When has a knee or hip replacement failed? A patient perspective

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Abstract

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

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 eight nominal groups with 42 participants, all of whom had undergone THR and/or TKR between 2016 and 2018. Of these, 48% were male, 17% 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: (1) refractory index joint pain (80 votes); (2) occurrence of post-operative 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 (QOL; 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).

Conclusions: 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 or more important than surgical failure. This patient perspective of TJR failure further confirmed their inclusion in core domain set for TJR clinical trials in people undergoing knee or hip replacements.

Keywords: Failure; Knee replacement; hip replacement; arthroplasty; qualitative; nominal group

Subtitle: Patient perspective: Knee/Hip replacement-failure

Introduction

Total joint replacements (TJR) are performed frequently as elective surgeries for people with symptomatic end-stage arthritis. Refractory pain, rest pain and functional limitation are the most common reasons for TJR (1-3). 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 (CMS) 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 program (4).

The TJR utilization rates continue to increase (5). 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 TJR (6). With an annual combined TJR utilization for knee and hip exceeding 1 million/year in the U.S. (7, 8), the number of people with an unfavorable knee/hip TJR outcome would range from 91,000 to 310,000 annually. This equates almost 1 million to 3.5 million Americans with an unfavorable TJR outcome over a decade. This 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 (9-13). In addition, persistent pain or persistent limitation of function or 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 TJR (14) highlighting the patient-surgeon discordance. Surveys of patient perspective of TJR have been published, but obtained little or no data addressing the question of TJR failure directly (15, 16). Qualitative studies focused on patient knowledge related to the TJR procedure and views about outpatient versus inpatient TJR (17), reasons for avoiding TJR (18), patient perspective of decision-making, postoperative care and rehabilitation

after knee TJR (19), patient experience of hospital stay, operation, and recovery of outcome after knee TJR (20), pre- and post-operative experience regarding knee TJR (21), and patient adjustment to chronic pain following knee TJR (22). 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 research (23).

The primary purpose of this study using nominal group technique (NGT) was to determine the themes that define TJR failure from the patients' perspective. 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 OMERACT (24), derived from multi-stakeholder input, including orthopedists, rheumatologists, patients, physical and occupational therapists, and patient advocacy leaders, including both clinicians and researchers.

Methods

We identified adults who had undergone elective knee or hip TJR at Hospital for Special Surgery (HSS), a high-volume orthopedic hospital (~10,000 TKR and THR performed annually) between 2016-2018. Potential participants eligible for the study, were identified by obtaining a list of all people who had undergone a primary, unilateral knee or hip replacement TJR by three participating surgeons (Drs. Figgie, Sculo, or Parks) without additional inclusion or exclusion criteria. The surgeons sent a letter to consecutive patients inviting them to participate in the nominal groups in January and February 2019. In case of non-response, the follow-up invitation was done with an e-mail or telephone call. In order to examine whether the perspective of younger patients differs from those across the age range, we conducted two nominal groups among participants aged 45 or younger. All participants provided informed consent. The study was approved by the institution's ethical review board (# 2018-2087). Refreshments were provided during the session.

The NGT is a highly structured group discussion format used to achieve group consensus around a specific topic (25), 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 nominal group question based on informal patient feedback in two clinics (JS and SG; authors), with patients choosing among three candidate questions. A 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 HSS patient conference room for NGT. After obtaining informed consent, participants completed a self-administered survey that included demographics, 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 blank sheet of paper with the question written on it and asked them to list as many items that they think of to answer the question, independently and quietly. Next, in a round-robin fashion, each participant presented one 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 three responses deemed most important from 1 to 3 on an index card, 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 nominal group 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 eight nominal groups 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; 592 people received a phone call and 42 people agreed to participate and were included in one of eight nominal groups. Among participants, 48% were men, the mean age was 66 years (standard deviation (SD), 14.6), 20 had undergone TKR, 19 had undergone THR, and 3 had had both THR and TKR. In our sample, 17% were African American, 64% were White, 5% were Hispanic, 2% were Asian and 7% were multi race. 79% had some college or more education, and 5% had high school education. 45% were employed for wages, 21% were self-employed, and 9% were retired (Table 1).

