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Understanding Medical Error in Surgical Stapler Use: A Philosophical and Scientific Analysis

Jacob E. Howard
University of Central Florida

UNDERSTANDING MEDICAL ERROR IN SURGICAL STAPLER USE: A PHILOSOPHICAL AND SCIENTIFIC ANALYSIS

by

JACOB EDWARD HOWARD

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ABSTRACT

Classified for decades as a "least risk medical device," surgical staplers have been recently associated with at least 41,000 injuries and 360 deaths in the last ten years (FDA Letter to Healthcare Providers, 2019). This shocking development has generated calls for a broad investigation into the errors involved in surgical stapler use and reform of the regulatory protocol for medical devices. Current regulatory infrastructure and framework operate with understandings that combine risk inherent to the device and that which is born by the operator (FDA Classification Call, 2019). This thesis explores the aforementioned classification error and its adverse outcomes from an epistemological standpoint. Social epistemic analysis is applied to FDA regulation and to the comparison of two scenarios in reference to the current status-quo classification and to the proposed risk reclassification of surgical staples. Expert versus novice error avoidance surgical performance capabilities are discussed under these two different classificatory scenarios and epistemic social roles.

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

INTRODUCTION

Medical error is estimated to be the third cause of death in the US (IOM, 1999). One particular area of concern is patient safety in the field of surgery. The surgical stapler was invented in the early 20th century and approved for use by the FDA in 1988 as a highly safe "Class 1 Medical Device" - an FDA category designed to encompass the "lowest-risk devices such as tongue depressors" (FDA Letter to Healthcare Providers, 2019). Yet, between 2011 and 2018, the FDA has received over 41,000 adverse event reports related to the use of surgical staplers. In this report, 360 deaths were associated with the use of surgical staplers stemming from "malformation of staples, misfiring, difficulty in firing, failure of the stapler to fire the staple, and misapplied staples" (FDA Draft Guidance, 2019). This is an unexpected and deadly turn of events for a "Class I Medical Device" (ECRI 2020 Report) that requires much investigation This thesis discusses the surgical stapler problem in both its scientific and epistemic dimensions in two chapters inclusive of premanufacturing and implementation aspects that influence or cause surgical stapler error.

The chapter on the scientific background addresses the purposes and functions of surgical staplers and the common types of medical errors made with them.

The chapter on epistemology articulates the epistemic goals and responsibilities of individual and group agents, institutions and regulatory bodies. The epistemic analysis is carried through the lens of systems-oriented social epistemology (SYSOR). The FDA regulatory body is discussed in the context of the analysis of epistemic systems and trust issues. This chapter also encompasses a reflection on judgment and decision-making in the context of performance and expertise. Accordingly, it examines the role of the surgeon's expertise and training levels in epistemic terms. The normative analysis provided by social epistemology lends an extended

reflection on the ethics of transparency in the regulation of medical devices and considerations on moral responsibility extend for the surgical stapler designer, the FDA approval process, and the surgeon.

Methodology and Ethics Statement

This is a theoretical study with philosophical analysis methodology applied in scientific context. review provided the background basis for each of the main sections.

For the scientific background, literature searches were performed with the use of PubMed database, utilizing the search terms “surgical stapler”, “surgical stapler error”, “medical device error”, “expert surgeon error”, “novice surgeon error”, “senior surgeon error”, “resident surgeon error”. Articles retrieved between 1988 (the beginning of FDA regulation of surgical staplers) and July 2020 were considered. These searches were supplemented by bulletins and data provided by the FDA and by the independent healthcare research organization Emergency Care Research Institute (ECRI) starting in 2018.

For the chapter on epistemology, literature from the same PubMed searches was utilized and included JSTOR database searches using the terms “medical error”, “surgical stapler”, “social epistemology”, “medical epistemology”, “expertise versus novice”, “transparency epistemology” and “trust epistemology”. The extended ethical considerations in this chapter on transparency in bioethics and responsibility were researched in the context of learning health systems..

Research team has no conflict of interest to declare in regards to stapler medical device, its commercialization and overall industry.

BACKGROUND

Risk classification is a key analytic task that requires scientific refinement for proper specification of norms aiming at preventing harms. It requires mapping the categorization of risk with evidence hierarchies into study models. The FDA has historically classified medical devices risk based on a threeclass system. The main classificatory criterion has been scoring the potential for inducing "harm." Class 1 risk classification encompasses devices that lead to minimal harm and, accordingly, experience the least regulatory control such as "limited… establishment registration and listing; prohibitions against adulteration and misbranding; records and reports; and good manufacturing practices (GMPs) (FDA, 2019). Class 2 risk classification is reserved to medical devices that require additional controls, such as abidance to specific performance standards, premarket notification, post-market surveillance, labeling and patient registries in order to maintain safety. Class 3 risk classified medical devices are deemed to have the potential to present higher risk of illness or injury. These devices are usually the "riskiest" and often encompass devices meant to sustain or support life (Lucas, 2019). Device categorization in all classifications is based on "intended use" and "indications for use."

