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A Randomized Controlled Trial to Establish Realistic Patient Expectations Following Total Knee Replacement Surgery

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Abstract

Objectives: To evaluate whether e-learning videos can affect whether patients felt their expectations were met and were satisfied with surgery 1 year following primary total knee replacement (TKR) (Chapter 3). In Chapter 4, we described characteristics of users and utilization patterns of the e-learning tool. In Chapter 5, we evaluated the internal consistency and construct validity of the new Knee Society Knee Scoring System (KSS) in a sample of TKR patients.

Methods: We recruited consecutive patients with osteoarthritis from the London Health Sciences Centre, Ontario, Canada (Chapter 3). We randomized patients with osteoarthritis to either control (n=207) they received our standard patient education, or intervention (n=209) they had access to the e-learning tool in addition to our standard patient education (Chapter 4). In Chapter 5 we pooled the RCT data to evaluate the measurement properties of the new KSS. We calculated the associations between KSS and Knee Injury and Osteoarthritis Outcome Score subscales to evaluate cross-sectional and longitudinal validity and divided patients into tertiles according to their Physical Component Score on the SF-12 and compared those scores to the scores on the KSS to determine known-groups validity. We also divided patients by their rating of pre- and post-operative expectations and compared their responses to those on the pre- and post-operative expectations scores of the KSS.

Results: There was no statistically significant difference between groups for expectations, RD=1.3% (95% CI -7.8% to 10.4%, p=0.78) or satisfaction, RD=0.6% (95% CI -8.4% to 9.6%, p=0.78) (Chapter 3). In Chapter 4 we found baseline characteristics of e-learning users were no different than nonusers and use of the tool was highest pre-operatively. Finally, surgeon videos that included content about expectations of surgery were most frequently viewed videos, pre- and post-operatively. In Chapter 5 we demonstrated the internal reliability, cross-sectional, longitudinal and known-groups validity of the KSS.

Conclusions: In Chapter 3, we failed to demonstrate the effectiveness of an e-learning tool and showed, in Chapter 4, a reduction in use of the tool over time. In Chapter 5 we provided evidence of the measurement properties of the new KSS, which was used throughout this thesis.

Keywords

Total Knee Replacement, Expectations, Satisfaction, Patient Education, E-Learning

Co-Authorship Statement

The three manuscripts within this dissertation are based on research conducted by the dissertation author, Sharon E. Culliton. Advisory committee members provided ongoing input for each of the three manuscripts. Sharon E. Culliton was the primary author of all the manuscripts, with advisory committee members providing editorial advice. We received funding from the Canadian Orthopaedic Research Legacy (CORL) and Western University, Department of Surgery Internal Research Fund (SIRF) to financially support this research.

Dedication

To my husband Robert Taylor for his love and support and in memory of my parents

George F. Culliton and Barbara M. Culliton.

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Chapter 1

1 Introduction

1.1 Overview

Aging is one of the most significant social forces that will shape our society over the next several decades [1]. Aging is the most important of all the known risk factors for osteoarthritis (OA) [2]. With it comes crippling pain in the affected joint, with loss of mobility. Total hip and knee replacement (THR/TKR) provide viable treatment options for individuals living and working with hip and knee arthritis [3]. The ultimate goal of TKR surgery is to relieve the arthritis knee pain, maintain or improve knee function and mobility, thereby improving quality of life and independence.

Successful TKR surgery improves the quality of life for those with chronic pain from OA by helping them function more independently [3]. Despite the success of TKR surgery, rates of patient 'dissatisfaction' with this procedure as high as 19% have been reported [4-14]. Consistent with this, TKR 'satisfaction' rates as low as 75% have been published [4-6, 8-18]. The differences in these percentages can be explained by variation in lumping strategies used for neutral and uncertain response options. These percentages for satisfaction with TKR surgery compare to 91% satisfaction for THR surgery [19].

Over the past several years the volume of TKRs in Canada has grown steadily [3]. In 2013-2014 there were 60,136 TKRs performed representing a five-year increase of 22.9% from 48,946 in 2009-2010 and a one year increase of 3.6% [3]. With this increase in the number of TKR surgeries in Canada, and the prevalence of OA predicted to affect over 10.4 million by 2040 [20] the number of patients who will be dissatisfied with their TKR will most certainly increase unless we address the problem in a way that allows surgeons to better manage patient expectations of TKR surgery.

1.2 Study Objectives

The primary objective of this doctoral research was to test an e-learning educational intervention tool among TKR recipients to determine if exposure to an e-learning tool

affects one year postoperative (i) patient expectations being met and (ii) satisfaction with surgical outcome in a randomized controlled trial (RCT). A secondary objective of this doctoral research was to use the intervention group data collected as part of the RCT to explore and describe the characteristics of users and their utilization of the e-learning tool. The e-learning tool provided information through videos to patients undergoing TKR surgery and followed them out 1 year postoperative. Patient education has been linked to promoting the recovery of and improved outcome following THR/TKR [21-23].

A third objective of this doctoral research was to evaluate the validity and internal consistency of the new Knee Society Knee Scoring System (KSS). This new metric was used in the RCT and it is a scoring system that was developed to better typify the current expectations, satisfaction, and physical activities of a younger, more varied population of TKR patients [24]. Ultimately, it is the patient's own assessment of satisfaction that is seen as an important measure of results after TKR [25, 26]. Therefore, an independent assessment of the new KSS tool adds to the body of knowledge for future researchers measuring patient expectations being met and satisfaction with TKR surgical outcome.

1.3 Structure of the Thesis

This thesis is organized into six chapters. Following the introductory chapter, Chapter Two presents a literature review, as it pertains to primary TKR surgery, patient expectations and satisfaction with TKR, managing expectations for TKR through patient education and the development of an e-learning tool. A conceptual framework is also provided in this chapter. Foundationally, the main outcomes of interest are patient expectations being met and satisfaction following TKR surgery.

The main results of this thesis are presented in a series of manuscripts written with the specific intent of submission to peer-reviewed journals. These manuscripts are presented in Chapters Three, Four and Five. Chapter Three includes the detailed methods and results from a RCT to determine if exposure to an e-learning tool affects patient expectations being met and satisfaction following TKR surgery. Chapter Four describes the characteristics and usage of the e-learning tool by patients assigned to the intervention arm of the RCT. Chapter Five was an evaluation of validity and internal consistency of

the new KSS tool. The new KSS tool provides a continuous measure of expectations and satisfaction and in the RCT, binary measures were used, it was highly relevant to determine the validity and internal consistency of this new tool, which was also used in the RCT of this thesis.

A discussion and conclusion of the thesis findings are presented in Chapter Six. The appendices provide supplementary material at a level of detail not typically required in peer-reviewed journal articles. Some duplication of material may be evident, specifically within the introductory and methods sections of the manuscript chapters. This is a consequence of using the integrated thesis format.

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Chapter 2

2 Literature Review

2.1 Introduction

2.1.1 Aging, Osteoarthritis and Total Knee Replacement

In 2015, for the first time in Canadian history, there were more people over the age of 65 than below 15 years of age. The aging proportion of the population is increasing and this trend will continue to accelerate as more baby boomers reach 65 years of age. This 'greying' of our society will have a profound impact on individuals, communities, and on our social and health services [1].

Osteoarthritis (OA) was formerly thought to be a usual consequence of aging [2]. It has been realized that OA is a result of a complex interplay of numerous factors, including joint integrity, genetics, local inflammation, mechanical forces, and cellular and biological processes [2]. For the majority of patients, OA is linked to one or more of these factors, such as aging, occupation, trauma, and repetitive, small insults over time [3]. These associations are greatest for OA of the knee and hand [3]. Osteoarthritis is characterized by pain and/or gradual loss of articular cartilage and changes to joint structures, leading to failure of the joint [4]. Osteoarthritis is one of the most frequent causes of pain, loss of function and disability in adults [5]. It is the pain and how it interferes with their quality of life that forces patients to seek medical help [6].

The greatest non-modifiable and modifiable risk factors for OA are aging and obesity respectively [7]. The Canadian population is aging. And as a result, OA, other chronic conditions and associated disabilities are expected to increase. The rising rate of OA and the aging population are expected to exert a significant burden on our health care and social systems [7]. Likewise, the increasing rate of obesity in the Canadian population is a major factor in the burden of chronic diseases in the aging population [3, 8, 9].

Felson et al. [10] found the association between weight and knee OA was stronger in women than in men. They found obesity was associated with the risk of developing both

symptomatic and asymptomatic OA [10]. More recently Blagojevic et al. [11] identified the main factors consistently associated with knee OA to be; obesity, previous knee trauma, hand OA, female gender and older age. They suggested, more longitudinal studies are needed to investigate the association of physical occupational and other patient-determined factors with future knee OA [11].

Age is the most important of all the known non-modifiable risk factors for OA [12]. Osteoarthritis is one of the primary causes of functional limitations in the aged with 10% of Canadians affected by this chronic condition [13]. Total hip and knee replacement (THR/TKR) are viable treatment options for those living and working with hip and knee arthritis [14]. Successful TKR reduces pain and improves physical function in over 90% of patients [15, 16].

Unicondylar or unicompartmental knee replacement (UKR) is the main surgical alternative to TKR in patients with end-stage UKR tibiofemoral OA of the knee [17]. Its advantages over TKR are; less tissue resection, lower morbidity and mortality and faster recovery [18-21]. Additionally, UKR restores the normal kinematics of the knee, providing better function [22-24].

However, in spite of these advantages, UKR is associated with a significantly higher rate of revision as reported by national joint registries [25-27]. Most knee surgeons perform no UKRs, and those who do often perform only a few UKRs [28]. Despite this, most knee surgeons believe UKR to be an effective operation for the ‘ideal’ patient [29].

Leta et al. [30] examined the state of revision UKR and revision TKR among patients in the Norwegian Arthroplasty Register. They found that the functional and survivorship outcomes of revision TKR did not appear to be much different from those of revision UKR. Leta et al. [30] identified that surgeons can expect revision TKR to be a lengthier, more difficult procedure with a greater risk of infection. And that patients facing the initial decision between UKR and TKR should likely focus more on differences in perioperative morbidity, clinical outcomes, and satisfaction [31, 32] and the likelihood of a future revision given their age and their level of activity [24].

Baker et al. [33] found no difference in improvement at six months in either knee-specific or general health patient-related outcome measures (PROMs) between UKR and TKR in a large cohort of registry patients. They identified PROMs data as being unique in reporting the patient's perception of outcome, and they identified this to be of prime interest to surgeons. Baker et al. [33] were concerned about the significantly higher revision rates for UKR observed in other registries worldwide. They therefore questioned the widespread use of UKR if it did not provide a significant clinical benefit to patients.

Surgical volume has previously been shown to be an important predictor of success after UKR [26, 28, 34]. Though, the prevailing principle has been to achieve the best results. UKR should be offered to only the most 'ideal' patients, these comprise as few as 4% to 6% of all patients presenting for arthroplasty of the knee [35-37].

The majority of patients with end-stage OA, if indicated, proceed to have TKR surgery. The result was a five-year increase of 22.9% in the number of TKR procedures in Canada for 2012-2013 [14]. With the prevalence of OA predicted to increase, reaching over 10.4 million Canadians by 2040 [38]. Recognizing these numbers are rising in Canada, the percentage of patients dissatisfied with TKR will most certainly increase, unless we address this problem of patient dissatisfaction, to allow surgeons to better manage patient expectations of TKR surgery.

2.2 Conceptual Framework

The conceptual framework for this thesis is based on two models; the Expectation Confirmation Theory (ECT) model (Fig. 2-1) developed by Oliver [39, 40] and the Health Related Quality of Life (HRQOL) model (Fig. 2-2) by Wilson and Cleary [41]. Following some key definitions, an overview of the ECT model and HRQOL model will be presented prior to a discussion of the application of both models (Fig. 2-3) as an explanatory conceptual framework for this thesis.

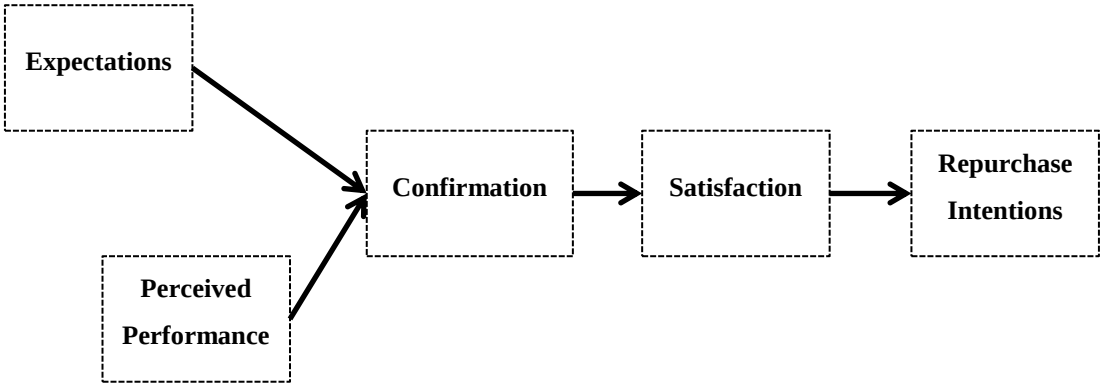


Figure 2-1: Expectation Confirmation Theory model.

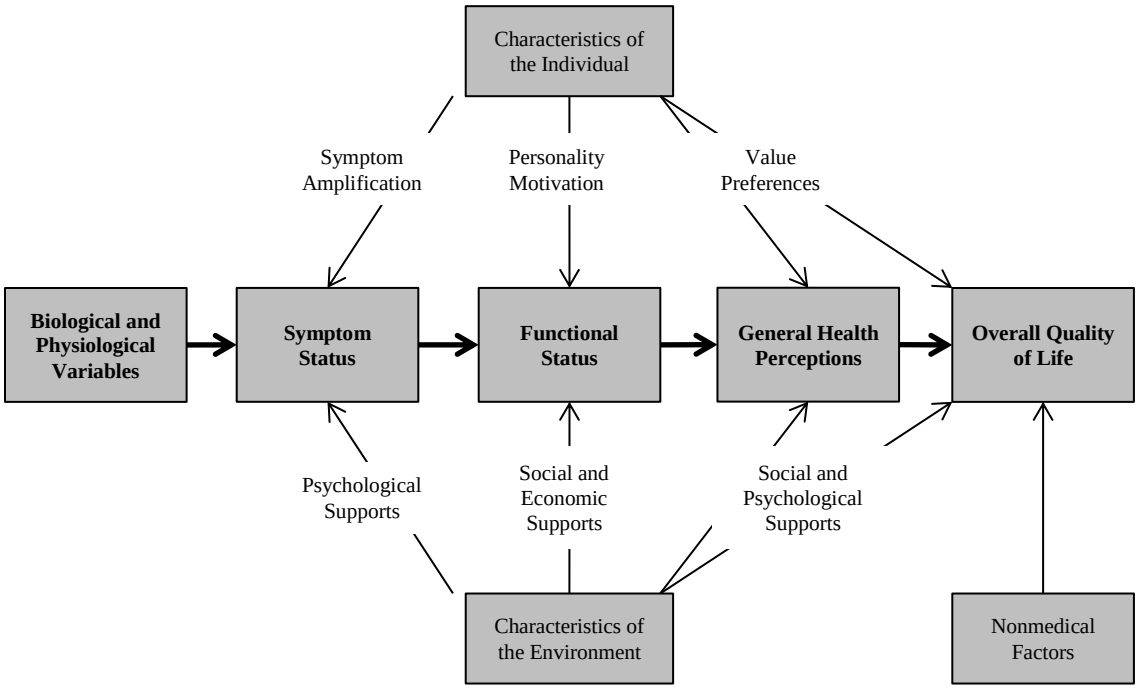
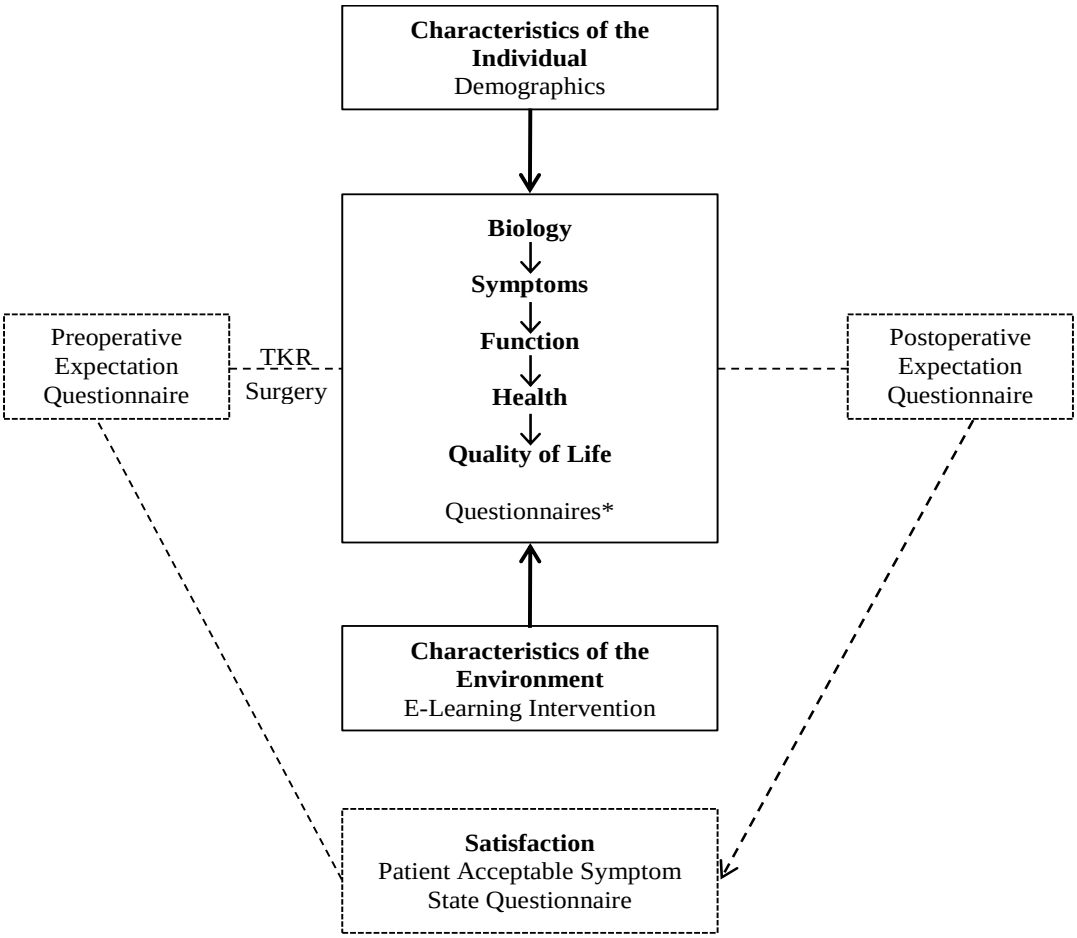


Figure 2-2: Health related quality of life model. From p.60 of Wilson IB, Cleary PD. Linking clinical variables with health related quality of life. A conceptual model of patient outcomes. JAMA. Jan 4 1995; 273(1):59-65. Used with permission by JAMA.



*Questionnaires:
SCQ: Self Administered Comorbidity Questionnaire
New KSS: New Knee Society Knee Scoring System
KOOS: Knee Injury and Osteoarthritis Outcome Score
SF-12: The Medical Outcomes Study 12-Item Short Form Health Survey, version 2
HADS: Hospital Anxiety and Depression Scale
PCS: Pain Catastrophizing Scale
SRPQ: Social Role Participation Questionnaire
UCLA: University of California Activity Scale Los Angeles

Figure 2-3: Revised Wilson and Cleary model for health related quality of life. Adapted from "Linking Clinical Variables with Health Related Quality of Life: A Conceptual Model of Patient Outcomes," by I.B. Wilson and P.D. Cleary, 1995. Copyright by JAMA. Used with permission by JAMA.

2.2.1 Definitions

Patient Expectations

A definition of *expectation* is a belief something will happen or is likely to happen [42]. Razmjou et al. [43] used the following as a working definition of expectation; it is 'anticipation' that a given event is likely to occur as a result of medical care. This is different than it being a 'desire' which reflects wishes that a given event would occur. More recently, Dyck et al. [44] also identified expectations could be interpreted in two ways: 1) Value based expectations expressed as what changes an individual 'would like' to have facilitated by the treatment; and 2) Probabilistic expectations meaning what an individual believes will be the 'most likely' result from the treatment. The term patient expectations used throughout this thesis applies to the definition by Razmjou et al. [43] and Dyck et al. [44] as an 'anticipation' of a value based expectation of what patients 'would like' to have as an outcome for their TKR surgery.

Patient Satisfaction

To define *satisfaction,* it is the act of providing or fulfilling what is needed or desired [42]. From a clinical perspective satisfaction has two related but separate concepts [45]. The first is the outcome of care or treatment referred to as the 'Product' [45]. The other concept of satisfaction refers to the process of care referred to as the 'Service' [45]. The measurement of patient satisfaction truly is an elusive and complex concept because it is a multidimensional construct that has not necessarily been well defined particularly for orthopaedic surgery [45]. With this in mind, the term patient satisfaction used throughout this thesis refers to the 'Product' or outcome the patient receives as a result of their TKR surgery. Bourne [46] and others [47-51] confirmed that meeting patient expectations was of the utmost importance in order to achieve patient satisfaction after primary TKR surgery.

E-Learning

Electronic learning or e-learning [52] is the application of information technology to education [53, 54]. The term e-learning used throughout this thesis uses the definition by

Gunasekaran et al. [52] meaning an electronic learning educational intervention tool provided to patients before and after surgery.

Health Related Quality of Life

Health related quality of life (HRQOL) refers to the extent an individual's usual or expected physical, emotional, and social wellbeing are affected by a chronic condition and/or by its treatment [55, 56]. This definition of HRQOL reflects the dimensions of health included by the World Health Organization [57]. The ultimate goal of health care is to restore or preserve an individual's functioning and wellbeing related to HRQOL. The purpose of HRQOL measurements is to quantify the degree to which a chronic condition like OA or a procedure such as TKR surgery impacts an individual's life [58]. HRQOL is an important indicator to capture the burden of a chronic condition [58].

