

CADTH Horizon Scan

Robotic Surgical Systems for Orthopedics

Authors: Andrea Smith, Lory Picheca, Quenby Mahood

Acknowledgement: Dr. Marcia Clark, MD, MSc, FRCSC, Dip. Sport Med.; Deputy Head of Surgery, Alberta Health Services; Clinical Professor, University of Calgary

ISSN: 2563-6596

Disclaimer: The information in this document is intended to help Canadian health care decision-makers, health care professionals, health systems leaders, and policy-makers make well-informed decisions and thereby improve the quality of health care services. While patients and others may access this document, the document is made available for informational purposes only and no representations or warranties are made with respect to its fitness for any particular purpose. The information in this document should not be used as a substitute for professional medical advice or as a substitute for the application of clinical judgment in respect of the care of a particular patient or other professional judgment in any decision-making process. The Canadian Agency for Drugs and Technologies in Health (CADTH) does not endorse any information, drugs, therapies, treatments, products, processes, or services.

While care has been taken to ensure that the information prepared by CADTH in this document is accurate, complete, and up to date as at the applicable date the material was first published by CADTH, CADTH does not make any guarantees to that effect. CADTH does not guarantee and is not responsible for the quality, currency, propriety, accuracy, or reasonableness of any statements, information, or conclusions contained in any third-party materials used in preparing this document. The views and opinions of third parties published in this document do not necessarily state or reflect those of CADTH.

CADTH is not responsible for any errors, omissions, injury, loss, or damage arising from or relating to the use (or misuse) of any information, statements, or conclusions contained in or implied by the contents of this document or any of the source materials.

This document may contain links to third-party websites. CADTH does not have control over the content of such sites. Use of third-party sites is governed by the third-party website owners' own terms and conditions set out for such sites. CADTH does not make any guarantee with respect to any information contained on such third-party sites and CADTH is not responsible for any injury, loss, or damage suffered as a result of using such third-party sites. CADTH has no responsibility for the collection, use, and disclosure of personal information by third-party sites.

Subject to the aforementioned limitations, the views expressed herein are those of CADTH and do not necessarily represent the views of Canada's federal, provincial, or territorial governments or any third-party supplier of information.

This document is prepared and intended for use in the context of the Canadian health care system. The use of this document outside of Canada is done so at the user's own risk.

This disclaimer and any questions or matters of any nature arising from or relating to the content or use (or misuse) of this document will be governed by and interpreted in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein, and all proceedings shall be subject to the exclusive jurisdiction of the courts of the Province of Ontario, Canada.

The copyright and other intellectual property rights in this document are owned by CADTH and its licensors. These rights are protected by the Canadian *Copyright Act* and other national and international laws and agreements. Users are permitted to make copies of this document for non-commercial purposes only, provided it is not modified when reproduced and appropriate credit is given to CADTH and its licensors.

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to Requests@CADTH.ca.

Table of Contents

Abbreviations	4
Key Messages	5
Purpose	5
Methods	6
Information Gathering and Synthesis	6
Peer Review.....	6
Background	6
What Are Robotic Surgical Systems?	7
Regulatory Status	8
Canada	8
The United States	8
Summary of Potential Clinical Benefit	9
Clinical Effectiveness	9
Economic Considerations.....	10
Patients’ and Clinicians’ Perspectives	11
Health System and Operational Considerations	12
Health System Considerations	12
Intraoperative Issues.....	12
Learning Curve, Training, and Technical Expertise.....	12
Legal Considerations.....	13
Concurrent Developments	13
The Potential for Remote Robotic-Assisted Surgeries	13
New and Improved Components and Related Technologies.....	14
Final Remarks	14
References	15

Abbreviations

PKA	partial knee arthroplasty
THA	total hip arthroplasty
TKA	total knee arthroplasty

Key Messages

- Robotic surgical systems for orthopedics are used primarily in procedures to treat osteoarthritis (either partial or full knee replacement or total hip replacement), and in procedures to treat degenerative spinal disease or spinal alignment or curvature abnormalities. Robotic-assisted orthopedic surgeries are intended to improve the accuracy and precision of implant placement and may lead to improved clinical outcomes, shorter recovery time, and fewer revisions. Evidence around their clinical effectiveness is still limited, however, the trend suggests that robot-assisted surgeries may be comparable, or marginally better, in clinical effectiveness when compared to conventional techniques. Robotic-assisted surgery can reduce the length of inpatient stay, but it involves longer operative times. Larger, long-term, randomized controlled trials are needed to confirm their comparative effectiveness.
- Robotic surgical systems for orthopedics are costly because their initial capital purchase is high, and each procedure requires the use of consumables. However, they may reduce length of stay, which can free up inpatient beds, and reduce rates of revision, which can be cost saving. While some evidence suggests that robotic-assisted knee and hip replacements can be cost-effective, there is limited cost-effectiveness information specific to Canadian contexts.
- There is a steep learning curve to adopting robotic surgical systems and teams require training and ongoing technical support to ensure that the unit is used to its full capacity. The roles of team members, particularly nursing staff, may change and require advanced technical knowledge.
- Robotic surgical systems are constantly evolving, integrating new and improved components such as augmented reality, artificial intelligence, digital imaging, and computer-assisted navigation. There will likely be many changes and refinements to these technologies over the coming years.

