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Research Article

Building a successful robotic-arm assisted orthopedic surgery program

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Building a successful robotics team is a long journey with much effort before the first surgery. It starts with sound business development and, in case of acquiring a system, an implementation plan, to make it a success. The pathway to a successful Robotics program is much more than choosing the desired robotic arm-assisted surgery (RAS) brand. Success also depends on the specific pathway optimization aspects of RAS. High-over, all systems introduce the computer and robotic-arm into the operating room. But all systems have subtle, but significant, differences. An essential aspect of a successful RAS project is the implementation phase.

After deciding to purchase a Robotic system, the following training and OR setup phase should be prepared and executed. When the robotic system enters the operating room, aspects like arm position using the arm board should be evaluated critically since the robot needs sufficient working space. A suboptimal positioning will disrupt the team dynamics and lead to preventable delay. RAS requires new or adjusted skills. Two crucial

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Conflicts of Interest Statement for Dr. Kort

b Peter Pilot started his scientific career in a teaching hospital at the orthopedic department. In those six years, he established the first non-academic based research department in an orthopedic teaching hospital, a perfect example implemented in the years after by many orthopedic partnerships.

He started in the teaching hospital his PhD research on physical recovery after total hip replacement. In this project, he combined Patient Blood management, Care pathway optimisation and exercise physiology. This research line also leads to the transition from business process reengineering to Medical process reengineering. The fascination for the recognition of surgical stress leads to the start of the rapid recovery program. This fast track program had the philosophy of improving the medical processes to do better, and doing better leads to more efficient health care. In this period, he published multiple peer reviewed papers and started his first two PhD projects as co-supervisor.

For the next 6 years, he continued developing a research department in a larger teaching hospital. Besides the two previously started PhD projects, he guided an additional 5 PhD projects as co-supervisor. In this period, he was also involved in the orthopaedic department's ISO-certification, including the research work. He also started with his first LEAN project. The decade after this teaching hospital experience, he worked for a large medical device supplier. For the first 5 years, he was involved with the European clinical team projects and the second part as the driver of innovation and scientific projects for the Dutch entity. In 2020 he started working for StichtingIMA (IMUKA) as chief innovation officer & Chief Officer officer. His focus is on (implementation of) healthcare innovation and science.

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aspects are eye-hand-feet coordination in combination with a different focus of the surgeon (also screen instead of 100% surgery field) and new cognitive decision making features.
Robotic surgery is a perfect example of how technology can change a surgical field. This data acquisition is probably the most fundamental, powerful aspect of adding the computer into the surgical process. The most used robotic-arm systems in hip and knee arthroplasty are semi-automatic systems, and practically all major orthopedic manufacturers offer a device.
ORs are a highly capitalized section of hospitals, generating high costs and critical revenues. Therefore, taking a closer look at workflows, inventory management, and team efficiencies is crucial. Improving these aspects in the OR has a high return on investment. RAS helps accurately observe everything occurring within and around the surgical process. These new data opportunities open the opportunity to work with surgical data science (SDS).

INTRODUCTION

Our society is changing in a fast pace. After an era of automatization, now the era of cyber physical working has started in 2015. More or less everything in our life is getting smart and WIFI has become part of our basic necessity of life. Some of these changes can be seen as disruptive. With technology it is an everlasting discussion in medicine: a logical evolution or a revolution? Robotic surgery is a perfect example of how technology can change a surgical field. Should we call this a logical evolution, or is it a revolution? At least it can be seen as an evolution of surgical instruments becoming smart instruments. But it can also be considered a revolution since the digital nature of the robot's system generates detailed data about and within the procedure, digitalizing the operating room. It creates highly sensitive electronic traces of the patient on the one hand and the surgical team on the other hand (Steil et al. 2019).

In several surgical fields, open surgery was followed by arthroscopic intervention, and now, the next stage is robotic-arm assistance. For orthopedic arthroplasty surgery, this development is slightly different. Besides the conventional implantation of arthroplasty, the development of Computer-assisted orthopedic surgery (CAOS) was ongoing. CAOS includes computerized tools, devices, and instrumentations, such as robotic assisted or navigation technology, patient-specific instrumentation and even sensors (Picard et al. 2019). In the last decade, the focus has been more on Robotic-arm assisted surgery (RAS) as the current most sophisticated form of CAOS. As stated by Merle et al "data acquisition is changing how evidence is gathered and utilized. Sensors are the pen and paper of the next wave of data acquisition" (Merle, Parent-Harvey, and Harvey 2022). This data acquisition is probably the most fundamental, powerful aspect of adding the computer into the surgical process.