2.2.2 Overview of Expectation Confirmation Theory Model

The ECT model originated from the business marketing field. The ECT was a model initially proposed by Oliver (1980) [39, 40]. It has been extensively used in the psychology and marketing literatures. It has since been adopted in many other fields, especially information systems and consumer behavior literature to study customer satisfaction, service marketing and repurchase intentions [40, 59-63].

The ECT model has five primary constructs: (1) expectations, (2) perceived performance, (3) dis/confirmation of beliefs, (4) satisfaction and (5) repurchase intentions. These constructs parallel the following measures used in this thesis (1) preoperative expectations, (2) postoperative PROMs, (3) postoperative expectations (4) patient satisfaction and (5) contralateral TKR surgery, respectively.

2.2.3 Application of ECT Model

Medical e-learning technology has been widely employed to create online platforms for patients and healthcare providers [64]. However, there are few if any studies that have tested an e-learning tool for patients undergoing TKR surgery. This study used the ECT model to better understand factors leading to patients' expectations being met and satisfaction at one year postoperative with TKR surgery.

The ECT model theorizes that satisfaction is determined by the interplay of prior expectations and the perception of a product. There are many applications in research and practice that employ an ECT model [65]. The following section provides an overview of the ECT model, and then explains the application of the ECT model in combination with the HRQOL model used as a conceptual framework for this thesis.

2.2.4 Conceptualization of ECT Model

The concept behind the ECT model is simple (Fig. 2-1). Prior to any event, individuals have expectations. An expectation refers to what a person anticipates will be associated with an entity such as a product or service. If that expectation is met in a positive manner, then they are satisfied. If that expectation is met in a negative manner, then they are dissatisfied. It is this simplicity that makes the ECT such a powerful explanatory theory [65]. This thesis was not intended to be a formal test of the ECT model. Its primary purpose is to use the ECT to identify the constructs of the model and their relationship to patient expectations being met and satisfaction with TKR surgery.

Based on the ECT, patients scheduled for TKR make a decision to proceed or not with this planned surgical procedure. Patients undergoing TKR, determine after having had TKR surgery if the ‘product’, the outcome of their TKR surgery, meets or exceeds their expectations. If so, then they are satisfied. If the ‘product’ the outcome of their TKR surgery fails to meet their expectations, then the patient is dissatisfied [65].

The two component considerations of the ECT model are prior expectations (preoperative expectations) and perceived performance (postoperative expectations) [63]. There are concerns about the measurement of any ‘gap’ between these two constructs, the true relationships of each of theses unique constructs to satisfaction, and the kinds of analytical methods used to measure the gap between pre- and postoperative expectations. According to the ECT model, satisfaction is affected by disconfirmation and expectations. Disconfirmation indicates the gap or the difference between preoperative expectations and perceived performance or satisfaction [63]. This gap measures quality of life and determines if a patient is satisfied or dissatisfied with their HRQOL following TKR surgery.

Foundationally, we began with the ECT model (Fig. 2-1) developed by Oliver [39, 40] with its five primary constructs. Before undergoing TKR, patients have expectations (top left box). Following TKR patients assess their TKR outcomes or perceived performance (bottom left box). The TKR outcomes or perceived performance(s) of most interest to the patient are improved physical function and reduced bodily pain [66]. This leads to confirmation or disconfirmation when expectations are met or not met, and in turn this determines if satisfaction or dissatisfaction is achieved. Satisfaction achieved or not, may affect whether a patient, if indicated, proceeds to have a contralateral TKR surgery. Proceeding to have a contralateral TKR, if indicated, is akin to repurchase intentions (right most box).

Total knee replacements have been associated with significant recovery in one's HRQOL [67, 68]. Bakas et al. [69] recommended Ferrans et al. [70] revision of Wilson and Cleary's [41] model because of their addition of individual and environmental characteristics to the Wilson and Cleary [41] model. This was done in an effort to better explain HRQOL. Bakas et al. [69] endorsed the use of one model such as the Ferrans et al. [70] model to assist in comparing HRQOL across studies and populations.

2.2.5 Overview of Health Related Quality of Life Model

Wilson and Cleary [41] proposed a conceptual model to specify how different types of patient outcome measures interrelate. They presented health status and HRQOL as a continuum of increasing biological, social and psychological complexity. Their model specifies the interconnected nature of these variables with the Characteristics of the Individual and the Characteristics of the Environment [41].

2.2.6 Application of HRQOL Model

The model (Fig. 2-2) is made up of five levels (five center boxes) and represents the continuum that exists between: biological and physiological factors, symptom status, functional status, general health perceptions, and, overall quality of life (QOL). Biological and physiological factors are all those aspects of the individual that are commonly measured in routine clinical practice: diagnoses, laboratory values, physical assessment findings [41]. Symptom status, generally causes individuals to seek health

care and are a valuable part of treatment along with biological and physiological factors [41]. Functional status assesses the ability of the individual to perform specifically defined tasks. The minimum four domains of functioning that are commonly measured are: physical function, social function, role function, and psychological function [41]. General health perceptions provide a subjective component, recognizing that individual perceptions are an important judge of functional status [41]. Overall quality of life is the outcome of the cumulative effects of all of the other levels that make up the model.

Characteristics of the Individual (top box), factor into the model as affecting symptoms, functional status, general health perceptions and the overall quality of life. This is indicated by the arrows aimed from Characteristics of the Individual identified as the psychological variables, such as personality, motivation and personal values influencing the biological and physiological levels in the middle of their model. Similarly, Characteristics of the Environment (bottom box), in terms of psychological, social and economic supports, impact each one of the levels as illustrated by the arrows directed from Characteristics of the Environment towards the biological and physiological levels in the center of their model [41] as well.

2.2.7 Conceptualization of HRQOL Model

In 1988, Cleary & McNeil [71] identified that researchers and clinicians were becoming increasingly attentive to the patients' perspectives on illness and medical care. They identified, understanding and fulfilling patients' needs as an inherent goal of medicine. Likewise, Graham et al. [45] recognized that clinicians have begun to acknowledge and understand the importance of PROMs. Measuring PROMs that concern patients are an important element in understanding patients' expectations and satisfaction as employed in this thesis.

Wilson and Cleary's model [41] provided an initial framework for identifying the relationship between the research hypotheses in this thesis and the impact of an e-learning tool. Ferrans et al. [70] published a revision of Wilson and Cleary's [41] HRQOL model. The five major domains of the original model were retained. Ferrans et al. [70] simplified the model by removing the non-medical factors and the labels on the

accompanying arrows that portrayed the relationships in Wilson and Cleary's [72] model, original figure (Fig. 2-2). Ferrans et al. [70] revised conceptual model has been applied to this thesis (Fig. 2-3) with only a single directional arrow used for both, the Characteristics of the Individual and the Characteristics of the Environment towards the biology, symptoms, function, health and QOL in the center of their model.

2.2.8 Measuring Patients' Expectations, Pre- & Postoperative & Satisfaction

Preoperative Expectations

Studies that have analyzed preoperative expectations in patients undergoing TKR are shown in Table 2-1. The table highlights how researchers in this area have used seven different instruments or sets of questions. Ordinal response scales have been used; but the analytic approach with these scales has varied from using the raw scale for individual items [43, 73], to summed scales across items [74-77], to dichotomized individual items [78-80] or pooled then dichotomized items [50], or summed and transformed to percentages [81], or simply using percentages [82].

Table 2-1: Preoperative Expectation Studies

Study (year)	Instrument used	Response scale Measured	Response scale Analyzed
Mancuso et al (2001)	HSS Knee Replacement Expectations Survey	17 Items; 5-point Ordinal	Summed scale
Mahomed et al (2002)	Toronto Western Hospital Scale	4 Items; 4-point Ordinal plus VAS	Pooled then dichotomized
Lingard et al (2006)	4 questions	4 Items; 5-point Ordinal	Dichotomized
Mannion et al (2009)	*Total Arthroplasty Outcome Evaluation Questionnaire	2 items; 3 & 4-point Ordinal	Raw scale
Razmjou et al (2009)	Holland Orthopaedic & Arthritic Centre Expectation Questionnaire	6 items; 4 & 5-point Ordinal	Raw scale
Vissers et al (2010)	3 questions & VAS	3 Items; 4-point Ordinal plus VAS	Dichotomized
Becker et al (2011)	*HSS Knee Replacement Expectations Survey	15 Items; 5-point Ordinal	Summed scale
Hepinstall et al (2011)	HSS Knee Replacement Expectations Survey	17 items; 5-point Ordinal	Summed scale
Yoo et al (2011)	HSS Knee Replacement Expectations Survey	17 Items; 5-point Ordinal	Dichotomized
Noble et al (2012)	new Knee Society KSS	3 items; 5-point Ordinal	Summed scale
Scott et al (2012)	*HSS Hip Replacement Expectations Survey	17 Items; 5-point Ordinal	Percentages
Tekin et al (2012)	*HSS Knee Replacement Expectations Survey	15 Items; 5-point Ordinal	Summed & transformed to percentages

* Used a modified version
HSS=Hospital for Special Surgery; VAS=Visual Analogue Scale; KSS=Knee Scoring System

Table 2-1 also emphasizes the diversity in the analytic approach used to quantify preoperative expectations as ordinal scales were used in six studies that measured preoperative expectations [74-76, 80-82]. These six studies used five-point ordinal response scales, where patients were asked to report the ‘level of importance’ for a

particular item in the treatment of their knee [74-76, 80-82]. All six studies employed the Hospital for Special Surgery (HSS) Knee Replacement Expectations Survey [74] or a modification of this survey [75, 81]. The HSS Knee Replacement Expectations Survey lists clinical outcomes as expectations and requests patients to assign a level of 'importance' to those specific expectations.

In contrast to this Razmjou et al. [43] took preoperative expectations that were important to patients undergoing TKR and distinguished between the concepts of 'hope' and 'realistic anticipation' or the 'likelihood' of an event taking place. A written explanation discerning between these terms was given in their questionnaire. Razmjou et al. [43] had created a six item, non-joint specific expectation questionnaire from the literature [50, 74, 83] and expert opinions. Razmjou et al. [43] found all but two items showed significant association with patients' preoperative expectations measured in their study. There were the four significant patients' preoperative expectations of (pain relief; ability to perform ADL; ability to return to previous leisure, recreational, or sports activities; and perception of the potential to achieve full recovery following surgery).

Mancuso et al. [74] and Noble et al. [84] are the only two studies that provided validation and reliability work on their instruments used for measuring TKR patients' preoperative expectations. Mancuso et al. [74] developed the HSS Knee Replacement Expectations Survey, to be used preoperatively for patients undergoing TKR. The tool was patient-derived therefore it provided face validity. An orthopaedic panel was consulted to review the questionnaire in order to guarantee content validity [74]. Preoperatively, patients were posed with open-ended questions about their expectations of TKR surgery. Patients' responses were then grouped to generate categories of expectations. These categories were then transformed into specific questions and organized into a draft survey for patients undergoing TKR. Mancuso et al. [74] enrolled a second sample of patients (n=163) for the survey-testing phase, these patients completed the draft survey on two separate occasions to establish test-retest reliability. Mancuso et al. [74] selected items for the final survey if the items were cited by $\geq 5\%$ of the patients, if they represented vital functional changes stemming from surgery, or if they represented inappropriate or possibly unrealistic expectations. All of the selected items demonstrated test-retest

reliability (kappa values = 0.4 to 0.8), or were considered clinically relevant by an orthopaedic panel [74]. Unfortunately, Mancuso et al. [74] asked patients to score the 'importance' of their preoperative expectations and this does not align with the ECT model. This is because the ECT model refers to patients' preoperative expectations as having a 'likelihood' of occurring.

Applying the ECT model (Fig. 2-1) to patients undergoing TKR meant recognizing patients develop their own preoperative expectations (top left box). The concepts of 'realistic anticipation' or 'likelihood' of an event occurring describe preoperative expectations that align with the ECT model. Therefore, the following studies that employed questionnaires using the term 'hope' or 'importance' of patients' preoperative expectations are not in alignment with the ECT model [73-76, 78, 80-82]. Mancuso et al. [74] used the word 'important' in the HSS Knee Replacement Expectations Survey, Lingard et al. [78] likewise used 'importance' in their response for patients ranking their preoperative expectations. Mannion et al. [73] used the word 'importance' to refer to patients' expectations of decreasing pain and increasing function, as described in the Total Arthroplasty Outcome Evaluation Questionnaire by Katz et al. [85]. Additionally, the studies by Becker et al. [75], Hepinstall et al. [76], Yoo et al. [80], Scott et al. [82], and Tekin et al. [81] all having used the HSS Knee Replacement Expectations Survey or a modification of it, do not align with the ECT model since the word 'important' was used in the HSS Knee Replacement Expectations Survey.

The remaining four studies [43, 50, 79, 84] measured patients' preoperative expectations as 'realistic anticipation' or the 'likelihood' of an event occurring. The first to do so was Mahomed et al. [50] who asked questions that included expectations of pain relief, limitations in activities of daily living (ADL), likelihood of overall success of the surgery, and likelihood of joint related complications. The following studies by Razmjou et al. [43], Vissers et al. [79] and Noble et al. [77] based their preoperative expectation questionnaires on the work done by Mahomed and colleagues [50]. All incorporated the terminology of 'likelihood' when posing preoperative expectation questions to patients to varying degrees. However, it was Razmjou et al. [43] that specifically defined

preoperative expectations as those referring to the ‘likelihood’ of an event occurring in their preoperative expectation questionnaire that most closely aligns with the ECT model.

Noble et al. [77] developed the new Knee Society Knee Scoring System (KSS). Initially, patients (n=101) who had undergone unilateral TKR were provided with a pool of generated questions. From the responses to these questions, a prototype knee-scoring tool was developed and was given to 497 patients (254 preoperative, 243 postoperative at 1 year). Both objective and subjective data were analyzed using standard statistical and psychometric procedures and then compared to the Knee Injury and Osteoarthritis Outcome Scores (KOOS) and the Medical Outcomes Study12-Item Short Form Health Survey, v2 (SF-12) scores for validation of the tool. The subjective component was developed as a patient-reported outcome measure from responses in the following domains: satisfaction, with outcome (12 items; 100 points), preoperative expectations (3 items; 15 points), or postoperative expectations (3 items; 15 points), and the ability to perform functional activities (21 items; 110 points).

Preoperative expectation questions queried the following: relief of pain, ability to perform leisure, recreational and sports activities and activities of daily living. After the statistical analysis, minor modifications were made producing the final tool. Noble et al. [77] found their statistical analysis confirmed internal consistency and cross sectional convergent validity, of the separate subscale measures in the new Knee Society KSS tool.

In contrast to Mancuso et al. [86], the preoperative expectations measured by Noble et al. [77] do align with the ECT model, as they refer to the perceived ‘likelihood’ of patients’ outcomes. Noble et al. [77] had developed the new Knee Society KSS tool to provide sufficient flexibility and depth in order to capture the diverse lifestyles and activities of current patients now undergoing TKR [77]. They had noticed that current patients often have expectations, demands, and functional requirements that were different from previous generations of patients who underwent TKR [77]. Unfortunately, the final version of the tool developed by Noble et al. [77] has not been independently validated.

Postoperative Expectations

Studies that have analyzed postoperative expectations in TKR recipients are shown in Table 2-2. This table shows how researchers in this area have used five different instruments or sets of questions and used; either nominal or ordinal response scales. The analytic approach has varied depending on the type of response scales used with the instruments or questions; nominal response scales were analyzed as trichotomized individual items [46, 87] or with both dichotomized and trichotomized individual items [51]. Ordinal response scales were analyzed in the following ways; using a change scale for individual items [73] or summed individual items [75, 88] [77], dichotomized individual items [79], to means transformed to trichotomized individual items [89], or simply using percentages [82].

Table 2-2: Postoperative Expectation Studies

Study (year)	Instrument used	Response scale measured	Response scale analyzed
Noble et al (2006)	Total Knee Function Questionnaire	3 items; Nominal	Dichotomized & Trichotomized
Mannion et al (2009)	*Total Arthroplasty Outcome Evaluation Questionnaire	2 items; 3 & 4-point Ordinal	Change scale
Bourne et al (2010a)	1 question	1 item; 3-point Nominal	Trichotomized
Bourne et al (2010b)	1 question	1 item; 3-point Nominal	Trichotomized
Scott et al (2010)	1 question	1 item; 6-point Ordinal	Summed scale
Vissers et al (2010)	4 questions	4 items; 4-point Ordinal	Dichotomized
Becker et al (2011)	*HSS Knee Replacement Expectations Survey	15 items; 5-point Ordinal	Summed scale
Noble et al (2012)	new Knee Society KSS	3 items; 5-point Ordinal	Summed scale
Scott et al (2012)	*HSS Hip Replacement Expectations Survey	17 items; 5-point Ordinal	Percentages
Kim et al (2015)	9 questions	9 items; 11-point VAS	Means transformed to Trichotomized

* Used a modified version
HSS=Hospital for Special Surgery; VAS=Visual Analogue Scale; KSS=Knee Scoring System

Postoperative expectations expressed as patients' expectations being met or fulfilled explicitly align with the ECT model. Of the 10 studies in Table 2-2, six studies measured patients' postoperative expectations after undergoing TKR using the terminology of postoperative expectations being met or fulfilled [46, 51, 77, 79, 87, 88]. However, the other four studies do not align with the ECT model because the terminology used for postoperative expectations do not refer to expectations being met or fulfilled [73, 75, 82, 89].

Aligning with the ECT model for patients' postoperative expectations being met or fulfilled were the following six studies. In Noble et al. [51] the Total Knee Function Questionnaire was used, a valid instrument that measured the fulfillment of patients' postoperative expectations with a response scale that analyzed responses that were either dichotomized or trichotomized. In Bourne et al. [46] [87] expectations were analyzed that were responded to by patients as having been met, not met or that they had no expectations. The one item addressing postoperative expectations in Scott et al. [88] used a summed scale and asked patients how their expectations were met. Vissers et al. [79] asked patients whether their expectations regarding pain, limitations of ADL, and the overall success of TKR surgery had been fulfilled. And Noble et al. [77] used the new KSS tool that summed the three items measuring the fulfillment of patients' postoperative expectations.

In contrast, there were four studies that did not align with the ECT model. The terminology used in these studies for patients' postoperative expectations and the response scales used to analyze patients' postoperative expectations did not align with the ECT model. First, in Mannion et al. [73] a change scale was used to compare preoperative expectations to postoperative expectations. Preoperatively, the baseline questionnaire enquired about the importance of expectations of TKR in relation to expected time until full recovery (open answer, in months), expected pain after recovery from TKR (not at all painful through to very painful), and expected limitations in ADL after recovery from TKR (not limited at all through to greatly limited) [73]. Two years after, TKR surgery patients completed the same items to assess their current status in relation to the preoperative expectations questionnaire (months required until recovered, pain, limitations in ADL) [73]. The difference between the preoperative expected score and the postoperative actual score provided a measure of the change in expectations had been fulfilled.

Second, in Becker et al. [75] a summed scale analyzed the importance of patients' postoperative expectations. Third, in Scott et al. [82] percentages were used to also measure the importance of patients' postoperative expectations. Finally, Kim et al. [89] referred to patients' postoperative expectations as being 'wished for improvements' and

therefore these questions do not align with the ECT model or expectations being met or fulfilled as indicated in the ECT model.

Not shown in the table (Table 2-2) is the limited psychometric work in this area. Only Noble et al. [77] confirmed internal consistency and cross-sectional convergent validity, of the postoperative expectation subscale measured in the new Knee Society KSS tool. In Noble et al. [77] postoperative expectation questions queried the fulfillment of each patient's expected outcomes in regard to; relief of pain, ability to perform leisure, recreational and sports activities and ADL. After the analysis, minor adjustments were made to the new KSS tool actually tested by Noble et al. [77]. As previously mentioned, the final version of the tool developed by Noble et al. [77] has not been independently validated.

Satisfaction

Studies that analyzed satisfaction in patients having undergone TKR are shown in Table 2-3. The table highlights how researchers in this area used six different instruments, sets of questions or a single question. The majority used ordinal response scales with only a single study using a visual analogue scale (VAS); but the analytic approach varied from using percentages [73] or either dichotomized scales for individual items [46, 51, 79, 81, 82, 87, 88] or trichotomized scales [89, 90] for individual items to mean scores across items [78] to simply using a summed scale across a total of 5 items measuring patient satisfaction [77].

Not shown in the table (Table 2-3) is the limited psychometric work in the area of satisfaction. Mahomed et al. [91] and Noble et al. [77] were the only studies measuring satisfaction that found their statistical analyses confirmed internal consistency and convergent validity. Noble et al. [77] found this specifically for the separate subscale measure of satisfaction in the new Knee Society KSS tool.

Table 2-3: Satisfaction Studies

Study (year)	Instrument used	Response scale measured	Response scale analyzed
Lingard et al (2006)	4 questions	4 items; 4-point Ordinal	Mean score
Noble et al (2006)	Total Knee Function Questionnaire	1 item; 4-point Ordinal	Dichotomized
Mannion et al (2009)	Total Arthroplasty Outcome Evaluation Questionnaire	1 item; 5-point Ordinal	Percentages
Bourne et al (2010a)	Satisfaction Questionnaire	3 items; 5-point Ordinal	Dichotomized
Bourne et al (2010b)	Satisfaction Questionnaire	3 items; 5-point Ordinal	Dichotomized
Scott et al (2010)	1 question	1 item; 4-point Ordinal	Dichotomized
Vissers et al (2010)	1 question	1 item; 5-point Ordinal	Dichotomized
Mahomed et al (2011)	4 questions	4 items; 4-point Ordinal	Mean score
Escobar et al (2012)	*PASS	1 item; 4-point Ordinal	Dichotomized
Judge et al (2012)	*PASS	1 item; VAS	Cut-off values
Noble et al (2012)	new Knee Society KSS	5 items; 5-point Ordinal	Summed scale
Scott et al (2012)	*HSS Hip Replacement Survey	1 item; 4-point Ordinal	Dichotomized
Tekin et al (2012)	Satisfaction Questionnaire	5 items; 5-point Ordinal	Dichotomized
Escobar & Riddle (2014)	*PASS	1 item; 4-point Ordinal	Dichotomized
Kim et al (2015)	9 questions	9 items; 11-point VAS	Trichotomized
Maratt et al (2015)	Anchor based question	1 item; 6-point Ordinal	Trichotomized
Naal et al (2015)	PASS	1 item; Yes/No	Dichotomized

* Used a modified version. HSS=Hospital for Special Surgery; VAS=Visual Analogue Scale; KSS=Knee Scoring System; PASS=Patient Acceptable Symptom State

Applying the ECT model (Fig. 2-1) to patients undergoing TKR meant confirmation or disconfirmation when expectations are either met or not met, and this determines if satisfaction or dissatisfaction is achieved with the outcome of TKR. Satisfaction indicates a sense of satisfaction or dissatisfaction obtained by a patient upon comparing the performance of the outcome after TKR to an expected level [63].

