Digital Thread and Analytics Model to Improve Quality Controls in Surgical Stapler

by

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Submitted to the MIT Sloan School of Management
Department of Electrical Engineering and Computer Science
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and

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Abstract

Ethicon, Inc. currently collects data in various stages of its supply chain, but the information is fragmented across the end-to-end chain, resulting in a reactive supply chain. This study seeks to understand the data maturity of Ethicon's surgical stapler through exploratory data analysis and experimental data modeling with machine learning techniques in order to provide recommendations on strategies for digital readiness in a medical device and outline potential opportunities digitization can bring.

The goals of this project are:

1. Enable end-to-end visibility into the current supply chain by building a digital thread for a surgical stapler product
2. Create visualizations to provide visibility and insight into the existing production process
3. Use advanced analytics models to identify key components or measurements that affect the product's Force to Fire final quality inspection results

The digital thread and models built laid the groundwork for the Ethicon team to understand the current state of their systems and will be used as the team conducts experiments to further understand the actual devices being built.

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Acronyms

AI artificial intelligence. 8, 30, 38, 40, 70–72

AR augmented reality. 37

CAD computer-aided design. 37

CAGR compound annual growth rate. 24, 32

DHF design history file. 34

DHR device history record. 34

DMR device master record. 34

DX digital transformation. 30–32, 35–37, 58

E2E end-to-end. 3, 9, 15, 17, 19, 35–37, 46, 48, 63, 64, 69, 73

ERP Enterprise Resource Planning. 48, 49, 64

Ethicon Ethicon, Inc.. 3, 9, 15, 16, 23, 26, 27, 46, 48, 63, 69, 73

ETL extract, transform, load. 8, 48

EU European Union. 71

FDA Food and Drug Administration. 34, 40

FTF Force to Fire. 3, 9, 17–19, 41, 46, 47, 50, 53, 54, 58, 59, 64, 67, 69, 72–74

GDPR General Data Protection Regulation. 71

GE General Electric. 40

IDC International Data Corporation. 31, 32

IIoT Industrial Internet of Things. 37, 39

IoT Internet of Things. 33, 40

J&J Johnson & Johnson. 5, 7, 15–17, 21, 23, 26, 45, 48

JJMD Johnson & Johnson Medical Devices Companies. 23

M&A mergers and acquisitions. 15

MAE mean average error. 61, 62

MD Medical Device. 15, 34, 40

MES Manufacturing Execution System. 48

ML machine learning. 8, 16, 30, 38, 40, 41, 43, 71, 72

MVP Minimum Viable Product. 9, 17, 18, 50, 74

OECD Organisation for Economic Co-operation and Development. 71

OLS ordinary least squares. 42, 59

PLM product lifecycle management. 9, 33, 37

POC proof-of-concept. 16, 19, 30, 46, 50, 58, 64, 74

R&D research and development. 5, 19, 23

RF random forest. 43, 59, 63, 65–67

RMSE root mean squared error. 61, 62

SME subject matter expert. 19, 46, 49, 54, 58, 69

SQE supplier quality engineer. 47

UNESCO United Nations Educational, Scientific and Cultural Organization. 71

USSC United States Surgical Corporation. 25, 26

WHO World Health Organization. 71, 72

Chapter 1

Introduction

1.1 Project Motivation

Ethicon, Inc. (Ethicon) is part of Johnson & Johnson (J&J)'s Medical Device business. It manufactures and distributes Medical Devices used by surgeons around the world to conduct surgeries safely and effectively. Ethicon's global supply chain includes manufacturing sites, distribution centers, packaging centers, and contract manufacturers. Through daily operations, Ethicon collects hundreds of data points for each batch of products, with data ranging from raw material manufacturing, assembly in-process testing, finished goods release, distribution information, all the way to customer feedback. However, given J&J's history of growing through a series of mergers and acquisitions (M&A) (more on J&J's history in section 2.1 of the thesis), the data of the end-to-end (E2E) value chain is often spread across many disparate systems. Within a product, the number of systems through a value chain depends on which sites the product flows through, but can often be in the dozens. Furthermore, the data is not leveraged end-to-end to understand the interaction and dependencies throughout the product manufacturing process.

In developing a strategy for Ethicon to better leverage information gained from the data that is currently being collected to improve the predictability of its manufacturing operations and improve product performance, this thesis offers a case study focusing on a product in the surgical stapler family as the platform for developing a proof-of-concept (POC) digitization process of a legacy product that has been on the market for over three decades.

Figure 1-1: Ethicon Circular Stapler

1.2 Project Overview

Starting with the surgical stapler shown in Figure 1-1, the project aims to build a proof-of-concept (POC) digital thread for the platform by leveraging data that is currently available to identify opportunities for insights that can be gained through digitization.

Currently, data is sampled on a batch level. From suppliers to the assembly process, different rules govern the required sample size, but most of the sampling is done on the magnitude of 20 samples per batch at the assembly plant, where each batch makes 10,000 devices. As J&J digitizes their data, transforming the data into information that can be used to generate insights that inform actions has the potential to improve process efficiency that ultimately leads to more finished products per batch, less scrap, and lower costs.

In this project, the digital thread offers improvements on the visualization and data connectivity from the current state. However, the hypothesis is that more work will need to be done to enable the creation of machine learning models with strong predictive capabilities that have a myriad of applications (e.g. flag potential components that could result in a failed device before the device reaches the end of the line). Furthermore, the focus of this project is on exploring the current capabilities and whether data gathered from suppliers and the assembly plant can be utilized to improve an end-of-line quality control performed on the staplers, the Force to Fire (FTF) test, further explained in section 1.5.