Purpose

This bulletin provides an overview of robotic surgical systems used in orthopedics, specifically total and partial knee and hip replacements and spine procedures. It describes what robotic surgical systems are; summarizes evidence around clinical effectiveness, economic considerations, patients' and clinicians' experiences; and identifies challenges with their implementation and adoption. This report does not provide a systematic review or critical appraisal of the clinical or economic evidence, and it does not provide a comprehensive review of patient and stakeholder perspectives, or of ethical, legal, and social considerations. As such, the information provided is not exhaustive or comprehensive of the considerations, issues, or implications posed by the use or adoption of robotic surgical systems for orthopedics. This bulletin is not intended to provide recommendations for or against a particular technology.

Methods

Information Gathering and Synthesis

An information specialist conducted a limited literature on key resources including MEDLINE, EMBASE, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were robotic surgical procedures and orthopedics. No filters were applied to limit retrieval by study type. Conference abstracts were excluded. Where possible, retrieval was limited to the human population. The search was completed on April 25, 2022, and limited to English-language documents published since January 1, 2017.

The primary author screened search results and reviewed the full text of potentially relevant citations. Additional information was retrieved through targeted internet searching and reference lists of relevant publications. Relevance was defined as including information on recent developments in robotic surgical systems for orthopedic uses. Three CADTH Rapid Reviews on robotic surgical systems for orthopedic procedures¹⁻³ were used as the primary sources of information describing the clinical and economic effectiveness. The primary author synthesized the identified information using content analysis.⁴

Peer Review

A draft version of this bulletin was reviewed by Dr. Marcia Clark. Manufacturers of robotic systems of orthopedic surgeries were also given the opportunity to comment on the draft.

Background

Within Canada, wait times for orthopedic surgeries continue to worsen and have been exacerbated by the COVID-19 pandemic.⁵ Compared to the previous year, the number of hip and knee replacements performed across Canada decreased in 2020 to 2021 by 12.9% and 26.4%, respectively.⁶ This situation has not improved as health systems continue to struggle with staffing and capacity issues. The Canadian Institute of Health Information (CIHI) reports that the lower volume of replacement surgeries was likely caused by the cancellation of planned surgeries, such as most knee and hip replacements, to enable hospitals to free up capacity for patients with COVID-19.⁶ The proportion of patients across Canada who received a knee or hip replacement within the medically recommended time frame of 6 months decreased in 2020 to 2021 to 62% from 71%.⁵ This problem is likely to worsen with an aging population at increased risk of developing osteoarthritis, the main indication for orthopedic surgeries.^{6,7}

Canadian health systems are working to address surgical backlogs for knee, hip, and spinal surgeries in a variety of ways. Similarly, more knee and hip replacements were done as day surgeries to make inpatient beds available for the care of patients with COVID.⁵ Nova Scotia increased its capacity to provide hip and knee replacements by expanding access to day surgery and added additional nursing and rehabilitation support to assist patients.⁵ Alberta is expanding the use of private knee and hip replacement clinics,⁸ while Saskatchewan

has announced its intentions to put a request for proposals out for a private knee and hip replacement clinic in the province.⁹ Manitoba is paying for 300 patients to receive spinal surgery in the US.¹⁰

While there has been slower adoption of robotic surgical systems in Canada than in the US, there appears to be increasing interest in robotic surgical systems for orthopedics, particularly as new systems come to the market. As health care systems wrestle with recovering from the impact of the COVID-19 pandemic, some Canadian health care institutions are adopting robotic surgical systems for orthopedics. For example, several hospitals have purchased robotic surgical systems for knees or hips or are considering doing so (e.g., St. Joseph's Healthcare in Hamilton,¹¹ Health Sciences North in Sudbury,¹² and Queen Elizabeth II Health Science Centre in Halifax¹³). The impact of robotic systems for orthopedic surgeries on wait times is currently unclear; however, the technology has been reported to be beneficial in improving patient outcomes, lowering the rates of revision surgeries, and shortening duration of hospital stays.

What Are Robotic Surgical Systems?

Robotic surgical systems, sometimes called robotic surgical platforms, refer to programmable devices used to perform a wide variety of surgical tasks.^{14,15} While the specifics of each system vary by manufacturer, they typically are machines that physically guide the surgeon's hand through the operation or are remote-controlled machines that guide the trajectory of or directly manipulate instruments or implants.¹⁶ They do not replace the surgeon who remains in control of the procedures, but rather are part of the devices used by the surgeon.¹⁷⁻¹⁹ For the purposes of this report, the term *robotic surgical systems* is used to refer to the set of technologies that use robotics to support and perform surgical procedures. Robotic surgical systems differ from computer-assisted navigation and guidance systems. Although they share many features, such as 3D augmented reality and navigation guidance, and provide real-time feedback on implant and joint alignment, computer-assisted navigation and guidance systems cannot be programmed to perform surgical tasks.¹⁸

Robotic surgical systems have multiple components, and can include digital optics, digital imaging, visual displays, computer-assisted navigation systems, software applications (that sometimes include AI), augmented reality, and robotic arms. Image-based systems often use software to convert anatomical images from preoperative imaging (typically CT scan) or intraoperative imaging into a virtual 3D reconstruction of joints or spine for implant or pedicle screw placement.¹⁵ This 3D model enables surgeons to plan the surgery and ensure accurate and precise implant and instrument positioning to improve limb or spine alignment while minimizing soft-tissue and bony injuries.^{17,19}

Others are "imageless," and use preoperative imaging for surgical planning, then register and establish bony landmarks during surgery.¹⁵ The level of the surgeon's active involvement during resection varies by systems. In some systems, the surgeon is active or partially active during resection, and in others, the robotic surgical system is active in conducting the resection.

As a category of technologies, robotic surgical systems enable more precise and accurate implant placement during orthopedic surgeries, which results in improved mobility and

function, fewer complications (such as blood loss), and less need for early revision surgery.^{14,17,18} There are robotic systems developed for 3 major categories of orthopedic surgeries: knee replacement (partial and total), hip replacement (total), and spinal, which is primarily the placement of pedicle screws during spinal fusion procedures.