Of the 17 studies in Table 2-3 measuring patients' postoperative satisfaction, 11 studies measured patients' satisfaction after undergoing TKR that did not align with the terminology of the ECT model for satisfaction or dissatisfaction [46, 51, 77, 79, 81, 82, 87, 88, 92-94]. There were six studies that did not align with the ECT model because the terminology used for postoperative satisfaction did not distinguish explicitly between patients being satisfied or dissatisfied [73, 78, 89-91, 95]. Rather they provided more of a level of, or degree to which, patient satisfaction or dissatisfaction was achieved with the outcome of TKR surgery.

Ten of the 11 studies that measured patient satisfaction did not align with the ECT model as they dichotomized the response scale into either being satisfied or dissatisfied with TKR outcome. All began with either a 4-point ordinal scale [51, 82, 88, 92, 93] or 5-point ordinal scale [46, 77, 79, 81, 87] then these scales were reduced to being dichotomized as either satisfied or dissatisfied with TKR outcome or a summed score. This meant 'neutral' or 'unchanged' were assigned to not being satisfied with TKR outcome.

Noble et al. [51], Scott et al. [88], Scott et al. [82], Escobar et al. [92] and Escobar and Riddle [93] began with 4-point ordinal response scales then they were transformed to a dichotomized scale of dissatisfied or satisfied. In Bourne et al. [46] [87], the two-category outcome (satisfied, not satisfied/neutral) was used as the measure of overall satisfaction. Likewise, in Vissers et al. [79] the two category outcome (very satisfied, less satisfied) became the measure of satisfaction. In Tekin et al. [81] the two-category outcome (bad to average, good to excellent), was used as the measure of overall satisfaction. Finally, Noble et al. [77] used their five-question, 40-point summed scale for satisfaction that could was used to determine very dissatisfied (0) to very satisfied (40). It was after their final analysis that minor modifications were made that provided the final tool. This final

tool had not been independently tested for validity and internal consistency [77]. None of the above studies specifically aligned with the ECT model of patient satisfaction being determined by a yes, confirmation or no, disconfirmation patient response.

There were another six studies that also did not align with the ECT model. The terminology used in these studies for patients' postoperative satisfaction and the response scales used to analyze patients' postoperative satisfaction do not align with the ECT model. First, Lingard et al. [78] used a satisfaction score as the mean of four questions about patient satisfaction, this was then transformed to a 100-point scale. This type of satisfaction scoring does not align exactly with the ECT model because it does not clearly distinguish between a sense of satisfaction or dissatisfaction by the patient referring to their performance or outcome after TKR. In the second and third studies respectively, Mannion et al. [73] and Mahomed et al. [91] the ratings of satisfaction were expressed as percentages or the un-weighted mean of the scores respectively, with the results of TKR being reported as; very satisfied, somewhat satisfied, somewhat dissatisfied or very dissatisfied. This does not align with the ECT model of satisfaction that enables the patient to discern between being either satisfied or dissatisfied. These two studies provide more of a level of satisfaction and dissatisfaction for patients to categorize the outcome of their TKR. In the fourth study, Judge et al. [95] used a cut-off of $\geq$50/100 as an indication of satisfaction with the results of TKR. Further for sensitivity analysis, they repeated the analyses using higher and lower cut-offs for being satisfied of >60 and >40 respectively. Using the multiple levels of cut-off for indicating patients who were satisfied or not with TKR does not align with the ECT model.

The fifth and sixth studies used trichotomized scales for satisfaction. These scales do not clearly distinguish between patients being either satisfied or dissatisfied with the outcome of their TKR surgery. Maratt et al. [90] administered a satisfaction survey categorizing patients who were substantially improved from those who were not substantially improved. The responses were categorized into; improved, unchanged and deteriorated with respect to quality of life. In Kim et al. [89] patient satisfaction was determined using an 11-point visual analogue scale (VAS) rating postoperative satisfaction from extremely

dissatisfied (0) to extremely satisfied (10), then categorized the mean scores; as low (0-3), moderate (4-7), and high (8-10).

Naal et al. [94] was the only study in the table (Table 2-3) measuring patient satisfaction to align explicitly with the ECT model. They used the Patient Acceptable Symptom State (PASS) question. This question addresses the concept of the wellbeing of an individual, as being in an acceptable symptom state or being satisfied with the performance outcome of their TKR surgery. They simply asked patients whether they considered themselves to be in a satisfactory health status. The two response options provided were ‘yes’ or ‘no’.

This level of satisfaction or ‘acceptability’ is defined by the PASS question. The satisfaction question asked was, “Taking into account your level of pain and also your functional impairment, if you were to remain for the next few months as you are today, would you consider your current state satisfactory?” [96].

Ultimately, it was the PASS that aligned the best with the conceptual framework of the ECT model in regard to patient satisfaction with TKR. The idea that patients make the determination that their current state is ‘acceptable’ (i.e. satisfactory) and is determined to be so, for a particular time period, aligns best with the ECT model.

2.2.9 Conclusion

The literature review shows there is no universally accepted way of measuring patients’ preoperative expectations, postoperative expectations or satisfaction following TKR surgery. Measurement of these constructs consists of multi-item domains or single questions and binary or continuous responses. There is limited psychometric work on tools that measure these constructs. Noble et al. [77] merits further investigation having introduced the new Knee Society KSS tool in 2012. The tool measures both pre- and postoperative expectations and satisfaction using continuous measures, prior to minor modifications it was shown to have internal consistency and convergent validity. However, the final version of the tool has not been independently validated.

2.3 Present State of Knowledge

2.3.1 Satisfaction & Pain/Function Outcomes

Satisfaction with TKR surgery has been shown to be related to both pain and physical function outcomes after TKR surgery [97]. Patients having undergone TKR with worse pain and function after surgery had lower levels of satisfaction [50], with ongoing complaints of pain being a strong predictor of dissatisfaction [98, 99]. Research has also shown postoperative dissatisfaction is associated with higher preoperative pain and lower postoperative range of motion [89, 100]. Additionally, dissatisfaction with TKR results have correlated not only with decreased physical function and increased bodily pain but also with poorer mental health [66].

2.3.2 Satisfaction & Expectations of Surgery

In a review of the satisfaction and expectation literature for TKR patients by Culliton et al. [101] preoperative expectations did not correlate with satisfaction when other factors were controlled for in the analysis [73, 78]. Lingard et al. [78] noted patients from different countries had different expectations of TKR, which were not fully explained by differences in sociodemographic factors, clinical characteristics, and pain and functional status. Mannion et al. [73] found patient's actual health status was more predictive than preoperative expectations when satisfaction or global outcome was modeled using multivariable techniques.

With adjusted analyses, patient satisfaction was predicted by how well patients' postoperative global or overall expectations were met following TKR surgery [46, 51, 79]. Noble et al. [51] reported that satisfaction with TKR was primarily determined by patients' postoperative expectations being met, and not by their absolute level of function. Bourne et al. [46] reported the strongest predictors of patient dissatisfaction after primary TKR were expectations not being met, a poor one year WOMAC, a postoperative complication requiring hospital readmission and preoperative pain at rest. Vissers et al. [79] found patients were more often satisfied when they had better preoperative self-reported mental functioning, experienced less pain and had their expectations fulfilled regarding pain postoperatively.

Kim et al. [89] found satisfaction levels were correlated positively with functional outcomes, pain relief and restoration of activities of daily living activities. Maratt et al. [90] found patients with greater preoperative pain and disability and less severe degradation in HRQOL were more likely to be satisfied with their TKR surgery. Scott et al. [88] found satisfaction correlated most accurately with pain relief, followed by expectations and then functional ability. Additionally, Scott et al. [82] found fulfillment of expectations were highly correlated with satisfaction.

2.4 Managing Expectations of TKR Surgery with Patient Education

Orthopaedic surgeons realize expectations for TKR surgery can be handled by education. Mancuso et al. [102] examined two groups of patients who attended a standard preoperative class addressing recovery immediately following surgery. The intervention group also received a preoperative joint-specific module addressing recovery over the first year after surgery. Most notably, the end-point of the study was prior to surgery. Their results demonstrated that preoperative expectations were modifiable with patient education. Therefore, if educational interventions can modify preoperative expectations, it is reasonable to come to the conclusion that they can be designed to affect postoperative expectations as well.

2.4.1 Rationale for Patient Education Before & After Surgery

Postoperative satisfaction was predicted by how well postoperative expectations had been met after TKR surgery. Therefore, patient education programs for managing expectations should span part of the postoperative rehabilitation and recovery period [101]. Patient education needs to be designed for coordinated delivery before and after TKR. E-learning tools should be created, taking adult learning principles [103-106] into consideration.

2.4.2 Timing & Delivery of Patient Education

Recent evidence supports the development of patient education both before and after surgery for TKR recipients. Soever et al. [107] found it was important to patients that information be made available at both pre- and postoperative phases of the continuum of

care. They [107] confirmed that patients' expectations needed to be considered and addressed with patient education.

Johansson et al. [108] recognized the need to study patient education from the point of view of empowerment. Lin et al. [109] found the opportunity to repeat content and have more time for an educational program for TKR patients was helpful, particularly for older patients. Koekenbier et al. [110] and others [111-114] recognized orthopaedic hospital care periods have shortened, making it important to support patients' active participation in their education.

2.4.3 Phenomenon of Response Shift

Further evidence suggests education modules should be structured over a clinically relevant time period lies in the phenomenon called 'response shift' [115]. Response shift is a well-known phenomenon in life-threatening disorders [72, 115-125], and is gaining recognition as a phenomenon in chronic musculoskeletal conditions [126-130]. Individuals with chronic conditions can sustain a stable quality of life and adapt to their limitations by using a number of strategies such as: redefining internal standards of what constitutes health, changing their values and priorities, or redefining their QOL [117-119]. These internal changes in a patient's perspective are also referred to as recalibration, reprioritization, and re-conceptualization response shifts, respectively.

Response shift is a psychological phenomenon that occurs following a negative change in health status. Events or experiences occurring after medical or surgical treatments can change the metrics of measurement and alter the person's ratings [117-119]. Patients may have less context for, or understanding of, the constructs being measured prior to an event (e.g., TKR surgery). As patients gain insight during the course of recovery or as they adjust to their condition, their metric for assessing the impact of treatment may shift. As a result of recalibration response shift, a patient's judgment of their present health situation may stay stable or show substantial improvement (despite some disability following surgery) [131].

There is some information on the direction of recalibration in patients with life-threatening disorders. Generally, patients overrate their pretreatment disability [121, 122, 125]. However, limited information in the field of orthopaedics indicates this phenomenon takes place in patients with arthritis [126, 127]. Woolhead et al. [132] and Razmjou et al. [43] identified recalibration response shift as a potential confounding effect following TKR. They felt to concede that a 'response shift' had occurred would mean that patients have learned to cope or that they have changed their expectations [43]. This confounding is compounded by the possibility that not all patients may adapt to the same degree nor in the same direction, thus making it difficult to interpret observed changes in quality of life. Therefore, response shift may represent a paradigm shift for self-report measurement. A recommendation is for response shift to be examined using polynomial regression analysis as a means of analyzing this complex relationship in future research studies [120]. As response shift could lead to invalid conclusions when HRQOL measures are analyzed, clinical investigators should include response shift assessment in the design of clinical trials.

The Health Education Impact Questionnaire (heiQ) was developed and validated as a patient-friendly, relevant, and psychometrically sound instrument to enable the evaluation of patient education programs [133]. It was designed to be used after a patient education intervention, to maximize the chance that any observed pre-post differences were due to 'true' improvement rather than a change in content knowledge, health literacy or a response shift [133]. The heiQ provides a comprehensive profile of the potential impacts of patient education programs. However, there are issues regarding its use and scoring [133]. This may provide a direction for future studies to investigate this phenomenon when implementing a patient education tool or program.

2.4.4 E-learning as Patient Education in the 21st Century

E-learning has been used as an effective tool for educational delivery in corporate and healthcare environments [134]. In patient education, applications of e-learning are more commonly found in larger disease populations [135-140]. By bringing information to the patient at the place and time of their choosing, e-learning has the potential to broaden the reach of existing services and is a promising intervention for patients [64]. E-learning

could be an effective means of delivering education to patients undergoing TKR, both pre- and postoperatively.

2.4.5 Rationale for E-Learning

E-learning can be used to create engaging learning experiences. Additionally, presentations combining text and the spoken word are more highly valued by users than those containing only text [141, 142]. Many support and rehabilitation programs offer print-based resources and/or classes, but both of these have important limitations such as language spoken, level of literacy and comprehension of presented material [141].

The use of an e-learning tool with patients undergoing TKR surgery provided challenges due to the timing for the implementation of this tool and the introduction of new technologies with this patient population. This was identified in an Ipsos Reid report at the time (2012) of the implementation of this study:

> "It's clear that Canada's Baby Boomer generation is not taking to new media and technologies at the same rate or with the same commitment as the younger generation of Digital Natives," says Dave Pierzchala, Senior Vice President with Ipsos Reid. "However, we are seeing online Boomers becoming more comfortable as their adoption of new devices is trending upwards" [143].

The pilot work provided evidence that this patient population was using computers but their level of familiarity and facility with computers and new technologies may have been limited. Therefore, contact information (phone and email) was provided to the patients in the study by the researcher and the website designer. This was provided in an effort to assist with any technological difficulties during the study. Details of the pilot work to create and the development of a locally designed e-learning tool are described in Appendix A.

2.4.6 Summary

In summary, the aging proportion of the population is increasing and this trend will continue, as a result, OA and other chronic conditions and disabilities are expected to increase. Total knee replacement (TKR) is a viable treatment option for those individuals living and working with knee arthritis. However, dissatisfaction with TKR has been

related to both pain and physical function after TKR surgery. Therefore, the ability to manage patients' preoperative expectations of TKR surgery may be provided with a locally developed e-learning tool that modifies patients' preoperative and postoperative expectations and improves their satisfaction. Understanding patient characteristics and usage of an e-learning tool may assist as the demand for TKR surgery continues to increase in the future. Development of a locally designed e-learning tool, to evaluate its ability to affect whether patients felt their expectations were met and the degree of satisfaction with their TKR surgery after one year is the focus of this thesis.

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Chapter 3

3 A Randomized Controlled Trial to Establish Realistic Patient Expectations Following Total Knee Replacement

3.1 Introduction

Total hip and knee replacement (THR/TKR) provide viable treatment options for individuals living and working with hip and knee arthritis [1], by reducing pain and improving physical function in over 90% of patients [2, 3]. Despite the success of the procedure, rates of patient 'dissatisfaction' with TKR as high as 18% have been reported [3-7]. Consistent with this, TKR patient 'satisfaction' rates as low as 75% have been published [3-6]. This compares to a 91% patient satisfaction rate for THR surgery [8].

There was a five year increase of 21.5% in the number of TKR procedures in Canada for 2012-2013 [1]. The prevalence of osteoarthritis (OA) is predicted to reach over 10.4 million Canadians by 2040 [9]; thus the number of patients who are dissatisfied with their TKR surgery will most certainly increase. Perhaps one way to address the problem of TKR dissatisfaction is to develop an effective way for surgeons to manage patient expectations of their TKR surgery.

Satisfaction with TKR surgery is related to both pain and physical function outcomes after surgery. TKR patients with worse pain and function after surgery have lower levels of satisfaction. Ongoing complaints of pain were strongly related to this dissatisfaction [5, 10]. Research has also shown that postoperative dissatisfaction is associated with higher preoperative pain and lower postoperative range of motion [11, 12].

In a review of the literature pertaining to patient satisfaction and expectations following TKR [13], preoperative expectations did not correlate with satisfaction when the analysis adjusted for other factors [14, 15]. In the adjusted analyses, satisfaction was predicted by how well postoperative expectations were met following TKR [4, 16, 17].

Orthopaedic surgeons recognize that patient expectations of TKR surgery can be managed through education. Mancuso et al. [18] conducted two randomized controlled trials, one for THR and one for TKR. In the TKR trial, (n = 146) two groups of patients both attended a standard preoperative class addressing recovery immediately after surgery. The intervention group (n = 71) also received a preoperative joint-specific education module addressing recovery during the first 12 months. Results demonstrated that patients' preoperative expectations were lowered with patient education. Thus, if through education we can modify expectations so that they are more realistic, it is reasonable to assume that preoperative education to manage expectations can affect postoperative satisfaction.

E-learning is the application of information technology to education. E-learning has been used as an effective tool for educational delivery in corporate and healthcare environments [19]. Bringing information to the patient at the place and time of their choosing, e-learning has the potential to broaden the reach of existing services for patients [20].

Thus, this study evaluated the ability of a series of educational videos to affect whether patients felt their expectations were met and the degree of satisfaction with their TKR surgery after one year.

3.2 Methods

We collected data on a consecutive sample of patients undergoing elective primary TKR under the care of one of seven orthopaedic surgeons at the London Health Sciences Centre, University Hospital, London, Ontario, Canada. Our study was approved by the Health Sciences Research Ethics Board at the University of Western Ontario (see Appendix B). Patients diagnosed with OA scheduled to undergo primary TKR were recruited at the Pre Admission Clinic (PAC) from April 2013 to April 2014. To be considered for participation, patients had to be greater than 20 years of age and booked for an elective primary TKR and of sound cognitive capacity to give informed consent. We excluded patients who were undergoing revision TKR, patellar resurfacing, hemi or unicompartmental (unicondylar) knee arthroplasty, high tibial osteotomy (HTO), or knee

surgery to address a tumor. We randomized patients using a web-based system stratified by surgeon and by first or second TKR surgery.

3.2.1 Control Condition

Patients allocated to the control group were provided the standard method of patient education, which meant that they were provided a 31-page hard copy of 'My Guide to Total Knee Joint Replacement' at their PAC visit. They were also informed of the availability of an electronic copy of this manual on the hospital website. We did not remind patients to read the manual or monitor whether they read the manual.

3.2.2 Intervention Condition

Patients allocated to the intervention group were provided access to the e-learning tool in addition to the standard method of patient education. During their PAC visit patients were asked to complete their baseline questionnaires and they were given access to this e-learning tool. Access to the e-learning tool remained active until the study end-point of one year postoperative.

The e-learning tool consisted of custom-made professionally filmed and edited videos. The content was designed in consultation with our surgeons, physical therapists and patients who had already been through TKR. Patients were sent an email inviting them to access the e-learning tool 24 hours after each of the following: PAC visit, TKR surgical date and at six weeks and three months postoperative. Follow up emails were sent one week after each of the initial emails. Details of the pilot work to create and the development of a locally designed e-learning tool are described in Appendix A.

3.2.3 Data Collection Protocol

Preoperative measures were completed following the patients' PAC visit and prior to accessing the e-learning tool. Postoperative patient reported outcome measures (PROMs) were completed at scheduled postoperative consultation time periods of six weeks, three months and one year after TKR surgery. Patients had the option of completing electronic questionnaires online or paper questionnaires by mail. Patients received email reminders

to complete the questionnaires, one week prior to the due date, on the due date and one week after the due date, if the electronic questionnaire had not been completed.

3.2.4 Primary Outcomes

We used the Postoperative Expectation Questionnaire to measure the degree to which patient expectations had been met at each of the postoperative time periods (e.g. six weeks, three months, and one year) using the following question, “Overall, at this time did the results of your most recent replacement surgery meet your expectations?” The two response options were ‘yes’ or ‘no’ [16].

We measured patient satisfaction using the Patient Acceptable Symptom State (PASS) question [21, 22]. The PASS is a feasible, acceptable, reliable, and valid assessment of patient-reported satisfaction with current health state [23]. It is the following question: “Taking into account your level of pain, and also your functional impairment, if you were to remain for the next few months as you are today, would you consider that your current state is satisfactory?” The response options to this question were ‘yes’ or ‘no’.

3.2.5 Secondary Outcomes

We collected several PROMs for descriptive purposes including: new Knee Society Knee Scoring System (KSS); (Pre-Op and Post-Op versions) [24, 25], Knee injury and Osteoarthritis Outcome Score (KOOS) [26, 27], the Medical Outcomes Study 12-Item Short Form Health Survey, version 2 (SF-12) [28, 29], Hospital Anxiety And Depression Scale (HADS) [30, 31], Pain Catastrophizing Scale (PCS) [32], University of California at Los Angeles (UCLA) Activity Score [33]and the Social Role Participation Questionnaire (SRPQ) [34, 35]. For descriptions of alphabetized questionnaires see Appendix C.

We also collected demographic characteristics, surgical procedures and information about comorbidities using the Self-Administered Comorbidity Questionnaire (SCQ) [36].

3.2.6 Statistical Analysis & Sample Size

Descriptive statistics were calculated for all relevant patient demographics. Patient preoperative characteristics values were expressed as means ± standard deviations for continuous variables and frequencies and percentages for categorical variables.

We used risk difference to analyze the between-group difference for patient expectations being met and patient satisfaction following TKR surgery at one year postoperative. Data were analyzed using SAS 9.4 (SAS Institute Inc. Cary, North Carolina).

An *a priori* sample size calculation was based on an estimated 15% rate of dissatisfaction with TKR surgery [37] and a desired 10% reduction in the proportion of patients who were dissatisfied [38] at the one year endpoint. Following Fleiss [39]; with an alpha = 0.05, power = 80% and $p_{e\text{-}learning} = 0.05$ and $p_{control} = 0.15$; the number of participants per group =160. With a 30% adjustment (+ 48) for loss to follow up we required 208 patients per group, for a total sample size of 416 patients.

3.3 Results

We screened 835 consecutive patients, and 416 patients were randomized to the control group (n=207) or the intervention group (n=209) (Fig. 3-1). Within the control group, two patients did not undergo TKR surgery, 19 did not complete their preoperative questionnaire, and 21 did not complete one of the postoperative questionnaires at either six weeks or three months or one year. One hundred sixty-five patients completed both the preoperative questionnaire and at least one of the postoperative questionnaires.

