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Quality of Life for Patients Who Have Undergone Hip Replacement Surgery with and without an Enhanced Recovery Program

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Abstract

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by

Patrick Servat

MS, Leicester University, 2012

BS, Saint Joseph University, 2006

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health

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Abstract

The World Health Organization considers hip replacement one of the main public health concerns of this 21st century. An enhanced recovery after surgery (ERAS) approach has proved to be an effective and efficient approach to treat patients in need of a hip replacement. The quality of life (QOL) of patients who have undergone a hip replacement surgery with an ERAS approach has not been documented due to its recent development as a possibility for hip surgery. The objective of this study was to compare QOL, length of stay (LOS), and surgery risks of patients undergoing hip replacement surgery with or without an ERAS approach. The study design used was a research control trial based on a secondary data set containing 224 participants. Multivariate analysis results demonstrate a significant difference in EQ-5D-5L scores before and after surgery in both traditional and ERAS surgery. LOS of patients was significantly reduced with an ERAS LOS mean of 4.4 days (SD = 1.44) compared to 11.45 days (SD = 3.57) for the traditional approach. Additionally, ERAS participants had 6% less risk of developing a post-surgery complication compared to the traditional approach. The findings of this research highlight positive social change implications as this study demonstrates that the ERAS approach improves the QOL of elderly people who have undergone a hip surgery. Findings will help orient public health resource allocation toward ERAS hip replacement surgery.

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Dedication

I would like to dedicate this work to all scholarly practitioners around the world who are trying to implement social change in their communities. Sometimes we forget to give them tribute as they work daily to ensure that our way of life is preserved and that our beloved ones are healthy. To my entourage thank you for your understanding and diligence during my doctoral journey.

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Chapter 1: Introduction to the Study

The World Health Organization (WHO, 2017) considered population ageing one of the most pressing public health problems in the 21st century. Some aging-related health problems include osteoporosis and osteoarthritis. Osteoporosis and osteoarthritis affect the hips of elderly people, which in turn limit their daily activities (Guirant et al., 2018). Enhanced recovery after surgery (ERAS) is one of the most promising population-based approaches for improving quality of life (QOL) in populations affected by painful hip joints with arthritis (Merchea & Larson, 2018). This study attempts to better understand determinants of QOL in patients who have undergone hip replacement surgery with or without an ERAS program.

In this chapter, the theoretical background of the study is presented, including epidemiological information about total hip replacement, different surgery techniques o, and interactions with QOL of patients. Subsequently, the problem statement and purpose of the study sections identify the importance of examining current issues concerning total hip replacement and QOL. This study intends to answer three research questions. The theoretical foundation of the study is the integrative theory of global QOL, which incorporates several existing QOL theories. In this chapter, the origin of the integrative theory of global QOL, its conceptual relevance to the proposed study, and the rationale for adopting this theoretical framework are discussed. Finally, the nature of the study, assumptions, scope, and delimitation are described. Definitions of key terms are also included to describe various terminologies used to aid understanding of major concepts in this study.

Theoretical Background

Total hip replacement is the surgical orthopedic procedure that reduces pain and restores lost function due to fractures caused by osteoporosis and osteoarthritis, which are both considered global public health problems (Endo, Baer, Nagao, & Weaver, 2018; Popa, Goldberg, & Wera, 2017). Furthermore, people with osteoporosis or osteoarthritis are considered a high risk population because they tend to have health complications, such as associated diseases like adult obesity, diabetes, mental diseases, as well as heart diseases, which are all major preventable public health problems (Nüesch et al., 2011; Palazzo, Nguyen, Lefevre-Colau, Rannou, & Poiraudeau, 2016). Incidence rates of total hip replacement vary considerably depending on population, race, and gender, but increase exponentially with age (Burgess & Wainwright, 2018). Total hip replacement in France affected 241/100,000 patients in 2014 and is estimated to have increased by 15% per year, compared to 88/100,000 patients in the United States (Katsoulis et al., 2017; Putman et al., 2017). The lifetime risk of total hip replacement is 16% to 18% for women and 5% to 6% for men; the mortality rate after hip fracture in the first 30 days is approximately 10% and 28% during the first year (Kannus et al., 1996; Rapp et al. 2019). France as a nation is an aging society where 25.7% of the current population is over 60 years old; thus, the incidence and prevalence of total hip replacement will continue to increase, as the median age of people who undergo total hip replacement is 70.1 years old (std +/- 11.6; Breton, Barbieri, Albis, Mazuy, & Shapiro, 2017; Nemes, Gordon, Rogmark, & Rolfson, 2014). Furthermore, Breton et al. (2017) said that total hip replacement affects one fourth of the French population and has direct repercussions on

public health since mortality, morbidity, and associated costs are a burden to society as a whole.

Due to the lack of preventive public health strategies to reduce the causes of hip dysfunction, total hip replacement is the endorsed treatment for elderly people, even though total hip replacement still presents detrimental consequences for all aspects of the health status of the aging person, leading to increased public health expenditures (Hektoen et al., 2016; Melton, 1996). Kremers et al. (2015) said that hip replacement is unexpectedly more predominant than chronic diseases such as stroke (46.7/100,000) and heart failure (49/100,000). Individuals over 60 years old living with a replaced hip are a surprisingly normal condition in France; this pattern will probably increase in the coming years because of the aging baby boomer population and improvements in longevity (He & Kinsella, 2020).

Little progress regarding the prevention or treatment of osteoarthritis is likely to be planned in the near future by public health organizations; thus, it is likely that hip replacement surgery will become more prevalent in the coming decades (Johnson & Hunter, 2014). The surgical traits of hip replacement surgeries are similar worldwide; however, access to the surgery and related costs might differ from one country to another. In France, patients undergo a hip replacement surgery to reduce joint pain and improve their QOL as the population has access to a universal healthcare coverage system that guarantees free access to hip surgery (Geeraert, 2018). With the current rate and coming increase in hip replacement surgery, financial burdens due to the associated healthcare

costs of hip replacement surgeries will profoundly impact the sustainability of publicly sponsored healthcare programs.

The application of ERAS in hip replacement patients is based on the success of the ERAS approach in digestive surgery performed in the late 1990s. In general, the ERAS routine starts a few weeks before the surgery by preparing the patient while continuing his routine activities, then the patient undergoes adapted anesthesia and surgery techniques. During post-surgery, patient care is revised to facilitate fast recovery. ERAS is an approach to comprehensive care of the patient which favors reduced stays in hospital, improved pain management, and reduced nausea and vomiting (Brennan & Parsons, 2017; Wainwright, Pollalis, Immins, & Middleton, 2016). These practices in turn improve the likelihood of the patient having an early recovery after surgery.

Only a small number of studies have specifically examined the impact of ERAS on patient QOL, and most of these investigated patients undergoing digestive surgery. Whether ERAS in hip replacement patients has a direct effect on QOL of patients remains an open question. Thus, it is essential to explore the QOL of patients undergoing a hip replacement ERAS program so that it can become the standard of care in hip surgery. This study will contribute to the knowledge of healthcare practitioners by determining how ERAS in hip surgery affects patients' QOL. This study examines both the direct QOL impact on patients and whether sociodemographic factors or hospital stay complications moderate the QOL impact on patients.

Problem Statement

With an aging population, hip replacement surgery becomes more prevalent in society, and current techniques involving conducting this surgery negatively affect patients' QOL and are a financial burden due to associated high medical costs (Abeles et al., 2017; Kremers et al., 2015). For these reasons, an ERAS for hip surgery based on the already existing ERAS approach in digestive surgery was implemented in numerous hospitals across Europe. Despite favorable results regarding morbidity and mortality and a reduction of length of hospital stay, little is known about how ERAS affects QOL of patients. The specific problem is that the healthcare community lacks knowledge of how ERAS affects QOL in hip surgery patients.

Moreover, despite an increased interest in hip replacement ERAS approach, little empirical investigation has been conducted on the topic.

As total hip replacement became a major public health issues in France due to the ageing population, an ERAS program for hip replacement was implemented in 2016 and is assumed by public health authorities to improve the overall public health expenditure and increase patient health status. There is a lack of scientific evidence in terms of how ERAS impacts patients' health status at the population level. It is possible to conduct a research control trial comparing the health status of patients using conventional and ERAS total hip replacement, leading to subjective and objective relevant health status information regarding the total hip replacement population.

Purpose of the Study

ERAS is an approach that has been demonstrated to improve patient clinical outcomes and reduce the financial burden of surgeries (Abeles et al., 2017). The purpose of this study is to improve healthcare professionals understanding of total hip replacement's capacity to affect the health status of the aging population and how to reduce its burden on public health. To address this gap and better understand the total hip replacement population's subjective and objective health status, this study will involve using a research control trial design to compare conventional to ERAS total hip replacement results once patients are within their community. Based on the integrative theory of global QOL, this study will compare outcomes of hip surgery approaches in terms of their impact on QOL while controlling for age, LOS, and gender in a group of individuals undergoing hip surgery at a French hospital. Hip surgery approach is defined in terms of the traditional or ERAS technique, in which the traditional technique involves the routine care of an individual admitted for a surgery in a hospital, while the ERAS technique involves revised pre and postsurgery medical and paramedical interventions. QOL is defined as individual level of satisfaction of a patient and is comprised of three aspects: subjective, objective, and existential (Ventegodt, Merrick, & Andersen, 2003a). These aspects can be measured using the EQ-5D-5L and EQ-VAS scales, and their results indicate QOL of patients.

Research Questions and Hypotheses

The research questions for this study are:

RQ1: Accounting for the effects of mobility, self-care, usual activity, pain or discomfort, and anxiety or depression, is the average EQ-5D-5L index as a measure of QOL significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery technique?

$H_0$1: Accounting for the effects of mobility, self-care, usual activity, pain or discomfort, and anxiety or depression, the average EQ-5D-5L index as a measure of QOL does not significantly differ among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery technique.

H_a1: Accounting for the effects of mobility, self-care, usual activity, pain or discomfort, and anxiety or depression, the average EQ-5D-5L index as a measure of QOL does significantly differ among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery technique.

RQ2: Is average LOS significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery?

$H_0$2: Average LOS is not significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery.

H_a2: Average LOS is significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery.

RQ3: Is risk of complications due to surgery significantly different among patients who have undergone an ERAS hip replacement surgery compared to traditional surgery?

$H_0$3: Risk of complications due to surgery is not significantly different among patients who have undergone an ERAS hip replacement surgery compared to traditional surgery.

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H_a3: Risk of complications due to surgery is significantly different among patients who have undergone an ERAS hip replacement surgery compared to traditional surgery.

Theoretical Foundation

The primary theory employed in this study is the integrative theory of global QOL developed by the Danish Quality of Life Center, which is used to study global QOL of numerous European countries. The origin of the integrative theory of global QOL is based on Abraham Maslow's QOL theory. Maslow based the development of his theory on the concept of human needs; a good life is the fulfillment of those needs. Maslow's hierarchy of needs provides information regarding personal happiness and better QOL. To fulfill Maslow's described needs, an individual must fulfill eight needs one by one hierarchically. Maslow (1943) argued that a person could not fulfill these eight needs entirely, so rarely do individuals obtain self-actualization and transcendence). Maslow's philosophy is based on the idea that healthcare practitioners can help an individual

improve QOL, health, and general ability to work and function by making the individual become more conscious of his existential choices to ultimately attain self-actualization.

Other QOL theories in the health and social sciences do not take into account the depth of life. Some patients improve their QOL even though the success of the surgery is limited; others suffer from a decrease in their QOL even though the surgery is a success. Thus, it is necessary to evaluate the subjective and the objective QOL in a well-defined spectrum of time that is proper to each individual.

The major difference between the integrative QOL theory and other theories is that it stresses the introduction of an existential depth into the public health and social sciences to respect the richness and complexity of human life. To better understand QOL, public health authorities should evaluate QOL of hip replacement patients using subjective QOL approaches by questioning individuals on how they perceive their mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Moreover, objective QOL should be determined by the success of the intervention by using physician evaluations of the surgery's success.

Nature of the Study

The aim of this research is to compare the QOL of patients having a total hip replacement surgery depending on their surgery approach. The research control trial is the best approach to answer the research questions. During this research control trial, one group received the ERAS approach and the other group did not. Patients participating in this experimental design were randomly assigned to the experimental or control group. The experimental group was composed of patients undergoing the ERAS surgery

approach; the control group was composed of patients who received a traditional hip surgery approach.

Additionally, the research control trial design included a pretest, posttest, and control experimental group comparison. Participants in this research were assessed multiple times during the trial period. The first assessment of QOL was done during hip replacement diagnostics. Then before the hip replacement surgery, participants were randomized into one of the two groups, the experimental ERAS approach group or the control traditional approach group. Once the surgery was completed, medical data were collected regarding LOS and surgical complications. Finally, after a 3-month period, the QOL of patients was assessed during surgeon checkups for hip replacement surgery. This design approach includes randomized groups and a control for most issues of internal research validity. This design allowed comparison, control, and manipulation between the two compared groups. Thus, a randomized control trial design was best suited to this research.

Participants were selected from a French hospital that is implementing the ERAS approach for hip replacements after a successful implementation of the ERAS in gynecology and digestive surgeries. Sampling participants was done on a random basis where participants were included in the ERAS group and participants were included in the traditional surgery approach group. The size of the sample was defined using G*Power with a two-tailed approach and an alpha of .05 with a power of 80%. As collected data were analyzed using descriptive and multivariate statistical tests, a total of 205 participants were targeted to achieve required statistical validity.

QOL of participants was assessed by using the EQ-5D-5L and EQ-VAS, in which the 5-levels version significantly increases reliability and sensitivity of these scales while maintaining practicality of the survey and reducing ceiling effects compared to the former 3EQ-3D-3L. The EQ-VAS records respondents' self-rated health status using a visual analogue scale. The EQ-5D-5L is validated for a French sample population. Additionally, data from medical records of participant in n this study were gathered to identify gender, LOS, surgical complications, and medical and social backgrounds.

