The Bioethics of Implantable Engineered Mechanisms in Orthopedic Surgery

by
Sarani Chatterjee

A PROJECT

submitted to

Oregon State University

University Honors College

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degree of

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(Honors Scholar)

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Ravi Balasubramanian

The ethics of implant technology is a wide-ranging topic in the field of bioethics. This paper intends to add to the ethical discourse of implant technology by addressing a new class of implants applicable to orthopedic surgery. These new implants are engineered mechanisms that attach muscles to tendons and bones with the goal of improving postoperative joint function when compared with the state of the art method using sutures to connect biological tissues. This technology has significant engineering challenges including material and device design, determining the metrics to evaluate the implant, validating the procedure, and reducing risk. While considering these engineering issues, this thesis will primarily focus on the following bioethical issues regarding the implants: How will hybridizing the human body, or combining mechanistic and biological components, affect an individuals' sense of self and cultural identity? What are the risks and benefits of using these implants and how do they affect a patient's decision to consent to the new procedure? What are the social justice issues of this new implant technology?

Key Words: implant, ethics, engineered, mechanisms, orthopedic, surgery

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I understand that my project will become part of the permanent collection of Oregon State University, University Honors College. My signature below authorizes release of my project to any reader upon request.

Sarani Chatterjee, Author

I. Introduction

A variety of implantable medical devices have been developed over the last few decades to help restore human function for different medical conditions. For example, bone-shaped implants are used in hip and knee replacement surgery, neural implants reduce tremors in patients with Parkinson's disease, and rechargeable pacemakers correct irregular heartbeats (Hansson 2004). Each one of these implants has significantly impacted society by enabling patients to live independent lives and improving quality of life. The bioethics of using these different implants have been analyzed before (Hansson 2004). This paper explores the bioethics of a new class of implants that have the capacity to reengineer the body and create a paradigm shift in orthopedic surgery.

The Robotics and Human Control Systems Laboratory at Oregon State University has developed a new class of passive implants in the form of engineered mechanisms, such as pulleys, levers, and artificial tendon networks, for attaching muscles to tendons and bones. They present an alternative to the suture, which has been the mainstay of surgery for attaching biological tissues for 30,000 years (Mackenzie 1973). These implants are designed to be used in surgeries to restore joint function for medical conditions such as stroke, palsy, spinal cord injury, congenital defects, and trauma. The key advantage of these implants is that they enable the customized transmission of forces and movement between muscles, tendons, and bones for improving joint function, allowing the patient greater control in movement. This would provide a significant advantage over the current method of using a suture to attach the muscle to tendons and bones. Specifically, the suture couples the movement and forces of the muscle and tendons and joints, where the tendon's excursion is equal to the muscle's contraction. Also, the suture provides limited ability to scale and distribute the muscle's force across the tendons. In contrast, these implants would provide the ability to scale up or scale down and distribute forces and movement between the muscles, tendons and joints. These implants are unique because such passive mechanisms have never been used as implants in surgery.

This paper focuses on the bioethical implications of using two specific implants: (i) implantable "differential" mechanisms such as hierarchical pulley mechanisms; here,

"differential" refers to the mechanism's property to transfer the forces and movement of one muscle across multiple tendons, while allowing each tendon to have different excursions in order to accommodate environmental constraints.

This is similar to an automobile using a differential transmission between one engine and four wheels. The differential mechanism enables the car to take a turn, even while the inner wheels travel at different velocities when compared with outer wheels. When such a differential mechanism is used between a hand muscle and multiple tendons in surgery, the implant enables better hand grasping function since the fingers can adapt to external constraints better; and (ii) implantable pulleys and linkage systems for knee-replacement surgery that scale up the quadriceps muscle forces to increase knee joint torque with the goal of improving postoperative knee function in daily activities such as stair-climbing and chair rising. The main purpose of this paper is to discuss medical ethics in clinical research to understand the risks and benefits of this new technology, the impact of using the implants on the concept of self and the social justice issues regarding the new implants.

II. Background

This section will discuss the technical details of the new implant technology, which is designed to modify the transmission of forces and movement within the body. Additionally, background information on existing implant technology, such as bone and neural implants and pacemakers, and the current ethical issues regarding existing implants will be briefly discussed.

A. Biomechanical Effect of Using Implantable Passive Engineered Mechanisms

This section briefly describes the two implants that are the focus of this paper. The purpose of the first implant, namely the differential implant for connecting one muscle to multiple tendons in upper-extremity tendon-transfer surgery, is to improve postoperative hand function following tendon-transfer surgeries. Tendon-transfer surgeries of the upper-extremity are performed for a variety of conditions such as stroke, palsy, spinal muscle atrophy, brain, nerve or muscle trauma, and congenital defects. The surgical procedure reroutes tendons from the affected muscle and directly sutures it to a functioning muscle to partially restore the lost

hand function. It is estimated that over 20,000 upper-extremity tendon-transfer surgeries are performed annually in the United States (Mardula 2014). The differential-mechanism implant is designed to restore finger flexion following tendon-transfer surgery where one muscle is attached to multiple tendons, such as in the procedure for high median-ulnar nerve palsy. The high median-ulnar nerve palsy condition renders the Flexor Digitorum Profundus (FDP) muscle non-functional, causing the loss of finger flexion in all four digits of the hand. The current surgical procedure to address this condition reroutes all four FDP tendons to the wrist Extensor Carpi Radialis Longus (ECRL) muscle with a suture as shown in Figure 1a. This surgical procedure directly couples the movement of all four fingers leading to poor hand function in fundamental tasks such as the grasping of objects. Specifically, following this surgery, the fingers cannot adapt to an object's shape naturally, and the patient has to perform compensatory movements or use excessive muscle force to create secure grasps (Mardula 2014).

