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Patients' values and preferences of the expected efficacy of hip arthroscopy for osteoarthritis: A protocol for a multinational structured interview-based study combined with a randomized survey on the optimal amount of information to elicit preferences

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Abstract:

INTRODUCTION: Symptomatic hip osteoarthritis (OA) is a disabling condition with up to 25% cumulative lifetime risk. Total hip arthroplasty (THA) is effective in relieving patient's symptoms and improving function. It is, however, associated with substantial risk of complications, pain and major functional limitation before patients can return to full function. In contrast, hip arthroscopy (HA) is less invasive, and can postpone THA. However, there is no evidence regarding the delay in the need for THA that patients would find acceptable to undergo HA. Knowing patients' values and preferences (VP) on this expected delay is critical when making recommendations regarding the advisability of HA. Furthermore, little is known on the optimal amount of information regarding interventions and outcomes needed to present in order to optimally elicit patients' VP.

METHODS AND ANALYSIS: We will perform a multinational, structured interview-based survey of preference in delay time for THA among patients with non-advanced OA who failed to respond to conservative therapy. We will combine these interviews with a randomized trial addressing the optimal amount of information regarding interventions and outcomes required to elicit preferences. Eligible patients will be randomly assigned (1:1) to either a short or a long format of health scenarios of THA and HA. We will determine each patient's VP using trade-off and anticipated regret exercises. Our primary outcomes for the combined surveys will be: 1) the minimal delay time in the need for THA surgery that patients would find acceptable to undertake HA, 2) patients satisfaction with the amount of information provided in the health scenarios used to elicit their VPs.

ETHICS AND DISSEMINATION: The protocol has been approved by Hamilton Integrated Research Ethics Board (HIREB13-506). We will disseminate our study findings through peer-reviewed publications and conference presentations, and make them available to guideline makers issuing recommendations addressing HA and THA.

BACKGROUND

Osteoarthritis and surgical options

Osteoarthritis: Osteoarthritis (OA) is the most common form of chronic arthritis. Approximately 15% of men and women suffer from symptomatic OA[1], representing a large burden on patients, the healthcare system and society. Symptomatic hip OA is a particularly disabling condition with a cumulative lifetime risk of up to 25%. Conservative management of hip OA includes exercise, weight reduction, physical therapy and medications focusing on relieving symptoms, improving joint function, and optimizing quality of life[2]. Pharmacological and non-pharmacological interventions for severe OA are, however, substantially less effective than surgical treatment[3]. Consequently, most patients with severe hip OA eventually need total hip arthroplasty (THA)[3].

Total hip arthroplasty: With an aging population increasingly interested in staying physically active [4], the frequency and cost of THA continues to grow. Currently more than a half million THA procedures are performed annually in the UK and USA alone, and in 2010 the global market was estimated as high as 4.7 billion USD[5].

After failure of conservative treatment, THA is usually effective in relieving patient's symptoms and improving function, with more than 95% prosthesis survivorship at 10-year follow-up and more than 80% survivorship at 25-year follow-up[6, 7]. However, THA is also a major procedure, associated with substantial risk of complications, and with weeks of pain and major functional limitations before patients can return to full function. Therefore, patients and caregivers are interested in less invasive interventions that could postpone THA.

Hip arthroscopy: Less invasive interventions include arthroscopy, partial replacements, and bone-preserving techniques. They have shown varying success rates among OA patients[8]. Hip arthroscopy (HA) is a new and the fastest growing procedure within orthopedic surgery[8]. Despite the lack of high quality evidence, the number of HAs performed is expected to double in the United States in 2013 compared to 2011[9]. HA is used to treat intra articular pathology of the hip, including mild hip OA. Compared to THA it has the advantages of being minimally invasive and having fewer complications [10]. Compared to THA, arthroscopy may help patients achieve higher level of function more quickly with, over the short term less restriction on exercise. The expectation, however, is that patients' underlying osteoarthritis will progress, and THA will ultimately become necessary. The question then arises: what delay in the need for THA would warrant a patient undergoing HA? This is a question of values and preferences.

Measuring patients` values and preference

There are a number of techniques available for eliciting patients direct choices of which the probabilistic version of the Threshold Technique (TT) also called probability trade-off (PTO) exercise is widely used [11]. Following descriptive and probabilistic information regarding benefits and harms associated with treatment choices - for example treatment A and B – in which the relative benefits of treatment A versus B are large, the respondent is asked to choose one option. Typically, patients will choose treatment A. The interviewer then presents an alternative situation in which the relative benefits of A versus B are very small, and patients typically choose B. The

interviewer than presents a small reduction in the probability of benefits, relative to the first scenario, for option A. If the patient continues to choose A, the next scenario presents a small increase in the benefits of A versus B relative to the second scenario. The process is repeated until the indifference point between A and B is established (ping pong approach)[12].

Utility elicitation uses a very different approach, presenting health states and using one of a variety of techniques to elicit the respondent's rating of the value of the health state on a scale between death (typically 0) and full health (typically 1.0 or 100). The patients' responses are used to build a decision model that calculates the treatment option that, given the patient's utilities, achieves the maximum utility-adjusted outcome [13, 14].

Complementary approaches to assess patients' decision-making integrate emotional aspects of the process. One such approach focuses on regret, an aversive emotion people experience when they believe their current situation would have been better had they acted differently in the past[15, 16]. In theory, regret is influenced by both intuitive, affect-based, and analytical, deliberative processes[17, 18]. Reflecting on the anticipated regret of particular decisions (e.g. choosing A versus B in the example above) may alert people to the choice that would be most likely to avoid this aversive emotion[19, 20]. The anticipated regret theory-based approach preserves a rational decision-making framework, while allowing anticipation of the effect of the decision on emotions[21].

Using both (direct choice) trade-off and anticipated regret exercises, our study will provide empirical evidence regarding the delay in the need for THA that patient would find acceptable to undergo HA.

Amount of information presented to elicit patients' values and preference

The choices patients make are critically dependent on how the health scenario (HS) that characterizes the processes and outcomes of the alternative management options (A and B in the above – THA and HA in the current project) are presented. Research in marketing has addressed some of the relevant issues. Information-processing framework[22] suggests that that there are limits to the human ability to assimilate and process information, and that once these limits are surpassed behavior becomes confused and dysfunctional[23]. Evidence suggests an inverted U-shaped relationship between information available and decision quality, in which individuals with too little or too much information made poorer decisions than those with an intermediate amount of information [24, 25].

Other indirect evidence comes from research on written consent forms [26, 27]. Individuals often skim over consent forms for clinical trials in oncology if they are longer than 1,000 words or 4 pages[28]. Twenty-seven oncology trials showed that patients obtain significantly higher objective knowledge when the consent form page count was seven or less [29].

In the area of pharmaceutical product choice, participants have had better understanding of shorter and easier information presentations[25]. One might expect, however, that if the information becomes too scanty, decision quality will deteriorate.

Patients' values and preferences on osteoarthritis surgical options

Given the existing evidence, both HA and THA represent reasonable choices for patients with non-

advanced OA. The choice may, however, be challenging. On one hand, HA is likely to achieve only transient improvement in function. On the other hand, the morbidity associated with THA is substantial.

Therefore, one of the key aspects in the choice between HA and THA is the duration of delay in the need for THA that patients may achieve with HA. If patients demand a delay time much greater than HA can realistically achieve, the procedure should seldom be considered. On the other hand, if patients would be satisfied with much shorter delay time, the procedure should be frequently considered. There is currently no empirical evidence addressing patients' values and preferences regarding the delay they would demand to undertake HA. Knowing typical patients' values and preferences regarding this expected delay is likely to be helpful for patients and health care providers in the clinical encounter and for guideline panelists when making recommendations regarding the advisability of HA.

The assessment of patients' values and preferences will be valid only to the extent patients receive sufficient accurate information on the outcomes of available treatment options presented in ways that they can easily process. Thus far, only limited indirect evidence informs us on the optimal amount of information to provide in scenarios when eliciting patients' preferences.

Our study will provide direct empirical evidence on the optimal amount of information to provide when eliciting patients' values and preferences. It may also provide insight into the amount of information to provide in shared-decision making, although our study only indirectly addresses that issue.

OBJECTIVES

General Objective: The purpose of this study is to improve the management of patients with non-advanced symptomatic hip osteoarthritis (OA) who failed conservative treatment by determining their values and preferences regarding the choice between immediate total hip arthroplasty (THA) versus hip arthroscopy (HA).

*In the **Pilot stage** of our study, we will assess the following feasibility issues:* (i) recruitment rate; (ii) length of time to conduct the interview and fill out all the study measurements; (iii) potential personnel and data management issues.

*In **Study 1*** – our primary objective is to determine the minimal delay time in the need for THA surgery that patients would find acceptable to undertake HA (which we will refer to as the "delay time"). Secondary objectives include assessing patients' anticipated regret if the delay would differ from their expectations, as well as potential determinants of their preference (e.g., age, gender, educational level, and socioeconomic status).

*In **Study 2*** – our objective is to assess the ease of understanding, optimal quantity of information, and patients' satisfaction regarding alternative formats of the HSs used to elicit their preferences.

METHODS

Study design

Pilot study

In a pilot study, we will assess the following feasibility issues: (i) recruitment rate; (ii) length of time to conduct the interview and fill out all the study measurements; (iii) potential personnel and data management problems in real-life setting. We will perform this study at the outpatient orthopedic clinic of the McMaster University Medical Center (Hamilton, ON, Canada).

Study 1: We will perform a multinational, cross-sectional, structured interview-based survey to assess the delay in THA that patients would demand to choose HA.

Study 2: Within Study 1, we will conduct a randomized trial comparing a short version versus a long version of HA and THA health scenarios.
Table 1 shows the study flow.

Setting: The study will take place at McMaster University Medical Center, Hamilton, Canada; St. Michael's Hospital, Toronto, Canada; Hospital de Sant Pau, Barcelona, Spain; and Sorocaba Hospitals, São Paulo, Brazil.

Study population

The population of interest consists of adults diagnosed with non-advanced hip OA. Table 2 presents the detailed inclusion and exclusion criteria.

Recruitment strategy

We will prospectively identify consecutive patients confirmed with non-advanced hip OA referred for consideration of HA. The orthopedic surgeon will send a letter in advance of their visit to inform patients about our research project and the possibility of being approached by our research assistant (RA) for this study. The RA will then make initial contact with all the patients by phone to explain the purpose of the study. When the patients come to the orthopedic clinic, we will ask patients for their written informed consent.

Participants interview

Baseline information

We will document patients' age, gender, ethnicity, educational level (not completed high school; completed high school only; some college/university; completed college or university), yearly income, and their impression of the experience of close relatives or friends who have undergone HA or THA (categorized as extremely dissatisfied; dissatisfied; neutral; satisfied; extremely satisfied, or differing across individuals).

Health scenarios

The health scenarios are designed to inform patients of the surgical options. Based on available evidence [30] we will include the following five sections in the HSs for THA and HA: [26] Brief introduction to the surgery; [31] Description of the surgical procedure; [iii] Post-operative recovery and rehabilitation; [iv] Expected benefits; [v] Risks and potential complications. *(See appendix: Script #1: Health scenarios)*

The short versions have approximately 850 words and the long versions approximately twice the

number of words; both versions use the same sub-headings.

To ensure we present accurate estimates of benefits and risks of THA and HA to patients[32], conveyed in the most simple and easy-to-understand way possible, we applied a rigorous process to develop these health scenarios.

Firstly, we performed a search on PubMed to retrieve relevant content from systematic reviews, randomized control trials (RCT), and observational studies. Evidence from systematic reviews was preferred if available.

Secondly, we reviewed THA booklets from Brant Community Healthcare System, Hamilton Health Sciences, Joseph Brant Memorial Hospital, Niagara Health System, St. Joseph's Healthcare Hamilton, National Institute of Arthritis and Musculoskeletal, and Skin Diseases (NIAMS) to inform SCENARIO design and content. For both THA and HA, we also reviewed information from other sources such as the Informed Medical Decisions Foundations (IMDF) [33] and National Institute of Health for both THA and HA HSs (when available).

Thirdly, we considered the following strategies to increase the ease of understanding and readability of our scenarios[34]. We focused the material on key concepts with consistent and simple words aiming for 1–2 syllables[35, 36]. A clear topic sentence are used at the beginning of each sub-heading with following details and examples[37]. We also used conversational style with the second person point of view (i.e., "you")[37].

Finally, we revised our scenarios based on feedback from 15 orthopedic surgeons (8 of them commented on THA, and 7 of them commented on HA); from 2 focus group (3 patients in each group) and 4 individual interviews with a total of 10 patients (5 for each surgery) who had undergone THA or HA; and 5 physiotherapists.

For the Spanish and Portuguese part of the study, an experienced medical translator will undertake the initial translation. In each language, one clinical epidemiologist and one orthopedic surgeon, native in the non-English language and fluent in English, will check the translation and discuss potential revisions with the translator. After we obtain the Spanish and Portuguese versions, back translations will be performed and checked by the epidemiologist and the orthopedic surgeon, with further revisions to the Spanish and Portuguese versions if necessary.

Randomization of the health scenarios

Participants will be randomized to receive the short format or long formats of the scenarios in coded packages that the interviewer will open at the start of the interview. We will use central randomization at McMaster University using an allocation ratio of 1:1 with random blocks size (2,4,8).

We will ask participants to read hard copies of the corresponding health scenarios (short or long). At the end of the interview – i.e., after the trade-off exercise, anticipated regret exercise, and a check for consistency and understanding that we will describe subsequently – the RA will show patients in each group the version they have not yet seen and ask about their preferred format. If participants have more content questions regarding the scenarios, the RA will instruct the patient

to ask the orthopedic surgeon for further assistance in the patient-doctor consultation after the interview.

Trade off exercise

After participants have read the initial health scenario (short or long version), we will assess the minimum acceptable delay (delay time) in THA that patients would find acceptable to undergo HA. We will use the following generic questions: "By how much longer should the arthroscopy postpone the need for hip replacement surgery for you to consider the hip arthroscopy worthwhile? Would you choose hip arthroscopy if it would delay the need for total hip replacement by [delay time in months/year]?" We will offer a range of delay times, alternating between short and long times in a ping-pong strategy, e.g.: 3 months – 12 years – 6 months – 10 years, etc. We will progressively narrow the range of the alternatives offered as we repeat the exercise.

The lower bound of delay time offered (i.e. 3 months) is just below the anticipated least stringent participants' demand and also corresponds to the shortest follow-up time in studies that evaluate the efficacy of HA[38]. For the upper bound initially offered, the literature suggests that the most optimistic estimate of the time which HA may delay THA is approximately 10 years[39]. If patients are not satisfied with the upper boundary of the delay time – that is, they would demand a delay of more than 12 years before they would undergo HA – there will be provision for them to express this preference.

Anticipated regret exercise

Following the trade-off exercise, we will assess participants' anticipated regret associated with choosing or not choosing a treatment alternative. We will measure anticipated regret using a 100 mm visual analog scale (VAS) called the Feeling Thermometer (FT)[40], anchored at no regret (0) to maximum regret (100). (Figure 1 anticipated regret VAS)

We will assess anticipated regret at five different time points (the patient personal threshold determined during trade-off exercise, as well as two shorter and two longer options). For example, if the patient chose 2 years as their shortest delay time, we will ask her: "*How much regret would you feel about choosing hip arthroscopy if you need to have a total hip replacement surgery after 12 months / 1.5 years / 2 years / 3 years / 4 years?*. This process allows us to check for inconsistent answers (see below).

Blinding

Since this is a patient educational trial, the interviewers (data collectors) cannot be blinded. The orthopaedic surgeons, patients (outcome assessors), and data analysts will be blinded to sequence of giving HSs.

Outcomes

Our primary outcome measures for the pilot stage regarding feasibility issues are the recruitment rate, length of time to conduct the interview and fill out all the outcome measurements. We will explore the potential personnel and data management problems in the McMaster Medical center to ensure the quality of the definitive stage of our study. We will note the number of participants

enrolled each week. The mean and standard error of the center`s recruitment rate over recruitment period will be our study recruitment rate. We will also calculate the percentage of eligible patients who agree to participate. We will time the length of the interview, the length of finishing interviewers` administrated or patients' administrated questions.

We will consider recruitment feasible for a large study if we will be able to recruit two patients at McMaster Medical center per week (i.e., 100 subjects over 50 weeks). We considered the pilot stage (approximately 2 month) to be successful, and a large multicenter RCT to be feasible; if we successfully (i) recruit 20% of our estimated sample size; (ii) we will be able to finish the interview and all the outcome assessment approximately one hour. (See table 3 for outcomes and corresponding objectives).

We will modify our protocols in response to limitations with respect to excessive length of the interveiew, difficulties with comprehension or ambiguities in the questions, and personnel or data management problems identified in the pilot.

For Study 1, our outcomes are:

Primary outcome: the minimal delay in the need for THA surgery that patients would find acceptable to undertake HA (which we will refer to as the "delay time").

Secondary outcomes:

(i) Independent predictors of the primary outcome including age, gender, educational level, and socioeconomic status.
(ii) Patients' anticipated regret scores on a 100mm VAS at five different time points (the one patients chose in the trade-off exercise, and two shorter and two longer options).

For Study 2 our outcomes are:

Primary outcome: patients' satisfaction on the scenarios after reading the initial scenarios. Interviewers will determine the degree of satisfaction participants place in the scenarios using a 7-point Likert-type scale with response options: completely dissatisfied, mostly dissatisfied, somewhat dissatisfied, neither satisfied nor dissatisfied, somewhat satisfied, mostly satisfied, completely satisfied.
Secondary outcomes:

1. Ease of understanding: we will assess participants impression of each of understanding of each scenario using a 7-point Likert-type scale with response options: extremely hard, very hard, hard, not easy not hard, easy, very easy, extremely easy.
2. Information quantity: we will ask participants to rate the quantity of the information displayed in the initial presented scenario by a 7-point Likert-type scale with response options: much too little, somewhat too little, slightly too little, about right amount of information, slightly too much, somewhat too much, much too much.
3. Patients' preference on length of format: After patients finishes reading both the long and short versions of scenarios we will ask them about their preference for the short or long version, using a 7-point Likert-type scale with response options: short version much better, short version somewhat better, short version little better, no preference, long version little better, long version somewhat better, long version much better.

Data collection

A trained interviewer will collect all the outcomes by completing the case-report forms (CRFs) at the end of the interview. No follow-up and further data collection will be involved.

Sample size calculation

Study 1:

Due to the paucity of similar studies in literature, we are unable to estimate the standard error (SE) of delay time precisely. If the data is normally distributed, 99.7% of the area under of the normal distribution curve lies within 3 standard deviations[41]. We assume the range of delay time (12 years) will be normally distributed. Therefore, we anticipate a SD of approximately 2 years. We developed the sample size estimation table using the SD and varying the confidence interval around the mean to obtain sample size using the formula below[42] (Table 4).

$$n = \frac{4z^2_{1-\frac{\alpha}{2}}\sigma^2}{L^2}$$

N represents the sample size, σ represents the SE, L represents the confidence interval around the mean.

At the end of the pilot stage we will calculate the SE of delay time in the 20 patients as a reference point to modify our earlier sample size estimation for the definite study.

Study 2:

Based on Cohen's rule of sums [43], we used "SD=0.5" to calculate the sample size to achieve a medium effect size. With a sample size of 62 in each group the trial is powered to detect a medium effect size of mean = 0.5 or larger given 80% power level and α= 0.05 in a two-sided test. Considering the result will be obtained immediately after the assessment and all outcomes will be interviewer administrated, we anticipate no loss to follow-up. We also made a sample size estimation table with different confidence intervals around the mean (Table 4). Sample size calculation is performed using SPSS (Statistical Package for the Social Sciences) version 21.0 for Windows.

After finishing the pilot stage of our study, we will compare the estimated sample size for study 1 and 2 and take the larger number as our final sample size for the combined studies.

Data analysis and interpretation

Study 1

Description of baseline characteristics:
We will present patients' age, gender, ethnical / cultural group, educational level, socioeconomic status and medical history[44]. Means and standard deviations (SD) will be used to present continuous variables and two-tailed T-test (or Mann-Whithey U test for non-normal distributions) to detect significant differences ($p<0.05$) between group means. We will use proportions and frequency tables to present categorical variables and a two-tailed Fisher's Exact test will be used to detect statistically significant ($p<0.05$) differences between two groups.

Primary and secondary outcome(s):

We will assess the distribution of the mean delay time and represent it graphically using histogram(s). If the data is normally distributed we will present the mean delay time and SD. We will also estimate 95% confidence intervals of the mean respectively. If the data is skewed, we will present the mode, median, and interquartile range.

Multiple variable linear regressions will be undertaken to determine statistically independent predictors of the threshold of delay time. In this analysis, the delay time will be the dependent variable and the independent variables will be the previous experience of THA and HA in friends and family, age, gender, socioeconomic status, educational level.

After presenting the health scenarios and recording participants' response with both "trade off" and anticipated regret exercise, we will compare results between these two measurements of participants' values and preferences.

We have defined three possible patterns of inconsistent response (See table 5 Inconsistency checking). If the participants' answers fall into any of these patterns, interviewers will review participants' original answers without, however, implying that they must modify their original choices. If the participants confirm their original answers, interviewers will determine and record the reasons of participants' inconsistent choices based on participants' explanation. If patients, following review of the relation between their trade off and regret choices, desire to modify their chosen delay time, interviewers will repeat the trade-off exercise.

For the analyses above, we will determine whether the delay time differs between those with an apparently high level of understanding and those who demonstrate any of the inconsistencies depicted in Table 2. If we find an important discrepancy between the results of patients categorized as understanding and not understanding, we will focus our primary analysis on the group of patients who apparently have a high level of understanding.

Study 2

Baseline characteristics description
We will summarize patients' age, gender, ethnical / cultural group, educational level, social economics status in a table.

Primary and secondary outcome(s):

Our primary outcome will be participants' satisfaction of the health scenarios assessed by a 7-point Likert scale. We will also visualize it by using histogram(s). We will conduct a two-sided student T-test will to compare mean satisfaction scores and ease of understanding between the short and long scenarios. We will also calculate the mean difference and 95% confidence intervals.

For information quantity, we will present a histogram depicting the proportion of participants' choice in each category. We will apply 2 approaches to analyze information quantity at the first assessment. First, we will determine if the distribution between two groups differ by greater than chance with two-sided student T-test (if its normally distributed) or Mann-Whitney U test(if its not normally distributed). Second, using a chi-square test we will determine if the proportions of participants who choose "about the right amount of information", in comparison to those who choose other response options, differ between groups.

