<u>Patient Health Status as an Indication for Primary Total Hip Arthroplasty: A Systematic Review and Meta-Analysis</u>

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Abstract

Purpose: Total hip arthroplasty (THA) is one of the most commonly performed orthopaedic procedures. It has been shown to be a cost-effective means of relieving pain and improving the function of patients with advanced joint disease. The number of procedures performed per year is increasing for reasons that are not fully explained by a growing and aging population. The purpose of this study was to determine the role of patient health status as an indication for surgery and determine if patients are undergoing surgery at a better health status than in the past.

Materials & Methods: To examine how pre-operative functional health status has changed over the past 20 years, a systematic review and meta-analysis of the Medline, Embase, and Cochrane databases was performed in accordance with the PRISMA guidelines. Health status was assessed using the physical component summary (PCS) score from the 36-item short-form health survey (SF-36). Only primary procedures were included; revisions were excluded. All articles were screened by two independent reviewers with conflicts resolved by consensus with a third reviewer. Meta-regression analysis was performed to determine the effect of time, patient age, and gender on the pre-operative SF-36 score. Subgroup analysis was performed to assess differences between countries.

Results: A total of 1,504 articles were identified in the initial search. Data from 172 independent groups representing 18,644 patients recruited from 1990-2013 and identified from 107 articles was included in the final analysis. The mean pre-operative PCS score was 31.2 (95% Confidence Interval: 30.5-31.9) with a 95% prediction interval of 22.6-39.8. The variance across studies was found to be statistically significant ($p = 0.000$) with 97.25% of this variance being accounted for by true variance. Neither year of patient enrolment, mean age, nor the percentage of females in each independent group were found to have any significant effect.

There were no significant differences between countries. Analysis of the regional distribution of the included patients showed significant underrepresentation of certain areas, primarily in the developing world.

Conclusions: Patients are undergoing THA at a similar health status to the past. Patient age and gender do not influence the functional status at which patients are indicated for surgery. There are no significant regional differences in pre-operative health status. A target PCS score at which patients should be indicated for surgery cannot be established due to the significant true variance among the included studies. Underrepresentation of patients from the developing world in the literature remains an ongoing concern.

Résumé

But : Les prothèses totales de la hanche (PTH) sont une des procédures les plus fréquemment exécuter par les orthopédistes. Elles ont été démontrées comme une façon rentable de soulager la douleur et améliorer la fonction des patients qui souffrent des maladies des articulations avancées. Le montant de procédures exécutées chaque année augmente pour des raisons qui ne sont pas complètement expliquées par une population qui grandit et vieillit. Le but de cette étude était de déterminer le rôle du statut de santé des patients comme une indication pour la chirurgie et de déterminer si les patients subissent la chirurgie à un meilleur statut de santé que dans le passé.

Matériels & méthodes : Pour étudier comment le statut de santé préopératoire a changé pendant les 20 derniers ans, une révision systématique et une méta-analyse des bases de données de Medline, Embase et Cochrane étaient exécutées selon les conseils de PRISMA. Le statut de santé était évalué en utilisant le score pour la composante physique (SCP) du questionnaire généraliste SF-36. Seulement les procédures primaires étaient inclues; les révisions étaient exclues. Tous les articles étaient évalués par deux critiques indépendants avec les conflits résolus par consensus avec un troisième critique indépendant. Des analyses de méta-régression étaient exécutées pour déterminer l'effet de temps, l'âge des patients et sexe sur le score préopératoire de la SF-36. Des analyses de sous-groupe étaient exécutées pour évaluer les différences entre les pays.

Résultats : Un total de 1 504 articles étaient identifiés par la recherche initiale. Les données de 172 groupes indépendants représentant 18 644 patients recrutés de 1990-2013 et identifiés de 107 articles ont été incluses dans l'analyse finale. Le SCP préopératoire moyen était 31,2 (l'intervalle de confiance de 95% : 30,5-31,9) avec un intervalle de prédiction de 95% de 22,6-39,8. La variance à travers les études était statistiquement importante (p = 0,000) avec 97,25% de cette variance représentant la vraie variance. Ni l'année d'inscription des patients, l'âge moyen des patients, ni le pourcentage de femmes dans chaque groupe avaient des effets importants. Il n'y avait pas de différences importantes entre les pays. L'analyse de la répartition régionale des patients inclus démontre une sous-représentation importante de certains endroits, surtout des pays en voie de développement.

Conclusions : Les patients subissent des PTHs à un statu de santé comparable à celui du passé. L'âge des patients et sexe n'influencent pas le statu fonctionnel à lequel les patients sont indiqués pour la chirurgie. Il n'y a pas de différences régionales importantes en statu de santé préopératoire. Un SCP ciblé à lequel les patients devraient être indiqués pour la chirurgie ne peut pas être établi à cause de la vraie variance importante entre les études incluses. Une sous-représentation des patients des pays en voie de développement dans la littérature reste un problème persistent.

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Introduction

Total hip arthroplasty (THA) is one of the most commonly performed procedures by orthopaedic surgeons. It has been shown to be cost-effective in relieving pain and improving the functional outcome of patients suffering from advanced joint disease, usually due to osteoarthritis.[1,2] The number of these procedures performed per year, however, has been steadily increasing, both in terms of total number and surgeon caseload, and is expected to do so well into the future.[2-5] While population aging and growth account for some of this increase, these factors do not fully explain the increase in volume.[6,7] The demand for THA in patients younger than 65, alone, is projected to increase from 32% in 1993 to 52% of primary procedures by 2030.[8] The purpose of this study was to examine whether changes in the indications for elective primary THA (replacement of the patient's native hip joint) account for the increasing number of procedures performed per year. Specifically, we sought to determine if patients were undergoing primary THA at a better health status than their counterparts in the past.

The objectives of this project were:

1. To determine if the indications, specifically patient health status, for primary THA have changed over the past 20 years.
2. To determine if patients are currently undergoing primary THA at a better pre-operative health status than they were in the past. Differences in patient health status could indicate changes in patient expectations and a desire to undergo surgery to remain active or a change in surgeon practice.
3. To determine if patient pre-operative health status varies between countries or genders. Differences in patient health could indicate differences in patient expectations or surgical practice.