1.3 Project Goals

In support of the objectives of the project, the three primary goals of the project are:

1. Build a batch level end-to-end digital thread for the surgical stapler
2. Create visualizations to provide visibility and insights into the existing production process
3. Use advanced analytics models to identify measurements of key components that correlate highly with the performance of the end-of-line quality test (Force to Fire) performed on each device that gets produced

Through building a digital thread that connects supplier data with assembly data and customer complaints data, the product lifecycle team can save weeks at the beginning of each investigation on figuring out how supplier lots map to manufacturing batches, as this information will already be readily available. With the supplier's support, near real-time updates can be established with the J&J system such that suppliers see how the lots they have provided translate into finished goods. The manufacturing plants can also have an easy way of querying which supplier lots were used in each batch. By connecting with customer complaints data, analysis can be done retroactively on potential causes of the complaint through measurements taken at the supplier level as well as during assembly. The long term goal is to reduce customer complaints by proactively addressing potential deviations in the production process.

Figure 1-2 is a process flow diagram showing the current physical processes in solid black lines, existing data flows in black dotted lines, and what the MVP digital thread aims to connect in dotted blue lines. As the diagram shows, the physical data systems are currently disjoint. They each store their respective data but the data is not being utilized to inform decision making or provide insights into the state of the overall system. Through creating the digital thread, data can be transformed into information and information can be turned into insights.

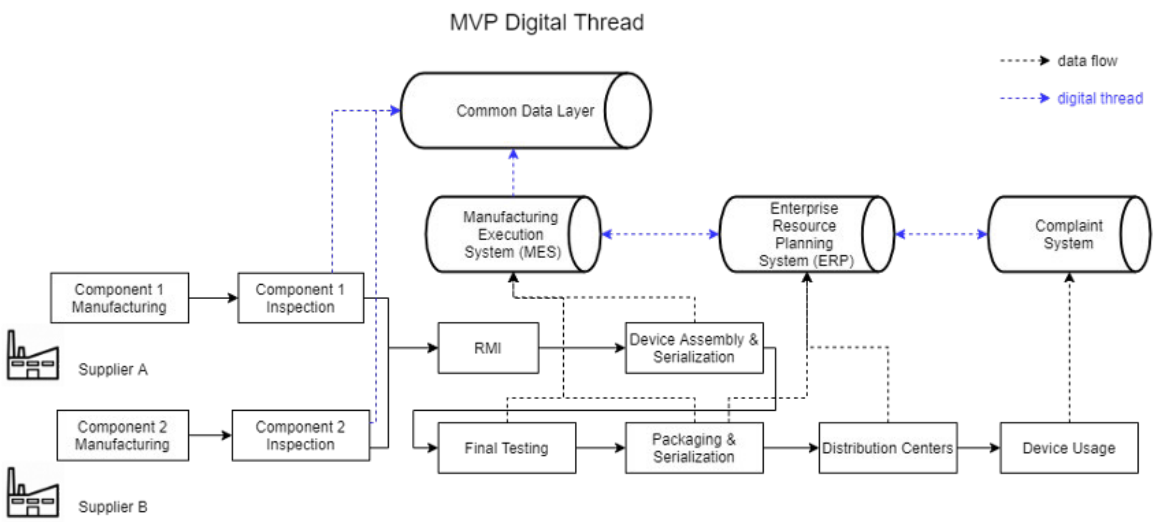

Figure 1-2: Process Flow of the Digital Thread MVP

As shown in Figure 1-2, the digital thread connects the disparate data systems together, but to bring it to the next level so that the information can be utilized in a useful way, visualizations that help users understand the data are a reasonable place to start. Visualizations can provide summaries and display patterns that may otherwise be challenging to notice in the raw data.

Finally, with the data cleaned up, models such as linear regressions and random forests were built as an attempt to predict the end of line Force to Fire. The results demonstrated the need to collect data on a more granular level, as it is difficult to obtain detailed understanding about a batch given the current sample rate. Therefore, serialization on the key components would be one of the first steps towards collecting more granular data that would allow more accurate models to be built.

1.4 Project Vision

The vision of the project is to enable a more proactive supply chain through utilizing data collected in the end-to-end supply chain. By extracting information from the data, the research and development (R&D) team gets insights into what happens in manufacturing, contract manufacturers upstream gain information about their product performances downstream, customer support has visibility into manufacturing, which creates a positive feedback loop through the whole supply chain, as demonstrated in Figure 3-6.

1.5 Project Scope & Limitations

The scope of the project focuses on one circular stapler product. Within the product, the focus of the project is on improving one end-of-line quality control, namely the Force to Fire (FTF) test. The FTF test is performed on every single device that gets assembled. If a device does not pass the test, it gets reworked or scrapped. Since this project's goal is to build a proof-of-concept digital thread and perform analytics on the data focusing on the results of one end-of-line test (FTF), the scope is also limited to a few key components in the product that influence the FTF outcome. From approximately 50 components that go into making the surgical stapler, the knife, driver/ guide sub assembly, and the washer were identified as key components for the project through conversations with SMEs.

Force to Fire (FTF) is an important feature of a surgical stapler, especially a manual stapler because the force required to fire the stapler has a direct impact on the outcome of the surgery. A particularly high FTF could result in instability and movement during the firing process, whereas an incredibly low FTF could result in misfiring, both of which are harmful to patients. When it comes to Force to Fire, consistency is key. As surgeons become experienced with a surgical stapler, muscle memory contributes to a surgeon's firing stroke and their knowledge of when the stroke has been completed.

Additional limitations to the work included limited data availability and supplier cooperation and willingness to share their data with us. Furthermore, the product in this project is a newer model of a previously existing product, so historical data on the newer model as well as the amount of data that is available is also limited.

