BMJ Open

How do surgeons trade-off between patient outcomes and risk of complications in total knee arthroplasty? A discrete choice experiment

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-029406
Article Type:	Research
Date Submitted by the Author:	28-Jan-2019
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Keywords:	Orthopaedic & trauma surgery < SURGERY, Medical decision-making, Discrete choice experiment, Total joint replacement

Title page

Title	**How do surgeons trade-off between patient outcomes and risk of complications in total knee arthroplasty? A discrete choice experiment**
Running head	Surgeon risk and outcome trade-offs
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Financial disclosures/ funding statements	Financial support for this study was provided entirely by a grant from the National Health and Medical Research Grant Project, Grant no. APP1058438 (www.nhmrc.gov.au, nhmrc@nhmrc.gov.au, phone: +61 2 6217 9000). The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report.
Ethical approval	This study was approved by the St. Vincent's Human Research Ethics Committee (HREC-A 177/15)
Potential conflicts of interest	All authors declare that no potential conflict of interests exist.
Word count	3498
Number of pages	19
Number of references	39
Number of figures	2
Number of tables	3
Supplementary file	Tables: 2

	Figures: 1
Acknowledgements	We acknowledge all the participants in the survey. We also acknowledge the surgeons, patients and other medical professionals who took part in the pre-testing phases and gave their time to the project. Associate Professor Michelle Dowsey holds an NHMRC Career Development Fellowship (APP1122526). Associate Professor Mandana Nikpour holds an NHMRC Career Development Fellowship (APP1126370). Professor Peter Choong holds an NHMRC Practitioner Fellowship (APP1154203). Dr Jinhu Li holds an ARC Discovery Early Career Researcher Awards (Project ID: DE170100829).

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ABSTRACT

Objective To measure the trade-off between risk of complications versus patient improvement in pain and function in orthopaedic surgeons' decisions about whether to undertake total knee arthroplasty (TKA).

Methods A discrete choice experiment asking surgeons to make choices between experimentally-designed scenarios describing different levels of operative risk and dimensions of pain and physical function. Variation in preferences and trade-offs according to surgeon-specific characteristics were also examined.

Results The experiment was completed by a representative sample of 333 orthopaedic surgeons (n=333): median age 52 years; 94% male; 91% fully qualified. Orthopaedic surgeons were willing to accept substantial increases in risk associated with TKA surgery for greater improvements in a patient's pain and function. The maximum risk surgeons were willing to accept was 40% for reoperation and 102% for the need to seek further treatment from a GP or specialist in return for a change from post-operative severe night-time pain at baseline to no night-time pain at 12-months. With a few exceptions, surgeon-specific characteristics were not associated with how much risk a surgeon is willing to accept in a patient undergoing TKA.

Conclusion This is the first study to quantify risk-benefit trade-offs among orthopaedic surgeons performing TKA, using a discrete choice experiment (DCE). This study provides insight into the risk tolerance of surgeons.

Key words Medical decision-making; discrete choice experiment; joint replacement; surgery.

Strengths and limitations of this study

- To the best of our knowledge, this study is the first to investigate the trade-offs between improvements in pain and function and risk of TKA surgery using a DCE in orthopaedic surgeons
- The choice task allows researchers to quantify how surgeons weigh up their trade-offs between defined benefits and risks of surgery
- This novel method reveals unique insights into the decision-making process of surgeons
- The DCE may lack external validity if surgeons do not make the same choices in real life
- The analysis of the DCE did not include a comparison to a 'status quo' patient

INTRODUCTION

The decision to undertake surgery is based on a consideration of the risks of complications as well as potential benefits to patients in terms of reduction in pain and improvement in physical function. Despite the daily demand for surgeons to make risk-benefit trade-offs there is limited research on the risk tolerance of surgeons and its influence on decisions to perform surgery. It is possible that surgeons focus on the risks of complications rather than benefit, as complications are more readily observed and documented, whereas improvements in post-operative pain and function are more subjective and are less easily observed and quantified. Alternatively, surgeons may overestimate the benefits and underestimate the risks of surgery (1).

The purpose of this study was twofold. Firstly, to understand how orthopaedic surgeons balance the post-operative improvements in patient outcomes (pain and/or function) and risk (surgical complications) when considering patients for TKA. Secondly, we sought to identify

whether surgeon characteristics are associated with preferences in terms of risk-benefit trade-offs.

Osteoarthritis (OA), one of the most disabling diseases in developed countries, affects over three million people worldwide (2). Total knee arthroplasty (TKA) is the mainstay of treatment for end-stage knee OA. TKA can improve quality of life and reduce pain, joint deformity and loss of function. In 2016, nearly 53,000 primary TKA surgeries were performed across Australia, an increase of 139.8% since 2003 (3). This rapid increased is witnessed throughout OECD countries, where on average the rate of knee replacements nearly doubled between 2000 and 2015 (4). The increased prevalence of OA and hence demand for TKA surgery is largely due to an ageing population.

METHODS

Study design

A discrete choice experiment (DCE) was administered to orthopaedic surgeons via a mailed and online survey, including orthopaedic fellows-in-training, to elicit the maximum acceptable risk they are willing to take in TKA. The survey took 30 minutes to complete and was divided into five sections in the following order: demographic information; surgical risk ranking; preferences and outcomes; work setting; and surgeon-specific characteristics. Respondents compared a series of hypothetical but realistic scenarios describing 12-month post-TKA outcomes and risks of complications. Figure 1 gives an example of a choice pair administered to participants.

Selection and development of attributes and levels for DCE

The attributes of the DCE were designed to reflect the most salient aspects of the risks of complications and patient outcomes for TKA (Figure 2) using accepted methods (5). This

was based on an extensive literature review, face-to-face interviews with patients and orthopaedic surgeons, and feedback from a panel of orthopaedics, rheumatology, primary care and health economics experts. Six attributes were included in the DCE each with three different levels, covering pain, physical function and risks associated with TKA surgery.

Pain and function attributes were derived from the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (6), a widely-used and validated questionnaire designed specifically to evaluate patient responses to knee OA treatment. The assigned levels were determined by the 12-month post elective primary TKA surgery WOMAC scores held by the St. Vincent's Melbourne Arthroplasty (SMART) registry for patients who underwent surgery at St Vincent's Hospital Melbourne (SVHM), a large metropolitan hospital in Australia. The SMART Registry captures information from surgeons performing joint arthroplasty and participants are demographically representative of the Australian patient population (7). Registry data collection started in 1998 and > 11,000 procedures are now registered with 800 new yearly registrations. The Registry has complete capture of all pre and postoperative encounters and achieves 98% follow-up of patient-reported outcome measures at 1 year.

The absolute risk attributes were developed by identifying the most common complications within 12-months post-TKA surgery using 2006 – 2012 SMART registry data (n=2,552). The numerous types of complications were aggregated into two categories for the DCE and worded so they could be easily understood by patients for the purposes of future use in a patient cohort and patient/surgeon comparisons (8): 'Risk of having to go back into hospital and having a second operation on your knee' and 'Risk of getting a complication that requires seeing your GP or specialist for further treatment'. The attribute levels varied by the minimum (0% for both risk attributes), median (7% for risk of re-operation and 10% for risk of a complication that requires a new specialist or GP visit) and maximum (13% for risk of

re-operation and 21% for risk of a complication that requires a new specialist or GP visit) rate of the identified risks according to the registry data. Following best practice in DCE design, the risk information was presented using icon arrays as visual aid to numerical presentation (Figure 1) (9, 10).

Experimental design

The six attributes and their corresponding levels (shown in Figure 2) have a possible $3^6 = 729$ different combinations of outcome scenarios (6 attributes with 3 levels each).All 729 scenarios were not presented to each respondent due to likely respondent fatigue and low response rates (11). Using Ngene 1.2 (12) software, a fractional factorial experimental design was used to reduce the number of scenarios whilst maximising the variation in the data (13). An efficient design was used, allowing for attributes to be independently varied over scenarios whilst minimising predicted standard errors of the parameter estimates. Specifically, we used a D-efficient design in which the D-error is minimized (14). The final optimal design included 12 choice pairs. To reduce the cognitive burden and fatigue for the respondents, these 12 choice pairs were "blocked" and allocated across two versions of the DCE questionnaire, each with six choice pairs. Participants were randomly allocated to one of the two versions of the questionnaire. Each choice pair consisted of two alternative scenarios (see Figure 1), which were labelled 'Choice A' and 'Choice B'. Respondents chose their preferred outcome, either 'Choice A' or 'Choice B', for each of the six choice pairs presented to them. Following each choice pair, an opt-out was offered to account for the voluntary nature of elective TKA. The respondent was asked, given their choice, whether they would prefer to perform the operation or rather their patient remained in their current health state.

Experimental design testing

The survey instrument underwent rigorous pre-testing at the design stage to verify the appropriateness of the precise wording and framing of the attributes and their corresponding levels followed by two phases of piloting. Phase 1 involved systematic face-to-face interviews with 5 orthopaedic surgeons. For phase 2, 21 orthopaedic surgeons completed the full pilot version of the survey. Patients undergoing TKA at SVHM were also involved in both phases of piloting. Prior information on the regression coefficients from the analysis of the pilot were used to help generate the final experimental design. The DCE was designed with the intention of being completed by both patients and surgeons.

Data collection

All orthopaedic surgeons across Australia were invited to participate. Participants were identified using a database provided by the Australian Medical Publishing Company (AMPCo) which holds contact details for all doctors in Australia. In October 2016, 1,257 orthopaedic surgeons, including fellows-in-training, were invited to participate in the study using a mixed mode of approach and completion (15). They were contacted via mail-out and, for those with a known email address, also by email. A postal invitation included a personalised letter explaining the study, a prepaid return envelope, instructions on how to complete the survey online and a hardcopy of a randomly allocated survey. Participants chose whether to fill out the hardcopy or online version. The email invite included information about the study and a link to access their online survey. The completion of the questionnaire implied their voluntary consent to participate in the research. For surgeons who responded twice, submitting both online and hardcopy versions of the survey, the most complete entry was chosen in the analysis. If both responses were completed equally the online version was chosen to minimise the risk of administrative error in entering the data. All responses were anonymous, and all information held in the strictest of confidence. This study was approved by the St. Vincent's Human Research Ethics Committee (HREC-A 177/15).

Study size

A target sample size of 400 surgeons and registrars was defined to support effective subgroup analysis for the DCE. Our Monte Carlo simulation indicated that the minimum required sample was 200 surgeons with 12 choice pairs. However, since the 12 choice pairs were blocked into two versions of DCE, the target sample size increased to 400 surgeons (16).

