DETERMINING PREDICTORS FOR UNSUCCESSFUL TOTAL KNEE ARTHROPLASTY OUTCOMES

by

Leslie Streeter

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As members of the DNP Project Committee, we certify that we have read the DNP project prepared by *Leslie Streeter*, titled *Determining Predictors for Unsuccessful Total Knee Arthroplasty Outcomes* and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

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STATEMENT BY AUTHOR

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DEDICATION

This project is dedicated to my father who taught me to question, look for answers, and always continue learning, to my mother who always believed in me, and especially to my husband who has sacrificed to support me financially and emotionally throughout all my endeavors.

Thank you for your love and encouragement.

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ABSTRACT

Background: Total knee arthroplasty (TKA) is the second most commonly performed orthopedic procedure in the United States (US). However, decreased functional ability and chronic pain remains a significant problem for 6% - 30% of patients after TKA. An understanding of factors affecting TKA outcomes may lead to better methods of patient management and selection, which would improve surgical outcomes. Therefore, this quality improvement (QI) project analyzed whether pre-surgery Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) sub scores for pain, stiffness, and function are reliable predictors of total WOMAC scores six months post-surgery.

Objective: The purpose of this QI project was to identify factors associated with post-TKA outcomes in patients at Banner – UMC's orthopedic clinic in Arizona during a retrospective five-year period (2010-2015)

Methods: This QI project analyzed data collected from 131 patients, 63.4% (n=83) were female. Average age was 65 years (range= 40-89). Patient's WOMAC scores were assessed pre- and post-surgery.WOMAC scores range from '0' to '96' with higher scores representing worse pain, stiffness, and functional ability. Unsuccessful TKA was defined as a post-surgery total WOMAC score greater than 24.3. Data were analyzed by multiple linear regression using IBM Statistical Package for the Social Sciences statistical analysis software version 25.

Results: Patients' average WOMAC scores pre-surgery and post surgery were 48.56 $\pm$ 16.898 and 15.24 $\pm$ 15.210 respectively. Twenty-six of the 131 patients in this QI project had a post-surgery total WOMAC score greater than 24.3, indicating that 20% of patients had unsuccessful TKAs. This regression model predicted 7.6% (R^2 =.076) of the variance in total WOMAC scores

six months after TKA and was statistically significant at alpha = .05 ($F_{1,125}$ =9.923, p=.002). None of the other variables in the model were significantly associated with total WOMAC scores six months after TKA.

Conclusions: The results of this QI project support previous studies indicating pre-surgery pain as a significant predictor of TKA outcomes, though it accounted for only a small percent of the variance. Further research is needed to determine if other factors such as body mass index and preexisting co-morbidities are more predictive of TKA outcomes. Also, objective methods for assessing pre- and post-TKA outcomes may be more reliable than the subjective WOMAC scores obtained.

INTRODUCTION

Background

In the past 20 years, total knee arthroplasty (TKA) rates have increased rapidly in the United States (US) due to increasing obesity rates and the aging population (Burns et al., 2015). TKA is now the tenth most commonly performed surgery and the second most common orthopedic procedure in the US (Desmeules et al., 2013). It is predicted that the need for TKA will continue to increase over the next two decades (Desmeules et al., 2013).

TKA is an effective procedure for reducing pain and improving functional ability and quality of life for most people with degenerative knee osteoarthritis (Potty et al., 2015). Primary TKA has a success rate of at least 80% and a 10-year survival rate of 95% (Potty et al., 2015). However, nearly 20% of TKA patients are not satisfied with the long-term results of surgery (Burns et al., 2015). Studies of patient-based outcome measures show that chronic pain remains a significant problem for 6 to 30% of patients after TKA (Burns et al., 2015). Additionally, 10 to 30% of patients report no improvement in functional ability after TKA (Desmeules et al., 2013).

An in-depth understanding of the factors affecting TKA outcomes may lead to better methods of patient management and selection, which would improve surgical outcomes and efficiently allocate resources for TKA patients (Potty et al., 2015). Identifying factors that affect outcomes after TKA is therefore a priority (Burns et al., 2015). However, identifying factors affecting TKA outcomes is complex and challenging (Desmeules et al., 2013). Studies of TKA have focused mainly on surgical complications and type of prosthesis used (Desmeules et al., 2013). Type of implant used may marginally affect outcomes of pain and functioning but appear to have a greater effect on prosthesis longevity (Desmeules et al., 2013). Surgical complications are uncommon but more directly affect the short-term than long-term outcomes of TKA (Desmeules et al., 2013). Preoperative BMI may be a negative indicator for TKA outcomes (Mackie, Muthumayandi, Shirley, Deehan, & Gerrand, 2015).

Preoperative functional status is the factor most consistently associated with variance in TKA outcomes (Desmeules et al., 2013). Patients who had low scores on performance tests and were 72 years or older had the poorest results in function after TKA (Bade, Wolfe, Zeni, Stevens-Lapsley, & Snyder-Mackler, 2012). Secondary predictors of poor outcomes were age and decreased mental health (Bade et al., 2012). Another study found pre-surgery Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores and sub-scores to be an accurate predictor of physical function after TKA (Wise et al., 2015). WOMAC is a standardized questionnaire (possible score range = 0-96) commonly used to assess pain, stiffness, and physical function in patients with knee osteoarthritis (KOA), with higher scores indicating worse pain, stiffness, and functional ability (Giesinger et al., 2015).

Other factors, including, gender, income, education level, comorbidities, and social support have been related to TKA outcomes however, findings have been inconsistent (Desmeules et al., 2013). Therefore, determining whether TKA is an appropriate intervention for diverse patients is a challenge (Desmeules et al., 2013). Riddle et al. (2015) investigated whether patient outcomes after TKA could be predicted using a rating scale based on pre-surgery risk factors. Patients were classified as appropriate, inconclusive, or inappropriate for TKA using an appropriateness algorithm (Riddle, Perera, Jiranek, & Dumenci, 2015). Patient’s post-surgery pain, stiffness, and physical function were measured using the WOMAC assessment (Riddle et al., 2015). Patient’s WOMAC scores showed significant agreement with their pre-surgery classification (Riddle et al., 2015). These results provide convincing evidence for establishing pre-surgery criteria for TKA to help determine which patients are likely to benefit from TKA surgery (Riddle et al., 2015)

Local Problem

Banner – University Medical Center (UMC) is an acute-care hospital affiliated with the University of Arizona in Tucson. This hospital performs hundreds of TKAs annually. Banner – UMC's orthopedic clinic offers a pre-surgery joint class to all patients undergoing TKA at Banner-UMC. Data were collected from all participants attending the pre-surgery joint class from 2010 through 2015 by the nurse instructing the class to ascertain the effectiveness of the class. The data consisted of WOMAC scores collected pre-surgery and WOMAC scores at six months post-surgery. Analysis of the data showed that out of the 133 TKA patients who attended the joint class and completed the WOMAC patient survey before surgery and again six months after TKA, that 20% did not show significant improvements in their WOMAC scores after surgical intervention. The purpose of TKA is to reduce pain and improve functional ability (Burns et al., 2015). Surgeries that do not result in improvements cause the patients unnecessary pain, and waste time and money (Desmeules et al., 2013). Currently, no data analysis has been conducted to ascertain if there are common factors among the patients that are predictive of post-TKA WOMAC scores. Without an understanding of the predictors of TKA results, little can be done to determine which patients are most likely or unlikely to benefit from TKA (Desmeules et al., 2013).

Purpose

The purpose of this quality improvement project was to identify and understand the underlying factors associated with post-TKA outcomes in patients at Banner – UMC's orthopedic clinic. The project aims to reduce the number of TKAs with unfavorable results by providing the health care team at Banner – UMC with additional information for screening patients to determine which patients are likely to experience negative results after TKA. The data would be used to more accurately determine which patients are not appropriate candidates for surgery and to know which patients may need added support to aid recovery after surgery. This would lead to improved patient outcomes and satisfaction with reduced pain and decreased expense due to unsuccessful surgeries (Riddle et al., 2015). Additionally, patients who are at risk for unsuccessful surgery could be provided additional surveillance and support to improve outcomes (Desmeules et al., 2013). Surgeons would also lose less time due to unsuccessful surgical outcomes and their ability to provide better quality care for patients would increase (Bade et al., 2012). Other benefits would be a reduction in hospital costs related to readmissions and improved patient satisfaction ratings (Potty et al., 2015). The impetus for this project was health care providers at Banner – UMC's orthopedics who requested further analysis of the data from the joint clinic QI project to improve patient satisfaction and understand the underlying factors that are predictive of post-TKA WOMAC scores.

Question

Are age, gender, and pre-surgery WOMAC sub-scores for joint stiffness, pain, and physical function predictive of total WOMAC score six months after TKA in patients who attended a pre-surgery joint class at Banner – University Medical Center Orthopedics during a retrospective five-year period (2010-2015)?

CONCEPTUAL FRAMEWORK AND SYNTHESIS OF EVIDENCE

Theoretical Framework

Nursing theory facilitates the development of nursing knowledge and translating that knowledge into practice (Reed & Shearer, 2011). Theories provide a basis for understanding patients, recognizing health problems, and planning interventions to help them (Zaccagnini & White, 2017). A theoretical framework guides research and should align with the purpose for the research (Terry, 2015).

The question in this quality improvement project was "Are age, gender, and pre-surgery WOMAC sub-scores for joint stiffness, pain, and physical function predictive of total WOMAC score six months after TKA in patients who attended a pre-surgery joint class at Banner – University Medical Center Orthopedics during a retrospective five-year period (2010-2015)?" The purpose and research question of this QI project are guided by the National Quality Strategy (NQS), (Figure 1). NQS establishes three overarching aims to address health concerns (Agency for Healthcare Research and Quality [AHRQ], 2017).

NQS's three broad aims were used to guide and give purpose to this QI project. They are, better care, healthy people and healthy communities, and affordable care (AHRQ, 2017). Better care is defined as improving the quality of care by "making health care more patient-centered, reliable, accessible, and safe" (AHRQ, 2017). This QI project aimed to identify and understand the underlying factors affecting patient-centered TKA outcomes of functional ability and pain. Understanding which factors influence TKA outcomes will results in better, more patient centered care by allowing providers to personalize patient recommendations for TKA and interventions after TKA based on individual risk factors for poor outcomes. This will also result in safer, more reliable care.

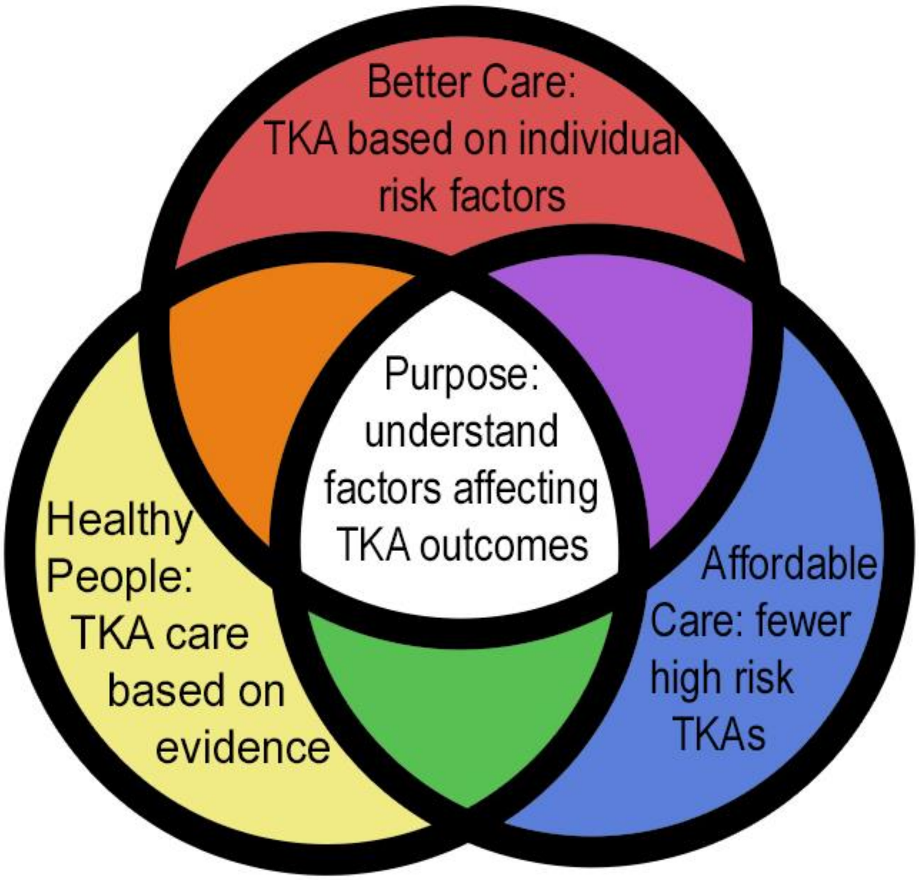


FIGURE 1. National quality strategy model.

The NQS aim of healthy people and healthy communities is defined as improving health by supporting proven interventions to delivering higher-quality care. This aligns with the purpose of this QI project because understanding the factors that affect TKA outcomes will facilitate development of evidenced based interventions and higher quality of care for TKA patients. Improving the success rate of TKA will increased patient productivity, physical activity, and independence.

The aim of affordable care is defined as reduced cost of quality health care through more efficient care (AHRQ, 2017). This QI project promotes affordable care for TKA patients by providing information for determining which patients are appropriate candidates for TKA. Thus, avoiding extra costs associated with unnecessary or unsuccessful surgeries. Also, understanding factors that influence TKA outcomes will aid in providing interventions to reduce TKA complications which will reduce costs.

