THE ETHICAL CONTROVERSY OF A FAULTY DESIGN:

SURGICAL ROBOTICS

Eliot Meeker (ewm15@pitt.edu)

INTRODUCTION: SURGICAL ROBOTS:

A NEW TECHNOLOGY

Intuitive Surgical, my employer, is the leading manufacturer of surgical robots in the United States. This company was the creator of the most widely used surgical robot on the market, the da Vinci® Surgical System [1]. The da Vinci Surgical System is currently the only surgical robot approved by the United States’ Food and Drug Administration. Currently, over 10,000 operations are performed each year in the United States using the da Vinci surgical system, and the number of cases is increasing by approximately 25% per year [2]. It is a large machine with four arms. Three of the robotic arms are used to hold various surgical tools required for the surgery to take place. The fourth arm is used to hold a small endoscopic camera that allows the surgeon to see what he is doing [3]. The International Anesthesiology Clinic describes, “With the da Vinci surgical system, the operator sits away from the surgical field in a console and controls the robotic surgical manipulator with the advantage of 3-dimensional vision” [2].

This procedure can be somewhat compared to a videogame control, but the repercussions are much more severe. Surgeons must be specially trained to use this robotic equipment, and it takes an average of ten surgeries before the surgeon can be accustomed to this new procedure [3]. In surgery, the surgeon makes three or four incisions in the abdomen of the patient that are close to one-fourth to three-fourth inches (similar to the size of the diameter of a pencil). Three to four stainless steel rods are then inserted into the incisions and are held in place by the robotic arms. Each time the surgeon moves one of the joysticks of the console, a computer sends an electronic signal to one of the instruments, which moves in sync with the movements of the surgeon's hands. Working together, the surgeon and robot can perform complete surgical procedures without the need for large incisions. Once the surgery is complete, the surgeons remove the rods from the patient's body and close the incisions [3].

**AN ENGINEER’S ETHICAL QUANDARY**

I am currently the Senior Mechanical Design Engineer for Intuitive Surgical. It is my job to help identify performance, cost, and reliability improvements for Intuitive Surgical’s surgical instruments and accessories, and complete the development, documentation, and verification of these improvements. I am required to resolve complex mechanical, materials and manufacturing design issues and have the ability to work in an interdisciplinary team to troubleshoot root causes of higher level system issues [4].  A strong sense of shared responsibility and shared reward is required as well as a commitment to high product quality. Recently, a colleague of mine reported to me with a new and improved design for the da Vinci Surgical System. The colleague asked for me to sign off on the new design. I told him I would look it over and get back to him as soon as possible. Immediately, the new design seemed troubling to me. The design entailed an improvement of the haptic feedback the surgeon receives while performing surgery with the robotic system. Although the improvement is exactly the innovation the company needed, it hindered the previous functional capabilities of the da Vinci Surgical System. With the new design, larger incisions on the patient would be required and the movements of the robot would be slightly impaired, potentially endangering future patients. The deadline for the design was quickly approaching, and a decision needed to be made.

**THE CODE OF ETHICS**

Ethical issues in engineering are often overlooked as a major problem in the engineering world. In reality, ethical issues such as the encounter with Intuitive Surgical occur on a daily basis to engineers all over the world. According to Charles J. Abate, there are three different categories of ethics. There is common morality, personal morality, and professional ethics. Engineering ethics is considered a subset of professional ethics within the different categories of ethics [5]. These professional ethics are a set of ethics adopted by a certain profession (engineering).

To help guide professional engineers to make the right decision, an organization called the National Society of Professional Engineers (NSPE) created *The Code of Ethics for Engineers.* Similarly, the different branches of engineering contain their own specific code of ethics in regard to their own practice. An example of this is the Biomedical Engineering Society Code of Ethics. These guideline are solely directed toward helping biomedical engineers make ethical decisions in their profession.

To make a decision about the signature of approval, it is important to reference *The Code of Ethics for Engineers* as previously mentioned. In code two, canon one, directory “b” of *The Code of Ethics for Engineers* it states that, “Engineers shall approve only those engineering documents that are in conformity with applicable standards” [6]. This code directly relates to the present ethically charged issue dealing with the signature needed for the questionable new design of the da Vinci Surgical Robot. The loose term of “applicable standards” might still make this ethically charged issue difficult to respond to. Ethics seem to boil down to a matter of opinion and point of view rather than an objective view. One must decide what the applicable standards are for a case such as this in order to make a clear decision on whether to approve this engineering document. Other codes of ethics must be referenced in order to make a clear decision. Code one, canon one, directory “a” states, “If engineers' judgment is overruled under circumstances that endanger life or property, they shall notify their employer or client and such other authority as may be appropriate” [7]. This code also applies to the situation, but in a more direct way. This code states that if lives become in danger, then the proper authority figure must be notified about the issue. The new design with improved haptic feedback could potentially injure or kill a future patient unless the flaws are reported to the correct people.

**THE PERSPECTIVE OF A BIOENGINEER**

Carl Mitcham describes, “Bioengineering, as the application of engineering methods and knowledge to biology and medicine, constitutes a decisive extension of engineering beyond its previous restriction to the non-human and even non-living world” [8] As previously mentioned, each engineering practice has their own individual code of ethics. An organization called the Biomedical Engineering Society (BMES) created a code of ethics based on their practice. Code one, canon one of the BMES Code of Ethics states, “Biomedical engineers in the fulfillment of their professional engineering duties shall use their knowledge, skills, and abilities to enhance the safety, health, and welfare of the public” [9]. Biomedical engineers are ethically responsible to use the knowledge that they have to improve the well-being of society. It is the engineer’s personal responsibility to decide what exactly enhances the safety, health, and welfare of the public. Deciding whether or not to sign off on the new design, it must be considered whether or not the new design will be beneficial or harmful to society based on the BMES Code of Ethics.