Statistical methods

The DCE was analysed using a mixed logit model. A well-defined mixed logit model can approximate any discrete choice random utility model (17) and therefore is preferred throughout the DCE literature (18) and widely applied in health economics (11, 19). Unlike other logit models, the mixed logit model can account for unobservable preference heterogeneity by including random coefficients. These random coefficients capture how preferences for each attribute will vary over individuals, allowing for the estimation of individual-specific coefficients that follow a pre-specified distribution. Hence the mixed logit model is associated with having better 'goodness of fit' than other logit models.

The DCE data contain 12 observations from six choice pairs per survey respondent. Each observation is one of the two alternatives from each of the six choice pairs presented, and with the dependent variable equal to one or zero for each choice pair. Observations from respondents with missing values of the dependent variable were excluded from the analysis. In the estimation of the model, categorical variables (i.e., the attributes and associated levels) were coded as dummy variables with 'severe' as the omitted reference category. The risk attributes were continuous variables. To examine the association between each attribute and surgeon characteristics, interaction terms were included in the mixed logit model. The inclusion of random coefficients in the model gives each individual their own regression coefficient (20). The results show the mean and standard deviation of these coefficients. A

statistically significant standard deviation shows that there is variation across individual surgeons in their preferences for the given attribute, that is, they do not 'agree' as to its relative importance.

To extract the relative importance of the attributes and their levels, the marginal rate of substitution (trade-offs) is calculated between one of the risk attributes and each quality of life attribute, by dividing the estimated coefficient of quality of life attribute (pain or function) by the estimated coefficient of risk attribute. This addresses the question of how much additional risk is equivalent to a health improvement, for example, from severe day time pain to no day time pain.

Surgeon-specific characteristics

Interaction terms between each attribute and the characteristics listed below allowed for the examination of surgeon-specific factors influencing preferences and trade-offs. From the literature, four characteristics were analysed. Procedure volume was analysed as a dichotomous variable where a high-volume surgeon was defined as a surgeon who performs above or equal to the median number of TKA surgeries per week in the sample (≥3.25), only surgeons who performed >0 TKA surgeries in their 'last usual working week' were included in the analysis. Experience, encompassing both age and seniority, was measured as a continuous variable by the number of years since the respondent became a Fellow of the Royal Australian College of Surgeons (FRACS). Given this definition, fellows-in-training were therefore had the least experience. Surgeon personality was measured using the Big Five Personality Index (BFI) (21); Mastery Locus of Control (LOC) (22); and Life Orientation Test-Revised (LOTR) (23). The BFI tests for a set of five broad trait dimensions (neuroticism, extraversion, openness to experience, agreeableness and conscientiousness), see Supplemental Table 1 for an overview. The LOC evaluates the control an individual has over

their everyday life and the LOTR measures optimism. Finally, to investigate whether risk attitudes vary between surgeons who perform more TKA procedures in a public compared with private hospital, the proportion of public to private TKAs performed in a surgeon's average week was included as an interaction term with each attribute. The majority of TKA surgery is performed in the private sector where doctors are remunerated on a fee for service basis (24). Fee for service may provide a financial incentive to surgeons and hence, could increase surgeons' propensity to overestimate the benefits and underestimate the risks.

RESULTS

Amongst the 1,257 surgeons contacted, 434 responded (34.5%). Seventy-two (16.6%) responses were refusals to complete the survey. Reasons for refusal included 'do not perform TKA' and 'being retired'. A total of 362 completed and 18 'return to sender' surveys were returned, a participation rate of approximately 29%. See Supplemental Figure 1 for consort diagram. Of the 362 who returned the survey, 333 selected at least one alternative from the each of the six choice pairs in the DCE. These 333 respondents provided 3,862 observations for the analysis, out of a possible 3,996 (333 x 12) observations. A comparison of the population of orthopaedic surgeons from the AMPCo sample frame with respondents is summarised in Table 1. The median age of respondents was 52 years (IQR 44 - 59 years). Most respondents were male (94%) and fully-qualified orthopaedic surgeons (91%). The survey sample was representative of the population except for fellows-in-training who were underrepresented and surgeons performing TKA in Victoria and Tasmania were overrepresented. Respondents had an average of almost 20 years of experience and performed an average of 4 TKAs per week. For every 10 TKAs performed in a private hospital, 4 were conducted in a public hospital (Table 1).

Table 1 Respondent demographic and personality/practice characteristics

	Estimation sample (n=333)	Sample frame (n=1257)
Characteristics		
Male, no. (%)	314 (94.3)	1199 (95.4)
Age, year (IQR)	52 (44 - 59)	50 (42 - 60)
Practice status, no. (%)		
Accredited registrar	16 (4.8)	120 (9.6)
Consultant	304 (91.3)	1124 (89.4)
Other	12 (3.6)	13 (1.0)
Australian states and territories, no. (%)		
Victoria	93 (27.9)	275 (21.9)
New South Wales	92 (27.6)	408 (32.5)
South Australia	23 (6.9)	113 (9.0)
Queensland	58 (17.4)	271 (21.6)
Northern Territory	3 (0.9)	6 (0.5)
Western Australia	29 (8.7)	136 (10.9)
Tasmania	12 (3.6)	24 (1.9)
Australian Capital Territory	6 (1.8)	23 (1.8)
Residency status, no. (%)		
Australian citizen	308 (92.5)	-
Permanent resident	19 (5.7)	-
Temporary resident	3 (0.9)	-

	Mean	Std. Dev.	Min	Max
Personality traits:				
BFI – extraversion	3.20	0.82	1	5
BFI – agreeableness	4.09	0.71	2	5
BFI – conscientiousness	4.45	0.54	2	5
BFI – neuroticism	2.62	0.87	1	4.67
BFI – openness	3.63	0.73	1.33	5
LOC	8.28	1.84	1.86	11
LOTR	23.84	4.00	11	30
Surgeon Experience:				
Years of experience	19.76	10.49	1	55
Surgeon Volume:				
TKA per week	3.65	4.56	0	60
Proportion of high volume surgeons	0.43	0.50	0	1
Public vs Private TKA surgery:				
Proportion of public to private	0.40	0.34	0	1

Note: Personality traits were standardised for the regression analysis, hence mean=0 and standard deviation=1. Zero observations were excluded in the regression analysis for the high-volume and proportion of public to private procedures performed interaction effects. The median number of TKA surgeries per week was used to determine high and low volume surgeons

The estimated mixed logit model results are presented in Supplemental Table 2. It is not possible to draw direct inferences from the coefficients however, the signs are as expected and significant at the 1% level: surgeons prefer patients to suffer from less pain, have better function and for there to be less risk of adverse events occurring. Shown by the standard deviations, there is statistically significant variation in surgeons' preferences for most attributes. The insignificant constant term illustrates no surgeon preference for 'Choice A' or 'Choice B' and tests for specification error.

The marginal rate of substitution between risk and patient outcomes are shown in Table 2. The relative size of these trade-offs indicates the relative importance of each health improvement to surgeons. Surgeons believe that the alleviation of night time pain is the most important attribute, compared to all other attributes they are willing to accept the maximum risk to achieve this. To improve a patient's night time pain from severe to no pain surgeons are willing to accept a 40% or 102% increase in the risk of re-operation or the risk of a complication which requires a specialist or GP visit, respectively. Reducing pain is generally more important to surgeons than improvements in functioning. The relative importance is similar when trading off the risk of a complication that requires a new specialist or GP visit. For each attribute, surgeons are willing to accept higher risks of complications requiring GP/specialist visits, compared to risk of re-operation which they consider to be more serious. For example, surgeons are prepared to accept an 87% increase in the risk of a complication requiring a specialist or GP visit to reduce day time pain from severe at baseline (pre-surgery) to no pain at 12 months. For the same improvement for patients they are only willing to accept a 34% increase in the risk of re-operation.

Table 2 Trade-offs between risk and patient outcomes: marginal rate of substitution

	Risk of re-operation		Risk of complication requiring a new GP/specialist visit	
	Coeff	Std. Error	Coeff	Std. Error
Pain outcomes:				
No day time pain	-34.06***	4.01	-87.02***	17.96
Moderate day time pain	-25.27***	3.18	-64.54***	14.19
No night time pain	-39.98***	4.72	- 102.13***	22.08
Moderate night time pain	-25.73***	2.86	-65.73***	13.44
Functional outcomes:				
No difficulty standing	-27.65***	5.00	-70.63***	18.62
Moderate difficulty standing	-17.33***	3.07	-44.28***	10.79
No difficulty moving	-20.62***	2.43	-52.67***	12.18
Moderate difficulty moving	-9.72***	1.56	-24.84***	6.09
Risk of complications:				
Risk of new GP/specialist visits	0.39***	0.06	-	-
Risk of reoperation	-	-	2.55***	0.41

*** p≤0.01, **p≤0.05, * p≤0.1

Coeff = coefficient, Std. Error = standard error

Note: the marginal rate of substitution is calculated between one of the risk attributes and each quality of life attribute, by dividing the estimated coefficient of quality of life attribute (pain or function) by the estimated coefficient of risk attribute. Categorical variables for pain and function were coded as dummy variables with 'severe' as the omitted reference category. The risk attributes were continuous variables.

Furthermore, a 1% increase in the risk of re-operation is shown to be equal to a 2.55% increase in the risk of new GP visits within the first year after TKA. The risk of re-operation is 2.55 times more important to surgeons than the risk of a complication requiring only a specialist or GP visit. Hence surgeons are less willing to risk patients being readmitted to undergo another surgery than seeing their GP or specialist.