This QI project defines underlying factors as root causes of TKA outcomes. These include pre-surgery pain and functional ability, surgical techniques, type of implant used, socioeconomic factors, demographics, psychological factors, complications, and comorbidities. Poor TKA outcomes are defined based on research by Giesinger, Hamilton, Jost, Behrend, and Giesinger (2015), that identified WOMAC cut-off scores for interpreting TKA success. Therefore, unsuccessful TKA was defined as a six-month post-surgery WOMAC total score of greater than 24.3 (Giesinger et al., 2015).

Synthesis of Evidence

TKA has become one of the most commonly performed surgeries in the US (Desmeules et al., 2013). TKA has a high success rate and increases functional ability and quality of life for most recipients (Potty et al., 2015). However, nearly 20% of TKA patients have unfavorable results after surgery (Burns et al., 2015). Understanding what pre-surgery factors are associated with post TKA outcomes aids providers in determining which patient will need greater support after TKA or are not viable candidates for surgery (Potty et al., 2015).

A literature review was conducted to assess the current knowledge about the underlying factors affecting TKA outcomes. The author searched PubMed, CINAHL, and Cochrane Library using the key terms “total knee arthroplasty and outcome predictors,” and “total knee arthroplasty and poor outcomes,” with the inclusion criteria: observational studies, randomized controlled trials, systematic reviews published within the past five years, English language, humans, and adults over 18 years of age. A total of 67 articles were found and 13 articles were chosen for inclusion based on their relevance to the outcomes measured by this QI project. The studies were critiqued, and their results were summarized and synthesized in this paper (Appendix A).

Pain and Functional Ability

Preoperative pain and functional ability were consistently associated with post-surgery TKA outcomes with seven studies reporting an association. Baseline pain and functioning appears to be a reliable indicator of TKA outcomes.

A secondary analysis of prospective randomized controlled trials (RCT) by Bade, Kittelson, Kohrt, and Stevens-Lapsley (2014), explored the predictive value of functional performance and range of motion measures on outcomes after TKA. The authors concluded that preoperative measures of knee ROM had some predictive value for TKA outcomes, but preoperative functional ability was a more consistent predictor for TKA outcomes (Bade et al., 2014). Similarly, a quasi-experimental study by Bade, Wolfe, Zeni, Stevens-Lapsley, and Snyder-Mackler (2012), found that low preoperative scores on the Timed Up and Go (TUG), the Stair Climb Test (SCT), and the 6-Minute Walk (6MW) functioning tests were all related to poorer performance on functional measure after TKA (Bade et al., 2012). A prospective cohort study by Desmeules et al. (2013), also reported an association between high pain scores and low functional ability pre-surgery and increased pain and low functioning after surgery. A systematic review by Lewis, Rice, McNair, and Kluger (2015), reported preoperative knee pain to be one of the strongest predictors of persistent pain after TKA. Lungu, Desmeules, Dionne, Belzile, and Vendittoli (2014), found that the best indicators of poor TKA outcomes were five items from the baseline WOMAC that assesses stiffness and functioning. Riddle, Perera, Jiranek, and Dumenci (2015), also studied pain and function as predictors of TKA outcomes and found that appropriateness for surgery could be predicted by pre-surgery pain and functional ability. However, while a systematic review by Lungu, Vendittoli, and Desmeules (2016), reported an association between high levels of pre-operative knee pain and disability on worse TKA outcomes, no conclusions could be made about the strength of the association.

Surgical Techniques and Type of Implant Used

Many studies have been done on the effect of various surgical procedures and the type of knee implant used on TKA outcomes. A RCT by Beaupre, Secretan, Johnston, and Lavoie (2012), reported no different in knee stiffness, pain, and function between TKA's that used patellar retention and those that used resurfacing. Desmeules et al. (2013), found that the type of implant used had a slight effect on post-surgery pain and functioning but did affect prosthesis longevity. Similarly, Li et al. (2015), found no significant difference in pain and functioning between TKAs using high-flex (HF) prostheses compared with standard (STD) implants. Based on current research, surgical procedures and the type of knee implant used are not reliable predictors of TKA outcomes.

Socioeconomic Factors and Demographics

The relationship between socioeconomic factors and demographics and TKA outcomes has also been studied. Bade et al. (2012), found older age to be a secondary predictor of worse

TKA outcomes. However, a systematic review by Kuperman, Schweizer, Joy, Gu, and Fang (2016), reported that while older patients have more complications and longer hospital stays after TKA, their improvement in pain and functional ability were similar to that of younger patients. Desmeules et al. (2013), found an association between being single, separated, divorced, widowed, unemployed, or retired and reduced functional ability after TKA. However, a systematic review by Lungu, Vendittoli, and Desmeules (2016), investigated the relationship between gender, income, education level, and social support and TKA outcomes and they were not able to draw conclusions on their effect on and TKA outcome because of the inconsistency in study results (Lungu et al., 2016). While several studies have explored the effect of socioeconomic factors and demographics on TKA results, no strong associations have been shown and findings have been contradictory. Therefore, socioeconomic factors and demographics cannot be considered reliable predictors of TKA outcomes.

Psychological Factors

Several studies investigated the effect of psychological factors on TKA outcomes. Burns et al. (2015), studied pain catastrophizing as a predictor of higher pain levels after TKA and found modest evidence that pain catastrophizing is indicative of increased pain after TKA. Khatib, Madan, Naylor, and Harris (2015), found psychological health to be a significant predictor of long term pain and motivation to increase functioning after TKA. Furthermore, a systematic review by Lewis, Rice, McNair, and Kluger (2015), reported pain catastrophizing, mental health status to be robust predictors of chronic pain after TKA. Bade et al. (2012), also found poor mental health to be associated with unfavorable TKA outcomes. However, a systematic review by Lungu et al. (2016), reported high variability between studies on pre-surgery psychological factors and TKA outcomes causing an inability to make conclusions based on current evidence. Though the research is inconclusive, psychological factors may contribute to reports of chronic pain after TKA. No evidence was found that indicates psychological factors are associated with lower improvement in functioning post-TKA.

Complications and Comorbidities

Few studies are available on surgical complications or comorbidities effects on long term pain and functioning after TKA. A systematic review by Lungu, Vendittoli, and Desmeules (2016), included studies on the effect of comorbidities, back pain, and decreased general health on TKA outcomes but was not able to report conclusive findings due to high variability in study results. Desmeules et al. (2013), found the number of complications to be associated with increased pain and disability post TKA. Comorbidities were associated with reduced quality of life after TKA, but not with pain or functional ability (Desmeules et al., 2013). These studies indicate that surgical complications and comorbidities may be factors in poor TKA outcomes. However, not enough evidence was found to assume a relationship.

Summary and Synthesis

A large amount of literature exists about factors affecting TKA outcomes including high-quality evidence from systematic reviews, and RCTs. Other research included was from quasi-experimental or observational studies. Patient reported measures of pain and function after TKA were the most often type of data collected. Patient report is subjective and can be influenced by patient outlook.

The concepts of interest for this QI project were pain and functional ability after TKA as measured by the WOMAC. Several of the studies cited also used the WOMAC to define pain and functioning which is consistent with this studies definition. Other methods for defining pain and functional ability were the TUG test, 6MW test, active knee flexion and extension range of motion, and the Knee Injury and Osteoarthritis Outcome Score (KOOS). The KOOS is like the WOMAC in that it uses patient reported measures or pain, function, and stiffness. The TUG test, 6MW test, active knee flexion and extension range of motion are clinically assessed measures of function rather than patient reported and are less subjective that the WOMAC. Subjective measures of pain and function are important to include because they provide patient-centered data.

Several findings were supported by multiple studies. Pre-surgery pain and functioning were found to be associated with TKA outcomes in six studies. There was also consensus that type of implant and surgical methods have marginal effects on TKA outcomes of pain and functioning. More than one study also reported an association between psychological factors and chronic pain after TKA. Pre-surgery pain and function were the most consistently reported predictor of TKA outcomes.

Varying results and contradictions exist between study results. Findings have been inconsistent regarding socioeconomic factors and demographics as predictors of TKA outcomes. Several studies found psychological factors to be associated with greater pain after TKA but other findings were inconclusive. Due to variability of findings, socioeconomic factors, demographics, and psychological factors do not appear to reliable predictors of TKA outcomes.

Although extensive research has been done on factors affecting TKA outcomes, gaps in the literature still exist. Research with TKA patient have focused mainly on surgical methods and type of prosthesis used. There are fewer studies about social economic or psychological factors affecting TKA results. There are few studies of any kind about long-term effects of surgical complications or comorbidities on pain and functioning after TKA. Also, more studies that use objective methods for evaluating TKA results would improve validity of the evidence. Pre-surgical pain and functional ability were most consistently supported by research as reliable predictors of TKA outcomes. Based on these findings this QI project will examine whether pre-surgery measures of pain and function were reliable predictors of total WOMAC scores six months after surgery.

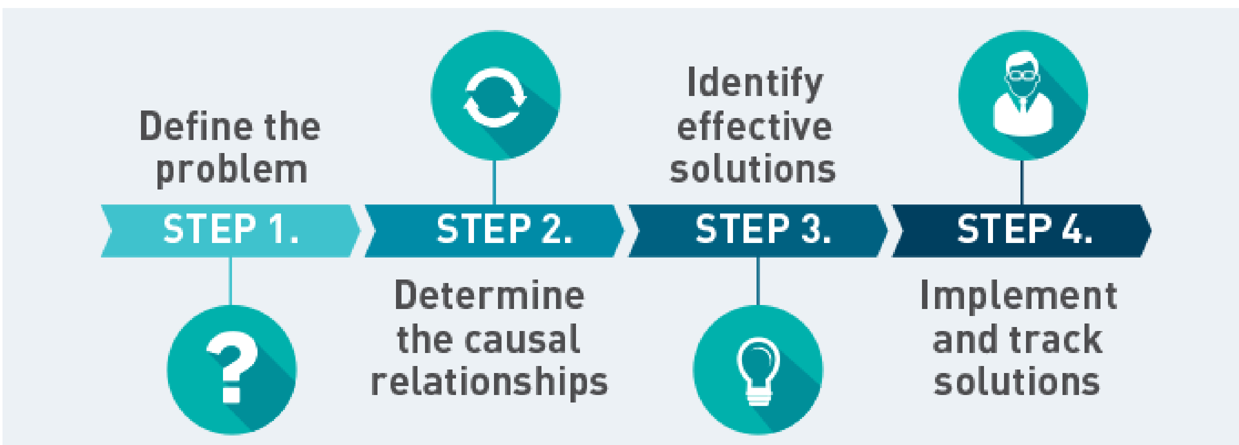
METHODS

Design

This DNP project used a quality improvement design to identify and understand underlying factors affecting TKA outcomes in patients at Banner -UMC's orthopedic clinic. Quality Improvement (QI) was an appropriate design choice for this project because QI aims to improve practice outcomes by changing methods in care delivery (Moran, Conrad, & Burson, 2017). This QI project aimed to improve outcomes of TKA by using data to identify factors that contribute to post TKA results, so changes in delivery of care can be made.

Root cause analysis (RCA), (Figure 2) is a QI methodology that uses retrospective analysis of unsuccessful outcomes (Moran et al., 2017). RCA was the methodology used to guide this QI project. RCA provides a process for identifying the causal factors contributing to variations in performance that produce undesirable outcomes (The Joint Commission, 2015). RCA is often used to investigate a sentinel event, but it can be applied to any study aimed at determining the processes or causes of variations that lead to patient outcomes (The Joint Commission, 2015). A root cause is an underlying reason for failure to achieve desired results

(The Joint Commission, 2015). The cause refers to the relationship between factors that enable the failure to occur (The Joint Commission, 2015). This project aimed to identify factors that predict TKA results in order to improve patients' functional outcomes. RCA's goal is to prevent the problem from recurring in the future (The Joint Commission, 2015). However, root cause failure analysis postulates that total prevention of the problem recurrence is usually not possible (The Joint Commission, 2015). RCA consists of a general process that can be adapted for the desired outcomes (The Joint Commission, 2015). This project was guided by four steps of the RCA process. Those are defining the problem, determining a relationship, identifying solutions, and implementing and tracking solutions (Figure 2).



(Retrieved from http://www.apollorootcause.com/about/apollo-root-cause-analysis-method/)

FIGURE 2. Root cause analysis process.

Ethical Considerations

Respect for Persons

Respect for person entails respecting QI project participants' autonomy and safeguarding their privacy (Polit & Beck, 2012). This QI project analyzed data that has already been collected by the nurse teaching the pre-surgery class for the purpose of quality improvement. The data was collected as part of a pre-surgery joint class that was offered to patients at Banner-UMC orthopedics prior to TKA. Participation in the joint class and completion of the before and after WOMAC surveys were completely voluntary and patients consented to collection and use of their data for quality improvement purposes. Informed consent was not obtained from patients because the U.S. Department of Health and Human Services (USDHHS) allows the institutional review board (IRB) to waive the requirements for obtaining informed consent for quality improvement studies that meet certain requirements (USDHHS, 2017). This QI project met the requirements of minimal risk to subjects and subjects' rights and welfare was not harmed (USDHHS, 2017). Subject privacy was protected by de-identification of all data by the nurse who collected it prior to submitting it to the researcher for analysis. Also, data was encrypted, password protected, and transmitted only via secure server.

