An Investigation of the Technical, Social, and Financial Limitations on the Implementation of Robotic Surgical Technology

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An Investigation of the Technical, Social, and Financial Limitations on the Implementation of
Robotic Surgical Technology

Sophia M. LeMaire

A Thesis in the Field of Biotechnology
for the Degree of Master of Liberal Arts in Extension Studies

Harvard University
November 2020
Abstract

The advent of laparoscopy was a revolution in surgery that had large impacts on the patient experience. Small incisions healed more quickly, less blood was lost, and time in the hospital was shortened without loss of precision. The mechanics can be awkward for the surgeon, however, and hope remained for something more ergonomic. The answer seemed to come in the late-1990s when surgical robots entered the picture. The field of new robots was quickly narrowed down to Intuitive Surgical’s da Vinci robot through a series of strategic buyouts, and da Vinci gained FDA approval for abdominal laparoscopy in 2000. It remained the only approved device in that category until 2017.

Since that time, robotic surgical system use and implementation has been shaped by three main factors: the regulatory process, the financial barriers to acquiring and maintaining a robot, and public perception from both clinicians and patients. The purpose of this study is to review and discuss the ways in which these factors influence the use, availability, and development of robot-assisted surgery.
Frontispiece

Dave Simonds for The Economist ("Who Wields the Knife?"), May 2016
Sophia LeMaire was born in Washington D.C. but spent her life from age five to eighteen in Longmeadow MA. She graduated from Cathedral High School in 2007 and went on to Princeton University where she received her bachelor’s degree in Mechanical Engineering and certificates in *Engineering Biology* and *Robotics and Intelligent Systems* in 2011. From 2011 – 2012 she lived and worked in Baltimore MD as a research assistant at the Bloomberg School of Public Health as part of Princeton’s Project 55 Fellowship. She then moved to Boston where she spent two years as a Technical Research Assistant at Brigham and Women’s Hospital, programming and running a Tecan testing robot to perform ELISA tests for heart failure research.

She moved back to D.C. in 2014, and from 2014 – 2015 she completed her Master’s Degree in Physiology and Biophysics at Georgetown University. She subsequently completed her M.D. at Howard University, graduating in 2019. During her time in medical school she completed a summer research fellowship at NIH’s National Heart, Lung, and Blood Institute, and she presented research on sickle cell disease at the American Society of Hematology 2018 national meeting as part of the ASH Minority Medical Student Award Program.

Her scientific interests include cardiovascular disease and the use of technology in medicine. She has been married to her husband Ricky since May 2019 and currently lives in Providence, RI where she is completing a surgical internship at Rhode Island Hospital.
Dedication

To Mommy, Daddy, & Peter, for teaching me to love learning and always being my cheerleaders.

To Ricky, for letting me bounce ideas off you, encouraging me when I most need it, and for being the best friend, husband, and wee-hours writing companion I could ask for.
Acknowledgments

I would like to thank Dr. Sujata Bhatia and Dr. Steven Denkin for helping shape my ideas and making it possible for me to complete this project after all these years. Thank you for your teaching, advising, and support.

I would also like to thank Drs. Cioffi, Harrington, and Miner at Rhode Island Hospital. I appreciate you inviting me to learn with you this year and giving me the tools to deepen my understanding of this interesting topic.

And thank you to all the friends, family, acquaintances, and strangers who have listened to me talk about this project for the past year. Your encouragement propelled me forward when finishing seemed out of reach.
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Chapter I
Introduction

Fully or semi-automated machines are becoming more common across all industries to relieve or assist the work of humans (Wilson, 2019) (Francis, 2018). In the healthcare setting, technology related to imaging, surgical approaches, and diagnostic testing continues to change the experience of both providers and patients. From remote surgery via the da Vinci operating system to data processing with IBM’s Watson, developments in technology have found applications across the medical field. One barrier to the growth of medical technology, however, is the disconnect between technical possibilities and the clinical, ethical, and economic desires of the people using and developing those devices. Also, regulations put in place by entities like the FDA to protect patients from the harms possible with experimental medical treatments need to be weighed against the possible benefits of the new device or therapy. On a social level, hesitation from both patients and medical providers about the encroachment of robotics into the human elements of medicine can also influence the ability for certain technologies to enter or succeed in the market.

Barriers to the Adoption of Medical Technology

Harvard Business Review published a piece in 2006 on the slow progress of medical technology titled “Why Innovation in Health Care Is So Hard” One factor cited
was the fact that physicians remain uncommonly independent among professionals. Over 50% of physicians in the U.S. work in practices with three or fewer doctors, a quarter of community hospitals and half of the nursing homes are independent, and the biotechnology industry consists of thousands of small independent companies. The inability to integrate the thousands of players in the healthcare industry means that burgeoning innovations can easily be lost to small fluctuations in the practice or company in which they arise and that supply is not always connected with demand (Herzlinger, 2006).

There is also the issue of cost. The da Vinci surgical system has a price tag of about $1.2 million, maintenance costs of $100,000 per year, and $1500 worth of disposable surgical instruments per patient, per case. There is some evidence that in high volume surgical centers the cost is offset by the ability to safely increase the volume of cases, but the steep upfront price tag and significant operating costs are prohibitive for smaller hospitals and surgical centers (Finkelstein, 2010).

On the user experience side, a significant barrier to the adoption of robotic surgical devices is the learning curve. In a piece in the journal Reviews in Urology, researchers compare the outcomes in patients who received prostate surgery using open (traditional surgical incisions), laparoscopic (manual surgery with small incisions) and robot assisted laparoscopic (robotic, using small incisions) approaches. They concluded that for a surgeon who has very little experience with manual laparoscopy (“laparoscopically naïve”), it can take 80 to 100 cases on the robot to feel proficient. For experienced laparoscopists, the learning curve is still 40 to 60 cases. The data on outcomes shows that this issue is not merely one of physician comfort, but of patient
safety. The risk of recurrence of prostate cancer was significantly increased (6.6 – 12% higher risk) when the surgery was done by an inexperienced surgeon, and the rate of morbidity and late urinary dysfunction was higher among surgeons with a low volume of cases vs surgeons with a high volume of cases (27% vs 32%, p = 0.03). One solution to this problem is the use of training interfaces, but the equipment costs, maintenance, and space requirements for dedicated training equipment can deter institutions from investing in this option. Plus, if a physician in training plans to practice in an area with low resources or plans to move to a smaller hospital or practice without a robot after training, the time and expense is even more difficult to justify (Finkelstein, 2010).

Regulatory and Market Concerns

While there has been a significant influx of new medical devices and software into hospitals and other medical facilities over the last several decades, the healthcare field has proven slow to adopt certain elements of technology that are common outside the hospital. Limitations on human trials as well as patient privacy laws can make medicine a challenging field into which to introduce new devices or software and, when they are introduced, adopting an unfamiliar technique can be challenging for even an experienced practitioner. On the other hand, when a long-awaited new piece of technology is finally implemented, there can be resistance to admit faults and shortcomings resulting in underreporting of important adverse outcomes. This inertia is at odds with the impetus to use our deepening understanding of robotics, artificial intelligence, and network systems to better diagnose and treat our patients.
The use of robotics in surgery has grown rapidly over the twenty years since Intuitive Surgical’s da Vinci robot earned FDA approval, growing particularly over the last decade from an estimated 136,000 cases in 2008 to nearly 900,000 cases per year in 2018 (Schwitzer, 2018). The growth of this industry has been met with optimism from some who view it as a path toward a new standard of care, and with concern from others who feel that regulation and proof of performance lags behind implementation. Critics also express concern that benefit does not always outweigh large costs associated with the installation and maintenance of these machines.