The working hypothesis is that the differential engineered mechanism will distribute the force and motion of the muscle across the tendons more effectively than the suture and prevent the patient from having to use excessive muscle force for grasping the object. In order to investigate this hypothesis, Oregon State University has conducted a cadaver study to compare the grasping and finger flexion capability enabled by a traditional suture-based surgery and a differential mechanism-based surgery (Fig 1b). The pulley-based and suture-based surgical procedures were conducted on six cadaver hands, where each hand grasped spheres of various sizes. The results of the cadaver study showed that (i) 45% less actuation force was required following the pulley-based procedure to create complete grasps when compared with the actuation force required following the suture-based procedure; and (ii) the pulley-based procedure significantly improved individual finger adaptation to the object's shape during the grasping process when compared with the suture-based procedure (Mardula 2014). This result is graphically represented in Figure 2, where a high number of phalanges grasping the ball indicates a better grasp (Chatterjee 2013). The results of this study support the hypothesis that an implantable engineered mechanism constructed from moving artificial pulleys, levers or tendon networks distributes the movement and forces from one muscle across multiple tendons, while enabling each finger to flex as needed during the grasping process, significantly improving postoperative hand function.

Fig 1. a) Tendon-transfer surgeries reroute tendons from the affected muscle to the functioning muscle. b) The pulley implants used in cadaver studies to test hand-grasping capability. Mechanism shown is made with off-the-shelf components. Latest design is withheld for intellectual property reasons. c) Incomplete grasps on the suture-based procedure and secure grasps on the pulley-based procedure.

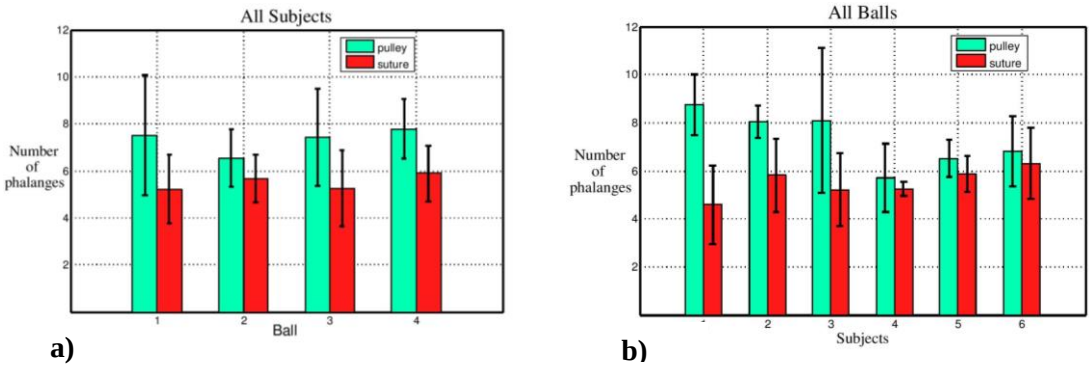

Fig 2. a) Mean contact points on all six cadaver subjects on each type of ball. b) Mean contact points of each subject on all the balls combined. For both graphs, the pulley-based procedure significantly improved contact points between the hand and the ball. This indicates hand-grasping ability increases with the pulley-based procedure.

The purpose of the second implant is to improve knee function by using it to scale the force applied by the quadriceps muscle to the patella following total knee-replacement surgery. About 600,000 knee replacement surgeries are performed annually in the United States (Carr 2012). Following knee-replacement surgery, patients experience decreased strength in the knee due to complications such as soft-tissue disruption and dislocation. The reduced knee function affects daily activities such as stair climbing and chair rising (Matsuda 2013). The implanted mechanism will attach the quadriceps muscle to the patella as shown in Figure 3. The goal is to attach a pulley device instead of a suture in such a way that the knee joint torque is increased while sacrificing some range of motion (See Fig 4). In the case of the knee joint, such reduction in the knee range of motion is acceptable as long as the knee joint has sufficient range of motion

for daily activities. Such force-scaling mechanisms can be applied to similar conditions at the elbow and hip as well.

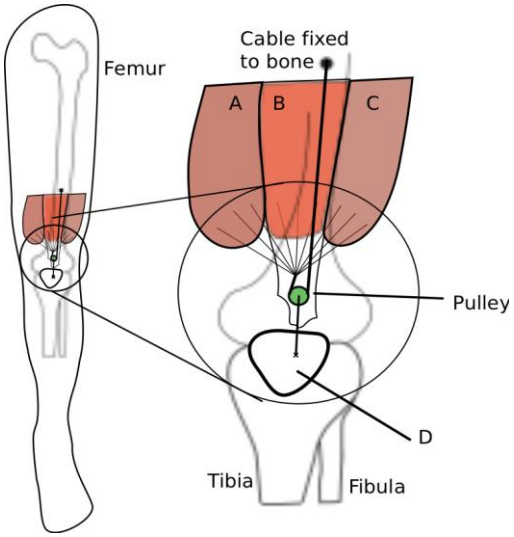

Fig 3. Schematic of the pulley mechanism between the quadriceps and the patella to increase knee joint torque. Key: A: Vastus Medialus; B: Vastus Intermedius; C: Vastus Lateralis: D: Patella.

