

Performance Improvements in Robotic Joint Surgery Systems in Total & Partial Knee Arthroplasty

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CONTENTS

| | |
|---|-----|
| Abstract..... | 04 |
| Acknowledgments..... | 05 |
| 1. Introduction | 06 |
| 1.1 Context..... | 06 |
| 1.2 Problem Statement..... | 08 |
| 1.3 Research Question and Objectives..... | 09 |
| 2. Material and Methods | 10 |
| 2.1 Material..... | 10 |
| 2.2 Methods | 10 |
| 3. Results..... | 11 |
| 3.1 Introduction to Total & Partial Knee Arthroplasty. | 11 |
| 3.2 Introduction to Robotic Systems in Medicine | 19 |
| 3.3 Advantages and Disadvantages of Robot-Assisted Surgery over Traditional Techniques.. | 30 |
| 3.4 Main Components & Parts..... | 36 |
| 3.5 Interconnection & Interaction among their Parts & Components | 47 |
| 3.6 Mode of operation and human-machine interaction..... | 51 |
| 3.7 Comparison between traditional and robot-assisted surgery regarding speed in various surgical techniques. Metrics and data | 61 |
| 3.8 Comparison between traditional and robot-assisted surgery in terms of accuracy. Metrics and data | 67 |
| 3.9 Comparison between traditional and robot-assisted surgery in terms of caused trauma. Metrics and data | 77 |
| 3.10 Assessments about robot-assisted surgery in terms of ease of handling, stress and fatigue generation, potential limitations, and human-machine interaction during operations. Metrics and data | 86 |
| 3.11 Assessment of patients' perceptions & experiences regarding robot-assisted surgery.... | 90 |
| 3.12 Hardware Improvement Proposals..... | 94 |
| 3.13 Software Improvement Proposals..... | 100 |
| 3.14 Calibration Improvement Proposals..... | 102 |
| 3.15 Sensors Improvement Proposals | 108 |
| 3.16 Optical Markers Improvement Proposals..... | 112 |
| 3.17 Operational Flow Improvement Proposals..... | 117 |
| 4. Discussion..... | 120 |
| 4.1 Interpretation of Results..... | 120 |
| 4.2 Correlation of Results to Research Questions | 120 |
| 4.3 Comparison of Findings to Other Studies..... | 122 |
| 4.4 Explanations for Differing Outcomes..... | 122 |
| 4.5 Strengths and Limitations | 123 |
| 4.6 Contribution to Existing Knowledge | 124 |
| 4.7 Future Steps | 125 |
| 5. Conclusions | 126 |
| References | 127 |

Abstract: Robot-assisted surgery has come into prominence in the last decade, supporting that it fortifies surgeons and patients with a powerful tool, which supposedly offers a more sophisticated approach in terms of precision, accuracy, enhanced speed, less caused trauma, and recovery time after the operation. In this Thesis, we will attempt to investigate these claims and shed light on the various parameters that provide a solid basis or disprove them.

The Introduction is dedicated to the description of Knee Arthroplasty, its various forms, and stages, the various implant types, the numerous techniques surgeons utilise in order to confront the challenges the disease raises, the contribution of robots to the enhancement of their endeavours, and finally, the numerous advantages and disadvantages that this technology brings forth.

In the second chapter, we are occupied with describing the Materials and Methods used for the drafting of this Thesis.

We proceed further in the third chapter with the investigation of Robotic Systems, the interconnection, and interaction among their parts and components, and finally, the Human-Machine interaction that constitutes those systems operational and assistive to the surgeons.

We keep on with the overall performance of those robots, by scrutinising the relevant bibliography to present a comparison between traditional and robot-assisted surgery regarding speed, accuracy, caused trauma, pain duration, and recovery time in various surgical techniques. We incorporate in this chapter's investigation the users' perception regarding Human-Machine interaction and whether these robots aid actually their work or produce, in certain cases, additional problems.

Then, we explore the patients views, who underwent such a procedure, regarding the value that a robot-assisted surgery added to their cases, compared to similar ones who have not experienced it. All those mentioned above are backed by cited metrics and data.

Finally, in the last part of this chapter, we provide our readers with our propositions regarding the improvement strategies that should, according to our opinion, be followed by the manufacturers, in order to present to the Medical World more sophisticated and developed systems in terms of hardware, software, calibration capabilities, sensors' sensitivity, reflectors' placement abilities and life span, and last, but not least, ways and methods towards the simplification of the operational flow.

In the fourth chapter, we open a discussion about the questions and matters arising from our investigation, our contribution to existing knowledge, and whether we have answered the main topics and subjects touched by this particular work of ours.

We end our Thesis content with the conclusions drawn from our investigation in chapter five.

Keywords—, robot-assisted surgery, knee arthroplasty, DoF (Degrees of Freedom), Navitrackers, sensors, robotic arm, Robot Stand, Camera Stand, components interaction, Human Machine interaction, interconnection, hardware, software, Umbilical Cord.

Acknowledgments: The author of this Thesis would like to submit his deepest thanks initially to all the Professors and Associate Professors of the Department, for their tireless efforts and unparalleled will to pass their knowledge to us, the students of this programme. Having studied in the same Department several years ago for my Bachelor's Degree, I am more than eligible to spot the differences and compare objectively the tremendous progress in every aspect. Knowledgeably, and willingly, in terms of attitude and understanding of the various facets of the students' lives, everything has changed and upgraded to a totally new level, approaching the standards of other, highly esteemed Universities around the globe. It was my utmost pleasure to meet all those wonderful people who have undertaken their duties towards students in the most responsible and honourable way.

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1. INTRODUCTION

1.1 Context

Pathology of the knee is one of the most common indications for orthopaedic surgery, worldwide, with the most prevalent condition necessitating surgical intervention in some cases comprising osteoarthritis, while others include trauma and various diseases of the bone and articular tissues [1]. As a result of the marked demand for synthetic joint replacements, knee surgery in particular has become the largest joint reconstruction market and therefore, receiving extensive interest in the academic and biotechnology fields [2].

This has also been reflected in growing publication trends in the literature, suggesting that there have been considerable advances in attempts to improve knee surgery techniques and related outcomes [3]. Demand for knee arthroplasty has been found to have increased by more than 300% over the past decade and as such, so have measures of disease morbidity [4]. On an international level, rising demand for knee surgery has been attributed to ageing populations and parallel increases in obesity, of which, are key risk factors for degenerative disease and thus, osteoarthritis of the knee in view of its being a functional weight-bearing and articular structure [5].

The prevalence of knee osteoarthritis can vary substantially across global regions and by case definition but on a global perspective, cases have been estimated to exceed 650 million, equating to an incidence of around 200 per 10,000 person-years [6]. The UK National Health Service (NHS), serves as the core example for such kind of operations due to the extensive literature and data keeping on the subject, and sets the basis for the rest of European countries that inevitably will follow its example in terms of the introduction of Robotic-assisted Arthroplasty Surgery in their healthcare services, both in extent and cost calculation. So far, almost all European Union countries have placed such systems in private hospitals.

In UK-NHS data, the extent of knee osteoarthritis is considerably high with more than 18% of persons attending primary care and aged over 45 years receiving treatment for knee osteoarthritis. The prevalence of this problem within primary care was reported to be as high as 15% for those aged greater than 85 years and ranging from 3.1-13.9% for those below this age but beyond the age of 45 years [7]. On a population level, records have revealed that over 10 million persons in the UK are living with osteoarthritis (more than 50% of cases affect the knee) and over 350,000 new cases are diagnosed each year [8].

There has also been data to show that the trends in the incidence of osteoarthritis-related hospital admissions in the UK have been steadily increasing over the last few decades, potentially as a result of inadequate care and treatment in primary care and/or due to delays in receiving restorative surgical intervention [9]. A proportion of these cases undergo knee arthroplasty usually in the form of partial or total replacement procedures, of which, more than 100,000 are performed each year: 90% being total replacements, 9% partial replacements and 1% are patellofemoral replacements [10].

In a recent analysis in England, almost 80,000 knee arthroplasty cases were performed in the year 2020/21 and notably, the mean length of stay was four days, although 20% of cases had a duration of stay that exceeded four days: this represents a potential area for improvement in view of the related morbidity incurred, and the associated costs and resource use [4]. Notably, the number of total knee arthroplasty cases is project to continue rising in the future as a result of persistently growing osteoarthritis diagnoses: this is going to incur significant pressures upon the surgical field and one warranting additional capacity and novel ways to meet the demand while improving outcomes [11].

This is, therefore, a key opportunity for robotic-assisted surgical approaches. However, such surgery may not offer a means to tackle the growing waiting lists for knee surgery. Over 730,000 persons within the NHS are currently awaiting knee or hip arthroplasty surgery, which has worsened considerably since the COVID-19 pandemic due to a growing backlog of cases and limited capacity to meet the extensive demand [12]. In Scotland, the number of total knee arthroplasty cases being performed has averaged over 3,000 for the last few years but the mean waiting time is a markedly unacceptable 316 days [12].

However, advances in knee surgery may offer a means to tackling the morbidity of the problem and the related costs and resource use. Indeed, the burden of knee osteoarthritis has been noted within analyses conducted by the Global Burden of Disease collaborators who have shown that the problem contributes to over 180 million disability-adjusted life years each year [13]. This represents around 80% of the total burden of osteoarthritis attributed to that of the knee and trends have shown that the impact upon individuals increases with both weight and age [14]. Thereby, osteoarthritis has been typically ranked in 12th place for the leading causes of disease burden on a global level [15].

Aside from the morbidity incurred by knee osteoarthritis, research has even demonstrated evidence to show that such persons encountered a significant risk of premature mortality. In a population study of the UK Clinical Practice Research Datalink, Swain, et al. [16] showed that the risk of all-cause mortality was 2-fold greater (adjusted hazard ratio 2.09; 95% CI 1.95, 2.21), than

compared to those lacking osteoarthritis. Other studies have also supported a heightened risk of mortality in those with knee osteoarthritis, which highlights an additional avenue for improvement through novel surgical methods [17,18].

Knee osteoarthritis incurs morbidity due to the distressing symptoms it can impose, mostly pain, but also as a result of the function-limiting issues with symptoms and articular destruction reducing mobility and the independence of living [19]. This explains the considerable demand for knee replacement surgery as this offers an effective means to achieving a desirable level of function; surgery tending to provide a normal or near-normal level of pre-morbid function for those affected by knee osteoarthritis. It is also effective in resolving the pain of knee osteoarthritis as surgery removes the underlying source of pain by replacing the diseased articular tissues that would otherwise induce nociception [20].

The adverse impact of knee osteoarthritis upon individuals has also been noted in various qualitative studies and syntheses, which highlight how the problem can impact almost all aspects of persons' prospects and lives on a daily basis [21]. Knee osteoarthritis also incurs a major impact upon healthcare costs with mean per-patient costs averaging £10,000 per year and total costs being in the order of tens of billions per annum [22]. Costs to the NHS average £5-10 billion per year [23]. The UK NHS is publicly funded and therefore, receives finite resources to assist in improving healthcare outcomes and in adopting new technologies due to the associated high costs [24].

1.2 Problem Statement

The core treatment approaches to knee osteoarthritis included conservative non-pharmacological strategies, pharmacotherapy inclusive of intraarticular injections and surgery [25]. Although the former methods are useful options in reducing symptoms and improving function, osteoarthritis is a progressive disease and ultimately, most patients go on to acquire moderate to advanced disease, which becomes resistance or poorly treatable using non-radical therapy and thus, promoting a need for surgical intervention. Non-surgical treatment also co-exists with a range of adverse effects and thereby, surgery can offer a means to avoiding these problems, which can be particularly important in those with comorbidities [26,27].

While knee replacement surgery has led to considerable improvements in outcomes including both clinically important and patient-reported measures, the intervention does possess some limitations with a risk of complications or persistent symptoms and rarely, implant failure or suboptimal implant survival duration [28,29]. Therefore, there remains a key opportunity to

improve outcomes further: robotic-assisted knee surgery potentially offering a valuable solution to achieving this vision.

1.3 Research Question and Objectives

In response to the uncertainty regarding the value and limitations of robot-assisted knee arthroplasty, this comprehensive review aimed to address this gap by summarising all key literature in the topic area. This aim was translated into a central research question using the population, intervention, comparator, and outcomes (PICO) method [30]. The question formulated comprised: *what value or lack thereof (outcomes) can robot-assisted knee arthroplasty (intervention) provide for patients with knee osteoarthritis (population), relative to those undergoing conventional arthroplasty procedures (comparator)?*

A series of sub-questions/objectives were used to answer the central question statement:

- *Is robot-assisted surgery effective in improving operative time/efficiency?*
- *Is robot-assisted surgery effective in enhancing surgical accuracy?*
- *Does robot-assisted surgery confer a benefit upon patient-reported and clinically important outcomes?*
- *What are the views and perceptions of surgeons regarding the value and limitations of robot-assisted knee arthroplasty?*
- *What are the views of patients regarding robot-assisted surgery?*
- *What are the key recommendations for ongoing robot-assisted system development?*

Additional objectives were:

- To explore the technical, practical, and calibration considerations for using robot-assisted surgery for knee arthroplasty
- To formulate recommendations for the ongoing development of software and hardware used in robot-assisted knee arthroplasty and for operational flow

2. MATERIALS AND METHODS

[2.1 Material](#)

The material used for the development and syntax of this Thesis is the existing literature on the subject, as retrieved from various sources like Google Scholar, Elsevier, Scopus, PubMed, ScienceDirect, IEEE, among others, as well as the various User Manuals, corporate web pages, and publicly shared figures, tables, diagrammes, and data obtained online. To summarise it:

- Published literature: Books, academic journals, magazines, newspapers, etc.
- Online sources: Websites, blogs, online databases, reports, etc.
- Government publications: Census data, statistical reports, policy documents, etc.
- Industry reports: Market research reports, company reports, industry surveys, etc.

[2.2 Methods](#)

Regarding the selected method chosen for the conduct of our research, we have used what is commonly coined as “Secondary Research”. Secondary research, also known as desk research, involves the collection and analysis of existing data and information that has been previously gathered by others.

During the conduct of our research, which lasted from **October 2023** to **August 2024**, we have used the following keywords in order to obtain the relevant for our purpose material from the various sources: **Knee Surgery, Robot-Assisted surgery, Robot-Assisted knee arthroplasty, Robotic DoF (Degrees of Freedom), Robotic Systems Markers, Robotic sensors, Robotic Arm, Robot Stand, Camera Stand, Robotic Knee Surgery Systems, Robotic Surgery components interaction, Robotic Surgery Human Machine interaction, Robotic Surgery Systems interconnection, Robotic Surgery Systems hardware, Robotic Surgery Systems software, Comparison of Robotic Assisted Knee Surgery vs Conventional Knee Surgery in terms of speed, accuracy, precision, caused trauma, of ease of handling, stress and fatigue generation.**

The **inclusion criteria** for the obtained papers in order to be utilised were:

Regarding Robotic Knee Arthroplasty, as latest to date as possible and not before 2020, when the four major players that dominate 95% of the current market (**Zimmer Biomet**, **Stryker**, **Smith & Nephew** and **DePuys Synthes** from Johnson & Johnson) released their platforms in a few months difference.

About Knee Arthroplasty Operation in general, we used the most comprehensive and easily assimilated by the reader material.

Concerning comparative analysis between systems and between conventional and Robotic-Assisted surgery, due to the scarcity of literature on the subjects, we used every possible review and work we could obtain.

Finally, in terms of the Fundamentals of Robotic Aspects, like the topic on Degrees of Freedom, we didn't pay attention to the date it was drafted but to its general acceptance, its number of citations and its formulation in order to be easily assimilated by the reader.

The **exclusion criteria** utilised for the rejection of several papers was their date when it was referring to Robotic-Assisted Knee Arthroplasty, as papers before 2020 offer little value to our purpose due to the initial phase of this innovation, and cases where the authors of relatively late drafted works seemed to promote a specific system by disregarding the findings of other comparative analyses. Finally, of course, we chose not to rely on papers that were presenting only the Abstract part, but on full texts, in order to be able to understand and present each topic in a complete and comprehensive way.

To summarise it, we appose the following diagramme below (Figure 2.1):

Secondary research relies on sources such as books, journals, government publications, industry reports, websites, and databases. It is used to gain insights, support findings, or inform decision-making without directly collecting new data through methods like surveys or experiments [30] and it comprises:

- Literature review: Analysing and synthesizing existing research and literature relevant to the topic of interest.
- Data analysis: Examining existing datasets to extract meaningful insights or trends.

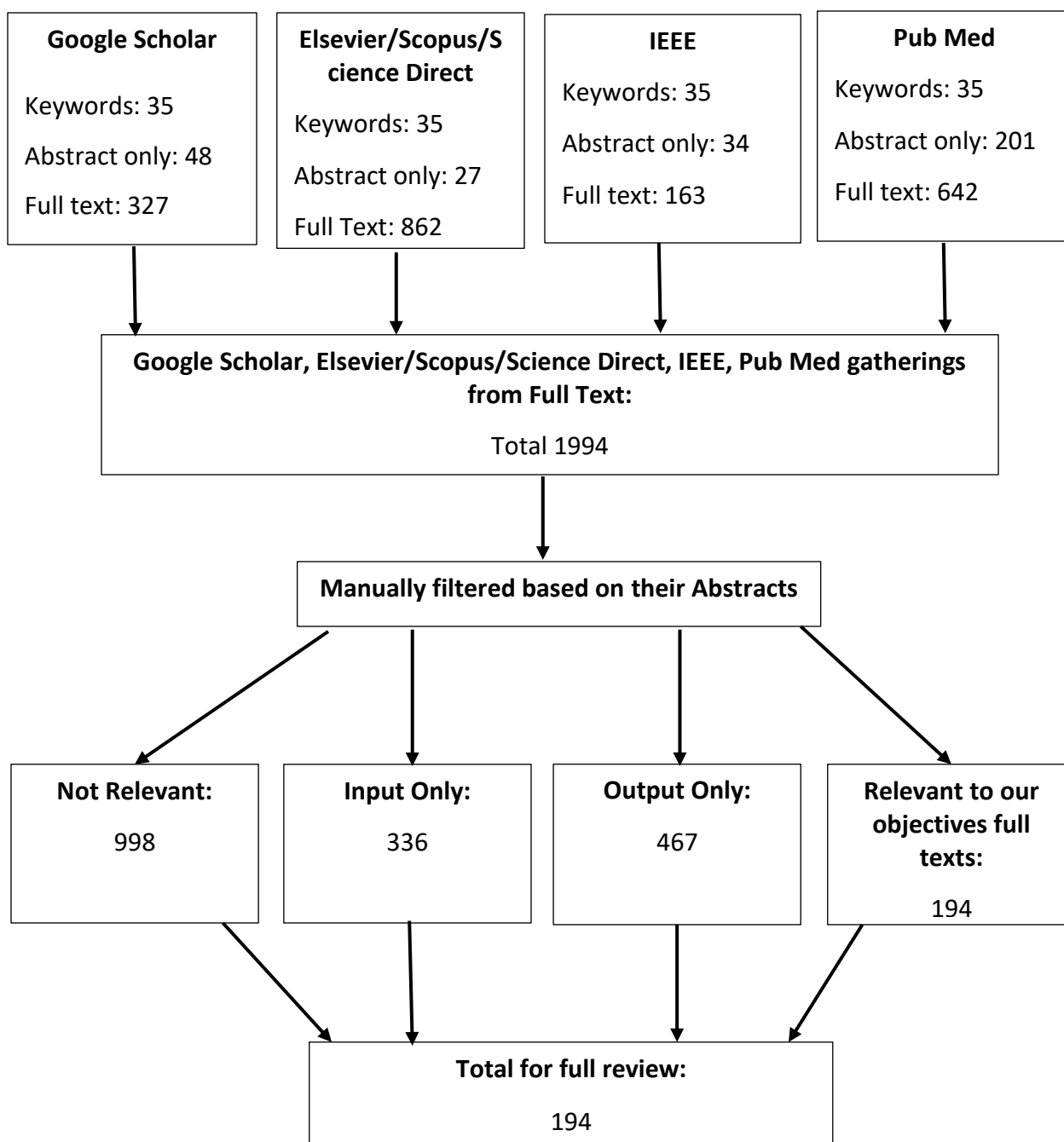


Figure 2.1 Diagramme of the Material obtained and scrutinized for the drafting of this Thesis.

- Content analysis: Analysing texts, documents, or media to identify themes, patterns, or attitudes.

- Meta-analysis: Statistical analysis that combines the results of multiple studies on the same topic to draw conclusions or identify patterns.
- Comparative analysis: Comparing different sources of information to identify similarities, differences, or trends.

Method of conducting secondary research:

- Identify research objectives: Clearly define the research questions or objectives to guide the search for relevant information.
- Search for sources: Use various search methods to locate relevant literature, data, and other sources. This can include online databases, library catalogues, search engines, etc.
- Evaluate sources: Assess the credibility, reliability, and relevance of the sources to ensure they meet the research needs.
- Extract and analyse data: Extract relevant data or information from the sources and analyse it to address the research objectives.
- Synthesize findings: Summarize and interpret the findings to draw conclusions or make recommendations based on the secondary research.

Secondary research is often used to gain a better understanding of a topic, support primary research findings, or inform decision-making in various fields such as business, academia, healthcare, and public policy, among others [30]. The search for literature was undertaken using several electronic databases and academic information sources. These included Google Scholar, Elsevier/Scopus/Science Direct, IEEE, Pub Med. A range of sources were searched to ensure the capturing of all key evidence needed to address the research question and objectives. The search terms were applied in accordance with best practices but were tailored according to the subtopics identified in the results chapter [31].

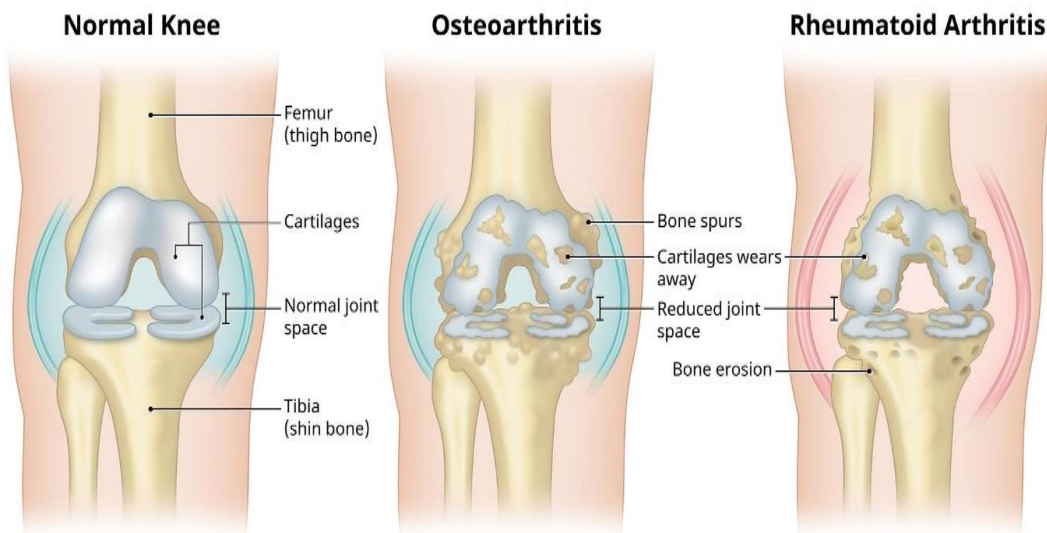
3. RESULTS

I. DESCRIPTION OF TOTAL & PARTIAL KNEE ARTHROPLASTY

3.1 Introduction to Total & Partial Knee Arthroplasty

Total or partial knee arthroplasty, also known as total or partial knee replacement, is a surgical procedure aiming to resurface a knee damaged by arthritis. It is commonly performed to relieve pain and improve function in patients with severe knee arthritis. This procedure involves replacing the damaged joint surfaces with metal and plastic components to restore the smooth motion of the knee. Total and partial knee arthroplasty has significantly improved the quality of life for many people suffering from debilitating knee arthritis. In this Thesis, we will explore the background, purpose, cases, and detailed procedure of total and partial knee arthroplasty.

Before delving into the details of the total knee arthroplasty procedure, it is important to understand the different types of knee arthritis that can lead to the need for this surgery. The most common forms of knee arthritis are osteoarthritis, rheumatoid arthritis, and post-traumatic arthritis (Figure 3.1) [32].



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Figure 3.1 Normal, Osteoarthritic & Rheumatoid Arthritis Knee [32].

Each of these conditions has its specific characteristics and may require different treatment approaches. Understanding the specific type of arthritis a patient is experiencing is crucial for determining the most appropriate course of action. When it comes to the cases where total (Figure 3.2) or partial knee arthroplasty may be considered, it is typically recommended for individuals who have not achieved sufficient relief with non-surgical treatments such as medications, physical therapy, and the use of walking supports. These individuals often experience significant pain, stiffness, and limited mobility due to their severe knee arthritis. Total and partial knee arthroplasty offers a long-term solution for improving the quality of life and restoring functionality in these cases [33].

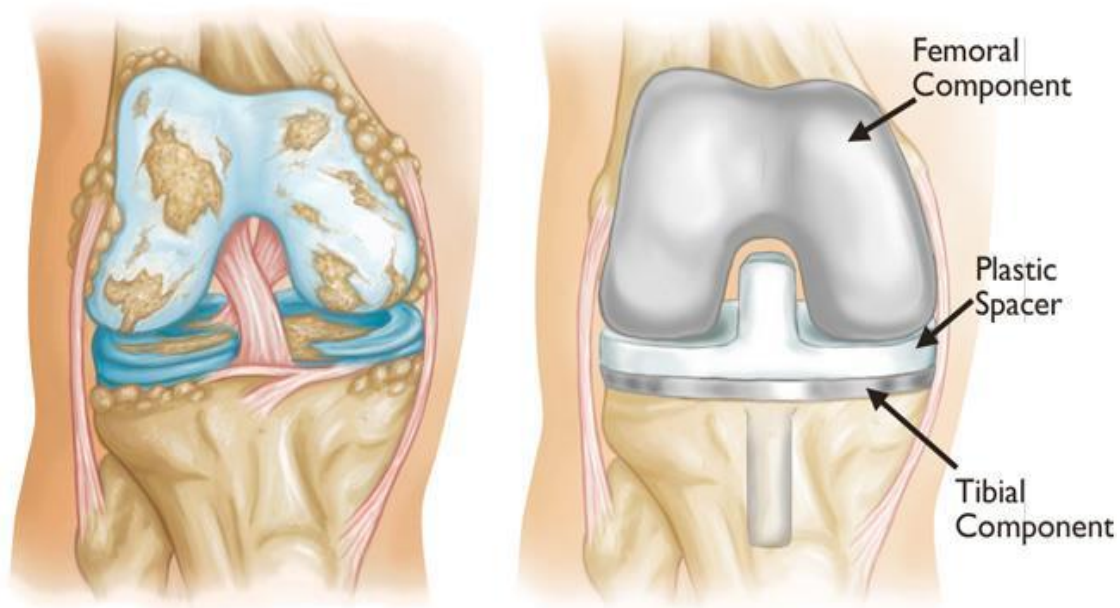


Figure 3.2 Total Knee Replacement Implant [33].

The procedure itself involves several key steps, including the removal of damaged cartilage and bone from the knee joint, shaping the remaining bone to accommodate the knee implant, and securing the artificial components in place. The precise details of the procedure may vary depending on the patient's specific condition and the surgeon's preferred techniques. It is essential for patients considering total or partial knee arthroplasty to consult with an experienced orthopedic surgeon to discuss the procedure in detail and address any concerns or questions they may have.

Recovery following total and partial knee arthroplasty typically involves a period of physical therapy to regain strength and mobility in the knee. Patients will also be given guidelines for activities to avoid and exercises to perform to support the healing process and optimize the long-

term outcome of the surgery. Patients need to adhere to their post-operative care plan and attend all follow-up appointments to ensure proper healing and monitor the function of the knee implant [34].

In addition to discussing the procedure with the orthopedic surgeon, patients should also inquire about the potential risks and complications associated with total and partial knee arthroplasty. While this surgery has proven to be highly effective for many patients, individuals need to understand the potential outcomes and make an informed decision about moving forward with the procedure.

In the following sections, we will delve into the specific details of the total and partial knee arthroplasty procedure, including the types of knee implants available, the surgical techniques involved, and the expected outcomes for patients undergoing this surgery. Understanding the intricacies of the procedure can provide patients with a comprehensive view of what to expect and help them make confident decisions about their treatment options.

A. Types of Knee Implants

There are several types of knee implants available for total knee arthroplasty, and the choice of implant depends on various factors such as the patient's age, activity level, and the severity of their arthritis. The most common types of knee implants include fixed-bearing implants, mobile-bearing implants, and unicompartmental implants (Figure 3.3). Each type has its unique design and benefits, and the orthopedic surgeon will determine the most suitable implant based on the patient's individual needs and condition [35].

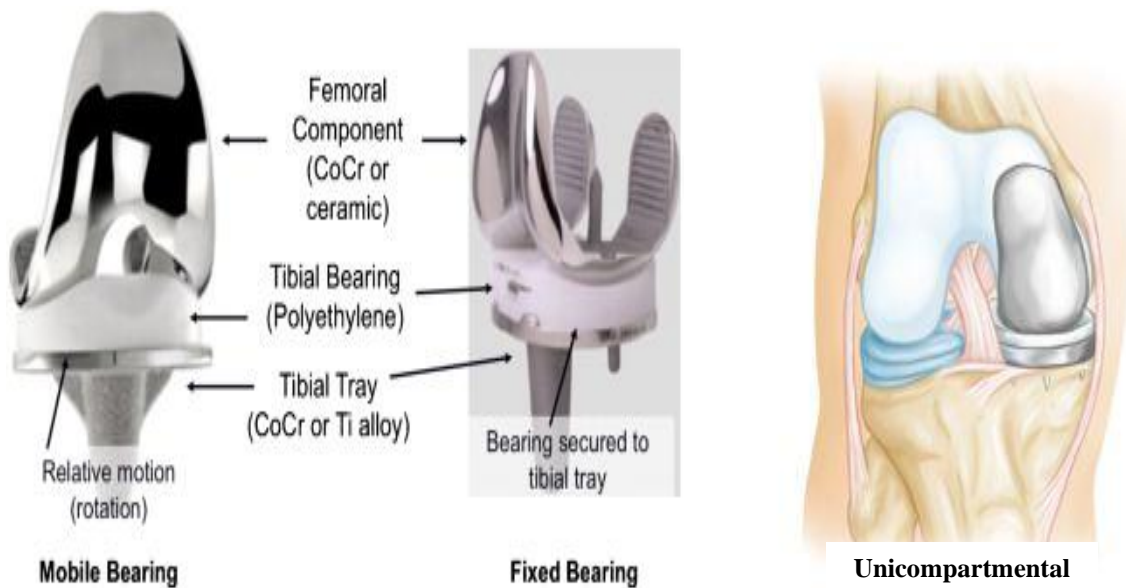


Figure 3.3 Fixed-Bearing, Mobile-Bearing & Unicompartmental (partial) Implants [35].

B. Surgical Techniques

The surgical techniques for total and partial knee arthroplasty have evolved over the years, leading to improved outcomes and reduced recovery times for patients. Some of the key advancements in surgical techniques include minimally invasive approaches, computer-assisted navigation, Robot-assisted surgery, and the use of patient-specific instrumentation (Figures 3.4 - 3.5). These techniques aim to optimize the alignment and positioning of the knee implant, resulting in better function and longevity of the prosthetic joint [36].



Figure 3.4 Zimmer Biomet Persona® Knee Kit & Figure 3.5 Zimmer Biomet NexGen® Knee Kit [36].

Patients undergoing total or partial knee arthroplasty can expect significant improvements in pain relief, mobility, and overall quality of life. The majority of patients experience a dramatic reduction in knee pain and stiffness, allowing them to resume activities that were previously limited by their arthritis. While individual outcomes may vary, total knee arthroplasty has a high success rate and has helped countless individuals regain independence and mobility [37].

By understanding the different types of knee implants, the advancements in surgical techniques, and the expected outcomes, patients can feel more informed and prepared as they consider total or partial knee arthroplasty as a treatment option for their severe arthritis. Patients need to have an open and thorough discussion with their orthopedic surgeon to address any specific concerns and ensure that they have a clear understanding of what the procedure entails (Figure 3.6).

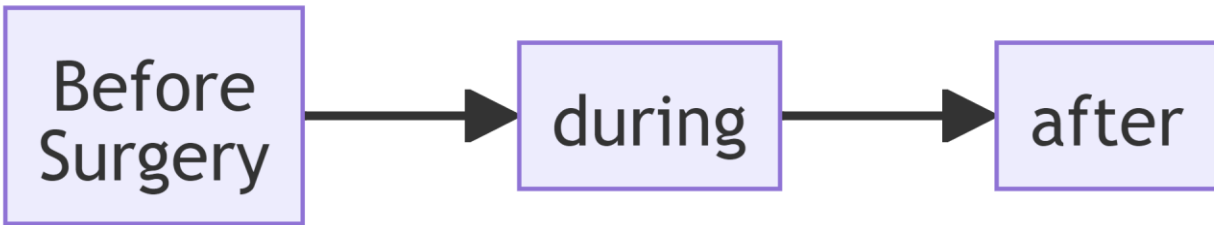


Figure 3.6 A diagramme of the essential steps and preparations that have to be addressed to the patient when deciding to undergo a Robotic-Assisted Total/Partial Knee Arthroplasty.

Before Surgery:

C. Psychological Preparation

Patients should also be aware of the psychological aspects of undergoing a major surgery. It is natural for individuals to experience a range of emotions, including anxiety and frustration, as they navigate the recovery process. Building a strong support network of family, friends, and healthcare professionals can provide valuable emotional support during this time.

In conclusion, the decision to undergo total or partial knee arthroplasty is a significant one, and patients need to be thoroughly informed about the procedure, recovery process, and long-term considerations. By understanding all aspects of the surgery and actively participating in their recovery and long-term management, patients can approach total or partial knee arthroplasty with confidence and a clear understanding of what to expect [\[43\]](#).

D. Setting Realistic Expectations

It is important for patients undergoing total or partial knee arthroplasty to have realistic expectations about the outcomes of the surgery. While the majority of patients experience significant improvements in pain relief and mobility, it's essential to understand that the recovery process may take time. Some patients may initially experience discomfort and stiffness, but with dedication to their rehabilitation program, these issues typically improve over time [\[40\]](#).

E. Lifestyle Modifications

Patients should also be prepared to make certain lifestyle modifications following total or partial knee arthroplasty. This may include adapting to new physical activity guidelines, avoiding high-impact sports, and being mindful of activities that put excessive stress on the knee joint. The orthopedic surgeon and physical therapist will provide specific recommendations tailored to the patient's circumstances.

Patients must have a thorough understanding of the recovery process, potential risks, and necessary lifestyle modifications as they prepare for total knee arthroplasty. Open communication with the medical team can help alleviate any concerns and ensure that patients are well prepared for the journey ahead [39].

During surgery:

F. Potential Risks and Complications

While total and partial knee arthroplasty has a high success rate, patients need to be aware of potential risks and complications associated with the surgery. These may include infection, blood clots, implant wear, stiffness, and nerve or blood vessel damage. Patients should have a thorough discussion with their surgeon about these potential risks and understand the measures taken to minimize them [33].

After Surgery:

G. Recovery and Rehabilitation

Following total or partial knee arthroplasty, a comprehensive rehabilitation program is essential for optimizing recovery and regaining strength and mobility in the knee. Physical therapy plays a crucial role in this process, and patients will work closely with a therapist to perform exercises that focus on improving the range of motion, strengthening the surrounding muscles, and promoting overall mobility. It is important for patients to actively participate in their rehabilitation program and adhere to the guidance of the physical therapist to achieve the best possible outcomes [38].

H. Home Recovery Tips

In addition to the structured rehabilitation program, patients should also be mindful of their home recovery. This includes following all post-operative care instructions, managing any discomfort with prescribed medications, and creating a safe and accessible environment at home to support their recovery. Simple adjustments such as removing tripping hazards and arranging for assistive devices can contribute to a smoother recovery process [41].

I. Long-Term Management

Total and partial knee arthroplasty is a transformative procedure that can significantly improve a patient's quality of life. However, it is important to recognize that the artificial knee joint may have a lifespan (Figure 3.7) and may require eventual revision surgery. Understanding the long-

term management of the knee implant, including regular follow-ups with the orthopedic surgeon and monitoring for any signs of implant wear or loosening, is crucial for ensuring the continued success and functionality of the prosthetic joint [42].