Within the intervention group two patients did not undergo TKR surgery, 25 did not complete their preoperative questionnaire and 26 did not complete one of the postoperative questionnaires at either six weeks or three months or one year. One hundred fifty four patients completed both the preoperative questionnaire and at least one of the postoperative questionnaires (Fig. 3-1).

There were 10% more females in the control group but other characteristics were well balanced between groups (See Table 3-1). Of the 345 patients included in this study the

majority were female (59% intervention; 69% control), had a mean age of 63 years, a mean body mass index (BMI) of 33 kg/m^2 and the majority were undergoing their first primary TKR surgery (66% intervention group, 69% control group).

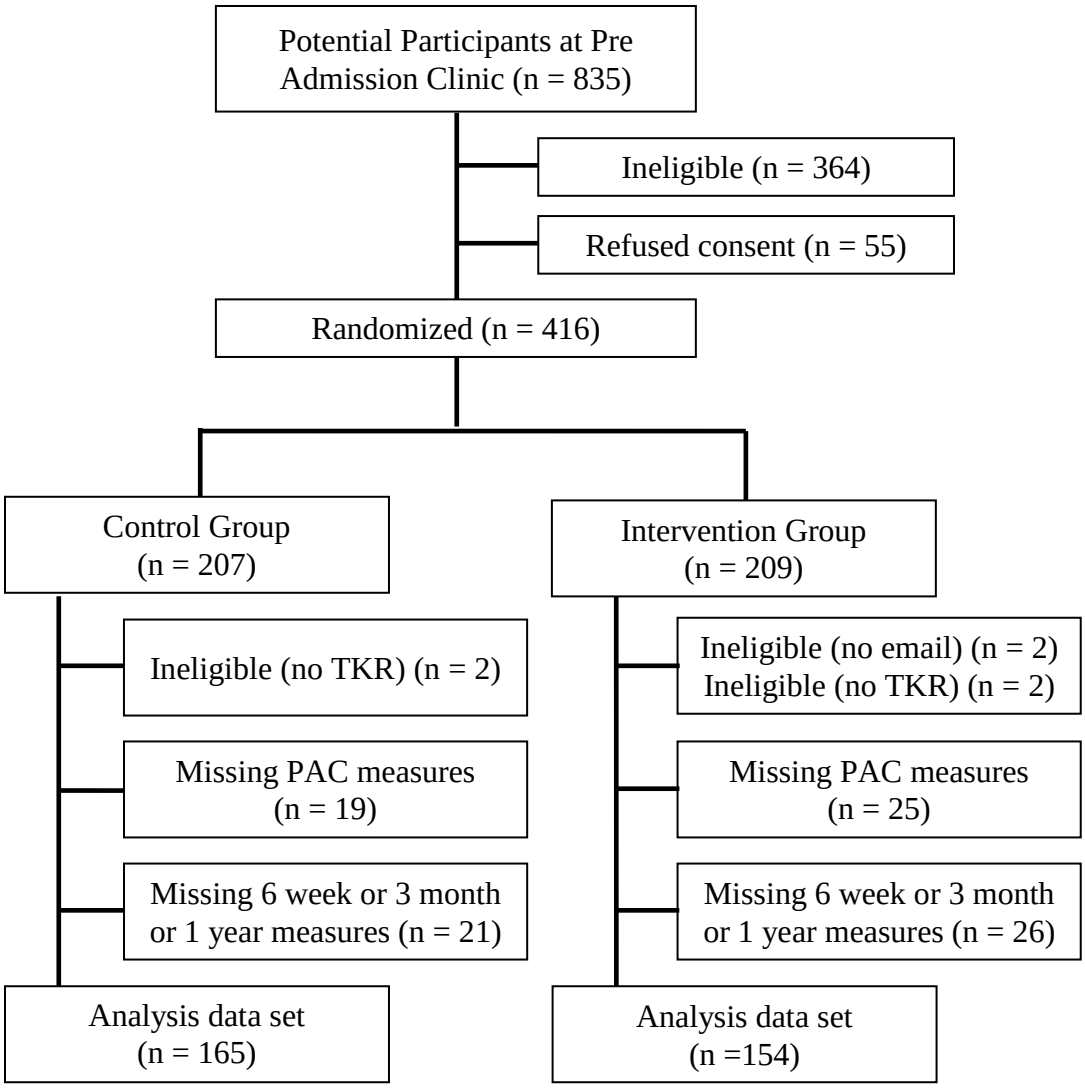

Figure 3-1: A flow diagram illustrating patient enrollment, randomization, follow up, and analysis. TKR = Total Knee Replacement; PAC = Pre Admission Clinic

Table 3-1: Patient preoperative characteristics

	Intervention (n = 167)	Control (n = 178)	p Value
Female sex	98 (59%)	123 (69%)	0.04
Age (years)*	64 ± 8	63 ± 9	0.28
BMI (kg/m^2)*	33 ± 8	33 ± 7	0.37
First primary TKR	107 (66%)	118 (69%)	0.68
Working, yes	51 (32%)	59 (35%)	0.59
Live alone, yes	25 (16%)	28 (16%)	0.83
Dependent on others, yes	31 (19%)	30 (18%)	0.69
Care giver, yes	40 (25%)	40 (23%)	0.73

*Values expressed as mean ± standard deviation; and absolute and relative frequencies for categorical variables. BMI = Body Mass Index; TKR = Total Knee Replacement

Both groups were similar with respect to their preoperative PROMs (Table 3-2). Overall, patients expected that their TKR would substantially reduce their pain (83% intervention group, 84% control group), allow them to return to activities of daily living (78%, intervention group, 76% control group), and improve their participation in sports, leisure or recreational activities (74% intervention group, 65% control group). Preoperative patient satisfaction was low, with few patients satisfied with their present state prior to TKR surgery (14% intervention group, 11% control group).

Table 3-2: Preoperative patient-reported outcome measures (PROMs) for intervention and control patients

	Intervention (n=167)	Control (n=178)	p Value
Self-Administered Comorbidity			
≤ 2 comorbidities	80 (48%)	88 (49%)	0.78
Pre-Op Expectation			
Pain Relief - Yes, a lot	133 (83%)	144 (84%)	0.79
Activities of Daily Living - Yes, a lot	124 (78%)	130 (76%)	0.68
Sport, Leisure, Recreation - Yes, as much as before	112 (74%)	104 (65%)	0.07
Full Recovery - Yes, complete	70 (44%)	63 (37%)	0.20
Knee Society Score: Pre-Op			
Symptoms	7.09	7.22	0.80
Patient Satisfaction	13.17	12.8	0.62
Patient Expectations	13.43	13.38	0.85
Functional Activities	33.43	32.01	0.39
Knee Injury & Osteoarthritis Outcome Score			
Symptoms	41.68	41.69	0.99
Pain	40.35	40.59	0.90
Activities of Daily Living	45.68	45.42	0.89
Sport and Recreational Activities	18.26	18.03	0.93
Quality of Life	19.84	18.90	0.58
SF-12 Health Survey			
Physical Health Composite Score	29.46	29.15	0.70
Mental Health Composite Score	52.91	53.03	0.93
Hospital Anxiety and Depression Scale			
Anxiety	5.23	5.88	0.29
Depression	4.47	4.87	0.31
Pain Catastrophizing Scale			
Rumination	5.30	5.67	0.39
Magnification	2.19	2.51	0.23
Helplessness	5.08	5.81	0.17
Social Role Participation Questionnaire			
Role Importance	3.85	3.85	0.96
Role Limitations	2.08	2.12	0.44
Role Performance	2.92	2.84	0.35
UCLA Activity Score			
Inactive to Impact	4.25	4.22	0.85
Patient Acceptable Symptom State			
Satisfied, Yes	22 (14%)	19 (11%)	0.49

*Mean (95% CI) for continuous variables, and absolute and relative frequencies for categorical variables. SF-12 Health Survey = The Medical Outcomes Study 12-item Short Form Health Survey; UCLA = University of California at Los Angeles Activity Score

At one year postoperative we found significant postoperative between-group differences in favour of the control group for the new KSS symptoms score ($p = 0.04$) and the functional activities score ($p = 0.04$). We also found that control patients had less anxiety ($p = 0.02$) and lower scores for rumination ($p = 0.02$), magnification ($p = 0.02$), and helplessness ($p = 0.02$) than intervention patients on the Pain Catastrophizing Scale (PCS) (Table 3-3).

At one year postoperatively, the risk that expectations were not met was 21.8% in the control group and 21.4% in the intervention group for a risk difference of 1.3% (95% CI -7.8% to 10.4%, $p = 0.78$). The proportion of patients who were satisfied with the TKR at one year postoperative was similar in the intervention group 78.6% and the control group 78.2%, and the risk difference 0.6% (95% CI -8.4% to 9.6%) was not statistically significant ($p = 0.78$).

Table 3-3: Postoperative patient-reported outcome measures (PROMs) for intervention and control patients; adjusted for baseline PROMs, surgeon and previous TKR

	Intervention (n = 154)	Control (n = 165)	p Value
Post-Op Expectations			
Yes, met	121 (79%)	129 (78%)	0.78
Knee Society Score: Pre-Op			
Symptoms	18.90	19.84	0.04
Patient Satisfaction	31.56	32.15	0.34
Patient Expectations	9.27	9.21	0.83
Functional Activities	64.75	68.18	0.04
Knee Injury & Osteoarthritis Outcome Score			
Symptoms	74.56	76.32	0.29
Pain	80.10	82.62	0.10
Activities of Daily Living	81.49	83.69	0.12
Sport and Recreational Activities	56.37	53.35	0.35
Quality of Life	63.89	65.83	0.34
SF-12 Health Survey			
Physical Health Composite Score	42.34	43.22	0.13
Mental Health Composite Score	55.32	55.54	0.99
Hospital Anxiety and Depression Scale			
Anxiety	3.40	2.81	0.02
Depression	2.52	2.49	0.59
Pain Catastrophizing Scale			
Rumination	2.16	1.51	0.02
Magnification	1.03	0.69	0.02
Helplessness	2.32	1.76	0.02
Social Role Participation Questionnaire			
Role Importance	3.87	3.88	0.55
Role Limitations	1.55	1.50	0.10
Role Performance	3.77	3.85	0.08
UCLA Activity Score			
Inactive to Impact	5.55	5.63	0.71
Patient Acceptable Symptom State			
Satisfied, Yes	121 (79%)	129 (78%)	0.93

*Mean (95% CI) for continuous variables, and absolute and relative frequencies for categorical variables. SF-12 Health Survey = The 12-item Short Form Health Survey; UCLA = University of California at Los Angeles Activity Score

3.4 Discussion

This study sought to determine whether exposure to an e-learning tool preoperatively and throughout the first year after surgery affects whether patients felt that the surgery had met their expectations and whether they felt satisfied at one year following TKR surgery.

First, our e-learning tool did not result in a between-group difference between the intervention and control groups for either the risk that expectations were not met or the proportion of patients who were satisfied with the TKR at one year postoperative. Other studies with educational components are conflicted as to whether education can affect expectations. For example, in a study similar to ours, Leal-Blanquet et al. [53] randomized 92 TKR recipients to a control group (50 patients) or a study group (42 patients) and measured preoperative expectations at baseline and at four weeks after the first visit, prior to TKR surgery. They found that patients' expectations preoperatively were not modified by the use of additional educational materials provided in an audiovisual videodisc [53].

In contrast to this, Mancuso et al. [18] conducted two randomized controlled trials one for THR (n = 177) and one for TKR (n = 143). The educational modules for both trials consisted of one standard class addressing recovery after surgery for the control group and the standard class plus a joint-specific module addressing recovery during the first year for the intervention group. Patients completed a joint-specific validated expectation survey before and after the class. They showed preoperative expectations could be lowered by classes administered before surgery. They found an educational module that focused on one year recovery, decreased expectations in patients undergoing TKR and had a greater proportion of patients with expectations similar to their surgeons' recommendations [18]. Both of these studies used preoperative study endpoints, making direct comparison with our work more difficult.

There are several potential explanations for our findings. First, the actual content of the intervention e-learning tool may not have sufficiently addressed patient expectations. We constructed video presentations of surgeons, physical therapists and past TKR recipients, and educational modules were linked to specific time periods during a patient's recovery

after TKR surgery. Video presentations made by surgeons specifically addressed what patients should expect regarding pain relief, stiffness, functionality and activities. Video presentations by physical therapists talked about what patients should expect when performing exercises, maintaining range of motion, and returning to activities. Videos by previous patients provided comments pertaining to their expectations regarding pain and stiffness and whether their own expectations were met. It may be that an even more explicit focus on postoperative expectations is needed to achieve the desired effect on patients' expectations being met as well as satisfaction following their TKR surgery.

Second, one year postoperative may not be a sufficient length of time for patients to fully establish feelings of satisfaction following their TKR surgery. Measuring satisfaction beyond the one year postoperative time point is supported by some [5-7, 40-42]. It is contradicted by others measuring satisfaction of TKR at one year postoperative or sooner [4, 38].

Third, it is possible that if we had limited our eligibility to only those patients with high expectations, we might have seen a between-group effect by simply increasing the event rate (i.e. increasing the proportion of patients within each group who are more likely to be affected by the intervention). Previous investigations have demonstrated a marked difference between patients and surgeons in preoperative expectations [43] and postoperative outcomes [44, 45]. These studies substantiated the importance of aligning patients' and surgeons' expectations for postoperative recovery. It's possible that the discretionary activity subscale of the new Knee Society scale [24, 25] could be used to provide a preoperative evaluation of patients' expectations that could be used to identify patients at a greater risk of unmet expectations after surgery that might benefit from further education regarding expectations.

A limitation of this study is that it was conducted in a single urban tertiary orthopaedic referral center and may therefore be less applicable to patients in other settings. However, this study found that 78% of patients were satisfied with their one year postoperative outcome which is similar to the literature where patient 'satisfaction' rates following TKR have been reported to be as low as 75% [4]. Additionally, the majority of patients

included in our study were females (59% intervention group; 69% control group) which is similar to the literature that consistently reports that about 60% of patients who undergo TKR are female [4, 12, 14, 17, 18, 38, 46]. Finally, this study reported a mean BMI of 33 kg/m^2 that is comparable to other studies [12, 17, 18, 46] thereby supporting the generalizability of the study sample.

Strengths of this study include the relatively large sample size and randomized design. In addition, the e-learning intervention utilized custom-made professionally created online educational videos that were brief and contained presentations by surgeons, therapists and past TKR recipients providing a unique level of familiarity for patients.

In addition, the educational content was produced in modules explicitly linked to specific time periods during the patient's recovery, from preoperative through to one year postoperative for TKR surgery. This type of approach is supported in the literature for comprehensive patient education tools being provided to patients undergoing THR and TKR surgery [47-49].

3.5 Conclusion

Our patient education e-learning tool did not result in a between-group difference for patient expectations or satisfaction at one year after TKR surgery. Perhaps the content of the e-learning tool was not specific enough to effect change on patients' expectations of TKR surgery at one year postoperative. Since our study endpoint was one year postoperative, it may be that this time period does not provide a sufficient amount of time for patients to fully establish feelings of satisfaction regarding their TKR surgery. Recognizing patients have high expectations of this surgical procedure perhaps a more appropriate baseline measure should be used to identify the patients at greater risk for not having their expectations met and for not being satisfied with their TKR surgery. Finally, the e-learning tool had been developed for material to be presented to patients at particular time periods during their episode of care. Knowing if patients accessed the tool, when, what and how frequently they accessed the e-learning tool would provide further insight for future studies evaluating the ability of an e-learning patient education tool to affect patients' expectations being met and satisfaction of TKR surgery.

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Chapter 4

4 Utilization of an E-Learning Tool by Patients Undergoing Total Knee Replacement

4.1 Introduction

Individuals living and working with end stage hip and knee osteoarthritis (OA) undergo total hip and knee replacement (THR/TKR) if indicated [1] to reduce pain and improve physical function. The education patients receive should be designed for coordinated delivery before and after surgery [2]. E-learning has been used as an effective tool for educational delivery in corporate and healthcare environments [3, 4].

Patient education through e-learning has demonstrated improved satisfaction [5] and better health outcomes [6] in patients with spinal cord injury [7, 8], hypertension [9], rheumatology [10], diabetes [11, 12] and cancer [13, 14]. By bringing information to the patient at the place and time of their choosing, e-learning has the potential to broaden the reach of existing services and is a promising intervention for patients [15]. Education for patients undergoing TKR usually includes a description of the surgery, expected outcomes, possible adverse outcomes and instruction and timelines related to recovery. E-learning tools could be a useful means of delivering this information, with the added benefit of repeated accessibility on demand throughout the recovery period (usually more frequent leading up to and during the first few weeks following surgery and sometimes up to one year postoperative). However, we are unaware of studies that have investigated the use of e-learning applications for TKR recipients.

Therefore, our purpose was to describe the characteristics of users and the utilization of an e-learning tool that provided information through videos to patients undergoing TKR surgery. Data were collected as part of a randomized controlled trial (RCT) designed to determine if exposure to an e-learning tool could affect patient expectations and patient satisfaction following TKR surgery (see Chapter 3).

4.2 Methods

4.2.1 Sample

Details of the RCT methodology are described elsewhere (see Chapter 3). Briefly, patients who were undergoing primary TKR were asked to participate in the study. Patients were randomized to either the standard method of patient education or the intervention arm, where they were provided the standard method of patient education and had continuous access to an e-learning tool (Fig. 4-1) from before their TKR until one year postoperative.

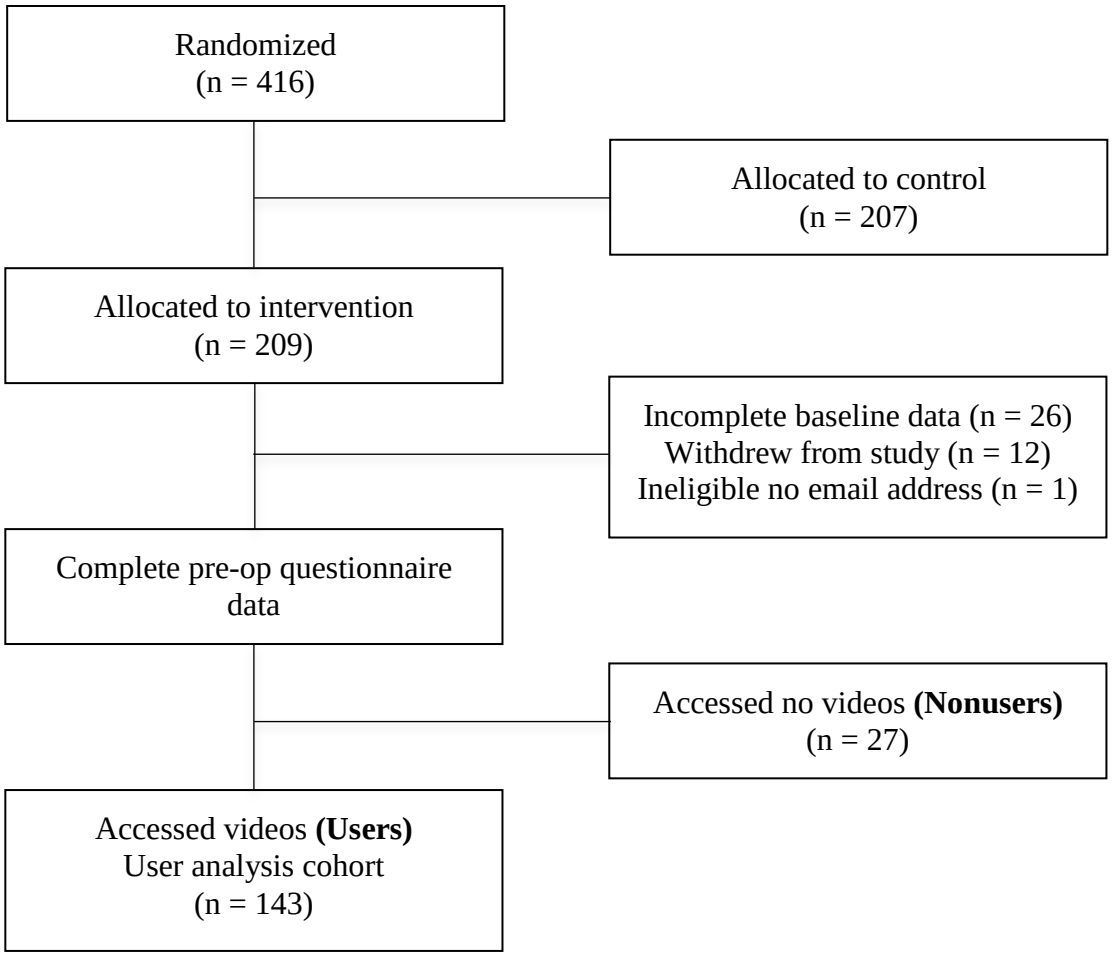

Figure 4-1: A flow diagram illustrating the patients in the trial

4.2.2 Intervention Condition

Login information was provided to patients at their pre admission clinic (PAC) visit. Patients received email reminders to access the e-learning tool and view the time appropriate videos. Preoperative reminders were sent 24 hours after patients' PAC visit and one week later.

Postoperative reminders were sent, immediately after surgery, at six weeks and three months after surgery. Participants were sent a second reminder one week after each of these initial reminders. Access to the e-learning tool continued for patients allocated to the intervention group to the study endpoint of one year postoperative.

4.2.3 Locally Developed E-Learning Tool

The e-learning tool used was comprised of 32 brief (1-2 minutes) educational videos. The educational content was produced with topics that addressed issues most relevant to the following time periods: PAC visit to surgery (Time 1), surgery to six weeks postoperative (Time 2), six weeks to three months postoperative (Time 3), and three months to one year postoperative (Time 4). The topics presented in the videos were: expectations, complications, restrictions, limitations, experiences, exercises, activities and returning to activities.

Presented within the different time periods, there were three types of presenters used in the videos: surgeons, therapists and patients. All presenters were in videos of the four time periods. Videos presented by surgeons (6 videos) focused on the following topics: what patients should expect regarding; pain reduction and management, regaining range of motion and returning to activities of daily living (ADL), and resuming recreational pursuits.