Classification 1	**Classification 2**	**Classification 3**
"Lowest Risk" General controls	General Controls Possible Special Controls Possible Premarket Notice	"Greatest Risk" General & Special Controls Premarket Notice (510k)

Elastic bandages, examination gloves, tongue-depressors, surgical staplers	Syringes, medical lasers, endoscopes, radiofrequency ablation systems.	Breast implants, dermal fillers, dry heat sterilizers,

Table 1: Classification of Medical Devices by the Food and Drug Administration, adapted from the FDA online guide "Classify your Medical Device" (FDA, 2020)

A surgical stapler intended typically is used to simultaneously cut and ligate tissue while that same surgical stapler indications for use could specify a subset of intended uses (i.e. use only on pulmonary tissue). The FDA specifies that indications for use can be provided "in the devices labeling but may also be conveyed orally during sale of the product." (FDA, 2020)

Staplers are currently a Class 1 risk medical device that fulfill a dual role of sealing tissues and separating them. While recent calls have increased to classify surgical staplers under classification 2, hand-held surgical instruments have been historically deemed Class 1, and staplers specifically have been categorized in this group by the FDA since 1988 (FDA, 2019). Surgical staplers are used in a multitude of surgical situations. Historically a common problem facing surgeons in the 19th century was incomplete anastomosis or leakages due to a lack of equipment to properly cut and seal tissue. A stapler solution to this problem was presented in 1908 by surgeons Humfer Hultl and Victor Fischer, and since then, surgical staplers have expanded from simple designs to multiple ergonomic varieties and electric/mechanical variants (Nakayama et al, 2019). Some models will instantly fire the staples after enough force has been exerted while others require a second trigger to fire. Staplers differ in the way the anvil is shaped and the way the stapler and knife mechanism work. Although there are five main categories

(circular, linear, linear cutting, ligating, and skin staplers), variations of these designs allow different size stapler lines specific to the tissue and situation (McGuire et al, 2019). Additionally, the trigger mechanism for firing the stapler can be mechanical or motorized.

While malfunctioning staplers have been the culprit in numerous situations where error occurred in the context of surgical stapler use, previous investigations have found that the majority of poor surgical outcomes related to surgical staplers are due to human factors (Rimmer, 2019;Lucas, 2019;Miller, 2019; Elgeidie et al, 2013). These human factors involve limitations of expertise of the surgeon.

In fact, if the scientific explanation for stapler effectiveness and variability can be discussed in the philosophical context of the study of models of mechanics and motorized phenomena, in way of deterministic, probabilistic, statistical explanations, their external validity depends on anticipatory studies and on systematically ranking the evidence available for their safe use, to countervail the limitations of asystematic expertise and tradition, in an Evidence-Based Medicine platform (Worrall, 2007) (Garbayo & Stahl, 2017).

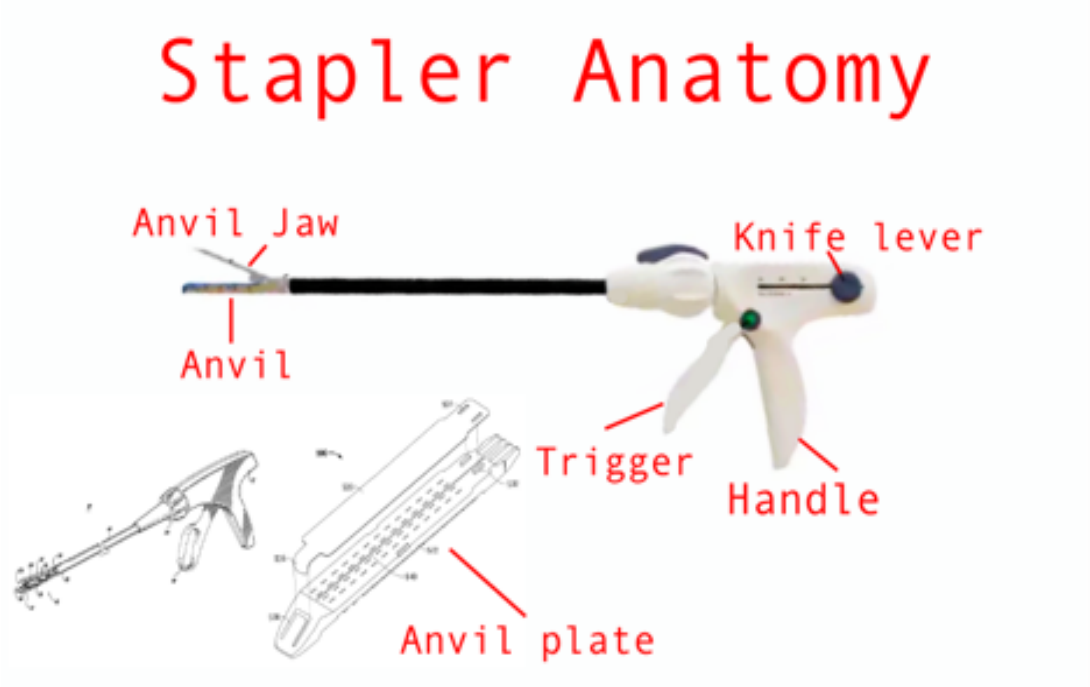

Figure 1: Linear Stapler Anatomy. Illustrations from Patent US7950561B2, (Aranyi, 2009)

High-risk situations in which surgical staplers are utilized are multiple.and independent investigative agencies such as the Emergency Care Research Institute (ECRI) have outlined specific situations where surgical staplers have been involved in harm to patients repeatedly (Lucas, 2019). These include improper firing of the stapler that results in an improper seal of the tissue and can cause bleeding. In some reported cases, the stapler will clamp down and fail to release or disengage, which will destroy the tissue clamped and necessitate manual sewing of the tissue around the stapler. In other situations, the surgical stapler managed to clamp properly and cut cleanly, but it was malformed or no staples were fired. Though many case studies have found issues with proper stapler functioning, independent investigatory agencies have found that "in most incidents…investigated, the stapler was found to have functioned as intended" (Miller,

2019). This outcome further supports the notion that surgical stapler error is largelyrelated to the limitation of expertise or knowledge of the user.