For the participants who had undergone THR, 96% and 90% reported no/mild pain on stairs or walking on uneven surface, respectively. For the participants who had undergone TKR, 74%, 87% and 70% reported no/mild pain on twisting/pivoting, straightening knee fully, or climbing stairs, respectively.

Satisfaction was very high among the group participants, overall 88% reported that they were very satisfied overall (Table 2). Satisfaction with pain relief, ability to do housework, ability to do recreational activities and improved QOL were 95%, 90%, 88%, and 83%, respectively (Table 2). Only three participants reported a post-operative complication after TKR or THR (worsening of diabetes, urinary retention, tachycardia/chest pain without cardiopulmonary complication).

The distribution of votes from the nominal group participants responding to the question "When would you consider a hip or knee replacement to be a failure?" were as follows (Appendix 1): 1) Refractory index joint pain (80 votes); 2) occurrence of post-operative 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). All participant nominated responses/responses are listed under Appendix 2 (see details).

Refractory Pain (80 votes): The most highly ranked response that emerged from all eight nominal groups 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 NG#1 participant said "Going into surgery there is so much pain that after surgery you expect it to be reduced." A NG#4 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 for no reason". A NG#5 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 Post-operative Complications/Adverse events (54 votes): This was the second most highly ranked response that emerged from seven of the eight nominal groups and received 54 votes. This included infection, implant rejection, nerve damage, implant allergy, medical complications including worsening of pre-existing medical conditions, long-term or irreversible complication, and new health issues/problems that start after TJR. In NG#1, 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". A NG#4 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 that emerged from five of the eight nominal groups and received 38 votes. This included inability to resume normal activities as before the arthritis impacted the joint, continuation or persistence of the physical disability, or inability to regain normal function. In NG#1, 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?" A NG#3 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 quality of life (QOL) (35 votes): This was the fourth most highly ranked response that emerged from six of the eight nominal groups and received 35 votes. This included no improvement in QOL, a continuing impact on QOL, and/or a low QOL. A NG#1 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 my back my life. Things are important to me like going to the theater and cooking. It's social, mental, physical and emotional." A NG#2 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 join pain and disability. Said a participant from NG#3 "It's a failure when my quality of life Is still impacted. It's about function and participation; when resumption of normal lifestyle has not happened". A NG#6 participant said "One of the chief purposes of having the surgery is to regain my quality of life. I wouldn't want to reduce the quality of life because it didn't turn out to have a great outcome." A NG#6 participant said "It's a failure when you can't return to your activities. Whatever your activity is — painting, working, stand on your feet all day at work."

Early Revision Surgery (35 votes): This was the fifth most highly ranked response that emerged in all eight nominal groups 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 NG#7, one participant said that "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 NG#7 participant said "That (early revision)

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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 that emerged from two of the eight nominal groups and received seven votes. One group 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. A NG#4 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 two votes to nurse/physician negligence and one vote to outcome-expectation mismatch and one to continuation of the secondary depression, from one of the six nominal groups each.

Comparing the NG#7 and NG#8 that included younger participants to other six nominal groups, similar responses for definition of TJR failure were nominated by the younger participants, i.e., persistent pain, no improvement of quality of life, the occurrence of post-operative complications. Compared to six NGTs including all participants, in NGTs with younger people, pain, quality of life deficits and complications received a higher proportion of all votes, 66% versus 90%.

Discussion

In a qualitative study using nominal groups, 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 that had a wide range in age group (young and old), both sexes, education level and racial/ethnic mix racial/ethnic minorities. Our study cohort with a mean age of 66 years, with >50% women, and 64% Whites is very similar to the U.S. national cohorts undergoing THR (26) or TKR (27) from the National Inpatient Sample (NIS), and the 2017 American Joint Replacement Registry (AJRR) (28). Our current work to define as to what constitutes a TJR-failure identified several core domains listed in the recently finalized Outcomes

Measures in Rheumatology (OMERACT) TJR clinical trial core domain set of pain, function, satisfaction, revision, adverse events, and death (24, 29), which was based on literature review and an iterative process with key stakeholder input (30). These study findings further endorse the TJR core domain set in an independent qualitative research with our study participants, who were unaware of the OMERACT TJR core domain set. Moderators chose the nominal group process in order to avoid bias, since this process mandates only listing of patient-generated responses, without modification, or interpretation.

