Robotic Surgery: Transforming Patient Care in the 21st Century?

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Abstract

Inspired by a notion that machines can emulate human touch, the paper first examines the adoption of surgical robots in operating rooms at the global and local levels. The adoption of the technology has occurred almost concurrently in many countries without much time lag, and this near-simultaneous acceptance of the technology invites us to rethink technological supremacy in relation to patient care in the field of surgery. With focus on the da Vinci surgical system, this paper presents social and ethical implications of how (not) to regulate robotic surgery with potential and invisible risks with respect to patient care. Based on documentary analysis of news media in combination with literature review of medical journals, Korean news media, and Korean technology assessment reports on surgical robots, the paper explores how prevalently the idea of social progress is embedded in the promotion of advanced technology at the societal and governmental levels. I contend that the ideology of social enhancement has served to shape regulatory practices (or their absence) at the expense of patient care in emergent technologies such as robotic surgery in South Korea. Thus, social scientists and bioethicists should be involved in articulating ethical dimensions of the technology even from the stage of development in order to remedy the gap between technical advancement in surgery and patient care.

Keywords: da Vinci Surgical System, Robotic Surgery, Human Touch, Patient Care

I. Introduction: High-Technologization of Patient Care

In the age of mechanical automation and computerization that devices and software programs can replace or complement human capacities, what makes a good surgeon and a good surgical operation? A good surgery can be translated into improved quality of life from the perspective of the patient. The surgeon’s skillful hands and trained eyes are crucial to

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perform good surgical operations, as the core task of surgery used to be cutting and sewing with hand instruments such as scalpels and knives. The surgeon needs dexterous hands to touch the surgical site, being able to manipulate tactile information in operational terms along with good vision and wise judgment. However, human eyes and hands have limited capacities to penetrate into the inside of the body, and medical devices have been brought into the operating room to improve precision and accuracy of surgery. As a way to overcome the limits of human beings’ capabilities, automatic and computing machines have been introduced into the hospital care, to which I refer as high-technologization. Contemporary technologies, whether surgical or biomedical, have been contrived to extend human capacities and minimize human errors in order to enhance human performance. The underlying assumption is that the mechanization of surgical procedures and operations helps enhance human dexterity as well as quality of surgery.

As surgical innovations continue to emerge, they are regularly introduced into operating rooms not simply because of their inventiveness. Rather their adoption is contingent on social, economic, interpersonal, and administrative circumstances as well as on marketing efforts. When the medical innovation enters into the operating room, it is portrayed, via media and commercial channels, to minimize pain and invasiveness by advertising its invention with technical and scientific details. That techno-focused portrayal of the

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technology speaks positively to potential patients, surgeons, and hospital administrators that the technologized surgical procedure would enhance the quality of care by replacing or complementing human beings’ hands and vision. It is this technologically deterministic belief that has directed the displacement of human’s touch with the patient in the operating room. Hence, hospital administrators, surgeons, or patients may feel pressured to use them because of their perceived promises, meanings, and utility values.9

In this paper I pay particular attention to high-technologization of patient care with focus on the da Vinci surgical system, as the hospital is the center for patient care in the twenty first century. The da Vinci surgical system is an iconic representation of a latest medical innovation that has been widely adopted in hospitals worldwide because of its supposed enhancement in perioperative and functional outcomes.10,11,12 In South Korea the surgical system has gained wide popularity at major teaching hospitals almost at the same pace, since its first adoption in 2005. Over a short period of time its operable areas have been extended to numerous cancers and general surgery from prostate cancer.13,14,15,16

High technologization of surgical procedures poses new challenges to hospital administrators, professional surgeons, and patients regarding how surgeons’ new skills are credentialled and how patient care in terms of safety and treatment is guaranteed.17 In


17 Pradarelli C. J., Campbell A. D. & Dimick B. J., “Hospital Credentializing and Privileging of Surgeons a
case of the da Vinci surgical system, it is the manufacturer, Intuitive Surgical, Inc. based in California, USA, who trains and instructs the surgeon to get acquainted with the surgical system, which is required by the hospital as a credentialing process. Considering that the manufacturing company is deeply involved with patient care at multiple levels from development to training, we can and should ask who is liable to secure safety of innovative technologies and surgical procedures? On the other hand, we can also ask to what extent the surgeon’s skills can be translated into the mechanical parts and vice versa? It is well observed that the acquisition of skills involves informal and tacit knowledge that is hard to articulate and it is not written in the manual instructions.\textsuperscript{18,19,20} The delicacy of personal knowledge is hard to quantify and measure and may be left out in the process of translating human’s dexterity to the mechanical device. If so, how do we know that the mechanical hand performs better than the human’s hand?

In the following the paper first examines the adoption of surgical robots in operating rooms at the global and local levels. The adoption of the technology has occurred almost concurrently in many countries without much time lag, and this near-simultaneous acceptance of the technology invites us to critically rethink the relationship between medical innovation and patient care. Can and will the machine replace human touch and human care? What are ethical consequences of the technologization of patient care?

\textbf{II. Research Methods and Data Collection}

The paper is based on the data extracted from literature review of medical journals, popular newspapers and magazines, and South Korean government’s policy reports.