The central research question for this thesis centers around the rise of robotic technology in the healthcare setting at large, focusing particularly on the increase in robotic surgical technology over the past twenty years. Questions of implementation, cost, outcomes, and regulation linger while the field grows rapidly. In medicine where independent practice or participation in a siloed health system is common, it can be difficult to aggregate data to produce generalizable conclusions on outcomes. The aim of this report is to examine the factors – from regulation and implementation to clinical and patient experience – that influence the development, adoption, and application of robotic devices in the surgical field.
Chapter II.
Research Methods

Because this is a topic for which economics, tradition, and perception mingle so inextricably, the sources for this thesis range from peer reviewed analyses to FDA briefs to newspaper reports and blog posts. The sources selected for inclusion are meant to paint the overall picture of each element. The three areas of interest are the research to application pipeline focusing on FDA approval of devices, issues of cost and sustainability for hospitals and patients, and perception and social impact.

To assess the research to application pipeline this study will outline the steps in the FDA approval process and review some recent successful device applications as well as rejected applications. FDA regulations for bringing medical technology to market, and how those rules may be enforced or circumvented will be discussed. For this element information was gathered from the FDA website and published documents, and commentary was collected from news briefs and articles discussing the approval or rejection of recent applications.

Issues of sustainability and cost were evaluated by reviewing literature and news about the implementation of robots in hospital settings and the costs associated with them. Financial information for specific institutions is not often accessible publicly, but analyses of cost have been performed that piece together the overall economic picture of the industry. This study will discuss how future costs and profits may be factored into research and development, and this study will examine how or if patient morbidity and
mortality influences the development of and investment in new technology in the medical field. This section also includes information about how difficult it is for physicians to feel comfortable using this technology, and discusses how this may factor into implementation and outcomes. For this element of the study, economic analyses performed by research labs as well as journalistic investigations into the costs were collated and discussed.

Perception and social impact was assessed by reviewing published surveys of both clinicians and non-clinicians regarding ease of use, perception of impact, and outcomes. This topic is more subjective, and thus subject to bias. The surveys included are representative of major players and represent two main perspectives on this topic. One perspective is that of providers: how physicians – both attending physicians and those in training – perceive the user-friendliness, efficacy, and future of robotics. The other element is the perception of patients and how their experience shapes their perspectives.

For background, Table 1 in the appendix lists and describes procedures listed as approved for da Vinci, some of which are referenced in this thesis.
Chapter III.
Results and Discussion

Research to Application Pipeline

History of the FDA

The FDA began its life as a wing of the US Patent office in 1862, focusing on improving wine, fertilizers, and other products related to agriculture and food products. They soon moved on to food safety, investigating and proposing regulation on contaminants in consumable products. In 1901 the office branched off on its own to become the Bureau of Chemistry, and it began its oversight of pharmaceuticals in 1906 as part of the Pure Food and Drug Act. After several more iterations, it became the Food and Drug Administration in 1930. They jumped around the agencies, from the USDA to the Federal Security Agency, finally settling in the Department of Health and Human Services in 1979 (U.S. Food and Drug Administration, 2018). In 1976 the Federal Food Drug and Cosmetics act added medical devices to the agency’s purview (Van Norman G. A., Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices, 2016). Today, the FDA serves as the ultimate gatekeeper between the public and consumable products and medical devices. The requirements for FDA approval vary depending on the product and the purpose. For the purposes of this analysis, the focus will be on FDA approval process for devices, with some description of the approval arc for drugs for comparison.
Figure 1: The FDA Regulatory Process for Drugs

This graph outlines the approval process, timeline, and costs associated with bringing a drug to market. A drug is most likely to fail in Phase II. This is the first step in which the drug is assessed for safety at therapeutic levels (as opposed to smaller doses focused on assessing safety alone), and the stage at which lesser known side effects may present themselves. The 11.7% final approval rate is as of 2014. (NDA: New Drug Application) (Van Norman G. A., 2016)
The trajectory of drug approvals is important context for the newer realm of device approvals because it demonstrates how disruptive technological shifts can lead to a sudden inability for regulation to keep pace with innovation.

For drugs, the approval process takes more than a decade on average. While the length and difficulty of gaining approval is explained as a desire for the agency to continue to properly vet products before they reach consumers, some fear that the complex process and significant expenses related to the necessary research and development – some estimates state an average of $1 billion dollars from inception to approval – may be responsible for a “drug lag” that prevents important drugs from getting to market in a timely fashion. This “lag” is not a new phenomenon, however. FDA approvals of new drugs dropped from an average of 50 per year in the 1950s to 17 per year by 1965, remaining at this level in the subsequent decades (Van Norman G. A., 2016). Drug approvals experienced a renaissance from 1996 to 2000, with a surge to over 35 approvals per year driven by now well-known drugs for cholesterol (Lipitor), hypertension (Diovan), HIV-AIDS (Crixivan, Norvir), asthma (Accolate, Allegra), cancer (Gemzar, Taxotere), acid reflux (Prilosec, Prevacid), and erectile dysfunction (Viagra). This golden age did not last, however, and over the next decade approvals dipped back to an average of 23 per year (LaMattina, 2019).

The lag in the 2000s has a possible explanation that is significant to the topic of medical technology in general. Concurrent with that dip, consumer and market-driven changes across the industry were fundamentally changing the types of drugs that resulted in commercial success. Previously, drug companies relied on small molecule drugs, releasing new pharmaceuticals in a drug class with incremental improvements in
performance. But as early members of a drug class became generic (drug patents last 20 years from filing), it became difficult to market their more expensive brand-name descendants. Without the breakthrough new drug classes that characterized the late 90s, successfully bringing a drug to market became more challenging. The second blow was another disruptive technology: the advent of biologics (Van Norman G. A., 2016).

Biologics are drugs are defined as being derived from living organisms, and require more complex techniques to study and produce. The first biologic was human insulin, introduced to market in 1982. Unlike traditional small-molecule drugs which are consistently reproducible with a fixed chemical reaction, biologics require access to the biological system from which the drug is derived as well as pricier biotechnology capabilities such as recombinant DNA technology (Academy of Managed Care Pharmacy, 2017). Much like devices, their development relies on work on the cutting edge, challenging regulation to keep pace.
Regulation of Devices

Figure 2: The FDA Regulatory Process for Medical Devices

This process takes 3 – 7 years on average. When a de novo device is introduced, preliminary bench testing, animal testing, and redesign take 2 – 3 years and costs $10 - $20 on average. The Clinical trial stage requires multiple trial types, starting from smaller “first in human” trials and ramping up to multicenter prospective randomized controlled trials. Study time and post-treatment follow up can take 2 – 3 additional years. An interesting situation is when the FDA approves a device for use on the condition that they complete additional controlled trials. The issue is that the timeline is not set in stone, and research has shown that five years after approval, only 18% of devices that achieved conditional approval had undergone the required post-market studies. (Rathi, Krumholz, Masoudi, & Ross, 2015) (Van Norman G. A., Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices, 2016)
Devices, on the other hand, have less of a regulatory history and as of now have more straightforward definitions and a shorter time to market than drugs. The average length of time it takes to bring a device to market is 7 years, significantly shorter than the average of 12 years for drugs. The first step in the approval process is qualifying as a “device” as defined by the Center for Devices and Radiological Health. CDRH is the division within the FDA under which all device regulation falls, and they define a device as “an instrument, apparatus, implement, machine, contrivance, implant or an in vitro reagent” that meets three criteria: that it is recognized in the official National Formulary of the U.S. Pharmacopeia, it’s purpose is the diagnosis, cure, mitigation, treatment, or prevention of disease, and it affects the structure and function of the human body. They also cannot use chemical or metabolic activity to achieve their goal (in that case, they would fall under the drug category). If a person seeking approval is unsure of whether their device meets these criteria, there is a dedicated Device Determination officer who can assist in this first step.