Regulatory Status

New robotic surgical systems for orthopedics are increasingly coming onto the market. The information provided here is intended to cover the robotic systems available in Canada. This report also covers information identified in the literature about some of the robotic surgical systems recently approved for use in the US, though not exhaustively.

Canada

Health Canada has authorized 4 robotic systems for orthopedic surgeries in Canada as of the time of writing this bulletin.

Knee and Hip Arthroplasty

The Mako SmartRobotics System (Stryker) for partial and total knee replacement and total hip replacement received authorization for use in Canada on July 23, 2020.²⁰ It uses the RESTORIS knee implant system for single or multi-compartmental knee replacement (authorized for use on January 29, 2020).²¹

The ROSA Knee System (Zimmer Biomet) for total knee arthroplasty (TKA) received authorization from Health Canada on September 5, 2019.²² It uses the following for single or multi-compartmental knee replacements: NexGen CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona CR, Persona PS, Vanguard CR, and Vanguard PS.²² The ROSA Partial Knee System and the ROSA Hip System for total hip arthroplasty (THA) are not authorized for use in Canada at the time of this bulletin's writing.

The CORI Surgical System (Smith+Nephew) was authorized for TKA and partial knee arthroplasty (PKA) by Health Canada in November 22, 2021.²³ It is compatible with a selection of implants from different manufacturers.²³

Spinal Surgeries

The Mazor X System (Medtronic) integrates navigation and robotic guided instruments for spinal surgeries and received authorization for use in Canada in October, 2021.²⁴

The United States

Knee and Hip Arthroplasty

The VELYS Robotic-Assisted Solution (DePuy, Ireland) received FDA 501k clearance in January 2021. It is indicated for use with the ATTUNE Total Knee System.²⁵

The first generation Mako Rio (Stryker) for Partial Knee Application received FDA 501k clearance in March, 2015,²⁶ and the Total Knee Application was cleared July 20, 2020, to be

used with the Triathlon and Kinetis series of knee implants.²⁷ The Mako Total Hip Application was cleared by the FDA in April 2017.²⁸

The ROSA Total Knee System (Zimmer Biomet) was cleared by the FDA in January 2019 and is to be used with NexGen CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona CR, Persona PS, Vanguard CR, and Vanguard PS.²⁹ The ROSA Partial Knee System was cleared for US use in April 2019 and is to be used with the Personal Knee System. The ROSA Hip System received FDA 501k clearance in August, 2021.³⁰

The CORI Surgical System (Smith+Nephew) was cleared by the FDA for PKA in February, 2020³¹ and for TKA in June, 2020.³² The CORI Surgical System is meant to be used with cemented implants.^{31,32}

The second generation TSolution One robotic system (THINK Surgical, California) received FDA clearance for Total Knee Replacement in November 2020 and is approved for use the Zimmer Persona Knee System, Corin Unity Knee System, Aesculap Columbus Knee System, DJO Surgical EMPOWER 3D Knee System, and United U2 Knee System.³³

Spinal Surgeries

The ROSA One Spine system (Medtech SA) received FDA 501k clearance in March, 2019.³⁴ The Mazor X Stealth Edition (Medtronic) received FDA 501k clearance in August 2019,³⁵ and the Cirq spine system (Brainlab AG) received FDA clearance in September, 2019.³⁶ CUVIS-spine (Curexo, Seoul, Republic of Korea) received FDA 501k clearance in May 2021.³⁷

Summary of Potential Clinical Benefit

Clinical Effectiveness

Overall, evidence about the clinical benefits and harms of robotic-assisted orthopedic surgeries is still evolving. The evidence available tends to be of low quality with high potential for bias due to patient population variables and access to private health care where most current robotic-assisted surgeries are offered. Large, longitudinal studies and adequately powered randomized controlled trials can further establish the comparative clinical benefits of robotic-assisted orthopedic surgeries for short- and long-term outcomes. A summary of clinical evidence for each type of orthopedic surgery is provided in the following.

Knee Arthroplasty

The findings of a CADTH Rapid Review suggest that robotic-assisted knee arthroplasty was associated with decreased length of hospital stay, though it increased operative time. However, there was no consensus in the evidence to indicate that robotic-assisted knee arthroplasty provided superior or worse clinical outcomes when compared to conventional techniques.¹⁷ The authors suggested that further adequately powered studies are needed to establish the short-term and long-term clinical benefits of robotic-assisted knee arthroplasty.¹⁷

Hip Arthroplasty

A CADTH rapid review found no statistically significant difference in measures of functionality, quality of life, pain, mortality, and complications in patients who underwent robotic-assisted THA versus those who had conventional THA.² Most of the included studies of that review reported that robotic-assisted THA had lower rates of early revision than conventional THA. Patients who underwent robotic-assisted THA had shorter length of stay in hospital compared to those who had conventional THA.² Findings around the surgical time were not consistent, with some studies suggesting longer times with robotic-assisted procedures, and other studies finding no statistically significant differences in procedure time between the 2 modalities.

