



**What determines patient satisfaction with surgery? A
PROSPECTIVE COHORT STUDY OF 4709 PATIENTS
FOLLOWING TOTAL JOINT REPLACEMENT**

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Complete List of Authors:	Hamilton, David; University of Edinburgh, Orthopaedics Lane, Judith; Queen Margaret University, Physiotherapy Gaston, Paul; NHS Lothian, Orthopaedics and Trauma Patton, James; NHS Lothian, Orthopaedics and Trauma MacDonald, Deborah; University of Edinburgh, Department of Orthopaedics Simpson, Hamish; University of Edinburgh, Department of Orthopaedics Howie, Colin; NHS Lothian, Orthopaedics and Trauma
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What determines patient satisfaction with surgery?

A PROSPECTIVE COHORT STUDY OF 4709 PATIENTS FOLLOWING TOTAL JOINT REPLACEMENT

Hamilton DF, Lane JV, Gaston P, Patton JT, MacDonald D, Simpson AHRW, Howie CR

Department of Orthopaedics, University of Edinburgh, Edinburgh, EH164SB, UK
DF Hamilton, Research Fellow; D MacDonald, Research Co-ordinator; AHRW Simpson, Professor of
Orthopaedics and Trauma

Department of Physiotherapy, Queen Margaret University, Edinburgh, EH21 6UU, UK
JV Lane, Lecturer

Royal Infirmary of Edinburgh, Little France Crescent, Edinburgh, EH16 4SA, UK
CR Howie, Consultant Orthopaedic Surgeon; P Gaston, Consultant Orthopaedic Surgeon; JT Patton, Consultant
Orthopaedic Surgeon

Correspondence to: d.f.hamilton@ed.ac.uk

Article Summary;

Article focus

Patient satisfaction rates have been quoted following surgical intervention; and these used to assess the success of interventions.

Clinical care and patient outcomes have improved over recent years, however satisfaction with surgical services has remained constant over this timeframe.

Many factors have been suggested to influence patient satisfaction, however little is known as to what actually determines the satisfaction response.

Key messages

Our study identifies 5 factors that explain the patient's overall satisfaction following lower limb joint arthroplasty; (1) meeting of pre-operative expectations, (2) the achievement of satisfactory pain relief, (3) patients subjective hospital experience, and to a lesser extent (4) one year Oxford Score and (5) pre-operative Oxford Score.

Factors thought to influence clinical outcome scores (PROMS) such as age, gender and co-morbidities do not impact upon satisfaction.

Clinical teams currently aim to manage pre-operative expectations and post-operative pain relief. Management of the patient's hospital experience may then be a key factor in optimizing overall patient satisfaction, which has implications for service delivery.

Strengths and Limitations

This study benefits from a large prospective patient cohort at a single NHS orthopaedic centre with multiple surgeons.

As most patients report high satisfaction with joint arthroplasty there is some doubt as to how discriminating this measure is, and caution has been advised in the use of a standardised instrument for the measurement of satisfaction.

ABSTRACT

Objectives: To investigate the factors which influence patient report of satisfaction with surgical services and to explore the relationship between the overall level of patient satisfaction, satisfaction with specific facets of outcome and measured clinical outcomes (Patient Reported Outcome Measures).

Design: Prospective cohort study

Setting: Single NHS teaching hospital

Participants: 4709 individuals undergoing primary lower limb joint replacement over a four year period (Jan 2006 – Dec 2010)

Main Outcome Measures: Overall patient satisfaction scale, clinical outcomes as measured by PROMS (Oxford Hip or Knee Score, SF12), satisfaction with 5 specific aspects of surgical outcome, attitudes towards further surgery, patient demographics, length of hospital stay.

Results: Overall patient satisfaction was predicted by; (1) meeting pre-operative expectations [Odds Ratio 2.88 (95% CI, 2.48-3.34)], (2) satisfaction with pain relief [2.68 (2.26-3.17)], (3) satisfaction with the hospital experience [1.4 (1.17-1.56)], (4) one year [1.07 (1.05-1.10)] and (5) pre-operative [0.96 (0.93-0.98)] Oxford Scores. These 5 factors contributed to a model that was able to correctly predict 97% of the variation in overall patient satisfaction response. The factors having the greatest effect were the degree to which the patient's expectations were met and the satisfaction with pain relief, whereas the Oxford Scores carried little weight in the regression algorithm. Various factors previously reported to influence clinical outcomes; patient age, gender, co-morbidities, length of post-operative hospital stay, mental health, ability to perform heavy activities and whether the hip or knee joint was replaced did not help explain variation in overall patient satisfaction.

Conclusions: Three factors broadly determine the patient's overall satisfaction following lower limb joint arthroplasty; meeting pre-operative expectations, achieving satisfactory pain relief, and a satisfactory hospital experience. Pain relief and pre-operative expectations are managed by clinical teams; however a fractured access to surgical services also impacts on the patient's hospital experience which reduces overall satisfaction. In the absence of complications, how we deliver healthcare may be of key importance as well as the specifics of what we deliver. With the political importance of patient satisfaction gaining prominence, this has clear implications for units providing surgical services.

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3 Satisfaction with NHS surgical services has recently declined¹ despite more rapid access to, and
4 fewer measurable complications from surgical care. There are few procedures or treatments where
5 the monitoring of outcomes and satisfaction has been consistent enough to investigate this
6 apparent paradox. Joint replacement is an example of a high volume service that has been closely
7 monitored over recent years.
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11 Traditionally, clinical success has been measured by lack of complications or by specific clinical
12 parameters, e.g. ranges of motion or blood pressure control. More recently, clinical outcomes have
13 been assessed by patient reported outcome measures (PROMS). Despite the many studies on the
14 clinical outcome of joint arthroplasty, very few assess overall patient satisfaction with outcome². In
15 the few that have, the majority of patients are reported to be satisfied with the outcome of their hip
16 or knee replacement; though consistent reports of 10-20% dissatisfaction with joint arthroplasty
17 persist²⁻⁶. Patient reported satisfaction is perhaps the more important criterion of success. This is
18 well recognised in service industries, though remains a nebulous concept in clinical care. A number
19 of authors have suggested various factors that may influence satisfaction with arthroplasty, such as
20 post-operative pain or joint stiffness, though our current understanding as to why some patients are
21 satisfied and others are not remains limited⁶⁻⁸. Indeed some patients reporting a bad clinical
22 outcome, in terms of pain and function, may report good levels of satisfaction with their surgical
23 outcome and vice versa². Clearly satisfaction is a broad concept that encompasses more than clinical
24 outcome.
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35 Our aim was to explore the relationship between patient's level of overall satisfaction, satisfaction
36 with specific facets of surgical outcome and measured clinical outcomes (Patient Reported Outcome
37 Measures).
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43 **METHODS**

44 During a four year period (January 2006 to December 2010) all patients undergoing lower limb joint
45 replacement at a single hospital were entered into a prospectively collected arthroplasty database,
46 for which regional ethical approval had been obtained (11/AL/0079). The study questionnaire was
47 completed by 4709 (95%) patients. This comprised 2462 patients receiving total hip replacement and
48 2247 receiving total knee replacement. All data were included in the analysis.
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54 All patients completed pre-operative PROM questionnaires, Oxford Hip or Knee Score^{9, 10} and
55 Medical Outcomes Study Short Form 12 (SF-12) health assessment¹¹, and were sent postal follow-up
56 questionnaires at 6 and 12 months post-operation to assess outcome and satisfaction. Procedures
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3 were carried out by multiple consultant orthopaedic surgeons and their supervised trainees. All data
4 was collected independently from the clinical team by the arthroplasty outcomes research unit of
5 the University of Edinburgh and NHS Lothian.
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9 The Oxford Scores consist of 12 questions relating to the patients perceived pain and functional
10 ability, answered on a Likert scale with values from 0 to 4. The score ranges from 0-48, with overall
11 score calculated from the responses to the 12 questions. A score of 0 is the worst possible outcome
12 suggesting severe symptoms and dysfunction, while 48 is the best possible outcome. The SF-12
13 results in two scores, the physical and mental component summary (PCS and MCS) scores. This score
14 is calculated using norm-based methodology and population mean scores. Both PCS and MCS have a
15 population mean score of 50 with standard deviation of 10.
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21 Pre-operative information was collected as to the patient's age, gender and presence of co-
22 morbidities. Post-operative length of stay was recorded upon discharge. At 12 months patients were
23 also asked to rate their overall satisfaction with their operated hip or knee on a 4 point scale (very
24 satisfied, satisfied, unsure or dissatisfied). Data on satisfaction with 5 specific facets of surgical
25 outcome were obtained with the following questions, answered on a 6 point scale (excellently, very
26 well, well, fairly, poorly, don't know); (1) "how well did the surgery relieve the pain in your affected
27 joint?" (2) "How well did the surgery increase your ability to perform regular activities?" (3) "How
28 well did the surgery allow you to perform heavy work or sport activities?" (4) "How well did the
29 surgery meet your expectations?" We then asked our patients to indicate their satisfaction with the
30 care they received at the hospital with the question (5) "rate your overall hospital experience" using
31 the response scale; excellent, very good, good, fair, poor or unknown. We also asked a further 2
32 questions that enquired as to the patient's attitude towards further surgery; (1) "would you have
33 this operation again if it were required on another joint?" and (2) "would you recommend this
34 operation to someone else?" (Possible responses: Definitely yes, possibly yes, probably not, certainly
35 not or not sure). These were included to mimic the modelling done in marketing research, where
36 return visits are considered a successful outcome.
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47 **Statistical analysis**

