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The uptake of new knee replacement implants in the UK: Analysis of 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.

<u>http://www.njrcentre.org.uk/njrcentre/Research/Researchrequests/tabid/305/Default.aspx</u> contains information on research data access request to the National Joint Registry.

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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.

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.

Contributors

CP, AB, AJ and MW designed the study. CP, AB, JMW, AJ and MW reviewed the published work. CP conducted the statistical analysis. All contributed to writing the report. CP had full access to all the data. AB and JMW are the guarantors.

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Introduction

Partial (unicondylar or patellofemoral) or total knee replacements (KR) are mainly performed to treat end-stage knee arthritis [1]. It is a highly successful surgical procedure with typical 10-year revision rates <5% [2]. However, younger patients are more likely to require revision surgery; the lifetime revision risk for men having a KR in their 50s is ~35% compared with 5% in their 70s [3]. Such patients may benefit the most from developments in KR that lead to reduced revision rates or improved outcomes, but may also face higher risk of complications if new implants perform poorly.

New KR implant designs are introduced with no evidence that they have lower revision rates than established prostheses [4,5], and more than a quarter have higher revision rates than existing designs [4]. Although there have been no high-profile failures of knee implant design on the scale of metal-onmetal total hip replacements, patellofemoral KRs have a 3.6x higher annual revision rate compared with TKR [6]. Furthermore, the evidence to support decisions about KR implants is limited [7]. The IDEAL collaboration, an influential agenda for surgical research, developed a framework for investigations into surgical innovations in which they recommended new medical devices have a phased introduction into surgical practice [8]. However, we do not know the rate of uptake of new KR implants, whether this is compatible with a phased introduction, how many surgeons are using them, and which patients are receiving new KR implants.

Variation between and within regions for common surgical procedures can be wide [9]. Within knee replacement surgery, the large number of different implant brands used in primary KRs (e.g. 103 brands for total KRs recorded in the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) in 2016 [10]) may be an important source of variation. Research to understand variation in surgical activity may help to understand and reduce avoidable differences in outcomes for patients.

Aims

We aimed to:

- 1. Describe the uptake of new implants for KRs in the NJR and how this varies between consultants
- 2. Compare consultants who use new compared with established KR implants
- 3. Compare patients who receive new compared with established KR implants

Material and methods

Data Source

The NJR was established in 2003 [2]. Data entry for Northern Ireland and the Isle of Man commenced in 2013 and 2015 respectively and therefore they are excluded from this analysis.

Study sample

We included patients who received a primary KR for osteoarthritis (OA) with or without other indications between 1st January 2008 and 26th February 2017. We used NJR data from 2003 onwards to calculate the date each knee implant brand was first used and the total number of implantations. We excluded people who had not given consent for recording of personal details and where the brand of their KR implant was uncertain.

Patient involvement

This study was designed and undertaken without patient involvement.

Definition of new and established implant brands

We identified the implant brand from component labels recorded in the NJR and categorised all implant brands with a first recorded use by any surgeon on or after 1st January 2008 as 'new'. Implant brands with a first recorded use before 2008 were categorised as 'established'. We did not separate posterior stabilised and cruciate retaining versions of a brand but did consider brands to be separate based on mode of fixation (cemented or uncemented) or whether the brand could be used in more than one type of knee replacement (TKR, unicondylar or patellofemoral).

Consultant 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. Since consultant surgeons are ultimately responsible for the choice of implant we have focussed on the uptake by consultant rather than operating surgeon. We summarised each consultant's activity across each calendar-year in which they performed ≥ 1 KR. We considered seven consultant-level factors which may be associated with their use of a new implant brand in a calendar-year:

- 1. Total volume of KRs performed in that year
- 2. Proportion of those KRs performed on patients <55 years old
 - a. Any KRs performed on people <55 years old? 'Some' or 'none'

- b. Percentage of KRs performed on patients <55 years old
- 3. Source of funding for KRs
 - a. Any KRs funded privately? '100% NHS funded' or 'some or all privately funded'
 - b. Percentage funded privately
- Proportion of KRs performed on patients with an American Society of Anaesthesiologists (ASA) grade III-V (<25% and ≥25%)
- 5. Number of KR implant brands used in that calendar-year (continuous)
- Number of different types of KR procedures performed (TKR, unicondylar and/or patellofemoral: scale 1-3)
- 7. Time since the surgeon became a consultant (≤ 2 years, > 2 years)

Patients receiving new implant components

We used date of surgery to order patients within implant brands and within consultants. We categorised patients according to whether the implant they received was new or established. We considered five patient-level factors which may be associated with their receipt of new implants:

- 1. Age at the time of KR (<55, 55-80, and 80+ years)
- 2. Gender
- 3. Body mass index (BMI)
- 4. ASA grade
- 5. Source of funding for procedure: NHS or private

We selected these categories for age to reflect patients who were having a primary KR at a relatively young or relatively old age, the median age at the time of primary KR was 70 years (25%-75% 63-76 years).[11]

Statistical analyses

We described the use of KR components in primary KRs performed since January 1st 2008, the cumulative use of new implants in patients, and the count of consultants who used new implants.

Consultant-level factors

We included only those people with complete exposure and outcome data for the consultant-level and patient-level analysis models (i.e. complete-case analysis). We assumed that data were missing at random. We 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 consultant used a new implant at least once for a KR in a calendar-year. The unit of analysis was consultant calendar-years and exposure variables were those consultant-level factors defined previously. We used unadjusted and multivariable adjusted multilevel logistic regression models, with calendar-years nested within surgeons.

Patient-level factors

Our outcome was whether a patient received a new rather than established implant. The unit of analysis was patients and exposure variables were those patient-level factors defined previously. Patient-level factors were included in multivariable adjusted multilevel logistic regression models, with patients nested within surgeons.

We calculated the proportion of variance in selection of new implants attributable to differences among surgeons assuming that this reflected an underlying latent trait, applying the method described by Goldstein et al [12].