Chapter 2

Background

2.1 Johnson & Johnson Company Overview

Johnson & Johnson (J&J) is a family of companies. It was founded in 1866 as a company that manufactures medical syringes and in 1877, becomes the world's first company to mass-produce antiseptic surgical supplies [25]. Since then, J&J has grown to become the world's largest diversified healthcare company that develops medical devices, pharmaceuticals, and consumer packaged goods with roughly 250 subsidiaries operating in over 60 countries, products sold in over 175 countries [28], and more than 134,500 employees [47].

From Johnson & Johnson's early days of expanding overseas first in Canada and then in England, the company has seen success in the dencetralized global structure, so a decentralized company structure became the guiding principle as J&J expanded its operations across the world [25]. In November 2021, Johnson & Johnson announced that it would split into two publicly traded companies – the Consumer Health business will become a separate publicly traded company while the Pharmaceutical and Medical Devices businesses would remain as the J&J we know today [27][38].

At Johnson & Johnson, the culture is centered around the company's Credo crafted by Robert Wood Johnson II, a former chairman from 1932 to 1963 and a member of the founding family. The Credo was created in 1943, shortly before J&J became a publicly traded company, but long before "corporate social responsibility" became a popular concept across corporations[24].

The Credo states:

> *We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.*
>
> *We are responsible to our employees who work with us throughout the world. We must provide an inclusive work environment where each person must be considered as an individual. We must respect their diversity and dignity and recognize their merit. They must have a sense of security, fulfillment and purpose in their jobs. Compensation must be fair and adequate and working conditions clean, orderly and safe. We must support the health and well-being of our employees and help them fulfill their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders and their actions must be just and ethical.*
>
> *We are responsible to the communities in which we live and work and to the world community as well. We must help people be healthier by supporting better access and care in more places around the world. We must be good citizens — support good works and charities, better health and education, and bear our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.*
>
> *Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed, investments made for the future*

and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

The Credo provides a clear priority in terms of the company's responsibilities: first to the patients, doctors, and nurses, then to the employees, and finally to the stakeholders. The company culture is deeply rooted in The Credo. To this day, The Credo continues to be the guiding philosophy that informs all aspects of work.

2.1.1 Ethicon Overview

Ethicon, Inc. (Ethicon) is a subsidiary of Johnson & Johnson, part of Johnson & Johnson Medical Devices Companies (JJMD). Ethicon's predecessor is G. F. Merson Ltd., a Scotland-based company that manufactured sterile surgical sutures originally founded by pharmacist George. F. Merson in 1915. In 1947, J&J acquired G. F. Merson Ltd. to grow J&J's capacity in the suture business [25].

Today, it is headquartered in Bridgewater, New Jersey and Cincinnati, Ohio, where most of the R&D for Ethicon is located. Ethicon provides a suite of surgical products primarily in wound closure, endomechanical, and biosurgery. It continues to be the market leader in the surgical sutures and surgical staplers space [10] [11].

2.2 Medical Devices Industry Overview

From the advent of medicine, dating back to 8,000 years ago, many ancient civilizations developed tools such as knives, scalpels, saws, needles for medical procedures. For most of history, medical devices were used to treat soldiers injured in the battlefield or the rich who can afford treatment. In the 19th century, with the discovery of germ theory by Louis Pasteur and Joseph Lister's publication of "Antiseptic Principle of the Practice of Surgery," the success rate of medical treatments skyrocketed. In the same century, devices such as the stethoscope, the hypodermic syringe, and nitrous oxide as anesthetic were introduced to the market, significantly improving the health outcome for the general public [58].

In 2020, the global market size of medical devices was 432.23 billion USD, with the United States having the largest market size of 168.76 billion USD. Due to the COVID-19 pandemic, the medical devices industry saw a decline of 3.7% in 2020 compared to the average year-over-year growth from 2017-2019, primarily due to the decline in elective surgeries that use particular medical devices. However, when the pandemic subsides, the market is projected to grow at a compound annual growth rate (CAGR) of 5.4% in the 2021-2028 period. The projected growth is attributed to higher demand for medical devices as chronic diseases become more prevalent and the growing emphasis around early diagnosis and treatment leading to more surgeries and more medical devices used in surgeries. On the other hand, high costs for medical devices continue to be a barrier to entry for some potential customers and therefore limits adoption [12].

2.3 History of Surgical Staplers

The concept of "surgeries" can be traced back to 6,500 BC, where evidence of trepanation, the practice of drilling or cutting a hole through the skull to expose the brain, was found in France [40]. However, surgery as we understand today did not come about until the 1800s [57]. Until the 1900s, the likelihood of surviving the surgery was lower than the likelihood of dying from a surgical complication that arises from undergoing the surgery [5].

From the early days of surgery, there was a concern that procedures that involve abdominal organs not only require a lot of time but also often lead to more complications due to the tissue trauma involved in repairing the damage [52]. Therefore, when the first mechanical surgical stapler was developed in 1908, the device was widely received even though it was heavy and difficult to construct.

Surgical staplers are used today for wound closure, organ or tissue resection, and anastomoses. They are used as methods of "mechanical suturing" to create anastomoses in an efficient and sterile manner. The current global market for surgical staplers is estimated to be around 3.65 billion dollars in 2020 [39] and is estimated to be around 4.80 billion dollars by 2025 [51].

In Gaidary Et al.'s journal article titled "The History of Surgical Staplers: A Combination of Hungarian, Russian, and American Innovation" in The American Surgeon's June 2019 issue, the authors provide a good overview of the history of surgical staplers, which will be summarized in the paragraphs below.

The first surgical stapler was developed in 1908 by Hungarian surgeon and professor Hümér Hültl and designed by Victor Fischer, a businessman and designer of surgical instruments. In Hültl and Fischer's original design, there are two features that continue to be used in surgical staplers today: staples with an incomplete "B" shape (Figure 4-6) to allow blood flow through the tissue within the staple line, and staples arranged in two staggered rows [14].

