Review of Clinical Outcomes-Based Anchors of Minimum Clinically Important Differences in Hip and Knee Registry-Based Reports and Publications

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Abstract: Patient-reported outcome measures are tools that allow clinicians and researchers to gauge patients' level of satisfaction and quality of life after a medical intervention. The use of patient-reported outcome measures and the clinically relevant score differentials over time as they relate to outcomes (minimum clinically important differences) has been proposed as a way to understand success and failure rates in orthopaedics. We conducted a systematic appraisal of literature in peer-reviewed journals and registry reports to measure the use that registries and other large data repositories make of minimum clinically important differences and to understand methodological approaches for such uses. Of the nineteen registry reports and 1052 articles examined, we found that only one report and two studies mentioned the use of patient-reported outcome measures and minimum clinically important differences in the context of revision rates of total knee arthroplasty and total hip arthroplasty. We conclude that although the infrastructure and efforts to routinely collect patient-reported outcome measures at registry levels do exist, there is limited use of minimum clinically important differences to understand and potentially predict clinical outcomes. We suggest advancing the global infrastructure such as the International Consortium of Orthopaedic Registries to address how research related to patient-reported outcome measures can help individual registries collaborate in the development of tools and allow aggregation of data.

Patient-reported outcome measures have been used extensively to evaluate patients' own perception of their preoperative functioning as well as the impact of surgical procedures and devices on postoperative function, satisfaction, and other outcomes related to quality of life¹⁻³. Some of the best-known instruments used to collect this information have been created for specific procedures, and their usefulness and accuracy have been validated to minimize the bias related to comorbidities⁴⁻⁶. In spite of the need for further research to obtain consensus on what a good score is under a given set of circumstances (patient population, setting, and so forth)⁷, there is little doubt that newer post-market surveillance efforts such as registries capturing rates of failure or revision would be made more complete if patient-reported data were captured and were taken into consideration while evaluating outcomes⁸. Patient-reported outcome measures uniquely provide patients' experience and perception and may aid in the detection of dysfunctional or underperforming implants, ideally before revision is performed, which may take several additional years, if undertaken at all. In the United States, where from 2003 to 2010, around 500,000 people received a potentially inferior

metal-on-metal hip implant, improvement in registries and other infrastructure that captures patient-reported outcome measures is much needed to ensure that high-revision implants are identified in a timely and cost-effective manner^{9,10}.

Furthermore, the relationship between population-based patient-reported outcome measure scores and specific patient-centered clinical outcomes, while examined in the context of cardiothoracic surgery outcomes¹¹, has not been widely systematically evaluated in orthopaedics. A case study in knee replacement shortcomings in this regard relates not only to the lack of use of patient-reported outcome measures but also to the understanding of adequate end points and the reliable interpretation of scores as they relate to individual clinical judgment^{7,12}.

The lack of evidence on the additional value of the patient-reported outcome measures limits the use of these very important tools. This is particularly urgent today when stakeholders or funders demand efficiencies in building national systems for evaluations of surgery and devices. Although patient-reported outcome measures can be considered as valuable outcomes in their own right, it is important to provide strong evidence of validity of these measures in the context of complications and failures that occur

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after surgery or device use months or years after initial interventions. One of the key issues that can help achieve this objective is determining the size or magnitude of change in a patient-reported outcome measure score that is really meaningful from clinical and statistical perspectives. Hence, the term “minimum clinically important difference” has been defined as a helpful concept that shows the minimal changes in patient-reported outcome measurement scales that translate into clinically meaningful outcomes^{13,14}. Defining minimum clinically important differences on the basis of another widely used and independent measure (i.e., one that is not part of the instrument) of success or failure in orthopaedics, such as all-cause revision surgery, can bridge the gap in evidence and can alleviate the concerns and skepticism that stakeholders and regulators have.

The objective of this project is to provide a systematic overview of patient-reported outcome measures and their relationship with revision surgery occurrence reported by orthopaedic registries worldwide. The registries or registry-based studies are likely to be the only source of cohorts that are large enough to allow such investigations. Additionally, we sought to evaluate the methodological approaches currently being used to collect and to interpret the data obtained through patient-reported outcome measurement tools in relation to revision surgery occurrence.