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49 Data were assessed with SPSS version 17 (IBM). Data were not normally distributed and therefore
50 variables have been presented as median and inter-quartile ranges. The satisfaction score at 1 year
51 was simplified into a binary variable of whether or not the patient was satisfied with the surgery.
52 86.6% of patients were either very satisfied or satisfied, and 13.4% were unsure or not satisfied.
53 Bivariate analysis was undertaken to determine whether differences in outcome were associated by
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3 satisfaction status. Logistic regression analysis was then performed to determine the variables
4 associated with satisfaction at one year. Multivariate modelling, using a stepwise binary building
5 technique, was employed with predictive variables selected if their bivariate significance was $p = 0.1$
6 to accommodate the possibility of variable achieving statistical significance once the confounding
7 effect of another variable was controlled.
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11 12 13 14 **RESULTS**

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16 Demographic details are described in table 1. Age and gender and length of stay were not
17 associated with differences in satisfaction, however a significantly higher proportion of the THA
18 group were satisfied than the TKA group (Table 1, $\chi^2 = 49.85$, $p < 0.001$).
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22 All patient reported outcome scores (including pre-operative scores) were significantly greater in the
23 satisfied group. Satisfaction with the specific aspects of surgical outcome, the hospital experience
24 and the attitude towards further surgery were all significantly greater ($p = 0.001$) in those who
25 reported overall satisfaction with outcome.
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Table 1: patient demographics and outcomes by satisfaction

Variable	Satisfied	Not satisfied	Sig.
Age (Median, IQR)	70.3 (13.8)	70.0 (14.4)	0.829
Gender			0.473
	Female, n = 2354 (87%)	354 (13%)	
	Male, n = 1725 (86%)	276 (14%)	
Joint			<0.001
	THA, n = 2215 (90.0%)	247 (10.0%)	
	TKA, n = 1864 (83.0%)	383 (17.0%)	
Number of co-morbidities	2 (2)	2 (2)	<0.001
Length of stay (days)	5 (3)	6 (2)	< 0.001
Satisfaction with specific facets (median scores)			
Pain relief in affected joint	excellent	fair	< 0.001
Ability to perform activities	very good	fair	< 0.001
Ability to perform heavy work or sports	good	poor	< 0.001
Meeting of expectations	very good	poor	< 0.001
Rating of hospital experience	very good	good	< 0.001
Attitudes towards further surgery			
Would you have the surgery again (yes)	3688 (92%)	223 (36%)	< 0.001
Would you recommend the operation to another (yes)	3936 (97%)	292 (48%)	< 0.001
Patient Reported Outcome Questionnaires			
Pre-operative			
SF-12 PCS, median (IQR)	28.6 (9.4)	27.2 (8.1)	0.001
SF -12 MCS, median (IQR)	50.9 (19.2)	43.8 (20.3)	< 0.001
Oxford Score, median (IQR)	19.0 (12.0)	15.9 (10.0)	< 0.001
6 months			
SF-12 PCS, median (IQR)	41.6 (16.7)	30.4 (9.3)	< 0.001
SF -12 MCS, median (IQR)	56.5 (12.6)	43.2 (19.2)	< 0.001
Oxford Score, median (IQR)	39.0 (12.0)	24.0 (14.0)	< 0.001
12 months			
SF-12 PCS, median (IQR)	44.1 (8.7)	29.4 (8.7)	< 0.001
SF -12 MCS, median (IQR)	56.2 (12.7)	41.7 (16.9)	< 0.001
Oxford Score, median (IQR)	41.0 (11.0)	23.0 (12.0)	< 0.001

Highly significant correlations of modest-strong strength were found between overall satisfaction and the satisfaction with the specific aspects of surgical outcome (Table 2). Highly significant correlations of modest-strong strength were also apparent between overall satisfaction and the attitudes towards further surgery; 'Would you have the surgery again' ($r = 0.59$, $p = <0.001$) and 'Would you recommend the operation to another' ($r = 0.63$, $p = <0.001$).

Table 2: correlations between overall satisfaction response and satisfaction with individual facets of surgical outcome

Correlation with overall satisfaction	<i>rho</i>	Sig.
meeting of expectations	0.74	<0.001
pain relief in affected joint	0.72	<0.001
ability to perform activities	0.65	<0.001
ability to perform heavy work or sports	0.43	<0.001
rating of hospital experience	0.43	<0.001

All 21 variables were entered into a stepwise binary regression model. 5 variables were predictive of overall satisfaction with outcome; (1) Meeting pre-operative expectations, (2) satisfaction with pain relief, (3) satisfaction with the overall hospital experience, (4) pre-operative and (5) one year Oxford Scores (Table 3). There was no statistically significant difference between the observed probabilities and those predicted by the model (Hosmer-Lemeshow goodness-of-fit test, $\chi^2 = 5.704$, $p = 0.680$). Thus the model could be considered as a good fit. Overall, the model was able to correctly predict 97% of those who were satisfied. A change of 1 category (on the 0-6 category scale) of meeting expectations or satisfaction with pain relief resulted in being 2-3 times more likely to be satisfied with outcome.

Table 3: Significant predictors of being satisfied with outcome

Variable	Sig.	Odds ratio	CI
having expectations met	<.001	2.88	2.475 – 3.343
satisfaction with pain relief	<.001	2.68	2.258 – 3.174
satisfaction with the hospital experience	<.001	1.35	1.170 – 1.559
one-year Oxford Score	<.001	1.07	1.047 – 1.095
pre-op Oxford Score	<.001	0.96	0.933 – 0.978

DISCUSSION

We have shown that patient satisfaction following total joint arthroplasty is primarily based on three facets; meeting pre-operative expectations of surgery, achieving satisfactory pain relief following

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3 surgery and the overall hospital experience. These three factors drove a model which was able to
4 explain 97% of the variation in the patient's overall satisfaction response. It is important to note that
5 various factors previously reported to influence clinical outcome (as measured by PROM scores);
6 such as patient age, gender, co-morbidities, length of post-operative stay, mental health (SF12 MCS),
7 general physical health (SF12 PCS) and whether the hip or knee joint was replaced did not help
8 explain variation in overall patient satisfaction.
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14 Despite national efforts of categorisation, using patient reported assessment tools, patient outcome
15 following joint arthroplasty remains poorly understood and a highly complex construct to measure.
16 Indeed Carr et al¹² speculate that it is highly unlikely a single universal instrument that is valid for all
17 aspects and domains of outcome will ever be developed. Current patient report instruments do not
18 account for satisfaction, though this is possibly the most important metric of patient outcome, and
19 drives political discussions as to the relative benefits of procedures.
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24 Satisfaction as a concept has its origins in marketing and can be defined as "an attitude like
25 judgement following an act, which is based on a series of product-consumer interactions"¹³. It has
26 previously been used as a performance indicator in a health context for cancer care in the USA¹⁴, and
27 is known broadly to relate to outcome scores^{3, 15}, though this relationship is not well established.
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31 Patient outcome scores and patient satisfaction, though associated, are not the same metric.
32 Recently Judge et al^{4, 16} have assessed the relevant change in Oxford Score that corresponds to
33 satisfaction with surgery using receiver operating characteristic (ROC) curve analysis. A threshold of
34 38 points at 12 months and 11 point change in Oxford Hip Score or 14 point change in Oxford Knee
35 Score (from pre-operative score) is suggested as being predictive of satisfaction^{4, 16}. The thresholds
36 presented however vary with the pre-operative score. Judge et al¹⁶ also show how the widespread
37 attempts to use PROMs data to prioritise patients for arthroplasty surgery is ineffective,
38 demonstrating that pre-operative Oxford Scores in isolation have no predictive accuracy in deriving
39 post-operative satisfaction. In the analysis presented here, both pre-operative and one year Oxford
40 Scores contributed to the final regression model, reflecting the patient's change in outcome score,
41 though neither carried a large influence with odds ratios of close to 1.
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50 Mental health¹⁷ has been suggested to influence outcome (as measured by PROMS), and though our
51 data highlights that dissatisfied patients generally reported worse mental health scores, it was not a
52 predictor of overall satisfaction in multivariate modelling controlling for confounding. Neither were
53 differences in satisfaction between patients undergoing THA and those undergoing TKA surgery
54 relevant to the final model.
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3 Baker et al² suggest that failure to meet optimistic expectations is associated with dissatisfaction,
4 and the fulfilment of expectation has been correlated to satisfaction with outcome⁸. Mannion et al¹⁸
5 however suggest that actual status (pain and function) of the individual may be more predictive of
6 satisfaction than expectations of outcome using multivariate techniques. We suggest that the
7 meeting pre-operative expectations is an equally important factor as achieving satisfactory pain
8 relief post-operatively, with each factor demonstrating an odds ratio of around 3 points. Perhaps
9 most interesting is the inclusion of the rating of overall hospital experience as the only other factor
10 in the model. This aspect has not been well investigated previously and reflects the important role of
11 the patient's experience of their interaction with hospital services as to their final satisfaction with
12 the service provided.
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20 PROM scores are useful tools for the assessment of clinical outcome, in which they focus primarily
21 on pain relief^{19, 20}. This analysis highlights that while pain relief is very relevant to patient
22 satisfaction, it is not the sole driver; the meeting of expectations demonstrated the same influence,
23 while the patient's 'hospital experience' of care was also significant. Satisfaction is clearly an
24 important concept; in a healthcare environment it reflects the patient's perception of success. Three
25 components to healthcare satisfaction have been suggested previously; structure, process and
26 outcome²¹. Three similar 'quality domains' have also been described – safety, outcomes, and the
27 patient experience²². Our findings quantify these broad concepts for joint replacement.
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37 **Strengths and Limitations**

