6 7 8 9 10	Outcome data	#15	Report numbers of outcome events or summary measures over time. Give information separately for exposed and unexposed groups if applicable.	See note 6					
11 12 13 14 15 16	Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	See note 7					
17 18 19		#16b	Report category boundaries when continuous variables were categorized	See note 8					
20 21 22 23		#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	See note 9					
24 25 26 27	Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	9-11					
28 29	Key results	#18	Summarise key results with reference to study objectives	11-12					
30 31 32 33 34	Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	12					
35 36 37 38 39 40	Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	12-13					
41 42	Generalisability	#21	Discuss the generalisability (external validity) of the study results	14					
43 44 45 46 47 48	Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	3					
49 50	Author notes								
51 52 53	1. n/a - not releva	1. n/a - not relevant							
54 55	2. n/a - not releva	ant							
56 57	3. n/a - not releva	ant							
58 59 60	4. 10 and Fig S2	For	peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml						

- 5. n/a - not relevant
- 6. Tables 1 & 2
- Tables S6 & S7 7.
- n/a - not needed 8.
- 9. n/a - not needed

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Understanding the uptake of new hip replacement implants in the UK: A cohort study using data from the National Joint Registry for England and Wales

Journal:	BMJ Open
Manuscript ID	bmjopen-2019-029572.R1
Article Type:	Original research
Date Submitted by the Author:	03-Sep-2019
Complete List of Authors:	Penfold, Chris; University of Bristol, Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School; University Hospitals Bristol NHS Foundation Trust and University of Bristol, National Institute for Health Research Bristol Biomedical Research Centre Blom, AW; University of Bristol, Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School; University Hospitals Bristol NHS Foundation Trust and University of Bristol, National Institute for Health Research Bristol Biomedical Research Centre Sayers, Adrian; University of Bristol, Muscloskeletal Research Unit, Translational Health Sciences, Bristol Medical School; University of Bristol, Population Health Sciences, Bristol Medical School; University of Bristol, Population Health Sciences, Bristol Medical School Wilkinson, J. Mark; Northern General Hospital, Metabolic Bone Unit, Sorby Wing; University of Sheffield, 5. Department of Oncology and Metabolism and The Mellanby Centre for Bone Research Hunt, Linda; University of Bristol, Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School Judge, Andrew; University of Bristol, Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School Judge, Andrew; University of Bristol, Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School Judge, Andrew; University of Bristol, Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School; University Hospitals Bristol NHS Foundation Trust and University of Bristol, National Institute for Health Research Bristol Biomedical Research Centre Whitehouse, Michael; University of Bristol, Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School; University Hospitals Bristol NHS Foundation Trust and University of Bristol, National Institute for Health Research Bristol Biomedical Research Centre
Primary Subject Heading :	Surgery
Secondary Subject Heading:	Health services research
Keywords:	Orthopaedic & trauma surgery < SURGERY, Joint replacement, Implant, Patient, Surgeon, National Joint Registry



Understanding the uptake of new hip replacement implants in the UK: A cohort study using data from the National Joint Registry for **England and Wales**

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Keywords

Orthopaedics, joint replacement, implant, patient, surgeon, national joint registry

Data sharing statement

Access to the data analysed in this study required permission from the National Joint Registry for England, Wales and Northern Ireland Research Sub-committee. http://www.njrcentre.org.uk/njrcentre/Research/Researchrequests/tabid/305/Default.aspx contains information on research data access request to the National Joint Registry.

Acknowledgements

This study was funded by the NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. We thank the patients and staff of all the hospitals who have contributed data to the National Joint Registry. We are grateful to the Healthcare Quality Improvement Partnership, the National Joint Registry Steering Committee, and staff at the National Joint Registry for facilitating this work.

Disclaimer

The views expressed represent those of the authors and do not necessarily reflect those of the National Joint Registry Steering Committee or Healthcare Quality Improvement Partnership, who do not vouch for how the information is presented. The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

Ethics approval 🧪

Patient consent was obtained for data collection by the National Joint Registry. According to the specifications of the NHS Health Research Authority, separate informed consent and ethical approval were not required for the present study.

Author Contributions

CP, AB, AJ and MW designed the study. CP, AB, AS, JMW, LH, AJ and MW reviewed the published work. CP conducted the statistical analysis and wrote the manuscript. All authors contributed to critical review of the manuscript and its revision. CP had full access to all the data and AB is the guarantor.

Conflicts of Interest

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work. AB and MW are involved in a separate grant to the University of Bristol funded by Stryker. All other authors declare no financial relationships with any organisations that might have an interest in the submitted work in the previous three years. All authors declare no other relationships or activities that could appear to have influenced the submitted work.

Funding

This study was funded by the NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol. Adrian Sayers was supported by a MRC fellowship MR/L01226X/1.

Word count

4055 words

Abstract

Objectives

Primary: describe uptake of new implant components (femoral stem or acetabular cup/shell) for total hip replacements (THRs) in the National Joint Registry for England and Wales (NJR). Secondary: compare the characteristics of: a) surgeons b) patients who used/received new rather than established components.

Design

Cohort of 618,393 primary THRs performed for osteoarthritis (±other indications) by 4,979 surgeons between 2008-2017 in England and Wales from the NJR. We described the uptake of new (first recorded use >2008, used within 5 years) stems/cups, and variation in uptake by surgeons (primary objectives). We explored surgeon-level and patient-level factors associated with use/receipt of new components with logistic regression models (secondary objectives).

Outcomes

Primary outcomes: total number of new cups/stems, proportion of operations using new versus established components. Secondary outcomes: odds of: a) a surgeon using a new cup/stem in a calendar-year, b) a patient receiving a new rather than established cup/stem.

Results

Sixty-eight new cups and 72 new stems were used in 47,606 primary THRs (7.7%) by 2,005 surgeons (40.3%) 2008-2017. Surgeons used a median of one new stem and cup (25%-75%=1-2 both, max=10

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cups, max=8 stems). Surgeons performed a median total of 22 THRs (25%-75%=5-124, range=1-3,938) in the period 2008-2017. Surgeons used new stems in a median of 5.0% (25%-75%=1.3-16.1%) and new cups in a median of 9.4% (25%-75%=2.8-26.7%) of their THRs. Patients aged <55 years old versus those 55-80 had higher odds of receiving a new rather than established stem (OR=1.83, 95%CI=1.73-1.93) and cup (OR=1.31, 95%CI=1.25-1.37). Women had lower odds of receiving a new stem (OR=0.87, 95%CI=0.84-0.90), higher odds of receiving a new cup (OR=1.06, 95%CI=1.03-1.09).

Conclusions

Large numbers of new THR components have been introduced in the NJR since 2008. 40% of surgeons have tried new components, with wide variation in how many types and frequency they have been OPPC + used.

Article Summary

Strengths and limitations of this study

- This study provides a nationally representative description of the uptake of new implant components for total hip replacements in England and Wales.
- This is the first study to describe the variation in uptake of new components by surgeons, and surgeon characteristics which may be associated with the use of new components.
- Although implant component brand names were checked by the authors, some components • may have been reclassified or we may still have misclassified some components as either new or established, but the introduction of unique device identifiers should remove this problem in future.
- The surgeon assigned as lead operating surgeon in the NJR may not be correct, although consistency between our sensitivity and primary analyses indicate that this is unlikely to have substantially affected our findings.
- Hospital-level or regional variation in suppliers may be important factors affecting implant uptake, but these were beyond the scope of this study.

Background

Total hip replacements (THRs) are mainly performed to treat pain and functional limitation due to osteoarthritis (OA).[1] It is a highly successful surgical procedure with typical 10-year revision rates <5%,[2] the current NICE benchmark.[3] However, younger patients are more likely to require revision surgery; the lifetime revision risk for men having a THR in their 50s is ~35% compared with 5% in their 70s.[4] Such patients may benefit the most from developments in THR that lead to reduced revision rates or improved outcomes. However, they may also be affected for the longest time if these developments lead to poorer outcomes.

Some new implant designs intended to benefit these more active and/or younger patients have been high-profile failures, for example metal-on-metal THRs [5] including the Articular Surface Replacement (ASR) prostheses in particular.[6] Many new implants, the ASR included,[7] were introduced with minimal supporting evidence of their effectiveness [8] and may offer at best no improvement over preexisting components.[9] An influential agenda for surgery research (IDEAL) was developed, providing a framework for future investigations into surgical innovations, which recommended the phased introduction of new medical devices.[10] The rapid uptake of ASR hip replacements before the publication of supporting evidence bypassed IDEAL Stages 2a ('Development') and 2b ('Early dispersion and exploration'). Instead, long-term monitoring was relied on to monitor outcomes (Stage 4).[7] It is not clear whether the uptake of newer implants has also been rapid.

There is wide variation between and within regions in the use of common surgical procedures, which are only explained to a small degree by differing patient demands and diagnostic practices.[11] The large number of different components used in primary THRs (127 femoral stems and 105 acetabular cups recorded in the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) in 2016) [12] may be an important source of variation. Many registries describe the volume of different implant components used annually but not the variation in uptake of new implants between surgeons or which patients receive them. More research is needed to understand and reduce avoidable variation in outcomes created by differences in surgical activity.

We aimed to:

- 1. Describe the uptake of new implants for THRs in the NJR
- 2. Describe how this uptake varies by surgeons
- 3. Compare surgeons who use new compared with established components

4. Compare patients who receive new compared with established components

Methods

Data Source

The NJR was established in 2003.[2] Data entry for Northern Ireland and the Isle of Man did not commence until 2013 and 2015, respectively therefore they are excluded from this analysis. Key markers of NJR data quality were high and stable from 2008 onwards [13].