Table 3 summarises the direction and statistical significance of the interactions between surgeon preferences for each attribute, and the volume of TKA, personality traits, experience, and public-private mix. Overall, there were few statistically significant associations. There was a weak negative relationship between high-volume surgeons and improvement in the function outcome (difficulty standing and walking on a flat surface) from moderate to no

Table 3 Summary of mixed logit interaction effects

	Pain outcomes				Function outcomes				Risk of complications	
	No day time	Moderate day time pain	No night time	Moderate night time pain	No difficulty standing	Moderate difficulty standing	No difficulty moving	Moderate difficulty moving	Re-operation	New GP visits
Surgeon Personality Traits										
BFI - Openness	[-] ns	[-] ns	[-] ns	[+] ns	[+] **	[+] **	[-] ns	[-] ***	[+] ns	[+] ns
BFI - Consciousness	[+] ns	[+] ns	[-] ns	[-] ns	[-] ns	[-] ns	[+] ns	[+] ns	[-] ns	[+] ns
BFI - Extraversion	[-] ns	[-] ns	[-] ns	[+] ns	[-] ns	[-] ns	[+] ns	[-] *	[+] ns	[+] ns
BFI - Agreeableness	[+] ns	[+] ns	[+] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+]**	[-] ns	[-] ns
BFI - Neuroticism	[-] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+] ns
LOC	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[+] ns	[-] ns	[+] ns
LOTR	[+] ns	[+] ns	[+] ns	[+] ns	[+] ns	[+] ns	[+] ns	[+] *	[-] *	[-] ns
Surgeon experience										
Years of experience	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[-] *	[+] ns	[+] ns
Surgeon volume										
High volume surgeons	[+] ns	[+] ns	[+] ns	[-] ns	[+] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+] ns
Public vs private TKA surgery										
Proportion of public to private	[-] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+] ns

***p≤0.01, **p≤0.05, *p≤0.1, ns = not significant, sign of coefficient in square brackets

Note: The sample size of each model varies from between 2892 and 3680 observations, from between 245 and 310 respondents.

difficulty. There was no statistically significant association between public-private mix and any of the attributes.

Surgeons with more experience were less likely to value an improvement of severely to moderately impaired functioning and moderate day-time to no-day time pain, but there was no association with the risk attributes.

More 'open' surgeons were likely to find the ability to stand more important but the ability to move less important. There was no association with LOC and only weak association between 'optimism' (LOTR) and severe to moderately impaired function.

DISCUSSION

This study is the first of its kind to investigate the trade-offs between improvements in pain and function and risk of TKA surgery using a DCE in orthopaedic surgeons. The choice task allows the elicitation of risk tolerance to be quantified by weighing up the different outcome alternatives (pain, function and risk).

Surgeons are willing to accept a large increase in the risk of complication requiring a return to hospital for a follow up knee operation up to a maximum of 40%, to achieve the elimination of night time pain (from severe to none 12 months after the procedure). This figure is 102% for a complication that requires a GP or specialist visit for further treatment. These trade-offs show that across all attributes, surgeons are willing to accept higher risks of GP/specialist visits in comparison to reoperation. This is unsurprising as complications requiring reoperation are likely to be much more severe than those that can be treated in an ambulatory visit.

Surgeons were willing to accept the same amount of risk for improvements in each attribute regardless of personality type, experience, procedure volume or whether a surgeon performed

TKA surgery in a public or private setting. Suggesting that their preferences for risk and patient outcomes, and how they trade them off, do not vary along these dimensions, though preferences do vary due to other unobserved factors.

With regards to surgeon personality, the literature is conflicted. Despite evidence that surgeon personality influences risk tolerance (25) and decision making (26), the 'surgical personality' (27-30) suggests that all surgeons have inherent personality traits that are different to non-surgeons. Hence there may be less variation within surgeons, especially within specialities such as orthopaedic surgeons. The 'surgical personality' is a consequence of surgeons' self-selection into the profession and their continual rigorous standardised training throughout their career. Though Table 1 suggests some variation in personality, this may not have been sufficient variation to influence their preferences.

The finding that neither experience nor volume of TKAs influenced their preferences, suggests that surgeons are homogenous with respect to the importance they place on risk and patient outcomes. Though the risk of adverse events is associated with volume (31-34) and experience (35) through a broader and more refined skillset of high-volume surgeons compared to low-volume surgeons (36, 37), surgeons may be unaware of this relationship such that the importance of risk does not vary. We were not able to collect data on the extent to which respondents had patients who had experienced adverse events.

Our hypothesis that surgeons in the private sector may overestimate the benefits and underestimate the risks was not supported. It is uncommon for surgeons to exclusively operate in either a public or private hospital in Australia and unlikely that individual surgeons have specific 'public' and 'private' surgeon behaviours which are different. Additionally, evidence suggests that the quality of care among TKA patients is not compromised regardless of whether the surgery is performed by a public or private healthcare provider (38).

There are several limitations to this study. Firstly, the DCE may lack external validity if surgeons do not make the same choices in real life. Despite the outcome choices presented in the DCE being realistic and based on real data, the choice task was hypothetical. However, a recent systematic review and meta-analysis showed that choice experiments provide a reasonable approximation to actual choices (39). DCEs are especially useful in situations where data on actual choices are difficult to collect.

Secondly, data were also collected on whether the surgeons, conditional on their choice of A or B, would rather not perform the operation (Figure 1). These data were not analysed in this paper which was focussed more on the trade-offs between risk and patient outcomes. This option was not included as a potential third 'status quo' alternative in the analysis since no specific attribute levels could be assigned to this. In addition, the question was framed as an additional question (conditional on choice of A or B), rather than being included as a third mutually exclusive alternative.

This study is part of a larger project exploring risk-preferences of surgeons and patients. Moving forward, research into risk-benefit trade-offs of patients considering TKA as a treatment option for end-stage OA will be undertaken. This research has implications for both clinicians and policy makers and provide insight into whether surgeon and patient preferences are aligned. In turn, this will allow for improvements in surgical outcomes and greater patient satisfaction.

Patient and public involvement statement: This study is part of a larger study which will additionally investigate the maximum acceptance of risk of patients in TKA. The DCE for both surgeons and patients were defined by the same attributes and levels. Patients were involved in the pretesting of the survey instrument. Participants had end-stage OA and were recruited at

the orthopaedic preoperative assessment clinic after being consented and waitlisted for primary TKA at SVHM.

The initial pretesting phase with patients consisted of detailed face-to-face interviews with 15 patients. For the second phase, 40 patients completed the pilot survey. Patient feedback was sought for the ease of comprehension of wording and framing of the attributes and their corresponding levels, efficacy figures, icon arrays and the length of questionnaire. The main issues raised were around the language used, the wording of the attributes was consequently changed to improve understanding.

Contributors: SS was an investigator, conducted the literature search and statistical analysis, contributed to data interpretation and drafted and revised the paper. PC was a chief investigator, was involved in the design of the study, provided management oversight of the whole trial, contributed to data interpretation and drafted and revised the paper. JL was an investigator, wrote the statistical analysis plan, conducted statistical analysis, contributed to data interpretation and drafted and revised the paper. EN was the study co-ordinator, responsible for participant recruitment, provided technical support to participants, monitored data collection for the whole trial, drafted and revised the paper. MN and VS were chief investigators, designed the study, contributed to data interpretation and drafted and revised the paper. AS was a chief investigator, designed the study, provided management oversight over the statistical analysis, contributed to data interpretation and drafted and revised the paper. MD was the lead investigator, initiated the collaborative project, designed the study, monitored data collection for the whole trial, provided management oversight of the whole study, contributed to data interpretation, drafted and revised the paper, and is the guarantor.

All authors contributed to redrafts of the report. All authors had full access to the study data and take responsibility for the integrity of the data and the accuracy of the data.

Acknowledgements: Associate Professor Michelle Dowsey holds an NHMRC Career Development Fellowship (APP1122526). Associate Professor Mandana Nikpour holds an NHMRC Career Development Fellowship (APP1126370). Professor Peter Choong holds an NHMRC Practitioner Fellowship (APP1154203). Dr Jinhu Li holds an ARC Discovery Early Career Researcher Awards (Project ID: DE170100829).

Data sharing: Reasonable requests for surgeon level data should be made to the corresponding author and will be considered by the trial Chief Investigators. Consent for data sharing has not yet been obtained and ethics approval would be required from the study institution for future use of individual surgeon level data.

Competing interest statement: All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

Transparency declaration: The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Ethical approval: This study was approved by the St. Vincent's Human Research Ethics Committee (HREC-A 177/15)

Funding: This research is funded by a National Health and Medical Research Grant Project, Grant no. APP1058438 (www.nhmrc.gov.au, nhmrc@nhmrc.gov.au, phone: +61 2 6217 9000). The funding source had no role in the study design, and will not have any role during its conduct, collection, analyses and interpretation of data, or in the writing of reports and decision to submit for publication.

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Figure Legend

Figure 1 Example of a discrete choice experiment

Figure 2 Attributes and levels included in the discrete choice experiment

Supplementary file

Supplementary figure 1 (SF1) Big Five personality domains and description of traits

Supplementary figure 2 (SF2) Consort diagram

Supplementary table 1 (ST1) Mixed logit model results

Imagine you have performed a TKR on a patient and the following scenarios describe:

- the level of pain and function experienced **at 12 months after surgery**; and
- the likelihood of complications **during the first 12 months** after surgery.

The scenarios are based on actual data 9 to 12 months post-surgery. Data was acquired from a prospective longitudinal cohort of patients undergoing TKR.

Some of the scenarios presented below may be better than you expect, while others may be worse.

In each of the questions in this section you are asked to compare two possible outcomes, *Choice A* and *Choice B*, and each question has two parts.

First, for each question you are asked to choose which of the two post-operative outcomes (A or B) you consider to be better overall.

Second, assuming Choice A or Choice B are the *only* two possible outcomes, you are asked to decide whether you would still obtain consent from the patient for surgery, or choose not to waitlist the patient, whereby they would remain in their current state of health.

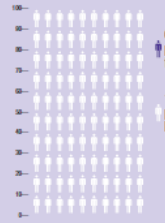
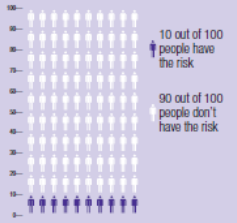
You will be asked to complete six activities.

There are no right or wrong answers.