Results from the EQ-5D-5L were recorded for each dimension and coded according to mobility, self-care, activity, pain, and anxiety which were rated on the following scale: no problem, slight problems, moderate problems, severe problems, unable to, and missing value. The EQ-VAS scale then assigns a number from 0 meaning "no QOL" to 100 meaning "best QOL" given by the participant. These variables were then compared within the ERAS and traditional groups to determine if QOL of patients were affected by the ERAS approach and, if so, how. Additionally, medical and social data helped determine if these factors influence QOL.

Definitions

The following definitions were used for this study:

Enhanced Recovery After Surgery (ERAS): According to the ERAS Society (2018), ERAS is a perioperative care program designed by healthcare professionals to enhance recovery for patients undergoing a surgical procedure. This approach involves reexamining traditional practices based on best practices and has been demonstrated to

provide improved QOL, reduced surgery complications, decreased LOS and rehospitalization, reduced financial costs, and increased patient satisfaction.

Quality of life (QOL): According to the World Health Organization (WHO, 1998), QOL is defined as an individual's awareness of life situation, accounting for his culture and values as it affects physical health, psychological state, personal beliefs, social relationships, and relationships to the environment.

Mobility: According to the WHO (2008), mobility is the ability to move or be moved freely and easily Impaired mobility has numerous health consequences and is a predictor of physical disability, loss of independence, institutionalization, and death (Von Bonsdorff, Rantanen, Laukkanen, Suutama, & Heikkinen, 2006).

Self-care: According to Bhuyan (2004), self-care is activity which involves deliberately taking care of one's mental, emotional, and physical health.

Usual activity: A term that refers to a daily activity such as feeding, dressing, grooming, working, homemaking, cleaning, and leisure (Schmal et al., 2018).

Assumptions

It was assumed that an individual did not differentiate between ERAS and traditional total hip replacement surgery technique since the ERAS in orthopedics is a new approach. This study assumed that the physician enrolling a patient that required a hip replacement surgery into group using the ERAS or the traditional surgery technique did not reduce his potential chances to get better after surgery. Thus, enrolling a patient into ERAS or the traditional group for this study assessment did not represent an ethical issue because there is no problematic difference in medical results.

Scope and Delimitations

Limitations outside of the control of this study may have affected the internal validity of the study. The research control trial study design was most adequate to examine associations between QOL in patients who have undergone hip replacement surgery and the ERAS approach among a local population in a French hospital.

Due to the research control trial nature of the study design, a possible selection bias, even though a strict randomization procedure was followed, should be taken into consideration because results might be due to differences that existed between participants before surgery was conducted. In addition, the study lacks generalizability because participants may have not been representative of the whole French population due to the limited availability of participants.

Limitations

Limitations of this study involve sampling techniques. The research sample were developed through a randomization process in which cases were arbitrarily assigned to one of the two groups. However, collecting racial data in France is illegal; for this reason, this study might have limitations in terms of identifying differences between participants. Data collection by the surgeons and nurses have not been considered to develop a potential bias because they administered the French EQ-5D-5L and EQ-VAS.

Significance of the Study

This research fills a gap in knowledge by enhancing public health stakeholders' understanding of how total hip replacement affects the health status of the elderly population. Additionally, this research will support French public health professionals

who introduced the ERAS total hip replacement program in 2016 to reduce total hip replacement burdens in France.

If more is known about how total hip replacement affects the elderly population, data can play a major role in providing and disseminating relevant information about elderly health status and can be used as a rationale to improve the allocation of public health resources. As total hip replacement is an increasing public health problem due to population aging, preventive strategies can be developed to reduce the impact of associated diseases such as mental illness, social isolation, total hip replacement-associated infections, and reduced quality of health. This research will lead to positive changes as clinical healthcare providers will be able to identify preventive healthcare actions that hinder the burden of traditional total hip replacement and its associated diseases. In terms of patients, this research will increase their knowledge to improve their coping capacity. Findings of this research will provide insights into optimal allocation of resources to public health programs that reduce the burden of total hip replacement on the elderly population.

Summary

The objective of this study is to better understand the quality of life in patients who have undergone hip replacement surgery with or without an ERAS program. This is a public health issue, as hip replacement affects a large portion of the aging society of France, and numerous European public health authorities are exploring the ERAS approach. In order to address the research questions, a research control trial was implemented. The study was set in a French hospital that is implementing the ERAS

approach on behalf of the French public health agency. Patients requiring a hip replacement surgery were allocated to one of two groups with or without ERAS. QOL was assessed before and 3 months after surgery. Information gathered due to this research will provide valuable insight regarding QOL of patients. Chapter 2 includes a literature review involving hip replacement surgery in general and ERAS in particular.

Chapter 2: Literature Review

The purpose of this study is to compare QOL of patients who have undergone a hip replacement surgery using the ERAS versus traditional surgery techniques. There is a limited amount of literature addressing this topic. This study focuses on QOL from the perspectives of patients undergoing ERAS and traditional total hip replacement services. In this chapter, I critically evaluate peer-reviewed articles and other sources that pertain to my topic of investigation to demonstrate the presence of a knowledge gap related to the problem.

Literature Search Strategy

The literature was gathered through Walden University's library through databases such as ProQuest Central, PubMed, Eurostat, CINAHL, EBSCOHost, SAGE Journals, and PsycINFO.

Key words were used to research these different databases. Additionally, Boolean syntaxes were added into research fields to better target the research subject. The keywords employed for the literature review were: *quality of life, hospital quality of life, quality of life indicators, quality of life instruments, elderly and quality of life, enhanced recovery and quality of life, enhanced recovery, enhanced health, enhanced surgery, enhanced hospital discharge, enhanced orthopedics, enhanced surgery complications, enhanced recovery after surgery, enhanced recovery program, hip surgery, hip and elderly, osteoporosis, osteoarthrosis, community,* and *hip*.

This literature review focuses on peer-reviewed journals published between 2015 and 2019. However, some seminal research published before the 1990s was integrated into this study due to its importance to the field of study.

Theoretical Foundation

The integrative QOL theory is the theoretical foundation for this study. The origins of this theory date back to 1995 when Ventegodt Soren, a Danish physician, started his research on Danish people's quality of life because he pointed out that medical jargon narrows the definition of QOL.

According to Ventegodt et al. (2003a) notions of QOL are linked to the culture in which an individual participates; thus, QOL can be divided into three loosely separate notions. The first notion is subjective QOL, in which each individual evaluates how he or she views his or her own life. The second notion is existential QOL, which reflects how an individual balances QOL assessment between subjective and the objective notions to live in harmony with his current state. The third notion is objective QOL, that is perceived by other persons than the individual. This is influenced by the culture in which this individual resides. These three notions are grouped and overlap to deliver an approach that measures how human lives with respect the richness and complexity of human life.

Ventegodt's integrated QOL theory is based on the concept that each individual has the potential to improve QOL. Additionally, public health policies can help individuals acknowledge their life needs and how they wish to improve it by acting not

only on their needs but also by connecting with their innermost self and having a balance between the subjective and objective found in existential QOL (Ventegodt et al., 2003b).

Additionally, hip replacement surgeries, aside from traumatic surgeries, are normally scheduled operations that intervene to improve QOL of an individual at a specific time. However, this leads to the occurrence of after-surgery disagreements that will impact QOL of the individual.

The success of a hip surgery is evaluated by the physician in an objective way by assessing the physiological capacities of the patient to bend his hip, but it does not take into account the holistic approach of the patient that can affect his or her QOL (Grammatopoulos et al., 2017). The integrative QOL theory can help frame RQ1 by comparing two groups using a QOL scale that can measure subjective and objective levels. RQ2 and RQ3 involve exploring LOS and complication due to both types of surgery and how they impact QOL of individuals.

Literature Review

Medical advances have improved the ability of healthcare professionals to reduce the burden of numerous diseases and hinder chronic diseases. Individuals benefitting from these improvements are more centered toward the quality of life that the medical improvements have provided them (Estes & Sirgy, 2019). For example, a total hip replacement surgery performed on an elderly patient will affect his mobility over a time period, and due to complications, it might result in an increased rate of mortality within the first month to one year, thus the quality of life of an individual might be affected. Public health practitioners view quality of life of individuals as an important aspect of his

health and use quality of life as a valid and appropriate indicator of public health services. Additionally, the evaluation of intervention outcomes can estimate the success of a public health intervention.

Total hip replacement is a common surgery procedure that has been developed with an aging society and has become a significant public health problem throughout the world due to high mortality, morbidity, and disability rates. For these reasons, total hip replacement patients constitute an ongoing challenge for public health systems and society at large. In order to assess the impact of a hip fracture and the efficacy of surgical interventions, a measurement of patient-based outcomes, such as health status and quality of life outcomes, has been developed. Moreover, after conducting a literature review on quality of life, one is rapidly confronted by the usage of two major terms that are used interchangeably: quality of life and health status, demonstrating that this concept is central to public health.

During this literature review, approximately 8,000 articles were identified across all databases when using quality of life and health status as keywords. It is clearly indicated by metanalysis research that there is a confusion in the literature about the denotation of the terms quality of life and health-related quality of life, and little agreement exists on their definitions in the public health field. It is clear that better understanding of what each term is referring to is essential for a solid foundation of this study.

Quality of Life

The term quality of life has been discussed in the medical literature since the 1960s and became important in the public health sector as medical treatments were able to extend individuals' length of life, sometimes at the expense of improving their quality of life. Thus, measures of morbidity and mortality were no longer sufficient to measure fluctuations in global population health. The need to measure quality of life started to carve an important place in public health approaches as a desire to measure outcomes of interventions beyond the biological functioning of an individual began to dominate medical and public health discourse. In the 1970s, the term health status quality of life was employed more often and was motivated by a desire to measure the output of public health intervention on individual quality of life. Kaplan and Bush (1976) went further and pioneered the use of the term "quality-adjusted life years" as a measure of the value of a year in full health. According to Kaplan and Bush (1976), the term "well-year" is more appropriate than the term "quality of life in years" because it implies a more direct connection to health conditions. However, the concept seems to not have been used widely in public health, as numerous limitations and validity concerns have been identified. Subsequently, at the end of the 1980s the World Health Organization began the development of the medical outcomes study short form family measure (such as the SF-36) to compare "quality of life" on a worldwide scale. The intervention of the WHO was followed by numerous national or regional associations developing a more comprehensive measure of quality of life, such as the ED-5D-5L in Europe. These measures regarded social well-being at the same level of the absence of disease.

Currently, there is an ongoing debate in the public health community on the inclusion of social well-being in the definition of health, wherein Patrick (2003) defined quality of life as “an individual’s optimum level of functioning” where “optimum functioning” is judged in comparison to “society’s standards of physical and mental well-being.”, Ventegodt et al. (2003a) defined quality of life as a means to the good life, where an individual lives his life with high quality, while notions of good life quality are closely linked to the culture in which the individual is a member.

Within different communities across the world the term quality of life commonly encompasses a large range of societal and individual approaches that are influenced by norms and values of the society in which an individual takes part. However, some of these approaches are not generally addressed by public health professionals; this might be explained by the over-medicalization of the term “quality of life” (Wallace & Murphy, 2019). Quality of life goes beyond the health status, clinical symptoms, or functional ability of an individual and has an aspect that is holistic for an individual. Undeniably, the numerous definitions of quality of life found in the literature review accepted factors that are not part of the definition of health, defined by the WHO (2018) as a state of complete physical, mental, and social well-being, and not merely the absence of disease and infirmity. For example, the use of marital status, economic circumstances, and satisfaction with life of an individual are an important aspect of the quality of life of an individual.

The term “health status” focuses primarily on the physical, emotional, and social well-being after diagnosis and treatment of a disease. It is defined by Karimi and Brazier

(2016) as how well a person functions in their life and his or her perceived wellbeing in physical, mental, and social domain of health. Thus, health status represents the individual's perceived impact of his disease on the level of physical, emotional, and social functioning. In other terms, "health status" refers to internal experiences of an individual's perceived functioning. Additionally, the term "health status" is used increasingly by public health professionals as a valid health indicator; however, it gives only a partial picture of public health needs and prevention outcomes as measures of a population's well-being based on mortality and morbidity rates (de Munter et al. , 2019).

Qualitative research has demonstrated that individuals consider a wide variety of non-health factors when evaluating quality of life (Marrero & Delamater, 2020). The aforementioned definition of health status seems to be missing an important aspect of a more complex, existential aspect of an individual's quality of life. On the contrary, the use of the term quality of life reflects not only the aspects of mortality and morbidity but also the value of health perceived by an individual. Individuals with a hip replacement surgery are impacted in both the physical and psychological dimensions, and the recovery of their health status might be lengthy.

Integrated QOL Theory

Ventegodt et al. (2003) defined QOL as a good life, and that an individual believes that a good life is the same as living a life with a high quality. The integrated quality-of-life theory views an individual's quality of life as it can be perceived from both subjective and objective spectrums. These spectrums are well-being, satisfaction with life, happiness, meaning of life, the biological balance, realizing life potential, fulfilling

needs, and objective factors. The integrative quality-of-life theory is based on Maslow's hierarchy of needs, in which to fulfil a need, an individual must realize them in order to move from one level to the next. Ventegodt (2003) said that self-actualization and transcendence (top of the pyramid) in Maslow's hierarchy of needs is rarely obtained, and thus, a good quality of life is rarely obtained, whereas in the integrated quality-of-life in individuals can perceive themselves with a good quality of life without attaining all of Maslow's needs. Moreover, Ventegodt (2003) asserts that people with chronic diseases, such as a hip replacement, often do not have all of their diseases disappear in spite of the best biomedical treatments available; however, some individuals adapt to their status of life and live with great happiness and consider themselves to have a good quality of life.

Concepts such as well-being, positive and active aging, and aging well are public health concerns as the world population is increasingly aging, and quality of life within society has become a high priority to the medical community (Goldman et al., 2018; Smith, Jackson, Kobayashi & Steptoe, 2018). To add quality to years of life, public policies are increasingly concerned with empowering older people to preserve their mobility, independence, and active involvement with society to respond effectively to their physical, psychological, and social needs. There is a plethora of research on a wide range of objective and subjective indicators of quality of life; however, there is no widely acceptable supported theory or measurement instrument of quality of life (Brown, Bowling and Flynn, 2004). Moreover, quality of life is a dynamic, multi-level, and complex concept reflecting objective, subjective, macro-societal, and micro-individual positive and negative influences that interact together (Lawton, 1991).

