Achieving Consensus on Total Joint Replacement Trial Outcome Reporting Using the OMERACT Filter: Endorsement of the Final Core Domain Set for Total Hip and Total Knee Replacement Trials for Endstage Arthritis

Jasvinder A. Singh, Michelle M. Dowsey, Michael Dohm, Susan M. Goodman, Amye L. Leong, Marieke M.J.H. Scholte Voshaar, and Peter F. Choong

ABSTRACT. ***Objective.*** Discussion and endorsement of the OMERACT total joint replacement (TJR) core domain set for total hip replacement (THR) and total knee replacement (TKR) for endstage arthritis; and next steps for selection of instruments.

Methods. The OMERACT TJR working group met at the 2016 meeting at Whistler, British Columbia, Canada. We summarized the previous systematic reviews, the preliminary OMERACT TJR core domain set and results from previous surveys. We discussed preliminary core domains for TJR clinical trials, made modifications, and identified challenges with domain measurement.

Results. Working group participants (n = 26) reviewed, clarified, and endorsed each of the inner and middle circle domains and added a range of motion domain to the research agenda. TJR were limited to THR and TKR but included all endstage hip and knee arthritis refractory to medical treatment. Participants overwhelmingly endorsed identification and evaluation of top instruments mapping to the core domains (100%) and use of subscales of validated multidimensional instruments to measure core domains for the TJR clinical trial core measurement set (92%).

Conclusion. An OMERACT core domain set for hip/knee TJR trials has been defined and we are selecting instruments to develop the TJR clinical trial core measurement set to serve as a common foundation for harmonizing measures in TJR clinical trials. (J Rheumatol First Release January 15 2017; doi:10.3899/jrheum.161113)

Key Indexing Terms:

OMERACT	FILTER	OUTCOME MEASURES
CORE SET	TOTAL JOINT REPLACEMENT	ARTHROPLASTY

Total joint replacement (TJR) is an effective treatment option for endstage arthritis refractory to medical treatment. However, the cost and rising use of this procedure worldwide are contributing to a major public health burden[1,2].

The OMERACT TJR Working Group (WG), an international group of patient partners, orthopedic surgeons, physical therapists, rheumatologists, and methodologists, was formed in 2008[3]. This group performed systematic reviews[3,4,5], which identified that the lack of harmonized measures or a consensus universal core outcome set was hampering the ability to compare data between TJR randomized controlled trials in both hip and knee joints[4]. Combining these

From the University of Alabama at Birmingham and Birmingham Veterans Affairs Medical Center, Birmingham, Alabama; Department of Orthopedics, Mayo Clinic College of Medicine, Rochester, Minnesota, USA; University of Melbourne Department of Surgery, St. Vincent's Hospital, Melbourne, Australia; Department of Orthopedic Surgery and Department of Medicine, University of Arizona, Tucson, Arizona; Weill Cornell Medical School and Hospital for Special Surgery, New York, New York; Healthy Motivation, and Global Alliance for Musculoskeletal Health, the Bone and Joint Decade, Santa Barbara, California, USA; Department of Psychology, Health and Technology, University of Twente, Enschede, the Netherlands.

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J.A. Singh, MBBS, MPH, Professor of Medicine and Epidemiology, University of Alabama at Birmingham and Staff Physician, Birmingham Veterans Affairs Medical Center, and Research Collaborator, Department of Orthopedics, Mayo Clinic College of Medicine; M.M. Dowsey, PhD, National Health and Medical Research Council Clinical Research Fellow, University of Melbourne Department of Surgery, St. Vincent's Hospital; M. Dohm, MD, Assistant Professor, Department of Orthopedic Surgery and Department of Medicine, University of Arizona; S.M. Goodman, MD, Associate Professor of Clinical Medicine, Weill Cornell Medical School and Associate Attending Hospital for Special Surgery; A.L. Leong, MBA, President and CEO, Healthy Motivation, and Director of Strategic Relations, Global Alliance for Musculoskeletal Health, the Bone and Joint Decade; M.M. Scholte Voshaar, PhD, Research Fellow, Department of Psychology, Health and Technology, University of Twente; P.F. Choong, MBBS, MD, FRACS, FAOrthA Professor of Surgery, University of Melbourne, and Head of Department of Surgery, and Director of Orthopedic Surgery, St. Vincent's Hospital.