Review of the Relevant Literature

Total hip arthroplasty was first developed in the early 20th century in an attempt to find a surgical solution for disabling hip arthritis.[1,9] At the time, hip arthritis was in no way a new condition, as it has been diagnosed in ancient skeletons, but few good treatment options were available.[1] The push toward the modern total hip replacement – which involves the replacement of the patient's native hip joint with an artificial femoral ball and acetabular socket – began with Smith-Peterson and Wiles in the early 1900s.[9] Sir John Charnley catapulted THA into the modern era in 1961 with the development of his low friction arthroplasty.[10] The success of this operation, particularly in terms of long-term survivorship, lead to THA being considered the orthopaedic operation of the century.[1,11-17] Today, THA is one of the most commonly performed orthopaedic procedures with an estimated 370,770 primary procedures being performed in the United States in 2014[18] and 498,000 projected for 2020.[19] This number is projected to further increase to 635,000-909,900 primary THA per year by 2030.[18] While the success of this operation as well as the growing, ageing, and increasingly obese population are certainly partially responsible for this increasing volume of cases being performed per year, they do not fully explain the increasing incidence.[6,7,20]

In its infancy, THA was considered a salvage procedure indicated for only the most infirm and elderly patients.[1,2] As technology and survivorship of the implants have improved, however, the indications have expanded to render this operation one of the key ways arthritic patients are able to maintain their quality of life in spite of developing advanced disease.[1] The precise indications as to when in the disease process a patient should undergo surgery, however, remain poorly defined. There are currently no evidence-based indications that can be uniformly applied to clinical practice, and the guidelines that do exist are primarily founded on poor-quality evidence.[20 21] It is generally agreed that pain, functional impairment, radiographic changes, and failed non-operative management should guide the decision to proceed with surgery, but it is not well defined how to measure these criteria or how these criteria should be combined to determine the optimal timing of surgery.[2 20-26] Furthermore, as patients' outcome expectations have increased, the effect of their unwillingness to tolerate a significant functional decline on the decision to proceed with surgery has not been well studied.[1] In spite of the high global volume of THA performed per year, the decision to proceed with surgery remains a highly subjective decision that is made after a detailed conversation between the surgeon and patient.

The high degree of subjectivity in the indications paves the way for significant practice variance. A multinational European study, for example, found that significant variability exists not only among orthopaedic surgeons but also among referring physicians as to the severity of disease, the impairment of activities of daily living, and the extent of joint destruction that merits surgery.[21] Similarly, an epidemiological study of hip arthroplasty rates in countries of the Organisation for Economic Cooperation and Development found substantially different rates between countries that were not likely explained exclusively by differences in rates of osteoarthritis, age structure, or health expenditure per capita.[27] Wait times may also significantly impact the decision to indicate a patient for surgery. Longer wait times have been associated with poorer functional outcomes,[28] so surgeons with longer waiting lists may choose to indicate patients for surgery earlier in the disease process in order to prevent too much functional decline prior to the procedure itself. The converse of too short wait times to the point that a surgeon has difficulty filling his or her elective OR time could also affect the indications as it could provide motivation to operate on healthier patients. The end result of this variability is that identical patients may or may not be offered surgery depending on the surgeon to which they are referred and in which country they reside.[21] While appropriate patient-centered care involves weighing both patient preferences and the best available evidence, this degree of variability is not acceptable in the modern era of evidence-based medicine. It is for this reason that we chose to study the indications for THA, specifically patient health status, and track how they have changed over time.

Materials and Methods

To study how the pre-operative functional health status of patients undergoing primary THA has changed over the past 20 years, a systematic review and meta-analysis of the available literature was performed. Pre-operative health status was assessed using the 36-item short-form health survey (SF-36). This general health survey was developed in 1992 out of the Medical Outcomes Study, a four-year study designed to assess the influence of specific factors on the outcomes of care and develop practical tools for monitoring patient outcomes.[29-31] It was designed to produce data relevant for both research and clinical practice and generates eight individual scale scores – (1) physical functioning, (2) role limitations due to physical problems, (3) social functioning, (4) bodily pain, (5) general mental health, (6) role limitations due to emotional problems, (7) vitality, and (8) general health perceptions.[29] Each score ranges from 0 to 100 with higher scores reflecting better health status. The eight individual scores can be combined into two aggregate scores – the physical component summary (PCS) and mental component summary (MCS) scores. These aggregate scores offer the advantages of reducing the number of analyses while producing smaller confidence intervals and smaller floor and ceiling effects.[30 32]

The SF-36 scoring system was chosen for this study for several reasons. First, it is the only scoring system that permits comparisons across multiple decades. Although multiple derivations of the SF-36 have been developed, the traditional SF-36 scoring system has remained predominantly unchanged since 1993.[30] The only significant change was the development of the SF-36 version 2 in 1996, but the results of this newer version have been shown to be comparable to the original SF-36 survey.[30 33] Second, the SF-36 survey has been extensively used in the orthopaedics literature and has been shown to be useful in the assessment of THA patients.[30 34]

Finally, the SF-36 scoring system has been translated into over 170 languages.[30 33] Therefore, using the SF-36 for this study allows a global assessment of patient health status prior to primary THA.

The systematic review and meta-analysis was performed in accordance with the PRISMA guidelines.[35] After consultation with a health sciences librarian, a literature search of the Medline, Embase, and Cochrane databases was performed on January 12, 2018, and the results were stored in EndNote. Detailed descriptions of the search strategies can be found in Appendix I. No restrictions were placed on the search, including no language restrictions. After the removal of all duplicates, potentially eligible abstracts were screened by two independent reviewers. The main inclusion criterion was primary THA. Exclusion criteria for abstract screening were:

1. No elective THA. THA performed for fractures or as part of a tumour reconstruction were excluded.
2. No SF-36 scores.
3. Revision THA.
4. Conference proceeding only, published abstract only, or protocol only.

Conflicts between the two reviewers regarding the inclusion of an article were resolved by consensus with the assistance of a third independent reviewer.

After abstract review, all potentially eligible articles underwent full manuscript review by the same independent reviewers. Additional exclusion criteria that were applied to the full manuscript review were:

1. No pre-operative SF-36 scores.

2. Incomplete scale scores to calculate the PCS, if this score was not explicitly stated in the article.
3. SF-36 scores reported for THA patients combined with patients who underwent other procedures (ie. total knee arthroplasty).
4. SF-36 scores for patients whose data had been reported in other publications that were already included in this meta-analysis.
5. Review articles.
6. Meta-analyses.
7. Letters to the editor or editorials.

Conflicts between the reviewers were again resolved by consensus with the assistance of a third independent reviewer. Articles in languages not spoken fluently by the main reviewers were discussed with individuals fluent in the respective languages. Google Translate (Mountain View, California, United States) was employed as needed to confirm parts of the translations. The reference lists of all relevant articles, including review articles and meta-analyses, were manually cross-referenced to identify potential papers missed by the literature search. Articles that were found to satisfy both the inclusion and exclusion criteria were added into the analysis.

Data from all included articles was extracted by the two independent reviewers and then compared to ensure accuracy. Extracted data included earliest year of patient enrolment, sample size, region from which the patients were sampled (divided as US vs non-US and by continent), age of the patients, percentage of female patients, percentage of patients diagnosed with primary osteoarthritis, and the PCS and MCS scores. If the year of patient enrolment was not provided, it was estimated based on either the date of publication or the date the manuscript was received by the publisher. For example, if an article reported two-year follow-up data at the time of publication in 1997, year of enrolment was estimated as 1995. If the PCS and MCS scores were not directly reported, they were calculated from the eight scale scores using the algorithm provided by Laucis.[30] The orthogonal method of calculation was used as this is the most commonly used method,[30] and therefore the results are most comparable with the PCS scores explicitly reported in the literature.