Recommendations posited by the FDA and independent review agencies on the reclassification of surgical staplers to "Class 2" follow a common theme: 1) supporting proper surgeon training and education and 2) focusing on surgeons building a familiarity with the surgical stapler tools they will use during surgery. Familiarity with the surgical staplers entails knowing how much force is required to fire the stapler, the correct stapler sizes to choose from, and how to properly manipulate the stapler to delicately handle tissue. There is still a paucity of research on exactly what the best way to become familiar with surgical staplers is (Rimmer, 2019).

Moreover, there is a lack of consensus in terms of data and case studies outlining error related to the use of surgical staplers. One main issue stems from the FDA holding separate public and private data banks in which accident and error reports can be submitted to. This makes post-market surveillance difficult. While multiple independent regulatory agencies have ramped up research efforts, a lack of centralized discussion on the issue has hampered these goals (Hofer et al, 2016). The FDA hopes to mitigate this through a series of meetings convening different authorities on the crisis, such as sending a "Letter to Healthcare Providers" about the Safe Use of Surgical Staplers and Staples in March of 2019, issuing a draft guidance on surgical staplers in April of 2019, and holding an FDA CDRH General And Plastic Surgery Devices Advisory Committee meeting in May of 2019. The FDA hopes to make a decision on recategorizing surgical staplers in Class 2 instead of Class 1 early in 2020 (Lucas, 2019), yet as of July 2020 no decision has been reached.

SCIENTIFIC BACKGROUND

The development of a surgical tool such as a stapler is built upon a multitude of sciences and disciplines. As mentioned in the overall background, the surgical stapler was originally designed to allow a surgeon to both cut and ligate simultaneously, allowing for anastomosis or sealing of tissue with minimal loss of fluid (Nakayama et al, 2019). Designing any one variant of a surgical stapler must take into consideration the purpose, safety of use, and accessibility solutions that draw from universal design. Immediately after the invention of the surgical stapler in 1908, users such as Aladár Petz set to refining the original design in order to achieve a cheaper, more ergonomic, lightweight version (Gaidry, 2019). It is apparent that from the advent of the surgical stapler that scientists and engineers have concerned themselves with refining the surgical stapler to be more comfortable and intuitive in a surgeon's hand (McGuire, Wright, Leverment, 1997).

Surgical Stapler Design

the linear surgical stapler is generally composed of five distinct parts: anvil, anvil jaw, trigger, handle, and knife lever. In some models the knife lever is manually engaged, while in others the knife is automatically deployed upon sufficient force applied to the trigger handle.