38 This study includes a large patient cohort from a single NHS orthopaedic centre with multiple
39 surgeons. Valid and reliable instruments for assessing change in health status and outcome of joint
40 arthroplasty have been used, and data has been collected prospectively with a good rate of follow-
41 up. The level of satisfaction we report is strikingly similar to that recorded in the 2005 national joint
42 registry postal survey⁵ (90% satisfaction with hip replacement and 82% satisfaction with knee
43 replacement). As we have pre-operative data we were able to model how the change in pain and
44 function related to satisfaction. This is important, as it is likely that satisfaction depends not on the
45 post-operative status, but on the change in status². As most patients report high satisfaction with
46 joint arthroplasty there is some doubt as to how discriminating this measure is, and caution has
47 been advised in the use of a standardised instrument for the measurement of satisfaction²³. It is
48 recommended that satisfaction questions should be context and objective specific rather than
49 generic. Although the additional questions we asked were not formally validated as a measure of
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3 satisfaction, they were directed explicitly at aspects relating to joint arthroplasty allowing a more in-
4 depth analysis of the individual factors that contribute to overall satisfaction. Satisfaction is what the
5 public perceive as the eventual outcome. It is significantly influenced by clinical outcome (pain relief,
6 and the avoidance of complications). However it is also significantly influenced by the pathway to
7 care and the hospital experience. The relative proportions to which these factors contribute
8 towards overall satisfaction are likely to differ by condition or treatment depending on the success
9 of treatment for different conditions.
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17 Recently there has been a focus on quality in the NHS (improving clinical outcomes and reducing
18 complications) which has been highly successful. Significant reductions in hospital acquired
19 infections, waiting times and specific procedure related problems such as dislocation following hip
20 replacement are all reported, yet patient satisfaction with outcome has remained constant over this
21 timeframe²⁻⁶, and overall satisfaction with the NHS recently declined²⁴. In marketing, it is considered
22 that focussing on service quality alone, without appreciating how it is delivered, is misguided; failure
23 to appreciate the critical role that interfacing departments play in customer satisfaction is setting
24 the stage for '*lower customer retention*'²⁵. This is equally true when applied to healthcare
25 environment, indeed Baker et al²⁶ note that better performance (in delivering joint replacement
26 outcomes) may bring the reward of more customers as patients and commissioners seek out high
27 performers for their elective procedures. We suggest that the national reduction in satisfaction may
28 in part be due to fragmented pathways of care to surgery and a concentration on administering time
29 targets rather than managing patient care in its wider context within a general NHS facility.
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42 In conclusion, overall patient satisfaction following joint arthroplasty is significantly affected by
43 fulfilment of pre-surgical expectations, symptomatic pain relief achieved following surgery and the
44 hospital experience. The Oxford Scores contributed a minimal additional influence in a model which
45 explained 97% of the variation in overall satisfaction response. Focussing on administration of
46 waiting lists as opposed to managing the patient's experience may be influencing the observed
47 reduction of satisfaction with healthcare delivery. This is particularly evident for joint replacement in
48 NHS facilities, where emergency admissions often de-prioritise "elective" surgeries leading to
49 measurable differences in satisfaction between units focussed on the patient pathway for one
50 condition or treatment and those providing the generality of care where focus has been blurred and
51 priority is given to emergency services.
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Declaration of competing interests

“All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; The arthroplasty database is supported by an educational grant to the University of Edinburgh (AHRW Simpson) by Stryker Orthopaedics, P Gaston has previously worked as a consultant for Stryker Orthopaedics, CR Howie is the president elect of the British Orthopaedic Association. The authors declare no additional potential conflict of interest with the submitted work. ”

Contributorship statement

DFH, JL and CRH conceived the study, all authors were involved in the study design, DM collated the data, JL performed the analysis, DFH and JL were primarily responsible for interpretation of data, DFH drafted the article, all authors revised it critically for important intellectual content and all approved the final text. CRH is the guarantor.

Data Sharing

The dataset is available via the corresponding author though is subject to approval of the data manager due to NHS restrictions in place to protect patient confidentiality.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	2,3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4,5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4,5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4,5
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	4,5
Bias	9	Describe any efforts to address potential sources of bias	4,5
Study size	10	Explain how the study size was arrived at	4,5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5,6
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	5
		(d) If applicable, explain how loss to follow-up was addressed	5
		(e) Describe any sensitivity analyses	
Results			

Participants	13*	(a) 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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	5
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	6,7
Outcome data	15*	Report numbers of outcome events or summary measures over time	6
Main results	16	(a) 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 (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	6,7,8
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9,10,11
Generalisability	21	Discuss the generalisability (external validity) of the study results	9,10,11
Other information			
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	12

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.



**What determines patient satisfaction with surgery? A
PROSPECTIVE COHORT STUDY OF 4709 PATIENTS
FOLLOWING TOTAL JOINT REPLACEMENT**

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What determines patient satisfaction with surgery?

A PROSPECTIVE COHORT STUDY OF 4709 PATIENTS FOLLOWING TOTAL JOINT REPLACEMENT

Hamilton DF, Lane JV, Gaston P, Patton JT, MacDonald D, Simpson AHRW, Howie CR

Department of Orthopaedics, University of Edinburgh, Edinburgh, EH164SB, UK
DF Hamilton, Research Fellow; D MacDonald, Research Co-ordinator; AHRW Simpson, Professor of
Orthopaedics and Trauma

Department of Physiotherapy, Queen Margaret University, Edinburgh, EH21 6UU, UK
JV Lane, Lecturer

Royal Infirmary of Edinburgh, Little France Crescent, Edinburgh, EH16 4SA, UK
CR Howie, Consultant Orthopaedic Surgeon; P Gaston, Consultant Orthopaedic Surgeon; JT Patton, Consultant
Orthopaedic Surgeon

Correspondence to: d.f.hamilton@ed.ac.uk

Article Summary;

Article focus

Patient satisfaction rates have been quoted following surgical intervention; and these used to assess the success of interventions.

Clinical care and patient outcomes have improved over recent years, however satisfaction with surgical services has remained constant over this timeframe.

Many factors have been suggested to influence patient satisfaction; however there is little consensus as to which areas of care actually influence overall satisfaction response.

Key messages

Our study identifies 5 factors that explain 97% of the variation in the patient's overall satisfaction following lower limb joint arthroplasty; (1) meeting of pre-operative expectations, (2) the achievement of satisfactory pain relief, (3) the patient's subjective hospital experience, and to a lesser extent (4) pre-operative physical status (Oxford Score) and (5) 12 month physical status (Oxford Score).

Factors that influence clinical outcome scores (PROMS) such as age, gender and co-morbidities do not impact upon satisfaction.

Clinical teams currently aim to manage pre-operative expectations and post-operative pain relief. Management of the patient's hospital experience may then be a key factor in optimizing overall patient satisfaction, which has implications for service delivery.

Strengths and Limitations

This study benefits from a large prospective patient cohort at a single NHS orthopaedic centre with multiple surgeons.

As most patients report high satisfaction with joint arthroplasty there is some doubt as to how discriminating this measure is, and caution has been advised in the use of a standardised instrument for the measurement of satisfaction.

The wider generalisability of these results from joint arthroplasty to other surgical procedures is assumed but unconfirmed

ABSTRACT

Objectives: To investigate the factors which influence patient satisfaction with surgical services and to explore the relationship between overall satisfaction, satisfaction with specific facets of outcome and measured clinical outcomes (Patient Reported Outcome Measures).

Design: Prospective cohort study

Setting: Single NHS teaching hospital

Participants: 4709 individuals undergoing primary lower limb joint replacement over a four year period (Jan 2006 – Dec 2010)

Main Outcome Measures: Overall patient satisfaction, clinical outcomes as measured by PROMS (Oxford Hip or Knee Score, SF-12), satisfaction with 5 specific aspects of surgical outcome, attitudes towards further surgery, length of hospital stay.

Results: Overall patient satisfaction was predicted by; (1) meeting pre-operative expectations [Odds Ratio 2.62 (95% CI, 2.24-3.07)], (2) satisfaction with pain relief [2.40 (2.00 -2.87)], (3) satisfaction with the hospital experience [1.7 (1.45-1.91)], (4) 12 month [1.08 (1.05-1.10)] and (5) pre-operative [0.95 (0.93-0.97)] Oxford Scores. These 5 factors contributed to a model able to correctly predict 97% of the variation in overall patient satisfaction response. The factors having greatest effect were the degree to which patient expectations were met and satisfaction with pain relief; the Oxford Scores carried little weight in the algorithm. Various factors previously reported to influence clinical outcomes such as age, gender, co-morbidities, length of post-operative hospital stay did not help explain variation in overall patient satisfaction.

Conclusions: Three factors broadly determine the patient's overall satisfaction following lower limb joint arthroplasty; meeting pre-operative expectations, achieving satisfactory pain relief, and a satisfactory hospital experience. Pain relief and expectations are managed by clinical teams; however a fractured access to surgical services impacts on the patient's hospital experience which may reduce overall satisfaction. In the absence of complications, how we deliver healthcare may be of key importance along with the specifics of what we deliver, which has clear implications for units providing surgical services.