Study sample

We included the cohort of patients who received a primary THR for OA (± other indications) between 1st January 2008 and 26th February 2017. We used NJR data from 2003 onwards to calculate the date each implant component was first used and the total number of implantations. We excluded people who had not given consent for recording of personal details, where the brand of their acetabular or femoral components was uncertain, and those who received a resurfacing rather than stemmed THR. Resurfacing THRs were excluded since patients who receive these are a very different demographic from those receiving stemmed THRs (significantly younger and more likely to be male), and the annual volume is very low (~550 in 2017) and decreasing [14].

Patient involvement

This study was designed and undertaken without patient involvement.

Definition of new and established implant components

We identified the implant component brand from component labels recorded in the NJR. We used the earliest recorded use by any surgeon in the NJR of each femoral (stem) or acetabular (cup or shell) component to define an implant component's start date. We classified implant components with a start date between the beginning of NJR data collection (2003) and the end of 2007 as 'established'. This allowed implant components which were in use before the NJR started but which may have only been used occasionally to be recorded in the NJR and classified appropriately as 'established'. NJR data quality was also high and stable from 2008 onwards. Implant components with a start date on or after 1st

January 2008 and which were used within five years of this start date were classified as 'new'. Those used later than five years after their start date were classified as 'established'.

Surgeon uptake of new implant components

All surgeons with operations recorded in the NJR are assigned an anonymised identifier and their role in the operation ("consultant in charge" or "operating") is recorded. We summarised each operating surgeon's activity across each calendar-year in which they performed \geq 1 THR. We considered five potential surgeon-level factors which may be associated with use of a new component in a calendaryear: total volume of THRs performed in that year, proportion of those THRs performed on patients <55 years old (<10% and \geq 10%), source of funding for THRs ('100% NHS funded' or 'some or all privately funded'), proportion of THRs performed on patients with an American Society of Anaesthesiologists (ASA) grade III-V (<25% and \geq 25%), and the range of different stem-cup combinations used in that calendar-year (' \leq 3', '4-6', '7-10' and '>10'). Surgeons who performed \geq 10% of their THRs on patients aged <55 years old and those who performed \geq 25% of their THRs on patients with ASA III-V were in approximately the upper quartile of these distributions.

Patients receiving new implant components

We used date of surgery to order patients within implant components and within surgeons. We categorised patients according to whether the component they received was new or established. We considered five potential patient-level factors which may be associated with their receipt of new components: age at the time of THR (<55, 55-80, and 80+ years), gender, body mass index (BMI), ASA grade, and NHS or private funding. We selected these categories for age to reflect patients who were having a primary THR at a relatively young or relatively old age, the median age at the time of primary THR was 69 years (25%-75% 61-76 years).[14]

Statistical analyses

We described the use of unique stems and cups in primary THRs performed since January 1st 2008, the cumulative use of new components in patients, and the count of surgeons who used new components. We also described the total number of all and new cups, stems, and combinations.

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Surgeon-level factors

In analyses of surgeon-level and patient-level factors associated with use of or receipt of new implants we included only those people with complete exposure and outcome data for the surgeon-level and patient-level analysis models (i.e. complete case analysis). We assumed that data were missing at random but did not use multiple imputation to account for these missing data since there were no variables in the NJR dataset which were not already in our regression models and which may have carried information about the missing data (particularly BMI).

Our outcome was whether a surgeon used a new component at least once for a THR in a calendar-year (stems and cups analysed separately), unit of analysis was surgeon calendar-years and exposure variables were those surgeon-level factors defined previously. We used multivariable logistic regression models, accounting for the clustering of calendar-years within surgeons.

Patient-level factors

Our outcome was whether a patient received a new rather than established component (stems and cups analysed separately), unit of analysis was patients and exposure variables were those patient-level factors defined previously. Patient-level factors were included in multivariable mixed-effects logistic regression models, with patients nested within surgeons.

Sensitivity analyses

We conducted three sensitivity analyses. To determine whether the lack of variability in patients operated on by low volume surgeons affected our results we repeated our surgeon-level analysis excluding calendar-years for surgeons in which they performed <10 THRs. We also considered that the choice of component was made by the consultant in-charge rather than the operating surgeon (the consultant in-charge was not the operating surgeon for ~16% of THRs). We repeated our surgeon-level analysis by consultant in-charge and repeated our patient-level analysis with patients clustered within consultant in-charge.

In order to determine the extent to which patients with complete data for all exposures and outcome variables differed from those missing some exposure data (mainly BMI) we compared these groups using chi-square tests. We also repeated our patient-level analyses for those patients with complete data for all exposure variables (including BMI) but excluding BMI from the model, and for those with complete data for all exposure variable (excluding BMI).

All analyses were performed using Stata v15 (StataCorp).

Results

Overall use of implant components

Between 1st January 2008 and 26th February 2017, 618,393 primary THRs were performed for OA in England and Wales and recorded in the NJR, corresponding to 23,887 calendar-years in which surgeons performed ≥1 THR. The mean age of the patients was 68.5 years (SD=11.1 years), 60.7% were female, their ASA grades were I:14.2%, II:69.9%, III:15.5% and IV/V:0.5%. Twenty-three percent had a normal/underweight BMI, 39.6% were overweight and 37.6% obese. THRs were performed by 4,979 surgeons using 189 different stems, 187 cups and 2,026 stem-cup combinations. Surgeons used a median of three different stems (25%-75%=2-5, max=21), four cups (25%-75%=2-7, max=27) and five combinations (25%-75%=2-9, max=60). They performed a median total of 22 THRs between 2008 and 2017 (25%-75%=5-124, range 1-3,938), although this includes surgeons who started part way through this period, retired or changed their practice. Excluding calendar-years in which a surgeon performed no THRs, the median number of THRs surgeons performed per year was 11 (25%-75%=3-35, range 1-584) and in 47% of surgeon calendar-years (11,164 of 23,887) surgeons performed <10 THRs.

Use of new implant components

During this period 68 new cups (47 uncemented, Table S1) and 72 new stems (51 uncemented, Table S2) were first used. The rate of introduction of new cups and stems remained stable (~16 new components/year, Figure S1). Eight percent (n= 47,606) of THRs performed used a new stem, cup, or combination. Forty percent (n=2,005) of surgeons who performed a THR in this period used at least one new implant component.

New cups were used in 5.8% (n= 35,885) THRs performed by 34.1% (n=1,699) surgeons (Table S1), new stems in 2.9% (n= 18,159) THRs by 22.3% (n=1,111) surgeons (Table S2) and new combinations in 1.0% (n= 6,438) THRs by 8.7% (n=433) surgeons. Most new cups (n= 19,775, 55.1%) and almost all new stems (n= 15,361, 84.6%) were uncemented. The median number of new stems, cups and combinations used by surgeons was one (25%-75%=1-2, cups max=10, stems max=8 and combinations max=9; Table S3, Table S4 & Table S5). The median THRs performed using new stems was three (25%-75%=1-11, max=637) and new cups was three (25%-75%=1-14, max=867). The median proportion of a surgeon's

THRs performed using new stems was 3.4% (25%-75%=1.0-10.6%), new cups 6.3% (25%-75%=2.0-18.8%) and new combinations 2.4% (25%-75%=0.7-9.1%).

The five most frequently implanted new stems were used in 9,049 THRs (49.8% of THRs using a new stem, Table S2). The five most frequently implanted new cups were used in 26,962THRs (75.1% of THRs using a new cup, Table S1). Uptake of the two most popular new cups was rapid (5,000 uses of Exeter X3 Rimfit 1,016 days, 5,000 uses of Trinity 1,651 days after first use, Figure 1) but was slower for new stems (2,000 uses of Polarstem Cementless 1,670 days, Figure 1). Conversely, a third of the new stems and cups (n=26/72 new stems, n=25/69 new cups) have been used in \leq 10 THRs, and most of these have been used in \leq 5 THRs (n=22 stems, n=20 cups).

Surgeon-level and patient-level factors associated with new implant components

Our complete case analysis included 431,955 out of a possible 618,393 THRs (69.8%) and 20,410 out of a possible 23,887 surgeon calendar-years (85.4%, Figure S2). We were missing patient-level data for BMI (n=186,308, 30.1%) and source of funding (n=1,514, 0.2%). The characteristics of the subset of patients with complete data are shown in Table S6. There were minor differences between people with complete data and those with incomplete data (Table S6). Compared with people with incomplete data, a smaller proportion of people with complete data were aged \geq 80 years old (14.8% vs 16.4%), female (60.3% vs 61.6%) and had their operation funded through the NHS (86.9% vs 89.4%).

Characteristics of surgeons using new implant components

Multivariable associations between surgeon-level factors and their use of new components in a calendar-year were consistent between stems and cups (Table 1, unadjusted Table S7). Surgeons who treated more younger patients had 47% higher odds of using a new stem (OR=1.47, 95%CI 1.30-1.66, p<0.001) and 39% higher odds of using a new cup (OR=1.39, 95%CI 1.25-1.53, p<0.001) in a calendar-year. Those who performed more THRs/year had 6% higher odds of using new cups (OR=1.06, 95%CI 1.04-1.08, p<0.001) and 2% higher odds of using new stems (OR=1.02, 95%CI 1.00-1.05, p=0.03), although the confidence interval crossed the null. Private funding was associated with 23% increased odds of using new stems (OR=1.23, 95%CI 1.05-1.43, p=0.010) and weakly associated with 9% increased odds of using new cups (OR=1.09, 95%CI 0.96-1.23, p=0.187) with confidence intervals crossing the null value. Use of more stem-cup combinations was strongly associated with increased use of new components (ORs for '>10' vs. '≤3' combinations: 27.4 and 13.3 for stems and cups respectively, p values <0.001. Proportion of patients with ASA grades III-IV was weakly associated with 12% higher odds of

using new cups (OR=1.12, 95%Cl 1.01-1.25, P=0.034) but not with using new stems (OR=1.01, 95%Cl 0.89-1.16, p=0.843).