The level of evidence of each study included in the final analysis was assessed using the guidelines provided by The Journal of Bone & Joint Surgery.[36] As the purpose of this study was to examine the trend in the pre-operative SF-36 scores over time rather than examine the effects on the SF-36 score of any individual study, both experimental and observational studies were included in the final analysis. For the same reason, the risk of bias in each study was not assessed as it was not considered relevant to the analysis.

Descriptive statistics of the included studies were calculated using RStudio (Boston, Massachusetts, United States). Inter-rater reliability was assessed using Cohen's kappa after both the abstract and full manuscript review and calculated using RStudio.

The analysis of the extracted data was performed using Comprehensive Meta-Analysis Version 3 (Biostat, Englewood, New Jersey, United States). The overall PCS score across all studies was calculated using the mean and standard deviation, 95% confidence interval, or mean and standard error, depending on which metric was reported in the included studies. Missing standard deviation values were imputed using a weighted mean of the reported standard deviations. This mean was calculated using the sample size of the studies with reported standard deviations as weights. The validity of this imputation technique was tested in two ways. First, the means of the standard deviations with and without the imputed values were compared using a Mann-Whitney U test after testing each group for normality using a Shapiro-Wilk test to ensure the imputed values did not fundamentally change the population characteristics. Second, once the results of the meta-analysis were obtained using the imputed weighted mean, the analysis was re-run using the true mean of the reported standard deviations as the imputed value. This procedure was performed to ensure the results were not fundamentally different. As no definitive technique is described for imputing missing standard deviations in meta-analyses, this technique is supported by the literature.[37-39] The analysis of the standard deviations was performed using RStudio. The PCS scores were combined using a random-effects model. The variance in the PCS scores was assessed using the Q-value and I^2 statistic. The 95% prediction interval was calculated using the formula provided by the Comprehensive Meta-Analysis program.

The associations of year of patient enrolment, mean patient age, and percentage of females in each group with the PCS score were assessed through separate meta-regression analyses using Comprehensive Meta-Analysis Version 3. The effect of region of patient enrolment was assessed by performing subgroup analyses of the overall PCS scores and comparing the groups using the Q-value and I^2 statistic. A mixed-effect model was used to perform the subgroup analyses. The within-group estimate of τ^2 was not pooled for the comparison of the United States versus the rest of the world as a significant number of studies were available for each group. This value was pooled for the more detailed comparison by region due to the small number of studies representing some locations. A p-value less than 0.05 was considered significant.

Results

Description of Included Studies

As summarized in Figure 1, the literature search retrieved a total of 1,504 articles – 499 from Medline, 629 from Embase, and 376 from Cochrane. Three hundred and thirty-five articles were automatically removed by EndNote as duplicates. An additional 120 duplicate studies were manually removed. This left a total of 1,049 articles for title and abstract review. Application of the initial exclusion criteria resulted in the removal of 526 studies. One study was removed as the EndNote link was found to be dead and not associated with an abstract or article. Cohen's kappa was calculated to be 0.78. Five hundred and twenty-two articles proceeded to full manuscript review. Four hundred and sixteen studies were excluded. In addition to the established exclusion criteria, one paper was removed as the library could not locate the full manuscript, and two papers were excluded as the patient sample size could not be accurately determined. Cohen's kappa for the manuscript review was 0.63. Manual cross-referencing produced one article that satisfied both the inclusion and exclusion criteria but had not previously been identified in the search. This result left 107 studies to be included in the final analysis. A complete list of the included studies can be found in Appendix II. Seventeen of these studies were randomized controlled trials (RCTs). Figure 2 shows counts of the main reason for exclusion of the removed studies.

Fig. 1 Included Studies

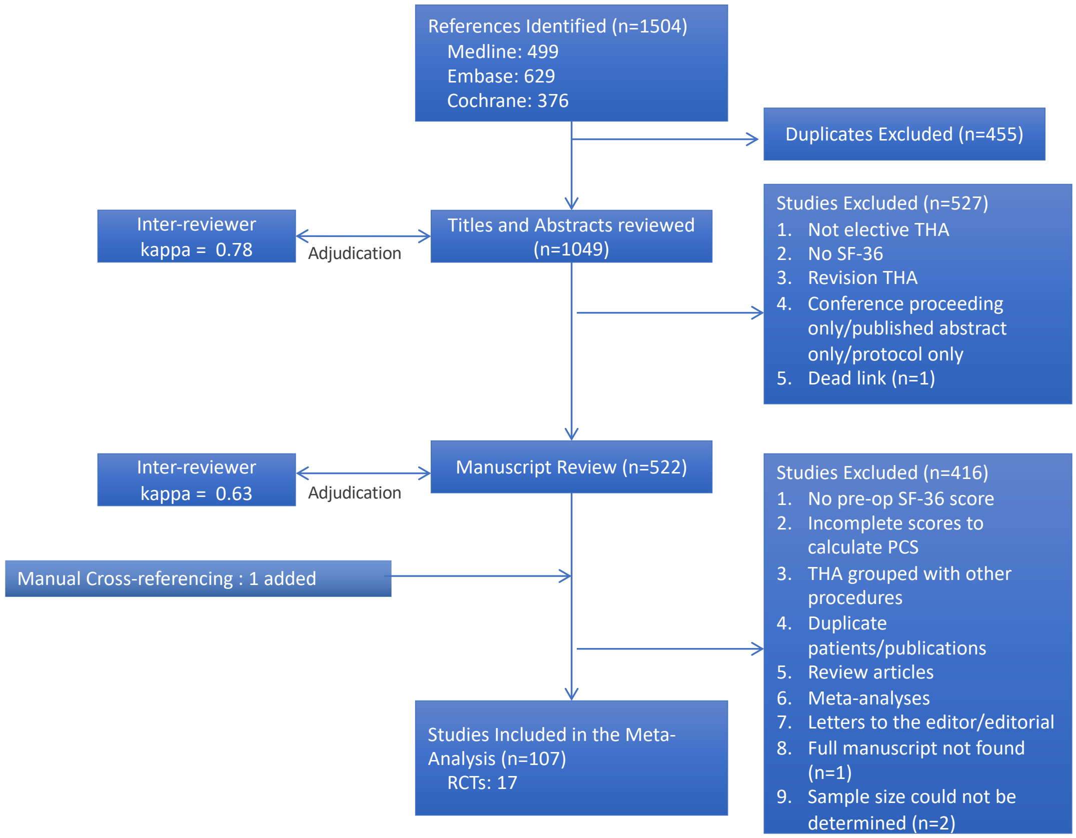


Fig. 2 Counts of Main Reason for Exclusion

Reason for Exclusion	Number of Studies
Not elective THA	297
No SF-36	93
Revision THA	36
Conference proceeding/published abstract/protocol only	131
No pre-op SF-36 score	126
Incomplete score to calculate PCS	94
THA grouped with other procedures	69
Duplicate patients/publications	43
Review articles	27
Meta-analyses	16
Letter to the editor/editorial	7
Dead link	1
Full manuscript not found	1
Sample size could not be determined	2