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3 Satisfaction with NHS surgical services has recently declined¹ despite more rapid access to, and
4 fewer measurable complications from surgical care. There are few procedures or treatments where
5 the monitoring of outcomes and satisfaction has been consistent enough to investigate this
6 apparent paradox. Joint replacement is an example of a high volume service that has been closely
7 monitored over recent years.
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11 Traditionally, clinical success has been measured by lack of complications or by specific clinical
12 parameters, e.g. range of motion or blood pressure control. More recently, clinical outcomes have
13 been assessed by patient reported outcome measures (PROMS). Patient satisfaction is perhaps the
14 most important criterion of success. This is well recognised in the service industries, though remains
15 something of a nebulous concept in clinical care. Despite the extensive literature on clinical
16 outcomes following joint arthroplasty, comparatively few studies address patient satisfaction².
17 Where this is reported, the majority of patients are described as being satisfied with surgical
18 outcome; though consistent reports of 10-20% dissatisfaction with joint arthroplasty persist²⁻⁶. A
19 number of authors have suggested various factors that may influence satisfaction with arthroplasty,
20 such as post-operative pain or joint stiffness, though our current understanding as to why some
21 patients are satisfied and others are not remains limited⁶⁻⁸. Indeed some patients reporting a bad
22 clinical outcome, in terms of pain and function, may report good levels of satisfaction with their
23 surgical outcome and vice versa². In the wider surgical literature various factors such as meeting of
24 expectations, staff politeness, the surgeon's communication skills and surgical waiting times have all
25 been suggested as influencing eventual satisfaction⁹⁻¹¹ though again consensus is elusive. Clearly
26 overall satisfaction is a broad concept that encompasses more than simply the clinical outcome.
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38 Our aim was to explore the relationship between patient's level of overall satisfaction with their hip
39 or knee replacement, satisfaction with specific facets of outcome and measured clinical outcomes
40 (Patient Reported Outcome Measures).
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46 **METHODS**

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48 During a four year period (January 2006 to December 2010) all patients undergoing lower limb joint
49 replacement at a single hospital were entered into a prospectively collected arthroplasty database,
50 for which regional ethical approval had been obtained (11/AL/0079). The study questionnaire was
51 completed by 4709 (95%) patients. This comprised 2462 patients receiving total hip replacement and
52 2247 receiving total knee replacement. All data were included in the analysis.
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3 All patients completed pre-operative PROM questionnaires, Oxford Hip or Knee Score^{12, 13} and
4 Medical Outcomes Study Short Form 12 (SF-12) health assessment¹⁴, and were sent postal follow-up
5 questionnaires at 6 and 12 months post-operation to assess outcome and satisfaction. Procedures
6 were carried out by multiple consultant orthopaedic surgeons and their supervised trainees. All data
7 was collected independently from the clinical team by the arthroplasty outcomes research unit of
8 the University of Edinburgh and NHS Lothian.
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12 The Oxford Scores consist of 12 questions relating to the patients perceived pain and functional
13 ability, answered on a Likert scale with values from 0 to 4. The score ranges from 0-48, with overall
14 score calculated from the responses to the 12 questions. A score of 0 is the worst possible outcome
15 suggesting severe symptoms and dysfunction, while 48 is the best possible outcome. The SF-12
16 results in two scores, the physical and mental component summary (PCS and MCS) scores. This score
17 is calculated using norm-based methodology and population mean scores. Both PCS and MCS have a
18 population mean score of 50 with standard deviation of 10.
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21 Pre-operative information was collected as to the patient's age, gender and presence of co-
22 morbidities. Post-operative length of stay was recorded upon discharge. At 12 months patients were
23 also asked to rate their overall satisfaction with their operated hip or knee on a 4 point scale (very
24 satisfied, satisfied, unsure or dissatisfied). Data on satisfaction with 5 specific facets of surgical
25 outcome were obtained with the following questions, answered on a 6 point scale (excellently, very
26 well, well, fairly, poorly, don't know); (1) "how well did the surgery relieve the pain in your affected
27 joint?" (2) "How well did the surgery increase your ability to perform regular activities?" (3) "How
28 well did the surgery allow you to perform heavy work or sport activities?" (4) "How well did the
29 surgery meet your expectations?" We then asked our patients to indicate their satisfaction with the
30 care they received at the hospital with the question (5) "rate your overall hospital experience" using
31 the response scale; excellent, very good, good, fair, poor or unknown. We also asked a further 2
32 questions that enquired as to the patient's attitude towards further surgery; (1) "would you have
33 this operation again if it were required on another joint?" and (2) "would you recommend this
34 operation to someone else?" (Possible responses: Definitely yes, possibly yes, probably not, certainly
35 not or not sure). These were included to mimic the modelling done in marketing research, where
36 return visits are considered a successful outcome.
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52 **Statistical analysis**

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55 Data were assessed with SPSS version 17 (IBM). Data were not normally distributed and therefore
56 variables have been presented as median and inter-quartile ranges. The satisfaction score at 1 year
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3 was simplified into a binary variable of whether or not the patient was satisfied with the surgery.
4 Those who reported 'satisfied' or 'very satisfied' were categorised as satisfied. Those who were
5 either 'unsure' or 'not satisfied' were categorised as 'not satisfied'. 86.6% of patients were either
6 very satisfied or satisfied, and 13.4% were unsure or not satisfied. Bivariate analysis was undertaken
7 to determine whether differences in outcome were associated by satisfaction status. Logistic
8 regression analysis was then performed to determine the variables associated with satisfaction at
9 one year. Multivariate modelling, using a stepwise binary building technique, was employed with
10 predictive variables selected if their bivariate significance was $p = 0.1$ to accommodate the possibility
11 of variable achieving statistical significance once the confounding effect of another variable was
12 controlled.
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22 RESULTS

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24 Demographic details are described in table 1, split dichotomously into satisfied or unsatisfied patient
25 groups. Age and gender were not associated with differences in satisfaction, however a significantly
26 higher proportion of the THA group were satisfied than the TKA group (Table 1, $\chi^2 = 49.85$, $p <$
27 0.001). The median number of co-morbidities (2) was the same though is reported as being
28 statistically different between groups; as the Mann-Whitney test does not actually compare the
29 medians but looks at the ranking of all of the data, which allows for this apparent contradiction.
30 Median length of stay differed by a single day between those who were satisfied and those who
31 were not, which was statistically significant. All patient reported outcome scores (including pre-
32 operative scores) were significantly better in the satisfied group. Satisfaction with the specific
33 aspects of surgical outcome, the hospital experience and the attitude towards further surgery were
34 all significantly greater ($p = 0.001$) in those who reported overall satisfaction with outcome.
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Table 1: Patient demographics and outcomes (Median, IQR) by overall satisfaction response

Variable	Satisfied	Not satisfied	Sig.
Age	70.3 (13.8)	70.0 (14.4)	0.829
Gender			
Female, n =	2354 (87%)	354 (13%)	
Male, n =	1725 (86%)	276 (14%)	0.473
Joint			
THA, n =	2215 (90.0%)	247 (10.0%)	
TKA, n =	1864 (83.0%)	383 (17.0%)	<0.001
Number of co-morbidities	2 (2)	2 (2)	< 0.001
Length of stay (days)	5 (3)	6 (2)	< 0.001
Satisfaction with specific facets (median scores)			
Pain relief in affected joint	excellent	fair	< 0.001
Ability to perform activities	very good	poor	< 0.001
Ability to perform heavy work or sports	good	poor	< 0.001
Meeting of expectations	very good	poor	< 0.001
Rating of hospital experience	very good	good	< 0.001
Attitudes towards further surgery			
Would you have the surgery again (yes)	3688 (92%)	223 (36%)	< 0.001
Would you recommend the operation to another (yes)	3936 (97%)	292 (48%)	< 0.001
Patient Reported Outcome Questionnaires			
Pre-operative			
SF-12 PCS, median (IQR)	28.6 (9.4)	27.2 (8.1)	0.001
SF -12 MCS, median (IQR)	50.9 (19.2)	43.8 (20.3)	< 0.001
Oxford Score, median (IQR)	19.0 (12.0)	16.0 (10.0)	< 0.001
6 months			
SF-12 PCS, median (IQR)	41.8 (16.7)	30.4 (9.3)	< 0.001
SF -12 MCS, median (IQR)	56.5 (12.6)	43.2 (19.2)	< 0.001
Oxford Score, median (IQR)	39.0 (12.0)	24.0 (14.0)	< 0.001
12 months			
SF-12 PCS, median (IQR)	44.1 (17.9)	29.4 (8.7)	< 0.001
SF -12 MCS, median (IQR)	56.2 (12.7)	41.7 (16.9)	< 0.001
Oxford Score, median (IQR)	41.0 (11.0)	23.0 (12.0)	< 0.001

Highly significant correlations of modest-strong strength were found between overall satisfaction and the satisfaction with the specific aspects of surgical outcome (Table 2). Highly significant correlations of modest-strong strength were also apparent between overall satisfaction and the attitudes towards further surgery; 'Would you have the surgery again' ($r = 0.59$, $p = <0.001$) and 'Would you recommend the operation to another' ($r = 0.63$, $p = <0.001$).