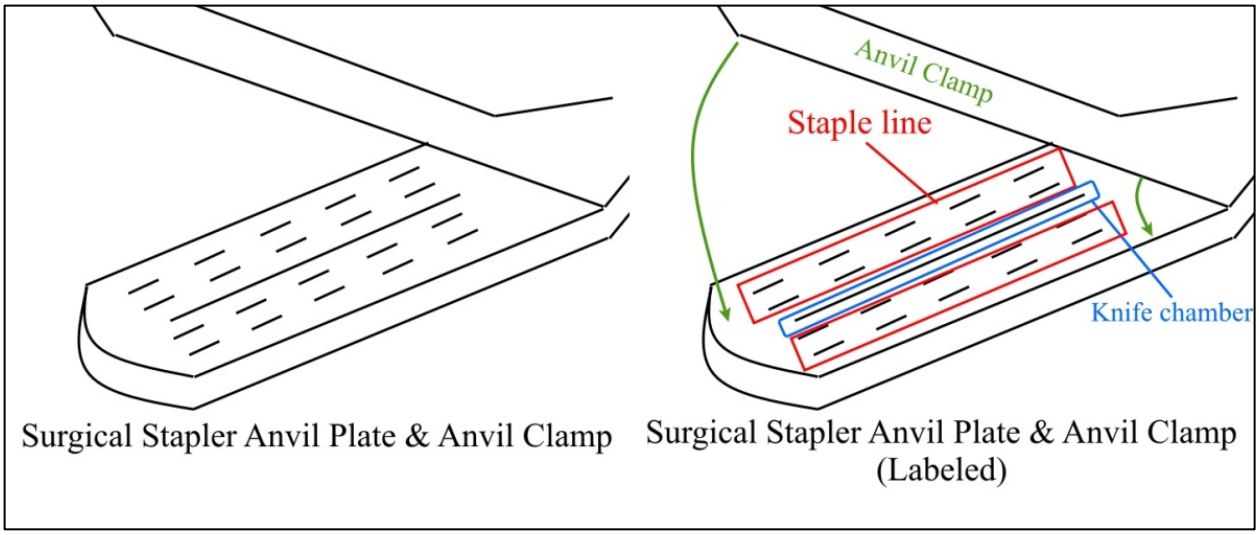

Figure 2: Close-up Illustration of Surgical Stapler Anvil Assembly

The anvil is the specialized segment of the tool that varies from each surgical stapler model. In the linear variant (Figure 2) there is a small straight slit (knife chamber) for a small knife to slide across and cut tissue. The knife chamber is flanked on both sides by the stapler function. In the majority of linear staplers, the staple cartridges will fire first, sealing the tissue or vessels, and then the knife lever will be activated to move a small knife across the knife chamber, separating the tissue cleanly without any leakages from either side. Beyond housing both the stapling and knife apparatus of the tool, one major feature of the anvil plate and clamp is that when compressed together the edges act as a hemostat, by pressing down on the tissues surrounding the site of wound closure and effectively closing any immediate vasculature.

Surgical Stapler in Action

Among the arsenal of tools at a surgeon's disposal to close wounds or ligate tissue, surgical staplers are often chosen over conventional surgical sutures. The surgical stapler combines and colocalizes multiple tools in one for a surgeon's use, instead of requiring a surgeon

to manipulate different tools such as a hemostat, sutures, and surgical knife separately. This can significantly reduce the operative time of virtually all surgeries where a surgical stapler is chosen over hand sutures (Catena et al, 2004). Skin stapling and end-to-end anastomosis are some of the earliest and most common uses for surgical staplers (Kaintanov, Petrova, Iurasova, 1966). Modification of surgical staplers for laparoscopic surgery by the inclusion of a long neck has increased their popularity among a diversity of surgical sub-disciplines, even becoming an "indispensable tool for thoracic surgery" (Murakawa, Nakajima, 2014).

Surgical Staplers vs. Classic Sutures

The benefits of choosing to use a surgical stapler are complicated by ongoing research comparing the patient outcomes to situations when surgical sutures are used instead. One study compared sutured and stapled gastrointestinal anastomoses (Gaidry, 2019) and found that while operative times were shorter for surgeries where a surgical stapler was chosen, anastomotic leaks and intra-abdominal abscesses were more likely to occur compared to the use of sutures (Brundage et al, 2001). Other studies argue that surgical staplers leave smaller wounds and incur less local inflammation, allowing tissues to experience quicker healing time (Zhang et al, 2015). One meta-analysis of randomized controlled trials comparing sutures versus staples when managing surgical wounds (including obstetrics, gynecological, general, neck/head, and emergency operations but excluding orthopedic surgeries) found that the use of surgical staplers was associated with significantly fewer wound infections and less time for wound closure. Surgical staplers did not differ from sutures in terms of cosmetic result and patient satisfaction but were associated with more pain as perceived by the patient (Iavazzo et al, 2011).

The debate of sutures versus surgical stapler use can even be complicated in the same medicinal field. In orthopedic surgery, two meta-analysis have found that surgical staplers are "associated with higher risk of developing wound infection" than sutures (Smith, Sexton, Mann, Donnell, 2010) (Kirby, 2010). Another meta-analysis of surgical staples in orthopedic surgery found that there is no significant difference between sutures and surgical stapler use, concluding that the decision to use a surgical stapler "should be based on… local availability, surgeon preference, and cost" (Krishnan et al, 2019).

Advantages of Surgical Staplers	**Debated Aspects**	**Disadvantages of Surgical Staplers**
- Reduced operative time (Catena et al, 2004) - Smaller holes versus suture - Less Local Inflammation (Zhang et al, 2015)	- Higher risk of wound infection (Brundage et al, 2001) (Smith, Sexton, Mann, Donnell, 2010) - Lower risk of wound infection (Iavazzo et al, 2011)	- More Painful (Iavazzo et al, 2011)

Table 2: Comparison of Surgical Stapler versus Sutures

Common Errors in Surgical Stapler Utilization

There are two main categories of error at play: user error and device error/ malfunctioning. In the FDA's summary of data collected on surgical stapler error over the last 10 years, total injuries due to both types of error doubled from around 1,000 per year in 2013 to nearly 2,000 per year in 2018 (FDA Classification Call Figure 5, 2019). The 412 deaths from injuries over this time period most commonly occurred in cardiothoracic, bariatric, or hindgut

procedures with 65% of total deaths due to surgical stapler error. Among these deaths the most common causes were anastomotic leaks, abscess, sepsis, and peritonitis. It is difficult to distinguish user error from device malfunctioning given that some surgical stapler malfunction classifications do not specify if it was due to human error or not. The cause is often only determined by subsequent investigation (ECRI, 2019).

TYPE OF SURGICAL MALFUNCTION	**NUMBER REPORTED**	**PERCENTAGE OF TOTAL**
Malformed Staples/Staple Line	62	32%
Staple Line not Forming/staples missing	38	20%
Sticking/Locking/Jamming	31	16%
Tissue Damage/Leaks	29	15%
Misfire	20	10%
Stapler not Cutting	6	3%
Cartridge not Loading/Not properly loaded	4	2%
Stapler Broke	5	2.5%
Total	195 Cases Surveyed	

Table 3: Types of Stapler Malfunctions Reported (FDA Stapler Classification Call, 2019)

For example, the most common type of surgical stapler malfunction reported by the FDA is “malformed staples/staple line” (32% of total malfunctions surveyed). Within this category, there is no specification if the malformed staples are due to misuse on the surgeon’s part. In fact, the FDA stated in their 2019 report that this specific malfunction can be caused by both “complications associated with use error”, “improper device selection and use”, “user difficulty in firing stapler”, “wrong tissue”, as well as “complications associated with device failure”, and “device malfunctions”. Post-operative investigations of surgical staplers by ECRI revealed that in most cases where surgical stapler errors were logged as “device failure/malfunction”, that human error or improper use were to blame instead (Miller, 2019).