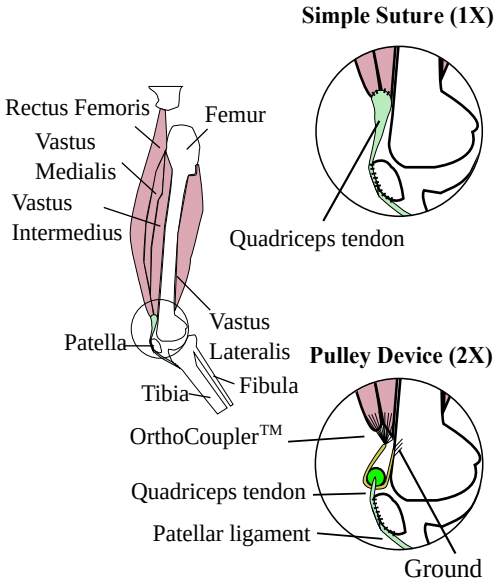

Fig 4. Side-view comparison of attachment of quadriceps to the patella with a suture or a pulley device. Pulley device enables twice the amount of force than the suture.

B. Innovative aspects of the new implant technology

There are several aspects of the proposed implants that expand the boundaries of current medical and engineering technology. Current orthopedic implants primarily take two forms: (i) rigid passive implants that interface between bones, such as implants for hip and knee replacement surgeries and joint replacement prostheses (Lynch 1982); and (ii) passive implants that attach two soft-tissue elements (such as tendons or muscles) to each other. The proposed implantable mechanisms are different from existing technology because they modify the force and transmission inside of a patient's body. Additionally, there are unique engineering challenges associated with these implants, such as finding the right metrics to evaluate the implants and determining the optimal design and materials for the device.

Furthermore, the new implants must provide the required force and movement transmission and be (i) compatible with the anatomical spaces within which they move, (ii) have minimal interaction with the surrounding tissue, and (iii) be lightweight, durable, and biocompatible to limit the body's foreign-body response to the implant. Finally, each embodiment of the implant, whether a pulley, lever and tendon-network implants, has unique advantages and disadvantages. For example, the pulley and lever implants are relatively straightforward to design, but could cause discomfort to the patient when implanted since they are rigid. In contrast, the tendon network is soft and flexible and can reduce discomfort. However, the stretching of the network when forces are applied can reduce the efficiency of the transmission of movements.

Overall, the new implants have the potential to change the current surgical paradigm. The unique challenges associated with the new implants trigger ethical issues that require discussion.

C. Ethical Considerations of Current Implant Technology

The primary ethical issues regarding orthopedic implants are safety (relating to bone loss and allergic reactions), device longevity given that the device must operate for over ten years and the risks and benefits associated with the implant (Lynch 1982).

Orthopedic implants, like hip and knee replacement implants to treat severe fractures and silicone-based joint implants to treat arthritis, have existed for over half a century (Lynch 1982). However, there exist risks in using these implants even today. The long-term use of bone implants in total knee replacement (TKR) and total hip replacement (THR) surgery is dependent on the material and the careful implantation of the artificial joints. Massive polyethylene wear at the implant-bone interface in TKR patients cause serious complications, while metallic TKR and THR implants are the primary causes of severe allergic and inflammatory reaction after surgery (Kręcisz 2012; Spinelli 2010). These issues draw researchers and ethicists to focus on implant biocompatibility in order to maximize the benefit of the treatment and minimize serious risks (Klinkmann 1994).

The design and material of construction for any implant must ensure device longevity. Recently, prosthetic limbs for leg amputees send control signals to remnant nerves, enabling the patient to walk more naturally (Hargrove 2013). The prosthetic hardware and software must be built to last many loads and cycles of movement. Additionally, brain implant technology is being developed to combat Parkinsons, depression and even allow persons with loss of limb function to turn appliances off and on, check email and play games without any assistance (McGee 2007). In addition to the safety and long-term use of brain and neural implants, methods to deliver the necessary upgrades to the implant software must be available to the users to minimize the need for further surgical intervention (Maguire 1999). These issues are common among all types of implant technology, including the new implants described in this paper. Minimizing surgical intervention after implantation, ensuring biocompatibility and reliability are all issues that need to be solved before distributing and using the new implantable engineered mechanisms.

In addition to these ethical issues, the new implant technology developed by the OSU Robotics and Human Control Systems lab leads to other ethical issues, such as the possibility of augmenting human capability and changing the current surgical paradigm by providing additional options in surgery. This paper will now discuss the ethical issues relating to the new implants by addressing three topics: (i) the risks and benefits of using implants in the body by addressing medical ethics in clinical research, (ii) the social justice issues regarding new technology, and (iii) the hybridization of the human body and impact on self.

III. Medical Ethics in Clinical Research

This section will describe the ethical considerations of clinical research regarding the new implantable engineered mechanisms. I will outline seven requirements for a clinical research study testing to be considered ethical (Emanuel 2000). These requirements, originally meant for drug studies, can be applied towards implants and medical devices. Additionally, I will briefly discuss the process to develop medical devices through FDA guidelines of current good lab practices and quality systems requirements (CFR-21, FDA). The first requirement to an ethical clinical research is that the outcomes of the study must have scientific or social value. Many

agree that exposing human subjects to risk can be justified only if society will gain new knowledge from the study (Emanuel 2000). Testing the new implants will provide the scientific community with a wide range of information on human muscle and tendon function including quantitative evaluation of hand function in grasping objects following tendon-transfer surgery and, an understanding of muscle strength, excursion capability and tendon length. These measurements could help the scientific community understand musculoskeletal function after surgery, and understand how the body responds to shear stress within soft tissue. The successful testing and implementation of the new implants will grant surgeons and patients an improved option in treating diseases and injuries requiring orthopedic surgery. Additionally, knowledge of the biomechanics of tendons and muscles can inspire other implant or prosthetic technology.