Table 2: correlations between overall satisfaction response and satisfaction with individual facets of surgical outcome

Correlation with overall satisfaction	<i>rho</i>	Sig.
meeting of expectations	0.74	<0.001
pain relief in affected joint	0.72	<0.001
ability to perform activities	0.65	<0.001
ability to perform heavy work or sports	0.43	<0.001
rating of hospital experience	0.43	<0.001

All 21 variables were entered into a stepwise binary regression model. 5 of these variables were predictive of overall satisfaction with outcome; (1) Meeting pre-operative expectations, (2) satisfaction with pain relief, (3) satisfaction with the overall hospital experience, (4) pre-operative and (5) 12 month Oxford Scores (Table 3). There was no statistically significant difference between the observed probabilities and those predicted by the model (Hosmer-Lemeshow goodness-of-fit test, $\chi^2 = 5.654$, $p = 0.686$). Thus the model could be considered as a good fit. Overall, the model was able to correctly predict 97% of those who were satisfied. A change of 1 category (on the 0-6 category scale) of meeting expectations or satisfaction with pain relief resulted in being 2-3 times more likely to be satisfied with outcome.

Table 3: Significant predictors of being satisfied with outcome

Variable	Sig.	Odds ratio	CI
having expectations met	<.001	2.62	2.237 – 3.073
satisfaction with pain relief	<.001	2.40	1.999 – 2.867
satisfaction with the hospital experience	<.001	1.67	1.454 – 1.908
12 month Oxford Score	<.001	1.08	1.052 – 1.103
pre-op Oxford Score	<.001	0.95	0.927 – 0.973

A noted ceiling effect on post-operative Oxford Scores (that is potentially problematic when performing regression modelling) led us to review our data. Ceiling effects are of concern if 15% or more of respondents report the highest value. In our data 374 patients (only 8% of the total number of respondents) reported the highest possible score.

DISCUSSION

This study demonstrates high levels of overall patient satisfaction following total joint arthroplasty and suggests that this is primarily based on three facets; meeting pre-operative expectations of surgery, achieving satisfactory pain relief following surgery and the overall hospital experience. These three factors drove a model which was able to explain 97% of the variation in the patient's overall satisfaction response. It is important to highlight that various factors previously reported to influence clinical outcome (as measured by PROM scores); such as patient age, gender, co-morbidities, length of post-operative stay, mental health (SF-12 MCS), general physical health (SF-12 PCS) and whether the hip or knee joint was replaced did not help explain variation in overall patient satisfaction.

Despite national efforts of categorisation, using patient reported assessment tools, patient outcome following joint arthroplasty remains poorly understood and a highly complex construct to measure. Indeed Carr et al¹⁵ speculate that it is highly unlikely a single universal instrument that is valid for all aspects and domains of outcome will ever be developed. Overall patient satisfaction following joint arthroplasty is thought broadly to relate to PROM scores^{3, 16} however this relationship is not well established. Studies in general medicine have found conflicting associations between the patient's experience of intervention and the technical quality of the care delivered as measured by other means¹⁷⁻¹⁹. Though associated, outcome and satisfaction are not the same metric; current patient report instruments do not account for satisfaction, though this is perhaps the most important criterion of operative success.

The concept of satisfaction is most widely employed in consumer marketing and can be defined as "an attitude like judgement following an act, based on a series of product-consumer interactions"²⁰. It has been used as a health care performance indicator for surgery in the UK¹⁷, Europe⁹ and notably for cancer services²¹ and cosmetic procedures in the USA²². Mira et al⁹ report 75% satisfaction in a large sample of patients (undergoing urology, traumatology, ophthalmology and general surgery) discharged in a two month period from multiple Spanish hospitals. They found that in addition to successful surgical procedure other facets relating to the experience of the surgical episode such as previous explanation of the procedure, provision of information at admission and at discharge, and quickness of response on the ward all substantially influenced the patients overall satisfaction response. Recently Judge et al^{4, 23} have assessed the relevant change in Oxford Score that corresponds to satisfaction with joint arthroplasty using receiver operating characteristic (ROC) curve analysis. A threshold of 38 points at 12 months and 11 point change in Oxford Hip Score or 14 point change in Oxford Knee Score (from pre-operative score) is suggested as being predictive of

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3 satisfaction^{4, 23}. The thresholds presented however vary with the pre-operative score. Judge et al²³
4 also show how the widespread attempts to use PROMs data to prioritise patients for arthroplasty
5 surgery is ineffective, demonstrating that pre-operative Oxford Scores in isolation have no predictive
6 accuracy in deriving post-operative satisfaction. In the analysis presented here, both pre-operative
7 and one year Oxford Scores contributed to the final regression model, reflecting the patient's change
8 in outcome score, though neither carried much influence, with odds ratios close to 1. Mental
9 health²⁴ has been suggested to influence outcome (as measured by PROMS), and though our data
10 highlights that dissatisfied patients generally reported worse mental health scores, it was not a
11 predictor of overall satisfaction in multivariate modelling controlling for confounding. Neither were
12 differences in post-operative length of hospital stay or level of satisfaction between patients
13 undergoing THA and those undergoing TKA surgery relevant to the final model.
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22 PROM scores are useful tools for the assessment of clinical outcome, in which they focus primarily
23 on pain relief^{25, 26}. This analysis highlights that while pain relief is very relevant to patient
24 satisfaction; it is not the sole driver. It is quite possible for patients to report good levels of pain
25 relief and overall dissatisfaction or vice versa. Marrying of expectations and resultant perception of
26 outcome has been suggested as a model for understanding satisfaction response in the marketing
27 literature¹⁰. Baker et al² suggest that failure to meet optimistic expectations is associated with
28 dissatisfaction following joint arthroplasty, and the fulfilment of expectation has been correlated to
29 satisfaction with outcome⁸. Mannion et al²⁷ however suggest that actual status (pain and function) of
30 the individual may be more predictive of satisfaction than expectations of outcome using
31 multivariate modelling techniques. We suggest that the meeting pre-operative expectations is an
32 equally important factor as achieving satisfactory pain relief post-operatively, with both factors
33 demonstrating an odds ratio of close to 3 points. Perhaps most interesting is the inclusion of the
34 rating of overall hospital experience as the only other factor in the model. This aspect has not been
35 well investigated in the arthroplasty literature and reflects the important role of the patient's
36 experience of their interaction with hospital services as to their final satisfaction with the service
37 provided.
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49 Three 'pillars of quality in healthcare' for the NHS have been recently defined; patient safety, clinical
50 effectiveness, and the patient experience^{17, 28}. The patient experience metric is thought to help
51 assess the strengths and weaknesses of patient safety and clinical effectiveness and drive
52 improvements in these components¹⁷. Interestingly, these 'Pillars' are notably similar to previously
53 proposed 'components of healthcare satisfaction'; structure, process and outcome²⁹. Taken
54 together, these suggestions emphasise that the patient's satisfaction following a surgical procedure
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3 is not limited to the outcomes of the intervention, but influenced by the experience of the event as a
4 whole, from pre-operative consultation to post-operative review. Our findings perhaps help
5 quantify these broad concepts in the context of joint replacement.
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10 11 **Strengths and Limitations**

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13 This study includes a large patient cohort from a single NHS orthopaedic centre with multiple
14 surgeons. Valid and reliable instruments for assessing change in health status and outcome of joint
15 arthroplasty have been used, and data has been collected prospectively with a good rate of follow-
16 up. The level of satisfaction we report is strikingly similar to that recorded in the 2005 national joint
17 registry postal survey⁵ (90% satisfaction with hip replacement and 82% satisfaction with knee
18 replacement). As we have pre-operative data we were able to model how the change in pain and
19 function related to satisfaction. This is important, as it is likely that satisfaction depends not on the
20 post-operative status, but on the change in status². A noted ceiling effect on post-operative Oxford
21 Scores may unduly influence regression modelling such as is reported here. Terwee³⁰ suggests that
22 ceiling effects can be considered as present in a health status measure if 15% or more of
23 respondents report the highest value. We are confident that our analysis has not been limited by
24 this as less than 10% of our data was at the upper score limit.
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34 As most patients report high satisfaction with joint arthroplasty there is some doubt as to how
35 discriminating this measure is, and caution has been advised in the use of a standardised instrument
36 for the measurement of satisfaction²³. It is recommended that satisfaction questions should be
37 context and objective specific rather than generic. Although the additional questions we asked were
38 not formally validated as a measure of satisfaction, they were directed explicitly at aspects relating
39 to joint arthroplasty allowing a more in-depth analysis of the individual factors that contribute to
40 overall satisfaction. Though probably reflective of other interventions, the actual generalizability of
41 these findings to other surgical procedures is not known. Satisfaction is significantly influenced by
42 clinical outcome (pain relief, and the avoidance of complications). However it is also significantly
43 influenced by the pathway to care and the hospital experience. The relative proportions to which
44 these factors contribute towards overall satisfaction are likely to differ by condition or treatment
45 depending on the success of treatment for different conditions. The most appropriate time point for
46 assessing satisfaction has not been described; with some authors reporting satisfaction immediately
47 post discharge. We chose to survey our patient's satisfaction with outcome 12 months following the
48 index procedure as this is a time commonly agreed to represent the final outcome and is consistent
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3 with other arthroplasty studies. Waiting times for surgery are also thought to influence satisfaction,
4 though we were not able to assess this in our study, as all patients were operated on within 12
5 weeks of being listed for procedure, as is a requirement of planned surgical intervention in Scotland.
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11 Recently there has been a focus on quality in the NHS (improving clinical outcomes and reducing
12 complications) which has been highly successful. Significant reductions in hospital acquired
13 infections, waiting times and specific procedure related problems (such as dislocation following hip
14 replacement) are all reported, yet patient satisfaction with outcome has remained constant over this
15 timeframe²⁻⁶, and overall satisfaction with the NHS as a whole has actually declined³². In marketing it
16 has been suggested that, focussing on service quality alone, without appreciating how it is delivered,
17 is setting the stage for *'lower customer retention'*³³. This remains true when applied to healthcare
18 environment, indeed Baker et al³⁴ note that better performance (in delivering joint replacement
19 outcomes) may bring the reward of more customers, as patients and commissioners seek out high
20 performers for their elective procedures. We speculate that as surgical outcomes have been
21 consistent, and complications reduced, the national reduction in satisfaction with the NHS may in
22 part be due to fragmented pathways of care to surgery and a concentration on administering time
23 targets rather than managing patient care in its wider context.
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33 In conclusion, overall patient satisfaction following joint arthroplasty is significantly affected by
34 fulfilment of pre-surgical expectations, symptomatic pain relief achieved following surgery and the
35 hospital experience. The Oxford Scores contributed a minimal additional influence in a model which
36 explained 97% of the variation in overall satisfaction response. Focussing on administration of
37 waiting lists as opposed to managing the patient's experience may be influencing the observed
38 reduction of satisfaction with healthcare delivery. This is particularly evident for joint replacement in
39 NHS facilities, where emergency admissions often de-prioritise "elective" surgeries leading to
40 differences in satisfaction between units focussed on the patient pathway for one condition or
41 treatment and those providing the generality of care where focus has been blurred and priority is
42 given to emergency services.
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53 **Executive licence**