In multiple surgical fields, the master-slave type of robot is used. This differs in orthopedics and neurosurgery, where the semi-automatic robot is the most seen solution. The semi-automatic robot arm is a digital update in the surgical instruments for prosthesis implantation. These semi-automatic co-bots play, in contrast to the master-slave robots that give the surgeon, a fundamentally different role in how we perform surgery. In hip and knee arthroplasty, the robotic-arm is introducing SMART instruments in the operating room. It is comparable to the evolution of our phones into smartphones: adding new functions to an existing product and, by doing so, changing the nature of the device. Thus should we keep on comparing the traditional function of the phone or should we look at the other tasks that a smartphone has? A natural evolution of our phone to a smartphone, narrowing the phone part. From this point of view, we should be looking at RAS. In 2011, Atul Gawande nicely stated that the distance medicine has travelled in a couple of generations is almost unfathomable for us today.

But, if you think too long about the future, it is already in full swing. However, medicine has been slow to grasp why this is a struggle or how the discovery volume has changed our work and responsibilities (Gawande 2011).

We have learned from aviation with time-out procedures and incident analysis (Kapur et al. 2015; Patankar and Brown 2019; Bhangu et al. 2013). But with the currently available technology, we can adopt other generally accepted aspects from aviation, like flight data analysis (surgical data analysis), simulation training and certification work, and advanced analytics. We notice this same approach in other worlds that have been conservative for a long time. In professional sports, like cycling, a significant advancement is seen due to technological developments. McParland et al showed the potential of advanced analytics and asked whether healthcare can replicate the success of professional sports (Mcparland, Ackery, and Detsky 2020). Healthcare is like professional sports in many ways, and examples of how high-functioning sports teams, such as those of Formula One teams or cycling, may pave the way for healthcare improvement have sparked widespread discussion.

From this view, telemetry data, data science, and simulator training possibilities will enormously impact health care. As outlined in this article's first paragraphs, surgeons considering stepping towards RAS should expect a longer journey focused on a longer time span. This article describes a narrative description of essential steps in becoming a successful robotics team. First, the orientation and selection phases are described before the implementation and evaluation phases are addressed. The MAKO system is the robotic system currently most used and developed in orthopedics; This system is used as example for this article, but most aspects are generalizable to other robotic systems on the market. It is all about the idea of using smart instruments and the potential of working with smart instruments. In 2004, Marohn et al already stated that we need to assess our current technologies and skills and then ask what technologies we need for the future. What solutions will improve the outcome of surgery, and what role will robotic-arm assisted surgery play (Marohn and Hanly 2004)? This modern way of thinking fits nicely in the current era: the start of the fourth phase of the Industrial Revolution characterized by cyber physical working.

It is a different approach to look at new possibilities that are added to the traditional discussion on the merits of RAS. Robotics in arthroplasty is at the cusp of a real breakthrough. Studies and metanalysis on RAS all state that although robotic assistance affords improved component positioning, its benefits regarding clinical scores, patient satisfaction and implant survivorship remain to be confirmed. However, a significant point in all these reviews is that this meta-analysis does not consider technology matureness and experience (Kort et al. 2021a, 2021b). The success of implementing new technology depends on using its full potential and using it in its strength. Often, this means you must adapt to the way you are working. And on top of that, you must think about the business and implementation plan. Before successfully working with RAS, you have to travel a long way. This article describes the phase of this pathway.

ORIENTATION & SELECTION PHASE

The most used robotic-arm systems in hip and knee arthroplasty are semi-automatic systems, and practically all major orthopedic manufacturers offer a device (Sousa et al. 2020). High-over, all systems introduce the computer and robotic-arm into the operating room. But all systems have subtle, but significant, differences. For instance, the cutting tool type for each robot, is the Robot-arm positioning a saw guide (Jig) or the saw itself? What are the possible requirements for preoperative or intraoperative (advanced) imaging? Do you need preoperative x-rays, CT, MRI, or only intraoperative imaging? And what are the positive and negative sides of these choices? Finally, what are the options for implant selection? Is my desired Robotic System available with my current prosthetic choice, or do you need to switch (Sousa et al. 2020)? As described by Vermue et al each System has a unique set of design characteristics, which cannot be overlooked (Vermue et al. 2022). But does it fit your set of requirements? It is good to compare all these features.

