A Virtue Ethics Analysis of Medtronic INFUSE Bone Graft

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

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Spring 2023

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

The INFUSE Bone Graft was a procedure designed by Medtronic to replace the use of donor tissue in spinal surgeries (*Infuse bone graft: Off label uses, side effects & lawsuits*, n.d.). Many studies were done on the INFUSE Bone Graft, but an article written in *The Spine Journal* found that the original studies were obscuring the risks of the procedure (Llamas, 2013). This led to many patients experiencing complications as a result of using the INFUSE Bone Graft. In particular, Dr. Jeffrey Wang was sued by patients who experienced post-surgical complications after receiving the INFUSE Bone Graft for off-label use. Dr. Wang was being paid by Medtronic at the time (Collier, 2016).

The occurrence of complications experienced by patients who received the INFUSE Bone Graft is often attributed to bias within the original research studies in combination with an inadequate design of the clinical trials. However, this current understanding fails to take into account the morality of the doctors who are being paid by Medtronic and using the INFUSE Bone Graft on patients. If we continue to view this case as a failure of research design due to bias, we will fail to understand how a lack of morality can cause patients to experience medical complications.

Through the use of virtue ethics, I will demonstrate that Dr. Wang acted immorally due to his lack of two virtues of medical professionals: discernment and trustworthiness. Virtue ethics is a framework that sets up a group of virtues that a person must show in order to be considered virtuous and moral in a specific profession. If the person does not exhibit these virtues, they are considered immoral. To support my argument, I will analyze email exchanges, United States Senator statements, and patient statements to support my argument. Using virtue ethics, I will

analyze how Dr. Wang's actions demonstrate he does not exhibit discernment and trustworthiness and is thus considered immoral.

Background

The INFUSE Bone Graft was developed and sold by Medtronic for bone formation and modeling without needing to harvest bone from other areas of the body (*Infuse bone graft*, n.d.). It is a protein that encourages cells to migrate to the site of implantation in order to build bones (*Infuse bone graft*, n.d.). The INFUSE Bone graft was only approved for use in anterior lumbar interbody fusion and oblique lateral interbody fusion. Despite this, doctors who were being paid by Medtronic used it for unapproved procedures known as "off-label" use (Pedersen, 2019). This led to complications such as cancer, neck swelling, airway compression, and death (Migliore, n.d.). In addition to off-label use, studies conducted on the INFUSE Bone Graft were authored by doctors who were financially compensated by Medtronic. These studies were found to "downplay" adverse side effects and "omit" discussion of these side effects (Raymond, 2017). This was brought to light by a report in *The Spine Journal* which led to a United States Senate investigation into the INFUSE Bone Graft, Medtronic, and the doctors being paid by Medtronic (*Report: Medtronic influenced studies on infuse bone grafts*, 2012). Dr. Wang was a spinal surgeon at the University of California, Los Angeles who "received at least $275,000 in unreported royalty and consulting payments from Medtronic from 2002 to 2009" (Qian, 2016). Dr. Wang was financially compensated by Medtronic when he performed operations on Jerome Lew and Ralph Weiss using the INFUSE Bone Graft on the patient's cervical spine, an off-label use (*Lew v. medtronic, inc.*, 2014). This resulted in complications that included recurring pain and additional surgeries (Terhune, 2016).

Literature Review

Several scholars have analyzed factors that led to patients experiencing complications caused by the INFUSE Bone Graft by examining the inadequate design of INFUSE bone graft clinical trials. The following analyses focus on the presence of bias within clinical trials and testing of the INFUSE Bone Graft. These analyses fail to take into account the morality of the doctors who are being paid by Medtronic and using the INFUSE Bone Graft on patients

In a review of the INFUSE Bone Graft posted in *The Spine Journal*, Carragee et al. examined 13 original studies sponsored by Medtronic on the safety and efficacy of the INFUSE Bone Graft. Carragee et al. conducted a "retrospective review of complications and adverse events as reported in FDA and other documents" to determine how the risk of complication increased by 10 to 50 times the estimate of risk from the original studies. Carragee et al. specifically examined the possibility of bias against control samples by pinpointing possible surgical protocol bias used with the INFUSE Bone Graft and the control graft, which was an iliac crest bone graft. The surgical protocol for the placement of these two grafts in the research study did not require that they be fused, however, iliac crest bone grafts need to be fused for optimal function. Carragee et al. concluded that the grafts in the control sample were not optimally placed due to poor surgical protocols, so this introduced bias into the clinical trials in favor of the INFUSE Bone Graft (Carragee et al., 2011).