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First, I surveyed professional publications dealing with ‘robotic surgery’ to get myself familiarized with the robotic surgical system and its clinical application, using ScienceDirect, MedlinePlus, PubMed, and reviewed articles that have been published from the 1990s to 2013. Second, Korea medical literature was reviewed from 1990 to 2013, including Korean journal of bronchoesophagology, Korean journal of endoscopic & laparoscopic surgeons, and related journals that popped up with the keyword search of robotic surgery. I reviewed professional journals written in English, while the analysis of Korea popular media was done to see a changing value of robotic surgery in the Korean society. Major national newspaper articles were reviewed from 1990 to 2013 using digital archival resource (www.kinds.or.kr), a national database of newspapers and magazines. A keyword search of ‘robotic surgery,’ ‘robot-assisted surgery,’ ‘da Vinci,’ and ‘surgical robot’ in Korean was done to trace how the media has depicted robot-assisted surgery given the time periods. Third, the paper draws on three technology assessment reports about the da Vinci surgical system.

As many more medical devices, either domestically produced or imported, have entered into various health-related institutions, the South Korean government was under pressure to strengthen regulatory standards and principles to assess the safety of innovative technologies from interested professional and consumer groups. Hence, when the da Vinci surgical system has gained popularity at major general hospitals, the South Korean government commissioned National Evidence-based healthcare Collaborating Agency (NECA) to evaluate and assess potential risks and safety of medical devices and technologies. In 2008, the Agency created a technology assessment committee whose membership is comprised of healthcare experts. New Health Technology Assessment (nHTA) is a government agency to assess and evaluate the safety and effectiveness of new health technologies. Based on a systematic meta-analysis of published literature, nHTA’s purpose is to investigate “safety” and “effectiveness” of the emerging technology. In 2010, the Agency published a first report of meta-analysis of robotic surgery in Korea and continues updating the analysis regularly. Lastly, consultation with surgeons and engineers were conducted between 2007 and 2016 on and off at a university teaching hospital in downtown Seoul and a technical university located in east coast of Korea in order to gain a better sense of how the technologization of society could be appreciated in a respective field.
III. A Brief Overview of the da Vinci Surgical System

Surgical robots refer to medical devices that perform invasion, cutting, suturing, and the like in lieu of the surgeon’s hand. The robots can either be controlled by the surgeon or be autonomous so that they function in accordance with preprogrammed operational procedures.\textsuperscript{21,22} In the past two decades, machines labeled as surgical robots have developed in directions that are purported to enhance surgeon’s performance. For instance, AESOP (Automatic Endoscopic System for Optimal Positioning) was a first surgical robot approved by the US FDA in 1994, whose main function was to help the surgeon better peek into the inside of the patient’s body. When it turned out that surgeon’s active engagement with the machine was necessary to use it, the machine got the verdict that it was inefficient. Accordingly, the next version of surgical devices was to minimize human’s action by introducing voice command to activate visualization process.\textsuperscript{23}

The emergence of the da Vinci surgical system dates back to the moment when two concepts, telepresence (virtual reality) and telemanipulation were merged.\textsuperscript{24,25} In 1972, the US National Aeronautics and Space Administration (NASA) was interested in developing a system that could provide surgical care to orbiting astronauts. NASA experimented with the concept of telepresence surgery, which referred to the remote operation of a machine to perform a surgical procedure.\textsuperscript{26} In the 1980s, the Army sponsored Stanford Research Institute (SRI), a research institute based in California, USA, to work on improving the latest surgical techniques of that time, namely minimally invasive surgical techniques (MIS), or laparoscopic surgery. In MIS endoscopic instruments are inserted into the body through small

\textsuperscript{21} Rha Koon Ho 나군호, \\Euiryogigi Yimsangsheom protocol gaebal 의료기기 임상시험 프로토콜 개발: 복강경수술로봇 [Development of Clinical Investigation Protocol for Medical Instruments: Surgical Robotic System] (Seoul: Korea Food and Drug Administration, 2008).

\textsuperscript{22} De Wilde L. R. & Herrmann A., “Robotic surgery-- Advance or gimmick?” Best Practice & Research Clinical Obstetrics and Gynaecology 27 (2013): 457-69. The term “robot” was derived from the Czech word “robota,” meaning “forced labor” or “serf.”

\textsuperscript{23} Rha, Euiryogigi 의료기기 [Medical Instruments].


\textsuperscript{26} http://www.sri.com/engage/products-solutions/m7-surgical-robot.
incision, and long manipulators are used to perform operations under manual guidance. As compared with open surgical techniques, this surgical procedure was touted to minimize the collateral surgical trauma of an access incision and thereby to ensure quicker postoperative recovery. What the SRI research team aimed to technologically fix were such drawbacks associated with MIS as loss of wrist articulation, poor haptic feedback, the fulcrum effect, loss of 3-dimensional vision, and poor ergonomics of the tools.