We will use 2 approaches to compare participants' preferences for the short versus long formats after showing patients both scenarios. First, we will treat the outcomes on the 7-point scale as multinomial ordered outcomes. We will analyze the result using Mann-Whithey U test. Second, we will use a more conservative approach and compare the proportions of participants who prefer the short format to the proportion of participants who have either no preference or prefer the long format by using a chi-square test. (Table 3: Summary of analysis plan).

ETHICAL AND DISSEMINATION

This study will be performed in accordance with established guidelines for research involving human patients. The proposed study does not pose any safety risks to participating patients. The protocol has received Research Ethics Board approval at Hamilton Health Sciences (McMaster University Medical Centre) and will be submitted for approval at the other participating sites. The research objectives and study intervention will be explained to the patient verbally and in writing in easily comprehensible language. Written informed consent will be obtained from all patients. Patients will be informed of their right to ask for further information at any time and to withdraw from study without prejudice to their future care. In the unlikely event that participants find considering the above scenarios upsetting, the interview will be immediately stopped and support offered. We will ensure confidentiality of patient data by anonymizing patients by a unique numerical identifier. Records will be stored in a secure database. Access to the database will be restricted to those directly involved in the design, implementation, and analysis of the data. No patient will be identifiable in any publication arising from the study.

The reporting of Study 1 will conform to the STROBE statement [45], and reporting of Study 2 to the CONSORT statement[46]. We will disseminate our study findings widely through peer-reviewed publications and conference presentations, and make them available to guideline makers issuing recommendations on HA and THA.

DISCUSSION

Strength and weaknesses

The design of our study has several strengths. Firstly, we have incorporated the anticipated regret model as a new method in the exploration of patients' values and preferences. Based on considerable previously published theoretical work by members of our research team [47, 48] our study will be the first to evaluate and compare its results with other methodologies. The comparison will include differences in decisions, inconsistencies, and understanding.

Secondly, in developing health scenarios we obtained input from patients who have undergone both total hip replacement and HA and surgeons who have expertise on total hip replacement and HA. These processes ensured the accuracy of our health scenarios that will be used in the study.

Thirdly, we will be the first to explore the association between influence from family and friends' previous experience on patients' values and preferences on the minimal delay time in the need for THA surgery that patients would find acceptable to undertake HA. Indirect evidence suggests friends or family member's medical advice may influence patients' preference on medical decisions. Men, African-American men in particular, are more inclined to discuss their medication concerns and to seek medical advice from trusted friends more frequently than women[49]. Women are more often inclined to solicit medical advice from their family members. Identifying the factors that may

influence patients' preferences could provide valuable explanations for the variation on patients' values and preferences in future research. Knowing patients' previous perception on certain treatment options can help clinicians to explain certain things more clearly and makes clinical consultation more efficient.

Fourthly, we will check for consistency in the participants' choice on their threshold of how long HA can delay THA they think it worthwhile proceeding. If participants have discrepant answer between the trade off and anticipated regret exercise we will provide them the opportunity to change their responses. Interviewers will test patients` understanding of the information presented using standardized questions and rate respondents understanding based on their judgment. This ensures the validity of patients' values and preference elicitation.

Implications

Although there is increasing awareness regarding shared decision-making and patient centered care, the explicit consideration of values and preferences in the care of individual patients and in the recommendations made by clinical practice guidelines remains limited [31-36].

Given the existing evidence, the choice between HA and THA for patients with non-advanced OA is challenging. The research outlined in this protocol will provide explicit, quantitative expressions of patients' valuations of their expected delay of HA on THA. This information will alert clinicians to this issue and may provide guidance in their interactions with patients. It will certainly provide crucial information for guideline developers making recommendations for clinical practice. Identifying the factors that may influence patients' preferences could provide insight into variations in broader perspective of patients' values and preferences in future research.

Our protocol also addresses some of the limitations of the previous studies in the field of medical written information regarding using adequate amount of information in patients' values and preference assessment. Results will have implications for clinical practice in terms of providing patients' with the right amount of information in the shared decision-making process.

Table 1: Flow chart of study design

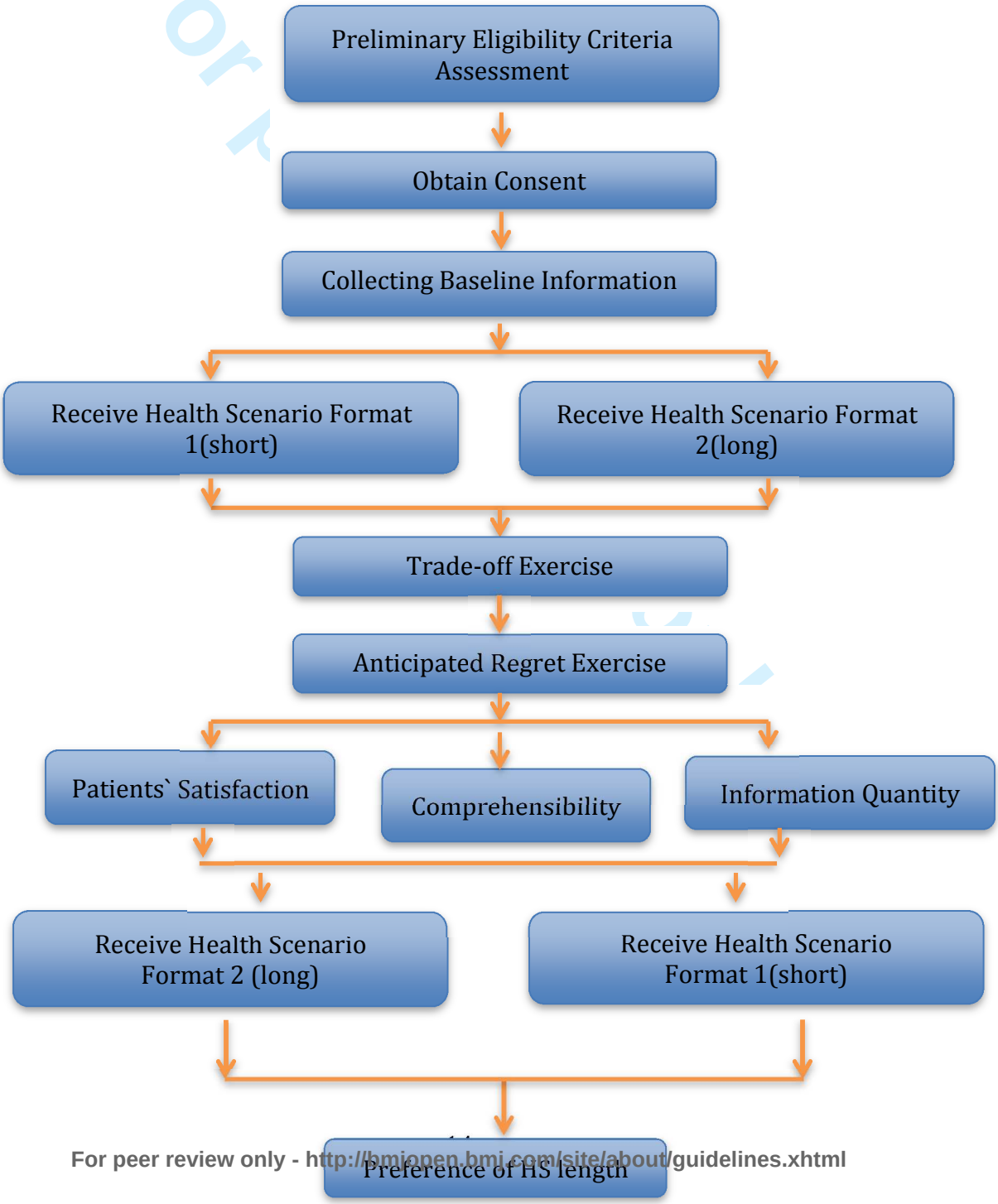

Table 2 Inclusion and Exclusion criteria

Inclusion criteria	*Exclusion criteria*
(i) Patient is at least 40 years old	(i) Patient has a history of prior hip surgery
(ii)Patient diagnosed by X-ray or magnetic resonance imaging (MRI) with mild or moderate (grades 1 and 2) OA based on Tonnis classification of OA**[50]** *Grade 0: No signs of OA.* *Grade 1: Mild: increased sclerosis, slight narrowing of the joint space, no or slight loss of head sphericity.* *Grade 2: Moderate; small cysts, moderate narrowing of the joint space, moderate loss of head sphericity.* *Grade 3: Severe: large cysts, severe narrowing of obliteration of the joint space, severe deformity of the head.*	(ii) Patient is unable of complete the research tasks due to cognitive impairment or language barriers
(iii) Patient has history of failed conservative management	(ii) Patient is unwilling or unable to provide informed consent.
(iv) Patient provides a written informed consent.	

]

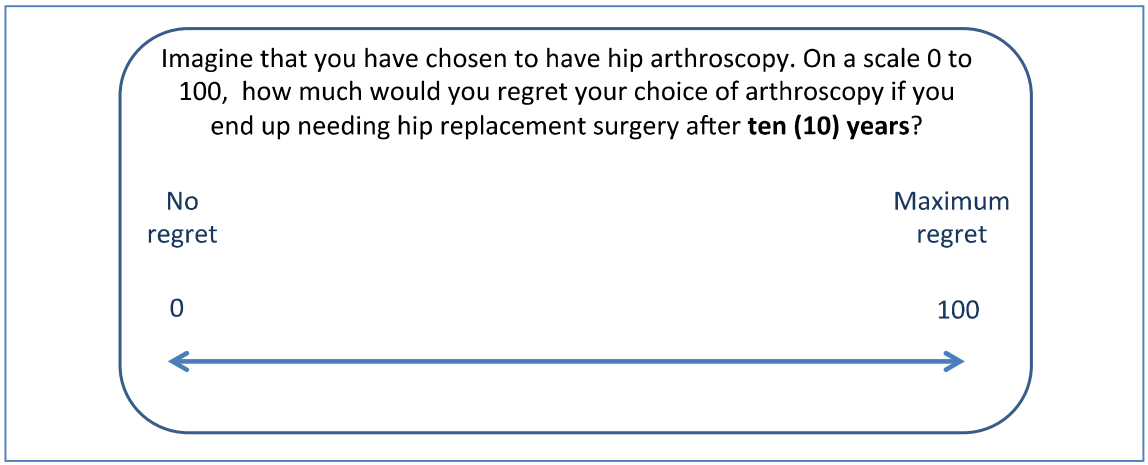

Table 3: Summary of analysis plan

Study	Objectives	Outcomes	Predictors	Hypothesis	Outcome Measure	Methods of Analysis
Pilot stage						
	Determine feasibility	a) Recruitment rate		2 subjects/week	Subjects per week	
		b) Time to conduct the interview and finish all the measurement		1hour would be optimal	Interview duration	
		c) Patients attrition		Less than 5%	Patients attrition rate	
Study one: Interview Study	Primary	a) Delay time	age, gender, ethnicity, educational level, social economics status and medical history		Trade-off exercise	Normally distributed: mean delay time +SD; mean delay time and confidence interval If data is skewed: mode, median, and interquartile range
	Secondary	a) Patients' anticipated regret scores			100mm Visual Analog Scale	T-test
Study two: RCT	Primary	a) Patients' satisfaction on the HSs		Higher satisfaction on short version	7-point Likert type scale	T-test
	Secondary	a) Understandability		Both have rated as 5/7	7-point Likert type scale	T-test
		b) Information quantity		Short will be rated as 4; Long will be rated as 5;	7-point Likert type scale	T-test
		c) Patients' preference on length of format		Prefer short version	7-point Likert type scale	T-test or Mann Whitney U test
Sensitivity Analyses		Patients' satisfaction on the HSs		Higher satisfaction on short version	7-point Likert type scale	Mann–Whitney U test
		Comprehensibility		Both have 5/7	7-point Likert type scale	Mann–Whitney U test
		Information quantity		Short will be 4; Long will be 5;	7-point Likert type scale	Mann–Whitney U test
		Patients' preference on length of format		Prefer short version	7-point Likert type scale	Mann–Whitney U test

Table 4: Sample size estimation tables

Study	α	SD	*L*(width of CI -years)	Sample size
Study one	0.05	2	0.5	246
			1	62
			2	16

Study	α	β	SD	Difference	Sample size (Per arm)
Study two	0.05	0.8	1	0.5	62
				1	16
				2	4

Table 5: Inconsistency checking

Definitions/criteria of inconsistencies	Explanations and Examples
(i) Participants anticipate regret score is higher when delay in need for THA is longer than it is at their threshold of delay time.	In the example we give that measures anticipated regret scores: we set the 5 time points as A (12 months), B (1.5 years), C (2 years), D (3 years) and E (4 years). The participant chose 2 years as the shortest delay time at which he/she can accept for processing HA. Then they placed scores 60 to represent their regret on VAS at 12months but scores 90 to represent his/her regret at 1.5years. In other words, the regret scores "r" on VAS shows: rA<rB, OR, rB<rC, OR rC<rD, OR rD<rE.
(ii) Participants anticipate substantial regret although the HA would delay THA longer than their threshold of delay time.	We define substantial as the anticipated regret score on VAS at the time point that they chose in the "trade off" exercise or any longer delay time point is bigger than (30) on the 100 VAS scale. The participant chose 2 years as the shortest delay time at which they can accept for processing HA. Then they still placed scores 60 to represent their regret on VAS at 2years, 3 years or 4years. In other words, the regret scores "r" on VAS shows: rC>0, OR rD>0, OR rE>0.
(iii) Patients do not anticipate any regret when delay in THA end up being shorter than what their threshold of delay time.	Comparing to the time point that participants chose in the "trade off" exercise, the anticipated regret score on VAS at any shorter delay time point is equal to (0). For example, the participant chose 2 years as the shortest delay time at which they can accept for processing HA. Then they place scores 0 to represent their regret on VAS at 12months and 1.5years. In other words, the regret scores "r" on VAS shows: rA=0, OR rB=0.

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Contributors: YZ, KAOT, TA and GHG designed the study. YZ drafted the manuscript, with substantial inputs from TA, KAOT and GHG. DY, AT and KAOT drafted the trade-off exercise and regret exercises. BDB, GHG provided feedback on the regret exercises. MI and YZ drafted the HSs. PA, KAOT, YZ conducted the interview to test HSs. All authors contributed to the refinement of the study protocol and approved the final manuscript. GHG is the principal investigator of the study.

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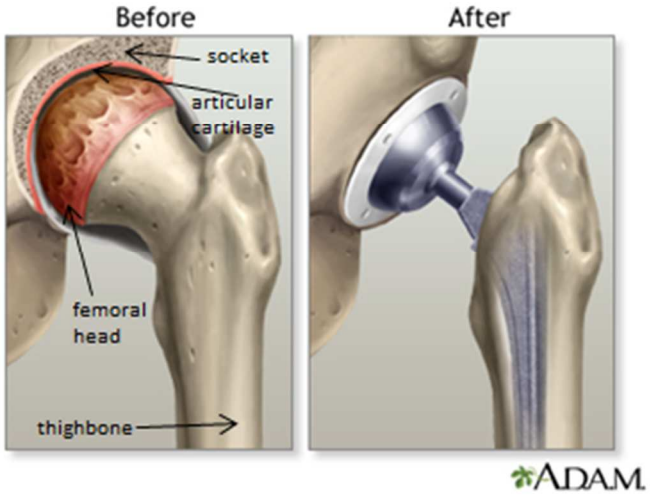
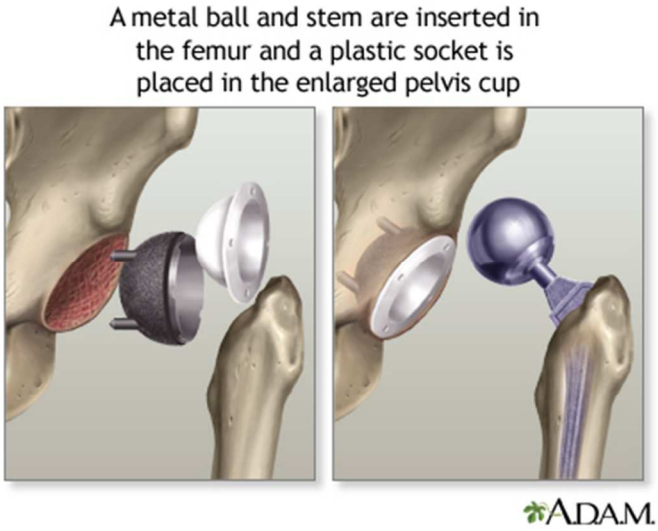
Total Hip Replacement for Hip Osteoarthritis (SHORT)

Introduction



Hip replacement is a surgery that aims to relieve arthritis pain, stabilize and improve the function of your hip. The most common cause for the pain is osteoarthritis (OA). Cartilage, which is the rubbery tissue that cushions your bones and joints, can break down and wear away. As a result, the bones rub together, causing pain, swelling, and stiffness. The surgeon will remove the old hip joint and put in a new joint. If other treatments such as physical therapy, pain medicines, and exercise have not helped, then hip replacement surgery might be an option for you.

Procedure:



- The anesthetist will put you to sleep if you request it, and you will not feel any pain during surgery.
- After you receive anesthesia, your surgeon will open up your hip joint and does the following:
  - Removes the damaged ball from the thighbone and cleans out the socket.
  - Replaces the natural joint with an artificial ball and socket.
- The surgery usually takes 1 to 3 hours.

Benefits:

- Main benefit:

- Relief of symptoms, including reduced pain, increased mobility and/or regained ability to perform activities of daily living.
- The above improvements depend on the severity of your OA and other preexistent diseases.

➢ Post-operative mobility:

- Most of you will have an increased range of movement 3 months after surgery. About 51 in 100 (51%) of you will not need an aid to walk and will be able to move your hip more than 160 degrees.
- About 77 in 100 (77%) of you will be able to walk without support, 21 in 100 (21%) will use a cane, and 2 in 100 (2%) will use crutches (Data from patients average age of 80; range, 56-98 years old) after 1 to 2 years.

➢ Pain relief:

- About 87 to 91 in 100 (87%-91%) of you will have great or complete pain relief, and 9 to 13 in 100 (9%-13%) of you will experience an unfavorable long-term joint pain after the procedure from 3 months to 5 years (Data from patients average age of 69 years old).

➢ Sleep:

- Your sleeping quality will improve significantly 10 weeks after surgery.

➢ Determinants regarding home management, mobility, and work will considerably improve after 3 months.

Recovery:

➢ Management:

- You may have great deal of pain requiring painkillers within the first days.
- You may have some pain for up to 2-3 weeks and the pain may persist for 3 months.

➢ Rehabilitation:

- You will have severe mobility restrictions and the types of restriction will depend on the specific procedure of your surgery. You will need a walker for the first days to weeks; then a cane or crutches for weeks up to 3-6 months.
- You will not be able to bend your hip over 90 degrees for 3 months.
- Physical therapy is an important part of the recovery process. You will work with a physical therapist to develop an exercise and rehabilitation program while your stay in the hospital.

- The rehabilitation program generally includes exercises to stretch and strengthen the muscles surrounding the hip joint, as well as training in activities of daily living.
- Most of you will be able to resume your activities of daily living within 3 to 6 months.

Long-term outlook:

- 90 out of 100(90%) of your hip replacements will last longer than 10 years.
- 85 out of 100(85%) of your hip replacements will last longer than 20 years.
- Over the course of 15 to 20 years, the artificial hip joint will loosen and you may need a second replacement.

Possible Risks and complications:

- In 6 months post operation, about 30 in 100 (30%) of you will have at least one complication.
- While some complications can be a bit more serious, most can be treated successfully.
- Urine retention: About 20 to 35 in 100 of you (20-35%) will experience it.
- Infections: About 1 in 100 of you (1%) will develop a wound or deep infection after the operation.
- Death: 0.3 out of 100(0.3%) will die.
- Blood clots in the legs or pelvis: About 0.5 in 100 (0.5%) of you may experience it before hospital discharge.
  - *The blockage causes pain and swelling in the affected leg that typically gets better in about a month.*
- Blood clots in the lungs: About 0.9 in 100(0.9%) during the first 6 months.
  - *This leads to shortness of breath, sometimes severe, which with anticoagulant treatment resolves in about 2 weeks. Anticoagulant treatment will be used for 3 months.*
- Dislocation of the hip: About 4 in 100(4%) at the first 6 months.
  - *You could experience sharp, pain that become worse if the joint has moved. Your orthopedic surgeon will pull on the leg to reposition the hip within the socket under anesthesia.*
- Nerve damage: About 1 to 3 in 100 (1%-3%).

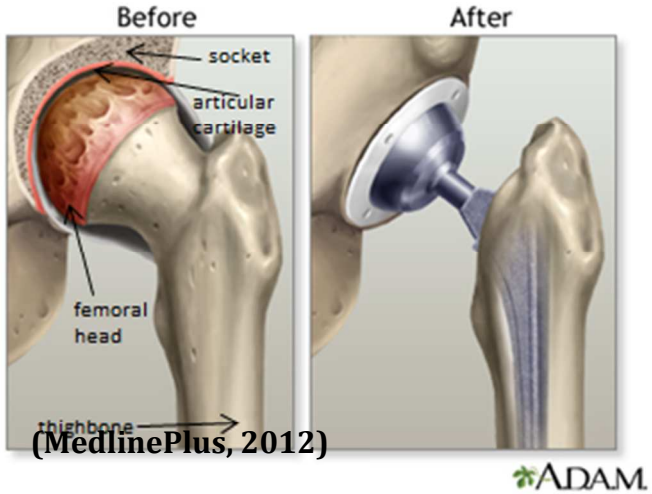
- *If there is nerve damage, you will have decreased feeling or loss of strength in the leg, foot or ankle area.*

- Different leg lengths: Less than 1 in 100(1%) of you will need another operation because one leg is longer than the other.

Total Hip Replacement for Hip Osteoarthritis (LONG)

Introduction

Hip replacement is a surgery, also called Total Hip Arthroplasty, which aims to relieve arthritis pain, improve function, and make your hip more stable. The most common cause for the pain is osteoarthritis (OA), and the reason for OA is unknown. Cartilage, which is the rubbery tissue that cushions your bones and joints, can break down and wear away. As a result, the bones rub together, causing pain, swelling, and stiffness. During the operation, the surgeon will remove the old hip joint and put in a new joint. If other treatments such as physical therapy, pain medicines, and exercise have not helped, then hip replacement surgery might be an option for you.