Characteristics of patients receiving new implant components

A higher proportion of recipients of new compared with established implant components were aged <55 years old (10.5% established vs. 21.3% new stems; 10.5% established vs. 14.8% new cups; Table 2), although the main recipients of all components were aged 55-80 years. Fifteen percent of recipients of established stems (15.0%) were ≥80 years old compared with 8.3% of recipients of new stems, but there was little difference in the proportion of older recipients of established (14.9%) and new (13.3%) cups. Across all components and component age, women were the main recipients of THRs. There was no difference in BMI between recipients of established and new stems or cups. A higher proportion of recipients of new components had ASA grade I (20.3% new vs. 14.3% established stems; 17.1% new vs. 14.3% established cups). A higher proportion of people with privately funded THRs had new components (stems: 19.6% new vs. 12.9% established; cups: 19.5% new vs. 12.7% established).

Multivariable mixed effects logistic regression models (Table 2, unadjusted Table S8) found that patients <55 years old, compared with those 55-80, had 83% and 31% higher odds of receiving a new rather than established stem (OR=1.83 95%CI 1.73-1.93, p<0.001) and cup (OR=1.31, 95%CI 1.25-1.37, p<0.001). Women had 13% lower odds than men of receiving a new stem (OR=0.87, 95%CI 0.84-0.90, p<0.001), but 6% higher odds of receiving a new cup (OR=1.06, 95%CI 1.03-1.09, p<0.001). There was weak evidence that people with higher BMI had 10% higher odds of receiving a new stem (OR for underweight/normal vs. Class II Obese=1.10, 95%CI 1.02-1.19, p=0.011) and weak evidence for the converse association between BMI and receiving a new cup (e.g. OR for underweight/normal vs. Class II Obese=0.94, 95%CI 0.89-1.00, p=0.042). Higher ASA grade was associated with 36% lower odds of receiving new stems (OR for ASA grades 'IV + V' versus 'I' = 0.64, 95%CI 0.46-0.90, p=0.010), but was not associated with receiving new cups (OR for ASA grades 'IV + V' versus 'I' = 1.02, 95%CI 0.82-1.26, p=0.881). Patients with private versus NHS funding had nine percent higher odds of receiving new cups (OR=1.09, 95%CI 1.04-1.14, p<0.001), but there was no association between source of funding and receiving new stems (OR=1.02, 95%CI 0.95-1.08, p=0.642).

Sensitivity analyses

Results of our first sensitivity analyses (excluding calendar-years for surgeons with <10 THRs) differed only minimally from our primary analyses (Table S9), indicating that our results were not biased by low-

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volume surgeons. In our second sensitivity analyses ('consultant in-charge' as the clustering variable) associations between source of funding and receipt of new stem/cup were stronger, otherwise they differed only minimally differed from our primary analyses (Table S10 & Table S11). Our comparison of regression models without BMI as an exposure, with complete cases as defined previously (n=431,955) and complete cases defined without BMI (n=616,879) found only minor differences. This suggests that associations between the exposures and outcomes for the population missing BMI differ only slightly from the population with BMI.

Discussion

Sixty-eight new cups and 72 new stems were first used in THRs in the NJR for OA between 2008 and 2017. Most THRs used components introduced before 2008 but 12% used a new stem or cup. Uptake of some new implant components was very rapid. Conversely, uptake of a third of new components has been slow. Most surgeons used a maximum total of seven different cups or stems, of which one or two were new components. A small number of surgeons used a wide variety of different components, including new stems, cups and combinations.

Strengths of our study include the use of the NJR dataset, the largest arthroplasty register with comprehensive data capture (>95% in the period studied). This is the first to describe the variation in factors associated with uptake of new implant components by surgeons and receipt of new components by patients. Our study has several weaknesses. We classified a component as new based on the first record of a brand name in the NJR, but this does not exclude the possibility that a component was introduced earlier to other markets outside the UK. Furthermore, new components may constitute procedures not uploaded to the NJR (missing primary THRs estimated <5%). Also, some of these components may be minor modifications or a rebadged/renamed version of an existing component and some may also cover successive versions of a component. The correct operating surgeon may not be assigned to every operation. The extent to which this applies is unknown but may result in inaccurate estimates of surgeon-level associations, although our sensitivity analyses indicate that this is unlikely. The associations we have reported may be confounded by unmeasured factors (residual confounding) and in the absence of pre-existing literature on the uptake of new implants the findings from the regression models should be considered exploratory. We were missing BMI data for some people and elected not to use multiple imputation to account for these missing data, however our sensitivity

analyses suggest that people with BMI data did not differ substantially from those without BMI across our other measures. Finally, we did not have data on hospital-level factors or regional variation in suppliers in our analyses, which may be drivers of selection.[15]

Approximately 16 new implant components/year (stems and cups) were introduced in the NJR between 2008-2017. Comparisons with Australia (34 implant components/year 2003-2008) [16] and Finland (2-4 components/year 1980-2013) [17] suggest that this rate is not unusual, but that there is large variation internationally. The rapid uptake of some new components indicates that phased introduction, as recommended in the IDEAL Framework and others,[18] is unlikely to be happening. It is unclear whether 16 new implant components/year is of itself a good or bad thing. However, a healthcare system which supported a graduated introduction of new components, where the use of new components is restricted to specialised centres,[18] would provide a natural limit on the rate of introduction of new components until satisfactory and robust evidence is generated to support their more widespread use. Conversely, a third of new implant components have not yet accrued more than ten uses. Postmarket surveillance of THRs, due to their longevity, performs a safety monitoring role which cannot easily be replaced by pre-approval clinical data. Since the statistical methods are not applicable to components used in small numbers collaboration between international arthroplasty registries may allow more effective monitoring for low-volume components.

Over half of surgeons in our study used ≤5 different stems, cups, or combinations, similar to a median of two different implant brands reported by surgeons in the USA in 1997.[19] The volume of THRs performed by surgeons using new components was often low (median ≤3 THRs with new components versus median 22 THRs in total), but the proportion of their THRs using any new components varied from one percent (lower quartile) to 19% (upper quartile). Surgeons who use a wider range of prosthesis combinations in THRs may have higher revision rates [20] and early THRs performed after switching implants may have a higher revision risk (a.k.a. 'learning-curve').[21] While this suggests that surgeons should rely on a narrow range of implant components and rarely switch, a phased introduction of new implant designs, as is done in Sweden, may mitigate the learning-curve effect.[22] Since there are no contemporary comparisons of the range of implant components surgeons use and their relative volumes, it is unclear whether the between-surgeon variation we have reported may be associated with worse implant survival and warrants further research.

We found that newer components were being used in patients likely to be more active (i.e. younger and/or male patients). There has been increasing evidence that uncemented implants, particularly

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stems, should not be used in older patients, but some uncertainty remains about their use in young patients (especially uncemented cups).[23–25] Since the majority of new cups and stems are uncemented, the decision to use these implant components in younger patients may increase the already high lifetime risk of revision surgery for these patients. Associations between BMI or ASA grade and receipt or use of new components were inconsistent between stems and cups and did not provide clear support for the use of new implant components in patients likely to be more active (i.e. lower BMI and ASA grades). It may be of interest to further investigate the implant component choices made for patients with higher BMI or ASA grades.

The most comparable previous work used NJR data to explore patient-level and hospital-level determinants that patients receive uncemented versus cemented implants.[15] Uncemented components were less likely to be used in women and older patients, and hospitals treating older patients were less likely to use them. Our results indicate that surgeons who treat a higher proportion of younger patients are more likely to use newer components. Our most marked finding, that surgeons who used a wide variety of stem-cup combinations (either established or new) were much more likely to try a new component, may be somewhat self-evident but suggests that there may be a subset of surgeons who change components more quickly than their peers. Whether this behaviour, alongside the previously discussed learning-curve, is related to outcomes of THRs is currently unclear.

Proposals for how new implant components should be introduced have been made previously, largely focussed on phased introduction through high-volume centres and surgeons, and reliance on registries for long-term monitoring. It seems unlikely that 16 new THR implant components/year, as we found in our study, could be sustained through such an approach. Alongside the potential benefits of phased introduction discussed elsewhere, this approach would probably reduce the number of implant components used only in very low numbers. Since these are not monitored in the same manner as higher volume components this would probably be a good thing for patients, providing implant components intended for use in specialist cases are not adversely affected.

Further research could build on the findings of this study in several ways. Extending our analysis of surgeon-level factors associated with uptake of new components to include factors associated with risk of revision after THR would be valuable to surgeons and patients. Specifically, the 'learning curve' associated with changing implants and the complex relationship between surgeon's volume and outcomes. In addition, widening our study to cover hospital-level factors or regional variation in suppliers may highlight other drivers of selection.