Spinal Surgeries

Several systematic reviews have found that robotic-assisted spine fusion surgery was associated with statistically significant improvements in accuracy of pedicle screw placement and lower rates of revision surgery than conventional fluoroscopy-assisted placement or freehand techniques.^{16,38-40} Also, emerging evidence suggests that robot-assisted pedicle screw placement results in significant reductions in perioperative complications, such as blood loss.¹⁶ However, there is some evidence that indicates that the clinical outcomes and complications following robot-assisted pedicle screw placement are not significantly different from those of conventional techniques.^{39,40}

Contradictory evidence exists around whether robotic-assisted spine surgeries are associated with reduced radiation exposure through shorter intraoperative radiation time and fewer radiation dose than with conventional techniques.^{16,38,39}

Economic Considerations

Adopting robotic surgical systems for orthopedics is a resource-intensive endeavour. Publicly available information on the costs of robotic-assisted orthopedics is limited; however, estimates range between US\$500,000 and US\$2,000,000, depending on the system.^{41,42} Increased competition on the market has led to changes in pricing⁴¹ and some newer systems promise to be less costly.⁴¹ Similar to other large, capital purchases within Canadian health care systems, individual hospitals typically purchase robotic surgical systems using funding by hospital foundations.⁴³

The reduced length of stay, lower infection rates, and fewer revision surgeries potentially associated with robotic-assisted procedures will likely have an impact on costs.⁴⁴ According to Canadian Institute of Health Information (CIHI), patients undergoing revision surgery stayed in hospital more than twice as long as patients undergoing primary surgery (9.2 days versus 3.8 days, respectively). Estimated average inpatient costs for revision surgery (excluding rehabilitation) were nearly 75% higher than for a primary replacement surgery (i.e., more than \$19,600 versus \$11,258). Therefore, shorter hospital stays, and lower surgery revisions rates could contribute to making robotic-assisted orthopedic surgeries cost-effective options.

Currently, the evidence regarding the cost-effectiveness of robot-assisted orthopedic surgeries compared to conventional surgery is limited,¹⁻³ and of unclear generalizability to the Canadian public health care systems.² Overall there is a need for future study of the cost-effectiveness of robotic-assisted orthopedic surgeries to understand their place in value-based care.^{3,44,45}

Knee and Hip Arthroplasty

A CADTH Rapid Review found that models using improved quality of life and reduced rates of surgical revisions as clinical inputs consistently showed that robotic-assisted knee arthroplasty was cost-effective compared to conventional techniques, with 1 study reporting using a willingness-to-pay threshold of US\$50,000.¹ Similarly, another CADTH Rapid Review found 4 studies that reported that robotic-assisted hip arthroplasty was cost-effective compared to conventional techniques, using a range of willingness-to-pay-thresholds from US\$50,000 to US\$100,000.²

Spinal Surgeries

There is limited economic evidence on the cost-effectiveness of robotic-assisted spine surgeries.^{3,44,45} Some evidence suggests that currently, robotic-assisted pedicle screw placement may not be cost-effective due to the potential need for surgeon training, longer operative time, capital costs of purchasing robotic surgical systems, and rates of peri-surgical complications.^{44,46} A CADTH Rapid Review on robotic spine surgery found no systematic reviews, health technology assessments, or economic evaluations relating to robotic-assisted spine surgeries that did not involve pedicle screw placement.³

Patients' and Clinicians' Perspectives

Patients are likely to appreciate robotic-assisted orthopedic surgeries due to the potential for quicker recovery time and fewer complications.⁴⁷ However, the early discharge afforded by robotic-assisted surgeries may not align with the preferences and experiences of all patients.⁴⁸ A smooth discharge after a shorter length of stay post-replacement surgery requires patients to have support at home, be informed about their recovery and rehabilitation journey, and be able to access post-discharge support.⁴⁸ Those who experience complications or face uncertainty in their self-recovery can struggle with appropriate pain management and negative emotions.⁴⁸ This highlights the importance of thorough discharge planning to support patients post-replacement with their recovery and rehabilitation at home.

Clinicians sometimes struggle with decision-making around knee and hip replacements in patients who are described as obese.⁷ These patients are at greater risk of surgical complications; however, they can also benefit greatly from replacement surgery.⁴⁹ It is possible that they may benefit from the reduced risk of surgical complications promised by robotic procedures.⁷

For some procedures, robot surgical systems have been described as reducing surgeons' upper limb fatigue,¹⁵ and may lead to ergonomic and occupational benefits for clinicians. Thus, robotic-assisted surgeries could change the surgical experience for surgeons. According to the clinical expert consulted for this report, the ability for surgeons to receive immediate and ongoing data on precision of implant changes improves implant accuracy. Also, the opportunities to use big data to further improve surgical planning and predictions of outcomes present an exciting chance to potentially improve patient-centred outcomes from orthopedic surgeries.

Health System and Operational Considerations

Health System Considerations

No evidence was identified that examined whether the introduction of a robotic surgical system for orthopedics affected health services and surgical volume.

Purchasing a robotic surgical system is often seen as positioning an institution as a leading facility and aiding in recruiting specialists.^{43,47} However, it has been suggested that the steep learning curve on robotic platforms could limit the time available for fellows to also learn conventional or minimally invasive techniques.⁵⁰ Therefore, the introduction of robotic platforms could change the availability of expertise in open and minimally invasive procedures and make it more challenging to train and eventually recruit surgeons to perform conventional techniques.^{43,50}

Another issues to consider is that many of the robotic systems for knee and hip arthroplasty have been described as “closed systems” as they only allow for the use of proprietary joints.¹⁵ Open systems (i.e., those that do not limit the type of joint implant used) have been described as trading off specificity and precision to enable generalizability to a wider range of implants.¹⁵ In choosing a closed system, surgeons may experience greater specificity and precision, but do not have freedom to choose the joint implant use; thus, forgo the ability to personalize the surgery in this way.¹⁵