Next is the prototype stage. There are two major classes: novel devices, and improvements on already-approved devices. Medical device companies often deal in iterations of previously-made devices, whereas brand new devices are typically the domain of venture-backed start-ups due to the high costs. For a brand new device, the pre-clinical stage can cost $10 to $20 million prior to formal clinical trials (Van Norman G. A., Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices, 2016). This means that for academic centers that don’t have unlimited funds or biotechnology startups running on finite venture capital, ideas
that may have significant clinical promise could be scrapped early in development for economic reasons.

The final pre-market stage is Clinical Trials. The regulatory requirements are: Establishment registration, Medical Device Listing, Premarket Notification 510(k) (unless exempt) or Premarket Approval (PMA), Investigational Device Exemption (IDE) for clinical studies, Quality System (QS) regulation, Labeling requirements, and Medical Device Reporting (MDR) (U.S. Food and Drug Administration, 2019). Establishment registration consists of notifying the FDA of your intent to distribute medical devices and subsequently being approved, and Medical Device Listing itemizes the devices the company intends to market.

The first major review comes at the Premarket Notification/Premarket Approval Step. During the review process, each device is put into one of three categories – Class I, Class II, and Class III – and the classification determines the regulation required for that device type. Class I devices require the least amount of regulation and are often exempt from Premarket Notification 510(k), meaning they are often allowed to go to market without additional screening. The majority of Class II devices need Premarket Notification 510(k), which means that they must wait for FDA to review their device and issue a “letter of substantial equivalence” stating that their device is equivalent or superior to the market standard in that category. Most Class III devices are required to have Premarket Approval. Premarket approval also requires proof of substantial equivalence, but in addition the manufacturer needs to provide significant clinical data to prove the efficacy and safety of their particular product. This highlights one of the major shortcomings of the FDA’s method for assessing new devices: they more commonly rely
on comparison to the standard of care than on controlled randomized trials. This creates a barrier for completely novel technologies struggling to find a comparable item on the market, and also allows theoretically low-risk devices and implants to enter the market with limited testing (Van Norman G. A., Drugs and Devices: Comparison of European and U.S. Approval Processes, 2016).

International Markets

The U.S. is one of three major markets for medical device production and use, the other two being the EU and Japan. Each system has a different ethos backing their regulatory body which results in different approaches to their regulatory pathways. Japan’s analog to the FDA, the Pharmaceutical and Medical Device Agency (PMDA), uses a risk-based classification system similar to what is used in the US. They stratify the devices into four classes based on potential risk (Class I is lowest risk, Class IV is highest risk). Unlike the US, however, the devices are independently assessed for risk and not subject to the same comparison to products already on the market. Because Japan is a small nation with a rapidly aging population, the demand for new devices far outpaces their ability to produce them, and there is incentive to allow novel products to enter the market (Reg Desk, 2019).

In the EU, the regulatory process is less centralized in order to retain the autonomy of their member states. Assessments from the appropriate governing body in each country reports data to the European Council (or Conformite Europeenne, CE), who puts their seal of approval on it. Like Japan, they do not require comparison to the standard of care. The European system has been criticized for favoring the market over patient safety because a CE seal does not come with consistent oversight, and with a
decentralized approval and regulation system there is potential for dangerous devices to be used unrestricted by accountability (Van Norman G. A., Drugs and Devices: Comparison of European and U.S. Approval Processes, 2016). As the world becomes smaller and ideas are shared more freely, the challenge of assessing devices approved in other markets becomes an additional regulatory concern.

Concerns about Safety

Categorizing and approving devices can be a lengthy process for companies waiting for their creation to turn them a profit, and the FDA is sometimes criticized for their slow turnaround (EMERGO, 2017). In response to those complaints, the FDA announced in November 2018 that they are further expediting the process by overhauling their 510(k) requirement in response to concerns that their criteria for approval were stifling the market without improving patient safety (LaVito, 2018). However, as mentioned above, the 3 – 7 year time course for the approval of medical devices is a brief wait compared to the time course of marketing new drugs. For some, it seems like an inadequate amount of time to properly assess safety.

One of the challenges of assessing the use and safety of medical technologies including robotics is that there is a dearth of randomized trials to assess effectiveness, and user variation appears to influence the perceived ease and outcomes significantly. Because of this, it can be difficult to separate out the influence of surgical skill level, experience, and machine error when considering patient outcomes. Additionally, the variation in anatomy, body habitus, and medical comorbidities between patients lends a high degree of variability between different instances of the same type of surgery, which further muddies the comparisons in use and outcomes.
Competition for da Vinci

Since the approval of the original da Vinci robot in 2000, its parent company Intuitive Surgical has used the 510(k) pathway to bring updates to the central robotic system as well as nearly one hundred arms, tools, and imaging attachments to market (Medevnet, 2018). Between 2000 and 2017 da Vinci enjoyed a near monopoly on the robot-assisted abdominal surgery market, and the fact that many attachments were existing laparoscopic tools modified for the robot meant that they moved rapidly through the 510(k) process. In 2015 Intuitive had its first real challenger since it bought out Computer Motion in 2003—a startup medical device company called TransEnterix.

TransEnterix was founded in 2006 on venture capital with the primary intent of commercializing the SurgiBot Surgical Robotic System, a single-port laparoscopic surgical platform with “robotic enhancement” (Verdict Medical Devices, 2017). The operation was similar to traditional laparoscopy, with the surgeon standing at the bedside as depicted in Figure 1. The setup for da Vinci, in which the operator sits at a console often across the room from the patient, is depicted in Figure 2 for comparison. The estimated upfront cost would be around $500,000, a quarter of the cost of the da Vinci system, and the familiar physical mechanics would theoretically flatten the steep learning curve that plagues new operators of the da Vinci. The plan was for SurgiBot to be marketed to smaller hospitals and outpatient surgery centers, facilitating a significant expansion in access to robotic surgical systems. The company submitted their device for 510(k) approval based on its similarity to traditional laparoscopy and the inspiration they drew from da Vinci’s existing products, and it was rejected. According to a brief
statement put out by TransEnterix, the FDA did not agree that their device met criteria for substantial equivalence. If they were to bring this device to market it would need to be via the longer, more expensive, and more complex de novo pathway.

