

## **Research Article**

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# Reported Complications Following Total Knee Arthroplasty-Do We Need to Reconsider What, and How, to Measure and Classify Them?

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### Abstract

**Background:** Inadequate data is available regarding the patients' perspective of complications following total knee arthroplasty. A recent physiotherapy feasibility trial provided opportunity to explore patients' perspective of complications following total knee arthroplasty, and to reflect upon the extent to which these concur with the Knee Society's new Standardized List and Definitions of complications.

#### Purposes:

1. To explore if self report patient data collected post-operatively would provide a different picture of complications than is usually reported using data from medical notes.

2. To develop and describe an approach for a classification system to measure and report post-operative complications that is relevant for physiotherapists, surgeons and patients.

**Methods:** Prospective survey of patients' self reported complications and retrospective comparison of patient and medical record accounts of complications was performed during a prospective single blind randomised clinical trial (n=107). Patients were asked to self report complications at 3 and 12 months follow ups. Medical notes of patients reporting major specific complications were examined. Descriptive statistics were used. Self report data was classified into major and minor surgical and non-surgical complications.

**Results:** 12% (n=11/96) of participants self reported a total of 17 major complications at 3 months and 23% (n=22/96) reported 24 major complications at 12 months. 58% (n=56/96) reported 83 further complications. 38% (n=36/96) participants reported no further complications. Self reported data described greater variety regarding complications than previously seen. Data varied according to source (self report versus medical notes) and differed widely from the Knee Society's list. A possible classification system is presented and discussed.

**Conclusions:** Data are presented to stimulate debate regarding how complications should be defined and reported following interventions. Complications following arthroplasty are still being defined and measured by expert opinion. Discussion is needed regarding the collection, interpretation and relevance of complications data to both patients and all healthcare professionals.

Keywords: Arthroplasty; Physiotherapy; Complications

## Introduction

Inadequate data is available regarding the patients' perspective of complications following joint arthroplasty. The limited available research suggests the possibility that, as for expectations and outcomes of arthroplasty surgery [1,2], patients and health care providers may define and view complications differently [3]. The difficulty in defining what constitutes a complication is acknowledged [4]. UK data regarding complications currently concentrates upon intra-operative and acute post-operative complications plus joint prostheses survival rates [5,6] although the National Joint Registry is now collecting patient reported outcome data for future report. The Scottish Arthroplasty Project also collects data for anaesthetic complications such as stroke, acute myocardial infarction and acute renal rates; in addition to complications such as infection, mortality, deep vein thrombosis and pulmonary emboli. Earlier this year the Knee Society published its list and definitions of 22 complications and adverse events following knee arthroplasty to assist the evaluation of surgical results and patient outcomes [7]. This list was developed via a literature review and survey of Knee Society members, relying on expert opinion and not validated as yet by an analysis of patients with knee arthroplasty/ies or with the views of patients themselves.

Due to lack of data generated from a user's perspective it is unclear

what patients consider as complications following surgery. Evidence suggests between 15-30% of patients report little/no improvement, or dissatisfaction, following arthroplasty [8]. Problems following lower limb arthroplasty include persistent pain, impairment and functional limitations [9,10]; however we do not know if these are perceived as complications. Pain itself is not present on the Knee Society's recent list of complications which, though concerned with patient outcome, also does not include poor functional ability or dissatisfaction [7]. Explorations of patients' perspectives of outcome following elective orthopaedic surgery show areas of contradiction: participants reporting good outcome may also recount continuing pain and mobility problems [11] and orthopaedic patients may 'optimise' and

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re-interpret negative experiences and voice them more positively [12] . There is an evident need to understand complications that are perceived as important to patients, so that complications can be reported and addressed with the aim of improving patient outcome.

Whether patients and health care providers identify and view complications differently matters; complication rates provide information to assist patients and health care professionals with decision making about surgery [5]. The need to ensure that information is relevant to both patients and health care providers is clear. Additionally, the provision of information regarding complications that is relevant to patients is necessary to minimise the risks of provoking distress due to incongruence between patients' expectations and reality regarding recovery [13].