**THE BENEFITS OF ROBOTIC SURGERY**

The safety and benefits of the Da Vinci surgical robot should be looked at in greater depth to fully understand this ethically charged issue. Surgical robots are beneficial not only to the patients undergoing surgery, but also to the surgeons who are utilizing the robotic technology. The use of surgical robots in surgery makes the procedure much safer and easier for the patient and the surgeon. Many people focus on the limitations created by using surgical robotics. The International Anesthesiology Clinics stated that, “The limitations of the da Vinci system have been primarily cost related, which requires a substantial investment by a medical center. In addition, there is a lack of tactile sensation and force feedback to the surgeon. The lack of surgical feedback is the object of ongoing research and advancements in technology should address this deficit” [2]. This is the haptic feedback issue addressed in the previous scenario. The benefits of robotic surgical systems include improved dexterity and degrees of freedom for the surgeon, 100% tremor-free movements, ambidexterity, and the avoidance of the fulcrum effect that occurs when using long endoscopic instruments [10]. The two principle benefits on surgical robotics are enhanced visualization and precision. These robots are capable of high-resolution, three-dimensional optics at ten times magnification, and ultra-precision with 100% tremor elimination and up to 5:1 motion scaling [10].

Robotic operations have evolved from minimally invasive operations and offer similar theoretical benefits, such as less pain, shorter length of stay in hospital, faster healing, and quicker return to normal level of functional activity [11]. With the robotic arms, the incisions and cuts made on the body are significantly smaller than of a surgery achieved directly by the surgeon. The infinitely smaller incisions result in less blood loss, minimal scarring, and reduced risk of infection in the incision. With these smaller incisions, the body is able to heal much faster making the hospital stay shorter than normal. These surgical robots are specifically engineered to create a much less invasive procedure. The robotic arms have the dexterity to complete a complicated procedure without completely cutting the human body open.

A design in which some of the equipment’s greatest benefits are retracted seems to be a very poor design. The potential new design revolutionizes the da Vinci Surgical Robot by creating better haptic feedback to the machine. Haptic feedback is the use of advanced vibrations to communicate with the user. One problem with the da Vinci Surgical System is the surgeon is not able to tell how hard or soft certain tissue in the body is. Surgeries performed directly by the surgeon eliminate this problem. In the ethically charged scenario, the new proposal creates larger incisions in the body and reduces the movements of the robotic arms. Losing all of these benefits does not seem as though it will be worth the new haptic feedback, which is a small problem compared to the problems that it could cause. Looking at these facts could help me make the moral decision.

**A SIMILAR DILEMMA**

An important way to provide a solution to an ethical dilemma is by looking at previous examples that are similar to the situation. Almost certainly someone else has needed to make the same decision in the past. In the 1930’s, a man named Thomas Midgely invented CFC 12, which was the most commonly used coolant for household refrigerators. At first, the design was accepted, but over the next sixty years it was discovered that CFC’s were harmful to the environment and contributed to the depletion of the Earth’s ozone layer. In 1987, the Montreal Treaty greatly reduced the amount of CFC’s that were allowed, and as time went on, it was decided that a new coolant was needed to be engineered because of the adverse effects on the environment [12]. This example may seem far off when comparing to the approval of an improved surgical robot, but the two cases are somewhat parallel. Although the disapproval of the design for CFC’s was delayed by sixty years, it was still changed when the horrible effects on the environment was discovered. It was recognized that this CFC 12 design was harmful to society, so things were changed and a new design was made improve the world.

**THE FINAL DECISION**

It has been said that when an ethical decision arises, there are two things that can be done. The first thing is to ask for a revision of the notion of responsibility in engineering. The second is to seek out an engineer who is strong enough to deal with any ethical dilemma that may arise. Ideal engineers represent someone able to act alone and single-mindedly by using his or her own resources [13]. Ethical decisions are made based on outside factors. These outside factors could consist of basic morals, an ethical code or even a similar previous ethical decision that was made a long time ago. With the deadline for the new design quickly approaching, I must make a decision on the new design almost immediately. Looking at the previous information, I have decided not approve the new design for the da Vinci Surgical system. The best and most ethically responsible decision is to take the design to the higher authorities and explain the potential risks of the new design without letting it go through. The code of ethics for engineers states that if lives are endangered than the employer or proper authority must be informed about the issue. The Biomedical Engineering Code of Ethics state engineers shall only use their knowledge to benefit society. Approving a design that could potentially cause surgical complications does not abide by that code. The current design creates excellent benefits by decreasing hospital stay and recovery time by making smaller incisions. Taking those benefits away would not be a fair thing to do. Looking at the coolants in old refrigerators helped me make the final decision. Once engineers realized the current design of CFC was harmful to the environment, they decided to make a new design as they were abiding the code of ethics. Once I realized the new da Vinci design was potentially harmful to future patients, I decided to veto the new design. Even though, this could possibly be harmful to my job, it is my ethical responsibility as an engineer to do the right thing to ensure the safety of the people.

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