Clinical research study must prove scientific validity in their methods (Emanuel 2000). The study must have a null hypothesis, meaning there is not a consensus within a community if the researched technology is better than the standard technology. Currently, there is no indication of how the suture causes a disadvantage in surgery compared to the implant, proving that this study is worth undertaking. As stated previously in this paper, the pulley implants have been tested in cadavers and have shown significant improvement in grasp formation (Chatterjee 2013). Pre-clinical trials will be based on a rat model to test the biocompatibility of the implants before engaging with clinical trials. Additionally, the new technology would need to be tested through simulation and animal trials to justify the procedure. The animal trials will indicate the biocompatibility and efficacy of the implant by measuring the fibrotic growth using HE staining, and the force required to use the muscle with the implant. The goal is to ensure the resistance to the movement of the implant caused by the surrounding fibrosis is minimized. Specifically, the animal trials must indicate that resistance force must be 5% or less than the maximum force capability of the muscle. This is a possible measurement from animal studies that will validate clinical testing of the new implants.

Fair subject selection in clinical trials is an essential requirement to justify clinical research. There are several aspects to this requirement: (i) stigmatized and vulnerable individuals should not be targeted for risky research, (ii) scientific goals of the study must be the primary basis for determining groups and individuals that will be recruited, (iii) groups must

share both risks and benefits of the study, (iv) results must be generalizable to the population that will use the technology (Emanuel 2000). The subject selection has not been specified yet for this study because the lab is drafting protocols for the rat model animal study. However, the intended use of the implant will be to treat a population with musculoskeletal dysfunction due to orthopedic surgery. This population must include a diverse demographic, including minors and elderly. The clinical study must be organized to fully represent all populations in an unbiased and non-discriminatory way.

The fourth requirement is that research needs to focus on a favorable risk-benefit ratio. The study must have pre-clinical data and protocol that show the minimization of risks and benefits to the subject (Emanuel 2000). The sole focus of the risk-benefit ratio is the health of the patient. The new implants and current orthopedic and neural implants have similar risks and concerns regarding long-term use and biocompatibility. However, the new implants are unique because they are mechanisms that reconfigure within the body, creating an additional challenge to the implantation and long-term use of these devices. The reconfiguration of the implant could apply shear stress to the surrounding tissue, exacerbating the fibrosis around the mechanism, which could restrict the implant's operation. In order to limit fibrotic growth, the implants could be encapsulated inside a flexible silicone casing filled with hyaluronic acid in order to reduce the foreign-body response. This will ensure the benefits of the procedure, including restorative function of the hand and knee to perform daily activities and lead independent lives, and minimize any risks mentioned.

After the first four requirements are met, the research must go through independent review (Emanuel 2000). A nonaffiliated professional must evaluate the protocol for the research study, the pre-clinical data, subject population and the risk-benefit ratio. If this research is carried out at OSU or in the United States, the Institutional Review Board must approve the protocol. This will hold the research investigators accountable for their protocol and scientific method. The research team is planning on conferring with physicians, surgeons, engineers and rehabilitation experts to confirm the design and methodology of the research.

Informed consent and respect for subjects are the sixth and seventh requirements to consider clinical research ethical. In order to give proper consent, the patient would need to understand how the risks and benefits of the procedure. Long-term use of the implant might require subsequent surgeries and increase risk to the patient. If the patient is a minor, there could be additional complications as the patient grows and the tissues around the implant changes. Consent for a minor is a complex issue because their parents or guardians must understand the technology and decide if the procedure is right for the child. Parents will only give consent to the procedure if they are fully convinced that this will benefit their child. Therefore, it is essential that they are given enough information to understand the benefits and advantages as well as the risks associated with this new technology. The subject must have the right to withdraw from the research trial and must be informed of any new information regarding the risks and benefits of the procedure. Overall, the focus of the clinical trial must maintain the welfare of the subjects.

The FDA regulates clinical trials by providing guidelines to clinically test orthopedic implants for efficacy and safety. Current good laboratory practices (cGLPs) are in place for pre-clinical trials testing a new food, drug or medical device intended for human use or consumption (CFR-21, FDA). cGLPs keep manufacturers accountable for their lab facilities, treatment of animal subjects, and reliability of their tests and data. In general, pre-clinical trials for medical devices need to demonstrate a state of control in the design and manufacturing process. This differs from good manufacturing practices (GMPs) for drugs because GMPs have more explicit laboratory controls and detailed building controls. cGLPs for medical devices focus on manufacturing, design and process validation. For example, hip and knee implants have specific evaluation criteria, test procedures and end points that must be met in order to get FDA approval. The mechanical properties of a hip implant must have a specific shear fatigue, static tensile and static shear strength before being manufactured ("Guidance Document for Testing Orthopedic Implants", FDA). If new materials or surface coatings are used on the device, it must exhibit an acceptable biological response equal or better than existing implants. Research on hip implants material assessed biocompatibility using SEM, HE staining, and cell adhesion and proliferation assays. Additionally, unidirectional compression tests are commonly used to assess the strain and stress capacity of a material (Xu 2015). It is likely that the lab at OSU will comply with cGLPs and quality system requirements to develop these implants. Data will be collected using

compression and fatigue tests, HE staining, SEM and proliferation assays to understand the biocompatibility and durability of the new implants. Information from these tests will be given to the patients to ensure that all ethical requirements are met before starting clinical trials.