A recent trial comparing two physiotherapy interventions following elective primary total knee arthroplasty provided opportunity to ask patients about their post-operative complications [14]. We anticipated that self reported patient data at 3 and 12 months post-operatively would provide a broader picture of complications than is usually reported. We anticipated there would be both a difference in the reported rates of complications after surgery between patients' perception and hospital notes, and differing opinion about whether these health issues should be linked to the surgical episode. This is despite the hospital being recognised as an exemplar of good practice with a culture of high reporting for in-patient occurring incidents [15]. We intended to begin developing an approach to measure and report complications which would have relevance for both health professionals and patients and to stimulate debate amongst the orthopaedic community regarding the collection, presentation, interpretation and relevance of complications data.

## **Materials and Methods**

A contemporaneous record of patients' self reported complications plus a retrospective comparison of patient and hospital medical record accounts of complications was performed. The research was undertaken during a prospective single blind randomised clinical trial. This trial explored a post discharge functional physiotherapy intervention designed to improve patient function, versus usual physiotherapy, for osteoarthritis patients undergoing primary elective total knee arthroplasty (n=107) [14]. The primary outcome was the Oxford Knee Score [16] at baseline, 3, 6, 12 months. Data analysis included descriptive statistics and group differences between the two arms in mean/median change from baseline to each follow up point were calculated with 95% confidence intervals. The findings showed that, while groups were similar at baseline, the intervention group subsequently reported more major co-morbidities and underwent more other limb arthroplasties and revisions.

During all follow up trial assessments, occurring three month and twelve months post-operatively, participants were firstly asked directly whether they had experienced specific complications (Table 1). The specific complications included in the study were those already discussed with patients during existing follow up clinics (such as deep vein thrombosis) plus complications already identified in existing available literature (such as stroke).

Patients were then asked to tell the assessor about any other complications they had experienced. The assessors were senior physiotherapists who deliberately used the term "complications" with participants. The assessors did not define the term "complication" with patients; the latter were allowed to mention anything they wished and the assessor recorded patient's responses verbatim. The medical notes of patients who reported specific complications at their follow up assessments were examined by the lead author for all complications excepting transfusions (considered a minor complication by the hospital when less than two units) and superficial would infections (usually managed in primary care so unlikely to be in hospital notes). The three month time point was used because the majority of such complications were reported within the first three months with most patients discharged from hospital care by this time point. The medical notes were hand searched and any complications pertaining to the patient were recorded by the lead author. The data provided from both sources was discussed in depth by all authors. As a result of this discussion, a further literature review was conducted to inform the discussion regarding other classification schemes used to classify complications following orthopaedic surgery. PubMed searches included combinations of the following search

Complication	0-3 Month Follow up		4-12 Month Follow up	
No of participants with Percentage of no	No of participants with complications/ no of participants for which data was obtained	Percentage of no of participants for for which data was obtained	No of participants with complications/no of participants for which data was obtained	Percentage of no of participants for for which data was obtained
Deep infection	2/91	2%	0	
Deep vein thrombosis	2/91	2%	0	
Pulmonary embolus (requiring anticoagulants)	1/92	1%	0	
Intra-operative fracture	1/92	1%	0	
Chest infection	3/92	3%	16/93	17%
Haemorrhage requiring additional/ unexpected transfusion	10	11%	0	
Heart attack	1/92	1%	1/92	1%
Stroke /TIA	3/92	3%	2/92	2%
Pressure sores	3/92	3%	0	
Nerve damage with foot drop	1/92	1.1%	1/89	1%
Superficial wound infection (requiring antibiotics)	15/92	16%	0	
Further knee surgery (one revision TKA, one patellar resurfacing)	0		2/89	2%
Awaiting further investigation	0		2/89	2%

 Table 1: Patient self reported complications, given in response to specific questions following knee arthroplasty, for 0-3 months (n=92) and 4-12 months (n=93) post operative follow up periods.

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terms: complication/s, classification, orthopaedics, model, score, scale, scheme, self report, patient perspective. One evidence based classification of complications following total ankle arthroplasty was located which allocated intraoperative and post operative ankle related complications into high, medium or low grade complications depending upon their likelihood of leading to prosthetic failure [17]. Non ankle complications, such as anaesthetic events, emboli, or any additional complications likely to adversely influence outcome were not included within this classification.