Conclusions

A large number of new THR implant components have been introduced into use in the NJR since 2008. The majority of THRs performed since 2008 used components which have been in use for a long time, but a large number of surgeons have tried new components, with wide variation in how many types and how often they have been used. The impact of this variation on patient outcomes is currently unclear. New rather than established implant components are more likely to be used in patients who are younger and/or male, although whether this will reduce the high lifetime risk of revision for this population is unclear.

References

- 1 Dreinhöfer KE, Dieppe P, Stürmer T, *et al.* Indications for total hip replacement: Comparison of assessments of orthopaedic surgeons and referring physicians. *Annals of the Rheumatic Diseases* 2006;**65**:1346–50. doi:10.1136/ard.2005.047811
- 2 National Joint Registry for England, Wales and Northern Ireland. 14th Annual Report 2017. 2017.
- 3 National Institute for Health and Care Excellence. Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip. NICE 2018.
- 4 Bayliss LE, Culliford D, Monk AP, *et al.* The effect of patient age at intervention on risk of implant revision after total replacement of the hip or knee: a population-based cohort study. *The Lancet* 2017;**389**:1424–30. doi:10.1016/S0140-6736(17)30059-4
- 5 Smith AJ, Dieppe P, Vernon K, *et al.* Failure rates of stemmed metal-on-metal hip replacements: Analysis of data from the National Joint Registry of England and Wales. *The Lancet* 2012;**379**:1199–204. doi:10.1016/S0140-6736(12)60353-5
- de Steiger RN, Hang JR, Miller LN, *et al.* Five-Year Results of the ASR XL Acetabular System and the ASR Hip Resurfacing System. *The Journal of Bone and Joint Surgery-American Volume* 2011;93:2287–93. doi:10.2106/JBJS.J.01727
- 7 Reito A, Lehtovirta L, Lainiala O, *et al.* Lack of evidence—the anti-stepwise introduction of metal-onmetal hip replacements. *Acta Orthopaedica* 2017;**88**:478–83. doi:10.1080/17453674.2017.1353794
- 8 Kynaston-Pearson F, Ashmore AM, Malak TT, *et al.* Primary hip replacement prostheses and their evidence base: systematic review of literature. *BMJ* 2013;**347**:f6956. doi:10.1136/bmj.f6956
- 9 López-López JA, Humphriss RL, Beswick AD, et al. Choice of implant combinations in total hip replacement: systematic review and network meta-analysis. BMJ (Clinical research ed) 2017;359:j4651. doi:10.1136/bmj.j4651

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36 37 38 39 40 41	2
42 43 44 45	2
45 46 47 48	2
49 50 51 52 53	2
54 55 56 57	
58 59 60	

- 10 McCulloch P, Altman DG, Campbell WB, *et al.* No surgical innovation without evaluation: the IDEAL recommendations. *The Lancet* 2009;**374**:1105–12. doi:10.1016/S0140-6736(09)61116-8
- 11 Birkmeyer JD, Reames BN, McCulloch P, *et al.* Understanding of regional variation in the use of surgery. *The Lancet* 2013;**382**:1121–9. doi:10.1016/S0140-6736(13)61215-5
- 12 National Joint Registry for England W and NI. Prostheses used in hip, knee, ankle, elbow and shoulder replacement procedures 2016. 2017.
- 13 National Joint Registry for England, Wales and Northern Ireland. Data Completeness and quality. 2018.http://www.njrreports.org.uk/Data-Completeness-and-quality (accessed 7 Aug 2019).
- National Joint Registry for England. 15th Annual Report 2018. 2018.
 http://www.njrreports.org.uk/Portals/0/PDFdownloads/NJR%2015th%20Annual%20Report%20201
 8.pdf (accessed 30 Apr 2019).
- 15 Davies C. An analysis of choice: a case study on hip prostheses. 2011.
- 16 Anand R, Graves SE, de Steiger RN, *et al.* What Is the Benefit of Introducing New Hip and Knee Prostheses? *The Journal of Bone and Joint Surgery-American Volume* 2011;**93**:51–4. doi:10.2106/JBJS.K.00867
- 17 Peltola M. Impact of technological change on quality of care: Studies on total hip and knee replacement. 2016.
- 18 Zywiel MG, Johnson AJ, Mont MA. Graduated Introduction of Orthopaedic Implants. *The Journal of Bone & Joint Surgery* 2012;**94**:e158. doi:10.2106/JBJS.K.01675
- 19 Sharkey PF, Sethuraman V, Hozack WJ, *et al.* Factors influencing choice of implants in total hip arthroplasty and total knee arthroplasty: Perspectives of surgeons and patients. *Journal of Arthroplasty* 1999;**14**:281–7. doi:10.1016/S0883-5403(99)90052-9
- Australian Orthopaedic Association. Hip, Knee & Shoulder Arthroplasty: Annual Report 2017. Australian Orthopaedic Association 2017. https://aoanjrr.sahmri.com/documents/10180/397736/Hip%2C%20Knee%20%26%20Shoulder%20 Arthroplasty
- 21 Peltola M, Malmivaara A, Paavola M. Hip prosthesis introduction and early revision risk. *Acta Orthopaedica* 2013;**84**:25–31. doi:10.3109/17453674.2013.771299
- 22 Mohaddes M, Björk M, Nemes S, *et al.* No increased risk of early revision during the implementation phase of new cup designs: Analysis of 52,903 hip arthroplasties reported to the Swedish Hip Arthroplasty Register. *Acta Orthopaedica* 2016;**87**:31–6. doi:10.1080/17453674.2016.1181818
- Mäkelä KT, Matilainen M, Pulkkinen P, *et al.* Failure rate of cemented and uncemented total hip replacements: Register study of combined Nordic database of four nations. *BMJ (Online)* 2014;**348**:1–10. doi:10.1136/bmj.f7592

- 24 Stea S, Comfort T, Sedrakyan A, et al. Multinational comprehensive evaluation of the fixation method used in hip replacement: Interaction with age in context. Journal of Bone and Joint Surgery -American Volume 2014;96:42-51. doi:10.2106/JBJS.N.00463
- 25 Hailer NP, Garellick G, Kärrholm J. Uncemented and cemented primary total hip arthroplasty in the Swedish Hip Arthroplasty Register: Evaluation of 170,413 operations. Acta Orthopaedica 2010;**81**:34–41. doi:10.3109/17453671003685400

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Table 1 Results from multivariable logistic regression models showing the association between surgeon-level factors and use of new stems and cups

				Cups						
Exposure	Established (n=18,404) ³	New (n=2,006) ³	OR ¹	(95% CI)	p1	Established (n=17,167) ³	New (n=3,243) ³	OR ¹	(95% CI)	p1
Proportion of THRs performed on patients <55 years old		\sim								
<10% (ref.)	13,088 (71.1%)	940 (46.9%)	1	-	-	12,346 (71.9%)	1,682 (51.9%)	1	-	-
≥10%	5,316 (28.9%)	1,066 (53.1%)	1.47	1.30 - 1.66	<0.001	4,821 (28.1%)	1,561 (48.1%)	1.39	1.25 – 1.53	<0.001
Number of THRs performed in calendar year ² (per 10 additional cases)	8 (2, 24)	32 (12, 61)	1.02	0.99 - 1.04	0.206	7 (2, 22)	28 (10, 56)	1.06	1.04 - 1.08	<0.001
Proportion of THRs funded privately				l	10.					
100% NHS funded (ref.)	12,922 (70.2%)	966 (48.2%)	1	-		12,159 (70.8%)	1,729 (53.3%)	1	-	-
Some or all funded privately	5,482 (29.8%)	1,040 (51.8%)	1.23	1.05 - 1.43	0.010	5,008 (29.2%)	1,514	1.09	0.96 - 1.23	0.187
Number of stem- cup combinations used in calendar year	<u> </u>	<u> </u>								
≤3 (ref.)	14,259 (77.5%)	589 (29.4%)	1	-	-	13,599 (79.2%)	1,249 (38.5%)	1	-	-
4-6	3,394 (18.4%)	822 (41.0%)	4.91	4.25 – 5.67	<0.001	2,937 (17.1%)	1,279 (39.4%)	3.77	3.36 - 4.23	<0.001
7-10	675 (3.7%)	468 (23.3%)	12.5	10.1 – 15.4	<0.001	568 (3.3%)	575 (17.7%)	7.21	6.01 - 8.67	<0.001

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	76	127	27.4	17.9 – 41.7	<0.001	63	140	13.3	9.20 - 19.2	<0.001
>10	(0.4%)	(6.3%)				(0.4%)	(4.3%)			
Proportion of THRs										
performed on										
patients with ASA										
grade III-V										
	13,244	1,554	1	-	-	12,362	2,436	1	-	-
<25% (ref.)	(72.0%)	(77.5%)				(72.0%)	(75.1%)			
	5,160 🧹	452	1.01	0.89 - 1.16	0.843	4,805	807	1.12	1.01 – 1.25	0.034
≥25%	(28.0%)	(22.5%)				(28.0%)	(24.9%)			

1 – odds ratios, 95% confidence intervals and p-values are from logistic regression models adjusted for all exposure variables, 2 - median (lower to upper quartile), 3 - proportions displayed are based on surgeon-calendar years

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Table 2	Results from multivariable mixed-effects regression models (patients nested within surgeons) of age, gender, categorised BMI, ASA grade and source of funding on stem
age and	cup age, with category proportions