Building on the research outcomes, in 1995 the Intuitive Surgical Corporation based in California, US, was founded to commercialize telerobotic surgical system. From the beginning the company’s goal was explicit to make human-robot interface transparent in order for a surgeon to use one’s full set of skills “in natural and instinctive manner” (Camarillo 2004, 10S). The company invoked the image and imagination that the technology was no different from human hands with advanced precision and accuracy. Naming after Leonardo da Vinci, the da Vinci surgical robot was born. The da Vinci Surgical® system was consisted of three major parts in the form of a master-slave system: a surgical cart that performs the procedures with robotic arms, a vision cart, and the surgeon’s console. According to the description of the company’s website, core technologies were as follows: 3D enhanced vision, a micro-electro-mechanical joint namely EndoWrist®, and motion technology. EndoWrist was functionally akin to a human wrist and designed to simulate surgeon’s hand movements. As compared with existing mechanical devices, EndoWrist was engineered to retain higher mobility with 7 degrees of freedom. Its mechanically adjusted precision could reduce or minimize blood loss, infection, and side effects, as if “extending or enhancing human capabilities rather than replacing humans” (Camarillo 2004, 3S). Furthermore, the surgical system was equipped with 10-15 times more upgraded vision than naked eyes. The enhanced vision was expected to see fine blood vessels and neural nerves, which would redefine and refine surgical accuracy. To sum up, regardless of how difficult or easy

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it was for the surgeon to synchronize with the robotic system, mechanical accuracy and
precision was understood to stand for enhanced human performance.

In 2000, when the company sought regulatory clearance for sales on the market, it applied
to the US Food and Drug Administration (USFDA) for premarket approval by labeling the
surgical system as minimally invasive techniques. The USFDA granted sales permission
under “premarket notification.” When seeking premarket notification, the company needed
to demonstrate that the da Vinci surgical system was, at least, as safe and effective as existing
MIS techniques in terms of its intended use, performance, and functionality. Premarket
approval can be a controversial process, because manufacturers of medical devices can avoid
undergoing rigorous trials of safety and efficacy with a claim that an innovation is similar to
the ones already existing on the market. To be accepted as a standard procedure in the fields
of surgery, it is a common sense that objective clinical evidence should be established. In the
fields of medical and pharmaceutical innovations, double-blind randomized clinical trials
(RCTs) have been devised to minimize the variability of clinical evaluation and to provide
unbiased evaluation of the innovation. Hence, RCTs are taken as a gold standard to assess
the safety and efficacy of medical innovations. As stated above, da Vinci surgical system
was approved via premarket notification, which means that the company was exempt from
conducting rigorous RCTs for approval. Rather the company supported various sorts of
clinical research such as retrospective study, prospective study, and cohort study to build the
evidence that the surgical system is effective and safe to use. Only small portion of

33 Suresh K. P., “An Overview of Randomization Techniques: An Unbiased Assessment of Outcome in
34 Aboumarzouk O. et al., “Robotic versus Laparoscopic Partial Nephrectomy: A Systematic Review and Meta-
38 Sgabura O. V., Blajut C. T. & Popescu I., “A 5-Year Perspective over Robotic General Surgery: Indications,
research has been done to compare robotic surgery with laparoscopy in terms of safety and effectiveness, but showing no obvious difference between short-term outcome measures.\(^\text{39,40}\) Despite the lack of systematic evaluation and assessment, physicians as well as patients prefer to do robotic surgery given a choice because of expectations about “new” technology.\(^\text{41}\) The reason can be attributed to the company’s aggressive marketing. Similar to pharmaceutical corporations’ marketing strategies of new drugs,\(^\text{42,43}\) Intuitive Surgical Inc. has diversified its marketing tactics from regulatory clearance strategies. When seeking sales approval from the regulatory agency, it spoke to safety and effectiveness comparable to existing technologies rather than labeling it as a new invention incomparable to existing ones. However, when marketing the technology to hospitals, surgeons, and patients, it employed repertoires and tactics drawing on technologically advanced details of its product. In the domain of robotic surgery, the company presently monopolizes the global market, and its revenues are derived from the sales of the surgical system and its expendable parts.\(^\text{44}\)

The surgical system has been used for more than 1.5 million operational procedures. First applied to prostatectomy, operable areas of surgery has been extended to various specialties to include urology (over 45% reported surgeries are done in the field), cardiothoracic surgery (next common surgery accounting for about 15%), gynecological surgery, pediatric surgery, gastric surgery, and the like.\(^\text{45}\)

Notwithstanding wide usage of the surgical system, it is still controversial to define what it means to be safe with highly mobile electromechanical devices, and thereby it

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41 Ibid.


45 http://www.intuitivesurgical.com/company/clinical-evidence/.
is challenging to impose standard regulatory guidelines across the fields.\textsuperscript{46,47} The lack of consensus within the expert community poses a major hurdle as to how to train surgeons, let alone defining what is good and successful surgery, on the one hand. On the other hand, it poses a more fundamental question about patient care with respect to the innovation.

\section*{IV. Robotic Surgery in South Korea}

A history of surgery in biomedical practices in South Korea dates back to late nineteenth century when an American missionary successfully treated a deadly wounded royal prince. That memorable event took place at the time when the Korean society was about a doorstep away from entering into unavoidable historical processes of modernization. The surgery went well to everyone’s amazement, whose success served as a “landing gear”\textsuperscript{48} for Western medicine. In particular, it worked favorably for surgical practices to land where Korean medicine with origins in China had been practiced as an orthodox medicine. In 1885 the first Western hospital of its kind was founded under the aegis of the royal court and began treating patients with Western medicine in conjunction with Korean medicine.\textsuperscript{49} About 125 years later, physicians at Yonsei Severance hospital, which is a forerunner of Western biomedicine, proudly announced that they began to export surgical skills and knowledge. Evoking emotional sentiment of collective national community, the hospital expressed to the press that they finally began to stay ahead in a race for frontier technology.\textsuperscript{50} Started as an imported profession, South Korea surgeons felt that they began to lead the robotic surgical field in


\textsuperscript{49} Yonsei University Health System 연세대학교 의료원. \textit{Sajineuro bon Hanguk Geundaeuihak 120nyun (1885–1957) 사건으로 본 한국 근대의학 120년 (1885~1957) [A Photographic One Hundred Twenty Years of Korean Modern Medicine (1885-1957)]} (Seoul: Yonsei University Health System, 2007).