We considered the approach of Paley in attempting to describe and classify complications after limb lengthening surgery as an exemplar [18]. Paley's approach explored the difficulties created from the lack of both standardisation and consensus regarding complications relating to surgery following Ilizarov limb lengthening procedures. Paley sub classified post operative difficulties into 3 categories; problems (difficulties that required no operative intervention to resolve), obstacles (difficulties that required an operative intervention) and complications. Complications were subdivided into "minor" and "major"; providing the basis of the development of a possible new way to incorporate and present complications following orthopaedic surgery in an attempt to facilitate discussion amongst patients, health care professionals and researchers, and to enable both healthcare professional and patient perspectives to be included as appropriate. This approach uses the term complication throughout because all the trial participants appeared to easily understand and relate to this term. Following discussions by the research team, the team decided to extend the known surgical complications and, by the inclusion of nonsurgical complications, enable the inclusion of medical conditions and other complications affecting rehabilitation and outcome. The self reported data for the specific and patient reported complications were sub-classified into major and minor surgical and non-surgical complications as follows:

#### I. Surgical complications: Ia) Major and Ib) Minor

**Ia) Major:** any local or systematic intraoperative or perioperative complication that either leads to a further operative procedure, is collected as national bench mark data or permanently limits the outcome of the surgery. Examples might include an intra-operative fracture or deep infection.

**IIa) Minor:** any local or systematic intraoperative or perioperative complication that does not require any further operative procedure or permanently limit the outcome of the surgery. Examples might be

a superficial wound infection, or unplanned blood transfusion being required.

#### II. Non-surgical complications: IIa) Major and IIb) Minor

**IIa) Major:** any non-surgery related post perioperative local or systemic problem which is either life threatening, delays discharge from hospital or which effects all stages of the rehabilitation process and is considered by patients &/or health care professionals or to permanently limit outcome. Examples might be new co-morbidities, such as stroke.

**IIb) Minor:** any non-surgical post perioperative local or systemic problem which resolves during the rehabilitation process and has no permanent effect on outcome, for example, swelling.

## Results

One hundred and seven participants were randomised in the trial. 98 participants underwent surgery within the trial period and were followed up. One participant withdrew and 1 participant died of causes unrelated to the trial in an accident. 96% (n=92/96) participants provided data about their complications three months after surgery and 97% (n=93/96) participants twelve months after surgery.

The self reported data described greater variety of complications than previously seen in the literature. Table 1 shows the findings for the specific questions. When minor complications (superficial wound infections and transfusions) were removed from this list, 12% (n=11/96) of participants reported a total number of 17 major complications occurring in the first three months. Another 83 further complications were reported by 56 (58%) participants when asked if they had experienced any further complications, with a minority of 36 (38%) participants reporting no further complications (Table 3).

The self reported number of major complications varied from the medical notes data when checked for the relevant participants (Table 2). The medical notes made no mention of deep infections for the two participants reporting them. These patients were not admitted to the Trust's Bone Infection Unit and did not need to attend clinics to manage bone infection; or receive IV antibiotic therapy. The medical notes also record the presence of a pulmonary embolus and deep vein thrombosis unreported by participants. The three early post-operative chest infections reported by participants were not mentioned in their medical records. Of the three pressure sores reported by patients, one was recorded in the medical records; other trial data sources, namely patient resource use diaries used during the trial, listed multiple

Complication	0-3 months Follow Up		4-12 months Follow Up	
	Mentioned by Self Report Yes/No	Mentioned in Medical Notes Yes/No	Mentioned by Self Report Yes/No	Mentioned in Medical Notes Yes/No
Deep Infection	Yes (n=2)	No (n=2)		
Deep Vein Thrombosis	Yes (n=2)	No (n=2)		
Pulmonary Embolus	Yes (n=1)	Yes (n=1) <sup>a</sup>		
Intra-operative fracture	Yes (n=1)	Yes (n=1)		
Heart attack	Yes (n=1)	Yes (n=1)	Yes (n=1)	No (n=1) <sup>b</sup>
Stroke/ TIA	Yes (n=3)	Yes (n=2) <sup>c</sup>	Yes (n=2)	No (n=1)°
Pressure sores	Yes (n=3)	Yes (n=1), No (n=2)		
Nerve Damage with foot drop	Yes (n=1)	Yes (n=1)		
Awaiting investigation			Yes (n=2)	Yes (n=2)
Further knee surgery			Yes (n=2)	Yes (n=2)

<sup>a</sup>medical notes included a DVT for this patient which was unreported by the patient.

<sup>b</sup>same patient reported this at both follow ups. Medical notes included a PE for this patient which was unreported by the patient. <sup>c</sup>n=1 medical notes unavailable to check.