In 1920, Aladár Petz, one of Hültl's students, made modification to the Fischer-Hültl stapler that resulted in a much lighter model. The modifications included using two staple lines instead of four and nickel-silver clips instead of steel wires. The new device became known as the Petz clamp. It received direct endorsement from Hültl in 1921 and was patented in 1924. The device still had shortcomings, however, namely that it could only be used once in an operation because after the device was fired, it had to be cleaned, reloaded, and re-sterilized before the next use. Furthermore, the staple line tended to leak and bleed [14].

In 1934, Dr. H. Friedrich of Germany designed the instrument that becomes the direct predecessor to the modern linear staplers. The most important innovation of Friedrich's design is the removable, replaceable cartridge that allowed a stapler to be used multiple times in the same operation [14].

In the following decades, the Petz clamp remains the most widely used stapling device in surgery until the 1960s, when American staplers originally based on Russian designs begin to gain popularity in the market. United States Surgical Corporation (USSC) was founded in 1964 by Mark Ravitch of Johns Hopkins and Leon Hirsch, an entrepreneur sensing an opportunity in surgical devices. The team at USSC continued to make improvements to the stapling devices and developed the stapling designs used today: the linear stapler, the linear cutting stapler, and the circular staplers. USSC was extremely successful through the 1960s and 1970s. In 1977, Ethicon joined the market and became one of USSC's competitors. In 1998, USSC bought by Tyco Healthcare and eventually becomes Covidien in 2007 [14].

2.4 Surgical Stapler Production at J&J

Ethicon, Inc. started making surigcal staplers in the 1970s and in 1978, introduced the first preassembled disposable surgical stapler - the PROXIMATE® Disposable Skin Stapler, which closed wounds ten times faster than traditional sutures. Furthermore, the disposable nature of the stapler eliminated risks of cross-infection between patients [26]. The newer, lighter, and more reliable staplers produced pushed the United States into a leadership position in the surgical stapler manufacturing field [52]. Today, Ethicon still designs and develops surgical staplers of all types: linear staplers, linear cutters, and circular staplers. Figure 2-1 shows the collection of surgical staplers currently being offered by Ethicon.

2.4.1 Surgical Stapler Supply Chain Structure

Ethicon has traditionally worked with many contract manufacturers to provide components of the surgical staplers. In the past, assembly of the components would occur in house but in recent years, an increasing proportion of the entire production process is being outsourced. Furthermore, due to the complexity of achieving dual sourcing of components, 0% of the components in the stapler is dual sourced. Figure 2-2 shows a high-level overview of the supply chain architecture of the surgical stapler.

Figure 2-1: Ethicon Surgical Stapler Products

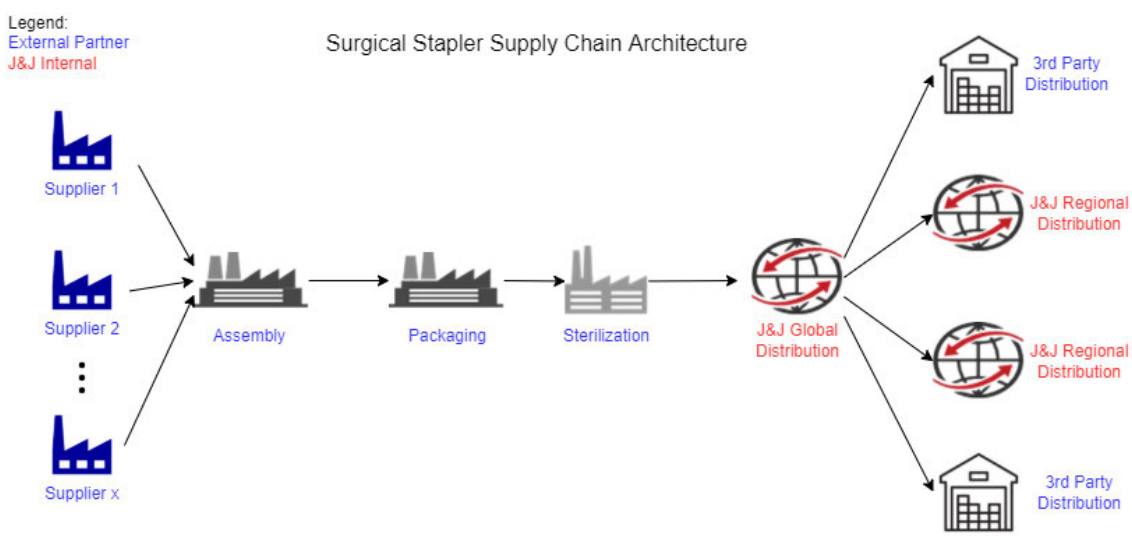

Figure 2-2: High Level Supply Chain Architecture

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Chapter 3

Literature Review

3.1 Digital Transformation

3.1.1 Overview

As defined by Accenture, "Digital transformation is the process by which companies embed technologies across their business to drive fundamental change" [1].

Two vocabularies that could often get mixed-up are worth defining here: *digitization* and *digitalization* [1]. *Digitization* is the process of translating analog data into a digital form such as typing numbers on a sheet of paper into a spreadsheet or scanning a document and storing it on a computer. *Digitalization* is the use of digital technologies to change business processes such as training employees on new software that will enable them to perform their jobs faster and provide the business more visibility into processes.

Until recently, many manufacturing companies were still largely operating with the paper-based documentation methodology. Design documents, process documents, and floor plans stored in the forms of paper-based binders. Efforts of digitization included transcribing handwritten paper values into a spreadsheet that is then saved somewhere on a computer's local drive and shared through email if necessary. The paper-based documentation methodology in an increasingly digital world has lagged in progress made in data availability and data quality as documents are more likely to be lost and harder to locate. Before the COVID-19 pandemic hit, many companies have started efforts towards digitalization. The pandemic certainly underscored the need of digitalization and accelerated investments into organizational digital transformation.