	Stems					Cups	Cups					
	Established	New	OR ¹	(95% CI)	р	Established (n=406,072)	New	OR ¹	(95% CI)	р		
	(n=418,831)	(n=13,124)			•		(n=25,883)					
Age												
<55 years old	43,780	2,793	1.83	1.73 – 1.93	< 0.001	42,752	3,821	1.31	1.25 - 1.37	< 0.001		
	(10.5%)	(21.3%)				(10.5%)	(14.8%)					
55 to 80 (ref.)	312,205	9,246	1	-	-	302,823	18,628	1	-	-		
	(74.5%)	(70.5%)				(74.6%)	(72.0%)					
≥ 80 years old	62,846	1,085	0.60	0.56 - 0.64	< 0.001	60,497	3,434	0.91	0.87 – 0.95	< 0.001		
	(15.0%)	(8.3%)				(14.9%)	(13.3%)					
Gender			N,									
Male (ref.)	165,607	5,768	1		-	161,248	10,127	1	-	-		
	(39.5%)	(44.0%)				(39.7%)	(39.1%)					
Female	253,224	7,356	0.87	0.84 – 0.90	<0.001	244,824	15,756	1.06	1.03 - 1.09	<0.002		
	(60.5%)	(56.0%)				(60.3%)	(60.9%)					
BMI												
Underweight and	95,306	2,911	1	-	40.	91,863	6,354	1	-	-		
normal (ref.)	(22.8%)	(22.2%)				(22.6%)	(24.5%)					
Overweight	165,849	5,138	1.02	0.97 – 1.08	0.373	160,834	10,153	0.95	0.91 – 0.99	0.007		
	(39.6%)	(39.1%)				(39.6%)	(39.2%)					
Class I Obese	105,670	3,391	1.06	1.00 - 1.12	0.067	102,781	6,280	0.93	0.90 – 0.97	0.001		
	(25.2%)	(25.8%)				(25.3%)	(24.3%)					
Class II Obese	38,995	1,276	1.10	1.02 – 1.19	0.011	37,977	2,294	0.94	0.89 - 1.00	0.042		
	(9.3%)	(9.7%)				(9.4%)	(8.9%)					
Class III Obese	13,011	408	0.99	0.87 – 1.11	0.808	12,617	802	0.94	0.86 - 1.02	0.135		
	(3.1%)	(3.1%)				(3.1%)	(3.1%)					
ASA grade												
l (ref.)	60,022	2,661	1	-	-	58,265	4,418	1	-	-		
	(14.3%)	(20.3%)				(14.3%)	(17.1%)					
II	293,142	8,940	0.81	0.77 – 0.86	<0.001	284,437	17,645	0.98	0.95 - 1.03	0.461		
	(70.0%)	(68.1%)				(70.0%)	(68.2%)					

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	63,904	1,482	0.66	0.61 - 0.72	< 0.001	61,681	3,705	1.00	0.94 – 1.05	0.935
	(15.3%)	(11.3%)				(15.2%)	(14.3%)			
IV + V	1,763	41	0.64	0.46 – 0.90	0.010	1,689	115	1.02	0.82 – 1.26	0.881
	(0.4%)	(0.3%)				(0.4%)	(0.4%)			
Source of funding										
	364,928	10,553	1	-	-	354,642	20,839	1	-	-
NHS	(87.1%)	(80.4%)				(87.3%)	(80.5%)			
	53,903	2,571	1.02	0.95 – 1.08	0.642	51,430	5,044	1.09	1.04 - 1.14	< 0.001
Private	(12.9%)	(19.6%)				(12.7%)	(19.5%)			

1 – odds ratios, 95% confidence intervals and p-values are from mixed-effects logistic regression models adjusted for all exposure variables

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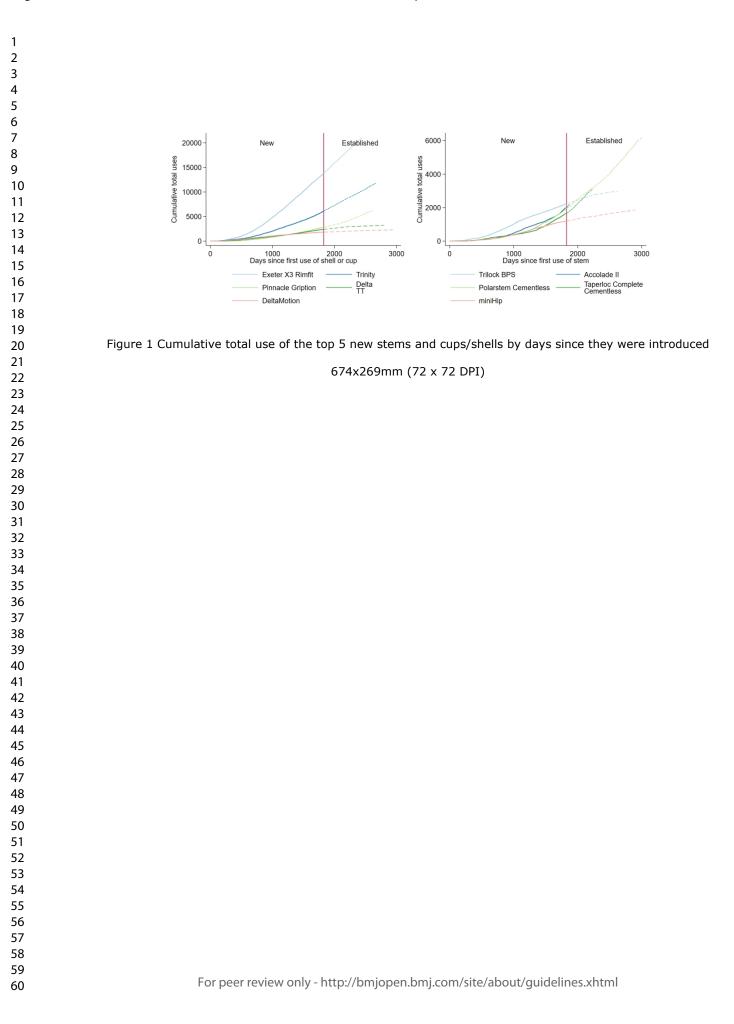
Figure 1 Cumulative total use of the top 5 new stems and cups/shells by days since they were introduced

.ems and cups/shells by doys since they were introduced

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Supplementary material

Table S1 Uptake of new cups first used between January 1st 2008 and 26th February 2017

Cup/shell brand	UC ¹	Patients	Percent	Surgeons	Month first used
Exeter X3 Rimfit		13,821	38.5%	781	Jun 2010
Trinity	1	6,133	17.1%	197	Nov 2009
Pinnacle Gription	1	2,817	7.9%	375	Dec 2009
Delta TT	1	2,368	6.6%	145	Jun 2009
DeltaMotion	1	1,823	5.1%	152	Feb 200
Versafit CC Trio	1	1,442	4.0%	47	Mar 201
RM Pressfit Vitamys	1	731	2.0%	33	Aug 201
G7 Cementless Acetabular	1	621	1.7%	36	Aug 201
Component					
AEON Cemented Acetabular Cup		568	1.6%	43	Sep 201
Exceed ABT Cemented		556	1.5%	57	Jun 201
Plasmafit Cementless Cup		546	1.5%	50	Nov 201
Duracel		465	1.3%	45	Mar 201
Allofit IT	1	367	1.0%	19	Jan 201
ADES Cemented		342	1.0%	72	Feb 201
XLFit Acetabular Cup	1	293	0.8%	56	Apr 201
Regenerex Ringloc+	1	220	0.6%	55	Feb 200
April - Polyethylene	1	214	0.6%	33	Jan 201
ADES	1	205	0.6%	39	May 201
Delta PF	1	198	0.6%	9	Mar 201
MIHR Cup	1	197	0.5%	12	Mar 200
RM Pressfit	1	184	0.5%	24	May 200
Tribofit	\	174	0.5%	9	Jul 201
seleXys TH+	1	174	0.5%	13	Nov 200
OptiCup CEP		147	0.4%	18	Nov 201
Delta One TT	1	129	0.4%	61	Jun 201
Gyros	1	129	0.4%	28	Jan 201
Restoration ADM Cup	1	127	0.4%	31	May 201
EcoFit Cementless Cup	1	102	0.3%	5	Feb 201
Novation	1	93	0.3%	10	Nov 200
Allofit-S IT	1	91	0.3%	21	Aug 201
M2A Magnum	✓	79	0.2%	30	Feb 200
Freedom		75	0.2%	17	May 200
Captiv DM	1	68	0.2%	8	Aug 201
Trident Constrained Cup		65	0.2%	30	Jan 200

seleXys DS Cementless		56	0.2%	16	Mar 2
MMC Resurfacing	1	36	0.1%	10	Aug 2
ASR 300 Cup	1	36	0.1%	1	Jan 2
MPACT	1	25	0.1%	8	Dec 2
Restoration Gap2		23	0.1%	14	Mar 2
Fixa Ti-Por	1	20	0.1%	4	Apr 2
seleXys DS Cemented		20	0.1%	12	Feb 2
Fixa Duplex	1	17	0.0%	1	Mar 2
Cormet Prime	1	12	0.0%	5	Jan 2
Delta Revision TT	1	9	0.0%	6	Nov 2
Equateur	1	9	0.0%	5	Jul 2
U-Motion II	1	8	0.0%	4	Apr 2
A Class		7	0.0%	3	Feb 2
Zimmer Cemented Cup		6	0.0%	4	May 2
Regenerex Revision	1	4	0.0%	3	Jan 2
Capitole C	5	3	0.0%	3	Jan 2
Sirius Cementless Cup	1	3	0.0%	2	Aug 2
Horizon		3	0.0%	2	Jul 2
2M Dual Mobility	-	3	0.0%	2	Nov 2
Par-5	1	3	0.0%	3	Jan 2
Solution Cemented Cup		2	0.0%	1	Dec 2
J-Loc	1	2	0.0%	2	Mar 2
XPE Cup		2	0.0%	1	Jun 2
Evidence		2	0.0%	1	Oct 2
FIXA Duplex Cemented		1	0.0%	1	Jan 2
Endurance Cemented Cup		1	0.0%	1	Oct 2
Mitre Cup		1	0.0%	1	Nov 2
Capitole T	1	1	0.0%	1	Nov 2
Polymax	1	1	0.0%	1	Oct 2
Ringloc	1	1	0.0%	1	Jan 2
Charnley KS		1	0.0%	_1	Jul 2
Arden		1	0.0%	1	Feb 2
Versacem		1	0.0%	1	Oct 2
Versafit DM	1	1	0.0%	1	May 2
Total		35,885			

