

When Has a Knee or Hip Replacement Failed? A Patient Perspective

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ABSTRACT. Objective. To define the patient perspective of what constitutes a failure of total joint replacement (TJR) in a qualitative study.

Methods. We used the nominal group technique (NGT) with participants who had undergone elective total hip replacements (THR) and/or total knee replacements (TKR) to answer the question, "When would you consider a knee or hip replacement to be a failure?"

Results. We performed 8 nominal groups with 42 participants, all of whom had undergone THR and/or TKR between 2016 and 2018. Of these, 48% were male, 17% were Black, 79% had college education or above, and 76% had had osteoarthritis as the underlying diagnosis. The nominated responses/themes that were ranked the highest by the participants were as follows: (1) refractory index joint pain (80 votes); (2) occurrence of postoperative adverse events (54 votes); (3) unable to resume normal activities or go back to work (38 votes); (4) little or no improvement in quality of life (35 votes); (5) early revision surgery (35 votes); (6) death (7 votes); and (7) other, including nurse or physician negligence (2 votes) and expectation-outcome mismatch (1 vote).

Conclusion. Lack of relief of pain or restoration of function or quality of life, or the occurrence of surgical complications after TJR were defined as TJR failure by participants. Functional TJR failure seems as important or more important than surgical failure. This patient perspective emphasizing pain, function, satisfaction, adverse events, and revision as critical domain components of TJR failure independently validated their inclusion in the TJR core domain set for clinical trials in people undergoing knee or hip TJR.

Key Indexing Terms: arthroplasty, failure, hip replacement, knee replacement

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Total joint replacements (TJR) are performed frequently as elective surgeries for people with symptomatic endstage arthritis. Refractory pain, rest pain, and functional limitation are the most common reasons for TJR^{1,2,3}. For a patient undergoing TJR, the objective is relief of pain and improvement in function and quality of life (QOL)¹. Shared decision making by the patient in consultation with the surgeon is critical for TJR. A better understanding of patient perceptions of elective knee or hip TJR failure can make the discussions and the decision making more informed. The Centers for Medicare and Medicaid Services now collects information about patients' perspectives of their hospital experience with the goal of improving care, and also providing data that contribute to the annual hospital payment schedule update through the Hospital Value Based Purchasing program⁴.

The TJR utilization rates continue to increase⁵. While most TJR are successful, failure occurs. In a systematic review, long-term joint pain ranged from 7% to 23% after hip and 10% to 34% after knee TJR⁶. With an annual combined TJR utilization for knee and hip exceeding 1 million/year in the United States^{7,8}, the number of people with an unfavorable knee/hip TJR outcome would range from 91,000 to 310,000 annually. This equals almost 1 million to 3.5 million Americans with an unfavorable TJR outcome over a decade, and represents a significant public health problem.

The most common surgical reasons for early knee or hip TJR failure are infection, fracture, instability, aseptic loosening, stiffness, loosening and wear, surgical error and metal-on-metal implants^{9,10,11,12,13}. In addition, persistent pain or persistent limitation of function/QOL may occur in the absence of radiographic, clinical, or histologic evidence of surgical failure, and still lead to patient dissatisfaction with TJR outcome. Only 36% of patients and surgeons agree on assessments of failure for TJR¹⁴, highlighting the patient-surgeon discordance. Surveys of patient perspective of TJR have been published, but yield little or no data addressing the question of TJR failure directly^{15,16}. Qualitative studies have focused on patient knowledge related to the TJR procedure and views about outpatient vs inpatient TJR¹⁷; reasons for avoiding TJR¹⁸; patient perspective of decision making; postoperative care and rehabilitation after knee TJR¹⁹; patient experience of hospital stay, operation, and recovery or outcome after knee TJR²⁰; pre- and postoperative experience regarding knee TJR²¹; and patient adjustment to chronic pain following knee TJR²². Qualitative research to define the patient perspective of what constitutes a failure of TJR is lacking. Recognition of knowledge gaps in patient outcomes in TJR have led to federal funding for the creation of a patient-centered consortium in TJR effectiveness research²³.