From the included studies, we were able to extract a minimum of year of enrolment, sample size, and PCS score for 172 independent patient groups. Some studies contributed more than one group as separate arms of the same study (i.e. in a study comparing different implants or surgical techniques) were extracted separately, provided sufficient data was reported for each group. These groups represent the data from 18,644 patients first enrolled between 1990 and 2013. One study[40] was able to calculate scores back to 1990 by using an early version of the SF-36 questionnaire combined with the standard method of calculation developed in 1993. The PCS score was explicitly reported for 106 groups and calculated for the remaining 66 groups. Figure 3 shows the regional distribution of the groups. Of the 62 groups from North America, 56 were from the United States. The remaining six groups were from Canada. No groups were from Mexico or Central America. Three groups were from South America, 79 from Europe, 18 from Asia, and 10 from Australia and New Zealand. No groups were from Africa. Figure 4 shows the distribution of the levels of evidence from which each group's data was extracted. Thirty-seven groups were extracted from the RCTs.

Fig. 3 Regional Distribution of Groups Included in Analysis

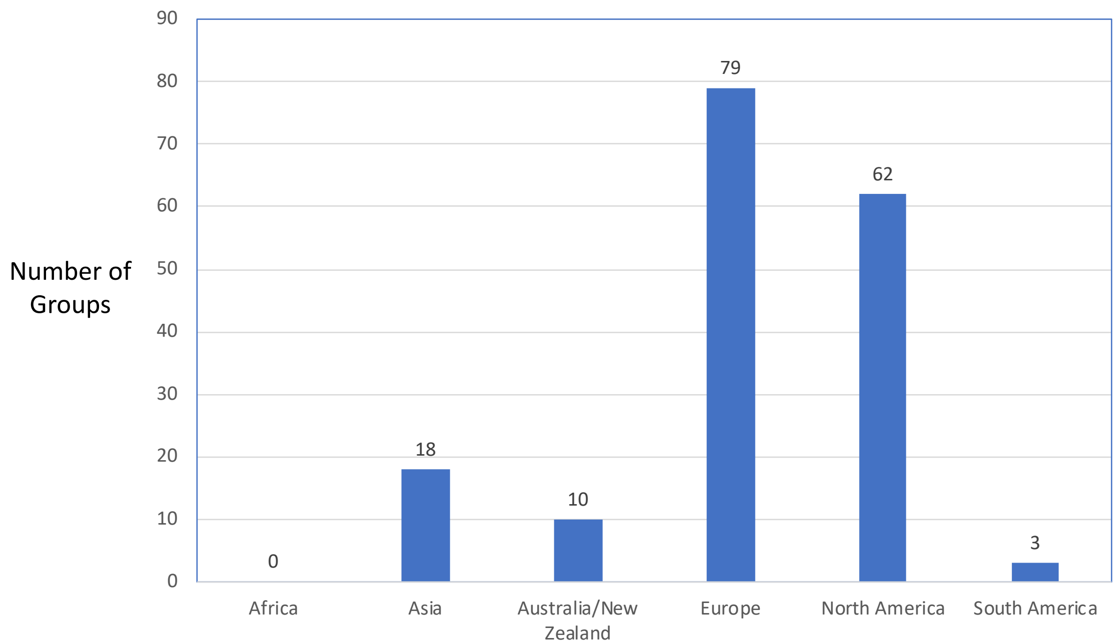
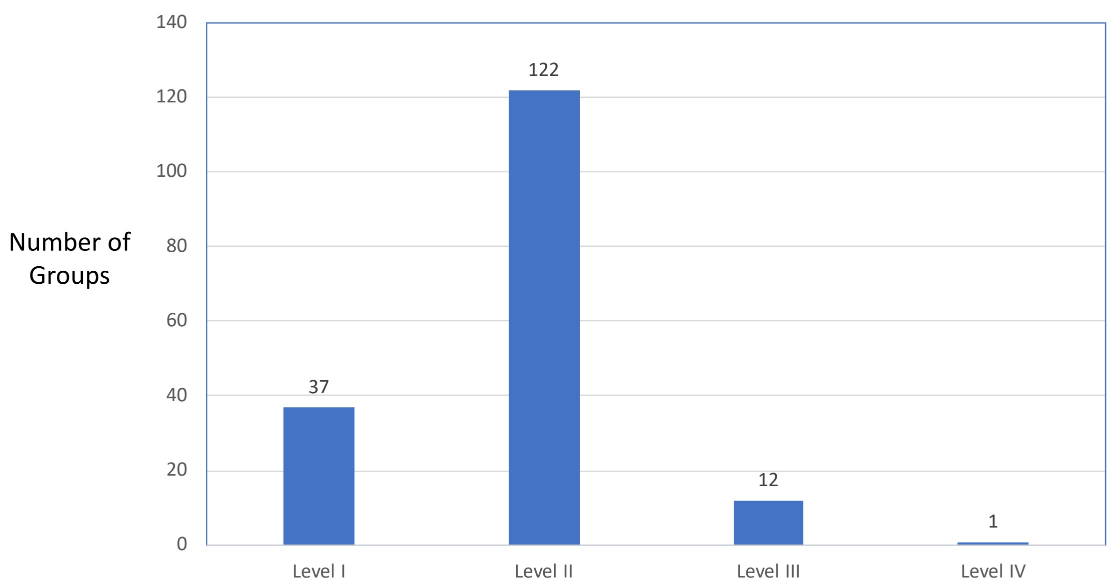


Fig. 4 Levels of Evidence Represented by the Included Studies



The gender distribution was reported for 134 groups. The overall population therefore contains data from at least 8,526 women and 5,879 men. The mean age was reported for 125 groups. Mean age ranged from 17.6 years to 83.6 years, and the weighted mean for the groups of known age was 64.7 years. The percentage of patients diagnosed with primary osteoarthritis was reported for 116 groups. Therefore, the data of at least 11,176 patients with primary osteoarthritis was included in the final analysis.