\textsuperscript{50} Geum Gi Chang 금기창, “Usuldo suchulsaneop” 의술도 수출산업 [Surgery as an Export Business]. \textit{Seoul Sinmun} 서울신문, December 14, 2009. In the press, the hospital used such collective identity as “we,” as though their achievement were representative of national pride. In 2010, Gary Guthart, the president of Intuitive Surgical, Inc., visited Yonsei Severance hospital to establish good working partnership with South Korea hospitals.
terms of surgical skills and numbers of performed surgical operations. More significantly, they emphasized that some of innovative procedures were listed as international standard procedures in the fields of gastric cancer, rectal cancer, and thyroid cancer.51

Many surgeons, who were interested in robotic surgery, went abroad to get training and turned into avid advocates of robot-assisted surgery.52,53,54,55,56,57,58 Partly because of their lobby and support, in July 2005 Korea FDA approved the da Vinci Surgical system. Yonsei Severance Hospital was active to adopt robot-assisted surgical techniques and introduced da Vinci system into surgery in 2005. By 2011, more than 30 general hospitals across the country competitively installed the da Vinci system for surgical operations. Once in competition for domestic and international clientele, a race to fast-follow seems to take place at an unstoppable speed as long as the technologically deterministic belief prevails that the degree of technologization helps build the public image of the hospital as a competent and reliable place to get surgery.59 Over the course the number of patients who received robotic


59 Choi, “Ttaedon” 터돈 [A Huge Profit]. Around that time major hospitals across the nation opened da Vinci Surgical Robot centers with more appeal to personalized medicine. See also at http://www.cmceseoul.or.kr/examination/center_20_02.jsp.
surgery has exponentially increased from 17 patients in 2005 to 6,318 patients in 2011. The operable areas of the robotic surgery have been expanded from prostate cancer to rectal cancer, esophageal cancer, bladder cancer, colon cancer, thyroid cancer, pancreatic cancer, and general surgery. Many hospitals offer robotic surgery as a primary option, despite the fact that the surgical operation is not covered under the national medical insurance scheme yet. The capital investment and maintenance costs are reflected in exorbitantly high prices of robotic surgery, though the prices of robotic surgery have been lowered because of highly competitive market in the past five years or so. The initial costs of purchasing da Vinci system are estimated to be around 2.5-3.5 billion KRW, in addition to the costs of preparing the operating room to accommodate the bulky system. Thus, one can ask a simple question: “Who should adopt robotic surgery, and for whom?”

The Korean medical and allied society is eager to get ahead in the fields of applied robotics including surgical robots. When interviewed at Asan Medical Center in 2006, one of the largest teaching hospitals in Korea, physicians were proud to say that “the Korean (Western) medical system is far ahead of, if not as good as, advanced Western countries like the United States.” When pursued, they pointed to the highly technologized hospital system in South Korea, quoted as saying “as far as advanced medical technologies are concerned, South Korea is one of the best in the world” (field notes at the ward of radiology, Asan Medical Center, July 2006). Being recognized abroad has obsessed domestic

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60. Glimpsing through a range of prices, prostatectomy costs around 10-20 million KRW, 5-7 million KRW for thyroid cancer surgery. Lately, the price for prostate surgery has been lowered to 7 million KRW, and other types of cancer followed suit price wise.

61. Maintenance costs are another matter to consider. For instance, four arms of the system require the highest degree of sterilization free of absolute infection, and thereby they need replacing every tenth use. The cost of single use amounts to between 300 and 400 million KRW.

62. Smyth et al., “Who Should Adopt Robotic Surgery, and When?” The Annals of Thoracic Surgery 96 (2013): 1132-7. The authors carefully gauge the pros and cons of robotic surgery, with a hypothetical case in which an experienced surgeon considers switching to robotic surgery not because of the deficiency of existing techniques. But rather the hypothetical surgeon feels the need to adopt the newest invention out of competition. A best compromise is to conclude that the surgeon makes the best ethical decision not to harm the patient and that the surgeon is aware that the advantages and disadvantages of the newest invention can be known partially.


actors, including governmental officials and physicians, to prove competitiveness in their chosen fields, which in turn contributes to obsession with hardware technology to borrow a robotic engineer’s phrase. A robotic engineer, whose expertise lies in robots in extreme environments, expressed a concern that “national R & D investments in the field of robotics are done to develop so-called hardware technology” (Interview with Y, March 27, 2014).  