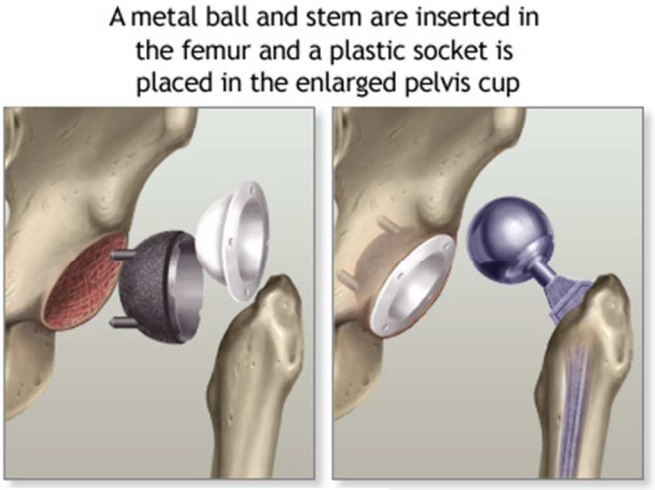
(MedlinePlus, 2012)

Procedure

- The hip joint is made up of two major parts. One or both parts may be replaced during surgery.
  - The hip **socket**, which is cup-shaped, and sits in the pelvis.
  - The **ball**, which is the upper end of the thighbone (called the femoral head).
- The new hip that replaces the old one is made up of these parts:
  - A socket, which is usually made of strong metal.
  - A liner, which fits inside the socket and usually, is made of either plastic, ceramic, or metal.
  - A metal or ceramic ball that will replace the top of your thighbone.
  - A metal stem that is attached to the thighbone to make the joint more stable.

- If you would like to sleep during the surgery, the anesthetist will put you in sleep, and you will not feel any pain during surgery.
- Anesthesia:
  - You will not feel any pain during surgery due to one of two types of anesthesia that you will receive
    - General anesthesia: you will be 'asleep' (unconscious) for the procedure and not have any memory of the surgery.
    - Regional anesthesia: local anesthesia will be put in your lower back to make your body numb so you won't feel the procedure. Although you will still be awake and aware of the procedure the anesthesiologist can give you sedation medication to make you quite sleepy so you aren't anxious and mostly unaware of the procedure.

- After you receive anesthesia, your surgeon will make a surgical cut to open up your hip joint. Then you surgeon will:
  - Cut and remove the head of the thighbone.
  - Clean out your hip socket and remove the rest of the cartilage and damaged bone.
  - Put the new hip socket in place, then insert the metal stem into your thighbone.
  - Place the correct-sized ball for the new joint.
  - Secure all parts with cement.
  - Repair the muscles and tendons around the new joint.
  - Close the surgical cut.
- The surgery usually takes 1 to 3 hours.



(MedlinePlus, 2012)

Benefits

- Main benefit:
  - Relief of symptoms, including reduced pain, increased mobility and regained ability to perform activities of daily living.
  - Function improvement and pain relief are depending on the severity of your OA and other preexistent diseases.

- Mobility postoperatively:
  - Most of you will have an increased range of movement 3 months after surgery. About 51 in 100 (51%) of you will not need

assistance to walk and will be able to move your hip more than 160 degrees.
- About 49 in 100 (49%) of you will require assistance to walk and will be able to move your hip less than 160 degrees after 3 months.
- About 64 in 100 (64%) of you will be able to walk longer distances compare to pre-operatively after 3 months (Data from patients age 55-84 years old).
- About 77 in 100 (77%) of you will be able to walk without support, 21 in 100 (21%) will use a cane, and 2 in 100 (2%) will use crutches (Data from patients average age of 80; range, 56-98 years old) after 1 to 2 years.

- Pain relief:
  - About 87 to 91 in 100 (87%-91%) of you will have great or complete pain relief, and 9 to 13 in 100 (9%-13%) of you will experience an unfavorable long-term joint pain after the procedure from 3 months to 5 years follow-up (Data from patients average age 69 years).
  - About 25 in 100 (25%) of you will only have occasional pain 3 months after operation.

- Sleep:
  - Your sleeping quality will improve significantly 10 weeks after surgery.

- Psychological improvements:
  - Your psychosocial quality of life will improve regarding social interaction, communication, alertness behavior, and emotional behavior immediately and 6 months after the operation.

- Factors such as home management, mobility, and work will considerably improve after 3 months.

Recovery:

- Management:
  - After surgery, you may experience a great deal of pain within the first days and you may need to take painkillers.
  - You may be given pain medication intravenously using a pump (patient-controlled-analgesia).
  - You may have some pain for up to 2-3 weeks and the pain may persist for 3 months.

- You are likely to have problems with constipation from painkillers in the first weeks after surgery.
- You will be given an antibiotic to prevent infection.
- You may also be given a medication or compression boots and stockings to prevent blood clots in the legs.

➢ Rehabilitation:

- You will have severe mobility restrictions and the types of restriction will depend on the specific procedure of your surgery. You will need a walker for the first days to weeks; then a cane or crutches for weeks to 3-6 months.
- You will not be able to bend your hip over 90 degrees for 3 months. This means you cannot bring your knee up to your chest and you also cannot bend forward at the hip past 90 i.e. if tying your shoes.
- You may also have restricted adduction (moving your leg past midline) and any twisting (internal/external rotation) of the leg.
- Your surgeon will determine the timeline for these restrictions.
- You will also have difficulties for dressing and need for mechanical aids.
- Physical therapy is an important part of the recovery process. The length of stay in the hospital for most of you will be about 1 to 3 days, during which time you will work with a physical therapist to develop exercises and follow a rehabilitation program.
- You may need physiotherapy up to 3 month depending on your condition.
- The rehabilitation program generally includes exercises to stretch and strengthen the muscles surrounding the hip joint, as well as training in activities of daily living, such as stair climbing, and walking.
- Most of you will be able to resume your activities of daily living within 3 to 6 months.
- Your ability to perform household, domestic tasks (for example cutting toenails, having a bath, climbing stairs) will improve.
- About 84 in 100 (84%) of you will be able to maintain your own home, 6 in 100 (6%) of you will live at home with assistance, and only 10 in 100 (10%) will need someone to take care of you full-time 20 years after operation (Data from patients average age 80 years; range, 56-98 years).
- You might be able to return to recreational sports after 6 months after discussion with your surgeon.

Long-term Outlook:

- About 90 out of 100 (90%) of your hip replacement will last longer than 10 years.
- About 85 out of 100 (85%) of your hip replacements will last longer than 20 years.
- Over the course of 15 to 20 years, the artificial hip joint will loosen and you may need a second replacement.

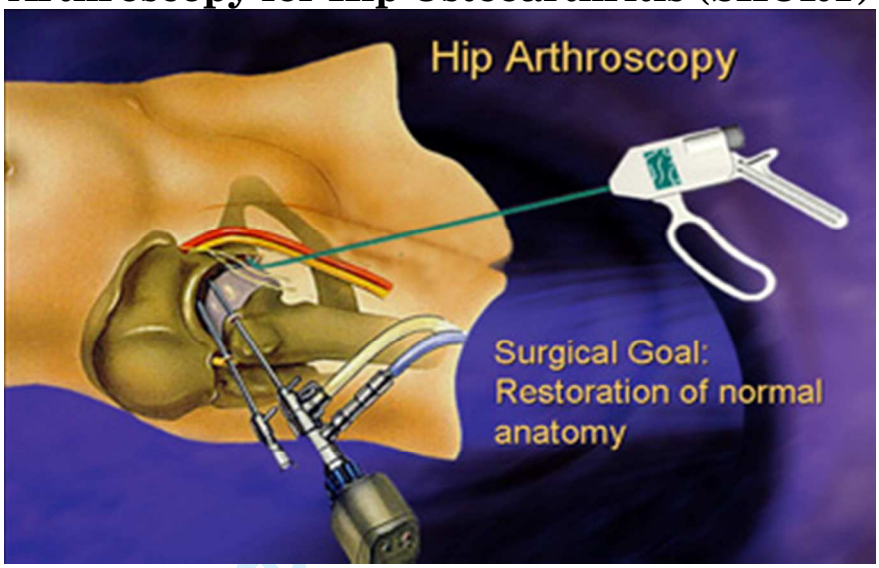
Risks and complications:

- 6 months post operation, about 30 in 100 (30%) of you will have at least one complication.
- While some complications can be a bit more serious, most can be treated successfully, such as blood clots.
- Urine retention: About 20 to 35 in 100(20-35%) of you will experience it.
    - *You may urinate frequently; you may feel an urgent need to urinate but have little success when you get to the toilet; or you may feel you still have to go after you've finished urinating.*
- Infections: About 1 in 100 (1%) of you will develop an infection after the operation.
    - It may occur in the wound or deep around the artificial implants.
- Deep joint infection: 0.2 in 100(0.2%) in first 90 days.
    - *You will experience fever or chills due to the infection, unusually swelling of the hip joint. The hip replacement will be removed, and you will be without a hip joint and receiving antibiotics for months.*
- Risk of a complication will be higher if you have other diseases. For instance, 40-50 in 100 (40-50%) of you who have at least three other conditions, such as heart disease, urinary tract infection, or obesity will experience a complication.
- Death: 0.3 out of 100(0.3%) patients who undergo hip replacement surgery will die.
- Blood clots in the legs or pelvis: About 0.5 in 100 (0.5%) before hospital discharge.
    - *The blood clot, due to immobilization, causes pain and swelling in the affected leg that typically gets better in about a month. About 17% to 50% of you will have persisting leg swelling, pain, vein swelling, and skin induration, for a longer period, up to 2 years.*

- If you are older, overweight, have cancer, or have experienced blood *clots before, you will be more likely to get blood clots after surgery*.
- This clot can potentially lead to another complication, which is localized swelling in the leg due to clot and decreased flow of blood to the heart.

- Dislocation of the hip: About 1 in 100 (1%) of you will have dislocated the hip by first week, 3 in 100 (3%) by eighth week, and about 4 in 100(4%) at the first 6 months
  - *You could experience sharp, pain that become worse if the joint has moved. These symptoms will last until the damaged tissue has been allowed to rest and heal completely, and will require use of painkillers. Your orthopedic surgeon will have to pull on the leg to reposition the hip within the socket under anesthesia.*
- Nerve damage: 1 to 3 in evey100 (1%-3%) of you.
  - *If there is nerve damage, you will have decreased feeling or loss of strength in the leg, foot or ankle area. Around 0.5% of the patients will have the nerve damage permanently.*
- Different leg lengths: Less than 1 in 100(1%) of you will need another operation because one leg is longer than the other.
  - You might need another surgery because the difference length of your legs will cause severe post surgery problems such as walking difficulty, pain, or dislocation.

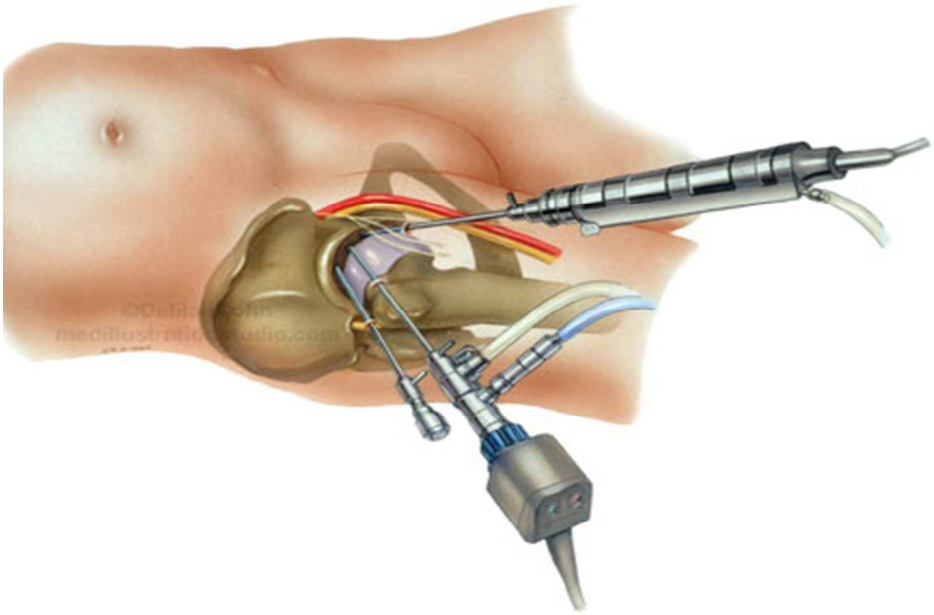
Arthroscopy for Hip Osteoarthritis (SHORT)



Introduction

Hip arthroscopy is a surgical procedure that gives doctors a clear view of the inside of the hip joint. This helps them diagnose and treat joint problems. The surgeon will make small cuts around your hip and look inside using a tiny camera. Other medical instruments may also be used inside to fix your hip. Patients with Osteoarthritis and hip pain who do not respond to conservative treatment and have no evident cause on standard radiographs, might be candidates for a hip arthroscopy. Arthroscopy has also been used to diagnose and evaluate other diseases affecting the hip, such as Femoroacetabular Impingement, Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Perthes Disease, Synovial Chondromatosis, and Ankylosing Spondylitis of the hip.

Procedure:



- Hip arthroscopy is performed through small incisions (about 0.5 to 1cm in length each) using a camera to visualize the inside of the hip joint.
- The tiny camera splits the muscle fibers. When the camera is removed, the muscle fibers return to their normal position and alignment.
- Surgeons will be able to see the joint through the camera, identify the problem(s), and
  - Repair torn cartilage
  - Remove loose pieces of cartilage, bone or ligaments
  - Reshape the bones
- The operation typically takes 60-90 minutes.

Benefits:

- Arthroscopy can potentially delay the need for Total Hip Replacement surgery in the future.
- Minimally invasive procedure: You will have very small incisions (0.5-1cm in length each, two to four in total) around the hip.
- Outpatient procedure: You usually go home the same day that you have surgery.
- Short rehabilitation period: On the first day after surgery, you will begin the rehabilitation process. This includes getting out of bed and walking. You may be able to bear some weight on the treated leg right away.

- You will have greater chance of going back to play competitive sports and a high functional level compare to total hip replacement surgery.
- Early return to sport: Most patients find they are back to full activities 3-4 months following hip arthroscopy.

Recovery:

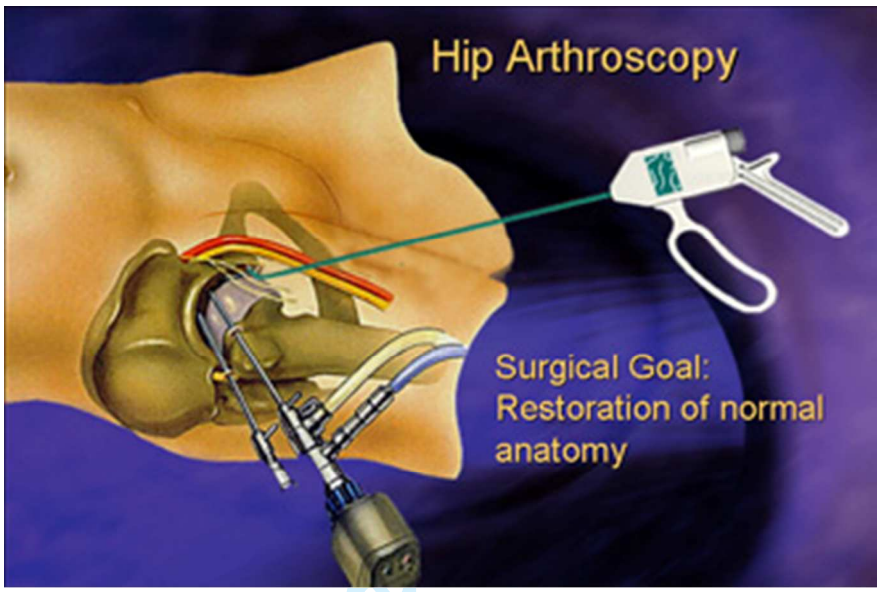
- Management:
  - You may have some pain and discomfort following your surgery. You will be given a prescription for pain medication which can be taken as needed.
  - You will need to leave the patches on your wound and keep it dry for 24 hours.
- Rehabilitation:
  - You can have protected weight bearing (weight bearing as tolerated with crutches) immediately following surgery.
  - You will need to begin physiotherapy as early as 48 hours after surgery with the guidance of your physiotherapist.
  - The rehabilitation will involve exercises to improve range of motion of the hip as well as strengthening exercises.
  - Your physiotherapist will help you decide when and how to progress your exercises in the long run.
  - It is very important that you will use crutches for the first two weeks after surgery to help protect the repair and improve gait mechanics following surgery
  - You may require assistance with driving for up to 6 weeks.
  - Exercises like stationary bike are a part of the rehab and may begin as soon as 48 hours after surgery.
  - Sedentary work can be partially resumed in one to two weeks. Labor-intensive work may require 3 months.
  - You can resume full physical activity will resume up to 3 to 6 months depending on your goals.

Possible Risks and complications:

Hip arthroscopy appears to be safe. The overall complication rate with hip arthroscopy was 4 in 100 (4.0%) of you with the vast majority of complications being non-life or limb threatening in nature. Here are rare complications that can occur:

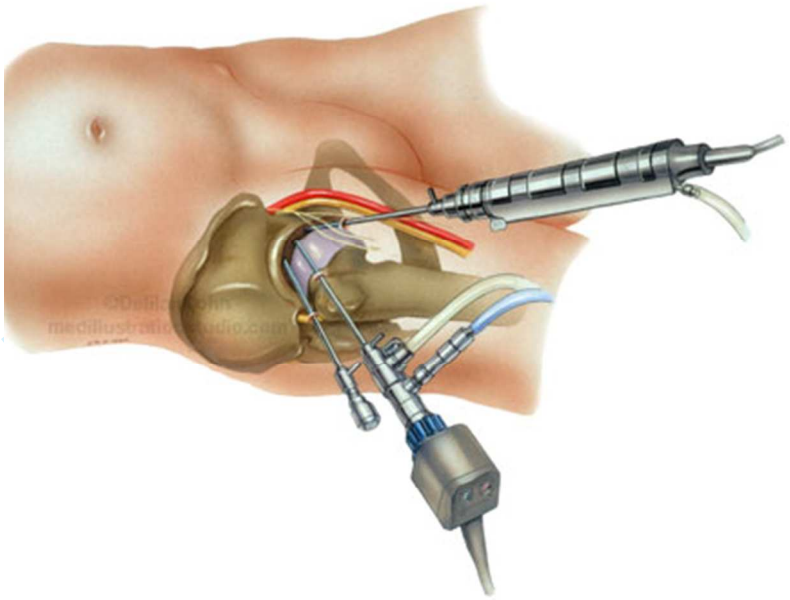
- Neurologic traction injury: About 0.3 in 100(0.3%) of you will experience it.
  - *This is the least severe form of nerve injury.. The actual structure of the nerve remains intact, but there is a transient interruption in the sensations being conducted through the injured nerve fiber. You could have decreased feeling or loss of strength in the skin on the lateral part of your leg and genital area, but there is usually a complete recovery.*
- Intra-abdominal Fluid Extravasations: About 0.15 in 100(0.15%) of you will experience it.
  - *During the procedure, when fluid is removed from the hip joint by the arthroscopy, some fluid may leak into the abdomen. You could experience the sense of increased abdominal pressure and discomfort that involves a measurable change in the circumference of your abdomen sometimes with swollen legs.*
- Dislocation of the hip: About 0.03 in 100(0.03%) of you will experience it.
  - *You could experience sharp, pain that become worse if the joint has moved. These symptoms will last until the damaged tissue has been allowed to rest and heal completely, and will require use of painkillers. Your orthopedic surgeon will have to pull on the leg to reposition the hip within the socket under anesthesia.*
- Blood clots in the legs or pelvis: About 0.06 in 100 (0.06%) of you will experience it during the first 6 months.
  - *The blood clot, due to immobilization, causes pain and swelling in the affected leg that typically gets better in about a month. About 17% to 50% of you will have persisting leg swelling, pain, vein swelling, and skin induration, for a longer period, up to 2 years.*

Arthroscopy for Hip Osteoarthritis (LONG)



Introduction

Hip arthroscopy is a surgical procedure that gives doctors a clear view of the inside of the hip joint. This helps them diagnose and treat joint problems. The surgeon will make small cuts around your hip and look inside using a tiny camera. Other medical instruments may also be used inside to fix your hip. Patients with Osteoarthritis and hip pain who do not respond to conservative treatment and have no evident cause on standard radiographs, might be candidates for a hip arthroscopy. Arthroscopy has also been used to diagnose and evaluate other diseases affecting the hip, such as Femoroacetabular Impingement, Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Perthes Disease, Synovial Chondromatosis, and Ankylosing Spondylitis of the hip.



Procedure:

- The hip joint is made up of two major parts. The hip joint is a ball and socket joint that not only allows flexion and extension, but also rotation of the thigh and leg.
  - The hip **socket**, which is cup-shaped, sits in the pelvis.
  - The **ball** is the upper end of the thighbone (called the femoral head).
- If you would like to sleep during the surgery, the anesthetist will put you to sleep, so you will not be awake and therefore will have no memory of the procedure.
- Anesthesia:
  - There are two anesthesia options for this procedure, you can either have a general or a regional (spinal) anesthetic. Both options are safe and your pain will be managed with both.
    - General anesthesia: you will be 'asleep' (unconscious) for the procedure and not have any memory of the surgery.
    - Regional anesthesia: local anesthesia will be put in your lower back to make your body numb so you won't feel the procedure. Although you will still be awake and aware of the procedure the anesthesiologist can give you sedation medication to make you quite sleepy so you aren't anxious and mostly unaware of the procedure.
- After you receive anesthesia, your surgeon will put your leg in traction.

- This means that your hip will be pulled away from the socket enough for your surgeon to insert instruments, see the entire joint, and perform the treatments needed.
- The bones of the hip joint (the ball and socket) are separated by approximately 1cm by applying traction to the foot while wearing a special boot.

- Initially, air and/or fluid are injected into the hip, under x-ray guidance. Once correct placement of the instrument has been confirmed typically small incisions are made around the hip.
- Each of these incisions generally are approximately 0.5 to 1 cm in length.
- Through these small holes, the tiny camera ('arthroscope') and instruments are passed into the joint under x-ray guidance.
- The tiny camera will split the muscle fibers. When the camera is removed, the muscle fibers return to their normal position and alignment.
- Surgeons will be able to see the joint through the camera and identify the problems. Depending on the problem encountered, your surgeon will perform the appropriate procedures such as:
  - Repair torn cartilage
  - Remove loose pieces cartilage, bone or ligaments
  - Reshape the bones
- The operation typically takes 60-90 minutes but duration will vary depending on the problem in the hip joint but can last up to 120 minutes.
- After surgery, you will stay in the recovery room for 1 to 2 hours, then stay in the surgery area before being discharged to go home.