Sensitivity analyses

We conducted two sensitivity analyses. To determine whether the lack of variability in patients operated on by low volume consultants affected our results, we repeated our consultant-level analysis excluding calendar-years for consultants in which they performed <10 KRs. We also considered that the demographics of patients receiving total, unicondylar and patellofemoral KRs are different, which may affect our patient-level analyses. We therefore repeated these analyses by type of KR procedure.

All analyses were performed using R v3.5.3 [13], using the 'Ime4' package [14] to fit the mixed effects models, 'performance' package [15] to estimate model performance and 'finalfit' package [16] to produce output tables.

Results

Overall use of implant components

Between 1st January 2008 and 26th February 2017, 722,178 primary KRs were performed for OA in England and Wales and recorded in the NJR. The mean age of the patients at the time of their primary operation was 68.9 years (sd = 9.5 years), 56.4% were female, their ASA grades were I:11.0%, II:73.6%, III:15.1% and IV/V:0.3%. Eleven percent had a normal/underweight BMI, 35.0% were overweight and

54.0% obese. KRs were performed by 2,675 consultants using 155 different implants. Consultants used a median of four different implants (IQR = 2-7, max=23) and performed a median of 142 KRs over the period (IQR = 25-403, max=2,578).

Use of new implant components

During this period 65 new implants were first used : 44 TKR, 16 unicondylar, four patellofemoral, one multi-compartmental system (TKR + unicondylar + patellofemoral). They were introduced at a reasonably constant rate of ~7/year (Figure 1). Twenty-two thousand, one hundred and thirty-four primary KRs were performed using new implants (3.1% of all primaries in this period). Twenty-eight percent (n=759) of consultants who performed a KR in this period used at least one new implant. The median number of new implants used by consultants was one (IQR=1-2, max=8). Consultants used new knee implants in a median of seven KRs (IQR=2-26, max=707), these comprised a median of 2.5% (IQR=0.7-8.4%) of a consultant's total KR volume.

The five most frequently used new implants were used in 14,905 KRs (67.0% of KRs using a new implant, Table S1 and Figure 3). The most frequently used new implant was the Attune Knee System (DePuy Synthes, Raynham, Massachusetts), which was used in 10,036 KRs. Uptake of this implant was rapid compared with other implants (2,000 uses within ~1,200 days). In contrast, nearly half of all new implants (n=26) have been used in 10 or fewer KRs.

Consultant-level and patient-level factors associated with new implants

Our complete case analysis included 502,015 out of a possible 722,178 (69.5%) KRs and 15,422 consultant calendar-years. We were missing data for BMI (n=210,143, 29.1%), knee implant (n=16,591, 2.3%), source of funding (n=1,815, 0.3%), and gender (n=2, 0.0%).

Characteristics of consultants using new knee implant brands

Consultant-level factors associated with a higher odds of using a new rather than established implant brand in a calendar-year were treating a higher proportion of patients aged <55 years old (OR/10 percentage points=1.16, 95%Cl 1.07-1.25, Table 1), performing more KRs per year (OR/10 KRs/year=1.07, 95%Cl 1.05-1.10), receiving private funding for some or all of their KRs (OR=1.41, 95%Cl 1.16-1.72), and using more different implant brands in a calendar-year.

The odds of using a new rather than established implant brand increased substantially as the number of different implant brands increased (OR/additional implant/year=2.57, 95%Cl 2.37-2.79). There was evidence of a 51% increase in the odds of using a new implant brand by consultants who performed

three (i.e. at least one total, unicondylar and patellofemoral KR) compared with one type of KR (1 vs 3 KR types/year: OR=1.51, 95%CI 1.10-2.08). There was weak evidence of a 17% decrease in the odds of using a new implant brand by consultants who had a higher compared with lower proportion of patients with a high ASA grade (OR=0.83, 95%CI 0.68-1.02). Notably, there was a 63% decrease in the odds of using a new implant brand for surgeons who had been a consultant for <2 years, compared with those who had been a consultant for longer (OR=0.37, 95%CI 0.28-0.50).

Characteristics of patients receiving new knee implant brands

A higher proportion of recipients of new versus established implant brands were aged <55 years old (8.7% established vs. 14.3%; Table 2), although the main recipients were aged 55-80 years. There was no difference in BMI between recipients of established and new implant brands. A higher proportion of recipients of new implant brands had ASA grade I (13.0% new vs. 10.9% established). A higher proportion of people with privately funded KRs had new implant brands (19.7% new vs. 10.7% established).

Multivariable adjusted multilevel logistic regression models (Table 2) found that patients <55 years old, compared with those 55-80, had 63% higher odds of receiving a new rather than established implant brand (OR=1.63, 95%Cl 1.54-1.72). Women had 17% higher odds than men of receiving a new implant brand (OR=1.17, 95%Cl 1.13-1.22). People with higher BMI had lower odds of receiving a new implant brand (OR for underweight/normal vs. Class III Obese=0.83, 95%Cl 0.76-0.91). Higher ASA grade was associated with 47% lower odds of receiving new implants (e.g. OR for ASA grades 'IV + V' versus 'I' = 0.53, 95%Cl 0.35-0.82). Patients with private versus NHS funding had 42% higher odds of receiving new implants (OR=1.42, 95%Cl 1.35-1.50).

The proportion of variance in the selection of new implants which is attributable to differences among consultants was high in both the consultant-level (adjusted R^2 =65%, Table 1) and patient-level (adjusted R^2 =83%, Table 2) models.

Sensitivity analyses

Results of our first sensitivity analysis (excluding calendar-years for consultants with <10 KRs) were consistent with findings from our primary analyses (Table S2), suggesting that low-volume consultants did not bias our results. Our second sensitivity analysis ('patient-level' analysis by KR procedure type) highlighted the expected differences in the demographics of patients receiving the different KR procedures, i.e. patients receiving unicondylar and patellofemoral KRs were generally younger, less

likely to be obese and had a lower ASA grade (Tables S3-S5). Notable differences in factors associated with receiving a new implant were: the weaker gender association with receiving a new unicondylar implant (OR=1.17, 95%CI 0.95-1.45, Table S4) which was largely due to wide confidence intervals, whereas women had ~12% higher odds of receiving a new TKR implant (OR=1.12, 95%CI 1.08-1.17, Table S3).