Beneficence

Beneficence is the concept that the welfare of the research participant should be a priority of the researcher and that the research should be of benefit to a specific population (Polit & Beck, 2012). The QI project should be designed to maximize benefits and reducing harm (Polit & Beck, 2012). This QI project had the aim of decreasing poor outcomes for TKA patients. It was designed to accomplish its objectives while ensuring subject safety. As this QI project used previously collected data that was handled securely, there was no foreseeable risks to subjects. Furthermore, understanding factors associated with TKA outcomes could potentially benefit future prospective TKA patients at Banner-UMC.

Justice

Justice in research ethics is fairness in the selection of research participants (Polit & Beck, 2012). Research participants should be selected based on risks and benefits and the objectives of the study (Polit & Beck, 2012). Recruitment should not target a vulnerable population or allow preferential treatment to select privileged participants (Polit & Beck, 2012). The study should set criteria for inclusion such that participants equitably share the risks and benefits of the study (Polit & Beck, 2012). Participation in the pre-surgery class was offered to all Banner-UMC orthopedic patients prior to TKA surgery regardless of race, age, gender or socioeconomic factors. All participants received equal treatment.

Population Vulnerability

Vulnerable populations are study participants who require special considerations to protect their safety and well-being (Shivayogi, 2013). These include human fetuses, infants, children, pregnant women, and persons with cognitive impairment or educational disadvantage (Shivayogi, 2013). Vulnerable populations can also include any group of participants who are in some way dependent on the entity conducting the research, for example: employees, students, or prisoners (Shivayogi, 2013). All participants in this QI project were consenting adults without cognitive impairment. None of the participants were pregnant or had a dependent relationship with the researcher or Banner-UMC. Thus, no vulnerable populations were represented in this QI project.

This is a QI project which did not require IRB approval (HHS, 2017). A Determination of Human Research form was submitted to the IRB and it was determined that this project did not meet the definition of 'research' or 'human subject' as defined by 45 CFR 46.102(d) and 45 CFR

46.102(f) (Appendix B). Also, the Non-Research Data Use Committee (NRDUC) at Banner Hospital reviewed and approved the project (Appendix C.). Permission to use the data was obtained from the Department Administrator for University of Arizona College of Medicine Orthopedic Surgery and director of the Banner-UMC Orthopedic Clinic who are the owners and managers of the data (Appendix D).

Setting

This retrospective QI project analyzed data that was collected from a Banner-UMC pre-surgery joint class from 2010 through 2015. The data collection and joint class were conducted by a nurse at the orthopedic outpatient clinic at Banner-UMC hospital. TKA surgeries were performed at Banner-UMC hospital. Banner -UMC is an acute-care hospital affiliated with the University of Arizona in Tucson. This hospital performs hundreds of TKAs annually.

Sample

The QI project participants were a convenience sample of 171 TKA patients who attended a pre-surgery joint class at Banner-UMC orthopedics between February 2010 and June 2015. All patients undergoing elective TKA surgery at Banner-UMC Tucson hospital and Banner-UMC South Tucson hospital were invited to attend the weekly joint class prior to surgery. Prospective TKA patients attended one session of the hour-long class. The class consisted of a power point presentation designed to provide patients, their family, and friends with education about their upcoming surgery and to allow them to ask questions and express their concerns. WOMAC scores were collected prior to the presentation for all willing participants in the class and at six months after surgery.

The only criteria for inclusion in the original QI project were attending the joint class prior to TKA surgery at Banner-UMC Tucson hospital and being willing to participate. Of the 171 patients recruited to the QI project, 133 completed both the pre- and post-surgery WOMAC questionnaires. Data from the 38 participants who did not complete the post-surgery WOMAC questionnaire were not included in this analysis. Also, two patients' scores were excluded from the analysis due to their ages (17 & 20 years old) being 20 years or greater below the next youngest participant (age 40). KOA is the most common cause of knee joint dysfunction leading to the need for TKA (Bhatia, Bejarano, & Novo, 2013). Onset of OA before age 40 years is rare (Morden, Jinks, Ong, Porcheret, & Dziedzic, 2014). Patients under the age of 40 who undergo TKA usually do so due to acute injury or pathology other than OA and their outcomes would be expected to be different from those over 40 who undergo TKA (Parvizi et al., 2014). Of the 131 participants whose data were included in this retrospective analysis, 83 (63.4%) were female, average age was 65 years (S= 11.227); all were from Arizona, 87 were from Tucson (66.4%), 43 (32.8%) were from rural communities, 59 (45.0%) had right knee TKA, 63 (48.1%) had left knee TKA, and 9 (6.9%) had bilateral TKA (Table 1 & Figure 3). Patients' average WOMAC scores pre-surgery and post surgery were 48.56 $\pm$ 16.898 and 15.24 $\pm$ 15.210

TABLE 1. *Age*

	N	Minimum	Maximum	Mean	Std. Deviation
Age	131	40	89	65.24	11.227
Valid N (listwise)	131				

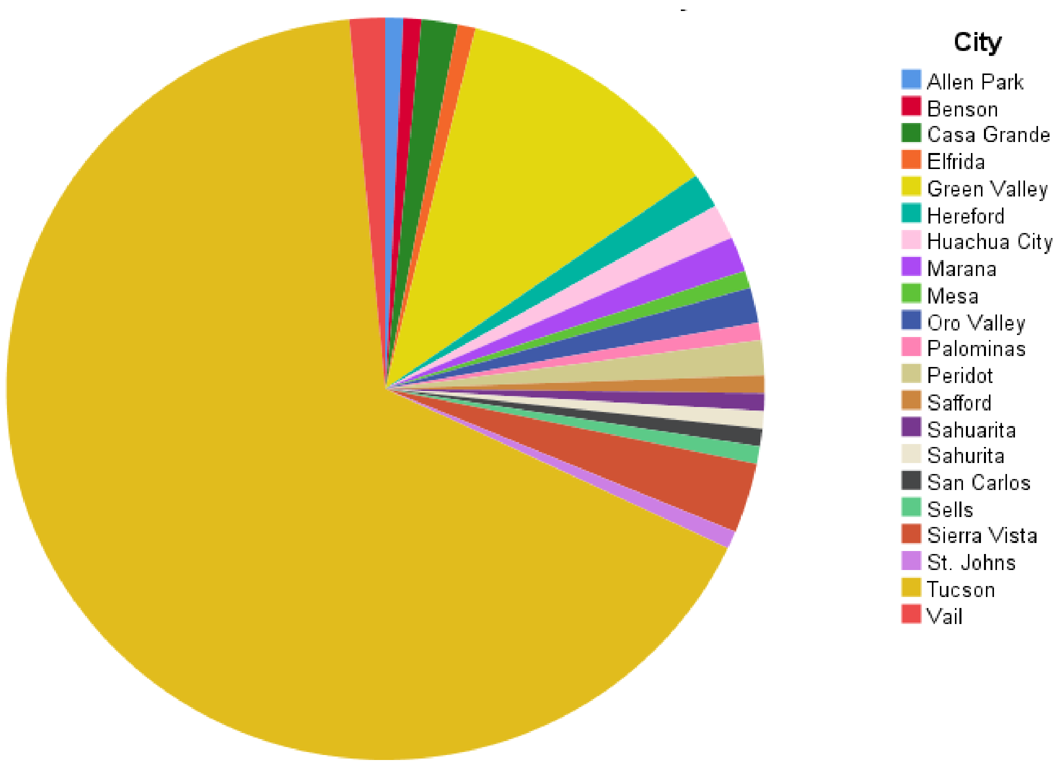


FIGURE 3. Participation by city.

Data Collection

Tools for Data Collection

Patient's pre-and post-surgery pain, stiffness, and physical function were measured using the WOMAC questionnaire (Appendix E). The WOMAC uses a Likert Scale for patient self-report of 24 items divided into the three subscales of pain, stiffness, and physical function (Giesinger, Hamilton, Jost, Behrend, & Giesinger, 2015). The five items of the pain subscale assess pain during walking, using stairs, in bed, sitting or lying, and standing (Giesinger et al., 2015). Two items of the stiffness subscale assess stiffness after first waking and later in the day (Giesinger et al., 2015). The physical function subscale consists of 17 items that assess functional ability with stair use, rising from sitting, standing, bending, walking, getting in and out of a car, shopping, putting on and taking off socks, rising from bed, lying in bed, getting in and out of bath, sitting, getting on and off toilet, heavy household duties, and light household duties (Giesinger et al., 2015).

The Likert Scale uses the following descriptors: none, mild, moderate, severe, and extreme for all items (Giesinger et al., 2015). The descriptors correspond to ‘0’ to ‘4’ on the ordinal scale (Giesinger et al., 2015). The scores are totaled for each subscale and the subscales are summed for total WOMAC score (Giesinger et al., 2015). Scores range from ‘0’ to ‘96’ with higher scores representing worse pain, stiffness, and functional ability (Giesinger et al., 2015).

The WOMAC was developed specifically for patients with knee OA and has been used widely to evaluate changes following osteoarthritis interventions (Giesinger et al., 2015). It is the most often used tool for collecting patient reported data after TKA (Giesinger et al., 2015).

Process for Data Collection

Data was collected using pre-and post-WOMAC questionnaires. The pre-surgery score was collected at the joint class. Post-surgery WOMAC surveys were mailed to patients’ homes by the nurse conducting joints class six months after surgery. All WOMAC scores were recorded in an excel spread sheet along with patients’ ages, gender, surgery year, and which knee the TKA was performed on. The Excel spread sheet was made available for data analysis for this QI project following IRB approval.

Data Analysis

Unsuccessful TKA was defined as a six-month post-surgery total WOMAC score of greater than 24.3. Twenty-six of the 131 patient in this QI project had post-surgery total WOMAC scores greater than 24.3, indicating that 20% of patient had unsuccessful TKAs. Prior to this QI project, no analysis of the data from the joint class had been conducted to ascertain if there were common factors that were predictive of WOMAC scores six months post-TKA. Without an understanding of the predictors of TKA outcomes, little can be done to determine which patients are most likely to benefit from TKA and which patients are most likely to have poor TKA out comes in order to prevent future unsuccessful TKA surgeries.

Initially the deidentified data was screened to identify and correct outliers, data entry errors, or other logical inconsistencies. Of the 171 patients who originally agreed to participate in the joint class QI project and took the pre-surgery WOMAC, 133 also completed the post-surgery WOMAC. Only data from participants who completed both the before and after surgery WOMAC questionnaires were included in this secondary analysis. Also, two other participants' data were excluded for being outliers for age as described above. After data cleaning, the data were imported into SPSS version 25 and descriptive statistics were calculated to ensure the quality of the data (check distributions, examine outliers) and describe the sample.

Current studies indicate that pre-surgical pain and functional ability are most consistently supported by research as reliable predictors of TKA outcomes. Therefore, this QI project analyzed whether pre-surgery WOMAC sub scores for pain, stiffness, and function are reliable predictors of total WOMAC scores six months after surgery. Associations between age and gender and total WOMAC score six months after TKA were also assessed. Data analysis was done by stepwise multiple linear regressions using SPSS. Multiple regression is used to determine an association between potential predictor (independent) variables and a criterion (dependent) variable (Kellar & Kelvin, 2013). The dependent variable is modeled as a function of multiple independent variables with corresponding coefficients, along with the constant term

(Kellar & Kelvin, 2013). Total WOMAC score six months after TKA was the criterion variable for this QI project. Predictor variables were pre-surgery WOMAC sub scores for pain, stiffness, and physical function, patient age, and gender. The WOMAC scores can be linearly transformed to a 0-120 continuous scale (Giesinger et al., 2015).

RESULTS

Outcomes of Assumption Diagnostics

Based on current research results, this QI project hypothesized that pre-TKA WOMAC sub-scores for pain and function would significantly predict total WOMAC scores six months after TKA and that pre-TKA WOMAC sub-score for joint stiffness, age and gender would have a less significant relationship with total WOMAC scores six months after TKA. The alpha level for this QI project was set at .05 using data from n=131 patients. The F-distibution with k and (n-k-1) degrees of freedom can be used to test the significance of R^2 (k= number of independent variables; n= number of participants) (Kellar & Kelvin, 2013). The critical value for the R^2 F_{crit} with k=5 and (n-k-1) = 125 is 2.29. The Fcrit for the regression coefficients with 1 and 125 is 3.92 (Kellar & Kelvin, 2013).

For a multiple linear regression to be valid, some assumptions must be met (Kellar & Kelvin, 2013). The sample must be representative of the population to which the inferences will be applied (Kellar & Kelvin, 2013). The population for this QI project was TKA patients at Banner-UMC orthopedics and the results will influence care of future TKA patients at Banner-UMC orthopedics. The dependent variable should have a normal distribution and should be normally distributed for every value of each independent variable (Kellar & Kelvin, 2013). The distribution of the dependent variable for this QI project, total WOMAC score six months after

TKA is skewed to the left (skewedness = 1.857) (Figure 4). Linear transformation using natural log of total WOMAC score six months after TKA was done to correct for the skewedness of the dependent variable (Figure 5). The distributions of all independent variables were normal (Figures 6-10).