Videos presented by physical therapists (21 videos) focused primarily on demonstrating ADL and exercises under the direct supervision of a physical therapist. Additionally, therapist videos presented stepwise approaches for returning to ADL and re-engaging in general and specific recreational activities (i.e. gardening, golfing, cycling and hiking).

Animations (2 videos) included information about what to expect prior to and following TKR surgery and an animation of the TKR surgical procedure.

Videos presented by patients (3 videos) provided information on their own expectations regarding pain, stiffness and whether their own expectations were met. All videos contained content that addressed what patients can expect preoperatively through to one year following their TKR surgery. For more details and an outline of all videos in the e-learning tool, see Appendix A.

All of the presenters were from the study site, with the exception of the animator videos. The animator videos were provided by a digital communications agency that creates visual content for healthcare, education, media, pharmaceutical and medical device companies. These videos gained pre-approval by the orthopaedic surgeons at our site.

At the patient level, we defined a ‘user’ of the e-learning tool by having accessed a minimum of one content video. A maximum user or ‘max user’ of the tool was a user having accessed all of the videos within a category, for example by presenter (surgeon, physical therapist, animator, patient) or time period or topic (expectations, complications, restrictions, limitations, experience, exercises, activities and returning to activities). Those patients in the intervention group having never accessed even one content video were defined as a ‘nonuser’ of the e-learning tool.

4.2.4 Data Collection Protocol

Patient demographics and baseline patient reported outcome measures (PROMs) were collected preoperatively at the patients’ Pre Admission Clinic (PAC) visit and prior to the patient accessing the e-learning tool.

Patient utilization of the e-learning tool was captured using a graphic statistics system that provided complete online activity logs of the users. Using these logs, we were able to identify which video the patient viewed, the date the patient viewed a particular video, and the number of times they accessed the video(s). This enabled us to establish frequency counts and percentages of patients accessing specific types of videos by content, presenter and observation time period.

4.2.5 Patient-Reported Outcome Measure

We used the following patient-reported outcome measures (PROMs) to capture data on potential predictors of 'users' and 'nonusers'. We measured comorbidities with the Self-Administered Comorbidity Questionnaire [16] pain coping characteristics, social role participation and mental status using the Pain Catastrophizing Scale [17], Social Role Participation Questionnaire [18, 19], Hospital Anxiety And Depression Scale [20, 21] and scales to measure satisfaction, expectations, symptoms, quality of life, pain and participation in activities of daily living (ADLs) and sports using the Knee Injury and Osteoarthritis Outcome Score [22, 23], Knee Society Score (Pre-Op and Post-Op versions) [24, 25], University of California at Los Angeles (UCLA) Activity Score [26], the Patient Acceptable Symptom State (PASS) Questionnaire [27, 28], the Preoperative Expectation Questionnaire [29], SF-12 Health Survey [30, 31]. For descriptions of questionnaires in alphabetical order see Appendix C.

4.2.6 Statistical Analysis & Sample Size

We described utilization of the e-learning tool in the following manner. First at the level of the tool, we described overall access by counting the total number of 'hits' (i.e. video was accessed) at each time interval, regardless of the presenter or video content selected. Then, based on the number of hits on specific videos within the e-learning tool, we identified the most commonly accessed presenters and video topics at each time interval.

We used descriptive statistics to report patient demographics and preoperative characteristics for users and nonusers of the e-learning tool. They were expressed as means $\pm$ standard deviations for continuous variables and frequencies and percentages for categorical variables. Between-group comparisons were made using unpaired t tests for continuous variables and chi-square tests for categorical variables. Data analyses were performed using SAS 9.4 (SAS Institute Inc. Cary, North Carolina).

Sample size was calculated to adequately power the analysis for the RCT (see Chapter 3).

4.3 Results

This study analyzed data from the 209 patients who were randomized to the e-learning arm of the RCT. The following patients were excluded from the analysis: 26 patients did not complete their baseline questionnaires, 12 patients requested to be withdrawn, and one patient was ineligible because they did not provide an email address which was required to access the online e-learning tool. One hundred seventy patients completed the preoperative questionnaire. Twenty-seven patients did not access any video content and were classified as 'nonusers'. The remaining 143 patients accessed at least one video of content during their preoperative to one year postoperative time period and were classified as 'users'.

The patients classified as user and nonuser were similar in terms of demographic and baseline characteristics (Table 4-1). Furthermore, both user and nonuser groups were similar with respect to baseline PROMs (Table 4-2).

Table 4-1: Patient preoperative characteristics of users and nonusers of an e-learning tool

	Users (n = 143)	**Non-Users (n = 27)**	**p Value**
Female sex	85 (59%)	15 (56%)	0.71
Age (years)*	64 $\pm$ 8	65 $\pm$ 9	0.74
BMI (kg/m^2)*	33 $\pm$ 8	34 $\pm$ 8	0.69
First primary TKR, yes	97 (68%)	15 (56%)	0.22
Working, yes	47 (33%)	10 (37%)	0.67
Live alone, yes	26 (18%)	1 (4%)	0.59
Dependent on others, yes	26 (18%)	6 (22%)	0.62
Care giver, yes	32 (22%)	8 (30%)	0.42

*Values expressed as mean $\pm$ standard deviation; for continuous variables, and absolute and relative frequencies for categorical variables. BMI = Body Mass Index; TKR = Total Knee Replacement

Table 4-2: Preoperative patient-reported outcome measures (PROMs) for users and nonusers of an e-learning tool

	Users (n = 143)	Nonusers (n = 27)	p Value
Self-Administered Comorbidity			
≤ 2 comorbidities	65 (46%)	15 (56%)	0.25
Pre-Op Expectations			
Pain Relief - Yes, a lot	118 (83%)	21 (81%)	0.78
Activities of Daily Living - Yes, a lot	111 (78%)	18 (69%)	0.12
Sport, Leisure, Recreation - Yes, as much as before	95 (70%)	21 (91%)	0.09
Full Recovery - Yes, complete	60 (42%)	14 (52%)	0.39
Knee Society Score: Pre-Op			
Symptoms	7.05	6.85	0.92
Patient Satisfaction	16.18	15.25	0.88
Patient Expectations	13.36	13.20	0.43
Pain Relief	4.60	4.50	0.51
Activities of Daily Living	4.51	4.41	0.56
Return to Sports	4.25	4.29	0.83
Functional Activities	34.25	31.08	0.80
Knee Injury & Osteoarthritis Outcome Score			
Symptoms	41.00	37.26	0.62
Pain	39.70	37.19	0.74
Activities of Daily Living	44.87	43.86	0.94
Sport and Recreational Activities	16.79	22.39	0.38
Quality of Life	19.06	20.10	0.41
SF-12 Health Survey			
Physical Health Composite Score	29.41	29.67	0.77
Mental Health Composite Score	52.99	49.85	0.46
Hospital Anxiety and Depression Scale			
Anxiety	5.36	6.11	0.74
Depression	4.48	5.07	0.92
Pain Catastrophizing Scale			
Rumination	5.20	5.80	0.93
Magnification	2.15	2.73	0.44
Helplessness	4.87	7.15	0.08
Social Role Participation Questionnaire			
Role Importance	3.88	3.69	0.09
Role Limitations	1.94	1.81	0.07
Role Performance	2.45	2.64	0.09
UCLA Activity Score			
Inactive to Impact	4.22	4.07	0.93
Patient Acceptable Symptom State			
Satisfied, Yes	18 (13%)	4 (15%)	0.71

*Mean (95% CI) for continuous variables, and absolute and relative frequencies for categorical variables. SF-12 Health Survey = The 12-item Short Form Health Survey; UCLA = University of California at Los Angeles Activity Score

Users viewed videos in all four of the time periods from preoperative to one year postoperative. We observed a reduction in the number of hits over time, with usage being highest (1598 hits) during the preoperative time period (Fig. 4-2).

The top three most frequently viewed videos in each of the four time periods were the surgeons. The topic presented by the surgeons that was the most frequently viewed was patient expectations. In time 1, surgeon topics most frequently accessed were expectations (185 hits), then complications (141 hits), and finally restrictions (115 hits). Patients generally viewed content designed for a specific time period, during that actual time period. The only exception to this, was a video of a surgeon discussing expectations designed for time 3 (113 hits), that was frequently viewed during time 3 then frequently viewed again, during time 4 (40 hits) (Table 4-3).

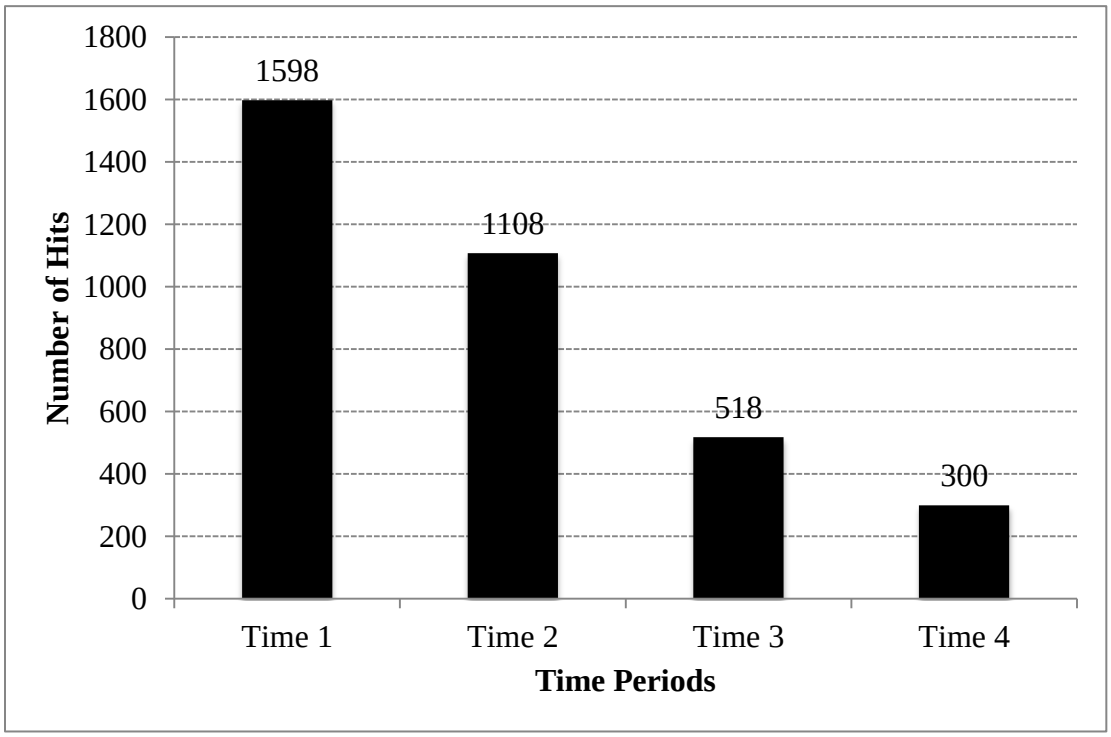

Figure 4-2: Total number of videos viewed (Hits) by users in the following four time periods: PAC visit to surgery (Time 1), surgery to six weeks postoperative (Time 2), six weeks to three months postoperative (Time 3), three months to one year postoperative (Time 4)

Table 4-3: Top three most frequently accessed videos in each of the following four time periods: PAC visit to surgery (Time 1), surgery to six weeks postoperative (Time 2), six weeks to three months postoperative (Time 3), three months to one year postoperative (Time 4)

	Time period video viewed			
	Time 1	**Time 2**	**Time 3**	**Time 4**
1st				
Presenter Topic # of Hits	Surgeon Expectations 185	Surgeon Expectations 130	Surgeon Expectations 113	Surgeon Expectations 46
2nd				
Presenter Topic # of Hits	Surgeon Complications 141	Therapist Activities 63	Therapist Activities 69	Surgeon Expectations 40*
3rd				
Presenter Topic # of Hits	Surgeon Restrictions 115	Patient Experience 63	Therapist Activities 68	Therapist Activities 39

* Video corresponds to content of Time 3; All other frequently accessed videos viewed at designed time period.

For all presenter types, the frequency of hits decreased over time (Fig. 4-3). The largest percent of patients accessing videos presented by surgeons at time 1 (PAC-surgery) was 88% down to time 4 (3 mos-1 yr) at 41%. A similar trend was seen with the percent of users having accessed videos by different presenters (Therapists, Animators and Patients) for each of the four time periods from time 1 (PAC-surgery) to time 4 (3 mos-1 yr).

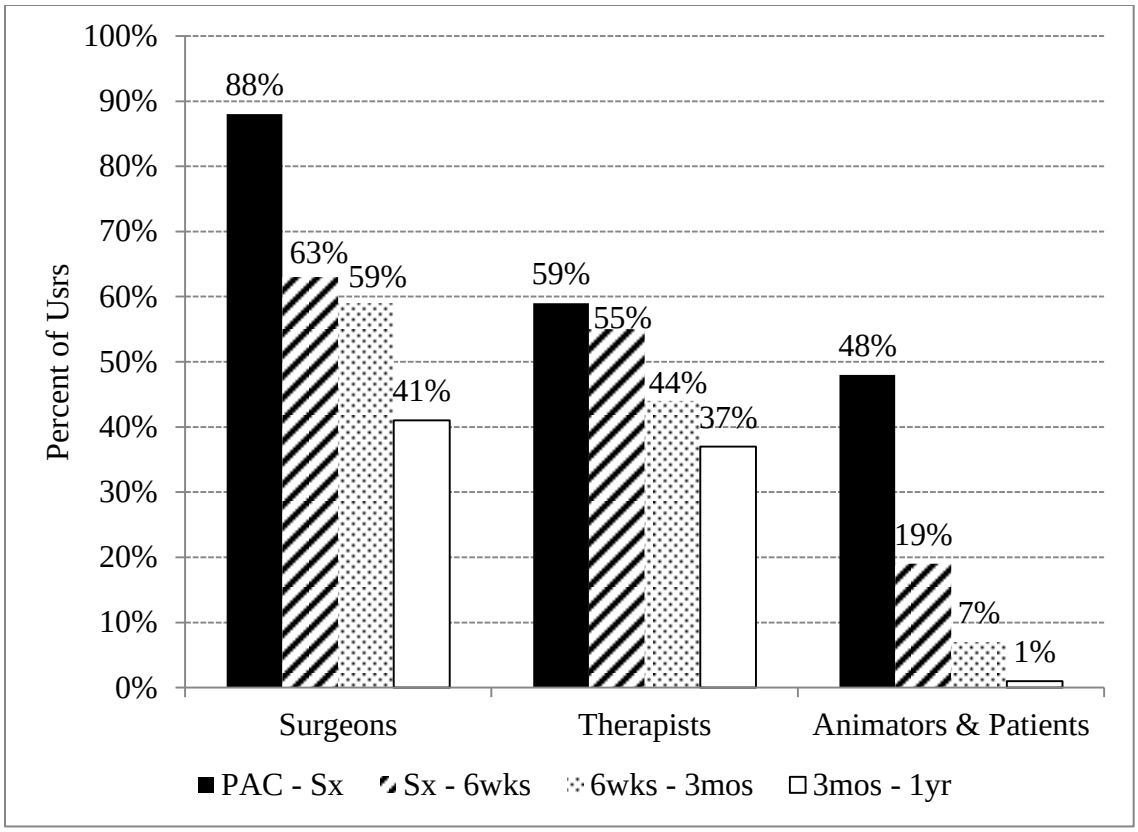

Figure 4-3: The percent of users having accessed videos when grouped by different presenters in each of the four time periods: PAC visit to surgery (Time 1), surgery to six weeks postoperative (Time 2), six weeks to three months postoperative (Time 3), three months to one year postoperative (Time 4)

There were only six (4.2%) max users within the 143 users; or six (3.5%) of the 170 patients who had access to the e-learning tool. A total of 43 of the 143 users (30.1%) accessed all eight preoperative videos, only eight of the 143 users (5.6%) accessed all 24 postoperative videos. The video presenter category with the smallest number of videos (two animator videos) was watched in its entirety by the largest percent of maximum users (52%), while the presenter category with the largest number of videos (21 physical therapist videos) was watched in its entirety by the smallest percent of maximum users (8%) (Fig. 4-4). The video content presented by the surgeon and physical therapist videos were covered in the standard method of patient education provided at the study site. The content of the animator and patient videos was above and beyond the standard patient education and manual.

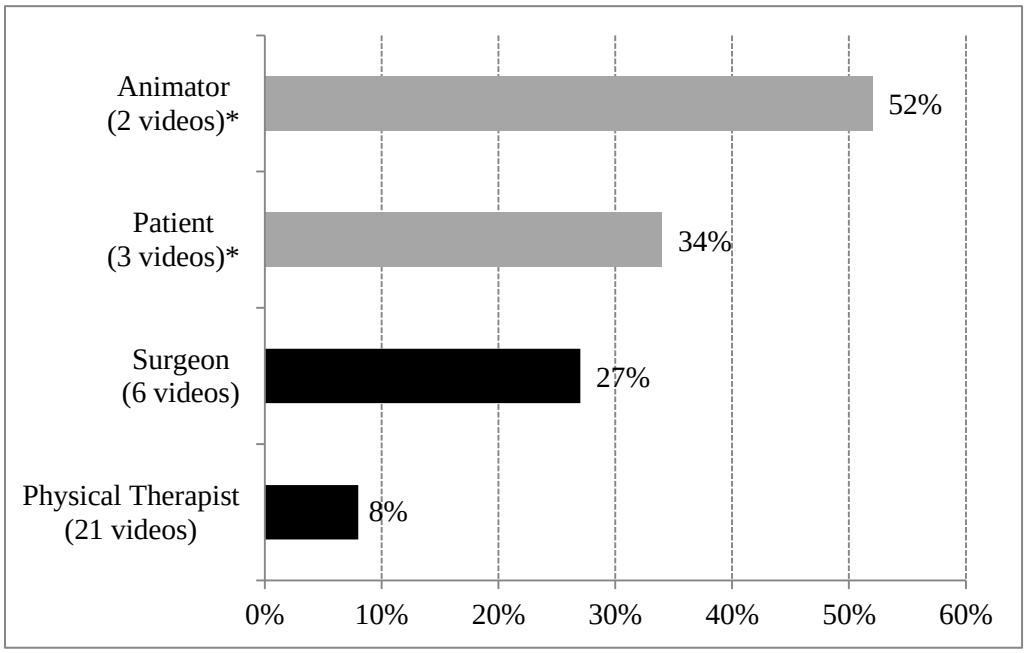

Figure 4-4: Percent of maximum users viewing all videos in each of the four categories of presenters. *Animator and patient videos are in addition to the standard method of patient education.

4.4 Discussion

The current study described the characteristics and utilization of a patient education e-learning tool designed for patients undergoing TKR surgery. Over a one year time period, use of the e-learning tool steadily declined with the lowest access levels found between three months and one year postoperative. Surgeon presented content regarding expectations of surgery were the top ranked videos based on number of hits, regardless of the time period. When use was defined as the number of patients accessing at least one video; the decline in access over time and the preference for surgeon content was still evident. When use was defined as accessing all videos within a content category, it was the two animator videos along with the three patient videos combined that were accessed by the largest proportion of users. Of note, only 8% of the e-learning users accessed all 21 of the therapist videos, an important rehabilitation component of the e-learning offering in this tool.

Declining use of the e-learning tool during the first year of recovery, suggests that patients were feeling more confident in their recovery and that the surgery and recovery were no longer at the forefront of their thoughts. It is also possible that content relevant for the later recovery period was viewed by patients preoperatively or during the early postoperative period. If surgeons and therapists believe that there is relevant content patients should review between three months and one year postoperative, then strategies should be developed to encourage use of the tool during the later phases of recovery. Strategies should take the form of increasing the frequency of follow-up email reminders, timing the release of information, or offering incentives to review information during certain time periods.

The top three most frequently accessed videos from preoperative to one year postoperative were those presented by a surgeon. This affirms that surgeons' views are important to patients. Our e-learning utilization data suggest that surgeons should educate their residents and fellows about the importance of their role in the education of patients undergoing TKR surgery. Furthermore, given that the top-ranked content category pertained to surgeons' comments about expectations, it would seem important for

surgeons to convey their opinion of reasonable expectations at multiple time points if the message is to have an impact on patient expectations of TKR surgery.

We also found the percent of users accessing all videos in a presenter category was largest for educational offerings not provided in the standard patient education and manual. It is possible that patients only accessed the e-learning tool after reading the content handed out in hard copy and only accessed content not offered in the written material. It is also possible that patients preferred the material within those categories (animator and patient). In addition, it also may have been the relatively small number of videos in these categories two animator and three patient videos) that made it more likely that all of the videos would be accessed.

Of potential concern was the finding that of the 21 videos hosted by a physical therapist, only 8% of patients accessed the entire category. Patients may not understand the progressive nature of physical therapy; first toward reducing swelling and pain and regaining basic range of motion, then to regaining strength, and finally to resuming more challenging movements that may make it possible to return to recreational activities. Perhaps ensuring that surgeon and therapist content provides reinforcement for the importance and progressive nature of physical therapy would increase the number of hits in this category. Or, perhaps patients were satisfied with their actual physical therapy experience following their TKR surgery and did not feel the necessity to access the videos presented by a physical therapist.

This study had certain limitations. First, we assumed if users ‘clicked’ on a video then they watched the video. While our behind-the-scenes software did capture ‘clicks’ pertaining to actual video access, we were not able to quantify the length of time a video was open. Therefore, it is possible that videos were not viewed to completion once they were started. At the very least, we believe the analysis probably reflects TKR recipients’ general level of interest for e-learning content pertaining to their surgery.

A second limitation was our reliance on emails to remind patients to watch videos. It is possible that some patients did not receive the email reminders (automatically filtered to spam) or they were not regular users of email. We could have sent email reminders more

frequently, asked for confirmation that the emails were received, which may have stimulated greater video usage and helped identify patients who may have needed other forms of reminders (i.e. postcards).

Third, as this was an exploratory study there were no formal sample size calculations performed for this study. Therefore, it may be that no differences were found between the users and the nonusers because the study was underpowered to detect between-group differences. For example, the group comparison of preoperative expectations for sport, leisure and recreational activities failed to reach statistical significance at p=0.09 (see Table 4-2). A post hoc power analysis for this comparison yielded 60% power to detect the between-group difference.