In another review of the INFUSE Bone Graft, Hashmi et al. also examined the role of bias within INFUSE Bone Graft clinical trials. When the clinical trials were being conducted, patients, surgeons, and researchers all knew which groups were the control groups and which groups were the experimental groups. This is known as a "nonblinded" study. Hashmi et al.

concluded that this resulted in observer bias in favor of the experimental groups which received the INFUSE Bone Graft as the treatment (Hashmi et al., 2014). Observer bias is when a researcher's expectations or opinions influence what they record or perceive in a study (Bhandari, 2021). They note that this nonblinded approach exaggerated the effects of the INFUSE Bone Graft, citing the cause as an inferiorly designed study leading to bias (Hashmi et al., 2014).

An additional review of the INFUSE Bone Graft by Skovrlj et al. draws attention to the sample size of the studies. A study sponsored by Medtronic had 49 subjects within the experimental group who received the INFUSE Bone Graft. Skovrlj et al. state that the sample size for the INFUSE Bone Graft was too small to draw any conclusions on the safety and effectiveness of the INFUSE Bone Graft (Skovrlj et al., 2014).

All of the scholarly sources previously mentioned focus on bias within the studies sponsored by Medtronic. While each source focuses on different areas of bias within the study, from surgical protocol bias to observer bias to bias caused by inadequate sample size, they all conclude that there is some type of bias present within these inadequately designed studies. While it is important to examine inadequately designed studies and how that can lead to bias, this fails to understand the role that morality plays in facilitating the consequences resulting from the INFUSE Bone Graft. I will use the framework of virtue ethics to analyze how Dr. Wang's actions demonstrate he does not exhibit discernment and trustworthiness and is thus considered immoral.

Conceptual Framework

My analysis of the morality of the actions carried out by Dr. Wang draws on virtue ethics, which allows me to examine how this doctor failed to exhibit key virtues of medical professionals. Virtue ethics was developed by Aristotle who defined it as the desire to strive for

the most good and to act the most morally by exhibiting certain virtues (van de Poel & Royakkers, 2011). A virtue is a character trait that indicates the moral quality of a person. Aristotle also asserted that virtues contain an equilibrium position between two extremes of that virtue. For example, courage is the equilibrium position between cowardice and recklessness. People are not born with these virtues, but rather they are learned by performing actions related to those virtues (van de Poel & Royakkers, 2011).

Certain virtues are required in certain circumstances. Professions can require a group of virtues needed to be a virtuous and moral person when looking at actions within that profession (van de Poel & Royakkers, 2011). These sets of virtues for professions shape a person's approach to their work (Pritchard, 2001). In the healthcare field, medical professionals have a list of virtues they must exhibit in order to be considered virtuous. Tom Beauchamp and James Childress have compiled five virtues for medical practitioners (Gardiner, 2003). While these five virtues are the most common for medical professionals, some modern philosophers have created lists with as many as 24 virtues for medical professionals (Gardiner, 2003). The five virtues are:

1. Trustworthiness
2. Integrity
3. Discernment
4. Compassion
5. Conscientiousness

Figure 1: Virtues for Medical Professionals

Failure to exhibit these sets of virtues results in a professional that is immoral and cannot competently practice in their profession (Pritchard, 2001). Drawing on virtue ethics, in the analysis that follows I will examine the actions taken by Dr. Wang concerning two virtues of medical professionals: discernment and trustworthiness. In doing so, I will analyze the morality

of Dr. Wang during the time that he was being financially compensated by Medtronic while using the INFUSE Bone Graft on patients.