1 – Uncemented fixation, Rows in **bold** = five most commonly used new cups

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Stem brand	UC ¹	Patients	Percent	Surgeons	Month firs used
Trilock BPS	1	2,232	12.3%	121	Dec 200
Accolade II	1	1,997	11.0%	165	Jan 201
Polarstem Cementless	1	1,969	10.8%	93	Dec 200
Taperloc Complete Cementless	1	1,658	9.1%	104	Jan 201
Stem					
miniHip	√	1,193	6.6%	79	Mar 200
Metafix Stem	 ✓ 	1,171	6.4%	93	Feb 200
AMIStem-H	1	1,003	5.5%	32	Aug 200
Exeter No.1 125mm stem Line		836	4.6%	211	Aug 201
Extension					
TriFit TS hip stem	1	684	3.8%	44	Sep 201
Aeon Cemented Stem		673	3.7%	50	Sep 201
SPS Evolution		654	3.6%	48	Jan 201
C-Stem AMT Line Extension		428	2.4%	127	Jul 201
H-Max S Monoblock Stem	1	401	2.2%	34	May 201
H-Max M Modular Stem	1	316	1.7%	20	Mar 201
Finsbury Type C		302	1.7%	39	Aug 200
EcoFit Cementless Stem	1	240	1.3%	11	Sep 201
Silent	1	199	1.1%	17	Feb 200
Metha Monoblock Stem	1	195	1.1%	25	Aug 201
Corail Cemented		170	0.9%	32	Apr 200
OptiStem		165	0.9%	22	Nov 201
Trilliance		156	0.9%	10	Jul 201
Sirius stem		138	0.8%	10	Apr 201
Profemur L Classic	1	132	0.7%	17	Mar 201
Profemur TL	1	120	0.7%	23	Jan 200
AMIStem-C		110	0.6%	3	Jul 201
Master SL	1	102	0.6%	8	Jul 201
Corail Revision Stem	1	92	0.5%	69	Jul 201
Novation Element Stem		90	0.5%	9	Nov 200
CBC Evolution	1	83	0.5%	8	Jan 201
Nanos	1	78	0.4%	5	Dec 201
Amoda	1	67	0.4%	1	Apr 201
Harmony Modular	1	65	0.4%	6	Mar 201
ABG II Cementless Stem	1	52	0.3%	9	Apr 200
SL	1	51	0.3%	5	Sep 200
XActa		47	0.3%	5	Jan 201
Avenir Muller Cementless	1	33	0.2%	6	Jun 201
Harmony Cemented		25	0.1%	8	Feb 201

Table S2 Uptake of new stems first used between January 1st 2008 and 26th February 2017

miniMax		24	0.1%	2	Apr
SMS	1	22	0.1%	2	Jul
FTS	1	20	0.1%	5	Feb
Profemur TL Classic	1	19	0.1%	5	Jan
SMF	1	17	0.1%	1	Oct
Profemur Preserve	1	12	0.1%	5	Feb
AMIStem HP	1	12	0.1%	1	Dec
METS Cemented		12	0.1%	10	Dec
GMRS		11	0.1%	9	Aug
Harmony Cementless	1	10	0.1%	4	Apr
UCP Stem		10	0.1%	5	Apr
Echelon Cemented Stem		8	0.0%	6	Mar
Exception Cementless		6	0.0%	3	Feb
METS Cementless		5	0.0%	5	Feb
Novation Stem	1	5	0.0%	2	Mar
G2 Cementless Stem	1	5	0.0%	5	Dec
Securus		4	0.0%	4	Dec
Profemur Gladiator	-	4	0.0%	3	Mar
Arcad Cementless	1	4	0.0%	4	Sep
Euros Cementless	1	3	0.0%	2	Aug
Atlantis	1	3	0.0%	3	Dec
Quadra-C		3	0.0%	2	Oct
Restoration Cemented Stem		1	0.0%	1	Feb
Wagner Revision Stem	1	1	0.0%	1	Apr
Initiale Cemented Stem		1	0.0%	1	Jul
Integrale	1	1	0.0%	1	Jun
optimys	1	1	0.0%	1	Feb
Prodigy	1	1	0.0%	1	Jul
CDH Stem	1	1	0.0%	1	Nov
Friendly		1	0.0%	1	Jul
Regulus Cemented Stem		1	0.0%	1	Oct
Arcad Cemented		1	0.0%	1	Feb
Endurance Cemented Stem		1	0.0%	1	Sep
Furlong HAC Hemiarthroplasty	1	1	0.0%	1	Oct
C2 Stem	1	1	0.0%	1	Feb
Total	+	18,159			

1 – Uncemented fixation, Rows in **bold** = five most commonly used new stems

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Number of new cups used	Number of surgeons	Percent	Cumulative percent
1	1,113	65.5%	65.5%
2	351	20.7%	86.2%
3	138	8.1%	94.3%
4	61	3.6%	97.9%
5	18	1.1%	98.9%
6	8	0.5%	99.4%
7	9	0.5%	99.9%
10	1	0.1%	100.0%
Total	1,699		

Table S4 Nun	nber of different pos	t-2008 stems used	d by surgeons
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Number of new stems				Cumulative
used		Number of surgeons	Percent	percent
1	1	771	69.4%	69.4%
2	2	210	18.9%	88.3%
3	3	77	6.9%	95.2%
2	1	33	3.0%	98.2%
5	5	9	0.8%	99.0%
6	5	8	0.7%	99.7%
	7	1	0.1%	99.8%
5	3	2	0.2%	100.0%
Total		1,111		

			Cumulative
Stem-cup combinations	Number of surgeons	Percent	percent
1	311	71.8%	71.8%
2	78	18.0%	89.8%
3	22	5.1%	94.9%
4	10	2.3%	97.2%
5	5	1.2%	98.4%
6	2	0.5%	98.9%
7	1	0.2%	99.1%
8	2	0.5%	99.5%
9	2	0.5%	100.0%
Total	433	100%	

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	Incomplete (n=186,438)	Complete (n=431,995)	P*
Age	(11-100,400)	(11-431,333)	
<55 years old	19,561 (10.5%)	46,573 (10.8%)	< 0.001
55 to 80	136,370 (73.1%)	321,451 (74.4%)	
≥ 80 years old	30,507 (16.4%)	63,931 (14.8%)	
Gender			
Male	71,676 (38.4%)	171,375 (39.7%)	<0.001
Female	114,762 (61.6%)	260,580 (60.3%)	
BMI		6	
Underweight and normal	31 (23.8%)	98,217 (22.7%)	0.097
Overweight	43 (33.1%)	170,987 (39.6%)	
Class I Obese	33 (25.4%)	109,061 (25.2%)	
Class II Obese	14 (10.8%)	40,271 (9.3%)	
Class III Obese	9 (6.9%)	13,419 (3.1%)	A.
ASA grade			
	24,893 (13.4%)	62,683 (14.5%)	<0.001
II	130,223 (69.8%)	302,082 (69.9%)	
III	30,180 (16.2%)	65,386 (15.1%)	
IV + V	1,142 (0.6%)	1,804 (0.4%)	
Source of funding			
NHS	165,394 (89.4%)	375,481 (86.9%)	<0.001
Private - P-values from chi square t	19,530 (10.6%)	5,6474 (13.1%)	

Table S6 A comparison of people with complete data and those missing some data

		Stems			Cups	
	OR ¹	(95% CI)	р	OR ¹	(95% CI)	р
Exposure						
Proportion of THRs performed on patients <55 years old						
<10% (ref.)	1	-	-	1	-	-
≥10%	2.79	2.49 - 3.13	<0.001	2.38	2.16 – 2.62	<0.001
Number of THRs performed in	1.19	1.16 – 1.22	<0.001	1.20	1.18 – 1.23	<0.001
calendar year² (per 10 additional cases)						
Proportion of THRs funded privately		60				
100% NHS funded (ref.)	1	-	<u>-</u>	1	-	-
Some or all funded privately	2.54	2.21 – 2.91	<0.001	2.13	1.90 – 2.37	<0.001
Number of stem-cup combinations used in calendar year			· C			
≤3 (ref.)	1	-	-	1		-
4-6	5.86	5.16 - 6.66	<0.001	4.74	4.27 – 5.26	<0.001
7-10	16.8	14.1 - 20.0	<0.001	11.0	9.39 – 12.9	<0.001
>10	40.5	27.2 - 60.1	<0.001	21.2	17.1 - 34.2	<0.001
Proportion of THRs performed on patients with ASA grade III-V						2/
<25% (ref.)	1	-	-	1	-	
≥25%	0.75	0.66 - 0.85	<0.001	0.85	0.77 – 0.95	0.003