A fourth limitation of this exploratory study of an e-learning tool was that the tool had not been independently validated. Face and content validity had been established prior to the use of the tool in this study, see Appendix A. This has been the only study to date that has used this e-learning tool. Establishing independent validity and reliability, for use in future studies would add greatly to the literature regarding the effect of patient e-learning tools on expectations being met and satisfaction of TKR surgery.

A major strength and positive finding of this study was that there was high utilization of the e-learning tool, particularly during the preoperative time period of the study. Early indications were this e-learning tool was indeed being used by the patient population in this study. By one year after TKR surgery, 44% of the patients accessing the intervention tool were still engaged in viewing the surgeon content videos.

Previous research studies have reported change in knowledge acquired by patients when provided access to computer-based learning programs [2, 4, 32-36]. Soever et al. [37] found it was important to THR/TKR patients that information be made available at both pre- and postoperative times of the continuum of care. They [37] recommended clinicians provide a comprehensive range of educational information for patients, families and their caregivers. Lin et al. [38] found the opportunity to repeat content after surgery and have more time for learning using an educational program for TKR patients was helpful, particularly for older patients.

4.5 Conclusion

Baseline characteristics of TKR recipients who were users of an e-learning tool were no different than those who were nonusers. Use of the e-learning tool was highest during the preoperative time period with declining use thereafter to one year postoperative. There are a number of reasons that could be cited for the decline in usage of the tool. Initially email reminders were sent immediately following TKR surgery, then at six weeks and three months after surgery. A second email reminder was sent one week after each of these initial reminders. Patient access of this e-learning tool may have been sustained if the email reminders had been maintained until patients reached the one year postoperative time period.

Patients may not have found the videos to be of interest to them or helpful for their particular situation. Surgeon videos that included expectations of surgery were the most frequently viewed regardless of the time period. The perspective of the arthroplasty surgeons in the videos of this e-learning tool was an opportunity for patients prior to and after undergoing TKR to see and hear these experts beyond their patient consultation visits. Videos in the two categories, presented by an animator and presented by a patient that provided content beyond the standard method of patient education were the most frequently accessed in the study. Perhaps patients undergoing TKR are looking for more information than what is presently being provided in the manual given to patients undergoing TKR surgery.

4.6 Recommendations

Recognizing that initially patients were frequently accessing the information on this e-learning tool, we recommend a locally developed e-learning tool with specific content for particular time periods related to TKR surgery. Further, we recommend increasing the frequency of email reminders to patients to access the e-learning tool as a function of postoperative recovery time. Independently evaluating the validity and reliability of an e-learning tool is also recommended for future studies.

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Chapter 5

5 Validity and Internal Consistency of the New Knee Society Knee Scoring System

5.1 Introduction

Patient-reported outcome measures (PROMs) gauge health changes in patients undergoing total knee replacement (TKR). A key objective of PROMs is to assist healthcare providers and other healthcare stakeholders to improve quality of care [1]. Increasingly PROMs are being used to evaluate functional outcomes and patient expectations and satisfaction following TKR surgery [2]. Traditionally, TKR outcome measures focused on objective parameters; radiographic analysis and/or clinical tests [3]. In the past few decades the development of PROMs have provided for patient involvement in assessing the outcome of medical treatment [4-6].

The Knee Society Clinical Rating System was developed in 1989 to be a simple, objective scoring system to rate the knee and patient's functional abilities such as walking and stair climbing before and after TKR surgery [7]. Since its development the Knee Society Clinical Rating System has been a useful method of tracking and reporting both total and partial knee replacements globally [8]. Over time, uncertainties and insufficiencies with the original Knee Society Clinical Rating System have emerged questioning its utility and validity with current patients undergoing TKR [8] and revision TKR surgery [9].

In 2012, a new Knee Society Knee Scoring System (KSS) was introduced to meet the need for a scoring system that better characterizes the expectations, satisfaction and physical activities of a current, younger and more varied population of TKR recipients [10]. The new tool was developed and validated from responses to the survey provided to patients (n = 497) in 15 medical institutions in the United States and Canada [10]. The new KSS is based on information from two domains: objective measures, which are surgeon-generated measures; and subjective measures, completed by the patient and include a symptoms (pain) score, satisfaction score, expectation score, and functional

activity score. The functional activity score is subdivided into four subscales: walking and standing, standard, advanced, and discretionary activities [10]. The tool measures both pre- and postoperative expectations and satisfaction, which few if any other tools can perform as an outcome measure for patients undergoing TKR. The long form [8, 10] is recommended for research studies [11] and the short form is expected to increase the rate of patient completion in clinical use. Additionally the long form was used in this thesis as no expectations data are captured with the short form.

This study sought to perform an independent validation of the new KSS in a sample of patients undergoing primary TKR. A secondary objective was to evaluate the internal consistency of the new KSS. The pooled control group and intervention group data are from a randomized controlled trial (RCT) designed to determine if exposure to an e-learning tool affected postoperative patient expectations and patient satisfaction following TKR surgery (see Chapter 3).

5.2 Methods

5.2.1 Participants

Specific details of the RCT methodology are identified elsewhere (see Chapter 3). There were 345 patients in the analysis data set for this study. Control (n = 178) and intervention (n = 167) groups from the RCT with no between-group differences were pooled (Fig. 5-1.). The combined control and intervention group baseline patient demographic characteristics were collected at the Pre Admission Clinic (PAC) visit, time 1 (Table 5-1).

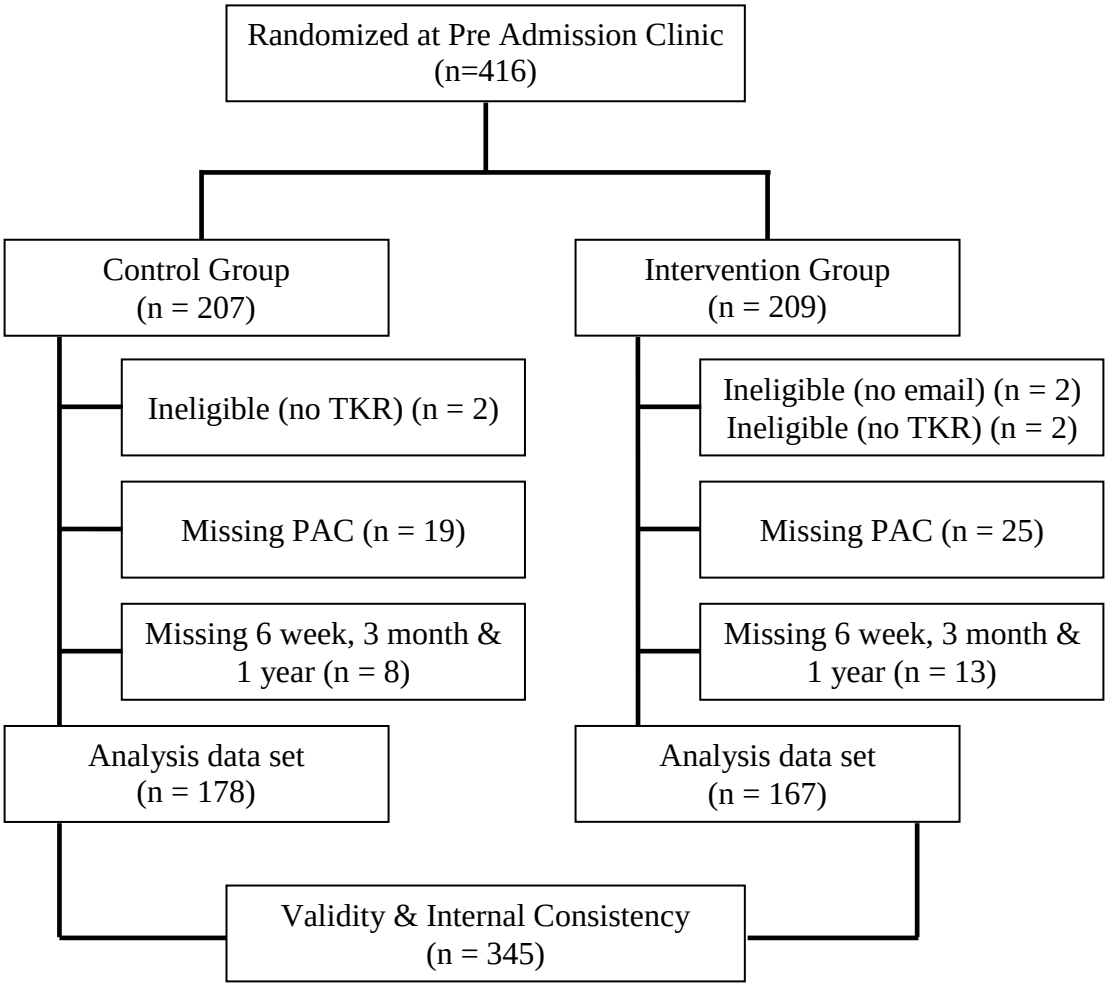

Figure 5-1: A flow diagram illustrating patient enrollment, randomization and pooled analysis. TKR = total knee replacement; PAC = Pre Admission clinic

Table 5-1: Preoperative demographics collected at time 1 (n = 345)

	Frequency (%) of patients**
Female sex	221 (64)
Age (years)*	64 (8.56)
BMI (kg/m^2)*	32.9 (7.47)
First primary TKR, yes	225 (68)
Working, yes	110 (33)
Live alone, yes	53 (16)
Dependent on others, yes	61 (18)
Care giver, yes	80 (24)

*Mean (SD); **except where noted.

5.2.2 Data Collection Protocol

Patient demographics and baseline PROMs were collected preoperatively at the patient's PAC visit (time 1). Postoperative PROMs were completed at the scheduled postoperative consultation time periods of six weeks (time 2) and one year (time 3) after TKR surgery for both groups.

5.2.3 Patient-Reported Outcome Measures

Patients completed all of the patient-reported components of the new KSS, the Knee Injury and Osteoarthritis Outcome Score (KOOS), the Short Form (SF)-12, two independent questions (preoperative and postoperative) about their expectations of surgery and the Patient Acceptable Symptom State (PASS) satisfaction question. For descriptions of the new KSS, KOOS, and SF-12 questionnaires, see Appendix C.

5.2.4 Statistical Analysis & Sample Size

Sample size was determined for the RCT (see Chapter 3). Our sample size exceeded the calculated minimum required sample size of n = 189 for identifying correlation coefficients of 0.60 with a confidence interval width of 0.20, alpha = 0.05 [12]. Descriptive statistics were calculated for all relevant patient demographics. They were expressed as means for continuous variables, and frequencies for categorical variables.

We calculated all change scores in order to report positive values as representing improvement for patients.

5.2.5 Cross-Sectional & Longitudinal Validity

Cross-sectional validity (time 1) and longitudinal validity (time 1 or time 2 versus time 3) were evaluated by calculating Spearman's rank order correlation coefficient as a measure of the strength of the correlation between the scores of the different scales and subscales in the new KSS and the KOOS subscales [13, 14]. We hypothesized a positive association between the new KSS patient derived subscales scores for symptoms, functional activities score and satisfaction score with the KOOS subscale scores for pain, other symptoms, function in activities of daily living (ADL), function in sport and recreation (Sport/Rec) and knee-related quality of life (QOL). Given the direction of the scores and the dimensions measured, we expected positive moderate ($r \geq 0.30$) to strong ($r \geq 0.50$) correlations [15] between the three new KSS subscale scores and the five KOOS subscale scores (Table 5-2).

5.2.6 Known-Groups Validity

SF-12 Physical Component Score

To determine known-groups validity at time 1, we compared the new KSS scores for symptoms and functional activities across three tertiles or subgroups (low, medium, high) of the SF-12 physical component score (PCS) using a one-way ANOVA with pairwise comparisons made using Tukey's multiple comparisons post hoc procedure [16, 17]. A significant difference indicated that a new KSS measure could differentiate across known groups of physical function in the SF-12 PCS.

We hypothesized that when the SF-12 PCS increased from a low (worse) score to a high (better) score the new KSS subscale scores for symptoms, functional activities and the subscales scores within the functional activities would also increase from a low or worse score to a high or better score.

Preoperative Expectations

We compared the new KSS preoperative expectations score across response categories of our preoperative expectation question. It uses a single question related to expectations for each of the following; pain relief, ability to perform activities of daily living (ADL), ability to participate in sports and global recovery from surgery scored as ‘No/somewhat’ indicating low expectations and ‘A Lot’ being indicative of high expectations. A between group difference was tested with an unpaired t-test.

We hypothesized that when preoperative expectations were low for patients as measured by our single question, the new KSS preoperative expectation subscale value would likewise be low. Alternatively when preoperative expectations were high for patients as measured by our single question, the new KSS preoperative expectation subscale score would be high for patients.

Postoperative Expectations

We compared the new KSS postoperative expectations score (time 3) across response categories of our postoperative expectation question that determined whether postoperative expectations were ‘not met’ or ‘met’. A between group difference was tested with an unpaired t-test.

We hypothesized that when postoperative expectations were ‘not met’ for patients as measured by our postoperative expectation question, the new KSS postoperative expectation subscale score would likewise be low indicating postoperative expectations were ‘not met’. Alternatively, when postoperative expectations were ‘met’ for patients as measured by our single question, the new KSS preoperative expectation subscale score would be high indicating postoperative expectations were ‘met’ for patients.

Satisfaction

Finally, we compared the new KSS satisfaction subscale score across response categories of the Patient Acceptable Symptom State Question (PASS). This question asked, “Considering all of the activities you do during your daily life, your level of pain, and

also your functional impairment, do you consider that your current state is satisfactory?" (Response options, 'yes' or 'no'. A between group difference was tested with an unpaired t-test.

We hypothesized that when patients indicated they were not satisfied following TKR surgery as measured by the PASS question, the new KSS satisfaction subscale score would be low. Alternatively when patients indicated they were satisfied following TKR surgery as measured by the PASS question, the new KSS satisfaction subscale score would be high indicating a greater level of satisfaction.

Statistical significance was set at $p < 0.05$. Data analyses were done using SAS 9.4 (SAS Institute Inc. Cary, North Carolina).

5.2.7 Internal Consistency

We calculated Cronbach's alpha [18, 19] values for time 1 of the new KSS preoperative satisfaction, expectations and the functional activity subscales (walking and standing, standard, advanced and discretionary activities) and at time 3 for postoperative expectations.

5.3 Results

Mean new KSS and KOOS values over the testing time period are shown in Table 5-2. They show an improvement in the new KSS subscales and the KOOS subscale scores; from the preoperative time period to the one year postoperative time period.

5.3.1 Cross-Sectional & Longitudinal Validity

In the cross sectional validity analysis, correlation coefficients varied from 0.60 to 0.73 across the KOOS pain and ADL subscales and from 0.41 to 0.58 across the remaining KOOS subscales (Table 5-3). A similar pattern was found in the longitudinal validity analysis; correlation coefficients varied from 0.63 to 0.73 across the KOOS pain and ADL subscales and from 0.47 to 0.65 across the remaining three subscales (Table 5-3).

Table 5-2: The new Knee Society Score (KSS) and the Knee Injury & Osteoarthritis Outcome Score (KOOS) PROMs are reported for each consultation time period

	Testing Time Period: mean (SD)				
	Time 1 PAC PreOp	**Time 2 Six weeks PostOp**	**Time 3 One year PostOp**	**Change Score (n = 345)**	**Effect Size† (95% CI)**
Knee Society Score					
Symptoms*	7.2 (4.8)	15.4 (5.6)	19.4 (4.9)	12.2 (6.2)	2.0 (1.8, 2.2)
Satisfaction*	13.0 (6.7)	24.8 (8.3)	31.9 (8.4)	18.8 (10.1)	1.9 (1.7, 2.1)
Expectations Pre Op**	13.4 (1.9)				
Expectations Post Op***		8.3 (2.6)	9.2 (2.8)	0.9 (2.9)	0.3 (0.2, 0.4)
Functional*	32.7 (15.2)	40.4 (20.2)	66.5 (20.2)	33.7 (20.8)	1.6 (1.5, 1.8)
Walking*	12.1 (7.l)	13.0 (7.4)	21.8 (8.0)	9.7 (7.8)	1.2 (1.1, 1.4)
Standard*	11.5 (4.9)	18.4 (5.7)	23.0 (5.1)	11.6 (6.0)	1.9 (1.7, 2.1)
Advanced*	4.4 (3.6)	5.5 (5.0)	11.4 (5.8)	6.8 (5.7)	1.2 (1.1, 1.4)
Discretionary*	5.3 (3.0)	6.2 (4.6)	11.1 (3.2)	5.8 (3.9)	1.5 (1.3, 1.7)
Knee Injury & Osteoarthritis Outcome Score*					
Symptoms	41.7 (17.3)	58.7 (16.5)	75.5 (15.7)	33.7 (19.6)	1.7 (1.6, 1.9)
Pain	40.5 (16.9)	61.1 (17.6)	81.4 (17.3)	40.7 (20.6)	2.0 (1.8, 2.2)
Daily Living	45.5 (17.6)	68.0 (17.7)	82.6 (16.4)	36.9 (20.3)	1.8 (1.6, 2.0)
Sports & Recreation	18.1 (24.6)	32.3 (30.6)	54.8 (28.8)	36.4 (32.6)	1.1 (1.0, 1.3)
Quality of Life	19.4 (15.3)	45.1 (20.4)	64.9 (21.7)	45.1 (24.3)	1.9 (1.7, 2.0)

*T3-T1 to indicate +ve change score = Improvement
**Change score not applicable
***T3-T2 to indicate +ve change score = Improvement
†Effect size: change score divided by standard deviation of the change score

Table 5-3: Measures of KSS components and KOOS subscales; Spearman correlation coefficient (95% CI)

	KSS components		
	Symptoms	**Functional**	**Satisfaction**
Cross-sectional validity (PAC visit)			
KOOS subscales			
Pain	0.67 (0.61, 0.73)	0.60 (0.52, 0.66)	0.73 (0.68, 0.78)
ADL	0.67 (0.60, 0.72)	0.69 (0.63, 0.74)	0.66 (0.60, 0.72)
Symptoms	0.43 (0.35, 0.52)	0.41 (0.32, 0.50)	0.49 (0.41, 0.57)
Sports	0.51 (0.42, 0.58)	0.53 (0.45, 0.60)	0.43 (0.34, 0.51)
QoL	0.58 (0.50, 0.65)	0.57 (0.50, 0.64)	0.53 (0.45, 0.60)
Longitudinal validity (PAC visit to 1 year)			
KOOS subscales			
Pain	0.71 (0.65, 0.76)	0.63 (0.56, 0.69)	0.73 (0.67, 0.78)
ADL	0.68 (0.61, 0.73)	0.69 (0.60, 0.73)	0.70 (0.64, 0.75)
Symptoms	0.48 (0.39, 0.56)	0.47 (0.38, 0.55)	0.53 (0.44, 0.61)
Sports	0.51 (0.42, 0.59)	0.50 (0.40, 0.58)	0.47 (0.38, 0.55)
QoL	0.60 (0.52, 0.66)	0.65 (0.58, 0.71)	0.61 (0.53, 0.67)

*Unless otherwise indicated, all $p<0.001$
Correlation between PAC values

5.3.2 Known-Groups Validity

SF-12 Physical Component Score

Looking at the new KSS subscale scores across the three known groups of physical function as measured by the SF-12 PCS, all post hoc pairwise comparisons reached statistical significance ($p < 0.01$). When the SF-12 PCS increased the new KSS subscale scores also increased (Table 5-4). Patients with worse physical function as measured by the SF-12 PCS had worse symptoms and functional activities scores as measured by the new KSS. Likewise, patients with better physical function as measured by the SF-12 PCS had better symptoms and functional activities scores as measured by the new KSS.

Table 5-4: Known Groups Physical Function

	Pre SF-12 PCS			
	Low Mean (SD) (n = 110)	**Medium Mean (SD) (n = 110)**	**High Mean (SD) (n =109)**	**p Value**
Knee Society Score				
Symptoms*	4.4 (3.3)	7.1 (4.4)	9.8 (4.6)	<0.01
Functional*	24.6 (12.0)	32.1 (13.3)	42.3 (13.9)	<0.01
Walking*	8.8 (6.5)	11.6 (6.8)	15.8 (6.2)	<0.01
Standard*	9.3 (4.1)	11.3 (4.4)	13.9 (4.7)	<0.01
Advanced*	2.9 (2.8)	5.9 (3.4)	6.5 (3.7)	<0.01
Discretionary*	3.8 (2.6)	5.2 (2.8)	6.7 (2.8)	<0.01

*Tertile values: low $\leq$ 26.122; medium 26.123 to 31.871; high > 31.871

Preoperative Expectations

When preoperative expectations were low as measured by our single preoperative expectation question, the new KSS preoperative expectation subscale scores were worse ($p < 0.01$). Alternatively, when preoperative expectations were high as measured by our single preoperative expectation question, the new KSS preoperative expectation values were better (Table 5-5).

Postoperative Expectations

When postoperative expectations were low, meaning 'not met' as measured by our single postoperative expectation question, the new KSS postoperative expectation subscale scores were worse ($p < 0.01$). Alternatively, when postoperative expectations were high meaning 'expectations met' as measured by our single postoperative expectation question, the new KSS postoperative subscale scores were better (Table 5-6).

Satisfaction

When preoperative satisfaction was absent as measured by our single preoperative satisfaction question, the new KSS preoperative satisfaction subscale scores were low, indicating worse patient satisfaction with their current state ($p < 0.01$). Alternatively, when preoperative satisfaction was present as measured by our single preoperative satisfaction question, the new KSS preoperative satisfaction values were high, indicating better patient satisfaction with their current state (Table 5-7).

Internal Consistency

The value of Cronbach's alpha for the satisfaction construct was 0.80 for preoperative data (Table 5-8). Similar values were observed for the expectation construct (preoperative: 0.81; postoperative; 0.94). Values for the individual scores of the functional activities subscale varied from 0.68 to 0.81, an acceptable level of internal consistency.

