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SURVEY

# Success After Treatment of Periprosthetic Joint Infection: A Delphi-based International Multidisciplinary Consensus

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**Abstract**

*Background* The lack of agreement regarding what constitutes successful treatment for periprosthetic joint infections (PJI) makes it difficult to compare the different strategies of management that are used in clinical practice and in research studies.

*Questions/purposes* The aims of this study were to create a consensus definition for success after PJI treatment, and to provide a universal, multidimensional framework for reporting of studies regarding PJI treatment.

*Methods* A two-round basic Delphi method was used to reach a consensus definition. We invited 159 international experts (orthopaedic surgeons, infectious disease specialists, and clinical researchers) from 17 countries to participate; 59 participated in the first round, and 42 participated in the second round. The final definition consisted of all statements that achieved strong agreement (80% or greater of participants considering a criterion relevant for defining success).

*Results* The consensus definition of a successfully treated PJI is: (1) infection eradication, characterized by a healed wound without fistula, drainage, or pain, and no infection recurrence caused by the same organism strain; (2) no subsequent surgical intervention for infection after reimplantation surgery; and (3) no occurrence of PJI-related mortality (by causes such as sepsis, necrotizing fasciitis). The Delphi panel agreed to defining midterm results as those reported 5 or more years after the definitive PJI surgery, and long-term results as those reported 10 or more years after surgery. Although no consensus was reached on the definition of short-term results, 71% of the participants agreed that 2 years after the definitive PJI surgery is acceptable to define it.

*Conclusions* This multidimensional definition of success after PJI treatment may be used to report and compare results of treatment of this catastrophic complication.

*Level of Evidence* Level V, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

**Electronic supplementary material** The online version of this article (doi:10.1007/s11999-013-2866-1) contains supplementary material, which is available to authorized users.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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## Introduction

Periprosthetic joint infections (PJI) are a major cause of failure and revision surgery after knee [21] and hip arthroplasties [27, 40], and the incidence appears to be increasing [19]. PJIs are catastrophic for patients [8], challenging for clinicians [10, 22, 30], and expensive for the healthcare system [5, 20].

The goal of treating patients with a PJI is multidimensional and includes eradication of the infection [15, 17]

improvement in function, [9, 24, 28, 31], patient satisfaction [3], and quality of life [32]. Avoidance of medical and surgical complications can also be considered a goal of the PJI treatment [11, 18].

There is no consensus regarding what constitutes successful treatment of a PJI. Diverse criteria to define success or failure have been proposed (Table 1). This disagreement precludes an adequate comparison among the different strategies of treatment. Therefore, the concept of success after PJI treatment requires further investigation.

The aim of this study was to generate a multidimensional definition of success after PJI treatment, by establishing consensus among members of an international multidisciplinary group of experts in the field.

## Materials and Methods

We performed the study following the recommended checklist [38] and guidelines [16] for studies using the Delphi method, which corresponds to an iterative questionnaire designed to measure consensus among individual responses [26]. Additional recommendations for survey studies also were followed [39].

During April and May 2012, 159 international experts from 17 countries on five continents were identified and invited to participate in this study. Three independent inclusion criteria determined who was asked to participate: (1) author or coauthor of a PubMed®-cited article or book related to PJI that was published between 2007 and 2012 (using MeSH® terms: "Prosthesis-Related Infections", "Arthroplasty", "Replacement, Hip, Knee"); (2) author or coauthor of current PJI clinical guidelines [1]; or (3) a recognized academic career in hip and knee arthroplasties with special interest in management of PJI. We contacted the participants via e-mail and invited them to participate in the study. The identities of the principal investigator and institution and the objective of the study were included in the invitation.

A nonsystematic literature review was conducted in PubMed® and Google Scholar® to update one of our previous publications regarding successful outcomes for PJI treatment [12]. We found 10 different definitions of success or failure in PJI treatment (Table 1) [2, 6, 13, 14, 17, 23, 29, 37, 41, 42]. These definitions and various potential criteria proposed by the authors of the present study were assessed in two internal rounds at our institution. Staff members of the joint replacement division and clinical fellows took part in these internal rounds, conducted via e-mail. After the internal rounds, the criteria were organized in different dimensions. In addition, the conceptualization of the temporality for outcome measurement was achieved during these internal rounds. Using the reorganized potential criteria, we created an electronic questionnaire with 26 items structured in seven dimensions to define success in PJI treatment (Table 2). It was sent to the participants via e-mail using a commercially available Internet-based survey system (AdobeFormsCentral™; Adobe Systems Inc, San Jose, CA, USA) to manage the questionnaires. The participants were requested to rank each criterion from 1 to 9, where 1 had the lowest and 9 had the highest relevance to the definition of success in PJI treatment. The identities of the other participating individuals and institutions were not disclosed to the participants.