Pain and Function items use the following scale:

None | Mild | Moderate | Severe | Extreme

Q3. Choice 1 of 6:

	Choice A	Choice B
Standing and walking on flat surface 9–12 months after surgery	No difficulty standing and walking	Severe difficulty standing and walking
Bending to floor, rising from sitting, going up and down stairs 9–12 months after surgery	No difficulty bending to floor, rising from sitting, going up and down stairs	Severe difficulty bending to floor, rising from sitting, going up and down stiars
Risk of having to go back into hospital and have a second operation on your knee (e.g. due to knee stiffness, wound/ joint infection)		
Risk of getting a complication that requires seeing your GP or specialist for further treatment (e.g. blood clot, skin infection, confusion)		
Day-time pain 9–12 months after surgery	Moderate day-time pain	No day-time pain
Night-time pain 9–12 months after surgery	No night-time pain	Moderate night-time pain

i. Which of the possible outcomes above do you think is better? ☐ Choice A ☐ Choice B

ii. Given your choice above, would you still perform the operation? ☐ Yes ☐ No (Patient to remain in current health state)

Figure 2 Attributes and levels included in the discrete choice experiment

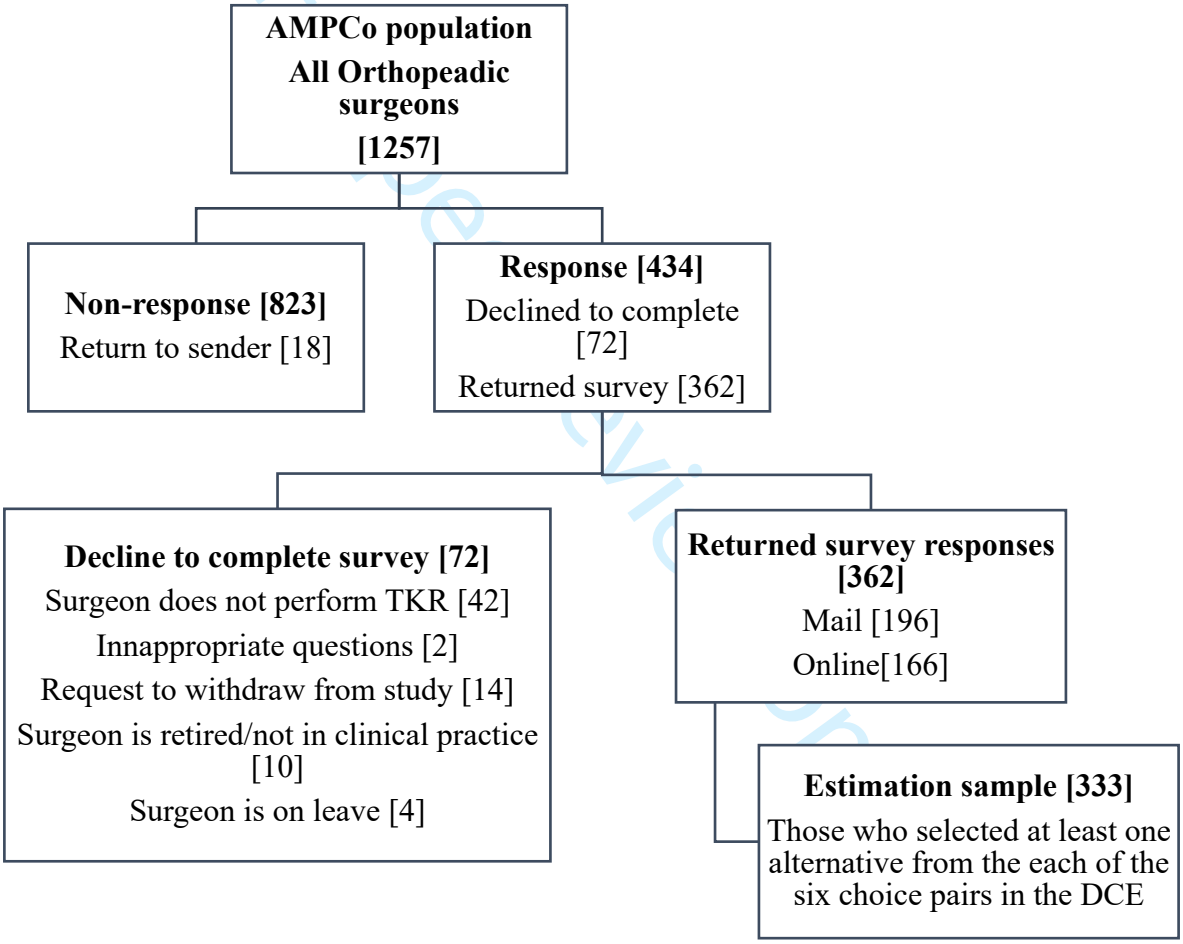
Attributes	Levels	Variable coding for analysis
Pain outcomes:		
1. Day-time pain 9-12 months after surgery	No day-time pain; moderate day-time pain; and severe day-time pain.	Dummy variable – 'severe day-time pain' was the omitted reference group
2. Night-time pain 9-12 months after surgery	No night-time pain; moderate night-time pain; and severe night-time pain.	Dummy variable – 'severe night-time pain' was the omitted reference group
Functional outcomes:		
3. Standing and walking on a flat surface 9-12 months after surgery	No difficulty standing and walking; moderate difficulty standing and walking; and severe difficulty standing and walking.	Dummy variable – 'severe difficulty standing and walking' was the omitted reference group
4. Bending to the floor, rising from sitting and going up and down stairs 9-12 months after surgery	No difficulty bending from the floor, rising from sitting and going up and down stairs; moderate difficulty bending to the floor, rising from sitting and going up and down stairs; and severe difficulty bending from the floor, rising from sitting and going up and down stairs.	Dummy variable – 'severe difficulty bending from the floor, rising from sitting and going up and down stairs' was the omitted reference group
Risk of complications:		
5. Risk of having to go back into hospital and have a second operation on your knee (e.g. due to knee stiffness, wound/joint infection)	0%, 7%, 13%	Continuous
6. Risk of getting a complication that requires seeing your GP or specialist for further treatment (e.g. blood clot, skin infection, confusion)	0%, 10%, 21%	Continuous

Supplementary file

Supplementary Table 1 Big Five personality domains and description of traits

Big Five dimensions	Description
Openness to experience	Open-minded, curious, creative
Conscientiousness	Organised, diligent, responsible
Extraversion	Sociable, enthusiastic, out-going
Agreeableness	Good natured, altruistic, cooperative
Neuroticism	Anxious, stressed, irritable

Supplementary Figure 1 Consort diagram



Supplementary Table 2 Mixed logit model results

	Parameter	Coeff	Std. Error
Pain outcomes:			
No day time pain	Mean	4.88***	0.71
	Std. Deviation	1.71***	0.35
Moderate day time pain	Mean	3.62***	0.52
	Std. Deviation	0.10	0.07
No night time pain	Mean	5.72***	0.76
	Std. Deviation	1.88***	0.39
Moderate night time pain	Mean	3.68***	0.52
	Std. Deviation	0.93***	0.33
Functional outcomes:			
No difficulty standing	Mean	3.96***	0.61
	Std. Deviation	0.70	0.62
Moderate difficulty standing	Mean	2.48***	0.43
	Std. Deviation	-0.04	0.09
No difficulty moving	Mean	2.95***	0.45
	Std. Deviation	1.41*	0.70
Moderate difficulty moving	Mean	1.39***	0.24
	Std. Deviation	-0.21	0.23
Risk of complications:			
Risk of new GP/specialist visits	Mean	-0.14***	0.03
	Std. Deviation	0.07***	0.02
Risk of reoperation	Mean	-0.06***	0.02
	Std. Deviation	-0.04*	0.02
Constant term	Mean	0.01	0.14
Number of responses		3862	
Number of respondents		333	
Log-likelihood		-796.85	
Prob > Chi2		0.0000	

*** p≤0.01, **p≤0.05, * p≤0.1

Coeff = coefficient, Std. Error = standard error

Notes: Categorical variables for pain and function were coded as dummy variables with 'severe' as the omitted reference category. The risk attributes were continuous variables.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1	A discrete choice experiment
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1	methods, results and conclusion
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2	
Objectives	3	State specific objectives, including any prespecified hypotheses	2	
Methods				
Study design	4	Present key elements of study design early in the paper	3	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5	
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5	
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	N/A	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3/4/7/8	

Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	3/4/7/8	
Bias	9	Describe any efforts to address potential sources of bias	4/5	
Study size	10	Explain how the study size was arrived at	6	study size
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6/7	
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6/7	
		(*b*) Describe any methods used to examine subgroups and interactions	6/7	
		(*c*) Explain how missing data were addressed	N/A	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	N/A	No follow-up
		(*e*) Describe any sensitivity analyses	N/A	
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	8	
		(b) Give reasons for non-participation at each stage	8	
		(c) Consider use of a flow diagram	Supplementary file figure 2 (SF2)	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8/9	
		(b) Indicate number of participants with missing data for each variable of interest	N/A	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A	No follow-up

Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	N/A	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	N/A	
		Cross-sectional study—Report numbers of outcome events or summary measures	N/A	
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	11	Table 3
		(*b*) Report category boundaries when continuous variables were categorized	7	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11	
Discussion				
Key results	18	Summarise key results with reference to study objectives	13	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14/15	
Generalisability	21	Discuss the generalisability (external validity) of the study results	14	
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	17	

*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.

BMJ Open

How do surgeons' trade-off between patient outcomes and risk of complications in total knee arthroplasty? A discrete choice experiment in Australia

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-029406.R1
Article Type:	Research
Date Submitted by the Author:	23-May-2019
Complete List of Authors:	Szawlowski, Sandie; The University of Melbourne Institute of Applied Economic and Social Research Choong, Peter; The University of Melbourne St Vincent's Department of Surgery; St Vincent's Hospital, Department of Orthopaedics Li, Jinhu; Deakin University, Department of Economics Nelson, Elizabeth ; The University of Melbourne St Vincent's Department of Surgery Nikpour, Mandana; The University of Melbourne St Vincent's Department of Medicine Scott, Anthony; The University of Melbourne Institute of Applied Economic and Social Research Sundararajan, Vijaya; La Trobe University, Department of Public Health Dowsey, Michelle; The University of Melbourne St Vincent's Department of Surgery; St Vincent's Hospital, Department of Orthopaedics
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Surgery
Keywords:	Orthopaedic & trauma surgery < SURGERY, Medical decision-making, Discrete choice experiment, Total joint replacement

Title page

Title	**How do surgeons' trade-off between patient outcomes and risk of complications in total knee arthroplasty? A discrete choice experiment in Australia**
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Address for reprints	Same as corresponding author (see above)
Financial disclosures/ funding statements	Financial support for this study was provided entirely by a grant from the National Health and Medical Research Grant Project, Grant no. APP1058438 (www.nhmrc.gov.au, nhmrc@nhmrc.gov.au, phone: +61 2 6217 9000). The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report.
Ethical approval	This study was approved by the St. Vincent's Human Research Ethics Committee (HREC-A 177/15)
Potential conflicts of interest	All authors declare that no potential conflict of interests exist.
Word count	4205
Number of pages	19
Number of references	41
Number of figures	1
Number of tables	4
Supplementary file	Tables: 2

	Figures: 1
Acknowledgements	We acknowledge all the participants in the survey. We also acknowledge the surgeons, patients and other medical professionals who took part in the pre-testing phases and gave their time to the project. Associate Professor Michelle Dowsey holds an NHMRC Career Development Fellowship (APP1122526). Associate Professor Mandana Nikpour holds an NHMRC Career Development Fellowship (APP1126370). Professor Peter Choong holds an NHMRC Practitioner Fellowship (APP1154203). Dr Jinhu Li holds an ARC Discovery Early Career Researcher Awards (Project ID: DE170100829).