Intraoperative Issues

During surgery, patient movement (including respiration) can lead to inaccurate placement of implants. This is especially true for the majority of systems that use preoperative CT scans for registration and surgical planning.⁴⁴ As a result, systems and surgical protocols that account for patient movement are necessary. Also, good team communication and trust have been described as essential to robot-assisted surgeries.⁴⁷ Depending on the robotic surgical system, the surgeon may be separated from the rest of the team and behind a console, which means they must rely on their team to communicate information outside their field of vision about the patient and the robot. Some suggest that a dedicated robotic surgery team is one means of ensuring a positive relationship based on trust and good communication.⁴⁷

Radiation exposure during surgery is a particular concern for spinal surgeries, which have been estimated to involve 10 to 12 times the radiation exposure than non-spinal procedures, as the surgeon needs to visualize the bony landmarks, typically using fluoroscopy.⁴⁴ Robotic-assisted spinal surgeries may reduce radiation exposure to patients, surgeons, and operating room staff through improved imaging⁵¹ and navigational systems, which together improve accuracy.

Learning Curve, Training, and Technical Expertise

Comprehensive training and education can address the challenges of a steep learning curve for robotic-assisted surgeries. Clinicians have appreciated training that is compulsory, supervised, and structured and that on-the-job training is not sufficient.⁴⁷ This training should be for the full surgical team, including surgeons, surgical residents and nurses, and anesthesia professionals.⁴⁷

As longer operating times are associated with a higher risk of complications, including infection, there will likely be a continued desire to reduce operative time with robotic-assisted procedures.¹⁷ Some reduction in the length of operating time is expected as surgeons and their teams become more experienced.

The use of robotic systems requires access to technicians and engineers who are able to maintain and set up the systems and provide support during surgery.^{17,47,52} A CADTH qualitative Rapid Review on robot surgical systems found nursing staff were challenged by these new and increasing demands and responsibilities, particularly due to the set-up phase and the longer operating time.⁴⁷ The time required for robot set up, docking, and patient positioning affected workflow, and the increased technical knowledge and expanded surgical duties meant changes to their role.⁴⁷ In the US, Surgical Technologist is a professional designation for those who are trained to undertake these responsibilities.⁵³ Establishing adequate support internally and from the manufacturer is essential to ensure that robotic surgical systems are fully used after purchase,^{47,54} including the correct installation of software updates.¹⁷

Legal Considerations

Robotic surgical systems are connected devices, often requiring connectivity to internal or external networks through the internet. This introduces potential security risks, including malware and privacy breaches.⁵² Some anticipate that the conversion to a 5G network will aid with the adoption of remote robotic surgeries as it will address issues of connectivity and security.^{52,55} As robotic surgical systems generate and use big data, they raise questions around data ownership, access, privacy, and storage.

Concurrent Developments

The Potential for Remote Robotic-Assisted Surgeries

Rural and remote areas often have less access to orthopedic surgeries, so there is interest in whether robot-assisted surgeries can facilitate access through remote robotic surgery. The potential for a widespread adoption of remote robotic-assisted surgeries was among the early promises of non-orthopedic applications of robotic surgical systems when they were first introduced in the early 2000s.^{55,56} Adoption lagged due to issues of cost, lack of connectivity, and operational and technical issues.⁵⁶

Conducting remote robotic-assisted surgeries requires a highly reliable network with high bandwidth and low latency, as any disruption can interrupt or halt the surgery.⁵⁵ Any lag in connectivity during remote surgery can have a huge impact and may introduce error and affect what the surgeon is able to visualize.⁵² Furthermore, there are unanswered questions about what should be done in the event of a disruption, particularly if the attending surgeon is not onsite and the patient's setting does not have capacity to convert to a manual or conventional technique.⁵² Moreover, many robotic surgical systems are technologically complicated and require access to advanced digital imaging, which may not be available in rural and remote settings.⁵⁷

New and Improved Components and Related Technologies

Other technologies, including augmented reality with computer navigation systems, are in development and aim to address challenges with orthopedic implant accuracy to reduce complications due to inaccurate implant placement.^{16,58} While augmented reality with computer navigation systems can often be used alongside or be integrated into robotic surgical systems, they may have a place in being used independently to improve implant accuracy (separate from robotic systems) during orthopedic surgeries.¹⁶

Individual components of robotic surgical systems are being refined and developed, and there are further opportunities for the integration of additional components. For example, improvements in digital optics and the integration of new digital imaging technologies means that there may be increased ability to register robotic systems to preoperative imaging,^{19,51} or coordinate intraoperative imaging systems with robotic systems.⁵⁹ Also under development are improved computer navigation systems with planning software that harnesses the availability of big data to use machine learning⁵¹ to improve patient-specific predictions of operating time, surgical planning and procedural accuracy, and potentially anatomic alignment, as well as to reduce the risk of surgical revisions.⁶⁰

Developments specific to robot systems for spinal surgeries include the potential to integrate automated rod bending and robot-assist for bone drilling.⁵¹ Improvements in the ability of robotic systems for spine procedures and surgeons to deal with soft tissues could expand the technology's indications beyond degenerative spinal disease.⁵⁴ There is interest and early experience in applying robotic systems for spinal surgery to conditions such as spinal alignment or curvature abnormalities, trauma, infection, and neoplasm of the spine.^{16,19,44,51}

Final Remarks

Robotic surgical systems for orthopedics are an active area of development, with new systems coming to the market and being adopted. Early indications point to their role in improving patient outcomes, including shorter hospital stays and the need for fewer revision surgeries; however, cost barriers to purchasing and maintaining robotic systems remain high. Future developments that reduce acquisition and operating costs and shorten operating time are needed. Research on the impact of increasing access to robotic surgeries and the potential to address wait times and surgical backlogs can help guide future decision-making. Training specialized technicians could help ensure efficient use of robot surgical systems at full capacity in Canadian contexts.