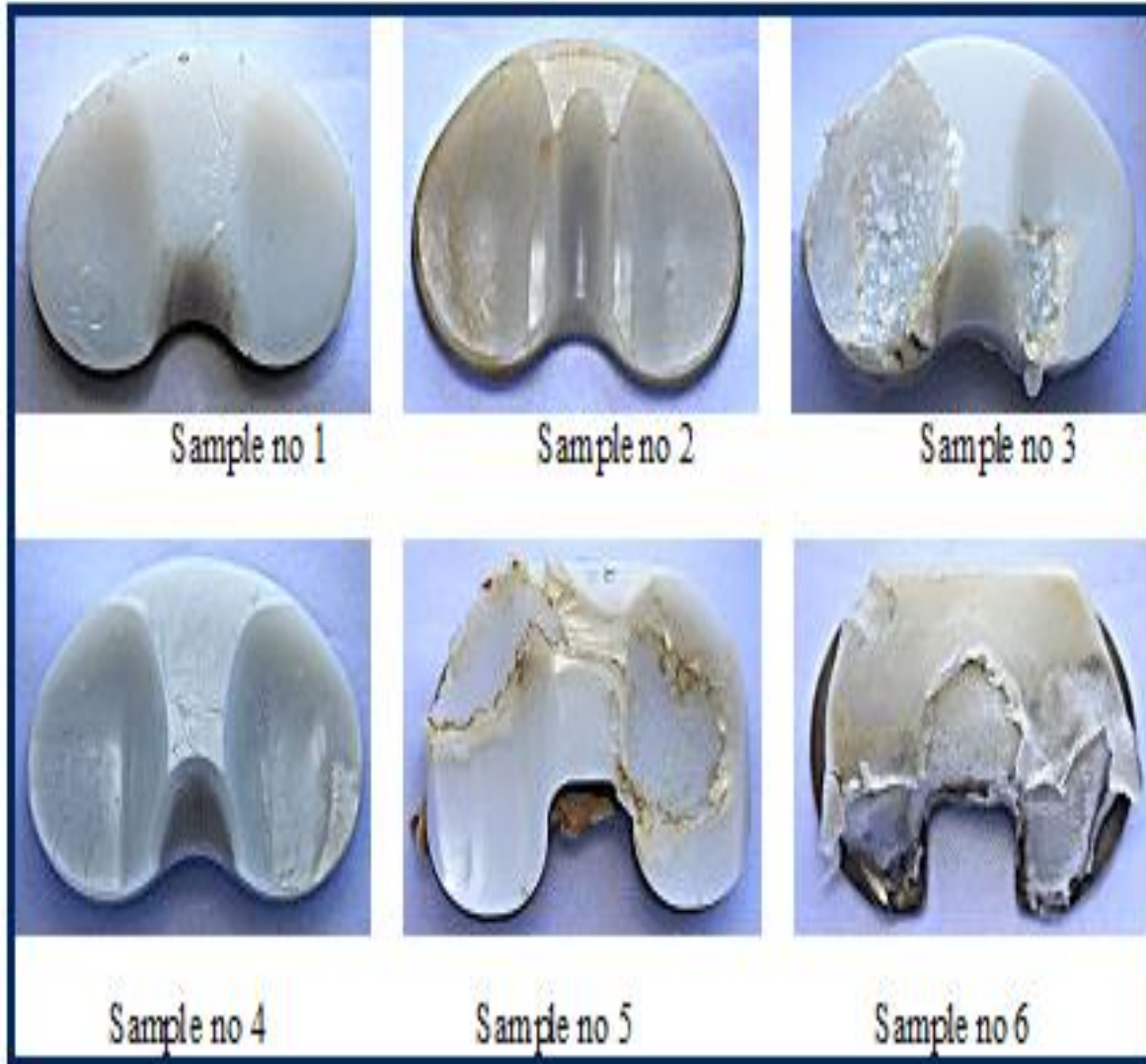


Figure 3.7 Macroscopic images of the failed polyethylene components from total knee prosthesis [42].

J. Conclusion

Total and partial knee arthroplasty is a life-changing procedure that has helped numerous individuals regain mobility and independence in their daily lives. By being well informed about the different types of knee implants, advancements in surgical techniques, and the expected

outcomes, patients can approach the decision to undergo total knee arthroplasty with clarity and confidence.

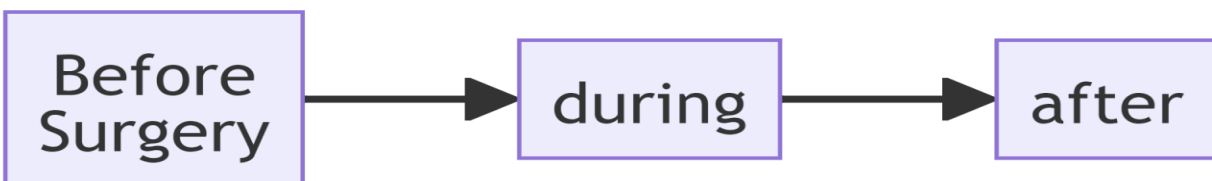
In addition to understanding the surgical aspects, patients need to actively engage in their rehabilitation program, adhere to lifestyle modifications, and recognize the long-term management involved in maintaining the functionality of the prosthetic joint.

Moreover, patients need to acknowledge the psychological aspects of undergoing a major surgery and seek support from their loved ones and healthcare professionals. With realistic expectations and dedication to the recovery process, patients can look forward to significant improvements in pain relief and mobility, leading to a better quality of life post-surgery.

Overall, total knee arthroplasty offers a path toward improved well-being for individuals struggling with severe arthritis, and by being proactive in their approach, patients can navigate this journey with confidence and a comprehensive understanding of what lies ahead [44].

3.2 Introduction to Robotic Systems in Medicine

Robotic systems have revolutionized the field of medicine, providing advanced guidance systems and precise intraoperative implant adjustments for various surgical procedures [45]. One area where robotic technology has made significant contributions is in total and partial knee arthroplasty [46]. In this topic, we will address the contributions of robotic systems to the improvement of total and partial knee arthroplasty, focusing on various aspects such as time, trauma, precision, accuracy, repeatability, doctors' efforts, stress and fatigue, and time of recovery, before, during and after surgery (Figure 3.8) [45]. Robotic-assisted total and partial knee arthroplasty have shown promising results in improving the overall outcomes of the surgery. Robotic systems have greatly affected the field of knee arthroplasty by enhancing the accuracy and reliability of implant placement, as well as improving early functional recovery compared to conventional manual knee arthroplasty [46].



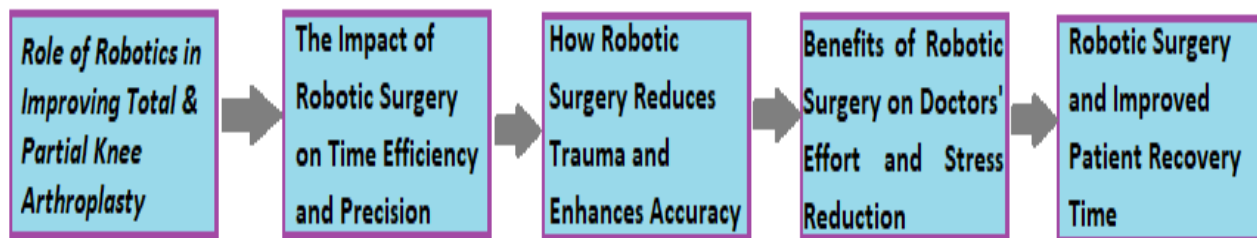


Figure 3.8 The various roles and impacts of Robotic Surgery in Total & Partial Knee Arthroplasty before, during, and after surgery.

Before Surgery:

A. Role of Robotics in Improving Total & Partial Knee Arthroplasty

Robotic systems have found their way into knee arthroplasty, aiming to improve various aspects of the surgery [47]. Over the years, there has been a surge of publications highlighting the early outcomes of robotic-assisted total knee arthroplasty. These studies have focused on the role of robotics in enhancing component positioning and implant placement accuracy. Studies have demonstrated that robotic-assisted total knee arthroplasty improves the accuracy and reliability of implant placement compared to conventional manual techniques [48].

The use of robotics in total and partial knee arthroplasty allows for pre-operative calculations for precise component placement and sizing, which are crucial to the success of the operation. Moreover, robotic systems in total or partial knee arthroplasty provide advanced imaging technologies such as computed tomography to guide the surgeon in making accurate intraoperative adjustments [49]. The precision offered by robotic systems in these procedures is unmatched by traditional manual techniques. Robotic-assisted procedures allow for meticulous planning and execution, leading to improved patient outcomes. The integration of advanced imaging technologies (Figure 3.9) not only assists the surgeon during the operation but also contributes to post-operative care and rehabilitation.



Figure 3.9 Stryker MAKO (up) & Zimmer Biomet ROSA (down) Knee Imaging Environment [50].

Furthermore, the use of robotic systems minimizes the margin for error in total and partial knee arthroplasty, thereby reducing the likelihood of complications and the need for revision surgery. This is particularly important for complex cases where the traditional manual approach may present challenges in achieving optimal results (Figures 3.9 – 3.10) [50].

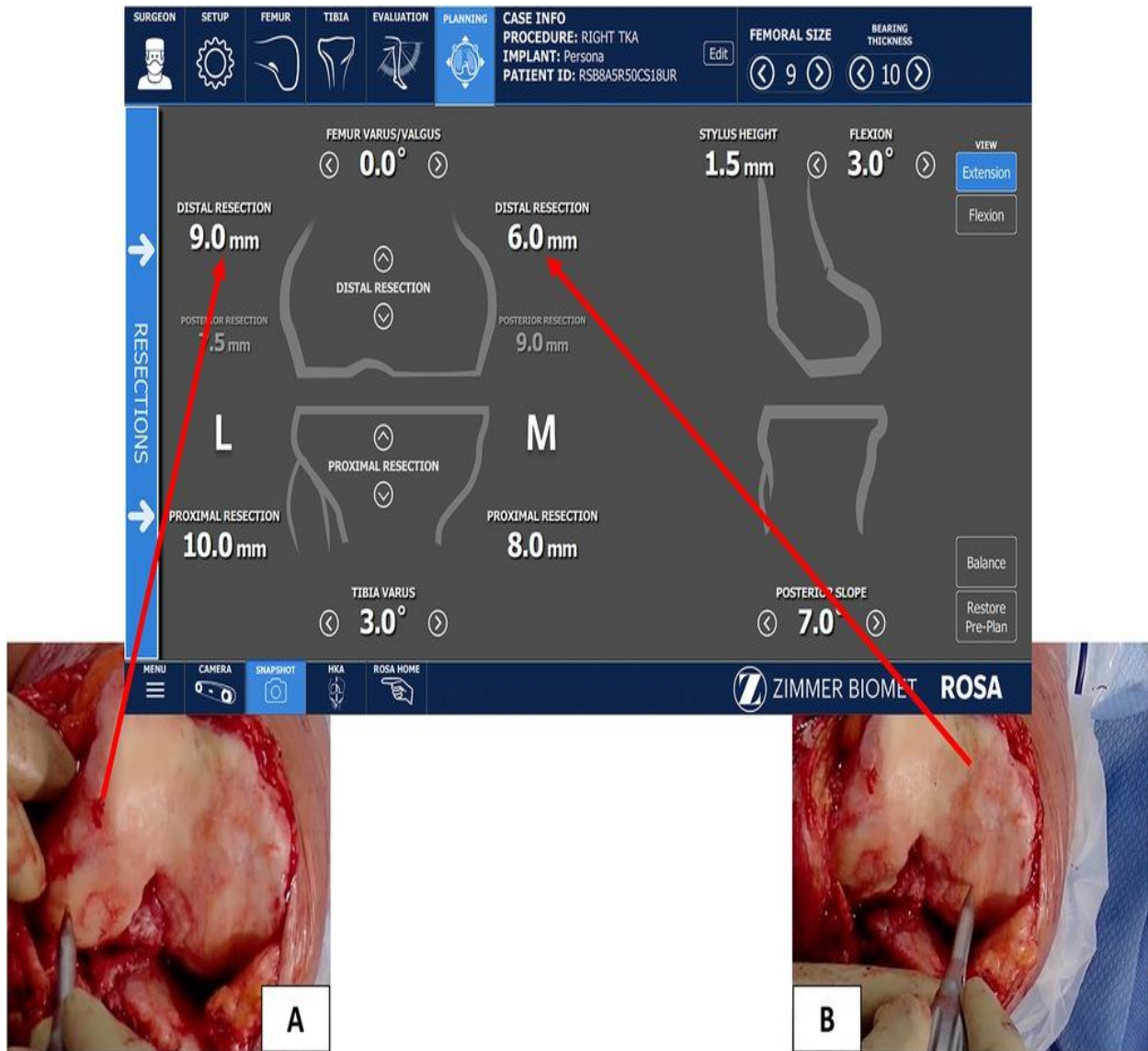


Figure 3.9 Individualized alignment and ligament balancing technique with the ROSA® robotic system for total or partial knee arthroplasty [50].

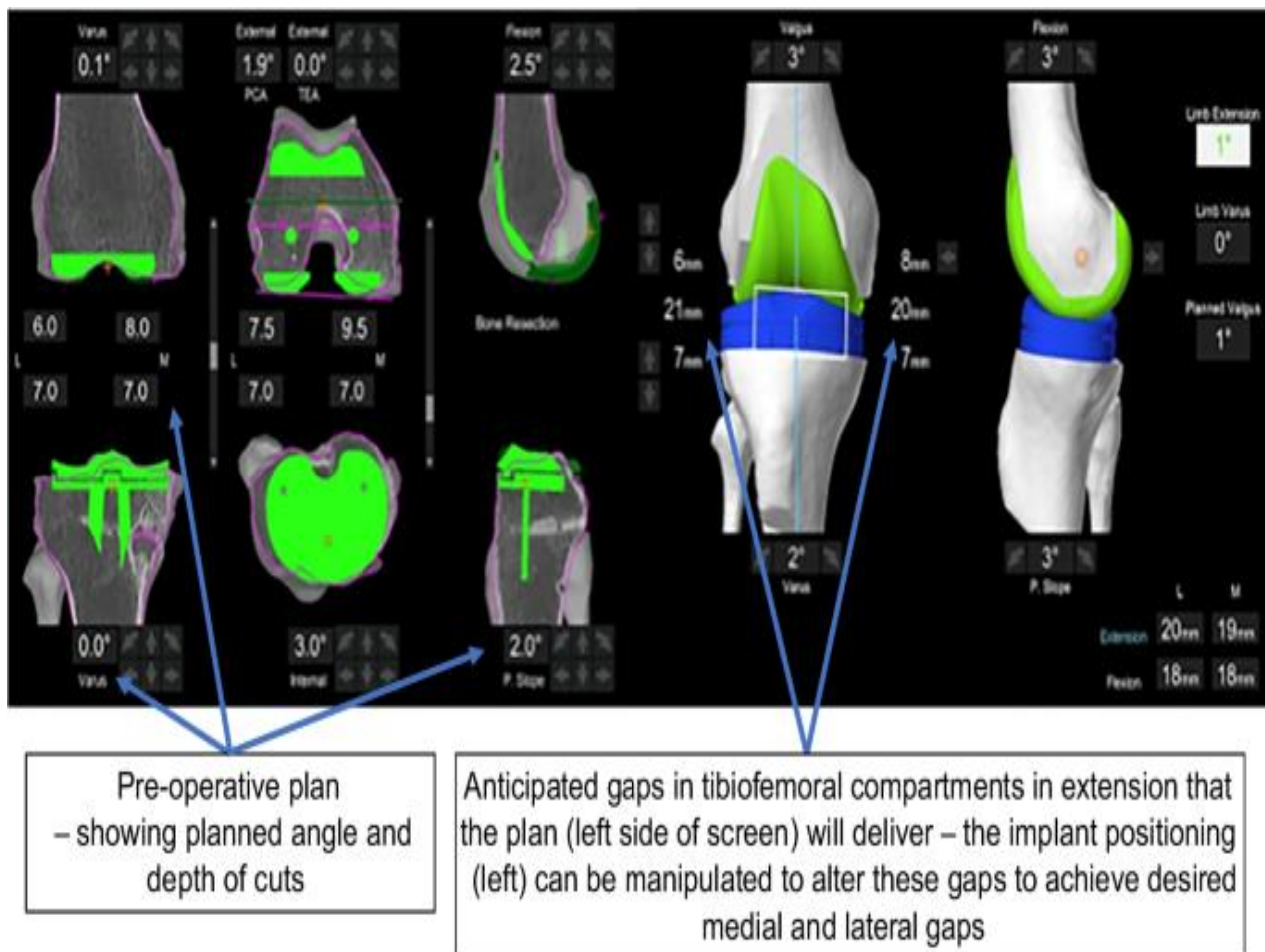


Figure 3.10 Individualized alignment and ligament balancing technique with the MAKO® robotic system for total or partial knee arthroplasty [51].

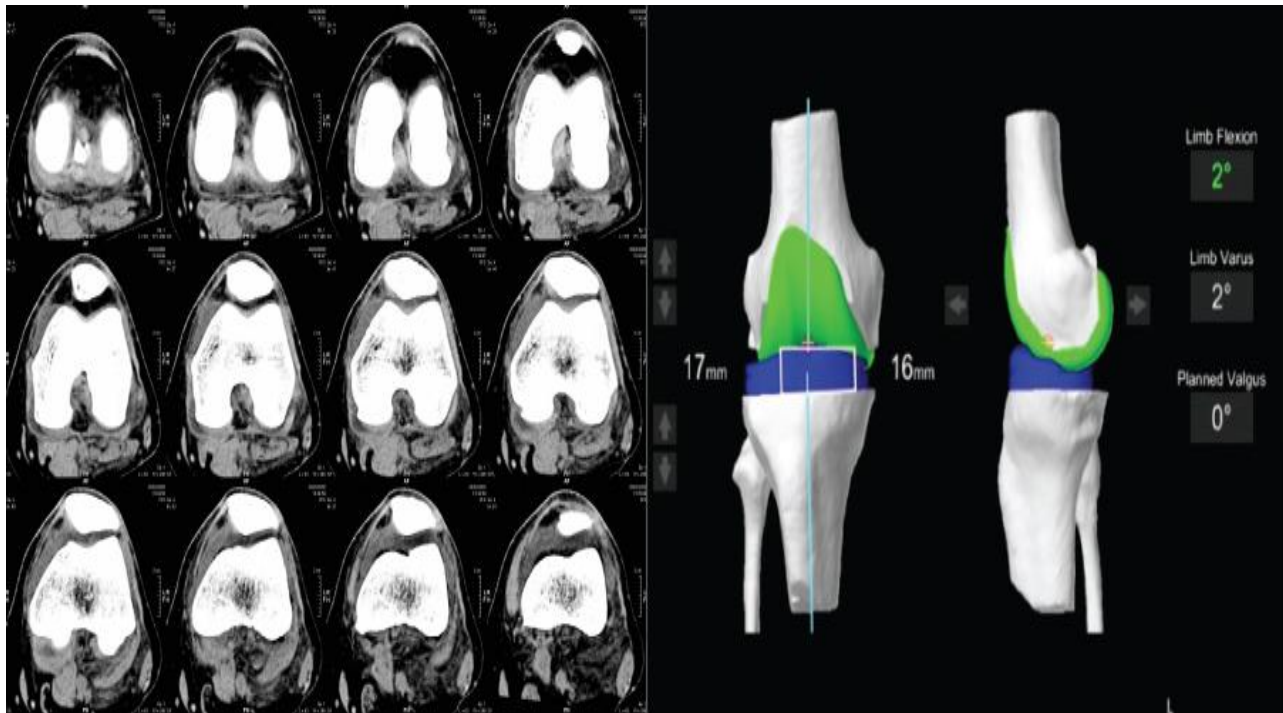
In addition to their technical advantages, robotic systems supposedly also play a pivotal role in reducing the physical demands on surgeons, thus mitigating stress and fatigue. By allowing for more precise and efficient procedures, robotic-assisted total knee arthroplasty enables surgeons to focus on decision-making and patient care, ultimately enhancing the overall experience for both the medical team and the patient [51].

The continuous evolution and integration of robotic technology in total knee arthroplasty holds great promise for further advancements in the field of orthopedic surgery. As research and development in this area continue to expand, the potential for improving patient outcomes and surgical efficiency through robotic systems remains an exciting prospect.

During Surgery:

B. The Impact of Robotic Surgery on Time Efficiency and Precision

Robotic surgery has revolutionized the field of total and partial knee arthroplasty by significantly improving time efficiency and precision. One of the primary benefits of robotic surgery in total knee arthroplasty is its impact on time efficiency. With the use of robotic systems, surgeons can streamline the surgical process, resulting in shorter operating times. This is achieved through the integration of advanced imaging technologies, such as computed tomography, which provides real-time feedback and guidance to the surgeon (Figure 3.11) [45].



CT Scan of Knee Joint

Mako 3D Model of Knee Joint

Figure 3.11 Integration of a CT scan to the MAKO® Software platform for preoperative calculations [45].

Moreover, robotic systems enable precise preoperative planning, leading to more accurate component placement and sizing during the surgery. This not only reduces the time spent on intraoperative adjustments but also ensures that the surgery is completed more efficiently. Additionally, robotic systems allow for improved precision in total and partial knee arthroplasty. The use of robotic systems provides surgeons with real-time information regarding soft tissue

tensioning and balance (Figure 3.12), which allows for accurate implant placement and optimization of component positioning [52].



Figure 3.12 Real-time calculations of the Zimmer Biomet ROSA® Knee platform [52].

This level of precision is difficult to achieve with traditional manual techniques, as they rely heavily on the surgeon's subjective judgment and skills. Furthermore, robotic systems offer the advantage of reproducibility. Surgeons can replicate the same precise movements and adjustments in subsequent surgeries, ensuring consistency in outcomes. The increased precision and reproducibility offered by robotic systems in total and partial knee arthroplasty have significant implications for patient outcomes. Patients who undergo robotic-assisted knee arthroplasty can benefit from improved implant placement, which contributes to better alignment and stability of the knee joint [53]. Table 3.1 below associates all major differences in a cumulative comparison between Manual and Robot-assisted Total & Partial Knee surgery.

Table 3.1 Comparison between Manual and Robotic Surgery in terms of various aspects of a surgical operation [51], [197].

| Resources | Manual surgery | Robotic surgery |
|------------------|---|--|
| Time | 99 minutes average time | 84 minutes average time |
| Materials | Only surgical tools | Surgical tools + reflectors placement tools |
| Equipment | Manual drills and shaws | Robotic-assisted drills and shaws |
| Money | 64737\$ | 67133\$ |
| Persons | 4-7 Healthcare personnel (2-3 surgeons and 2-4 nurses) | 5-8 Healthcare personnel (2-3 surgeons, 2-4 nurses plus one clinical specialist from the Robot Company) |

C. How Robotic Surgery Reduces Trauma and Enhances Accuracy

Robotic surgery has been pivotal in reducing trauma and enhancing accuracy in knee arthroplasty. The precise nature of robotic systems allows for minimally invasive procedures, which in turn reduces tissue trauma and accelerates the patient's recovery process. By utilizing advanced imaging and navigation technologies, robotic-assisted total and partial knee arthroplasty minimizes the disruption of surrounding healthy tissue, leading to less post-operative pain and a quicker return to normal function for patients. This reduction in trauma not only contributes to improved patient satisfaction but also lowers the risk of complications associated with traditional surgical methods [54].

Furthermore, the enhanced accuracy achieved through robotic systems plays a crucial role in the long-term success of total and partial knee arthroplasty. By providing real-time feedback and precise intraoperative guidance, robotic technology ensures optimal implant placement and alignment (Figure 3.13), which are essential for the functionality and longevity of the prosthetic joint. The ability of robotic systems to account for individual variations in anatomy and joint mechanics further enhances the accuracy of implant positioning, ultimately improving the overall performance and durability of the prosthetic knee [54].

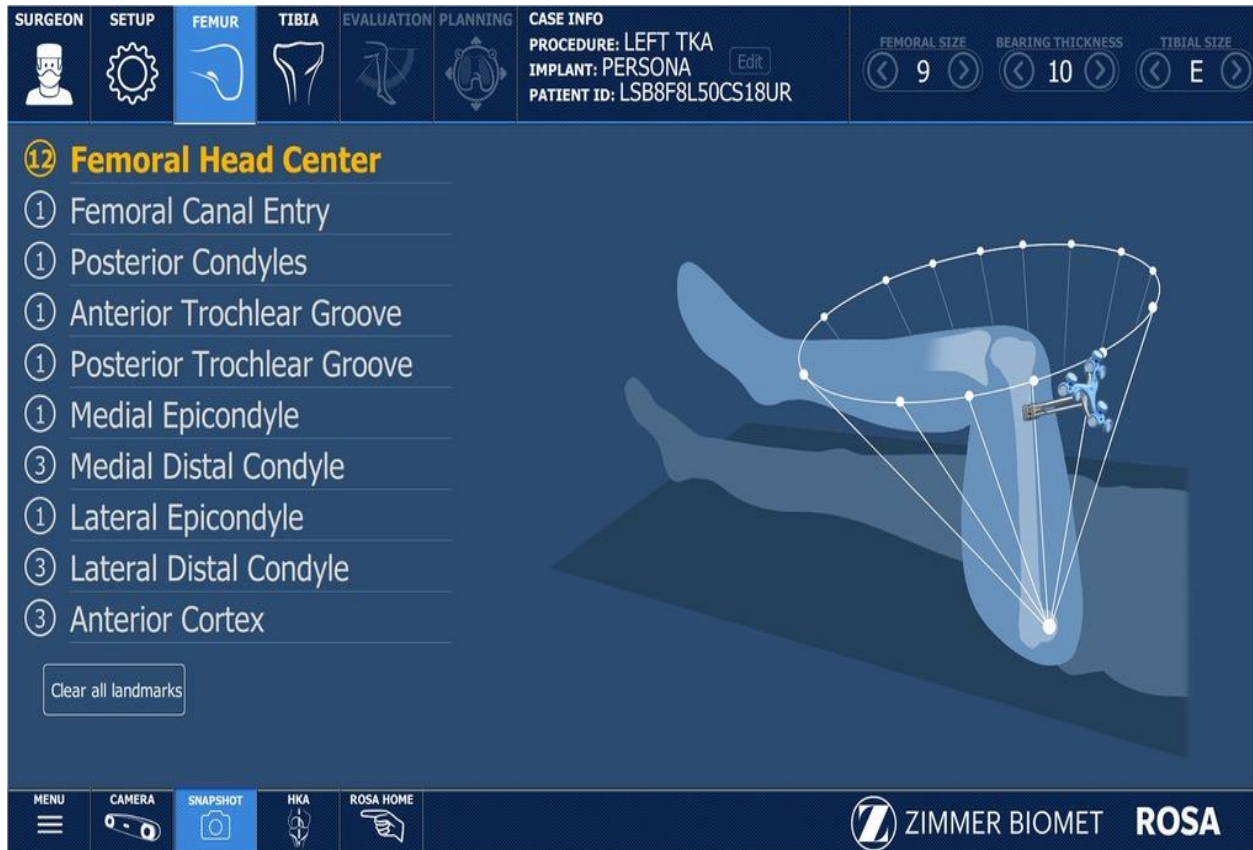


Figure 3.13 Personalized alignment for total knee arthroplasty using the ROSA[®] Knee and Persona[®] knee systems [54].

In addition to reducing trauma and enhancing accuracy during the surgical procedure, robotic systems also contribute to the post-operative phase by facilitating controlled rehabilitation and fostering early functional recovery. The combination of reduced trauma, improved accuracy, and personalized rehabilitation strategies tailored to each patient's specific implant positioning leads to better overall functional outcomes, ultimately maximizing the benefits of total and partial knee arthroplasty for individuals seeking relief from knee joint degeneration [55].

As research and development in robotic technology continue to advance, the ongoing refinement of robotic systems in knee arthroplasty holds great promise for further improving patient outcomes, minimizing surgical complications, and optimizing the long-term success of joint replacement procedures. The integration of robotic technology not only elevates the standard of care in orthopedic surgery but also paves the way for continued advancements in robotic-assisted total and partial knee arthroplasty [55].

D. Benefits of Robotic Surgery on Doctors' Effort and Stress Reduction

According to certain studies, robotic surgery not only offers significant benefits for patients but also plays a crucial role in reducing the physical demands on surgeons, thereby mitigating stress and fatigue. By allowing for more precise and efficient procedures, robotic-assisted total knee arthroplasty empowers surgeons to focus on decision-making and patient care, ultimately enhancing the overall experience for both the medical team and the patient.

Moreover, robotic systems can supposedly assist in reducing the physical strain on surgeons by minimizing the need for excessive force and repetitive tasks during surgery [56]. This reduction in physical strain can lead to a decrease in surgeon fatigue, allowing them to perform surgeries with greater accuracy and efficiency. Furthermore, the use of robotic systems in total and partial knee arthroplasty can help to alleviate the mental and emotional stress experienced by surgeons during complex procedures.

In addition, the precision and accuracy achieved by robotic systems in total knee arthroplasty not only enhance patient outcomes but also contribute to the reduction of surgical time. By allowing for more precise and controlled movements, robotic-assisted surgery reduces the need for surgeons to make adjustments or correct errors during the procedure [57].

This results in shorter surgical times, reducing the overall stress and fatigue experienced by surgeons [58]. In addition, robotic systems also provide real-time feedback and data to surgeons during the procedure, allowing them to make informed decisions and adjustments as needed [56].

After Surgery:

E. Robotic Surgery and Improved Patient Recovery Time

One of the notable benefits of robotic-assisted total knee arthroplasty is the potential for improved patient recovery time. Robotic systems offer several advantages that contribute to faster recovery for patients undergoing total knee arthroplasty, at least according to several studies performed on the subject. The precision and accuracy of robotic systems in total and partial knee arthroplasty aid in minimizing trauma to the surrounding soft tissues. This leads to reduced post-operative pain, swelling, and tissue damage, allowing patients to experience a faster rehabilitation process [59].

Additionally, robotic systems can ensure a more precise alignment and fit of the knee implant, which is crucial for optimal functionality and long-term success of the surgery. Furthermore, the

use of robotic assistance in total and partial knee arthroplasty allows for a more tailored and controlled rehabilitation process for each patient. By providing surgeons with real-time feedback on soft tissue tensioning and joint mechanics, robotic systems enable personalized rehabilitation strategies, which can expedite the recovery and functional restoration of the knee joint [53].

The potential for improved patient recovery time extends beyond the immediate postoperative period. Studies have shown that patients who undergo robotic-assisted total knee arthroplasty may experience better long-term outcomes, including improved range of motion, reduced risk of complications, and a faster return to their daily activities. The combination of reduced trauma, precise implant positioning, and tailored rehabilitation not only accelerates short-term recovery but also contributes to the overall success and longevity of the knee replacement [53].

As the field of robotic-assisted total and partial knee arthroplasty continues to evolve, ongoing advancements in robotic technology hold the promise of further enhancing patient recovery and functional outcomes. The integration of advanced artificial intelligence and predictive modeling into robotic systems could enable even more personalized and optimized rehabilitation strategies, ultimately leading to continued improvements in patient recovery time and long-term joint function [60].

The benefits of robotic surgery in knee arthroplasty extend beyond the operating room and recovery period, offering patients the potential for a faster return to an active and pain-free lifestyle. By harnessing the precision, accuracy, and personalized approach of robotic systems, surgeons can continue to redefine the standard of care for total and partial knee arthroplasty, ultimately improving the lives of individuals suffering from knee joint degeneration [60].

F. Conclusion

Robotic-assisted knee arthroplasty has proven, according to various studies, to be a revolutionary advancement in the field of orthopedic surgery, offering numerous benefits for both patients and surgeons. The precision and accuracy provided by robotic systems not only contribute to improved implant positioning and reduced trauma during surgery but also lead to enhanced post-operative rehabilitation and faster patient recovery. As the technology continues to evolve and integrate advanced artificial intelligence and predictive modeling, the potential for further personalized and optimized rehabilitation strategies becomes even more promising.

The impact of robotic technology extends beyond the operating room, offering patients the hope of a quicker return to an active and pain-free lifestyle. With ongoing advancements, the future holds the promise of minimizing the impact of knee osteoarthritis and further optimizing patient recovery following total or partial knee arthroplasty. Robotic systems are poised to continue

reshaping the landscape of joint replacement procedures and bettering the outcome for patients with knee joint problems. It has become increasingly reported that both surgeons and patients value robot-assisted surgery due to its growing evidence base to support improvements in key outcomes, while also enabling surgery to be performed more efficiently and ergonomically [61,62].

However, trialing and adopting robot-assisted surgery within hospital settings has received various resistance at the stakeholder level, which has mostly resulted due to the high costs of the systems, as well as the need for operational department reform and re-design and consuming significant training and resource demands upon operative staff [63,64]. Additional questions about the feasibility of robot-assisted surgery have also been raised from an ethical and regulatory perspective with concerns about autonomy and liability should surgery go wrong. This has called for legal teams around the globe to demand for sufficient regulation of robot-assisted systems, particularly in response to several cases of patient deaths and morbidity incurred by said interventions [65].

As such, the European Union have yet to develop a formal framework to ensure the proper regulation of robot-assisted surgical systems. Presently, the systems fall under the medical devices directives as class II devices, which essentially classifies them under the same category as relatively simple devices, such as scalpels [66]. Moreover, there is no formal recognition of training or qualifications in robot-assisted surgery for surgeons and this may be a key issue due to robot-assisted surgery requiring advanced and additional training to that of usual surgical practices [67].

Furthermore, there may be wider insurance and public health concerns as in countries where healthcare is dominantly supported by private insurance schemes; it is not clear whether this may include cover for robot-assisted surgery. On a divergent perspective, robotic surgical systems comprise computational processes and may therefore, be prone to hacking and other malicious cybersecurity threats. These threats could impose direct harm to patients or operators and therefore, require ongoing consideration in regulatory, legal and ethical discussions [67].

3.3 Advantages and Disadvantages of Robot-Assisted Surgery over Traditional Techniques

Robot-assisted surgery has revolutionized the field of medicine, offering numerous advantages over traditional surgical techniques. The integration of advanced technology into surgical procedures has paved the way for enhanced precision, shortened recovery times, and reduced scarring for patients. In this technological assessment, we will explore the various advantages

and disadvantages of robot-assisted surgery, shedding light on its impact on the medical landscape.

G. Advantages

Robot-assisted surgery offers numerous advantages over traditional manual techniques in the field of medicine. These advantages can be grouped into three major divisions (Figure 3.14), and include:

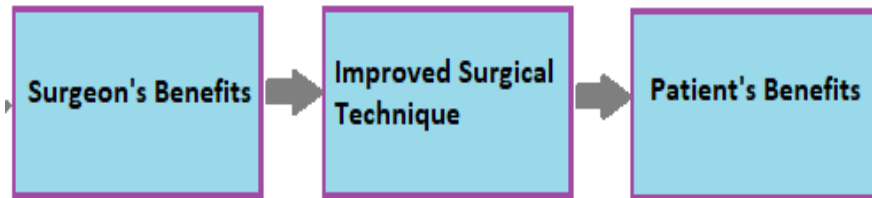


Figure 3.14 Benefits of Robotic Surgery according to their impact on surgeons, procedure, and patients.

Surgeon's Benefits:

- i. Enhanced Visualization: Robot-assisted surgery provides surgeons with a three-dimensional vision, offering improved depth perception and spatial awareness compared to traditional two-dimensional laparoscopic surgery [68].
- ii. Ergonomic Comfort for Surgeons: The use of robotic systems allows surgeons to operate from a seated position in a comfortable console, reducing the physical strain on the surgeon and minimizing fatigue during long procedures [69].

Improved Surgical Technique:

- iii. Improved Dexterity: Robotic systems allow for enhanced dexterity, providing the surgeon with increased precision and control during procedures [70].
- iv. Tremor Reduction: The robotic arms of the system can filter out any hand tremors, enabling steady and precise movements [70].
- v. Instrument Range of Motion: Robot-assisted surgery allows for a greater range of motion within the operative field, with the robotic arms able to rotate and articulate in ways that human hands cannot [70].

Patient's Benefits:

- vi. **Reduced Incision Size:** Robot-assisted surgery often requires smaller incisions compared to traditional open surgeries, resulting in reduced scarring and faster healing for patients. Furthermore, robot-assisted surgery minimizes blood loss and decreases the risk of infection, leading to shorter hospital stays and quicker recovery times for patients [70].
- vii. **Minimal Tissue Trauma:** With robot-assisted surgery, there is minimal trauma to surrounding tissues due to the precise and controlled movements of the robotic arms, resulting in less pain and faster healing for patients [70].
- viii. **Operational Complexity:** Ability to perform complex and delicate procedures in difficult-to-access areas of the body with greater precision and accuracy, ultimately improving patient outcomes [70].
- ix. **Delicate Tissue Dissection:** The robotic instruments can perform delicate and precise tissue dissection, reducing the risk of damage to surrounding structures [70].
- x. **Less Invasive Procedures:** Robot-assisted surgery offers the advantage of smaller incisions, resulting in minimal scarring and reduced post-operative pain for patients [70].
- xi. **Reduced Blood Loss:** The precise movements and cauterizing capabilities of robotic instruments can minimize blood loss during surgery, resulting in a safer procedure for the patient [70].
- xii. **Faster Recovery Time:** Due to the minimally invasive nature of robot-assisted surgery, patients often experience faster recovery times compared to traditional open procedures [70].
- xiii. **Improved Surgical Outcomes:** The precision and accuracy of robot-assisted surgery can lead to better surgical outcomes, including reduced complications and improved long-term prognosis [70].
- xiv. **Increased Safety:** Robot-assisted surgery reduces the risk of human error and potential complications during procedures, leading to safer surgical experiences for patients [70].

H. Disadvantages

Despite the numerous advantages, there are some disadvantages associated with robot-assisted surgery:

- i. **Increased Set-up Time:** Preparing and setting up the robotic system can take longer compared to traditional manual techniques, potentially causing delays in surgery start times and increasing overall operating room time [71].
- ii. **High Cost:** The initial cost of acquiring and maintaining robotic surgical systems is high, making them less accessible for some healthcare facilities [72].
- iii. **Lack of Tactile Feedback:** One major drawback of robot-assisted surgery is the absence of tactile feedback. Surgeons are unable to directly feel the tissues and rely solely on visual feedback, which may limit their ability to assess tissue characteristics like texture, tension, and consistency [74].
- iv. **Additional Learning Curve:** Surgeons and operating room staff need to undergo training and familiarize themselves with the robotic system, which can require extra time and effort [54].
- v. **Limited Variety of Instrumentation:** Robotic systems often have a limited selection of specialized instruments compared to traditional surgical tools, making certain procedures more challenging or time-consuming with robot-assisted surgery [75].
- vi. **Bulkiness and Size:** The robotic arms and equipment can take up a significant amount of space in the operating room, limiting the movement and access of the surgical team [75].