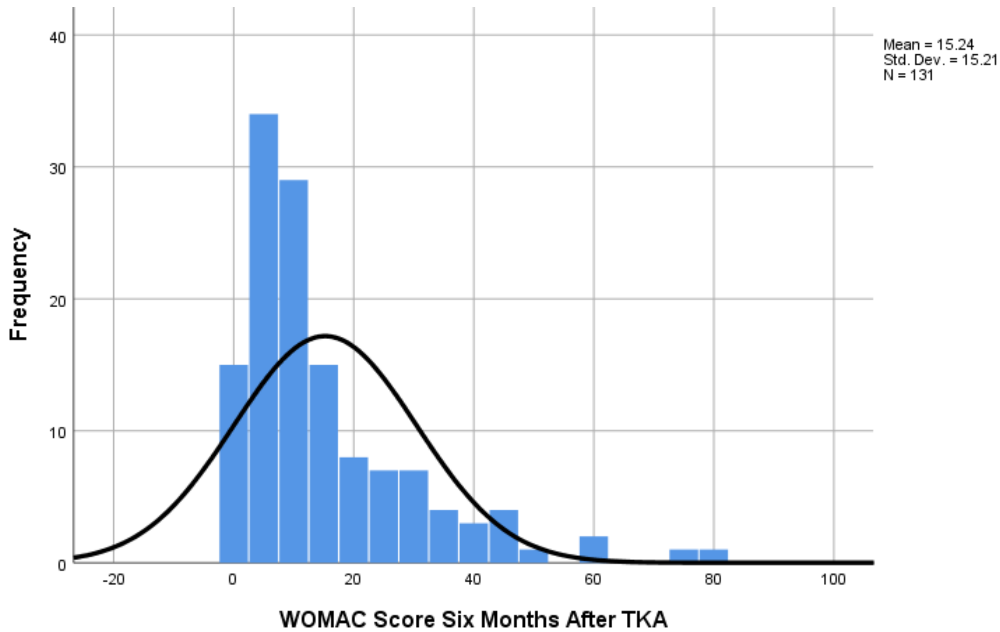


FIGURE 4. Distribution of total WOMAC score six months after TKA.

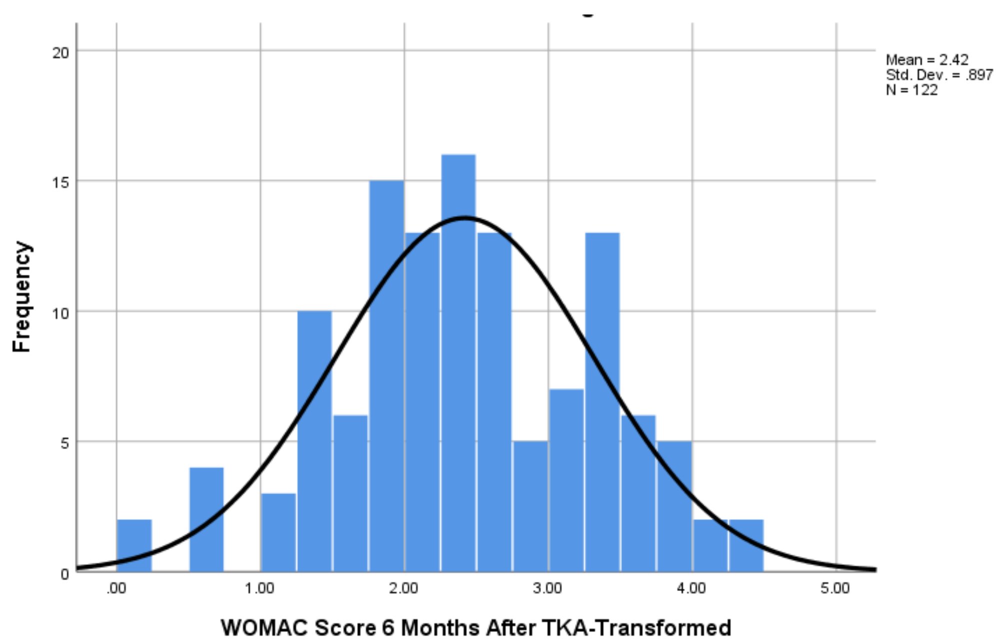


FIGURE 5. Distribution of transformed total WOMAC score six months after TKA.

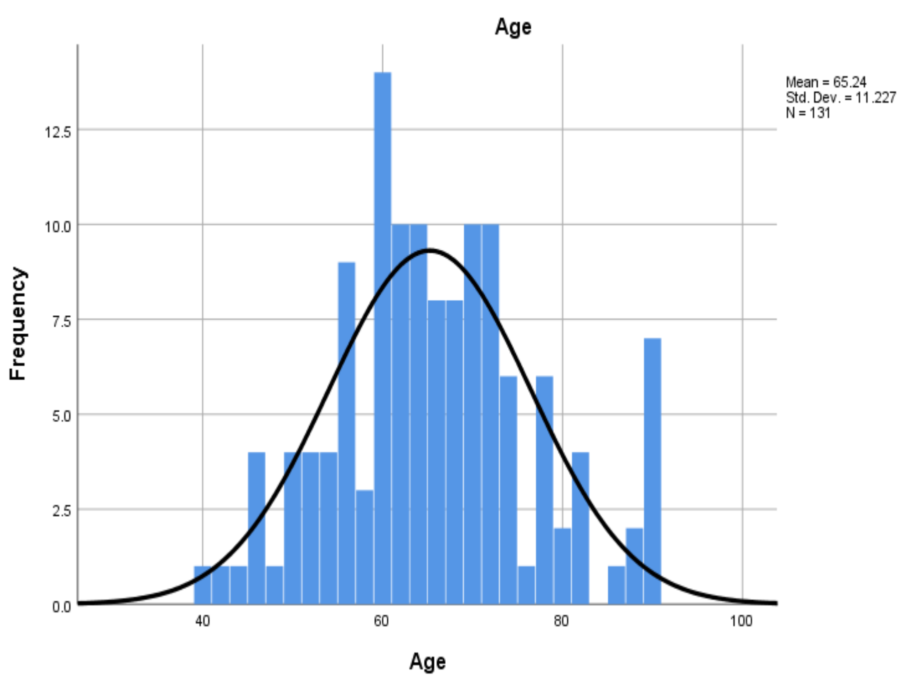


FIGURE 6. Distribution of age.

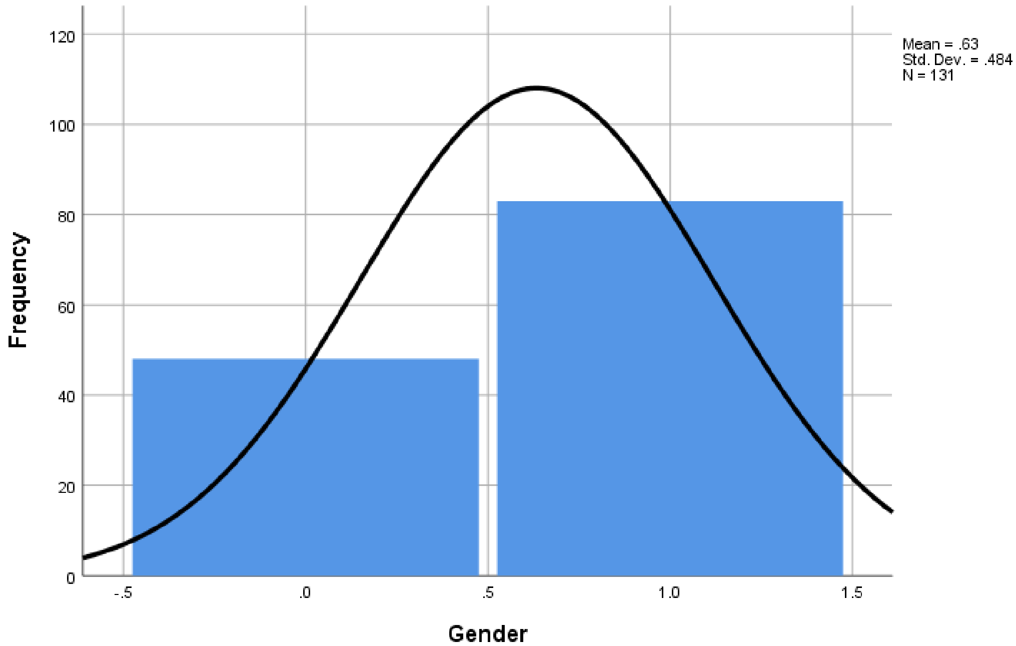


FIGURE 7. Distribution of gender.

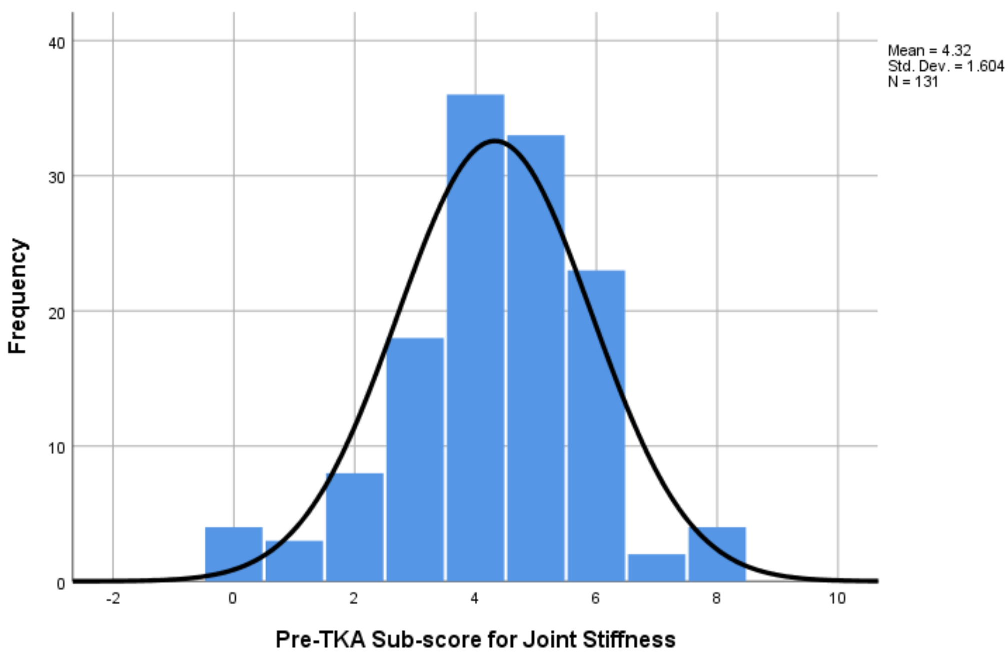


FIGURE 8. Distribution of pre-TKA joint stiffness sub-score.

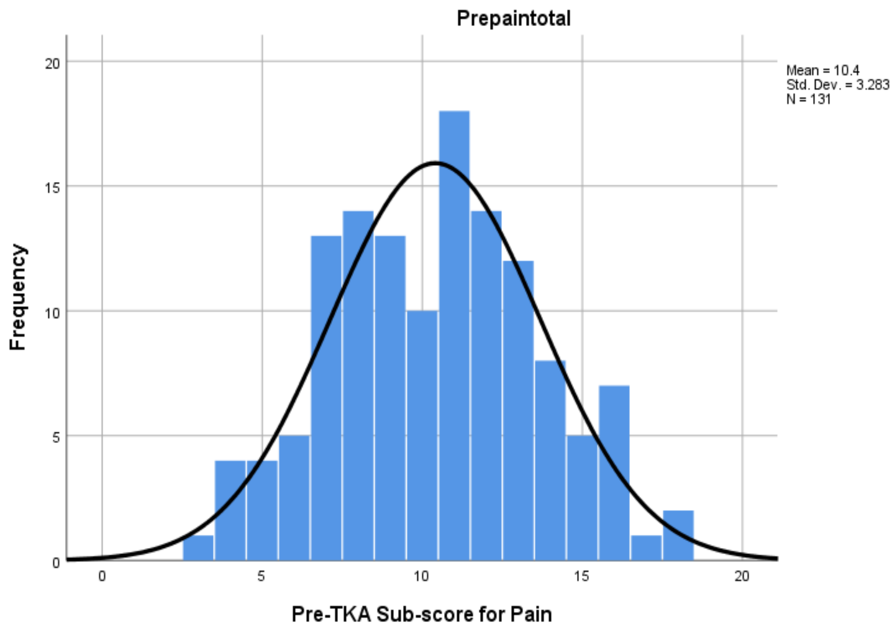


FIGURE 9. Distribution of pre-TKA pain sub-score.

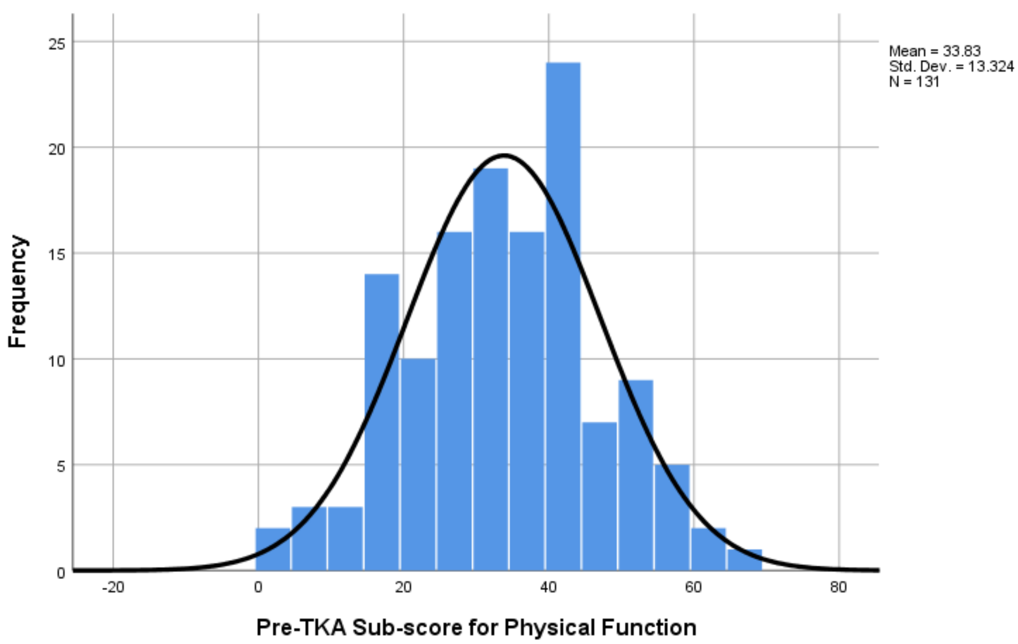


FIGURE 10. Distribution of pre-TKA physical function sub-score.