Discussion

We used data from the NJR to describe the uptake of new (first recorded use after 2008) knee implant brands for knee replacement surgery in the UK and how uptake varied between consultant surgeons. We also explored potential consultant-level and patient-level factors associated with the use of and receipt of new implant brands. We found 65 knee replacement implant brands that were first used in the NJR between 2008 and 2017. These new brands were used in only a small proportion (3%) of the KRs performed in this period and new brands were tried by around a quarter of KR consultants. The Attune Knee System comprised nearly half of all KRs which used a new implant brand.

The main strength of this study is the use of data from the NJR, the largest joint replacement registry with good data capture (capturing >95% primary knee replacements in the period studied [17]). We also describe in detail the uptake of new knee implant brands and the factors associated with their use at both the consultant and recipient level. This study has several limitations. Implant brands were defined as new based on their first recorded use in the NJR being later than 2008. However, this does not preclude their earlier introduction into other markets and unrecorded use in England and Wales (missing primary KRs \sim 5%). We have assumed that new implant brands are different from existing brands, but they may instead represent minor modifications or a rebadged/renamed version of an existing implant brand. We considered the posterior-stabilised and cruciate-retaining versions of the Attune Knee System and other brands to differ only minimally (recorded as separate brands in the NJR) and combined them in this study. Since we used observational data our findings may be the result of residual confounding. We also had limited consultant-level data beyond the details of their surgical practice and were therefore unable to include more consultant-level variables. Since the only comparable study to date used data on total hip replacements from the same NJR dataset (unpublished), the findings from this current study should be considered exploratory. Hospital-level factors and regional variation in suppliers may influence implant selection rather than a consultant's personal preference [18-20]. Beyond the operations they have performed, we do not have any

information about the surgeons themselves and we therefore were not able to incorporate any characteristics of surgeons in our analyses. Finally, we have not considered the clinical outcomes of new compared with established knee implant brands.

We also found that consultants who treated a higher proportion of younger patients had higher odds of using a new implant brand. Patients who were younger or had lower ASA grade had higher odds of receiving a new implant brand. These findings are consistent with new implant brands being used in patients with a higher lifetime risk of revision [3]. Private sector units tend to treat patients with fewer comorbidities than publicly funded units (i.e. NHS units) [21]. Our finding that new implants were more likely to be used by consultants who perform privately funded operations further supports our conclusion that new implant brands are used more often in patients who are healthier but this may also be due to other factors. The lower odds of receiving a new implant brand for people with higher ASA grades or who were more obese and that people who funded their operation privately had 42% higher odds of receiving a new implant brand also support this conclusion. After KR surgery there is a higher level of dissatisfaction with the results of surgery among women compared with men [22,23]. Our finding that women had slightly higher odds of receiving a new implant brand might represent an attempt by consultants to improve postoperative satisfaction among women.

We found that consultants who used more different implant brands had higher odds of trying a new brand. Frequently changing implant brand may lead to poorer outcomes for patients through three routes. Firstly, there may be a hospital-level learning-curve effect after switching to a new implant brand in which the earliest patients to receive an implant are at elevated risk of early revision [24]. It is unknown whether the learning-curve is weaker or stronger at the consultant-level. Secondly, patients treated by consultants who use a wide range of different implant brands may have a higher risk of early revision [25]. Thirdly, new implant brands may perform no better [5] or worse than established brands [4], although future developments may offer improvements in outcomes or cost-effectiveness. Using a wide range of implant brands and frequently switching to new brands may therefore conflict with one of the main reasons consultants change implant brand, which is to improve their clinical results [26]. However, the impact of this elevated risk to patients undergoing knee replacement surgery in the UK is likely to be small since only a quarter of consultants in our study tried a new implant brand and they used them in only 3% of their KRs.

We found that surgeons who had become a consultant in the previous two years were less likely to use a new implant brand compared with those who had been a consultant for longer. We anticipated that

new consultants might be more likely to use new implant brands while transitioning to their new role in the surgical team. Our finding of the converse suggests that the use of new implant brands is driven by more established consultants. We are not aware of any prior research on this topic. This finding should therefore be treated as exploratory and will need to be replicated in other studies.

Findings from our study could be developed further in several ways. There have been few previous studies which have described the uptake of new knee replacement implant brands. We found comparable findings in a study of new implant components for total hip replacements, particularly that surgeons who used a wide variety of implant components were much more likely to try a new component [27]. Similar studies in knees from other countries would allow us to compare our findings, and to consider how different health care systems influence the use of new implants. We described the uptake of new knee implant brands, but the relative performance of these brands with more established brands remains unexplored. Similarly, there may be a learning-curve associated with switching to a new implant, but findings have been limited to hospital-level rather than consultant-level learning-curves. In order to understand whether there is an inherent increase in revision risk when switching to a new implant it may therefore be valuable to explore the consultant-level learning-curve.

Conclusions

A large number of new knee replacement implant brands have been introduced into use in the NJR between 2008 and 2017, but they have been used in only a small proportion of primary knee replacement operations in this period. Patients who are younger and healthier are more likely to receive new implants. Consultant surgeons who already use a large number of different knee implant brands are more likely to use new brands.