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Declaration of competing interests

"All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; The arthroplasty database is supported by an educational grant to the University of Edinburgh (AHRW Simpson) by Stryker Orthopaedics, P Gaston has previously worked as a consultant for Stryker Orthopaedics, CR Howie is the president elect of the British Orthopaedic Association. The authors declare no additional potential conflict of interest with the submitted work. "

Contributorship statement

All authors contributed to the conception and design, or analysis and interpretation of data, drafting the article or revising it critically for important intellectual content and final approval of the version to be published. CRH is the guarantor.

Data Sharing

The dataset is available via the corresponding author though is subject to approval of the data manager due to NHS restrictions in place to protect patient confidentiality.

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What determines patient satisfaction with surgery?

A PROSPECTIVE COHORT STUDY OF 4709 PATIENTS FOLLOWING TOTAL JOINT REPLACEMENT

Hamilton DF, Lane JV, Gaston P, Patton JT, MacDonald D, Simpson AHRW, Howie CR

Department of Orthopaedics, University of Edinburgh, Edinburgh, EH164SB, UK
DF Hamilton, Research Fellow; D MacDonald, Research Co-ordinator; AHRW Simpson, Professor of
Orthopaedics and Trauma

Department of Physiotherapy, Queen Margaret University, Edinburgh, EH21 6UU, UK
JV Lane, Lecturer

Royal Infirmary of Edinburgh, Little France Crescent, Edinburgh, EH16 4SA, UK
CR Howie, Consultant Orthopaedic Surgeon; P Gaston, Consultant Orthopaedic Surgeon; JT Patton, Consultant
Orthopaedic Surgeon

Correspondence to: d.f.hamilton@ed.ac.uk

Article Summary;

Article focus

Patient satisfaction rates have been quoted following surgical intervention; and these used to assess the success of interventions.

Clinical care and patient outcomes have improved over recent years, however satisfaction with surgical services has remained constant over this timeframe.

Many factors have been suggested to influence patient satisfaction; however there is little consensus as to which areas of care actually influence overall satisfaction response.

Key messages

Our study identifies 5 factors that explain 97% of the variation in the patient's overall satisfaction following lower limb joint arthroplasty; (1) meeting of pre-operative expectations, (2) the achievement of satisfactory pain relief, (3) the patients subjective hospital experience, and to a lesser extent (4) pre-operative physical status (Oxford Score) and (5) 12 month physical status (Oxford Score).

Factors that influence clinical outcome scores (PROMS) such as age, gender and co-morbidities do not impact upon satisfaction.

Clinical teams currently aim to manage pre-operative expectations and post-operative pain relief. Management of the patient's hospital experience may then be a key factor in optimizing overall patient satisfaction, which has implications for service delivery.

Strengths and Limitations

This study benefits from a large prospective patient cohort at a single NHS orthopaedic centre with multiple surgeons.

As most patients report high satisfaction with joint arthroplasty there is some doubt as to how discriminating this measure is, and caution has been advised in the use of a standardised instrument for the measurement of satisfaction.

The wider generalisibility of these results from joint arthroplasty to other surgical procedures is assumed but unconfirmed

ABSTRACT

Objectives: To investigate the factors which influence patient satisfaction with surgical services and to explore the relationship between overall satisfaction, satisfaction with specific facets of outcome and measured clinical outcomes (Patient Reported Outcome Measures).

Design: Prospective cohort study

Setting: Single NHS teaching hospital

Participants: 4709 individuals undergoing primary lower limb joint replacement over a four year period (Jan 2006 – Dec 2010)

Main Outcome Measures: Overall patient satisfaction, clinical outcomes as measured by PROMS (Oxford Hip or Knee Score, SF-12), satisfaction with 5 specific aspects of surgical outcome, attitudes towards further surgery, length of hospital stay.

Results: Overall patient satisfaction was predicted by; (1) meeting pre-operative expectations [Odds Ratio 2.62 (95% CI, 2.24-3.07)], (2) satisfaction with pain relief [2.40 (2.00 -2.87)], (3) satisfaction with the hospital experience [1.7 (1.45-1.91)], (4) 12 month [1.08 (1.05-1.10)] and (5) pre-operative [0.95 (0.93-0.97)] Oxford Scores. These 5 factors contributed to a model able to correctly predict 97% of the variation in overall patient satisfaction response. The factors having greatest effect were the degree to which patient expectations were met and satisfaction with pain relief; the Oxford Scores carried little weight in the algorithm. Various factors previously reported to influence clinical outcomes such as age, gender, co-morbidities, length of post-operative hospital stay did not help explain variation in overall patient satisfaction.

Conclusions: Three factors broadly determine the patient's overall satisfaction following lower limb joint arthroplasty; meeting pre-operative expectations, achieving satisfactory pain relief, and a satisfactory hospital experience. Pain relief and expectations are managed by clinical teams; however a fractured access to surgical services impacts on the patient's hospital experience which may reduce overall satisfaction. In the absence of complications, how we deliver healthcare may be of key importance along with the specifics of what we deliver, which has clear implications for units providing surgical services.

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3 Satisfaction with NHS surgical services has recently declined¹ despite more rapid access to, and
4 fewer measurable complications from surgical care. There are few procedures or treatments where
5 the monitoring of outcomes and satisfaction has been consistent enough to investigate this
6 apparent paradox. Joint replacement is an example of a high volume service that has been closely
7 monitored over recent years.
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11 Traditionally, clinical success has been measured by lack of complications or by specific clinical
12 parameters, e.g. range of motion or blood pressure control. More recently, clinical outcomes have
13 been assessed by patient reported outcome measures (PROMS). Patient satisfaction is perhaps the
14 most important criterion of success. This is well recognised in the service industries, though remains
15 something of a nebulous concept in clinical care. **Despite the extensive literature on clinical
16 outcomes following joint arthroplasty, comparatively few studies address patient satisfaction².**

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18 Where this is reported, the majority of patients are described as being satisfied with surgical
19 outcome; though consistent reports of 10-20% dissatisfaction with joint arthroplasty persist²⁻⁶. A
20 number of authors have suggested various factors that may influence satisfaction with arthroplasty,
21 such as post-operative pain or joint stiffness, though our current understanding as to why some
22 patients are satisfied and others are not remains limited⁶⁻⁸. Indeed some patients reporting a bad
23 clinical outcome, in terms of pain and function, may report good levels of satisfaction with their
24 surgical outcome and vice versa². **In the wider surgical literature various factors such as meeting of
25 expectations, staff politeness, the surgeon's communication skills and surgical waiting times have all
26 been suggested as influencing eventual satisfaction⁹⁻¹¹ though again consensus is elusive.** Clearly
27 overall satisfaction is a broad concept that encompasses more than simply the clinical outcome.
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31 Our aim was to explore the relationship between patient's level of overall satisfaction with their hip
32 or knee replacement, satisfaction with specific facets of outcome and measured clinical outcomes
33 (Patient Reported Outcome Measures).
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47 **METHODS**