At the time the company had another robot in the pipeline, ALF-X (later called Senhance Surgical Robotic System), a multi-port abdominal laparoscopic robot which was a direct competitor for da Vinci’s multi-port system (U.S. Food and Drug Administration, 2017). They integrated haptic feedback and eye-sensing camera control – two major elements missing from da Vinci – and utilized the 510(k) process again to introduce the product along with a wide range of attachments. The price and mechanism were more similar to da Vinci, and this time they were successful, gaining FDA clearance in October 2017 (Verdict Medical Devices, 2019). The company initially stated that they were going to review the FDA’s rejection of SurgiBot and possibly resubmit, but shortly after the approval of ALF-X they reached a deal to release the technology to the Chinese company Great Belief International for $29 million (Perriello, 2017).

Despite seemingly being a match in technology, Sehnahce has struggled to break into the market in which da Vinci has put down such solid roots. In 2018, possibly in response to their new market challenge, Intuitive released a 2 minute video entitled “Intuitive by the Numbers” in which they boast 2700 da Vinci-related patents with almost 2000 more pending, 4409 da Vinci systems deployed across 66 countries, and 43,000 surgeons trained to use their device. In the first year of continuous operation, TransEnterix sold fifteen units, but the rollout in the U.S. was plagued with dissatisfaction with the user experience. After disappointing sales in 2018, the CEO of TransEnterix explained to investors in a second quarter conference call that their
shortcomings were likely due to negative user experience. He said “The U.S. robotics market is mature with the well-established competitor, so potential customers have high expectations. Early Senhance system experience did not consistently delight prospects and customers, which impacted early system evaluations and clinical use." He did not go into detail about the feedback they had gotten, but continued by saying that continued improvements and integration with imaging would lead to a "higher quality, more consistent surgeon experience." By August 2019 they had experienced a stretch of six months without a sale in the US (Taylor, 2019).

They are breaking into some non-US markets (Germany, Japan, and Taiwan), but sales still lag significantly behind the dominance of da Vinci. But despite the flagging sales in the U.S., small studies of implementation have generally positive things to say about the use of Senhance. A group from Imperial College, London looked at Senhance vs traditional laparoscopy, and stated that although the laparoscopic procedures ended up being shorter on average, the Senhance-assisted surgeries were “safe, feasible, and effective” (Aggarwal, et al., 2020). Physicians from Duke had similar sentiments to their counterparts in London. They found that after a few sessions on the Senhance using the Fundamental of Laparoscopic Surgery training modules (various dexterity exercises made to test proficiency with laparoscopic instruments), their small group of fellows, residents, and attendings felt satisfied with the progress they had made. They concluded that a larger scale study on implementation was warranted given this promising survey (Hutchins, et al., 2019). Organized studies highlighting specific issues with Senhance implementation were not found on literature review. This highlights an important issue with the robotic surgery market. De novo device development is pricey and complex, but
while jumping off a previously existing product brings newer ideas to market rapidly, relative familiarity as well as marketing power keep the direction of the market firmly in the hands of Intuitive.

Approval Landscape over the past 20 Years

Ten novel devices have been cleared or approved by the FDA for use in 2020. As devices are approved, the FDA updates their device approvals webpage with the details of each. In 2020 they range from endovascular stents to two new hepatitis B antibody testing systems (U.S. Food and Drug Administration, 2020). Each device title links to a summary of the product, listing the official product name, the company or entity that submitted the application, and the official date of approval as well as a copy of the letter sent from the FDA indicating approval. The page briefly describes the function of the device and the indications and contraindications for use. It also links to three important additional documents: the Summary of Safety and Effectiveness Data (SSED) detailing the results of pre-market safety and effectiveness studies, the product label and insert which describes what comes included with the device and the necessary information to set up and operate the device, and the PMA Database Entry which documents the device’s status as an officially approved device ready for release.

In comparison, 731 devices have been approved so far in 2020 through the 510(k) process, meaning they met the “substantial equivalence” criteria – the device manufacturer proved their product to fundamentally similar to a product already approved, and that it is functionally equal to or better than a similar product on the
market (U.S. Food and Drug Administration, 2020). The FDA states a goal of a review and response time of less than 90 days for 510(k) eligible products. They stuck to this timeline with good success through the early 2000s, with averages of 90 – 102 days between 2000 and 2007. From 2008 to 2010, however, the timeline steadily increased each year with an average of 116 days in 2008 to a peak of 154 days in 2011. To tighten up this timeline the FDA made two major moves: they re-upped their fee structure in 2012 with the Medical Device User Fee Amendments to the FDA Safety and Innovation Act (MDUFA III), and in 2013 they introduced the Refuse to Accept program which rejects applications that do not meet certain formatting and completeness requirements.

MDUFA III expanded the types of manufacturers that were required to pay a user fee which would net the agency an estimated $595 million in additional user fees over the five years from 2012 – 2017 (U.S. Food and Drug Administration, 2019). In exchange, the FDA set and worked toward performance goals, including aiming to get over 90% of 510(k) submissions to market within 90 days. The Refuse to Accept program eliminated some of the delays that came from reviewing applications that ultimately needed revision for completeness or had errors related to formatting (Lindsey, 2014). From 2012 to 2017 the length of time stabilized around 130 days (U.S. Food and Drug Administration, 2018). As mentioned earlier in this report, the FDA announced in 2017 in response to industry pressure that it had been continually working to streamline and shorten the 510(k) process to address ongoing concerns that the agency was delaying progress to market.

The push to get more devices to market began several years prior, with the agency hitting a record-high 98% for high-risk device approvals in 2015, up from 86% in 2014
and 70% in 2012 (Russell, 2015), but that shift has not been without its own concerns. At the behest of the FDA, the Institute of Medicine, an independent non-government agency, investigated the post-market performance of 510(k) devices, and found those devices to be 11 times more likely to be recalled than devices that underwent more detailed approval. David Challoner, the chair of the review committee, was quoted as saying “It’s not clear that the 510(k) process is serving the needs of either the industry or patients, and simply modifying it again will not help...The 510(k) process cannot achieve its stated goals – to promote innovation and make safe, effective devices available to patients in a timely manner – because they are fundamentally at odds with the statutes that govern how FDA must implement the process."

The increasing complexity of devices means that determining safety by comparison is not as simple as it once was, but the push from industry to speed up approval is at odds with adding more scrutiny to the process and continues to be the more successful force in FDA’s process modifications.

Economic Sustainability

After products successfully go to market, the next step is getting them into healthcare settings. The robotic surgery industry continues to grow rapidly and is estimated to bring in $3 billion in revenue annually (Schwitzer, 2018). However, even as the revenue grows, so too do doubts about the benefit of investing in this technology. The calculus of whether a new product is worth an institution’s investment is complex and can be challenging to predict.
In a research letter published in JAMA in 2018, researchers from the David Geffen School of Medicine at UCLA delved into the financial statements of Intuitive Surgical in an effort to accurately break down the costs associated with acquiring, maintaining, and utilizing a surgical robot. Their research was motivated by the scarcity of concrete cost information readily available to consumers and a concern that the economics of this technology was not always apparent to clinicians or administrators making the purchase decisions. They collected Intuitive Surgical’s Form 10-K reports from 1999 – 2017 (Form 10-K is the financial summary that companies are required to submit annually to the US Securities and Exchange Commission). They extracted information about unit sales, sources of revenue (systems, service contracts, instruments and accessories), and procedure volumes in Gynecology, General Surgery, and Urology. The researchers found that 52% of Intuitive’s revenue was derived from instruments and accessories (Christopher P. Childers & Melinda Maggard-Gibbons, 2018).