FDA Determined Risks to Health	Examples
Manufacturing/Design **Device Failure/ Malfunction** **Adverse Tissue Reaction**	Stapler breaks or staples fail to crimp properly, leads to prolonged surgical procedures, unplanned interventions. -Non-biocompatible parts lead to local tissue irritation, cytotoxicity, immune system reaction
Implementation/ Human Error **User Error/ Improper Device Selection** **Improper Sterilization**	-User difficulty firing staples -Wrong staple size chosen for tissue -Wrong stapler chosen for tissue -Incorrect clamping of tissue -Difficulty comprehending device labeling -Improper device maintenance or sterilization leads to infection

Table 4: Categorization of FDA "Risks to Health" (FDA Stapler Classification Call, 2019)

Error Outcomes

Surgical stapler error outcomes can vary from negligible, to injury or death. When error occurs, the most common response is to switch to a suture technique instead. This can be complicated by the fact that surgical staplers are used often in laparoscopic surgery (Elgeidie, Hak, Abdulla, 2013). Out of the FDA error reports collected, there is a common set of surgeon responses due to surgical stapler error, independent of user error/ device malfunction.

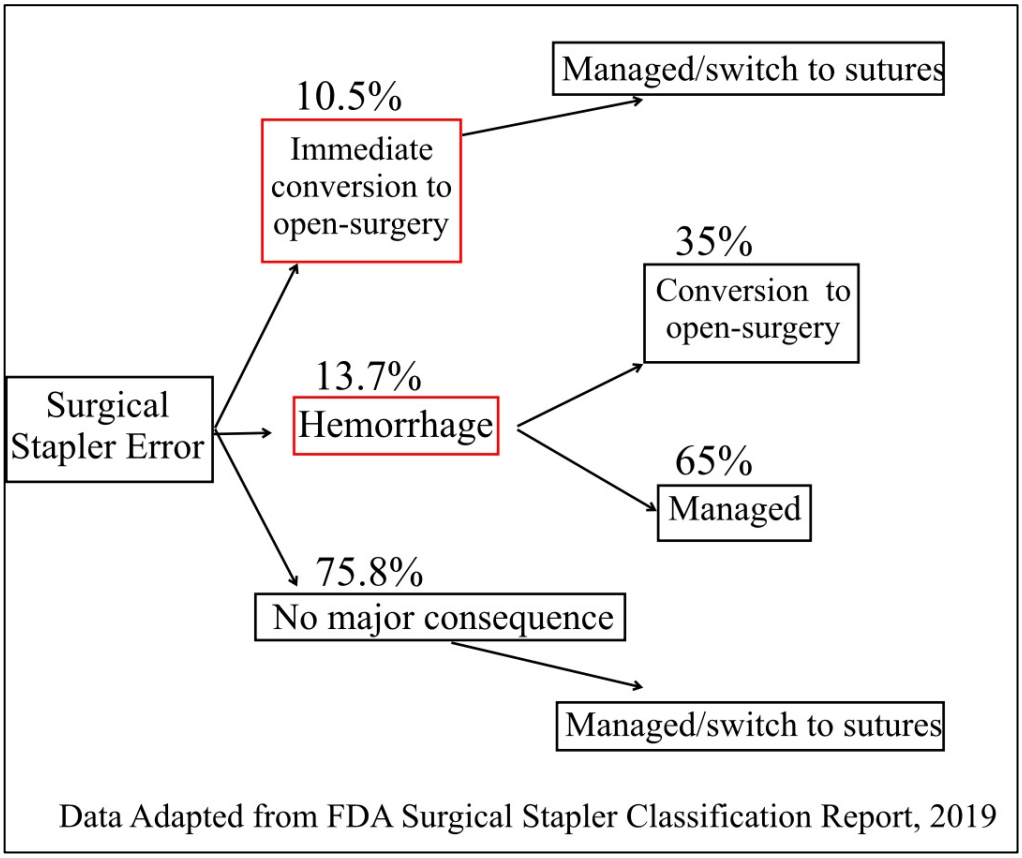

Figure 3: Common Responses to Surgical Stapler Error

As seen in Figure 3, the majority of stapler error is handled with no consequence, but when hemorrhage or other complications occur, a quick response to work around the surgical stapler error is required to increase positive patient outcomes (Whelan, 2014). When a quick response is needed, novice surgeons often take longer than their senior counterparts (Siam et al, 2017) and specifically with surgical stapler failure (Graafland, 2014). Graafland found that while more experienced surgeons addressed the equipment failure quicker than residents, more mistakes were made in the process. This is indicative of a "recognition primed decision model" that is found in experts across many professional domains. The RPD model explains when a quick

response is needed, experts will often respond in a way that is “satisficing” - not necessarily the best option but quick enough while still being largely effective (Phillips, Klein, Sleck,2008).