I. Opportunities for Technological Improvements in Robotic Surgery.

Technological improvements can enhance robot-assisted surgery in several areas:

- i. **Improved Ergonomics:** Developing more compact and lightweight robotic systems that take up less space in the operating room can provide the surgical team with better access to the patient and reduce physical strain and fatigue [69].
- ii. **Tactile Feedback:** Advancements in haptic technology could allow surgeons to receive sensory feedback, such as the sense of touch and resistance, during robotic-assisted surgery. This would enable surgeons to have a better understanding of tissue characteristics and enhance their precision and accuracy [74].

- iii. **Enhanced Instrumentation:** Expanding the range of specialized instruments available for robotic systems would allow for more complex and varied procedures to be performed with robot assistance, reducing the limitations posed by the currently limited variety of instrumentation [74].
- iv. **Artificial Intelligence and Machine Learning:** Integrating AI and machine learning algorithms into robotic systems can improve surgical precision by analyzing data in real-time and providing assistance and guidance to surgeons during procedures [76].
- v. **Improved Connectivity and Communication:** Enhancing the connectivity between robotic systems and other surgical devices, such as imaging systems or navigation tools, can improve visualization and real-time information sharing, enabling better decision-making during surgery [77].
- vi. **Improved Visualization:** Advancements in imaging technology, such as high-definition and three-dimensional visualization, can enhance the surgeon's ability to see and navigate anatomical structures during robot-assisted surgery, leading to improved precision and accuracy [78].
- vii. **Reduced Operating Time:** Streamlining robotic systems, improving instrument manipulation speed, and refining surgical workflows can contribute to a reduction in operating time, optimizing efficiency and minimizing patient trauma. Additionally, advancements in robotic control systems and algorithms can help reduce the learning curve associated with robot-assisted surgery, allowing surgeons to become proficient more quickly [78].
- viii. **Miniaturization:** Developing smaller robotic systems and instruments would allow for better maneuverability in tight spaces and potentially reduce trauma to surrounding tissues [79].
- ix. **Remote Surgery:** Advancements in teleoperated robotic systems can enable surgeons to perform procedures remotely, allowing expert surgical care to be provided in remote areas or areas with limited access to specialized surgical expertise [80].
- x. **Automation and Autonomy:** The future of robotic surgery lies in the development of semi or fully autonomous robotic systems. These systems would be capable of performing

surgical tasks with minimal human intervention, leading to increased precision, accuracy, and safety [81].

- xi. Improved Training and Education: The development of comprehensive and standardized training programs for robot-assisted surgery can help surgeons acquire the necessary skills and knowledge needed to perform procedures using robotic systems effectively and safely [82].
- xii. Cost Reduction: The development of more cost-effective robotic systems and instruments can increase accessibility to robot-assisted surgery for hospitals and clinics with limited financial resources and in underserved areas, potentially improving patient outcomes and reducing healthcare disparities (Figure 3.15) [72,73].

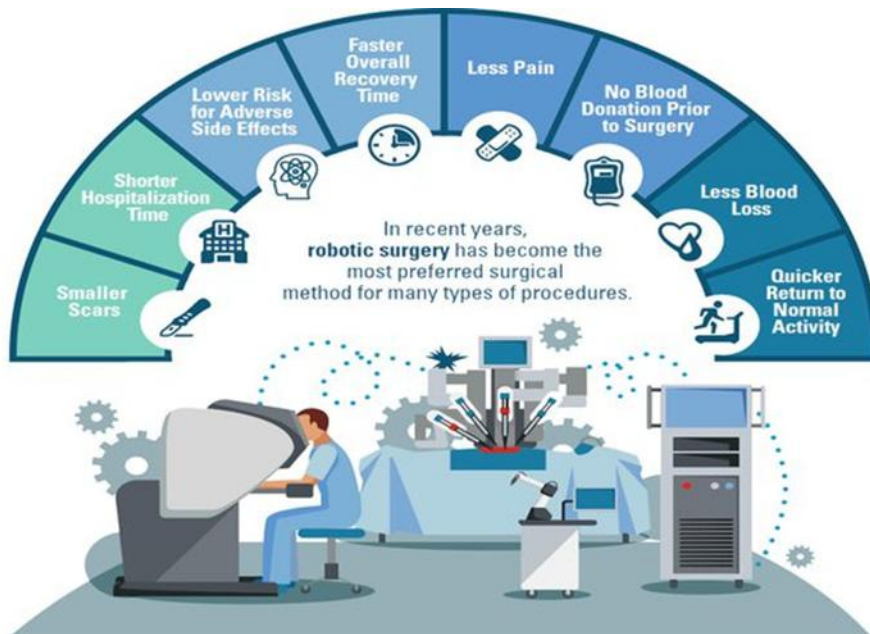


Figure 3.15 Overview of some of the key benefits to robot-assisted surgery [73].

J. Conclusion

In conclusion, robot-assisted surgery offers several advantages over traditional manual techniques, including increased precision, improved visualization, reduced physical strain and fatigue for surgeons, reduced incision size and shorter hospitalization for patients, and the potential for enhanced surgical skills through AI-enabled assistance. However, there are still a few disadvantages and areas for improvement in robot-assisted surgery. The disadvantages of robot-assisted surgery include the steep learning curve for surgeons, a loss of haptic sensation, limited variety of instrumentation, large bulky robotic systems, and the need for further

advancements in AI and machine learning integration, improved visualization, miniaturization, and remote surgery capabilities. However, it is important to note that researchers and developers in the field are actively addressing these disadvantages.

II. DESCRIPTION OF TOTAL & PARTIAL KNEE ARTHROPLASTY ROBOTIC SYSTEMS

3.4 Main Components & Parts

As described previously, orthopedic robotic systems are advanced technological tools designed to assist orthopedic surgeons in performing various procedures with enhanced precision and control. These systems consist of several key components and parts that work together to provide a high level of accuracy and improve patient outcomes. The main components and parts of an orthopedic robotic system are divided into two main categories. The ones that belong to the Robot Stand and the ones that belong to the Camera Stand, and comprise:

A. Robot Stand

- i. The Robotic Arm (Figure 3.16): This is a fundamental component of orthopedic robotic systems. It is responsible for the steering and precise movement of the robotic arm during surgery. The precision and accuracy of the robotic arm in orthopedic robotic systems are crucial in ensuring the success of surgical procedures. By mimicking the natural range of motion of a human arm, the robotic arm can navigate complex anatomical structures with greater precision than traditional surgical methods [83].



Figure 3.16 Robotic Arms of the ROSA[®] Knee and Mako[®] Knee systems [95], [175].

- ii. The Control System (Figure 3.17): It is the brain of the robotic system. It is comprised of the system's PC (or PCs) and the arm's controller. It is responsible for providing instructions to the robotic arm and monitoring its movements. It processes feedback data from various sensors and uses algorithms to calculate the optimal trajectory and position of the arm [83].



Figure 3.17 The Stäubli CS9 Robotic Arm Controller of the ROSA® Knee system [83].

- iii. The End-Effector (Figure 3.18): A tool or instrument attached to the robotic arm that directly interacts with the patient's anatomy during surgery. It can include tools such as surgical drills, saws, or instrumentation for implant placement [83].



(a) Cirq® system (courtesy of Brainlab)



(b) Navio Surgical System (courtesy of Smith & Nephew)



(c) ROSA® Knee System (courtesy of Zimmer Biomet)

Figure 3.18 Various End-Effectors of their respective systems [83].

- iv. Force Sensor (Figure 3.19): It provides feedback to the control system, allowing it to monitor and adjust the force and torque applied by the robotic arm [83].



Figure 3.19 The Force-Torque Sensor of the ROSA[®] Knee system (right image) attached on the Robotic Arm (left image) [83].

- v. User Interface (Figure 3.20): This is the interface (Touchscreen and Software) through which the surgeon interacts with the robotic system. It provides visual and auditory feedback, allowing the surgeon to control and monitor the movements of the robotic arm [83].



Figure 3.20 Various User Interfaces and their respective systems. At the upper left corner is the Velys[®] System, at the upper right the Smith & Nephew[®], at the bottom left the Stryker MAKO[®] and at the bottom right the Zimmer Biomet ROSA[®] system interface [83].

- vi. Stabilization System (Figure 3.21): It stabilizes the Robot Stand securely on the floor, providing the essential immovability through which the Robotic Arm, despite the vibrations it generates when sewing a bone, can operate with the necessary accuracy and precision needed. And this, without losing even the slightest contact with the anatomical structure it operates on [83].



Figure 3.21 The fully expanded stabilization system at the bottom of the ROSA® Knee Robot Stand [83].

- vii. Safety Button (Figure 3.22): This safety mechanism, if pressed, shuts off electronically the Robot’s Arm electrical power, in case of an abnormal movement noticed by the surgeon when in operation [83].



Figure 3.22 The Red Safety Button of the ROSA® Knee system [83].

viii. Trolley Wheels and Steering System (Figure 3.23): This is comprised of the handles and trolley wheels of the Robot Stand, which allow the user to place the Robot Stand at the exact point needed beside the patient, for the operation to take place. Each trolley wheel has its own stabilization mechanism that locks it individually in place [83].



Figure 3.23 The Trolley Wheels and Steering System (in blue) of the ROSA® Knee [83].

ix. The Foot Pedal or Omnidirectional Pedal (Figure 3.24) : Such devices, connected via a special 6-pin plug to the Robot Stand, provide the motion signals to the robotic arm. Surgeons, by pressing with their foot this particular switch, can move the robotic arm to the predefined position for cutting. The cutting margins are preset by the surgeon in the software, and the cutting motion of the robotic arm is constrained by the reflectors placed on the limb [83].



Figure 3.24 The Stryker MAKO® (left) & Zimmer Biomet ROSA® Knee (right) Foot Pedals [83].

B. Camera Stand

- i. The Camera Unit (Figure 3.25): This is the other fundamental component of orthopedic robotic systems. It is responsible for constantly reading the Robot's arm position in space-time, through feedback from a set of reflectors placed on the Robot Stand's chassis and patient's knee. The precision and accuracy provided by this constant reading are crucial in ensuring the success of surgical procedures. A set of infrared diodes placed on a rectangular box with two opaque windows at its sides, transmit and receive back a signal, which is then sent through a set of cable connectors to the Robot Stand (and more specifically to the Arm's controller), for further processing and analysis. In the end, this processed signal is being used to steer precisely the robotic arm during the operational procedure [83].



Figure 3.25 The Mako® Camera (middle stand) [83].

- ii. The Umbilical Cord (Figure 3.26): The set of cable connectors from the Camera Stand to the Robot Stand (and more specifically to the Arm's controller) that sends the camera's signal for further processing and analysis [83].



Figure 3.26 The Umbilical Cord of the ROSA[®] Knee system [83].

- iii. Trolley Wheels and Steering System (Figure 3.27): As in the Robot's Stand case, it is comprised of the handles and trolley wheels of the Camera Stand, which allow the user to place that Camera Stand at the exact point needed opposite the Robot Stand, for the operation to take place. Each trolley wheel has its own stabilization mechanism that locks it individually in place [83].



Figure 3.27 The Trolley Wheels and Steering System of the ROSA® Camera Stand (in blue) [83].

- iv. The Camera Arm (Figure 3.28): This is a mechanism that provides the necessary up, down, and rotational movement to the camera box, to be placed accurately on the exact point of view that will allow it to track precisely each reflector placed on the Robot's Stand chassis and patient's limb that is under operation [83].



Figure 3.28 The Camera Arm with its protruding handle of the Velys® Knee system [83].

- v. The Reflectors (Figure 3.29): This set of reflectors is placed upon the robot stand and the patient's limb, to provide the necessary points of reference for the guidance and steering of the Robotic Arm [83].

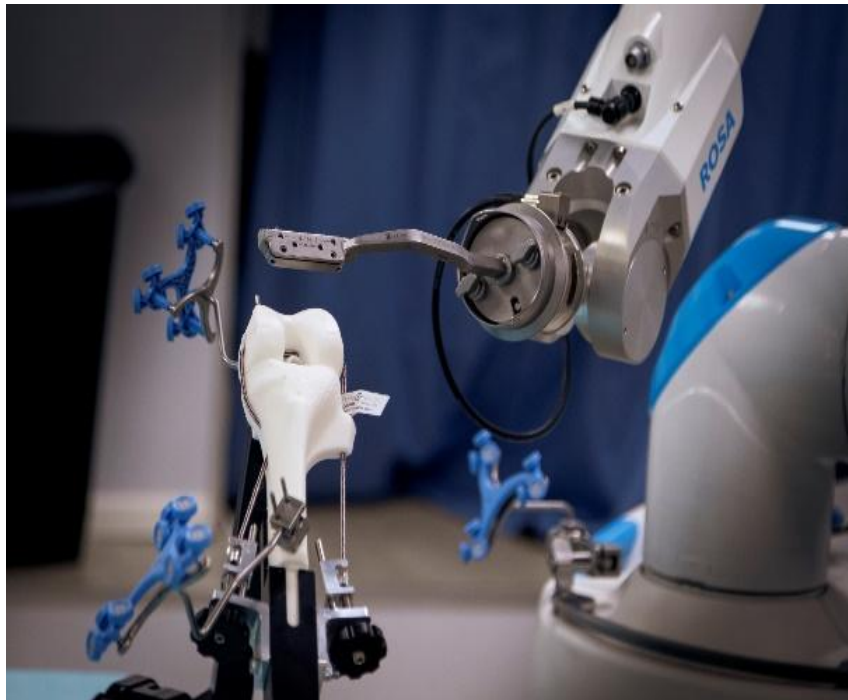


Figure 3.29 The various reflectors (blue plastic star-shaped items) of the ROSA® Knee system [83].

3.5 Interconnection and Interaction among its Parts and Components

It is established that the technical and mechanical operations of robots used in surgery conform to three core laws: a robot may not injure or cause harm to humans, a robot has to take and act upon human instructions to avoid conflict with the first law, and the existence of robots should be protected to avoid conflict with the first and second laws [84]. These laws ultimately govern the nature and mechanisms by which the technical and mechanical components of robots used in surgery are designed and used to perform various procedures.

Robotic components are constructed by connecting a series of bodies, also known as links, via joints (Figure 3.30), and such joints are triggered or programmed to move through electrical motors, known as actuators, which exert a force or torque upon said joints. The links are usually attached to end-effectors, such as graspers, and movements or the range of motion or articulation can be defined across a range of limits through configuration points based on mathematical concepts. In robotic arm-assisted surgery, and other forms of robotic surgery, the configuration of movement is represented by the number of degrees of freedom (DoF) and thus, the configuration covers all possible positions in which, robotic components may be placed or effected at any one time. The DoF (Figure 3.31) is normally calculated via the simple formula: the sum of freedoms of the points / the number of independent constraints. In essence, a rigid robotic body in three-dimensional space has six DoF, while a component moving within a two-dimensional plane has three DoF [85].

However, the number of DoF when accounting for the constraints of variant types of a robotic joint can be derived using Grubler's formula: $3(n-1)-2L-H$ with n representing the total number of links, L reflecting the total number of lower paired joints and H representing the total number of higher pair joints [86].

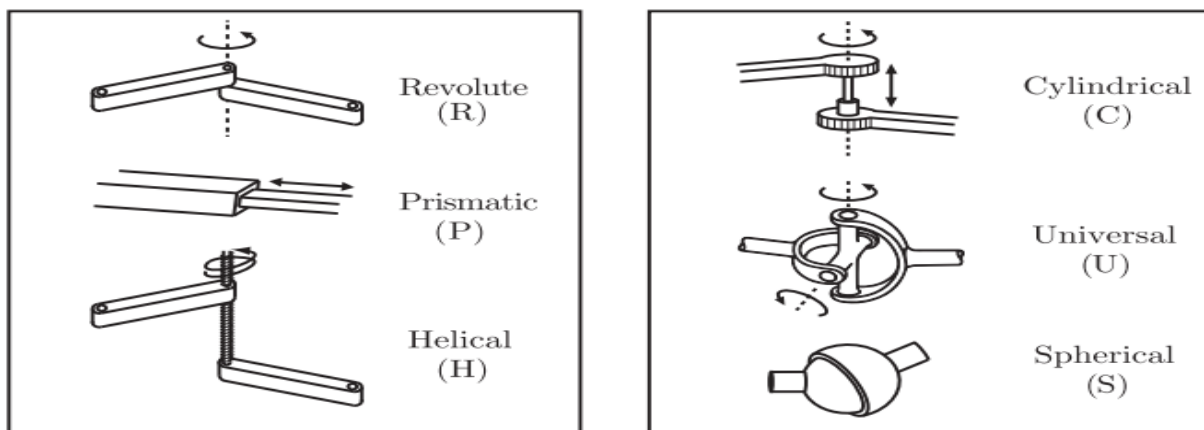


Figure 3.30 Schematic of the differing types of joints used in robotic components [85].

Configurations for robots also require delineation of the representation of space, motion velocity, and working space with the latter being particularly important as this restricts the operations of end-effector components. In knee surgery, the working space would be limited to pre-planned areas of bony tissue requiring cutting or resecting through bur-type end-effectors [86].

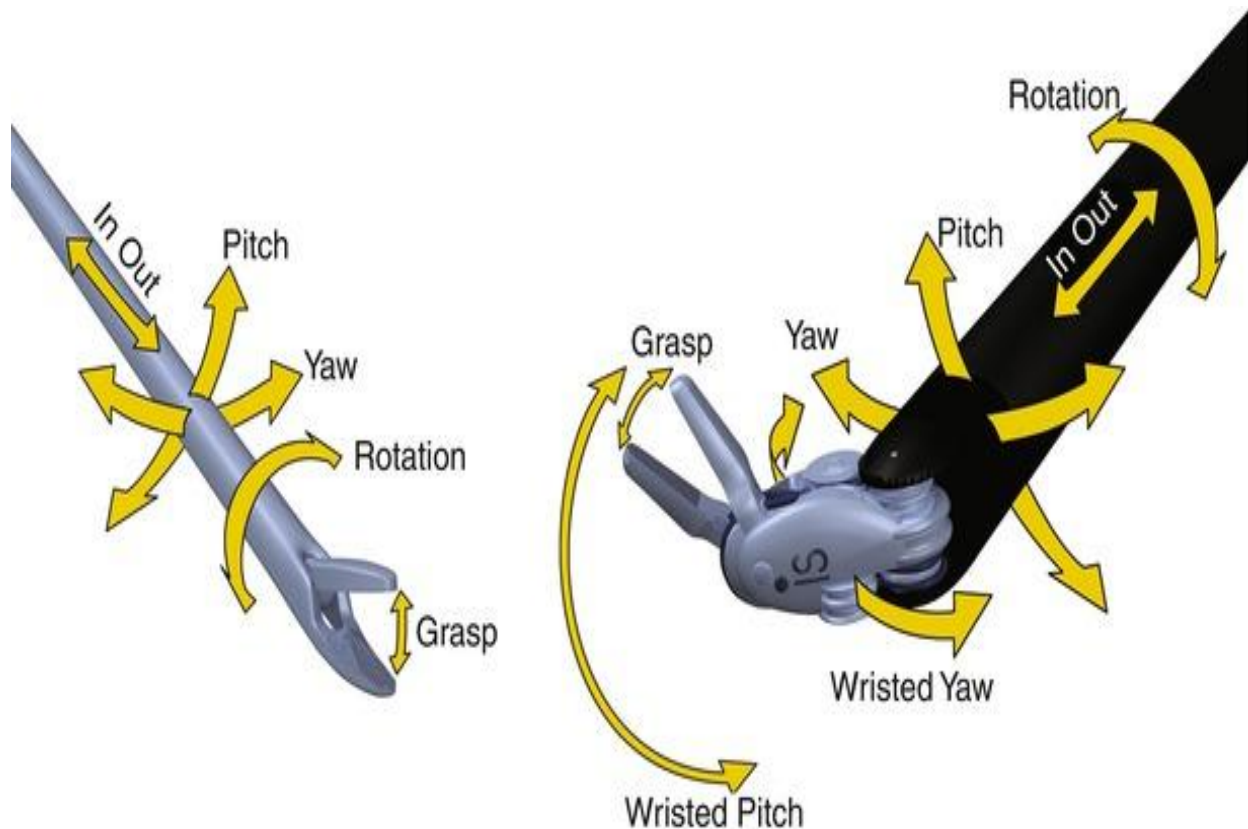


Figure 3.31 Pictorial demonstration of the possible degrees of freedom in surgical robotics. The degrees of freedom vary by the type of instrument [86].

Notably, the task and working spaces can be influenced or altered by the operator, thus, enabling interactions between robotic components and surgeons when performing specific procedures. In light of given configurations for varied robotic-arm-assisted devices, there is also a delineation of the position and orientation of end-effectors relative to the reference frame or body, and forward kinematics, which refer to the position and orientation of end-efforts relative to the respective joint position (Figure 3.32) [87].

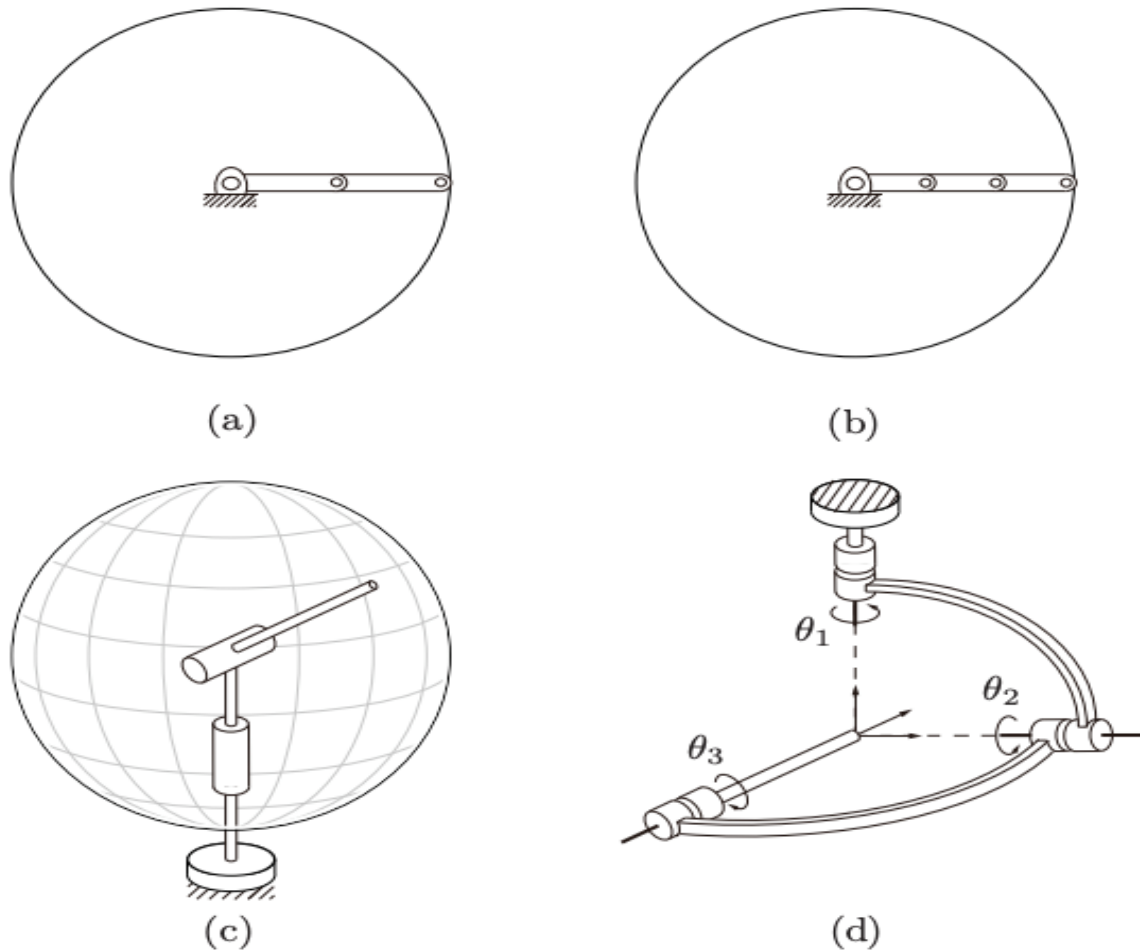


Figure 3.32 Schematic showing examples of configured working spaces for robotic components: a) Planar 2R open chain, b) planar 3R open chain, c) spherical 2R open chain, and d) 3R orientating [85].

Motion planning is perhaps one of the most integral elements of robotics in terms of surgical preparation and performance as components require motion from a starting or resting state to a goal state, whilst avoiding objects in the external environment and while satisfying specific limits, such as velocity and force. This also has implications for the safety of using robotics during surgery as configurations are also used to detect and avoid unwanted collisions with robotic components. Concerning the control of robotic components, it is the role of the operator to apply a stimulus upon the component/s, in order to induce conversion of the signal into a specific robotic task, action or effect.

This signal is transmitted to actuators that then apply a given force or torque to induce motion at one or more joints. Such motions can be achieved via motion control, force control, a hybrid of motion and force control, or through impedance control. Following one or more of these controls, feedback control can be applied to achieve desired robotic behaviour, such as via position, velocity, and force sensors that measure and compare effectors with the intended actions and modulate control through the actuators. An example of a typical robotic control system is shown below (Figure 3.33).

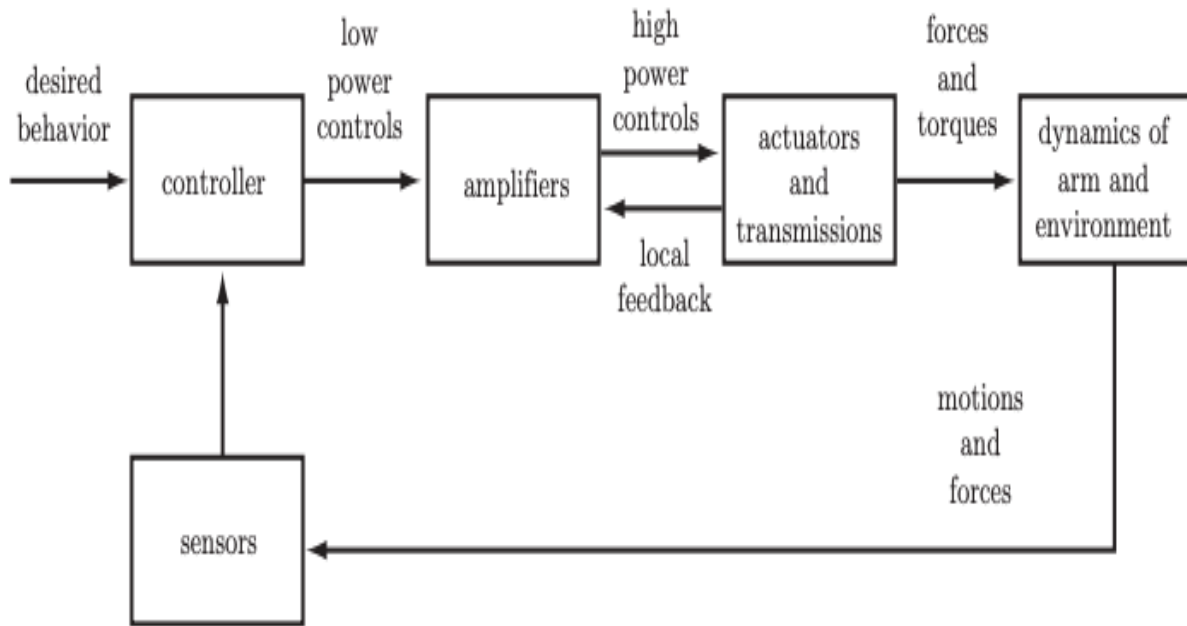


Figure 3.33 Overview of a typical robotic control system. An inner control loop that can be used to assist the amplifier and actuator in achieving the desired force or torque of effector components and with feedback relay control via sensors [85].

About motion control, there is a degree of control over the forces or torques applied via robotic joints, and the interactions influence joint acceleration and thereby, velocity. However, this simple motion control is usually limited to robotic components that are concerned with applying low levels of or predictable forces or torques. Thus, in motion control with force or torque input/feedback, the outputs of effectors are manipulated by the frequency of pulses propagated to the actuator, as amplifiers can regulate and manipulate the effectors through influencing responses of the actuator and thereby, the joint velocity and force.

Moreover, force control can also be applied when force at the end-effectors is also needed in addition to motion or velocity and is therefore, particularly relevant for effectors in surgery with bone-cutting ability; a high force is needed to apply the bur against body tissue to achieve

resection. This requires resistance forces to be applied and detected in all directions and indeed, precise and safe control of the extent of resection of bone tissue demands control of motion with hybrid motion-force control.

Furthermore, impedance control is needed to cope with the extremes of hybrid motion-force control with ideal motion reflecting high impedance and ideal force control reflecting low impedance to yield an impedance range. This enables robotic components to interact and exert effector actions upon human tissue with high accuracy, precision, and control. Of final relevance to this subsection is the control of grasping and manipulation actions of robotic effectors, which involve the application or configuration of contact kinematic parameters, contact force and friction parameters, and manipulation limits [85].

3.6 Mode of operation and human-machine interaction

Robots have become increasingly utilised during complex surgical procedures and to assist in replacing major surgery for minimally invasive approaches. This has demanded detailed insight into the interaction between surgeons operating robotic machinery and the motor outputs of robotic instruments [88]. The interaction between surgeons and robotic machines can vary considerably depending upon the robotic-assisted surgical system being utilised [89]. For example, the Da Vinci™ surgical system operates via the master-slave principle, in which, four robotic arms can be manipulated via the surgeon working at two consoles.

The robot has six DoF with a four DoF arm external to body cavities and a two DoF wrist-type joint at the tip that operates internally to those cavities. The surgeon is able to manipulate the DoF across these joints via remote slave arms through the master console. The hand motion of the surgeon is translated into highly accurate robotic movements and manipulations of instruments, essentially replicating the surgeon's hand movements, but scaled down to provide markedly enhanced precision. The surgeon can visualise the surgical field at the master console through the slave-arm camera (Figure 3.34) [90].

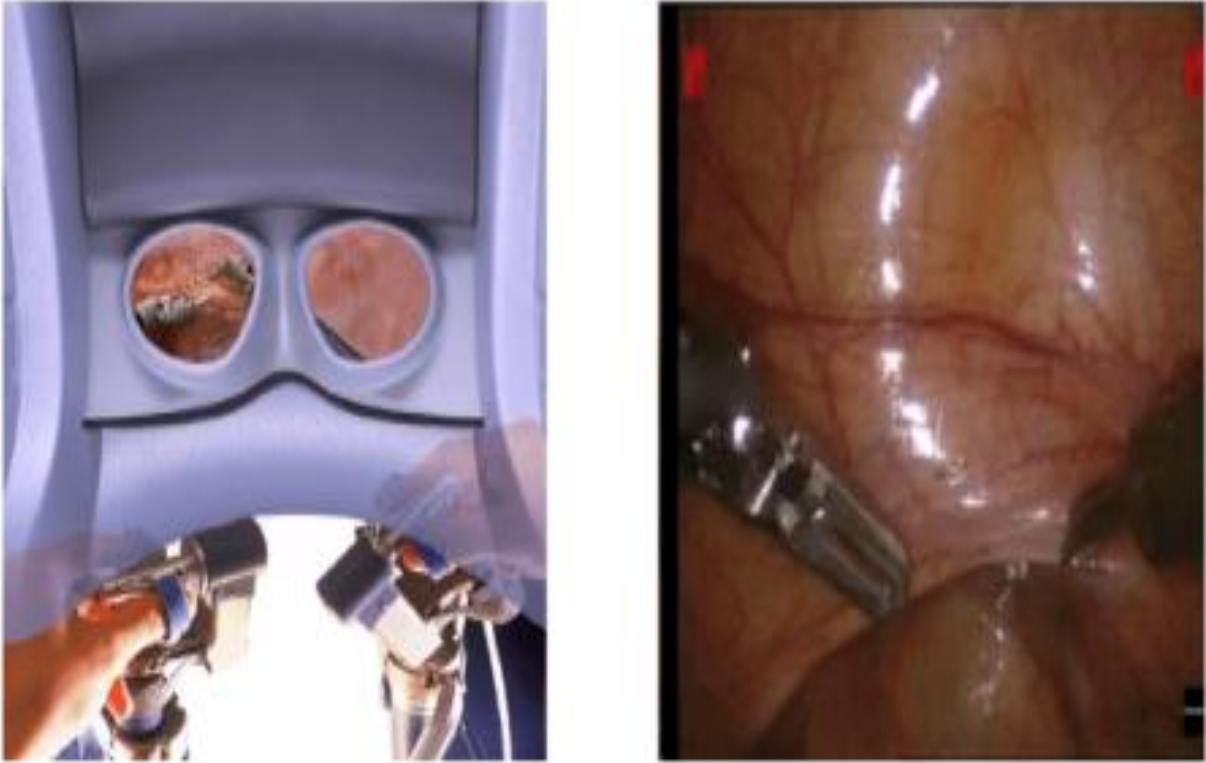


Figure 3.34 Representations of the surgeons' position and hands at the master console with the screen of the operative field (left) and the reflective robotic instrument view (right) [91].

However, this system is lacking of haptic-based feedback, which may diminish the ability of surgeons to adjust and respond to the vital sense of touch. Nonetheless, advances in robotic systems have led to the emergence of those able to provide haptic feedback. This is achieved by using pneumatic drive to provide an interaction between contact and grasping force on the slave side of the robot and to pressure forces applied proportionately to the hands of the surgeon via the console arms (Figure 3.35) [92].

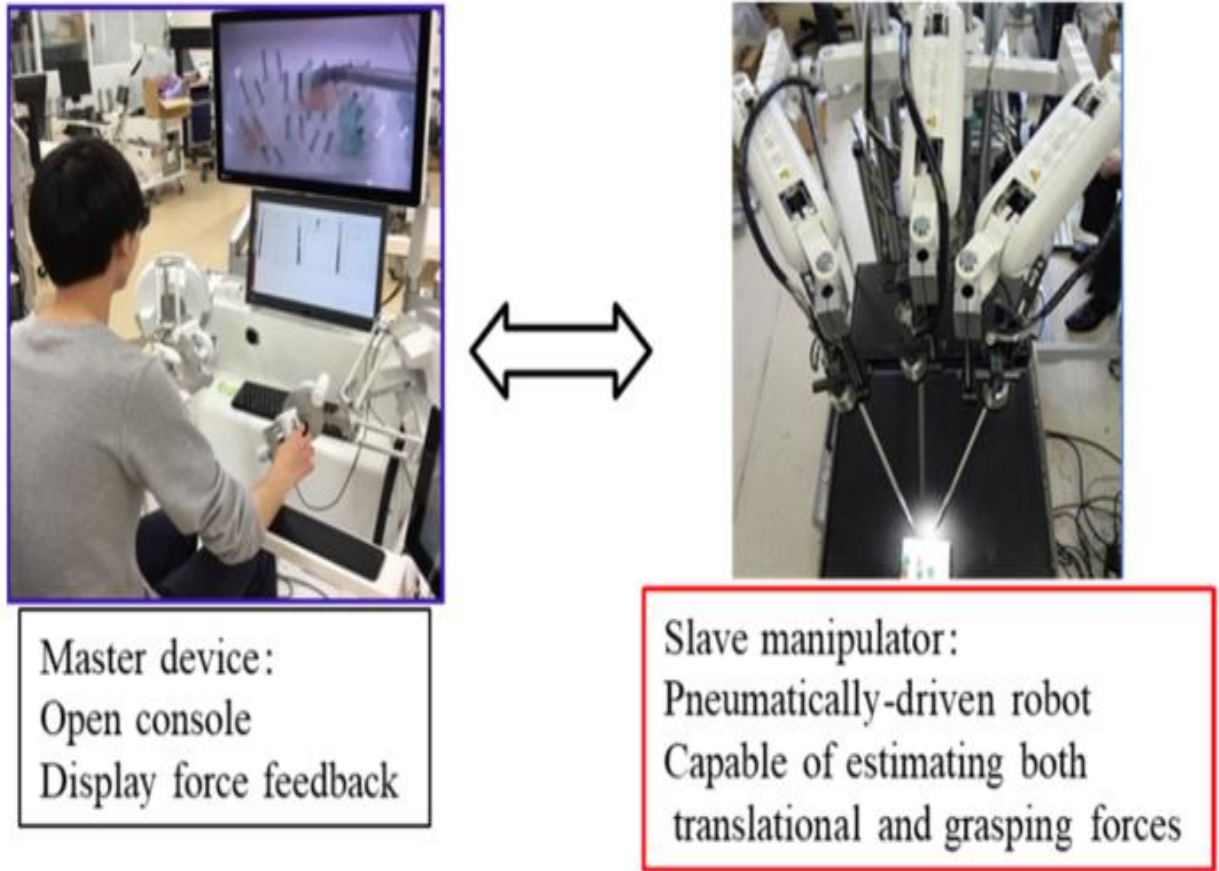


Figure 3.35 Pictorial representation of a master-slave system able to provide haptic feedback to the surgeon through pneumatic drive [92].

In the context of knee surgery, hand-held systems have been in greater operative use with a key example, for instance, the NAVIO system. This system comprises variable surgeon-robotic interactions to those described previously, although the principles remain similar in terms of scaled fine motor movements and control [93]. In generic terms, hand-held robotic instruments consist of electrically driven and computer-assisted forceps that are operated by the surgeons' hands either via external or wearable components. There have been advances in the power-to-weight ratio of actuators, allowing for greater comfort and ease of operation [92].

The NAVIO system (Figure 3.36) is one type of hand-held robotic assistive device being used in knee surgery, which enables manipulation of the instruments in six DoF, but while limiting cutting of tissue/bone to the confines of a pre-defined resectable area. In addition, limits are defined peri-operatively, to allow highly individualised operative planning [94].



Figure 3.36 The Smith & Nephew NAVIO® System [199].