 Table S7 Results from unadjusted logistic regression models showing the association between surgeon-level factors and use of new versus old stems and cups

1 – odds ratios, 95% confidence intervals and p-values are from unadjusted logistic regression models

	Stems	5		Cups		
	OR ¹	(95% CI)	р	O R ¹	(95% CI)	р
Age (years)						
<55 years old	1.95	1.85 – 2.05	<0.001	1.31	1.25 – 1.36	<0.001
55 to 80 (ref.)	1	-	-	1	-	-
≥ 80 years old	0.56	0.52 – 0.60	<0.001	0.93	0.89 – 0.97	<0.001
Gender						
Male (ref.)	1	- 04	-	1	-	-
Female	0.83	0.80 – 0.86	<0.001	1.05	1.02 - 1.08	0.001
BMI						
Underweight and		-	- (2		-	-
normal (ref.)	1			1		
Overweight	1.06	1.01 – 1.12	0.017	0.94	<u>0.9</u> 1 – 0.98	0.001
Class I Obese	1.12	1.06 – 1.18	<0.001	0.93	0.90 - 0.97	0.001
Class II Obese	1.18	1.09 – 1.27	<0.001	0.96	0.90 - 1.01	0.123
Class III Obese	1.04	0.93 – 1.17	0.513	0.97	0.89 - 1.05	0.456
ASA grade),
l (ref.)	1	-	-	1	-	1
II	0.69	0.65 – 0.72	<0.001	0.92	0.88 – 0.96	<0.001
III	0.51	0.48 – 0.55	<0.001	0.90	0.86 – 0.95	<0.001
IV + V	0.47	0.33 – 0.65	<0.001	0.91	0.74 - 1.13	0.390
Source of funding						
NHS	1	-	-	1	-	-
Private	1.01	0.95 – 1.07	0.777	1.08	1.03 - 1.13	0.001

Table S8 Results from unadjusted mixed-effects regression models (patients nested within surgeons) of age, gender, categorised BMI, ASA grade, and source of funding on stem and cup age

1 – odds ratios, 95% confidence intervals and p-values are from unadjusted mixed-effects logistic regression models

Table S9 Sensitivity analysis 1: Results from multivariable logistic regression models showing the association between surgeon-level factors and use of new versus old stems and cups, excluding surgeon calendar-years with <10 THRs

		Stems			Cups	
Exposure	OR ¹	(95% CI)	р	OR ¹	(95% CI)	р
Proportion of THRs performed on patients <55 years old						
<10% (ref.)	1	-	-	1	-	-
≥10%	1.30	1.13 – 1.49	<0.001	1.36	1.21 – 1.54	<0.001
Number of THRs performed in calendar year ² (per 10 additional cases)	1.01	0.99 - 1.04	0.359	1.04	1.01 – 1.06	0.001
Proportion of THRs funded privately		60				
100% NHS funded (ref.)	1	-		1	-	-
Some or all funded privately	1.24	1.05 – 1.47 🦷	0.012	1.04	0.91 – 1.19	0.546
Number of stem-cup combinations used in calendar year			. 6			
≤3 (ref.)	1	-	-	1	-	-
4-6	4.13	3.44 – 4.96	<0.001	3.22	2.82 - 3.69	<0.001
7-10	10.8	8.62 - 13.6	<0.001	6.23	5.15 – 7.53	<0.001
>10	24.3	15.8 - 37.4	<0.001	12.1	8.37 – 17.5	<0.001
Proportion of THRs performed on patients with ASA grade III-V						
<25% (ref.)	1	-	-	1	-	
≥25%	1.11	0.94 – 1.31	0.214	1.21	1.05 – 1.38	0.007

 1 – odds ratios, 95% confidence intervals and p-values are from logistic regression models adjusted for all exposure variables

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Table S10Sensitivity analysis 2a: Results from multivariable logistic regression models showing the association between surgeon-level factors (consultant in-charge) and use of new versus old stems and cups

		Stems			Cups	
	OR ¹	(95% CI)	р	OR ¹	(95% CI)	р
Exposure						
Proportion of THRs performed on						
patients <55 years old						
<10% (ref.)	1	-	-	1	-	-
≥10%	1.52	1.33 – 1.74	<0.001	1.46	1.30 – 1.64	<0.001
Number of THRs performed in	1.02	1.00 - 1.04	0.039	1.05	1.04 - 1.07	<0.001
calendar year ²						
(per 10 additional cases)		No				
Proportion of THRs funded						
privately			k			
100% NHS funded (ref.)	1	_	-	1	-	-
Some or all funded privately	1.27	1.08 – 1.50	0.004	1.15	1.01 – 1.31	0.042
Number of stem-cup combinations						
used in calendar year						
≤3 (ref.)	1	-	-	1	-	-
4-6	4.72	3.98 – 5.60	<0.001	3.47	3.04 - 3.97	<0.001
7-10	11.2	8.87 – 14.1	<0.001	6.16	5.06 – 7.49	<0.001
>10	26.7	17.9 – 39.9	< 0.001	11.3	7.91 – 16.1	< 0.001
Proportion of THRs performed on						1/5
patients with ASA grade III-V						
<25% (ref.)	1	-	-	1	-	-
≥25%	1.15	0.98 – 1.35	0.077	1.13	0.99 – 1.29	0.064

1 – odds ratios, 95% confidence intervals and p-values are from logistic regression models adjusted for all exposure variables

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Table S11 Sensitivity analysis 2b: Results from multivariable mixed-effects regression models (patients nested within 'consultant in-charge') of age, gender, categorised BMI, ASA grade, and source of funding on stem and cup age

	Stems	5		Cups		
	OR ¹	(95% CI)	р	OR ¹	(95% CI)	р
Age (years)						
<55 years old	1.89	1.79 – 1.99	<0.001	1.32	1.26 – 1.37	<0.001
55 to 80 (ref.)	1	-	-	1	-	-
≥ 80 years old	0.59	0.55 – 0.63	<0.001	0.92	0.88 – 0.96	<0.001
Gender						
Male (ref.)	1	-	-	1	-	-
Female	0.87	0.84 – 0.91	<0.001	1.05	1.02 – 1.09	<0.001
BMI						
Underweight and		-	· - (-	-
normal (ref.)	1			1		
Overweight	1.01	0.96 – 1.07	0.663	0.95	0.91 – 0.98	0.005
Class I Obese	1.05	0.99 – 1.11	0.123	0.93	0.89 - 0.97	<0.001
Class II Obese	1.09	1.01 – 1.17	0.031	0.94	0.89 - 1.00	0.039
Class III Obese	0.98	0.87 – 1.10	0.737	0.95	0.87 – 1.04	0.264
ASA grade						\mathbf{N}
l (ref.)	1	-	-	1	-	
II	0.80	0.76 – 0.84	<0.001	0.97	0.93 – 1.01	0.168
III	0.64	0.60 – 0.69	<0.001	0.97	0.92 – 1.03	0.338
IV + V	0.62	0.44 – 0.87	0.006	1.00	0.81 - 1.23	0.981
Source of funding						
NHS	1	-	-	1	-	-
Private	1.14	1.07 – 1.21	< 0.001	1.13	1.08 - 1.18	<0.001

1 – odds ratios, 95% confidence intervals and p-values are from mixed-effects logistic regression models adjusted for all exposure variables

Table S11 Sensitivity analysis 3: A comparison of results from multivariable mixed-effects regression models (patients nested within 'lead surgeon', excluding BMI) using a)
patients with complete data for all exposures and BMI and, b) patients with complete data for all exposures excluding BMI

	Stems						Cups					
	a)	Complete ca	•	b)	All cases ²		a)	Complete ca	-	b)		
		(n = 431,955)			(n = 616,879))		(n = 431,955)	(n = 616,879)		
	OR ³	(95% CI)	р	OR ³	(95% CI)	р	OR ³	(95% CI)	р	OR ³	(95% CI)	р
Age (years)												
<55 years old	1.83	1.74 – 1.93	<0.001	1.81	1.73 – 1.90	<0.001	1.31	1.25 – 1.37	<0.001	1.37	1.32 – 1.42	<0.001
55 to 80 (ref.)	1	-	-	1	-	-	1	-	-	1	-	-
≥ 80 years old	0.59	0.55 – 0.63	<0.001	0.61	0.61 – 0.57	< 0.001	0.92	0.88 – 0.96	<0.001	0.95	0.92 – 0.99	0.008
Gender			5									
Male (ref.)	1	-	- /	1	-	-	1	-	-	1	-	-
Female	0.86	0.83 - 0.90	< 0.001	0.84	0.82 – 0.87	< 0.001	1.07	1.04 - 1.10	<0.001	1.04	1.02 - 1.07	0.001
ASA grade					4							
l (ref.)	1	-	-	1		-	1	-	-	1	-	-
II	0.82	0.78 – 0.87	<0.001	0.82	0.78 – 0.86	<0.001	0.98	0.94 - 1.02	0.264	0.97	0.94 - 1.01	0.100
	0.67	0.62 - 0.72	< 0.001	0.66	0.62 - 0.70	< 0.001	0.99	0.94 - 1.04	0.641	1.01	0.97 – 1.06	0.591
IV + V	0.65	0.46 - 0.91	0.011	0.67	0.52 – 0.86	0.002	1.01	0.82 – 1.25	0.927	1.12	0.95 – 1.32	0.175
Source of funding						2						
NHS (ref.)	1	-	-	1	-	-	1	-	-	1	-	-
Private	1.01	0.95 – 1.08	0.688	1.02	0.97 – 1.08	0.403	1.09	1.04 - 1.14	<0.001	1.07	1.03 - 1.11	0.001