Aggernaes (1994) argued that Maslow's theory is not in accordance with facts because individual needs cannot be ordered in such a hierarchy as described in Maslow's pyramid. Moreover, life mission theory, explains humans may have internal power that can explain the negative attitudes that are widespread and are present in 25% of the population, and strongly correlate with poor physical and mental health (Ventegodt, 2003). For these reasons, self-respect is an essential precondition to have the individual's needs fulfilled by knowledge and understanding of his current status.

The integrative QOL theory includes a subject, objective, and existential measure of quality of life. The subjective quality of life spectrum is measured by how satisfactory life is perceived to be by each individual. It is a subjective interpretation of life happiness based on the well-being, satisfaction with life, happiness, and meaning in life. The objective quality of life spectrum is the outside world's perception of an individual's quality of life. Biological order, the realization of life potential, fulfillment of needs, and cultural norms encompass this spectrum. The existential quality of life is a broader spectrum that is between the subjective and the objective spectrums. It is assumed that a person has a deeper understanding of quality of life, and a harmony is sought within the subjective and objective spectrum. The fulfillment of needs in the subjective and objective spectrum is not an aim by moving from one state to another, such as in Maslow's pyramid, but rather, it is finding consistent balance between the two types of needs.

The integrative quality-of-life theory supports the idea that how an individual feels in his inner self is a dimension that cannot be rationally described. Some people

without the medically recommended hip replacement surgery are doing well, and some people who undergo the recommended total hip replacement surgery are doing poorly. The interesting question is whether one can have a hip replacement and still have a life that is meaningful. The connection between illness and quality of life is complex. The integrative theory of the global quality-of-life concept adds to Maslow's theory a notion of time and subjective, existential, and objective quality-of-life aspects based on the momentum of the life of an individual who might have undergone a hip surgery.

Measuring the mobility, self-care, usual activity, pain or discomfort, and anxiety or depression of an individual in different stages of their journey in the hip replacement surgery reflects the different existential spectrums of the objective and subjective quality of life. Moreover, socioeconomic factors, hospital journey, length of stay, and surgery complications might also influence the quality of life of people by impacting access to care, financial factors, and helper support. For these reasons, the integrative quality-of-life theory relates to this study that explores the quality of life in patients who have undergone an ERAS-style total hip replacement surgery.

The enormous volume of literature on the theme quality of life has created many concerns for makers of public health policy. The European Council of Health, challenged by an aging society, has oriented quality of life as an objective for meeting older people's needs (Liljas, Brattström, Burström, Schön, & Agerholm, 2019). In the case of the total hip replacement surgery, it is clear that this surgery is the preferred method of treatment in active elderly patients with long life expectancy. However, new surgeries approaches might have differences in health quality-of-life outcomes between traditional and ERAS

approaches. A research control trial with adequate measurement of quality of life using a combination of objective functioning and a subjective perception of quality of life is warranted by numerous papers. This study has implemented a research control trial to address these questions.

QOL and Total Hip Replacement

Total hip replacement surgery positively impacts individuals as the long-term self-reported physical quality of life and hip functionality; however, their physical performance and mobility are better compared to untreated patients with advanced hip complications (Mariconda, Galasso, Costa, Racano, & Cerbarsi, 2011). Numerous studies have confirmed that a hip replacement surgery is the best actual treatment for these complications; nonetheless, this approach negatively impacted the quality of life of the majority of the studied individuals (Hoekstra, Goosen, de Wolf, & Verheyen, 2011; Ryan, Enderby, & Rigby, 2006; Tidermark, et al. 2004). These studies focused on patients that did not have hip replacement surgery due to a traumatic hip fracture because traumatic hip fractures are emergencies that are not scheduled and thus cannot be assigned to one of the two groups (traditional or ERAS) for comparison. Thus, the primary indication of the total hip replacement in this study are perceived pain or discomfort and reduction of mobility and preventive surgery due to high levels of osteoporosis or osteoarthritis.

Individuals who receive a hip replacement surgery typically have a follow-up with their practitioner at different timeframes after the surgery; these schedules are dependent on the practitioner and often are scheduled around three months to one year

after the surgery. Researchers found that during the first follow-up around 3 to 6 months after surgery, individuals perceived a positive improvement in their quality of life; however, these researchers did not find an improvement of the quality of life after the first to second years following a traditional total hip surgery (Tidemark, Zethraeus, Svensson, Tornkvist, & Ponzer, 2003). Numerous studies used different timeframes for the follow-ups. Ryan et al. (2006) concluded that six or more face-to-face contacts per year did not result in an improved quality of life at three months of follow-up in comparison with three or fewer visits per year. Additionally, Beaupre, Jones, Johnston, Wilson, and Majumdar (2012) demonstrated that hip replacement patients have significantly lost their quality of life between three, six, and 12 months postoperatively. This demonstrates that the timeframes of the follow-ups are not relevant and do not impact the quality of life of the individual postoperatively. However, the choice of the timeframe is mostly discussed in the research as a choice of convenience and data accessibility.

Furthermore, it is reasonable to assume that there is a need to evaluate the population chosen in the different studies used in the literature review as they enrolled traumatic and scheduled hip replacement patients but excluded participants who died shortly after a hip replacement. Subsequently, numerous short-term studies included only survivors in their analysis, which may have caused sampling bias. Thus, the increase in the perceived quality of life of these individuals is probably elevated due to the participant selection in those studies. In the participant inclusion section of this study,

special treatment has been applied to patients that died during the hospitalization timeframe of the surgery as this is important to consider as a complication of the surgery.

The QOL of individuals after a total hip replacement in older individuals is probably worse than is presented in the different studies reviewed in this literature review. In their systematic literature review on quality of life in elderly patients that have undergone a hip replacement surgery, Peeters et al. (2016) explained that 50 studies that most of the research cites was prospective cohort and observational studies. The results of the studies reviewed by Peeters et al. (2016) sometimes lead to a large difference in the results of quality of life in the population studied. To illustrate this, Mariconda et al. (2016) found that quality-of-life functional status was regained by 57% of patients to the state before the surgery, while Comans et al. (2013) reported that only 11% regained their quality of life. There is a lack of information on why there is such a large difference between these studies that use the same quality-of-life instrument and a similar population. It seems that quality of life includes a subjective element in how a society perceives quality of life. The integrated quality-of-life theory might bring this explication and provide greater clarity to the fact that quality of life is complex and should be studied subjectively and objectively to be better understood. The use of an instrument to evaluate the quality of life must be specific to a geographic region and have both subjective and objective scores.

The population of hip replacement patients is a predominantly elderly one. Peter et al. (2015) demonstrated the presence of numerous comorbidities in patients after total hip replacement surgeries. Hypertension was present in 42% and diabetes in 10% of the

elderly individuals that had undergone a hip replacement surgery, while severe back pain and neck or shoulder pain was also reported by 15 to 20% of these patients. However, these incidences reported by patients are comparable to other studies dealing with an older population, so the incidences cannot lead to an association between total hip replacement surgery and these comorbidities (Mannion et al., 2020). Regardless if these comorbidities were directly associated or not with the total hip surgery, they negatively impacted the quality of life. Numerous researchers have used age, gender, length of stay in hospital, and socioeconomic status as covariables in their studies and did not take into account comorbidities.

Socioeconomic Determinants of QOL in Hip Replacement Patients

Age. Age overlaps with every nearly every other category, due to the high incidence of total hip replacement in elderly individuals; most studies have investigated groups of older people. Birdsall et al. (1999) found that with the increase of individual age, mobility, self-care, pain, and anxiety increased in the positive status, with an expected increase in social isolation that affects the usual activity at three months after intervention. Moreover, the older the patients complained less of pain but had worse mobility before surgery compared to “younger” individuals.

Nildotter and Lohmander (2002) demonstrated that patients with hip replacement surgery that were older than 72 years old had a degree of improvement similar in all dimensions expect mobility functions to that experienced by those younger than 72. Therefore, younger individuals are more subject to pain, and older patients have more negatively affected mobility.

Mobility. Numerous researchers have indicated that physical functioning was seriously affected in the first months after a total hip replacement procedure (Sawatzky, Miller & Noureai, 2019). A strong correlation has been determined between reduced mobility before and after total hip replacement.

Rehabilitation is an important part of reducing the hip replacement impairment, and improvements of mobility have been associated with patients having joined a rehabilitation home program, in which physiotherapy and strength training are utilized to reduce the impact of surgery. Using these techniques, practitioners have improved patients' quality of life by reducing the negative impacts of mobility (Zidén, Kreuter, & Frändin, 2010).

Nonetheless, according to Ryan et al. (2006) an intensive rehabilitation of mobility requiring daily treatment did not improve the mobility of patients compared to individuals having three to four visits per week. It is notable that while mobility is not affected, the increase in number of rehabilitation center visits decreased the quality of life of individuals during the rehabilitation time. Thus, the ERAS approach can improve the quality of life of patient who have undergone an ERAS hip replacement surgery by reducing the time he or she stays in a medical facility.

In particular, mobility was extremely affected in the first months after a total hip replacement surgery. Beaupre et al. (2012) demonstrated that the majority of the recovery of quality of life takes place in the first two to six months after a hip replacement surgery, while a majority of studies denote a recovery taking place within six months to one year. Gjertsen, Baste, Fevang, Furnes, and Engesæter (2006) reported that around 56% of

patients under 70 years reported problems with mobility that affected their quality of life. Hansson et al. (2015) reported 29% of patients regained their previous mobility status, which can be an indication that ERAS hip replacement positively affects patient mobility.

Self-care. Gjersten, Baste, Fevang, Furnes and Engesater (2016) compared the preoperative status of individuals at four months after the total hip replacement surgery and observed that the dimension of self-care rate has doubled its impact in patients over 80 years old and has increased at one year after the surgery. Additionally, Gjertsen et al. (2006) reported that around 23% of patients under 70 years old reported problems with self-care that affected their quality of life.

Usual activities. Usual activities are the ability of an individual to cope with day-to-day activities in order to maintain his needs. Usual activities have been approached differently in the different literature review of published studies as there is no clear consensus of what usual activities refers to. Some researchers have used daily activities measure instruments to define this variable, but the problem is that these researchers did not relate the findings to the quality-of-life impact. Instead, they used these activities scores to create a description of the studied population. While this approach might seem to be weak, it is argued by the medical community that usual activity is an important factor for individual balance. The integrative quality-of-life theory emphasizes that the ability to do what one wants physically improves a patient's ability to have control over his existential quality of life.

Gjertsen et al. (2006) reported that around 51% of patients under 70 years old reported problems with usual activity that affected their quality of life. Bowling (1995)

said that older individuals aged 75+ were less likely to mention relationships with family or others as important. Broadhead, Robinson, and Atkinson (1998) found that illness increases the importance of family presence, but individuals in need tend to desire not to be a burden to family, rather than increased importance of relationships per se. Additionally, being in poor health was also found to increase the importance of independence and social leisure activities to people (Hawes et al., 2019).

Usual activities are an important variable to be measured because hip replacement surgeries tend to limit the mobility of people and might alter the possibility of completing usual activities, such as driving a car, in the first three months. Wainwright, Immins, Antonis, Taylor, and Middleton (2017) studied individuals who lived in long stay institutions with a total hip replacement surgery and concluded that doing usual activities is important to retain a sense of autonomy in people's lives, in contrast to the routines given by the institutions. Zidén et al. (2010) suggested that an early transfer from acute to rehabilitation programs improved self-efficacy and positively affected the usual activity capacities of individuals. However, what remains to be studied is if a significant improvement exists between patients enrolled in an ERAS program compared to the traditional technique, and if ERAS improves the quality of usual activities as perceived by patients.

Pain and discomfort. A strong correlation has been found between pain before total hip replacement surgery and after the surgery. Gjertsen et al. (2016) reported that the group, under 70 years old, reported the best quality of life in all dimensions expect pain and discomfort at follow-ups compared to other age groups, whereas patients over 80

years-old reported significant problems.

Additionally, Zyweil, Prabhu, Perruccio, and Gandhi (2014) reported that individuals having two joint replacements–knee and/or hip–had more pain and worse physical mobility functioning compared to those with only one joint replacement surgery. However, only Zyweil et al. (2014) study has been conducted to date on multiple joint replacement that assessed the quality of life of individuals. The quality of life, especially on the levels of pain and mobility, reduces in the short and long term.

Anxiety and depression. The changes in the status of individual anxiety and depression is a less evident and more rarely developed socioeconomic determinant studied in the literature that was consulted. Studies demonstrated negative impact of cognitive state towards quality of life after a hip replacement surgery in the first three to six months. The issue is that the existing instrument for measuring the quality of life interrogates individuals about if they feel depressed or have anxiety, which can be limiting because anxiety and depression are medically instigated. This approach reduces the strengths of the research; however, as anxiety and depression are associated with the quality-of-life perception of individuals, this is important and, thus, is inevitable. It may be worthwhile for future research to determine whether removing this question from the questionnaires and introducing an assessment by a psychologist impacts the data. In this way, the results of this question would be more objective.

However, the analysis of anxiety or depression by a health professional might be controversial because some individuals suffer from anxiety related to their hip replacement surgery, but their quality of life is not impacted as they have coped with this

phenomenon. Happiness in the integrative quality-of-life theory is how an individual balances his anxiety that is induced by the surgery in his daily life. There is much that remains to be understood about how anxiety and depression affects quality of life; however, this exceeds the boundaries of this research, and a focus on anxiety or depression should be oriented toward the effects of the total hip replacement surgery implications.

What the medical research community has established now is that a relationship between anxiety or depression exists between an individual's pain state and his quality of life. Gambatesa et al. (2013) reported that psychological factors increase pain severity and emotional distress during hospitalization of patients as they are away from their normal day-to-day life. Furthermore, counseling during the rehabilitation time improves patients' pain perception and reduces the occurrence of anxiety and depression due to the surgery. The ERAS approach has implemented a mandatory visit to a psychologist to answer patient questions and adapt their prescription to reduce their post-surgery pain before the hip replacement surgery. However, no formal research has been done demonstrating the efficiency of this approach. In this study, the research question considers the individual's cognitive state to compare the ERAS and traditional total hip replacement approaches by using a preestablished and culturally validated scale.