Materials and Methods

In collaboration with an experienced information specialist, we conducted a thorough search of the literature available in PubMed, MEDLINE, Embase, Web of Science, Cochrane Library, and Cumulative Index to Nursing and Allied Health Literature (CINAHL), using various combinations of the terms (and alternatives) “hip arthroplasty,” “knee arthroplasty,” “patient-reported outcomes,” “minimum clinically important difference,” and “registry” (and combinations of these terms as specified in Appendix 1) as well as reports and publications listed on the web sites of more than forty orthopaedic registries worldwide and other publications on the Web using generic search terms. When available, reports were downloaded, and an overview of the contents page as well as a text search of key terms was conducted on the entirety of the reports. These terms included “patient-reported outcomes,” “patient-reported outcome measures,” and “minimum clinically important difference.” A separate search was conducted on PubMed for articles containing information on studies on minimum clinically important differences conducted at the registry level using the same terms but adding a registry search term (see Appendix 1). Search results and full-text assessment were independently evaluated by two reviewers (L.R. and M.N.) for eligibility for inclusion; in case of disagreement, a referee (A.S.) was consulted. Descriptive statistics are presented when feasible.

Results

We found nineteen registry reports on registry web sites and two articles relevant to our project (see Table I for the registry reports and Figure 1 for a review flowchart of the 1052 potentially relevant search results).

Registry Reports

Of the registry reports, only three contained information related to our pre-defined goal and search terms: those from the New Zealand National Joint Registry, the National Joint Registry for England and Wales, and the Swedish Knee Arthroplasty Register. The National Joint Registry for England and Wales and the

Fig. 1
Literature flow chart.

Swedish Knee Arthroplasty Register listed reports that contained sections dedicated to patient-reported outcomes. These sections explained the methodology of data collection and other data descriptive of their cohorts, such as statistics on patient satisfaction and quality of life collected preoperatively and postoperatively. No reports or publications in either of those registries investigated a connection between patient-reported outcome measures and outcomes such as revisions. The New Zealand National Joint Registry is the only registry to explicitly report on minimum clinically important differences and to use the Oxford hip score to determine the relationship of patient-reported outcome measures with revision occurrence after hip arthroplasty¹⁵.

Search Results

There were no reports associated with the relation among patient-reported outcome measures, revision surgery, and minimum clinically important differences published at a registry or national level. Two studies found online reported information related to our evaluation that we have included to illustrate the availability of source data potentially useful for the development of a minimum clinically important difference. Rothwell et al. illustrated the analysis conducted for the report of the New Zealand registry¹⁶, and Grosse et al. used prospectively collected data from the National PROMs (Patient-Reported Outcome Measures) Programme of the National Health Service (NHS) to investigate the validity of patient-reported outcome measures with regard to complications of surgery¹⁷ (Fig. 1).

TABLE I List of Registry Reports Found and Reviewed

Registry	Reports Viewed
Danish Knee Arthroplasty Register	2010
Portuguese Arthroplasty Register	2010
R.I.P.O. (Registro dell'Implantologia Protesica Ortopedica [Register of Orthopaedic Prosthetic Implants])	2010
Slovak Arthroplasty Register	2010
SoFCOT (Société de Française de Chirurgie Orthopédique et Traumatologique)	2011
Total Hip Arthroplasty Registry	
Swedish Knee Arthroplasty Register	2012
New Zealand Joint Registry	1999 to 2011
Catalan Arthroplasty Register	2005 to 2008
Norwegian Arthroplasty Register	2006 and 2010
Canadian Joint Replacement Registry	2007 and 2008
Swedish Hip Arthroplasty Register	2009 and 2010
Danish Hip Arthroplasty Register	2010 and 2011
Australian Orthopaedic Association National Joint Replacement Registry	2011
National Joint Registry for England and Wales	2012 and 2011

The New Zealand Joint Registry¹⁶**Hip Arthroplasty**

The New Zealand Joint Registry collected data from 78,283 primary hip procedures that took place from 1999 to 2011. An Oxford hip score 12-item questionnaire¹⁸ was administered six months, five years, and ten years after total hip arthroplasty to 20% of that cohort, and patients who had undergone revision surgery were excluded from participating. Using correlation and receiver operating characteristic (ROC) analysis, a relation and

potential cutoff points were found between Oxford hip scores at six months and five years and the risk of revision arthroplasty.

At six months, the risk for revision arthroplasty was fifteen times higher for those whose Oxford hip score was <27 points, compared with those whose score was >42 points. The cutoff for the groups was determined using the method created by Kalairajah et al.¹⁹ (Fig. 2).

Likewise, at five years after total hip arthroplasty, there was a higher risk of revision arthroplasty in the same groups

Fig. 2

A bar chart showing the Oxford score at six months as a predictor of hip arthroplasty revision¹⁵.