To reach consensus, we used a two-round simple Delphi method (self-administered questionnaire with no meetings among the participants) [4]. The first round started immediately after the invitation was sent to the participants. After 7 days, a second e-mail (reminder) was sent to the participants who did not respond to the first invitation. On Day 15, collection of responses for the first round was completed. To appraise the responses, we used a modification of the method of Rodriguez-Mañas et al. [35] (Fig. 1). The level of agreement in the responses was assessed as follows: strong agreement was considered if greater than 80% of the responders rated the criterion with a score of 7 or greater; moderate agreement was considered if 70% to 79% of the responders rated the criterion with a score of 7 or greater; low agreement was considered if 50% to 69% of the responders rated the criterion with a score of 7 or greater; and no agreement was considered if less than 50% of the responders rated the criterion with a score of 7 or greater. Criteria with strong agreement were immediately considered part of the definition (Fig. 1).

The second round was conducted 5 days after the first round was finalized. We invited only the responders who took part in the first round. In the invitation for the second round, we gave the participants the results of the first round and the methodology used, encouraging them to use the information when responding to the second-round survey. The second-round questionnaire included criteria with moderate agreement in the first round. Criteria with low and null agreement in the first round were tested for heterogeneity and dispersion. Those with heterogeneity in the responses (Wilcoxon rank sum test p value $< 0.05$) or dispersion (interquartile range $> 4$) were reviewed by the authors. We excluded them from the second round if greater than 50% of the responders considered the criteria not relevant ($\leq 3$), whereas the rest were included in the second round. The criteria with no heterogeneity or dispersion in the responses were excluded from the second round immediately. A reminder e-mail was sent at the 7$^{th}$ day, concluding the second round at Day 15. The second-round results were evaluated using the same method used for the first round. Only criteria that achieved strong agreement were included in the final definition (Fig. 1). We

**Table 1.** Different definitions of success and failure in treatment of PJIs

| Study | Setting/ treatment | Definition of success | Definition of failure |
|---|---|---|---|
| Volin et al. [41] | Two-stage revision | Treatment was considered successful if the patient was disease free at the latest followup | |
| Jämsen et al. [17] | Meta-analysis | Success in infection management was analyzed in three ways. First, the total number of infections appearing after treatment was recorded, supplemented by the number of recurrent infections and of new infections (that is, postoperative infections caused by an organism other than the one detected on treatment) | |
| Bradbury et al. [6] | Open débridement and component retention | Clinical resolution of infection and lack of further surgery. Patients who had clinical resolution of infection but were maintained on suppressive oral antibiotics were considered to have successful treatment | Need for subsequent infection-related surgery |
| Waagsbø et al. [42] | Open débridement and component retention | Treatment response was defined as postdébridement period free from PJI relapse during the time of followup | Need of further orthopaedic surgery |
| Azzam et al. [2] | Open débridement and component retention | Absence of symptoms and signs of infection until the date of the last followup | Need for resection arthroplasty or recurrent microbiologically proven infection |
| Estes et al. [14] | Two-stage revision | Success was considered as infection control. Serum inflammatory markers (ESR and CRP) had normalized and there were no clinical signs or symptoms of infection | Recurrence of infection requiring additional surgery or clinically apparent infection diagnosed with a positive aspiration or persistently elevated inflammatory markers and treated with long-term antibiotic suppression |
| Parvizi et al. [31] | Methicillin resistant *Staphylococcus aureus* PJI | Infection eradication | |
| Senneville et al. [37] | *S aureus* PJI | Remission was defined by the absence of local or systemic signs of infection assessed during the most recent contact with the patient and absence of the need to reoperate or to administer antibiotic therapy directed to the initial infected site from the end of treatment to the most recent contact | Any other outcome, including death related to the PJI. |
| El Helou et al. [13] | Two-stage revision | | Treatment failure was defined by one of the following criteria: (1) recurrence of PJI caused by the same strain of microorganism or a different microorganism at any time after reimplantation surgery; (2) death caused by prosthesis-related infection at any time after reimplantation surgery; (3) clinical failure defined as clinical, laboratory, or radiographic findings suggestive of PJI at any time after reimplantation surgery |