The primary purpose of our study was to determine the themes that define TJR failure from patient perspective using the nominal group technique (NGT). A secondary objective was to assess whether these themes, generated using an open-ended qualitative research method, further confirm the validity of the TJR core set domains endorsed by Outcomes in Rheumatology (OMERACT)²⁴, derived from multistakeholder input, including orthopedists, rheumatologists, patients, physical and occupational therapists, and patient advocacy leaders that include both clinicians and researchers.

MATERIALS AND METHODS

We identified adults who had undergone elective knee or hip TJR at the Hospital for Special Surgery (HSS), New York, a high-volume orthopedic hospital (~10,000 TKR and THR performed annually) between 2016 and 2018. Potential participants eligible for the study were identified from a list of all people who had undergone a primary, unilateral knee or hip replacement TJR by 3 participating surgeons (MPF, PS, or MP) without additional inclusion or exclusion criteria. The surgeons sent a letter to consecutive patients inviting them to participate in the nominal groups (NG) in January and February 2019. In case of nonresponse, a follow-up invitation was extended with an email or telephone call. To examine whether the perspective of younger patients differs from those across the age range, we conducted 2 NG among participants aged 45 years or younger. All participants provided informed consent. The study was approved by the institution's ethical review board (no. 2018-2087).

The NGT is a highly structured group discussion format used to achieve group consensus around a specific topic²⁵, a variant of the traditional focus discussion groups. The NGT allows the participants to define their priorities in response to a single question that is analyzed in depth for an hour and leads to a group consensus. A major benefit of using NGT is that the group can reach consensus. In this study, participants who had previously undergone TJR discussed and determined the definition of a knee or hip TJR failure from their perspective.

We chose the NG question based on informal patient feedback in 2 clinics (JS and SG), with patients choosing among 3 candidate questions.

Majority of the patients chose the following question to be most clear to them in formulation: "When would you consider a hip or knee replacement to be a failure?"

All interested participants were invited to the HSS for the NGT procedure. After providing informed consent, participants completed a self-administered survey that included demographic details, questions regarding their satisfaction with TJR, and knee/hip pain/function assessments with either the Hip Disability and Osteoarthritis Outcome Score (HOOS) Joint Replacement (JR), or the Knee Injury and Osteoarthritis Outcome Score (KOOS) JR, both validated short-form questionnaires^{9,10}.

The participant discussions during the 1-hour NGT session were aimed at eliciting the patient perspective or a patient-based definition of TJR failure. All groups were led by an experienced leader in NGT (JS, SG; neither known previously to participants) assisted by a research assistant (SM). Each NGT session began with introductions. At the beginning of the NGT session, we asked the group if the question was clear. The question was clarified, if necessary.

We provided each participant a sheet of paper with the question written on it and asked them to list as many items as they thought of, independently and silently, to answer the question. Next, in a round-robin fashion, each participant presented 1 response/idea at a time, and the responses/ideas were recorded verbatim by the facilitator on a flip chart visible to all participants. This phase continued until no new ideas were generated by the group. The groups then discussed and clarified the responses; responses were grouped together by NGT participants where thematically appropriate. In the final step, all ideas/responses were ranked and prioritized. Each participant voted for 3 responses deemed most important from 1 to 3 on an index card, with 3 being the highest vote; each participant had a total of 6 votes to distribute. We then created a rank-order for the listed ideas for each NG based on total votes/scores, with highest score corresponding to the top rank. All the discussions were recorded and transcribed; the accuracy of the wording of nominated responses was confirmed with these recordings. The sessions were continued until saturation was confirmed and no additional new responses were introduced.

RESULTS

We conducted 8 NG that included 42 participants (6 votes each; total 252 votes). Letter invitations to participate were sent to 746 potential participants who had undergone THR or TKR between 2016 and 2018; there were 592 people who received a phone call and 42 people agreed to participate and were included in 1 of 8 NG. Among participants, 48% were men, the mean age was 66 years (SD 14.6), 20 had undergone TKR, 19 had undergone THR, and 3 had had both THR and TKR. In our sample, 17% were Black, 64% were White, 5% were Hispanic, 2% were Asian, and 7% were multiracial; 79% had some college or more education, and 5% had high school education; 45% were employed for wages, 21% were self-employed, and 29% were retired (Table 1).