IV. Technological Distribution and Social Justice

The accessibility of new technology to promote care and service equally across society is an important issue relating to social justice. This section will discuss current problems in health care resource allocation, ethical frameworks on cost and distributive justice and the application of these ethical models towards the new implant technology.

A. Distribution of technology

While certain technologies are diffused quickly across global populations, like cell phones and computers, the distribution of medical technology can vary for several different reasons. Technological distribution can be based on the geographic location of care, allowing privileged society more access to technology and causing marginalization, exclusion and the maintenance of social and health inequality (Poland 2004). For example, economically disadvantaged people in Brazil are treated at a first-come first-serve basis, resulting in long waiting lines while economically advantaged people have greater access to care (Ivan Dieb 2012). In the United States, the health care system relies on employer-based insurance for individuals to gain access to care. However, gender, race and geographical location of birth has been shown to directly influence employment and health insurance (Trotochaud 2006). Additionally, limited government funding, new technology and health innovations and an aging population makes it more imperative to find a systematic method in justifying distribution to minimize social injustice.

Justifying the need for equitable health care services gives this ethical discussion more weight and significance. Norman Daniels provides reasonable arguments to why health care resource allocation should be considered as a need. He identifies two types of needs that is important to this discussion: course-of-life needs and adventitious needs. Course-of-life needs

are essential for people to function normally throughout their lives. Adventitious needs are things needed for any event, project or unanticipated event in life (Daniels 1981). Daniels stresses the importance of health care services satisfying course-of-life needs to promote and maintain "normal species functioning." The needs must satisfy adequate nutrition, shelter, sanitary and safe living and working conditions, exercise, rest and preventative measures, curative and rehabilitative medical services and social support groups (Daniels 1981). Additionally, Daniel argues that ethics of health care resource allocation is analogous to ethics of clinical research (Daniels 2006). Clinical research and health systems aim to improve the health of a society, but have the potential to impose health risks on a population. For example, manufacturing a novel drug under unreliable lab data or unequal distribution of vaccines can expose one part of society to unwanted and dangerous health calamities. Additionally, both clinical research and health care allocation needs to be transparent to the public, because both services directly affect the health and well-being of every citizen and individual in society. These reasons give reasonable justification to why equitable health care resources is a need and why an ethical discussion is necessary to promote and maintain the well-being of society.

There are two ethical frameworks that will be described in this section: (i) main principles of just allocation of health care resources and (ii), Norman Daniels's fair and equal opportunity principle. Previously, the cost-effectiveness principle of allocation was used to determine just allocation of resources, by evaluating the outcome and cost of the medical intervention to the quality of adjusted life years on the patient. The major flaws to this principle are that quality of adjusted life years is incommensurable and there is a lack of data on the cost and effectiveness of medical interventions. Emanuel proposes four principles of just allocation to replace the cost-effectiveness principle (Emanuel 2000):

1. Allocation decisions are justified by improvement in public health
2. Members and patients should be informed of allocation methods
3. Patients and members should consent to allocation methods that affect their health
4. Conflicts of interests should be minimized

These principles value patient dignity, professional integrity, and social solidarity. The first and fourth principle show value towards the professional integrity of the health care system. Health care is unique because it provides a social good that improves individual citizen's health

and life. This statement gives value to the health care profession, because the systems' purpose is to treat people and improve quality of life. The second and third principles show value towards patient dignity and social solidarity. Patients are described as autonomous moral agents capable of making moral decisions based on their own beliefs and desires (Emanuel 2000). If the public is informed and gives consent to a transparent allocation policy, the policy is moral because it was justified by the people that are directly affected by the allocation. Integrating these four principles into the health care system is one way of ensuring just allocation of resources.

While Emanuel's principles focuses on multiple values, the fair and equal opportunity principle proposed by Norman Daniels is a more utilitarian approach valuing human dignity. He proposes the "fair and equal opportunity" principle to justify why health care services should be allocated equally in society. Impairments, disease and dysfunction reduce opportunity to make life-plans and having a satisfying and happy life (Daniels 1981). Access to health care eliminates, treats and reduces impairments and gives the patient the opportunity to live a full life. Limiting health care services to one subgroup in a population gives them an unfair advantage over another group. Daniels specifies that the health care services should address needs directly impacting a patients' well-being, where only crucial needs are met. The crucial needs will only return the patient to "normal species functioning". This distinction ensures that all people are provided the same services for the same needs because it would be unjust to give people with extravagant preferences more social goods than others.

There are limitations and implications of this theory that need to be addressed. Elderly patients will have less opportunity than younger patients after any treatment, allowing younger people to have a greater advantage. The physician-patient relationship will change drastically because the physician would not be able to do all that he or she can to preserve the well-being of the patient. Instead, the physician will have to think of distributing resources to other patients to maintain the fair and equal opportunity principle (Daniels 1981). Lastly, maintaining "normal species functioning" as defined by Daniels requires health care services to include both therapeutic and preventative measures. Preventative includes, but is not limited to, actively improving patient environmental conditions or providing education and information on preventing disease. While these theories might be helpful to formulate a fair method to distribute

technology, it will take a considerable amount of time and effort for the ethical community to agree and implement one ideology. However, discussing existing ethical models will help find a just method in distributing the new implant technology.