The assumption of homoscedasticity must also be met and there must be a linear relationship between the dependent and independent variables (Kellar & Kelvin, 2013). Homoscedasticity and linear relationship between the dependent and independent variables for this QI project were assessed using scatter plots. Homoscedasticity was met for all variables and a near linear relationship was established (Figures 11-15).

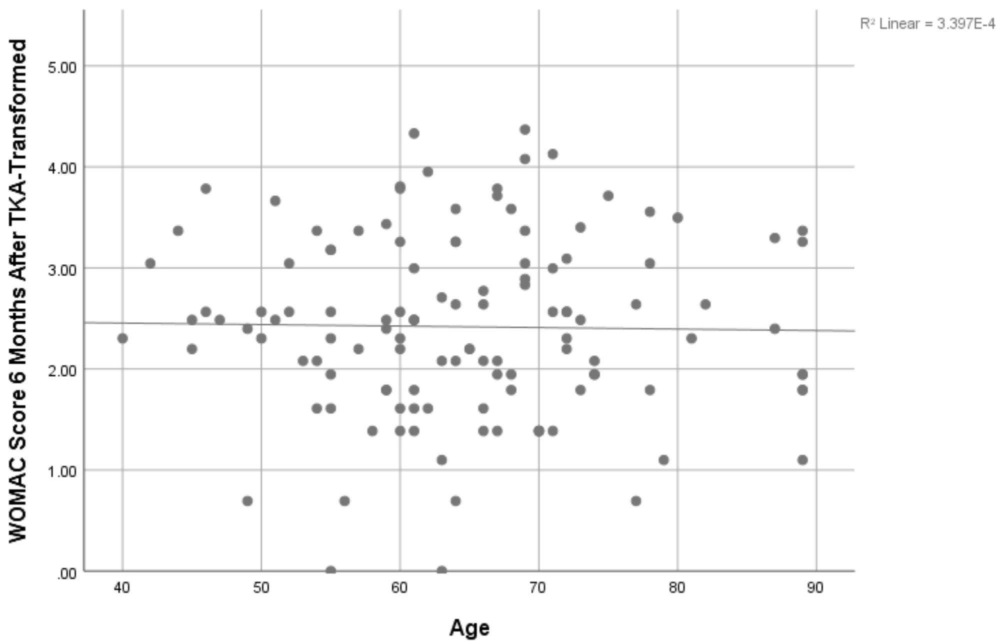


FIGURE 11. Homoscedasticity and linear relationship – age.

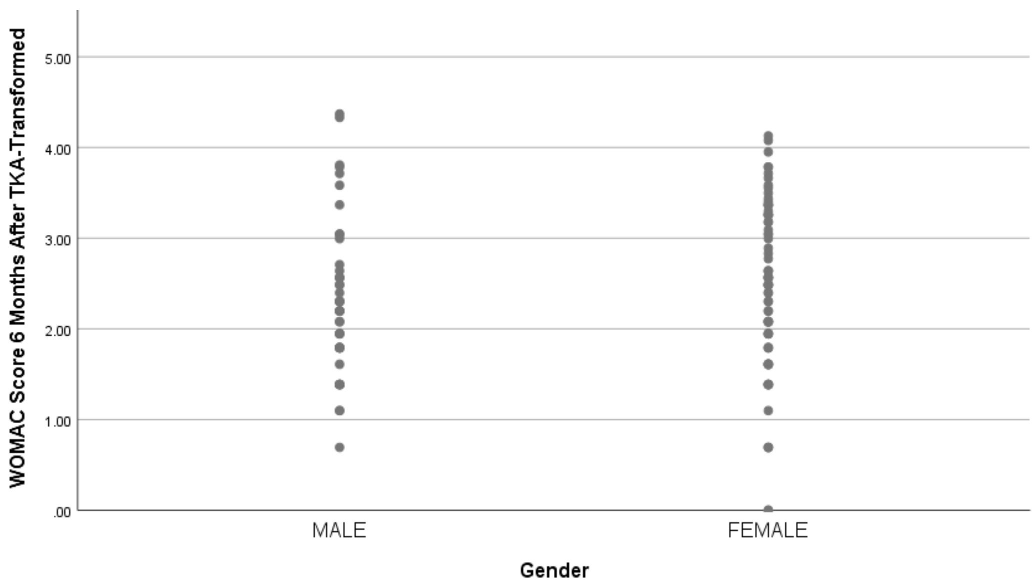


FIGURE 12. Homoscedasticity and linear relationship – gender.

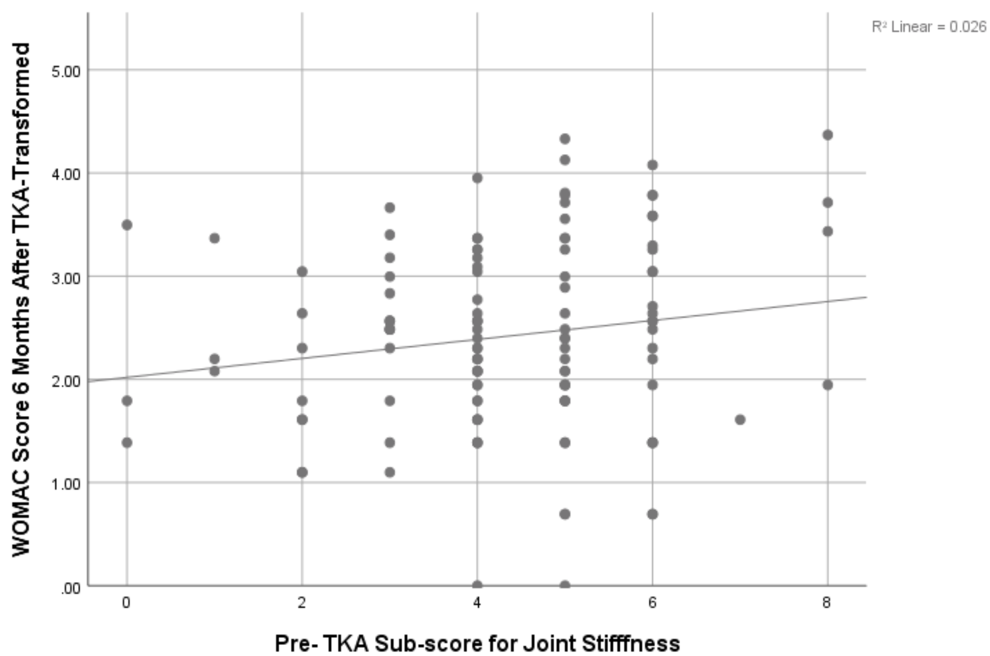


FIGURE 13. Homoscedasticity and linear relationship – sub-score for joint stiffness pre-TKA.

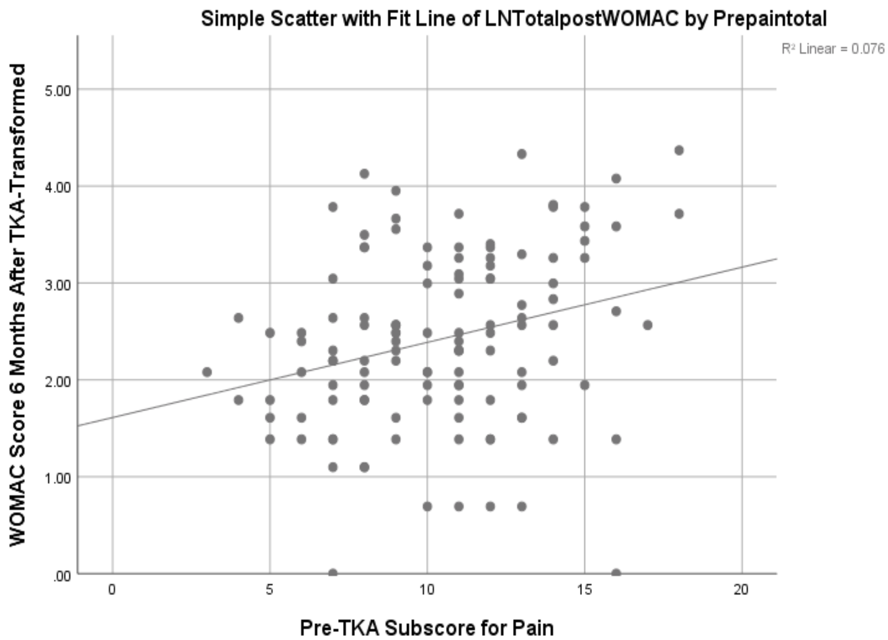


FIGURE 14. Homoscedasticity and linear relationship – sub-score for pain pre-TKA.

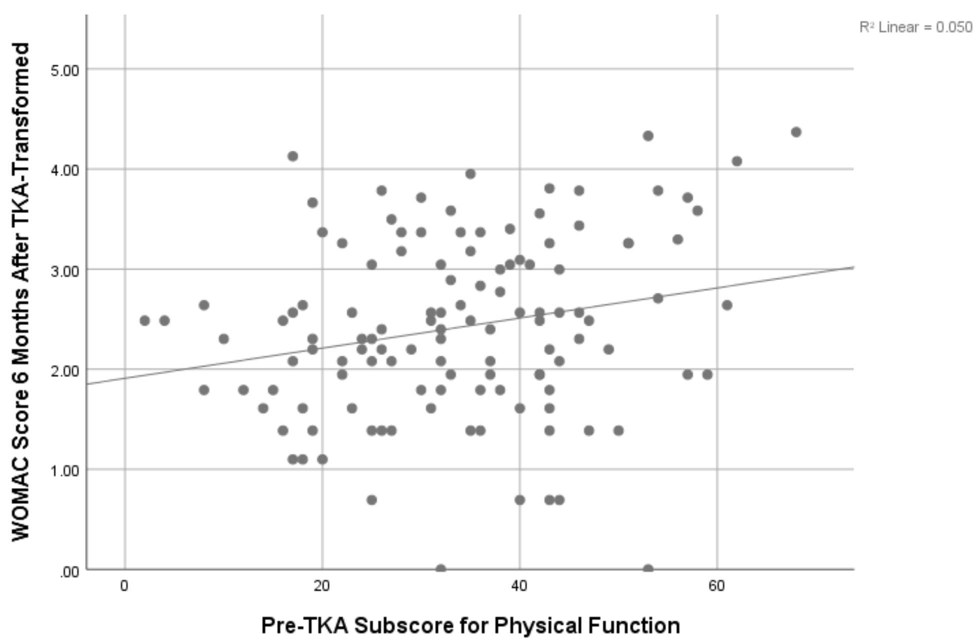


FIGURE 15. Homoscedasticity and linear relationship – sub-score for function pre-TKA.

Finally, multicollinearity between independent variables must be accounted for (Grove, 2007). Tolerance of a variable is the proportion of variance that is not accounted for by the other independent variables (Kellar & Kelvin, 2013). Tolerance can be used to measure collinearity (Kellar & Kelvin, 2013). Measures of tolerance were obtained by treating each independent variable as a dependent variable and regressing it on the other independent variables. Tolerance equals 1- R^2 (Kellar & Kelvin, 2013). Collinearity was low for gender (tolerance =.985) and age (tolerance =.980), moderate for pre-TKA sub-scores for joint stiffness (tolerance =.671), and pain (tolerance =.329), and high for pre-TKA sub-score for physical function (tolerance =.217) (Tables 2-6). The minimum recommended tolerance level for independent variables is between .10 and .20 (Kuhn & Johnson, 2013). All independent variables were within the recommended tolerance levels.