Benefits:

- Arthroscopy can potentially delay the need for Total Hip Replacement surgery in the future.
- Main possible benefits of arthroscopy compared to total hip arthroplasty:
  - Relief of symptoms, including reduced pain.
  - Functional improvement, meaning increased mobility and regained ability to perform activities of daily living, the

extent of which depend on the severity of your OA and other pre-existing conditions before the surgery.
- It helps to diagnose and treat early causes of arthritis, possibly preventing progression.
- Hip arthroscopy is a minimal invasive surgery compared to the open surgical alternatives. You will have very small incisions (about 0.5-1 cm each in length, two to four in total) around the hip, leading to minimal scarring.
- Outpatient procedure: You usually go home the same day or the next day that you have surgery.
- You will have chance of going back to activity at a high functional level. For example, playing competitive sports such as soccer or hockey.

- Less restriction on physical activities than after a hip replacement: On the day after surgery, you will begin the rehabilitation process. This includes getting out of bed and walking.
- You can bear some weight on the treated leg the day after surgery.
  - You will be able to ride the stationary bike 48 hours after your surgery.
- Early return to physical exercise: Most likely you will go back to full activities 3 to 6 months following hip arthroscopy.
  - *One to two weeks after the surgery after your wound has healed, you can walk in the pool.*
  - *Approximately six to eight weeks after the surgery, you maybe able to increase activities including light aerobic exercise.*
  - *Approximately 3-6 months after surgery, you will be able to do unrestricted exercise and* recreational sports after discussion with your surgeon.
  - *These sports may include soccer, football, tennis, etc.*

Recovery:

- Management:
  - After hip arthroscopy your wound is covered with patches.
  - You will need to leave the patches in place and to keep your wounds dry for 24 hours.
  - You will be given a prescription for pain medication following your surgery which you will take as needed.

- You will be given oral or intravenous antibiotics to prevent infection and you may also be given a medication to prevent blood clots in the legs.

➢ Rehabilitation:

- You are able to have protected weight bearing (weight bearing as tolerated with crutches) immediately following surgery.
- You will need to begin physiotherapy as early as 48 hours after surgery.
- Exercises like stationary bike are a part of the rehab and may begin as soon as 48 hours after surgery.
- Your physiotherapist will guide you through the rehabilitation program, which will involve exercises to improve range of motion of the hip as well as strengthening exercises.
- Your physiotherapist will help you decide when and how to progress your exercises in the long run.
- It is very important that you use crutches for the first two weeks after surgery to help protect the repair and improve gait mechanics following surgery. The rehabilitation progress, as well as the extent of the tear and/or associated problems, will determine the weaning process.
- Your joint can be quite sore at first, and it may need some time to settle. Therefore, you are not allowed to do movements/activities that may provoke the pain such as lifting, twisting, overstretching, and jarring.
- You may require assistance with driving for up to 6 weeks.
- In most occupations, such as sedentary job, you will be able to return to work in one to two weeks. However, since the return at this point will not be completely normal you may need some breaks in between. You may not be able to work they whole day, but you can be productive.
- If your job requires significant manual labor and lifting, the return may not occur completely until at least three months following surgery. A discussion with your surgeon may be needed too.
- Full physical activity will resume up to 3 to 6 months depending on your goals.

Risks and complications:

Hip arthroscopy appears to be safe. Although about 4 in 100 (4%) of you may present some kind of complication, most of the complications are not life or limb threatening.

- Neurologic traction injury: About 0.3 in 100 (0.3%) of you will experience neurologic traction injury
  - *This is the least severe form of nerve injury. The actual structure of the nerve remains intact, but there is a transient interruption in the sensations being conducted through the injured nerve fiber. You could have decreased feeling or loss of strength in the skin on the lateral part of your leg and genital area, but there is usually a complete recovery.*
  - *Most commonly, numbness will go away within a week or so. In some cases, smaller areas may continue to be numb for several weeks.*
- Intra-abdominal fluid collections: About 0.15 in 100 (0.15%) of you will experience fluid collections
  - *During the procedure, when fluid is removed from the hip joint by the arthroscopy, some fluid may leak into the abdomen. You could experience the sense of increased abdominal pressure and discomfort that involves a measurable change in the circumference of your abdomen sometimes with swollen legs.*
- Dislocation of the hip: About 0.03 in 100 (0.03%) of you will experience dislocation during the first 6 months
  - *You could experience sharp, pain that become worse if the joint has moved. These symptoms will last until the damaged tissue has been allowed to rest and heal completely, and will require use of painkillers. Your orthopedic surgeon will have to pull on the leg to reposition the hip within the socket under anesthesia.*
- Blood clots in the legs or pelvis: About 0.06 in 100 (0.06%) of you will experience blood clot during the first 6 months.
  - *The blood clot, due to immobilization, causes pain and swelling in the affected leg that typically gets better in about a month. About 17% to 50% of you will have persisting leg swelling, pain, vein swelling, and skin induration, for a longer period, up to 2 years.*

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Patients' values and preferences of the expected efficacy of hip arthroscopy for osteoarthritis: A protocol for a multinational structured interview-based study combined with a randomized survey on the optimal amount of information to elicit preferences

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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Surgery, Evidence based practice, Communication, Sports and exercise medicine
Keywords:	Patients' values and preference, Total Hip Arthroplasty, Orthopaedic & trauma surgery < SURGERY, Hip Arthroscopy, Patient Written Information, Decision Making

Patients' values and preferences of the expected efficacy of hip arthroscopy for osteoarthritis: A protocol for a multinational structured interview-based study combined with a randomized survey on the optimal amount of information to elicit preferences

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Keywords
Patients' values and preference, Total Hip Arthroplasty, Hip Arthroscopy, Osteoarthritis, Patient Written Information, Decision Making, Uncertainty

Word count: 5003

Abstract:

INTRODUCTION: Symptomatic hip osteoarthritis (OA) is a disabling condition with up to 25% cumulative lifetime risk. Total hip arthroplasty (THA) is effective in relieving patient's symptoms and improving function. It is, however, associated with substantial risk of complications, pain and major functional limitation before patients can return to full function. In contrast, hip arthroscopy (HA) is less invasive, and can postpone THA. However, there is no evidence regarding the delay in the need for THA that patients would find acceptable to undergo HA. Knowing patients' values and preferences (VP) on this expected delay is critical when making recommendations regarding the advisability of HA. Furthermore, little is known on the optimal amount of information regarding interventions and outcomes needed to present in order to optimally elicit patients' VP.

METHODS AND ANALYSIS: We will perform a multinational, structured interview-based survey of preference in delay time for THA among patients with non-advanced OA who failed to respond to conservative therapy. We will combine these interviews with a randomized trial addressing the optimal amount of information regarding interventions and outcomes required to elicit preferences. Eligible patients will be randomly assigned (1:1) to either a short or a long format of health scenarios of THA and HA. We will determine each patient's VP using trade-off and anticipated regret exercises. Our primary outcomes for the combined surveys will be: 1) the minimal delay time in the need for THA surgery that patients would find acceptable to undertake HA, 2) patients satisfaction with the amount of information provided in the health scenarios used to elicit their VPs.

ETHICS AND DISSEMINATION: The protocol has been approved by Hamilton Integrated Research Ethics Board (HIREB13-506). We will disseminate our study findings through peer-reviewed publications and conference presentations, and make them available to guideline makers issuing recommendations addressing HA and THA.

BACKGROUND

Osteoarthritis and surgical options

Osteoarthritis: Osteoarthritis (OA) is the most common form of chronic arthritis. Approximately 15% of men and women suffer from symptomatic OA[1], representing a large burden on patients, the healthcare system and society. Symptomatic hip OA is a particularly disabling condition with a cumulative lifetime risk of up to 25%. Conservative management of hip OA includes exercise, weight reduction, physical therapy and medications focusing on relieving symptoms, improving joint function, and optimizing quality of life[2]. Pharmacological and non-pharmacological interventions for severe OA are, however, substantially less effective than surgical treatment[3]. Consequently, most patients with severe hip OA eventually need total hip arthroplasty (THA)[3].

Total hip arthroplasty: With an aging population increasingly interested in staying physically active [4], the frequency and cost of THA continues to grow. Currently more than a half million THA procedures are performed annually in the UK and USA alone, and in 2010 the global market was estimated as high as 4.7 billion USD[5].

After failure of conservative treatment, THA is usually effective in relieving patient's symptoms and improving function, with more than 95% prosthesis survivorship at 10-year follow-up and more than 80% survivorship at 25-year follow-up[6, 7]. However, THA is also a major procedure, associated with substantial risk of complications, and with weeks of pain and major functional limitations before patients can return to full function. Therefore, patients and caregivers are interested in less invasive interventions that could postpone THA.

Hip arthroscopy: Less invasive interventions include arthroscopy, partial replacements, and bone-preserving techniques. They have shown varying success rates among OA patients[8]. Hip arthroscopy (HA) is a new and the fastest growing procedure within orthopedic surgery[8]. Despite the lack of high quality evidence, the number of HAs performed is expected to double in the United States in 2013 compared to 2011[9]. HA is used to treat intra articular pathology of the hip, including mild hip OA. Compared to THA it has the advantages of being minimally invasive and having fewer complications [10]. Compared to THA, arthroscopy may help patients achieve higher level of function more quickly with, over the short term less restriction on exercise. The expectation, however, is that patients' underlying osteoarthritis will progress, and THA will ultimately become necessary. The question then arises: what delay in the need for THA would warrant a patient undergoing HA? This is a question of values and preferences.

Measuring patients` values and preference

There are a number of techniques available for eliciting patients direct choices of which the probabilistic version of the Threshold Technique (TT) also called probability trade-off (PTO) exercise is widely used [11]. Following descriptive and probabilistic information regarding benefits and harms associated with treatment choices - for example treatment A and B – in which the relative benefits of treatment A versus B are large, the respondent is asked to choose one option. Typically, patients will choose treatment A. The interviewer then presents an alternative situation in which the relative benefits of A versus B are very small, and patients typically choose B. The

interviewer than presents a small reduction in the probability of benefits, relative to the first scenario, for option A. If the patient continues to choose A, the next scenario presents a small increase in the benefits of A versus B relative to the second scenario. The process is repeated until the indifference point between A and B is established (ping pong approach)[12].

Utility elicitation uses a very different approach, presenting health states and using one of a variety of techniques to elicit the respondent's rating of the value of the health state on a scale between death (typically 0) and full health (typically 1.0 or 100). The patients' responses are used to build a decision model that calculates the treatment option that, given the patient's utilities, achieves the maximum utility-adjusted outcome [13, 14].

Complementary approaches to assess patients' decision-making integrate emotional aspects of the process. One such approach focuses on regret, an aversive emotion people experience when they believe their current situation would have been better had they acted differently in the past[15, 16]. In theory, regret is influenced by both intuitive, affect-based, and analytical, deliberative processes[17, 18]. Reflecting on the anticipated regret of particular decisions (e.g. choosing A versus B in the example above) may alert people to the choice that would be most likely to avoid this aversive emotion[19, 20]. The anticipated regret theory-based approach preserves a rational decision-making framework, while allowing anticipation of the effect of the decision on emotions[21].

Using both (direct choice) trade-off and anticipated regret exercises, our study will provide empirical evidence regarding the delay in the need for THA that patient would find acceptable to undergo HA.

Amount of information presented to elicit patients' values and preference

The choices patients make are critically dependent on how the health scenario (HS) that characterizes the processes and outcomes of the alternative management options (A and B in the above – THA and HA in the current project) are presented. Research in marketing has addressed some of the relevant issues. Information-processing framework[22] suggests that that there are limits to the human ability to assimilate and process information, and that once these limits are surpassed behavior becomes confused and dysfunctional[23]. Evidence suggests an inverted U-shaped relationship between information available and decision quality, in which individuals with too little or too much information made poorer decisions than those with an intermediate amount of information [24, 25].

Other indirect evidence comes from research on written consent forms [26, 27]. Individuals often skim over consent forms for clinical trials in oncology if they are longer than 1,000 words or 4 pages[28]. Twenty-seven oncology trials showed that patients obtain significantly higher objective knowledge when the consent form page count was seven or less [29].

In the area of pharmaceutical product choice, participants have had better understanding of shorter and easier information presentations[25]. One might expect, however, that if the information becomes too scanty, decision quality will deteriorate.

Patients' values and preferences on osteoarthritis surgical options

Given the existing evidence, both HA and THA represent reasonable choices for patients with non-

advanced OA. The choice may, however, be challenging. On one hand, HA is likely to achieve only transient improvement in function. On the other hand, the morbidity associated with THA is substantial.

Therefore, one of the key aspects in the choice between HA and THA is the duration of delay in the need for THA that patients may achieve with HA. If patients demand a delay time much greater than HA can realistically achieve, the procedure should seldom be considered. On the other hand, if patients would be satisfied with much shorter delay time, the procedure should be frequently considered. There is currently no empirical evidence addressing patients' values and preferences regarding the delay they would demand to undertake HA. Knowing typical patients' values and preferences regarding this expected delay is likely to be helpful for patients and health care providers in the clinical encounter and for guideline panelists when making recommendations regarding the advisability of HA.

The assessment of patients' values and preferences will be valid only to the extent patients receive sufficient accurate information on the outcomes of available treatment options presented in ways that they can easily process. Thus far, only limited indirect evidence informs us on the optimal amount of information to provide in scenarios when eliciting patients' preferences.

Our study will provide direct empirical evidence on the optimal amount of information to provide when eliciting patients' values and preferences. It may also provide insight into the amount of information to provide in shared-decision making, although our study only indirectly addresses that issue.

OBJECTIVES

General Objective: The purpose of this study is to improve the management of patients with non-advanced symptomatic hip osteoarthritis (OA) who failed conservative treatment by determining their values and preferences regarding the choice between immediate total hip arthroplasty (THA) versus hip arthroscopy (HA).

*In the **Pilot stage** of our study, we will assess the following feasibility issues:* (i) recruitment rate; (ii) length of time to conduct the interview and fill out all the study measurements; (iii) potential personnel and data management issues.

*In **Study 1*** – our primary objective is to determine the minimal delay time in the need for THA surgery that patients would find acceptable to undertake HA (which we will refer to as the "delay time"). Secondary objectives include assessing patients' anticipated regret if the delay would differ from their expectations, as well as potential determinants of their preference (e.g., age, gender, educational level, and socioeconomic status).

*In **Study 2*** – our objective is to assess the ease of understanding, optimal quantity of information, and patients' satisfaction regarding alternative formats of the HSs used to elicit their preferences.

METHODS

Study design

Pilot study

In a pilot study, we will assess the following feasibility issues: (i) recruitment rate; (ii) length of time to conduct the interview and fill out all the study measurements; (iii) potential personnel and data management problems in real-life setting. We will perform this study at the outpatient orthopedic clinic of the McMaster University Medical Center (Hamilton, ON, Canada).

Study 1: We will perform a multinational, cross-sectional, structured interview-based survey to assess the delay in THA that patients would demand to choose HA.

Study 2: Within Study 1, we will conduct a randomized trial comparing a short version versus a long version of HA and THA health scenarios.
Table 1 shows the study flow.

Setting: The study will take place at McMaster University Medical Center, Hamilton, Canada; St. Michael's Hospital, Toronto, Canada; Hospital de Sant Pau, Barcelona, Spain; and Sorocaba Hospitals, São Paulo, Brazil.

Study population

The population of interest consists of adults diagnosed with non-advanced hip OA. Table 2 presents the detailed inclusion and exclusion criteria.

Recruitment strategy

We will prospectively identify consecutive patients confirmed with non-advanced hip OA referred for consideration of HA. The orthopedic surgeon will send a letter in advance of their visit to inform patients about our research project and the possibility of being approached by our research assistant (RA) for this study. The RA will then make initial contact with all the patients by phone to explain the purpose of the study. When the patients come to the orthopedic clinic, we will ask patients for their written informed consent.

Participants interview

Baseline information

We will document patients' age, gender, ethnicity, educational level (not completed high school; completed high school only; some college/university; completed college or university), yearly income, and their impression of the experience of close relatives or friends who have undergone HA or THA (categorized as extremely dissatisfied; dissatisfied; neutral; satisfied; extremely satisfied, or differing across individuals).

Health scenarios

The health scenarios are designed to inform patients of the surgical options. Based on available evidence [30] we will include the following five sections in the HSs for THA and HA: [26] Brief introduction to the surgery; [31] Description of the surgical procedure; [iii] Post-operative recovery and rehabilitation; [32] Expected benefits; [v] Risks and potential complications. *(See appendix: Script #1: Health scenarios)*

The short versions have approximately 850 words and the long versions approximately twice the

number of words; both versions use the same sub-headings.

To ensure we present accurate estimates of benefits and risks of THA and HA to patients[33], conveyed in the most simple and easy-to-understand way possible, we applied a rigorous process to develop these health scenarios.

Firstly, we performed a search on PubMed to retrieve relevant content from systematic reviews, randomized control trials (RCT), and observational studies. Evidence from systematic reviews was preferred if available.

Secondly, we reviewed THA booklets from Brant Community Healthcare System, Hamilton Health Sciences, Joseph Brant Memorial Hospital, Niagara Health System, St. Joseph's Healthcare Hamilton, National Institute of Arthritis and Musculoskeletal, and Skin Diseases (NIAMS) to inform SCENARIO design and content. For both THA and HA, we also reviewed information from other sources such as the Informed Medical Decisions Foundations (IMDF) [34] and National Institute of Health for both THA and HA HSs (when available).

Thirdly, we considered the following strategies to increase the ease of understanding and readability of our scenarios[35]. We focused the material on key concepts with consistent and simple words aiming for 1–2 syllables[32, 36]. A clear topic sentence are used at the beginning of each sub-heading with following details and examples[37]. We used conversational style with the second person point of view (i.e., "you")[37]. We also used the Flesch-Kincaid Grade Level test in Microsoft Word 2011 to ensure the English is understandable for people with grade 10 level education.

Finally, we revised our scenarios based on feedback from 15 orthopedic surgeons (8 of them commented on THA, and 7 of them commented on HA); from 2 focus group (3 patients in each group) and 4 individual interviews with a total of 10 patients (5 for each surgery) who had undergone THA or HA; and 5 physiotherapists.

For the Spanish and Portuguese part of the study, an experienced medical translator will undertake the initial translation. In each language, one clinical epidemiologist and one orthopedic surgeon, native in the non-English language and fluent in English, will check the translation and discuss potential revisions with the translator. After we obtain the Spanish and Portuguese versions, back translations will be performed and checked by the epidemiologist and the orthopedic surgeon, with further revisions to the Spanish and Portuguese versions if necessary.

Randomization of the health scenarios

Participants will be randomized to receive the short format or long formats of the scenarios in coded packages that the interviewer will open at the start of the interview. We will use central randomization at McMaster University using an allocation ratio of 1:1 with random blocks size (2,4,8).

We will ask participants to read hard copies of the corresponding health scenarios (short or long). At the end of the interview – i.e., after the trade-off exercise, anticipated regret exercise, and a check for consistency and understanding that we will describe subsequently – the RA will show

patients in each group the version they have not yet seen and ask about their preferred format. If participants have more content questions regarding the scenarios, the RA will instruct the patient to ask the orthopedic surgeon for further assistance in the patient-doctor consultation after the interview.

Trade off exercise

After participants have read the initial health scenario (short or long version), we will assess the minimum acceptable delay (delay time) in THA that patients would find acceptable to undergo HA. We will use the following generic questions: "By how much longer should the arthroscopy postpone the need for hip replacement surgery for you to consider the hip arthroscopy worthwhile? Would you choose hip arthroscopy if it would delay the need for total hip replacement by [delay time in months/year]?" We will offer a range of delay times, alternating between short and long times in a ping-pong strategy, e.g.: 3 months – 12 years – 6 months – 10 years, etc. We will progressively narrow the range of the alternatives offered as we repeat the exercise.

The lower bound of delay time offered (i.e. 3 months) is just below the anticipated least stringent participants' demand and also corresponds to the shortest follow-up time in studies that evaluate the efficacy of HA[38]. For the upper bound initially offered, the literature suggests that the most optimistic estimate of the time which HA may delay THA is approximately 10 years[39]. If patients are not satisfied with the upper boundary of the delay time – that is, they would demand a delay of more than 12 years before they would undergo HA – there will be provision for them to express this preference.

Anticipated regret exercise

Following the trade-off exercise, we will assess participants' anticipated regret associated with choosing or not choosing a treatment alternative. We will measure anticipated regret using a 100 mm visual analog scale (VAS) called the Feeling Thermometer (FT)[40], anchored at no regret (0) to maximum regret (100). (Figure 1 anticipated regret VAS)

We will assess anticipated regret at five different time points (the patient personal threshold determined during trade-off exercise, as well as two shorter and two longer options). For example, if the patient chose 2 years as their shortest delay time, we will ask her: "*How much regret would you feel about choosing hip arthroscopy if you need to have a total hip replacement surgery after 12 months / 1.5 years / 2 years / 3 years / 4 years?*. This process allows us to check for inconsistent answers (see below).

Blinding

Since this is a patient educational trial, the interviewers (data collectors) cannot be blinded. The orthopaedic surgeons, patients (outcome assessors), and data analysts will be blinded to sequence of giving HSs.

Outcomes

Our primary outcome measures for the pilot stage regarding feasibility issues are the recruitment rate, length of time to conduct the interview and fill out all the outcome measurements. We will

explore the potential personnel and data management problems in the McMaster Medical center to ensure the quality of the definitive stage of our study. We will note the number of participants enrolled each week. The mean and standard error of the center`s recruitment rate over recruitment period will be our study recruitment rate. We will also calculate the percentage of eligible patients who agree to participate. We will time the length of the interview, the length of finishing interviewers` administrated or patients' administrated questions.

We will consider recruitment feasible for a large study if we will be able to recruit two patients at McMaster Medical center per week (i.e., 100 subjects over 50 weeks). We will consider the pilot stage (approximately 2 months) to be successful, and a large multicenter RCT to be feasible if: (i) we successfully recruit 20% of the patients according to our estimated sample size in 2 months; (ii) we will be able to finish the interview and all the outcome assessment in approximately one hour. (See table 3 for outcomes and corresponding objectives)

We will modify our protocols in response to limitations with respect to excessive length of the interview, difficulties with comprehension or ambiguities in the questions, and personnel or data management problems identified in the pilot.

For Study 1, our outcomes are:

Primary outcome: the minimal delay in the need for THA surgery that patients would find acceptable to undertake HA (which we will refer to as the "delay time").

Secondary outcomes:

(i) Independent predictors of the primary outcome include age, gender, educational level, socioeconomic status, and family/friends' experiences with previous THA or/and HA.
(ii) Patients' anticipated regret scores on a 100mm VAS at five different time points (the one patients chose in the trade-off exercise, and two shorter and two longer options).