**Table 1.** continued

| Study | Setting/ treatment | Definition of success | Definition of failure |
|---|---|---|---|
| Mahmud et al. [23] | Two-stage revision | Any outcome different from failure (no clear definition was stated) | Any patient who required additional surgery for either septic or aseptic reasons following two-stage revision. Septic failure was defined as pain and/or loose prosthesis with an increased CRP and positive culture from joint aspiration, and/or intraoperative histology consistent with infection |

PJI = periprosthetic joint infection; ESR = erythrocyte sedimentation rate; CRP = C-reactive protein.

used SPSS 15.0 (SPSS Inc, Chicago, IL, USA) for statistical analysis. During the entire process, the responders were allowed and encouraged to give recommendations to the authors using a free-text recommendation field in the survey. We evaluated the recommendations and applied them if they were considered relevant.

After 6 months, the senior author sent a personalized e-mail invitation to the group of experts who did not participate in the first survey, to obtain their feedback regarding the reached definition, as a validation method. They were asked to respond regardless whether they agree with the definition.

## Results

Of the 159 international experts eligible for the study, 140 (88%) could be contacted via e-mail; all of them were invited to participate in the study. Among them, 59 (42%) responded to the questionnaire in the first round. This group consisted of 48 orthopaedic surgeons (81%), seven infectious diseases specialists (12%), and four clinical researchers (7%). The geographic distribution was: 33 experts (56%) from the North America, 13 (22%) from Europe, five from Asia (8%), seven from South America (12%), and one from Oceania (2%). Among the 140 people contacted, the response rate for orthopaedic surgeons was 42% (48 of 115 contacted), infectious diseases specialists was 33% (seven of 21 contacted), and clinical researchers was 100% (four of four contacted). In the second round, 54 participants (38%) were included (five were unavailable when contacted). Of those, 42 (30% from the contacted cohort) responded to the second questionnaire (Fig. 2).

The characteristics of responders versus nonresponders in terms of medical specialties (proportion of orthopaedic surgeons versus infectious diseases specialist versus clinical researchers) was assessed using Fisher's exact test. The p value was 0.05. If clinical researchers are excluded from the analysis, the proportion of orthopaedic surgeons and infectious diseases specialists between the responders and nonresponders is equivalent (Pearson's $\chi^2 = 0.52$; $p = 0.47$).

Six criteria were included in the final definition. Five criteria were selected after the first round and one after the second round (see Electronic Supplementary Material). The new multidimensional definition of success after PJI treatment is: (1) infection eradication, characterized by no clinical failure (healed wound without fistula or drainage and painless joint), and no infection recurrence caused by the same organism strain; (2) no subsequent surgical intervention after reimplantation surgery owing to

**Table 2.** Items included in the questionnaire sent to the participants

| Based on the following criteria, success in PJI treatment should be defined as: | |
|---|---|
| Dimension A Infection eradication, characterized by: | No clinical failure (healed wound without fistula or drainage and painless joint) |
| | Return to baseline (or to the normal level) of serologic markers (including C-reactive protein, erythrocyte sedimentation rate, white blood cells) |
| | No need for antibiotic suppression treatment |
| | No infection recurrence caused by the same organism strain |
| | No incident (new) infection with a different organism |
| | No concomitant PJI in other surgical site |
| Dimension B No subsequent surgical intervention after reimplantation surgery, characterized by: | No reoperation attributable to infection |
| | No revisions owing to aseptic causes in the proposed followup period (including aseptic loosening, instability, stiffness) |
| | No radical surgeries after reimplantation (including: lower limb amputation, hip/knee arthrodesis, hip resection arthroplasty) |
| Dimension C No presence of PJI-related morbidity or mortality, characterized by: | No death caused by a condition directly linked to PJI (including sepsis, necrotizing fasciitis). |
| | No death in a hospitalization owing to treatment of PJI, by causes not directly linked with PJI (including myocardial infarction, stroke, pneumonia) |
| | Hospital length of stay less than 3 months/year during treatment of PJI |
| | No medical complications associated with PJI intravenous or local antibiotic treatment (including systemic toxicity, renal insufficiency, peripherally inserted central catheter line complications) |
| Dimension D Maintenance of functional level after PJI treatment, characterized by: | Equal or better functional status than before the index arthroplasty (using any functional scale) |
| | Equal or better functional status than before the diagnosis of PJI (in patient with formerly well-functioning arthroplasty), using any functional scale |
| | Functional improvement equal or better than the minimal clinical important difference described for the used score or functional scale |
| | Patient satisfaction with the achieved outcome (binary score: satisfied versus not satisfied) |
| | Absence of psychiatric comorbidity (or deterioration of previous disease) caused by PJI or its treatment |
| Dimension E Definition of early results after PJI treatment (regarding peer-reviewed publications) | 1 year after PJI definitive surgery (last surgery performed for PJI) |
| | 18 months after definitive surgery |
| | 2 years after definitive surgery |
| Dimension F Definition of midterm results after PJI treatment (regarding peer-reviewed publications) | 3 years after definitive surgery |
| | 4 years after definitive surgery |
| | 5 years after definitive surgery |
| Dimension G Definition of long-term results after PJI treatment (regarding peer-reviewed publications) | Greater than 5 years after definitive surgery |
| | 10 years or more after definitive surgery |