Oregon State University has discovered a need in orthopedic surgery that has not been identified before. These new implants will restore a patient's ability to perform daily activities like stair-climbing, chair-rising and grasping objects. It will take time for the implant to be tested, manufactured and ready for clinical use because this technology is new and an innovative concept. The goal is to distribute these implants based on need and likelihood of benefit, regardless of the financial and socioeconomic condition of the patient. Patients heavily dependent on their hand or knee mobility for employment or financial security should also be given priority. The challenge is to make the implant technology inexpensive enough to be available for uninsured and insured patients. This would guarantee that all citizens that need this technology will be able to receive it, assuring fair and equal opportunity among every patient.

These implants can potentially be distributed to healthy individuals that wish to have customized force-scaling abilities in their knee, elbow or hand. Based on the fair and equal opportunity principle, enhancement technology is not characterized as a need to maintain normal functioning and should not be included in health care services (Daniels 1981). Nevertheless, distributive justice on enhancement technology is beyond the scope of this paper and more research is required to discuss the issue. The goal is to only distribute the implant for enhancement purposes after the initial need has been fulfilled. The discussion on social justice will be continued through the next section by addressing cost of technology and treatment over time.

B. Cost and Social Justice

Treating life-long disabilities can be a financial burden to many individuals. For example, the lifelong cost for treating a child with congenital hearing loss amounts to nearly 1 million dollars in the United States (Ivan Dieb 2012). Orthopedic procedures like total-hip replacement and total-knee replacement surgeries range from $1,800-$12,000 per case, depending on the patient's medical condition (Robinson 2012). However, there is evidence that

new medical technology can become cheaper and more accessible over time. For example, improvements to dialysis therapy have decreased the cost of treatment. Also, the developments of antibiotics have eliminated the previous cumbersome and costly treatment of tuberculosis (Kielstein 1995).

Cost and equal distribution are both applicable issues towards the new implantable engineered mechanisms. Since this implant is similar to bone or joint-replacement devices, we can assume that they will be distributed similarly to these existing implants. Medicare coverage is currently available for prosthesis to return functionality in a body part ("Prosthetic Devices"). The patient is required to pay 20% of the Medicare-approved cost for any external prosthetic. If orthopedic prosthetics are made affordable in Medicare, it is likely that these new implants could get covered as well. This would partially relieve some financial burden on the patient and make this technology more accessible. As mentioned previously in this paper, total-knee replacement and hand tendon-transfer surgeries are prevalent procedures in the surgical field, which suggests that access to this technology should be based on need and not cost. The new implants may be expensive in the initial stages of introduction, because each implant should be customized based on the patients' needs. This would make the implants less accessible for economically disadvantaged patients. It can be argued that the cost is justified because the technology improves quality of life. An individual would gain back their independence by performing daily activities that would be difficult without the implant. Each patient must decide whether or not to proceed with this implant technology, and that can only be possible if there is complete transparency in the risks and benefits of the implants. The fair and equal opportunity principle will push for the implants to be accessible for all people, despite the cost. Similar to other medical devices, the cost of these implants could potentially decrease over time, making it easier to implement the fair and equal opportunity principle.

V. The Hybridization of the Human Body

Based on an individual's cultural and philosophical beliefs, the use of mechanical, implantable prosthetics can alter an individual's sense of self or identity. This section will explore the concept of identity and self by discussing Cartesian dualism, Lockean ethics and the

relationship between technology and identity. This section will use the term "hybridization" to define implanting an artificial component into a purely biological organism. This does not imply that the implantation hybridizes the whole organism, only to describe the implantation of an artificial device into a biological system. Finally, the ideas generated from this discussion will be applied to the new implantable devices to understand how this new technology might affect the patient's identity.

A. Cartesian Dualism

Rene Descartes, a 17th century French philosopher, is most famously known for his work in *Meditations* and his theory on Dualism. Cartesian Dualism is the view that the universe contains two distinct types of substances: Physical substance and mental substance. Physical substance, also known as *res extensa,* is defined as an extended and unthinking substance comprised of matter while the mental substance, or *res cogitans,* is an unextended and thinking thing (Dicker 1993). Descartes theorized that the soul and body exist as opposite and independent forces and that the body, even though it belongs to him, was inessential to his being. He uses the method of doubt to analyze three existential beliefs that he is (i) a man, (ii) a being with a face, limbs and body and (iii) a being who was nourished and engaged in sense perception (Dicker 1993). He concludes that he can't be certain of these beliefs through the deceiver hypothesis, the idea that a greater force is deceiving him of the physical world, his body and his sense perceptions. While the deceiver can mislead him about the physical world, the deceiver can't dispel Descartes belief that he, as his own self, is thinking. This reinforces the separation between the physical and mental components of an individual. Additionally, Descartes explains that the concept of self as a purely thinking substance is no more difficult than the concept of an extended material body. For example, individuals can conceive of wax to take up many different forms without changing the identity of the wax. Similarly, a purely thinking substance is described to be something that can take up various thoughts, doubts, desires and beliefs (Dicker 1993). The key difference is the purely thinking substance and physical substance are separate and distinct from one another, meaning the mind and body must exist as opposite and independent entities.