Complications. To my knowledge, there is no existing research comparing QOL between traditional and ERAS surgery approaches in hip replacement. This can be explained by the fact that the hip replacement ERAS began only two years ago. Blomfeldt, Törnkvist, Ponzer, Söderqvist, and Tidermark (2005) followed hip replaced

patients for two to four years and did not find a significant difference impact on quality of life when quality-of-life comparison points were done at two and four year timeframes.

In general, the presurvey state of the individual requiring a total hip replacement is affected by the psychological state, gender, and length of stay in hospital. Taraldsen et al. (2015) found that it is less costly and more effective that a patient be treated with comprehensive geriatric care during hospitalization; they also found improved physical behavior and independent living in such patients when compared to those treated with orthopedic care. Peter et al. (2015) reported that some patients reported dizziness, one of the main reasons for a longer stay in hospital after surgery. This can be due to the presence of anemia, which is related to worse outcomes in hip fracture. What remains to be fully understood is a comparison of quality of life between non-rehabilitation hip replaced patients and surgical departments.

The literature presents conflicting evidence regarding the association between high body mass index and complications after surgery; however, morbidly obese patients (BMI >40) were found to be at greater risk for perioperative complications, such as infection and surgery revision, compared to patients with a BMI of less than 40 (Peter et al., 2015).

ERAS and QOL

Due to the recent advances in surgical techniques and anesthesia procedures, the standards of inpatient and outpatient surgery focus on reducing the impact on the body and reducing hospitalization time, thus resulting in a new paradigm in healthcare called ERAS (Wilmore & Kehlet, 2001). The literature review on ERAS indicated the use of

two terms that are defined in the same way but are designated differently. In the English-speaking countries, this procedure is referred to as ERAS, while in European ones it is referred to as an Enhanced Recovery Program (ERP). This naming difference might be instilled because of healthcare competition between public and private hospitals. However, for this study, the term ERAS will be used and will refer to both ERAS and ERP approaches.

The major advances in the ERAS approach is better patient preparation before surgery to reduce his needs post-surgery and an improvement in anesthesia management and delivery (Majholm et al., 2012). Moreover, the advancement of surgery techniques such as robotics, laparoscopic techniques, and small-size incisions have considerably decreased the burden on the body, thus resulting in reduced pain, increased mobility, and reduced social impact on patients (Mack, 2001). Discharge from hospitals has been reduced to a minimum due to better monitoring of anesthesia procedures, thus reducing anesthetic side-effects and reducing the impact on the mental state of patients, leading to faster discharges from the hospital (Majholm et al., 2001).

ERAS began its development in digestive surgeries in the 1990s, and numerous other specializations fully or partially adopted this approach, such as gynecology, urology, and head and neck specialties. However, orthopedics, especially total hip replacement, first utilized this development in 2017-2018. There are still some patients that cannot be enrolled in the ERAS procedure, including patients with social reasons rendering their preparation and discharge difficult and those with heavily impaired health status and surgery complications, such as postsurgical pain and bleeding. Savaridas et al.

(2013) reported high levels of safety of ERAS in orthopedic surgery for knee arthroscopies, which uses similar anesthesia and pre-surgery patient preparation as hip replacement.

Total hip replacement ERAS surgery reduces the length of stay in hospital and increases patient satisfaction while improving post-surgery patient disagreements. Additionally, Ramkumar et al. (2018) approached ERAS in total hip replacement from an economical perspective by evaluating the financial volumes of hip replacement surgery to its financial implications and concluded that there is a direct relationship between the volume and value of total hip replacement surgery and the volume performed by a surgeon: the more a surgeon or a hospital performs total hip replacement surgeries, the less it costs to the public as the surgery materials are used multiple times, and their usage is optimized. Moreover, Kehlet (2018) recommended that ERAS protocols in total hip replacement surgery be more specific on post-discharge comprehension because length of stay and the ERAS technique are already well understood. This reinforces that it is still unknown how ERAS affects the quality of life of individuals after an ERAS total hip replacement surgery compared to the traditional technique.

EQ-5D-5L

The EQ-5D-5L score gives only an indication of patients' levels of physical, emotional, and social functioning, but it does not measure patients' internal experiences or satisfaction with their functioning. The literature review on hip replacement and quality of life recognized an association with SF-36 and EQ-3D-3L quality-of-life measures for the ease of implementation on these scales. The rationale behind choosing

the EQ-5D-5L scale for this study is that the EQ-5D-5L is a standardized measure of quality of life that provides a simple generic measure of quality of health for clinical and economic appraisal developed by the EuroQol Group. This scale provides a simple descriptive profile and single index value that can be used in population surveys. It is also cognitively undemanding and takes only a few minutes to complete. This index contains five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/discomfort, which each have 5 levels that are evaluated. The numerals 1-5 do not have arithmetic properties and should not be used as cardinal scores. The EQ-5D-5L is validated in orthopedic surgeries and in numerous countries, especially in France where the research will be conducted. The explanation of why it is best suited to use the EQ-5D-5L compared to the EQ-5D-3L is explained in the literature review section and is basically been done to reduce celling effect and increase sensibility of the instrument.

Additionally, the EQ-5D-5L scale captures the quality of life of an individual while answering the questionnaire that represents the existential quality of life spectrum in the integrated quality-of-life theory. The EQ-5D-5L scale can be published and used without authorization, but a specific copyright statement for the specific EQ-5D-5L should be provided. Additionally, the EQ-5D-5L has introduced EQ-VAS, a self-rating that records the respondent's own assessment of their quality of life and is thus representative of the individual's personal evaluation that refers to the subjective spectrum of the integrative quality of life theory.

Summary

Chapter 2 illustrated that QOL in patients who have undergone a hip surgery have their QOL affected. Additionally, there is a gap in literature involving the impact of new hip surgery techniques such as ERAS on QOL among patients who have undergone hip replacement surgery. Therefore, it was important to examine the effects of an ERAS program on QOL in patients who undergo hip replacement surgery.

Secondly, the literature review illustrated demographic factors that affect QOL and related measures. This chapter also explained that the EQ-5D-5L and EQ-VAS are instruments that are used to measure QOL between the comparison group that had traditional hip replacement surgery and the intervention group who underwent an ERAS approach. Chapter 3 includes the study design, sampling strategies, sample size estimation, data collection methods, and statistical data analysis procedures.

Chapter 3: Research Method

This chapter includes the research design, methodology, and rationale with respect to the research questions and hypotheses. In this study, I used a quantitative research control trial approach to assess the effect of an ERAS program on QOL in patients who have undergone hip replacement surgery. For the purposes of this study, I gained access to data collected from a research control trial done in a hospital that compared ERAS to traditional hip replacements patients pain levels. The rationale behind using the secondary data set is discussed.

The study population as well as inclusion and exclusion criteria for study participants is described. Additionally, secondary data treatment and coding are detailed. Statistical tests and specific statistical techniques used are described, along with strategies for analyzing data. Furthermore, internal and external threats to research validity and how they were addressed are described. Finally, ethical consideration and participation privacy are discussed.

Research Design

In this study, a randomized control trial was undertaken because data originated from a research control trial done in a Parisian hospital. Aspects involving guaranteeing subsampling and treatment of data that were collected from the initial research control trial is addressed in this chapter. The research control trial of this study involved testing QOL of patients who have undergone hip replacement surgery using either the ERAS or traditional surgery technique. The required data to answer this study's research questions originated from initial research done in a Parisian hospital that assigned participants to

one of two groups: control (traditional surgery only) and experimental (surgery plus the ERAS program). Collected data were used for numerous analyses. All participants had already answered the EQ-5D-5L and EQ-VAS questionnaires before and after the surgery which was used to measure QOL.

Main Objectives

The primary aim of this study is to evaluate QOL of patients who have undergone hip replacement surgery with or without an ERAS. Because the data used in this research were not collected firsthand to answer the research questions, it is important to understand how data were collected and characteristics of the population being studied. For this reason, I have assumed that data extracted from electronic patient records can be categorized into two groups: patient identification and sociodemographic information and patient medical history, such as past diseases, interventions, and prescriptions. Patients are admitted to this hospital via the emergency department for urgent interventions or scheduled hospitalizations issued by a physician. Each patient answered an admission questionnaire conducted by a healthcare professional. This admission questionnaire evaluated numerous patient patterns, such as QOL, pressure ulcer risk, and suicide risk. Patients who were admitted to the emergency room were not required to answer to this questionnaire upon arrival; however, nurses working in postsurgical sectors completed the missing information after the surgery was complete. Three months after surgery and hospital discharge, a follow-up with patients was completed by a mandatory surgeon. During this visit, the assistant of the surgeon administered the EQ-5D-5L.

Qualifications of collecting personnel were important to reduce potential information collection bias during the research control trial. In France, registered nurses administer an entrance questionnaire to patients upon admission to the hospital, and they are trained for this task during their university training.

Additionally, hospital patient records referred to the items related to the EQ-5D-5L as the QOL scale. However, questions are identical to the published EQ-5D-5L and EQ-VAS scales. Therefore, answers did not need to be weighted. Instead, minor data modification was necessary, such as changing the age from a day-month-year format to decimal numbers.

Research Questions

RQ1: Accounting for the effects of mobility, self-care, usual activity, pain or discomfort, and anxiety or depression, is the average EQ-5D-5L index as a measure of QOL significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery technique?

$H_0$1: Accounting for the effects of mobility, self-care, usual activity, pain or discomfort, and anxiety or depression, the average EQ-5D-5L index as a measure of QOL does not significantly differ among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery technique.

H_a1: Accounting for the effects of mobility, self-care, usual activity, pain or discomfort, and anxiety or depression, the average EQ-5D-5L index as a measure of QOL does significantly differ among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery technique.

RQ2: Is average LOS significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery?

H_0*2:* Average LOS is not significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery.

H_a*2:* Average LOS is significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery.

RQ3: Is risk of complications due to surgery significantly different among patients who have undergone an ERAS hip replacement surgery compared to traditional surgery?

H_0*3:* Risk of complications due to surgery is not significantly different among patients who have undergone an ERAS hip replacement surgery compared to traditional surgery.

H_a*3:* Risk of complications due to surgery is significantly different among patients who have undergone an ERAS hip replacement surgery compared to traditional surgery.

Data Collection Procedures

Population

The site of the study is located in the western county of Paris in France with a total population of 1.4 million residents. According to the 2019 French National Institute of Statistics (2018) report, regionally, 21% of this population is aged 60 years or older, 59% of this population is aged between 15 and 59 years, and 20% is aged under 14 years. This region is fairly representative of the nationwide French demographic (26% aged 60

years or older, 55% aged between 15 and 59 years, and 19% aged under 14 years). Approximately 3,000 total hip replacement surgeries were performed in this county in 2018; this number is near the national incident numbers (241 total hip surgeries per 100,000 residents). Therefore, it can be concluded that this county has a similar demography to France.

Sampling Procedures

I used all participants from the secondary dataset that was provided by the aforementioned hospital respecting inclusion and exclusion criteria of this study. To my knowledge, no previous study has compared the quality of life of patients who underwent hip replacement surgery with or without an ERAS. Patients in this geographic area have access to three hospitals that can perform total hip surgery; however, more than half of these surgeries are completed at the selected hospital. Additionally, this is the only hospital that has both ERAS and non-ERAS total hip surgery. Therefore, the targeted population was adults who underwent hip replacement surgery in the western county of Paris, France at the selected hospital.

Data Collection

The hospital setup where the data were collected supported a random sampling approach. On odd-numbered weeks, patients had the hip replacement surgery without ERAS, and on even-numbered weeks, they had the surgery with ERAS. This setup ensured the randomization of the patients in the two groups: with ERAS, the intervention group, or without ERAS, the comparison group. Thus, the probabilistic simple random sampling strategy was appropriate because it allowed for the participants to be randomly

selected without specifying any criteria for selection from a secondary dataset that was readily available.

The baseline assessment of all patients was completed before the surgery for both groups, and the participants were followed over a three-month period by the surgeon and were assessed with the same questionnaire at the end of this period as stipulated in the variable coding book.

Regarding the sampling frame of the study, participant inclusion criteria were as follows: (a) aged 18 years or older; (b) legal resident in France; (c) able to read and understand French language; and (d) surgeries done between January and March 2018. Exclusion criteria were as follows: (a) aged less than 18 years; (b) diagnosed with traumatic hip fracture; (c) admitted via the emergency room, (d) did not have French social security (illegal immigrant).

Sample Size

I conducted power analyses using G*power3 statistical software based on inputs of the estimated effect size, population size, significant difference level, and statistical test. The required sample size was based on statistical needs estimates using the G*power software and the sample sizes for similar studies found during the literature review.

Analysis for RQ1 and RQ2 involved the use of multivariate statistical tests, a paired *t-test* was done. Sample size analysis for these two statistical tests was conducted using the guidelines established in G*Power3 to determine a sufficient sample size using an alpha of 0.05, a power of 0.80, a normal effect size (d = 0.5), and a two-tailed test. Based on the inputs into G*power3, a total sample size of 57 patients was needed (see

Appendix A). For RQ3, a risk estimate was conducted. There was no minimum sample size required for the test.

Based on these calculations, this research set a goal to investigate at least 144 participants. I based these estimates on those reported for similar studies in the literature review and the G*power3 results. The effect size was selected to ensure that the ERAS program was beneficial to the participants. A power of 80% minimized the opportunity for a type II error, and the selection of a significance level of 0.05 minimized the likelihood that a false finding was accepted as true.

The data of this study were collected from a secondary source provided by the hospital where the participants underwent hip replacement surgery. The public health system in France enforces that the family physician refers the patient to an orthopedic surgeon that confirms and schedules the surgery. During the surgeon consultation, the patient is required to fill in social security information (sociodemographic information) and medical information (EQ-5D-5L, EQ-VAS, and other scales) that are collected in the patient's medical record. Then, during hospitalization, all interventions by the healthcare professionals were recorded in the electronic medical patient file. All the patients who underwent hip replacement surgeries in this hospital during this period were recruited, and participation in this research was defined by the inclusion and exclusion criteria of this research setup. Detailed information of how the dataset was manipulated is explained in the data analysis plan subsection of this chapter.