Address correspondence to J.A. Singh, MBBS, MPH, University of Alabama, Faculty Office Tower 805B, 510 20th St. S., Birmingham, Alabama 35294, USA. E-mail: Jasvinder.md@gmail.com

systematic reviews with input including Delphi panels with patients, surgeons and others, the group derived a preliminary core domain set for clinical trials of TJR for knee/hip arthritis at OMERACT 2014 that included pain, function, patient satisfaction, revision, adverse events, and death[6].

Our systematic review had concluded that a large proportion of TJR trials did not measure core areas[6], and this did not improve from 2008 to 2013 (under review). The OMERACT Filter 2.0[7,8], arising since OMERACT 2014, provides a means for developing standardized core measurement sets through a transparent and generalizable framework and methodology for the evaluation, development, and validation of such sets.

The purpose of this report is to present the progress of the OMERACT TJR WG since OMERACT 2014 and to report the work that informed the recommendations of the 2016 OMERACT TJR WG meeting. These recommendations include (1) endorsing OMERACT TJR core domain set to move the field forward; (2) limiting the scope to total hip replacement (THR) and total knee replacement (TKR) but including all endstage arthritis refractory to medical treatment; (3) including general "adverse events" domain rather than specific adverse events, i.e., cardiac, pulmonary, or infectious complications; (4) adding range of motion as a research agenda domain; and (5) obtaining a clear mandate for the next step of instrument selection to use subscales of validated multidimensional instruments as candidate measures for core measurement set for TJR trials. These data have not been submitted or published elsewhere.

TJR Working Group Progress and Activities since OMERACT 12

Collaboration and consensus building toward endorsement. Singh and Dohm presented the OMERACT filter 2.0 framework and our current findings at the International Society of Arthroplasty Registries (ISAR) meeting in 2014 in Boston, USA; the ISAR meeting in 2015, Gothenburg, Sweden; and the American Academy of Orthropaedic Surgeons (AAOS) meeting in 2014, in New Orleans, USA, with a positive response.

Dohm and Singh have approached the American Association of Hip and Knee Surgeons (AAHKS) leadership for collaboration and final endorsement of the core domain set, and will communicate with Dr. William Jiranek, president of AAHKS, and Dr. Javad Parvizi, chairman of the AAHKS research committee, to share this core dataset with the membership.

Further endorsement of the OMERACT TJR core domain set. We are obtaining a wider endorsement of the OMERACT knee/hip TJR core domain set through international endorsement by orthopedic surgeons and patients. We surveyed orthopedic leaders and surgeons from the AAOS Outcome Special Interest Group and the Outcome Research Interest Group of the Orthopaedic Research Society (ORS; completed; under analyses). We surveyed OMERACT patient research partners (PRP) and an Australian cohort of 128 patients who underwent hip and knee arthroplasty and who were recruited through an institutional registry.

The OMERACT 2016 Working Group Meeting

Among the 26 working group participants there were 3 patients, 2 orthopedic surgeons, 2 physical/occupational therapists, 2 methodologists, and 15 clinicians/clinical researchers. After reviewing the working group background and recognizing the need for a core set of outcome measures and better trial reporting, 3 presentations were made.

Working group co-chairs (JS, PC) provided a rationale:

- TJR trials are currently reporting pathophysiological outcomes rather than life effects or mortality.
- Orthopedic surgeons and their professional bodies need to be engaged to establish a core set of measures.
- Separate Delphi surveys performed with surgeons, patients, and OMERACT PRP have established that strong consensus for TJR core domains existed, with strong agreement on which core domains should be included in TJR trials

Patient research partner (ALL) described the patient partner experience:

- A patient perspective of how her disease affects her life and the experience of undergoing multiple TJR, and her evolution from patient to advocate.