Chapter 2 of Rawden's thesis outlines the motivation for digital transformation (DX), stating that digital transformation of business processes can mitigate bottlenecks that limit firm growth and unlock opportunities on an unprecedented scale [44]. It can increase operational efficiency, improve business agility, and generate value for employees, customers, and stakeholders. Digital transformation can be applied in many areas of an organization. For example, artificial intelligence (AI) can be introduced to improve customer experience, machine learning (ML) can be utilized in a supply chain to help make decisions about resource planning, or ML can also be used in a manufacturing setting to improve efficiency and reduce scrap.

In a research report by Accenture released in November 2020 titled "The Race for Digital Operations Transformation," Accenture reports the average maturity of manufacturers' end-to-end operations overall to be 39% [4]. 600 companies from different parts of the world (North America, Asia, and Europe) across various industries were surveyed and evaluated on the status of their digital transformation in terms of their end-to-end capabilities in manufacturing operations. The companies surveyed represented eight industries - oil and gas, automotive, aerospace and defense, industrial equipment, chemicals, high-tech, life sciences, and consumer goods and services. 40 key indicators (Appendix A) were created by Accenture and used in the report to assess the digital capabilities of the companies, from not started to proof-of-concepts, pilots, scaling up, and finally to fully deployed. Figure 3-1 shows the various phases the companies surveyed are in in their digital transformation journey. Furthermore, Figure 3-2 shows the overall digital maturity by industry among the companies surveyed.

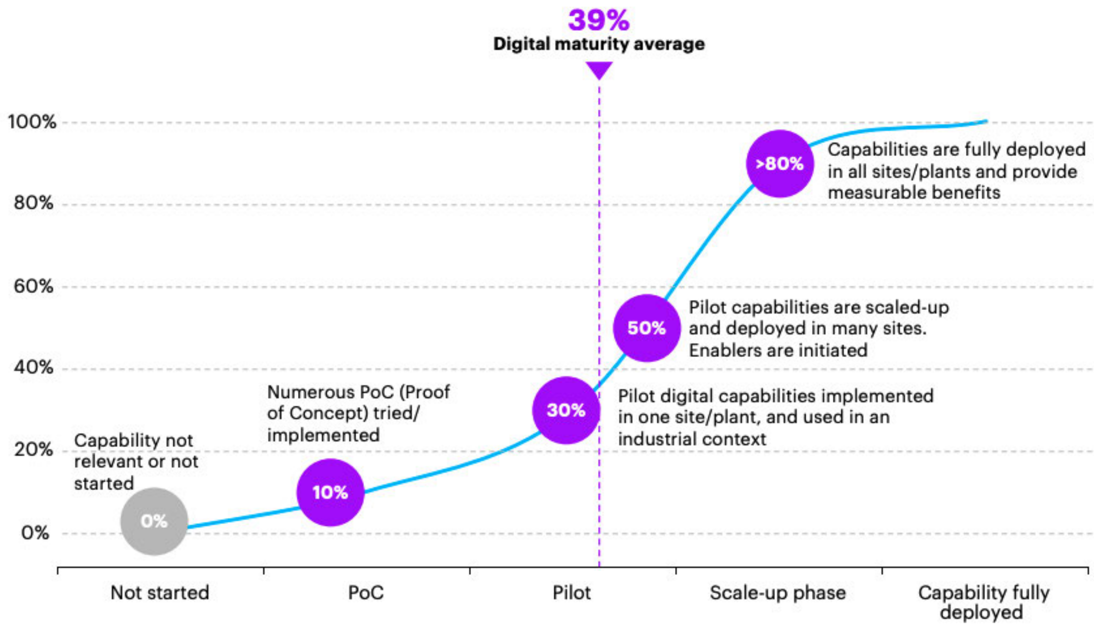

Figure 3-1: Digital Maturity Phase Breakdown [4]