This suggests that a higher level of expertise and training may be crucial for handling a surgical stapler that is surprisingly riskier than its given FDA classification. These recorded possible malfunctions and adverse reactions make its usage specially challenging to novice surgeons. In the next section we analyze assumptions of trust and belief in stapler risk that may affect performance and patient outcomes.

EPISTEMIC ANALYSIS

Epistemology is broadly defined as the philosophical study of human knowledge. Virtually all approaches to epistemology seek to better understand “cognitive successes” and “cognitive failures,” of which knowledge can be considered a type of cognitive success (Steup & Neta, 2020). Historically there has been controversy in determining if epistemology is compatible with medical knowing as medicine has been argued to be an “applied technology” and not a body of knowledge in and of itself (Duffin, 2001). Philosophers such as Mirko Grmek have disputed this argument by pointing out that the existence of ‘doxastic attitudes’ (beliefs), and informed decisions proves that medicine inherently relies on an epistemology that asks, “what do we think we know, and why?” (Grmek, 1977)

Epistemic agents in medicine can experience both cognitive success and failures in relation to the acquisition of propositional medical knowledge – a type of knowledge that is inferential - but also in relation to performative ‘know-how’ type of knowledge combined in medical practice (Garbayo & Stahl. 2017). These knowers who combine propositional and performative knowledge can be individual agents, such as surgeons, who know how to operate a surgical stapler in a way that benefits the patient’s health while aquiring propositional knowledge about its practice, or inventors who know how to design and create a surgical stapler, and infer outcomes. Individual agents may work "with the help of” or “in the face of” other individual epistemic agents together as “collective agents” in order to better obtain and evaluate doxastic attitudes or truths as a group (Goldman & Cailan, 2019). This is the case of surgical teams but also of institutions. Social epistemology concerns itself with the study of these collective agents and individual agents who have social justifications to their knowledge or beliefs. The FDA is an example of a collective agent that comprises itself of multiple organizational levels of individual

and group agents. Manufacturers, regulators, and medical device users, all interact as epistemic agents in a system of distributed responsibilities (Bird, 2014) to ascertain a high level of knowledge – justified true beliefs as a body of knowledge - about the safety, risk, and efficacy of medical devices such as surgical staplers.

Surgeons as individual epistemic agents form their beliefs based on their training grounded on their acquisition of the body of knowledge and take/interpretation of the trustworthiness of the epistemic regulatory system and the information provided by multiple epistemic agents, while considering their own personal performances and patient outcomes to build propositional knowledge and know-how on devices and techniques. Trusting social epistemic systems is arguably not automatic for all agents, but have a strong pragmatic component to accommodate both the interests of agents, level of preparation and the focus on outcomes. Phillip Nickels suggests a pragmatic account of trust as follows, that introduces trust as an outcome based on agent interests:

> "…trust should (a) be explained as the outcome of central concerns or interests of the relevant actors, and (b) explain the emergence and sustenance of cooperative practices and social institutions" (Nickels, 2017).

Different groups of epistemic agents in the overall collective group have differing goals but seek to trust and cooperate with each other. Manufacturers seek to create helpful tools that improve patient outcomes but remain profitable. The FDA seeks to facilitate the existence of a market for medical devices that avoids the introduction of harmful or faulty hardware. Surgeons and medical practitioners seek to use devices that will maximize the good and minimize bad

outcomes for their patients. All agents seek to cooperate in order to achieve their epistemic aims but can only do so with the emergence of a pragmatic sense of trust on the alignment of goals and outcomes. Individual agents swap information with each other, and systemwide epistemic norms are renegotiated when trust exists between agents in the overall system (Origi, 2008).

Two epistemic scenarios are proposed below for epistemic analysis: current FDA classification of surgical staplers as a class 1 (least risk device) scenario and reclassification of surgical staplers as class 2 scenario. These specific scenarios allow for the discussion of how different treatment of surgical staplers can affect the knowledge, trust, and subsequent decisions of four/three types of epistemic agents: the FDA, manufacturers, expert surgeons, and novice surgeons. These decisions lead to Table 3's FDA categorized outcomes of device malfunction or user error/ improper device selection and use (FDA Stapler Classification Call, 2019).

Scenario 1: Current Class 1 Classification	**Scenario 2: Proposed Class 2 Classification**
-Prohibitions against adulteration/misbranding - "Good Manufacturing Practices"	-Premarket Approval -Preclinical Testing, biocompatibility testing -Post market surveillance

Table 5: Epistemic Scenarios

Scenario 1: Current Class 1 Classification

Overall Regulatory System

The central tenet of classification 1 requirements is adherence to "good manufacturing practices" (GMPs) which are inherently designed to be flexible and function as an "umbrella

policy" for regulation of all class 1 medical devices. "Manufacturers should use good judgement when developing their quality system…operating within this flexibility, it is the responsibility of each manufacturer to establish requirements for each type or family of devices that will result in devices that are safe and effective." Under this regulatory framework, it is the responsibility of surgical stapler designers and manufacturers to self-regulate and monitor any post-market incident reports (FDA GMPs Bulletin, 2018). Under a SYSOR understanding, manufacturers and designers operate as "reliable informants" in the overall system and are expected to provide other actors within the system, such as the FDA, with accurate and reliable information.