Researcher (MMD) provided an update on recent advances.

- Development of a prognostic nomogram that predicts the probability of non-response to TKR, using outcome data from St. Vincent's Hospital Melbourne Arthroplasty Outcomes registry to identify modifiable risk factors for poor outcomes[9]. The nomogram demonstrates how elements of the core domains can be used to develop a prediction tool to aid decision making by surgeon and patients considering TJR.

Core Domains

WG participants additionally discussed and provided descriptions for core domains (Table 1).

Adverse events. Do we need to define the range and spectrum of adverse events? Should this include all adverse events or only surgical ones, because medical adverse events are rare? A more generic phrase, "adverse events," was selected for use.

Scope. Participants agreed that the scope should remain

Table 1. Core domain descriptions.

- The OMERACT TJR core domain set was defined as pain, function, patient satisfaction, revision, adverse events, and death and was endorsed, moving the field forward.
- The scope of this TJR core domain set should be limited to THR and TKR but include all endstage arthritis refractory to medical treatment, osteoarthritis or rheumatoid arthritis.
- General "adverse events" was kept as a core domain rather than specific adverse events.
- Range of motion was added as a research agenda domain.
- The next step of instrument selection for core domains using subscales of validated multidimensional instruments as candidate measures for the core measurement set for TJR trials was a clear mandate.

TJR: total joint replacement; THR: total hip replacement; TKR: total knee replacement.

restricted to TKR and THR. Once a TJR core measurement set has been developed for knee/hip, core measurement sets for other TJR should be developed. Other TJR are likely to differ in specifics, and core measurements used for THR/TKR may not be applicable to other joints such as the shoulder or ankle. This WG will work with other WG cooperatively (e.g., shoulder pain WG) to establish core domains for procedures such as shoulder TJR.

Clarification was sought and provided that core domains were inclusive of all endstage arthritis refractory to medical treatment, including OA and RA.

Early revision surgery. If early revision surgery is due to technical failure, it may be an adverse event and a separate domain, which might be difficult in reporting of clinical trials. An important point of discussion was the importance of patient-related outcome measures as surrogate markers for failure because not all poorly performing or symptomatic TJR are revised. Currently, because revision surgery is the only objective measure of failure, it may significantly underestimate the prevalence of failed TJR.

Death. Most participants agreed that this is an accepted standard for trials.

Range of motion. Participants added range of motion to the research agenda because there was no consensus regarding its value (Figure 1). Thus, the original core domain set figure from our previous publication[6] has been modified to include range of motion on the research agenda.

Patient participation. While this domain was a candidate for core domain, after several rounds of Delphi and WG participant discussions at the OMERACT 2014, this was moved to the middle circle.

Time scale. How long should the minimum followup be for trials? Dowsey, *et al* looked at trajectory of patient outcomes using latent class growth analysis, which showed that stabilization of outcomes occurred at about 1 year after surgery[10].

Participants agreed that sufficient attention and surveying had been applied to establishing core domains and it was time to decide on instruments and move to the next phase. Participants agreed that multidimensional scales could be used as measures for TJR trial core domains and the subscales