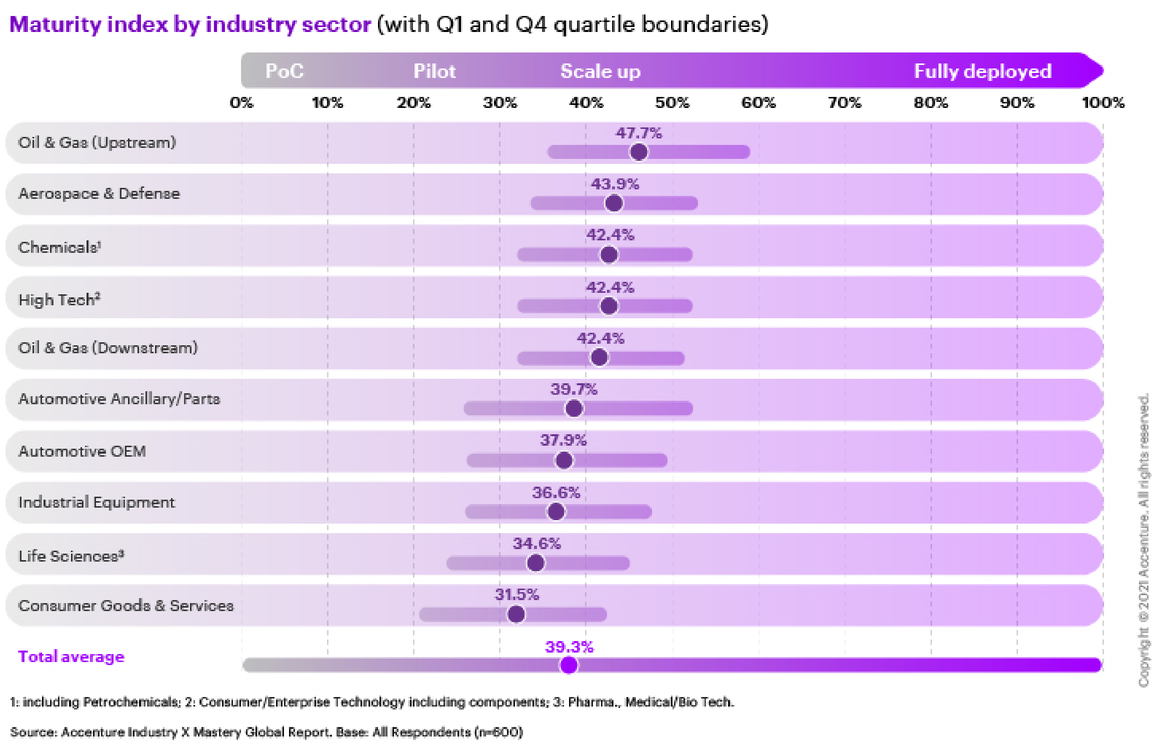

Figure 3-2: Digital Maturity by Industry [4]

According to an update to International Data Corporation (IDC)'s Worldwide Digital Transformation Spending Guide in November 2021, global spending on DX continued to grow throughout the COVID-19 pandemic with a CAGR forecast of 16.4% [21]. Not only has the growth in digital transformation continued, the COVID-19 pandemic actually pushed firms to increase their investment into various areas of digital transformation such as emerging tech, IT infrastructure, AI & automation, etc. as shown in Figure 3-3 from Accenture's recent report "Make the Leap, Take the Lead" [9]. IDC's report also forecasts that DX use cases in investment in robotic manufacturing, autonomic operations, and customer and client management are three strategic priorities that will receive the most spending. As for industries, IDC forecasts discrete and process manufacturing, professional services, and retail to be the top industries focusing on digital transformation in the coming years [21].

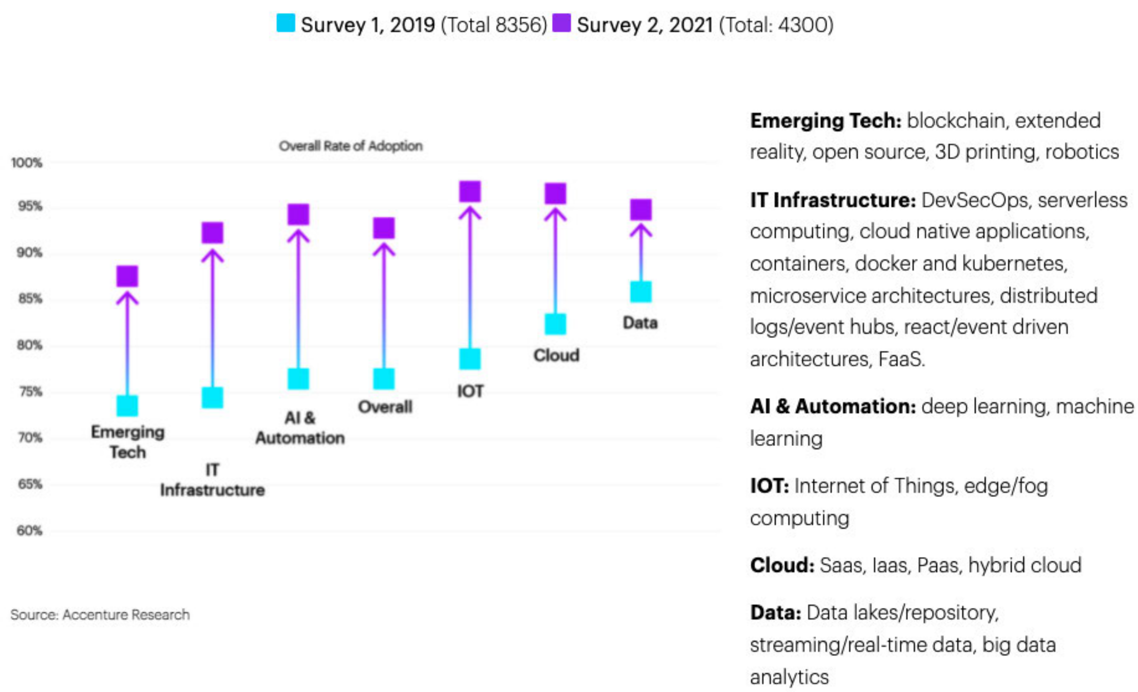

Figure 3-3: Digital Transformation Investments 2019 vs. 2021 [9]

3.1.2 Digital Threads and Digital Twins

The idea of digital threads and digital twins have existed for decades. As technology advances, capabilities continue to be unlocked, providing vast opportunities for enterprises to leverage data within their ecosystems to operate more efficiently and more resiliently, among other potential benefits.

The terms "digital thread" and "digital twin" sound similar, so what is the difference? A *digital thread* connects diverse yet interrelated data sources to uncover insights. It creates a single source of truth for the data and enhances data visibility across the value chain [18]. A *digital twin*, on the other hand, is a digital representation of the physical world. In order to have a complete digital representation of the physical world, a historical record for each of the components in the digital world must be connected together the same way they do in the physical world, which is what a digital thread achieves. Therefore, the process of unifying the data, i.e. building a digital thread, is a pre-requisite for building a digital twin [56]. Figure 3-4 shows how digital threads create a cycle of information sharing, specifically within a product supply chain as product lifecycle management, Internet of Things (IoT), maintenance, manufacturing, and quality will all have access to the data from other phases in a product's life cycle.