Analysis of Reported and Imputed Standard Deviations

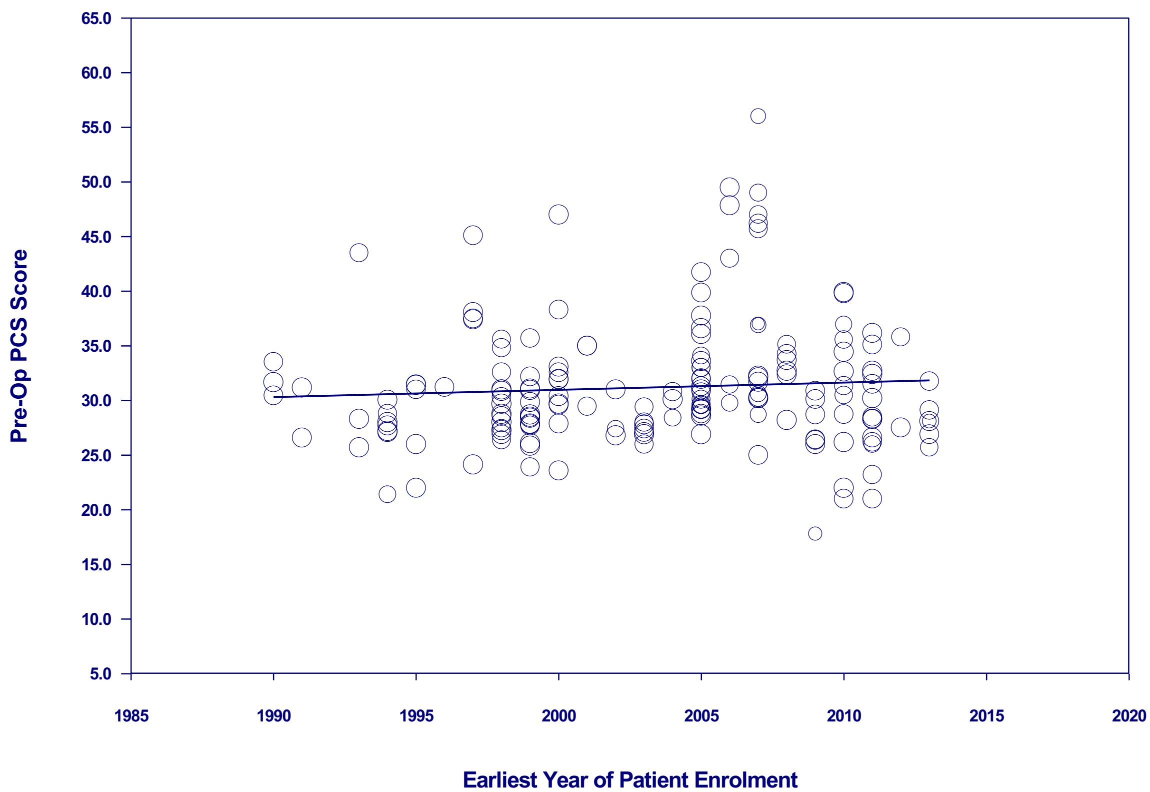
The standard deviation was clearly reported for 57 groups. Eight groups had a reported 95% confidence interval, and one group reported the standard error. Analysis of the reported standard deviations revealed a median of 7.5, a mean of 8.3, and a range of 1.9 to 19.0. The weighted mean that was used to impute the missing standard deviation values was 8.1. After the inclusion of the imputed standard deviations, the median standard deviation of 163 groups was 8.1 and the mean was 8.2. The weighted mean was 8.1. The Shapiro-Wilk Normality Test revealed $p < 0.05$ for the standard deviations both before and after the imputed standard deviations were added, so a Mann-Whitney U test was used to compare the means. The result of this test was $p = 0.08$, and therefore the imputed standard deviation was determined to have not significantly altered the population of standard deviation values.

Results of Meta-Analysis and Meta-Regression Analysis

Combining all of the PCS scores produced a mean score of 31.2 with a 95% confidence interval of 30.5 to 31.9. The 95% prediction interval was 22.6 to 39.8. The Q-value was 6,227.747 with 171 degrees of freedom and $p = 0.000$. The I^2 statistic was equal to 97.25. Therefore, these results indicate that the mean PCS score varied across the included studies and 97.25% of this variance is due to true variance and not due to chance.

The meta-regression analysis of year of enrolment is shown in Figure 5. The pre-op PCS score was found to not change significantly over time with a correlation co-efficient for year of enrolment of 0.07 and $p = 0.24$.

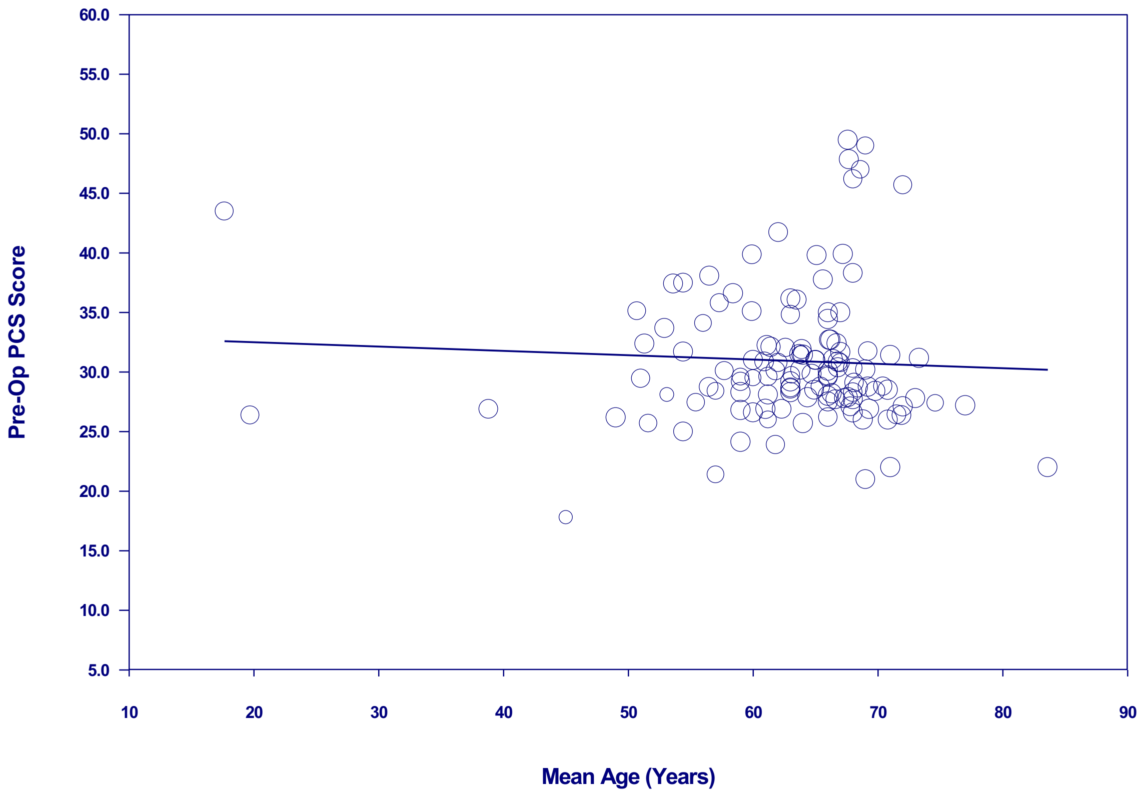
Fig. 5 Regression of PCS Score on Year of Enrolment



Each circle corresponds to a group included in the analysis. The size of the circle is proportional to the group's contribution to the analysis.

The meta-regression analysis of mean patient age is shown in Figure 6. The PCS score was not found to change significantly with patient age with a correlation co-efficient for mean age of -0.04 and p = 0.44.