The most mentioned disadvantage of RAS is the considerable capital investment and long-term contracts. The question is if the perceived benefits of the system justify these investments. It is a relevant question with no straightforward answer. Some basic questions need to be answered in the business and development plans to make it work. Will purchasing a RAS system include a supplier and/or implant change? What is the current annual volume per year, and what is the multi-year forecast? Will the RAS be for only knee- or also the hip implants? How many surgeons will work with the system, and how will the training and learning curve be managed? This aspect of training and learning curve is overlooked easily and can explain the initial reports on longer surgery times since most new skills are trained during routine surgeries. Longer surgery times and surgeon downtimes in the OR will lead to additional costs due to productivity loss. By using a good implementation plan this can be reduced to a minimum.

For RAS, both clinical and theoretical cost-effectiveness analyses are published (Vermue et al. 2022; Kirchner et al., n.d.), but the cost-effectiveness is debatable and enormously dependent on local circumstances, aims and implementation. Besides capital investment, loss of productivity in the starting phase due to the learning curve should be part of the development plan. Dealing with the ethical and practical aspects, like acquiring the desired robotic skills, should be described in detail before starting. Defining the potential saving is a significant challenge but possible. Literature on clinical results or modelling studies mainly considers survival, length of stay, complications, and gain in QALYs as variables. More tangible aspects that could lead to savings are the reduced stock due to more accurate prediction of sizes, less investment due to reduced sets and fewer costs for sterilization and wrapping of sets that originate I smaller sets needed with RAS. After finishing the learning curve, RAS can optimize the operating room capacity with higher predictability of surgeries, leading to a higher daily surgical capacity. Meticulous planning becomes possible since unpredictable surgical challenges leading to longer surgery times can mostly be avoided due to better preparation.

Before implementing a robotic-arm system, defining key performance indicators and critical factors in the business and development plans is recommended. Aspects of the learning curve, operating room flow parameters and setting specific indicators can help achieve goals in a predefined way. Without these indicators, evaluating the plans and justifying the investments will be challenging.

IMPLEMENTATION PHASE

An essential aspect of a successful RAS project is the implementation phase. After deciding to purchase a Robotic system, the following training and OR setup phase should be prepared and executed. New skills for the surgeon and the surgical team should be acquired. RAS implementation yields more detailed planning, pre-and intraoperative interpretation of new data types, and other important team dynamics. On top of that, other motor skills are needed since the surgeon must use monitors outside the routine surgical field during calibration and the surgery itself. The surgeon receives visual feedback from the monitor outside the surgical field and must learn to rely on this feedback. The team set-up differs from a standard procedure since the robot-arm must be placed at the table. Is there sufficient working space for the team, no strapped arm of the patient in the way, and no persons in front of the receiver are a few new aspects to consider? These aspects should be discussed and trained with the team. And with a highly variable surgical team often seen in hospitals, these aspects demand more attention.

Grau et al discussed a critical concept for improving OR efficiency, which can be applied to any robotic arm system. The section below outlines the essential aspects of the implementation phase you must understand before acquiring a system (Grau et al. 2019). Most systems come with mandatory certification lab training. Usually, this is a one-day training on the knee and one day on the hips if both are used. Most essential surgical aspects are trained, and in many cases, an anatomical specimens course is included. Although the training is mandatory in most cases, it is good to express that this is a minimum requirement, and making a more pronounced training plan before starting to operate on your patients is recommended.

RAS requires new or adjusted skills. Two crucial aspects are eye-hand-feet coordination in combination with a different focus of the surgeon (also screen instead of 100% surgery field) and new cognitive decision-making features. For both aspects, new training forms are or will become available. The new coordination skills are trainable with game-console-like solutions. This simulation-based surgical training has distinct advantages over the traditional surgical apprenticeship model: it offers training in a safe environment. It can be used for repeated, self-directed practice until a level of proficiency is achieved and the practice itself can be measured (Scott et al. 2020; Vestermark, Bhowmik-Stoker, and Springer 2018). The use of training simulators and apps has considerable potential to minimize the learning curve, improve operating room metrics and provide training opportunities in settings without patients. The latter is an ethical aspect that should be mentioned more often in the discussions on RAS.