As an aspiring nation-state, the South Korean state has vested interests in advancing science and technology as an engine for national economic development after the Korean War. In the process, the state has functioned as a venture capitalist to nurture and speed up the commercialization of technical knowledge and skills. National progress was imagined in close ties with economic gains, and market share and growth in global markets are commonly employed to measure the value of medical and technological innovations. Stakeholders such as the state, innovators, mechanical and biomedical engineers, and entrepreneurs invoked techno-political imaginary that machines are the embodiment of national progress and superiority capable of nurturing and generating innovations. In that regard, from the perspective of the government, it has been imperative to catch up with and fast-follow the latest innovation in a given field in order not to lag behind of technologically advanced countries. Accordingly, the state of the art is portrayed in terms of economic values that involve past and present revenues accrued and possible loss of future revenues to be accrued if not intervened at earlier stage.

In 2002, the government launched a seven-year project to haul up the robot industry and slotted about 82.1 billion KRW per year. The Ministry of Knowledge and Economy funded namely a “smart project” to research and develop the areas of applied robotics such as

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65 He is an engineering faculty member at the university, having been working with domestic and international research groups. His main observation and concern about Korea R & D policy directions is to do with little patience with building sustainable knowledge. The accumulation of certified and robust knowledge via falsification matters little to the funding agencies, because the funding cycle is dependent on the nature of political priorities. The intimate relationship between politics and R & D policies leads to two major consequences. First, the funding agencies are more interested in “presentable outcomes” within a funding cycle. Second, researchers get pushed to generate something visible to the outside world beyond their own areas of expertise.


68 The media scaled the size of investment to those of Europe and Japan, conveying a message that Korea should put more money into the robot industry.
surgical robots and disaster robots that could be turned into commercial products in a short period of time. Small-and medium-sized businesses seized funding opportunities, shaping the fertile ground for the industry to grow. About that time, Samsung and Hyundai seized the opportunity for the expansive robot market, and began to commercialize a “cleaning robot” and “RoboDoc.” In 2008, the government drafted a special bill to foster the robot industry with aspirations that the nation would emerge as one of three key players in the fields of industrial and surgical robotics. Similarly, the Ministry of Health and Welfare (MoHW) enticed local governments to strategize medical tourism to vitalize local economy. In 2010, the MoHW drafted a special bill to “attract foreign patients,” and robotic surgery was one of strategic investments along with cosmetic surgery. The Ministry of Trade, Industry and Energy has been also funding the related companies to develop domesticated robotic surgical system in order to stop the da Vinci system from monopolizing the market.

A drive to emerge as a leader in the field of surgery can be better understood in the context of valuating outward progress that can be measured and visualized in terms of numbers and mechanical hardware. For instance, a surgical history of prostate cancer per

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69 RoboDoc is a robot that cuts the bone automatically and mechanically before inserting artificial joints. The degree of precision and accuracy deems very much improved compared to doctors’ hands.


71 Ryu Si Hun 류시훈, “10nyeon dwicheojin susulrobot gisul . . . 1nyeonane mi chugyeok” 10년 뒤쳐진 수술로봇 기술 . . . 1년 안에 쾌 추격 [Robot That is 10 Years Behind will Get Ahead the U.S. within a Year]. The Korea Economy Daily 한국경제, July 27, 2009, http://news.hankyung.com/article/2009072767861.


se within Korea and worldwide is rather short. In South Korea, around the time when the surgical method of open surgery was about to be accepted as a standard procedure, minimally invasive surgical method (MIS) was introduced. And little time has passed between MIS and robotic surgery. Now at this moment three surgical options are available for surgeons, patients, and hospital administrators: open surgery, MIS, and robot-assisted surgery. Given that the US represented by Intuitive Surgical Inc. monopolizes the global market for robotic surgical systems, it was the government’s position that related technologies should be domesticated and inter-nationalized. Viewing that the field lagged far behind of perceived competitors such as the US, Japan, and European countries, the government believed that the problem lied in the lack of core technology that could be applicable across the related fields.

The potential risks associated with MIS are invisible from both public gaze and from the related professional circles, unless something goes terribly wrong. The media presentation of robotic surgery is favorable with little coverage about potential risks and long-term side- or

Figure 1. A public transportation stand at Yonsei Severance Hospital, Seoul. Taken on October 22, 2013, when ‘robotic surgery live 2013’ took place.


77 NECA, *Robotsusul* 로봇수술 [Clinical Effectiveness].

adverse-effects. Celebrities are recruited to raise the profile of the hospital, in which case aesthetic values of the system is highlighted with emphasis that the da Vinci system helps to quickly recover from the surgery without leaving any scar on the surface of the neck, for instance. Every hospital, where the da Vinci system is in use, is keen to report successful surgical operations via various means of media communication (See Figure 1, for instance). Accordingly, the emphasis is put on the number of successful cases, as if domestic hospitals ran a competition. It may not be surprising to observe ongoing competition, considering that South Korea in entirety records the second place after Sweden in the numbers of surgical operations per capita using the da Vinci system.

V. Da Vinci at Trial: Malpractices or Normal Procedure with Complications?

In May 2011, a local actress died of cancer. It could have gone relatively unnoticed unless her families and the media paid attention to her death. Earlier that year in January, she was diagnosed with renal pelvic cancer and three months later had an operation using da Vinci system at Yonsei Severance Hospital, Seoul, Korea. After surgery, she suffered from an acute postoperative pain in the duodenum. Her surviving family raised suspicion against the hospital and responsible surgeons about the cause of her sudden death and demanded for autopsy. Upon autopsy, it turned out that she had a perforation in the duodenum. The family and the hospital had conflicting interpretation as to how it transpired and what impacts it would have left on post-operation recovery. The family contended that the perforation caused intolerable postoperative pain, viewing it as evidence of mal-operation. Arguing that the perforation was the byproduct or the side effect of robot-assisted surgery inherent to the procedure, the family side contended that the surgeons should have switched to human hands.