Variables and Instrument

ERAS Intervention Information

The ERAS intervention was applied by the hospital staff. However, it is important to briefly describe the intervention as the literature review revealed that numerous researchers failed to describe the ERAS intervention studied. Additionally, a high level of heterogeneity regarding when an ERAS approach was used in the surgery of hip replacement, making it important to describe the ERAS procedure to better compare the studies. This part distinguishes the ERAS intervention from the traditional hip surgery as practiced in the selected hospital to provide a better understanding about this research and help guide future research.

One to two weeks before the surgery, the patients who underwent the ERAS intervention completed the following steps: (a) attended a half-a-day group (6 to 10 patients) meeting where an anesthesiologist, an orthopedic nurse, psychologist, and social worker described the ERAS procedure, (b) consulted with a psychologist who helped them work on how the hip replacement would affect their life and helped them reduce the anxiety and fear associated with the surgery, (c) attended a session with the physiotherapist to train for the use of a walking frame and a forearm crutch, and (d) obtained help from a social worker to finalize all required sick leave and rehabilitation center admission paperwork.

On the eve of the intervention procedure, patients receiving the ERAS intervention were admitted to the hospital to finalize blood tests and anesthesiology examinations. They were required to fast as of midnight; however, two hours before the

intervention, they were required to drink 500 ml of a high carbohydrate drink. No premedication was given to the patients, which enabled them to walk to the operating theater with an assistant nurse. The chosen anesthesia was an epidural one; the patients were given a headset to listen to relaxing music during the surgery. A high dose of steroids was injected intravenously to reduce the inflammation of the operation site. The surgery was performed using a smaller incision than the traditional approach, and the surgeon injected a high dose of anesthesia directly in the incision area. After the surgery and for the next 10 hours, ice was applied to the surgery site.

Ten hours after the surgery, the patients were required to stand up and walk with a walking frame assisted by a physiotherapist. Within 24 hours after surgery, patients were discharged home, followed by an admission to a rehabilitation center one week later. Surgeons followed up with patients 3 to 4 weeks after the surgery.

EQ-5D-5L Instrument

The EuroQol Group, an international multidisciplinary researcher network that was established in 1987, focuses on measuring health status and have developed tools and metrics used in clinical trials, observation studies, and health surveys. Numerous guides and country-by-country scale validations have been published by the EuroQol Group, increasing the validity and specificity of the EQ-5D-5L and EQ-VAS scales. The EQ-5D-5L scale (see Appendix C) is designed for self-completion by respondents, is ideally used in clinics and face-to-face interviews, is cognitively undemanding, and takes few minutes to complete. The EQ-5D-5L is translated into French, and the translated questionnaire has been tested and validated for French social and community traditions, so it can be

compared worldwide. The hospital where the data was collected was not able to deliver a formal document delivered from the EuroQol Group. For this reason, I contacted EuroQol and received formal authorization to use it in this research (see Appendix B)

EQ-5D-5L and EQ-VAS Scale Variables

The independent variable in this study are the different measures measured with the EQ-5D-5L that are aggregated to produce the EQ-index and EQ-VAS scale. The EQ-5D-5L measures five variables that are the dimensions of the scale: (a) mobility, (b) self-care, (c) usual activity, (d) pain or discomfort, and (e) anxiety or depression. Each dimension has five levels that indicate (a) no problem, (b) slight problems, (c) moderate problem, (d) severe problem, or (e) extreme problems. Each level description has been adapted to represent the dimension. For example, the participant had the option of choosing one of the following statuses on mobility: (a) I have no problem in walking about, (b) I have slight problems in walking about, (c) I have moderate problems in walking about, (d) I have severe problems in walking about, or (e) I am unable to walk about. The results from answering these questions will end in an EQ-5D-5L index that can be compared from one subject to another. With the EQ-5D-5L index, it is assumed that a participant having no problems, thus a good quality of life, will have an index of 5, while a participant with the maximum level of 25 will have an extremely affected quality of life.

Table 1 summarizes the studied variables, their measures, the level of measurement, and the coding procedure.

Table 1

Descriptions and Characteristics of the Variables

Variable type	Variable name	Measure	Level of measurement	Coding
Dependent	EQ-5D-5L index (before and after surgery)	The aggregated quality of life score	Scale	999 = missing data continual
Dependent	EQ-VAS	The level of health as self-assessed by the participant	Ordinal	100 = best health participant can imagine 0 = worst health a participant can imagine 999 = missing data
Dependent	Length of stay	The number of days a participant was hospitalized	Scale	Number of days
Dependent	Surgery complication	Surgery complication existence	Dichotomous	1 = No complications 2 = Complication
Independent	Type of surgery	Type of surgery traditional or ERAS	Binary	1 = Traditional 2 = ERAS

Demographic Variables

Demographic information was captured to reflect demographic variables (age, gender). This information was treated as the data file information input needed some transformation, such transforming from day-month-year birthday to number of years.

Table 2

Demographic Variables Measures and Coding

Variable type	Variable name	Measures	Level of measurement	Coding
Potential confounder	Age	The age of participants un years	Continuous	Numbers 999 = missing
Potential confounder	Gender	The sex of the participant	Nominal	1 = man 2 = women 9 = missing

Data Analysis

The collected dataset was delivered in a Microsoft Excel spreadsheet and had to be transformed using the coding shown in Table 1 into the Statistical Package for the Social Sciences (SPSS). There are no elements that make the identification of participants possible. Data cleaning was performed and concerned the following aspects: (a) variable transformation, the original dataset contained the date of birth of participants in the day-month-year format and needed to be transformed to number of years; (b) computing variable, the scores from the independent variable (mobility, self-care, usual activity, pain and discomfort, anxiety and depression tested before and after the intervention) were added to create the EQ-5D-5L index value to calculate the quality of life score; (c) splitting data was done to identify the control group from the experimental one; (e) application of the inclusion and exclusion criteria.

Descriptive Statistics

Descriptive statistical analysis was used to provide a summary of the demographics data, participant gender, surgery complication, and length of stay.

Table 3

Descriptive Variable Measures and Statistical Tests

Type	Variable name	Measures	Level of measures	Statistical test
Potential confounder	Age	Age in years	Ordinal	Mean and standard deviation
Potential confounder	Gender	Sex of the participants	Nominal	Percentage
Dependent variable	Surgery complication	Number of complications during the surgery	Ordinal	Percentage
Dependent variable	Length of stay	Number of days of participant stay in hospital	Ordinal	Mean and standard deviation

Table 4

Relationships of Type of Surgery Approach and Pre and Posttest EQ-5D-5L Scores

Dependent variable		Independent variable		Statistical test
Name	Type	Name	Type	
Type of surgery approach	Dichotomous	Pretest EQ-5D-5L index score	Scale	*Paired t-test*
		Posttest EQ-5D-5L index score	Scale	

Table 5

Relationships of surgery Approach and Length of Stay

Independent variable		Dependent variable		Statistical test
Name	Type	Name	Type	
Type of surgery approach	Dichotomous	Length of stay	Scale	Independent sample *t-test*

Table 6

Relationships Between Type of Surgery Approach and Surgery Complications

Independent variable		Dependent variable		Statistical test
Name	Type	Name	Type	
Type of surgery approach	Dichotomous	Surgery complications	Dichotomous	Risk estimate

Threats to Validity

External Validity

A post-test situation factor may threaten the external validity of this research as the post-test needed to be administered to the participants 3 months following their surgery, but the coding variable book did not stipulate how these cases were treated. I assumed that some participants for personal or organizational issues were not able to participate in the post-test at exactly three months after the surgery. To reduce this possible bias, participants that completed the posttest outside of this time frame (before the 3 months or 1 week or more after the 3 months) were excluded from the research. Additionally, racial data were not collected for this research as it is illegal in France to include racial information in research, thus limiting the ability to compare the results to those of other studies that analyzed racial data. The dataset did not include participant economic status; however, because France has universal healthcare coverage, the economic status of participants may not interfere in their abilities to access healthcare. Racial data and economic status of participants are two external validity issues that were identified and treated as limitations of the study.

Internal Validity

I used a research control trial. Participants were randomized into two groups; however, it was impossible to have a blind approach as the ERAS procedure requires participant involvement and healthcare professionals specific to the intervention. To reduce the potential bias for not applying blinding, the protocol of ERAS was followed by all the professionals, as patients assigned to the ERAS protocols had this information clearly stated in their records and a special colored hand bracelet was given to them. Attrition, diffusion, and maturation will not be an issue because the participant groups were not able to discuss with each other as the collected data was done twice on a three-month time frame. Thus, the effect of statistical regression and instrumentation will be limited. Nonetheless, a certain degree of possible experimenter bias exists because numerous healthcare professionals interacted with the participants, and therefore, different attitudes of healthcare professionals may have interfered with the participant experience. To reduce this bias, all healthcare professionals that were in contact with patients were trained on the ERAS approach as explained by the variable code book explanation guide.

Ethical Information

I used secondary data to answer the research question and hypotheses. Using secondary data for research is described as a highly ethical practice because it takes full advantage of the participants' investment in data collection and ensures the replicability and transparency of the research procedures and integrity of research work. To ensure that the data collection was conducted in an ethical way, I have investigated the following

two points: if the participants in the primary data collection gave their consent formally by signing an authorization of data collection at the hospital admission, and if the traditional and the ERAS surgery techniques are approved by the orthopedic board as the best currently available hip replacement treatments, so participants received the best available care.

The secondary dataset used for this research was de-identified before the release of the data file that was in a Microsoft Excel format. However, the file contained the social security number of the participants, and therefore, to enforce the anonymity and remove any possibility that a participant could be retraced, I deleted this field. The outcome of this study will deliver no information that can be used to retrace the participants. Due to the limited number of participants in the ERAS program in this geographic region, the name of the hospital and physicians have been redacted to reduce the ability to retrace the hospital where this data was collected. No conflict of interest or power differentials, incentives, or work environment conflicts existed for accessing this dataset. The dataset was entered on a safe laptop that uses biometric protection to secure the safety of the laptop and the data. I and the dissertation committee had access to the data during the elaboration of this study. After that, all related work will be stored for 5 years on an encrypted and password-secured USB flash drive that has government-approved medical record storage ability. The USB flash drive will be destroyed in five years by me. Additionally, consent from the institution that delivered the dataset was collected (see Appendix D). The Walden University Institutional Review Board (IRB) approved this study (#11-26-19-0545165) before I started the treatment of the data.

Summary

I used a quantitative research control trial approach to answer research questions and test hypotheses to evaluate the effect of the ERAS surgery approach, compared with the traditional approach, on patients who underwent total hip replacement surgery. The EQ-5D-5L and EQ-VAS instruments were used to evaluate QOL of patients before and after the surgery. Potential confounding variables were discussed based on the literature review in Chapter 2 and investigated during data analysis. Data analysis and strategies were determined to answer the research questions. Internal and external research validity were discussed, and strategies to limit their impact and some research limitations were identified. In Chapter 4, results of the conducted data analyses are presented.

Chapter 4: Results

The purpose of this study was to compare QOL of patients who have undergone a hip replacement surgery using the ERAS and the traditional surgery techniques in the western region of the city of Paris, France. The research questions are as follows:

RQ1: Accounting for the effects of mobility, self-care, usual activity, pain or discomfort, and anxiety or depression, is the average EQ-5D-5L index as a measure of QOL significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery technique?

$H_0 1$*:* Accounting for the effects of mobility, self-care, usual activity, pain or discomfort, and anxiety or depression, the average EQ-5D-5L index as a measure of QOL does not significantly differ among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery technique.

$H_a 1$*:* Accounting for the effects of mobility, self-care, usual activity, pain or discomfort, and anxiety or depression, the average EQ-5D-5L index as a measure of QOL does significantly differ among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery technique.

RQ2: Is average LOS significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery?

$H_0 2$*:* Average LOS is not significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery.

$H_a 2$*:* Average LOS is significantly different among patients who have undergone an ERAS hip replacement surgery compared to the traditional surgery.

RQ3: Is risk of complications due to surgery significantly different among patients who have undergone an ERAS hip replacement surgery compared to traditional surgery?

$H_0$3: Risk of complications due to surgery is not significantly different among patients who have undergone an ERAS hip replacement surgery compared to traditional surgery.

H_a3: Risk of complications due to surgery is significantly different among patients who have undergone an ERAS hip replacement surgery compared to traditional surgery.

In this chapter, I explain results of descriptive and multivariate analyses that have been performed to answer the research questions. First, I present descriptive analyses, which include demographic characteristics of sample participants. Second, I present for each research question its corresponding hypotheses, statistical tests, and results of multivariable analyses. The chapter ends with a summary.

Data Collection

This study involved a secondary dataset containing 300 individuals who participated between January 2017 and November 2019 in total hip replacement surgery with or without the ERAS approach. I sought permission to access this dataset from a hospital located in the western region of Paris, France. Once the hospital and Walden University IRB gave their consent to access the dataset, a data information technician employed by the hospital, with my assistance, extracted an anonymous data file respecting the inclusion criteria of this study. The hospital general database contained

300 patients who had total hip replacement surgery during the period. Only 224 patients were included in this study, which was an 84% retention rate. The major cause of exclusion was incomplete medical follow up, which rendered comparisons before and after surgery impossible.

G*power software was used to determine that to ensure multivariate results with at least a power of 80% and an $\alpha = 0.05$, and a sample size of 105 participants was required per group for the *t*-test and 57 participants for the Wilcoxon test to be statistically significant. The data set contained 224 participants; thus, the sample was enough for this study. Additionally, the 224 participants reside in western Paris, and incidences of hip surgery in western Paris is comparable to national statistics.

Study Results

Descriptive Data for Gender

As shown in Table 7, The ERAS group consisted of 117 participants or 52.2% of the total sample, and the traditional group consisted of 107 participants or 47.7%. The ERAS group consisted of 117 participants, of which 34% were male and 66% were female. The traditional group was constituted of 107 participants, of which 25.2% were male and 74.7% were female.