The surgeon can manipulate the device to “paint” a 3-dimensional model of the anatomy of interest, which is achieved via a point probe with infrared sensors (Figure 3.37) and collection of data through the holding down of a foot pedal. Further data is also collected via this interaction, so as to gain information regarding range of motion across articular confines, to establish additional resection areas, to identify optimal reference points for denoting the boundaries of the plateau and condyle.

The software then enables the modeling of the anatomy in order to formulate the individualised implant. The hand-piece is then used in a semi-autonomous manner to permit the resection of the bone. This can be achieved by two methods. First, with what is known as ‘exposure control’, the surgeon moves and triggers cutting (providing that the bur is within the designated resection area), and, second, with what is known as ‘speed control’, involves a similar interaction, but this time the rate of resection is automatically refined when approaching the resection borders.

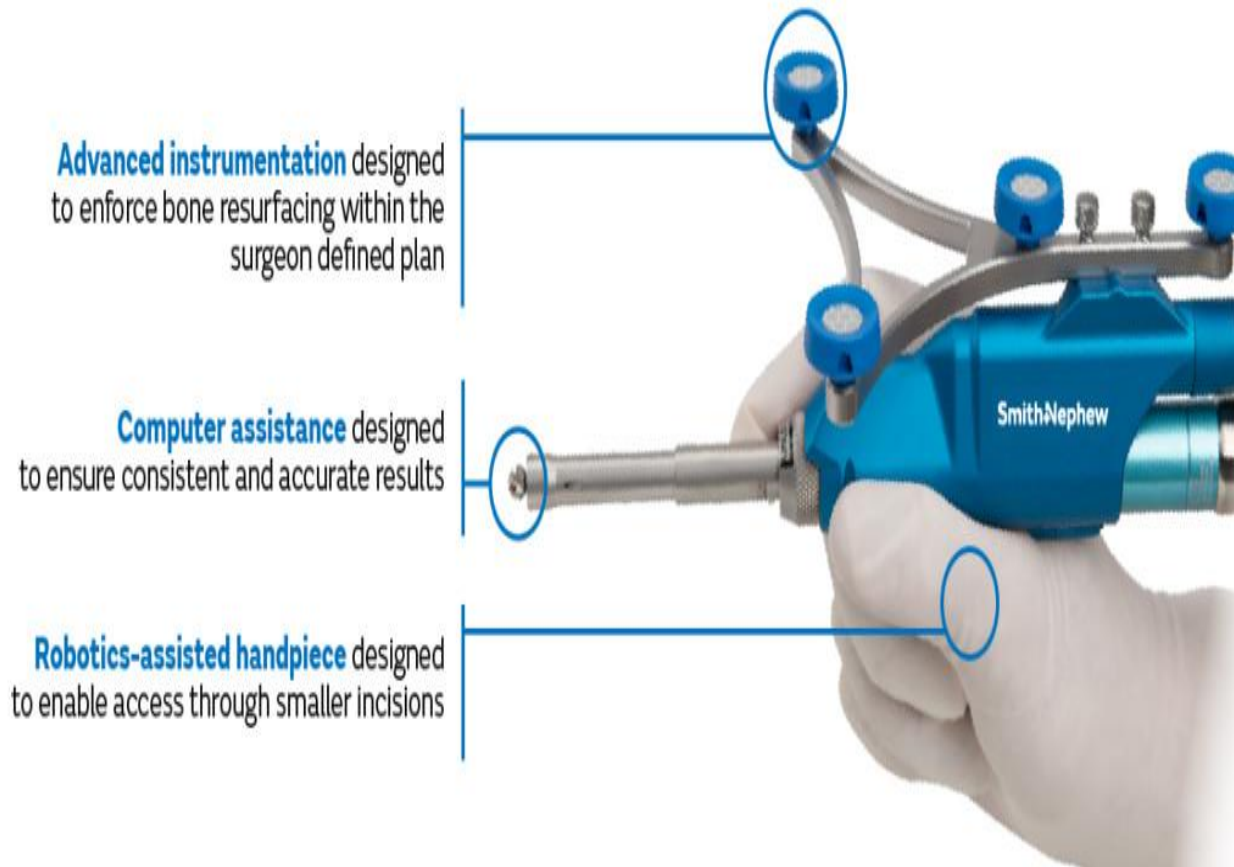


Figure 3.37 Hand-held NAVIO® robotic-assisted system for knee arthroplasty [94].

Visual representations demonstrate resected and bone remaining to be resected through the control screen (Figures 3.38 – 3.39). After manual implant placement, the NAVIO system enables a computer-generated assessment of the post-operative gap and in response to the data feedback, the surgeon can then decide whether or not to perform any further resection of bone by returning to the NAVIO-guided planning and resection stages [94].



Figure 3.38 Registration of femur anatomy using the NAVIO system with the infrared probe and foot pedal for data collection [94].

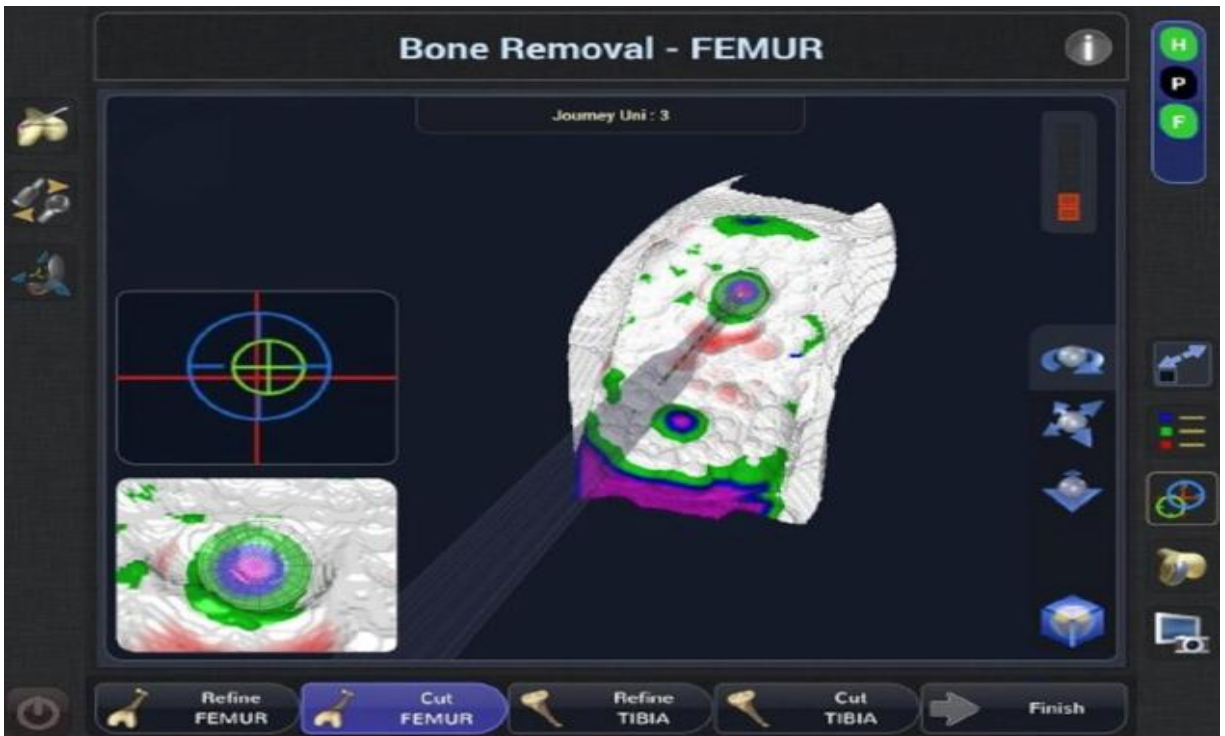


Figure 3.39 Screen-guided representation of resected bone and remaining bone for resection [94].

Another similar hand-held device is the ROSA Knee System (Figure 3.40), that also comprises an image-guided or image-less approach to surgery, and one comprising a hand-manipulated robotic arm with a touchscreen and an optical unit also with a touchscreen.



Figure 3.40 The Zimmer Biomet Rosa Knee® System [95].

Using this system, the surgeon can use the registration pointer to digitalise the bony landmarks, as with the NAVIO system, and the movement of the robotic arm is enabled through the use of a foot pedal. Depression and holding of the foot pedal can be used to record or digitalise data for surgical planning. NavitrackER® devices (Figure 3.41) are installed on the system to enable optical tracking.

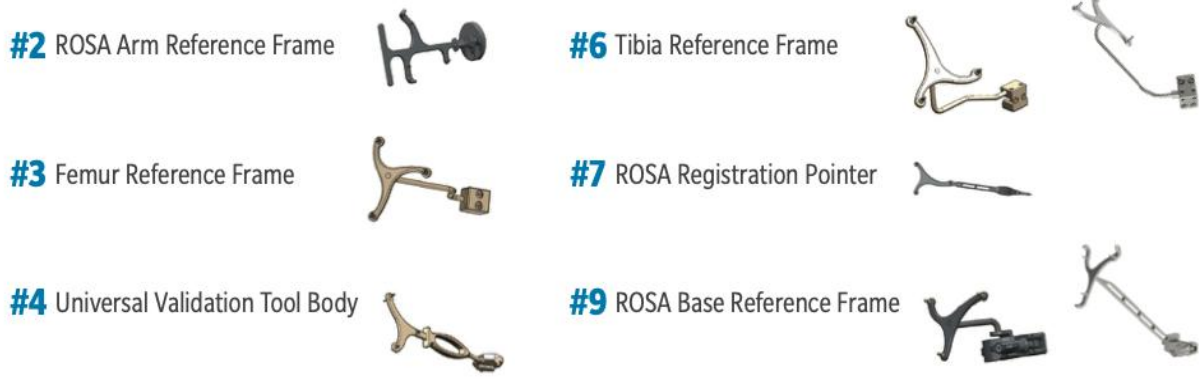


Figure 3.41 The 6 Zimmer Biomet ORTHOsoft® (Navitracker®) Kit & Registration Surgical Tools upon which are fit [95].

Movement of the robotic arm can be automated (pre-determined) or collaboratively where the surgeon can apply a gentle force to the end of the arm to assist in guiding it towards the desired position. This mode is also coupled to bone tracking to enable bone cutting in line with the planning resection areas. During land-marking, the robotic arm needs to be optimally positioned to ensure the points are within the target area and at a sufficient distance from one another as to avoid incurring a computer-detected error; points are too close, points outside of the defined area or incorrect laterality. Moreover, the Navitracker® needs to remain within the visual field of the camera and therefore, a clear path from the Navitracker® to the camera is needed at all times to avoid error and interruption to the operative flow (Figure 3.42).



Figure 3.42 The Zimmer Biomet Rosa Knee® System optimally placed during an operation [180].

This means that the surgeon may need to reposition the camera at various times during the operative or cutting phases; usually in some proximity to where the registration was performed/planned. Optimal position is provided as a visual light-based feedback to the surgeon. Green for optimal position and red for a non-optimal position requiring adjustment. The camera angle can also be adjusted to ensure the laser is directed toward the NavitrackER® on the robotic arm. Surgeons can also interact with the display panel to access and adjust operative parameters, such as the femoral rotation axis display, the evaluation of knee status, flexion angles, and bone reference checkpoints (Figure 3.43) [95].

6.6 Camera Positioning

Move the Robotic Arm to Camera Target Position

- Press and hold the foot pedal to move the robotic arm to the camera target position.



Risks of collision: When the robotic unit is in automatic mode, stay clear of the robotic arm and its path to the next position.

Position the Optical Unit

- The optical unit should be on the opposite side to the surgeon and robotic unit, as shown in the user interface.
- Follow the instructions on the screen to position the camera in the optimal position area and at the optimal height.
- The camera is red when it is not in the optimal position. It turns green when the position is optimal.

Adjust the Camera Angle

- Angle the camera so that the laser is aiming at the center of the Navitracker installed on the ROSA Arm Reference Frame (robotic arm).
- Click CONFIRM when the laser is centered on the Navitracker.



Figure 3.43 The Zimmer Biomet Rosa Knee® System proper Camera placement instructions [95].

Table 3.2 Comparison between the current available market Knee Robotic Systems [176],[198],[199].

| Variable | MAKO | NAVIO | ROSA | T SOLUTION ONE | VELYS |
|----------------------|---------------------------------|---------------------------------|---|--------------------------------|------------------------------------|
| Type | Semi-active | Semi-active | Semi-active | Active | Semi-active |
| Input | | | | | |
| Base | CT + mapping | Imageless, pure mapping | Imageless or plain film radiographs + mapping | CT + mapping | Imageless, pure mapping |
| Mapping | Handheld probes (sharp + blunt) | Handheld probe | Handheld probe (blunt) | Machine-connected RA | Handheld probe (blunt) |
| Dynamic info | Femur/tibia arrays | Femur/tibia arrays | Femur/tibia arrays | N/A | BalanceBot integrated gap analysis |
| Variability | | | | | |
| Planning | Pre-and-intra-and-postoperative | Pre-and-intra-and-postoperative | Pre-and-intra-and-postoperative | Preoperative | Pre-and-intra-and-postoperative |
| Ability to adapt | ✓ | ✓ | ✓ | N/A | ✓ |
| Implant | Brand restricted | Brand restricted | Brand restricted | Implant database/open platform | Brand restricted |
| Output | | | | | |
| Soft-tissue balance | Laxity pre- and post-cut | Laxity pre- and post-cut | Laxity pre- and post-cuts | N/A | Laxity pre- and post-cut |
| Measured resection | ✓ | ✓ | ✓ | ✓ | ✓ |
| Functional alignment | ✓ | ✓ | ✓ | N/A | ✓ |

| Variable | MAKO | NAVIO | ROSA | T SOLUTION ONE | VELYS |
|--------------------------------|-------------------------------------|---------------------------------|--------------------|-----------------------|--------------------------------------|
| | | | | | |
| Execution | | | | | |
| Execution | RA | Handheld | RA (jig) + manual | RA automatic | RA (jig) + manual |
| Soft-tissue protection | Haptic feedback /virtual boundaries | Smart burr / virtual boundaries | Handheld saw | Autonomous burring | Haptic feedback / virtual boundaries |
| Footprint | > 1 m ² | 0.5 to 1 m ² | > 1 m ² | >1 m ² | 0.5 to 1 m ² |
| Estimated cost (MSRP in USA\$) | 1,000,000 | 500,000 | 700,000 | 800,000 | 600,000 |

III. OVERALL PERFORMANCE

3.7 Comparison between traditional and robot-assisted surgery regarding speed in various surgical techniques. Metrics and data.

The key stages of robot-assisted knee arthroplasty can be generally divided into three key phases: pre-operative planning, bone preparation, and implant placement. Pre-operative planning may involve image-guided or non-image-guided methods depending upon the type of robotic system being utilised. However, real-time intra-operative planning (bone registration) may also occur following the incision. This stage is needed to permit the assessment, suitability, and selection of the implant. The next key stage involves bone preparation to permit readiness for implant insertion: this involves the excision of bone tissue in accordance with disease and implant needs. The final stage involves the insertion of the implant, performing landmark and functional checks, and closure [96].

Several studies have explored the effects of robot-assisted surgery on operative time compared to conventional (non-robotic) surgery, which is an important outcome measure, as this can influence service costs, resource use, and staffing management. The empirical literature specific to knee surgery has been discussed, although wider literature has also been used to corroborate the findings, given the current paucity of evidence in the field.

In a prospective cohort study of 101 patients who underwent total knee arthroplasty, Tay, et al. [97] examined the impact of robotic-arm-assisted surgery that three surgeons performed over a mean follow-up period of two years. In terms of operative time, the results showed that the use of robotic surgery during the surgical proficiency stage was associated with a significant 12-minute increase in time of surgery per patient, as compared to mean operative times during the learning stage (90.3 v. 78.4 minutes, $p < 0.01$).

This additional time was attributed to enhanced time using the robotic surgical approach and in using registration software to assist in operative planning (four minutes, as well as more time needed for bone preparation prior to resection (five minutes, $p < 0.0001$). Other additional time in using the robotic approach relative to the learning phase was needed for joint balancing, component trialing, cement implantation, and incision closure, although the differences between the learning and proficiency phases were not statistically significant (all $p > 0.05$). (Table 3.3).

Table 3.3 Overview of operative time in minutes by surgical phase as reported by Tay, et al [97].

| Surgical stage (mins) | Cases 1–10 (n = 30) | Cases 11–20 (n = 30) | Cases 21–30 (n = 22) | Cases 31–40 (n = 10) | Cases 41–50 (n = 9) | P-value |
|------------------------------|-------------------------|-------------------------|-------------------------|------------------------|------------------------|-----------|
| Approach + bone registration | 15.9 ± 5.3 (9–34) | 13.3 ± 3.3 (7–20) | 11.5 ± 2.8 (8–17) | 12.9 ± 1.6 (11–16) | 15.1 ± 2.4 (11–18) | 0.003 * |
| Joint balancing | 8.4 ± 4.3 (3–21) | 8.0 ± 3.7 (2–17) | 7.1 ± 3.4 (2–16) | 6.7 ± 1.7 (4–9) | 5.7 ± 2.1 (3–9) | 0.42 |
| Bone preparation | 13.0 ± 6.0 (6–26) | 8.8 ± 3.7 (1–23) | 8.5 ± 5.0 (2–25) | 8.2 ± 4.8 (5–21) | 8.2 ± 5.8 (5–23) | <0.0001 * |
| Component trialling | 18.7 ± 7.8 (6–47) | 18.6 ± 7.7 (7–38) | 17.8 ± 4.5 (12–28) | 17.1 ± 6.4 (8–29) | 20.4 ± 4.1 (17–27) | 0.86 |
| Cement Implantation | 11.3 ± 3.7 (3–16) | 12.5 ± 5.0 (4–21) | 9.2 ± 5.2 (3–17) | 9.8 ± 4.9 (3–15) | 12.8 ± 2.3 (9–15) | 0.20 |
| Closure | 21.8 ± 3.3 (16–28) | 20.5 ± 5.7 (12–35) | 21.7 ± 6.1 (15–38) | 18.4 ± 5.3 (11–26) | 19.8 ± 3.7 (14–25) | 0.27 |
| Total operative time | 92.1 ± 14.2 (69–140) | 84.4 ± 14.3 (63–121) | 79.0 ± 11.4 (58–102) | 75.3 ± 11.0 (57–91) | 77.8 ± 14.0 (51–97) | 0.003 * |

Finally, it is worth noting that the inflexion point for the three surgeons was observed at a mean of the 16th patient case: differentiating the learning from proficiency phases. However, the outcomes were based on comparisons between the said phases, and thus, a lack of comparison against non-robotic procedures precludes insight into this evidence area. There has also been a lack of evidence to identify the variances in attaining proficiency and operative time for robot-assisted knee arthroplasty across differing underlying pathologies: osteoarthritis versus other diseases of the knee (Figure 3.44).

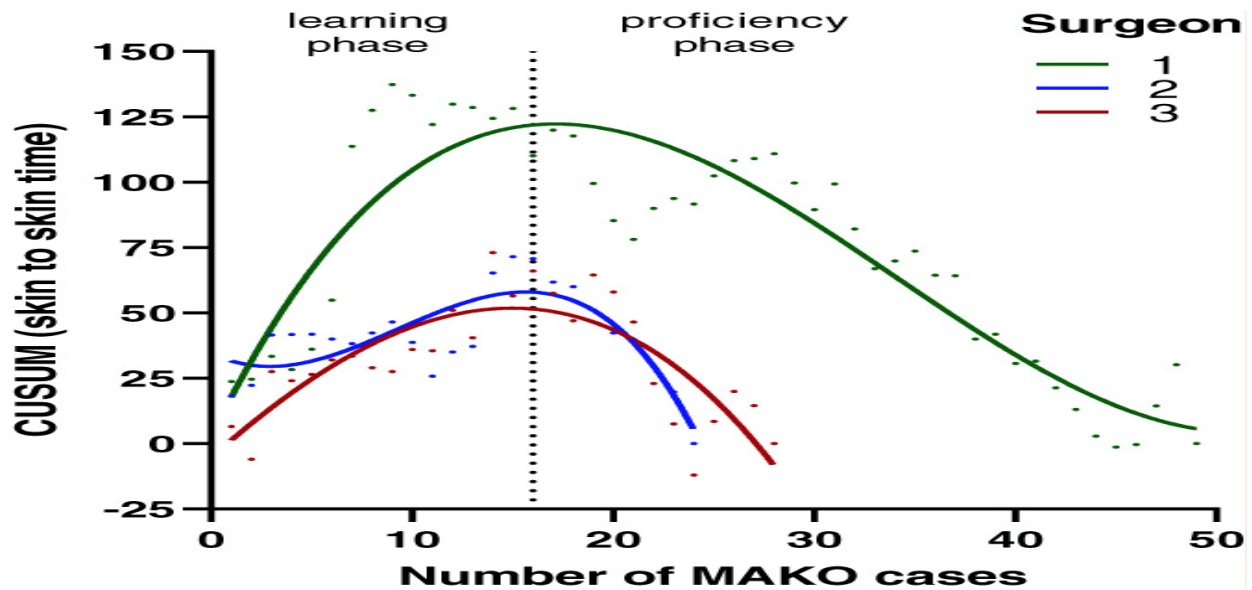


Figure 3.44 Analysis of learning curves for three surgeons performing robotic arm-assisted total knee arthroplasty; inflexion point shown at the 16th case [97]. The Horizontal Axis shows operative time in minutes and the Vertical Axis the number of operations per doctor.

A comparable inflection point has also been demonstrated by Zhang, et al. [98] where in a retrospective analysis of 90 patients who underwent robot-assisted total knee arthroplasty, the inflection points for the three surgeons were identified after 8, 9, and 16 cases, yielding a mean of 11 cases, which represents a 31% difference relative to that of Tay, et al. [97].

However, in this study, robot-assisted surgery cases were compared against the last 30 conventional surgical cases as to derive more insightful comparisons of the impact of the approaches upon operative time and efficiency. The mean operative time for all robotic-assisted cases was found to be significantly longer, than compared to the mean operative time for all conventional cases (111.0-113.6 v. 84.5-96.9 minutes, $p=0.021$), nonetheless, this became insignificant when limiting robotic-assisted cases to the last 10 cases (post-inflection points): 111.0-113.6 v. 93.7-105.9, $p=0.158$).

This suggests that robot-assisted total knee arthroplasty comprises a relatively non-inferior operative time as compared to conventional surgery. There were considerable variances in the operative times between surgeons, however, and this may present some uncertainty regarding the absolute differences in operative time between robot-assisted and conventional knee surgery. Greater duration of experience among surgeons tended to co-exist with faster operative times, indicating that sufficient training and use of surgical techniques is vital to optimising efficiency.

In contrast to the operative time differences reported by Zhang, et al., [98] (Figure 3.45), Eason, et al. [99] found that the mean operative time for robot-assisted total knee arthroplasty was significantly better than compared to conventional surgery (79 v. 75 minutes, $p=0.017$), although, it may be arguable as to whether the mean four-minute difference is meaningful.

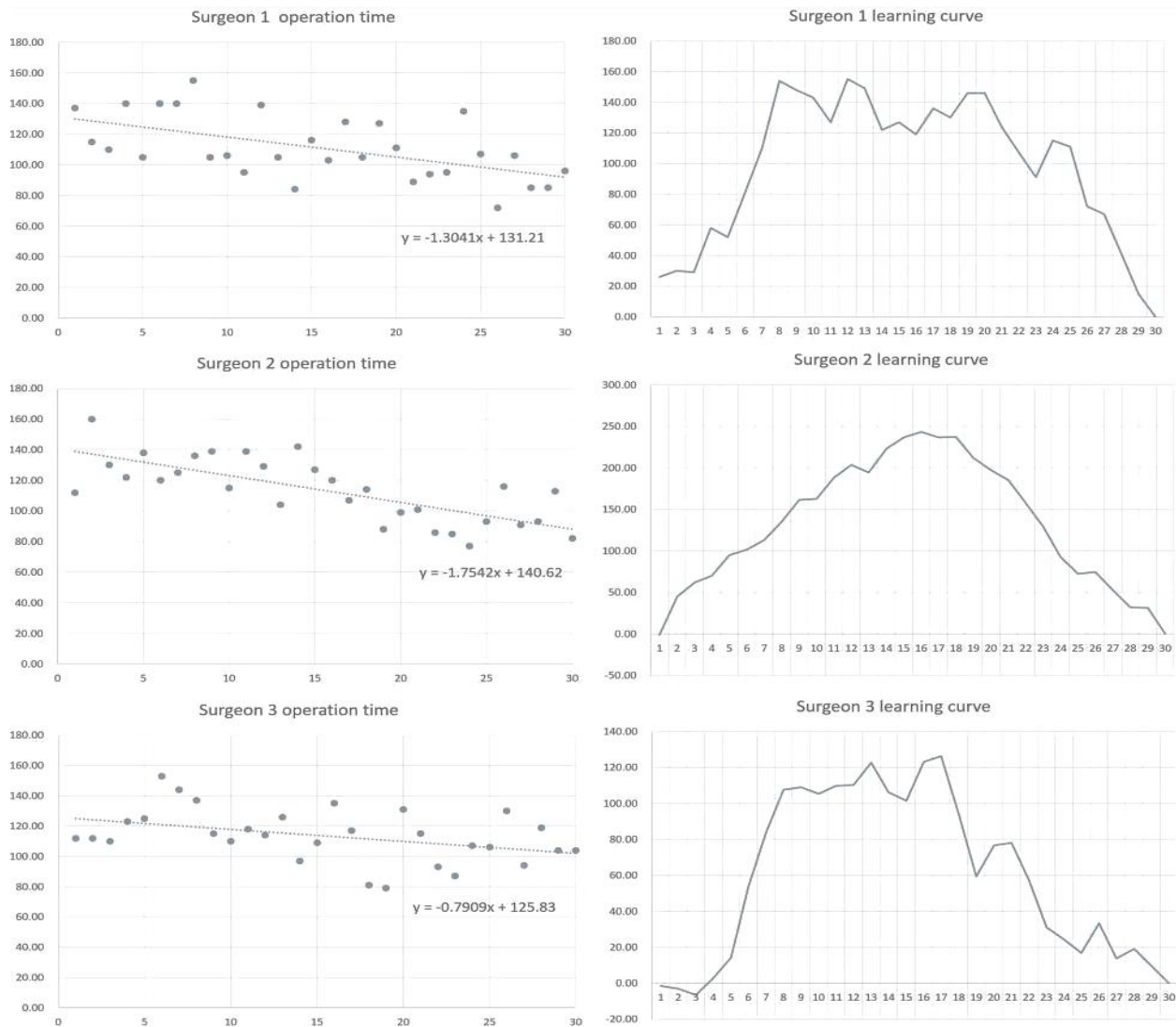


Figure 3.45 Overview of the learning curves for three surgeons using a robot-assisted surgical system for total knee arthroplasty with the associated improvements in operative time with gains in proficiency [99]. The Vertical Axis represents operational time in minutes and the Horizontal Axis the number of operations performed.

In another comparison of robotic-arm-assisted total knee arthroplasty versus conventional surgery, Kayani, et al. [100] (Figure 3.46) found that there was a sharp inflection point observed at a mean of the first seven cases and in keeping with the findings of Tay, et al., [97] there was a

significant difference in operative times between the learning and proficiency phases (89.2 v. 66.8 minutes, $p=0.01$).

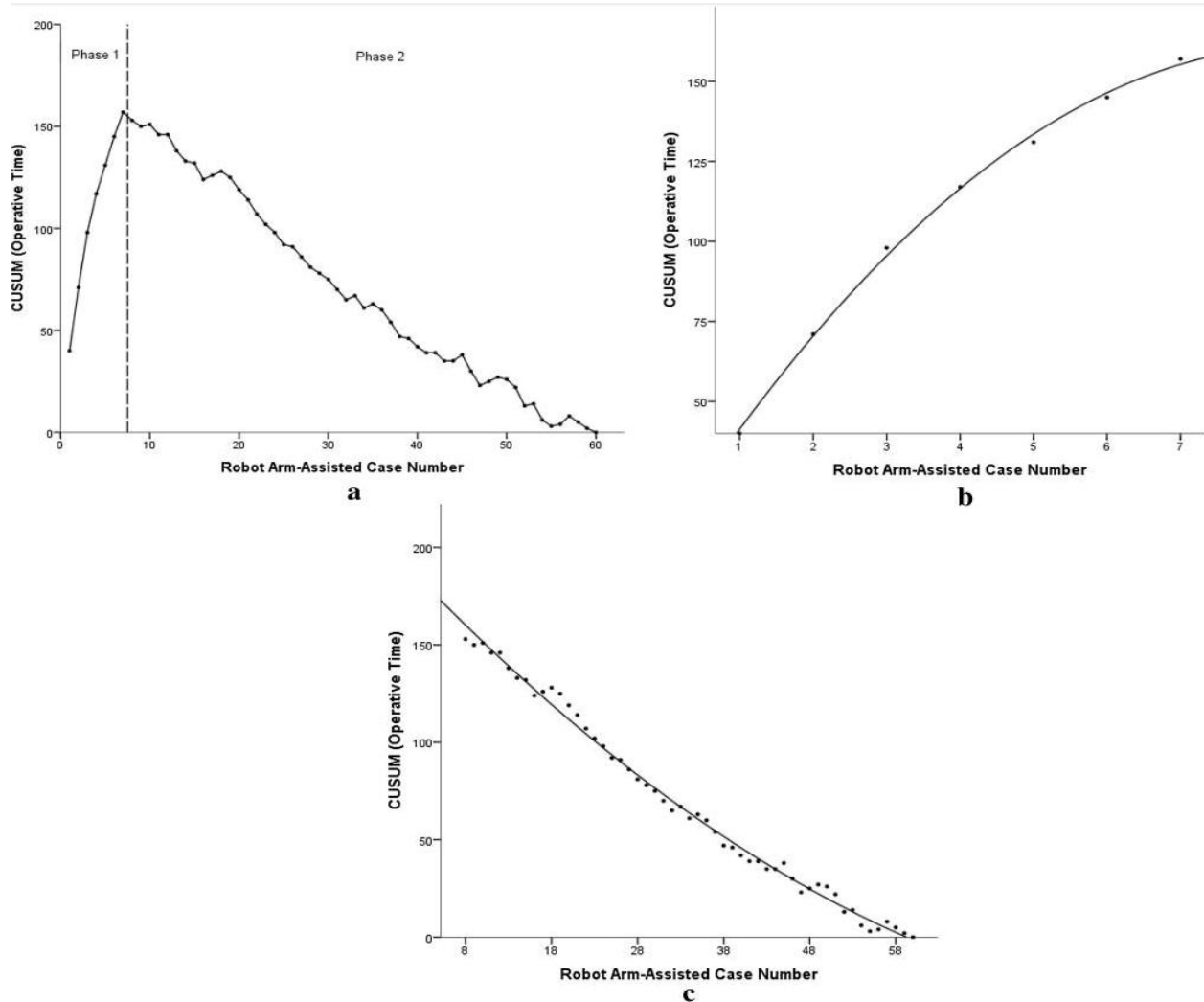


Figure 3.46 Graphical representations of the inflection point and improvements in operative time with proficiency [100]. The operative time on the Vertical Axis is in minutes.

The improvement in operative time was related to enhanced proficiency (speed) in performing robotic device setup, bone registration, joint balancing, and bone preparation as the differences in time to complete these tasks between the learning and proficiency phases were statistically significant (all $p<0.05$). No significant phase differences were observed for the surgical approach, implant trialing, cement implantation, and incision closure, although these are generally manual tasks as opposed to requiring or involving robotic assistance (all $p>0.05$).

In a retrospective cohort of 220 cases undergoing primary total knee arthroplasty with an equal comparison of robot-assisted and manual surgical approaches, Deckey, et al. [101] examined the

impact upon operative time based on tourniquet (Figure 3.47) time (the time from inflation of the tourniquet before skin incision to deflation following the placement of polyethylene inserts).

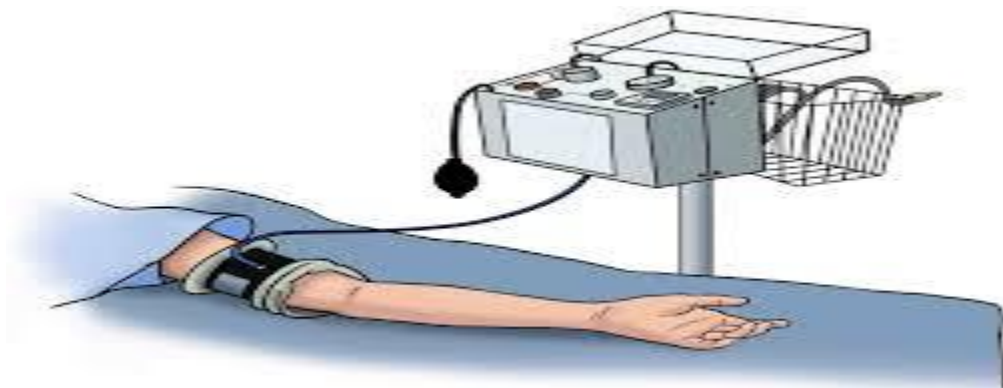


Figure 3.47 Operation Room Tourniquet Device [101].

The results showed that robot-assisted surgery was associated with a significantly longer tourniquet time, as compared to conventional surgery (99.3 v. 88.5 minutes, $p < 0.001$), however, the difference became insignificant after accounting for the mediating variables of assistant or trainee experience/involvement ($p > 0.05$). Moreover, when the surgeon was limited to residents and fellows, as opposed to consultants with the involvement of assistants and trainees requiring support, there were no significant differences in tourniquet time between robot-assisted and conventional surgery ($p > 0.05$).

Importantly, and unlike other studies in this work, the authors showed that the use of robot-assisted techniques for total knee arthroplasty was conducive to trainee involvement and teaching, enabling consultants to not only perform higher quality surgery but also advancing the capacity of orthopaedic services through increasing the number of proficient surgeons.

Similar improvements in operative time have also been observed for robot-assisted partial knee arthroplasty. The findings regarding operative time and learning inflection to those of Tay, et al. [57] for total knee arthroplasty have been supported in a more recent and updated study of partial knee arthroplasty surgery as reported by Tay, et al. [102].

The authors analysed 152 cases of robot-assisted primary medial uni-compartmental knee arthroplasty performed by five surgeons over a four-year period with the results showing a clear inflection point after 11 cases and with significant improvements in operative time between the learning and proficiency phases ($p < 0.01$). However, the complete text of this paper was not available at the time of this work as to elicit the mean operative times and differences between the learning and proficiency phase groups. Despite this, a recent meta-analysis of four papers,

excluding that of Tay, et al., [102] showed that there were no significant differences in operative time for uni-compartmental knee arthroplasty between robot-assisted and conventional surgery groups ($p>0.05$) [103].

3.8 Comparison between traditional and robot-assisted surgery in terms of accuracy. Metrics and data.

Accuracy in robotic techniques for knee surgery has been assessed using variable means across the literature and this heterogeneity presents some difficulties in formulating inter-study comparisons. In the previously discussed study reported by Tay, et al., [97] the authors found that the accuracy of polyethylene insert sizing improved significantly from 43% during the learning phase of robot use (first 10 cases) to 89% for the latter 10 cases during the proficiency phase.

This was a statistically significant improvement ($p=0.02$). Significant improvements in the accuracy of posterior lateral, proximal medial and proximal lateral resection planning were also observed; in favour of the proficiency phase (all $p<0.05$). Polyethylene inserts are the actual synthetic replacement/implants of tissue/bone used in knee replacement surgery and they have become the primary or first-line option for this purpose due to comprising high structural and functional integrity and having been consistently linked to positive long-term outcomes [104].

Optimal function and long-term outcomes associated with polyethylene inserts, along with other implants in knee surgery, ultimately depends upon the accuracy of placement during surgery and therefore, highlighting the value of robotic-assisted replacement as described [104]. Indeed, Tay, et al. [97] also showed that the accuracy of implant positioning significantly improved across the learning and proficiency phases (Figure 3.48).