References

- [1] Carr AJ, Robertsson O, Graves S, Price AJ, Arden NK, Judge A, et al. Knee replacement. The Lancet 2012;379:1331–40. doi:10.1016/S0140-6736(11)60752-6.
- [2] National Joint Registry for England, Wales and Northern Ireland. 14th Annual Report 2017. 2017.
- Bayliss LE, Culliford D, Monk AP, Glyn-Jones S, Prieto-Alhambra D, Judge A, 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.
- [4] Anand R, Graves SE, de Steiger RN, Davidson DC, Ryan P, Miller LN, 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.
- [5] Nieuwenhuijse MJ, Nelissen RGHH, Schoones JW, Sedrakyan A. Appraisal of evidence base for introduction of new implants in hip and knee replacement: a systematic review of five widely used device technologies. BMJ 2014;349:g5133–g5133. doi:10.1136/bmj.g5133.
- [6] Chawla H, van der List JP, Christ AB, Sobrero MR, Zuiderbaan HA, Pearle AD. Annual revision rates of partial versus total knee arthroplasty: A comparative meta-analysis. The Knee 2017;24:179–90. doi:10.1016/j.knee.2016.11.006.
- [7] Gagliardi AR, Ducey A, Lehoux P, Ross S, Trbovich P, Easty A, et al. Meta-Review of the Quantity and Quality of Evidence for Knee Arthroplasty Devices. PLOS ONE 2016;11:e0163032. doi:10.1371/journal.pone.0163032.
- [8] McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC, et al. No surgical innovation without evaluation: the IDEAL recommendations. The Lancet 2009;374:1105–12. doi:10.1016/S0140-6736(09)61116-8.
- [9] Birkmeyer JD, Reames BN, McCulloch P, Carr AJ, Campbell WB, Wennberg JE. Understanding of regional variation in the use of surgery. The Lancet 2013;382:1121–9. doi:10.1016/S0140-6736(13)61215-5.
- [10] National Joint Registry for England W and NI. Prostheses used in hip, knee, ankle, elbow and shoulder replacement procedures 2016. 2017.
- [11] National Joint Registry for England. 15th Annual Report 2018. 2018.
- [12] Goldstein H, Browne W, Rasbash J. Partitioning variation in multilevel models. Understanding Statistics n.d.;1:14.
- [13] R Core Team. R: A Language and Environment for Statistical Computing. Vienna, Austria: R Foundation for Statistical Computing; 2018.
- [14] Bates D, Mächler M, Bolker B, Walker S. Fitting Linear Mixed-Effects Models Using Ime4. Journal of Statistical Software 2015;67:1–48. doi:10.18637/jss.v067.i01.
- [15] Lüdecke D, Makowski D, Waggoner P. performance: Assessment of Regression Models. 2019.
- [16] Harrison E, Drake T, Ots R. finalfit: Quickly Create Elegant regression Results Tables and Plots when Modelling. R package version 0.9.5. 2019.
- [17] National Joint Registry for England, Wales and Northern Ireland. Annual progress: Data completeness and quality n.d. http://www.njrreports.org.uk/Data-Completeness-and-quality (accessed June 14, 2019).
- [18] Davies C. An analysis of choice: a case study on hip prostheses. University of East Anglia, 2011.
- [19] Burns LR, Housman M, Booth R, Koenig A. Physician preference items: what factors matter to surgeons? Does the vendor matter? Medical Devices: Evidence and Research 2018;Volume 11:39– 49. doi:10.2147/MDER.S151647.

- [20] Healy WL, Iorio R. Implant Selection and Cost for Total Joint Arthroplasty: Conflict between Surgeons and Hospitals. Clinical Orthopaedics and Related Research[®] 2007;457:57. doi:10.1097/BLO.0b013e31803372e0.
- [21] Mason A, Street A, Verzulli R. Private sector treatment centres are treating less complex patients than the NHS. Journal of the Royal Society of Medicine 2010;103:322–31. doi:10.1258/jrsm.2010.100044.
- [22] Dunbar MJ, Richardson G, Robertsson O. I can't get no satisfaction after my total knee replacement: rhymes and reasons. The Bone & Joint Journal 2013;95-B:148–52. doi:10.1302/0301-620X.95B11.32767.
- [23] Nam D, Nunley RM, Barrack RL. Patient dissatisfaction following total knee replacement: a growing concern? The Bone & Joint Journal 2014;96-B:96–100. doi:10.1302/0301-620X.96B11.34152.
- [24] Peltola M, Malmivaara A, Paavola M. Introducing a knee endoprosthesis model increases risk of early revision surgery. Clinical Orthopaedics and Related Research 2012;470:1711–7. doi:10.1007/s11999-011-2171-9.
- [25] Australian Orthopaedic Association. Hip, Knee & Shoulder Arthroplasty: Annual Report 2017. Australian Orthopaedic Association; 2017.
- [26] Sharkey PF, Sethuraman V, Hozack WJ, Rothman RH, Stiehl JB. 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.
- [27] Penfold CM, Blom AW, Sayers A, Wilkinson JM, Hunt LP, Judge A, et al. 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. BMJ Open n.d.; in press.

- 1 Table 1: Results from univariable and multivariable adjusted multilevel logistic regression models showing the association between consultant-
- 2 level factors and use of new knee implant brands

		Established	New		
Dependent: New implant used in calendar year		(n=13,553) ¹	(n=1,869)1	OR ² (univariable)	OR ² (multilevel)
Any KRs performed on people <55 years old?	No under 55s (ref.)	5,516	252	-	-
		(40.7%)	(13.5%)		
	Some under 55s	8,037	1,617	4.40	1.05
		(59.3%)	(86.5%)	(3.85-5.06, p<0.001)	(0.85-1.32, p=0.636)
Percentage of KRs performed on people <55	Median (IQR)	9.5%	11.1%	1.08	1.16
years old (median centered) ^{3,4}		(8.9)	(8.5)	(1.03-1.12, p<0.001)	(1.07-1.25, p<0.001)
Number of KRs performed in calendar year ⁵	Median (IQR)	17	46	1.16	1.07
		(36)	(62)	(1.15-1.18, p<0.001)	(1.05-1.10, p<0.001)
Any KRs funded privately?	100% NHS funded	7,784	579	-	-
	(ref.)	(57.4%)	(31.0%)		
	Some or all funded	5,769	1,290	3.01	1.41
	privately	(42.6%)	(69.0%)	(2.71-3.34, p<0.001)	(1.16-1.72, p=0.001)
Percentage of KRs privately funded (median	Median (IQR)	15.2%	13.9%	1.01	1.03
centred) ^{6,7}		(32.8)	(27.8)	(0.99-1.04, p=0.240)	(0.98-1.08, p=0.192)
Proportion of KRs performed on patients with	<25% (ref.)	10,148	1,564	-	-
ASA grade III-IV		(74.9%)	(83.7%)		
	≥25%	3,405	305	0.58	0.83
		(25.1%)	(16.3%)	(0.51-0.66, p<0.001)	(0.68-1.02, p=0.079)