Critics have discussed the two main problems with Cartesian Dualism: (i) how can we perceive pain and sensations if the mind and body are separate entities and (ii) if the mental and physical substances are separate and do not interact with each other, how do we know they both exist? The first problem, known as interactionism, can be addressed by understanding that the body is a casually closed system (Southwell 2008). This means that physical things act on physical things, while mental things only act on mental things. For example, my desire to move my hand has nothing to do with the physical action being performed. The brain signaling to the nerves to stimulate the muscle to move my hand is purely physical (Southwell 2008). Similarly, my thoughts can only lead to other thoughts, making my physical actions and mental desires separate. The second problem with Dualism is addressed using Descartes' conceivability argument. He argues that since it's possible to conceive of the mind as separate from the body, it must be separate. However, as noted by the critic Antoine Arnauld, just because we can't conceive of something, doesn't mean it doesn't exist or that it is the truth (Southwell 2008). Arnauld also believed the power of thinking is directly associated with the physical brain, while Descartes believed that the mind is indivisible while the body is not. Descartes theory can only be true if it can be shown that the brain is not needed in the thinking process, which would make thinking and the mind a non-physical entity.

Despite the flaws in his theory, Cartesian Dualism led the way to modern physics, science and the Judeo-Christian view of the soul (Dicker 1993). Dualism challenged the view of Aristotelian physics, which was the prominently held belief at that time that nature worked toward a purpose or goal. By stating the final causes and goals can only exist in *res cogitans* and not *res extensa,* Descartes provided powerful philosophical rationales to explain nature through concepts of modern physics rather than actions towards a purpose. Additionally, Descartes replaced the Aristotelian definition of soul, where the human soul includes all facets of life, like taking up nourishment, sensory perception, movement and rationality. Descartes separated the physical components, like movement and sensory perception, from the thinking element of a human being (Dicker 1993). The separation of the soul and the body implied that the soul was immortal, establishing religious beliefs still existing today. For all these reasons, Cartesian Dualism is still commonly studied and Rene Descartes is considered the father of modern philosophy.

B. John Locke and Personal Identity

While Descartes focused on the metaphysical question of human identity, John Locke, a 17th century politician and philosopher, approached human identity epistemologically. Epistemological questions on human identity address how we perceive something to be one continuous identity while metaphysical questions focus on what constitutes the essence of an individual being (Steup 2005). John Locke disagrees with the concept of identity belonging to a material or spiritual substance (Cope 1999). If this were the case, the soul could move from one body to another and multiple people could be the same person. Additionally, if the concept of identity belonged to a substance, individuals' identity remains the same during different states of consciousness. In other words, we would be the same person dreaming as we are awake.

Locke offers a more pragmatic theory to the concept of identity. His theory allows the percipients to decide when the original idea of an object persists or not. For example, when a car gets a part replaced, the original idea of the car persists, despite the internal change. The perception of an object's identity is focused on the organization process of the idea. The percipient looks at the overall idea of the old car to conclude that the idea of the old car persists, so the car's identity stays the same. This analysis is similarly applied to human identity, where human identity is directly attributed to memory and experience. Locke reasoned that personal identity is not an innate characteristic, but that it is defined by consciousness, where consciousness initiates our own self-awareness resulting in the distinction of one from other beings. His theory states personal identity is shaped by one's experiences and reflections in the world (Nimbalkar 2011).[19] Also, Lockean theory describes a person as a thinking and intelligent being that can consider itself the same thinking thing in different times and places (Cope 1999). An individual's experiences are stored in their memory. All memories can form ideas which an individual organizes in the mind to form a single identity. However, if an individual loses their memory, they do not have the same identity because all the past experiences and recollections that formed their identity are now lost. Therefore, Locke would say that as long as any technology doesn't influence the memory of the patient before the implementation of the technology, the personal identity of the patient will remain intact.

C. Identity, Body, and Enhancement Technology

While the new implants primary purpose is to restore joint function, the implants can potentially enhance joint capability, where the person with the implant would be able to customize the transmission of forces and movement in their arm, hand or leg. This fits the definition of enhancement technology, an intervention to improve human form or function that does not respond to genuine medical needs (DeGrazia 2005). The new implants, if used for enhancement, have different ethical implications than if it is used for treatment. The relationship between enhancement technology, the body and identity is worth engaging to understand the impact on human identity if these implants were a form of enhancement technology. I will approach this topic by discussing two perspectives, one from the conservative voice of Leon Kass and the other from David DeGrazia, a moral philosopher with a specialty in bioethics.

Leon Kass argues that society does not respect the body or bodily life. He recognizes enhancement technology, cosmetic surgery, surgical technology and implantable devices to prolong human life as ways society neglects human dependence on the body (Kass 1985). Human beings depend on the body to think, communicate, and act. Most importantly, Kass argues our awareness of the body teaches us vulnerability and rids any notion of individual autonomy (Kass 1985). He supports his argument by describing how individuals use language to communicate experiences with the body that overlooks any relationship between the body and identity (Kass 1985). For example, we can describe an event by saying, "the ball hit my arm" or by saying "the ball hit me." Both phrases are acceptable in describing the situation, but the former statement separates the body from the individual, while the latter statement describes the body and the individual as one. This confusion in language causes everyday citizens to overlook any relationship between the body and identity, and focus on more immediate concerns in their everyday lives. This use of language also suggests that it is easier to accept individual autonomy than understanding the dependence of the body to human existence. Additionally, Kass suggests that the body performs actions in an individuals' "lived space, which somehow belongs to and gives rise to [an individuals'] sense of self." (Kass, pg. 25). The actions of a person's body leads to the development of their identity by forming "new kinds of world-relations" through their actions (Kass, pg.25). The connection between human action and human identity is key to understanding Kass's strong opposition to enhancement technology.