TABLE 2. *Regression to assess tolerance of gender.*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.122[a]	.015	-.016	.488

a. Predictors: (Constant), Sub-score for Physical Function Pre-TKA, Age, Sub-score for Joint Stiffness Pre-TKA, Sub-score for Pain Pre-TKA
b. Dependent Variable: Gender

TABLE 3. *Regression to assess tolerance of age.*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.143[a]	.020	-.011	11.287

a. Predictors: (Constant), Gender, Sub-score for Physical Function Pre-TKA, Sub-score for Joint Stiffness Pre-TKA, Sub-score for Pain Pre-TKA
b. Dependent Variable: Age

TABLE 4. *Regression to assess tolerance of sub-score for joint stiffness pre-TKA.*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.574[a]	.329	.308	1.335

a. Predictors: (Constant), Age, Sub-score for Physical Function Pre-TKA, Gender, Sub-score for Pain Pre-TKA
b. Dependent Variable: Sub-score for Joint Stiffness Pre-TKA

TABLE 5. *Regression to assess tolerance of sub-score for pain pre-TKA.*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.759[a]	.576	.563	2.172

a. Predictors: (Constant), Sub-score for Joint Stiffness Pre-TKA, Age, Gender, Sub-score for Physical Function Pre-TKA
b. Dependent Variable: Sub-score for Sub-score for Pain Pre-TKA

TABLE 6. *Regression to assess tolerance of sub-score for physical function pre-TKA.*

Model	R	R Square	Adjusted R Square		Std. Error of the Estimate
1	.783[a]	.613	.600		8.424

a. Predictors: (Constant), Sub-score for Pain Pre-TKA, Gender, Age, Sub-score for Joint Stiffness Pre-TKAb. Dependent Variable: Sub-score for Physical Function Pre-TKA

Outcomes of Primary Regression

A stepwise multiple linear regression was performed to evaluate the role of age, gender, and pre-surgery WOMAC sub-scores for pain, joint stiffness, and physical function as contributory factors to total WOMAC score six months after TKA. Of the five independent variables, only pre-TKA sub-score for pain was entered into the regression model. Age, gender, and pre-TKA sub-scores for joint stiffness, and physical function were excluded by SPSS because the probability of F for each was greater than .05 and therefore not significant. The regression model showed significance for pre-TKA sub-score for pain ($F_{1,125}$=9.923, p=.002, R^2=.076) (Table 7 & Table 8). At an alpha level of .05, pain was a significant predictor of total WOMAC score six months after TKA. However, the coefficient of determination (R^2) was .076. Thus, pre-TKA sub-scores for pain predicted only 7.6% of variance in total WOMAC score six months after TKA. The regression equation for predicted total WOMAC score six months after TKA equals $Y' = (a + B_1)(X_1)$ or $Y' = (-1.534 + 1.612)(X_1) = .078$ (pre-TKA sub-scores for pain) (Table 9).

TABLE 7. *Significance of stepwise regression 1.*

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	7.432	1	7.432	9.923	.002[b]
	Residual	89.876	120	.749		
	Total	97.308	121			

a. Dependent Variable: WOMAC Scores 6 Months After TKA-Transformed
b. Predictors: (Constant), Pre-TKA Sub-score for Pain

TABLE 8. *Coefficient of determination for stepwise regression 1.*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.276[a]	.076	.069	.86543

a. Predictors: (Constant), Pre-TKA Sub-score for Pain
b. Dependent Variable: WOMAC Scores 6 Months After TKA-Transformed

TABLE 9. *Coefficients for stepwise regression 1.*

		Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B		Collinearity Statistics	
Model		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Tolerance	VIF
1	(Constant)	1.612	.267		6.025	.000	1.082	2.141		
	Pre-TKA Pain	.078	.025	.276	3.150	.002	.029	.126	1.000	1.000

a. Dependent Variable: WOMAC Scores 6 Months After TKA-Transformed

Outcomes of Residual Analysis

Residual analysis was performed to test the regression assumptions. The residual is the difference between the score predicted by the model and the actual score (Kellar & Kelvin, 2013). There was a strong correlation between the model's predictions and its actual results (standard deviation for standard residuals = .996). If assumptions for linearity and distribution were met, then the distribution of the residuals should be close to normal (Kellar & Kelvin, 2013). The residuals for the model followed a normal curve (Figure 16). Homoscedasticity was verified by plotting the predicted values against the independent variables using a P-plot which also indicated a normal distribution of residuals (Figure 17). Finally, the scatter plot showed a linear relationship between regression residuals and the dependent variables, further verifying that the model assumptions were met (Figure 18) (Kellar & Kelvin, 2013).

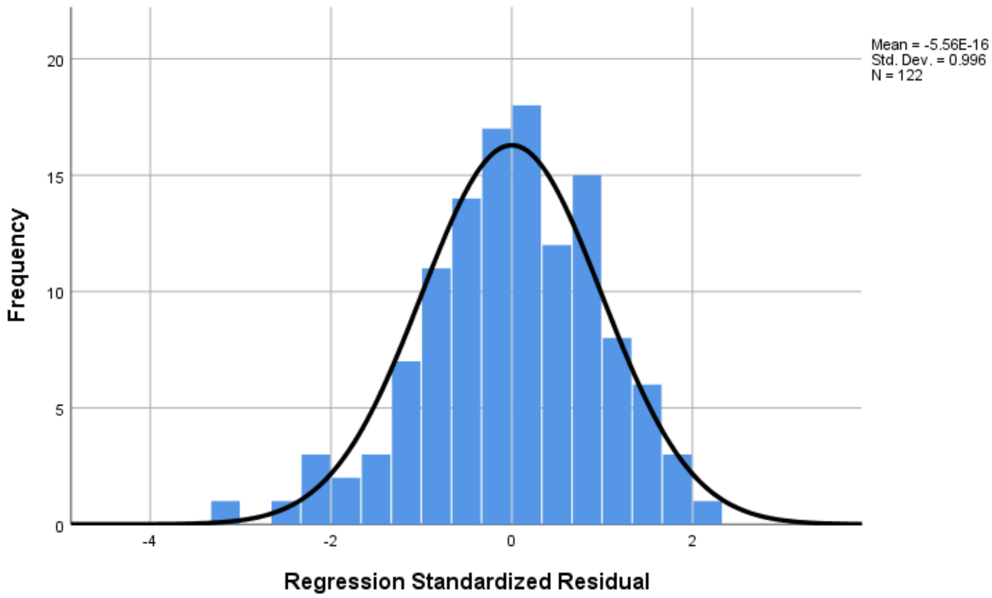


FIGURE 16. Distribution of regression standardized residuals.

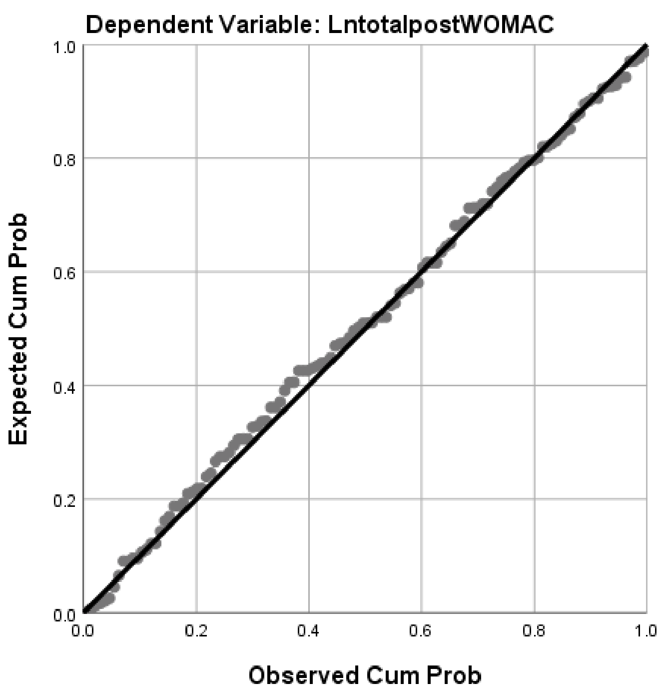


FIGURE 17. Normal p-plot of regression standardized residuals.

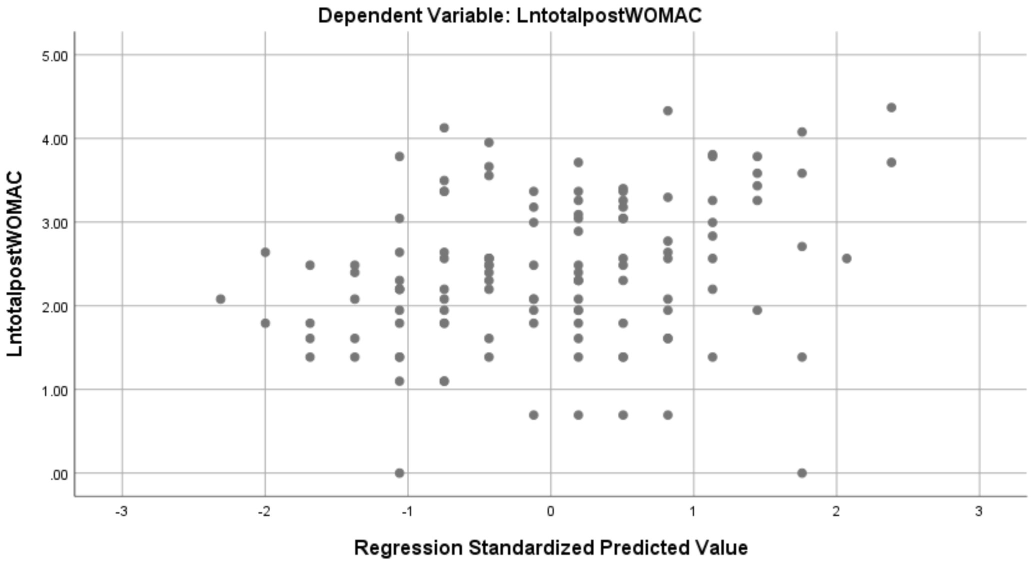


FIGURE 18. Scatter plot of regression standardized residuals.

Outcomes of Secondary Regression

Due to the high collinearity between pre-TKA sub-scores for pain and physical function (tolerance =.217) there was a significant amount of overlap between the percentage of variance in total WOMAC scores six months after TKA accounted for by the two variables. When pre-TKA sub-scores for pain and physical function were forced into a regression model together, they accounted for 7.7% of the variance in total WOMAC scores (Table 10). Pre-TKA sub-scores for pain alone accounted for 7.6% of the variance in total WOMAC scores. Thus, there existed an almost complete overlap of the variance predicted by the two variables.

TABLE 10. *Coefficient of determination for regression with pre-TKA sub-scores for pain and physical function.*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.278[a]	.077	.062	.86866

a. Predictors: (Constant), Prepaintotal, PrePFtotal

To compensate for this, a secondary stepwise multiple linear regression was performed with pre-TKA sub-scores for pain excluded from the model. Of the four remaining independent variables, only pre-TKA sub-score for physical function was entered into the regression model as being significant. This regression model showed significance for pre-TKA sub-score for physical function ($F_{1,125}$ =6.279, p=.014) (Table 11). At an alpha level of .05, and pre-TKA sub-score for pain excluded, physical function was a significant predictor of total WOMAC score six months after TKA. The coefficient of determination (R^2) was .050 (Table 12). Thus, pre-TKA sub-scores for physical function alone predicted 5% of variance in total WOMAC score six months after TKA.

TABLE 11. *Significance of stepwise regression, with pre-TKA sub-scores for pain excluded.*

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	4.839	1	4.839	6.279	.014[b]
	Residual	92.470	120	.771		
	Total	97.308	121			

a. Dependent Variable: LntotalpostWOMAC
b. Predictors: (Constant), PrePFtotal

TABLE 12. *Coefficient of determination for stepwise regression, with pre-TKA sub-scores for pain excluded.*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.223[a]	.050	.042	.87783

a. Predictors: (Constant), PrePFtotal

DISCUSSION

Summary

This regression model predicted 7.6% of the variance in total WOMAC scores six months after TKA and was statistically significant at alpha = .05. Pre-TKA pain score is positively associated with total WOMAC scores six months after TKA such that for each additional point on the pre-TKA pain score, the natural log of total WOMAC scores six months after TKA is predicted to increase by .078 points, and this association is statistically significant ($F_{1,125}$=9.923, p=.002) (Table 9). Higher WOMAC scores indicate worse outcomes. Age, gender, and pre-surgery WOMAC sub-scores for joint stiffness, and physical function (when run in regression with pre-TKA pain scores) were not significantly associated with total WOMAC scores six months after TKA.

The aim of this project was to identify and understand the underlying factors associated with post TKA outcomes in patients at Banner – UMC's orthopedic clinic. This QI project proposed that patient improvement in physical function, joint stiffness, and pain after TKA, as measured by WOMAC, could be predicted by patient characteristics before TKA. This QI project examined the relationships between age, gender, and pre-surgery WOMAC sub-scores for joint stiffness, pain and physical function, and total WOMAC score post TKA. Pre-surgery WOMAC sub-scores for pain and physical function were predicted to be the most reliable indicators of post-TKA WOMAC scores. The rationale for choosing these independent variables as predictors was based on several previous studies that found that high pre-surgical pain and low functional ability were most closely associated with negative TKA outcomes.

Results of this QI project showed that pre-TKA sub-score for pain and physical function are reliable predictors of post-surgery WOMAC scores, thus showing that patient improvement after TKA can be predicted by patient characteristics before TKA. However, pre-TKA sub-score for pain and physical function accounted for only 7.6% and 5.0% of variance in total post-TKAWOMAC scores respectively. This indicates that the pre-surgery factors considered by this QI project were not the best predictors of TKA outcomes. Therefore, the QI project had limited success with determining factors that predicted TKA outcomes.

Although the aims of this QI project were only partially fulfilled by the results, the QI project had several strengths. The rational for the regression model was heavily based on current literature and previous findings. Also, data for this QI project was collected consistently over a five-year period with a population that is similar to the population that the evidence is meant to benefit, making the results highly applicable for this setting and population. Another strength was the size of the project sample (n=131). Large samples increase the power of a QI project and give more reliable results (Kellar & Kelvin, 2013). The consistency of the data collected also strengthened the QI project, 131 project participants completed both the pre- and post-WOMAC questionnaires with a data omission rate of 0.2%. Consistency in data collection strengthens the reliability of study results (Kellar & Kelvin, 2013). A final strength was the method of data analysis used by this QI project. Multiple linear regression is a reliable method for determining an association between potential predictor variables and a criterion variable (Kellar & Kelvin, 2013). For the results of a multilinear regression to be valid, the data must conform to several assumptions (Kellar & Kelvin, 2013). This QI project carefully assessed the data to ensure that all regression assumptions were met.