For Study 2 our outcomes are:

Primary outcome: patients' satisfaction on the scenarios after reading the initial scenarios. Interviewers will determine the degree of satisfaction participants place in the scenarios using a 7-point Likert-type scale with response options: completely dissatisfied, mostly dissatisfied, somewhat dissatisfied, neither satisfied nor dissatisfied, somewhat satisfied, mostly satisfied, completely satisfied.
Secondary outcomes:

1. Ease of understanding: we will assess participants impression of each of understanding of each scenario using a 7-point Likert-type scale with response options: extremely hard, very hard, hard, not easy not hard, easy, very easy, extremely easy.
2. Information quantity: we will ask participants to rate the quantity of the information displayed in the initial presented scenario by a 7-point Likert-type scale with response options: much too little, somewhat too little, slightly too little, about right amount of information, slightly too much, somewhat too much, much too much.
3. Patients' preference on length of format: After patients finish reading both the long and short versions of scenarios we will ask them about their preference for the short or long version, using a 7-point Likert-type scale with response options: short version much better, short version somewhat better, short version little better, no preference, long version little better, long version somewhat better, long version much better.

Data collection

A trained interviewer will collect all the outcomes by completing the case-report forms (CRFs) at the end of the interview. No follow-up and further data collection will be involved.

Sample size calculation

Study 1:

Due to the paucity of similar studies in literature, we are unable to estimate the standard error (SE) of delay time precisely. If the data is normally distributed, 99.7% of the area under of the normal distribution curve lies within 3 standard deviations[41]. We assume the range of delay time (12 years) will be normally distributed. Therefore, we anticipate a SD of approximately 2 years. We developed the sample size estimation table using the SD and varying the confidence interval around the mean to obtain sample size using the formula below[42] (Table 4).

$$n = \frac{4z^2_{1-\frac{\alpha}{2}}\sigma^2}{L^2}$$

N represents the sample size, σ represents the SE, L represents the confidence interval around the mean.

At the end of the pilot stage we will calculate the SE of delay time in the 20 patients as a reference point to modify our earlier sample size estimation for the definite study.

Study 2:

Based on Cohen's rule of sums [43], we used “SD=0.5” to calculate the sample size to achieve a medium effect size. With a sample size of 62 in each group the trial is powered to detect a medium effect size of mean = 0.5 or larger given 80% power level and α= 0.05 in a two-sided test. Considering the result will be obtained immediately after the assessment and all outcomes will be interviewer administrated, we anticipate no loss to follow-up. We also made a sample size estimation table with different confidence intervals around the mean (Table 4). Sample size calculation is performed using SPSS (Statistical Package for the Social Sciences) version 21.0 for Windows.

After finishing the pilot stage of our study, we will compare the estimated sample size for study 1 and 2 and take the larger number as our final sample size for the combined studies.

Data analysis and interpretation

Study 1

Description of baseline characteristics:
We will present patients’ age, gender, ethnical / cultural group, educational level, socioeconomic status and medical history[44]. Means and standard deviations (SD) will be used to present continuous variables and two-tailed T-test (or Mann-Whithey U test for non-normal distributions) to detect significant differences ($p<0.05$) between group means. We will use proportions and

frequency tables to present categorical variables and a two-tailed Fisher's Exact test will be used to detect statistically significant ($p<0.05$) differences between two groups.

Primary and secondary outcome(s):
We will assess the distribution of the mean delay time and represent it graphically using histogram(s). If the data is normally distributed we will present the mean delay time and SD. We will also estimate 95% confidence intervals of the mean respectively. If the data is skewed, we will present the mode, median, and interquartile range.

Multiple variable linear regressions will be undertaken to determine statistically independent predictors of the threshold of delay time. In this analysis, the delay time will be the dependent variable and the independent variables will be the previous experience of THA and HA in friends and family, age, gender, socioeconomic status, educational level.

After presenting the health scenarios and recording participants' response with both "trade off" and anticipated regret exercise, we will compare results between these two measurements of participants' values and preferences.

We have defined three possible patterns of inconsistent response (See table 5 Inconsistency checking). If the participants' answers fall into any of these patterns, interviewers will review participants' original answers without, however, implying that they must modify their original choices. If the participants confirm their original answers, interviewers will determine and record the reasons of participants' inconsistent choices based on participants' explanation. If patients, following review of the relation between their trade off and regret choices, desire to modify their chosen delay time, interviewers will repeat the trade-off exercise.

For the analyses above, we will determine whether the delay time differs between those with an apparently high level of understanding and those who demonstrate any of the inconsistencies depicted in Table 2. If we find an important discrepancy between the results of patients categorized as understanding and not understanding, we will focus our primary analysis on the group of patients who apparently have a high level of understanding.

Study 2

Baseline characteristics description
We will summarize patients' age, gender, ethnical / cultural group, educational level, social economics status in a table.

Primary and secondary outcome(s):

Our primary outcome will be participants' satisfaction of the health scenarios assessed by a 7-point Likert scale. We will also visualize it by using histogram(s). We will conduct a two-sided student T-test will to compare mean satisfaction scores and ease of understanding between the short and long scenarios. We will also calculate the mean difference and 95% confidence intervals.

For information quantity, we will present a histogram depicting the proportion of participants' choice in each category. We will apply 2 approaches to analyze information quantity at the first assessment. First, we will determine if the distribution between two groups differ by greater than

chance with two-sided student T-test (if its normally distributed) or Mann-Whitney U test(if its not normally distributed). Second, using a chi-square test we will determine if the proportions of participants who choose "about the right amount of information", in comparison to those who choose other response options, differ between groups.

We will use 2 approaches to compare participants' preferences for the short versus long formats after showing patients both scenarios. First, we will treat the outcomes on the 7-point scale as multinomial ordered outcomes. We will analyze the result using Mann-Whithey U test. Second, we will use a more conservative approach and compare the proportions of participants who prefer the short format to the proportion of participants who have either no preference or prefer the long format by using a chi-square test. (Table 3: Summary of analysis plan).

ETHICAL AND DISSEMINATION

This study will be performed in accordance with established guidelines for research involving human patients. The proposed study does not pose any safety risks to participating patients. The protocol has received Research Ethics Board approval at Hamilton Health Sciences (McMaster University Medical Centre) and will be submitted for approval at the other participating sites. The research objectives and study intervention will be explained to the patient verbally and in writing in easily comprehensible language. Written informed consent will be obtained from all patients. Patients will be informed of their right to ask for further information at any time and to withdraw from study without prejudice to their future care. In the unlikely event that participants find considering the above scenarios upsetting, the interview will be immediately stopped and support offered. We will ensure confidentiality of patient data by anonymizing patients by a unique numerical identifier. Records will be stored in a secure database. Access to the database will be restricted to those directly involved in the design, implementation, and analysis of the data. No patient will be identifiable in any publication arising from the study.

The reporting of Study 1 will conform to the STROBE statement [45], and reporting of Study 2 to the CONSORT statement[46]. We will disseminate our study findings widely through peer-reviewed publications and conference presentations, and make them available to guideline makers issuing recommendations on HA and THA.

DISCUSSION

Strength and weaknesses

The design of our study has several strengths. Firstly, we have incorporated the anticipated regret model as a new method in the exploration of patients' values and preferences. Based on considerable previously published theoretical work by members of our research team [47, 48] our study will be the first to evaluate and compare its results with other methodologies. The comparison will include differences in decisions, inconsistencies, and understanding.

Secondly, in developing health scenarios we obtained input from patients who have undergone both total hip replacement and HA and surgeons who have expertise on total hip replacement and HA. These processes ensured the accuracy of our health scenarios that will be used in the study.

Thirdly, we will be the first to explore the association between influence from family and friends' previous experience on patients' values and preferences on the minimal delay time in the need for

THA surgery that patients would find acceptable to undertake HA. Indirect evidence suggests friends or family member's medical advice may influence patients' preference on medical decisions[49]. Men, African-American men in particular, are more inclined to discuss their medication concerns and to seek medical advice from trusted friends more frequently than women[50]. Women are more often inclined to solicit medical advice from their family members. Identifying the factors that may influence patients' preferences could provide valuable explanations for the variation on patients' values and preferences in future research. Knowing patients' previous perception on certain treatment options can help clinicians to explain certain things more clearly and makes clinical consultation more efficient.

Fourthly, we will check for consistency in the participants' choice on their threshold of how long HA can delay THA they think it worthwhile proceeding. If participants have discrepant answer between the trade off and anticipated regret exercise we will provide them the opportunity to change their responses. Interviewers will test patients` understanding of the information presented using standardized questions and rate respondents understanding based on their judgement. This ensures the validity of patients' values and preference elicitation.

Our study plan also has limitations. There are conceptual limitations to the anticipated regret exercise. For instance, no one has studied the relationship between anticipated regret and actual regret subsequently experienced. If we find important discrepancies between anticipated regret and the trade-off exercise the interpretation may be challenging; in particular, it may remain uncertain which method better represents patients' real preference. Subsequent studies may be needed to address such questions arising from our results..

Implications

Although there is increasing awareness regarding shared decision-making and patient centered care, the explicit consideration of values and preferences in the care of individual patients and in the recommendations made by clinical practice guidelines remains limited [31-36].

Given the existing evidence, the choice between HA and THA for patients with non-advanced OA is challenging. The research outlined in this protocol will provide explicit, quantitative expressions of patients' valuations of their expected delay of HA on THA. This information will alert clinicians to this issue and may provide guidance in their interactions with patients. It will certainly provide crucial information for guideline developers making recommendations for clinical practice. Identifying the factors that may influence patients' preferences could provide insight into variations in broader perspective of patients' values and preferences in future research.

Our protocol also addresses some of the limitations of the previous studies in the field of medical written information regarding using adequate amount of information in patients' values and preference assessment. Results will have implications for clinical practice in terms of providing patients' with the right amount of information in the shared decision-making process.

Table 1: Flow chart of study design

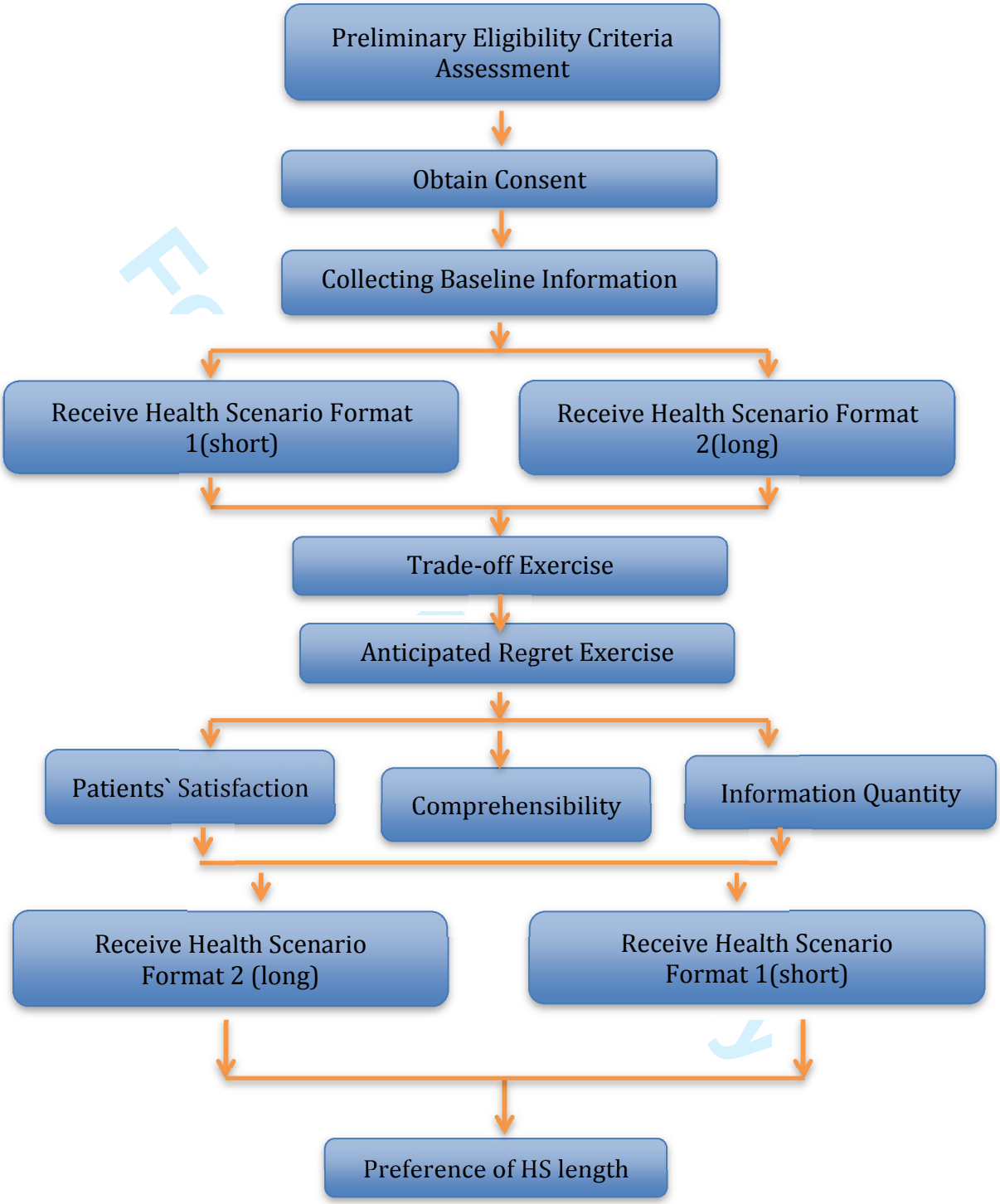

Table 2 Inclusion and Exclusion criteria

Inclusion criteria	*Exclusion criteria*
(i) Patient is at least 40 years old	(i) Patient has a history of prior hip surgery
(ii)Patient diagnosed by X-ray or magnetic resonance imaging (MRI) with mild or moderate (grades 1 and 2) OA based on Tonnis classification of OA**[51]** *Grade 0: No signs of OA.* *Grade 1: Mild: increased sclerosis, slight narrowing of the joint space, no or slight loss of head sphericity.* *Grade 2: Moderate; small cysts, moderate narrowing of the joint space, moderate loss of head sphericity.* *Grade 3: Severe: large cysts, severe narrowing of obliteration of the joint space, severe deformity of the head.*	(ii) Patient is unable of complete the research tasks due to cognitive impairment or language barriers
(iii) Patient has history of failed conservative management	(ii) Patient is unwilling or unable to provide informed consent.
(iv) Patient provides a written informed consent.	

Table 3: Summary of analysis plan

Study	Objectives	Outcomes	Predictors	Hypothesis	Outcome Measure	Methods of Analysis
Pilot stage						
	Determine feasibility	a) Recruitment rate		2 subjects/week	Subjects per week	
		b) Time to conduct the interview and finish all the measurement		1hour would be optimal	Interview duration	
		c) Patients attrition		Less than 5%	Patients attrition rate	
Study one: Interview Study	Primary	a) Delay time	age, gender, ethnicity, educational level, social economics status and medical history		Trade-off exercise	Normally distributed: mean delay time +SD; mean delay time and confidence interval If data is skewed: mode, median, and interquartile range
	Secondary	a) Patients' anticipated regret scores			100mm Visual Analog Scale	T-test
Study two: RCT	Primary	a) Patients' satisfaction on the HSs		Higher satisfaction on short version	7-point Likert type scale	T-test
	Secondary	a) Understandability		Both have rated as 5/7	7-point Likert type scale	T-test
		b) Information quantity		Short will be rated as 4; Long will be rated as 5;	7-point Likert type scale	T-test
		c) Patients' preference on length of format		Prefer short version	7-point Likert type scale	T-test or Mann Whitney U test
Sensitivity Analyses		Patients' satisfaction on the HSs		Higher satisfaction on short version	7-point Likert type scale	Mann–Whitney U test
		Comprehensibility		Both have 5/7	7-point Likert type scale	Mann–Whitney U test
		Information quantity		Short will be 4; Long will be 5;	7-point Likert type scale	Mann–Whitney U test
		Patients' preference on length of format		Prefer short version	7-point Likert type scale	Mann–Whitney U test

Table 4: Sample size estimation tables

Study	α	SD	*L*(width of CI -years)	Sample size
Study one	0.05	2	0.5	246
			1	62
			2	16

Study	α	β	SD	Difference	Sample size (Per arm)
Study two	0.05	0.8	1	0.5	62
				1	16
				2	4

Table 5: Inconsistency checking

Definitions/criteria of inconsistencies	Explanations and Examples
(i) Participants anticipate regret score is higher when delay in need for THA is longer than it is at their threshold of delay time.	In the example we give that measures anticipated regret scores: we set the 5 time points as A (12 months), B (1.5 years), C (2 years), D (3 years) and E (4 years). The participant chose 2 years as the shortest delay time at which he/she can accept for processing HA. Then they placed scores 60 to represent their regret on VAS at 12months but scores 90 to represent his/her regret at 1.5years. In other words, the regret scores "r" on VAS shows: rA<rB, OR, rB<rC, OR rC<rD, OR rD<rE.
(ii) Participants anticipate substantial regret although the HA would delay THA longer than their threshold of delay time.	We define substantial as the anticipated regret score on VAS at the time point that they chose in the "trade off" exercise or any longer delay time point is bigger than (30) on the 100 VAS scale. The participant chose 2 years as the shortest delay time at which they can accept for processing HA. Then they still placed scores 60 to represent their regret on VAS at 2years, 3 years or 4years. In other words, the regret scores "r" on VAS shows: rC>0, OR rD>0, OR rE>0.
(iii) Patients do not anticipate any regret when delay in THA end up being shorter than what their threshold of delay time.	Comparing to the time point that participants chose in the "trade off" exercise, the anticipated regret score on VAS at any shorter delay time point is equal to (0). For example, the participant chose 2 years as the shortest delay time at which they can accept for processing HA. Then they place scores 0 to represent their regret on VAS at 12months and 1.5years. In other words, the regret scores "r" on VAS shows: rA=0, OR rB=0.

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Contributors: YZ, KAOT, TA and GHG designed the study. YZ drafted the manuscript, with substantial inputs from TA, KAOT and GHG. DY, AT and KAOT drafted the trade-off exercise and regret exercises. BDB, GHG provided feedback on the regret exercises. MI and YZ drafted the HSs. PA, KAOT, YZ conducted the interview to test HSs. All authors contributed to the refinement of the study protocol and approved the final manuscript. GHG is the principal investigator of the study.

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FIGURE LEGENDS:

Figure 1: Anticipated Regret visual analog scale

Patients' values and preferences of the expected efficacy of hip arthroscopy for osteoarthritis: A protocol for a multinational structured interview-based study combined with a randomized survey on the optimal amount of information to elicit preferences

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Keywords
Patients' values and preference, Total Hip Arthroplasty, Hip Arthroscopy, Osteoarthritis, Patient Written Information, Decision Making, Uncertainty

Word count: 5003

Abstract:

INTRODUCTION: Symptomatic hip osteoarthritis (OA) is a disabling condition with up to 25% cumulative lifetime risk. Total hip arthroplasty (THA) is effective in relieving patient's symptoms and improving function. It is, however, associated with substantial risk of complications, pain and major functional limitation before patients can return to full function. In contrast, hip arthroscopy (HA) is less invasive, and can postpone THA. However, there is no evidence regarding the delay in the need for THA that patients would find acceptable to undergo HA. Knowing patients' values and preferences (VP) on this expected delay is critical when making recommendations regarding the advisability of HA. Furthermore, little is known on the optimal amount of information regarding interventions and outcomes needed to present in order to optimally elicit patients' VP.

METHODS AND ANALYSIS: We will perform a multinational, structured interview-based survey of preference in delay time for THA among patients with non-advanced OA who failed to respond to conservative therapy. We will combine these interviews with a randomized trial addressing the optimal amount of information regarding interventions and outcomes required to elicit preferences. Eligible patients will be randomly assigned (1:1) to either a short or a long format of health scenarios of THA and HA. We will determine each patient's VP using trade-off and anticipated regret exercises. Our primary outcomes for the combined surveys will be: 1) the minimal delay time in the need for THA surgery that patients would find acceptable to undertake HA, 2) patients satisfaction with the amount of information provided in the health scenarios used to elicit their VPs.

ETHICS AND DISSEMINATION: The protocol has been approved by Hamilton Integrated Research Ethics Board (HIREB13-506). We will disseminate our study findings through peer-reviewed publications and conference presentations, and make them available to guideline makers issuing recommendations addressing HA and THA.

BACKGROUND

Osteoarthritis and surgical options

Osteoarthritis: Osteoarthritis (OA) is the most common form of chronic arthritis. Approximately 15% of men and women suffer from symptomatic OA[1], representing a large burden on patients, the healthcare system and society. Symptomatic hip OA is a particularly disabling condition with a cumulative lifetime risk of up to 25%. Conservative management of hip OA includes exercise, weight reduction, physical therapy and medications focusing on relieving symptoms, improving joint function, and optimizing quality of life[2]. Pharmacological and non-pharmacological interventions for severe OA are, however, substantially less effective than surgical treatment[3]. Consequently, most patients with severe hip OA eventually need total hip arthroplasty (THA)[3].

Total hip arthroplasty: With an aging population increasingly interested in staying physically active [4], the frequency and cost of THA continues to grow. Currently more than a half million THA procedures are performed annually in the UK and USA alone, and in 2010 the global market was estimated as high as 4.7 billion USD[5].

After failure of conservative treatment, THA is usually effective in relieving patient's symptoms and improving function, with more than 95% prosthesis survivorship at 10-year follow-up and more than 80% survivorship at 25-year follow-up[6, 7]. However, THA is also a major procedure, associated with substantial risk of complications, and with weeks of pain and major functional limitations before patients can return to full function. Therefore, patients and caregivers are interested in less invasive interventions that could postpone THA.

Hip arthroscopy: Less invasive interventions include arthroscopy, partial replacements, and bone-preserving techniques. They have shown varying success rates among OA patients[8]. Hip arthroscopy (HA) is a new and the fastest growing procedure within orthopedic surgery[8]. Despite the lack of high quality evidence, the number of HAs performed is expected to double in the United States in 2013 compared to 2011[9]. HA is used to treat intra articular pathology of the hip, including mild hip OA. Compared to THA it has the advantages of being minimally invasive and having fewer complications [10]. Compared to THA, arthroscopy may help patients achieve higher level of function more quickly with, over the short term less restriction on exercise. The expectation, however, is that patients' underlying osteoarthritis will progress, and THA will ultimately become necessary. The question then arises: what delay in the need for THA would warrant a patient undergoing HA? This is a question of values and preferences.

Measuring patients` values and preference

There are a number of techniques available for eliciting patients direct choices of which the probabilistic version of the Threshold Technique (TT) also called probability trade-off (PTO) exercise is widely used [11]. Following descriptive and probabilistic information regarding benefits and harms associated with treatment choices - for example treatment A and B – in which the relative benefits of treatment A versus B are large, the respondent is asked to choose one option. Typically, patients will choose treatment A. The interviewer then presents an alternative situation in which the relative benefits of A versus B are very small, and patients typically choose B. The

interviewer than presents a small reduction in the probability of benefits, relative to the first scenario, for option A. If the patient continues to choose A, the next scenario presents a small increase in the benefits of A versus B relative to the second scenario. The process is repeated until the indifference point between A and B is established (ping pong approach)[12].