Table 7

Frequency Table by Gender and Type of Surgery

		Type of surgery		
		ERAS n (%)	Traditional n (%)	Total
Gender	Male	40 (34.1%)	27 (25.2%)	67 (30%)
	Female	77 (65.9%)	80 (74.7%)	157 (70%)
Total		117 (52.2%)	107 (47.7%)	224 (100%)

Table 8 shows the results of the chi-square analysis revealed a nonsignificant association between gender and type of surgery: $\chi 2(1, N = 224) = 2.13$, $p = .14$. Thus, I conclude that there is no statistically significant association between gender and type of surgery.

Table 8

Chi-Square Tests for Gender and Type of Surgery

	Value	Df	*p-value*
Pearson Chi-Square	2.13[a]	1	.14
Continuity Correction	1.73	1	.18
Likelihood Ratio	2.14	1	.14
Fisher's Exact Test			
Linear-by-Linear Association	2.12	1	.14
N of Valid Cases	224		

a. 0 cells (0.0%) have expected count less than 5.

The minimum expected count is 32.00.

b. Computed only for a 2x2 table

Descriptive Data for Age

Table 9 shows the mean age of the ERAS group was 78 years old (*SD* = 7.1). The traditional hip replacement group consisted of 107 participants, and the mean age of the group was 77.7 years old (*SD* = 7.2).

Table 9

Average Age by Type of Surgery

Type of surgery	N	M	SD
Traditional	107	77.72	7.24
ERAS	117	78.04	7.14
Total	224	77.89	7.17

Table 10 shows the frequency distribution of age of ERAS and traditional participants by age group.

Table 10

Number of Participants by Age and Type of Surgery

		Type of surgery		
		Traditional n (%)	ERAS n (%)	Total n (%)
Age group	65 – 74	38 (17%)	40 (18%)	78 (35%)
	75 – 84	44 (20%)	52 (23%)	96 (43%)
	85+	25 (11%)	25 (11%)	50 (22%)
Total		107 (47.7%)	117 (52.2%)	224 (100%)

Table 11 show the Chi-Square test results of age group and type of surgery. The results of the chi-square analysis revealed to be nonsignificant statistically between age and type of surgery: $\chi 2(2, N = 224) = .272$, $p = .873$. Thus, I conclude that there is no statistically significant association between age group and type of surgery.

Table 11

Chi-Square Tests Age and Type of Surgery

	Value	df	*p-value*
Pearson Chi-Square	.27[a]	2	.87
Likelihood Ratio	.27	2	.87
Linear-by-Linear Association	.00	1	.94
N of Valid Cases	22		

a. 0 cells (0,0%) have expected count less than 5. The minimum expected count is 23,88.

Research Question 1

224 participants were recruited to take part in the intervention designed to identify whether quality of life was significantly different among patients who have undergone an ERAS hip replacement surgery and those who have undergone the traditional surgery. The 224 participants that required a hip surgery were assigned to either the traditional surgery or the ERAS surgery group. Their QOL was measured before and after the surgery using the EQ-5D-5L as an objective measure, and EQ-VAS as a subjective measure.

First, the QOL was viewed under the scope of the EQ-5D-5L view. Table 12 shows the mean of the pre- and post-surgery EQ-5D-5L tests. The traditional group had an EQ-5D-5L mean of 15.2 (SD = 3.11) prior to intervention and improved to 19.6 (SD = 3.13) post-intervention. The ERAS group had an EQ-5D-5L mean of 15 (SD = 3.2) before the intervention and improved to 20.9 (SD = 2.5) post-intervention.

Table 12

Average of Pre and Posttest EQ-5D-5L Scores by Type of Surgery

	Type of surgery	N	M	SD
Pretest EQ-5D-5L	Traditional	107	15.26	3.11
	ERAS	117	15.04	3.21
	Total	224	15.15	3.16
Posttest EQ5D5L	Traditional	107	19.62	3.13
	ERAS	117	20.94	2.57
	Total	224	20.31	2.92

Table 13 shows the results of the paired samples *t-test* by type of surgery for the EQ-5D-5L pre- and post-test. There was a significant difference in the scores of traditional surgery type for EQ-5D-5L pre-test (M = 15.26, SD = 3.13) and EQ-5D-5L post-test scores (M = 19.62, SD = 3.13) conditions; t(106)=-10.29, p=.000. Additionally, there was a significant difference in the scores of ERAS surgery type for EQ-5D-5L pre-test (M = 15.04, SD = 3.21) and EQ-5D-5L post-test scores (M = 20.94, SD = 2.57) conditions; t(116)=-15.11, p=.000. These results suggest that type of surgery affects the quality of life after surgery. Specially, the results suggest that when a patient have an ERAS surgery, his objective quality of life post-surgery score increases more compared to the traditional surgery (see Figure 1).

Table 13

Paired Samples t-test by type of surgery for the EQ-5D-5L Pre and Posttest

Type of surgery			M	SD	$\sigma_{\bar{x}}$	95% CI LL	95% CI UL	t	df	*p-value*
Traditional	Pair 1	Pre-test EQ5D5L – Post-test EQ5D5L	-4.35	4.37	.423	-5.19	-3.51	-10.29	106	.000
ERAS	Pair 1	Pre-test EQ5D5L – Post-test EQ5D5L	-5.89	4.2	.390	-6.67	-5.12	-15.11	116	.000

Note. $\sigma_{\bar{x}}$ = Standard error mean; CI = confidence interval; LL = lower limit; UL = upper limit.

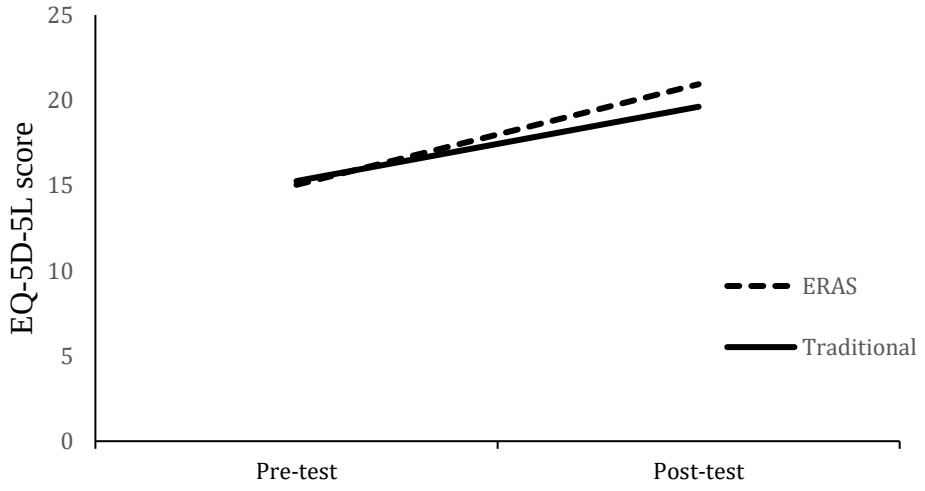

Figure 1. Pretest and posttest EQ-5D-5L mean results

Then, the QOL was viewed under the scope of the EQ-VAS view. Table 14 shows the mean of the pre- and post-surgery EQ-VAS tests showed that the traditional group had an EQ-VAS mean of 85.2 (SD = 6) before surgery and increased to 88.1 (SD = 5.9)

post-intervention. The ERAS group had an EQ-VAS mean of 84.1 (SD = 5.9) before surgery and improved to 91.6 (SD = 5.3) post-intervention.

Table 14

Average EQ-VAS Pre-Score and Posttest Score by Type of surgery

	Type of Surgery	N	M	SD
EQ-VAS Pre-test	Traditional	107	85.25	6.05
	ERAS	117	84.18	5.96
EQ-VAS Post-test	Traditional	107	88.15	5.94
	ERAS	117	91.67	5.37

Table 15 shows the results of the paired samples *t-test* by type of surgery for the EQ-VAS pre- and post-test. There was a significant difference in the scores of traditional surgery type for EQ-VAS pre-test (M = 85.25, SD = 6.05) and EQ-VAS post-test scores (M = 88.15, SD = 5.96) conditions; t(106)=94.45 , p=.000. Additionally, there was a significant difference in the scores of ERAS surgery type for EQ-VAS pre-test (M = 84.18, SD = 5.96) and EQ-VAS post-test scores (M = 91.67, SD = 5.37) conditions; t(116)=105.97, p=.000. These results suggest that type of surgery affects the quality of life after surgery. Specially, the results suggest that when a patient have an ERAS surgery, his subjective quality of life post-surgery score increases more compared to the traditional surgery.

Table 15

Paired Sample t-test by Type of Surgery for the EQ-VAS Pre – and Posttest

						95% CI				
			M	SD	$\sigma_{\bar{x}}$	LL	UL			
Traditional	Pair 1	EQ-VAS Pre-test – Post-test EQ5D5L	65.63	7.188	.695	64.25	67.01	94.45	106	.000
ERAS	Pair 1	EQ-VAS Pre-test – Post-test EQ5D5L	63.23	6.455	.597	62.05	64.42	105.97	116	.000

Note. $\sigma_{\bar{x}}$ = Standard error mean ; CI = confidence interval; LL = lower limit; UL = upper limit.

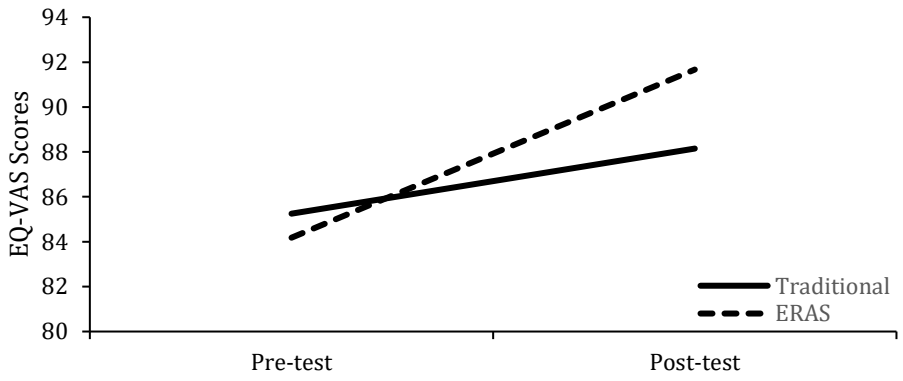

Figure 2. Pre and posttest EQ-VAS mean results

Further exploration for the EQ-5D-5L dimensions. Mobility, self-care, usual activity, pain or discomfort, and anxiety or depression are the five dimensions of ED-5D-5L. Table 16 shows collected traditional surgery and ERAS scores on two separate occasions. The initial occasion took place before the intervention and the second occasion was at three months after surgery. A McNemar test was used to seek if a greater proportion of patients having inability to moderate problem in the different EQ-5D-5L dimensions before intervention improved their status to slight or no problem after

surgery. Table 17, 18, and 19 shows significant differences in the proportions of responses to the mobility $\chi 2$ (10) = 46.84, p = .000, pain $\chi 2$ (10) = 40.55, p = .000, and anxiety or depression $\chi 2$ (10) = 29.68, p = .001 for the ERAS group.

Table 16

Proportions of EQ-5D-5L Dimensions Responses Before and After Surgery

	Before surgery		After surgery	
	Traditional n (%)	ERAS n (%)	Traditional n (%)	ERAS n (%)
Mobility				
Unable to walk	16 (15%)	15 (12.8%)	3 (2.8%)	2 (1.7%)
Severe problems	16 (15%)	25 (21.4%)	0 (0%)	3 (2.6%)
Moderate problems	28 (26.2%)	26 (22.2%)	16 (15%)	24 (20.5%)
Slight problems	27 (25.2%)	27 (23.1%)	43 (40.2%)	36 (30.8%)
No problems	20 (18.7%)	24 (20.5%)	45 (42.1%)	52 (44.4%)
Self-care				
Unable to wash or dress	7 (6.5%)	23 (19.7%)		
Severe problems	34 (31.8%)	35 (29.9%)	4 (3.7%)	3 (2.6%)
Moderate problems	30 (28%)	25 (21.4%)	27 (25.2%)	13 (11.1%)
Slight problems	19 (17.8%)	12 (10.3%)	32 (29.9%)	36 (30.8%)
No problems	17 (15.9%)	22 (18.8%)	44 (41.1%)	65 (55.6%)
Usual activity				
Unable to do usual activities	24 (22.4%)	22 (18.8%)		
Severe problems	26 (24.3%)	24 (20.5%)	7 (6.5%)	7 (6%)
Moderate problems	18 (16.8%)	31 (26.5%)	18 (16.8%)	12 (10.3%)
Slight problems	15 (14%)	21 (17.9%)	30 (28%)	38 (32.5%)
No problems	24 (22.4%)	19 (16.2%)	52 (48.6%)	60 (51.3%)
Pain				
Extreme pain/discomfort	20 (18.7%)	20 (17.1%)	2 (1.9%)	1 (0.9%)
Severe pain/discomfort	27 (25.2%)	24 (20.5%)	14 (13.1%)	6 (5.1%)
Moderate pain/discomfort	15 (14%)	25 (21.4%)	22 (20.6%)	23 (19.7%)
Slight pain/discomfort	21 (19.6%)	24 (20.5%)	32 (29.9%)	36 (30.8%)
No pain/discomfort	24 (22.4%)	24 (20.5%)	37 (34.6%)	51 (43.6%)
Anxiety/depression				
Extremely anxious/depressed	18 (16.8%)	17 (14.5%)	18 (16.8%)	4 (3.4%)
Severely anxious/depressed	23 (21.5%)	25 (21.4%)	13 (12.1%)	9 (7.7%)
Moderately anxious/depressed	18 (16.8%)	31 (26.5%)	21 (19.6%)	21 (17.9%)
slightly anxious/depressed	24 (22.4%)	21 (17.9%)	25 (23.4%)	31 (26.5%)
Not anxious/depressed	24 (22.4%)	23 (19.7%)	30 (28%)	52 (44.4%)

Table 17

McNemar Test for Mobility Pre and Post-Surgery

Type of surgery		Value	df	*p-value*
1	McNemar-Bowker Test	.	.	.[a]
	N of Valid Cases	107		
2	McNemar-Bowker Test	46.84	10	.000
	N of Valid Cases	117		
Total	McNemar-Bowker Test	78.68	10	.000
	N of Valid Cases	224		

a. Computed only for a PxP table, where P must be greater than 1.