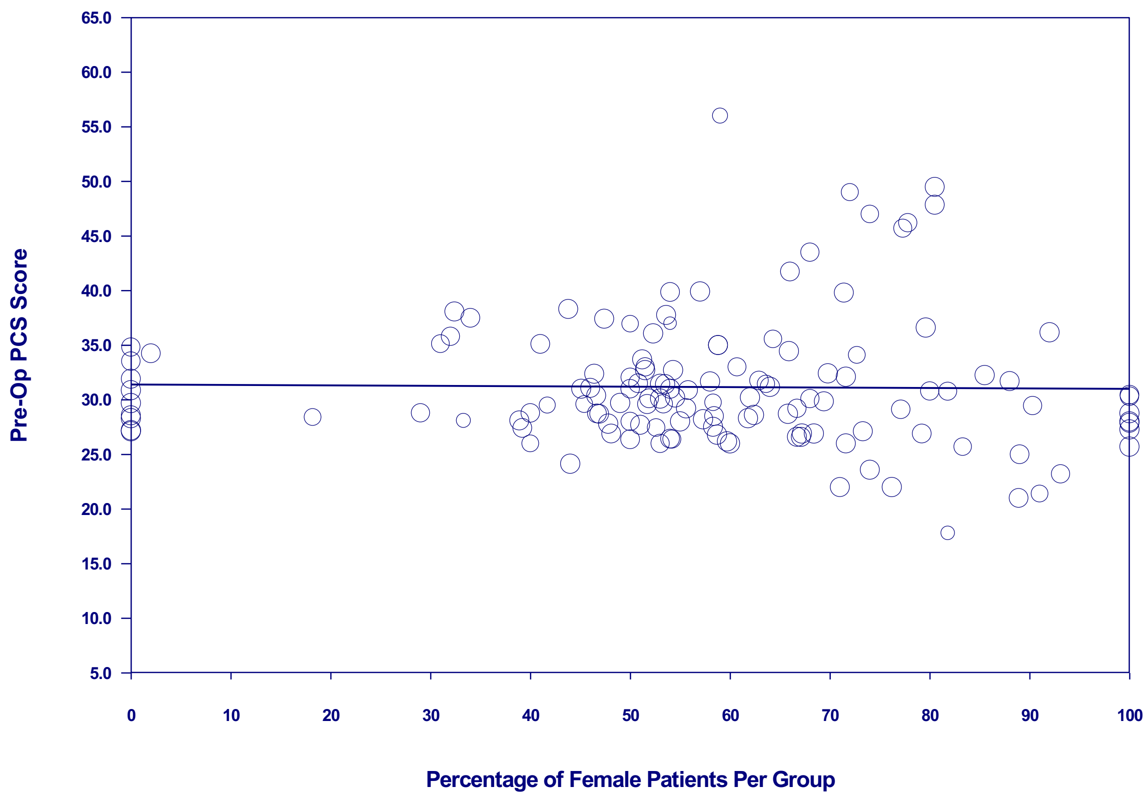
Fig. 6 Regression of PCS Score on Mean Patient Age



Each circle corresponds to a group included in the analysis. The size of the circle is proportional to the group's contribution to the analysis.

The meta-regression analysis of percentage of female patients per group is shown in Figure 7. The PCS score was not found to change significantly with the percentage of females with a correlation co-efficient of 0.004 and p = 0.81.

Fig. 7 Regression of PCS Score on Percentage of Female Patients



Each circle corresponds to a group included in the analysis. The size of the circle is proportional to the group's contribution to the analysis.

Subgroup analysis comparing the United States to the rest of the world did not reveal any significant differences in the pre-operative PCS scores. The 56 groups from the United States produced a mean PCS score of 31.3 with a 95% confidence interval of 30.1 to 32.5. The 116 groups from the rest of the world produced a mean PCS score of 31.2 and 95% confidence interval of 30.3 to 32.0. Comparing these two groups, the Q-value was 0.033 with 1 degree of freedom, thereby producing a p-value of 0.86.

Subgroup analysis by continent similarly showed no significant differences in PCS score. The 62 groups from North America produced a mean PCS score of 30.9 (95% Confidence Interval: 29.8-32.1). The three South American groups had a PCS score of 29.9 (95%

Confidence Interval: 24.9-34.9). The 79 European groups had a PCS score of 31.3 (95% Confidence Interval: 30.3-32.2). The 18 groups from Asia had a PCS score of 32.9 (95% Confidence Interval: 30.7-34.9). The ten groups from Australia and New Zealand had a PCS score of 29.7 (95% Confidence Interval: 26.9-32.5). Comparing these mean PCS scores across all groups, the Q-value was 3.769 with 4 degrees of freedom, thereby producing a p-value of 0.44. A similar result was found when the data from the United States was separated from the rest of North America and all regions were compared (Q-value = 6.958, df(Q) = 5, p = 0.22).

Discussion

Pre-Operative Functional Health Status

The analysis of the pre-operative PCS score revealed several interesting results. While the overall mean score of 31.2 had a fairly tight 95% confidence interval, the analysis of variance and wide 95% prediction interval suggest significant differences between the pre-operative scores reported by the included studies. Furthermore, very little of this variance is due to chance as our analysis revealed that 97.25% of the variance was true variance. The differences between the groups, however, were not due to differences in year of patient enrolment, mean age of the included patients, or the percentage of females in each group. Regional differences also fail to account for this variance as no significant difference was found when comparing the pre-operative scores between the United States and the rest of the world or between continents. Therefore, one or more additional factors not identified by our study has clearly had an influence on the pre-operative PCS scores. One potential factor could be BMI/obesity. Obesity rates have been steadily increasing, and obesity is a well-recognized contributing factor to the development of disabling joint disease.[41] Of course, this variability could also be the result of the currently subjective nature of determining when a patient should be indicated for surgery.

Given the significant amount of true variance between the pre-operative PCS scores, we would caution against over-interpreting the mean PCS score produced by this meta-analysis. While we had hoped that our analysis would reveal a target PCS score at which patients could be indicated for surgery, given the 95% prediction interval of 22.6 to 39.8, we do not believe such a recommendation can be made at this time. The 95% prediction interval estimates the range in which the results of similar studies will fall in the future.[42] Therefore, we consider a range of 17.2 points to be too large to make any recommendations, particularly as the minimal clinically important difference (MCID) in the PCS score is likely around 10 points. While a firm MCID has yet to be established for THA patients, 10 points is the MCID quoted in the knee arthroplasty literature.[43]