Number of different KR procedures performed	1 (ref.)	9,489	613	-	-
in calendar years		(70.0%)	(32.8%)		
	2	3,222	665	3.19	0.87
		(23.8%)	(35.6%)	(2.84-3.59, p<0.001)	(0.70-1.08, p=0.214)
	3	842	591	10.87	1.51
		(6.2%)	(31.6%)	(9.51-12.42, p<0.001)	(1.10-2.08, p=0.010)
Number of different implants used in calendar	Median (IQR)	2	4	2.09	2.57
year		(2)	(2)	(2.02-2.16, p<0.001)	(2.37-2.79, p<0.001)
Surgeon is a 'new' consultant (≤2 years)	No (ref.)	11,389	1,708	-	-
		(84.0%)	(91.4%)		
	Yes	2164	161	0.50	0.37
		(16.0%)	(8.6%)	(0.42-0.58, p<0.001)	(0.28-0.50, p<0.001)

3 Random effect variance (adjusted) = 0.652

- 4 1 proportions displayed are based on surgeon-calendar years,
- 5 2 odds ratios, 95% confidence intervals and p-values,
- 6 3 percentages exclude consultant-years with no KRs performed on patients <55 years old,
- 7 4 odds ratios and 95% confidence intervals are per additional 10% cases <55 years old,
- 8 5 odds ratios and 95% confidence intervals are per 10 additional cases,
- 9 6 percentages exclude consultant-years with no privately funded KRs,
- 10 7 odds ratios and 95% confidence intervals are per additional 10% cases privately funded

11 Table 2: Results from univariable and multivariable adjusted multilevel logistic regression models of age, gender, categorised BMI, ASA grade and

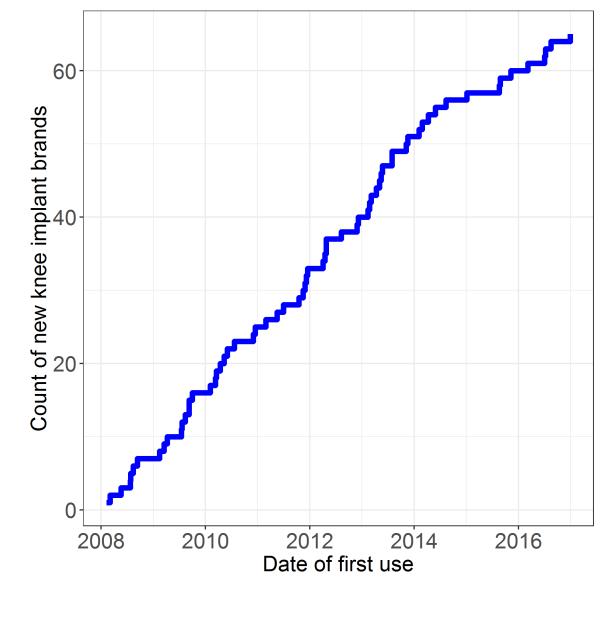
source of funding on receipt of a new knee implant, with category proportions

		Established	New		
Dependent: New implant received		(n=485,159)	(n=16,856)	OR ¹ (univariable)	OR ¹ (multilevel)
Age	55-80 years old (ref.)	390,223	12,943	-	-
		(80.4%)	(76.8%)		
	<55	42,400	2,414	1.72	1.63
		(8.7%)	(14.3%)	(1.64-1.79, p<0.001)	(1.54-1.72, p<0.001)
	≥80	52,536	1,499	0.86	0.81
		(10.8%)	(8.9%)	(0.81-0.91, p<0.001)	(0.76-0.87, p<0.001)
Gender	Male	213,239	6,896	-	-
		(44.0%)	(40.9%)		
	Female	271,920	9,960	1.13	1.17
		(56.0%)	(59.1%)	(1.10-1.17, p<0.001)	(1.13-1.22, p<0.001)
BMI	Underweight/normal (ref.)	53,243	2,001	-	-
		(11.0%)	(11.9%)		
	Overweight	169,596	5,991	0.94	1.03
		(35.0%)	(35.5%)	(0.89-0.99, p=0.018)	(0.97-1.09, p=0.355)
	Obese Class I	155,623	5,383	0.92	1.01
		(32.1%)	(31.9%)	(0.87-0.97, p=0.002)	(0.95-1.07, p=0.737)
	Obese Class II	75,597	2,509	0.88	0.97
		(15.6%)	(14.9%)	(0.83-0.94, p<0.001)	(0.91-1.04, p=0.438)
	Obese Class III	31,100	972	0.83	0.83

		(6.4%)	(5.8%)	(0.77-0.90, p<0.001)	(0.76-0.91, p<0.001)
ASA grade	l (ref.)	52,862	2,193	-	-
		(10.9%)	(13.0%)		
	П	356,139	12,465	0.84	1.07
		(73.4%)	(73.9%)	(0.81-0.88, p<0.001)	(1.01-1.13, p=0.022)
	Ш	74,841	2,176	0.70	0.95
		(15.4%)	(12.9%)	(0.66-0.74, p<0.001)	(0.88-1.02, p=0.141)
	IV	1,317	22	0.40	0.53
		(0.3%)	(0.1%)	(0.26-0.60, p<0.001)	(0.35-0.82, p=0.005)
Source of funding	NHS (ref.)	433,143	13,530	-	-
		(89.3%)	(80.3%)		
	Private	52,016	3,326	2.05	1.42
		(10.7%)	(19.7%)	(1.97-2.13, p<0.001)	(1.35-1.50, p<0.001)