According to Kass, enhancement technology degrades the dignity of human action, human identity and individuality, and disrespects the dignity of embodiment (Byrnes 2005). He argues performance enhancing technology makes an individual "less human". He believes that a human act is only considered human if it is done through conscious choice and by "disciplining [the body] and its natural gifts in pursuit of [a] goal" (Byrnes, pg.146). This statement stresses the difference between human goals and animal goals. Animals do not pursue goals consciously, only instinctively. For example, an athlete intentionally makes a goal and works toward that goal through self-will. Enhancement technology makes the athlete rely on an outside force to succeed in their goals. This undermines the worth of human action and disrespects embodiment. Kass adamantly states that " the body in question is a living body, not merely a machine, not just any animal body but a human body; each of us not only has a body; each of us is a body" (Byrnes, pg.147). In general, Kass believes there are moral limits to medicine which are solely for restorative purposes. He is against any biomedical intervention with enhancement capability because he believes it alters ones identity. Enhancement technology limits a person's self-will and consciousness in performing an act. Having an identity is equivalent to having limits and flaws. Finding a way to overcome these limits and flaws through self-will alone is the source of a person's identity. Using technology to enhance and overcome these limitations degrades individuality and human embodiment.

David DeGrazia describes a different analysis to the relationship of identity and enhancement technology. He states that identity is split into two components: numeric identity and narrative identity. Numeric identity pertains to the essence of an entity, where the identity of something stays the same throughout time. It allows an entity to exist with change (DeGrazia 2005). Narrative identity is how the individual defines and perceives of his or her self. DeGrazia claims that the analysis of identity with enhancement technology is mostly focused on the psychological approach to identity, where the continuity of consciousness and experience forms identity. This is essentially Lockean theory, where consciousness and memory dictate the integrity of an individuals' identity. DeGrazia argues that we should look at identity from a biological approach as well. The biological approach simply states that continuing existence requires no psychological continuity, only biological. In other words, as long as we are biologically alive, our identity and existence is intact. Through evaluating both biological and

psychological approaches, DeGrazia concludes enhancement technology only impacts narrative identity, which changes with time and through experience, without impacting numeric identity.

It can be reasoned, based on Cartesian dualism, that the proposed engineered mechanisms would not impact the identity of Self. Descartes' theory of Self, where the body and its actions are mechanistic in nature and separate from the Self, has been incorporated into western medicine and practice. The use of current orthopedic implants in total knee and hip replacement surgeries is a prime example of how society has morally accepted implants without considering the body and self-identity to be compromised. Additionally, the new implants are focused on one area of the body which, according to Descartes' theory, does not affect the identity of the individual. Based on Lockean theory, an individual is the same person if he or she remembers past experiences. The new implants will not affect the patients' memory, so the patient will be able to recall past experiences, memories and ideas that make up their identity. Furthermore, the new implants will be designed to be biocompatible and have limited physical effect on surrounding tissue so that the patient loses awareness of the device over time. The goal is to design these implants to provide the least amount of discomfort post-surgery and to improve the patient's joint function.

The new implants have two potential applications: to restore physical capability or to enhance physical movement. Both applications have different ethical implications. Restoring physical capability can enable a patient to live a more independent life. For example, the knee-implant empowers the patient to perform chair-rising and stair-climbing movements, increasing the patient's confidence to perform daily activities. Kass would agree that these implants will positively affect an individual's self-identity because this technology restores musculoskeletal function, allowing patients to perform actions that would have been impossible without the intervention. However, Kass would strongly oppose the use of this technology to enhance physical function in healthy individuals. He would argue that the implants will create an artificial ability, degrading the dignity of natural human action and altering identity. A possible counterargument could address the definition of natural human action. If we consider a runner, would it be a natural human action if the runner uses spikes during training or a race? Would it also be considered natural to consult a nutritionist and determine the best diet for an athlete?

Aren't expensive sports equipment, workout supplements and diet outside forces that help an athlete achieve his or her goal? The difference between these implants and sports supplements and equipment is that the implants are irreversible. Once they have been surgically implanted, the implants are meant to stay long-term. Ingesting sports supplements or using equipment is not permanent. It has less impact on an individuals' everyday life, while a mechanical pulley is a more invasive intervention.

DeGrazia would argue that these new implants will not change a person's identity because the patient's numeric identity will remain the same. The patients' thoughts, past experiences, desires, beliefs and character traits will remain to be continuous after the implantation. The patients' self-perception, or narrative identity, will change because of their newly acquired abilities, but the overall essence of their being will not be altered. It can be argued that an individuals' identity will be reinforced with their new abilities. An individual might desire the knee-implant to become a more efficient hiker or athlete. The ability to perform an action which brings meaning to someone's life will strengthen their identity.

VI. Conclusion and Future Directions

The objective of this paper was to address the bioethical issues of the new class of implants by discussing the risks and benefits of the implants through medical ethics of clinical research, the social justice issue of distributing technology and the impact on self through the hybridization of the human body. While these implants have similar ethical issues to orthopedic bone implant technology, they are unique because the implants reconfigure within the body, causing additional challenges. These challenges have been addressed in this paper. With any new technology, it is important to consider the social justice issues regarding the implants. While the initial cost of the implants will be high, the cost of implants typically decrease over time, allowing all patients to benefit from this new technology. The impact on self is minimized with this technology because it doesn't influence a person's consciousness or past experiences. I argue that the implants could strengthen identity, by allowing the patient to do activities that would have been impossible without the implant. Future ethical discussion should focus on how the ethics of these implants change when we consider them to be used as an enhancement technology and more perspective on different theories of personal identity.

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