References

- Edge R, Farrah K. Robotic-assisted surgical systems for knee arthroplasty. *Can J Health Technol.* 2022;2(3). <https://www.cadth.ca/sites/default/files/pdf/htis/2022/RC1411%20Robotic-Assisted%20Knee%20Arthroplasty.pdf>. Accessed 2022 May 16.
- Khangura SD, Farrah K. Robotic-assisted surgical systems for hip arthroplasty. *Can J Health Technol.* 2022;2(4). <https://www.cadth.ca/sites/default/files/pdf/htis/2022/RC1412-Robotic-Assisted%20Surgical%20Systems%20for%20Hip%20Arthroplasty.pdf>. Accessed 2022 May 18.
- Kumar D, Wells C, Picheca L. Robotic-assisted spinal surgery. *Can J Health Technol.* 2022;2(5). <https://www.cadth.ca/sites/default/files/pdf/htis/2022/RC1427%20RAS%20Spinal%20Final.pdf>. Accessed 2022 Jun 10.
- Booth A, Noyes J, Flemming K, et al. Guidance on choosing qualitative evidence synthesis methods for use in health technology assessments of complex interventions. Bremen (DE): Integrate-HTA; 2016: <http://esquiresheffield.pbworks.com/w/file/fetch/111070576/Guidance-on-choosing-qualitative-evidence-synthesis-methods-for-use-in-HTA-of-complex-interventi.pdf>. Accessed 2022 Jul 19.
- Canadian Institute for Health Information. Wait times for priority procedures in Canada. 2022 May 10; <https://www.cihi.ca/en/wait-times-for-priority-procedures-in-canada>. Accessed 2022 Jun 20.
- Canadian Institute for Health Information. CJRR annual report: hip and knee replacements in Canada. 2022 Jun 2; <https://www.cihi.ca/en/cjrr-annual-report-hip-and-knee-replacements-in-canada>. Accessed 2022 Jun 22.
- Bone & Joint Health Strategic Clinical Network. Arthroplasty for patients with osteoarthritis and obesity: position statement. Edmonton (AB): Alberta Health Services; 2019 Dec 10: <https://www.albertahealthservices.ca/assets/about/scn/ahs-scn-bjh-arthro-position-statement.pdf>. Accessed 2022 July 20.
- Lachacz A. Alberta to move some orthopedic surgeries to private facilities to reduce surgical backlog. *CTV News Edmonton.* 2021 Jul 25; <https://edmonton.ctvnews.ca/alberta-to-move-some-orthopedic-surgeries-to-private-facilities-to-reduce-surgical-backlog-1.5522718>. Accessed 2022 Jul 20.
- Guerrette K. Backlog in surgical procedures has Sask Party moving forward with private clinics. 2022 Jul 28; <https://globalnews.ca/news/9017705/surgical-backlog-sask-party-private-clinics/>. Accessed 2022 Jul 28.
- Kives B. Canadian Spine Society out of joint over Manitoba plan to send patients to North Dakota. *CBC News.* 2022 Jan 21; <https://www.cbc.ca/news/canada/manitoba/fargo-spinal-surgeries-unhappy-1.6322585>. Accessed 2022 Jul 19.
- Glanz M. Robot-assisted surgery widely embraced, but 'newer doesn't always mean better,' experts warn. *CBC News.* 2019 Mar 15; <https://www.cbc.ca/news/health/robot-assisted-surgery-might-not-always-be-best-option-1.5054873>. Accessed 2022 May 10.
- Moodie J. New robot assisting Sudbury surgeons. *Sudbury Star.* 2021 Jul 15; <https://www.thesudburystar.com/news/local-news/new-robot-assisting-sudbury-surgeons>. Accessed 2022 May 12.
- QEII Health Sciences Centre second hospital in Canada to receive orthopedic surgical robot. *Nova Scotia Health.* 2021 Nov 2; <https://www.nshealth.ca/news/qeii-health-sciences-centre-second-hospital-canada-receive-orthopedic-surgical-robot>. Accessed 2022 May 10.
- Robotic-assisted orthopedic surgical platforms for spinal surgery. Plymouth Meeting (PA): ECRI Institute; 2021: www.ecri.org. Accessed 2022 Jun 12.
- Innocenti B, Bori E. Robotics in orthopaedic surgery: why, what and how? *Arch Orthop Trauma Surg.* 2021;141(12):2035-2042. [PubMed](https://pubmed.ncbi.nlm.nih.gov/34811111/)
- Tovar MA, Dowlati E, Zhao DY, et al. Robot-assisted and augmented reality-assisted spinal instrumentation: a systematic review and meta-analysis of screw accuracy and outcomes over the last decade. *J Neurosurg Spine.* 2022;1-16. [PubMed](https://pubmed.ncbi.nlm.nih.gov/36811111/)
- Saber AY, Marappa-Ganeshan R, Mabrouk A. Robotic assisted total knee arthroplasty. *StatPearls.* Treasure Island (FL): StatPearls Publishing; 2022: <https://www.ncbi.nlm.nih.gov/books/NBK564396/>. Accessed 2022 Jun 22.
- Robotic-assisted orthopedic surgical platforms for knee arthroplasty. Plymouth Meeting (PA): ECRI; 2021. Accessed 2022 Jun 22.
- Huang M, Tetreault TA, Vaishnav A, York PJ, Staub BN. The current state of navigation in robotic spine surgery. *Ann Transl Med.* 2021;9(1):86. [PubMed](https://pubmed.ncbi.nlm.nih.gov/34811111/)
- Regulatory decision summary for Mako System. *Drugs, Health & Consumer Products. Review Decisions.* Ottawa (ON): Health Canada; 2020: <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS11042>. Accessed 2022 Jun 12.
- Regulatory decision summary for Restoris MCK (knee replacement system). *Drugs, Health & Consumer Products. Review Decisions.* Ottawa (ON): Health Canada; 2020: <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS10660>. Accessed 2022 Jun 12.
- Regulatory decision summary for ROSA Knee System. *Drugs, Health & Consumer Products.* Ottawa (ON): Health Canada; 2019: <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS10482>. Accessed 2022 Jul 12.
- Smith+Nephew launches Real Intelligence and CORI™ Surgical System; next generation handheld robotics platform in Canada. *Cision [Newswire].* 2021 Nov 24: <https://www.newswire.ca/news-releases/smith-nephew-launches-real-intelligence-and-cori-tm-surgical-system-next-generation-handheld-robotics-platform-in-canada-803958478.html>. Accessed 2022 Jun 12.
- Mazor Robotics Ltd: licence no. 106438. *Medical devices active licence listing (MDALL) 2022*; <https://health-products.canada.ca/mdall-himh/index-eng.jsp>. Accessed 2022 Jul 22.
- Ali S. (U.S. Food and Drug Administration). Letter to Stephanie Elvin (DePuy Ireland UC). [Re: K202769. VELYSTM Robotic-Assisted Solution]. 2021 Jan 14; https://www.accessdata.fda.gov/cdrh_docs/pdf20/K202769.pdf. Accessed 2022 Jul 19.

