An Analysis of the C-QUR Surgical Mesh Using Virtue Ethics

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By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

Since its introduction to the market in 2006, Atrium Medical Corporation's C-QUR surgical mesh has caused injury and complications in thousands of patients, many of whom required additional procedures to repair damage, until it was recalled by the United States Food and Drug Administration (FDA) in 2013. The C-QUR mesh is a polypropylene mesh coated with an Omega-3 fatty acid outer layer and is most commonly used for hernia repair operations by mending the abdominal wall. However, soon after use of the mesh began in a clinical setting, problems with the product were reported after implantation including infection, inflammation, bowel obstruction, and adhesion to the surrounding tissue. As a result of these complications, thousands of patients were injured, and there are still over 2,000 active lawsuits against Atrium for the C-QUR surgical mesh today.

Other researchers and scholars have attempted to identify the responsible actor for the mesh's failure, with some notable examples assigning blame to the FDA for lack of restrictions or surgeons for improper technique and lack of regulatory practices. However, there is very little discussion about the morality of the actions of the company that created and produced C-QUR mesh. Without examining the morality of those tasked with creating medical devices and holding them accountable for their action, it sets a dangerous precedent for healthcare moving forward that has the potential to harm patients. By examining the actions of Atrium's engineers and executives through the framework of virtue ethics, I will be able to determine if the conduct at key stages represents acceptable moral standards, which I will do by analyzing research studies about the properties and risk of C-QUR mesh, FDA regulatory and recall reports, as well as patient case studies. I will demonstrate that the actions of Atrium Medical administrators and executives were morally unacceptable and led to patient injury due to the lack of important

character traits necessary for morally responsible engineers in three key moments: the research and development of the C-QUR hernia mesh, its manufacturing and production, and the discovery of adverse effects.

Background

Operational hernia repair is one of the most common surgical procedures performed in the United States and accounts for almost 800,000 cases each year (Awad & Fagan, 2004). A hernia is classified as a weakness of the abdominal wall muscles that can allow surrounding tissue to dislocate, and in most cases, surgery is required to repair this defect and prevent further damage. Prior to the invention of surgical mesh, hernias were generally repaired using sutures to stitch the abdominal wall muscles together. However, in 1958 the idea of using mesh to reinforce the abdominal wall instead of stitching it together was introduced, which led to the technique known as the Lichtenstein repair becoming the most popular practice (Brown & Finch, 2011; Livingston, 2016).

Atrium Medical Corporation's C-QUR line of surgical mesh was approved by the FDA in 2006 and featured a polypropylene mesh covered with a protective outer coating made of Omega-3 fatty acid derived from fish oil ("FDA 510(k) premarket notification", 2006; "C-QUR mesh", n.d.). This was the first surgical mesh at the time to feature this protective outer coating, which aimed to decrease inflammation and the chance of adhesion to the abdominal wall after implantation (Deeken et. al, 2011). However, after use in patients began, multiple problems were found in the design and production of the mesh, which led to injuries in those who underwent implantation procedures. The issues reported in patients first began appearing in 2009 and included infection, inflammation, allergic reaction, adhesion of the mesh to surrounding tissue,

bowel obstruction, and seroma (subdermal fluid buildup) (Schreinemacher et. al, 2009; Kong et. al, 2016).

Following reports of adverse effects from Q-CUR mesh implantation in patients, the FDA visited Atrium's manufacturing plant on four separate occasions from 2009 to 2013. Each time, the investigators reported regulatory violations in production and sterilization (Turner, 2023). These violations included finding contaminants (including human hair) on the supposedly sterile mesh, as well as determining that at increased temperature or humidity, the Omega-3 coating would degrade, thus allowing the mesh to adhere to surrounding tissue in the patient (Turner, 2023). After each inspection, Atrium failed to address the problems surrounding the C-QUR mesh, which led to the FDA issuing a Class II recall on all C-QUR mesh devices in 2013, affecting over 100,000 units (" Class 2 device recall CQUR mesh", 2013). Later, the Department of Justice and the FDA filed a case together against Atrium Medical Corporation to stop the manufacture of C-QUR mesh, which was granted in 2015 (Turner, 2023).

Literature Review

Since the start of the 21st century there has been an abundance of published research works that explore the safety and effectiveness of surgical mesh for hernia repair. However, the majority of these productions have focused on a scientific-based approach to analyze the biomechanical properties and material factors that have led to failure in patients. Therefore, few publications have sought to make a determination on the responsible party and thus explore the moral shortcomings of that entity.