Utility elicitation uses a very different approach, presenting health states and using one of a variety of techniques to elicit the respondent's rating of the value of the health state on a scale between death (typically 0) and full health (typically 1.0 or 100). The patients' responses are used to build a decision model that calculates the treatment option that, given the patient's utilities, achieves the maximum utility-adjusted outcome [13, 14].

Complementary approaches to assess patients' decision-making integrate emotional aspects of the process. One such approach focuses on regret, an aversive emotion people experience when they believe their current situation would have been better had they acted differently in the past[15, 16]. In theory, regret is influenced by both intuitive, affect-based, and analytical, deliberative processes[17, 18]. Reflecting on the anticipated regret of particular decisions (e.g. choosing A versus B in the example above) may alert people to the choice that would be most likely to avoid this aversive emotion[19, 20]. The anticipated regret theory-based approach preserves a rational decision-making framework, while allowing anticipation of the effect of the decision on emotions[21].

Using both (direct choice) trade-off and anticipated regret exercises, our study will provide empirical evidence regarding the delay in the need for THA that patient would find acceptable to undergo HA.

Amount of information presented to elicit patients' values and preference

The choices patients make are critically dependent on how the health scenario (HS) that characterizes the processes and outcomes of the alternative management options (A and B in the above – THA and HA in the current project) are presented. Research in marketing has addressed some of the relevant issues. Information-processing framework[22] suggests that that there are limits to the human ability to assimilate and process information, and that once these limits are surpassed behavior becomes confused and dysfunctional[23]. Evidence suggests an inverted U-shaped relationship between information available and decision quality, in which individuals with too little or too much information made poorer decisions than those with an intermediate amount of information [24, 25].

Other indirect evidence comes from research on written consent forms [26, 27]. Individuals often skim over consent forms for clinical trials in oncology if they are longer than 1,000 words or 4 pages[28]. Twenty-seven oncology trials showed that patients obtain significantly higher objective knowledge when the consent form page count was seven or less [29].

In the area of pharmaceutical product choice, participants have had better understanding of shorter and easier information presentations[25]. One might expect, however, that if the information becomes too scanty, decision quality will deteriorate.

Patients' values and preferences on osteoarthritis surgical options

Given the existing evidence, both HA and THA represent reasonable choices for patients with non-

advanced OA. The choice may, however, be challenging. On one hand, HA is likely to achieve only transient improvement in function. On the other hand, the morbidity associated with THA is substantial.

Therefore, one of the key aspects in the choice between HA and THA is the duration of delay in the need for THA that patients may achieve with HA. If patients demand a delay time much greater than HA can realistically achieve, the procedure should seldom be considered. On the other hand, if patients would be satisfied with much shorter delay time, the procedure should be frequently considered. There is currently no empirical evidence addressing patients' values and preferences regarding the delay they would demand to undertake HA. Knowing typical patients' values and preferences regarding this expected delay is likely to be helpful for patients and health care providers in the clinical encounter and for guideline panelists when making recommendations regarding the advisability of HA.

The assessment of patients' values and preferences will be valid only to the extent patients receive sufficient accurate information on the outcomes of available treatment options presented in ways that they can easily process. Thus far, only limited indirect evidence informs us on the optimal amount of information to provide in scenarios when eliciting patients' preferences.

Our study will provide direct empirical evidence on the optimal amount of information to provide when eliciting patients' values and preferences. It may also provide insight into the amount of information to provide in shared-decision making, although our study only indirectly addresses that issue.

OBJECTIVES

General Objective: The purpose of this study is to improve the management of patients with non-advanced symptomatic hip osteoarthritis (OA) who failed conservative treatment by determining their values and preferences regarding the choice between immediate total hip arthroplasty (THA) versus hip arthroscopy (HA).

*In the **Pilot stage** of our study, we will assess the following feasibility issues:* (i) recruitment rate; (ii) length of time to conduct the interview and fill out all the study measurements; (iii) potential personnel and data management issues.

*In **Study 1*** – our primary objective is to determine the minimal delay time in the need for THA surgery that patients would find acceptable to undertake HA (which we will refer to as the "delay time"). Secondary objectives include assessing patients' anticipated regret if the delay would differ from their expectations, as well as potential determinants of their preference (e.g., age, gender, educational level, and socioeconomic status).

*In **Study 2*** – our objective is to assess the ease of understanding, optimal quantity of information, and patients' satisfaction regarding alternative formats of the HSs used to elicit their preferences.

METHODS

Study design

Pilot study

In a pilot study, we will assess the following feasibility issues: (i) recruitment rate; (ii) length of time to conduct the interview and fill out all the study measurements; (iii) potential personnel and data management problems in real-life setting. We will perform this study at the outpatient orthopedic clinic of the McMaster University Medical Center (Hamilton, ON, Canada).

Study 1: We will perform a multinational, cross-sectional, structured interview-based survey to assess the delay in THA that patients would demand to choose HA.

Study 2: Within Study 1, we will conduct a randomized trial comparing a short version versus a long version of HA and THA health scenarios.
Table 1 shows the study flow.

Setting: The study will take place at McMaster University Medical Center, Hamilton, Canada; St. Michael's Hospital, Toronto, Canada; Hospital de Sant Pau, Barcelona, Spain; and Sorocaba Hospitals, São Paulo, Brazil.

Study population

The population of interest consists of adults diagnosed with non-advanced hip OA. Table 2 presents the detailed inclusion and exclusion criteria.

Recruitment strategy

We will prospectively identify consecutive patients confirmed with non-advanced hip OA referred for consideration of HA. The orthopedic surgeon will send a letter in advance of their visit to inform patients about our research project and the possibility of being approached by our research assistant (RA) for this study. The RA will then make initial contact with all the patients by phone to explain the purpose of the study. When the patients come to the orthopedic clinic, we will ask patients for their written informed consent.

Participants interview

Baseline information

We will document patients' age, gender, ethnicity, educational level (not completed high school; completed high school only; some college/university; completed college or university), yearly income, and their impression of the experience of close relatives or friends who have undergone HA or THA (categorized as extremely dissatisfied; dissatisfied; neutral; satisfied; extremely satisfied, or differing across individuals).

Health scenarios

The health scenarios are designed to inform patients of the surgical options. Based on available evidence [30] we will include the following five sections in the HSs for THA and HA: [26] Brief introduction to the surgery; [31] Description of the surgical procedure; [iii] Post-operative recovery and rehabilitation; [32] Expected benefits; [v] Risks and potential complications. *(See appendix: Script #1: Health scenarios)*

The short versions have approximately 850 words and the long versions approximately twice the

number of words; both versions use the same sub-headings.

To ensure we present accurate estimates of benefits and risks of THA and HA to patients[33], conveyed in the most simple and easy-to-understand way possible, we applied a rigorous process to develop these health scenarios.

Firstly, we performed a search on PubMed to retrieve relevant content from systematic reviews, randomized control trials (RCT), and observational studies. Evidence from systematic reviews was preferred if available.

Secondly, we reviewed THA booklets from Brant Community Healthcare System, Hamilton Health Sciences, Joseph Brant Memorial Hospital, Niagara Health System, St. Joseph's Healthcare Hamilton, National Institute of Arthritis and Musculoskeletal, and Skin Diseases (NIAMS) to inform SCENARIO design and content. For both THA and HA, we also reviewed information from other sources such as the Informed Medical Decisions Foundations (IMDF) [34] and National Institute of Health for both THA and HA HSs (when available).

Thirdly, we considered the following strategies to increase the ease of understanding and readability of our scenarios[35]. We focused the material on key concepts with consistent and simple words aiming for 1–2 syllables[32, 36]. A clear topic sentence are used at the beginning of each sub-heading with following details and examples[37]. We ~~also~~ used conversational style with the second person point of view (i.e., "you")[37]. We also used the Flesch-Kincaid Grade Level test in Microsoft Word 2011 to ensure the English is understandable for people with grade 10 level education.

Finally, we revised our scenarios based on feedback from 15 orthopedic surgeons (8 of them commented on THA, and 7 of them commented on HA); from 2 focus group (3 patients in each group) and 4 individual interviews with a total of 10 patients (5 for each surgery) who had undergone THA or HA; and 5 physiotherapists.

For the Spanish and Portuguese part of the study, an experienced medical translator will undertake the initial translation. In each language, one clinical epidemiologist and one orthopedic surgeon, native in the non-English language and fluent in English, will check the translation and discuss potential revisions with the translator. After we obtain the Spanish and Portuguese versions, back translations will be performed and checked by the epidemiologist and the orthopedic surgeon, with further revisions to the Spanish and Portuguese versions if necessary.

Randomization of the health scenarios

Participants will be randomized to receive the short format or long formats of the scenarios in coded packages that the interviewer will open at the start of the interview. We will use central randomization at McMaster University using an allocation ratio of 1:1 with random blocks size (2,4,8).

We will ask participants to read hard copies of the corresponding health scenarios (short or long). At the end of the interview – i.e., after the trade-off exercise, anticipated regret exercise, and a check for consistency and understanding that we will describe subsequently – the RA will show

patients in each group the version they have not yet seen and ask about their preferred format. If participants have more content questions regarding the scenarios, the RA will instruct the patient to ask the orthopedic surgeon for further assistance in the patient-doctor consultation after the interview.

Trade off exercise

After participants have read the initial health scenario (short or long version), we will assess the minimum acceptable delay (delay time) in THA that patients would find acceptable to undergo HA. We will use the following generic questions: "By how much longer should the arthroscopy postpone the need for hip replacement surgery for you to consider the hip arthroscopy worthwhile? Would you choose hip arthroscopy if it would delay the need for total hip replacement by [delay time in months/year]?" We will offer a range of delay times, alternating between short and long times in a ping-pong strategy, e.g.: 3 months – 12 years – 6 months – 10 years, etc. We will progressively narrow the range of the alternatives offered as we repeat the exercise.

The lower bound of delay time offered (i.e. 3 months) is just below the anticipated least stringent participants' demand and also corresponds to the shortest follow-up time in studies that evaluate the efficacy of HA[38]. For the upper bound initially offered, the literature suggests that the most optimistic estimate of the time which HA may delay THA is approximately 10 years[39]. If patients are not satisfied with the upper boundary of the delay time – that is, they would demand a delay of more than 12 years before they would undergo HA – there will be provision for them to express this preference.

Anticipated regret exercise

Following the trade-off exercise, we will assess participants' anticipated regret associated with choosing or not choosing a treatment alternative. We will measure anticipated regret using a 100 mm visual analog scale (VAS) called the Feeling Thermometer (FT)[40], anchored at no regret (0) to maximum regret (100). (Figure 1 anticipated regret VAS)

We will assess anticipated regret at five different time points (the patient personal threshold determined during trade-off exercise, as well as two shorter and two longer options). For example, if the patient chose 2 years as their shortest delay time, we will ask her: "*How much regret would you feel about choosing hip arthroscopy if you need to have a total hip replacement surgery after 12 months / 1.5 years / 2 years / 3 years / 4 years?*. This process allows us to check for inconsistent answers (see below).

Blinding

Since this is a patient educational trial, the interviewers (data collectors) cannot be blinded. The orthopaedic surgeons, patients (outcome assessors), and data analysts will be blinded to sequence of giving HSs.

Outcomes

Our primary outcome measures for the pilot stage regarding feasibility issues are the recruitment rate, length of time to conduct the interview and fill out all the outcome measurements. We will

explore the potential personnel and data management problems in the McMaster Medical center to ensure the quality of the definitive stage of our study. We will note the number of participants enrolled each week. The mean and standard error of the center`s recruitment rate over recruitment period will be our study recruitment rate. We will also calculate the percentage of eligible patients who agree to participate. We will time the length of the interview, the length of finishing interviewers` administrated or patients' administrated questions.

We will consider recruitment feasible for a large study if we will be able to recruit two patients at McMaster Medical center per week (i.e., 100 subjects over 50 weeks). We will consider the pilot stage (approximately 2 months) to be successful, and a large multicenter RCT to be feasible if: (i) we successfully recruit 20% of the patients according to our estimated sample size in 2 months; (ii) we will be able to finish the interview and all the outcome assessment in approximately one hour. (See table 3 for outcomes and corresponding objectives)

~~We considered the pilot stage (approximately 2 month) to be successful, and a large multicenter RCT to be feasible; if we successfully (i) recruit 20% of our estimated sample size; (ii) we will be able to finish the interview and all the outcome assessment approximately one hour. (See table 3 for outcomes and corresponding objectives).~~

We will modify our protocols in response to limitations with respect to excessive length of the ~~interveiew~~interview, difficulties with comprehension or ambiguities in the questions, and personnel or data management problems identified in the pilot.

For Study 1, our outcomes are:

Primary outcome: the minimal delay in the need for THA surgery that patients would find acceptable to undertake HA (which we will refer to as the "delay time").

Secondary outcomes:

(i) Independent predictors of the primary outcome includ~~eing~~ age, gender, educational level, ~~and~~ socioeconomic status, and family/friends' experiences with~~on~~ ~~-~~ pre~~e~~r~~e~~vious THA or/and HA.

(ii) Patients' anticipated regret scores on a 100mm VAS at five different time points (the one patients chose in the trade-off exercise, and two shorter and two longer options).

For Study 2 our outcomes are:

Primary outcome: patients' satisfaction on the scenarios after reading the initial scenarios. Interviewers will determine the degree of satisfaction participants place in the scenarios using a 7-point Likert-type scale with response options: completely dissatisfied, mostly dissatisfied, somewhat dissatisfied, neither satisfied nor dissatisfied, somewhat satisfied, mostly satisfied, completely satisfied.

Secondary outcomes:

1. Ease of understanding: we will assess participants impression of each of understanding of each scenario using a 7-point Likert-type scale with response options: extremely hard, very hard, hard, not easy not hard, easy, very easy, extremely easy.
2. Information quantity: we will ask participants to rate the quantity of the information displayed in the initial presented scenario by a 7-point Likert-type scale with response

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options: much too little, somewhat too little, slightly too little, about right amount of information, slightly too much, somewhat too much, much too much.

3. Patients' preference on length of format: After patients finish~~es~~ reading both the long and short versions of scenarios we will ask them about their preference for the short or long version, using a 7-point Likert-type scale with response options: short version much better, short version somewhat better, short version little better, no preference, long version little better, long version somewhat better, long version much better.

Data collection

A trained interviewer will collect all the outcomes by completing the case-report forms (CRFs) at the end of the interview. No follow-up and further data collection will be involved.

Sample size calculation

Study 1:

Due to the paucity of similar studies in literature, we are unable to estimate the standard error (SE) of delay time precisely. If the data is normally distributed, 99.7% of the area under of the normal distribution curve lies within 3 standard deviations[41]. We assume the range of delay time (12 years) will be normally distributed. Therefore, we anticipate a SD of approximately 2 years. We developed the sample size estimation table using the SD and varying the confidence interval around the mean to obtain sample size using the formula below[42] (Table 4).

$$n = \frac{4z^2_{1-\frac{\alpha}{2}}\sigma^2}{L^2}$$

N represents the sample size, σ represents the SE, L represents the confidence interval around the mean.

At the end of the pilot stage we will calculate the SE of delay time in the 20 patients as a reference point to modify our earlier sample size estimation for the definite study.

Study 2:

Based on Cohen's rule of sums [43], we used "SD=0.5" to calculate the sample size to achieve a medium effect size. With a sample size of 62 in each group the trial is powered to detect a medium effect size of mean = 0.5 or larger given 80% power level and α= 0.05 in a two-sided test. Considering the result will be obtained immediately after the assessment and all outcomes will be interviewer administrated, we anticipate no loss to follow-up. We also made a sample size estimation table with different confidence intervals around the mean (Table 4). Sample size calculation is performed using SPSS (Statistical Package for the Social Sciences) version 21.0 for Windows.

After finishing the pilot stage of our study, we will compare the estimated sample size for study 1 and 2 and take the larger number as our final sample size for the combined studies.

Data analysis and interpretation

Study 1

Description of baseline characteristics:
We will present patients' age, gender, ethnical / cultural group, educational level, socioeconomic status and medical history[44]. Means and standard deviations (SD) will be used to present continuous variables and two-tailed T-test (or Mann-Whithey U test for non-normal distributions) to detect significant differences ($p<0.05$) between group means. We will use proportions and frequency tables to present categorical variables and a two-tailed Fisher's Exact test will be used to detect statistically significant ($p<0.05$) differences between two groups.

Primary and secondary outcome(s):
We will assess the distribution of the mean delay time and represent it graphically using histogram(s). If the data is normally distributed we will present the mean delay time and SD. We will also estimate 95% confidence intervals of the mean respectively. If the data is skewed, we will present the mode, median, and interquartile range.

Multiple variable linear regressions will be undertaken to determine statistically independent predictors of the threshold of delay time. In this analysis, the delay time will be the dependent variable and the independent variables will be the previous experience of THA and HA in friends and family, age, gender, socioeconomic status, educational level.

After presenting the health scenarios and recording participants' response with both "trade off" and anticipated regret exercise, we will compare results between these two measurements of participants' values and preferences.

We have defined three possible patterns of inconsistent response (See table 5 Inconsistency checking). If the participants' answers fall into any of these patterns, interviewers will review participants' original answers without, however, implying that they must modify their original choices. If the participants confirm their original answers, interviewers will determine and record the reasons of participants' inconsistent choices based on participants' explanation. If patients, following review of the relation between their trade off and regret choices, desire to modify their chosen delay time, interviewers will repeat the trade-off exercise.

For the analyses above, we will determine whether the delay time differs between those with an apparently high level of understanding and those who demonstrate any of the inconsistencies depicted in Table 2. If we find an important discrepancy between the results of patients categorized as understanding and not understanding, we will focus our primary analysis on the group of patients who apparently have a high level of understanding.

Study 2

Baseline characteristics description
We will summarize patients' age, gender, ethnical / cultural group, educational level, social economics status in a table.

Primary and secondary outcome(s):

Our primary outcome will be participants' satisfaction of the health scenarios assessed by a 7-point Likert scale. We will also visualize it by using histogram(s). We will conduct a two-sided student T-

test will to compare mean satisfaction scores and ease of understanding between the short and long scenarios. We will also calculate the mean difference and 95% confidence intervals.

For information quantity, we will present a histogram depicting the proportion of participants' choice in each category. We will apply 2 approaches to analyze information quantity at the first assessment. First, we will determine if the distribution between two groups differ by greater than chance with two-sided student T-test (if its normally distributed) or Mann-Whitney U test(if its not normally distributed). Second, using a chi-square test we will determine if the proportions of participants who choose "about the right amount of information", in comparison to those who choose other response options, differ between groups.

We will use 2 approaches to compare participants' preferences for the short versus long formats after showing patients both scenarios. First, we will treat the outcomes on the 7-point scale as multinomial ordered outcomes. We will analyze the result using Mann-Whithey U test. Second, we will use a more conservative approach and compare the proportions of participants who prefer the short format to the proportion of participants who have either no preference or prefer the long format by using a chi-square test. (Table 3: Summary of analysis plan).

ETHICAL AND DISSEMINATION

This study will be performed in accordance with established guidelines for research involving human patients. The proposed study does not pose any safety risks to participating patients. The protocol has received Research Ethics Board approval at Hamilton Health Sciences (McMaster University Medical Centre) and will be submitted for approval at the other participating sites. The research objectives and study intervention will be explained to the patient verbally and in writing in easily comprehensible language. Written informed consent will be obtained from all patients. Patients will be informed of their right to ask for further information at any time and to withdraw from study without prejudice to their future care. In the unlikely event that participants find considering the above scenarios upsetting, the interview will be immediately stopped and support offered. We will ensure confidentiality of patient data by anonymizing patients by a unique numerical identifier. Records will be stored in a secure database. Access to the database will be restricted to those directly involved in the design, implementation, and analysis of the data. No patient will be identifiable in any publication arising from the study.

The reporting of Study 1 will conform to the STROBE statement [45], and reporting of Study 2 to the CONSORT statement[46]. We will disseminate our study findings widely through peer-reviewed publications and conference presentations, and make them available to guideline makers issuing recommendations on HA and THA.

DISCUSSION

Strength and weaknesses

The design of our study has several strengths. Firstly, we have incorporated the anticipated regret model as a new method in the exploration of patients' values and preferences. Based on considerable previously published theoretical work by members of our research team [47, 48] our study will be the first to evaluate and compare its results with other methodologies. The comparison will include differences in decisions, inconsistencies, and understanding.

Secondly, in developing health scenarios we obtained input from patients who have undergone both

total hip replacement and HA and surgeons who have expertise on total hip replacement and HA. These processes ensured the accuracy of our health scenarios that will be used in the study.

Thirdly, we will be the first to explore the association between influence from family and friends' previous experience on patients' values and preferences on the minimal delay time in the need for THA surgery that patients would find acceptable to undertake HA. Indirect evidence suggests friends or family member's medical advice may influence patients' preference on medical decisions[49]~~[, 2008 #442]~~. Men, African-American men in particular, are more inclined to discuss their medication concerns and to seek medical advice from trusted friends more frequently than women[50]. Women are more often inclined to solicit medical advice from their family members. Identifying the factors that may influence patients' preferences could provide valuable explanations for the variation on patients' values and preferences in future research. Knowing patients' previous perception on certain treatment options can help clinicians to explain certain things more clearly and makes clinical consultation more efficient.

Fourthly, we will check for consistency in the participants' choice on their threshold of how long HA can delay THA they think it worthwhile proceeding. If participants have discrepant answer between the trade off and anticipated regret exercise we will provide them the opportunity to change their responses. Interviewers will test patients` understanding of the information presented using standardized questions and rate respondents understanding based on their judgement. This ensures the validity of patients' values and preference elicitation.

O~~There are some weaknesses in o~~ur study plan also ~~design~~ has limitations~~as well~~. There are conceptual limitations to the anticipated regret exercise. For instance, no one has studied the relationship between anticipated regret and actual regret subsequently experienced. ~~utilization of the anticipated regret exercise might bring in some conceptual difficulties for patients to understand the questions.~~ If we find important discrepancies between anticipated regret and ~~The possible discrepancy between~~ the trade-off exercise ~~and the anticipated regret exercise may also be~~ the interpretation may be challenging; in particular, it may remain uncertain ~~hard to interrupt and to draw conclusion on~~ which ~~of the~~ method better represents patient~~'s~~' real preference. Subsequent studies may be needed to address such ~~answer further~~ questions arising from our results.~~the results of our proposed studies~~.