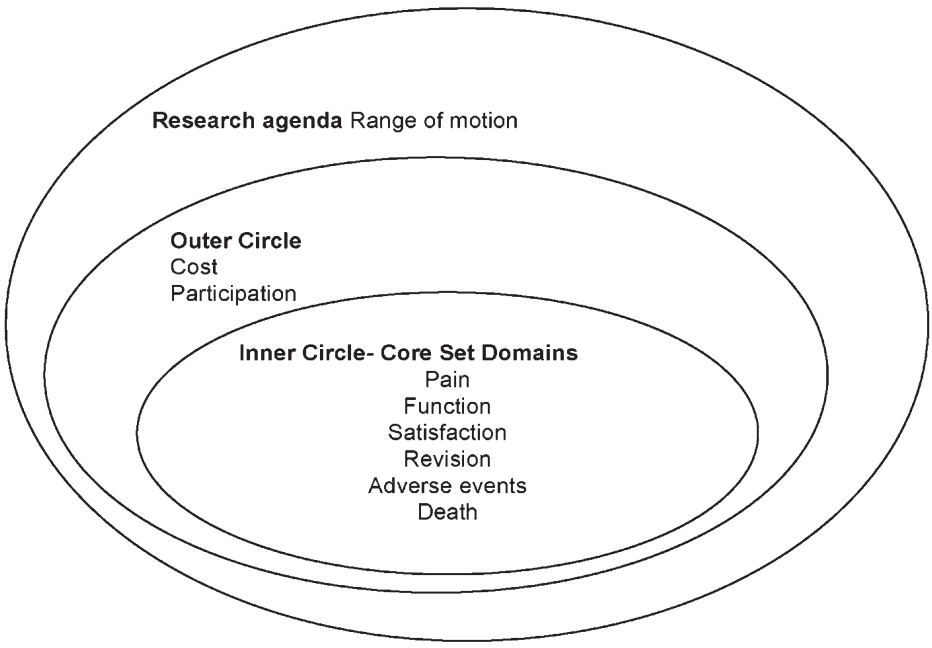

Figure 1. Core domain set for outcome domains for TJR clinical trials.

of such scales could be used as measures of core domain set.

There was agreement about the other core domains of pain, function, or functional limitation and patient satisfaction. The WG participants voted and endorsed our planned next steps: (1) are we ready to do eyeball and deep dive tests, that is, narrowing the list of instruments to the most viable ones and then taking them through the OMERACT filter of truth, discrimination, and feasibility for 1-2 top instruments mapping to the core domains of the TJR clinic trial core set? All voted "yes"; and (2) Can we use subscales of a validated multidimensional scale to do deep dive as measure/s of core domains for the TJR clinic trial core measurement set? There were 24 "yes" responses out of 26.

DISCUSSION

A collaboration among patients, members of OMERACT, ISAR, the American Joint Replacement Registry, AAOS, AAHKS, and the ORS has been established to identify and enable a core domain set for knee/hip TJR trials. Using the same measures in trials is mandatory to compare and evaluate knee/hip TJR. The Comprehensive Care for Joint Replacement Alternative Payment Model for Medicare and Medicaid increases this need for a core dataset for all involved[11].

We previously developed a preliminary core domain set for knee/hip TJR trials[6], which was modified after additional feedback. A novel contribution of the OMERACT 2016 WG activity was an endorsement of this TJR core domain set by a group that included patients, surgeons, therapists, rheumatologists, and methodologists, resulting from an in-depth discussion of each of the core domains, clarification of definitions of these core domains, and consideration with rejection of additional domains as potential core domains. This endorsement and our ongoing collaborations indicate that this core domain set is likely to be endorsed by other groups worldwide.

Moving the field forward, we achieved consensus to assess multidimensional outcome instruments for core domains of pain, function/functional ability, and use subscales of such instruments as measures of the core domains, to ultimately validate and endorse a TJR trial core measurement set. The group endorsed readiness to proceed with instruments for both the eyeball test and the deep dive.

Three parallel consensus activities are under way with orthopedists and 2 groups of patients for further buy-in and endorsement of this core domain set for hip/knee TJR trials. This final core domain set for hip/knee TJR trials will be shared with the membership of the AAHKS and OMERACT for final endorsement and possible co-branding as the OMERACT-AAHKS TJR core domain set for TJR trials. Once a core domain set is more broadly endorsed, we will identify candidate measures for knee/hip TJR clinical trials, and develop the TJR core measurement set.

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