Relation to Other Evidence

The findings of this QI project were consistent with several previous studies that showed pre-surgery pain and physical function were significant predictor of TKA outcomes. Seven studies reviewed reported an association between either preoperative pain and functional ability or both, with post-surgery TKA outcomes. Four of the articles reviewed used the WOMAC questionnaire to collect subjective data on pain and physical function (Desmeules et al., 2013; Lewis et al., 2015; Lungu et al., 2014; Lungu et al., 2016). Another study collected subjective data using WOMAC and KOOS (Riddle et al., 2015). Two other studies assessed objective data using Timed Up and GO (TUG), Stair Climb Test (SCT), and Six Minute Walk Test (6MW) (Bade, et al., 2012; Bade, et al., 2014).

The results of this QI project most closely reflected those of the other studies that collected data using WOMAC. One of those, a systematic review by Lewis et al., (2015), reported preoperative knee pain to be the strongest predictor of persistent pain after TKA, as this QI project did. Two other studies that used WOMAC and the one that used WOMAC and KOOS reported both pre TKA scores for pain and functional ability to be associated with physical functioning after surgery (Desmeules et al., 2013; Lungu et al., 2016; Riddle et al., 2015). The other WOMAC study by Lungu et al., 2014, found that the best indicator of poor TKA outcomes was baseline WOMAC for physical functioning.

This QI project found baseline pain to be a significant predictor of TKA outcomes which was congruent with the findings of the other studies. Physical function was not found to be a significant predictor of TKA outcomes when run in regression with pain. However, when pain was excluded from the regression, physical function was found to be a significant predictor ($F_{1,126}$=6.279, p=.014), accounting for 5% of variance (R^2=.05) in post- surgery WOMAC scores. When pain and physical function were entered together into the regression they accounted for 7.7 percent of the variance in post WOMAC scores (F =4.980, p= .008, R^2=.077,). Due to the collinearity between pain and physical function, there was an overlap in the portion of variance they accounted for in post-surgery outcomes. The amount of variance accounted for by physical function that was not already accounted for by pain was not significant, thus it was only shown to be a significant predictor of TKA outcomes when not run in regression with pre-TKA pain scores. This is consistent with the existing literature that reported both pain and function as significant predictors of TKA outcomes.

This is also consistent with the results of the two studies that collected only objective data. Both studies considered only the impact of physical function, as pain is a subjective measure. Both studies concluded that preoperative functional ability was a consistent predictor of TKA outcomes (Bade et al., 2012; 2014).

Results of this QI project indicated that patient characteristics before TKA can be used to predict outcomes after TKA. This is consistent with the study by Riddle et al. (2015), that found when patients were classified as appropriate, inconclusive, or inappropriate for TKA based on baseline WOMAC score, their post-TKA WOMAC scores showed significant agreement with their pre-surgery classification (Riddle et al., 2015).

This QI project did not find age or gender to be significantly associated with post TKA outcomes. This finding supports other studies that reported that older patients' TKA outcomes were similar to those of younger patients, and that no strong associations could be shown between age and gender on TKA outcomes (Desmeules et al., 2013, Kuperman et al., 2016). Conversely, Bade et al. (2012) found older age to be a secondary predictor of worse TKA outcomes.

Limitations

This QI project had several limitations. First, the QI project analyzed previously collected data and was thus limited by which data were originally collected. Data on other factors that might be predictive of TKA outcomes, such as BMI and comorbidities, were not available. Obesity is the leading cause of KOA and KOA is the main cause of knee joint dysfunction in adults (Litwic et al., 2013). Comorbidities, especially KOA, effect pain and function before and after TKA (Litwic et al., 2013). Diabetes, and cardiovascular disease can affect healing ability and thus TKA results (Litwic et al., 2013). Inclusion of BMI and comorbidities as independent variables would have strengthened this QI project. Also, no data were available on lifestyle factors such as exercise, eating, and smoking habits, which might influence TKA outcomes. An effort was made to obtain data on BMI, comorbidities, and lifestyle factors from patients' charts, however access to identifiable patient data was denied by Banner-UMC.

Another, limitation is inherent in this project's QI design. QI aims to improve practice outcomes and methods in care delivery in a specific setting. This QI project was conducted at a single hospital and results are intended to influence care at this location and are not generalizable to other settings (Ogrinc, et al., 2013).

Another, confounding variable may be inherent in the measurement used to gather data for this QI project. Although WOMAC is widely considered the gold standard for assessing knee pain, stiffness, and function, its main weakness is that it relies entirely on self-report (Giesinger et al., 2015). Research indicates that patients with depression, anxiety, and pain catastrophizing have higher WOMAC scores for pain and functioning (Lewis et al., 2015). Using objective assessment in conjunction with self-reported data might have increased the internal validity of this QI project.

The process of data analysis may also have contributed to limitations in validity. One assumption that must be met for a multiple linear regression to be valid is an even distribution of the dependent variable (Kellar & Kelvin, 2013). The dependent variable for this QI project, total WOMAC score six months after TKA, had a skewed distribution. To compensate, the data was transformed by taking the log of the dependent variable scores to obtain an even distribution. However, nine patients had post-TKA WOMAC scores of zero, so taking the log of the dependent variable caused these scores to be discounted. Zero is a perfect WOMAC score so the patients who had best TKA results were excluded from the data set. This may have biased the results of the regression. An alternative method for data analysis would have been to run the regression without transforming the dependent variable and then assess the distribution of the model residuals to determine validity of the model (Kellar & Kelvin, 2013).

A final limitation was retention to the QI project. A number of patients (n=174) completed the pre-TKA WOMAC questionnaire but only 133 of those completed the post- TKA WOMAC questionnaire. It is unknown why 41 patients did not complete the post- TKA WOMAC. If patients did not complete the second questionnaire because they were lost to follow-up, the validity of the QI project may have been affected. Research has found that patients who are consistent with follow-up after surgery have fewer complications and better results (Hirschmann, Testa, Amsler, & Friederich, 2013).

Interpretation and Implications

This QI project was guided by NQS's three broad aims of better care, healthy people and healthy communities, and affordable care. The results of this QI project have application to these aims. This QI project found that TKA outcomes can be predicted by assessable pre-TKA patient factors. The results of this QI project, combined with future research that determine other predictors of TKA outcomes, could be used to develop reliable criteria for determining which patients are at risk for poor TKA outcomes. Utilizing those criteria, healthcare providers at Banner – University Medical Center Orthopedics could effectively determine which patients are appropriate for TKA referral and which patients may require greater surveillance and care after surgery. Valid criteria for TKA appropriateness would result in better care for patients by enabling healthcare providers to effectively tailor care for individual patients. Establishing criteria would result in healthier patient by maximizing patients' prospects for successful TKA and would decrease wasteful spending by reducing the number of unproductive surgeries performed.

This project was also guided by four steps of the RCA process: defining the problem, determining a relationship, identifying solutions, and implementing and tracking solutions. The problem defined by this QI project was that 20% of TKA patients did not show significant improvement in WOMAC scores six months after surgical intervention. A relationship was determined between pre-TKA sub-scores for pain and functional ability and total WOMAC score six months after TKA. This relationship is only moderately helpful for identifying, implementing and tracking solutions because pre-surgery pain and physical function accounted for only 7.7% of variance in total post-TKA outcomes. Thus, an effective solution to the problem cannot be derived from this QI project alone. Further research is needed to determine other factors that affect TKA outcomes. Based on results from previous studies, possible independent variables to consider for future studies are BMI, comorbidities, psychological health, and pain catastrophizing (Bade et al., 2012; Burns et al., 2015; Desmeules et al., 2013; Khatib et al., 2015; Lewis et al., 2015; Mackie et al., 2015). Results of this QI project combined with future research results could contribute to identifying solutions by providing information on predictors of TKA outcomes. Once reliable guidelines for determining probable TKA outcomes are established, those guidelines can be implemented into practice in both primary care and orthopedic specialty practice to more accurately recommend patients for TKA. Patient results could be tracked to verify the validity of the guidelines.

Another implication for clinical practice and future research is whether other methods for assessing pain and function in TKA patient would be more reliable than WOMAC for predicting and assessing TKA outcomes and consequently more suitable for making clinical determinations on suitability of undergoing TKA. WOMAC was designed specifically to assess pain and function in patients with KOA (Giesinger et al., 2015). It has been widely used and validated for this purpose (Giesinger et al., 2015). However, it may not be the most robust measure for predicting TKA outcomes. Possible objective methods for assessing functional ability could be examined for stronger predictive value, such as the TUG test, 6MW test, active knee flexion, or extension range of motion. Functional tests have been found in some studies to more reliably assess functional ability than patient reported data (Bade et al., 2014)

The KOOS, like the WOMAC, relies on patient reported data (Roos & Lohmander, 2003). The KOOS combines questions from WOMAC with two additional subscales: ‘Sport and Recreation Function’ and ‘Quality of Life,’ which have been shown to be more sensitive and discriminative than the WOMAC subscales alone (Roos & Lohmander, 2003).

Several healthcare provides at Banner – UMC Orthopedics have already switched from using WOMAC to KOOS. Results from this QI project could be compared to results of future studies using KOOS data to determine which assessment tool more accurately predicts TKA outcomes. Clinically, this would aid healthcare providers at Banner – UMC in determining which tool would be most applicable to use with prospective TKA patients, when examining outcomes six months post TKA.

Nurse practitioners (NPs) diagnosis and manage patients with KOA both at Banner-UMC orthopedic outpatient offices and in other outpatient setting in the Tucson area. They refer KOA patients to orthopedic surgeons at Banner- UMC when surgery is considered an appropriate intervention. Having specific criteria to indicate which patients are most likely to benefit from surgery and should be referred, and which patient would be more affectively treated using nonsurgical interventions, would enable those NPs to more effectively manage KOA patients' care. This QI project found that pre-WOMAC scores for pain and function were valid predictors of post-surgery WOMAC scores, although those factors accounted for only a small percentage of the variance in WOMAC scores. The WOMAC is the most often used assessment for TKA patients in primary care, thus most NP would have access to patient WOMAC scores (Giesinger et al., 2015). Knowing that pre-surgery WOMAC scores for pain and function are better predictors of post-surgery outcomes than age, gender, or pre-surgery WOMAC scores for stiffness, might aid NPs in deciding which patients are appropriate candidates for surgery when considering referral.

More research is needed to determine the predictive value of other factors, such as BMI, for TKA outcomes. NP's working directly with KOA patients at Banner-UMC are optimally positioned to use the results of this QI project to plan and implements future QI projects to further explore factors associated with TKA outcomes in their patients. NPs as well as other practitioners have an obligation to improve the quality of care for their patients by conducting QI research that emphasizes improving patient outcomes and reducing risk.

Data for this QI project was collected by a nurse who taught the TKA pre-surgery class at Banner-UMC, in part, to enable her to improve patient teaching and better prepare patients for

TKA. Evidence from this QI project about factors that predict TKA outcomes would aid the nurses at Banner-UMC in developing and teaching the pre-surgery class. Acurate information on modifiable factors effecting TKA outcomes from this QI project and future studies would enable those nurses to better educate TKA patients to be proactive in their care and do what they can to have optimal results after TKA. Patient could be encouraged to make changes, such as increasing functional ability through exercice, prior to surgery.

Also, NPs working with the surgeons who perform TKAs at Banner-UMC orthopedics have a major role in managing KOA patients' care before and after surgery, including assessing patients' functional ability. Information from this QI project on risk factors that predict poor TKA outcomes would alert NP's to which patients may require closer follow-up and rehabilitation after TKA. This would improve patient outcomes by more closely monitoring patients at higher risk and providing interventions for those patients as needed. Also, information from this QI project and future studies may aid NP's in deciding which assessment tools are most predictive of TKA outcomes and thus are most effective for assessing patients before and after TKA. Choosing assessments that most accurately predict TKA outcomes would reduce costs by more effectively using NPs time and improve patient outcomes by focusing assessment on factors most associated with outcomes.

Conclusions

TKA is the second more common orthopedic procedure performed in the US, with TKA rates predicted to continue rising over the next decade. TKA aims to reduce pain and restore function in patients. However, in 20% of TKA patients at Banner-UMC this goal is not being met. This QI project aimed to examine which factors predict TKA outcomes in order to improve

TKA results. The results of this QI project indicate that it is possible to predict TKA outcomes based on patient characteristics before surgery. Pre-surgery pain was shown be a significant predictor of post TKA pain, stiffness, and function. Pre-surgical physical function was also a significant predictor of TKA outcomes when considered separately from pain scores. The results of this QI project support previous studies that showed pre-surgery pain and physical function to be significant predictor of TKA outcomes However, pre-surgery pain and function accounted for only a small percent of variance in TKA outcomes in this QI project. Thus, further research is needed to determine if other factors such as BMI, comorbidities, and psychological factors are more predictive of TKA outcomes. Also, further research is needed to determine if alternate tools for assessing pre and post-TKA functional ability and pain are more accurate than WOMAC scores for predicting TKA outcomes. Until then, pre-TKA sub-score for pain and function should be given some consideration in determining which patients at UMC-Banners are appropriate candidates for TKA.