79 At the entrance of the hospital, an electronic display board is placed to show the facts and data about the hospital. In a similar context, an interesting observation has been made that hospitals and physicians actively utilized the Internet as a marketing tool to advertise the benefits of robotic surgery. The content provided on the hospitals websites is not necessarily supported by scientific data, but it is rather strongly influenced by the industry. The research suggests that commercial force drives the dissemination of a surgical innovation. See, Schiavone B. M. et al., (2012). “The Commercialization of Robotic Surgery: Unsubstantiated Marketing of Gynecologic Surgery by Hospitals,” American Journal of Obstetrics & Gynecology 207, no. 174 (2012): e1-7.

as soon as the surgeon sensed the formation of the perforation.

However, the hospital did not concur with the family on the causes of her pain and death. The hospital repudiated the family’s contention that the perforation took shape during the operation, treating the perforation as likely complications associated with surgical operations. If and when the perforation is regarded as part of postoperative complications, the liability of the patient’s death neither lies with the hospital, the surgeons, nor the da Vinci surgical procedure. In other words, complications can occur due to complexities of internal organs that are closely attached to the kidney as opposed to being derived from malfunctioning of the robotic surgical system. The surgical team, via the press, expressed that the surgery went successfully well so that the patient’s post-operation vitals were just fine. Hence, a contentious and critical issue came down to when and how the perforation was made.

Because of its high profile contention, expert community and patients advocacy groups were consulted and propounded various opinions regarding safety and effectiveness of robotic surgery on the media. For instance, in an interview with the press, a representative of the Korea Society of Medical Robot shared his opinion about the difficulties of the concerned surgery and is quoted as saying, “A renal pelvic cancer occurs in a complex environment where adjacent organs are complicatedly networked, and the operation is extremely difficult and requires a highly skilled and experienced surgeon. Because of its complicatedness and difficulties, it is almost impossible to do robotic surgical operation without considering side-effects such as perforation. And MIS cannot be immune from that, either.” 81 Some surgeons also pointed to a desensitizing issue when using robotic arms. Although the company claims that robotic arms retain improved haptic feedback as compared with MIS, surgeon’s sensuous touch is much reduced with either robotic or mechanical arms. 82,83,84 Even the


prosecutors’ office looked into the case and analyzed the video-recorded surgical process to conclude that there was nothing suspicious with the procedure.\(^{85}\)

Korean patients did not stand alone to file a complaint against either the responsible hospital or against the manufacturer of the equipment. In the United States, a family of a deceased patient sued Intuitive Surgical Inc., after the patient died from a routine prostatectomy using da Vinci system. The US family suspected that the company was responsible for the death of the patient from a surgical operation, as the company trains surgeons to use the machine. The surgeon, who operated robotic surgery on the patient, was a board-certified urologist with ten years of experience in open prostatectomies. The patient after robotic surgery suffered from rectal laceration leading to reoperation and colostomy, sepsis, acute renal and respiratory failure, stroke, and incontinence. After settling down with the hospital and the surgeon, the patient’s lawyer filed a suit against Intuitive Surgical for negligence that the company did not train the surgeon properly. In 2013 a court ruling came out in favor of the manufacturer, concluding that Intuitive Surgical was not responsible for training the surgeon.\(^{86}\)

Two legal complaints both in Korea and in the United States bring to our attention that a systematic credentialing system, a training program, and ethical guidelines on mal-operations are absent at the responsible institutional level (hospital or university) as opposed to relying on the industry.\(^{87}\) Equally importantly, what two idiosyncratic cases suggest is that the hospitals and physicians are increasingly relied upon the information provided by the industry\(^{88,89}\) because of their complicated and complex nature of medical innovations. Most notably, patients are in a disempowered position to depend on surgeons’ explanation along


with online information and personal network, as the Korean patient’s side complained via
the press that they had limited information with respect to potential risks and effectiveness
of robotic surgery in comparison with alternative options. However, things are about to
change. Lately, the law sided with the patient that the hospital is liable to provide sufficient
information about complications and side-effects of the robotic surgery.

VI. Discussion: Enhanced Robotic Performance and Patient Care

When the innovation was introduced into the operating room, it was based on the
assumption that a shift from human hands to mechanical devices such as laparoscopy and
robotic surgery could reduce complication risks and improve patient care by lessening pain,
blood loss, and recovery length as compared with open surgical techniques. Technologically
speaking, the robotic system is engineered to provide the surgeon with more precise and
wider vision than naked eyes. A 3-dimensional camera is embedded in the system, scanning
thoroughly the surgical and surrounding areas and sending the image data to the operating
surgeon at a real time basis. Moreover, the dexterous robotic arms, the EndoWrist, are
designed to provide surgeons with a feeling and performance similar to human hands.
In other words, the mechanized parts should be well synchronized with the surgeons’
movements, as though the surgeons turn into a part of the system and vice versa. In that
regard, the da Vinci surgical system can be veered as mechanically sophisticated and
enhanced surgical procedure over two hundred years of surgical history. And yet, it is one thing
that the surgical system is technologically advanced; it is another matter that the technology
is safe to use and improves patient care. It is particularly harmful and disadvantageous to