This is of note because the da Vinci system has been criticized for building obsolescence into their parts (McNamee, 2014). Each robotic arm is recommended to be replaced after ten uses, and a lock-out feature on the robot ensures the robot cannot be used until expired attachments are replaced (Christopher P. Childers & Melinda Maggard-Gibbons, 2018). The researchers remark that Intuitive does not provide clinical data to support this limit – their reasoning is that reuse of instruments requires subjecting them to heat and solvents that may damage their function, and to ensure quality control, replacement is the safest option. In light of the additional $1701 cost per procedure associated with maintaining robotic assisted surgical systems vs laparoscopy, this limitation further creates economic barriers to accessibility.
While the realities of the material cost cannot be ignored, the more fundamental question is whether or not a robotic surgical system is contributing value derived from improvement of patient care. Some are not so sure, and the issue remains one of hot debate. The full set of reported adverse events associated with FDA approved devices is housed in the Manufacturer and User Facility Device Experience (MAUDE) database, maintained by the FDA. A 2016 collaboration of researchers at the University of Illinois at Urbana-Champaign, Rush University, and MIT dove into MAUDE data to summarize and analyze fourteen years of adverse effects related to robotic surgery (2000 – 2013). They found record of 144 deaths, 1391 injuries, and 8061 device malfunctions.

Notably, there were lower numbers of injuries, deaths, and conversions to open surgery per 100,000 procedures in specialties where the robot is more commonly used such as Gynecology and Urology, possibly due to better training because of the volume residents and attendings are exposed to. 30% of all reports were related to gynecologic surgeries, followed by urology (14.7%) then thoracic surgery (3.7%). This is partially explained by the distribution of the surgeries overall, with 86% of all robotic surgeries performed in the U.S. being in one of these three areas. An important caveat to this analysis is that nearly 50% of adverse events did not list the specialty and thus were excluded from their analysis, leaving open the possibility of a skew that the missing data would reveal. See Table 2 for a summary of the full data set.
Dr. James Breeden, the president of the American College of Obstetricians and Gynecologists, issued a strongly worded statement in 2013 urging patients to “separate marketing hype from the reality” when considering a robot-assisted hysterectomy. He argued that the data did not support superiority of robotic approaches, and in some cases showed that it was inferior to traditional minimally invasive approaches (Zimmerman, 2013). His remarks were in response to a paper in JAMA earlier that year comparing robotic-assisted hysterectomy with laparoscopic hysterectomy. The researchers aggregated data from 441 hospitals across the U.S. from 2007 – 2010 and found that despite statistically identical outcomes, robotically-assisted hysterectomy cost an average of $2189 more per case. Also of note, the proportion of cases that were robot-assisted grew during that time from 0.5% in 2007 to 9.5% in 2010. He warned that direct to consumer marketing was selling both patients and clinicians on a technique that was not proven to be superior, and not without new risk.

One of robotic surgery’s great success stories is in the world of Urology, specifically in the treatment of prostate cancer. Prostatectomies (removal of the prostate) have been part of the treatment for prostate cancer since Hugh Hampton Young and William Steward performed the first successful extracapsular perineal prostatectomy at Johns Hopkins in 1904 (Hatzinger, Hubmann, Moll, & Sohn, 2012). At the advent of laparoscopy Urologists were quick to attempt to adapt their procedure, with the first laparoscopic radical prostatectomy performed in 1992. Despite the initial excitement, unique technical challenges related to the anatomy and delicate nature of the structures involved put a damper on this new idea. In Europe where laparoscopy had taken root more fully at that time than in North America, physicians well-versed in those techniques
more readily made the conversion than their laparoscopically less-experienced American counterparts (Skarecky, 2013). In the U.S. prostatectomies continued to be primarily performed open even as laparoscopy rapidly became the gold standard for many bread-and-butter General and Gynecologic surgeries with 70% of cholecystectomies being performed using minimally invasive techniques by 1998 (Morgan K. Richards, Jarod P. McAteer, & F. Thurston Drake, 2015).

The pivotal moment came in 2000 with the introduction of the da Vinci system to market. The enhanced three-dimensional visualization, articulating surgical arms, and natural movements broke through that technical barrier that had stymied the adoption of laparoscopy. This advantage rapidly turned the robotic approach into the gold standard, with over 80% of all radical prostatectomies in the U.S. performed on the da Vinci robot by 2013 (Skarecky, 2013). For many, the hope was that robotic surgery would build on that momentum, opening up new surgical options for qualified patients and further minimizing the collateral tissue damage inflicted when trying to access difficult to reach structures in the body. However, this has not panned out as expected.

One issue is that robotic surgeries may replace what would have been laparoscopic surgeries. This means that rather than increasing the number of minimally invasive surgeries performed, one type of minimally invasive surgery is replaced with another which is more costly and less familiar to many operators. Researchers from the University of Michigan published a study in JAMA in 2019 looking at how the implementation of robotic surgical options in 73 hospitals in Michigan between 2012 and 2018 affected practices surrounding their most common procedures (Gavin, 2020). They found that during the study period the percentage of general surgeries that were robotic
assisted expanded rapidly from 1.8% in 2012 to 15% in 2018. They also noted that in the four years after a hospital acquires a robot they had a small but statistically significant decrease in laparoscopic procedures (0.3%), whereas in the years prior to acquiring a robot the hospitals saw an average yearly increase in laparoscopic procedures of 1.3% annually. This again raises the question of whether robotic surgery is filling a need, or merely replacing a successful technology with something more expensive.

The Lancet published the first fully randomized controlled trial of robotic vs non-robotic surgery for prostate cancer in 2016, and the results were less conclusive than those in favor of the robotic approach would have hoped. The researchers assessed urinary function, sexual function, and biochemical recurrence (positive cancer markers in blood), and found that functional outcomes were not statistically significant in their two groups over the two years of data collection (Coughlin, et al., 2018). They did see a difference in biochemical recurrence, with robotic prostatectomy demonstrating 3% recurrence compared to 13% for the traditional open technique. But they warned against over-emphasis on this finding due to the lack of standardized post-surgical treatment. The cost again comes into question in light of equivocal outcomes.

Perception and Social Impact

The ability to set appropriate expectations for both clinicians and patients depends on balancing perception with experience. Several surveys of physicians and patients have been deployed to assess and characterize how this technology is perceived by these
groups, with the idea that understanding how people see the technology will aid improving how information about options and outcomes are disseminated.

Patient Perception

In a paper published in European Urology in 2008, researchers at Duke surveyed 400 patients who underwent radical prostatectomy between 2000 and 2007. 19% regretted their choice to have surgery, and patients who underwent robot-assisted laparoscopic radical prostatectomy were significantly more likely to be dissatisfied than patients who underwent the traditional open approach, retropubic radical prostatectomy. Interestingly, outcomes in terms of potency and continence were not significantly different between the two groups. The researchers posited that the difference in satisfaction may be a matter of unmet expectations. Patients who are offered robotic surgery may expect that what they are getting is “cutting edge”, and may be more disappointed when they experience the complications that are common with any version of the procedure. The New York Times Well Blog touched on this topic in 2008 in a post “Regrets After Prostate Surgery” citing this study, and noting that patients’ dissatisfaction worsened the farther they were out from surgery, indicating that the persistence of symptoms was a significant source of their disappointment. This speaks to the challenge of communicating the technology to patients. It is important for clinicians to help give their patients realistic expectations, but the glow of technology that feels state of the art can still take root.