For participants who had undergone THR, 96% and 91% reported no/mild pain on stairs or walking on uneven surface, respectively. For participants who had undergone TKR, 74%, 87%, and 70% reported no/mild pain on twisting/pivoting, straightening knee fully, or climbing stairs, respectively (Table 2). Satisfaction was very high among the participants: 88% reported that they were very satisfied overall. Scores for satisfaction with pain relief, ability to do housework, ability to do recreational activities, and improved QOL were 95%, 91%, 88%, and 83%, respectively. Only 3 participants reported a postoperative complication after TKR or THR (worsening of diabetes,

Table 1. Baseline characteristics of study participants.

	Total, N = 42	Nominal Groups 1–6		Nominal Groups 7–8
		TKR or THR, n = 32	Both TKR and THR, n = 3	TKR or THR, n = 7
Age, yrs, mean \pm SD	66.0 \pm 14.6	71.1 \pm 9.6	66.3 \pm 5.4	40.1 \pm 6.1
Men	20 (47.6)	14 (43.8)	1 (33.3)	5 (71.4)
Race/ethnicity				
Black	7 (16.7)	6 (18.8)	–	1 (14.3)
Asian	1 (2.4)	–	1 (33.3)	–
Hispanic	2 (4.8)	–	–	2 (28.6)
Multiracial	3 (7.1)	2 (6.3)	–	1 (14.3)
White	27 (64.3)	22 (68.8)	2 (66.7)	3 (42.9)
Education				
High school	2 (4.8)	1 (3.1)	–	1 (14.3)
Some college	5 (11.9)	4 (12.5)	–	1 (14.3)
Trade/technical/vocational training	1 (2.4)	–	–	1 (14.3)
College or above	33 (78.6)	27 (84.4)	3 (100)	3 (42.9)
Employment				
Employed for wages	19 (45.2)	12 (37.5)	3 (100)	4 (57.1)
Self-employed	9 (21.4)	7 (21.9)	–	2 (28.6)
Homemaker	1 (2.4)	–	–	1 (14.3)
Out of work but not looking for work	1 (2.4)	1 (3.1)	–	–
Retired	12 (28.6)	12 (37.5)	–	–
Reason for surgery				
Osteoarthritis	32 (76.2)	24 (75.0)	3 (100)	5 (71.4)
Rheumatoid arthritis	3 (7.1)	3 (9.4)	–	–
Other arthritis	4 (9.5)	4 (12.5)	–	–
Fracture	1 (2.4)	–	–	1 (14.3)
Avascular necrosis of bone	2 (4.8)	1 (3.1)	–	1 (14.3)

Values are expressed as n (%) unless otherwise indicated. TKR: total knee replacement; THR: total hip replacement.

urinary retention, tachycardia/chest pain without cardiopulmonary complication).

The distribution of votes from group participants responding to the question, “When would you consider a hip or knee replacement to be a failure?” were as follows: (1) refractory index joint pain (80 votes); (2) occurrence of postoperative adverse events (54 votes); (3) unable to resume normal activities or go back to work (38 votes); (4) early revision surgery (35 votes); (5) little or no improvement in QOL (35 votes); (6) death (7 votes); (7) Other: nurse or physician issues/negligence (2 votes) and expectation-outcome mismatch (1 vote; Supplementary Table 1, available from the authors on request). All participant-nominated responses/responses are listed in Supplementary Table 2.

Refractory pain (80 votes). The most highly ranked response, which emerged from all 8 NG and achieved 80 of 252 total votes, was relief of pain. This construct included aspects such as no meaningful improvement in pain or worsening of pain or need to keep taking pain medication. A NG1 participant said, “Going into surgery there is so much pain that after surgery, you expect it to be reduced.” A NG4 participant commented, “In the beginning, before the surgery, when you have the pain and you try to turn at night, it wakes you. The idea of the surgery is to get rid of it. If it didn’t, then you arrive at the conclusion that you did [it] for no reason.” An NG5 participant said, “Pain is the primary factor for getting the surgery. Pain impacts every facet of my life. So, if you still have the same amount of pain as before the surgery, then it’s a failure.”