PJI = periprosthetic joint infection.

infection, and (3) no death caused by a condition directly linked to PJI (including sepsis, necrotizing fasciitis).

Regarding the appropriate time to report the results after PJI treatment, recommendations given by the participants were adopted by the authors. Originally, we proposed the index PJI surgery as the time zero to start the followup. After considering participants' recommendations, it was changed to definitive PJI surgery (ie, the reimplantation surgery in one- or two-stage revision arthroplasties). A consensus definition for short-term followup was not reached, however 71% of the participants agreed that 2 years after the definitive PJI surgery is acceptable to define it. To report midterm followup, 5 years after the definitive PJI surgery was recommended. Long-term followup was defined as 10 or more years after the definitive PJI surgery.

From the 81 experts who originally were invited but did not participate in the study, only 18 responded to the validation e-mail (22%). Among them, 15 (83%) agreed with the definition with or without minor concerns. Two (11%) agreed with major concerns. All of these concerns are topics that were included in the original survey. One (6%) did not include his or her approval in the e-mail response.

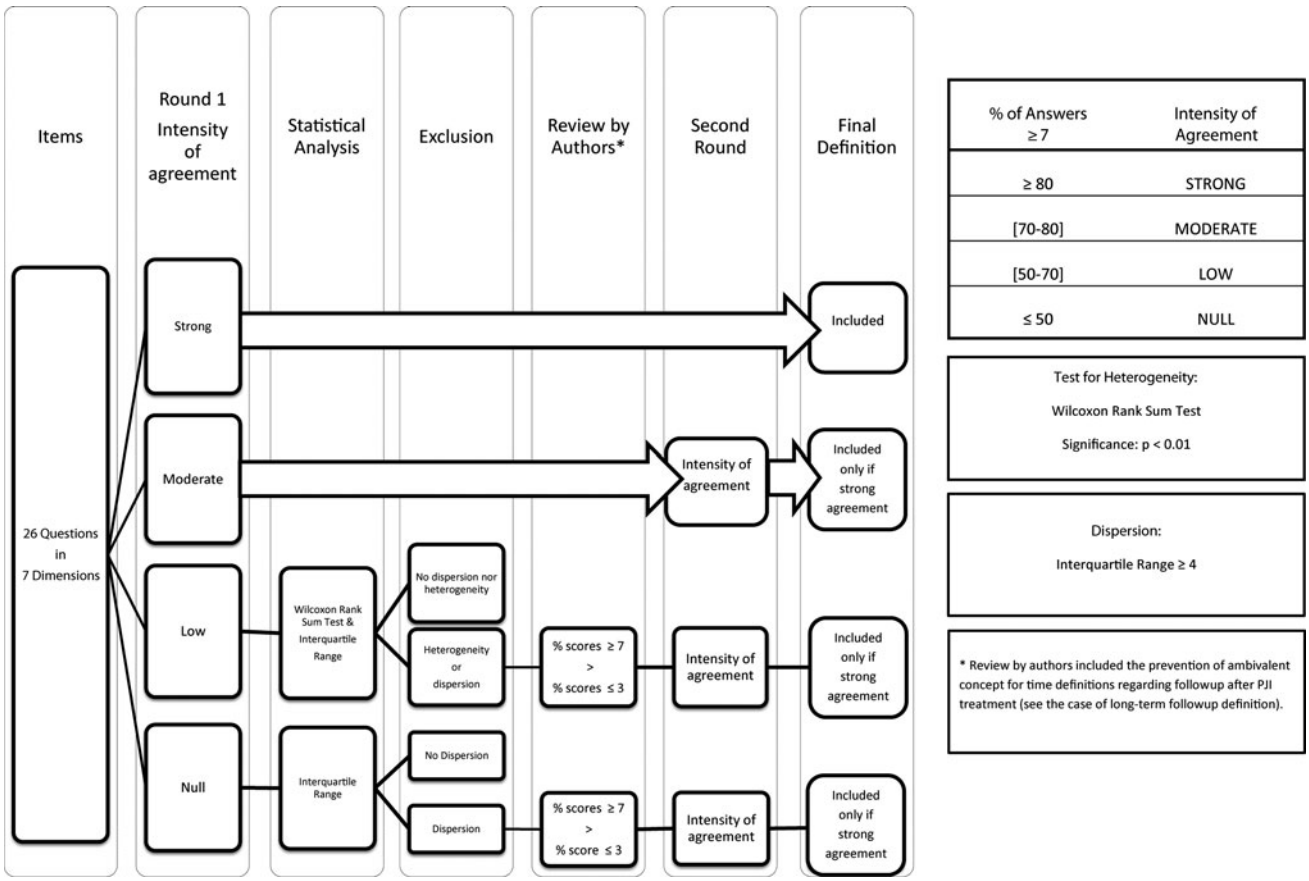
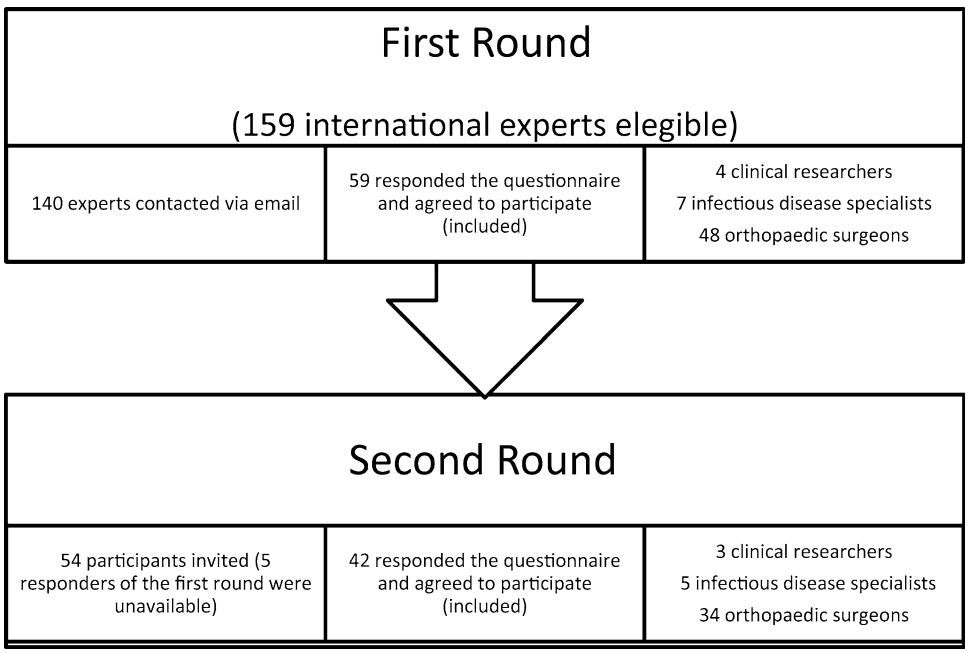



**Fig. 1** The diagram shows the study methodology and course of action regarding the management of responses.

**Fig. 2** The breakdown of individuals who participated in the first and second rounds of the Delphi survey is shown.



## Discussion

This study introduces a multidimensional definition for success after treatment of PJI, obtained by consensus using the Delphi method, in a multidisciplinary group of internationally recognized experts in the field. The definition was achieved using the opinion generated by the experts, who evaluated various different criteria that can be used to measure the performance of a treatment modality. Regardless, the contribution of the experts must be considered indirect, as they did not actively participate in study conception, data analysis, interpretation, or final recommendation.