A survey performed by physicians at Imperial College London looked at perception from the patient side as well, focusing on patient preferences for physician interaction before, during, and after a robotic surgery. 155 participants were surveyed,
and 52% said they were comfortable with the surgeon being present in the room but away from the operating table during the procedure. Notably, though, 68% stated that they would be uncomfortable if they did not see the surgeon in person before or after surgery. This highlights a key takeaway: while patients show interest in undergoing the most cutting-edge procedure, patient comfort is still tightly bound to the idea that a human, their physician, is present and in control.

Clinician Perception

One of the most fundamental issues for clinicians is their comfort level learning and using the robot. In a 2017 survey of 292 surgeons across different specialties in Kuwait, researchers sent participants a 28 question survey to assess their knowledge of robotic assisted surgery and their perception of its risks and benefits. One notable, but not unsurprising, fact is that younger respondents were more likely to express comfort using robotic technology. A contributor to this disparity may be the fact that older clinicians were required to learn this technique after they had become comfortable using other methods. It may also be that younger doctors who grew up on devices may just have a conceptual comfort with the idea of learning a new device, helping them assimilate this new method more readily than their elder counterparts. Another notable result of their survey was that 50% of respondents believed that laparoscopy was equally effective as robot-assisted surgery, reiterating the concern that robot-assisted techniques do not represent a significant enough departure from laparoscopy to justify the cost and education time necessary.
As discussed earlier in this report, the field of Gynecologic Oncology remains a particularly fierce battleground in implementation and acceptance of robotic surgery, especially as regards hysterectomy. Members of the society of Gynecologic Oncologists were surveyed to assess their opinion on the role of robotic experience in training, their personal experience performing robotic hysterectomy, their perception of the benefit of robotic surgery compared to traditional laparoscopic techniques, and their opinions on whether or not a robotic approach should be considered the “gold standard” for treatment of endometrial cancer. The results re-demonstrated the ongoing split. 40% of respondents felt that training on the robot was an important part of their career goals, 39% felt that robotic surgery was at least as good as laparoscopic surgery, and 23% felt that robot assisted surgery should be the gold standard. In light of the data suggesting that outcomes for robotic approaches have not proven superior to traditional minimally-invasive approaches, this further highlights the challenge as a clinician in balancing environmental influences with data to make decisions for your own practice.

The Trainee Experience

As new technologies are introduced into medicine, the question of integrating them into training immediately arises. The Accreditation Council for Graduate Medical Education (ACGME) is the governing body that sets the fundamental competencies necessary to complete training in each medical specialty. For surgical specialties and subspecialties, the crux of the core requirements is performing some minimum number of each of a set of required procedures before graduation. One problem is that as new technology is introduced into common procedures, what were once considered junior level surgeries may be reserved for upper level residents to give them preferential access
to this new training before they enter practice. A 2016 study of 185,335 surgical cases in the Journal of Surgical Education discussed this phenomenon, which they called “upward shift”. During the study period they noted a steady decline in the overall number of cases performed by residents at the time of graduation, with junior resident participation in cases declining by an average of 4.5% per year between 2005 and 2012 associated with a 6.1% per year in open surgeries. They posited that increased complexity of procedures may be responsible for less operative experience across the board. This indicates that upward shift affects senior residents as well – if an attending physician is still learning a new technique, a resident physician’s opportunity to train and practice is reduced.

In light of data suggesting that outcomes may be correlated to user experience and comfort (Finkelstein, 2010), it is important that training structure and requirements update along with the quickly changing field. This is important to keep new physicians’ skills in line with the available technology, but perhaps even more essential is that trainees see the technology through experience not just marketing. Personal experience with the risks and benefits is an important part of appropriately counseling patients on what would work best for their particular case, growing your own way of practicing, and giving meaningful feedback to manufacturers and developers that keep moving the field forward.

A concern about exactly how far the reach of robots will go underlies the whole issue. As of now, all approved indications for surgical robots are “robot assisted”. This means that each step is directly commanded by the human operator, and the robot acts just as a sophisticated instrument. There have been some moves to see if robots can be given some more control, however. In 2016, a group of researchers from the Sheikh
Zayed Institute for Pediatric Surgical Innovation at Children’s National Medical center published their work on supervised autonomous soft tissue surgery. They designed a “Smart Tissue Autonomous Robot” (STAR) which was used to do an anastomosis (re-sewing cut ends of intestine together after a section is removed) on pig intestine. The machine utilized adapted robotic suturing arms, fluorescent and 3D imaging to visualize the tissue, force sensors to adapt to the pliable tissue, and precise positioning motors. The metrics for assessment were consistency of suturing (average suture spacing), pressure at which the anastomosis could be caused to leak, the number of times the needle was removed from the tissue due to a mistake, completion time, and lumen reduction (also known as stenosis, which is a potential cause of intestinal blockage and rehospitalization after bowel resection). They compared the results to open suturing, laparoscopy, and robot-assisted surgery and found the STAR system to be superior (Strickland, 2016). The technology is still in its infancy but the authors, surgeons among them, state boldly that the operating room may someday be run by robots with surgeons overseeing them.

While the prospect of consistent, safe automated robotic assistance is an exciting idea for technology and patient outcomes, it would change the face of the surgical profession immensely. If safe and scalable, the surgeon’s primary focus would change from being skilled hands in the OR to primarily being the supervisor of the robot’s moves. It will likely always be necessary for the surgeon to be able to assume manual control in case of malfunction or complexity that the robot is unable to comprehend. But this brings the question of training to the fore again – as robots become more proficient it will not only become less necessary for surgeons to intervene, there will be fewer opportunities to learn to do so in the course of training. Simulation may be able to
supplant those experiences, but the lack of real-time, real-world training will fundamentally change the skill set that surgeons leave residency with.
Chapter IV:

Conclusions

The industry of robotic surgery has expanded quickly since its inception and continues to reshape the surgical field, particularly in General Surgery, Urology, and Gynecology. This examination demonstrates some of the ways in which regulatory, economic, and social factors influence the market and implementation landscape, even while conclusions regarding the clinical usefulness of robotic surgery remains an area of contention.

The da Vinci robot has dominated the industry since its approval in 2000, and its stronghold on the market poses a challenge for new devices struggling to get the financial or emotional foothold necessary to lure physicians away from the robot they have grown familiar with. The danger there is that challengers who intend to address da Vinci’s shortcomings (such as lack of haptic feedback) may not get the opportunity to truly bring their device head to head with Intuitive’s well-established suite of robots and tools. The case of Intuitive’s most recent challenger, TransEnterix, is a prime example – a hopeful innovation that promised to address complaints regarding cost and function was offloaded after one failed shot at approval, and the machine that ended up coming more easily to market was just as expensive as da Vinci, eliminating one of their biggest potential benefits to hospitals and consumers. And even though they were successful in producing an approved device, it has struggled in the shadow of its too-similar predecessor.
On the regulatory side, the opposing goals of maintaining rigorous evaluation for approval without discouraging innovation continues to be a challenge for the FDA. The relative speed of the 510(k) clearance process compared to lengthier and more expensive de novo product approval means that the regulatory structure favors incremental alterations, but may put up prohibitive barriers to novel ideas. With current technology, iterations of ideas can be produced quickly through machine learning and other digital development tools, likely more quickly than the FDA can update their regulatory structure. From an investment standpoint, both financial and time-wise, it may be more profitable to develop updates or attachments to existing systems than it is to see a new idea through to market. New ideas require significant investment, and this sometimes-opaque gate to the market can make that investment a hard sell. For academic institutions, the funding may not even be available to put into something so uncertain. But without that capital, an industry-disrupting new concept may be shelved regardless of clinical promise, robbing patients of its potential benefit.