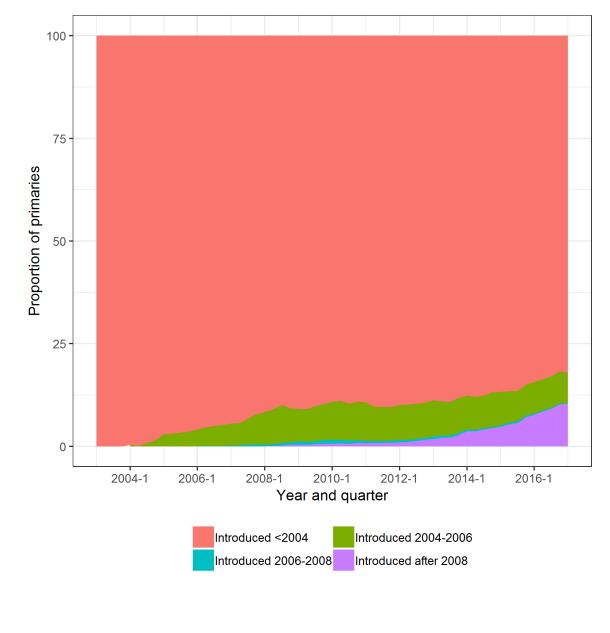
13 Random effect variance (adjusted) = 0.834

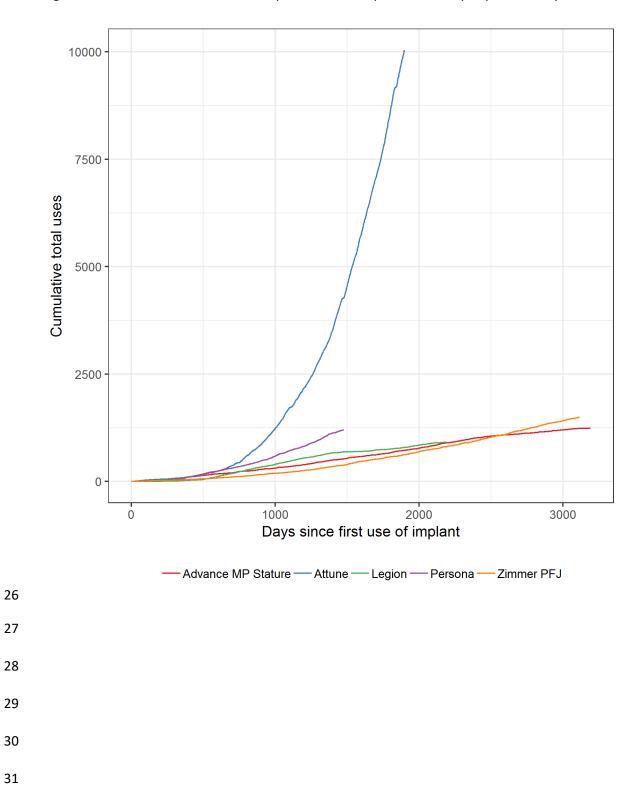
14 1 – odds ratios (95% confidence intervals and p-values)





- 20 Figure 2: Proportion of knee replacements between January 2008 and February 2017 using new
- 21 implants introduced in different time periods (before 2004, 2004-2006, 2006-2008, 2008 onwards)





25 Figure 1: Cumulative total use of the top 5 new knee implant brands by days since they were introduced

32 Supplementary material

33	Table S1: Uptake of new knee implants first used between January 1st 2008 and 26th February 2017

Knee implant brand	Implant type	Patients	Surgeons	Date first used
Attune	TKR	10,036	295	Dec-2011
Zimmer PFJ	Patellofemoral	1,501	183	Aug-2008
Advance MP Stature	TKR	1,242	59	May-2008
Persona	TKR	1,206	36	Feb-2013
Legion	TKR	920	46	Feb-2011
Journey II BCS Oxinium	TKR	884	56	Feb-2013
Triathlon Uni	Unicondylar	785	57	Apr-2009
Unity Knee	TKR	736	20	Apr-2012
Sphere	TKR	655	25	Nov-2011
Scorpio NRG	TKR	581	7	Apr-2013
EvolutionMP	TKR	554	11	May-2013
Saiph	TKR	554	17	Sep-2009
Journey Uni Oxinium	Unicondylar	519	65	May-2010
FHK	TKR	240	6	Nov-2013
iUni G2	Unicondylar	165	20	Apr-2012
Smiles Bicondylar	TKR	156	54	Sep-2008
CR Flex	TKR	153	12	Feb-2010
GMK	TKR	146	7	Mar-2008
Physica Knee System	TKR	136	7	Nov-2013
Genus	Unicondylar	131	5	Mar-2013
First	TKR	108	6	Feb-2014
Univation	Unicondylar	87	10	May-2014
Optetrak Unicondylar	Unicondylar	60	7	Apr-2010

Knee implant brand	Implant type	Patients	Surgeons	Date first used
Euros Bicondylar	TKR	58	2	May-2011
iTotal G2	TKR	55	12	Jul-2013
3D	TKR	49	3	Jul-2009
ACS Uni	Unicondylar	48	5	Dec-2012
Trecking Knee	TKR	44	6	May-2013
Ukneetec	Unicondylar	34	1	Dec-2010
GMK Unicondylar	Unicondylar	30	7	Mar-2009
Asdm TCK	TKR	29	1	Jul-2009
HLS Evolution	Unicondylar	26	1	Sep-2009
iTotal G2 XE	TKR	26	6	Feb-2014
Gemini	TKR	23	1	Jul-2008
EnduRo Hinge	TKR	20	12	Oct-2011
iBalance Unicondylar	Unicondylar	19	4	Aug-2012
Journey II CR Oxinium	TKR	19	6	Jul-2016
Vanguard XP	TKR	18	4	Aug-2014
Restoris	Unicondylar	16	2	Jul-2016
	TKR	1	1	Jan-2017
	Patellofemoral	1	1	Jan-2017
Gender PF	Patellofemoral	9	3	Apr-2012
Hemicap Patellofemoral	Patellofemoral	8	6	Jul-2013
Zimmer Segmental System	TKR	8	7	Feb-2009
Aequos G1	TKR	4	1	Dec-2011
Guardian Hinged/Linked Knee	TKR	4	3	Mar-2010
Euros Unicondylar	Unicondylar	3	1	Apr-2012
U2 Knee System	TKR	3	2	Nov-2015
Evolis	TKR	2	2	Dec-2010