Analysis

Dr. Wang is lacking in two virtues that are necessary for being a virtuous medical professional. These two virtues are discernment and trustworthiness. The lack of these two virtues is evident by the actions of Dr. Wang when he used the INFUSE Bone Graft while being financially compensated by Medtronic. When professional virtues are not present in a situation they are necessary for, it is reasonable to consider that professional immoral (Gardiner, 2003). Using the framework of virtue ethics, Dr. Wang was immoral by failing to practice the medical professional virtues of discernment and trustworthiness. In this section, I will analyze actions made by Dr. Wang as it pertains to discernment and trustworthiness to show an absence of those virtues.

Discernment

I will demonstrate that Dr. Wang acted immorally by analyzing the lack of discernment as it relates to the use of INFUSE Bone Graft on patients while being paid by Medtronic. Discernment is defined as the use of wise judgment in situations (Gardiner, 2003). While the INFUSE Bone Graft was only approved by the FDA for certain procedures, "at least three-quarters of the roughly 200 'adverse events' reported to the FDA involve off-label uses of Infuse" (Armstrong & Burton, 2008). Many adverse side effects resulted from the use of the INFUSE Bone Graft for off-label purposes. This can partially be attributed to doctors with

financial ties to Medtronic promoting off-label use in a variety of forums, such as in journals and at meetings (Armstrong & Burton, 2008).

A deposition from a court case against Dr. Wang states, "the second email exchange was between Dr. Wang and Mr. McClintock … During that exchange, Mr. McClintock provides Dr. Wang with pricing or smaller packaging of the Infuse product. These smaller packages were only FDA approved for use in dental procedures" (Teixeira, 2015). Something to note from this piece of evidence is that Dr. Wang is a spinal surgeon, but he is being told about an INFUSE Bone Graft that is only approved for dental work. This suggests that Mr. McClinton, a sales manager, is giving this information to Dr. Wang for off-label use since it does not pertain to Dr. Wang's specialty. Also, this suggests that Dr. Wang was at least entertaining the fact that he was going to buy this product by being provided the pricing for it. This evidence demonstrates that Dr. Wang did not exhibit the virtue of discernment because he is going against his better judgment. It is reasonable to believe that Dr. Wang would know not to use a dental product for spinal surgeries, but he decides to ignore his better judgment by communicating with a sales representative about a product used for dental procedures.

Dr. Wang showed his lack of discernment by consulting with a sales manager about an INFUSE Bone Graft for off-label use. One may argue that Dr. Wang could have been given the pricing without expressing interest in purchasing the product. This is unlikely because Mr. McClinton would not be forthcoming with the price of the product unless he thought he would be selling it. A statement made by Medtronic supports this idea because Medtronic "regards its pricing information to be highly proprietary and confidential" (Teixeira, 2015). Sales representatives from Medtronic would not give out pricing unless it was to an entity that they knew would buy their product.

Additionally, Dr. Wang has already shown from other actions that he would be willing to use the INFUSE Bone Graft for off-label purposes. Dr. Wang was financially compensated by Medtronic when he operated on Jerome Lew using the INFUSE Bone Graft on the patient's cervical spine (*Lew v. medtronic, inc.*, 2014). The INFUSE Bone Graft had only been approved for use in the lumbar spine, so this procedure was using the bone graft for off-label purposes. Following the surgery, Lew started experiencing complications that revealed a bony overgrowth due to the use of the INFUSE Bone Graft. This overgrowth was compressing his spinal cord, so he underwent additional surgeries (*Lew v. medtronic, inc.*, n.d.).

Dr. Wang has shown through his actions that he lacks the virtue of discernment. Dr. Wang has demonstrated that he is willing to go against his better judgment to consult with Medtronic sales managers about the use of the INFUSE Bone Graft when he knows it is not approved for his specialty. The use of the INFUSE Bone Graft for off-label purposes is known to increase the probability of post-surgical complications. He has also shown that he is willing to go against his better judgment to use the INFUSE Bone Graft on patients for off-label use while being financially compensated by Medtronic. This lack of discernment through Dr. Wang's actions demonstrates that he is acting immorally.