Table 18

McNemar Test for Pain and Pre and Post Surgey

		Value	df	*p-value*
Traditional	McNemar-Bowker Test	28.37	10	.002
	N of Valid Cases	107		
ERAS	McNemar-Bowker Test	40.55	10	.000
	N of Valid Cases	117		
Total	McNemar-Bowker Test	63.62	10	.000
	N of Valid Cases	224		

Table 19

McNemar Test for Anxiety Pre and Post Surgery

		Value	df	*p-value*
Traditional	McNemar-Bowker Test	10.32	10	.412
	N of Valid Cases	107		
ERAS	McNemar-Bowker Test	29.68	10	.001
	N of Valid Cases	117		
Total	McNemar-Bowker Test	26.44	10	.003
	N of Valid Cases	224		

Research Question 2

Exploration of length of stay data as shown in Figure 3 demonstrates that there is one extreme outlier detected in the traditional surgery group that was more than 3 box-lengths from the edge of the box in a boxplot. Inspection of this value revealed that this one entry was a genuinely unusual value, and it was kept in the analysis. Additionally, as shown in Figure 3, numerous outliers were detected (eight outliers, two extreme outliers) in the ERAS surgery participant sample. Inspection of their values revealed that these entries were genuinely unusual values, and they were kept in the analysis because the results were not affected when these outliers were removed compared to if there were kept. The differences between the distance ran in the traditional surgery and the ERAS surgery were normally distributed, as assessed by visual inspection of a normal Q-Q plot in Figure 4.

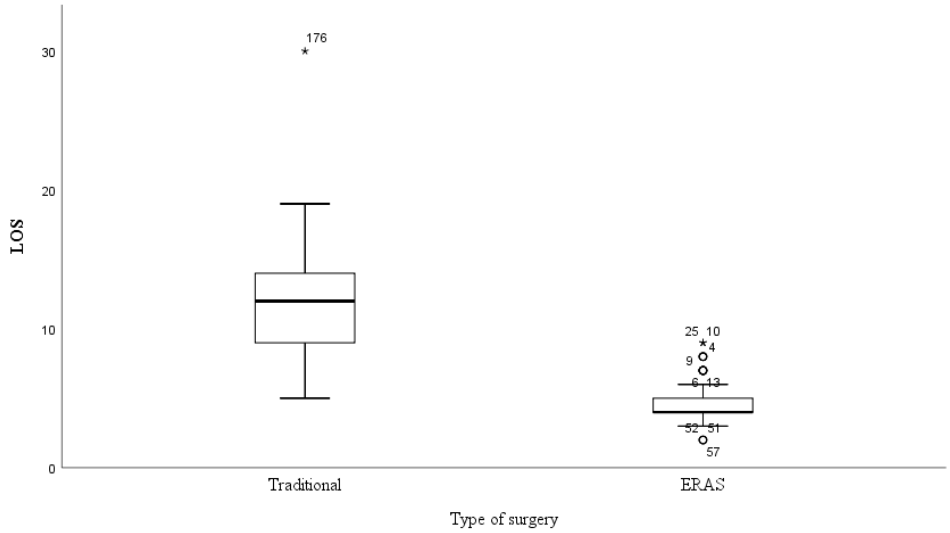

Figure 3. Boxplot of LOS of the ERAS surgery group

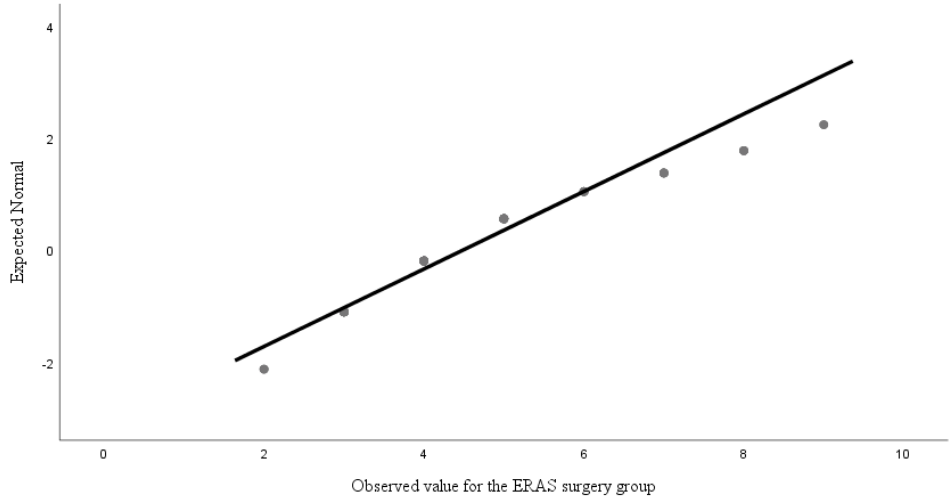

Figure 4. Q-Q plot of LOS in days for ERAS surgery

A *t*-test was conducted to determine whether there was a statistically significant mean difference between the length of stay in hospital after the surgery done by the traditional or the ERAS surgery approach. Sample size analysis for the *t*-test was conducted using the recommendations established in G*power to determine a sufficient sample size using an alpha of 0.05, a power of 0.80, a normal effect size (d = 0.5), and a two-tailed test. Based on the inputs into G*power3, a total sample size of 105 patients per group was needed; the sample size of this study was larger. Table 20 demonstrates the length of stay in the total group mean, which was 7.8 days (SD = 4.3). The ERAS group had a LOS mean of 4.4 days (SD = 1.4) days compared to the traditional group that had a mean of 11.4 days (SD = 3.5).

Table 20

Mean Table for Length of Stay by Surgery Approach in Days

Type of surgery	N	M	SD
Traditional	107	11.45	3.57
ERAS	117	4.49	1.44
Total	224	7.81	4.39

Results in Table 21 showed that the mean length of stay of patients having ERAS is M = 4.4 days (SD = 1.44), and traditional approach is M = 11.45 days (SD = 3.57) was statistically significant at the .05 level of significance $t(137.3) = 18.78$, $p = .00$, with ERAS length of stay shorter than the traditional surgery approach. In conclusion, there is a difference between the length of stay between patient undergoing the ERAS or the traditional hip replace surgery. Patient who undergo an ERAS approach had a shorter length of stay compared to the traditional surgery approach, as demonstrated in Figure 5.

Table 21

Independent Samples t-test LOS and Type of Surgery

		Levene's Test		*t-test* for Equality of Means						
									95% CI	
		F	Sig.	T	df	α	M	SD	LL	UL
LOS	Equal variances assumed	50.11	.000	19.39	222	.000	6.96	.359	6.25	7.66
	Equal variances not assumed			18.78	137.37	.000	6.96	.371	6.22	7.69

Note. CI = confidence interval; LL = lower limit; UL = upper limit.

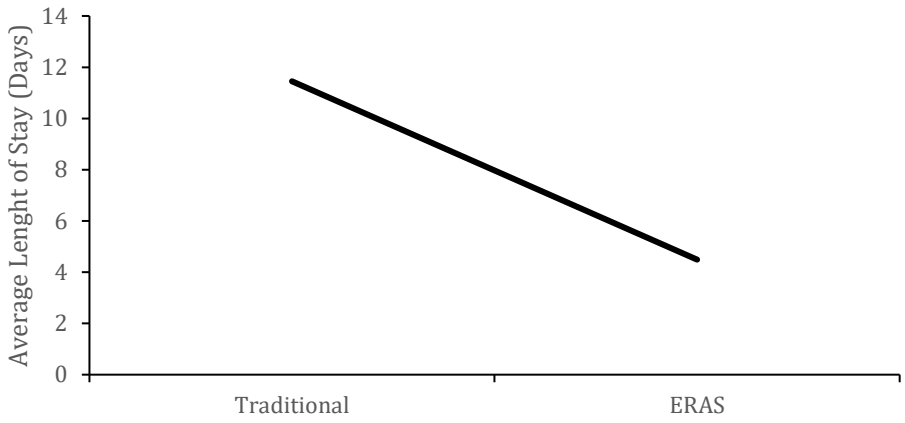

Figure 5. Average length of stay by surgery approach

Research Question 3

Table 22 shows descriptive statistics of surgery complication and type of surgery. In the whole sample, 79.5% of the total sample developed one or more complications after surgery. In the ERAS group, 80.3% of participants developed one or more complications after surgery, compared to 78.5% in the traditional group. Surgery complications were categorized into two categories based on the higher health French authority (2017) indication that total hip surgery should result in zero complications after surgery as an indicator of surgery quality and security. The first category is composed of no post-surgery complications, and the second category is composed of one or more post-surgery complications.

Table 22

Proportions of Surgery Complications by Type of Surgery

		Type of surgery		Total n (%)
		Traditional n (%)	ERAS n (%)	
Surgery complication	0	23 (21.5%)	23 (20%)	46 (20%)
	1or more	84 (78.5%)	94 (80%)	178 (80%)
Total		107 (100%)	117 (100%)	224 (100%)

As shown in Table 23, the results of the chi-square analysis revealed a nonsignificant association between length of stay and type of surgery: $\chi 2(1, N = 224) = .116$, $p = .734$. Thus, I conclude that there is no statistically significant association between surgery complication and type of surgery.

Table 23

Chi-Square Tests of Surgery Complications and Type of Surgery

	Value	df	*p-value*
Pearson Chi-Square	.116[a]	1	.734
N of Valid Cases	224		

a. 0 cells (0,0%) have expected count less than 5. The minimum expected count is 21,97.

b. Computed only for a 2x2 table

Table 24 shows that the odds ratio of traditional surgery approach participant to the ERAS surgery approach participant is 1.11, 95% CI [.85, 1.11]. This result is not statistically significant, however clinically it demonstrates that ERAS participants had 6% less risk of developing a post-surgery complication compared to the traditional approach.

Table 24

Risk Estimate Calculation

		95% Confidence Interval	
	Value	LL	UL
Odds Ratio for type of surgery (traditional / ERAS)	1.11	.58	2.14
For cohort complication = no complications	1.06	.65	1.83
For cohort complication = 1 complication and more	.94	.85	1.11
N of Valid Cases	224		

Summary

Two hundred twenty-four participants who underwent a hip replacement surgery were enrolled in the study and assigned to either the traditional surgery approach group or the ERAS surgery approach group. Regarding the results of the descriptive statistics, the results showed that the sample demographics represent the population of France.

The results demonstrated that there was a significant difference in the scores of traditional surgery type for EQ-5D-5L pre-test (M = 15.26, SD = 3.13) and EQ-5D-5L post-test scores (M = 19.62, SD = 3.13) conditions; t(106)=-10.29, p=.000. Additionally, there was a significant difference in the scores of ERAS surgery type for EQ-5D-5L pre-test (M = 15.04, SD = 3.21) and EQ-5D-5L post-test scores (M = 20.94, SD = 2.57) conditions; t(116) = -15.11, p = .000. Moreover, there was a significant difference in the scores of traditional surgery type for EQ-VAS pre-test (M = 85.25, SD = 6.05) and EQ-VAS post-test scores (M = 88.15, SD = 5.96) conditions; t(106)=94.45 , p=.000, and there was a significant difference in the scores of ERAS surgery type for EQ-VAS pre-test (M = 84.18, SD = 5.96) and EQ-VAS post-test scores (M = 91.67, SD = 5.37) conditions; t(116)=105.97, p=.000.

There was no statistical significance in gender when comparing it to QOL before or after surgery $\chi 2(1, N = 224) = 2.13$, $p = .14$. Moreover, age did not demonstrate a statistical significance $\chi 2(2, N = 224) = .272$, $p = .873$ when comparing it to quality of life results. Mobility $\chi 2\ (10) = 46.84$, $p = .000$, pain $\chi 2\ (10) = 40.55$, $p = .000$, and anxiety or depression $\chi 2\ (10) = 29.68$, $p = .001$ were statistically significant in the ERAS post -surgery group. Additionally, the ERAS surgery approach demonstrated a reduced length (M = 4.4 days, SD = 1.4) compared to the traditional approach (M = 11.44 days, SD = 3.57) and was statistically significant $t(137.3) = 18.78$, $p = .00$. Finally, ERAS participants had 6% less risk of developing a post-surgery complication compared to the traditional approach.

In Chapter 5, a discussion and summary of study results are provided along with study limitations, recommendations, and future research recommendation. Also, in the chapter, implications of the results are discussed, and conclusions are drawn.

Chapter 5: Discussion, Conclusions, and Recommendations

This research control trial was comprised of 224 participants who required a hip replacement surgery. I then divided the participants into one of two groups: traditional or ERAS surgery approach. The results demonstrated that QOL measured with objective (ED-5D-5L) and subjective (EQ-VAS) scales demonstrated an increase of QOL using the ERAS approach compared to the traditional approach. Additionally, the ERAS approach was associated with a reduced LOS compared to the traditional approach. However, it was less risky to develop a surgery complication by 6% to undergo a hip surgery using the ERAS approach compared to the traditional approach. In Chapter 5, interpretations of findings, limitations of the study, recommendation, and implications are discussed.

Interpretation of Findings

The theoretical foundation of this study is the integrated QOL theory. Thus, the study captured QOL within the sample of participants in this study. It was important to use an instrument that evaluated QOL both subjectively and objectively. The EQ-5D-5L is a standardized measure of QOL that objectively measures QOL, is standardized to surgery procedures, and validated in terms of cultural differences of the region where study was completed. The EQ-VAS is a self-rating scale that records participants' own assessment of QOL that reflects the subjective QOL spectrum. For these reasons, in this study, EQ-5D-5L and EQ-VAS scoring was done before and after hip replacement surgery for both the ERAS and traditional samples and 84% of the initial sample was retained during the follow up to participate in this study.

A traditional hip replacement surgery negatively impacts QOL (Goosen, de Wolf, Verheyen, 2011; Ryan et al., 2006). Mariconda et al. (2016) found that functional status was regained by 57% of patients to the state before the surgery. Comans et al. (2013) reported only 11% of their participants that had a traditional approach regained their QOL. There is no existing research comparing QOL of patients who underwent ERAS surgery approaches to patients who underwent traditional approaches in hip replacement; this can be explained by the fact that the hip replacement ERAS began only in 2018. This study extends the knowledge in this field as it compared traditional and ERAS hip replacement surgery participants.