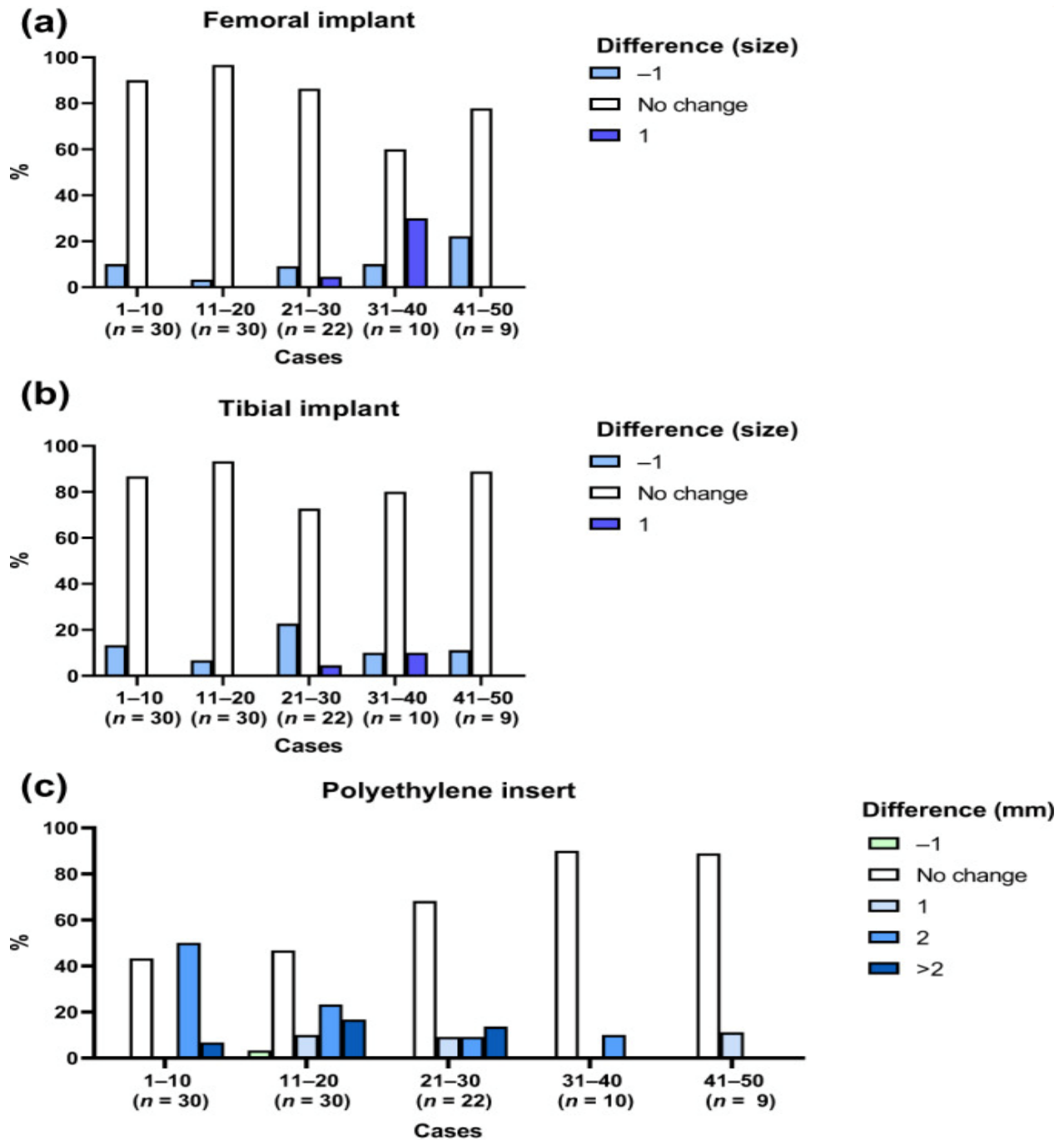


Figure 3.48 Proportionate change in implant position between the pre-operative planning and post-operative assessment by case number: a) positioning of femoral implants, b) positioning of tibial implants and c) positioning of polyethylene inserts [97]. The Vertical Axis displays the difference in mm percentage and the Horizontal Axis the number of cases.

However, in contrast to Tay, et al. [97], Zhang, et al. [98] showed that there was no inflection point about bone cutting accuracy when performing robotic-assisted total knee arthroplasty, suggesting that the robot-guided cutting of bone is markedly accurate from the outset of

approach use. The total bone-cutting error using the system was negligible and varied between 0.91-1.03mm across the three surgeons (Figure 3.49 & Table 3.4). There were no significant differences in bone-cutting accuracy between surgeons, suggesting that robot-guided arthroplasty is effective in mitigating inter-operator variances in performance and thus, accuracy.

Moreover, there were no significant differences in regard to the accuracy of limb alignment on the first postoperative day between the robot-assisted and conventional surgery comparisons (177° to 183°, $p>0.05$). However, the mean values and the standard deviation were smaller for the robot-assisted group, suggesting that there was less variance in alignment across patient cases. This was also observed for other alignment measures (all $p>0.05$) with smaller (more favourable) variances identified for the robot-assisted group.



Figure 3.49 Overview of the learning curves for bone cutting accuracy among three surgeons using robot-assisted surgical system for total knee arthroplasty [98]. The Vertical Axis represents the cutting error in millimeters and the Horizontal Axis the number of operations.

Table 3.4 Overview of bone cutting errors for the three surgeons in the study of Zhang, et al. [98]

| Error (mm) | Surgeon 1 | Surgeon 2 | Surgeon 3 | <i>P</i> value |
|-----------------------------------|-------------|-------------|-------------|----------------|
| Total error | 1.03 (0.36) | 0.91 (0.36) | 1.03 (0.38) | 0.319 |
| Medial distal femur | 0.98 (0.70) | 0.64 (0.49) | 1.09 (0.95) | 0.056 |
| Lateral distal femur | 1.02 (0.83) | 0.73 (0.72) | 0.98 (0.71) | 0.285 |
| Medial posterior femoral condyle | 1.03 (0.56) | 0.80 (0.55) | 0.91 (0.82) | 0.398 |
| Lateral posterior femoral condyle | 0.90 (0.85) | 1.04 (0.82) | 0.87 (0.64) | 0.667 |
| Medial tibial plateau | 1.20 (0.74) | 1.02 (0.84) | 1.38 (0.95) | 0.282 |
| Lateral tibial plateau | 1.07 (0.74) | 1.21 (0.83) | 0.97 (0.80) | 0.504 |

Limb alignment, as a measure of surgical accuracy, was also evaluated in a similar study by Kayani, et al., [100] although comparisons were performed between the learning and proficiency phases of robot use for total knee arthroplasty, as opposed to conventional surgery.

The results showed that there were no significant differences in various radiological measures of alignment between the learning and proficiency phases, again suggesting that robot-assisted surgery incurs no significant inter-case variances in implant position accuracy (all $p > 0.05$). The measures that were not significant between groups however, included mechanical alignment, posterior condylar offset ratio, posterior tibial slope, joint line, femoral coronal, femoral sagittal, tibial coronal, and tibial sagittal, and therefore, in support of those reported by Zhang, et al. [98] This again suggests that robot-assisted knee surgery can optimise the accuracy of knee arthroplasty surgery across patient cases from the initial outset of use (Figure 3.50).

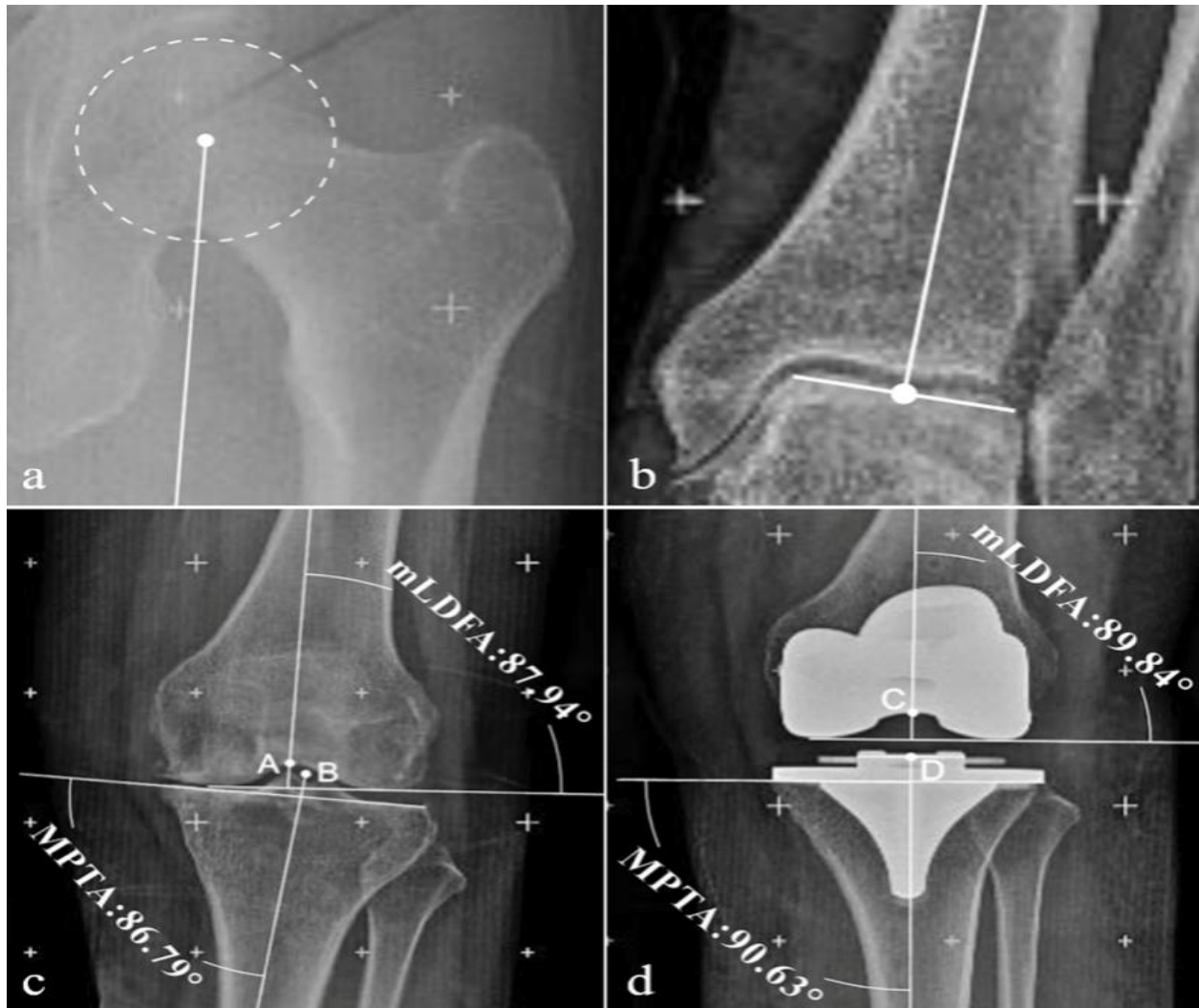


Figure 3.50 Use of CT imaging to support pre-operative planning using a Chinese-based robotic system known as HURWA; a) determination of the centre of the femoral head via a MOSE circle, b) centre of the ankle joint at the talus, c) pre-operative mechanical axis hip-knee-ankle angle and the medial proximal tibial angle and d) post-operative angles as for c) with C representing the apex of the intercondylar implant and D reflecting the centre of the tibial plateau implant [98].

In a larger cohort study of 220 primary total knee arthroplasty cases, Decker, et al. [105] conducted a direct comparison of conventional versus robot-assisted techniques and found that the latter group observed significantly improved measures of surgical accuracy, than the former group (Table 3.5).

These measures were assessed relative to parameters set during surgical planning and included mean femoral positioning (0.9° v. 1.7°), mean posterior tibial slope (-0.3° v. 1.7°), mean tibial positioning (0.3° v. 1.3°) and mean mechanical axis limb alignment (1.0° v. 2.7°), all $p < 0.001$). In addition, the greater accuracy of robotic-assisted surgery was reflected in significantly fewer patients requiring distal femoral recutting (10% v. 22%, $p = 0.033$) and in significantly fewer measures of deviation from the planned polyethylene thickness inserted (1.4mm v. 2.7mm, $p < 0.001$).

Table 3.5 Overview of the variances in mean limb position and alignment for comparisons of conventional versus robot-assisted total knee arthroplasty [105].

| <i>Position/Alignment Measures</i> | <i>Conventional</i> | <i>Robot-Assisted</i> |
|------------------------------------|---------------------|-----------------------|
| Femoral positioning | 1.7° | 0.9° |
| Posterior tibial slope | 1.7° | -0.3° |
| Tibial positioning | 1.3° | 0.3° |
| Mechanical axis limb alignment | 2.7° | 1.0° |

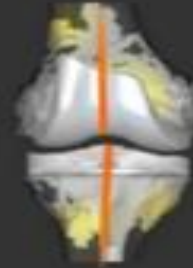
The minimal variances from planned parameters in knee arthroplasty relative to those achieved via the use of robotic-assisted devices have also been supported by Sicat, et al. [106] Based on an analysis of 435 cases, the cited authors found that the mean difference between the achieved and planned alignments of the lower limbs was $< 1^\circ$ (all $p > 0.05$) for patients with valgus alignment at baseline. The attained alignment and differences between the planned and achieved lower limb alignment for those with baseline Varus positioning were also significantly indifferent and minimal, albeit slightly greater, than patients with baseline valgus positioning (1.2-1.9°, all $p > 0.05$). The authors also evaluated whether any differences between first- and second-generation robotic devices impacted accuracy measures, but no significance was demonstrated (Figure 3.51 & Table 3.6).

ALIGNMENT

Flexion Range

Alignment

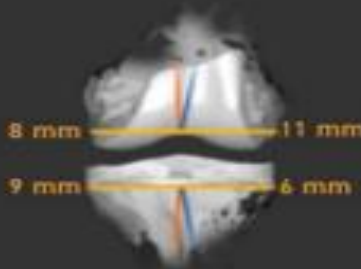
| | |
|--------------------------|------|
| PreOp Alignment Value | 2.4 |
| PreOp Neutral Flexion | -0.9 |
| Planned Alignment Value | 2.5 |
| Achieved Alignment Value | 0.0 |



Component

Varus/Valgus

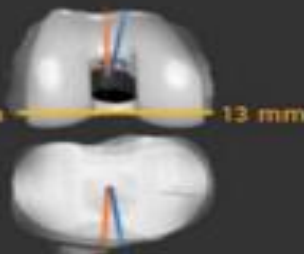
1° Varus



1° Varus

Rotation

4° External



0° External

Flexion/Slope

3° Flexion



4° Posterior

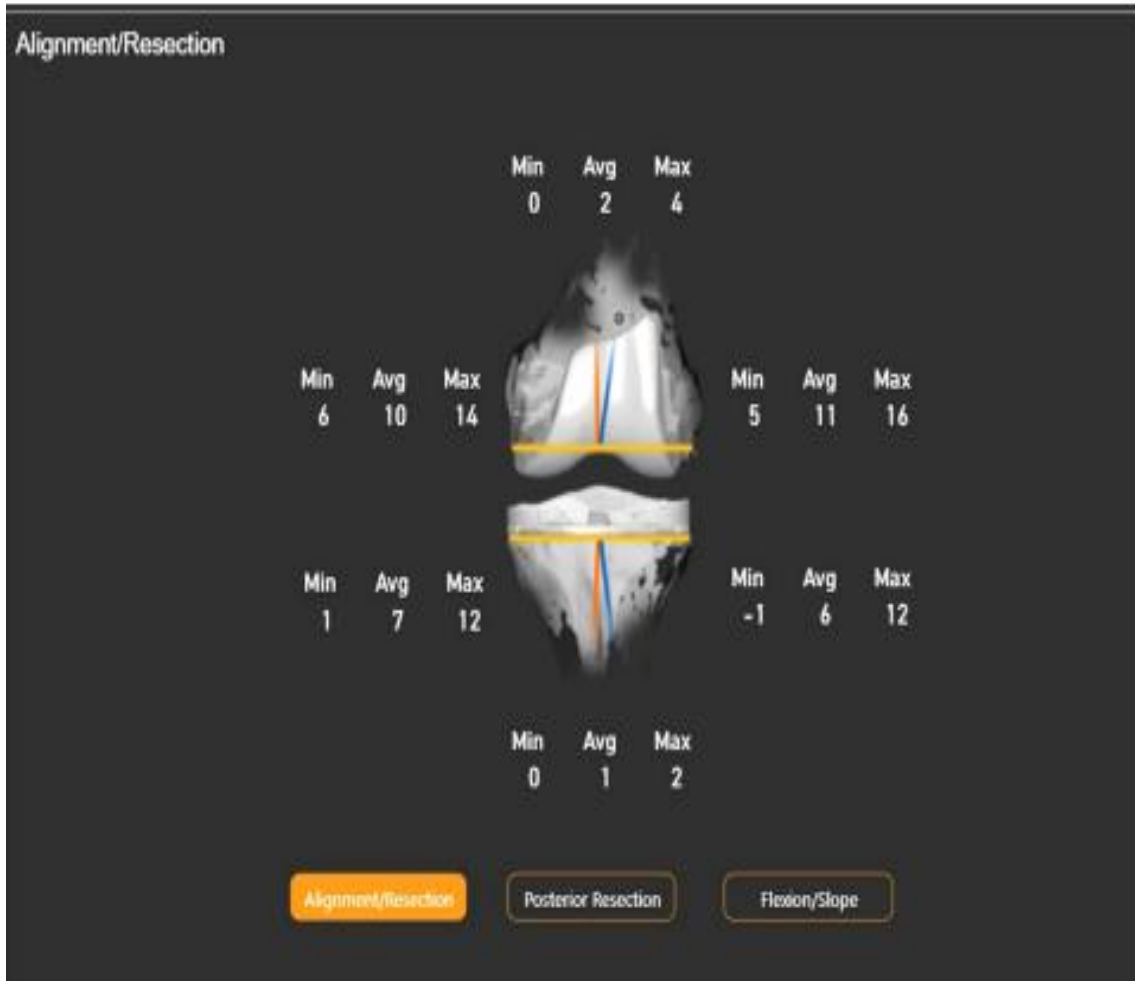


Figure 3.51 Overview of the planned (top image) versus achieved (bottom image) alignments using robotic-assisted total knee arthroplasty [106].

Table 3.6 Planned versus achieved alignment for robot-assisted knee arthroplasty with comparisons shown for patients with Valgus and Varus deformities of $<3^\circ$ and $>3^\circ$ in the pre-operative period [106].

| | Valgus | | Varus | | Overall | |
|---------------------------|-----------------------|----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| | < 3 (n = 58) | ≥ 3 (n = 70) | < 3 (n = 78) | ≥ 3 (n = 229) | < 3 (n = 136) | ≥ 3 (n = 299) |
| Planned alignment | | | | | | |
| Mean [SD] | -0.200 [0.940] | -1.18 [1.15] | 0.451 [1.17] | 2.22 [1.55] | 0.173 [1.12] | 1.42 [2.05] |
| Median [Min, Max] | -0.0150 [-2.01, 2.02] | -1.00 [-4.10, 1.12] | 0.415 [-1.72, 3.00] | 2.45 [-0.840, 5.98] | 0 [-2.01, 3.00] | 1.12 [-4.10, 5.98] |
| IQR | 0.815 | 2.00 | 1.00 | 2.50 | 1.50 | 3.00 |
| Achieved alignment | | | | | | |
| Mean [SD] | -0.262 [1.53] | -1.70 [2.42] | 0.356 [1.19] | 2.20 [2.32] | 0.0923 [1.38] | 1.28 [2.87] |
| Median [Min, Max] | -0.0900 [-4.32, 3.18] | -1.56 [-9.00, 4.30] | 0.0650 [-3.50, 4.76] | 2.07 [-7.60, 10.9] | 0 [-4.32, 4.76] | 1.07 [-9.00, 10.9] |
| IQR | 1.99 | 3.23 | 0.978 | 3.51 | 1.45 | 3.22 |
| Alignment accuracy | | | | | | |
| Mean [SD] | -0.0622 [1.33] | -0.526 [2.40] | -0.0949 [1.32] | -0.0206 [2.02] | -0.0810 [1.32] | -0.139 [2.12] |
| Median [Min, Max] | -0.0150 [-2.36, 2.35] | -0.170 [-9.00, 4.30] | -0.0200 [-3.28, 2.76] | 0.210 [-7.60, 8.36] | -0.0200 [-3.28, 2.76] | 0.190 [-9.00, 8.36] |
| IQR | 2.04 | 2.97 | 1.94 | 2.04 | 2.03 | 2.26 |

Several other studies but with lower sample sizes, and therefore, potentially less reliability, have supported the markedly high accuracy that robotic-assisted surgery can achieve for both partial and total knee arthroplasty [107-110]. However, one recent study has highlighted some key differences in accuracy outcomes across robotic systems and this may have some implications for ongoing research and practices, locally.

In that said study, Yee, et al. [111] compared the accuracy of the NAVIO or CORI and the MAKO robotic systems across 129 cases that underwent total knee arthroplasty. The NAVIO and CORI system was image-free, while the NAVIO system was image-less. The use and accuracy of imaging to assist surgical planning may explain the variances in outcomes reported here, although the findings may also reflect inter-system variances in accuracy (Table 3.7).

The results showed that superior and significantly more favourable accuracy was observed for some component positions and lower limb alignments. The image-based group observed significantly greater accuracy in posterior tibial slope, versus the image-less system (1.35° v. 2.59°, $p < 0.001$) but the converse was observed for lower limb alignment (-2.52° v. -1.55°, $p = 0.028$). However, the absolute difference in tibial slope favoured the image-free (NAVIO system) group (1.31° v. 2.66°, $p < 0.001$), although no significant between-group differences were noted for femoral or tibial component positioning (both $p > 0.05$).

Table 3.7 Comparison of key alignment and positional outcomes using the image-free and image-based robot-assisted surgical systems for knee arthroplasty [111].

| Measurements | Image-free | Image-based | p value |
|--|--------------|--------------|---------|
| Femoral component (coronal plane) | -0.56 ± 1.31 | -1.19 ± 2.09 | ns |
| Tibial component (coronal plane) | -0.59 ± 1.40 | -0.55 ± 1.40 | ns |
| Tibial slope | 2.59 ± 1.62 | 1.35 ± 1.88 | <0.001 |
| Lower limb alignment | -1.55 ± 2.69 | -2.52 ± 2.64 | 0.028 |
| Difference between planned and measured values | | | |
| Femoral component (coronal plane) | -1.16 ± 1.73 | 0.78 ± 2.14 | <0.001 |
| Tibial component (coronal plane) | -0.59 ± 1.40 | 1.23 ± 1.25 | <0.001 |
| Tibial slope | -1.42 ± 1.62 | -2.54 ± 1.85 | <0.001 |
| Absolute difference between planning and measured values | | | |
| Femoral component (coronal plane) | 1.41 ± 1.53 | 1.78 ± 1.41 | ns |
| Tibial component (coronal plane) | 1.16 ± 0.98 | 1.35 ± 1.12 | ns |
| Tibial slope | 1.31 ± 1.02 | 2.66 ± 1.62 | <0.001 |
| Outlier (%) | | | |
| Femoral component (coronal plane) | 9.4 | 12.5 | ns |
| Tibial component coronal plane) | 1.6 | 5.3 | ns |
| Tibial slope | 5.6 | 27.7 | <0.001 |

Finally, the accuracy of robot-assisted surgery for total knee arthroplasty has also been supported in a recent systematic review and meta-analysis where Zhang, et al. [112] pooled and collectively analysed data from six studies. Accuracy was determined in regard to the accuracy of component positions with the results showing that robot-assisted surgery was associated with significantly

fewer differences in the position of components between the pre- and post-operative time points, as compared to those incurred by conventional surgery (all $p < 0.05$).

Some meta-analyses were performed based on the type of components implanted. The mean difference in pre-and post-operative component position was greater (poorer) for conventional surgery in terms of coronal femur positioning (1.31; 95% CI 1.08, 1.55, $p < 0.0001$), coronal tibia positioning (1.56; 95% CI 1.32, 1.81, $p < 0.0001$), the tibia posterior slope (1.56; 95% CI 1.19, 1.94, $p < 0.0001$) and the posterior condylar offset ratio (0.06; 95% CI 0.02, 0.10, $p = 0.008$).

However, the findings were limited by a low number of studies included in each analysis and due to excess and significant inter-study heterogeneity being detected. This reduces confidence and certainty in the pooled effects. Superior accuracy of robot-assisted surgery for uni-compartmental arthroplasty has also been supported in a meta-analysis of 16 studies; greater accuracy was mostly observed for measures of lower limb alignment [110].

3.9 Comparison between traditional and robot-assisted surgery in terms of caused trauma. Metrics and data.

Several studies have investigated the impact of robotic knee surgery upon various clinical and patient-reported outcome measures, which are vital to understanding the key health effects of adopting such technical approaches. In the example cohort study of 101 patients who underwent total knee arthroplasty via a robotic-arm-assisted technique, Tay, et al. [97] showed that the rate of revision-free implant survival was 97-100% over the mean two-year follow-up period with variances observed across the learning and proficiency phases of the surgeon's experience.

A high rate of non-revision and re-operative-free survival was also observed; 95-98%. Over the study period, there was one revision (liner exchange) and four re-operations; one requiring manipulation under anaesthesia and three cases requiring washouts. In terms of patient-orientated outcomes, that were based on the Oxford Knee Score, the EuroQOL-5D, and the Forgotten Joint Score, significant improvements or more favourable scores were observed during the proficiency, than the learning phases (all $p < 0.05$).

Similarly, Tay, et al. [102] showed that EuroQOL-5D scores significantly improved among proficiency cases of uni-compartmental knee arthroplasty, relative to learning cases ($p < 0.01$), although no significant differences for other measures including physical function or implant survival were observed (all $p > 0.05$). However, this was an initial analysis based on only 11 cases

and therefore, the positive impact of robot-assisted surgery upon such outcomes may have been missed or underestimated.

In terms of partial knee arthroplasty surgery, a two-year randomised controlled trial conducted by Gilmour, et al. [113] was used to examine the effects of robot-assisted versus conventional surgery, as opposed to comparisons between learning and proficiency of robotic use as previously undertaken. A total of 139 cases were included in the analysis with the core patient-orientated outcomes including the Oxford Knee Score, the American Knee Society Score, and revision rates.

The results showed that there were no significant between-group differences for any of these measures (all $p > 0.05$). However, the robotic-assisted surgery group observed greater implant survival (100%), than the manual surgery group (95.3%), although this was not a significant difference ($p > 0.05$). Despite the non-significant effects for the entire cohort, a sub-group analysis of patients with a pre-operative UCLA (University of California-Los Angeles) score of > 5 , indicating greater functional activity at baseline, revealed that those who underwent robot-assisted surgery achieved significantly greater outcomes across the defined knee scores, as well as joint stiffness using the Visual Analogue Scale and joint awareness based on the Forgotten Joint score (all $p < 0.05$, Figure). However, this sub-analysis did not demonstrate any significant differences in terms of pain on the pain catastrophising scale (both $p > 0.05$). The pain catastrophising scale or PCS, consists of 13 statements containing a number of thoughts and feelings one may experience when having pain. The items are divided into the categories of rumination, magnification, and helplessness, with each item scored on a 5-point scale (Figure 3.52).

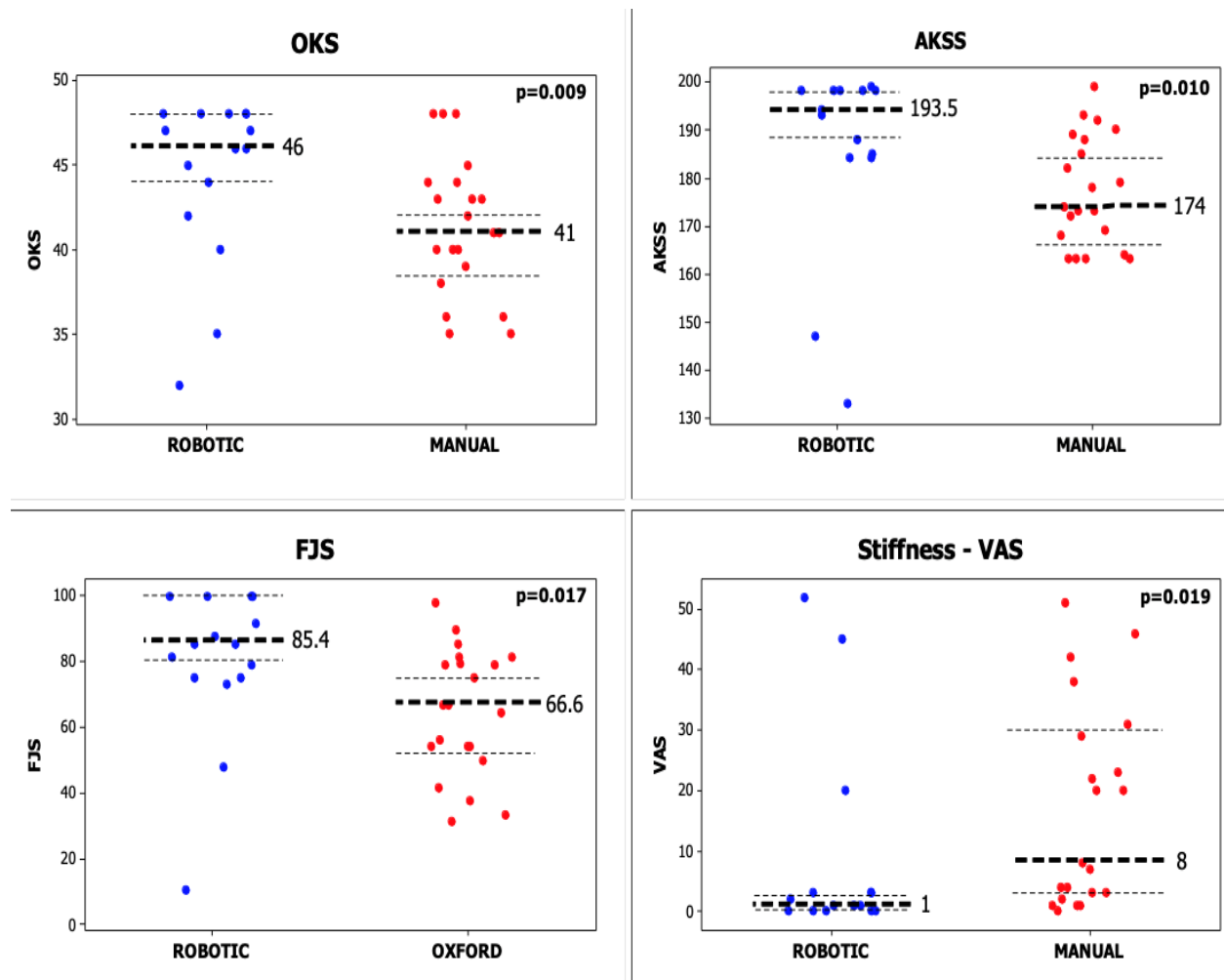


Figure 3.52 Graphical overview of the sub-analysis performed by Gilmour, et al. [114] showing significantly improved knee function, stiffness, and joint awareness favouring the robotic-surgery group, versus conventional surgery. OKS stands for 'Oxford Knee Score', AKSS for 'American Knee Society Score', FJS for 'Forgotten Joint Score', and Stiffness-VAS for 'Stiffness Visual Analogue Scale'.

In some contrast to the findings of Gilmour, et al. [113], Mulpur, et al. [114] examined the impact of robotic versus conventional surgery for 55 patients who underwent bilateral total knee arthroplasty (Table 3.8).

The primary outcome was the Oxford Knee Score with the results showing that the robot-assisted group attained more favourable mean scores, as compared to the conventional surgery group, although the difference was only significant at the alpha threshold level of 0.1; considered insignificant in most research studies (40.4 v. 39.8, $p=0.085$).

However, measures of joint perception using the Forgotten Joint Score assessment were significantly lower (poorer) for the conventional, than the robot-assisted surgery group (70.3 v. 73.0, $p < 0.01$). Despite this difference, the effect size may not be clinically meaningful based on wider reports [115].

Table 3.8 Overview of patient-reported outcome measures in a comparison between robot-assisted versus conventional total knee arthroplasty [114].

| Variable | Manual TKA | Robotic TKA | p-Value ^a |
|---|--------------|--------------|----------------------|
| Time taken to walk without support/aid after TKA (in days) Mean (SD) | 12.8 (4.1) | 10 (3.6) | < 0.01 |
| Mean Oxford Knee Score (OKS) | 39.76 (2.21) | 40.42 (1.85) | 0.085 |
| Mean Forgotten Joint Score (FJS) | 70.3 (10.66) | 73 (10.95) | < 0.01 |

Nonetheless, a significant improvement in the time to ambulate unaided was observed for the robot-assisted group, and this was related to a highly meaningful difference in time (10 v. 13 days, $p < 0.01$). Moreover, significantly fewer patients in the robot-assisted group reported worse pain post-operatively (9.1% v. 78.2%, $p < 0.01$) and significantly fewer patients experienced pain during active range of motion of the operated limb (20% v. 80%, $p < 0.05$) than the conventional surgery group.

At six-month follow-up, significantly more patients in the robot-assisted group reported greater comfort with the operated knee, as compared to the conventional surgery group (80% v. 3.6%, $p < 0.05$), of which, there was a sustained difference at one-year follow-up ($p < 0.05$). This was also reflected in patient satisfaction scores, which were significantly more favourable for the robot-assisted, than the conventional surgery group (72.7% v. 63.6%, $p = 0.026$).

More favourable measures of post-operative pain and function related to robot-assisted bilateral total knee arthroplasty versus conventional surgery have been supported by Song, et al., [116] although this was a smaller trial of only 30 patients, and notably, most of the literature has been conducted among cases of unilateral knee arthroplasty (Figure 3.53).

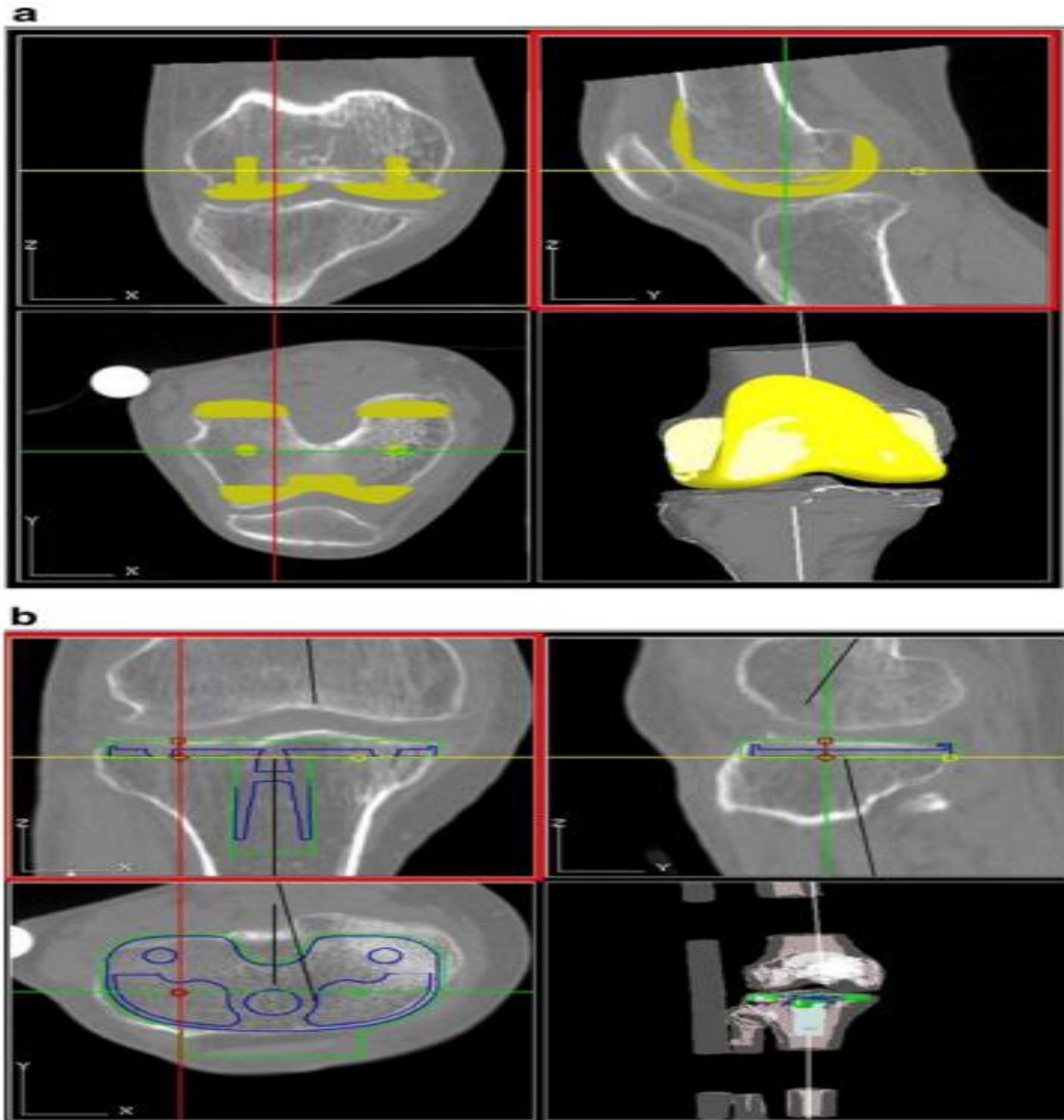


Figure 3.53 Use of CT-based pre-operative planning for total knee arthroplasty using the ROBODOC® system as used in the study of Song, et al. [116]: a) verification of femoral and b) tibial alignment and size relative to the mechanical axes.

Other research has reported upon additional and useful outcome measures. For example, Bhimani, et al. [117] found that robot-assisted total knee arthroplasty was associated with significantly lower post-operative pain at rest and during activity over two weeks follow-up, than the conventional surgery group (all $p < 0.01$), as well as significantly less post-operative opioid requirements (mean difference 3.2mg, $p < 0.001$) and opioid-free status at six weeks follow-up (70.7% v. 57.0%, $p = 0.02$). In addition, patients who received robot-assisted surgery had a significantly shorter inpatient length of stay (1.9 v. 2.3 days, $p < 0.001$) (Figures 3.54 – 3.55).

In contrast, Eason, et al. [99] showed that the use of robot-assisted total knee arthroplasty was associated with a significantly longer post-operative length of stay, although it is unlikely that the difference was meaningful (468 v. 412 minutes, $p < 0.001$). This may also be arguable for the study of Bhimani, et al. [117].