The current situation in global health has brought remote medicine to the fore in a new way. Doctor’s offices that have been able to quickly scale up their telemedicine capabilities have entered territory that had been discussed for years but has been accelerated by necessity. Laws that stifled telemedicine by limiting physicians to states in which they were licensed, even if seeing patients online, are being lifted. As of May 2020, 49 states, Guam, the Northern Mariana Islands, and Puerto Rico have waived the in-state license requirement for telehealth visits (Federation of State Medical Boards, 2020). Development of the tools needed to expand medical access into areas that struggle with physical accessibility has been propelled forward by the necessity brought on by
social distancing, and has the potential to change the landscape of medicine even after the COVID-19 pandemic restrictions are lifted.

On the surgical side, follow up visits have also benefitted from recent strides in telehealth, but many surgical services are accumulating ever-growing backlogs of elective surgeries. What’s more, hospital systems whose finances often rely heavily on the money brought in by those elective surgeries are taking a blow financially as the delays continue. Remote surgery is possible and has been done successfully, and proponents of robotic surgery often mention its potential to aid in bringing care to remote or dangerous areas. A 2014 story in BBC profiled Dr. Mehran Anvari, a Canadian General Surgeon who has performed over 20 operations on patients in remote community hospitals in Canada from his console at St. Joseph’s Hospital in Hamilton, Canada. Dr. Anvari states that with imperceptible 175 millisecond lag and well-established technology, the only thing holding us back from more widespread implementation is perception. People fear medical tourism, complex liability issues, and patient’s desire noted earlier in this thesis to come face to face with their surgeon during their hospital course (Eveleth, 2014). Perhaps this time in history is the chance to convert remote robotic surgery from curiosity to part of practice and increase the reach of expertise to patients who don’t currently have access to the healthcare system as it currently exists.

Robots have had a place in the world’s imagination since ancient times – the idea of an inanimate object dedicated to alleviating our work and smoothing over our human errors remains an alluring thought. Capturing the imagination of the public is an important part of selling anything – including science – but as surveys of both clinicians and patients show, excitement about (or suspicion of) technology can easily overtake
sparse outcomes data when making decisions of use and investment. There is a need for
diligent collection of outcomes data and further randomized controlled trials to give
patients and physicians the data they need to make educated decisions and help shape the
continually changing landscape of surgery in years to come.
Appendix 1:

Figures

Figure 3. TransEnterix SurgiBot Surgical System

*Physician position is at the bedside, similar to traditional laparoscopy (Peters, Armijo, & Krause, 2018)*

Figure 4. Intuitive Surgical da Vinci Surgical System

*Physician position is at a console, with tech and/or nurse at the bedside (Rush Health Systems, 2020)*
Figure 5: Prostatectomy

The red arrows in the image show the planes along which the prostate (center) must be freed from the surrounding tissue. Notice the close proximity of the neurovascular bundle (depicted as a red artery, blue vein, and yellow nerve plexus). These vessels and nerves supply the groin area and genitals, and damage can lead to impotence and incontinence. (Tower Urology at Cedars-Sinai, 2018)

Figure 6: Gallbladder anatomy relevant to cholecystectomy

Cholecystectomy involves removing the gallbladder, labeled above, by separating it from the liver bed and cutting the cystic duct. A common complication is injury to the adjacent common bile duct. (FV Hospital, 2016)
Figure 7: Hysterectomy

The image depicts a rendering the view of the uterus from the superior aspect during robotic surgery. This step shown is the colpotomy, an incision in the posterior portion of the vaginal canal, which is the start of the separation of the uterus from the vaginal canal. (3D Systems, 2017)
Appendix 2:

Tables

<table>
<thead>
<tr>
<th>Surgical Specialty</th>
<th>Procedure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac</td>
<td>Coronary artery bypass grafting</td>
<td>Surgery in which a partially or fully blocked coronary artery (artery supplying the heart tissue) is bypassed by grafting a piece of a vein above and below the blocked area of a coronary artery, enabling blood to flow around the obstruction. The veins are usually taken from the leg but may be taken from the chest.</td>
</tr>
<tr>
<td></td>
<td>Mitral valve repair</td>
<td>Mitral valve repair refers to a multitude of procedures that reinforce, repair, or rearrange parts of the mitral valve, the opening between the left atrium and left ventricle of the heart.</td>
</tr>
<tr>
<td>Colorectal</td>
<td>Colon resection</td>
<td>Removal of part of the large intestine (colon) which may be done to treat cancer of the colon or inflammatory conditions such as ulcerative colitis or diverticulitis.</td>
</tr>
<tr>
<td></td>
<td>Rectal resection</td>
<td>In this operation, the surgeon cuts through all layers of the rectal wall to take out the cancer as well as some surrounding normal rectal tissue. The hole in the rectal wall is then closed.</td>
</tr>
<tr>
<td></td>
<td>Rectocelepx</td>
<td>An operation in which the rectum (the part of the bowel nearest the anus) is put back into its normal position in the pelvis. One of the most common reasons for patients to undergo this surgery is external rectal prolapse (bowel coming out through the anus).</td>
</tr>
<tr>
<td>General Surgery</td>
<td>Bariatric surgery</td>
<td>The most common is “Roux-en-Y” gastric bypass, or RYGB. The surgeon leaves only a very small part of the stomach (called the pouch). That pouch can't hold a lot of food, and the food you eat bypasses the rest of the stomach, going straight from the pouch to your small intestine.</td>
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<tr>
<td></td>
<td>Cholecystectomy</td>
<td>Surgery to remove the gallbladder (a pear-shaped sac near the right lobe of the liver that holds bile). A gallbladder may need to be removed if the organ is prone to troublesome gallstones, if it is infected, or becomes cancerous.</td>
</tr>
<tr>
<td></td>
<td>Hernia repair</td>
<td>Hernias are when abdominal contents bulge through a weak area in the lower abdominal muscles or groin. Surgical repair pulls the intestine back to its original location and may reinforce the weak area with mesh.</td>
</tr>
<tr>
<td></td>
<td>Nissen fundoplication</td>
<td>A procedure to treat severe reflux in which the surgeon wraps the top of the stomach around the lower esophagus. This reinforces the lower esophageal sphincter, making it less likely that acid will back up in the esophagus.</td>
</tr>
<tr>
<td></td>
<td>Gastrectomy</td>
<td>Surgical removal of all or part of the stomach, most commonly for stomach cancer.</td>
</tr>
<tr>
<td></td>
<td>Whipple procedure</td>
<td>A complex operation to remove the head of the pancreas, the first part of the small intestine (duodenum), the gallbladder and the bile duct. It is used to treat tumors and other disorders of the pancreas, intestine and bile duct.</td>
</tr>
<tr>
<td></td>
<td>Small bowel resection</td>
<td>Surgical removal of a portion of the small intestine</td>
</tr>
<tr>
<td></td>
<td>Spleenectomy</td>
<td>Surgical removal of the spleen</td>
</tr>
<tr>
<td>Gynecology</td>
<td>Hysterectomy</td>
<td>Surgical removal of a woman's uterus. This may be done through an abdominal incision or vaginally. The ovaries may be removed at the same time.</td>
</tr>
<tr>
<td></td>
<td>Pelvic organ prolapse surgery</td>
<td>In cases of pelvic organ prolapse, there is laxity of vaginal support resulting in protrusion of the pelvic organs. The goal of laparoscopic colposuspension is to resuspend the vagina and associated pelvic organs through the key-hole incisions</td>
</tr>
<tr>
<td></td>
<td>Myomectomy</td>
<td>A surgical procedure to remove uterine fibroids, common noncancerous growths appear in the uterus.</td>
</tr>
<tr>
<td></td>
<td>Endometriosis resection</td>
<td>Abnormal implantations of uterine tissue in the abdomen (endometriosis) are excised or ablated with electrocautery.</td>
</tr>
<tr>
<td>Head and Neck</td>
<td>Resection of benign and malignant tumors of the mouth and throat &lt;4cm</td>
<td>Surgical removal of masses in the mouth or throat. For larger masses, and open approach is more appropriate for better visualization and dexterity.</td>
</tr>
<tr>
<td></td>
<td>Benign base of tongue resections</td>
<td>Surgical removal of part of the base of the tongue, usually secondary to cancer of that portion of the tongue</td>
</tr>
<tr>
<td>Thoracic</td>
<td>Lobectomy</td>
<td>Surgical removal of one or more lobes of the lung</td>
</tr>
<tr>
<td></td>
<td>Thymectomy</td>
<td>The surgical removal of the thymus gland, which has been shown to play a role in the development of myasthenia gravis. Roughly 10 percent of patients with myasthenia gravis have a thymoma, or a tumor on the thymus gland. While most of these slow-growing tumors are benign, some may be cancerous (malignant).</td>
</tr>
<tr>
<td>Urology</td>
<td>Prostatectomy</td>
<td>Operation to remove the prostate gland and tissues surrounding it. This usually includes the seminal vesicles and some nearby lymph nodes. Radical prostatectomy can cure prostate cancer in men whose cancer is limited to the prostate</td>
</tr>
<tr>
<td></td>
<td>Nephrectomy</td>
<td>Surgical removal of one or both of the kidneys</td>
</tr>
<tr>
<td></td>
<td>Renal cyst removal</td>
<td>Surgical removal of a large fluid filled sac in the kidney</td>
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<tr>
<td></td>
<td>Pyeloplasty</td>
<td>Pyeloplasty is the surgical reconstruction of the renal pelvis (a part of the kidney) to drain and decompress the kidney. In nearly all cases, the goal of the surgery is to relieve a uretero-pelvic junction (UPJ) obstruction.</td>
</tr>
<tr>
<td></td>
<td>Ureteral implantation</td>
<td>Ureteral reimplantation is a surgery to fix the tubes that connect the bladder to the kidneys. The surgery changes the position of the tubes at the point where they join the bladder to stop urine from backing up into the kidneys.</td>
</tr>
</tbody>
</table>
Table 1: Procedures Utilizing da Vinci