Knee implant brand	Implant type	Patients	Surgeons	Date first used
Evolution Unicondylar	Unicondylar	2	1	Aug-2015
iBalance PFJ	Patellofemoral	2	1	Dec-2016
OSS	TKR	2	2	Jan-2015
Stanmore Hinge	TKR	2	1	Jul-2011
913 System	TKR	1	1	Feb-2008
Axel II	TKR	1	1	Jun-2010
balanSys	TKR	1	1	Aug-2016
balanSys Revision	TKR	1	1	Mar-2016
Cinetique	TKR	1	1	Jul-2008
Columbus Revision Knee	TKR	1	1	Nov-2011
GMK Linked Knee	TKR	1	1	Aug-2015
LCS Complete Revision	TKR	1	1	Oct-2009
LCS Unicondylar	Unicondylar	1	1	Aug-2009
Mathys Unicondylar Knee	Unicondylar	1	1	May-2013
Mega System C	TKR	1	1	Mar-2010
Mets Hinged/Linked Knee	TKR	1	1	Nov-2012
PB Uni	Unicondylar	1	1	Apr-2014
Uni-Nat	TKR	1	1	Jul-2010

- 41 Table S2 Sensitivity analysis 1: Results from multivariable adjusted multilevel logistic regression models
- 42 showing the association between consultant-level factors and use of new knee implant brands,
- 43 excluding surgeon calendar-years <10 KRs

Dependent: New implant used in				
calendar year		Established ¹	New ¹	OR ² (multilevel)
Any KRs performed on people <55 years	No under 55s	1,721	100	-
old?	(ref.)	(19.7%)	(6.2%)	
	Some under 55s	6,993	1,511	1.41
		(80.3%)	(93.8%)	(1.04-1.90, p=0.025)
Percentage of KRs performed on people	Median (IQR)	8.3%	10.5%	1.26
<55 years old (median centered) ^{3,4}		(7.4)	(8.0)	(1.09-1.47, p=0.002)
Number of KRs performed in calendar	Median (IQR)	33	54	1.09
year ⁵		(37)	(56.5)	(1.06-1.12, p<0.001)
Any KRs funded privately?	100% NHS funded	4,179	428	-
	(ref.)	(48.0%)	(26.6%)	
	Some or all	4,535	1,183	1.85
	funded privately	(52.0%)	(73.4%)	(1.48-2.30, p<0.001)
Percentage of KRs privately funded	Median (IQR)	10.5%	12.7%	1.11
(median centred) ^{6,7}		(20.6)	(22.7)	(1.04-1.18, p=0.002)
Proportion of KRs performed on patients	<25% (ref.)	6,831	1,367	-
with ASA grade III-IV		(78.4%)	(84.9%)	
	≥25%	1,883	244	0.81
		(21.6%)	(15.1%)	(0.64-1.02, p=0.077)
Number of different KR procedures	1 (ref.)	5,093	439	-
performed in calendar years		(58.4%)	(27.3%)	
	2	2,802	598	0.74
		(32.2%)	(37.1%)	(0.58-0.95, p=0.017)
	3	819	574	1.25
		(9.4%)	(35.6%)	(0.89-1.74, p=0.193)
Number of different implants used in	Median (IQR)	2	4	2.53
calendar year		(2)	(2)	(2.33-2.76, p<0.001)
Surgeon is a 'new' consultant (≤2 years)	No (ref.)	7,595	1,490	-
		(87.2%)	(92.5%)	

Yes	1,119	121	0.47
	(12.8%)	(7.5%)	(0.33-0.66, p<0.001)

- 44 1 proportions displayed are based on surgeon-calendar years,
- 45 2 odds ratios, 95% confidence intervals and p-values,
- 46 3 percentages exclude consultant-years with no KRs performed on patients <55 years old,
- 47 4 odds ratios and 95% confidence intervals are per additional 10% cases <55 years old,
- 48 5 odds ratios and 95% confidence intervals are per 10 additional cases,
- 49 6 percentages exclude consultant-years with no privately funded KRs,
- 50 7 odds ratios and 95% confidence intervals are per additional 10% cases privately funded

52 Table S3 Sensitivity analysis 2a: Results from univariable and multivariable adjusted multilevel logistic regression models of age, gender,

53	categorised BMI, ASA grade and source	e of funding on receipt of a new	w knee implant, with category	proportions: TKR sub-analysis
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		Established	New		
Dependent: New implant received		(n=441,816)	(n=14,417)	OR (univariable)	OR (multilevel)
Age	55-80 years old (ref.)	358,778	11,469	-	-
		(81.2%)	(79.6%)		
	<55	32,433	1,524	1.47	1.27
		(7.3%)	(10.6%)	(1.39-1.55, p<0.001)	(1.19-1.36, p<0.001)
	≥80	50,605	1,424	0.88	0.85
		(11.5%)	(9.9%)	(0.83-0.93, p<0.001)	(0.79-0.90, p<0.001)
Gender	Male	191,351	5,938	-	-
		(43.3%)	(41.2%)		
	Female	250,465	8,479	1.09	1.12
		(56.7%)	(58.8%)	(1.05-1.13, p<0.001)	(1.08-1.17, p<0.001)
ВМІ	Underweight/normal (ref.)	47,790	1,638	-	-
		(10.8%)	(11.4%)		
	Overweight	152,894	5,032	0.96	1.08
		(34.6%)	(34.9%)	(0.91-1.02, p=0.161)	(1.01, 1.16, p=0.019)
	Obese Class I	141,972	4,623	0.95	1.11
		(32.1%)	(32.1%)	(0.90-1.01, p=0.080)	(1.04-1.19, p=0.003)
	Obese Class II	69,952	2,225	0.93	1.12
		(15.8%)	(15.4%)	(0.87-0.99, p=0.024)	(1.03-1.20, p=0.006)
	Obese Class III	29,208	899	0.90	0.99