Occurrence of postoperative complications/adverse events (54 votes). This was the second most highly ranked response, which emerged from 7 of the 8 NG and received 54 votes. This included infection, implant rejection, nerve damage, implant allergy, medical complications including worsening of preexisting medical conditions, long-term or irreversible complication, and new health issues/problems that start after TJR. In NG1, a participant said, “An infection sets you back, it’s a psychological event — when does it get cured, do I have to go back for surgery. You start questioning everything. It’s a big response and a serious issue.” An NG4 participant commented, “The surgery is a failure if other health issues developed post-op that I didn’t have pre-op and were related to the surgery.”

Unable to resume normal activities or go back to work (Function; 38 votes). This was the third most highly ranked response, which emerged from 5 of the 8 NG and received 38 votes. This included inability to resume normal activities as before the arthritis affected the joint, continuation or persistence of the physical disability, or inability to regain normal function. In NG1, a participant said, “The whole purpose of surgery is to regain function. If you had the surgery and don’t have the range of motion, why do the surgery?” An NG3 participant said, “Going into surgery, we all expected a different amount of disability, but post-surgery you expect to regain your strength and mobility.”

Little or no improvement in QOL (35 votes). This was the fourth most highly ranked response, which emerged from 6 of the 8 NG and received 35 votes. This included no improvement in QOL, a

Table 2. HOOS/KOOS JR total and subscale scores and satisfaction in nominal group participants.

Instrument	Overall Score	Nominal Groups 1–8	
		None/Mild, n (%)	Moderate/Severe/Extreme, n (%)
HOOS JR, mean \pm SD	92.3 \pm 12.7, n = 21	n = 22	n = 22
Pain: on stairs		21 (95.5)	1 (4.5)
Pain: walking on uneven surface		20 (90.9)	2 (9.1)
Function: rising from sitting		20 (90.9)	1 (4.5)
Bending to the floor/pick up an object		20 (90.9)	–
Lying in bed		20 (90.9)	–
Sitting		20 (90.9)	1 (4.5)
KOOS JR, mean \pm SD	81.2 \pm 17.6, n = 18	n = 23	n = 23
Pain: twisting/pivoting		17 (73.9)	3 (13.0)
Pain: straightening knee fully		20 (87.0)	2 (8.7)
Pain: going up or down stairs		16 (69.6)	5 (21.7)
Function: standing up		17 (73.9)	4 (17.4)
Rising from sitting		17 (73.9)	4 (17.4)
Bending to floor/picking up an object		16 (69.6)	4 (17.4)
Stiffness		17 (73.9)	6 (26.1)
Nominal Groups 1–8, n = 42			
		Satisfied (very/somewhat), n (%)	Neutral or Dissatisfied (very/somewhat), n (%)
Satisfaction			
Pain		40 (95.2)	–
Ability to do housework or yard work		38 (90.5)	1 (2.4)
Ability to do recreational activities		37 (88.1)	3 (7.1)
Overall satisfaction		37 (88.1)	–
Improved quality of life		35 (83.3)	3 (7.1)

HOOS JR and KOOS JR are validated measures of hip and knee joint pain, and function/activity limitation. They were developed from the original, long versions of HOOS and KOOS, respectively, using Rasch analysis. HOOS JR contains 6 items (2 pain, 4 function items) and KOOS JR, 7 items (1 stiffness, 4 pain, 2 function items). Each item is scored 0 to 4, none to extreme, respectively, leading to raw total scores of 0–24 for HOOS JR and 0–28 for KOOS JR. These scores are converted to an interval score of 0–100, 0 representing total hip/knee disability and 100 representing total hip/knee health. Total number of participants was 42 (19 with THR, 20 with TKR; 3 had both TKR and THR). Of these, 19 provided data on HOOS JR survey only, 20 on KOOS JR only, and 3 provided answers on both HOOS and KOOS JR surveys. An overall score could be calculated on 21 HOOS and 18 KOOS, since 6 left before completing every question on the survey. Also, 37 participants provided complete data on satisfaction questionnaires; data here represent the total who answered each question. HOOS: Hip Disability and Osteoarthritis Outcome Score; JR: joint replacement; KOOS: Knee Injury and Osteoarthritis Outcome Score; THR: total hip replacement; TKR: total knee replacement.