Table 2: Consistency between specific self reported complications and patient's medical notes.

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primary health care visits to have pressure sores dressed for the remaining two participants.

The number of specific complications reported from the start of month four until the end of twelve months increased to 24 in 22 (24%) participants, largely due to 16 (17%) participants reporting chest infections during this time. One participant had undergone revision

Complication	0-3 Months Follow Up	4-12 Months Follow Up	
	Number of participants reporting complication		
Swelling & inflammation	4	6	
Continued pain		7	
Clips/Stitches (undissolved, left in, difficult to remove, causing ulcer)	6		
Excessive pain/nerve pain &/ or bruising	6		
Falls	5		
Limited flexion/range of motion	4		
Ankle pain and/or swelling limiting mobility	3		
Drain not working/falling out	3		
Haemarthrosis, haematoma	3		
Anaemia requiring medication (not transfusion)	2		
Blisters	2		
Cellulitis	2		
Depression, panic attacks	2	1	
Heat in knee since operation	2	1	
Numbness	2	1	
Chest pain	1		
Angina	1		
Foot coldness since operation	1		
Hamstring clicking during extension	1		
Ineffectual nerve block	1		
Joint clicking with pain	1		
Leg length discrepancy	1		
Post operative hypotension	1		
Problematic scar tissue	1		
Stomach bug	1		
Varicose eczema	1	1	
Wound Bleeding	1		
Knee cap rubbing on prosthesis		1	
Tibia and foot pain–awaiting scan results		1	
Knee itchiness		1	
Knee ligament injury after twisting knee		1	
Intermittent redness		1	
Opposite knee arthritis		1	
Partial Achilles rupture opposite leg		1	
Knee giving way		1	
Rash on knee		1	
Ruptured Bakers cyst		1	
Scar tissue in lateral ligament		1	

Table 3: Additional complications following knee arthroplasty self reported by patients, for 0-3months (n=92) and 4-12 months (n=93) post operative follow up periods.

arthroplasty, one participant had undergone patellar resurfacing and two further were awaiting the results of further investigations relating to their arthroplasties. Additional complications reported by participants are detailed in Table 3. The number of minor complications reported lessened over time, with 32 complications reported by a minority of 23 (24%) patients. The most common of these were 7 (8%) participants complaining of continued knee pain and 6 (7%) with swelling/inflammation.

The self report data was then classified into major and minor surgical and non-surgical complications. Table 4 shows the overall rates for the major specific complications presented in this way and the usefulness of this approach is debated in the discussion section.

## Discussion

Data is limited regarding the patient's perspective of complications following joint arthroplasty. This study asked patients about any complications they experienced following surgery, predicting that the findings would reveal a wider description of complications than previously reported and that patient self report data would vary from medical records. The development of an approach to capture and record complications, from the perspectives of patients and health professionals, was planned.

The study data is necessarily limited, being from one small trial exploring rehabilitation following total knee joint arthroplasty from a subsection of patients in one hospital. The data reported by patients is unrepresentative of the Trust's overall reported post-operative complications rates for this group and cannot be meaningfully related to national complication rates. It was not possible to further explore discrepancies between self report and medical records for some complications, notably patients reporting deep infection which, despite frequent clinical monitoring, were not recorded in the medical notes. This research aimed to identify and discuss an underresearched, clinically important topic and to capture the patient perspective, not to specify which complications should be measured. The research successfully rises questions contributing to the debate regarding what complications should be measured, by whom, and how. Also, the study did not ask patients or professionals to rank their perceived importance of complications or define them as minor or major.

As predicted, self report data (Table 2) demonstrated a wider variety of additional patient perceived complications than previously published. While well known complications, such as continued pain and restricted mobility [11] and stiffness [19], are included, so too are lesser known/unreported ones. These include relevant complications for rehabilitation such as depression and panic attacks following surgery [20], early falls [21], later falls, heat [22] and ankle pain. The data in Table 1 relates to complications identified from the literature before the start of the study. These complications, generally associated with surgery, are often similar to those in the recent Knee Society's list which also began with a literature review [7]. The most frequently raised complications in Table 3 however, pain, falls, long term

Complication type	0-3 months post op	4-12 months post op
Surgical Major la	5	5
Surgical Minor Ib	31	0
Non-surgical Major IIa	3	3
Non-surgical Minor IIb	3	16