Current mobile device technology, smartphones, and tablets, have given us applications (apps) as learning medium for surgical trainees. The planning of a prosthesis and the outcomes of the simulations in the planning software offer the possibility to practice in simulation apps. First, studies about simulation with apps show that they provide better information recall than traditional training methods (Vestermark, Bhowmik-Stoker, and Springer 2018). In addition to these new learning opportunities, expert visits and master-mind sessions can help the surgeon better prepare and reduce the learning curve. Expert visits are recommended and, depending on the complete roadmap, can fit at multiple time points in the total journey. Mastermind sessions with experienced RAS surgeons will help create a continuous learning environment.

Several systems need preoperative imaging, some use intraoperative imaging. In our case, the MAKO (Stryker, Michigan USA), one needs CT. It is essential to make a suitable arrangement with radiology departments about the CT protocol and workflow. Set a timeline to process and approve the image to prevent delays or surgery cancellations.

Advanced analytics of the new data forms that come with robotic systems make it possible to improve preoperative planning and intraoperative performance. This unique, fascinating development was not possible with CAS solutions like patient specific instruments (PSI). A product specialist for the MAKO does the initial planning, but for other systems, you must do it yourself before or during the intraoperative surgery. The surgeon always needs to review the case before surgery and adjusts during surgery.

OR SET UP

Patient positioning is a significant responsibility that requires the cooperation of the entire surgical team (Breyer 2018). The purpose of patient positioning in the operating room is to facilitate the surgical procedure. When the robotic system enters the operating room, aspects like arm position using the arm board should be evaluated critically since the robot needs sufficient working space. Once the robot is docked, direct access to the patient is limited. Therefore, it is imperative that all monitors, and lines are placed before docking the robot and that proper padding and positioning are completed (Breyer 2018). A suboptimal positioning will disrupt the team dynamics and lead to preventable delay.

Every robotic-arm system has its own specific devices. How will these components influence the set-up? Where do you need to place all devices? Are they in the sterile field or outside? At the start of the surgery, most systems require array placement to connect the patient to the computer.

The surgical guidelines will instruct how to place them; this routine should be practiced since adequate arrangement, and no disruption during the procedure is essential. The surgeon monitor should be placed in a comfortable viewing location for the surgeon. In contrast to conventional surgery, where the surgeon looks mostly into the surgery field, the surgeon spends during RAS considerable time looking at the monitor instead of the surgical field. This monitor directly serves as a monitor for the patient to follow the surgery. For the robotic-arm the surgical guidelines will help you define the right place, although dry practice is essential to find the optimal positions within each local operating room setup. Most systems also work with a guidance module, which should be strategically positioned. However, this placement is less critical to the process than the camera stand and robot arm.

Most robotic-arm procedures are facilitated with the leg positioner in knee arthroplasty. This positioner is more or less mandatory while using the RAS system. Does this leg positioner fit on the table, and how does it influence the procedure? All aspects should be tested and predetermined. Further, the roles of the sterile staff member and circulating nurse are essential. In most cases, the surgeon must follow mandatory certification lab, but the complete team training is often overlooked on experience is gained during surgical procedures, leading to longer surgery time and disruption of the flow. Therefore, an adequate training tool should be provided.

Finally, there is a debate about whether body exhaustion suits help prevent infections (Rahardja et al. 2022). Modern space suits are considered personal protection systems against blood spatter and debris, not primarily as aids for decreasing periprosthetic joint infection (Vermeiren, Verheyden, and Verheyden 2020). With RAS, there is another crucial aspect to consider. The surgeon is with his hands and face closer to the joint during sawing; thus, protecting yourself and the staff for personal health reasons should be considered.

TEAM TRAINING

Effective teamwork in the operating theatre is essential for safe patient care. In many decades of modern hip and knee arthroplasty, the roles and members of the surgery team have been established. With the introduction of robotic surgery, new positions and team members are seen. If every team member should know all the steps of the process, this helps prevent delays during the procedure because not all actions must be taken serially and need preparation. A working parallel can prevent delays if the team works as a pit crew (Merry, Weller, and Mitchell 2014). Practice the complete procedure in sessions without a patient like a pit crew. Where should all the robot system components be placed, at what position, and how is robotic-arm repositioned or removed during surgery? To which position? Finding optimal strategic positions of the camera stand plus surgeon monitor is essential not to disturb the flow. These team dynamics can be practiced like a Formula One pitstop. This saves much time during actual procedures in the patient's and economic interest.