That our meta-regression analysis revealed no significant changes in pre-operative PCS score over time is interesting as it indicates patients are undergoing THA at a similar health status to their counterparts in the past. Changes in patient health status therefore cannot account for the steadily increasing volume of THA performed per year. This result is surprising as we anticipated technological improvements in implant longevity and an unwillingness to accept significant declines in function to entice patients to undergo surgery earlier in their disease process. Additional studies will be necessary to determine the as-yet-unidentified variables contributing to this rise. One potential factor that could be at play is the number of surgeons performing primary THA. Both the total number of orthopaedic surgeons and the number of surgeons per capita have been generally increasing in Canada and the United States.[44-48] A similar trend has been found among physicians and surgeons in Europe.[49] As primary THA is performed by both general orthopaedic surgeons as well as arthroplasty sub-speciality-trained surgeons, an increase in the number of surgeons will inherently lead to an increase in the volume of THA performed per year. The most reassuring finding from our results is that even though more surgeons are available to perform primary THAs, they do not seem to be allowing the increased availability of surgical expertise to erode the indications for surgery by operating on healthier patients simply to fill operating room time. That the volume of THA is increasing without patients being at a better health status also suggests there is an ongoing unmet need for THA in the community. If more surgeries are being performed, but the patients' pre-operative level of function remains the same, it suggests the existence of a reservoir of patients who would benefit from surgery. This result is consistent with population surveys that have attempted to determine the need for arthroplasty in the community[50 51] as well as a prevalence study that attempted to determine the prevalence of hip and knee arthroplasty in the United States.[52] Maradit Kremers et al.[52] found the prevalence of total joint replacement to be on par with stroke and myocardial infarction, thereby suggesting disabling joint disease is extremely common. Further, as few alternative treatments for advanced osteoarthritis exist aside from surgery,[52] it would not be surprising that a large group of patients with unmet surgical needs exist.

That age, gender, and regional distribution were also found to have no significant relationship to the pre-operative PCS score is interesting because it implies a certain global uniformity in terms of the functional status at which patients are indicated for surgery. While significant true variance does exist in the PCS scores, no specific patterns or biases are revealed when these variables are considered. With respect to gender, this result mildly contradicts previous studies that have found that arthroplasty tends to be significantly more underused by women than men.[50 51] The difference, however, is likely due to the point in time at which our data was collected. These studies[50 51] surveyed populations to determine the need for and use rates of arthroplasty in the community. Our study assessed the functional status of both genders once they were indicated for surgery. Our results suggest that once evaluated by an orthopaedic surgeon, the functional status at which the decision to proceed with surgery is made is the same, however barriers to accessing this evaluation may still exist.

The lack of regional differences is surprising, particularly with regard to the United States. Given the United States has some of the highest obesity and chronic disease burden rates in the world coupled with the highest healthcare expenditures as a percentage of gross domestic product and a population generally intolerant to long wait times,[53] we expected the American pre-operative PCS score to be significantly higher than other regions. Our results, however, suggest the United States is on par with the rest of the world.

While we do not believe that it likely had a significant impact on our results, particularly given the significant amount of true variance in the PCS scores and wide 95% prediction interval, one potential limitation of this study is that the floor effects of the PCS score in the evaluation of patients undergoing THA are not well defined. Several studies have found floor effects for some of the SF-36 scale scores that contribute to the PCS score.[54-56] While one study found the PCS score to be unaffected by floor effects, this result was based on only 19 patients.[56] Without a better understanding of the floor effects in the context of THA, we cannot definitively state that they did not contribute to the lack of any statistically significant differences in our results. If floor effects had significantly affected our results, we would have anticipated a much narrower 95% prediction interval and lower true variance among the PCS scores. As a result, we believe their impact to be minimal at best, but they remain a potential limitation notwithstanding.

Regional Distribution of Included Patients

The regional distribution of the groups of patients included in the analysis reveals some interesting trends. Europe and North America, particularly the United States, were the biggest contributors. South America contributed only three groups to the analysis, and Africa did not contribute any. These results are consistent with other studies that have analysed the geographic distribution of studies in the medical literature.[57-60] These results, however, highlight the ongoing problem of poor representation of developing countries in the literature. While English as a language barrier has been used as an explanation for this under-representation,[61] we did not impose any language restrictions on our search and yet the results remain the same. The cost of performing elective arthroplasty[62] is almost certainly a contributing factor as hospitals in resource-poor environments must dedicate their resources to trauma care,[63] but even nations such as South Africa and Mexico are not represented in our analysis. Our results, therefore, point to an ongoing lack of support for a strong research culture in developing countries. This is a problem that desperately needs to be addressed because not only does it mean that valuable patient information is not being represented in the literature but data that most accurately reflects certain populations (i.e. those on the African continent) is not available to guide clinical practice. All patients deserve to be treated according to the best available evidence, and this goal cannot be achieved if large segments of the world's population are missing from the literature.

Inter-Rater Reliability and Quality of the Literature

The inter-rater reliability for both the abstract and full manuscript reviews were lower than expected. While Cohen initially suggested a kappa value of 0.41 or greater was acceptable, most sources recommend 80% as a minimum value of good inter-rater agreement.[64] Examining the articles that produced conflicts between the reviewers reveals some general trends. For the abstract review, a significant source of conflict was vague terminology with regard to the method of assessment of either patient health status or quality of life and the likelihood that the terms employed (i.e. simply stating that function or quality of life were assessed) would translate into SF-36 scores in the full manuscript. While both reviewers tended toward including vague abstracts, some differences contributed to the lowering of the inter-rater reliability.

For the manuscript review, the main sources of conflict were papers that presented duplicate data of patients already included in the analysis and papers that reported their SF-36 results using vague terms. Determining if a patient's data has already been reported in another study can present a significant challenge. While some papers clearly indicate that the data therein has been reported in whole or in part in previous publications, most of the 43 studies deemed to contain duplicate patients did not. Cross-referencing of the full list of authors, years of enrolment, site of enrolment, patient demographics, and inclusion and exclusion criteria was often necessary. The complexity of this task contributed to the discrepancies between the reviewers. When duplicate patient data was identified, the study with either the largest sample size or most complete dataset was included.

Poor or vague reporting of the SF-36 scores was the other main source of conflict between the reviewers. Studies vary widely in the components of the SF-36 that they report when providing data on functional status or quality of life. Many papers report only select scale scores and not the full SF-36 results. Ninety-four studies were excluded from our analysis for this reason. Other papers report their SF-36 results in vague terms such as the "physical" and "mental" score. As "physical functioning" and "general mental health" are scale scores that contribute to the PCS and MCS aggregate scores, it can be very difficult to determine the exact nature of the results the authors are presenting. The subjective nature of attempting to determine the authors' true intent contributed to the discrepancies between the reviewers and necessitated the input of the third reviewer.

This vagueness highlights the generally poor quality of the surgical literature. Historically, the surgical literature has lagged behind the quality of that produced by the medical community.[65] Initially dominated by case reports and case series,[66] even by the early 2000s, RCTs only accounted for 3.4% of the studies reported in major surgical journals.[67] Looking specifically at the orthopaedics literature, one study found that the proportion of RCTs published in five leading journals declined from 6% to 4% between 2006 and 2010 and less than 1% of these RCTs provided data on ten methodological criteria the authors used to assess bias.[68] The results of our analysis are consistent with these findings. Only 17 RCTs met the criteria for inclusion in our analysis, and many studies report results in vague or confusing terms that render extraction difficult or impossible. A reasonable number of papers were also noted as having typos or other errors in data reporting that rendered interpretation difficult. For example, some studies were noted to report a different sample size for their PCS scores than for their demographic description of the patients included in the study. Other papers would provide detailed demographic descriptions of the initial group of patients included in the study, but then note that patients were lost and fail to describe the characteristics of the patients included in the final analysis. These errors and inconsistencies are problematic for multiple reasons. First, if a surgeon cannot determine if the patients included in a study reflect his or her own patients, then it becomes impossible to accurately apply the results in an evidence-based fashion.[65] Second, it compromises researchers' ability to extract data and synthesize studies together to generate higher quality evidence. In the era of evidence-based medicine, this poor level of quality is not acceptable, and therefore our study also serves to highlight the importance of precise and accurate data reporting.