26. Melkerson MN. (U.S. Food and Drug Administration). Letter to Jonathan Reeves (MAKO Surgical Corp). [Re: MAKO partial knee application letter of clearance]. 2015 Sep 16; https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142530.pdf. Accessed 2022 Jun 17.
27. Ali S. (U.S. Food and Drug Administration). Letter to Shikha Khandelwal (Mako Surgical Corp). [Re: K193515. Mako total knee application]. 2020 Jul 14; https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193515.pdf. Accessed 2022 Jun 17.
28. Melkerson MN. (U.S. Food and Drug Administration). Letter to Shikha Khandelwal (Mako Surgical Corp). [Re: K170593. Mako total hip application]. 2017 Apr 18; https://www.accessdata.fda.gov/cdrh_docs/pdf17/K170593.pdf. Accessed 2022 Jun 17.
29. Muir J. (U.S. Food and Drug Administration). Letter to Paul Hardy (Orthosoft Inc). [Re: K182964. ROSA Total Knee Replacement letter of clearance]. 2019 Jan 24; https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182964.pdf. Accessed 2022 Jun 17.
30. Mills TT. (U.S. Food and Drug Administration). Letter to Paul Hardy (Orthosoft d/b/a/ Zimmer CAS). [Re: K210998. ROSA Hip System letter of clearance]. 2021 Aug 17; https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210998.pdf. Accessed 2022 Jun 17.
31. Ali S. (U.S. Food and Drug Administration). Letter to Corrine Herlinger (Blue Belt Technologies, Inc). [Re: K193120. Real Intelligence Cori letter of FDA clearance]. 2020 Feb 14; https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193120.pdf. Accessed 2022 Jun 17.
32. Ali S. (U.S. Food and Drug Administration). Letter to Corrine Herlinger (Blue Belt Technologies Inc). [Re: K201022. Real Ingelligence CORI total knee replacement letter of clearance]. 2020 Jun 12; https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201022.pdf. Accessed 2022 Jun 17.
33. Ali S. (U.S. Food and Drug Administration). Letter to Meliha Mulalic (THINK Surgical, Inc). [Re: K203040. TSolution One Total Knee application. Letter of clearance]. 2020 Nov 13; https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203040.pdf. Accessed 2022 Jul 21.
34. Muir J. (U.S. Food and Drug Administration). Letter to Serge Tabet (Medtech S.A.). [Re: K182848. ROSA One Spine application] 2019 Mar 22; https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182848.pdf. Accessed 2022 Jun 20.
35. Melkerson MN. (U.S. Food and Drug Administration). Letter to Kelly J. Baker (Globus Medical Inc). [Re: K171651. Excelsius GPS]. 2017 Aug 16; https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171651.pdf. Accessed 2022 Jun 20.
36. Brainlab. Robotic surgical assistant from Brainlab receives FDA clearance. 2019 Sep 19; <https://www.brainlab.com/press-releases/robotic-surgical-assistant-from-brainlab-receives-fda-clearance/#:~:text=Cirq%20now%20available%20to%20support,United%20States%20for%20spinal%20applications>. Accessed 2022 Jun 20.
37. Muir J. (U.S. Food and Drug Administration). Letter to Do Hyum Kim (Cureux, Inc). [Re: K201569. CUVIS-spine]. 2021 May 19; https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201569.pdf. Accessed 2022 Jun 20.
38. Li HM, Zhang RJ, Shen CL. Accuracy of pedicle screw placement and clinical outcomes of robot-assisted technique versus conventional freehand technique in spine surgery from nine randomized controlled trials: a meta-analysis. *Spine*. 2020;45(2):E111-E119. [PubMed](#)
39. Li C, Li W, Gao S, et al. Comparison of accuracy and safety between robot-assisted and conventional fluoroscope assisted placement of pedicle screws in thoracolumbar spine: a meta-analysis. *Medicine*. 2021;100(38):e27282. [PubMed](#)
40. Fu W, Tong J, Liu G, et al. Robot-assisted technique vs conventional freehand technique in spine surgery: a meta-analysis. *Int J Clin Pract*. 2021;75(5):e13964. [PubMed](#)
41. Condon A. A breakdown of 7 robots in spine surgery. *Becker's Spine Review* 2021; <https://www.beckersspine.com/robotics/item/52042-a-breakdown-of-7-robots-in-spine-surgery.html>. Accessed 2022 May 10.
42. Malham GM, Wells-Quinn T. What should my hospital buy next? Guidelines for the acquisition and application of imaging, navigation, and robotics for spine surgery. *J Spine Surg*. 2019;5(1):155-165. [PubMed](#)
43. Dowsett L, Egunsola O, Mastikhina L, et al. Open radical prostatectomy, laparoscopic radical prostatectomy, and robotic-assisted radical prostatectomy: health technology reassessment. Calgary (AB): Health Technology Assessment Unit, University of Calgary; 2020: <https://www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/health-care-partners/health-authorities/bc-health-technology-assessments/prostatectomy-hta.pdf>. Accessed 2022 May 22.
44. D'Souza M, Gendreau J, Feng A, Kim LH, Ho AL, Veeravagu A. Robotic-assisted spine surgery: history, efficacy, cost, and future trends. *Robot Surg*. 2019;6:9-23. [PubMed](#)
45. Lee TJ, Thomas AA, Grandhi NR, et al. Cost-effectiveness applications of Patient-Reported Outcome Measures (PROMs) in spine surgery. *Clin Spine Surg*. 2020;33(4):140-145. [PubMed](#)
46. Passias PG, Brown AE, Alas H, et al. A cost benefit analysis of increasing surgical technology in lumbar spine fusion. *Spine J*. 2021;21(2):193-201. [PubMed](#)
47. Martinello N, Loshak H. Experiences with and expectations of robotic surgical systems: a rapid qualitative review. Ottawa (ON): CADTH; 2020: <https://www.cadth.ca/sites/default/files/pdf/htis/2020/RC1251%20RSS%20for%20Gyno%20Uro%20Surgery%20Final.pdf>. Accessed 2022 May 10.
48. Specht K, Agerskov H, Kjaersgaard-Andersen P, Jester R, Pedersen BD. Patients' experiences during the first 12 weeks after discharge in fast-track hip and knee arthroplasty: a qualitative study. *Int J Orthop Trauma Nurs*. 2018;31:13-19. [PubMed](#)
49. Zhang S, Liu Y, Yang M, et al. Robotic-assisted versus manual total hip arthroplasty in obese patients: a retrospective case-control study. *J Orthop Surg Res*. 2022;17(1):368. [PubMed](#)
50. Varghese S. Could robotic surgeons be the key to speeding up NHS waiting times? *New Statesman*. 2018 Jan 12; <https://www.newstatesman.com/health-science/2018/01/could-robotic-surgeons-be-the-key-to-speeding-up-nhs-waiting-times>. Accessed 2022 Jul 20.