Implications

Although there is increasing awareness regarding shared decision-making and patient centered care, the explicit consideration of values and preferences in the care of individual patients and in the recommendations made by clinical practice guidelines remains limited [31-36].

Given the existing evidence, the choice between HA and THA for patients with non-advanced OA is challenging. The research outlined in this protocol will provide explicit, quantitative expressions of patients' valuations of their expected delay of HA on THA. This information will alert clinicians to this issue and may provide guidance in their interactions with patients. It will certainly provide crucial information for guideline developers making recommendations for clinical practice. Identifying the factors that may influence patients' preferences could provide insight into variations in broader perspective of patients' values and preferences in future research.

Our protocol also addresses some of the limitations of the previous studies in the field of medical written information regarding using adequate amount of information in patients' values and

preference assessment. Results will have implications for clinical practice in terms of providing patients' with the right amount of information in the shared decision-making process.

Table 1: Flow chart of study design

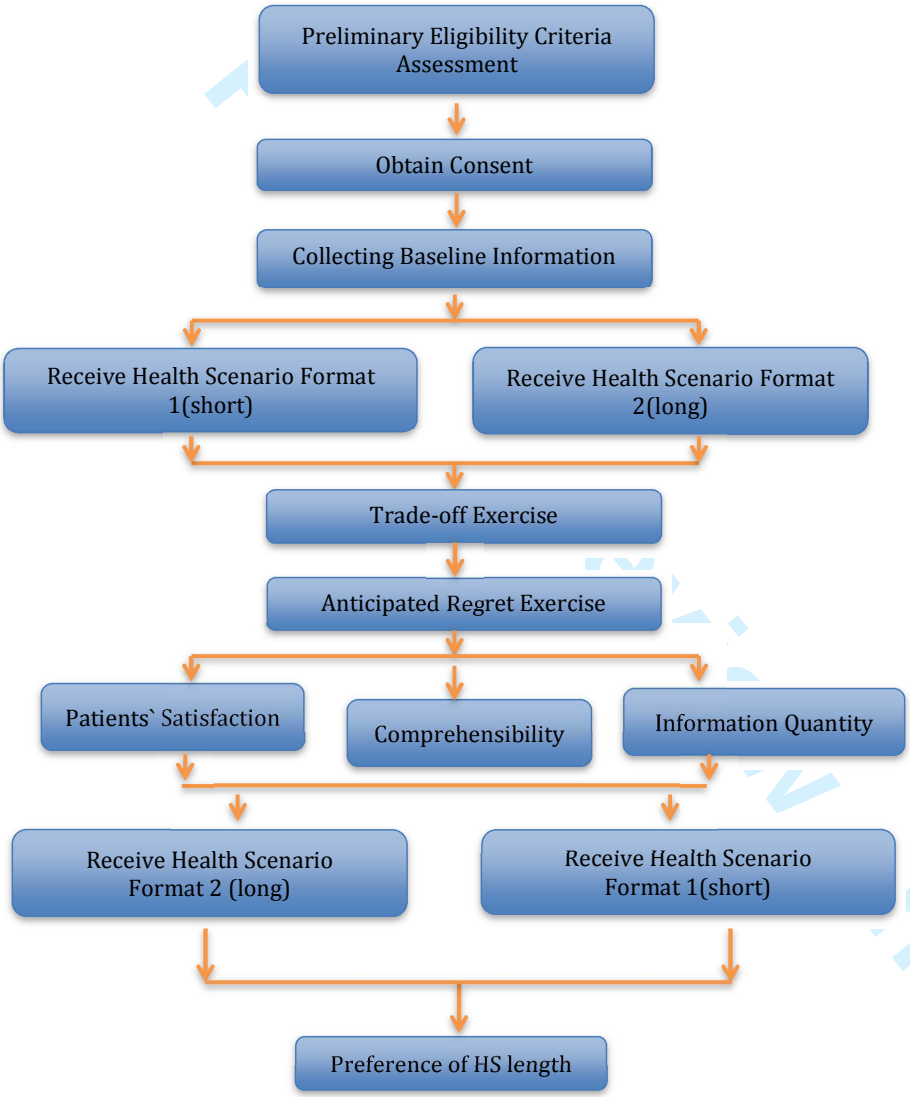

Table 2 Inclusion and Exclusion criteria

Inclusion criteria	*Exclusion criteria*
(i) Patient is at least 40 years old	(i) Patient has a history of prior hip surgery
(ii)Patient diagnosed by X-ray or magnetic resonance imaging (MRI) with mild or moderate (grades 1 and 2) OA based on Tonnis classification of OA**[51]** *Grade 0: No signs of OA.* *Grade 1: Mild: increased sclerosis, slight narrowing of the joint space, no or slight loss of head sphericity.* *Grade 2: Moderate; small cysts, moderate narrowing of the joint space, moderate loss of head sphericity.* *Grade 3: Severe: large cysts, severe narrowing of obliteration of the joint space, severe deformity of the head.*	(ii) Patient is unable of complete the research tasks due to cognitive impairment or language barriers
(iii) Patient has history of failed conservative management	(ii) Patient is unwilling or unable to provide informed consent.
(iv) Patient provides a written informed consent.	

Figure 1: Anticipated Regret visual analog scale

See separate file

Table 3: Summary of analysis plan

Study	Objectives	Outcomes	Predictors	Hypothesis	Outcome Measure	Methods of Analysis
Pilot stage						
	Determine feasibility	a) Recruitment rate		2 subjects/week	Subjects per week	
		b) Time to conduct the interview and finish all the measurement		1hour would be optimal	Interview duration	
		c) Patients attrition		Less than 5%	Patients attrition rate	
Study one: Interview Study	Primary	a) Delay time	age, gender, ethnicity, educational level, social economics status and medical history		Trade-off exercise	Normally distributed: mean delay time +SD; mean delay time and confidence interval If data is skewed: mode, median, and interquartile range
	Secondary	a) Patients' anticipated regret scores			100mm Visual Analog Scale	T-test
Study two: RCT	Primary	a) Patients' satisfaction on the HSs		Higher satisfaction on short version	7-point Likert type scale	T-test
	Secondary	a) Understandability		Both have rated as 5/7	7-point Likert type scale	T-test
		b) Information quantity		Short will be rated as 4; Long will be rated as 5;	7-point Likert type scale	T-test
		c) Patients' preference on length of format		Prefer short version	7-point Likert type scale	T-test or Mann Whitney U test
Sensitivity Analyses		Patients' satisfaction on the HSs		Higher satisfaction on short version	7-point Likert type scale	Mann–Whitney U test
		Comprehensibility		Both have 5/7	7-point Likert type scale	Mann–Whitney U test
		Information quantity		Short will be 4; Long will be 5;	7-point Likert type scale	Mann–Whitney U test
		Patients' preference on length of format		Prefer short version	7-point Likert type scale	Mann–Whitney U test

Table 4: Sample size estimation tables

Study	α	SD	*L*(width of CI -years)	Sample size
Study one	0.05	2	0.5	246
			1	62
			2	16

Study	α	β	SD	Difference	Sample size (Per arm)
Study two	0.05	0.8	1	0.5	62
				1	16
				2	4

Table 5: Inconsistency checking

Definitions/criteria of inconsistencies	Explanations and Examples
(i) Participants anticipate regret score is higher when delay in need for THA is longer than it is at their threshold of delay time.	In the example we give that measures anticipated regret scores: we set the 5 time points as A (12 months), B (1.5 years), C (2 years), D (3 years) and E (4 years). The participant chose 2 years as the shortest delay time at which he/she can accept for processing HA. Then they placed scores 60 to represent their regret on VAS at 12months but scores 90 to represent his/her regret at 1.5years. In other words, the regret scores "r" on VAS shows: rA<rB, OR, rB<rC, OR rC<rD, OR rD<rE.
(ii) Participants anticipate substantial regret although the HA would delay THA longer than their threshold of delay time.	We define substantial as the anticipated regret score on VAS at the time point that they chose in the "trade off" exercise or any longer delay time point is bigger than (30) on the 100 VAS scale. The participant chose 2 years as the shortest delay time at which they can accept for processing HA. Then they still placed scores 60 to represent their regret on VAS at 2years, 3 years or 4years. In other words, the regret scores "r" on VAS shows: rC>0, OR rD>0, OR rE>0.
(iii) Patients do not anticipate any regret when delay in THA end up being shorter than what their threshold of delay time.	Comparing to the time point that participants chose in the "trade off" exercise, the anticipated regret score on VAS at any shorter delay time point is equal to (0). For example, the participant chose 2 years as the shortest delay time at which they can accept for processing HA. Then they place scores 0 to represent their regret on VAS at 12months and 1.5years. In other words, the regret scores "r" on VAS shows: rA=0, OR rB=0.

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Contributors: YZ, KAOT, TA and GHG designed the study. YZ drafted the manuscript, with substantial inputs from TA, KAOT and GHG. DY, AT and KAOT drafted the trade-off exercise and regret exercises. BDB, GHG provided feedback on the regret exercises. MI and YZ drafted the HSs. PA, KAOT, YZ conducted the interview to test HSs. All authors contributed to the refinement of the study protocol and approved the final manuscript. GHG is the principal investigator of the study.

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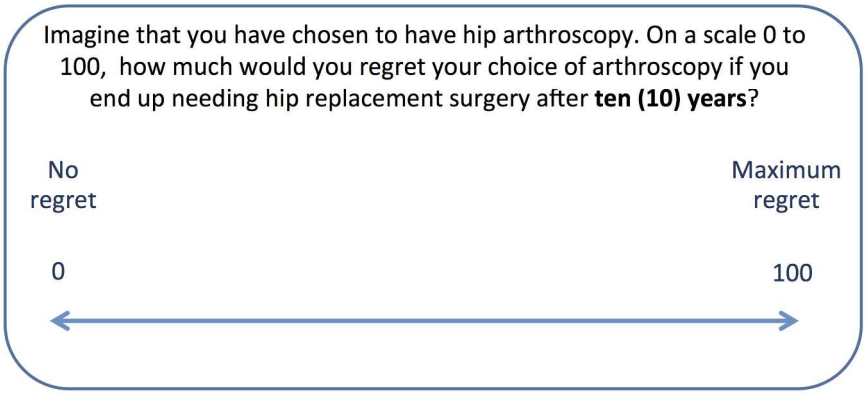


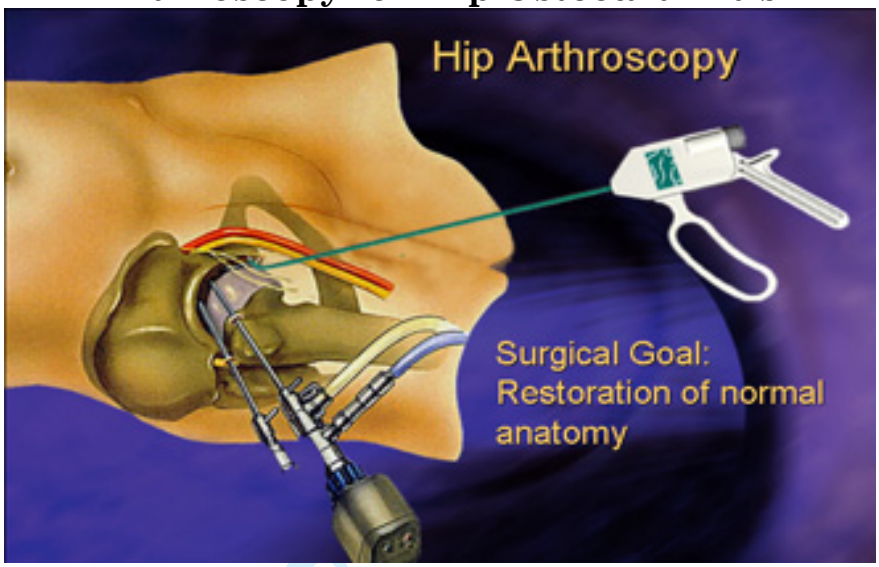
Patient's regret in scale 0-100 (0=no regret, 100=maximum regret)

Regret (0-100) _____

205x131mm (300 x 300 DPI)

Appendix: Script #1: Health scenarios

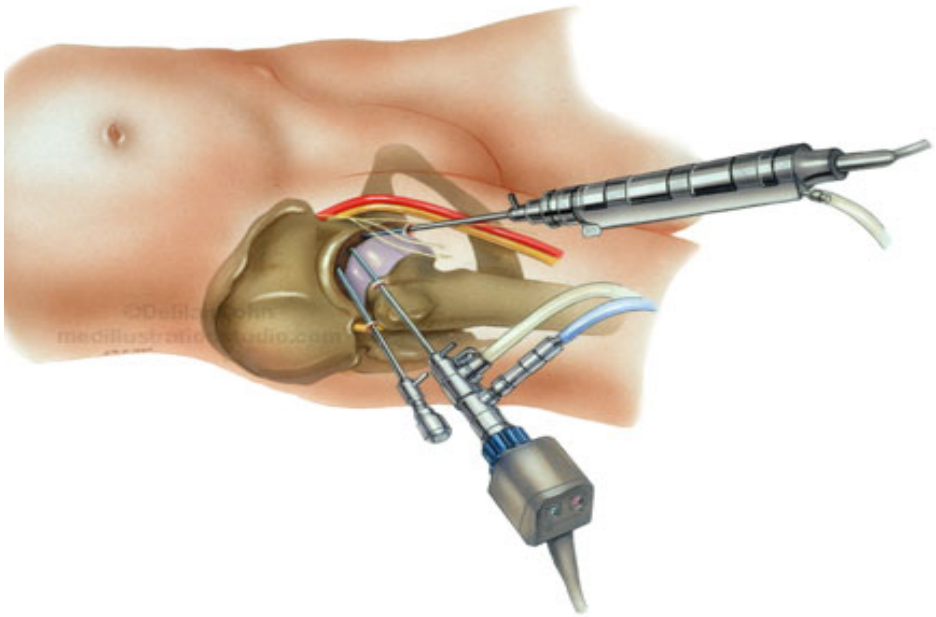
Arthroscopy for Hip Osteoarthritis



Introduction

Hip arthroscopy is a surgical procedure that gives doctors a clear view of the inside of the hip joint. This helps them diagnose and treat joint problems. The surgeon will make small cuts around your hip and look inside using a tiny camera. Other medical instruments may also be used inside to fix your hip. Patients with Osteoarthritis and hip pain who do not respond to conservative treatment and have no evident cause on standard radiographs, might be candidates for a hip arthroscopy. Arthroscopy has also been used to diagnose and evaluate other diseases affecting the hip, such as Femoroacetabular Impingement, Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Perthes Disease, Synovial Chondromatosis, and Ankylosing Spondylitis of the hip.

Procedure:



- Hip arthroscopy is performed through small incisions (about 0.5 to 1cm in length each) using a camera to visualize the inside of the hip joint.
- The tiny camera splits the muscle fibers. When the camera is removed, the muscle fibers return to their normal position and alignment.
- Surgeons will be able to see the joint through the camera, identify the problem(s), and
  - Repair torn cartilage
  - Remove loose pieces of cartilage, bone or ligaments
  - Reshape the bones
- The operation typically takes 60-90 minutes.

Benefits:

- Arthroscopy can potentially delay the need for Total Hip Replacement surgery in the future.
- Minimally invasive procedure: You will have very small incisions (0.5-1cm in length each, two to four in total) around the hip.
- Outpatient procedure: You usually go home the same day that you have surgery.
- Short rehabilitation period: On the first day after surgery, you will begin the rehabilitation process. This includes getting out of bed and walking. You may be able to bear some weight on the treated leg right away.

- You will have greater chance of going back to play competitive sports and a high functional level compare to total hip replacement surgery.
- Early return to sport: Most patients find they are back to full activities 3-4 months following hip arthroscopy.

Recovery:

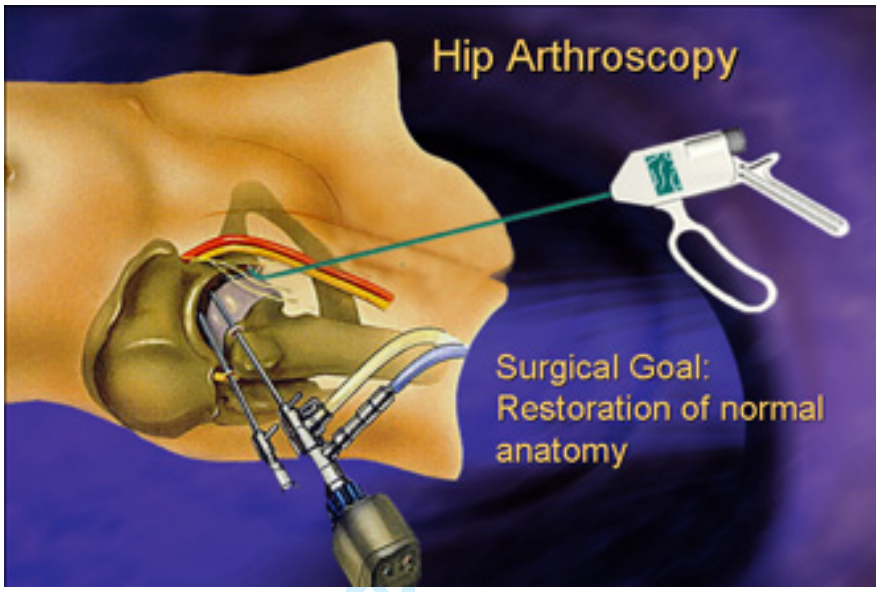
- Management:
  - You may have some pain and discomfort following your surgery. You will be given a prescription for pain medication which can be taken as needed.
  - You will need to leave the patches on your wound and keep it dry for 24 hours.
- Rehabilitation:
  - You can have protected weight bearing (weight bearing as tolerated with crutches) immediately following surgery.
  - You will need to begin physiotherapy as early as 48 hours after surgery with the guidance of your physiotherapist.
  - The rehabilitation will involve exercises to improve range of motion of the hip as well as strengthening exercises.
  - Your physiotherapist will help you decide when and how to progress your exercises in the long run.
  - It is very important that you will use crutches for the first two weeks after surgery to help protect the repair and improve gait mechanics following surgery
  - You may require assistance with driving for up to 6 weeks.
  - Exercises like stationary bike are a part of the rehab and may begin as soon as 48 hours after surgery.
  - Sedentary work can be partially resumed in one to two weeks. Labor-intensive work may require 3 months.
  - You can resume full physical activity in 3 to 6 months depending on your goals.

Possible Risks and complications:

Hip arthroscopy appears to be safe. The overall complication rate with hip arthroscopy was 4 in 100 (4.0%) with the vast majority of complications being non-life or limb threatening in nature. Here are rare complications that can occur:

- Neurologic traction injury: About 3 in 1000(0.3%) of you will experience it.
  - *This is the least severe form of nerve injury.. The actual structure of the nerve remains intact, but there is a transient interruption in the sensations being conducted through the injured nerve fiber. You could have decreased feeling or loss of strength in the skin on the lateral part of your leg and genital area, but there is usually a complete recovery.*
- Intra-abdominal Fluid Extravasations: About 15 in 10,000(0.15%) of you will experience it.
  - *During the procedure, when fluid is removed from the hip joint by the arthroscopy, some fluid may leak into the abdomen. You could experience the sense of increased abdominal pressure and discomfort that involves a measurable change in the circumference of your abdomen sometimes with swollen legs.*
- Dislocation of the hip: About 3 in 10,000(0.03%) of you will experience it.
  - *You could experience sharp, pain that become worse if the joint has moved. These symptoms will last until the damaged tissue has been allowed to rest and heal completely, and will require use of painkillers. Your orthopedic surgeon will have to pull on the leg to reposition the hip within the socket under anesthesia.*
- Blood clots in the legs or pelvis: About 6 in 10,000 (0.06%) of you will experience it during the first 6 months.
  - *The blood clot, due to immobilization, causes pain and swelling in the affected leg that typically gets better in about a month. About 17% to 50% of you will have persisting leg swelling, pain, vein swelling, and skin induration, for a longer period, up to 2 years.*

Arthroscopy for Hip Osteoarthritis



Introduction

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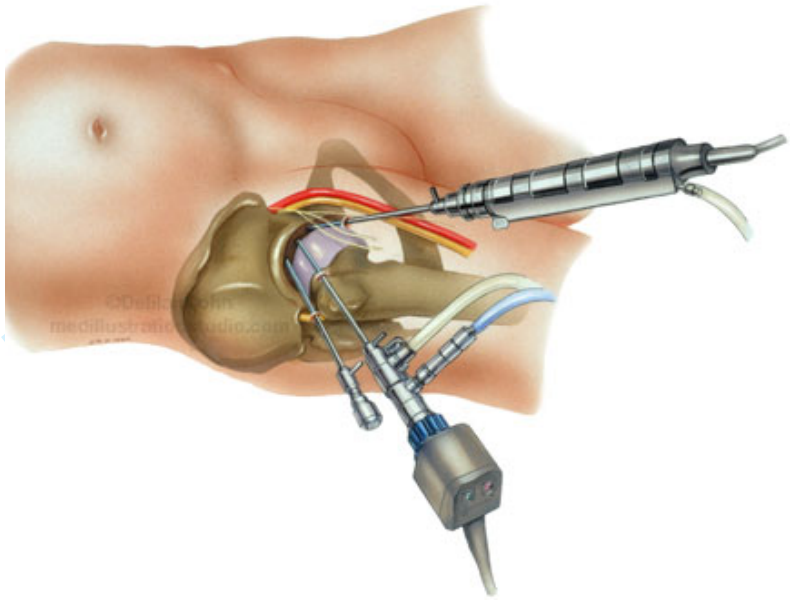


Procedure:

- The hip joint is made up of two major parts. The hip joint is a ball and socket joint that not only allows flexion and extension, but also rotation of the thigh and leg.
  - The hip **socket**, which is cup-shaped, sits in the pelvis.
  - The **ball** is the upper end of the thighbone (called the femoral head).
- If you would like to sleep during the surgery, the anesthetist will put you to sleep, so you will not be awake and therefore will have no memory of the procedure.
- Anesthesia:
  - There are two anesthesia options for this procedure, you can either have a general or a regional (spinal) anesthetic. Both options are safe and your pain will be managed with both.
    - General anesthesia: you will be 'asleep' (unconscious) for the procedure and not have any memory of the surgery.
    - Regional anesthesia: local anesthesia will be put in your lower back to make your body numb so you won't feel the procedure. Although you will still be awake and aware of the procedure the anesthesiologist can give you sedation medication to make you quite sleepy so you aren't anxious and mostly unaware of the procedure.
- After you receive anesthesia, your surgeon will put your leg in traction.