continuing effect on QOL, and/or a low QOL. An NG1 participant said, “If I can’t go back to work, I can’t work and I can’t walk. The purpose of the surgery is to get back my life. Things are important to me, like going to the theater and cooking. It’s social, mental, physical and emotional.” An NG2 participant commented, “If one suffers from depression now, if depression has remained after the surgery, it would not be a success, it’d be a failure.” Participants attributed depression to index joint pain and disability. Said a participant from NG3, “It’s a failure when my QOL is still impacted. It’s about function and participation; when resumption of normal lifestyle has not happened.” An NG6 participant said, “One of the chief purposes of having the surgery is to regain my QOL. I wouldn’t want to reduce the QOL because it didn’t turn out to have a great outcome.” An NG6 participant said, “It’s a failure when you can’t return to your activities. Whatever your activity is—painting, working, stand[ing] on your feet all day at work.”

Early revision surgery (35 votes). This was the fifth most highly ranked response, which emerged in all 8 NG and received 35 votes. Most participants expected the joint replacement to last at least the 15–30 years that they were told the replacement would last and provide ongoing relief. In NG7, one participant said, “It’s considered a failure if revision happened sooner than later. Initially they said 10 years, so anything under 10 years would be bad.” Another NG7 participant said, “That (early revision) was a fear of mine, I did not want to go through it again. It brings on lack of confidence in physician and hospital.”

Death (7 votes). This was the sixth most highly ranked response, which emerged from 2 of the 8 NG and received 7 votes. One group stated death after the joint replacement as the definition of TJR failure regardless of any reason for death (if patient was otherwise healthy prior to the surgery). Another group specified that death has to be proven to be related to the operation itself or be related to infection, for it to be considered a failure of the

knee or hip replacement surgery. An NG4 participant said, “It’s a failure if you have definite proof that the operation itself caused death.”

Other: nurse/physician negligence (2 votes), outcome-expectation mismatch (1 vote). Among other domains, participants gave 2 votes to nurse/physician negligence, 1 vote to outcome-expectation mismatch, and 1 vote to the continuation of secondary depression; each of these were voted by 1 NG only.

Comparing NG7 and NG8, which included younger participants compared to the other 6 nominal groups, similar responses for definition of TJR failure were nominated by the younger participants (i.e., persistent pain, no improvement of QOL, and the occurrence of postoperative complications). Compared to 6 NG including all participants, in nominal groups with younger people, pain, QOL deficits, and complications together accounted for a higher proportion of all votes (66% vs 90%, respectively).

DISCUSSION

In a qualitative study using NG, we examined the patient perspective of a failed knee or hip TJR. Although we did not use a sampling technique, our sample included a diverse group of participants with a wide range in age (young and old), both sexes, different education levels, and a racial/ethnic mix of minorities. Our study cohort, with a mean age of 66 years, with > 50% women, and 64% White, was very similar to the US national cohorts undergoing THR²⁶ or TKR²⁷ from the National Inpatient Sample, and the 2017 American Joint Replacement Registry²⁸. Our investigation to define what constitutes a TJR failure identified several core domains listed in the recently finalized OMERACT TJR clinical trial core domain set of pain, function, satisfaction, revision, adverse events, and death^{24,29}, which was based on literature reviews and an iterative process with stakeholder input³⁰. Our findings further endorse the TJR core domain set in independent qualitative research with our study participants, who were unaware of the OMERACT TJR core domain set. Moderators chose the NG process in order to avoid bias, since this process mandates recording only patient-generated responses, without modification or interpretation.