1 – The study sample for 'Complete cases only' was defined as those cases with complete data for all exposure variables (age, gender, ASA grade and source of funding) and BMI

2 - The study sample for 'All cases' was defined as those cases with complete data for all exposure variables (age, gender, ASA grade and source of funding)

3 – odds ratios, 95% confidence intervals and p-values are from mixed-effects logistic regression models adjusted for all exposure variables

Figure S1 The cumulative introduction of new brands of cup and stem components for THRs, between January 1st 2008 and 26th February 2017

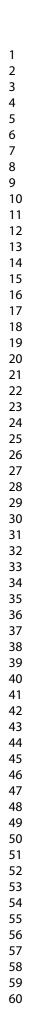
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Figure S2 STROBE Flow diagram

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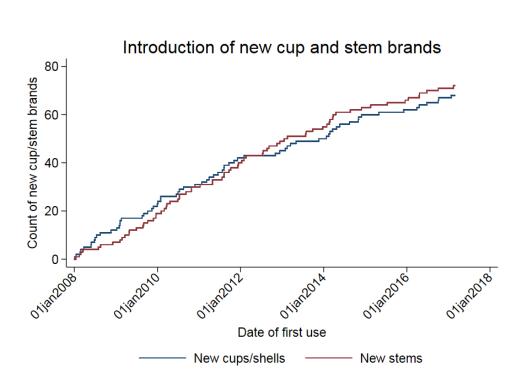
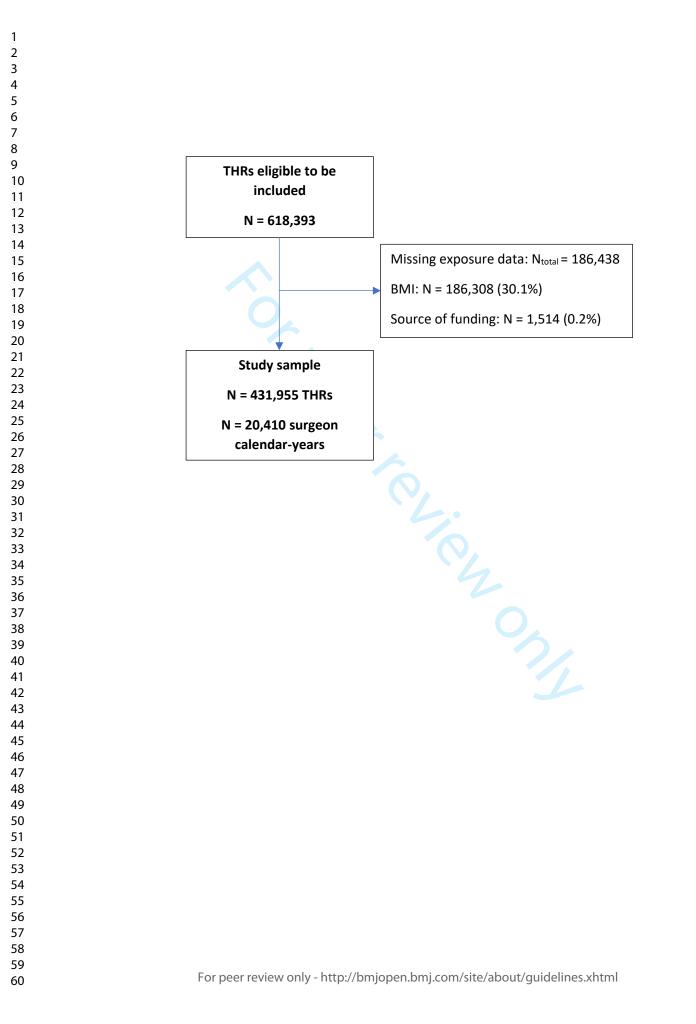


Figure S1 The cumulative introduction of new brands of cup and stem components for THRs, between January 1st 2008 and 26th February 2017

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Page

Reporting checklist for cohort study.

Based on the STROBE cohort guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below. Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation. Upload your completed checklist as an extra file when you submit to a journal. In your methods section, say that you used the STROBE cohort reporting guidelines, and cite them as: yon Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening

the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for

reporting observational studies.

44 45 46			Reporting Item	Number
47 48 49 50 51	Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
52 53 54 55 56 57	Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	4
58 59 60		For p	eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2	Background /	#2	Explain the scientific background and rationale for the	6
3 4 5	rationale		investigation being reported	
6 7	Objectives	#3	State specific objectives, including any prespecified	6
8 9 10			hypotheses	
11 12 13 14	Study design	#4	Present key elements of study design early in the paper	7
15 16	Setting	#5	Describe the setting, locations, and relevant dates, including	7
17 18 19			periods of recruitment, exposure, follow-up, and data collection	
20 21	Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of	7
22 23 24			selection of participants. Describe methods of follow-up.	
25 26		#6b	For matched studies, give matching criteria and number of	See note
27 28 29			exposed and unexposed	1
30 31	Variables	#7	Clearly define all outcomes, exposures, predictors, potential	7-8
32 33 34			confounders, and effect modifiers. Give diagnostic criteria, if	
35 36			applicable	
37 38 39	Data sources /	#8	For each variable of interest give sources of data and details of	7-8
40 41	measurement	<i>#</i> 0	methods of assessment (measurement). Describe	7-0
42 43	measurement		comparability of assessment methods if there is more than one	
44 45				
46 47			group. Give information separately for for exposed and	
48 49			unexposed groups if applicable.	
50 51 52	Bias	#9	Describe any efforts to address potential sources of bias	8-9
53 54 55	Study size	#10	Explain how the study size was arrived at	See note
56 57				2
58 59 60		For pe	eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2	Quantitative	#11	Explain how quantitative variables were handled in the	8-9
3 4	variables		analyses. If applicable, describe which groupings were chosen,	
5 6 7			and why	
8 9 10	Statistical	#12a	Describe all statistical methods, including those used to control	8-9
11 12	methods		for confounding	
13 14 15		#12b	Describe any methods used to examine subgroups and	8-9
16 17			interactions	
18 19		#40-		0
20 21		#12c	Explain how missing data were addressed	8
22 23 24		#12d	If applicable, explain how loss to follow-up was addressed	See note
24 25 26				3
27 28 29		#12e	Describe any sensitivity analyses	8-9
30 31	Darticipanta	#13a	Papart numbers of individuals at each stage of study as	9-10
32 33	Participants	#15a		9-10
34 35			numbers potentially eligible, examined for eligibility, confirmed	
36 37			eligible, included in the study, completing follow-up, and	
38 39			analysed. Give information separately for for exposed and	
40 41 42			unexposed groups if applicable.	
43 44 45		#13b	Give reasons for non-participation at each stage	9-10
46 47		#13c	Consider use of a flow diagram	Figure
48 49 50				S2
51 52 53	Descriptive data	#14a	Give characteristics of study participants (eg demographic,	9-10
53 54 55			clinical, social) and information on exposures and potential	
56 57 58			confounders. Give information separately for exposed and	
58 59 60		For pe	eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2			unexposed groups if applicable.	
3 4		#14b	Indicate number of participants with missing data for each	Figure
5 6 7			variable of interest	S2
8 9 10		#14c	Summarise follow-up time (eg, average and total amount)	See note
11 12				5
13 14 15	Outcome data	#15	Report numbers of outcome events or summary measures	See note
16 17			over time. Give information separately for exposed and	6
18 19 20			unexposed groups if applicable.	
21 22 23	Main results	#16a	Give unadjusted estimates and, if applicable, confounder-	See note
23 24 25			adjusted estimates and their precision (eg, 95% confidence	7
26 27			interval). Make clear which confounders were adjusted for and	
28 29 30			why they were included	
31 32 33		#16b	Report category boundaries when continuous variables were	See note
34 35			categorized	8
36 37 38		#16c	If relevant, consider translating estimates of relative risk into	See note
39 40 41			absolute risk for a meaningful time period	9
42 43	Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and	9-12
44 45 46			interactions, and sensitivity analyses	
47 48 49	Key results	#18	Summarise key results with reference to study objectives	13
50 51 52	Limitations	#19	Discuss limitations of the study, taking into account sources of	13
53 54			potential bias or imprecision. Discuss both direction and	
55 56 57			magnitude of any potential bias.	
58 59		Earma	er review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	
60		i oi pe	certeview only - http://bhijopen.bhij.com/site/about/guidelines.xhthi	

1 2	Interpretation		#20	Give a cautious overall interpretation considering objectives,	13-15
3 4				limitations, multiplicity of analyses, results from similar studies,	
5 6 7				and other relevant evidence.	
8 9 10	Generalisability		#21	Discuss the generalisability (external validity) of the study	15
11 12 13 14 15				results	
	Funding		#22	Give the source of funding and the role of the funders for the	3
16 17				present study and, if applicable, for the original study on which	
18 19 20				the present article is based	
21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 50 51 52 53 45 56 57	Au	thor notes			
	1.	n/a - not releva	ant		
	2.	n/a - not releva	ant		
	3.	n/a - not releva	ant		
	4.	10 and Fig S2			
	5.	n/a - not releva	ant		
	6.	Tables 1 & 2			
	7.	Tables S6 & S	7		
	8.	n/a - not neede	ed		
	9.	n/a - not neede	ed		
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	CC-BY. This checklist was completed on 31. January 2019 using https://www.goodreports.org/, a tool				
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