How do surgeons' trade-off between patient outcomes and risk of complications in total knee arthroplasty? A discrete choice experiment in Australia

ABSTRACT

Objective To measure the trade-off between risk of complications versus patient improvement in pain and function in orthopaedic surgeons' decisions about whether to undertake total knee arthroplasty (TKA).

Methods A discrete choice experiment asking surgeons to make choices between experimentally-designed scenarios describing different levels of operative risk and dimensions of pain and physical function. Variation in preferences and trade-offs according to surgeon-specific characteristics were also examined.

Results The experiment was completed by a representative sample of 333 orthopaedic surgeons (n=333): median age 52 years; 94% male; 91% fully qualified. Orthopaedic surgeons were willing to accept substantial increases in absolute risk associated with TKA surgery for greater improvements in a patient's pain and function. The maximum risk surgeons were willing to accept was 40% for reoperation and 102% for the need to seek further treatment from a GP or specialist in return for a change from post-operative severe night-time pain at baseline to no night-time pain at 12-months. With a few exceptions, surgeon-specific characteristics were not associated with how much risk a surgeon is willing to accept in a patient undergoing TKA.

Conclusion This is the first study to quantify risk-benefit trade-offs among orthopaedic surgeons performing TKA, using a discrete choice experiment (DCE). This study provides insight into the risk tolerance of surgeons.

Key words Medical decision-making; discrete choice experiment; joint replacement; surgery.

Strengths and limitations of this study

- To the best of our knowledge, this study is the first to investigate the trade-offs between improvements in pain and function and risk of TKA surgery using a DCE in orthopaedic surgeons
- The choice task allows researchers to quantify how surgeons weigh up their trade-offs between defined benefits and risks of surgery
- This novel method reveals unique insights into the decision-making process of surgeons
- The DCE may lack external validity if surgeons do not make the same choices in real life
- The analysis of the DCE did not include a comparison to a 'status quo' patient

INTRODUCTION

The decision to undertake surgery is based on a consideration of the risks of complications as well as potential benefits to patients in terms of reduction in pain and improvement in physical function. Despite the daily demand for surgeons to make risk-benefit trade-offs there is limited research on the risk tolerance of surgeons and its influence on decisions to perform surgery. It is possible that surgeons focus on the risks of complications rather than benefit, as complications are more readily observed and documented, whereas improvements in post-operative pain and function are more subjective and are less easily observed and quantified. Alternatively, surgeons may overestimate the benefits and underestimate the risks of surgery (1).

The purpose of this study was twofold. Firstly, to understand how orthopaedic surgeons balance the post-operative improvements in patient outcomes (pain and/or function) and risk (surgical complications) when considering patients for TKA. Secondly, we sought to identify whether surgeon characteristics are associated with preferences in terms of risk-benefit trade-offs.

Osteoarthritis (OA), one of the most disabling diseases in developed countries, affects over three million people worldwide (2). Total knee arthroplasty (TKA) is the mainstay of treatment for end-stage knee OA. TKA can improve quality of life and reduce pain, joint deformity and loss of function. In 2016, nearly 53,000 primary TKA surgeries were performed across Australia, an increase of 139.8% since 2003 (3). This rapid increased is witnessed throughout OECD countries, where on average the rate of knee replacements nearly doubled between 2000 and 2015 (4). The increased prevalence of OA and hence demand for TKA surgery is largely due to an ageing population.

METHODS

Study design

A discrete choice experiment (DCE) was administered to orthopaedic surgeons via a mailed and online survey, including orthopaedic fellows-in-training, to elicit the maximum acceptable risk they are willing to take in TKA. The survey took 30 minutes to complete and was divided into five sections in the following order: demographic information; surgical risk ranking; preferences and outcomes; work setting; and surgeon-specific characteristics. Respondents compared a series of hypothetical but realistic scenarios describing 12-month post-TKA outcomes and risks of complications. Figure 1 gives an example of a choice pair administered to participants.

Selection and development of attributes and levels for DCE

The attributes of the DCE were designed to reflect the most salient aspects of the risks of complications and patient outcomes for TKA (Table 1) using accepted methods (5).

Table 1 Attributes and levels included in the discrete choice experiment

Attributes	Levels	Variable coding for analysis
Pain outcomes:		
1. Day-time pain 9-12 months after surgery	No day-time pain; moderate day-time pain; and severe day-time pain.	Dummy variable – 'severe day-time pain' was the omitted reference group
2. Night-time pain 9-12 months after surgery	No night-time pain; moderate night-time pain; and severe night-time pain.	Dummy variable – 'severe night-time pain' was the omitted reference group
Functional outcomes:		
3. Standing and walking on a flat surface 9-12 months after surgery	No difficulty standing and walking; moderate difficulty standing and walking; and severe difficulty standing and walking.	Dummy variable – 'severe difficulty standing and walking' was the omitted reference group

4. Bending to the floor, rising from sitting and going up and down stairs 9-12 months after surgery	No difficulty bending from the floor, rising from sitting and going up and down stairs; moderate difficulty bending to the floor, rising from sitting and going up and down stairs; and severe difficulty bending from the floor, rising from sitting and going up and down stairs.	Dummy variable – 'severe difficulty bending from the floor, rising from sitting and going up and down stairs' was the omitted reference group
Risk of complications:		
5. Risk of having to go back into hospital and have a second operation on your knee (e.g. due to knee stiffness, wound/joint infection)	0%, 7%, 13%	Continuous
6. Risk of getting a complication that requires seeing your GP or specialist for further treatment (e.g. blood clot, skin infection, confusion)	0%, 10%, 21%	Continuous

Six attributes, determined by an extensive literature review, face-to-face interviews with patients and orthopaedic surgeons, and feedback from a panel of orthopaedics, rheumatology, primary care and health economics experts, were included in the DCE. Each attribute covered pain, physical function and risks associated with TKA surgery had three different levels.

Pain and function attributes were derived from the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (6), a widely-used and validated questionnaire designed specifically to evaluate patient responses to knee OA treatment. The assigned levels were determined by the 12-month post elective primary TKA surgery WOMAC scores held by the St. Vincent's Melbourne Arthroplasty (SMART) registry for patients who underwent surgery at St Vincent's Hospital Melbourne (SVHM), a large metropolitan hospital in Australia. The SMART Registry captures information from surgeons performing joint

arthroplasty and participants are demographically representative of the Australian patient population (7). Registry data collection started in 1998 and > 11,000 procedures are now registered with 800 new yearly registrations. The Registry has complete capture of all pre and postoperative encounters and achieves 98% follow-up of patient-reported outcome measures at 1 year.

The absolute risk attributes were developed by identifying the most common complications within 12-months post-TKA surgery using 2006 – 2012 SMART registry data (n=2,552). The numerous types of complications were aggregated into two categories for the DCE and worded so they could be easily understood by patients for the purposes of future use in a patient cohort and patient/surgeon comparisons (8): 'Risk of having to go back into hospital and having a second operation on your knee' and 'Risk of getting a complication that requires seeing your GP or specialist for further treatment'. Patients may have to undergo re-operation on their knee if they have stiffness in the knee or for treatment of surgical site infection. If the patient suffers from a blood clot, ongoing pain or a superficial wound complication they would have to have to see their GP or specialist. The attribute levels varied by the minimum (0% for both risk attributes), median (7% for risk of re-operation and 10% for risk of a complication that requires a new specialist or GP visit) and maximum (13% for risk of re-operation and 21% for risk of a complication that requires a new specialist or GP visit) rate of the identified risks according to the registry data. Following best practice in DCE design, the risk information was presented using icon arrays as visual aid to numerical presentation (Figure 1) (9, 10).

Experimental design

The six attributes and their corresponding levels (shown in Table 1) have a possible $3^6 = 729$ different combinations of outcome scenarios (6 attributes with 3 levels each). All 729

scenarios were not presented to each respondent due to likely respondent fatigue and low response rates (11). Using Ngene 1.2 (12) software, a fractional factorial experimental design was used to reduce the number of scenarios whilst maximising the variation in the data (13). An efficient design was used, allowing for attributes to be independently varied over scenarios whilst minimising predicted standard errors of the parameter estimates. Specifically, we used a D-efficient design in which the D-error is minimized (14). The final optimal design included 12 choice pairs. To reduce the cognitive burden and fatigue for the respondents, these 12 choice pairs were "blocked" and allocated across two versions of the DCE questionnaire, each with six choice pairs. Participants were randomly allocated to one of the two versions of the questionnaire. Each choice pair consisted of two alternative scenarios (see Figure 1), which were labelled 'Choice A' and 'Choice B'. Respondents chose their preferred outcome, either 'Choice A' or 'Choice B', for each of the six choice pairs presented to them. Following each choice pair, an opt-out was offered to account for the voluntary nature of elective TKA. The respondent was asked, given their choice, whether they would prefer to perform the operation or rather their patient remained in their current health state.

Experimental design testing

The survey instrument underwent rigorous pre-testing at the design stage to verify the appropriateness of the precise wording and framing of the attributes and their corresponding levels followed by two phases of piloting. Phase 1 involved systematic face-to-face interviews with 5 orthopaedic surgeons. For phase 2, 21 orthopaedic surgeons completed the full pilot version of the survey. Patients undergoing TKA at SVHM were also involved in both phases of piloting. Prior information on the regression coefficients from the analysis of the pilot were used to help generate the final experimental design. The DCE was designed with the intention of being completed by both patients and surgeons.

Data collection

All orthopaedic surgeons across Australia were invited to participate. Participants were identified using a database provided by the Australian Medical Publishing Company (AMPCo) which holds contact details for all doctors in Australia. In October 2016, 1,257 orthopaedic surgeons, including fellows-in-training, were invited to participate in the study using a mixed mode of approach and completion (15). They were contacted via mail-out and, for those with a known email address, also by email. A postal invitation included a personalised letter explaining the study, a prepaid return envelope, instructions on how to complete the survey online and a hardcopy of a randomly allocated survey. Participants chose whether to fill out the hardcopy or online version. The email invite included information about the study and a link to access their online survey. The completion of the questionnaire implied their voluntary consent to participate in the research. For surgeons who responded twice, submitting both online and hardcopy versions of the survey, the most complete entry was chosen in the analysis. If both responses were completed equally the online version was chosen to minimise the risk of administrative error in entering the data. All responses were anonymous, and all information held in the strictest of confidence. This study was approved by the St. Vincent's Human Research Ethics Committee (HREC-A 177/15).