Table 5-5: Known Groups for Preoperative Expectations

Preoperative Expectation Questions	No/Somewhat Mean (SD)	A Lot Mean (SD)	p Value
Knee Society Score: Preoperative			
Expectations*			
Pain Relief*	10.9 (2.4) n = 54	13.9 (1.4) n=277	<0.01
Activities of Daily Living*	11.3 (2.3) n = 78	14.1 (1.2) n = 253	<0.01
Sports*	12.5 (2.2) n = 96	14.0 (1.4) n = 216	<0.01
Full Recovery*	12.7 (2.1) n = 199	14.5 (1.0) n = 133	<0.01

*Change score not applicable

Table 5-6: Known Groups for Postoperative Expectations

Postoperative Expectation Question	Not Met Mean (SD)	Met Mean (SD)	p Value
Knee Society Score: Postoperative			
Expectations*	6.1 (2.0) n = 52	9.9 (2.5) n = 250	<0.01

*T3-T1 to indicate +ve change score = Improvement

Table 5-7: Known Groups for Satisfaction

Patient Acceptable Symptom State Question	No Mean (SD)	Yes Mean (SD)	p Value
Knee Society Score: Preoperative			
Satisfaction*	12.4 (6.5) n = 290	16.2 (7.1) n = 41	<0.01

*T3-T1 to indicate +ve change score = Improvement

Table 5-8: The Cronbach's alpha values for satisfaction, expectation and the subscales of the functional activity compared to the new Knee Society Knee Scoring System (KSS)

Knee Scoring System	Cronbach's alpha
Satisfaction Score*	0.80
Expectation Score*	0.81
Expectation Score**	0.94
Functional	
Walking and Standing *	0.81
Standard Activities*	0.84
Advanced Activities*	0.73
Discretionary Activities*	0.68

*Preoperative new KSS
**Postoperative new KSS

5.4 Discussion

This study sought to perform an independent validation of the new KSS in a sample of patients undergoing primary TKR surgery. Findings support the validity of the new KSS symptoms subscale of the objective knee score and the subjective measures patient-reported subscales.

Credibility of the current study findings can be found by comparing our new KSS measures with those published by the original developer [10]. For example, our mean value for the preoperative expectations subscale was 13.4. Noble et al. [10] reported a mean value of 13.8. Our preoperative functional activities mean was a similar order of magnitude as Noble et al. [10] (32.7 vs. 37.2, respectively), as was our preoperative mean for the walking and standing subscale (12.1 vs. 14.2, respectively) and the advanced activities subscale (4.4 vs. 6.1, respectively). Closer concordance between studies for these values may not be possible because the functional activity score for the prototype instrument in Noble's study had a maximum score of 110. This compares to the maximum score of 100 presently in the new KSS and this may have contributed to the slightly larger mean scores in Noble's study [10].

Integrity of the current findings is also supported by the demographic profile of our sample. Our study sample (n = 345) was similar to Noble et al. [10] (n =254) with women accounting for 62% of TKR recipients; an average age of 64 years and a preoperative BMI of 32.9 kg/m^2. Similar values were reported by Noble et al. [10] with women accounting for 64% of TKR recipients; an average age of 66 years and a preoperative BMI of 31.4 kg/m^2, respectively.

5.4.1 Cross-Sectional & Longitudinal Validity

Cross-sectional validity was supported (all correlations $p<0.01$). For the new KSS symptoms, functional activities and satisfaction subscale scores, correlation coefficients with the KOOS pain subscale varied from 0.60 to 0.73. Values were similar for associations with the KOOS function in daily living (ADL) subscale and less (0.41 to 0.58) for correlations with the other three KOOS subscales. Correlations among change scores were similar supporting longitudinal validity.

Some comparison of the preoperative cross-sectional correlations published by Noble et al. [10] can be made. When comparing the association between the new KSS preoperative satisfaction subscale scores and the five KOOS subscales, our correlations varied from 0.43 to 0.73. These values were similar in order of magnitude to those reported by Noble et al. [10] (0.32 to 0.65).

5.4.2 Known-Groups Validity

Known-groups validity was supported by significant between-group differences for the symptoms and functional activities subscale score comparisons (Table 4) as well as the comparisons with the expectations and satisfaction subscale scores of the questionnaire (Table 5). All comparisons across known groups were in the anticipated direction. These findings add to the work done by Noble et al. [10], as they did not perform known-groups validity nor has there been any other independent reports identifying the testing of known-groups validity for the new KSS.

5.4.3 Internal Consistency

Internal consistency results were similar in order of magnitude to those reported by Noble et al. [10]. Satisfaction and expectation subscale scores yielded Cronbach alpha values from 0.81 to 0.94, compared to 0.79 to 0.90 reported by Noble et al. [10]. For the functional subscales, values ranged from 0.68 to 0.84, this compared to 0.68 to 0.88 by Noble et al. [10]. These values suggest an acceptable level of internal consistency with 0.70 to 0.80 [19] for the new KSS.

5.4.4 Limitations

We acknowledge certain limitations in our study. We limited our data collection to patients undergoing primary TKR surgery from preoperative to one year postoperative. Therefore, the measurement characteristics of the new KSS instrument that we have reported are confined to the target population of a one year follow up. Furthermore, we did not evaluate test-retest reliability. To date we are unaware of whether there has been any test-retest reliability data published for the new KSS tool [8]. We recommend that test-retest reliability of the new Knee Society KSS tool occur in future research studies.

Finally, there may be a better comparator for the new KSS than the KOOS. The KOOS [13, 20] was developed to respond to more demanding physical functions, smaller differences in outcome and both short and long-term results of treatments of a knee injury or knee osteoarthritis in younger patients but it has weak validity regarding the sport and recreation subscale [21]. The new KSS is intended to overcome these weaknesses, but it may be too early to determine whether or not the new KSS will become responsive for TKR evaluation in younger and more physically active patients now and in the future.

5.5 Conclusion

Moderate-sized correlation coefficients, and consistent differences between known groups support the validity of the new Knee Society KSS tool. Internal consistency values were also acceptable. The patient-reported components of the new Knee Society KSS tool are a valid and internally consistent outcome assessment for TKR surgery. In particular, known-groups validity and internal consistency have been established for pre-

and postoperative expectations and satisfaction scores. The study results support the foundational psychometrics reported by Noble et al. [10], increasing the confidence in the new Knee Society KSS tool for patients having undergone TKR out to one year postoperative. We suggest test-retest reliability of the new Knee Society KSS tool take place in the future.

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Chapter 6

6 Discussion

The following sections in this chapter contain additional discussion that pertains to this doctoral research. It focuses on the results of each of the three papers presented in this thesis as well as the applicability of the work done to date and recommendations for future research with patients undergoing TKR surgery.

6.1 Randomized Controlled Trial

Although our patient education e-learning tool did not result in a between-group difference for patient expectations or satisfaction at one year after TKR surgery, many lessons were learned from this research. We recognized that patients generally have high expectations before TKR surgery. Clinicians need to recognize and use this patient characteristic and take this into consideration when creating patient education e-learning tools in the future.

The trend for patients undergoing TKR surgery presently and anticipated in the future will be: younger in age, living longer and having expectations of this surgical procedure to enable them to return to an active and healthy lifestyle. In the literature Yoo et al. [1] found the top three patient expectations of their five patient expectation categories were: first was relief from pain, second was psychological well-being, and third was the restoration of baseline activities. Likewise, Muniesa et al. [2] concluded that expectations for improvement in patients before TKR are high and may be classified as expectations for; reducing pain, restoring basic functional activities and resuming a sense of general well-being.

As a primary outcome of this study, satisfaction was measured by the Patient Acceptable Symptom State (PASS) question [3]. The PASS was developed as a method for evaluating clinically relevant states in patient-reported outcomes in knee and hip osteoarthritis (OA). It is known as the value beyond which patients can consider themselves well [3]. It was used as a binary measure for patient satisfaction, a satisfactory

state (concept of PASS) [3]. Additionally, Dougados et al. [4] studied the PASS as an absolute threshold proposed for symptomatic variables in OA to determine the point beyond which patients would consider themselves well and, as such, reported they were satisfied with their treatment. The PASS captures the patient's opinion of their state by having them respond 'Yes' or 'No' to a question about whether or not they consider their current state as acceptable or satisfactory [3].

Another concept that reflects a meaningful clinical response from the patient's perspective has recently been developed and tested for clinical trials. This concept measures the Minimal Clinically Important Improvement (MCII), defined as the smallest change in a measurement which signifies an important improvement in a patient's symptom score [3]. While complementary to the PASS, the MCII is a measure of meaningful improvement and not satisfaction [5]. The PASS had previously been used in studies with patients undergoing TKR [6-9], but it had not been used in a study with patients undergoing TKR testing a patient e-learning tool.

This aligns with the results of our first study. To effect change in patients undergoing TKR surgery with an e-learning tool requires patient engagement. Achieving and sustaining patients' active participation in their rehabilitation and recovery following their TKR surgery is imperative. This may require the employment at baseline of a tool such as the Patient Activation Measure (PAM) [10, 11]. The PAM originally was a 22-item measure that assessed a patient's knowledge, skill, and their confidence for self-management. A 13-item measure that had psychometric properties similar to the original version was found to be both reliable and valid [11]. Using a tool such as the PAM may assist in screening and identifying patients willing to engage in patient education. This may be a next step before testing educational e-learning tools for patients undergoing TKR surgery.

6.2 E-Learning & 21st Century Adult Learning Principles

The primary observation from our second study was a decreased usage of the e-learning tool with the passage of time after TKR surgery. We suggested additional reminders be sent more frequent or ask for confirmation the email was received to encourage more

patient engagement after surgery. We acknowledged the specific time period between three months and one year following TKR would require additional email reminders. We proposed email reminders be sent every six weeks to help patients remain engaged and continue to access videos throughout the first year following TKR surgery.

The definition of a ‘user’ may need to be redefined. We initially defined ‘user’ of the e-learning tool as a patient having accessed a minimum of one content video. This definition may not reflect a patient who should be considered a ‘true user’ of an e-learning tool. Patient engagement or a ‘true user’ of an e-learning tool may need to be re-defined as a patient having accessed more than one content video within a category.

The principles of 21st century adult learning suggest that learning is associated with experience and is a response to personal need. The self-determined learner learns on their own terms [12] and the latest technologies serve as the agents for supporting this type of learning. The learner is a partner in building the content. Learning needs to be a flexible, non-linear process. This type of learning is individualized and enables patients as learners to situate their own learning [12-14].

The content of the videos for our study were designed in consultation with and incorporated the input provided by patients that had undergone TKR surgery at the hospital study site. The e-learning tool was user-friendly and enabled patients to access any videos that were of interest to them at any time that was of their own choosing. This provided a familiar and flexible learning tool for patients in our study.

Perhaps the e-learning tool could have been more personalized, such as directing the patient to specific content as to whether or not they were a 1st or 2nd TKR patient. The contralateral knee patient (2nd TKR patient) has already been through the experience of the surgery and knows what to expect and they have ‘lived’ the experience. This is not true for the patient about to undergo their first primary TKR surgery. These patients can only infer what may or may not occur based on what they have read about, learned from others or been educated about, prior to undergoing or actually experiencing TKR surgery.

The e-learning tool could be customized to the activities that a patient is expecting to return to after TKR surgery (i.e. golf, swimming, cycling, hiking). It could be tailored to direct participants specifically to the daily activities they participate in at home or work. For example, a number of patients provided feedback indicating they only take showers and no longer take baths. So allowing patients to choose to watch a video about getting in and out of the bathtub versus choosing to watch a video about getting in and out of the shower may help increase use with these types of personalization of the videos.

This could enable patients to recognize that their 'expectations matter' (a tag line on the e-learning tool). An e-learning tool in the future should be tailored to assist patients to achieve their own expectations of TKR surgery. Therefore, every attempt should be made in the creation and development of an e-learning tool to meet the expectations of patients so that they can be as satisfied as possible with the outcome of their TKR surgery.

Like many online shopping sites, once you 'click' on an item or make a purchase an email is sent either acknowledging your interest in an item or verifying your purchase. After purchasing an item, an email is sent extending appreciation for your purchase. Likewise, in an e-learning tool once a patient 'clicks' on a video they could receive an email recognizing or extending appreciation for their participation and/or their active involvement with the e-learning tool. This more interactive feature may assist with sustaining greater patient usage of an e-learning tool over time.

The utilization of a tablet-based 'application' (app) could create and sustain more patient usage of an e-learning tool. A tablet-based app would provide greater mobility and ease of accessibility for an e-learning tool than a desktop computer. Desktop computers may limit a patient's accessibility to it, depending on where it is located in the patient's home. Likewise, having a home computer that is up-to-date with current programs and software is imperative for the ease of patient usage of an online video based e-learning tool.

6.3 Validation of Patient-Reported Outcome Measures

In the randomized controlled trial (RCT) the patient-reported outcome measures (PROMs) for patient expectations and patient satisfaction were both binary measures. A

recommendation for future research would be to consider using a validated, continuous patient expectation measure and additionally, a validated continuous patient satisfaction measure. Such a tool exists with the new Knee Society Knee Scoring System (KSS).

Our third study added to foundational psychometrics and raised confidence in the new Knee Society Knee Scoring System tool for patients having undergone TKR out to one year postoperative. However, Barlow et al. [15] identified that there is no consensus to date on how expectations or satisfaction should be measured. Barlow et al. [15] suggested that further clarification and agreement on how to measure patient expectations and satisfaction would aid in this area of study and we would concur with this statement.

We recognize that information may be lost when transforming continuous data into a binary response measure. This can translate into a loss of power to detect differences between treatments. We acknowledge that binary outcome measures are therefore less sensitive to change than continuous measures [16]. This may explain the non-significant between-group difference in expectations met and satisfaction, found in Chapter 3. We recommend the use of validated continuous measures for future research use. This could be achieved with the new Knee Society KSS, given the encouraging validation results presented in Chapter 5.

To date no single, validated, reliable patient-reported outcome measure exists to address the priorities pertaining to patient expectations and satisfaction of TKR recipients [17]. Furthermore, a clear and concise unanimous definition of a successful TKR procedure that satisfies all patients has yet to be established [17].

6.4 Summary

We recognize that the prevalence of OA is estimated to be over 10.4 million Canadians by 2040 [18] and that the number of TKR procedures in our country will continue to increase [19]. Therefore, it is imperative to know that unless something is done to improve dissatisfaction with TKR surgery, it will affect more and more patients in the future. Tools must be developed that will provide surgeons and patients the opportunity to better manage expectations of TKR. In the future, patient educational e-learning

interventions that engage and sustain patient usage need to be tested further in RCTs with patients undergoing TKR surgery.

6.5 Future Directions/Areas for Future Research

Future research in this area should employ larger studies or studies with multiple sites that evaluate educational e-learning tools for patients undergoing TKR surgery. Additionally, future studies should use the latest technologies to capture, engage and sustain patients' involvement throughout their recovery and rehabilitation after TKR surgery. Finally, researchers should continue to examine how best to measure patient expectations and satisfaction of TKR surgery.

6.6 References

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Appendices

Appendix A: Pilot Study and Development of E-Learning Tool

Pilot study: Expectations of patients undergoing primary total knee replacement

Methods

In this pilot work the objectives were: (1) to determine patient expectations for total knee replacement (TKR) surgical outcome, and (2) to identify sources of information used by patients to establish their expectations of TKR, their computer accessibility and interest in accessing a locally developed e-learning tool.

Patients scheduled for a primary TKR were recruited at the Pre Admission Clinic (PAC), University Hospital, London Health Sciences Centre. Initial contact was made with patients to arrange an in-home telephone interview and provide them with a survey. Additionally, a copy of the survey was mailed to them. Patients were contacted a few days after their PAC visit with a telephone call to verify date and time previously scheduled for the in-home telephone interview. During this conversation, patients were asked to confirm receipt of the mailed survey. Final contact was made with patients in order to conduct primary data collection during the in-home telephone interview and to verify that patients had completed and mailed back the survey of socio-demographic factors in the self-addressed envelope.

Primary data collection occurred during a 20-minute telephone interview. This measured four distinct patient expectation domains with a single question for each related to pain relief; ability to perform activities of daily living (ADL); ability to participate in sports and global recovery from surgery. Responses were given using four to five possible options. The telephone interview was used to establish the following: information sources used by patients, their computer accessibility and interest in using an e-learning tool and suggestions for content to be included in the e-learning tool.

Results

Data collection resulted in 25 questionnaires completed and returned (n=12 females, n=13 males). The same 25 patients participated in the in-home telephone interview. The mean age of the patients was 63 years, a mean body mass index (BMI) of 32 kg/m^2, the majority of the patients were; retired, living with others, and not dependent on others for their ADL.

Patients' preoperative expectations about how they felt their TKR would ultimately affect their knee pain and quality of life were generally high (Table A-1). The majority of the patients' (n=25) expectations of their TKR put a lot of emphasis on the TKR surgery to do the following: help with pain relief, improve their ability to carry out activities of daily living (ADL), to allow them to participate in leisure, sports or recreation activities, as they had done before their problem started, and to return the area operated upon back to the way it was before they began having problems there (Table A-1).

Additionally, the in-home telephone interview responses were informative and useful regarding the sources used by patients to establish preoperative expectations; computer accessibility and content ideas for and interest in using a locally developed e-learning tool (Table A-2). Speaking to others, such as friends who had undergone a TKR surgical procedure was the most frequently used source by patients to establish their preoperative expectations. The majority of patients (n=21) indicated having a computer, and the majority of patients (n=22) identified they would use a locally developed e-learning tool if it were provided for them. The most frequently stated ideas by the patients for inclusion in a locally developed e-learning tool were; patient experiences, surgeon and therapist perspectives, the actual TKR surgical procedure. Patient requests were made for content in the e-learning tool such as; expectations after TKR surgery and long-term postoperative expectations after TKR surgery (Table A-2).

Measuring patients' expectations is necessary for a number of reasons. Being aware of and knowing patients preoperative expectations helps physicians to provide more focused clinical care, identifies areas for patient education, and generates shared decision-making when several treatment options are available [1-3].

Table A-1: Expectation Questionnaire: Preoperative

Do you expect your TKR surgery to:	Frequency
Help with pain relief	
A lot	20
Somewhat	5
A little	0
No	0
Improve your ability to carry out ADLs	
A lot	19
Somewhat	5
A little	1
No	0
Allow you to participate in leisure, sports or recreation activities as you did before your problem started	
As much as before	14
Not as much as before	10
No	1
Return the area operated upon back to the way it was before you began having problems there	
Completely	7
Somewhat improved	17
A little improved	1
No	0

Table A-2: Telephone interview questions

Interview Question	Frequency
Sources used by patients to establish expectations*	
Friends	14
Internet	10
Family	8
Co-workers	3
Surgeon	3
Nurse	1
Television	1
Medical books	1
Do you have a computer?	
Yes	21
No	4
Would you use an e-learning tool?	
Yes	22
No	3
Patient requests for content in e-learning tool*	
Patient experiences	8
Surgeon perspectives	6
Therapist perspectives	5
Actual surgical procedure	3
Recovery exercises	3
Rehabilitation expectations	3
Pain expectations	2
Activities of daily living	1
Animation of surgery	1
Long term expectations	1
After surgery expectations	1
Had no ideas	1

* Some patients provided more than one response

Development of the e-learning tool

Methods

Beginning in July 2012, using input from the pilot study, a locally developed e-learning tool was created for use by patients undergoing TKR surgery from preoperative to 1 year postoperative. The content of the e-learning tool was accessible to patients allocated to the intervention group once they were provided with a username and password for the website. The e-learning tool was developed in consultation with an e-learning design company that specializes in medical education and interactive e-learning tools and representative staff from orthopaedic surgery, physical therapy, occupational therapy, and previous TKR recipients.

The e-learning design company employed to assist in the development of this e-learning tool worked with a number of qualified team members with a combined 30 years of clinical experience creating digital curriculum and developing e-learning tools. These e-learning tools have engaged patients from diverse medical backgrounds (i.e. heart and stroke and diabetes) and were created for those with advanced computer skills and those with developing levels of computer competencies.

The e-learning design company used a cycle of development to design the e-learning tool. This involved the following five phase approach: (1) Needs Assessment, (2) Storyboarding, (3) Design and Development, (4) Testing and Revision, and (5) Implementation. The benefits of this approach included; the active involvement of all stakeholders throughout the process to ensure accuracy, opportunities to review content, interactions, visual elements, appropriateness of language at each stage of development, and feedback from a representative group of previous TKR recipients that took place in the final phase, of development. The goal was to develop an e-learning tool that would encompass the information provided by the patients in the pilot study, cover the content of the 31-page hard copy of ‘My Guide to Total Knee Joint Replacement’ and integrate the feedback provided by representative staff from orthopaedic surgery, physical therapy, occupational therapy, and previous TKR recipients that could be viewed in under one

hour. Transcripts were available for reading or reproducing that provided a word for word account of each and every one of the videos.

Results

The e-learning tool was ultimately made up of 32 brief (1-2 minutes) educational videos (Table A-3). Filming of the videos was done under the direction of a professional videographer recommended by the e-learning design company, while on location, at the hospital site. Filming took place using three types of presenters for the videos: surgeons, therapists and patients (previous TKR recipients). Filming of previous TKR recipients focused primarily on them demonstrating ADL and doing exercises, while under the direct supervision of a physical therapist. Two medical animations provided visual, auditory and animated experiences for patients to learn about the TKR surgical procedure.