90 The company’s website provides a wide range of information pertaining to surgical risks and complications
including general surgery, MIS, and robotic surgery. The site further specifies the risks associated with minimally
invasive surgery including da Vinci Surgery as follows: temporary pain/nerve injury associated with positioning;
temporary pain/discomfort from the use of air or gas in the procedure; a longer operation and time under anesthesia
and conversion to another surgical technique. See more at, http://www.intuitivesurgical.com/safety. In Korean,

91 Kim, “Baeu go Park Joo A” 배우 故 박주아 [Why Should the Late Actress].

92 Kim Da Hye 김다혜, “Beop ‘Robotsusul bujagyong seolmyeong anhan byeongwon, wijaryo jwoya” 法 ‘로
봇수술 부작용 설명 안 한 병원, 위자료 줄야 [The Court Ruled the Hospital to Pay Compensations Blaming
articles/?3188187.
patients if the latest innovation is valued mostly in terms of technical sophistications and articulations without carefully gauging and assessing benefits, costs, potential side effects and risks associated with the technology.

What harm can be done? First and foremost, it has to do with informed choice and unequal distribution of information from the patient’s perspective. Patients are faced with three surgical options to choose, open surgery, laparoscopy, and robotic surgery. Ideally, patients should be provided with a thorough overview of benefits and potential risks associated with each surgical method in order to make an informed and rational choice. Interestingly it has been noted that more individual choices do not necessarily translate into better or quality care because of the uneven distribution of information between healthcare providers and users. Nor does the amount of health information help patients make rational and informed choices regarding treatment options and daily routines. Bombarded with a great deal of information about a latest technology, patients are rather left helpless without knowing what is the best surgical option for his or her condition. Under the circumstances, surgeons’ bias toward new technology can be very influential over patient’s choices about the surgical method, and physicians’ favoritism is well reflected in rapid spread of the da Vinci system. Physicians tend to assess or rather legitimates the safety of the new technology based on their prior experience.

An interesting finding has been reported that physicians take the improvement of 3-D vision and instrument articulations as the merits of robotic surgery. In the same survey, almost all responding surgeons view the transition from laparoscopy to robotic surgery to be not challenging. What makes the surgeons to think that the transition to robotic surgery is

not difficult? One can find a clue from a research on learning curve. There is a research with indications that surgeons have a learning curve of about 100-150 cases to obtain stabilized operating time in the performance of laparoscopic radical prostatectomy procedures, whereas a learning curve with robotic surgery needs about 20-25 cases (Hermsen 2010).\(^9\) Another prospective study is also supportive of a learning curve hypothesis, in particular with respect to background knowledge and skills. Cho et al.\(^10\) conducted randomized trials to see how effectively and fast the transfer of skills and knowledge takes place in robotic surgery to novice trainees whose experiences in laparoscopic surgeries varied with differential degrees. According to their observation, the role of manual dexterity is critical to determine the success of surgery. Even needle control and knot tying are not simple tasks to perform and need experience to build confidence in doing so. Because of the lack of tactile feedback from the mechanical arms from suture and tying with thin suture materials, novices tend to struggle. The more experienced the surgeon is, the quicker and easier it becomes to translate tactile information to meaningful surgical information. Although the machine arm can reach into the site where human hands cannot directly palpate, they do better with humans’ input when critical decision is to be made. When suturing the wound after surgery, the surgeon may feel tension on the fingertips, whose timing can be critical to the patient’s life and death situation. The feeling at the right moment can be hardly replaced by the mechanical arms, as such feeling requires years of clinical experience to acquire.\(^11\)

As provisioned, does enhanced vision with improved hands movements guarantee better surgical performance and quality care? At the bare minimum, a practical question remains as to how to abstract, calibrate, and standardize personalized skills into impersonal and


thus objectified skills.\textsuperscript{102} Surgical skills and competence are built on experience involving personal and tacit knowledge,\textsuperscript{103,104} in particular when adopting new technology. Moreover, as suggested in the studies of learning curve, surgeons need to use new surgical tools as often as possible to acquaint and to personalize them. Even the most skilled surgeon would perform the same procedure with slight variations depending, for instance, either on the degree of fatigue s/he would feel on that particular day or on whatever inexplicable reasons.\textsuperscript{105} Laparoscopic surgery serves as a reference point to contrast, compare, and project the positive effects of robotic surgery, as da Vinci system is labeled as an enhanced minimally invasive surgical (MIS) techniques. MIS techniques were introduced to fix the drawbacks of open surgery. Even open surgery, the most common and oldest surgical technique, is reported to have various sorts of complications and side effects during and after surgery. Commonly observed are the following symptoms: post-operation pain, infection, hernia, intestinal adhesions, scars, and complications near or on the surgical site. Compared with open surgery, the techniques of minimal access incision are said to help patients to recover relatively quickly from surgery, let alone little post-surgery complications. Minimal access incision directly affects blood loss during the surgery. For instance, while laparoscopy causes about 100-1500cc loss of blood by volume, robotic surgery reduces the amount of blood loss to 40-50cc. To achieve intended uses and functions, laparoscopic surgeries require good “hand-eye coordination,” because the surgeon performs operations via a video screen. Given that the da Vinci system is equipped with four mechanical arms, the system is more demanding that harmonious synchronization should be in place between foot, hand, and eye

\textsuperscript{102} The Korean Surgical Society (KSS) is a professional organization of licensed surgeons and provides ethical guidelines for the members of the society. KSS is keen to harmoniously standardize a diverse range of surgical skills based on apprenticeship. Viewing that training potential surgeons with standardized techniques is fundamental to improve the quality of surgical care, KSS has invested to build an Osong surgical training belt. As to the questions when to adopt a new technology, the surgeon can find an ethical guideline in the following professional code: “Surgeons always respect a patient’s free choice and prioritize a patient’s health and safety” (An ethical code of conduct for surgeons, clause 1). Though the Society provides overall codes of conduct, it is individual hospitals and surgeons who are responsible to come up with implementable standards and guidelines.