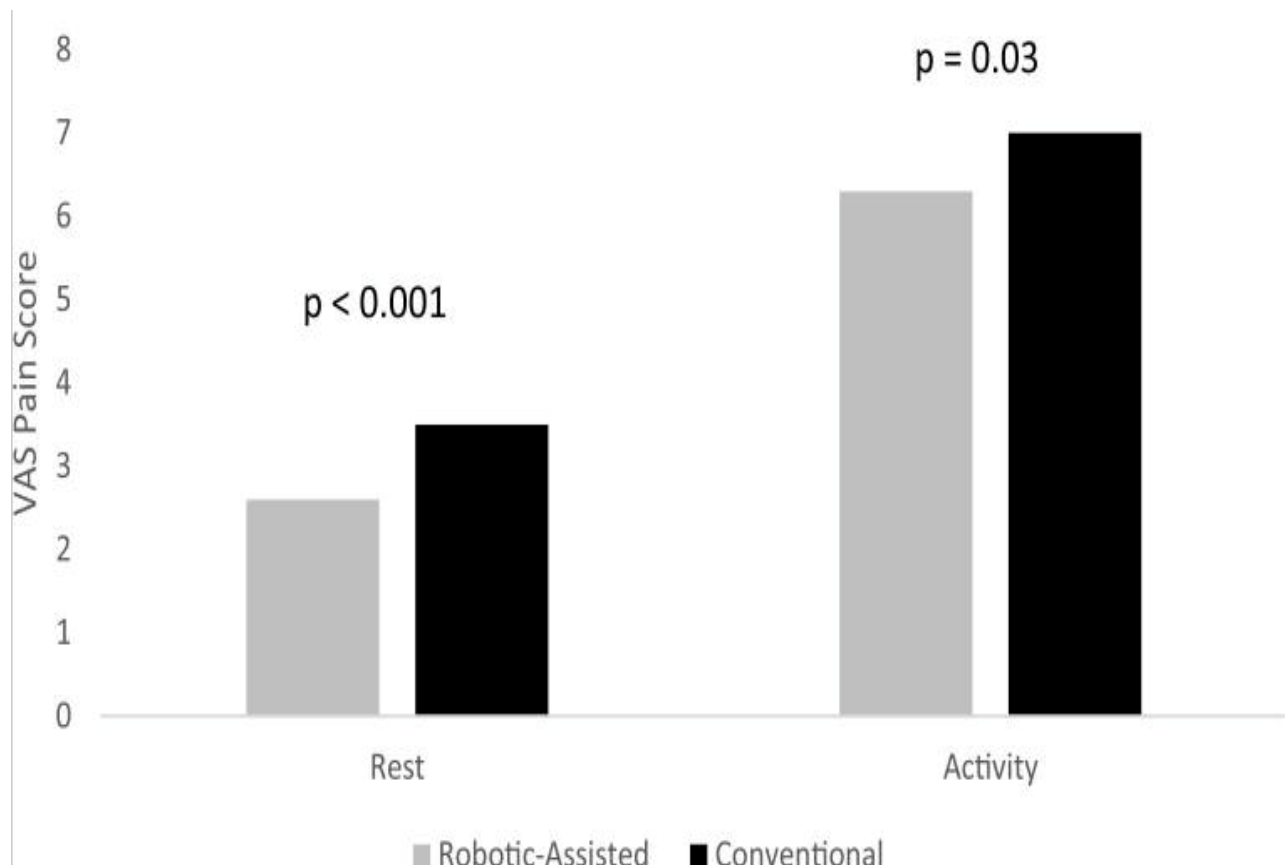


Figure 3.54 Summary of the variances in VAS (Visual Analogue Score) pain scores at two weeks follow-up between types of total knee arthroplasty surgery [117].

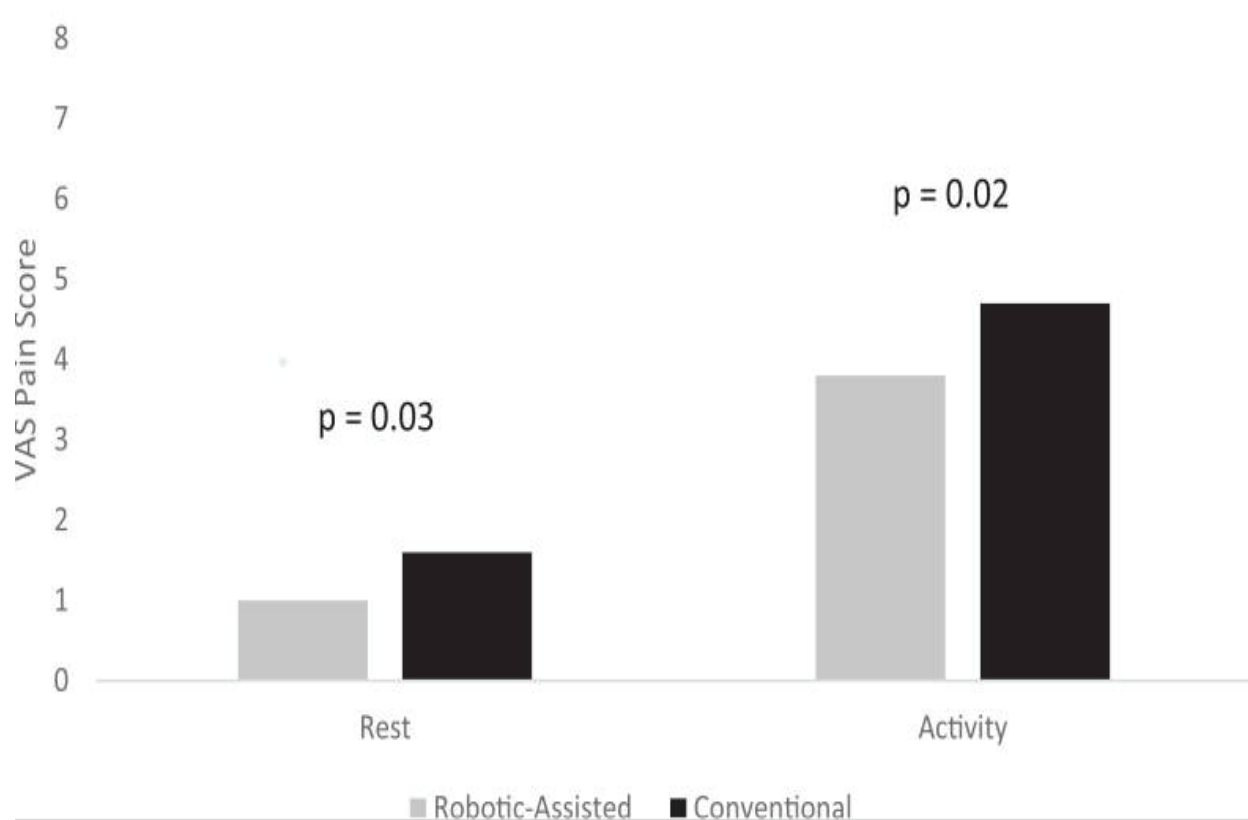


Figure 3.55 Summary of the variances in VAS (Visual Analogue Score) pain scores at six weeks follow-up between types of total knee arthroplasty surgery [117].

In another study, Kayani, et al. [100] found that complication rates were similar between conventional and robot-assisted groups for cases of total knee arthroplasty. One complication in each group was observed, comprising minor wound dehiscence. Insignificant differences in short-term complication rates have been supported by Eason, et al. [99] who noted a post-operative follow-up period of 12 weeks. The authors also failed to find any between-group (robot-assisted versus conventional surgery) differences concerning re-operations and re-admissions (all $p > 0.05$). Furthermore, Marchand, et al. [118] found that measures of post-operative pain and function at one-year post-operatively were significantly more favourable for those who underwent robot-assisted surgery, as compared to conventional surgery (all $p < 0.05$).

The meta-analysis of Zhang, et al. [112], as previously discussed, also found support for greater improvements in functional outcomes related to robotic-assisted total knee arthroplasty, as compared to conventional surgery. Due to marked variance in the outcome measures utilised, meta-analysis was limited to two core instruments: the WOMAC (Western-Ontario and McMaster Universities Arthritis Index) physical function and pain instrument and the Knee Society Score function and satisfaction subscales (Figure 3.56).

Two studies using the former were pooled and this revealed that robotic surgery was associated with significantly more favourable function and pain scores, than compared to conventional surgery (mean difference -3.72; 95% CI -5.72, -1.72, $p=0.009$). Similarly, another two studies using the latter instruments also supported robotic over manual surgery (mean difference -1.23; 95% CI -1.94, -0.51, $p=0.004$). However, excess inter-study heterogeneity was detected, limiting confidence and certainty in the pooled effects.

Despite more favourable patient-reported outcomes, the complication rates were not found to be significantly different between robotic and conventional surgery groups (odds ratio 1.36; 95% CI 0.63, 2.94, $p=0.84$), although a higher short-term complication rate trended towards the conventional surgery group. The respective range of complications for robotic and conventional surgery was as follows: arthrofibrosis 0-7.5% and 0-8.7% and infections 0-1.4% and 0-2.5%.

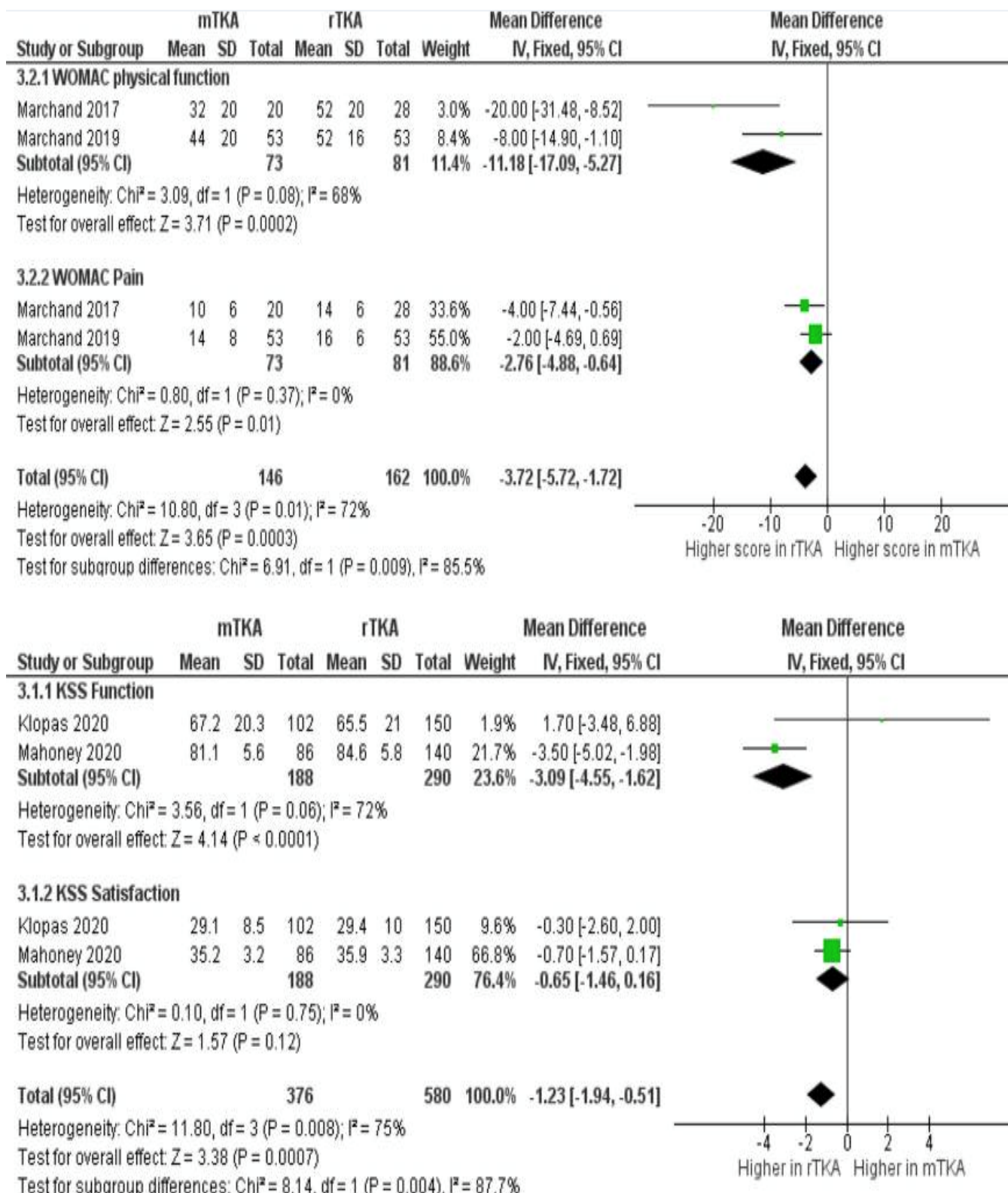


Figure 3.56 Forest plots showing the meta-analyses of robot-assisted versus conventional total knee arthroplasty upon functional outcome measures [112].

3.10 Assessments about robot-assisted surgery in terms of ease of handling, stress and fatigue generation, potential limitations, and human-machine interaction during operations. Metrics and data.

Studies exploring the views, perceptions, and experiences of surgeons in using robotic-assisted approaches to knee surgery are scarce. One study measured the impact of using robotic-assisted surgery for total knee arthroplasty based on anxiety levels among surgeons (Figure 3.57) [119].

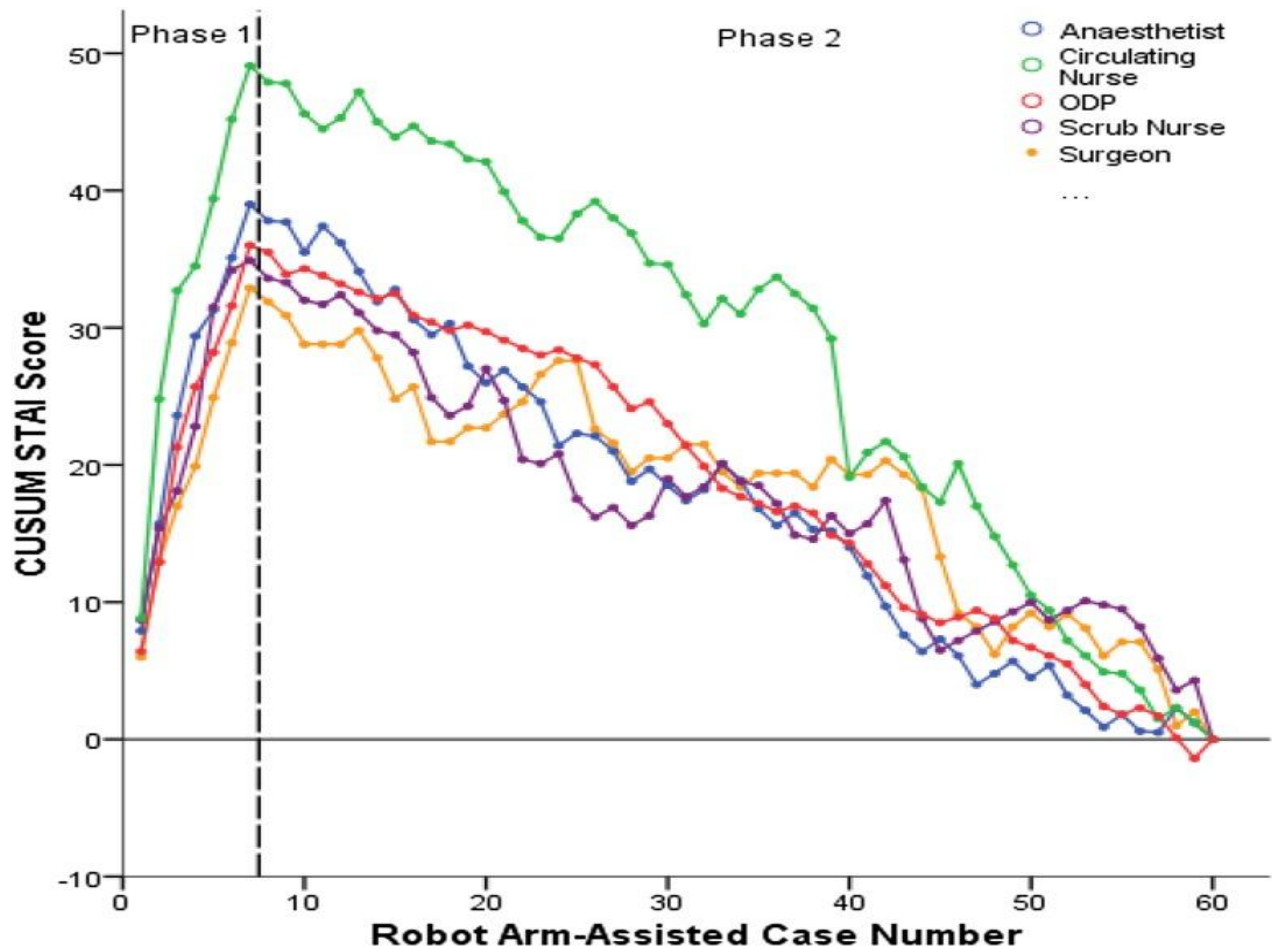


Figure 3.57 Overview of variances in cumulative summary state anxiety index scores (CUSUM STAI Score) across the operative team involved in robot-assisted knee arthroplasty by case number [119].

The State-Trait Anxiety Inventory [119] was used to collect such data and the results showed that surgeons observed greater (worse) anxiety scores during the learning phase of robot device use prior to the inflection point with a significant improvement in anxiety being observed following this point during the proficiency phase (mean score 17 v. 9, $p=0.02$). This suggests that surgeons

may encounter some initial apprehension when using robot-assisted systems for the first few cases or until proficiency is achieved. This is a natural phenomenon in view of learning in clinical practice tending to be achieved and mastered through experience, exposure, and practice [120].

In an opinion piece of surgeons with experience in using robotics within knee surgery, Balaguer-Castro, et al. [121] also recognised that there was an important learning curve in which surgeons had to embrace and master the use of the systems, in order to optimise efficiency and to enhance self-confidence in adopting new operative techniques. However, the surgeons reported that robotic-assisted surgery provided much greater precision in pre-implant planning through deriving a 3-dimensional reconstruction of the anatomy, accurately computing the precise cutting of bone, and optimising implant selection. As a result, the surgeons believed that this would enhance functional recovery and reduce the risk of complications, particularly through providing in-depth peri-operative information regarding bone resection extent, implant position, and ligament balance control, which could then be refined and optimised prior to closure.

Nonetheless, the surgeons also alluded to some limitations of using robotics for total and partial knee arthroplasty, which included the need to have sufficient knowledge regarding configuration values for operative planning and acquiring accurate bone reference points, which is noted to be the highest source of technical error. Moreover, errors can also arise during implant placement and cementing, as is shared with conventional surgery. Furthermore, the surgeons highlighted that some robotic systems for knee arthroplasty requiring a pre-operative computed tomography (CT) scan and this co-existed with additional radiation exposure of around 5 mSv. [121]. This was reported to as a limitation of the MAKO® robotic system, while other systems, such as NAVIO®, CORI® and ROSA®, benefit from image-less operative planning methods [122].

The avoidance of ionising radiation cannot be undermined in view of excessive exposure being associated with adverse stochastic effects, which can incur damage to genetic material and with the most pertinent risks being radiation-induced malignancy [123]. Although a CT scan of the knee to support pre-operative planning for arthroplasty is minimal (5 mSv), some patients may have been exposed to ionising radiation previously and the additional exposure would contribute to stochastic risk due to the accumulation of induced damage. Indeed, a 5 mSv CT scan amounts to around 40 plain radiographs or 18 months of background radiation exposure and thus, even a low dose scan may not be insignificant as any exposure could induce carcinogenesis [124]. The greatest risk of radiation-induced malignancy has been evident in those exposed to doses in excess of 10 mSv and mostly, >50 mSv, however, due to statistical challenges in extrapolation risk, it is difficult to ascertain the absolute risk in those exposed to doses <10 mSv. [125].

Some studies have explored the views and experiences of surgeons in using robotic surgery more generally and often outside of the context of orthopaedic surgery, but such information is of value to this work as the evidence has some applicability to the context of interest herein.

In one example, Lawrie, et al. [126] conducted a series of interviews with 35 surgeons and theatre staff to explore the challenges and opportunities in using robotic-assisted techniques. Participants recruited into the study had been working across a range of specialties including colorectal, gastrointestinal, head and neck, urological, gynaecological and orthopaedic surgery and thus, the findings cannot be reliably applied to the sole orthopaedic context (Figure 3.58).

Despite this, the responses of subjects revealed that robotic-assisted surgery was a rapidly growing field and one major subject to some hesitancy in adopting it, was due to variability in the availability of empirical literature, insufficient regulatory and governance policies, having a resource impact upon operative areas, the pre-operative surgical planning, and last, but not least, the co-ordination of operations along with the demanding extensive time for education and training.

These findings have also been corroborated in a realist review of adopting robot-assisted surgery into routine surgical practice, although again, this was not limited to orthopaedic surgery and thereby, applicability to the context of interest may be restricted [127].

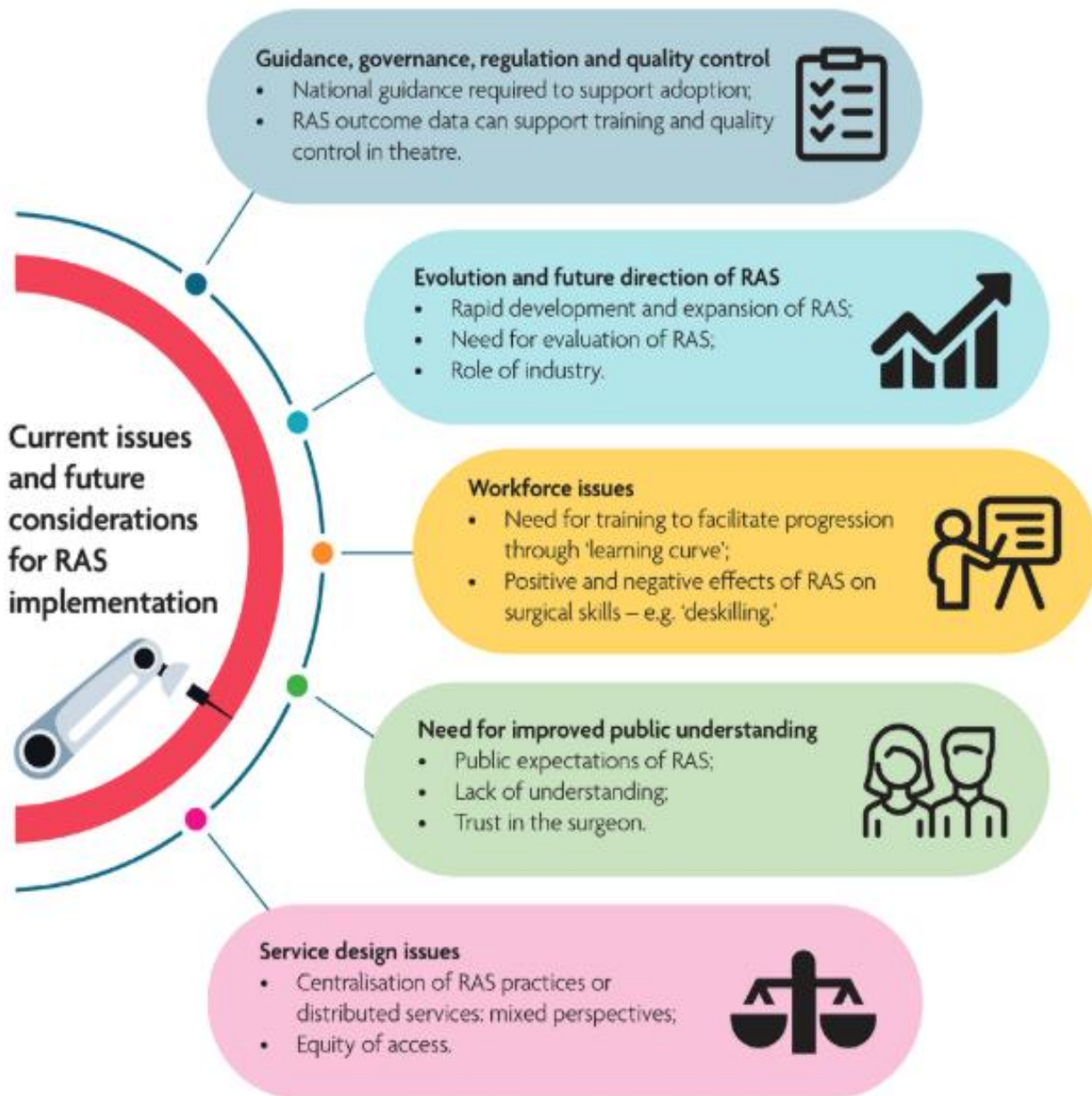


Figure 3.58 Overview of the key themes emerging from interviews with clinicians involved in robot-assisted surgery [126].

Lawrie, et al. [126] also found that surgeons highlighted how there was a need to master the use of robotic surgery, as reflected within the learning phase of use that was previously described across other evidence in this work. Moreover, surgeons expressed some concerns about how the use of robotic surgery in routine practice could lead to deskilling in manual techniques, which could prove problematic in situations where robotic systems may encounter technical issues or system disruptions.

In addition to those, the research revealed that there was a greater need for public understanding of the role, purpose, and safety of robotic surgery in view of surgeons' reports, regarding patient anxiety in undergoing operations facilitated by robotic devices. A degree of hesitancy among surgical staff in adopting robot-assisted techniques has also been noted in a cross-sectional survey of staff working within a large tertiary hospital, where knowledge about such surgery was limited, and overall, staff held neutral views about whether the approach would confer a positive impact upon patient outcomes [128].

Similarly, an interview study of surgeons, theatre staff, and other key stakeholders showed that several barriers and enablers to the effective adoption and use of robotic-assisted surgery were identified [129]. The key barriers included the high costs of robotic systems and costs attributed to the re-design and adjustment of operation rooms to accommodate such systems and working procedures. However, the key enablers in favour of the utilisation of such systems, included better ergonomic working conditions for surgeons, the potential to optimise the accuracy and precision of surgery, improving surgical outcomes, and enhancing operative time and efficiency.

3.11 Assessment of patients' perceptions and experiences regarding robot-assisted surgery

This final subchapter explores the views and experiences of patients who have thought about or have undergone knee surgery via robot-assisted means. Exploring such accounts is important in terms of helping to corroborate and build upon the more objective outcomes that are typically measured and reported in efficacy studies. Patient-reported outcomes are a vital source of evidence in health systems where there has been a shift from a paternalistic model of care to one that is orientated to enhancing patient health and wellbeing from a 'whole' perspective [130].

Indeed, patients may value outcomes related to quality of life over surgically important or long-considered outcomes, such as implant survival or length of hospital stay [131]. Although qualitative studies exploring the views and experiences of patients who have undergone robot-assisted knee arthroplasty have been scarce, the evidence may hold weight in influencing recommendations for ongoing practices and related research.

In an open-ended survey of 440 patients who were potential candidates for total knee arthroplasty, Abdelaal, et al. [132] found that most subjects held value in robotic surgery due to beliefs in the greater accuracy of implant placement and the likely enhanced benefits upon symptoms and function (Figures 3.59 & 3.60). In addition, participants were eager to undergo

such surgery in view of a faster recovery time. These are persons valuing their lives and being keen to return to their usual routines soon. However, some participants also expressed concerns about the decreased role and input of the surgeon during surgery, as well as potentially incurring harm due to robot malfunction and general anxiety related to insufficient research, as was communicated to them by surgeons guiding the decision-making process.

Despite these anxieties and concerns, the majority of patients reported a willingness to undergo robot-assisted surgery, thus, conveying important views about trust and beliefs in new techniques. However, as this study relied upon a self-reported survey, there may have been a risk of response and non-response biases, although, on the other hand, the sample was large and sufficiently representative enough to apply to the group of interest to this work.

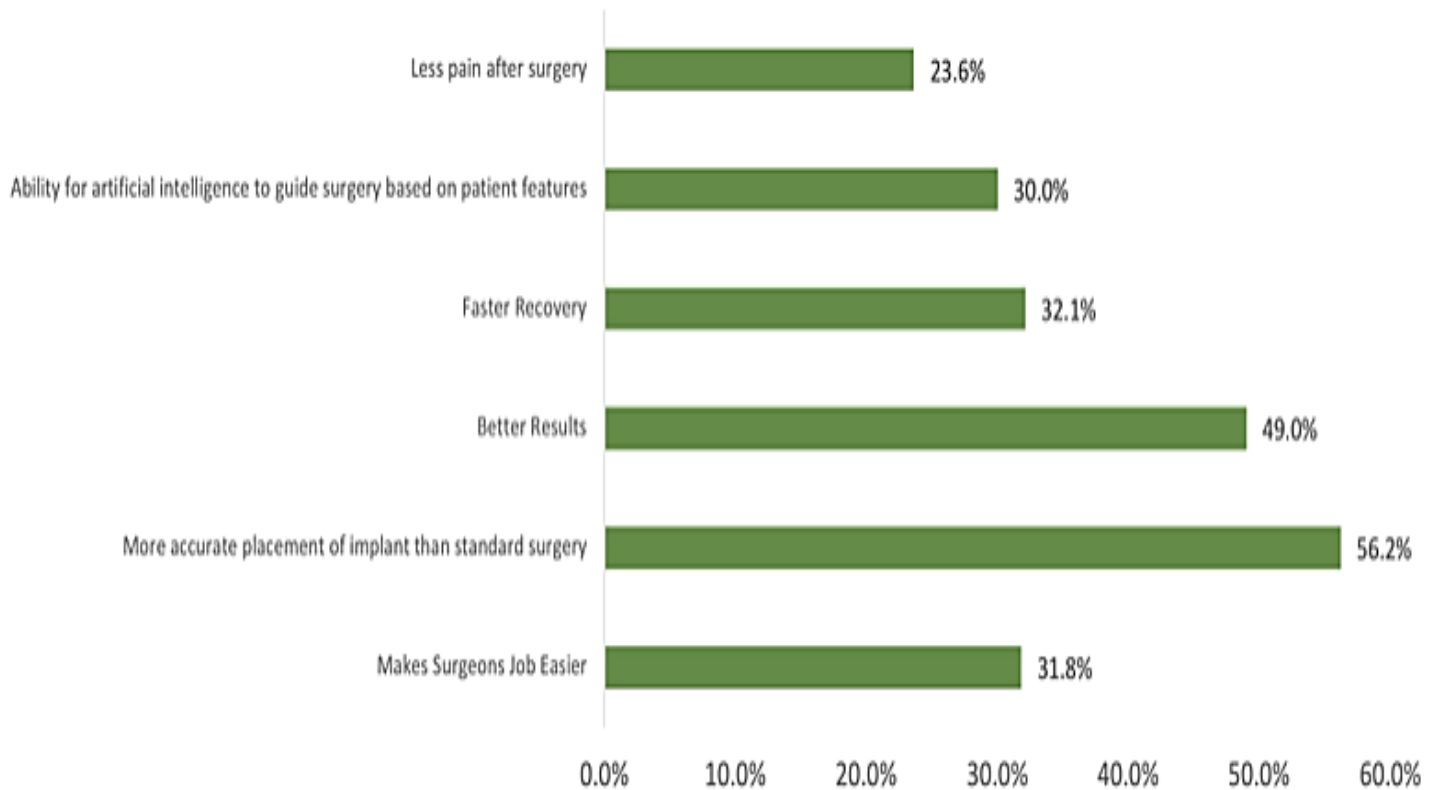


Figure 3.59 Summary of patient perceptions regarding the benefits of robot-assisted total knee arthroplasty [132].

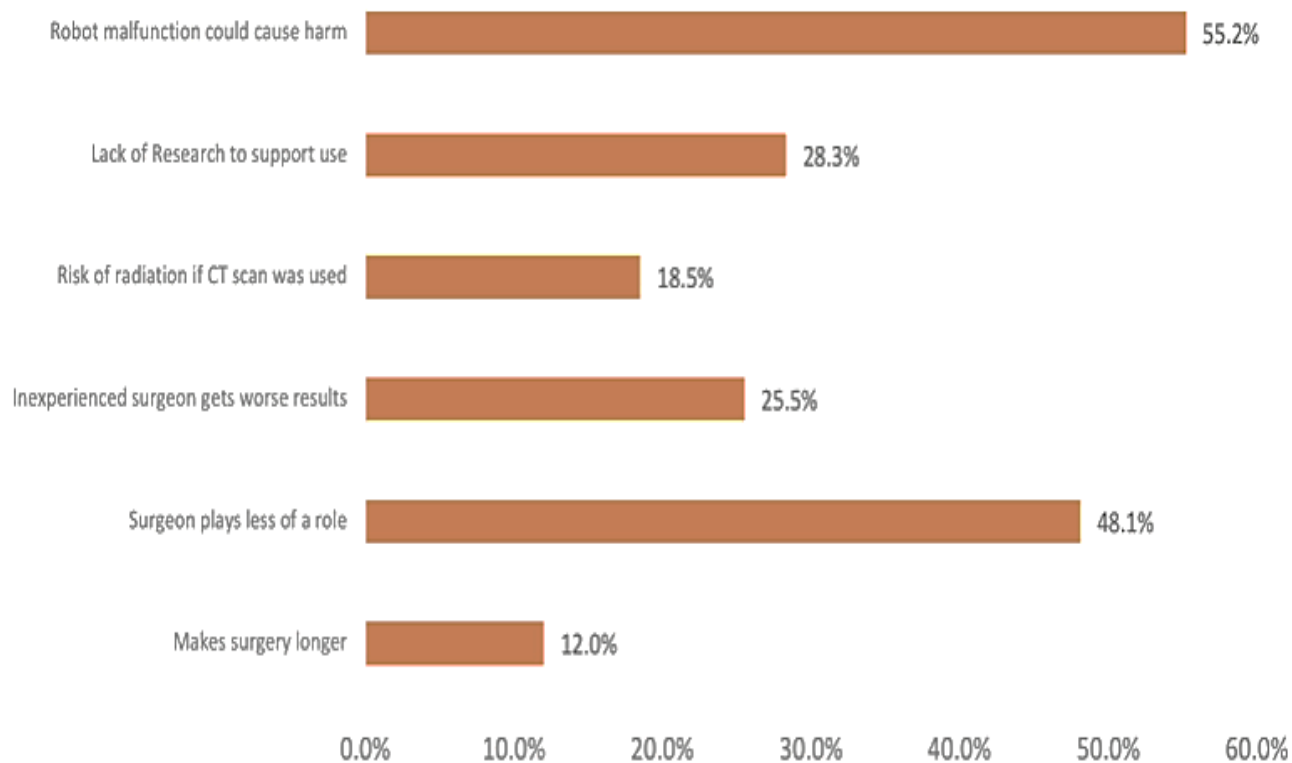


Figure 3.60 Summary of patient concerns regarding robot-assisted total knee arthroplasty [132].

In another study, Gould, et al. [133] explored the views of patients regarding a novel and promising future avenue for robot-assisted knee replacement surgery; the use of artificial intelligence (AI) for predicting risk and outcomes. Based on interviews with 20 participants, of whom, 50% had acquired a post-operative complication, subjects tended to hold promise in AI for assisting surgical decision-making, as this could offer a more reliable means of predicting and realising the taken risk. Therefore, decision-making may become easier for patients when collaborating with surgeons on how to proceed. This was seen as an important factor, as patients wanted to retain a level of function that enabled them to have the freedom to act as they desired in life.

Moreover, patients' thoughts were reflective of the principles of self-determination as they felt they needed the most accurate and reliable information to support decisions about surgery that could have a major impact on their ongoing lives. As such, uncertainty in decision-making was not welcomed and this simply presented them with a dilemma, and potentially placed them in a difficult position, considering that a wrong choice could compromise their health and well-being.

However, patients also valued the promise of AI in supporting surgical decision-making, as this was conducive to enhancing relations with their surgeon, and in turn, it helped to establish trust and comfort in the final decision that was attained. The findings of this study provide some initial insight into the potential applications of AI in robot-assisted knee surgery, although it is prone to some limitations regarding trustworthiness; a common criticism of qualitative studies.

Some qualitative studies have been conducted outside of the orthopaedic setting but retain some transferability due to reflecting views and experiences of robot-assisted surgery, which represents a shared intervention or exposure. In one example, Moloney, et al. [134] interviewed 12 patients who had undergone robot-assisted colorectal, urological, or gynaecological surgery, in order to explore their experiences regarding the process, trust in robotics, expectations of surgery, and any barriers or limitations.

The accounts revealed that most patients held positive faith and beliefs in robotic surgery, particularly as they knew that surgeons remained in control but had greater precision in performing the surgical procedures. Moreover, patients were not fazed by the sight of robots in the operation room, due to prior speculation that the appearance and structure of the devices could induce anxiety. As a result, patients held considerable trust in robotic surgery, as they felt that the accuracy and precision that the devices could induce, optimise surgeons' efforts, and this helped to mitigate anxiety about the invasiveness of surgery and any potential risks or complications.

In addition, patients trusted the views and recommendations of their responsible surgeons, and, therefore, adopted a similar level of trust when offered a robotic surgical approach. However, some minor limitations of robotic surgery were noted, including the limited availability of information to assist in the background reading and operative decision-making, a lack of counselling to provide support and address any psychological issues prior to surgery, heightened anxiety due to misinformation about robotic surgery seen online, or in lay, and non-credible information sources.

This study may have been limited by insufficient methods to enhance the trustworthiness of the findings, nonetheless, its transferability to the orthopaedic context is desirable in the context that most patients underwent handheld forms of robotic surgery, which is commonly used in uni-compartmental and total knee arthroplasty.

Other qualitative studies have also suggested that patients who have undergone robotic surgery, hold trust and faith in the approach in guiding safer and more accurate surgery, and notably, such views appear to reflect the quality of information communicated to patients by surgeons

[135,136]. However, it is important to highlight that there remains a paucity of qualitative literature in the field of robot-assisted knee arthroplasty. This is a key evidence gap and one that requires addressing through future research, as such information may help to corroborate and validate the quantitative patient-reported outcome measures.

IV. IMPROVEMENT STRATEGIES & PROPOSALS

3.12 Hardware Improvement Proposals

In response to the research reported by surgeons involved in the use of robotic devices that assist them in performing surgical procedures, a considerable number of recommendations for hardware development and improvement have been formulated. The present robotic hardware co-exists with various limitations, although having been found to be optimised as much as possible on the ground of its ergonomic conditions, in which surgeons can perform more precise surgery in the absence of strain or fatigue.