- This means that your hip will be pulled away from the socket enough for your surgeon to insert instruments, see the entire joint, and perform the treatments needed.
- The bones of the hip joint (the ball and socket) are separated by approximately 1cm by applying traction to the foot while wearing a special boot.

- Initially, air and/or fluid are injected into the hip, under x-ray guidance. Once correct placement of the instrument has been confirmed typically small incisions are made around the hip.
- Each of these incisions generally are approximately 0.5 to 1 cm in length.
- Through these small holes, the tiny camera ('arthroscope') and instruments are passed into the joint under x-ray guidance.
- The tiny camera will split the muscle fibers. When the camera is removed, the muscle fibers return to their normal position and alignment.
- Surgeons will be able to see the joint through the camera and identify the problems. Depending on the problem encountered, your surgeon will perform the appropriate procedures such as:
  - Repair torn cartilage
  - Remove loose pieces cartilage, bone or ligaments
  - Reshape the bones
- The operation typically takes 60-90 minutes but duration will vary depending on the problem in the hip joint but can last up to 120 minutes.
- After surgery, you will stay in the recovery room for 1 to 2 hours, then stay in the surgery area before being discharged to go home.

Benefits:

- Arthroscopy can potentially delay the need for Total Hip Replacement surgery in the future.
- Main possible benefits of arthroscopy compared to total hip replacement:
  - Relief of symptoms, including reduced pain.
  - Functional improvement, meaning increased mobility and regained ability to perform activities of daily living, the extent of which depend on the severity of your OA and other pre-existing conditions before the surgery.

- It helps to diagnose and treat early causes of arthritis, possibly preventing progression.
- Hip arthroscopy is a minimal invasive surgery compared to the open surgical alternatives. You will have very small incisions (about 0.5-1 cm each in length, two to four in total) around the hip, leading to minimal scarring.
- Outpatient procedure: You usually go home the same day or the next day that you have surgery.
- You will have chance of going back to activity at a high functional level. For example, playing competitive sports such as soccer or hockey.

➢ Less restriction on physical activities than after a hip replacement: On the day after surgery, you will begin the rehabilitation process. This includes getting out of bed and walking.

➢ You can bear some weight on the treated leg the day after surgery.

- You will be able to ride the stationary bike 48 hours after your surgery.

➢ Early return to physical exercise: Most likely you will go back to full activities 3 to 6 months following hip arthroscopy.

- *One to two weeks after the surgery after your wound has healed, you can walk in the pool.*
- *Approximately six to eight weeks after the surgery, you maybe able to increase activities including light aerobic exercise.*
- *Approximately 3-6 months after surgery, you will be able to do unrestricted exercise and* recreational sports after discussion with your surgeon.
- *These sports may include soccer, football, tennis, etc.*

Recovery:

➢ Management:

- After hip arthroscopy your wound is covered with patches.
- You will need to leave the patches in place and to keep your wounds dry for 24 hours.
- You will be given a prescription for pain medication following your surgery which you will take as needed.

- You will be given oral or intravenous antibiotics to prevent infection and you may also be given a medication to prevent blood clots in the legs.

➢ Rehabilitation:

- You are able to have protected weight bearing (weight bearing as tolerated with crutches) immediately following surgery.
- You will need to begin physiotherapy as early as 48 hours after surgery.
- Exercises like stationary bike are a part of the rehab and may begin as soon as 48 hours after surgery.
- Your physiotherapist will guide you through the rehabilitation program, which will involve exercises to improve range of motion of the hip as well as strengthening exercises.
- Your physiotherapist will help you decide when and how to progress your exercises in the long run.
- It is very important that you use crutches for the first two weeks after surgery to help protect the repair and improve gait mechanics following surgery. The rehabilitation progress, as well as the extent of the tear and/or associated problems, will determine the weaning process.
- Your joint can be quite sore at first, and it may need some time to settle. Therefore, you are not allowed to do movements/activities that may provoke the pain such as lifting, twisting, overstretching, and jarring.
- You may require assistance with driving for up to 6 weeks.
- In most occupations, such as sedentary job, you will be able to return to work in one to two weeks. However, since the return at this point will not be completely normal you may need some breaks in between. You may not be able to work the whole day, but you can be productive.
- If your job requires significant manual labor and lifting, the return may not occur completely until at least three months following surgery. A discussion with your surgeon may be needed too.
- Full physical activity will resume up to 3 to 6 months depending on your goals.

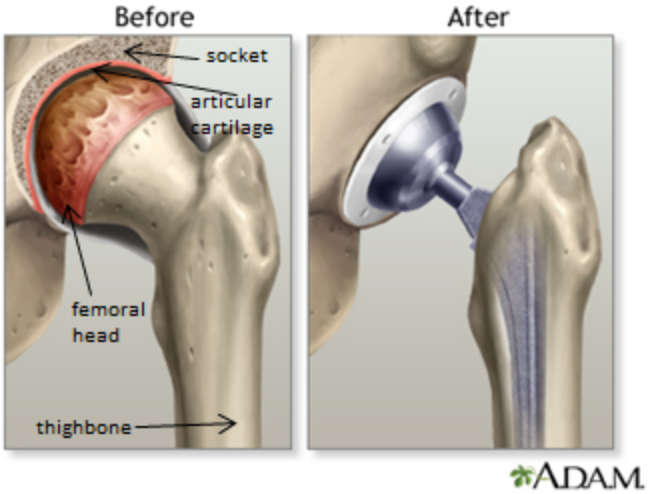
Risks and complications:

Hip arthroscopy appears to be safe. Although about 4 in 100 (4%) of you may present some kind of complication, most of the complications are not life or limb threatening.

- Neurologic traction injury: About 3 in 1000 (0.3%) of you will experience neurologic traction injury
  - *This is the least severe form of nerve injury. The actual structure of the nerve remains intact, but there is a transient interruption in the sensations being conducted through the injured nerve fiber. You could have decreased feeling or loss of strength in the skin on the lateral part of your leg and genital area, but there is usually a complete recovery.*
  - *Most commonly, numbness will go away within a week or so. In some cases, smaller areas may continue to be numb for several weeks.*
- Intra-abdominal fluid collections: About 15 in 10,000 (0.15%) of you will experience fluid collections
  - *During the procedure, when fluid is removed from the hip joint by the arthroscopy, some fluid may leak into the abdomen. You could experience the sense of increased abdominal pressure and discomfort that involves a measurable change in the circumference of your abdomen sometimes with swollen legs.*
- Dislocation of the hip: About 3 in 10,000 (0.03%) of you will experience dislocation during the first 6 months
  - *You could experience sharp, pain that become worse if the joint has moved. These symptoms will last until the damaged tissue has been allowed to rest and heal completely, and will require use of painkillers. Your orthopedic surgeon will have to pull on the leg to reposition the hip within the socket under anesthesia.*
- Blood clots in the legs or pelvis: About 6 in 10,000 (0.06%) of you will experience blood clot during the first 6 months.
  - *The blood clot, due to immobilization, causes pain and swelling in the affected leg that typically gets better in about a month. About 17-50% of you will have persisting leg swelling, pain, vein swelling, and skin induration, for a longer period, up to 2 years.*

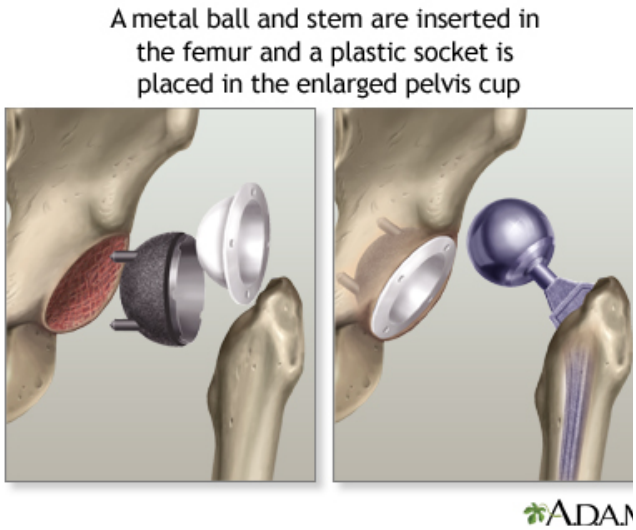
Total Hip Replacement for Hip Osteoarthritis

Introduction



Hip replacement is a surgery that aims to relieve arthritis pain, stabilize and improve the function of your hip. The most common cause for the pain is osteoarthritis (OA). Cartilage, which is the rubbery tissue that cushions your bones and joints, can break down and wear away. As a result, the bones rub together, causing pain, swelling, and stiffness. The surgeon will remove the old hip joint and put in a new joint. If other treatments such as physical therapy, pain medicines, and exercise have not helped, then hip replacement surgery might be an option for you.

Procedure:



- The anesthetist will put you to sleep if you request it, and you will not feel any pain during surgery.
- After you receive anesthesia, your surgeon will open up your hip joint and does the following:
  - Removes the damaged ball from the thighbone and cleans out the socket.
  - Replaces the natural joint with an artificial ball and socket.
- The surgery usually takes 1 to 3 hours.

Benefits:

- Main benefit:

- Relief of symptoms, including reduced pain, increased mobility and/or regained ability to perform activities of daily living.
- The above improvements depend on the severity of your OA and other preexistent diseases.

➢ Post-operative mobility:

- Most of you will have an increased range of movement 3 months after surgery. About 51 in 100 (51%) of you will not need an aid to walk and will be able to move your hip more than 160 degrees.
- About 77 in 100 (77%) of you will be able to walk without support, 21 in 100 (21%) will use a cane, and 2 in 100 (2%) will use crutches (Data from patients average age of 80; range, 56-98 years old) after 1 to 2 years.

➢ Pain relief:

- About 87 to 91 in 100 (87%-91%) of you will have great or complete pain relief, and 9 to 13 in 100 (9%-13%) of you will experience an unfavorable long-term joint pain after the procedure from 3 months to 5 years (Data from patients average age of 69 years old).

➢ Sleep:

- Your sleeping quality will improve significantly 10 weeks after surgery.

➢ Determinants regarding home management, mobility, and work will considerably improve after 3 months.

Recovery:

➢ Management:

- You may have great deal of pain requiring painkillers within the first days.
- You may have some pain for up to 2-3 weeks and the pain may persist for 3 months.

➢ Rehabilitation:

- You will have severe mobility restrictions and the types of restriction will depend on the specific procedure of your surgery. You will need a walker for the first days to weeks; then a cane or crutches for weeks up to 3-6 months.
- You will not be able to bend your hip over 90 degrees for 3 months.
- Physical therapy is an important part of the recovery process. You will work with a physical therapist to develop an exercise and rehabilitation program while your stay in the hospital.

- The rehabilitation program generally includes exercises to stretch and strengthen the muscles surrounding the hip joint, as well as training in activities of daily living.
- Most of you will be able to resume your activities of daily living within 3 to 6 months.

Long-term outlook:

- 90 out of 100(90%) of your hip replacements will last longer than 10 years.
- 85 out of 100(85%) of your hip replacements will last longer than 20 years.
- Over the course of 15 to 20 years, the artificial hip joint will loosen and you may need a second replacement.

Possible Risks and complications:

- In 6 months post operation, about 30 in 100 (30%) of you will have at least one complication.
- While some complications can be a bit more serious, most can be treated successfully.
- Urine retention: About 20 to 35 in 100 of you (20-35%) will experience it.
- Infections: About 1 in 100 of you (1%) will develop a wound or deep infection after the operation.
- Death: 3 out of 1000(0.3%) will die.
- Blood clots in the legs or pelvis: About 5 in 1000 (0.5%) of you may experience it before hospital discharge.
  - *The blockage causes pain and swelling in the affected leg that typically gets better in about a month.*
- Blood clots in the lungs: About 9 in 1000(0.9%) during the first 6 months.
  - *This leads to shortness of breath, sometimes severe, which with anticoagulant treatment resolves in about 2 weeks. Anticoagulant treatment will be used for 3 months.*
- Dislocation of the hip: About 4 in 100(4%) at the first 6 months.
  - *You could experience sharp, pain that become worse if the joint has moved. Your orthopedic surgeon will pull on the leg to reposition the hip within the socket under anesthesia.*
- Nerve damage: About 1 to 3 in 100 (1%-3%).

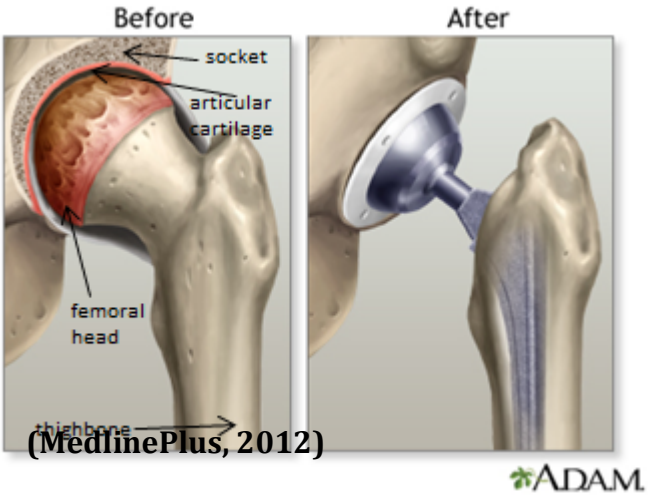
- *If there is nerve damage, you will have decreased feeling or loss of strength in the leg, foot or ankle area.*

- Different leg lengths: Less than 1 in 100(1%) of you will need another operation because one leg is longer than the other.

Total Hip Replacement for Hip Osteoarthritis

Introduction

Hip replacement is a surgery, also called Total Hip Arthroplasty, which aims to relieve arthritis pain, improve function, and make your hip more stable. The most common cause for the pain is osteoarthritis (OA), and the reason for OA is unknown. Cartilage, which is the rubbery tissue that cushions your bones and joints, can break down and wear away. As a result, the bones rub together, causing pain, swelling, and stiffness. During the operation, the surgeon will remove the old hip joint and put in a new joint. If other treatments such as physical therapy, pain medicines, and exercise have not helped, then hip replacement surgery might be an option for you.



(MedlinePlus, 2012)

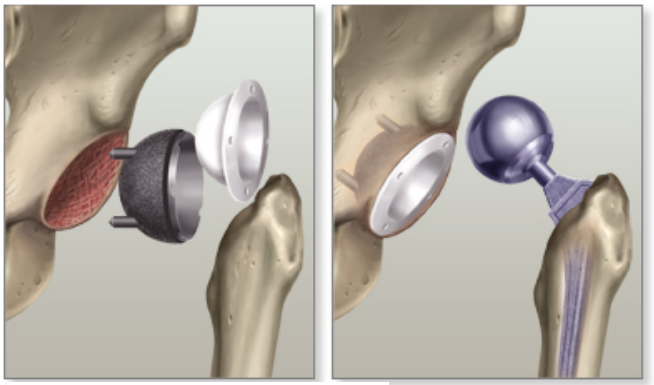
Procedure

- The hip joint is made up of two major parts. One or both parts may be replaced during surgery.
  - The hip **socket**, which is cup-shaped, and sits in the pelvis.
  - The **ball**, which is the upper end of the thighbone (called the femoral head).
- The new hip that replaces the old one is made up of these parts:
  - A socket, which is usually made of strong metal.
  - A liner, which fits inside the socket and usually, is made of either plastic, ceramic, or metal.
  - A metal or ceramic ball that will replace the top of your thighbone.
  - A metal stem that is attached to the thighbone to make the joint more stable.
- If you would like to sleep during the surgery, the anesthetist will put you in sleep, and you will not feel any pain during surgery.
- Anesthesia:
  - You will not feel any pain during surgery due to one of two types of anesthesia that you will receive
    - General anesthesia: you will be 'asleep' (unconscious) for the procedure and not have any memory of the surgery.

- Regional anesthesia: local anesthesia will be put in your lower back to make your body numb so you won't feel the procedure. Although you will still be awake and aware of the procedure the anesthesiologist can give you sedation medication to make you quite sleepy so you aren't anxious and mostly unaware of the procedure.

- After you receive anesthesia, your surgeon will make a surgical cut to open up your hip joint. Then you surgeon will:
  - Cut and remove the head of the thighbone.
  - Clean out your hip socket and remove the rest of the cartilage and damaged bone.
  - Put the new hip socket in place, then insert the metal stem into your thighbone.
  - Place the correct-sized ball for the new joint.
  - Secure all parts with cement.
  - Repair the muscles and tendons around the new joint.
  - Close the surgical cut.
- The surgery usually takes 1 to 3 hours.

A metal ball and stem are inserted in the femur and a plastic socket is placed in the enlarged pelvis cup



(MedlinePlus, 2012) ADAM.

Benefits

- Main benefit:
  - Relief of symptoms, including reduced pain, increased mobility and regained ability to perform activities of daily living.
  - Function improvement and pain relief are depending on the severity of your OA and other preexistent diseases.

- Mobility postoperatively:
  - Most of you will have an increased range of movement 3 months after surgery. About 51 in 100 (51%) of you will not need assistance to walk and will be able to move your hip more than 160 degrees.
  - About 49 in 100 (49%) of you will require assistance to walk and will be able to move your hip less than 160 degrees after 3 months.
  - About 64 in 100 (64%) of you will be able to walk longer distances compare to pre-operatively after 3 months (Data from patients age 55-84 years old).

- About 77 in 100 (77%) of you will be able to walk without support, 21 in 100 (21%) will use a cane, and 2 in 100 (2%) will use crutches (Data from patients average age of 80; range, 56-98 years old) after 1 to 2 years.

➢ Pain relief:

- About 87 to 91 in 100 (87%-91%) of you will have great or complete pain relief, and 9 to 13 in 100 (9%-13%) of you will experience an unfavorable long-term joint pain after the procedure from 3 months to 5 years follow-up (Data from patients average age 69 years).
- About 25 in 100 (25%) of you will only have occasional pain 3 months after operation.

➢ Sleep:

- Your sleeping quality will improve significantly 10 weeks after surgery.

➢ Psychological improvements:

- Your psychosocial quality of life will improve regarding social interaction, communication, alertness behavior, and emotional behavior immediately and 6 months after the operation.

➢ Factors such as home management, mobility, and work will considerably improve after 3 months.

Recovery:

➢ Management:

- After surgery, you may experience a great deal of pain within the first days and you may need to take painkillers.
- You may be given pain medication intravenously using a pump (patient-controlled-analgesia).
- You may have some pain for up to 2-3 weeks and the pain may persist for 3 months.
- You are likely to have problems with constipation from painkillers in the first weeks after surgery.
- You will be given an antibiotic to prevent infection.
- You may also be given a medication or compression boots and stockings to prevent blood clots in the legs.

➢ Rehabilitation:

- You will have severe mobility restrictions and the types of restriction will depend on the specific procedure of your surgery.

You will need a walker for the first days to weeks; then a cane or crutches for weeks to 3-6 months.

- You will not be able to bend your hip over 90 degrees for 3 months. This means you cannot bring your knee up to your chest and you also cannot bend forward at the hip past 90 i.e. if tying your shoes.
- You may also have restricted adduction (moving your leg past midline) and any twisting (internal/external rotation) of the leg.
- Your surgeon will determine the timeline for these restrictions.
- You will also have difficulties for dressing and need for mechanical aids.
- Physical therapy is an important part of the recovery process. The length of stay in the hospital for most of you will be about 1 to 3 days, during which time you will work with a physical therapist to develop exercises and follow a rehabilitation program.
- You may need physiotherapy up to 3 month depending on your condition.
- The rehabilitation program generally includes exercises to stretch and strengthen the muscles surrounding the hip joint, as well as training in activities of daily living, such as stair climbing, and walking.
- Most of you will be able to resume your activities of daily living within 3 to 6 months.
- Your ability to perform household, domestic tasks (for example cutting toenails, having a bath, climbing stairs) will improve.
- About 84 in 100 (84%) of you will be able to maintain your own home, 6 in 100 (6%) of you will live at home with assistance, and only 10 in 100 (10%) will need someone to take care of you full-time 20 years after operation (Data from patients average age 80 years; range, 56-98 years).
- You might be able to return to recreational sports after 6 months after discussion with your surgeon.

Long-term Outlook:

- About 90 out of 100 (90%) of your hip replacement will last longer than 10 years.
- About 85 out of 100 (85%) of your hip replacements will last longer than 20 years.
- Over the course of 15 to 20 years, the artificial hip joint will loosen and you may need a second replacement.

Risks and complications:

- 6 months post operation, about 30 in 100 (30%) of you will have at least one complication.

- While some complications can be a bit more serious, most can be treated successfully, such as blood clots.
- Urine retention: About 20 to 35 in 100(20-35%) of you will experience it.
    - *You may urinate frequently; you may feel an urgent need to urinate but have little success when you get to the toilet; or you may feel you still have to go after you've finished urinating.*
- Infections: About 1 in 100 (1%) of you will develop an infection after the operation.
    - It may occur in the wound or deep around the artificial implants.
- Deep joint infection: 2 in 1000(0.2%) in first 90 days.
    - *You will experience fever or chills due to the infection, unusually swelling of the hip joint. The replaced hip will be removed, and you will be without a hip joint and receiving antibiotics for months.*
- Risk of a complication will be higher if you have other diseases. For instance, 40-50 in 100 (40-50%) of you who have at least three other conditions, such as heart disease, urinary tract infection, or obesity will experience a complication.
- Death: 3 out of 1000(0.3%) of you who undergo hip replacement surgery will die.
- Blood clots in the legs or pelvis: About 5 in 1000 (0.5%) before hospital discharge.
    - *The blood clot, due to immobilization, causes pain and swelling in the affected leg that typically gets better in about a month. About 17% to 50% of you will have persisting leg swelling, pain, vein swelling, and skin induration, for a longer period, up to 2 years.*
    - If you are older, overweight, have cancer, or have experienced blood *clots before, you will be more likely to get blood clots after surgery*.
    - This clot can potentially lead to another complication, which is localized swelling in the leg due to clot and decreased flow of blood to the heart.
- Dislocation of the hip: About 1 in 100 (1%) of you will have dislocated the hip by first week, 3 in 100 (3%) by eighth week, and about 4 in 100(4%) at the first 6 months
    - *You could experience sharp, pain that become worse if the joint has moved. These symptoms will last until the damaged tissue*

has been allowed to rest and heal completely, and will require use of painkillers. Your orthopedic surgeon will have to pull on the leg to reposition the hip within the socket under anesthesia.

- Nerve damage: 1 to 3 in evey100 (1%-3%) of you.
    - *If there is nerve damage, you will have decreased feeling or loss of strength in the leg, foot or ankle area. Around 0.5% of you will have the nerve damage permanently.*
- Different leg lengths: Less than 1 in 100(1%) of you will need another operation because one leg is longer than the other.
    - You might need another surgery because the difference length of your legs will cause severe post surgery problems such as walking difficulty, pain, or dislocation.