Interestingly, nonsurgical themes (pain, function, QOL) received 61% (153/252) of votes, compared to the 35% (89/252) of votes for the surgical themes (complications, early revision, death). Participants identified functional TJR failure as important as, or more important than, a surgical TJR failure. Despite a wealth of literature on the modes of TJR failure^{10,31,32,33,34,35}, patient-reported outcomes post-TJR^{36,37,38}, and the predictors of persistent pain post-TJR³⁹, there are only limited qualitative data on the patient perspective^{17,18,19,20,21,22}. These studies focused on the patient’s journey through the entire process of TJR, covering a broad experience. To our knowledge, none of the previously published qualitative studies focused on defining TJR failure from a patient’s perspective. Patients aim to improve pain, function, QOL, productivity, and social participation with TJR. Our study provides insight into the patient perspective of TJR failure.

The most prominent contributors to a participant’s definition

of TJR failure were persistent joint pain, postoperative complications, functional limitation, little or no improvement of QOL, early revision surgery, and death. These findings have several important clinical and research implications.

By helping surgeons take the patient’s perspective of TJR into account, these findings can inform shared decision making for TJR. If participant, disease, and/or comorbidity factors indicate a very high probability of persistent index joint pain and/or functional limitation post-TJR, then shared decision making with the surgeon may lead to a decision not to perform TJR in some cases. In some people with functional TJR failure without a surgical failure, a consultation with a psychologist/psychiatrist for treatment of a mental health disorder, or a social worker to enhance social support, may be indicated.

Another clinical implication of our data is that a surgeon’s belief that surgical success equates to clinical success of TJR, and that surgical failure is the main cause of TJR failure, needs to be reexamined. While participants agreed that another surgery and/or post-TJR complications were important, they were far more focused on pain, function, and QOL as definitions of TJR failure, since these were the reasons that brought them to the surgeon and to TJR in the first place. The presence of perfect anatomic implant alignment with no surgical complications would still be called a TJR failure by patients if refractory pain, significant functional limitation, or QOL deficits were present, and/or failed to improve after TJR. In addition to understanding the surgical modes of TJR failure, the preoperative discussions must include a discussion of persistent pain and functional limitations and the likelihood of this outcome, considering patient characteristics. Thus, if the underlying patient-reported outcome deficits that led to the TJR persisted, it would be considered a TJR failure by most patients.

In this study, we recruited 2 NG of young people, since this group is increasingly receiving TJR⁴⁰. It was reassuring to see that the same responses were nominated in these groups as in the other 6 groups, with only a slightly higher emphasis on nonsurgical failures. Future studies are needed to determine if patient perceptions of success or failure of TJR differ by age and other patient characteristics.

Our study has several limitations. Participants may not have been representative of all patients undergoing knee/hip TJR, given high educational levels in our population and the geographic location (New York); however, they were similar in age and sex to patients in other knee/hip TJR studies, indicating the representativeness of this group. It is possible that the more satisfied TJR patients were more inclined to participate, and their views may not reflect the entire range of patient perspectives. Moreover, patients who undergo surgery at high-volume hospitals are reported to be more satisfied than those from lower volume hospitals, with similar functional outcomes⁴¹. We have included the results of patient-reported outcome measures so that characteristics of the cohort are clear. Few participants in our nominal group had postarthroplasty complications, which is expected, since TJR is mostly an elective surgery. We did not include or exclude participants based on the occurrence of postoperative complications, so it is unlikely that our sample over- or

underrepresents people with complications. Purposely sampling to identify more people with poor outcomes would be a consideration for future studies. A single high-volume surgical center is likely not representative of low-volume centers. We included 2 NG with younger participants, since their expectation of outcomes may have differed from those of older adults, and found similar responses in this group.

In conclusion, our qualitative study defined the patient perspective (definition) of a failed knee or hip TJR. The most prominent themes that emerged were refractory index joint pain, postoperative complications, functional limitation, little or no improvement of QOL, early revision surgery, and death. Participants defined constructs of what may be viewed as functional TJR failure. While the nominated responses for failed TJR included revision surgery and postoperative complications (intuitive reasons), they also included critical patient-reported outcomes that expect to see improvements with TJR. Participants identified a functional TJR failure as being as important as or more important than a surgical TJR failure.

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