Fig. 3

A bar chart showing the Oxford score at five years as a predictor of hip arthroplasty revision¹⁵.

(5.88% for scores of <27 points compared with 0.37% for scores of >42 points) (Fig. 3).

National PROMs Programme, England

An observational study of 68,391 hip replacements performed from April 2009 to December 2010 was conducted by analyzing the responses to questionnaires administered preoperatively and at three months and six months postoperatively¹⁷. Health was evaluated postoperatively using the complete Oxford hip score¹⁸, and quality of life was evaluated through the use of the EuroQol-5D (EQ-5D) index score.

Grosse and colleagues¹⁷ concluded that readmission, further surgery after hip replacement, and four general complications (drug reaction, urinary problems, bleeding, and wound problems) were associated with a 3-point differential in the Oxford hip score, meaning that those patients who experienced complications reported an improvement of only 17 points compared with an improvement of 20 points among those who experienced no complications. Additionally, one or more complications were associated with a lower quality of life as reflected in a score 0.07 point lower on the EQ-5D for those with complications compared with those who did not experience any complications. No conclusions were reached as to the minimum clinically important difference scores or the potential use of the data collected for the purpose of the development of minimum clinically important differences.

Discussion

Our review shows that there is a very limited body of evidence at this time that uses patient-centered outcome measures such as revision occurrence or complications as anchors to determine the minimum clinically important differences for

patient-reported outcome measures. The lack of evidence is appalling when more than thirty instruments of patient-reported outcome measures are available to researchers and clinicians to study the outcomes of hip replacement.

The establishment of minimum clinically important differences of patient-reported outcome measures with revision as an anchor substantially contributes to the potential of patient-reported outcome measures in orthopaedic implant evaluation. When implant revision is necessary, this is usually undertaken after a relatively long time, if the implant is revised at all in a physically demanding surgical procedure in elderly patients. However, underperformance of the implant may be detected earlier by low or decreasing scores for patient-reported outcome measures that may be used as an early evaluation of implant performance and potential long-term revision rates. In addition, patient-reported outcome measures could then be used for a comparison of new implants to benchmark patient-reported outcome measures of well-established, well-performing implants.

The importance of understanding the minimum clinically important differences for patient-reported outcome measures using other patient-centered outcomes measures is hard to underestimate as strongly validated estimates of minimum clinically important differences can help make better decisions by clinicians and regulators and improve the delivery of health care. Efforts by the New Zealand Joint Registry show that a minimum clinically important difference can be studied and a relationship can be established between scores of patient-reported outcome measures and the probability of revisions after total hip arthroplasty. Similarly, the National PROMs Programme of the NHS in the United Kingdom also exemplifies the relationship between patient-reported outcome measures and

complications associated with hip replacement. This kind of evidence can establish patient-reported outcome measures as valuable tools and can support the use and collection of patient-reported outcome measures at the national level within registries or other systems. More effort needs to be made to generate more evidence from national registries and to address this important gap.

It is important to note that there is a need to establish guidelines for study design related to patient-reported outcome measures, particularly in relation to revision surgery or surgery complications as anchors. The absence of guidance on collection strategies for patient-reported outcome measures limits the ability of researchers to aggregate data for the analyses of various registries to determine the relevant range of estimates of minimum clinically important differences. Furthermore, in areas in which data can be utilized for calculations of minimum clinically important differences, such as the article by Grosse et al.¹⁷, no such estimate has been analyzed, highlighting the need for a better approach to analysis when infrastructure exists to collect raw data. Importantly, once a minimum clinically important difference has been estimated, the prospective validation of the estimated minimum clinically important difference is essential. Only large collaborative efforts such as ICOR have the potential to do so, especially if analysis methods and collection infrastructure are regulated and are relatively similar.

As the infrastructure for the collection and processing of patient-reported outcome measures continues to develop, it will be of utmost importance for researchers and especially registry leads to agree upon and to implement specific methodologies that will allow for robust understanding of minimum clinically important differences. Furthermore, advancing the global infrastructure such as the ICOR effort²⁰ to address research related to patient-reported outcome measures can help individual registries collaborate and allow aggregation of data. In turn, this can increase the likelihood of developing more robust minimum clinically important difference estimates that are useful in the evaluation of procedures and devices, in which age, sex, and cultural difference may be taken into account. The global initiatives can also cut the costs of administering instruments for patient-reported outcome measures in each individual country to study relationships with revision surgery, which can be time-consuming and somewhat burdensome. The global effort can also refine the methodological approaches in data collection, analyses, and the ability to implement those approaches within registries or other national systems around the world.