In *Lack of Regulations and Conflict of Interest Transparency of New Hernia Mesh Surgery Technologies*, Olavarria et. al investigate the FDA regulations for bringing a novel

medical device to market, specifically looking at hernia mesh technology that was approved for clinical use but later proved to be faulty (Olavarria et. al, 2020). Hernia mesh is classified as a class II medical device by the FDA, as it is considered to pose a moderate to high risk for the patient due to the surgical implantation required for use ("Class II special controls documents", 2022). Class II medical devices must obtain approval from the FDA in the form of a 510(k) premarket notification before they can be sold or used in a clinical setting. The 510(k) application requires that the device exhibits substantial equivalence to another device that has already been approved by demonstrating that the new device has the same functionality and safety considerations as the device it is being compared to ("Class II special controls documents", 2022). Therefore, many medical devices can bypass the rigorous testing the FDA requires by demonstrating that their device is functionally similar to an existing design, so it does not have to undergo testing for safety, efficacy, or toxicity. Olavarria et. al argue that this process poses an ethical problem, as these unproven devices can have negative effects on patients that go undiscovered until thorough research is conducted, at which time patients have already been treated with this technology. Therefore, this research holds the FDA morally accountable for a device failure based on a lack of regulation and quality testing, however it does not explore the ethical role of the device company in ensuring that its product is safe and effective for patients.

Another work that focuses on the ethical accountability of a party other than that of the device's manufacturer is David Taylor's study *The Failure of polypropylene surgical mesh in vivo*. This research analysis is primarily focused on the mechanical properties of polypropylene mesh and examining product failure due to strain, but it also discusses the role of surgeons in device failure. Incorrect placement, lack of training, and damaging the mesh during implantation are all ways in which the surgeon can negatively affect the patient (Taylor, 2018). Additionally,

in the 2021 lawsuit Africano v. Atrium Med. Corp. surrounding patient injury from a defective surgical mesh implantation, it was revealed that the surgeon did not read the instructions accompanying the mesh used in the procedure, nor did they read the instructions for any other mesh product (Africano v. Atrium Medical Corporation, 2021). Therefore, surgeons who lack ethical virtues such as competence or expertise can demonstrate unacceptable morals that lead to patient injury and complications. This analysis supports the idea that the surgeon is an ethically accountable entity in the case of surgical mesh failure, but it also fails to demonstrate the importance of the morality of the medical device company and its responsibility to its consumers.

Conceptual Framework

To analyze the actions of Atrium Medical Corporation from the time its C-QUR surgical mesh was approved by the FDA in 2006 to the recall and subsequent injunction to stop production in 2013, the virtue ethics framework can be applied to determine if the company acted with good ethical values. Virtue ethics was a common subject in ancient Greece that was first defined by the philosopher Aristotle and is based on the idea of achieving what is known as "the good life" (van de Poel & Royakkers, 2011). This can be accomplished by conducting one's life according to positive virtues that can be discerned through reason. These moral virtues are not present with us at birth, but are instead developed by actions taken throughout our life, and consequently they can be learned and practiced (van de Poel & Royakkers, 2011). To have a positive moral virtue, one must exhibit a balance between two evils, as in order to possess courage, they must maintain and equilibrium between recklessness and cowardice (van de Poel & Royakkers, 2011). While the idea of virtue characteristics covers a wide range of behaviors

and attributes, Michael Pritchard focuses specifically on values in engineers as he proposes the notion of virtues for morally responsible engineers, which include striving for quality, competence, and the ability to communicate clearly and informatively (Pritchard, 2001). The presence (or absence) of engineering virtues plays an important role in determining the quality of technology, as well as the relationship between the engineers and those influenced by their innovations (van de Poel & Royakkers, 2011). In order to analyze the decisions made by Atrium Medical Corporation and make a determination on whether it acted in a morally acceptable manner, I will focus on the virtues of responsible engineers along the lifespan of the C-QUR mesh, from its initial research and development to its eventual recall and end of production.

Analysis

Throughout the lifespan of the C-QUR surgical mesh, from its creation to its eventual recall, engineers and executives at Atrium Medical Corporation exhibited a lack of virtues required for responsible engineers in three specific instances: the research and development of C-QUR mesh, its production and manufacturing, and adverse event reporting. In each such situation, the actions and decisions undertaken demonstrated a deficit of one or more of the virtues set forth by Pritchard, therefore making those choices unacceptable from a moral standpoint. The presence of such virtues is known to have an impact on the quality and reliability of innovative output, and in this case, it can be shown that their absence led to the ultimate failure of the C-QUR surgical mesh and its harmful impact on those who it was committed to helping. By lacking virtues required to be considered a moral actor through the framework of virtue ethics, the company and its associates can be deemed immoral. In the proceeding sections,

several key situations will be analyzed to determine the virtues Atrium's engineers and executives were devoid of to be considered unethical entities.