Under classification 1, surgical stapler manufacturers have historically been able to choose to file error incident reports publicly through FDA database MAUDE or through an FDA internal "Alternative Summary Database" that is not publicly accessible. "Although the Food and Drug Administration maintains a Manufacturer and User Facility Device Experience (MAUDE) database to track such voluntary reports, many events are not reported and the true incidence of adverse events is unknown" (Kwazneski & Stahlfield, 2013). As predicted, "epistemic incompetence and private interest often lead to inaccurate, insincere, deceptive, or incomplete information" when accountability and incentivization are lacking for individual agents acting in an overall social epistemic system (Goldman, 2009). There is a tension between the goals of individual agents (manufacturers, regulatory officials, and operators) and the overall epistemic goals of the system: to ascertain the level of risk and safety involved with the use of specific medical devices. The fact that manufacturers have additional interests and goals such as profitability do preclude them from benefiting the overall epistemic system, as with the proper regulations these individual goals can align with the overall epistemic goals (Kitcher, 1993).

Under this scenario, public information flow is lacking and communication between different agents in the overall system is not encouraged, affecting trust.

Expert and Novice Operators

The lack of public information and required surveillance of surgical staplers post market inherently affects the knowledge and decision making of experts. "[Operating with surgical staplers] without data [on error incidents] is inherently dangerous" (Kwazneski, 2013). Even more so, for novices who struggle to develop new strategies when the unexpected occurs (Glaser, 1996) and struggle to manage uncertainty (Schmitt and Klein, 1996).

Under Scenario 1, the status quo, experts and novice surgeons rely on GMPs from manufacturers to reduce the "Device failure/malfunction" and are given limited resources or information in order to reduce "Use error/improper device selection and use" as defined by the FDA as the two main routes for injury to patients by surgical stapler devices. Expert surgeons as individual epistemic agents may distrust the medical stapler information from manufacturers and the FDA based on both accumulation of personal anedoctal experience with adverse outcomes and/or on propositional knowledge of the limitations of epistemic systems, as research surgeons that examine the lack of data (MAUDE data). In contrast, the novice surgeon may be more likely to trust the epistemic systems and assume that the risk level is adequate and be therefore underprepared to react to adverse outcomes due to the stapler medical device issues during surgery.

Scenario 2: Reclassification to Class 2

Overall Regulatory System

There are three main regulatory changes and safety precautions introduced in classification 2 for surgical stapler devices; premarket approval, preclinical testing, and postmarket surveillance. At a systems level these are crucial for eliminating any incentive for manufacturers to procure incomplete or poor information on the efficacy of their own devices. Premarket approval and preclinical testing require a demonstrated efficacy according to specific standards (FDA Call for Classification, 2019). Additionally, preclinical testing opens the door for simulation of the impacts of surgical stapler use that can better equip organizations and users that are adopting such technology to anticipate all outcomes (Söderholm et al, 2019; Garbayo, Stahl, 2017). The key advantage that a SYSOR analysis provides in this scenario is the prediction in this instance that the removal of the "fallible process" of assigning "indicator properties" in order to establish "reliable informants" is transformative to establish trust (Goldman, 2009). There is in this scenario required mechanisms to generate trust in manufacturers that are required and comply in making public all device error incidents, as all relevant error information is now obligated. Under classification one error reports are sent from the surgeon/hospital to manufacturers, which then report to the FDA. Classification two rearranges this flow of information from the surgeon directly to the FDA.

Another factor added in the class 2 reclassification is the inclusion of post market surveillance. This development is crucial when integrating regulatory information and information on medical devices into a learning health system – a health system focused on early data collection for the improvement of quality and patient safety. Continued data collection and

post market surveillance of surgical staplers not only provides information to regulators such as the FDA but also data and information for continued improvement of the delivery of care and of the use of surgical staplers (Stucki & Bickenback, 2017). Communication, trust, and reliability of information between agents in the system is markedly enhanced through the added post market surveillance information and feedback loop increased transparency and accountability that classification 2 provides.

Expert and Novice Operators

Classification 2 restrictions, such as performance testing and special labeling requirements, benefit both novices and experts. One of the major sources of error found by independent review agency ECRI and the FDA were issues related to labeling of devices and staples (Lumpkin & Jewitt, 2019). Some surgical stapler manufacturers color code their staple sizes a certain way while other manufacturers use the same colors in a different way. Additionally, investigations posited that unclear labeling of different devices and suggested protocol for stapler loading may have contributed to a significant number of cases (Rimmer, 2019).

Novices can be especially susceptible to these mix-ups and lack of clear labeling. Novices demonstrate much more variable performance and longer time taken when identifying different protocols for the use of surgical devices (Graafland, 2014). Additionally, novices regardless of the discipline often struggle to self-monitor and check progress while performing tasks and problem solving (Larkin, 1983). For novices, classification 2 has the strongest capability to reduce FDA established risks for "Complications associated with use error/

improper device selection" specifically because an increased focus on labeling requirements responds to this deficit in the novice's skillset.