The present study provided a systematic appraisal of the literature concerning the use of revision-anchored minimum clinically important differences in patient-reported outcome measures for total hip and knee replacements. As such, it was limited in its conclusion by the scarcity of relevant studies that could have been included and by their quality. Consequently, except the fact that a paucity of data regarding this aspect exists, strong conclusions could not be inferred, but the potential and future directions of patient-reported outcome measures in this particular aspect are discussed. We concluded that, although

the infrastructure and efforts to routinely collect patient-reported outcome measures at registry levels do exist, there is limited use of minimum clinically important differences to understand and to potentially predict clinical outcomes. We suggest advancing the global infrastructure such as ICOR to address how research related to patient-reported outcome measures can help individual registries collaborate in the development of tools and allow aggregation of data.

Appendix 1

Search Strategy: Registry, Patient-Reported Outcome Measure (PROM), Minimum Clinically Important Difference (MCID) PubMed

- **Long Search 1:** ("Arthroplasty, Replacement, Hip"[Mesh] OR "Hip Prosthesis"[Mesh] OR "hip arthroplasty" OR "hip arthroplasties" OR "hip prosthesis" OR "hip prostheses" OR "hip replacement arthroplasties" OR "hip replacement arthroplasty" OR "hip replacement" OR "hip replacements" OR "THA" OR "total hip" OR "total hip arthroplasty" OR "total hip replacement" OR "total hip prosthesis" OR "total hip prostheses" OR "hip prosthesis" OR "hip prostheses" OR "hip implant" OR "hip endoprosthesis" OR "hip endoprostheses" OR "artificial hip" OR ((hip) AND (arthroplasty OR replacement OR "joint replacement" OR prosthesis OR prostheses)) AND (registry) AND (Patient-reported outcomes)

- **Long Search 2:** ("Arthroplasty, Replacement, Hip"[Mesh] OR "Hip Prosthesis"[Mesh] OR "hip arthroplasty" OR "hip arthroplasties" OR "hip prosthesis" OR "hip prostheses" OR "hip replacement arthroplasties" OR "hip replacement arthroplasty" OR "hip replacement" OR "hip replacements" OR "THA" OR "total hip" OR "total hip arthroplasty" OR "total hip replacement" OR "total hip prosthesis" OR "total hip prostheses" OR "hip prosthesis" OR "hip prostheses" OR "hip implant" OR "hip endoprosthesis" OR "hip endoprostheses" OR "artificial hip" OR ((hip) AND (arthroplasty OR replacement OR "joint replacement" OR prosthesis OR prostheses)) AND (registry) AND ((Patient-reported outcomes) AND (MCID))

- **Long Search 3:** ("Arthroplasty, Replacement, Knee"[Mesh] OR "Knee Prosthesis"[Mesh] OR "knee arthroplasty" OR "knee arthroplasties" OR "knee prosthesis" OR "knee prostheses" OR "knee replacement arthroplasties" OR "knee replacement arthroplasty" OR "knee replacement" OR "knee replacements" OR "TKA" OR "total knee" OR "total knee arthroplasty" OR "total knee replacement" OR "total knee prosthesis" OR "total knee prostheses" OR "knee prosthesis" OR "knee prostheses" OR "knee implant" OR "knee endoprosthesis" OR "knee endoprostheses" OR "artificial knee" OR ((knee) AND (arthroplasty OR replacement OR "joint replacement" OR prosthesis OR prostheses)) AND (Patient reported outcomes) AND (Registry)

- **Long Search 4:** ("Arthroplasty, Replacement, Knee"[Mesh] OR "Knee Prosthesis"[Mesh] OR "knee arthroplasty" OR "knee arthroplasties" OR "knee prosthesis" OR "knee prostheses" OR "knee replacement arthroplasties" OR "knee replacement arthroplasty" OR "knee replacement" OR "knee replacements" OR "TKA" OR "total knee" OR "total knee arthroplasty" OR "total knee

replacement" OR "total knee prosthesis" OR "total knee prostheses" OR "knee prosthesis" OR "knee prostheses" OR "knee implant" OR "knee endoprosthesis" OR "knee endoprostheses" OR "artificial knee" OR ((knee) AND (arthroplasty OR replacement OR "joint replacement" OR prosthesis OR prostheses)) AND (Patient reported outcomes) AND ((Registry) AND (MCID)) ■

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