Research and Development

From the time that the C-QUR surgical mesh products obtained FDA approval and entered the market, they contained design flaws that led to injury and health complications in patients, thus meaning that Atrium engineers lacked the virtues of expertise and persistence in the research and development phase before the invention was introduced to the public. As argued by Pritchard, an engineer's responsibility to society is much more important than their dedication to innovation, and therefore the safety of those who may be impacted by such designs are to be held paramount in the consideration of a technology's potential societal impact (Pritchard, 2001). In order to put the welfare of potential users at the forefront of all considerations during the design process, it is necessary for new devices to undergo ample device testing before becoming available for clinical use.

The issues that arose from the C-QUR device design point to a lack of persistence exhibited by the engineers during testing. The C-QUR hernia mesh featured an Omega-3 fatty acid protective layer around the polypropylene mesh structure in an attempt to decrease inflammation and reduce adhesions to the surrounding tissue ("C-QUR mesh", n.d.). Omega-3 fatty acids have been shown to possess anti-inflammatory properties when incorporated into a diet, as well as having no significant reactions with existing drugs, which initially led to its consideration as an effective outer layer (Covington, 2004). However, it was found that the Omega-3 outer layer degraded after being implanted. Without the outer coating, the polypropylene structure is exposed to the surrounding tissue, which can cause the denaturation of

cellular proteins that lead to the formation of granulomas and adhesions (Kong et. al, 2016; "MAUDE adverse event report: Atrium Medical Corporation C-QUR mesh", 2015). In one particular study it was discovered that the C-QUR mesh resulted in adhesions in 50% of subjects, with 38% of the mesh covered in adhesions after 30 days (Schreinemacher et. al, 2009). This shows that not only did the mesh not perform its intended role of repairing the abdominal wall in half of the cases, but it also caused harm to patients that required further procedures to fix. The adverse effects that arose from this design should have been discovered by extensive premarket testing. However, based on the fact that these issues were not reported prior to production, it can be concluded that Atrium engineers lacked persistence in testing their design and its effect on potential users.

In the development of the C-QUR mesh, Atrium engineers also demonstrated a lack of expertise in some instances. Previous mesh designs had been shown to cause many of the same complications including infections and adhesions, with some studies supporting the notion that other surgical procedures posed lower risk of adverse post-operative events (Falagas & Kasiakou, 2005). Therefore, while Atrium's novel design that included the addition of the Omega-3 outer coating sought to limit inflammation, the design took no noticeable consideration to address the risks demonstrated in prior designs ("C-QUR mesh", n.d.). This failure to protect the user represents a lack of competence and expertise in the design engineers, which ultimately led to the detrimental impacts of the design on the consumers that they were foremost tasked with protecting.

By introducing a new mesh that failed to address some of the primary issues with previous designs, the engineers of Atrium demonstrated a lack of expertise, which is one of the virtues for morally responsible engineering. However, it can be argued that the primary blame for

the design's adverse effects can be attributed to another entity: the FDA. In order for a surgical mesh product to be approved for clinical use, it is only required to show substantial equivalence to a similar device that has been previously granted approval. This allows companies to bypass testing devices based on a number of criteria, such as cytotoxicity, if they use the same materials as a predicate device. This approval process has been a large subject of debate, as it is viewed by many to lack stringency and allow devices onto the market without ample testing (Olavarria et. al, 2020). In the case of C-QUR mesh, Atrium fulfilled all FDA requirements before the product was marketed and there is no evidence that problems with the design were known by engineers at its inception, so there can be no suggestion of malice in the design. However, engineers are not only evaluated by their intentions, but also by their professionalism and expertise, and by lacking that core virtue, their actions can still be deemed unacceptable in an ethical lens.

Production and Manufacturing

Over the course of Atrium's production and manufacturing of C-QUR surgical mesh, the company demonstrated a lack of the virtues of commitment to quality and openness to correction. This caused many problems surrounding the product output that had dangerous consequences for its users. These issues mainly surrounded the manufacturing process and storage of meshes, and even after the FDA conducted multiple investigations starting in 2009 to explore these problems, Atrium did not adequately address them, which culminated in the FDA issuing a class II recall on all C-QUR products in 2013 ("Class 2 device recall CQUR mesh", 2013). Therefore, due to the insufficient standard of production as well as the company's inability to address regulatory concerns, Atrium's engineers and executives acted in a morally

unacceptable manner demonstrated by their lack of multiple virtues for morally responsible engineers.

In the later injunction filed by the FDA and Department of Justice against Atrium to stop the production of C-QUR surgical mesh, the case proceedings document the findings of the FDA examination group over the course of their four inspections from 2009 to 2013. The primary issues found were the improper sterilization process of mesh during production, the lack of product validation, and the unsuitable storage conditions of finished products (United States v. Atrium Medical Corporation, 2015). Ineffective sterilization procedures are unacceptable for surgical implantable devices due to their potential to cause infection in patients, and without proper control mechanisms to verify product output, the entire manufacturing process poses a serious threat to its intended users. Additionally, it was found that the Omega-3 fatty acid outer coating could adhere to the device's packaging if stored in warm, humid conditions, leaving the structural integrity of the mesh compromised and leading to an increased chance of the mesh adhering to the abdominal wall after implantation (Turner, 2023). In all such instances of faulty or improper manufacturing practices, Atrium demonstrated a lack of concern for the quality of their devices.