MAKING THE ROBOTIC SYSTEM COSTS EFFECTIVE

As mentioned, the initial capital investment of RAS seems high. In the business plan, the costs of instruments, stock and OR efficiency are essential aspects to consider. ORs are a highly capitalized section of hospitals, generating high costs and critical revenues. Therefore, taking a closer look at workflows, inventory management, and team efficiencies is crucial. Improving these aspects in the OR has a high return on investment. With the pre-planning and high precision of RAS systems, surgical instrument sets and stock can be reduced. Reduced sets will lead to fewer initial costs for these sets and fewer sterilization and wrapping costs after each procedure (Hermena et al. 2021).

With a good training and implementation plan, RAS can give predictable operating times and efficient OR days. With all the data, opportunities, insight, and further improvement in the specific steps during surgery can be achieved. An efficient and transparent process, supported by validated data, is vital to create a sustainable environment in which different points of view are objectively aligned. RAS can help set up a predictable, transparent, and efficient OR flow.

DIGITAL TRANSFORMATION

Today, machine learning (ML) has revolutionized almost all healthcare areas. However, success stories, like in radiology, appear to be lacking in surgery (Maier-Hein et al. 2022). RAS is a significant step forward since data availability is needed for ML. RAS helps accurately observe everything occurring within and around the surgical process. These new data opportunities open the opportunity to work with surgical data science (SDS). To make SDS effective, we have the presumption of a high quality data set, i.e. data hygiene (minimal error in collection and storage) and data integrity (consistency, completeness and accuracy) (Houtmeyers, Jaspers, and Figueiredo 2021). Using this concept, newly available data sources can be incorporated into traditional Evidence-based Medicine. Traditionally, we successfully use descriptive analytics showing what happened in specific groups or cohorts. Currently, we are in the process of predictive analytics, trying to predict what will happen if we do particular interventions. Once we have objectified with data what will happen, we need to understand these new data types; we can make the step to prescriptive analytics, enabling us to think about what to do to change things in a more controlled matter. With these new data fields, data will serve as an intuition enhancing tool. To do so, it is crucial to think beyond just applying traditional statistical or machine learning methods to ordinary problems in conventional ways (Delen and Ram 2018).

SDS's unique characteristic is the focus on procedural data, including Robotic-arm assisted surgery (Maier-Hein et al. 2022). It observes everything occurring within and around the treatment process and will provide the surgeon with quantitative support to aid decision-making and surgical actions. And, importantly, it will link decisions to measured patient outcomes (Maier-Hein et al. 2022). As an example, in TKA, understanding of alignment and its interaction with soft-tissue balance are widely considered to be the two most crucial surgical factors in reducing current rates of patient dissatisfaction after TKA (MacDessi et al. 2023). The chosen alignment, including chosen settings, and execution of the surgeon are essential in determining the outcomes. Stulberg found in general surgery that there is wide variation in technical skill among practicing surgeons, accounting for more than 25% of the variation in patient outcomes (Stulberg et al. 2020). A lot of intra-operative information used to make decisions during conventional knee and hip arthroplasty is not all acquired. On top of that, not all data that could be acquired is recorded, stored and available for analysis. Only a fraction of patient-related data and information is stored in a predefined manner and available, like in implant registers (Maier-Hein et al. 2022).

Where the RAS discussions are mainly focused on clinical benefit and (short term) cost-effectiveness, RAS will give us performance data on the surgery. In general, RAS can optimize the OR capacity with higher predictable surgeries and more insight into the OR efficiency. With meticulous planning, surprises that lead to longer surgery times can be avoided. On top of that, all steps of the complete surgical process can be made transparent, helping to optimize workflows in the OR. Therefore, the team dynamics, the defined KPIs, and OR workflow outcomes should be reviewed periodically. This will help reduce the longer surgical times often mentioned in publications in RAS (Kort et al. 2021a, 2021b). But moreover, it can help to do more surgeries within a OR session, helping to fight the staff shortage problem globally seen.

CONCLUSION

Building a successful robotics team is a long journey with much effort before the first surgery. It starts with sound business development and, in case of acquiring a system, an implementation plan, to make it a success. The pathway to a successful Robotics program is much more than choosing the desired RAS brand. Success also depends on the specific pathway optimization aspects of RAS. Further, it is essential to highlight that more data options become available with the introduction of the robotic arm in the OR. It can provide the surgeon with quantitative support to aid decision-making and surgical actions and will link decisions, backed with data, to patient outcomes. With the established OR flow metrics, the robotic systems bring new data possibilities to make the patient journey more data-driven. Quick wins are the objectivation of the OR process and insight into OR performance. This could lead to higher quality for our patients and more daily cases, justifying the capital investment.

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