The results demonstrated that there was a significant statistical difference between traditional surgery scores for the EQ-5D-5L pre- (M = 15.26, SD = 3.13) and posttest scores (M = 19.62, SD = 3.13; t(106)=-10.29, p = .000). Additionally, there was a statistical significant difference between ERAS surgery scores for the EQ-5D-5L pretest (M = 15.04, SD = 3.21) and posttest scores (M = 20.94, SD = 2.57; t(116)=-15.11, p=.000). This study demonstrated that there is a statistical difference between hip replaced surgery participants' QOL. Moreover, there was a statistical significant difference between traditional surgery type scores for the EQ-VAS pre- (M = 85.25, SD = 6.05) and posttest scores (M = 88.15, SD = 5.96; t(106)=94.45, p = .000), and there was a statistical significant difference between ERAS surgery type scores for the EQ-VAS pre- (M = 84.18, SD = 5.96) an posttest scores (M = 91.67, SD = 5.37; t(116)=105.97, p=.000). Hip surgery done using the traditional or ERAS approach both lead to a better

QOL after surgery; however, ERAS patients had higher EQ-5D-5L and EQ-VAS scores compared to the traditional approach.

Additionally, there was no statistical significance in terms of gender between QOL before or after surgery ($\chi 2(1, N = 224) = 2.13$, $p = .14$). Moreover, age did not demonstrate a statistical significance ($\chi 2(2, N = 224) = .272$, $p = .873$) when comparing it to QOL results of the studies sample. Mobility ($\chi 2\ (10) = 46.84$, $p = .000$), pain ($\chi 2\ (10) = 40.55$, $p = .000$), and anxiety or depression ($\chi 2\ (10) = 29.68$, $p = .001$) were statistically significant in the ERAS post-surgery group.

Abeles et al. (2017) said that ERAS programs in digestive and gynecology surgery reduce LOS for patients compared to the traditional surgery technique; however, no data is available regarding ERAS hip replacement surgery. This research demonstrates that participants who underwent an ERAS surgery had their length of stay in hospital reduced by 6.96 days (± 2) compared to the traditional approach. This can be explained by the fact that ERAS participants were prepared before the surgery by a multidiscipline paramedical and medical team, thus reducing in-hospital stay. Preparations were done using groups of patients, thus reducing costs of the whole surgery procedure.

The odds ratio of traditional to ERAS surgery approach participants is 1.11, with 95% CI [.85, 1.11]. This result is not statistically significant; however, clinically it demonstrates that ERAS participants had 6% less risk of developing a post-surgery complication compared to the traditional approach.

After the comprehensive literature review, it was assumed that this study is the first study that evaluated risk calculations for complications comparing traditional and ERAS hip replacement surgery approaches.

Limitations of the Study

This study was limited to legal French residents who were 18 years or older and live in the western area of the city of Paris. Therefore, findings from this study cannot be generalized to other populations ethnicities, or ages, although the findings of the current study may be applicable to another French region. However, recommendations from this study could represent national French population characteristics.

Secondly, this study was a research control trial in nature; therefore, caution should be used when drawing conclusions about relative risk calculations of post-surgery complications, as the larger the sample is, the more precise the risk calculation will be. It is important to note that the relative risk calculation might change if the sample size is larger.

Third, the ERAS hip replacement surgery approach is a recent approach that is not well documented, and thus some of the information about the covariates might evolve depending on results of future studies.

Recommendations

For future research, it might be recommended to have multiple QOL evaluations during different timeframes after surgery at one, two and three years to evaluate if there is a statistically significant change in participant QOL over time.

It is advisable to increase the number of participants in future research control trial studies to have better effect size results. Additionally, it is recommended to investigate why ERAS hip replacement surgery participants had more post-surgery complications after surgery compared to traditional surgery participants. Moreover, it might be interesting to explore the actions of the ERAS protocol that most reduced LOS after surgery. The larger the sample size is, the more accurate the relative risk calculation is, and thus it is recommended to increase the sample size of each ERAS surgery approach to have more reliable results.

Implications

Positive social change may be accomplished through healthcare professionals better understanding the ERAS hip replacement approach to improve patients' quality of life and reduce length of stay in hospitals. An ERAS approach in hip surgery may increase quality of life of affected people by applying proven strategies to reduce patient burdens before, during, and after the surgery by associating and combining the efforts of multiple healthcare professionals in an orderly manner throughout the process. Patients who improve their QOL and reduce their length of hospital stay will be able to get back to their daily activities faster, reducing their and public health financial burdens. The ERAS approach will also positively affect the healthcare sector, as surgery departments will be able to include more patients requiring this surgery because the LOS is reduced compared to the traditional approach, and the demand for this surgery is increasing by the day. Finally, public health spending and use of community resources will be reduced as

ERAS patients require less assistance, and thus, the ERAS approach is a key element to better invest in other health preventive actions.

Conclusions

The life expectancy of people is increasing, and thus, hip replacement surgery will continue to increase. The ERAS approach applied to hip replacement surgery has been demonstrated to increase patients' quality of life after surgery and to reduce the in-hospital length of stay compared to the traditional hip replacement surgery. However, the ERAS surgery applied to hip replacement demonstrated the same risk of complication after surgery as the traditional surgery; thus, further investigation might be helpful. Additionally, the ERAS approach has side effects, such as reduced cost of hip replacement surgery and reduced length of stay, which decreases the burden on the public health finances. ERAS also impacts societal change as elderly individuals undergoing a hip replacement surgery will be back to their daily routines and families faster than the actual traditional approach.

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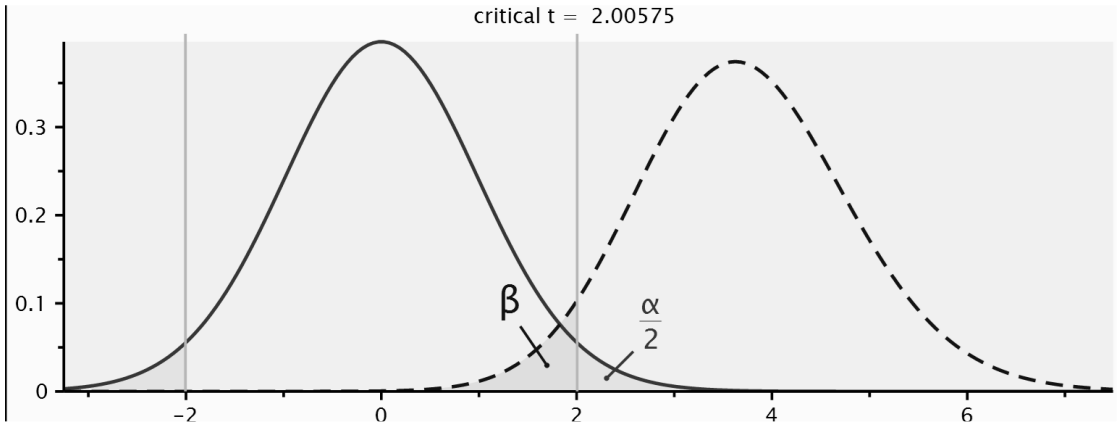
Appendix A: Power Analysis and Sample Size Estimation for Paired *t*-Test

t tests – Means: Difference between two dependent means (matched pairs)

Analysis:	A priori: Compute required sample size		
Input:	Tail(s)	=	Two
	Effect size dz	=	0.5
	α err prob	=	0.05
	Power (1−β err prob)	=	0.95
Output:	Non centrality parameter δ	=	3.6742346
	Critical t	=	2.0057460
	Df	=	53
	Total sample size	=	54
	Actual power	=	0.9502120



Appendix B: EuroQol Authorisation Letter

Dear Mr. Patrick SERVAT,

Thank you for your registration.
The study / project titled "Quality of life in patient undergone hip replacement surgery with or without an enhanced recovery program" you registered fulfils the conditions for you to use the requested version(s) free of charge.

Below you find our Terms of Use. We will provide you with the requested versions free of charge once we have received your agreement with our Terms of Use. You can indicate your agreement by pressing the green “Agree” button below. If you do not agree, please press “Disagree”.

If you have any questions please contact us by sending an email to userinformationservice@euroqol.org.

Thank you in advance.

Kind regards,

Best regards,

Bernhard Slaap
Executive Director
EuroQol Research Foundation

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Appendix C: EQ-5D-5L Instrument

Under each heading, please check the ONE box that best describes your health TODAY.

MOBILITY

I have no problems walking ❑
I have slight problems walking ❑
I have moderate problems walking ❑
I have severe problems walking ❑
I am unable to walk ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

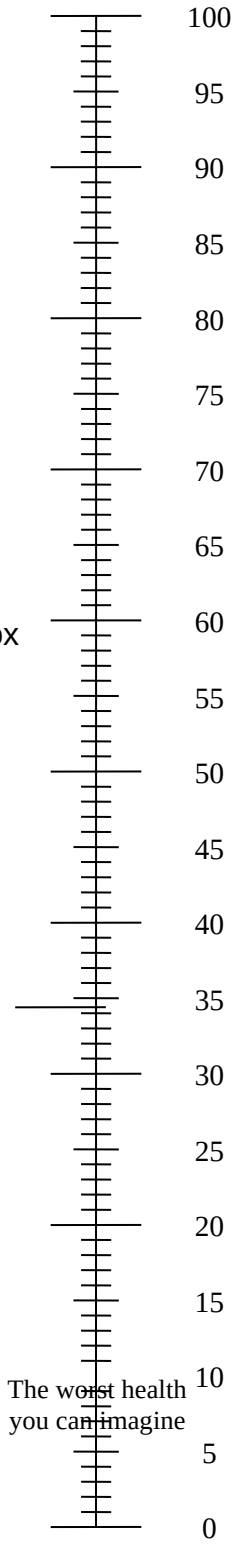
ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.

YOUR HEALTH TODAY = ☐

- Now, please write the number you marked on the scale in the box below.



Appendix D: Consent of Secondary Data Access

DATA USE AGREEMENT

This Data Use Agreement ("Agreement"), effective as of 3 November 2019 ("Effective Date"), is entered into by and between SERVAT Patrick ("Data Recipient") and Trappes Hospital ("Data Provider"). The purpose of this Agreement is to provide Data Recipient with access to a Limited Data Set ("LDS") for use in research in accord with the HIPAA and FERPA Regulations.

1. Definitions. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the "HIPAA Regulations" codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.

2. Preparation of the LDS. Data Provider shall prepare and furnish to Data Recipient a LDS in accord with any applicable HIPAA or FERPA Regulations

Data Fields in the LDS. **No direct identifiers such as names may be included in the Limited Data Set (LDS).** The researcher will also not name the organization in the doctoral project report that is published in Proquest. In preparing the LDS, Data Provider or designee shall include the **data fields specified as follows**, which are the minimum necessary to accomplish the research:

The hospital Trappes represented by Dr Denis Prevot (Head physician and information and medical records department director) approves the release of a Microsoft Excel Sheet containing the following information to the student Patrick SERVAT in order to use the data in his research for obtaining a Ph.d. in public health.

The Microsoft excel file will have the following information:

- Case number
- The gender of the patient
- The age of the patient
- The type of the intervention (ERAS or traditional)
- The EQ-5D-5L and EQ- VAS before surgery
- The EQ-5D-5L and EQ-VAS after surgery
- The length of stay of the patient in the hospital
- The health complications during the hospitalization

The Microsoft excel sheet will contain data for 250 cases.
The data is extracted from our clinical database and will be prepared as such for the student.

The data set is in French it is up to the student to ensure it translation to English, as his dissertation is in English. The hospital is not responsible for translation costs.

We require from the student that he do not state the hospital name in the research but refer to it using the geographic region of "a hospital in the Yvelines" or something similar.

We require that the student uses his university IRB to approve his research.
No hospital internal ethical procedures are required because the data given to the student are anonymous, the student will not be able to know who the participants are, the student will not access the patients.

The student should not sell or use the findings of his research in any kind for his own financial interest. However, the student can share the findings of his research to however he seems fits for free.

The student is a French Licensed nurse and is allowed by the French public health rules and regulations to run independent research under the French regulation and the Nurses order.
We have verified Mr SERVAT Patrick holds a nursing degree and is registered under the number 916763527, and his nurses order number is 2423658.

3. Responsibilities of Data Recipient. Data Recipient agrees to:

a) Use or disclose the LDS only as permitted by this Agreement or as required by law;
b) Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;
c) Report to Data Provider any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law;
d) Require any of its subcontractors or agents that receive or have access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to Data Recipient under this Agreement; and
e) Not use the information in the LDS to identify or contact the individuals who are data subjects.

4. Permitted Uses and Disclosures of the LDS. Data Recipient may use and/or disclose the LDS for its research activities only.

5. Term and Termination.

a) Term. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as Data Recipient retains the LDS, unless sooner terminated as set forth in this Agreement.

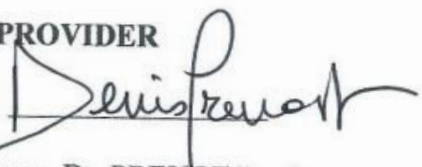
b) Termination by Data Recipient. Data Recipient may terminate this agreement at any time by notifying the Data Provider and returning or destroying the LDS.
c) Termination by Data Provider. Data Provider may terminate this agreement at any time by providing thirty (30) days prior written notice to Data Recipient.
d) For Breach. Data Provider shall provide written notice to Data Recipient within ten (10) days of any determination that Data Recipient has breached a material term of this Agreement. Data Provider shall afford Data Recipient an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for the immediate termination of this Agreement by Data Provider.
e) Effect of Termination. Sections 1, 4, 5, 6(e) and 7 of this Agreement shall survive any termination of this Agreement under subsections c or d.

6. Miscellaneous.

a) Change in Law. The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section 6.
b) Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.
c) No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
d) Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
e) Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

DATA PROVIDER

Signed: 

Print Name: Dr. PREVOT Denis

Print Title: Physician

DATA RECIPIENT

Signed: 

Print Name: SERVAT Patrick

Print Title: Ph.d. Student @ walden