APPENDIX A:

FACTORS THAT INFLUENCE TKA OUTCOMES

Reference	Research Question	Theoretical Framework	Study Design	Sample (N)	Data Collection	Findings
Bade, Kittelson, Kohrt, & Stevens-Lapsley, 2014	What is the predictive value of functional performance and range of motion measures on outcomes after TKA?	Not stated	Secondary analysis of two pooled prospective RCTs	N=64 (32 men, 32 women) with end-stage KOA prior to primary TKA	Active knee flexion and extension range of motion TUG time 6MW distance	Preoperative measures of knee ROM have some prognostic value for TKA outcomes Preoperative functional performance data have useful prognostic value for TKA outcomes
Bade, Wolfe, Zeni, Stevens-Lapsley, & Snyder-Mackler, 2012	What is the value of a preliminary decision algorithm for predicting functional performance outcomes after TKA	Not stated	Quasi-experimental with a regression tree analysis	N= 119 patients undergoing primary unilateral TKA	Pre-surgery and 6 mo. TUG test, 6MW, and SCT	Low preoperative scores on the 6MW, SCT, and TUG, were related to poorer performance in the same measure after TKA. Age and decreased mental health were secondary predictors of poorer performance at 6 months on the TUG and SCT.
Barrack et al., 2014	Are (1) socio-economic factors, (2) demographic factors, or (3) implant factors associated with satisfaction and functional outcomes after TKA	Not stated	Therapeutic study: Level of Evidence III,	N= 661 patients (average age, 54 years; range, 61% female) 104 years after TKA	Survey with questions on satisfaction, pain, and function after TKA and socioeconomic factors.	Socioeconomic factors are more strongly associated with satisfaction and functional outcomes than demographic or implant factors.
Beaupre, Secretan, Johnston, & Lavoie, 2012	How does knee stiffness, pain, function differ between patellar retention and resurfacing up to 10 years after primary TKA	Not stated	RCT	N= 38 subjects randomized at primary TKA surgery to receive patellar resurfacing (n=21) or to retain their native patella (n=17)	Pre-surgery and 1,5, and 10-year post surgery WOMAC scores	No difference between 2 groups WOMAC score at 1, 5, 10 years postoperatively.

Reference	Research Question	Theoretical Framework	Study Design	Sample (N)	Data Collection	Findings
Burns et al., 2015	Is pain catastrophizing a prospective predictor of chronic pain following TKA.	Not stated	Systematic review	6 prospective longitudinal studies with small-to-mid-sized samples	Search of databases to identify articles related to pain catastrophizing, TKA, risk models, and chronic pain.	Moderate-level evidence for pain catastrophizing as an independent predictor of chronic pain post-TKA.
Desmeules et al., 2013	What are pre- and perioperative determinants of pain, functional limitations and health-related quality of life (HRQoL) 6 months after TKA.	Not stated	Prospective cohort study	N= 138 TKA patients	Pain and functional limitations: WOMAC HRQoL: SF-36 Health Survey.	Variables significantly associated with worse outcomes 6 months after TKA: Pain: Higher preoperative pain, cruciate retaining implants and the number of complications Function: lower preoperative functional lability, being single, separated, divorced or widowed, being unemployed or retired and the number of complications HRQoL: lower preoperative HRQoL, contralateral knee pain, higher psychological distress and comorbidities
Khatib, Madan, Naylor, & Harris, 2015	Do psychological factors may play a role in patient dissatisfaction with TKA outcomes?	Not stated	Systematic review	19 studies (17 cohort studies and two cross-sectional surveys) containing data on 9046 TKAs performed in 8704 adult patients	Search of databases to identify articles related to postoperative dissatisfaction, pain, or limited function of the patients.	Psychological health was deemed a significant predictor of satisfaction, pain, or function at 6 months after TKA Baseline mental health factors may affect patient satisfaction,

Reference	Research Question	Theoretical Framework	Study Design	Sample (N)	Data Collection	Findings
						their long-term perception of pain, and their motivation to return to the desired level of function.
Kuperman, Schweizer, Joy, Gu, & Fang, 2016	What are the age-related differences in perioperative morbidity and mortality after TKA	Not stated	Systematic review	22 studies were included	Databases were searched for relevant studies that compared primary TKA outcomes of mortality, and functional status, of geriatric patients (>75 years old) with a younger control group (<65 years old	older patients had higher rates of mortality, morbidity, and length of stay compared to younger patients Improvement in pain and functional status was equal in older and younger patients.
Lewis, Rice, McNair, & Kluger, 2015	What predictor variables are associated with persistent pain after TKA?	Not stated	Systematic review	32 studies were included	Database were searched for studies that measured predictor variables pre and post-surgery, including a pain outcome measure. Separate meta-analyses were performed to determine the effect size of each predictor on persistent pain.	Catastrophizing, mental health, preoperative knee pain, and pain at other sites are the strongest independent predictors of persistent pain after TKA.
Li et al., 2015	Are patients benefited buy use of high-flex (HF) prostheses compared with standard (STD) implants for TKA	Not stated	meta-analysis of RCTs	18 RCT were included (1906 patients)	Databases were searched for relevant studies that compared HF prostheses STD implants for TKA	No statistically significant difference was found between the two designs in terms of ROM, knee scores (KSS, HSS, WOMAC, and SF-36), patients' satisfaction and complications.
Lungu, Desmeules, Dionne, Belzile, &	Can a preliminary prediction rule identify patients who are at the greatest risk	Not stated	Prospective Quasi-experimental	N=141 patients scheduled for TKA	Knee pain, stiffness and function were measured using WOMAC	The best prediction was provided by 5 items of the baseline WOMAC: preoperative difficulty of

Reference	Research Question	Theoretical Framework	Study Design	Sample (N)	Data Collection	Findings
Vendittoli, 2014	of poor outcomes 6 months after TKA?					taking off socks, getting on/off toilet, performing light domestic duties and rising from bed, and degree of morning stiffness after the first wakening
Lungu, Vendittoli, & Desmeules, 2016	What is the status of the literature evaluating preoperative determinants of early and medium-term patient-reported pain and disability following TKA?	Not stated	Systematic review	33 prognostic explanatory studies were included.	Databases were searched. Selection criteria included: participants undergoing primary unilateral TKA with a follow-up from 6 months to 2 years, validated disease-specific patient-reported outcome measures assessing pain and/or function used as outcome measure and identification of preoperative determinants obtained via multivariate analyses. Risk of bias was assessed using a modified version of the Methodology checklist for prognostic studies.	No conclusions can be reached regarding the sociodemographic and psychosocial determinants including greater socioeconomic deprivation, greater levels of depression and/or anxiety, and greater preoperative pain catastrophizing. Significant clinical determinants were: worse pre-operative knee pain or disability, presence or greater levels of comorbidity, back pain, and lower general health. Strength of the associations between significant determinants and TKA results could not be determined because of heterogeneity of study methodologies and results.

Reference	Research Question	Theoretical Framework	Study Design	Sample (N)	Data Collection	Findings
Riddle, Perera, Jiranek, & Dumenci, 2015	Can surgical appropriateness criteria be used to examine outcomes of TKA?	Not stated	Quasi-experimental	N=167 patients undergoing primary TKA	Pre-operative and 1 tear post-operative WOMAC and KOOS scores	The inappropriate group was unchanged 2 months after surgery and on average improved by 2.3 WOMAC function points from pre-surgery to 1 year following surgery Appropriate and inconclusive groups improved by an average of 19.8 WOMAC function points at 1-year post-surgery.

Note: TKA= total knee arthroplasty; RCT=randomized clinical trial; KOA=Knee osteoarthritis; TUG=Timed up and go test; 6MW=6-min walk test; ROM=range of motion; SCT=stair climb test; WOMAC =Western Ontario and McMaster Universities Arthritis Index; HRQoL=health-related quality of life; HF= high flex; STD=standard; KSS= Knee-Society-Score; HSS= Hospital for Special Surgery Score; SF-36=Short Form-36 Health Survey; KOOS =Knee injury and Osteoarthritis Outcome Score

APPENDIX B:

THE UNIVERSITY OF ARIZONA INTERNAL REVIEW BOARD APPROVAL LETTER

Research
Office for Research & Discovery

Human Subjects
Protection Program

1618 E. Helen St.
P.O.Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
http://rgw.arizona.edu/compliance/home

Date:	December 12, 2017
Principal Investigator:	Leslie Streeter
Protocol Number:	1712089094
Protocol Title:	DETERMINING PREDICTORS FOR UNSUCCESSFUL TOTAL KNEE ARTHROPLASTY OUTCOMES
Determination:	Human Subjects Review not Required

The project listed above does not require oversight by the University of Arizona because the project does not meet the definition of 'research' and/or 'human subject'.

- **Not Research as defined by 45 CFR 46.102(d):** As presented, the activities described above do not meet the definition of research as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "research means a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge".
- **Not Human Subjects Research as defined by 45 CFR 46.102(f):** As presented, the activities described above do not meet the definition of research involving human subjects as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention *or* interaction with the individual, or identifiable private information".

Note: Modifications to projects not requiring human subjects review that change the nature of the project should be submitted to the Human Subjects Protection Program (HSPP) for a new determination (e.g. addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the research question). Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

APPENDIX C:

BANNER APPROVAL LETTER

Banner Health®

December 13, 2017

Leslie Streeter

RE: **NRDUC Project**: 1712089094: DETERMINING PREDICTORS FOR UNSUCCESSFUL TOTAL KNEE ARTHROPLASTY OUTCOMES
New Project UA Determination of Human Research Application Version 2016-07; forwarded to Non-Research Data Use Committee on 12/12/2017
Non-Research Data Use Committee Evaluation: Approved on 12/13/2017

Dear Leslie,

Thank you for your submission of the UA Determination of Human Research Form which outlined the above noted project. On 12/12/17 UA IRB concluded that this project was not research and subsequently forwarded it to the Banner Health Non-Research Data Use Committee (NRDUC) for oversight and review.

The project information you provided was reviewed and subsequently approved on December 13, 2017 by the BH NRDUC. Should you have any questions or concerns please feel free to reach out to the NRDUC chair at any time.

PLEASE NOTE

The NRDUC determination is based on the information you provided to the committee on your application version 2016-07 and supporting documents forwarded to the NRDUC on 12/12/2017. If the project is modified in any way, including re-analysis of data, the determination is no longer valid. You must resubmit the project to the NRDUC for review and approval.

Please note: As part of continuing process improvement, random audits could be conducted to assess compliance and adherence with submitted/approved applications.

FYI - to be a considered a "quality improvement" activity under HIPAA, information needs to be provided back to Banner for quality/performance improvement purposes. Please make sure you work with the appropriate Banner internal owner or applicable Banner committee to share results.

A copy of this letter will be placed in the NRDUC project file.

Sincerely,

Kristen Eversole, BS, RHIA, CHPC
Banner Health Privacy Program Director – University Medicine, NRDUC Chair

APPENDIX D:

PERMISSION TO USE DATA LETTER

THE UNIVERSITY OF ARIZONA.
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Orthopaedic Surgery

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November 13, 2017

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November 11, 2017

To Whom It May Concern:

We have reviewed Leslie Streeter's proposal for a quality improvement research project to identify and understand the underlying factors associated with poor total knee arthroplasty outcomes in patients at Banner – UMC's orthopedic clinic. The project will analysis deidentified data collected by Cecilia Anderson, a retired nurse at University of Arizona College of Medicine Orthopaedic Surgery Group.

As the Department Administrator for University of Arizona College of Medicine Orthopaedic Surgery and director of the Orthopeadic Study Group we are the owner and manager of the data. We give permission for Leslie Streeter to analyze this data as part of a quality improvement research project and use the findings in her research paper.

Sincerely,

Amy Van Hoesen,
Department Administrator

Michael Dohm, MD
Assistant Professor, University of Arizona College of Medicine

APPENDIX E:

WOMAC QUESTIONNAIRE

Banner
University Medicine

WOMAC Osteoarthritis Index
6 Month Post-Op Questionnaire

Knee: Right ☐ Left ☐ Both ☐

Hip: Right ☐ Left ☐ Both ☐

Name **Today's Date**

Please answer every question by filling in the appropriate response. If you are unsure about how to answer a question, please give the best answer you can. Please mark your answers with an "X".

Section A: Pain

The following questions concern the **amount of pain** you have experienced in the last 48 hours in your artificial knee/hip.

QUESTION: HOW MUCH PAIN DO YOU HAVE?

	None	Mild	Moderate	Severe	Extreme
1. Walking on a flat surface					
2. Going up or down stairs					
3. At night while sleeping					
4. Sitting or lying					
5. Standing upright					

Section B: Joint Stiffness

The following questions concern the **amount of joint stiffness** (not pain) you have experienced in the last 48 hours in your artificial knee/hip. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

QUESTION: HOW SEVERE IS YOUR STIFFNESS?

	None	Mild	Moderate	Severe	Extreme
1. When you wake up in the morning					
2. After sitting, lying or resting later in the day					

Please see other side

Section C: Physical Function

The following questions concern your **physical function**. By this we mean your ability to move around and take care of yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours in your artificial knee/hip. Please mark your answers with an "X".

QUESTION: WHAT DEGREE OF DIFFICULTY DO YOU HAVE WITH:

	None 0	Mild 1	Moderate 2	Severe 3	Extreme 4
1. Descending stairs					
2. Ascending stairs					
3. Rising from sitting					
4. Standing					
5. Bending to floor					
6. Walking on a flat surface					
7. Getting in/out of car					
8. Going shopping					
9. Putting on socks/stockings					
10. Getting out of bed					
11. Taking off socks/stockings					
12. Lying in bed					
13. Getting in/out of bath					
14. Sitting					
15. Getting on/off toilet					
16. Heavy household chores					
17. Light household chores					

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