In the wake of the FDA's findings, Atrium was notified of all documented violations following each inspection. However, these problems were never addressed and manufacturing processes continued as before with no effort taken to rectify the potentially dangerous factors in production and distribution (United States v. Atrium Medical Corporation, 2015). With their lack of effort to address shortcomings and issues noted with the production process, Atrium demonstrated a lack of openness to correction, which is further described as the ability to admit to mistakes and acknowledge oversight (Pritchard, 2001). In fact, they showed a complete

disregard for regulations and seemed unwilling to cooperate, as the finding of all four inspections were not addressed, which later forced the FDA to take more serious action to protect consumers. Due to both their lack of quality in the production process and their unwillingness to correct documented problems, Atrium acted in a morally unacceptable manner, which put patients at risk of harm. In engineering design, the welfare of the users is of foremost importance, and so the safety of the public must be protected above any other consideration (Pritchard, 2001).

Adverse Event Reporting and Patient Harm

After the C-QUR mesh was released for surgical use and subsequently began causing harm to patients, Atrium did not take proper steps in adverse event reporting, therefore lacking the ability of being able to communicate clearly, which is one of the virtues for morally responsible engineers. The primary concern of engineers when designing technology, especially in the medical field, should be the health and safety of society and all potential users (van de Poel & Royakkers, 2011). While there are many aspects of safety in medical device regulation, one of the most important ideas is that patients are informed about any potential risks associated with a procedure or device. Informed consent in a medical setting ensures that the patient understands all of the necessary information to allow them to make a decision in their best interest. However, without adequate communication of risks, patients are not provided with all the information needed to make an informed decision. By not adequately reporting on the risks and problems found with the C-QUR mesh, Atrium's actions were morally unacceptable due to their deficit in communication between the company and its potential users.

As early as 2009, less than three years after Atrium obtained FDA approval for its C-QUR surgical mesh, patients and research studies began reporting adverse effects after

implantation. Some of these discoveries were made in the form of scientific studies analyzing the mechanical properties and biological ramifications of the C-QUR mesh, which concluded that the mesh caused significant adhesions after implantation and led to other symptoms such as bowel obstruction, inflammation, and tissue damage (Schreinemacher et. al, 2009). Other complications also emerged from adverse event reports filed with the FDA. These reports outline the type of injury or complications associated with a given case, as well as describe the failure and patient intervention required to rectify the issue ("MAUDE adverse event report: Atrium Medical Corporation C-QUR mesh", 2015).

Due to the various research studies published about the damages caused by the C-QUR mesh, as well as the large number of FDA reports, it is reasonable to assume that Atrium was aware of such issues as they began emerging. Even if there was no internal adverse findings or knowledge of the research studies that found negative results, companies are notified when an FDA event report is made against one of their devices. Additionally, as discussed in the previous section about the production of C-QUR surgical mesh, the FDA reported manufacturing violations on four separate occasions. Therefore, Atrium was made aware of issues, but it did not communicate them to the public.

Through their failure to inform the public about negative findings that had been found against the C-QUR mesh, they prevented potential users from making decisions based on all available information, which has serious implications on their health and freedom of choice. Therefore, Atrium's actions demonstrated a lack of communication between two of the most important actors in any technological network: the producer and its consumer. In this case, the lack of the virtue of the ability to efficiently communicate had greater implications than just the knowledge of the public, but it also had the potential to impact its health and safety, which

should be protected above all else (Pritchard, 2001). Not sharing crucial information and data constitutes moral wrongdoing by breaching the values required for responsible engineering, which also compromised the integrity of the product.

Conclusion

During the period in which C-QUR mesh was used for surgical hernia repair, it demonstrated many issues in its design and production as a result of the actions taken by Atrium's engineers and executives. The actions that led to problems with the device's efficacy and integrity were present in three main instances: research and development, manufacturing and production, and adverse effects reporting. By examining the virtues for morally responsible engineers set out by the virtue ethics framework, the actions of Atrium were deemed immoral, as it lacked one or more of such virtues in each specific situation, which ultimately led to failure and patient harm. Determining the entity responsible for a product's failure is important because when creating engineering designs, the health and safety of potential users, as well as society, must be placed above all other considerations. Therefore, in the healthcare industry, as well as other sectors, the company responsible for a product's development must be held accountable for its effect on users. When this is not the case, it allows for the development of technology that negatively impacts specific people or groups. Therefore, holding the creators of such technology accountable for the morality of their decisions during the design process is imperative for creating innovations that benefit all people.

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