Our study has the following methodologic limitations. First, the number of experts who agreed to participate in the study was lower than expected. Although selection criteria were broad and inclusive to ensure representation from various orthopaedic surgeons, infectious disease specialists, and clinical researchers throughout the world, the response rate of the first round was less than 50%. To our knowledge, a response rate threshold to invalidate the results obtained using the Delphi method has not been established; however, a response rate greater than 70% generally is known to decrease biased results [39]. Even though a relatively low response rate may introduce an inherent unmeasurable bias, other studies that have used the Delphi method obtaining valid results have had similar response rates [34, 36]. Additionally, the response rate in our study exceeded the response rate observed in other studies [33, 39]. The use of a modified Delphi method (with one round having participants interacting directly) [4] may have reached a higher rate of response. However, getting experts from three different areas and 17 countries together in a single meeting requires use of resources far greater than those available to us. Another alternative that could have increased the response rate is the use of surveys using other methods such as postal surveys, fax, or phone. Nevertheless, we determined that the advantages offered by electronic surveys outweigh the disadvantages [39]. Second, a larger number of orthopaedic surgeons responded to the survey, compared with infectious diseases specialists and clinical researchers. The inclusion criteria established for the study may explain this observation; our search yielded more orthopaedic surgeons than it did infectious diseases specialists and clinical researchers. To verify that the larger number of orthopaedic surgeons who responded to the survey did not lead to biased results, we performed a post hoc analysis comparing the three groups' responses; it revealed no changes in the six criteria that were included in the final definition. In addition, when the group of responders was compared with the group of nonresponders in terms of medical specialties, there was only a borderline significant difference. For this reason, we believe that the larger number of orthopaedic surgeons who participated in the study does not necessarily implicate bias.

We believe the use of a standardized, multidimensional definition of PJI will contribute to scientific reporting on this subject. A lack of standardization among studies on this subject limits the comparison of one treatment approach over another. Moreover, none of the previous definitions included a multidimensional concept, which may lead to theoretical problems and conflicts pertaining to the definition of success. For example, the definition of infection eradication might include amputation; our multidimensional approach limits problems of this nature. In a recent Level-1 study involving patients undergoing two-stage revision for PJI, the use of intravenous daptomycin was compared with standard-of-care therapy [7]. The primary end point was creatine phosphokinase (used to measure the safety of the intervention). Success was defined as resolution or improvement of baseline clinical and radiologic findings and negative cultures at the "test-of-cure visit" (conducted at hospital discharge or within 2 weeks after reimplantation if still hospitalized). Byren et al. [7] concluded that daptomycin "was considered safe and appeared to be effective in managing staphylococcal PJI using a two-stage revision arthroplasty technique." From the perspective of the current study definition, the cited randomized controlled trial evaluated the results using an extremely short time. In addition, the use of negative cultures to define success is worrisome. Mortazavi et al. [25] reported that negative intraoperative cultures at the reimplantation time do not exclude the possibility of future reoperation to treat infection.

The Delphi group reached consensus on three dimensions to describe success: (1) eradication of infection, (2) no subsequent surgical intervention, and (3) no mortality related to PJI. The group agreed on the definition of midterm followup (5 years) and long-term followup (10 years or more). Although no agreement was achieved regarding short-term followup; based on the results, we advocate the use of 2 years after the definitive PJI surgery. The lack of agreement observed in the short-term definition may reflect little interest for studying the short-term results after PJI treatment. Another explanation may be that the given alternatives (1, 1.5, or 2 years) were not deemed adequate. However, despite providing numerous alternatives to responders, no consensus was reached on an important dimension: functional results. We believe that further investigation is necessary on this topic. The inclusion of patients' opinions and expectations can add important information regarding the way functional recovery should be evaluated after PJI treatment.

To validate our obtained results by an external group, we asked the researchers who were invited but did not participate in the original survey to give us feedback. Although the rate of response was low, the majority of them agreed to the definition completely or with minor concerns. In addition,

all the minor and major concerns that have been presented were addressed in the first survey. For this reason, we believe that the definition is valid and applicable. We also would like to reinforce the fact that the definition of success after PJI treatment proposed in this paper must be used only for biomedical research, excluding any potential application for commercial, legal, or advertising purposes.

We recommend using this multidimensional definition of success for reporting and comparing results after PJI treatment.

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