Figure 3-4: Traditional PLM to PLM with Digital Threads [32]

In the age of digital transformation, digital threads offer a solution towards enhancing decision-making, speed, and agility of a business through transforming data into information that can be understood and used. Furthermore, with digital twins, teams can not only assess the past and current performance of systems, but also perform simulations and hypothesis testing in the digital world to understand the impact of potential future changes to the system before physical processes and products are developed.

3.1.3 Challenges and Opportunities

Opportunities

Potential opportunities that digital threads combined with digital twins can bring is vast. In an article on recent medical developments, the author provides an overview of how medical device companies can benefit from leveraging the digital thread [37]. In the Medical Device industry, companies can use the digital thread to create, manage, and automate the documentation process for their design history file (DHF), device master record (DMR), and staying within Food and Drug Administration (FDA) regulations, the device history record (DHR), which are all types of documents that record the life cycle of a medical device from stakeholder requirements to design, all the way through finished goods (Figure 3-5).

On the design level, the digital thread can provide electronic change approvals that are automatically captured, stored, and readily available to all parties with access to the digital thread, upstream and downstream to the process. The system can also help ensure everything fulfills the regulatory requirements. On the manufacturing level, digital thread can be combined with the use of a digital twin to provide risk assessment and mitigation, predictive maintenance, and root cause analysis functionalities while seamlessly providing feedback to the engineering and design teams about product improvement opportunities. The digital thread systematically connects every phrase of the life cycle, providing users in different domains visibility into any other process in the life cycle, allowing incremental improvement through a continuous feedback loop. Figure 3-6 shows how the digital thread improves traceability back to requirements, which is typically a cumbersome and fairly manual process, provides an audit of the products produced, operates in a continuous feedback loop, which ultimately improves quality and possibly decreases time to market and the iteration cycle time.

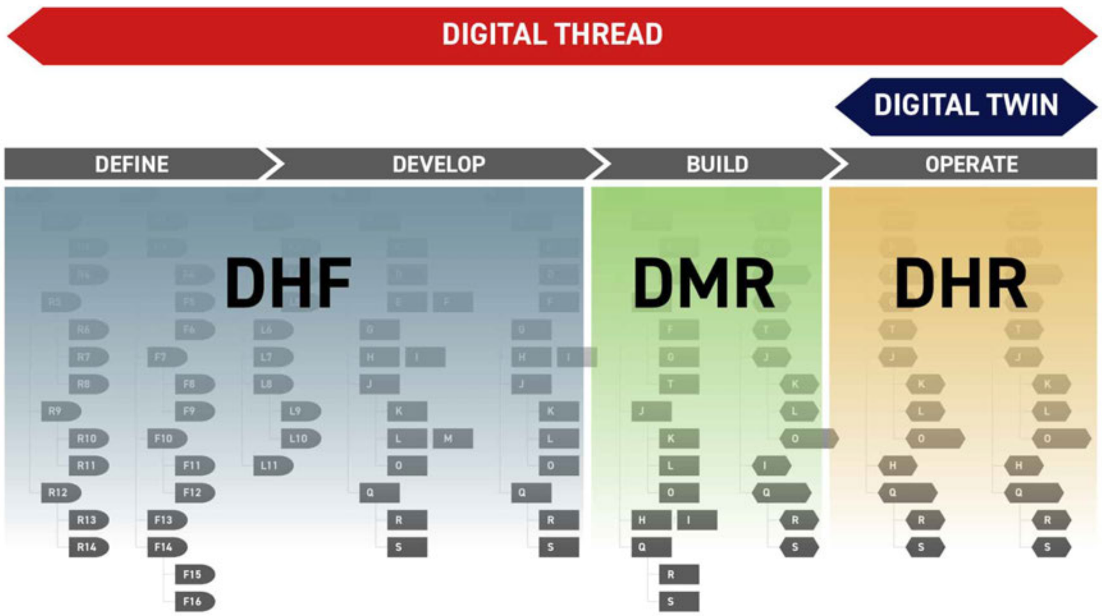

Figure 3-5: Digital Thread as a Central Location for Document Management [37]

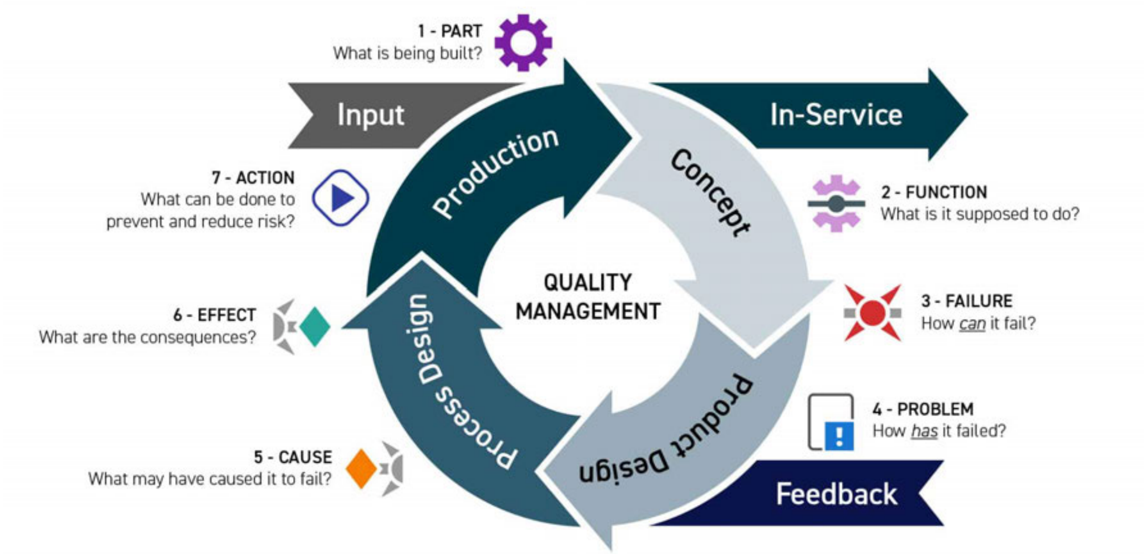

Figure 3-6: Digital Thread's Cyclical Nature Provides E2E Visibility into the Product Life Cycle [37]

In summary, digital transformation initiatives provide measurable business outcomes by adopting digital technologies and enabling digital capabilities that will transform organizations through increased connectivity, agility, and resilience, setting up the organization for long-term success and prepare the organization to navigate market challenges as they arise.