51. Khalsa SSS, Mummaneni PV, Chou D, Park P. Present and future spinal robotic and enabling technologies. *Oper Neurosurg (Hagerstown)*. 2021;21(Suppl 1):S48-S56. [PubMed](#)
52. Koon J. Risks rise as robotic surgery goes mainstream: new technology requires robust security, bandwidth, and electronic systems. *Semiconductor Engineering*. 2022 Jun 30; <https://semiengineering.com/risks-rise-as-robotic-surgery-goes-mainstream/>. Accessed 2022 Jul 19.
53. AST guidelines for best practices on the perioperative role and duties of the surgical technologist during robotic surgical procedures. Littleton (CO): Association of Surgical Technologists: https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/ASTGuidelinesRoboticSurgicalProcedures.pdf. Accessed 2022 Jul 19.
54. Costs curbing the rise of robotics in spinal surgery. *Spinal News International*. 2018 Nov 13; <https://spinalnewsinternational.com/robotics-spinal-surgery/>. Accessed 2022 Jul 19.
55. Madder R. Robot surgery could be the future of health care in remote areas. *Fortune* 2020 Feb 11; <https://fortune.com/2020/02/11/tele-robotics-surgery-5g-health/>. Accessed 2022 Jul 19.
56. Mohan A, Wara UU, Arshad Shaikh MT, Rahman RM, Zaidi ZA. Telesurgery and robotics: an improved and efficient era. *Cureus*. 2021;13(3):e14124. [PubMed](#)
57. Chao YS, Sinclair A, Morrison A, Hafizi D, Pyke L. The Canadian Medical Imaging Inventory 2019-2020. *Can J Health Technol*. 2021;1(1). <https://www.cadth.ca/sites/default/files/ou-tr/op0546-cmii3-final-report.pdf>. Accessed 2022 Jul 19. [PubMed](#)
58. Felix B, Kalatar SB, Moatz B, et al. Augmented reality spine surgery navigation: increasing pedicle screw insertion accuracy for both open and minimally invasive spine surgeries. *Spine*. 2022;47(12):865-872. [PubMed](#)
59. Schroeder JE, Hourri S, Weil YA, Liebergall M, Moshioff R, Kaplan L. When giants talk; robotic dialog during thoracolumbar and sacral surgery. *BMC Surg*. 2022;22(1):125. [PubMed](#)
60. Motesharei A, Batailler C, De Massari D, Vincent G, Chen AF, Lustig S. Predicting robotic-assisted total knee arthroplasty operating time: benefits of machine-learning and 3D patient-specific data. *Bone Jt Open*. 2022;3(5):383-389. [PubMed](#)