Conclusion

Patients are undergoing THA at the same health status as in the past. Changes in pre-operative functional status, therefore, do not explain the increasing volume of THA being performed per year. Mean age of the included patients and the percentage of female patients in each group were similarly found to have no significant relationship with the PCS score. Subgroup analysis revealed no significant regional differences. These results imply a certain degree of uniformity in the patients indicated for surgery. While the overall mean pre-operative PCS score was 31.2, we caution against setting this value as the target for indicating patients for THA given the significant true variance among the groups included in the analysis. Further studies are needed to determine the nature of this variance and determine the optimum PCS score at which patients should undergo surgery. Analysis of the region of origin of the data reveals an ongoing underrepresentation of the developing world in the surgical literature.

Appendix I – Search Strategies

Medline

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily <1946 to Present>
Search Strategy:

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1 Arthroplasty, Replacement, Hip/ (24424)
2 Hip Prosthesis/ (22947)
3 hip prosthesis.mp. (23826)
4 hip replacement.mp. (10988)
5 hip arthroplast$.mp. (20611)
6 1 or 2 or 3 or 4 or 5 (46244)
7 SF 36.mp. (20086)
8 Short Form 36.mp. (9850)
9 SF36.mp. (1230)
10 SF-36.mp. (20086)
11 MOS 36.mp. (209)
12 MOS-36.mp. (209)
13 medical outcomes study 36.mp. (1315)
14 Short Form-36.mp. (9850)
15 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 (25629)
16 6 and 15 (499)

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Embase

Database: Embase <1996 to 2018 Week 02>

Search Strategy:

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1 hip arthroplasty/ (14930)

2 total hip prosthesis/ (24160)

3 hip prosthesis/ (6742)

4 hip arthroplast$.mp. (28441)

5 hip replacement.mp. (11420)

6 hip replacement/ (1342)

7 hip prosthesis.mp. (30304)

8 1 or 2 or 3 or 4 or 5 or 6 or 7 (43443)

9 Short Form 36/ (20948)

10 SF 36.mp. (28031)

11 Short Form 36.mp. (24590)

12 SF36.mp. (2778)

13 MOS 36.mp. (248)

14 MOS-36.mp. (248)

15 Medical Outcomes Study 36.mp. (1337)

16 SF-36.mp. (28031)

17 Short Form-36.mp. (24590)

18 medical outcomes study-36.mp. (1337)

19 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 (39353)

20 8 and 19 (629)

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Cochrane

Search Name: Total Hip and SF-36 - Cochrane Narrower
Date Run: 12/01/18 19:17:59.950
Description:

ID	Search	Hits
#1	MeSH descriptor: [Arthroplasty, Replacement, Hip] explode all trees	2008
#2	MeSH descriptor: [Hip Prosthesis] explode all trees	1179
#3	hip replacement	4366
#4	hip arthroplasty	3961
#5	hip prosthesis	2681
#6	searches #1 or #2 or #3 or #4 or #5	5953
#7	SF 36	7494
#8	Short Form 36	9982
#9	SF-36	6626
#10	Short Form-36	4513
#11	SF36	647
#12	MOS 36	501
#13	MOS-36	63
#14	MOS36	1
#15	Medical Outcomes Study 36	13600
#16	Medical Outcomes Study-36	465
#17	searches #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16	20578
#18	search #6 and #17	376

There are 349 Cochrane Reviews
18 Other Reviews
1 Trial
4 Economic Evaluations
4 Cochrane Groups

Appendix II – List of Studies Included in Meta-Analysis

1. Adie S, Dao A, Harris IA, et al. Satisfaction with joint replacement in public versus private hospitals: A cohort study. *ANZ Journal of Surgery* 2012;82(9):616-24. doi: http://dx.doi.org/10.1111/j.1445-2197.2012.06113.x
2. Austin MS, Urbani BT, Fleischman AN, et al. Formal physical therapy after total hip arthroplasty is not required: A randomized controlled trial. *Journal of Bone and Joint Surgery - American Volume* 2017;99(8):648-55. doi: http://dx.doi.org/10.2106/JBJS.16.00674
3. Ayers DC, Greene M, Snyder B, et al. Radiostereometric analysis study of tantalum compared with titanium acetabular cups and highly cross-linked compared with conventional liners in young patients undergoing total hip replacement. *Journal of Bone and Joint Surgery - American Volume* 2015;97(8):627-34. doi: http://dx.doi.org/10.2106/JBJS.N.00605
4. Bachmeier CJ, March LM, Cross MJ, et al. A comparison of outcomes in osteoarthritis patients undergoing total hip and knee replacement surgery. *Osteoarthritis Cartilage* 2001;9(2):137-46.
5. Badura-Brzoza K, Zajac P, Kasperska-Zajac A, et al. Anxiety and depression and their influence on the quality of life after total hip replacement: Preliminary report. *International Journal of Psychiatry in Clinical Practice* 2008;12(4):280-84. doi: http://dx.doi.org/10.1080/13651500802095012
6. Becerra Fontal JA, Bago Granell J, Garre Olmo J, et al. Evaluation of health-related quality of life in patients candidate for spine and other musculoskeletal surgery. *European Spine Journal* 2013;22(5):1002-09. doi: http://dx.doi.org/10.1007/s00586-012-2617-0
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13. Cho YJ, Lee CH, Chun YS, et al. Outcome after cementless total hip arthroplasty for arthritic hip in patients with residual poliomyelitis: A case series. *HIP International* 2016;26(5):458-61. doi: http://dx.doi.org/10.5301/hipint.5000372

14. Cinotti G, Della Rocca A, Sessa P, et al. Thigh pain, Subsidence and survival using a short cementless femoral stem with pure metaphyseal fixation at minimum 9-year follow-up. *Orthopaedics and Traumatology: Surgery and Research* 2013;99(1):30-36. doi: http://dx.doi.org/10.1016/j.otsr.2012.09.016
15. Coulter C, Perriman DM, Neeman TM, et al. Supervised or Unsupervised Rehabilitation After Total Hip Replacement Provides Similar Improvements for Patients: A Randomized Controlled Trial. *Archives of Physical Medicine and Rehabilitation* 2017;98(11):2253-64. doi: http://dx.doi.org/10.1016/j.apmr.2017.03.032
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