VII. Conclusion: Visualizing Potential Risks and Ethical Implications

As the da Vinci system has become widely used, in the past few years concerns and worries have been raised from individual surgeons and regulatory agencies. Reviewing professional and popular literature, there are concurring worries revolving around two major issues across the board. First, it is pointed out that there is the lack of systemic, evidence-based assessment and evaluation of effectiveness of robotic surgery in comparison with existing procedures. Second, there is the lack of systematic analysis of benefits versus costs of da Vinci system. Despite the lack of conclusive, scientific evidence about its safety and effectiveness, there is a widely held perception that robotic surgery is safer, more effective, and more exquisite than traditional surgical methods. The ever-increased use of innovative medical instruments prompted the South Korean government to design regulatory and clinical protocols that could be used by multi-parties including developers, patients, regulators, and hospitals. Considering that the da Vinci surgical system is a product of multidisciplinary collaboration between computer engineering, robotics, and biomedical engineering, a practical question comes down to how we can visualize potential risks that are not imminent or evident at the time of development and adoption. The involvement of cross-disciplines poses challenges to regulatory agencies whose primary concern is to establish the data supportive of safety and effectiveness of the innovation.

To the eyes of regulatory agencies in South Korea, surgical robots stand somewhere between mechanical and clinical devices, signifying that they are being treated as the

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107 NECA, *Hangukjeok sanghwang* 한국적 상황 [The Medical Technology Assessment].


subjects of both mechanical examination and clinical effectiveness.\textsuperscript{110} That is, before putting on sale, a robotic surgical system is required to undergo mechanical examination both on individual parts and on the entire system. Mechanical examination is carried out to evaluate efficiency, safety, and precision of the system in accordance with characteristics of surgical robots. At the same time a surgical robot is required to prove its clinical effectiveness and safety as compared with existing technologies. In sum, the criteria in use to assess and measure clinical effectiveness and safety of robotic surgical systems include the following factors such as completion rate, adverse effects, procedure time, surgical time, total operation time, conversion rate, blood loss, and post-operative hospital stay.\textsuperscript{111} Evidently, quantifiable criteria only are used to assess and evaluate the technology, leaving out non-quantifiable factors such as pain, care, and operating skills from regulatory considerations.

What is missing in the process? In the field of surgery, it is noted that the face-to-face transfer of operating skills plays a crucial regulatory role than clinical guidelines.\textsuperscript{112} The acquisition of skills involves informal and tacit knowledge that is hard to articulate and it not written in the manual instructions. Delicate tacit knowledge may be left out in the process of translating human’s dexterity to the mechanical device. Under the circumstances, how can we be sure that the mechanical hand performs better than the human’s touch? For that matter, it seems worthwhile being reminded of a warning against the technologization of the hospital. In the early twentieth century America, when the use of X-ray for the diagnosis of fractures was introduced, Howell pointed out that even some advocates of the technology expressed the value of bedside diagnostic acumen over the X-ray. “No one will for a moment suppose that the vacuum-tube and induction-coil [which produced X-rays] will, or ever can, displace the sense of touch guided by a well-balanced and experienced mind.”\textsuperscript{113}

As a way to safeguard the quality of patient care, the research on public perception of nanotechnology solicits us to think more seriously how badly we need to make unforeseeable risks associated with medical innovations visible in appropriate terms and images. Lay

\textsuperscript{110} Rha, \textit{Euiryogigi Yimsangsiheom protocol} 의료기기 임상시험 프로토콜 [Development of Clinical Investigation Protocol].

\textsuperscript{111} Ibid., 6.


\textsuperscript{113} Howell, \textit{Technology in the Hospital}, 108.
people tend to view “frontier” or “new” technology and associated products as inherently good, regardless of their misunderstanding or lack of understanding about the embedded technology.\textsuperscript{114,115} Partly because of the corporation’s marketing strategies, “new” is translated into “better” or “improved/enhanced” to the patient as well as to the surgeon. It is, however, more troublesome to find social acceptance or lack or critical consciousness that being new is equalized with being improved. What should be done is to keep on going “dialogue and deliberation amongst affected parties about a potentially controversial technological issue at an early stage of the research and development process and in advance of significant applications or social controversy.”\textsuperscript{116} In conclusion, it is high time to set up ethical standards and guidelines of clinical governance to monitor practice and outcomes of the new skill.\textsuperscript{117} The paper argues that social scientists and bioethists should be involved in articulating ethical dimensions of the technology even from the stage of development.

Received: February 28, 2018
Revised: May 15, 2018
Accepted: June 14, 2018