		(6.6%)	(6.2%)	(0.83-0.98, p=0.011)	(0.90-1.09, p=0.855)
ASA grade	l (ref.)	43,808	1,642	-	-
		(9.9%)	(11.4%)		
	Ш	325,549	10,802	0.89	1.10
		(73.7%)	(74.9%)	(0.84-0.93, p<0.001)	(1.04-1.18, p=0.002)
	Ш	71,187	1,952	0.73	0.98
		(16.1%)	(13.5%)	(0.68-0.78, p<0.001)	(0.91-1.07, p=0.667)
	IV	1,272	21	0.44	0.57
		(0.3%)	(0.1%)	(0.28-0.66, p<0.001)	(0.36-0.91, p=0.018)
Source of funding	NHS (ref.)	399,444	11,654	-	-
		(90.4%)	(80.8%)		
	Private	42,372	2,763	2.24	1.50
		(9.6%)	(19.2%)	(2.14-2.33, p<0.001)	(1.41-1.60, p<0.001)

56 Table S4 Sensitivity analysis 2b: Results from univariable and multivariable adjusted multilevel logistic regression models of age, gender,

57 categorised BMI, ASA grade and source of funding on receipt of a new knee implant, with category proportions: unicondylar sub-analysis

		Established	New		
Dependent: New implant received		(n=39,501)	(n=1,354)	OR (univariable)	OR (multilevel)
Age	55-80 years old (ref.)	29,391	943	-	
		(74.4%)	(69.6%)		
	<55	8,330	366	1.37	1.43
		(21.1%)	(27.0%)	(1.21-1.55, p<0.001)	(1.11-1.86, p=0.006)
	≥80	1,780	45	0.79	0.87
		(4.5%)	(3.3%)	(0.57-1.05, p=0.123)	(0.53-1.45, p=0.604)
Gender	Male	21,007	720	-	-
		(53.2%)	(53.2%)		
	Female	18,494	634	1.00	1.17
		(46.8%)	(46.8%)	(0.90-1.11, p=0.997)	(0.95-1.45, p=0.604)
вмі	Underweight/normal (ref.)	4,749	189	-	-
		(12.0%)	(14.0%)		
	Overweight	15,310	542	0.89	0.81
		(38.8%)	(40.0%)	(0.75-1.06, p=0.174)	(0.59-1.11, p=0.183)
	Obese Class I	12,553	432	0.86	0.77
		(31.8%)	(31.9%)	(0.73-1.03, p=0.102)	(0.55-1.08, p=0.131)
	Obese Class II	5,172	153	0.74	0.81
		(13.1%)	(11.3%)	(0.60-0.92, p=0.007)	(0.54-1.22, p=0.311)
	Obese Class III	1,717	38	0.56	0.47

		(4.3%)	(2.8%)	(0.39-0.78, p=0.001)	(0.26-0.86, p=0.015)
ASA grade	l (ref.)	8,067	296	-	-
		(20.4%)	(21.9%)		
	II	28,058	920	0.89	0.87
		(71.0%)	(67.9%)	(0.78-1.02, p=0.098)	(0.67-1.14, p=0.323)
	Ш	3,337	138	1.13	1.00
		(8.4%)	(10.2%)	(0.91-1.38, p=0.255)	(0.65-1.54, p=0.995)
	IV	39	0	0.00	0.00
		(0.1%)	(0.0%)	(0.00-0.01, p=0.937)	(0.00-0.01, p=0.803)
Source of funding	NHS (ref.)	30,711	988	-	-
		(77.7%)	(73.0%)		
	Private	8,790	366	1.29	2.36
		(22.3%)	(27.0%)	(1.14-1.46, p<0.001)	(1.80-3.10, p<0.001)

Table S5 Sensitivity analysis 2c: Results from univariable and multivariable adjusted multilevel logistic regression models of age, gender, categorised BMI, ASA grade and source of funding on receipt of a new knee implant, with category proportions: patellofemoral sub-analysis

Dependent: New		Established	New	OR	OR
implant received		(n=3 <i>,</i> 842)	(n=1,085)	(univariable)	(multilevel)
Age	55-80 years old (ref.)	2,054	531	-	-
		(53.5%)	(48.9%)		
	<55	1,637	524	1.24	1.54
		(42.6%)	(48.3%)	(1.08-1.42,	(1.09-2.17,
				p=0.002)	p=0.014)
	≥80	151	30	0.77	1.06
		(3.9%)	(2.8%)	(0.50-1.13,	(0.43-2.62,
				p=0.201)	p=0.900)
Gender	Male	881	238	-	-
		(22.9%)	(21.9%)		
	Female	2,961	847	1.06	1.16
		(77.1%)	(78.1%)	(0.90-1.25,	(0.79-1.70,
				p=0.490)	p=0.451)
ВМІ	Underweight/normal	704	174	-	-
	(ref.)	(18.3%)	(16.0%)		
	Overweight	1,392	417	1.21	1.11
		(36.2%)	(38.4%)	(1.00-1.48,	(0.70-1.77,
				p=0.058)	p=0.654)
	Obese Class I	1,098	328	1.21	1.31
		(28.6%)	(30.2%)	(0.98-1.49,	(0.81-2.14,
				p=0.072)	p=0.272)
	Obese Class II	473	131	1.12	1.57
		(12.3%)	(12.1%)	(0.87-1.44,	(0.85-2.91,
				p=0.381)	p=0.147)
	Obese Class III	175	35	0.81	0.50
		(4.6%)	(3.2%)	(0.54-1.19,	(0.22-1.13,
				p=0.298)	p=0.096)
ASA grade	l (ref.)	987	255	-	-
		(25.7%)	(23.5%)		

	Ш	2,532	743	1.14	1.38
		(65.9%)	(68.5%)	(0.97-1.33,	(0.93-2.05,
				p=0.119)	p=0.109)
	Ш	317	86	1.05	1.16
		(8.3%)	(7.9%)	(0.79-1.38,	(0.60-2.27,
				p=0.728)	p=0.659)
	IV	6	1	0.65	2.54
		(0.2%)	(0.1%)	(0.03-3.80,	(0.18-35.43,
				p=0.685)	p=0.489)
Source of funding	NHS (ref.)	2,988	888	-	-
		(77.8%)	(81.8%)		
	Private	854	197	0.78	1.15
		(22.2%)	(18.2%)	(0.65-0.92,	(0.73-1.82,
				p=0.004)	p=0.539)