Study size

A target sample size of 400 surgeons and registrars was defined to support effective subgroup analysis for the DCE. Our Monte Carlo simulation indicated that the minimum required sample was 200 surgeons with 12 choice pairs. However, since the 12 choice pairs were blocked into two versions of DCE, the target sample size increased to 400 surgeons (16).

Statistical methods

The analysis of the DCE was conducted by estimating a mixed logit model using Stata 15.0. A well-defined mixed logit model can approximate any discrete choice random utility model (17) and therefore is preferred throughout the DCE literature (18) and widely applied in health economics (11, 19). Unlike other logit models, the mixed logit model can account for unobservable preference heterogeneity by including random coefficients. These random coefficients capture how preferences for each attribute will vary over individuals, allowing for the estimation of individual-specific coefficients that follow a pre-specified distribution. Hence the mixed logit model is associated with having better 'goodness of fit' than other logit models.

The DCE data contain 12 observations from six choice pairs per survey respondent. Each observation is one of the two alternatives from each of the six choice pairs presented, and with the dependent variable equal to one or zero for each choice pair. Observations from respondents with missing values of the dependent variable were excluded from the analysis. In the estimation of the model, categorical variables (i.e., the attributes and associated levels) were coded as dummy variables with 'severe' as the omitted reference category. The risk attributes were considered as continuous variables in the final model. This is necessary to calculate the risk-benefit trade-offs (marginal rates of substitution). The assumption of linearity of the risk attributes was tested in a sensitivity analysis that estimated two models which relaxed the linearity assumption for each risk attribute one at a time. These models re-coded risk as a categorical variable using the levels of the attribute and comparing goodness of fit with the main model using AIC and BIC. To examine the association between each attribute and surgeon characteristics, interaction terms were included in the mixed logit model. The inclusion of random coefficients in the model gives each individual their own regression coefficient (20). The results show the mean and standard deviation of these

coefficients. A statistically significant standard deviation shows that there is variation across individual surgeons in their preferences for the given attribute, that is, they do not 'agree' as to its relative importance.

To extract the relative importance of the attributes and their levels, the marginal rate of substitution (trade-offs) is calculated between one of the risk attributes and each quality of life attribute, by dividing the estimated coefficient of quality of life attribute (pain or function) by the estimated coefficient of risk attribute. This addresses the question of how much additional risk is equivalent to a health improvement, for example, from severe day time pain to no day time pain.

Surgeon-specific characteristics

Interaction terms between each attribute and the characteristics listed below allowed for the examination of surgeon-specific factors influencing preferences and trade-offs. From the literature, four characteristics were analysed. Procedure volume was analysed as a dichotomous variable where a high-volume surgeon was defined as a surgeon who performs above or equal to the median number of TKA surgeries per week in the sample (≥3.25), only surgeons who performed >0 TKA surgeries in their 'last usual working week' were included in the analysis. Experience, encompassing both age and seniority, was measured as a continuous variable by the number of years since the respondent became a Fellow of the Royal Australian College of Surgeons (FRACS). Given this definition, fellows-in-training therefore had the least experience. Surgeon personality was measured using a Likert-scale approach by the Big Five Personality Index (BFI) (21); Mastery Locus of Control (LOC) (22); and Life Orientation Test-Revised (LOTR) (23). The BFI tests for a set of five broad trait dimensions (neuroticism, extraversion, openness to experience, agreeableness and conscientiousness), see Supplemental Table 1 for an overview, using a 15-item questionnaire

across a 5-point scale, where 1=disagree strongly to 5=agree strongly. The LOC, a 7-item questionnaire using an 11-point scale ranging from 1=strongly agree to 11=strongly disagree, evaluates the control an individual has over their everyday life and the LOTR, a 10-item questionnaire, measures optimism using a 5-point scale where 1=I agree a lot and 5=I disagree a lot. Finally, to investigate whether risk attitudes vary between surgeons who perform more TKA procedures in a public compared with private hospital, the proportion of public to private TKAs performed in a surgeon's average week was included as an interaction term with each attribute. The majority of TKA surgery is performed in the private sector where doctors are remunerated on a fee for service basis (24). Fee for service may provide a financial incentive to surgeons and hence, could increase surgeons' propensity to overestimate the benefits and underestimate the risks.

Patient and public involvement

This study is part of a larger study which will additionally investigate the maximum acceptance of risk of patients in TKA. The DCE for both surgeons and patients were defined by the same attributes and levels. Patients were involved in the pretesting of the survey instrument. Participants had end-stage OA and were recruited at the orthopaedic preoperative assessment clinic after being consented and waitlisted for primary TKA at SVHM.

The initial pretesting phase with patients consisted of detailed face-to-face interviews with 15 patients. For the second phase, 40 patients completed the pilot survey. Patient feedback was sought for the ease of comprehension of wording and framing of the attributes and their corresponding levels, efficacy figures, icon arrays and the length of questionnaire. The main issues raised were around the language used, the wording of the attributes was consequently changed to improve understanding.

RESULTS

Amongst the 1,257 surgeons contacted, 434 responded (34.5%). Seventy-two (16.6%) responses were refusals to complete the survey. Reasons for refusal included 'do not perform TKA' and 'being retired'. A total of 362 completed and 18 'return to sender' surveys were returned, a participation rate of approximately 29%. See Supplemental Figure 1 for consort diagram. Of the 362 who returned the survey, 333 selected at least one alternative from the each of the six choice pairs in the DCE. These 333 respondents provided 3,862 observations for the analysis, out of a possible 3,996 (333 x 12) observations. A comparison of the population of orthopaedic surgeons from the AMPCo sample frame with respondents is summarised in Table 2. The median age of respondents was 52 years (IQR 44 - 59 years). Most respondents were male (94%) and fully-qualified orthopaedic surgeons (91%). The survey sample was representative of the population except for fellows-in-training who were underrepresented and surgeons performing TKA in Victoria and Tasmania were overrepresented. Respondents had an average of almost 20 years of experience and performed an average of 4 TKAs per week. For every 10 TKAs performed in a private hospital, 4 were conducted in a public hospital (Table 2).

Table 2 Respondent demographic and personality/practice characteristics

	Estimation sample (n=333)	Sample frame (n=1257)
Characteristics		
Male, no. (%)	314 (94.3)	1199 (95.4)
Age, year (IQR)	52 (44 - 59)	50 (42 - 60)
Practice status, no. (%)		
Accredited registrar	16 (4.8)	120 (9.6)
Consultant	304 (91.3)	1124 (89.4)
Other	12 (3.6)	13 (1.0)
Australian states and territories, no. (%)		
Victoria	93 (27.9)	275 (21.9)
New South Wales	92 (27.6)	408 (32.5)
South Australia	23 (6.9)	113 (9.0)
Queensland	58 (17.4)	271 (21.6)
Northern Territory	3 (0.9)	6 (0.5)
Western Australia	29 (8.7)	136 (10.9)

Tasmania	12 (3.6)	24 (1.9)
Australian Capital Territory	6 (1.8)	23 (1.8)
Residency status, no. (%)		
Australian citizen	308 (92.5)	-
Permanent resident	19 (5.7)	-
Temporary resident	3 (0.9)	-

	Mean	Std. Dev.	Min	Max
Personality traits:				
BFI – extraversion	3.20	0.82	1	5
BFI – agreeableness	4.09	0.71	2	5
BFI – conscientiousness	4.45	0.54	2	5
BFI – neuroticism	2.62	0.87	1	4.67
BFI – openness	3.63	0.73	1.33	5
LOC	8.28	1.84	1.86	11
LOTR	23.84	4.00	11	30
Surgeon Experience:				
Years of experience	19.76	10.49	1	55
Surgeon Volume:				
TKA per week	3.65	4.56	0	60
Proportion of high volume surgeons	0.43	0.50	0	1
Public vs Private TKA surgery:				
Proportion of public to private	0.40	0.34	0	1

Note: Personality traits were standardised for the regression analysis, hence mean=0 and standard deviation=1. Zero observations were excluded in the regression analysis for the high-volume and proportion of public to private procedures performed interaction effects. The median number of TKA surgeries per week was used to determine high and low volume surgeons

The estimated mixed logit model results are presented in Supplemental Table 2. It is not possible to draw direct inferences from the coefficients however, the signs are as expected and significant at the 1% level: surgeons prefer patients to suffer from less pain, have better function and for there to be less risk of adverse events occurring. Shown by the standard deviations, there is statistically significant variation in surgeons' preferences for most attributes. The insignificant constant term illustrates no surgeon preference for 'Choice A' or 'Choice B' and tests for specification error.

The marginal rate of substitution between risk and patient outcomes are shown in Table 3. Linearity of risk was confirmed (according to AIC and BIC: results available on request) by

comparing models with risk re-coded as a categorical variable. The relative size of these trade-offs indicates the relative importance of each health improvement to surgeons. Surgeons believe that the alleviation of night time pain is the most important attribute, compared to all other attributes they are willing to accept the maximum risk to achieve this. To improve a patient's night time pain from severe to no pain, surgeons are willing to accept a 40% or 102% increase in the absolute risk of re-operation or the risk of a complication which requires a specialist or GP visit, respectively. Reducing pain is generally more important to surgeons than improvements in functioning. The relative importance is similar when trading off the risk of a complication that requires a new specialist or GP visit. For each attribute, surgeons are willing to accept higher risks of complications requiring GP/specialist visits, compared to risk of re-operation which they consider to be more serious. For example, surgeons are prepared to accept an 87% increase in the risk of a complication requiring a specialist or GP visit to reduce day time pain from severe at baseline (pre-surgery) to no pain at 12 months. For the same improvement for patients they are only willing to accept a 34% increase in the risk of re-operation.