 Table 4: Rates of patient self reported complications using the classification system, given in response to specific questions following knee arthroplasty, for 0-3 months (n=92) and 4-12 months (n=93) post operative follow up periods.

swelling/inflammation are not included in the Knee Society's list. The absence of pain in the Knee Society's list is particularly difficult to comprehend since the reported proportion of people with an unfavourable postoperative long-term pain outcome in studies ranges from about 10% to 34% after knee arthroplasty [23]. Even in the best quality studies about 20% of patients report long term pain following knee arthroplasty [23]. The Knee Society's list is predominantly concerned with initial and subsequent surgical interventions. The development of the list did not seek to include the opinions of patients directly or verify the validity of the list with them and therefore seems to miss out important complications regarding patient outcome. Although the purpose of the Knee Society's list does not specify an aim to assist patients to evaluate outcome following arthroplasty, the list does not appear to meet its stated purpose of assisting "surgeons, researchers, health plans, and government officials" to evaluate the "surgical results and patient outcomes after knee arthroplasties" [7] because important complications affecting outcome are absent.

The source of complication data influenced the data provided. Hospital notes generally included complications considered important to surgeons, such as DVT or deep infection, whilst patients reported a diverse list of complications perceived as important to their recovery. Patient perceptions regarding complications may and did vary from medical opinions of importance. Many medically considered "minor" complications were given great import by patients. The opposite was also seen when one participant never mentioned a medically important deep vein thrombosis and one did not mention having had a pulmonary embolus (recorded in their medical notes). The differing ratings of importance between patients and healthcare professionals is notable; generally medically perceived important complications are reported and patient perceived ones ignored, yet these may be highly correlated with satisfaction with outcome and need to be pursued, understood and managed.

There was no one accurate source of complications. Hospital notes did not always include complications reported by patients. Two out of three patients reporting pressure sores did not have this mentioned in their medical notes, although they were detailed in the trial's patient resource diaries. Self reported complications may also lack accuracy [3]. Two patients reported deep infections not included in the medical notes; it seems likely these were superficial infections since the Trust houses a specialist bone infection unit plus regular clinics specifically managing post-operative infection providing multiple recording routes. Additionally, complications arising post discharge in primary care did not always get recorded in hospital notes or in correspondence between primary and secondary care and it may be that surgeons remain unaware of them. This supports recent findings demonstrating that 65% of patients with complications did not present at their original treatment sites [3].

Another question is when should a co-morbid disease be classified as a complication? [4]. Some participants developed new co-morbidities during follow up and older people are at risk for multiple, comorbid conditions [4]. These co-morbidities, in some instances, were perceived by patients as permanently effecting postsurgical outcome. In this trial a comprehensive picture regarding complications appeared to be obtained using both hospital notes and patient self report; but it is unknown if using this combination would provide an adequate overview if the hospital data was collected prospectively, rather than retrospectively as in this study.

The study aimed to suggest a possible classification system for complications that arise following orthopaedic surgery

and rehabilitation. This approach aims to capture and describe postoperative complications of known relevance to surgeons, as well as non-surgical complications (incorporating the patients' perspective). In Table 3 and 4 the wealth of data from Table 1 and 2 is presented, breaking down the overall complications to more meaningful categories for the different groups of interested parties. For example, the rate of major surgical complications was much closer to that described in the hospital notes, the major non-surgical complications were of particular importance to us as rehabilitation trial lists during the research, whilst the variety of complications of concern to patients were also conveyed. The rates can be described briefly and in a format enabling planned subgroup analyses to evaluate the effect of complication rates upon outcome. Seemingly by chance, participants experienced more major complications than expected, thus becoming unrepresentative of the hospital population as a whole and possibly confounding trial findings. Further research is required to develop this classification system to become fit for purpose, to reconcile the classification of conflicting information from multiple data sources and to allow for the differing central reporting approaches in different countries, to adapt it for international use. Additionally, categories have not been tested to determine the extent to which they are predictive of outcome following surgery. Consensus work would be needed with patients and health professionals regarding which complications should fit within the four categories, as illustrated in Table 3: the bottom right hand cell number 16 is striking and predominantly refers to pneumonias/serious chest infections reported by patients as affecting their rehabilitation. Health professionals may consider a chest infection so long after surgery as unrelated to outcome and not a complication; the patient may still perceive this as seriously complicating their recovery. There is a clear need for both health professional and patient perspectives regarding complications to be further explored.

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