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49 During a four year period (January 2006 to December 2010) all patients undergoing lower limb joint
50 replacement at a single hospital were entered into a prospectively collected arthroplasty database,
51 for which regional ethical approval had been obtained (11/AL/0079). The study questionnaire was
52 completed by 4709 (95%) patients. This comprised 2462 patients receiving total hip replacement and
53 2247 receiving total knee replacement. All data were included in the analysis.
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3 All patients completed pre-operative PROM questionnaires, Oxford Hip or Knee Score^{12, 13} and
4 Medical Outcomes Study Short Form 12 (SF-12) health assessment¹⁴, and were sent postal follow-up
5 questionnaires at 6 and 12 months post-operation to assess outcome and satisfaction. Procedures
6 were carried out by multiple consultant orthopaedic surgeons and their supervised trainees. All data
7 was collected independently from the clinical team by the arthroplasty outcomes research unit of
8 the University of Edinburgh and NHS Lothian.
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12 The Oxford Scores consist of 12 questions relating to the patients perceived pain and functional
13 ability, answered on a Likert scale with values from 0 to 4. The score ranges from 0-48, with overall
14 score calculated from the responses to the 12 questions. A score of 0 is the worst possible outcome
15 suggesting severe symptoms and dysfunction, while 48 is the best possible outcome. The SF-12
16 results in two scores, the physical and mental component summary (PCS and MCS) scores. This score
17 is calculated using norm-based methodology and population mean scores. Both PCS and MCS have a
18 population mean score of 50 with standard deviation of 10.
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21 Pre-operative information was collected as to the patient's age, gender and presence of co-
22 morbidities. Post-operative length of stay was recorded upon discharge. At 12 months patients were
23 also asked to rate their overall satisfaction with their operated hip or knee on a 4 point scale (very
24 satisfied, satisfied, unsure or dissatisfied). Data on satisfaction with 5 specific facets of surgical
25 outcome were obtained with the following questions, answered on a 6 point scale (excellently, very
26 well, well, fairly, poorly, don't know); (1) "how well did the surgery relieve the pain in your affected
27 joint?" (2) "How well did the surgery increase your ability to perform regular activities?" (3) "How
28 well did the surgery allow you to perform heavy work or sport activities?" (4) "How well did the
29 surgery meet your expectations?" We then asked our patients to indicate their satisfaction with the
30 care they received at the hospital with the question (5) "rate your overall hospital experience" using
31 the response scale; excellent, very good, good, fair, poor or unknown. We also asked a further 2
32 questions that enquired as to the patient's attitude towards further surgery; (1) "would you have
33 this operation again if it were required on another joint?" and (2) "would you recommend this
34 operation to someone else?" (Possible responses: Definitely yes, possibly yes, probably not, certainly
35 not or not sure). These were included to mimic the modelling done in marketing research, where
36 return visits are considered a successful outcome.
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51 52 **Statistical analysis**

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55 Data were assessed with SPSS version 17 (IBM). Data were not normally distributed and therefore
56 variables have been presented as median and inter-quartile ranges. The satisfaction score at 1 year
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3 was simplified into a binary variable of whether or not the patient was satisfied with the surgery.
4 Those who reported 'satisfied' or 'very satisfied' were categorised as satisfied. Those who were
5 either 'unsure' or 'not satisfied' were categorised as 'not satisfied'. 86.6% of patients were either
6 very satisfied or satisfied, and 13.4% were unsure or not satisfied. Bivariate analysis was undertaken
7 to determine whether differences in outcome were associated by satisfaction status. Logistic
8 regression analysis was then performed to determine the variables associated with satisfaction at
9 one year. Multivariate modelling, using a stepwise binary building technique, was employed with
10 predictive variables selected if their bivariate significance was $p = 0.1$ to accommodate the possibility
11 of variable achieving statistical significance once the confounding effect of another variable was
12 controlled.
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22 RESULTS

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24 Demographic details are described in table 1, split dichotomously into satisfied or unsatisfied patient
25 groups. Age and gender were not associated with differences in satisfaction, however a significantly
26 higher proportion of the THA group were satisfied than the TKA group (Table 1, $\chi^2 = 49.85$, $p <$
27 0.001). The median number of co-morbidities (2) was the same though is reported as being
28 statistically different between groups; as the Mann-Whitney test does not actually compare the
29 medians but looks at the ranking of all of the data, which allows for this apparent contradiction.
30 Median length of stay differed by a single day between those who were satisfied and those who
31 were not, which was statistically significant. All patient reported outcome scores (including pre-
32 operative scores) were significantly better in the satisfied group. Satisfaction with the specific
33 aspects of surgical outcome, the hospital experience and the attitude towards further surgery were
34 all significantly greater ($p = 0.001$) in those who reported overall satisfaction with outcome.
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Table 1: Patient demographics and outcomes (Median, IQR) by overall satisfaction response

Variable	Satisfied	Not satisfied	Sig.
Age	70.3 (13.8)	70.0 (14.4)	0.829
Gender			
Female, n =	2354 (87%)	354 (13%)	
Male, n =	1725 (86%)	276 (14%)	0.473
Joint			
THA, n =	2215 (90.0%)	247 (10.0%)	
TKA, n =	1864 (83.0%)	383 (17.0%)	<0.001
Number of co-morbidities	2 (2)	2 (2)	< 0.001
Length of stay (days)	5 (3)	6 (2)	< 0.001
Satisfaction with specific facets (median scores)			
Pain relief in affected joint	excellent	fair	< 0.001
Ability to perform activities	very good	poor	< 0.001
Ability to perform heavy work or sports	good	poor	< 0.001
Meeting of expectations	very good	poor	< 0.001
Rating of hospital experience	very good	good	< 0.001
Attitudes towards further surgery			
Would you have the surgery again (yes)	3688 (92%)	223 (36%)	< 0.001
Would you recommend the operation to another (yes)	3936 (97%)	292 (48%)	< 0.001
Patient Reported Outcome Questionnaires			
Pre-operative			
SF-12 PCS, median (IQR)	28.6 (9.4)	27.2 (8.1)	0.001
SF -12 MCS, median (IQR)	50.9 (19.2)	43.8 (20.3)	< 0.001
Oxford Score, median (IQR)	19.0 (12.0)	16.0 (10.0)	< 0.001
6 months			
SF-12 PCS, median (IQR)	41.8 (16.7)	30.4 (9.3)	< 0.001
SF -12 MCS, median (IQR)	56.5 (12.6)	43.2 (19.2)	< 0.001
Oxford Score, median (IQR)	39.0 (12.0)	24.0 (14.0)	< 0.001
12 months			
SF-12 PCS, median (IQR)	44.1 (17.9)	29.4 (8.7)	< 0.001
SF -12 MCS, median (IQR)	56.2 (12.7)	41.7 (16.9)	< 0.001
Oxford Score, median (IQR)	41.0 (11.0)	23.0 (12.0)	< 0.001

Highly significant correlations of modest-strong strength were found between overall satisfaction and the satisfaction with the specific aspects of surgical outcome (Table 2). Highly significant correlations of modest-strong strength were also apparent between overall satisfaction and the attitudes towards further surgery; 'Would you have the surgery again' ($r = 0.59$, $p = <0.001$) and 'Would you recommend the operation to another' ($r = 0.63$, $p = <0.001$).

Table 2: correlations between overall satisfaction response and satisfaction with individual facets of surgical outcome

Correlation with overall satisfaction	<i>rho</i>	Sig.
meeting of expectations	0.74	<0.001
pain relief in affected joint	0.72	<0.001
ability to perform activities	0.65	<0.001
ability to perform heavy work or sports	0.43	<0.001
rating of hospital experience	0.43	<0.001

All 21 variables were entered into a stepwise binary regression model. 5 of these variables were predictive of overall satisfaction with outcome; (1) Meeting pre-operative expectations, (2) satisfaction with pain relief, (3) satisfaction with the overall hospital experience, (4) pre-operative and (5) 12 month Oxford Scores (Table 3). There was no statistically significant difference between the observed probabilities and those predicted by the model (Hosmer-Lemeshow goodness-of-fit test, $\chi^2 = 5.654$, $p = 0.686$). Thus the model could be considered as a good fit. Overall, the model was able to correctly predict 97% of those who were satisfied. A change of 1 category (on the 0-6 category scale) of meeting expectations or satisfaction with pain relief resulted in being 2-3 times more likely to be satisfied with outcome.

Table 3: Significant predictors of being satisfied with outcome

Variable	Sig.	Odds ratio	CI
having expectations met	<.001	2.62	2.237 – 3.073
satisfaction with pain relief	<.001	2.40	1.999 – 2.867
satisfaction with the hospital experience	<.001	1.67	1.454 – 1.908
12 month Oxford Score	<.001	1.08	1.052 – 1.103
pre-op Oxford Score	<.001	0.95	0.927 – 0.973

A noted ceiling effect on post-operative Oxford Scores (that is potentially problematic when performing regression modelling) led us to review our data. Ceiling effects are of concern if 15% or more of respondents report the highest value. In our data 374 patients (only 8% of the total number of respondents) reported the highest possible score.

DISCUSSION

This study demonstrates high levels of overall patient satisfaction following total joint arthroplasty and suggests that this is primarily based on three facets; meeting pre-operative expectations of surgery, achieving satisfactory pain relief following surgery and the overall hospital experience. These three factors drove a model which was able to explain 97% of the variation in the patient's overall satisfaction response. It is important to highlight that various factors previously reported to influence clinical outcome (as measured by PROM scores); such as patient age, gender, co-morbidities, length of post-operative stay, mental health (SF-12 MCS), general physical health (SF-12 PCS) and whether the hip or knee joint was replaced did not help explain variation in overall patient satisfaction.

Despite national efforts of categorisation, using patient reported assessment tools, patient outcome following joint arthroplasty remains poorly understood and a highly complex construct to measure. Indeed Carr et al¹⁵ speculate that it is highly unlikely a single universal instrument that is valid for all aspects and domains of outcome will ever be developed. Overall patient satisfaction following joint arthroplasty is thought broadly to relate to PROM scores^{3, 16} however this relationship is not well established. Studies in general medicine have found conflicting associations between the patient's experience of intervention and the technical quality of the care delivered as measured by other means¹⁷⁻¹⁹. Though associated, outcome and satisfaction are not the same metric; current patient report instruments do not account for satisfaction, though this is perhaps the most important criterion of operative success.