In a recent systematic review of surgical ergonomics comprising over 5,100 survey surgeons across numerous specialities, Stucky, et al. [137] found that those performing open surgery, as often the case for uni-compartmental and total knee arthroplasty, were associated with significantly higher odds of repetitive strain injury, relative to minimally invasive surgery. The odds ratios for strain injury at various anatomical sites were as follows: neck (2.77; 95% CI 1.30, 5.93), arm and shoulder (4.59; 95% CI 2.19, 9.61), hands (2.99; 95% CI 1.33, 6.71) and legs (12.3; 95% CI 5.43, 28.06). In addition, surgeons encountered a significantly higher likelihood of fatigue (8.09; 95% CI 5.60, 11.70) and numbness (6.82; 95% CI 1.75, 26.65), and in those with pre-existing repetitive strain, open surgery was linked to an exacerbation of symptoms in over 60% of cases (Figures 3.61 & 3.62).

Notably, almost 30% of surgeons sought treatment for pain related to repetitive strain injuries, and an equal proportion were compelled to alter the operative procedure to mitigate pain during the peri-operative period. Although these findings cannot be completely applied to the sole orthopaedic setting and knee arthroplasty surgery, they highlight a key problem, in which, robotic devices may worsen or could improve upon the problem. However, the data from surgeons using hand-held robotic devices, as with knee arthroplasty, implies that the rate and severity of repetitive strain injury could increase due to the undesirable weight of such devices [138].

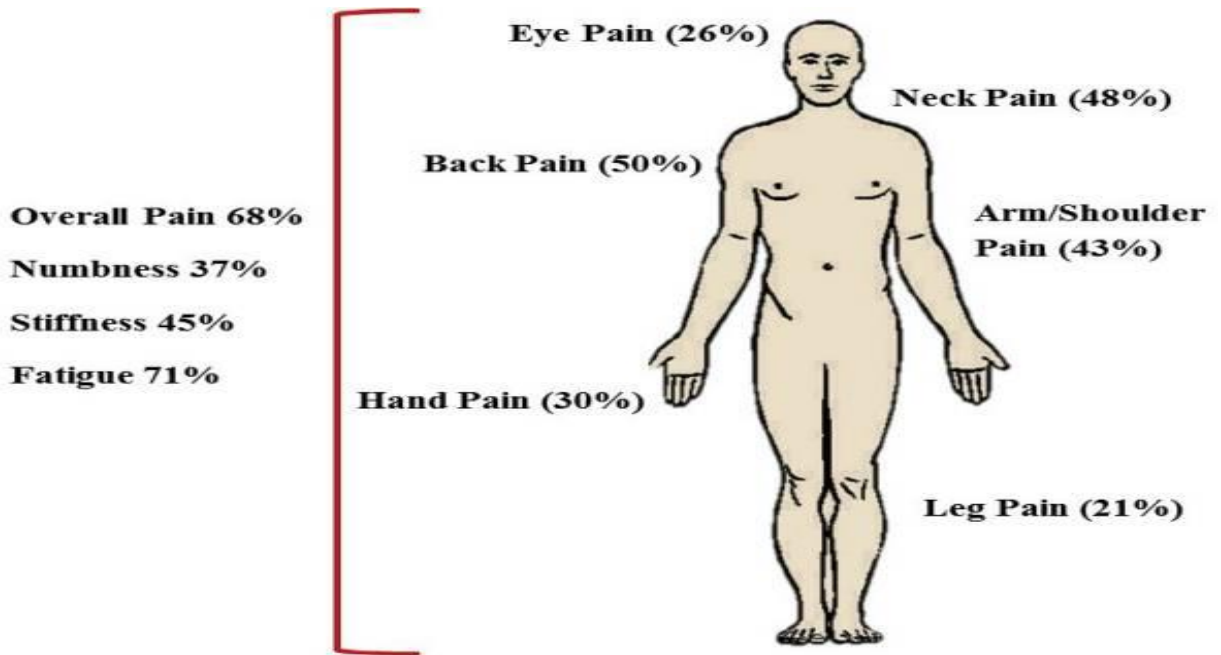


Figure 3.61 Overview of the frequency of surgeon-related strain injuries by anatomical site [137].

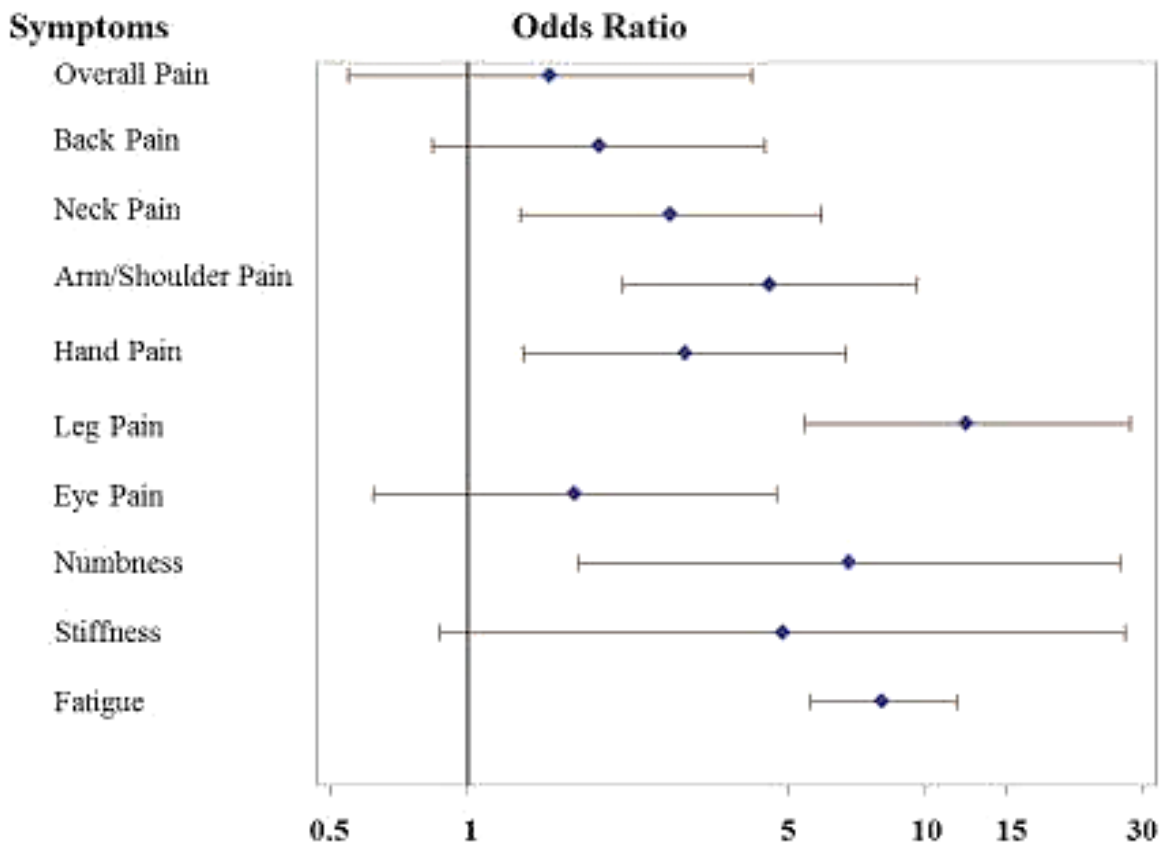


Figure 3.62 Overview of the likelihood of surgery-related injury pain among surgeons [137]. The units is the odd ratio: an odds ratio of 1 is highlighted with a line as this is the standard threshold that means the exposure/intervention does not affect the odds of the outcome. Greater than 1 implies it does, less than 1 implies it does not.

The demands of robotic-assisted surgery and therefore, a need for hardware improvement, have been reflected across several studies examining surgeon fatigue and positioning. For example, Haffar, et al. [138] found that surgeons performing robotic-assisted uni-compartmental knee arthroplasty encountered significantly higher degrees of shoulder abduction, heart rate, and energy expenditure, than compared to those performing manual knee arthroplasty. This implies that the robotic device was not overly beneficial to surgeons from an ergonomic and physiological perspective; a lighter-weighted device may go some way in offsetting these issues.

In another example, although a survey of 236 surgeons across varied specialities, Lee, et al. [139] showed that 56% of subjects reported physical symptoms or discomfort in keeping with repetitive-type strain (Figure 3.63). The commonest symptoms were neck stiffness and finger and eye fatigue, followed by lower back stiffness, which was correlated significantly with a higher annual robotic case volume. Given this data and the limited availability of research exploring the ergonomic effects of surgeons performing robotic-assisted knee arthroplasty, the benefits or limitations may not yet be realised.

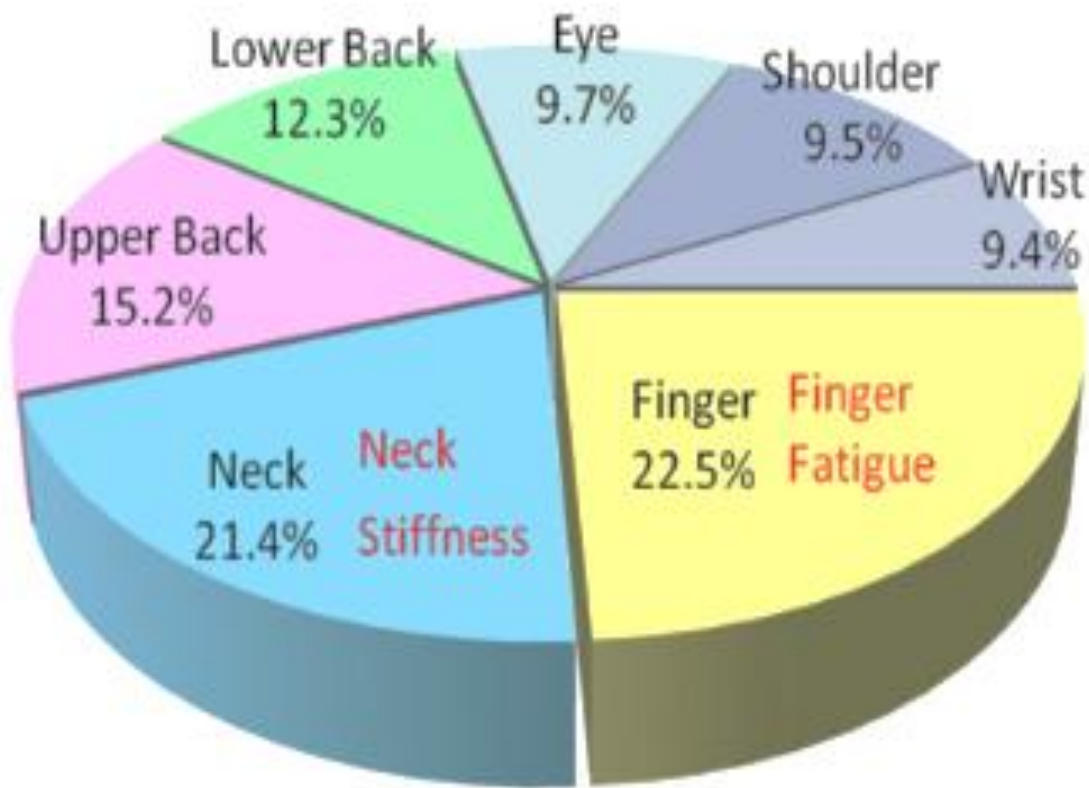


Figure 3.63 Rate of strain related physical symptoms caused by robot-assisted surgery [139].

In contrast to the former studies, Scholl, et al. [140] found that the performing of robot-assisted total knee arthroplasty was associated with significantly more favourable thoracic and cervical ergonomics, than compared to surgeons performing manual surgery.

Mixed effects of robotic surgery have also been observed in a systematic review comparing robot-assisted approaches to laparoscopic surgery where the former was linked to higher strain upon some muscle groups but not others but conferred a significantly lower cognitive demand, as compared to laparoscopic techniques [141]. This has also been supported in another comparison of robot-assisted surgery versus laparoscopic approaches whereby, surgeons using the former observed greater fatigue of the shoulder and neck muscles, while the latter had greater fatigue of muscles in the forearm [142].

There has been an even greater paucity of literature examining the impact of robotic-assisted surgery upon mental fatigue and cognitive function during surgery, and this represents an important gap for future research to explore. In a similar study comparing measures of mental and physical fatigue among surgeons performing robotic surgery, González-Sánchez, et al. [143] found that a higher rate of physical and mental fatigue was observed, as compared to those

performing manual laparoscopic surgery (Table 3.9). The extent of fatigue during robotic surgery varied from 10-16%, as compared to 3-12% for the laparoscopic condition. However, the authors were unable to determine whether the difference was significant from a statistical perspective, thus, contributing to uncertainty regarding the ergonomic effects of using robotic hardware. Given these problems and ongoing research and development initiatives that appear to be designing robotic-assisted devices that can provide force-feedback for surgeons, there may be an increasing risk of such techniques losing their ergonomic potential.

Table 3.9 An example of the data regarding muscle fatigue in surgeons performing robot-assisted versus conventional laparoscopic surgery [143].

| | Robotic | | | Laparoscopic | | |
|--------------------------------|---------|-------|-----------|--------------|-------|-----------|
| | Pre | Post | Dif. | Pre | Post | Dif. |
| PRO | | | | | | |
| POMS | | | | | | |
| POMS Index | 6.00 | 13.50 | 7.50*** | 3.50 | 17.00 | 13.50*** |
| Anger | 0.00 | 2.00 | 2.00** | 0.50 | 2.50 | 2.00** |
| Depression | 0.00 | 0.00 | 0.00** | 0.00 | 0.50 | 0.50* |
| Fatigue | 0.00 | 1.00 | 1.00* | 0.00 | 1.50 | 1.50* |
| Vigor | 2.50 | 4.50 | 2.00** | 1.50 | 5.50 | 4.00** |
| Friendliness | 2.50 | 5.00 | 2.50** | 1.50 | 5.50 | 4.00** |
| Anxiety | 0.50 | 1.00 | 0.50* | 0.00 | 1.50 | 1.50* |
| Confusion | 0.50 | 1.00 | 0.50* | 0.00 | 0.00 | 0.00** |
| QPFS | 16.00 | 53.50 | 37.50*** | 16.50 | 57.50 | 41.00*** |
| VAS | 20.35 | 54.90 | 34.55*** | 21.20 | 51.80 | 30.60** |
| Functional test | | | | | | |
| Handgrip (kg) | | | | | | |
| Maximum left | 39.50 | 35.50 | 4.00** | 39.50 | 35.00 | 4.50** |
| Maximum right | 41.50 | 38.00 | 3.50** | 41.50 | 37.50 | 4.00*** |
| Single-leg balance test | | | | | | |
| Dominant leg | | | | | | |
| Opened eyes | | | | | | |
| Time (seg) | 30.00 | 23.49 | -7.11*** | 30.00 | 21.93 | -8.07*** |
| Displacement (°) | | | | | | |
| Flex/Ext | 2.28 | 17.24 | 14.96*** | 3.08 | 17.33 | 14.25*** |
| Incl. L/R | 9.68 | 20.11 | 10.43*** | 9.68 | 20.29 | 10.61*** |
| Rot L/R. | 9.67 | 29.35 | 19.68*** | 9.67 | 29.37 | 19.70** |
| Velocity (°/s) | | | | | | |
| Flex/Ext | 41.89 | 44.47 | 2.58 | 41.89 | 43.45 | 1.56 |
| Incl. L/R | 23.51 | 25.15 | 1.64 | 23.51 | 25.23 | 1.72 |
| Rot L/R | 55.57 | 57.80 | 2.23 | 55.57 | 56.47 | 0.90 |
| Closed eyes | | | | | | |
| Time (seg) | 30.00 | 12.87 | -16.53*** | 30.00 | 11.69 | -18.31*** |
| Displacement (°) | | | | | | |
| Flex/Ext | 9.41 | 38.18 | 28.77*** | 9.41 | 39.10 | 29.69*** |
| Incl. L/R | 14.43 | 54.03 | 39.60*** | 14.43 | 43.52 | 29.09** |
| Rot L/R | 15.35 | 47.36 | 32.01*** | 15.35 | 46.18 | 30.83** |
| Velocity (°/s) | | | | | | |
| Flex/Ext | 42.26 | 43.88 | 1.62 | 42.26 | 43.30 | 1.04 |
| Incl. L/R | 28.56 | 31.67 | 3.11* | 30.56 | 31.71 | 1.15 |
| Rot L/R | 54.97 | 56.75 | 1.78 | 54.97 | 55.69 | 0.72 |

The absence of force feedback in current systems represents a noted limitation of such surgery, as surgeons are unable to perceive and respond to tactile information, which is quite often necessary to ensure precision during various procedures [144,145]. This may be an important development avenue in being able to reduce grip force during robotic device use, although the potential adverse effects upon ergonomics and the risk of repetitive strain are unclear [146].

Notably, some authors in the field have alluded to the use of ergonomic training for surgeons to assist in adapting to and reducing the risk of repetitive-type strain injuries due to robotic device use, although its efficacy has yet to be realised [147]. Aside from issues of robotic device weight and ergonomics, other potential development issues and avenues remain under-reported.

Trends in the evidence suggest that current systems have desirable or even optimal camera motion and surgical field visualisation, as well as a range of motion. However, patient positioning and placement and movement of robotic systems within operating theatres remains a challenge, and one often incurs high costs due to the need to renovate operating environments [148].

Moreover, there may be a need to enhance the hardware to reduce the incidence of technical faults and malfunctions, which have been reported to range between 0.4-4.7% [148]. This appears to be an excessive rate and one that requires development modifications and considerations for the development of additional generations or new robotic surgical systems.

3.13 Software Improvement Proposals

Modifying and further developing the software integrated into robotic surgical systems represents an additional means by which the potential of this approach could help to maximise surgical safety and efficacy for service users. However, identifying the specific issues with current robotic software likely requires a system-based approach through gathering the feedback of surgeons regarding the limitations and desirable features of software when using robotic systems to plan and perform surgery.

There is a lack of literature on this topic area, and this precludes a detailed evaluation of the common issues and the system-specific issues. Again, this is another avenue for ongoing research to explore in the field and one that may have promising implications for ongoing system development [148].

One emerging area of optimising software for robotic-assisted surgery is the use of Artificial Intelligence with deep learning models and artificial neural networks. These may be able to guide

and perform pre-programmed surgery, as well as in gathering vast amounts of data to assist in a continuous process of learning and refining approaches, in order to reduce risk and enhance outcomes [148]. Deep learning models would essentially gather data regarding procedures linked to good and less good outcomes and tailor future approaches linked to the more desirable outcomes. However, it is unclear whether such learning models may harbour an ability for surgeons to override particular surgical tasks in response to clinical and/or surgical indications that may not be sensed, perceived, or understood by a computer system [149].

Machine learning protocols may also assist in surgical training, via the measurement and feedback of automated performance metrics; allowing trainees to refine and master various surgical skills within a safe and controlled setting [150]. Despite the potential of deep learning, the vast amounts of data needed can co-exist with significant limitations related to the how, where, and cost of storing such data [151]. In surgery, this may require considerable expansion and renovation or a complete redesign of operating suites. The potential of deep learning, however, has been realised in the automotive industry with self-driving vehicles, although again, some limitations, and often significant issues, can exist when complete autonomy is granted to a non-human system [152].

In the context of surgery, several studies have investigated the impact of using deep learning to assist laparoscopic surgery and have found that the systems can provide a reliable means of identifying key issues and organ structures. However, the overall accuracy indices have not been as initially expected, thus, posing uncertainty about whether deep learning may offer benefits to surgical performance and safety [153,154]. Such studies, to the authors' best knowledge, have not been conducted in orthopaedics or knee surgery, hence, highlighting another avenue for future research.

On the other hand, artificial neural networks are described as being the computer equivalent of the central nervous system and one that is able or at least has the potential to develop completely autonomous robots [149]. This appears to be the primitive source of concern among sceptics. Laypersons and even academics and clinicians express some concerns over how much control robotic surgical systems could or should have, particularly as there may be direct implications for patients undergoing surgery that is largely autonomous to robotic and artificial intelligence algorithms [150].

Autonomy in robotics has been categorised into levels within a six-phase framework proposed by Han, et al. [155], and Yang, et al. [156], which may be needed to guide ongoing software development in robotic surgical systems in order to remain compliant with regulatory and ethicolegal principles. In effect, level 0 represents a lack of autonomy with robotic components

that respond to the commands of surgeons and level 1 involves robotic-assisted devices that provide assistance but with predominant surgeon management, which, conforms to the current robotic devices being used in knee arthroplasty. There is also some overlap with such systems with the level 2 category: a task performed autonomously by a robot that is started by a human.

This is congruent with the surgeon-guided instigation of bone cutting, while the robotic burr attachment performs and directs said cutting via the attached instrumentation. Higher levels of autonomy have not emerged into considered surgical practices but may remain a potential avenue to assist in offloading the burden upon surgeons.

Level 3 is conditional autonomy, in which, robots perform system-selected tasks but one that relies upon a human to select a plan. Level 4 is a highly autonomous category, in which, robots make decisions during surgery and thus, rely upon programmed artificial neural networks. This level co-exists with direct surgical supervision. Finally, level 5 is a fully autonomous category where robots perform tasks and make decisions independent of human involvement or supervision [155,156].

Notably, the Smart Tissue Autonomous Robot (STAR) has developed artificial intelligence capabilities and has a high level of autonomy. It has been shown to perform highly repeatable, accurate, and efficient suturing of soft tissues and organs within experimental and animal models, thus, highlighting the promise of such software for human use.

There remains a long way to go before artificial intelligence is used in routine human surgical practice and considerable barriers to using robots or robotic devices with a high level of autonomy may not prove acceptable or feasible. Although much of the emerging evidence has been conducted in elective situations, artificial intelligence may also facilitate the ability to utilise robotic systems in emergency surgical situations, although this may have little relevance for elective knee surgery and would require considerable research and external validation, in order to elicit its feasibility for this purpose [148].

In elective surgery, deep learning and artificial neural networks in combination may help to reduce the risks of surgery in situations where it may be difficult for the human eye to visualise key structures, such as nerves, vessels, or tumour margins, which could eliminate a degree of uncertainty regarding surgical success and patient outcomes/prognosis [150].

3.14 Calibration Improvement Proposals

The calibration of robotic systems and related instrumentation is a vital component of the pre-operative routine as this ensures the maintenance of the accuracy, standardisation and reliability of effects or results; the actions of robotically-assisted surgical procedures [157].

At present, most robotic systems used within knee surgery have relatively extensive and time consuming calibration procedures, which can have a major impact upon operative planning and patient throughput, as well as incurring excess costs and resource use related to changes in efficiency. Maintaining calibration protocols is however, vital to protecting patient safety as any considerable or even subtle variances in robotic accuracy and reliability could amount to direct harm through surgical trauma. Poor calibration could also pose threats to surgeons and other operative staff as a result of regulating the movement of robotic components [158].

In industries external to healthcare, such as the automotive industry, the calibration of robotic systems has been largely automated and in some cases, robotic systems have also been developed to facilitate automation of this vital process [157]. Such technology has yet to emerge within healthcare, although conveying such control over accuracy and reliability constraints may co-exist with key ethicolegal issues regarding responsibility and accountability for patient outcomes [159].

Therefore, questions remain about whether it may be safe to eliminate or accelerate the completion of a number of calibration steps in robotic surgery. However, such views may be held by surgeons and operative managers, in terms that high operative efficiency is fundamental to meeting demand, while ensuring practice remains in keeping with budgeting constraints. This is vital in the National Health Service (NHS) where the system remains reliant upon public-funding and has been under-funded for decades, which has resulted in challenges in funding and resource allocation across clinical fields [160].

Although most calibration methods in current operative practice remain reliant upon the manual completion of tasks, some research has begun to elicit the feasibility of automated calibration methods. For example, Yuan [159] has proposed a method for the rapid and automated calibration of a robotic surgical system that has been designed for puncture-assisted surgery.

The method was developed to assist in the calibration of both hand-eye co-ordination and that of surgical tools with the system being guided by an infrared camera. Notably, the system is not too dissimilar from the robotic-assisted devices used in knee arthroplasty (Figure 3.64) and thus, holding value in this evidence in guiding the ongoing development of orthopaedic robotic systems.

The results of the cited authors showed that the re-positional precision of the automated calibration method was high (0.91 +/- 0.03mm) and this only took around one minute to complete. The actual automated method of calibration comprised a range of computational and mathematical principles and thereby, indicating that system-specific and likely, operation-specific automated calibration procedures would be needed for robotic systems designed to facilitate knee arthroplasty.

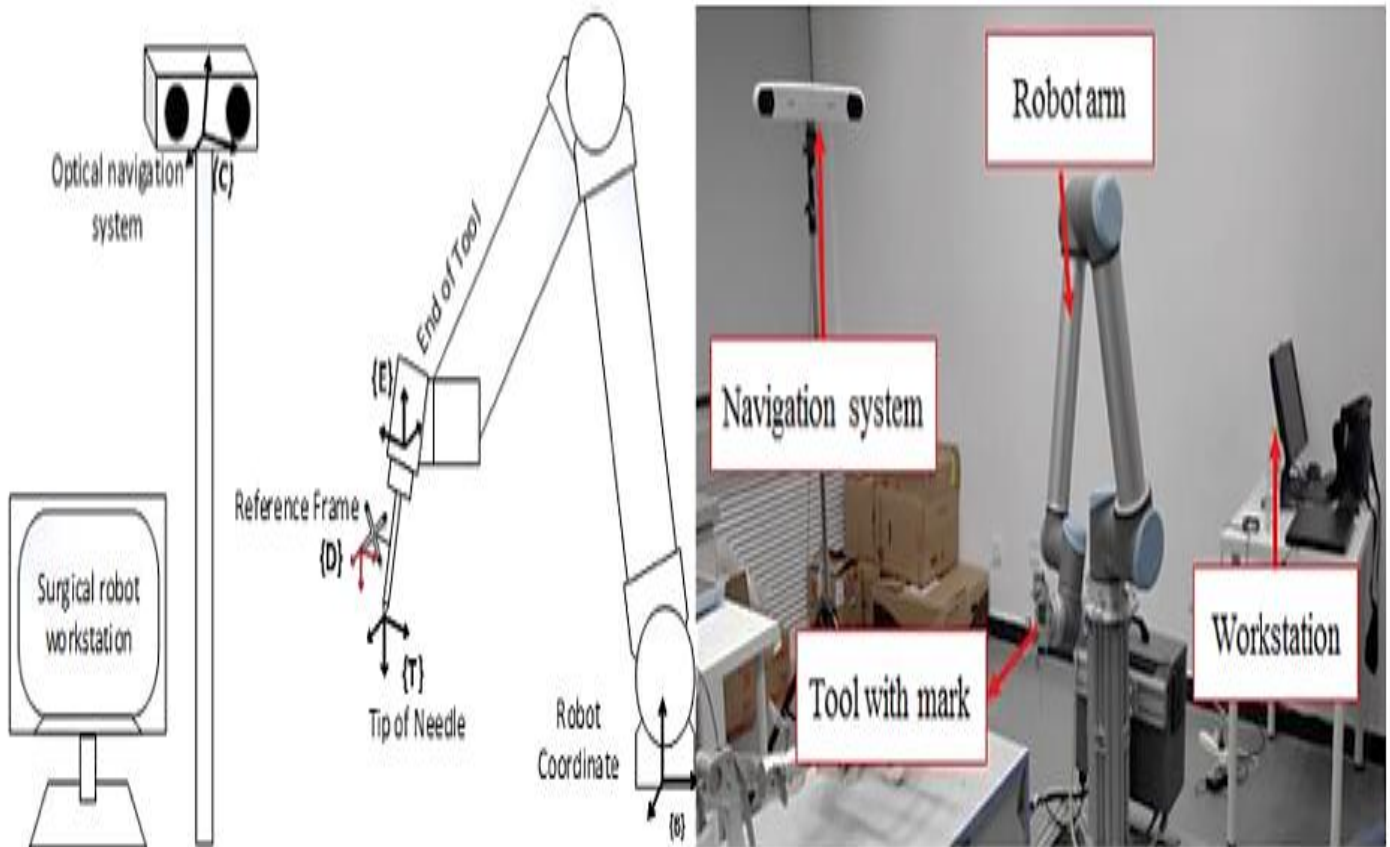


Figure 3.64 Overview of the spatial axes of the robotic system assessed for automated calibration in the study of Yuan [159].

Previous authors have proposed calibration methods for the hand-eye co-ordination setup of surgical robotic systems and while supporting high accuracy, the process could not avoid human involvement in the process and thereby, a degree of human error may have resulted, as with any non-automated calibration method. The references to the papers have been cited in the study of Yuan [159] but could not be directly accessed by the author of this work.

In another recent assessment of the potential to automate the calibration of a surgical robotic system, Özgüner, et al. [161] examined a computational and semi-autonomous method for the Da Vinci robotic device. The authors reported the potential for error during the calibration of hand-eye movements as this required highly precise manipulations of the actuator arm. The results, based on 300 trials, showed that the calibration method was associated with a mean rotational error of 3.2°, with the standard deviation being 3.42° and the maximum error incurred being 6.0°.

This degree of error may be insufficient to ensure optimal accuracy and precision during surgical procedures and thereby, highlights some of the problems and limitations of the non-autonomous calibration methods.

Regarding the needle-grasping experiments, the authors showed that grasping occurred successfully in 90% of cases and thus, failed in 10%, which may also be an unacceptable level for calibration purposes. Positioning errors were also evident with a mean error of 2.0mm (standard deviation 0.7mm and maximum error 4.0mm) and notably, the calibration process typically lasted around 40 minutes.

This is a significant amount of time and one demanding reduction, in order to help improve the efficiency of surgical operations both locally and worldwide [161]. However, other research has shown that semi-autonomous methods of calibration can yield satisfactory results for surgical robotic systems; positional errors typically being <0.1mm. (Figures 3.65, 3.66, and Table 3.10) [161-163].

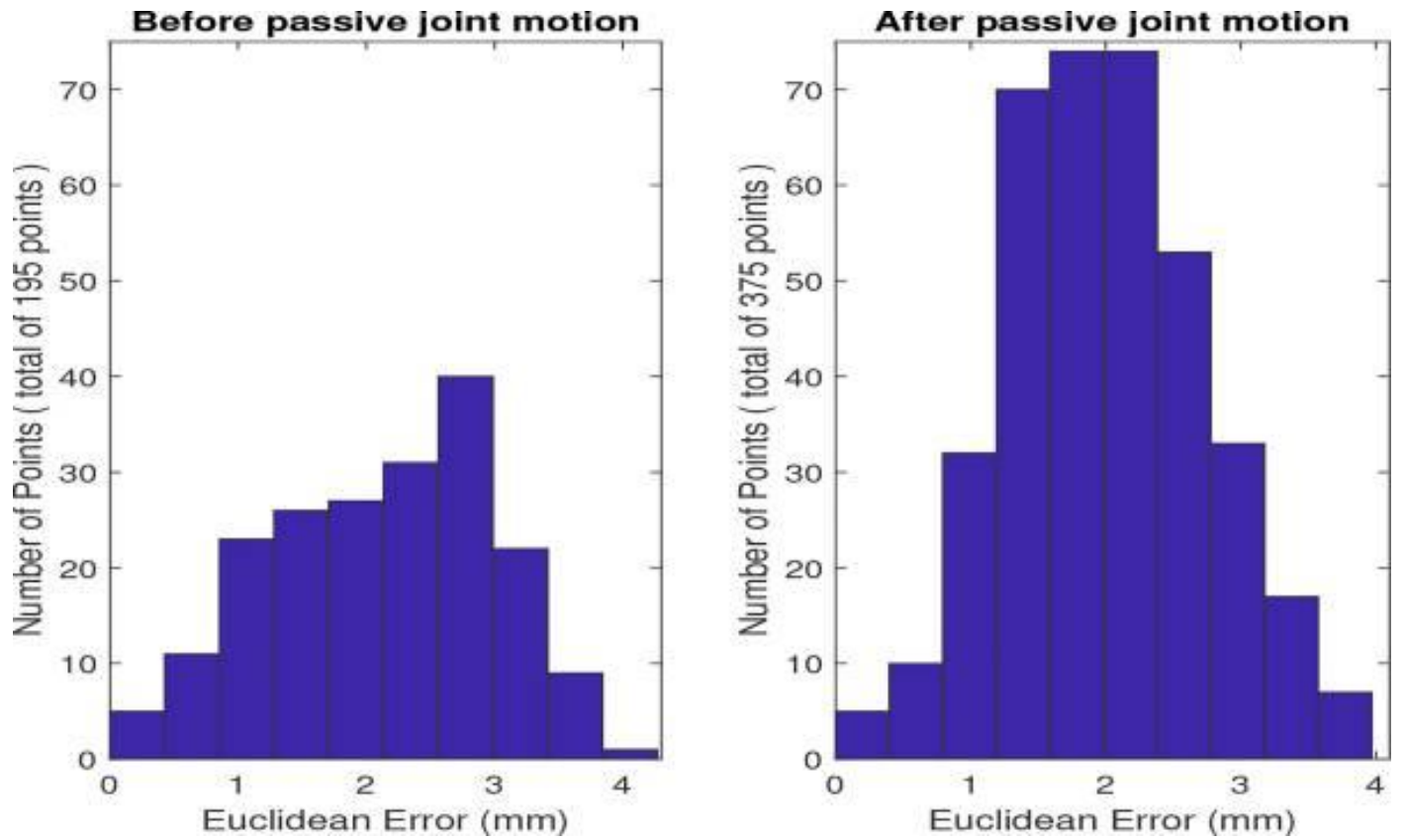


Figure 3.65 Overview of the errors in calibration of the Da Vinci robotic device [161].

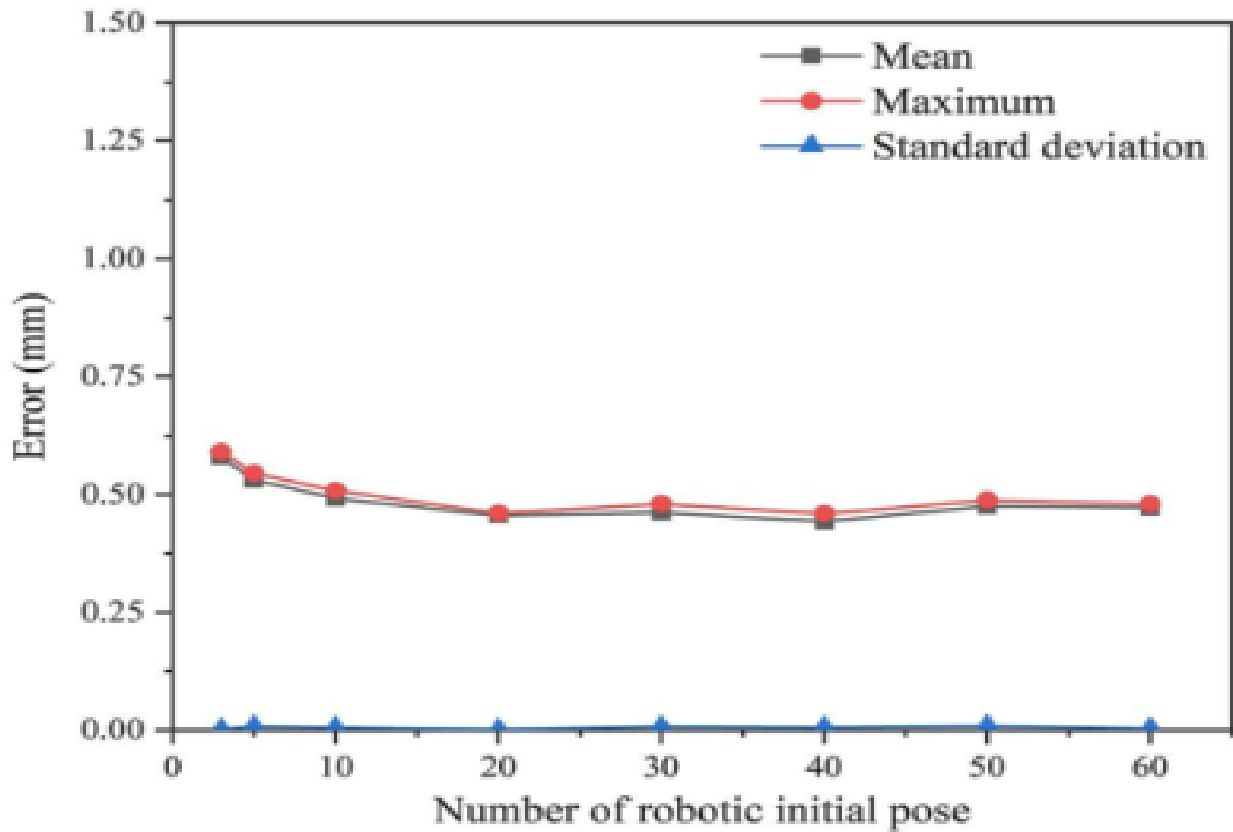


Figure 3.66 Overview of the errors in calibration of a robotic surgical puncture system [162].

Table 3.10 Summary of error values in the analysis of calibrating a robotic system for hip joint testing [163].

| Direction | x_R | y_R | z_R |
|--------------------|-------------------------|-------------------------|-------------------------|
| Position 0 | - 0.003 | 0.378 | 0.218 |
| Position 1 | - 0.002 | 0.667 | 0.126 |
| Position 2 | 0.000 | 0.104 | - 0.025 |
| Position 3 | 0.001 | - 0.159 | 0.041 |
| Position 4 | 0.184 | - 0.241 | 0.178 |
| Position 5 | 0.001 | - 0.089 | 0.005 |
| Average value | 0.030 | 0.110 | 0.091 |
| Standard deviation | 0.069 | 0.321 | 0.126 |
| Max deviation | 0.184 | 0.667 | 0.218 |
| Min deviation | - 0.003 | - 0.241 | - 0.025 |

Automated methods of calibration may however, prove superhuman in attaining optimal surgical accuracy and precision as has been recently demonstrated by Hwang, et al. [164].