Trustworthiness

I will demonstrate that Dr. Wang acted immorally by analyzing the lack of trustworthiness as it relates to the use of INFUSE Bone Graft on patients while being paid by Medtronic. Trustworthiness is the ability of a person to avoid unfairly exploiting another (Willinger, 2015). According to the American Medical Association, "physicians must disclose fully the nature of their financial arrangement with a manufacturer or supplier to sell

health-related products" (*AMA code of medical ethics' opinions on physicians' financial interests*, 2015). This ensures that the patients are fully aware of the bias that might drive a doctor to make certain medical decisions (Bluth, 2018). For doctors who also participate in research, the disclosure of financial ties is critical in ensuring the articles that they publish are honest about the possible implications those ties might have on the article (Deangelis, 2015).

In a statement made by Dr. Wang's patient who suffered complications after receiving the INFUSE Bone Graft, Ralph Weiss states "[Dr. Wang] didn't tell me he is getting royalty, stock options … and paid hundreds of thousands of dollars for the product" (Qian, 2016, p. 5). Something to note from this is Dr. Wang knowingly chose not to disclose his conflict of interest to his patient prior to his surgery. He kept his patient from knowing the truth about his financial ties to Medtronic while using the INFUSE Bone Graft on him. Had Mr. Weiss known about Dr. Wang's financial ties to Medtronic, he would have been able to make a more informed decision of whether or not to go through with the procedure using the INFUSE Bone Graft. This suggests that Dr. Wang was willing to exploit his patients by hiding the truth from them. He did this in order to use the INFUSE Bone Graft in his procedures. Dr. Wang did not inform his patients that he was being paid by Medtronic, violating the patient's trust in him.

In addition to withholding the truth about being paid by Medtronic from his patients, Dr. Wang also did not inform the University of California, Los Angeles (UCLA) of his financial ties. United States Senator Charles Grassley sent a letter to UCLA's chancellor stating, "[Dr. Wang] didn't inform the school of $459,500 he was paid by companies from 2004 through 2007" (Armstrong & Burton, 2008). One thing to note from this statement is that despite being paid hundreds of thousands of dollars, Dr. Wang chose not to inform his institution of this. He is exploiting the institution's support by willingly withholding the truth of his financial ties from

the institution where he does his research. Because Dr. Wang decided not to reveal his conflict of interest, other physicians and people reading his research are unaware that his research could have been impacted by his financial ties.

This evidence demonstrates that Dr. Wang did not exhibit the virtue of trustworthiness because he exploited his relationships by choosing not to disclose his financial ties to his patients, UCLA, and the general public. This leads to distrust between him and the people he is withholding information from because he is not willing to tell them the truth about his conflicts of interest. They are unable to trust that he will follow guidelines and tell them important information. It is reasonable to believe that Dr. Wang knew he should disclose his conflicts of interest to both UCLA and his patients, but he decided to keep the truth from both of them. This lack of trustworthiness in Dr. Wang's actions demonstrates that he is acting immorally.

Conclusion

Through the use of virtue ethics, it was determined that Dr. Jeffrey Wang acted immorally by failing to practice the medical professional virtues of discernment and trustworthiness. The lack of these two virtues is evident in the actions of Dr. Wang when he used the INFUSE Bone Graft while being financially compensated by Medtronic. Through his actions, Dr. Wang showed that he was willing to use the INFUSE Bone Graft for off-label purposes despite his better judgment. He also showed that he was willing to keep his financial ties to Medtronic a secret from his patients and UCLA. This analysis allows for the understanding of how Dr. Wang did not exhibit some virtues of medical professionals. This resulted in his patients experiencing medical complications following the use of the INFUSE Bone Graft. It also allows readers to better understand the role that immorality plays in the occurrence of medical complications for patients.

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