Table 3 Trade-offs between risk and patient outcomes: marginal rate of substitution

	Risk of re-operation		Risk of complication requiring a new GP/specialist visit	
	Coeff	Std. Error	Coeff	Std. Error
Pain outcomes:				
No day time pain	-34.06***	4.01	-87.02***	17.96
Moderate day time pain	-25.27***	3.18	-64.54***	14.19
No night time pain	-39.98***	4.72	-102.13***	22.08
Moderate night time pain	-25.73***	2.86	-65.73***	13.44
Functional outcomes:				
No difficulty standing	-27.65***	5.00	-70.63***	18.62
Moderate difficulty standing	-17.33***	3.07	-44.28***	10.79
No difficulty moving	-20.62***	2.43	-52.67***	12.18
Moderate difficulty moving	-9.72***	1.56	-24.84***	6.09
Risk of complications:				
Risk of new GP/specialist visits	0.39***	0.06	-	-

Risk of reoperation	-	-	2.55***	0.41

*** p≤0.01, **p≤0.05, * p≤0.1

Coeff = coefficient, Std. Error = standard error

Note: the marginal rate of substitution is calculated between one of the risk attributes and each quality of life attribute, by dividing the estimated coefficient of quality of life attribute (pain or function) by the estimated coefficient of risk attribute. Categorical variables for pain and function were coded as dummy variables with 'severe' as the omitted reference category. The risk attributes were continuous variables.

Furthermore, a 1% increase in the risk of re-operation is shown to be equal to a 2.55% increase in the risk of new GP visits within the first year after TKA. The risk of re-operation is 2.55 times more important to surgeons than the risk of a complication requiring only a specialist or GP visit. Hence surgeons are less willing to risk patients being readmitted to undergo another surgery than seeing their GP or specialist.

Table 4 summarises the direction and statistical significance of the interactions between surgeon preferences for each attribute, and the volume of TKA, personality traits, experience, and public-private mix. Overall, there were only a few surgeon-specific characteristics, namely personality traits, shown to affect surgeon preferences.

A more 'open' surgeon is likely to find the ability to stand more important but the ability to move less important and an 'agreeable' surgeon finds the ability to move more important, significant at the 5% level. However, being more conscientious, neurotic or the level of control a surgeon feels they have in their everyday life has no effect on any of the outcomes. Neither does a surgeon's public-private mix or procedure volume. Weak negative associations between a patient improvement from severe difficulty to moderate difficulty moving with a surgeon's experience and level of extraversion are illustrated in table 4. The LOTR variable, measuring surgeon optimism, also illustrates a relationship at 10% level. A more optimistic surgeon places greater weight on the importance of a patient's improvement in function from severe to moderate difficulty moving and places a lower weight on the importance of risk of reoperation than a less optimistic surgeon.

Table 4 Summary of mixed logit interaction effects

	Pain outcomes				Function outcomes				Risk of complications	
	No day time pain	Moderate day time pain	No night time pain	Moderate night time pain	No difficulty standing	Moderate difficulty standing	No difficulty moving	Moderate difficulty moving	Re-operation	New GP visits
Surgeon Personality Traits										
BFI - Openness	[-] ns	[-] ns	[-] ns	[+] ns	[+] **	[+] **	[-] ns	[-] ***	[+] ns	[+] ns
BFI - Conscientiousness	[+] ns	[+] ns	[-] ns	[-] ns	[-] ns	[-] ns	[+] ns	[+] ns	[-] ns	[+] ns
BFI - Extraversion	[-] ns	[-] ns	[-] ns	[+] ns	[-] ns	[-] ns	[+] ns	[-] *	[+] ns	[+] ns
BFI - Agreeableness	[+] ns	[+] ns	[+] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+]**	[-] ns	[-] ns
BFI - Neuroticism	[-] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+] ns
LOC	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[+] ns	[-] ns	[+] ns
LOTR	[+] ns	[+] ns	[+] ns	[+] ns	[+] ns	[+] ns	[+] ns	[+] *	[-] *	[-] ns
Surgeon experience										
Years of experience	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[-] ns	[-] *	[+] ns	[+] ns
Surgeon volume										
High volume surgeons	[+] ns	[+] ns	[+] ns	[-] ns	[+] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+] ns
Public vs private TKA surgery										
Proportion of public to private	[-] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+] ns	[-] ns	[-] ns	[+] ns	[+] ns

***p≤0.01, **p≤0.05, *p≤0.1, ns = not significant, sign of coefficient in square brackets

Note: The sample size of each model varies from between 2892 and 3680 observations, from between 245 and 310 respondents.

DISCUSSION

This study is the first of its kind to investigate the trade-offs between improvements in pain and function and risk of TKA surgery using a DCE in orthopaedic surgeons. The choice task allows the elicitation of risk tolerance to be quantified by weighing up the different outcome alternatives (pain, function and risk).

Surgeons are willing to accept a large increase in the absolute risk of complication requiring a return to hospital for a follow up knee operation, up to a maximum of 40%, to eliminate night time pain (improvement from severe to none 12 months after the procedure). This figure is 102% for a complication that requires a GP or specialist visit for further treatment. With regards to improvements in a patients' function, a surgeon is willing to accept a 10% and 21% increase in the risk of re-operation for an improvement from severe difficulty walking to moderate and no difficulty, respectively. These trade-offs show that across all attributes, surgeons are willing to accept higher absolute risks of GP/specialist visits in comparison to reoperation. This is unsurprising as complications requiring reoperation are likely to be much more severe than those that can be treated in an ambulatory visit.

Surgeons were willing to accept the same amount of risk for improvements in each attribute regardless of personality type, experience, procedure volume or whether a surgeon performed TKA surgery in a public or private setting. Suggesting that their preferences for risk and patient outcomes, and how they trade them off, do not vary along these dimensions, though preferences do vary due to other unobserved factors. With regards to surgeon personality, the literature is conflicted. Despite evidence that surgeon personality influences risk tolerance (25) and decision making (26), the 'surgical personality' (27-30) suggests that all surgeons have inherent personality traits that are different to non-surgeons. Hence there may be less variation within surgeons, especially within specialities such as orthopaedic surgeons. The

'surgical personality' is a consequence of surgeons' self-selection into the profession and their continual rigorous standardised training throughout their career. Though Table 2 suggests some variation in personality, this may not have been sufficient variation to influence their preferences.

The finding that neither experience nor volume of TKAs influenced their preferences, suggests that surgeons are homogenous with respect to the importance they place on risk and patient outcomes. Though the risk of adverse events is associated with volume (31-34) and experience (35) through a broader and more refined skillset of high-volume surgeons compared to low-volume surgeons (36, 37), surgeons may be unaware of this relationship such that the importance of risk does not vary. We were not able to collect data on the extent to which respondents had patients who had experienced adverse events.

Our hypothesis that surgeons in the private sector may overestimate the benefits and underestimate the risks was not supported. It is uncommon for surgeons to exclusively operate in either a public or private hospital in Australia and unlikely that individual surgeons have specific 'public' and 'private' surgeon behaviours which are different. Additionally, evidence suggests that the quality of care among TKA patients is not compromised regardless of whether the surgery is performed by a public or private healthcare provider (38).

There are several limitations to this study. Firstly, the DCE may lack external validity if surgeons do not make the same choices in real life. Despite the outcome choices presented in the DCE being realistic and based on real data, the choice task was hypothetical. However, a recent systematic review and meta-analysis showed that choice experiments provide a reasonable approximation to actual choices (39). DCEs are especially useful in situations where data on actual choices are difficult to collect.

Another limitation may be that data were also collected on whether the surgeons, conditional on their choice of A or B, would rather not perform the operation (Figure 1). These data were not analysed in this paper which was focussed more on the trade-offs between risk and patient outcomes. This option was not included as a potential third 'status quo' alternative in the analysis since no specific attribute levels could be assigned to this. In addition, the question was framed as an additional question (conditional on choice of A or B), rather than being included as a third mutually exclusive alternative.

The response rate of 34.4% may be considered as an additional limitation. However, physician response rates are notably lower than the general population (40). Our survey compares favourably with the Medicine in Australia: Balancing Employment and Life (MABEL) survey which has had response rates varying from 20.6% to 33.9%, between 2010 to 2017, for specialists who have not previously completed the survey (41). The sample analysed in this paper is representative of the population in terms of age and gender, except for fellows in training who were underrepresented and surgeons performing TKA in Victoria and Tasmania who were slightly overrepresented, see Table 2. Moreover, a high response rate is not the only indicator of survey quality, since response bias may still be a cause for concern in surveys with high response rates if certain sectors of the population fail to respond.

Finally, despite the expectation of risk to be non-linear, the estimated mixed logit model included the risk attributes as continuous variables. The sensitivity analysis conducted supported the linearity assumption of risk. However, the evidence of linearity may be a consequence of the DCE design. During the design phase risk was included as continuous variable to reduce the number of questions a surgeon would have to answer, and the sample size required. Increasing the number of questions would have decreased the response rate by increasing the time burden on surgeons. There is, therefore, potential that there is insufficient variation in the data to show non-linearity and properly test this assumption.

This study is part of a larger project exploring risk-preferences of surgeons and patients. Moving forward, research into risk-benefit trade-offs of patients considering TKA as a treatment option for end-stage OA will be undertaken. This research has implications for both clinicians and policy makers. Anecdotal evidence suggests that surgeon and patient expectations of surgery are often misaligned; our findings will help improve the shared decision-making process, vital to providing high quality patient-centred healthcare. In turn, this will allow for improvements in surgical outcomes and greater patient satisfaction.

Contributors: SS was an investigator, conducted the literature search and statistical analysis, contributed to data interpretation and drafted and revised the paper. PC was a chief investigator, was involved in the design of the study, provided management oversight of the whole trial, contributed to data interpretation and drafted and revised the paper. JL was an investigator, wrote the statistical analysis plan, conducted statistical analysis, contributed to data interpretation and drafted and revised the paper. EN was the study co-ordinator, responsible for participant recruitment, provided technical support to participants, monitored data collection for the whole trial, drafted and revised the paper. MN and VS were chief investigators, designed the study, contributed to data interpretation and drafted and revised the paper. AS was a chief investigator, designed the study, provided management oversight over the statistical analysis, contributed to data interpretation and drafted and revised the paper. MD was the lead investigator, initiated the collaborative project, designed the study, monitored data collection for the whole trial, provided management oversight of the whole study, contributed to data interpretation, drafted and revised the paper, and is the guarantor.

All authors contributed to redrafts of the report. All authors had full access to the study data and take responsibility for the integrity of the data and the accuracy of the data.