Based on an evaluation of over 3,300 surgical peg transfer trials, the authors showed that deep-learning automated calibration of the surgical robotic system was able to achieve superhuman consistency and the lowest collision rates. The authors noted that they produced the first known study to show how autonomous calibration methods can maximise robotic surgical system safety.

Advances in robotic systems and related hardware and software are also realising that improvements to calibration can be achieved, as has been evident for additional generation systems [165]. As noted, enhancing calibration speed, as well as accuracy, is vital to supporting the uptake and feasibility of robotic system use in routine future practice. These efficiencies and measures of safety are needed in view of the high costs and significant demand in healthcare.

Finally, optimising the timing of calibration methods for robotic surgery may not only offer marked improvements to operative efficiency and costs but also in enhancing the feasibility of

robotic use for emergency surgical indications. In the absence of rapid calibration, such surgery will not be possible, however, a range of artificial intelligence systems including deep learning may be able to assist with supporting highly accurate and rapid calibration [164].

3.15 Sensors Improvement Proposals

Sensors in robotic surgery are critical to their feasibility and utilisation and indeed, the various types of sensors include mechanical sensors, such as those detecting and responding to force or torque, vision-based sensors, such as optical cameras needed to visualise the surgical field, and haptic feedback sensors, as discussed in a later section of this chapter [166].

Each individual sensor offers advantages to supporting robotic surgery but there are also limitations, which represent areas for sensor development (Table 3.11). For example, strain gauges are highly accurate in detecting changes in strain or the deformation of tissues, while piezoelectric sensors can provide markedly high precision in detecting force and optical sensors provide an accurate means to measuring force in degrees of freedom.

Position sensing is an additional and vital component of surgical robots as it enables precise motion tracking and control over the robot position and the manipulation of maneuverable components that may be used to direct surgical procedures. However, there is a need for real-time feedback as to optimise performance but this has remained a key challenge in sensor development.

This is required to ensure sufficient interaction between the robotic operations and the external environment (conditions of surgery and any peri-operative actions). This interaction and ability to optimise performance can be constrained by the challenges of actuator types and the size of robot components. In addition, integrating new sensors into robotic systems can be complex and may incur considerable costs [166].

Table 3.11 Summary of the types of sensors used in robot-assisted surgery [166].

| Sensors | Description |
|----------------------------------|---|
| Capacitive sensors | Capacitive sensors detect force by measuring changes in capacitance resulting from the deformation of a dielectric layer between two electrodes, and has good reproducibility, and stability in warm and wet environments. |
| Biofeedback sensors | Biofeedback sensors can be integrated into surgical tools to monitor tissue oxygen saturation levels and alert surgeons if levels fall below acceptable thresholds, and strain gauges are used to measure the applied force of surgical tools. |
| Optical sensors | Optical sensing enables force measurement in up to six degrees of freedom (DOFs) by detecting changes in the intensity or phase of light passing through a flexible tube to a compliant structure reducing hysteresis and reproducibility in magnetic environments. |
| Thermal sensors | Thermal sensors are combined into thin and flexible elastomer platforms that is attached to target tissues or organs, providing data on thermal distribution, blood flow, contact pressure, and other physiological parameters. These sensors, comprising micro-thermistors enables a real-time monitoring of temperature and thermal distribution during medical procedures. |
| Force sensors | Force sensors are very effective for measuring forces and torques in many teleoperation applications. Adding force sensors to existing robotic surgical instruments is challenging due to constraints such as size, geometry, cost, biocompatibility, and sterilizability. Specialized grippers design can enable the use of force sensors. |
| Tactile sensors | Tactile feedback systems in robotic minimally invasive surgery (RMIS) require both a sensor and a display. Tactile sensing aims to detect mechanical properties of tissue or provide feedback to the operator, but sensor design constraints include cost, size, geometry, biocompatibility, and surface finish. Various tactile sensors, such as capacitive sensors and force-sensitive resistors can be used. |
| Proprioception Sensors | Proprioception sensors involves in monitoring the state and position of surgical instruments which is crucial in robotic surgery. Parameters such as strain and end position are commonly monitored. Strain information aids in closed-loop motion control, while end-position information assists in precise navigation. |
| Environmental Perception Sensors | Environmental perception in robotic surgery currently focuses on image perception of the surgical environment. Medical image-sensing technologies are categorized into structure-based imaging (e.g., fluoroscopy and ultrasound) and surface-based optical imaging. |
| Interactive Perception Sensors | Interactive perception sensors in robotic surgery involves collecting information about the magnitude and distribution of force between surgical instruments and surrounding tissues. Thin-film pressure sensors and flexible, stretchable tactile sensors are commonly used for this purpose. |

Optimising the optical sensors of robotic systems is likely to be one key development avenue in response to surgeons reporting that more autonomous control of sensors would be needed to enhance surgeon-focus upon the surgical field and direct surgical tasks. This has emerged from current robotic-assisted surgical systems that rely on master-slave modes whereby, direct

surgeon control or input is needed to initiate and control robotic actions. Thereby, the control and position of the camera requires surgeon manipulation, in order to provide optimal visualisation of the surgical field [167].

Other robotic systems can provide a high level of detail of the surgical field even in minimally invasive surgery through internal cameras, much like laparoscopic surgery, nonetheless, a robotically-assisted camera can readily overcome issues of surgical assistant fatigue and any deviance or change in the surgical field [168]. This is important as it has been previously recognised that surgical errors often result due to issues of misperception, as opposed to insufficient experience or judgement, and therefore, highlighting the promise of optimising robotic sensors upon patient safety [169].

However, surgeon manipulation of the robotic arm holding the camera is still needed to avoid issues of misperception, as this can create an interruption to the surgical process and one that could lead to error, in theory.

It has been proposed that camera systems could be improved to avoid this issue through using voice-dictated commands with a controller on the foot pedal to potentially activate and initiate surgeon commands without them having to interrupt the actual operative procedure [170,171]. This may assist and provide a benefit to any future robot-assisted laparoscopic knee surgery, although it may be of little value to arthroplasty requiring an open wound to gain access to the relevant anatomy.

In addition, or as an alternative to voice commanded robotic camera control, researchers in the field have also proposed to develop and trial automated camera-positioning systems. Such systems may be of value in enabling knee surgery to be performed by a single surgeon, as opposed to two surgeons, which could spare time, costs and resource use, while also enhancing capacity to meet demand.

Automated camera position sensors are able to compute visual information in real time and respond to this data, in order to autonomously manipulate the camera position. This is projected on the fact that currently the instruments are being manipulated by the surgeon and not autonomously by the robot while performing actual surgery. There is, however, a need to optimise the zooming ratios, in order to enable a seamless process, in which, surgeons may be able to exert commands to rapidly adjust the depth of the field, although this may also be pre-set in line with surgeon preferences [168].

Some studies have explored the feasibility of such systems. For example, Wagner, et al. [172] explored the feasibility of a learning robot for cognitive camera control in minimally invasive surgery and found that camera guidance quality improved meaningfully as to adapt to the surgeons needs in a better way, than systems lacking such guidance.

In another example, Paul, et al. [173] evaluated the impact of a voice-enabled automated camera control system that had been adapted onto the da Vinci surgical robotic system. Surgeons were tasked with commanding the system to complete a series of tasks using the camera system. Yet, the results showed that human-operated camera controls outperformed the automated system to a significant level ($p < 0.05$).

Despite this, the findings were not excessively different between groups, and thereby, they provide some promise for further development with a step towards the greater adoption of more autonomous robotic systems in practice. As previously mentioned, however, this may co-exist with some ethicolegal concerns, meaning that although automated control should be restricted to indirect operative tasks, their adoption may prove useful, and hence, acceptable and feasible (Table 3.12).

Table 3.12 Summary of demand-related measures between the human-operated camera controls (HOCC) and the automated system (VACC) [173].

| | VACC | HOCC |
|------------------------|------|------|
| Score | 13 | 15 |
| Mental Demand | 2 | 13 |
| Physical Demand | 2 | 14 |
| Temporal Demand | 2 | 12 |
| Performance | 5 | 11 |
| Effort | 4 | 14 |
| Frustration | 4 | 12 |

Finally, intelligent sensor systems, such as those providing haptic feedback, are also of growing interest within the field of robotic surgery as such feedback may enable the surgeon to enhance the accuracy and precision of surgery through reacting to sensory responses related to tissue pressure [174]. A recent meta-analysis showed that the application of haptic feedback to robotic

assisted surgical systems could significantly reduce the mean and peak forces applied to tissues and thus, potentially reducing the extent of trauma during surgery and the risk of complications [175].

In addition to such benefits, haptic feedback may also improve the ergonomics and comfort for surgeons, which could reduce the risk of strain and stress related injuries [176]. Nonetheless, the role and value of haptic feedback within robot-assisted knee arthroplasty remains unclear, and therefore, warrants ongoing research.

3.16 Optical Markers Improvement Proposals

Regarding the systems that are in local use for knee arthroplasty surgery, Navitracker® (Zimmer Biomet) and similar Optical Marker (Stryker MAKO®, Johnson & Johnson Velys®) devices are reflective trackers that are installed on the system and the patient to permit optical tracking.

As previously noted, movement of the robotic arm can be semi-automated (pre-determined) where the surgeon can apply a gentle force to the end of the arm to assist in guiding it towards the desired position. This mode is also coupled to bone tracking to ensure bone cutting in line with the planning resection areas. Every company that develops its own system, reports that using reflective trackers other than their specifically designed components, could lead to a loss of accuracy and therefore, limiting the benefits of these devices to the confines in which they permit optical tracking.

For example, the Zimmer Biomet Navitracker® are single-use and disposable components and due to being system-specific, they currently incur high costs, with each unit costing \$475. Similar appears to be the cost for the Stryker MAKO® reflectors or the PURESIGHT™ Hydrophobic Optical Reflectors (Johnson & Johnson Velys®) [175,176]. Therefore, one proposal is that these markers are manufactured in ways that can lower the costs and/or that trackers are designed to withstand surgical sterilisation to permit re-use. This may be important in enhancing the long-term cost savings and cost-effective outcomes related to adopting a robotic-assisted surgical system for knee arthroplasty in the future [95], [175,176] (Figure 3.67).

As also noted, during land-marking, the robotic arm needs to be optimally positioned to ensure the points are within the target area and at a sufficient distance from one another as to avoid incurring a computer-detected error; points are too close, points outside of the defined area or incorrect laterality. Moreover, the optical markers need to remain within the visual field of the camera and therefore, a clear path from the markers to the camera is needed to avoid error and interruption to the operative flow. Therefore, the surgeon may need to reposition the camera

during surgery and mostly, during the bone cutting phase to within a proximity of the initial registration.

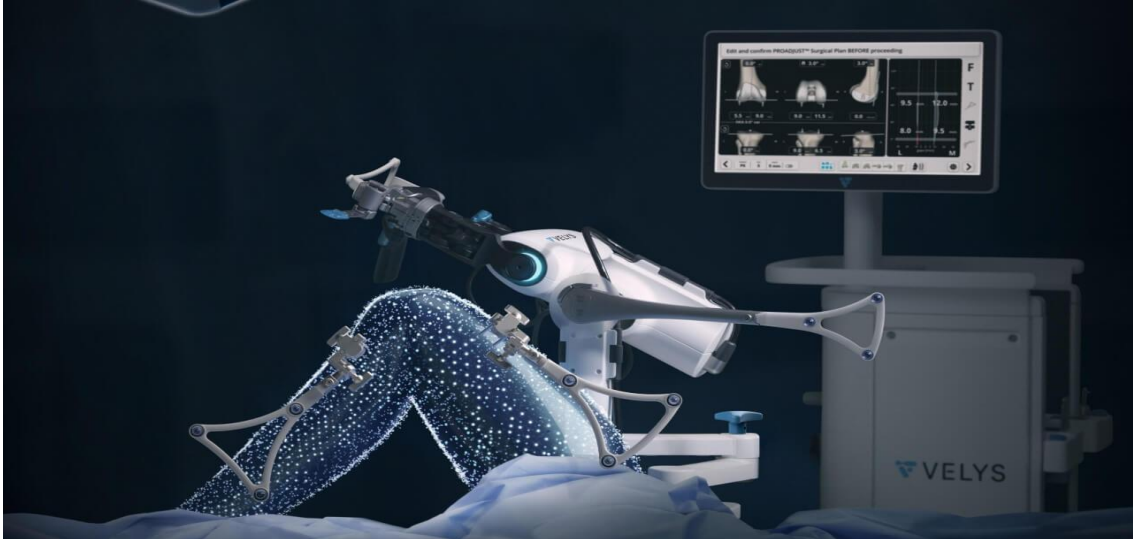


Figure 3.67 The various markers of ROSA® (Top), MAKO® (Middle), and Velys® (Bottom) [95], [175], [176].

Clarification of the optimal position is light-based and thus, no significant improvements to this feedback appear to be needed at present. The surgeon is also able to interact with the display to view the markers and their status, which is also useful during the pre-operative phases (Figure 3.68). Repositioning the camera represents an interruption to operative flow and this could distract the surgeon performing the surgery. Therefore, one key area for development and in keeping with subsection 3.12 is to incorporate automated optical tracking technology, in order to avoid the need for surgeon-guided re-positioning of the camera. [95], [175], [176]

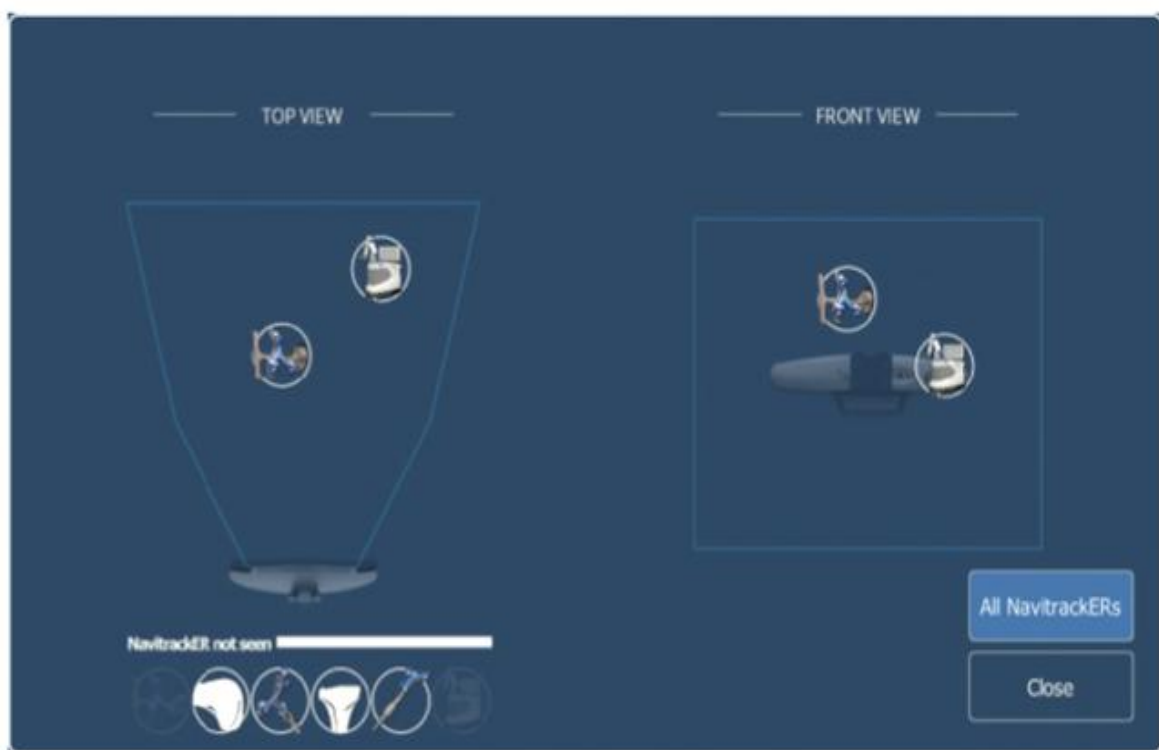


Figure 3.68 Overview of the ROSA® system display showing the NavitrackerER viewing and status options [95].

There is also a need for the markers to be in a position that remains outside of the vicinity of any infrared sources or infrared reflectors. This is needed to prevent interference and error. Infrared sources may be present in surgery involving image-guidance, as with near-infrared fluorescence, as well as infrared emitted with laparoscopic equipment and through infrared thermography [177,178].

However, not all, if any, of these sources are used during knee arthroplasty. It is unclear therefore, whether there may be a need to develop or modify the optical marker devices to possess infra-red resistant properties. While some of these markers are placed on the robotic system itself (registration pointer, reference arm, reference frame and validation body), the other markers are placed on patients femoral and tibial landmarks (Figures 3.66 and 3.69).

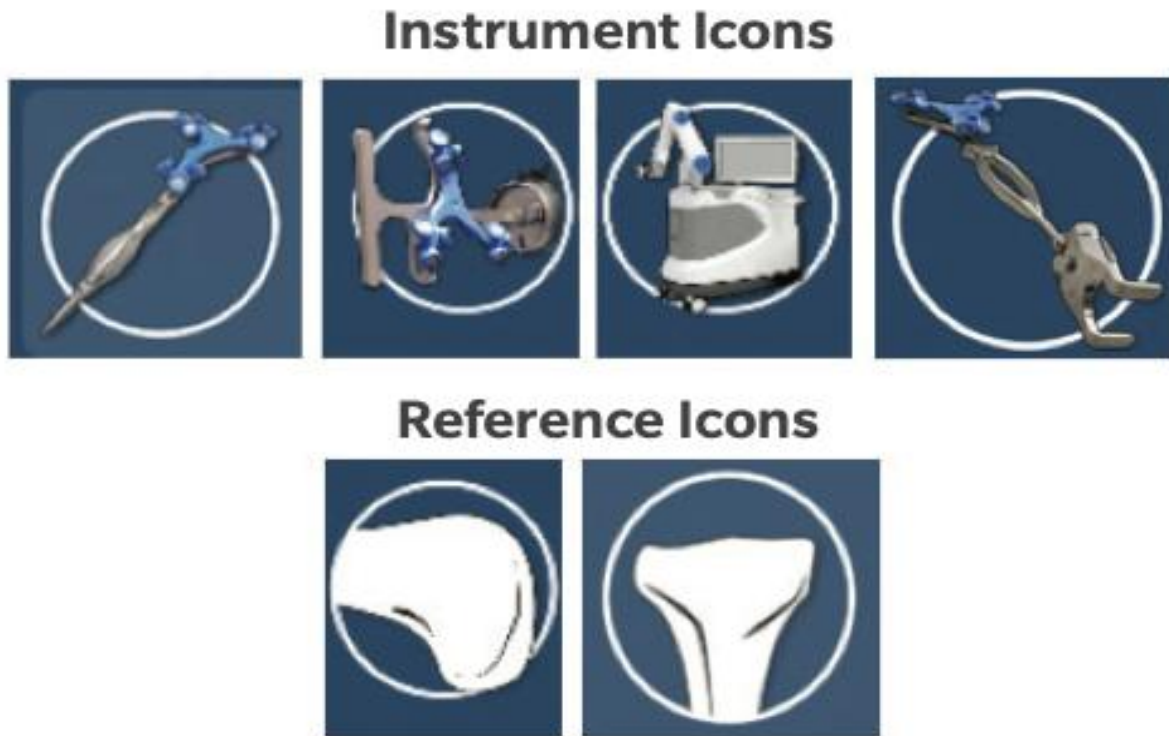


Figure 3.69 Summary of reference icons used to depict the location of the NavitrackerES on the ROSA® System [95].

Fixed fluted pins (Figure 3.70) are used to install the reference trackers with a bicortical placement and therefore, this requires incurring additional trauma to bone. In patients with osteoporotic bone, insertion may be a problem and one not only incurring additional tissue damage but an issue that may lead to markers placement failure.

To avoid these problems, it is proposed that the developers re-design or re-configure the reference trackers to permit non-invasive placement; potentially through a wire-based tie solution or similar alternatives that do not involve breaching the integrity of the cortical bone.

As an interim alternative, the author asked whether it may be possible to use just once reference tracker and as such, this would reduce bone trauma by 50% and save time in setting up the optical markers and reduce the rate of marker related errors during the key phases of knee arthroplasty.

However, as it was explained by the developers of the ROSA® Knee System, this is simply impossible, due to the fact that it would deprive the system from the ability to calculate the Flexion Angle and the Varus – Valgus ratio (Figure 3.11), as it needs both markers to obtain the reference points for this specific calculation [95]. In addition, such configuration applies for all Robotic Knee Surgery systems.



Figure 3.70 Fixed Fluted Pin 3.2 x 80mm for Optical Marker placement [95].

Few papers have reported upon the issues and proposals for the ongoing development of the trackers used on those systems, and thus, the proposals are largely based on the authors' experience in using the devices and knowledge gained from the manufacturers' operational manuals.

It is important that such trackers can be used for a highly accurate and precise impact in terms of sparing patients of radiation exposure, which may be needed, should the image-guided mode of those systems be required [179]. The cited authors also expressed concern about operative duration, with a component of excessive time being attributed to the setting up of the trackers. Other authors have also noted that the reference trackers should be placed in areas of bone without major erosion or underlying disease, and therefore, supporting the proposals to develop trackers that can be placed without invasive breaches of the cortical bone [180].

First experience data of surgeons using the ROSA system have also failed to highlight any major flaws with the tracker components, although the case series design and potential conflicts of interest may affect the validity of this evidence [181].

3.17 Operational Flow Improvement Proposals

Optimising and maintaining operation flow is a vital consideration for the management of surgical practices and the co-ordination of care, which is critical to meeting patient demand in the presence of finite capacity and funding and resource limitations. In addition, evidence has shown that the number of backlog cases, and particularly for elective orthopaedic surgery, have risen substantially since the disruptions incurred by the COVID-19 pandemic [182].

The extent of backlogged cases is significant at all levels of the system as this may be contributing to impairments in patient safety and outcomes, as well as placing increasing pressure and burden upon care staff and related operations, which have already been strained for several decades [182]. Insufficient reform and investment in healthcare in the UK, along with population growth and ageing, has contributed to the marked demand-capacity gaps that remain in existence today [183].

The current number of backlogged cases awaiting surgery has been reported to exceed three million, which has increased by a staggering two-fold since the pre-pandemic period [184]. Operational flow is a vital concept in which an understanding of the ways in which demand can be met by capacity can be attained [185]. In addition, operational flow is a key measure of service efficiency and has therefore, received considerable attention in the UK NHS due to the finite funding and resource constraints; demanding optimal efficiency, while reducing wasted time, costs and resources. This has been outlined within prior policies demanding efficiency savings for the NHS in excess of £20 billion [186].

This information is important as it may highlight the limitations of adopting robotic surgical systems into routine operative practices across the NHS. Such adoption may demand complete privatisation of the NHS to enable funding through regulated insurance premiums, as it largely endorsed across other international healthcare systems [187]. For this reason, it is proposed that wider reforms to the NHS are needed to support changes to operational flow that are crucially needed to optimise the integration of robotic-assisted surgery into routine practices, particularly on a large population-accessible scale.

On a practice level, additional considerations for operational flow are needed. This is due to the need to support optimal co-ordination of operative procedures across the pre-, peri-, and post-

operative phases, as well as to ensure operative areas are adapted to accommodate the hardware and software requirements of robotic surgical systems.

Studies have shown that various factors impact workflow in the context of robot-assisted surgery with two core categories relating to direct flow disruptions, such as due to the increased time to setup and perform operations, and non-technical issues, whereby additional challenges to efficient working emerge, such as impairments to communication and situational awareness [188]. Indeed, embedding robot surgery into usual practices has even been described as an under-recognised challenging impacting patient safety through inducing additional complexity in the division of labour across surgical teams [189].

Moreover, flow research theory reveals that optimal performance in surgical teams relies upon the mindfulness of individual members of the team regarding task action and control, and having situational awareness of potential issues and instigating measures to mitigate risks [190]. Common issues impacting surgical flow may comprise distractions or stressors and while efforts have been instigated over the years to avoid these problems, the introduction of robotic surgery is likely to result in their re-emergence, at least for a transient period of time until such operations become normalised [191].

Disruptions to flow are also expected to occur across a range of categories including communication, co-ordination, training, equipment, instrument changes, spatial configuration, situational awareness, and decision making. Spatial configuration issues are a particular concern for interrupting operational flow as operating suites require considerable changes to accommodate the hardware of robots and to facilitate their safe motion and setup in theatre [190].

These issues are important to overcome in view of research showing that around 20% of total operative time is incurred because of flow disruptions. This percentage is likely to increase with the adoption of robotic surgery. Thereby, a wider adverse impact upon operative flow is predicted [191].

These predictions are plausible in light of the information discussed in previous subsections of this work. Additional time is needed for robot device setup, pre-operative planning and potentially in performing surgery and therefore, this is likely to lead to an initial reduction in operative flow and the ability to meet current capacity targets. In effect, the number of persons undergoing knee arthroplasty per unit time may decrease until operative flow is optimised in line with a period prior to the adoption of robotic surgery.

However, improvements to the design and configuration of key hardware and software components may help to minimise such flow disruptions, although it is not clear whether the prior proposals are feasible for the manufacturers and engineers to consider with actual intent. Despite the noted issues of robot surgery in impacting operative flow, some benefits to workflow and efficiency could be observed.

For example, set members of a team with the appropriate training and experience may perform robotic surgery and therefore, there may be less discontinuity of team working, which could enhance efficiency, as well as the quality of inter-professional communication. Studies have suggested that due to the nuances of robotic surgery, communication across team members is greater compared to non-robotic surgery and thus, highlighting potential benefits to patient safety and operative flow[[189,190](#)].

In another instance, operative flow may be enhanced as much as possible through diligent consideration of the factors needed to provide an efficient robotic surgical service during pre-adoption discussions and planning. Moreover, effective leadership may help to enhance the integration, management and monitoring of robotic surgical practices and therefore, ensure safety and efficiency are promoted as much as possible [[190](#)].

4. DISCUSSION

4.1 Interpretation of Results

In summary, this thesis aimed to investigate the technological advances in robot-assisted total and partial knee arthroplasty surgery. The results of the literature review revealed that such surgery has been associated with improvements in operative time and efficiency, as well as surgical accuracy and patient-reported and clinically important outcomes. In addition, the evidence suggests that robot-assisted knee arthroplasty can offer such benefits based on the accounts and expenses of patients and surgeons.

This provides a convergence of findings across the data sources, which enhances the validity of conclusions drawn in this thesis. Based on some issues, limitations and challenges to using robot-assisted surgery for routine knee arthroplasty surgery, a number of proposals for ongoing system development, as well as operative flow were formulated. Please refer to the specific subsections for further detail.

4.2 Correlation of Results to Research Questions

This thesis generated a series of questions to assist in exploring a number of focal areas of pre-existence evidence regarding the value, limitations and challenges of robot-assisted surgery for knee arthroplasty surgery. These questions have been summarised below and correlated against the key findings:

Q1: Is robot-assisted surgery effective in improving operative time/efficiency?

The evidence showed that robot-assisted knee arthroplasty tends to be associated with enhanced operative time and reduced efficiency, relative to conventional surgery in view of the additional task-related demands that require human input or interaction and thereby, consume time within the operational workflow. It was clear that surgeons using robot-assisted devices for the initial time required a period of learning optimisation, which was evident through a clear inflection point discriminating learning from proficiency in using the systems.

The typical number of cases taken to achieve proficiency averaged around 12 cases, but this differed based on surgeon expertise and experience. Typical increases in operative time were 10-20 minutes, although this reduced and was non-inferior to conventional surgery in some research where proficiency had been acquired.

Q2: Is robot-assisted surgery effective in enhancing surgical accuracy?

The evidence presented for this question showed that robot-assisted knee arthroplasty yielded superior accuracy outcomes, than compared to the learning stage of proficiency and to conventional surgery. The key outcomes used to ascertain this conclusion included the accuracy of bone cutting and implant insertion and measures of limb alignment post-implant insertion.

Q3: Does robot-assisted surgery confer a benefit upon patient-reported and clinically important outcomes?

Robot-assisted knee arthroplasty was found to confer a range of benefits upon clinical outcomes, of which, most were centred on patient-reported measures. Benefits included high rates of implant survival, improvements in pain symptoms and knee function, and increases in quality of life. These outcomes were also supported in comparative evidence; suggesting that robot surgery could improve outcomes relative to those achievable through conventional knee surgery.

Q4: What are the views and perceptions of surgeons regarding the value and limitations of robot-assisted knee arthroplasty?

Surgeons tended to hold some anxiety and apprehension in using robotic devices during the learning phase of proficiency, although these issues ameliorated upon attaining proficiency. Surgeons also believed that the enhanced accuracy and precision of bone cutting and implant planning and placement would confer meaningful benefits upon patients' symptoms, function and recovery, while also reducing the risk of complications. However, surgeons also highlighted some key challenges to robot device use including education and training requirements, and complexities around operative planning.

Q5: What are the views of patients regarding robot-assisted surgery?

Patients who either were due to undergo robot-assisted surgery or had undergone said surgery reported some surprising insights that were contrary to potential expectations of anxiety and fear in undergoing such surgery. Instead, patients valued the enhanced accuracy and precision that robots could offer and valued the optimized outcomes that could be attainable. Patients having considerable trust in their responsible surgeons augmented such views.

Q6: What are the key recommendations for ongoing robot-assisted system development?

Based on the evidence explored, a number of proposals for software and hardware development were identified, along with proposals for calibration, sensor development and operative flow. It was not clear whether such proposals would be feasible for manufacturers and engineers to consider, and much were gathered through the author's experiences and knowledge of the current evidence. This was due to a paucity of literature.

4.3 Comparison of Findings to Other Studies

The findings of this thesis are in keeping with a number of similar works, which mostly include systematic and scoping-type reviews of the pre-existing literature. Not all of this supportive work has been conducted in specific relation to robot-assisted knee arthroplasty but the principle findings may be applicable/generalisable to the surgical field of interest herein. Longer operative times linked to robot device use have been corroborated in a systematic review of Hoeffel, et al. [192] where the mean increase in time was 18 minutes.

Superior accuracy and clinical outcomes have been noted in various reviews and fall in similar relation to implant positioning, mechanical alignment and patient-reported outcomes based on symptom scores, function, and quality of life [193,194]. Support for the perceptions and experiences of surgeons and patients regarding robotic surgery have also been evident with some initial anxiety and apprehension but the benefits of enhanced accuracy and precision mitigating these problems and generating hope and promise in enhancing outcomes for the foreseeable future [121], [158], [195].

4.4 Explanation for Differing Outcomes

A number of factors may account for some of the mixed effects of robot-assisted knee arthroplasty in this work, as well as some variances in the outcomes measured. It is speculated that much of this variance is explained by differences in the methodological approaches to addressing key research aims.

The present literature has utilised a range of research methodologies and there is also variable heterogeneity regarding the research methods utilised. These issues may not only account for variances in outcomes but also explain some of the limitations described in the proceeding subsection of this discussion. However, variable outcomes across studies may also be due to additional factors.

First, the literature has explored outcomes in relation to differing robot-assisted surgical systems, such as ROSA®, MAKO®, VELYS®, and NAVIO®, and due to clear differences in such technology,

the differences in outcomes are expected. This may be caused by variable accuracy in how the robotic systems perform or assist pre-arthroplasty planning (bone cutting extent and implant selection) and in conducting actual surgery in terms of the accuracy and extent of bone cutting relative to the planned implant. There is also variance in how the robotic systems guide such planning: image guided versus real-time tracked guidance. This could also account for differences in outcomes across some of the studies in this work.

The second key factor is inter-operator factors. Variances in outcomes may be related to the level of education, experience and training that the surgeons had received. This may have produced variable outcomes both within and between research studies.

Finally, the characteristics of patients undergoing robot-assisted surgery may have also been a factor contributing to outcome variance. For example, the severity of knee pathology at baseline, as well as comorbid bone disease and age, could have acted as confounding or mediating variables.

4.5 Strengths and Limitations

While the findings of this work add useful information to the current evidence base, they implications should be interpreted in view of some methodological strengths and limitations.

The key benefits of this work include the summarising of the technological advances and role, value and limitations of robot-assisted surgery within the specific context of partial and total knee arthroplasty surgery. Such summaries can be useful for surgeons and academics in the field who may require rapid access to the latest information due to time constraints.

Additional strengths include a detailed analysis of evidence across varied research questions and elicitation of uncertainties and gaps in the current literature, in order to guide ongoing research. Moreover, a number of key proposals for robotic system development were formulated, which could act as key drivers for improvement in the area.

However, some of the limitations to this work include a reliance upon secondary methodology with the analysis being limited to pre-existing evidence/data, of which, was not always of the highest quality or reliable applicable to knee arthroplasty surgery. There was also a paucity of literature for set research questions, limited the ability to answer said questions to a confident and certain extent, although this led to the recognition of avenues for ongoing research.

Another limitation is the absence of pooling data and meta-analysis; this was not considered feasible due to excess inter-study heterogeneity and because of small study sizes for each research question. This would have diminished certainty in any pooled effect generated.

Finally, the search for pre-existing evidence could have co-existed with errors or bias because of missing one or more relevant papers for review.

4.6 Contribution to Existing Knowledge

This work contributes useful knowledge to the current literature base by having summarised evidence specific to robot-assisted knee arthroplasty surgery regarding the impact upon operative time and efficiency, surgical accuracy, and patient-reported and clinically important outcomes.

In addition, the work explored the views and perceptions of surgeons and service users regarding the role, benefits, and challenges of robot-assisted surgery and through a critical evaluation of the evidence, key proposals for hardware and software development were identified.

Moreover, proposals for optimising sensor development, calibration, and operational flow were derived, as were proposals for the improvement of the optical markers components for the various systems.

The earlier elements of this work also provide a technological summary of robot-assisted devices both in generic surgical terms and in regard to knee arthroplasty surgery specifically. Therefore, the work may prove useful for a range of surgeons involved or who may become involved in robot-assisted surgery in the near future. As such, the work may have broad audience reach and could therefore, have a key positive influence and impact upon ongoing practices, research, robot development and related policies and guidelines.

As interest and the utilisation of robot-assisted surgery within orthopaedics continues to grow, it is vitally important that research to support its feasibility, efficacy and safety continues to emerge, in order to optimise the complex adaptations needed to introduce and sustain the use of robot-assisted surgery going forwards.

4.7 Future Steps

In view of a number of evidence gaps that were identified from the evaluation of literature across the noted research questions, some recommendations for ongoing research have been formulated.

First, there is a need for more research to evaluate the benefits and limitations of robot-assisted knee arthroplasty within specific UK settings, in order to help generate more evidence that is generalisable. This is vitally important as the UK NHS is a markedly resource and funding finite system and with various operational complexities and nuances, which may reveal additional barriers to robotic surgery to those already described in the literature. These barriers would need to be considered during any service development proposals.

Second, there is a need for more research across the board, in terms of studies evaluating the impact of robot-assisted knee arthroplasty upon operative efficiency and time, surgical accuracy and patient outcomes. In particular, this research should be focused upon partial knee arthroplasty surgery as much of the current evidence has been centred on total knee arthroplasty.

Third, there is also a need to explore such outcomes through comparative research of different robotic systems; this is needed to elicit any variances in outcomes that may be attributed to robotic technology and limitations thereof. This could further help to guide ongoing development initiatives.

Fourth, additional qualitative research may be useful in identifying further avenues for robotic-assisted surgery development through interviews with experienced surgeons. This may help to corroborate some of the evidence presented herein. In addition, interviews with patients who have undergone robot-assisted knee arthroplasty may provide additional evidence to bolster improvement drives into the future.

Fifth, cost-effective analyses are needed to help determine whether the large-scale adoption of robot-assisted surgery for knee arthroplasty, as well as for other orthopaedic indications, is viable. This is necessary in the NHS where funding remains finite and markedly limited due to the reliance upon public taxation.

Finally, the benefits of robot-assisted surgery have also become realised within paediatric contexts, however, its role in supporting surgical interventions for uncommon orthopaedic conditions in this group is not well known and there is a significant lack of data from this particular target group [196]. Therefore, more research is needed to explore the utility and limitations of robot-assisted surgery in this area.

5. CONCLUSIONS

As extensively described above, robotic systems in knee arthroplasty offer increased precision and reproducibility. The use of robotic arms and advanced imaging technology allows for more accurate bone cuts and implant positioning, reducing the risk of errors and complications. This level of precision is especially important in complex cases or when dealing with patients with unique anatomical variations.

Moreover, robotic systems can assist in achieving optimal soft tissue balance during the procedure. By accurately assessing the tension in the ligaments and muscles surrounding the knee joint, the robotic system can help the surgeon achieve a more balanced and stable joint, which is crucial for long-term success and patient satisfaction.

Another advantage of robotic-assisted knee arthroplasty is the potential for faster recovery and rehabilitation. The precise implant placement and improved alignment provided by robotic systems can lead to a more natural and functional knee joint, allowing patients to regain their mobility and return to their daily activities sooner. This can significantly improve the overall patient experience and quality of life.

Furthermore, the use of robotic systems can enhance the surgeon's capabilities and confidence in performing knee arthroplasty. The real-time feedback and guidance provided by the robotic system can help surgeons make more informed decisions during the procedure, leading to improved surgical outcomes and reduced surgical time.

Additionally, the integration of robotic systems with computer-assisted navigation technology allows for seamless communication and data sharing between the surgeon, robotic system, and other surgical tools. This integration enhances the overall efficiency and accuracy of the procedure, reducing the risk of human error and improving patient safety. In conclusion, the use of robotic systems in knee arthroplasty offers numerous advantages over traditional methods.

From personalized surgical planning to improved implant placement and soft tissue balance, robotic-assisted knee arthroplasty has the potential to revolutionize the field and provide better outcomes for patients. As technology continues to advance, and with the prospecting integration of Artificial Intelligence-assisted applications, we can expect further advancements in robotic-assisted knee arthroplasty, ultimately benefiting both patients, institutions and healthcare providers.

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