*A list of the most commonly performed da Vinci procedures, from the manufacturer’s website. The procedures in bold are the most common overall, and relevant to the current discussion. Of note: appendectomy is left off this list. The speed/relative simplicity of open or laparoscopic appendectomy means that the setup associated with robot assistance could more than double the length of time in the operating room. (Mayo Clinic, 2020) (Intuitive Surgical, 2020)*

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Gynecology</th>
<th>Urology</th>
<th>Cardiothoracic</th>
<th>Head &amp; Neck</th>
<th>Colorectal</th>
<th>General</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>3,194</td>
<td>1,565</td>
<td>393</td>
<td>71</td>
<td>301</td>
<td>197</td>
<td>4,903</td>
</tr>
<tr>
<td>% of Overall</td>
<td>(30.1)</td>
<td>(14.7)</td>
<td>(3.7)</td>
<td>(0.7)</td>
<td>(2.8)</td>
<td>(1.9)</td>
<td>(46.2)</td>
</tr>
<tr>
<td>95% Confidence</td>
<td>[29.2–31.0]</td>
<td>[14.0–15.4]</td>
<td>[3.3–4.1]</td>
<td>[0.5–0.9]</td>
<td>[2.5–3.1]</td>
<td>[1.6–2.2]</td>
<td>[45.3–47.1]</td>
</tr>
<tr>
<td>Event Type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>46</td>
<td>30</td>
<td>25</td>
<td>14</td>
<td>11</td>
<td>11</td>
<td>7</td>
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<td>Nephrectomy (138)</td>
<td>Lobectomy (67)</td>
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<td>Pyeloplasty (31)</td>
<td>Mitral valve repair (54)</td>
<td>Transoral robotic (18)</td>
<td>Low anterior resection (44)</td>
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<td>Oophorectomy (120)</td>
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<td>Cystectomy (48)</td>
<td>Coronary artery bypass (23)</td>
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Table 2: Robotic Surgery Adverse Events 2000 - 2013

*All adverse events associated with robotic-assisted surgery recorded in the MAUDE database from 2000 – 2013 (Alemzadeh, Raman, Leveson, Kalbarczyk, & Iyer, 2016)*
Works Cited


Academy of Managed Care Pharmacy. (2017). *What Are Biologics?* Retrieved from biosimilarsresourcecenter.org:
https://www.biosimilarsresourcecenter.org/faq/what-are-biologics/


EMERGO. (2017, March). How long it takes the US FDA to clear medical devices via the 510(k) process. Retrieved from


https://www.mayoclinic.org/tests-procedures

McNamee, D. (2014, August 1). *Are robots the future of surgery, or a pricey marketing gimmick?* Retrieved from Medical News Today:
https://www.medicalnewstoday.com/articles/280518

http://510k.medevnet.com/applications/index.cfm?fuseaction=list&applicant=INTUITIVE%20SURGICAL%2C%20INC%2E


https://www.therobotreport.com/transenterix-deals-surgibot-assets-29m-chinas-great-belief-international/


How Drugs are Developed and Approved. Retrieved from FDA.gov: https://www.fda.gov/drugs/development-approval-process-drugs/how-drugs-are-developed-and-approved


https://www.medicaldevice-network.com/comment/robotic-surgery-companies/

Wilson, T. (2019). *No longer science fiction, AI and robotics are transforming healthcare*. Retrieved from PWC.com:

https://www.wbur.org/commonhealth/2013/03/15/ob-gyns-beware-marketing-hype-on-robotic-hysterectomy
References


EMERGO. (2017, March). How long it takes the US FDA to clear medical devices via the 510(k) process. Retrieved from


https://www.mayoclinic.org/tests-procedures

McNamee, D. (2014, August 1). *Are robots the future of surgery, or a pricey marketing gimmick?* Retrieved from Medical News Today:

https://www.medicalnewstoday.com/articles/280518


http://510k.medevnet.com/applications/index.cfm?fuseaction=list&applicant=INTUITIVE%20SURGICAL%20INC


https://www.therobotreport.com/transenterix-deals-surgibot-assets-29m-chinas-great-belief-international/


https://www.medicaldevice-network.com/comment/robotic-surgery-companies/

Wilson, T. (2019). *No longer science fiction, AI and robotics are transforming healthcare*. Retrieved from PWC.com:

https://www.wbur.org/commonhealth/2013/03/15/ob-gyns-beware-marketing-hype-on-robotic-hysterectomy