Acknowledgements: Associate Professor Michelle Dowsey holds an NHMRC Career Development Fellowship (APP1122526). Associate Professor Mandana Nikpour holds an NHMRC Career Development Fellowship (APP1126370). Professor Peter Choong holds an NHMRC Practitioner Fellowship (APP1154203). Dr Jinhu Li holds an ARC Discovery Early Career Researcher Awards (Project ID: DE170100829).

Data sharing: Reasonable requests for surgeon level data should be made to the corresponding author and will be considered by the trial Chief Investigators. Consent for data sharing has not yet been obtained and ethics approval would be required from the study institution for future use of individual surgeon level data.

Competing interest statement: All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

Transparency declaration: The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Ethical approval: This study was approved by the St. Vincent's Human Research Ethics Committee (HREC-A 177/15)

Funding: This research is funded by a National Health and Medical Research Grant Project, Grant no. APP1058438 (www.nhmrc.gov.au, nhmrc@nhmrc.gov.au, phone: +61 2 6217 9000). The funding source had no role in the study design, and will not have any role during its conduct, collection, analyses and interpretation of data, or in the writing of reports and decision to submit for publication.

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Figure Legend

Figure 1 Example of a discrete choice experiment

Supplementary file

Supplementary Table 1 (ST1) Big Five personality domains and description of traits

Supplementary figure 1 (SF1) Consort diagram

Supplementary table 2 (ST2) Mixed logit model results

Imagine you have performed a TKR on a patient and the following scenarios describe:

- the level of pain and function experienced **at 12 months after surgery**; and
- the likelihood of complications **during the first 12 months** after surgery.

The scenarios are based on actual data 9 to 12 months post-surgery. Data was acquired from a prospective longitudinal cohort of patients undergoing TKR.

Some of the scenarios presented below may be better than you expect, while others may be worse.

In each of the questions in this section you are asked to compare two possible outcomes, *Choice A* and *Choice B*, and each question has two parts.

First, for each question you are asked to choose which of the two post-operative outcomes (A or B) you consider to be better overall.

Second, assuming Choice A or Choice B are the *only* two possible outcomes, you are asked to decide whether you would still obtain consent from the patient for surgery, or choose not to waitlist the patient, whereby they would remain in their current state of health.

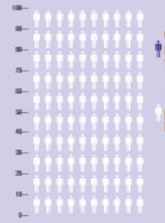
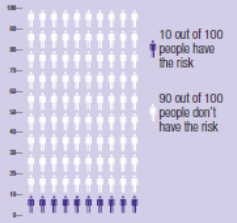
You will be asked to complete six activities.

There are no right or wrong answers.

Pain and Function items use the following scale:

None | Mild | Moderate | Severe | Extreme

Q3. Choice 1 of 6:

	Choice A	Choice B
Standing and walking on flat surface 9–12 months after surgery	No difficulty standing and walking	Severe difficulty standing and walking
Bending to floor, rising from sitting, going up and down stairs 9–12 months after surgery	No difficulty bending to floor, rising from sitting, going up and down stairs	Severe difficulty bending to floor, rising from sitting, going up and down stiars
Risk of having to go back into hospital and have a second operation on your knee (e.g. due to knee stiffness, wound/ joint infection)		
Risk of getting a complication that requires seeing your GP or specialist for further treatment (e.g. blood clot, skin infection, confusion)		
Day-time pain 9–12 months after surgery	Moderate day-time pain	No day-time pain
Night-time pain 9–12 months after surgery	No night-time pain	Moderate night-time pain

i. Which of the possible outcomes above do you think is better? ☐ Choice A ☐ Choice B

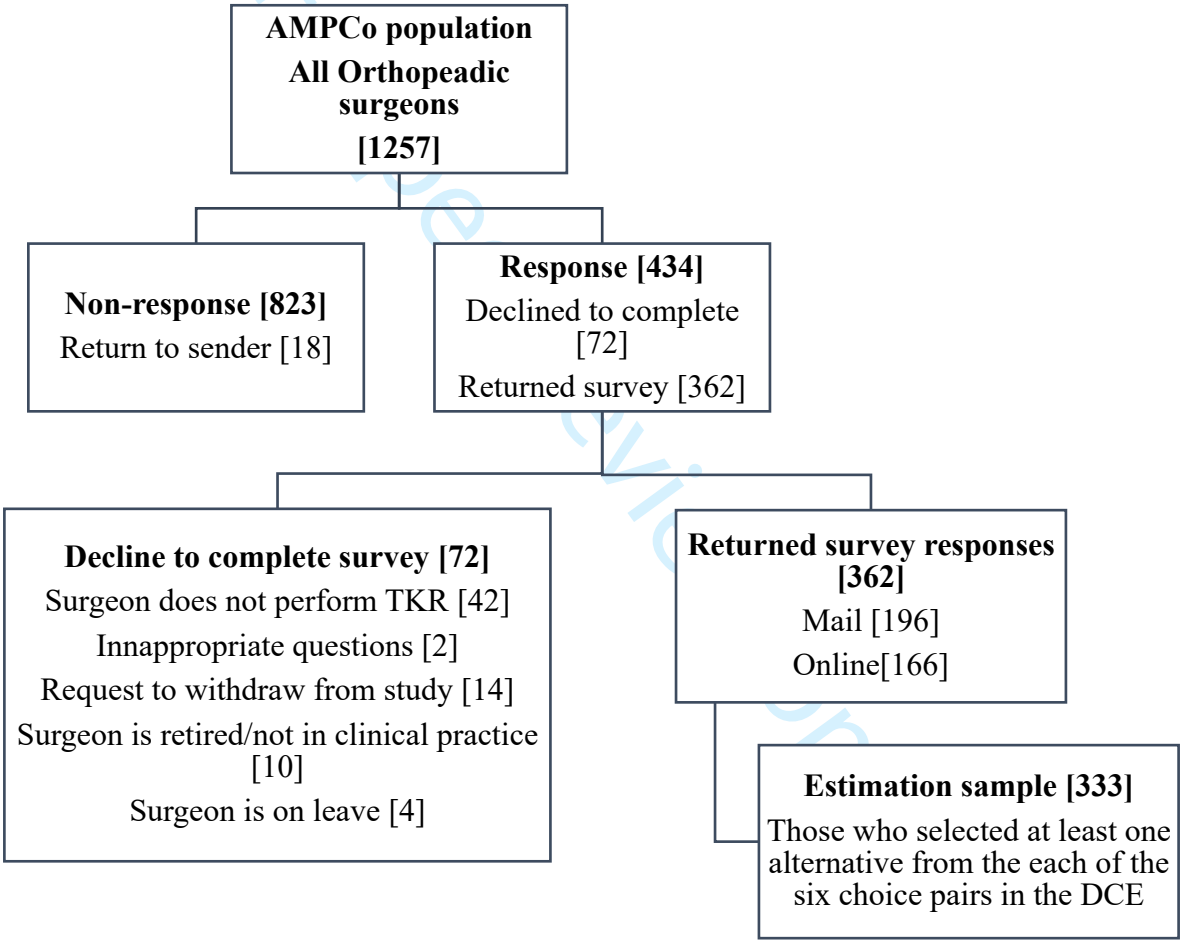
ii. Given your choice above, would you still perform the operation? ☐ Yes ☐ No (Patient to remain in current health state)

Supplementary file

Supplementary Table 1 Big Five personality domains and description of traits

Big Five dimensions	Description
Openness to experience	Open-minded, curious, creative
Conscientiousness	Organised, diligent, responsible
Extraversion	Sociable, enthusiastic, out-going
Agreeableness	Good natured, altruistic, cooperative
Neuroticism	Anxious, stressed, irritable

Supplementary Figure 1 Consort diagram



Supplementary Table 2 Mixed logit model results

	Parameter	Coeff	Std. Error
Pain outcomes:			
No day time pain	Mean	4.88***	0.71
	Std. Deviation	1.71***	0.35
Moderate day time pain	Mean	3.62***	0.52
	Std. Deviation	0.10	0.07
No night time pain	Mean	5.72***	0.76
	Std. Deviation	1.88***	0.39
Moderate night time pain	Mean	3.68***	0.52
	Std. Deviation	0.93***	0.33
Functional outcomes:			
No difficulty standing	Mean	3.96***	0.61
	Std. Deviation	0.70	0.62
Moderate difficulty standing	Mean	2.48***	0.43
	Std. Deviation	-0.04	0.09
No difficulty moving	Mean	2.95***	0.45
	Std. Deviation	1.41*	0.70
Moderate difficulty moving	Mean	1.39***	0.24
	Std. Deviation	-0.21	0.23
Risk of complications:			
Risk of new GP/specialist visits	Mean	-0.14***	0.03
	Std. Deviation	0.07***	0.02
Risk of reoperation	Mean	-0.06***	0.02
	Std. Deviation	-0.04*	0.02
Constant term	Mean	0.01	0.14
Number of responses		3862	
Number of respondents		333	
Log-likelihood		-796.85	
Prob > Chi2		0.0000	

*** p≤0.01, **p≤0.05, * p≤0.1

Coeff = coefficient, Std. Error = standard error

Notes: Categorical variables for pain and function were coded as dummy variables with 'severe' as the omitted reference category. The risk attributes were continuous variables.

STROBE Statement—checklist of items that should be included in reports of observational studies (using the document with the title page)

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	4	A discrete choice experiment
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	4	methods, results and conclusion
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6	
Objectives	3	State specific objectives, including any prespecified hypotheses	6	
Methods				
Study design	4	Present key elements of study design early in the paper	7/8	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	11	
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	11	
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	N/A	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7/8/9/12/13	

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	7/8/9	
Bias	9	Describe any efforts to address potential sources of bias	11	
Study size	10	Explain how the study size was arrived at	11	study size
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	12	
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	12	
		(*b*) Describe any methods used to examine subgroups and interactions	12	
		(*c*) Explain how missing data were addressed	N/A	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	N/A	No follow-up
		(*e*) Describe any sensitivity analyses	N/A	
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	15	
		(b) Give reasons for non-participation at each stage	15	
		(c) Consider use of a flow diagram	Supplementary file figure 2 (SF2)	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	15	
		(b) Indicate number of participants with missing data for each variable of interest	N/A	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A	No follow-up

Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	N/A	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	N/A	
		Cross-sectional study—Report numbers of outcome events or summary measures	N/A	
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	17	Table 3
		(*b*) Report category boundaries when continuous variables were categorized	17	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12/18	
Discussion				
Key results	18	Summarise key results with reference to study objectives	20/21	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	21/22	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	21	
Generalisability	21	Discuss the generalisability (external validity) of the study results	23	
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	25	

*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.