Table A-3: Content and presenters of e-learning tool videos by time period

Time 1 (PAC to surgery)	
Expectations of Surgery	Surgeon
Complications of Surgery	Surgeon
Restrictions After Surgery	Surgeon
Daily Exercises After Surgery	Therapist
Daily Activities After Surgery	Therapist
About Surgery - Returning to Your Active Lifestyle	Therapist
Animation of Surgery - Total Knee Replacement	Animator
Prior To and After Surgery - Total Knee Replacement	Animator
Time 2 (surgery to 6 weeks postoperative)	
6 Weeks After Surgery	Surgeon
6 Weeks After Surgery - Returning to Your Active Lifestyle	Therapist
Activity 1 - Getting In & Out of Bed	Therapist
Activity 2 - Using the Toilet	Therapist
Activity 3 - Dressing	Therapist
Activity 4 - Walking with a Walker & Crutches	Therapist
Activity 5 - Standing & Sitting with a Walker	Therapist
Activity 6 - Standing & Sitting with Crutches	Therapist
Activity 7 - Going Up & Down the Stairs	Therapist
Activity 8 - Bathing	Therapist
Exercise 1 - Improving the bend of your knee	Therapist
Exercise 2 - Stretching your calf muscle	Therapist
Exercise 3 - Strengthening your thigh muscle	Therapist
Exercise 4 - Strengthening your thigh muscle	Therapist
Exercise 5 - Stretching your hamstrings	Therapist
4 Weeks After Surgery - Patient Experience	Patient
Time 3 (6 weeks to 3 months postoperative)	
3-6 Months After Surgery	Surgeon
3-6 Months After Surgery - Returning to Your Active Lifestyle	Therapist
3-6 Months After Surgery – Steps to Resume Your Active Lifestyle	Therapist
3-6 Months After Surgery - Patient Experience	Patient
Time 4 (3 months to 1 year postoperative)	
1 Year After Surgery & Beyond	Surgeon
1 Year After Surgery & Beyond - Returning to Your Active Lifestyle	Therapist
1 Year After Surgery & Beyond - Reasons to Engage in an Active Lifestyle	Therapist
1 Year After Surgery - Patient Experience	Patient

Conclusion

The pilot study enabled the development of a valid e-learning tool for TKR recipients. The e-learning tool was locally developed with input, review and feedback from arthroplasty surgeons, therapists and patients who were either undergoing or had undergone TKR surgery. This tool was patient-derived therefore providing face validity. Additionally, it was created using content from the manual ‘My guide to total knee joint replacement’ used at the hospital study site since 2002 and updated annually. The content of the e-learning tool was provided to and reviewed by an expert panel of subject matter experts. These experts included arthroplasty surgeons, physical therapy professors, physical and occupational therapists and patients thus providing content validity.

References

1. Kravitz, R.L., Measuring patients' expectations and requests. *Ann. Intern. Med.*, 2001. **134**(9 Pt 2): p. 881-8.
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3. Uhlmann, R.F., T.S. Inui, and W.B. Carter, Patient requests and expectations. Definitions and clinical applications. *Med. Care*, 1984. **22**: p. 681-5.

Appendix B: Research Ethics Board Approval Forms

Research Ethics Board Approval Letter

Western Research

Research Ethics

Use of Human Participants - Revision Ethics Approval Notice

Principal Investigator: Dr. Bert Chesworth
File Number:103027
Review Level: Delegated
Protocol Title:A randomized controlled trial to establish realistic patient expectations of total knee replacement
Department & Institution: Schulich School of Medicine and Dentistry\Epidemiology & Biostatistics,Western University
Sponsor:
Ethics Approval Date: January 31, 2014 **Expiry Date:**July 31, 2015
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Revised Western University Protocol	2014 01 22 Revision Submission - Final Copy	
Revised Western University Protocol	2014 01 22 Summary of Revision Page 14 (Highlighted changes)	

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Ethics Officer to Contact for Further Information

Erika Basile (ebasile@uwo.ca)	Grace Kelly (grace.kelly@uwo.ca)	Mina Mekhail (mmekhail@uwo.ca)	Vikki Tran (vikki.tran@uwo.ca)

This is an official document. Please retain the original in your files.

Letter of Information and Consent – Control Group

Research Study: **A randomized controlled trial to establish realistic patient expectations of total knee replacement surgery**

Study Investigators:
Graduate supervisor:
Bert M. Chesworth, PhD
School of Physical Therapy
xxx-xxx-xxxx, extension xxxxx

Co-investigators:
Steven J. MacDonald, MD, FRCSC
Site Chief, Division of Orthopaedic Surgery
University Hospital, London Health Sciences Centre
xxx-xxx-xxxx, extension xxxxx

Dianne M. Bryant, PhD
School of Physical Therapy
xxx-xxx-xxxx, extension xxxxx

Kathryn M. Hibbert, PhD
Faculty of Education
xxx-xxx-xxxx, extension xxxxx

Graduate student investigator
Health and Rehabilitation Sciences Program:
Sharon E. Culliton, PhD Candidate
xxx-xxx-xxxx

Background Information and Purpose
You are being invited to participate in a research study to compare the expectations and satisfaction of patients undergoing total knee replacement (TKR) surgery scheduled by the Joint Replacement Institute at University Hospital, London Health Sciences Centre. The purpose of this letter is to provide you with information that will allow you to make an informed decision about participating in this study.

Details of the Study

We are asking you to participate because we wish to compare patient education on expectations and satisfaction of patients prior to this surgical intervention and following this surgical intervention at 6 weeks, 3 months and 1 year. We would like to know the effect of patient education on expectations and satisfaction for this surgical intervention.

We are giving this letter of information only to people who are scheduled for primary total knee replacement at University Hospital and have access to a computer. If this situation does not apply to you, we would request you not take part in this study.

This study is being conducted under the direct supervision of Dr. Bert Chesworth, who works at the School of Physical Therapy at the University of Western Ontario. He will supervise this study along with the following three co-investigators: Dr. Steven MacDonald, Site Chief, Division of Orthopaedic Surgery, University Hospital; Dr. Dianne Bryant, Associate Professor, School of Physical Therapy; Dr. Kathryn Hibbert, Assistant Professor, Faculty of Education and Ms. Sharon Culliton, Doctoral Graduate Student, Health and Rehabilitation Sciences Program, Faculty of Health Sciences, University of Western Ontario.

If you agree to participate in this project you will be initially contacted by Ms. Heather Trotter the Peri-Operative Coordinator at University Hospital or one of the nurses in the Pre Admission Clinic at University Hospital. Ms. Trotter or one of the Pre Admission Clinic nurses will introduce you to Ms. Sharon Culliton our Co-Principal investigator who will be collecting the information for this project. Ms. Culliton will explain the study and ask for your phone number and home address, then arrange for you to be allocated to a patient education group. You will receive a survey either online or by mail to be completed before your primary total knee replacement surgery and up until 1 year after this surgical intervention.

Primary data collection will occur immediately following your visit to the Pre Admission Clinic. You will receive a questionnaire either online or by mail. You will be asked to complete and return it within one week after your Pre Admission Clinic visit. This will include a total of 11 questionnaires and will include the following patient demographics: age, sex, height and weight.

The questionnaires will be sent to you either online or by mail to you prior to this surgical intervention and following this surgical intervention at 6 weeks, 3 months and 1 year. You will be provided with reminders either by online or mail or telephone to complete and return these questionnaires to Ms. Sharon Culliton. If you have any questions or difficulty completing the survey you may contact Ms. Culliton at any time by email or by phone. We will be collecting data from no more than 352 participants.

Benefits
There will be no personal benefit to you. However, your participation will assist orthopaedic surgeons and other health care clinicians understand the expectations and satisfaction of patients planning to undergo primary total knee replacement. The ultimate goal is to increase patient satisfaction following this surgical procedure. Your participation in this project will not involve any additional costs to you, and you will not receive compensation for your participation.

Confidentiality
Your confidentiality will be respected. Your first and last name and phone number will be taken to arrange a phone call for the purpose of contacting you if paper questionnaires have not been received by the due dates. This is similar to receiving email reminders if electronic questionnaires have not been received by the due dates. This information will always be kept in a locked cabinet. This information will have no health information associated with it. No information that discloses your identity will be released or published, without your explicit consent to the disclosure. All records will be given a code number to be used on all data collection forms. All of the information collected will be kept in locked filing cabinets and shredded seven years after the project is completed.

Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

Voluntary Nature of Study/Freedom to Withdraw or Participate
Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. You do not waive any legal rights by signing the consent form.

If you agree to participate in this project, please sign the attached consent form, complete the contact information requested and return it to the person who gave this letter to you.

You may keep this letter of information for future reference.

Questions
If at any time you have questions about this research, please contact Dr. Bert Chesworth at xxx-xxx-xxxx xxxxxx or Ms. Culliton at xxx-xxx-xxxx. If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute at xxx-xxx-xxxx.

Principal Investigator
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Assistant Professor
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London, Ontario
(xxx) xxx-xxxx ext. xxxxx
xxxxxxxx@xxx.xx

CONSENT FORM

'A Randomized Controlled Trial to Establish Realistic Patient Expectations of Total Knee Replacement Surgery' Study

Principal Investigator:
Dr. Bert M. Chesworth, School of Physical Therapy, The University of Western Ontario

I have read the Letter of Information, have had the nature of the study explained to me and I have agreed to participate. All questions have been answered to my satisfaction.

Name of participant (Print)

--- ---
Signature of participant Date

Name of person obtaining consent (Print)

--- ---
Signature of person obtaining consent Date

Letter of Information and Consent – Intervention Group

Research Study: **A randomized controlled trial to establish realistic patient expectations of total knee replacement surgery**

Study Investigators:
Graduate supervisor:
Bert M. Chesworth, PhD
School of Physical Therapy
xxx-xxx-xxxx, extension xxxxx

Co-investigators:
Steven J. MacDonald, MD, FRCSC
Site Chief, Division of Orthopaedic Surgery
University Hospital, London Health Sciences Centre
xxx-xxx-xxxx, extension xxxxx

Dianne M. Bryant, PhD
School of Physical Therapy
xxx-xxx-xxxx, extension xxxxx

Kathryn M. Hibbert, PhD
Faculty of Education
xxx-xxx-xxxx, extension xxxxx

Graduate student investigator
Health and Rehabilitation Sciences Program:
Sharon E. Culliton, PhD Candidate
xxx-xxx-xxxx

Background Information and Purpose
You are being invited to participate in a research study to compare the expectations and satisfaction of patients undergoing total knee replacement (TKR) surgery scheduled by the Joint Replacement Institute at University Hospital, London Health Sciences Centre. The purpose of this letter is to provide you with information that will allow you to make an informed decision about participating in this study.

Details of the Study

We are asking you to participate because we wish to compare patient education on expectations and satisfaction of patients prior to this surgical intervention and following this surgical intervention at 6 weeks, 3 months and 1 year. We would like to know the effect of patient education on expectations and satisfaction for this surgical intervention.

We are giving this letter of information only to people who are scheduled for primary total knee replacement at University Hospital and have access to a computer. If this situation does not apply to you, we would request you not take part in this study.

This study is being conducted under the direct supervision of Dr. Bert Chesworth, who works at the School of Physical Therapy at the University of Western Ontario. He will supervise this study along with the following three co-investigators: Dr. Steven MacDonald, Site Chief, Division of Orthopaedic Surgery, University Hospital; Dr. Dianne Bryant, Associate Professor, School of Physical Therapy; Dr. Kathryn Hibbert, Assistant Professor, Faculty of Education and Ms. Sharon Culliton Doctoral Graduate Student, Health and Rehabilitation Sciences Program, Faculty of Health Sciences, University of Western Ontario.

If you agree to participate in this project you will be initially contacted by Ms. Heather Trotter the Peri-Operative Coordinator at University Hospital or one of the nurses in the Pre Admission Clinic at University Hospital. Ms. Trotter or one of the Pre Admission Clinic nurses will introduce you to Ms. Sharon Culliton our Co-Principal investigator who will be collecting the information for this project. Ms. Culliton will explain the study and ask for your phone number and home address, then arrange for you to be allocated to a patient education group. You will receive a survey either online or by mail to be completed before your primary total knee replacement surgery and up until 1 year after this surgical intervention.

Primary data collection will occur immediately following your visit to the Pre Admission Clinic. You will receive a questionnaire either online or by mail. You will be asked to complete and return it within one week after your Pre Admission Clinic visit. This will include a total of 11 questionnaires and will include the following patient demographics: age, sex, height and weight.

The questionnaires will be sent to you either online or by mail to you prior to this surgical intervention and following this surgical intervention at 6 weeks, 3 months and 1 year. You will be provided with reminders either by online, mail or telephone to complete and return these questionnaires to Ms. Sharon Culliton. If you have any questions or difficulty completing the survey you may contact Ms. Culliton at any time by email or by phone. We will be collecting data from no more than 352 participants.

Description of the intervention
Immediately after the Pre Admission Clinic visit and after submitting the baseline questionnaires the patient will have access to an e-learning patient education program. This e-learning patient education program will be in addition to the current method of patient education. Currently, at Pre Admission, patients are provided a 31 page hard copy of *My Guide to Total Knee Joint Replacement (Revised January, 2008)* and they are made aware of an electronic copy of this document available at the following website: http://www.jointreplacementinstitute.com/patients.html
The e-learning patient education program extends beyond simple access to information and includes interactive features. The information spans surgery and rehabilitation aftercare for patients undergoing TKR. Patient usage of this e-learning patient education program will be monitored and collected for research purposes. Once patients have been randomized to the Intervention group, they will be able to log into the site www.newknees.ca as registered users. When they view a video, link or download a transcript this will be captured by a statistics recording and report system. This program logs what action they did, and the date they did it. This will enable Ms S Culliton to see when during the course of each patient's surgical journey they have clicked on a video, link or transcript before and/or after their TKR surgery. Access to this e-learning patient education program will continue until 1 year after TKR surgery. At one year after TKR surgery each patient will no longer be a registered user and will no longer be able to access this site.

Benefits
There will be no personal benefit to you. However, your participation will assist orthopaedic surgeons and other health care clinicians understand the expectations of patients planning to undergo primary total knee replacement. With this knowledge we plan to develop an e-learning patient education program for patients undergoing primary total knee arthroplasty. The ultimate goal is to increase patient satisfaction following this surgical procedure. Your participation in this project will not involve any additional costs to you, and you will not receive compensation for your participation.

Confidentiality
Your confidentiality will be respected. Your first and last name and phone number will be taken to arrange a home phone call for the purpose of contacting you if paper questionnaires have not been received by the due dates. This is similar to receiving email reminders if electronic questionnaires have not been received by the due dates. This information will always be kept in a locked cabinet. This information will have no health information associated with it. No information that discloses your identity will be released or published, without your explicit consent to the disclosure. All records will be given a code number to be used on all data collection forms. All of the information collected will be kept in locked filing cabinets and shredded seven years after the project is completed. Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

Voluntary Nature of Study/Freedom to Withdraw or Participate

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. You do not waive any legal rights by signing the consent form.

If you agree to participate in this project, please sign the attached consent form, complete the contact information requested and return it to the person who gave this letter to you.

You may keep this letter of information for future reference.

Questions

If at any time you have questions about this research, please contact Dr. Bert Chesworth at xxx-xxx-xxxx xxxxxx or Ms. Culliton at xxx-xxx-xxxx. If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute at xxx-xxx-xxxx.

Principal Investigator
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CONSENT FORM

'A Randomized Controlled Trial to Establish Realistic Patient Expectations of Total Knee Replacement Surgery' Study

Principal Investigator:
Dr. Bert M. Chesworth, School of Physical Therapy, The University of Western Ontario

I have read the Letter of Information, have had the nature of the study explained to me and I have agreed to participate. All questions have been answered to my satisfaction.

Name of participant (Print)

--- ---
Signature of participant Date

Name of person obtaining consent (Print)

--- ---
Signature of person obtaining consent Date

Appendix C: Description of Patient Reported Outcome Measures

Hospital Anxiety and Depression Scale (HADS)

The HADS is a 14-item self-assessment scale developed to assess the levels of anxiety and depression that a patient is experiencing in a non-psychiatric population. The HADS generates ordinal data. Seven of the items refer to anxiety and seven refer to depression [1]. It is meant to differentiate symptoms of depression from those of anxiety. It is a reliable instrument for detecting states of depression and anxiety in people with physical health problems [1]. It has been used with joint replacement recipients [2]. The HADS is easy to score and administer (5 minutes) it is to be used as a screening instrument [1].

Knee Injury and Osteoarthritis Outcome Score (KOOS)

The KOOS is a 42 item knee-specific self-administered questionnaire consisting of five subscales: pain (9 items), stiffness (2 items), other symptoms (5 items), activities of daily living (17 items), sports and recreational activities (5 items), and knee related quality of life (4 items). Each item is measured on a scale from 0-4. Each subscale is scored by summing its' items and transforming that score into a 0-100 scale (worst to best state) [3]. The KOOS has been validated, has achieved reliability and has demonstrated responsiveness for various types of knee problems including OA [4-6].

Knee Society Score: (KSS) Pre-Op and Post-Op

In 1989, The Knee Society Clinical Rating System was developed to rate both the knee prosthesis function and patients' functional abilities after TKR [7]. While this scoring system became the most popular method of reporting outcomes after partial and TKR it was felt to not provide enough detail specifically in documenting the functional capabilities of more contemporary patients. The original score was only physician-derived, leaving unresolved the poor correlation between objective physician-assessed knee scores and patient-derived satisfaction scores. It became clear that an updated and validated Knee Society scoring system, with improved responsiveness and reliability was needed [7].

The new Knee Society Knee Scoring System (KSS), copyrighted in 2011 has addressed these issues. It is a validated system that combines an objective physician-derived component with a subjective patient-derived component that evaluates ‘symptoms’ (e.g. pain relief), expectations, satisfaction, and functional abilities [8, 9]. The new Knee Society KSS in its entirety is composed of five components: 1) Patient demographics, 2) Objective Knee Score completed by the surgeon, 3) Patient Expectations completed by the patient, 4) Patient Satisfaction completed by the patient, and 5) Functional Knee Score completed by the patient [10]. This score prioritizes the patient perspective, to better track patient expectations, satisfaction, and activity levels than was possible with its predecessor [8, 9].

The new KSS consists of an informational component for completion by the surgeon and the patient and then a PROMs component. Only the PROMs component of the new KSS was used in our study to generate a knee score [11]. In our study we used the following: one category of the ‘Objective Knee Score’ component was used; ‘Symptoms’ it contains two, 10-level pain scales and an additional question regarding how ‘normal’ the knee feels to the patient, with the maximum allowed being 25 points, ‘Patient Expectations’ a three-question fifteen-point scale collected pre- and postoperatively, ‘Patient Satisfaction’ a five-question 40-point scale collected pre- and postoperatively, and the ‘Functional Knee Score’ composed of four subgroups: Walking and Standing (30 points), Standard Activities (30 points), Advanced Activities (25 points) and Discretionary Activities (15 points) with a maximum score of 100 points [10].

Pain Catastrophizing Scale (PCS)

The PCS is a 13-item questionnaire that individuals take themselves, answering questions about how they feel and what they think about when they are in pain. Each item is measured on a scale from 0-4, with 0=not at all, 1= to a slight degree, 2=to a moderate degree and 4=all the time [12]. It is one of the most widely used instruments for measuring catastrophic thinking related to pain. It was developed to assess three components of catastrophizing: rumination (e.g. “I can’t stop thinking about how much it hurts”), magnification (e.g. “I’m afraid that something serious might happen”), and helplessness (e.g. “There is nothing I can do to reduce the intensity of my pain”). The

PCS is used extensively in clinical practice and in research [12-15]. More than two hundred papers have been published on the use of the PCS in acute and chronic pain populations, and the PCS has been translated into ten languages.

Preoperative Expectation Questionnaire

The Preoperative Expectation Questionnaire has been used before with TKR recipients [16] and was administered to all study participants. The Preoperative Expectation Questionnaire was used to measure four of the six original domains using single questions related to expectations of surgery: 1) to help with pain relief; 2) to improve ability to perform activities of daily living (ADL); 3) to be able to participate in leisure, sports, or recreational activities and 4) for the area operated upon to return to the way it was before having problems or in other words 'global recovery' from surgery. Responses were given using a 0 to 4 scale, with 0= not applicable: 1= no, I do not expect surgery to help with my pain/ADLs/etc., 2= yes, but just a little, 3= yes, somewhat, 4= yes, a lot. The other two original domains (e.g. expectation of improved range of motion and expectation of improved interaction and ability to provide care), were not used as neither were significantly associated with any baseline variable in their sample [16]. This instrument has shown moderate to substantial reliability on candidates for shoulder surgery [16, 17].

Self-Administered Comorbidity Questionnaire (SCQ)

The SCQ is a self-administered measure of comorbidity used in clinical and health services research settings. It is a short, easily understood questionnaire that may be completed by individuals without having any medical background. The SCQ asks patients to indicate if they are suffering from 13 medical conditions and their perception of its impact on functioning [18]. The conditions are: heart disease, high blood pressure, lung disease, diabetes, ulcer or stomach disease, kidney disease, liver disease, anaemia or other blood disease, cancer, depression, OA, back pain, rheumatoid arthritis, and an option to add three other non-specified medical problems. The test-retest reliability of the questionnaire has been reported at 0.91 with the intraclass correlation coefficient, and 0.73 (P=0.0001) as measured with the Spearman coefficient [19].

The Medical Outcomes Study 12-Item Short Form Health Survey, v2 (SF-12)

The SF-12 is a 12-item generic general health instrument that evaluates eight domains including restrictions or limitations on physical and social activities, normal activities and responsibilities of daily living, pain, mental health and well being and perceptions of health. The SF-12 has been extensively used, and has been shown to be valid, reliable, and responsive in a wide variety of populations and contexts including patients with orthopaedic conditions [20, 21]. It is generally accepted that the minimally important difference for the SF-12 ranges from 3-5 points.

Social Role Participation Questionnaire (SRPQ)

The SRPQ calculates three social role dimensions (role salience, role limitations, and role satisfaction) in 12 domains. It is a used to assess an individual's perceptions of the following: 1) Importance of their participation in diverse roles; 2) Restrictions in their role participation; and 3) Satisfaction with their performance in social roles [22] Each item is measured on a scale from 1-5. Mean scores are calculated separately for each of the three social role dimensions. Participants are also asked whether they are currently employed, attending school, involved in an intimate relationship, or have children, step-children or grandchildren. These questions were designed for individuals to think about their health generally or to think about a more specific health condition (e.g. joint problems related to arthritis). The words "joint problems" in the items can be substituted with other conditions (e.g. multiple sclerosis) or with "thinking about your health" [22]. The measure has been used in interviewer-administered and self-administered formats. It has been used in samples of healthy adults and with people who have various forms of arthritis [23].

University of California at Los Angeles (UCLA) Activity Score

The UCLA activity score is a one-item score that individuals use to best describe their current activity level (1-10), where '1' = Wholly inactive, dependent on others, and cannot leave residence, to '10' = Regularly participates in impact sports. It has been shown to have the strongest correlations with the other measures of activity levels

($r = -0.55$ to 0.23 for TKR) and distinguishes between insufficiently and sufficiently active patients undergoing TKR [24, 25]. The UCLA scale has the best reliability, provides the highest completion rate, and it seems to have no floor effect [24]. It appears to be the most suitable scale for assessment of physical activity levels in patients undergoing total joint replacement surgery [24, 25].

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