Expert operators are affected more by the shared informational and transparency component of the classification 2 regulations. Classification 2 regulations bolster the public release of data related to surgical stapler error for surgeons and hospitals to access. This not only provides better data for the selection of specific surgical staplers, but a better representation of the types of error and common malfunctions associated with specific surgical staplers. Even one hour of engagement with a simulation designed to represent a specific equipment-related problem during surgery significantly improved surgical performance with equipment-related problems in real world applications overall (Graafland, 2017). Classification 2 provides the data and information necessary to not only create these simulations, but to provide information in advance for users so that errors can be anticipated. Experts are able to better integrate declarative information into a sense of typicality and associations that can be recognized and responded to (Ericsson & Smith, 1991). In addition to training simulations, classification 2 also provides key additional information for the better modeling of computational simulations towards generating anticipatory knowledge for improved implementation of medical devices and improved guidelines with both propositional and know-how types of knowledge (Garbayo &Stahl, 2017).

Overall, this epistemic analysis suggests that the FDA and the structure of the regulatory system is fundamentally changed under classification 2, by the obligation of specific agents to better communicate data and adverse event reports, which improves not only the investigatory abilities of the system but also the performance outcomes of the individual agents who have access to the information. Novices benefit from a more robust system of labeling and protocol reminders that can better anticipate improper device selection and use. Experts have a more

robust pool of information and data to integrate into mental models and declarative information that can inform not only their use of surgical staplers, but judgement and decision making in response to errors that occur.

Epistemic Recommendations: Regulatory Transparency for Reducing Stapler Adverse Outcomes in Learning Health Systems

In the modern operating room, the surgeon is dependent not just on advanced technology and tools available but also on advanced and reliable types of information flowing in adequate operational systems. This includes sophisticated data on device reliability and information about the patient as well as their options and choices. Regulatory agencies ought to bear part of the ethical obligation to be transparent about information and data that may affect the assessments of impacts on patients involved in a learning health system. Epistemic Recommendations can improve information flow and adjustment of care for improving stapler health outcomes. This thesis suggests three such recommendations within the scope of this investigation:

1. Epistemic recommendations to reduce stapler device error in learning health systems include early data collection on adverse events and training in close integration with the regulatory body as a transparent epistemic system. A learning health care system is defined by the Institute of Medicine as a health care system "in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care." (IOM, 2007) A learning health care system seeks to integrate both research and clinical practice for the sake of improving delivery of care and can

improve training and team work to mitigate the limitations on expertise and human errors (Largent, Joffee & Miller, 2011).

2. Epistemic recommendations on creating new modalities of information to prevent adverse stapler outcomes and refinement of surgical guidelines. The provision of in silico experiments with computational simulations that can be pursued safely to learn how to prevent or reduce harm are recommended for learning health systems (Garbayo & Stahl, 2017).
3. Epistemic recommendations to improve pragmatic trust (and transparency by integrating FDA stapler information and epistemic resources into the learning health system under classification risk 2. As evidenced in the chapter on epistemology, regulatory bodies hold key power in providing information crucial in making decisions that affect the health outcomes of medical procedures.

Epistemic recommendations also include the reflection on strengthening an adequate ethical framework for knowledge flow that recognizes that regulatory agencies and manufacturers ought to bear part of the ethical obligation to be transparent about information and data that may affect the assessments of impacts on patients involved in a learning health system.

CONCLUSIONS

Surgical staplers have been a crucial device in the surgeon's toolbox since their invention in the early 1900s, and they do not appear to be leaving any time soon.

Scientifically, available research on the advantages and risks of surgical stapler use is still not definitive. Not only is information dependent on FDA data collections and classification systems about surgical stapler efficacy murky, but understandings of wound infection risk are still debated (Smith, Sexton, Mann, Donnell, 2010; Brundage et al, 2001; Iavazzo et al, 2011). Error related to surgical staplers is complicated by the fact that experts and novices experience different patterns and typicality of error, as well as respond differently to error.

Epistemically, this thesis focused on the FDA and the effect of regulatory decisions on the cognitive successes of expert and novice surgeons. FDA classification forms part of the representations and declarative information about surgical stapler use and risk that informs the decision making of both expert and novice surgeons. FDA misclassification can affect the epistemic success of expert surgeons by challenging their trust in the epistemic authority of the regulatory body (Nickels, 2017 ;Origi, 2008). Uncertainty posed by misclassification and failure to be transparent about surgical stapler error can pose a danger for expert surgeons (Kwazneski, 2013) and their ability to assess proper risk. Novices in any domain often find obtaining expertise difficult when complete and up to date information does not exist (Klein, 1998) (Shanteau, 1992). This can become more of an issue when novice surgeons may overly trust the epistemic authority of the FDA (Schmitt & Klein, 1998). Additionally, transparency in terms of error data is important for creating a repository of situations for training simulations that have been proven to assist novice and expert surgeons (Graafland, 2017).

Ethically, if the adoption of data-driven operation settings within a learning health system should be a serious consideration, then regulatory bodies such as the FDA must bear some of the obligations towards providing honest, accurate data and proper classification in order to support other stakeholders such as researchers and practitioners who must assess the level of risk or danger patients face when participating in the delivery of healthcare.

More laboratory-based research is needed to understand the types of error associated with surgical staplers, as well as patterns of error associated with expert and novice surgeons. Improved data collection and transparency that differentiates between user-borne and manufacturer-borne error is crucial to create solutions that minimize overall error associated with surgical staplers.

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