Interestingly, non-surgical themes (pain, function, QOL) received 61% votes (153/252 votes), compared to the 35% votes (89/252 votes) for the surgical themes (complications, early revision, death). Participants identified functional TJR failure as or more important than a surgical TJR failure. Despite a wealth of literature on the modes of TJR failure (10, 31-35), PROs post-TJR (36-38) and the predictors of persistent pain post-TJR (39), limited qualitative data exist on the patient perspective (17-22). These studies focused on the patient 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 an insight into the patient perspective of TJR failure.

The top contributors to participant's definition of TJR failure were persistent joint pain, postoperative complications, functional limitation, little or no QOL improvement, 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 psychologist/psychiatrist for the treatment of a mental health disorder, or a social worker to enhance social support, may be indicated.

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Another clinical implication of our data is that surgeons' belief that surgical success equates clinical success of TJR and that the surgical failure is the main cause of TJR failure needs to be re-visited. While participants agreed that another surgery and/or post-TJR complications were important, participants 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 the 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 still present and/or failed to improve with the TJR. In addition to understanding of the surgical modes of TJR failure, the pre-operative discussions must include a discussion of persistent pain and functional limitations and the likelihood of this outcome, considering patient characteristics. Thus, if the underlying PRO deficits that led to the TJR persisted, it would be considered a TJR failure by most of the patients.

In this study, we recruited two nominal groups of young people, since this group is increasingly getting TJR (40). It was reassuring to see the same nominated responses in these groups as the other six groups, with only a slightly higher emphasis on non-surgical failures. Future studies need to explore if patient perceptions of success or failure of TJR differs by age, and other patient characteristics.

Our study has several limitations that must be considered while interpreting the findings.

Participants may not be representative of all patients undergoing knee/hip TJR, given high educational level in our study population and the geographical location (New York); however, they are similar in age and sex to TJR patients in other knee/hip TJR studies indicating 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 perspective. Moreover, patients who undergo surgery at high volume hospitals are reported to be more satisfied than those from lower volume hospitals with similar functional outcomes (41). We included the results of the patient reported outcome measures for transparency, so that the characteristics of the cohort would be clear to the readers. Few participants in our nominal group had postarthroplasty complications, which is expected, since TJR is mostly elective surgery. We did not include or

exclude participants based on the occurrence of postoperative complications, so it's unlikely that this sample over- or under-represents people with complications. Purposively sampling to capture the more people with poor outcomes would be a design consideration for future studies. A single high-volume center is likely not representative of low-volume orthopedic centers. We included two nominal groups with younger participants, since their expectation-outcomes may have differed from the 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 top-ranked themes were refractory index joint pain, post-operative complications, functional limitation, little or no QOL improvement, 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), it also included critical PROs that expect to see improvements in with TJR. Participants identified functional TJR failure as or more important than a surgical TJR failure.

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Table 1. Baseline characteristics of the study participants

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

SD=standard deviation; TKR=total knee replacement; THR=total hip replacement

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

Instrument	Overall	Nominal Groups #1-8	
	score	None/Mild	Moderate/Severe/Extreme
		N (%)	N (%)
HOOS JR* (mean ± SD)	92.3 ± 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 ± SD)	81.2 ± 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)
Sumess			nal Groups #1-8
		N=42	
		Satisfied	Neutral or Dissatisfied
		(very/somewhat)	(very/somewhat)
		N (%)	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 QOL		35 (83.3)	3 (7.1)
Ability to do housework or yard work Ability to do recreational activities Overall satisfaction		38 (90.5) 37 (88.1) 37 (88.1)	3 (7.1)

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The total number of participants was 42 (19 THR; 20 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 answer 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, the numbers above represent the total who answered each question.

*HOOS JR and KOOS JR are validated measures of hip and knee joint pain, and function/activity limitation. They were each developed from the original, long versions of HOOS and KOOS, respectively, using Rasch analysis. The 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 from 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.