The concept of satisfaction is most widely employed in consumer marketing and can be defined as "an attitude like judgement following an act, based on a series of product-consumer interactions"²⁰. It has been used as a health care performance indicator for surgery in the UK¹⁷, Europe⁹ and notably for cancer services²¹ and cosmetic procedures in the USA²². Mira et al⁹ report 75% satisfaction in a large sample of patients (undergoing urology, traumatology, ophthalmology and general surgery) discharged in a two month period from multiple Spanish hospitals. They found that in addition to successful surgical procedure other facets relating to the experience of the surgical episode such as previous explanation of the procedure, provision of information at admission and at discharge, and quickness of response on the ward all substantially influenced the patients overall satisfaction response. Recently Judge et al^{4, 23} have assessed the relevant change in Oxford Score that corresponds to satisfaction with joint arthroplasty using receiver operating characteristic (ROC) curve analysis. A threshold of 38 points at 12 months and 11 point change in Oxford Hip Score or 14 point change in Oxford Knee Score (from pre-operative score) is suggested as being predictive of

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3 satisfaction^{4, 23}. The thresholds presented however vary with the pre-operative score. Judge et al²³
4 also show how the widespread attempts to use PROMs data to prioritise patients for arthroplasty
5 surgery is ineffective, demonstrating that pre-operative Oxford Scores in isolation have no predictive
6 accuracy in deriving post-operative satisfaction. In the analysis presented here, both pre-operative
7 and one year Oxford Scores contributed to the final regression model, reflecting the patient's change
8 in outcome score, though neither carried much influence, with odds ratios close to 1. Mental
9 health²⁴ has been suggested to influence outcome (as measured by PROMS), and though our data
10 highlights that dissatisfied patients generally reported worse mental health scores, it was not a
11 predictor of overall satisfaction in multivariate modelling controlling for confounding. **Neither were**
12 **differences in post-operative length of hospital stay or level of satisfaction between patients**
13 **undergoing THA and those undergoing TKA surgery relevant to the final model.**

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16 PROM scores are useful tools for the assessment of clinical outcome, in which they focus primarily
17 on pain relief^{25, 26}. **This analysis highlights that while pain relief is very relevant to patient**
18 **satisfaction; it is not the sole driver. It is quite possible for patients to report good levels of pain**
19 **relief and overall dissatisfaction or vice versa. Marrying of expectations and resultant perception of**
20 **outcome has been suggested as a model for understanding satisfaction response in the marketing**
21 **literature¹⁰. Baker et al² suggest that failure to meet optimistic expectations is associated with**
22 **dissatisfaction following joint arthroplasty, and the fulfilment of expectation has been correlated to**
23 **satisfaction with outcome⁸. Mannion et al²⁷ however suggest that actual status (pain and function) of**
24 **the individual may be more predictive of satisfaction than expectations of outcome using**
25 **multivariate modelling techniques. We suggest that the meeting pre-operative expectations is an**
26 **equally important factor as achieving satisfactory pain relief post-operatively, with both factors**
27 **demonstrating an odds ratio of close to 3 points. Perhaps most interesting is the inclusion of the**
28 **rating of overall hospital experience as the only other factor in the model. This aspect has not been**
29 **well investigated in the arthroplasty literature and reflects the important role of the patient's**
30 **experience of their interaction with hospital services as to their final satisfaction with the service**
31 **provided.**

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Three 'pillars of quality in healthcare' for the NHS have been recently defined; patient safety, clinical
effectiveness, and the patient experience^{17, 28}. The patient experience metric is thought to help
assess the strengths and weaknesses of patient safety and clinical effectiveness and drive
improvements in these components¹⁷. Interestingly, these 'Pillars' are notably similar to previously
proposed 'components of healthcare satisfaction'; structure, process and outcome²⁹. Taken
together, these suggestions emphasise that the patient's satisfaction following a surgical procedure

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3 is not limited to the outcomes of the intervention, but influenced by the experience of the event as a
4 whole, from pre-operative consultation to post-operative review. Our findings perhaps help
5 quantify these broad concepts in the context of joint replacement.
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10 11 **Strengths and Limitations**

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13 This study includes a large patient cohort from a single NHS orthopaedic centre with multiple
14 surgeons. Valid and reliable instruments for assessing change in health status and outcome of joint
15 arthroplasty have been used, and data has been collected prospectively with a good rate of follow-
16 up. The level of satisfaction we report is strikingly similar to that recorded in the 2005 national joint
17 registry postal survey⁵ (90% satisfaction with hip replacement and 82% satisfaction with knee
18 replacement). As we have pre-operative data we were able to model how the change in pain and
19 function related to satisfaction. This is important, as it is likely that satisfaction depends not on the
20 post-operative status, but on the change in status². A noted ceiling effect on post-operative Oxford
21 Scores may unduly influence regression modelling such as is reported here. Terwee³⁰ suggests that
22 ceiling effects can be considered as present in a health status measure if 15% or more of
23 respondents report the highest value. We are confident that our analysis has not been limited by
24 this as less than 10% of our data was at the upper score limit.
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34 As most patients report high satisfaction with joint arthroplasty there is some doubt as to how
35 discriminating this measure is, and caution has been advised in the use of a standardised instrument
36 for the measurement of satisfaction²³. It is recommended that satisfaction questions should be
37 context and objective specific rather than generic. Although the additional questions we asked were
38 not formally validated as a measure of satisfaction, they were directed explicitly at aspects relating
39 to joint arthroplasty allowing a more in-depth analysis of the individual factors that contribute to
40 overall satisfaction. Though probably reflective of other interventions, the actual generalizability of
41 these findings to other surgical procedures is not known. Satisfaction is significantly influenced by
42 clinical outcome (pain relief, and the avoidance of complications). However it is also significantly
43 influenced by the pathway to care and the hospital experience. The relative proportions to which
44 these factors contribute towards overall satisfaction are likely to differ by condition or treatment
45 depending on the success of treatment for different conditions. The most appropriate time point for
46 assessing satisfaction has not been described; with some authors reporting satisfaction immediately
47 post discharge. We chose to survey our patient's satisfaction with outcome 12 months following the
48 index procedure as this is a time commonly agreed to represent the final outcome and is consistent
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3 with other arthroplasty studies. Waiting times for surgery are also thought to influence satisfaction,
4 though we were not able to assess this in our study, as all patients were operated on within 12
5 weeks of being listed for procedure, as is a requirement of planned surgical intervention in Scotland.
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11 Recently there has been a focus on quality in the NHS (improving clinical outcomes and reducing
12 complications) which has been highly successful. Significant reductions in hospital acquired
13 infections, waiting times and specific procedure related problems (such as dislocation following hip
14 replacement) are all reported, yet patient satisfaction with outcome has remained constant over this
15 timeframe²⁻⁶, and overall satisfaction with the NHS as a whole has actually declined³². In marketing it
16 has been suggested that, focussing on service quality alone, without appreciating how it is delivered,
17 is setting the stage for 'lower customer retention'³³. This remains true when applied to healthcare
18 environment, indeed Baker et al³⁴ note that better performance (in delivering joint replacement
19 outcomes) may bring the reward of more customers, as patients and commissioners seek out high
20 performers for their elective procedures. We speculate that as surgical outcomes have been
21 consistent, and complications reduced, the national reduction in satisfaction with the NHS may in
22 part be due to fragmented pathways of care to surgery and a concentration on administering time
23 targets rather than managing patient care in its wider context.
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33 In conclusion, overall patient satisfaction following joint arthroplasty is significantly affected by
34 fulfilment of pre-surgical expectations, symptomatic pain relief achieved following surgery and the
35 hospital experience. The Oxford Scores contributed a minimal additional influence in a model which
36 explained 97% of the variation in overall satisfaction response. Focussing on administration of
37 waiting lists as opposed to managing the patient's experience may be influencing the observed
38 reduction of satisfaction with healthcare delivery. This is particularly evident for joint replacement in
39 NHS facilities, where emergency admissions often de-prioritise "elective" surgeries leading to
40 differences in satisfaction between units focussed on the patient pathway for one condition or
41 treatment and those providing the generality of care where focus has been blurred and priority is
42 given to emergency services.
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11
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13

14 **Declaration of competing interests**

15
16 “All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf
17 (available on request from the corresponding author) and declare: no support from any organisation for the
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19 (AHRW Simpson) by Stryker Orthopaedics, P Gaston has previously worked as a consultant for Stryker
20 Orthopaedics, CR Howie is the president elect of the British Orthopaedic Association. The authors declare no
21 additional potential conflict of interest with the submitted work. ”
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27 **Contributorship statement**

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29 All authors contributed to the conception and design, or analysis and interpretation of data, drafting the article
30 or revising it critically for important intellectual content and final approval of the version to be published. CRH
31 is the guarantor.
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35 **Data Sharing**

36
37 The dataset is available via the corresponding author though is subject to approval of the data manager due to
38 NHS restrictions in place to protect patient confidentiality.
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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1,3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4,5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4,5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4,5
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	4,5
Bias	9	Describe any efforts to address potential sources of bias	4,5
Study size	10	Explain how the study size was arrived at	4,5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5,6
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	5
		(d) If applicable, explain how loss to follow-up was addressed	5
		(e) Describe any sensitivity analyses	
Results			

Participants	13*	(a) 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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	5
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	6,7
Outcome data	15*	Report numbers of outcome events or summary measures over time	6
Main results	16	(a) 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 (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	6,7,8
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9,10,11
Generalisability	21	Discuss the generalisability (external validity) of the study results	9,10,11
Other information			
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	12

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.