Challenges

In an article published in IndustryWeek, the author explains potential benefits of digital threads and digital twins, provides some use cases, possible future scenarios, and outlines potential challenges as well [34]. With increased E2E connectivity within a system, can people upstream in the lifecycle functions understand the needs of the people in downstream functions? Can third party vendors see beyond the need to hold on to their data as means to ensure continued market share? Could they agree to open data exchange to facilitate a more complete E2E digital thread? Industry's adoption of the design-for-manufacturing concept shows that some level of consideration between upstream and downstream is possible, digital threads and digital twins are the next step in the process - bringing more functions together, looking beyond the manufacturing process, towards the E2E value chain.

Implementing digital transformation means adopting a new mindset for employees as business processes change, so having an open, collaborative, and experimental mindset is seminal to the process. Therefore, recognizing the change and fostering a culture of continuous improvement and collaboration will be key. In an article published by MIT Sloan School of Management, "When training for new tech, don't ignore employee hierarchies," the author cites research on the importance of how technology is introduced in the workplace and how training takes place. More specifically, the introduction of new technologies can create friction between the junior, more technical savvy employees and their senior coworkers, upsetting the fundamental power hierarchies. When the senior employees feel their status undermined, it is natural to become resistant to the change. One way to address the challenge, as suggested by the paper, is to create a peer-training program where the senior and junior employees rotate through taking up the role of the "trainer." The rotating peer-training program could then provide a sense of deference to the existing power structures while everyone gets used to a new way of doing things [54].

With all the benefits that digital threads and digital twins can bring, there are also challenges that companies must keep in mind when executing digital transformation strategies. While it is important to introduce new technologies that have the potential of improving business processes and preparing an organization for long term success, it is equally, if not more important, to bring everyone in the organization along on the journey of learning to fully deploy digital projects and realize the gains.

3.1.4 Digital Transformation in Manufacturing

For many decades, the aerospace industry has invested in digital threads and digital twins as means of ensuring safety and keeping the cost of development relatively low, among many other reasons, through extensive simulation during the new product design, product launch, and maintenance. In a paper published by Dr. Kraft in the United States Airforce, he highlights the use of digital threads and digital twins to "merge physics-based modeling and experimental data to provide analysis capabilities and support to decision making over the entire lifecycle of air vehicles"[33].

More recently, the Volvo Group, one of the world's leading manufacturers of trucks, buses, construction equipment, and industrial engines, developed an E2E solution for creating and scaling a digital thread through technologies such as augmented reality (AR), Industrial Internet of Things (IIoT) to integrate data across software systems, computer-aided design (CAD) iterations, and downstream PLM systems in addition to other manufacturing operations systems to create a digital thread that has real-time data synchronicity. As a result, the Volvo Group has seen 60% reduction in training time and thousands of Euros saved per station per year. Furthermore, not only has the digital thread removed the cost and risk of the traditional paper-based approach of managing processes, operations, and QA, the inclusion of AR technology has enabled QA technicians to capture specific defects and send the information to upstream teams that can respond and start making engineering and manufacturing process improvements [43].

3.2 Artificial Intelligence and Machine Learning in Manufacturing

As technologies advances, software incorporating artificial intelligence (AI), particularly the subset of AI known as machine learning (ML), has become an increasingly important part of industries across the board. Manufacturing is no different.

It is important to first define the vocabularies. *Artificial Intelligence*, as defined by Merriam-Webster, is an area of computer science dealing with the simulation of intelligent behavior in computers, to give machines the ability to seem like they have human intelligence. Types of problems that researchers have been creating systems to simulate include problem-solving, learning, and planning. For example, self-driving cars contain all of the aforementioned aspects of artificial intelligence. Techniques that can be used in building an artificially intelligent system include statistical analysis models, expert systems that primarily rely on if-then statements, machine learning, etc. *Machine Learning* is a subset of AI that allows machines to learn from (and possibly act on) data without being programmed explicitly. For example, image recognition software that identifies objects in a picture would be an application of machine learning.

Many artificial intelligence and machine learning techniques can be applied in manufacturing to automate or improve the process flow of a production floor because of the vast amounts of data that gets collected and stored in databases. Applications of ML can also be further extended to areas such as product design, product planning, assembly, scheduling, and maintenance. Pham and Afify provide a sample classification of machine learning techniques (Figure 3-7) and go into detail explaining the various techniques and their applications in manufacturing [42].

In recent years, the concept of "Smart Factory" expresses the end goal of digitization in manufacturing. Gartner defines smart factories as "an opportunity to create new forms of efficiency and flexibility by connecting different processes, information streams and stakeholders (frontline workers, planners, etc.) in a streamlined fashion [15]." It is a highly digitized shop floor that continuously collects and shares data through connected machines, devices, and production systems, essentially a factory that has the digital thread and digital twin capabilities built in. In a nutshell, a smart factory is the most optimized application of technologies such as Industrial Internet of Things (IIoT), sensors, cloud computing, and big data analytics, brought about by the fourth industrial revolution, also known as Industry 4.0 (Figure 3-8) [53].

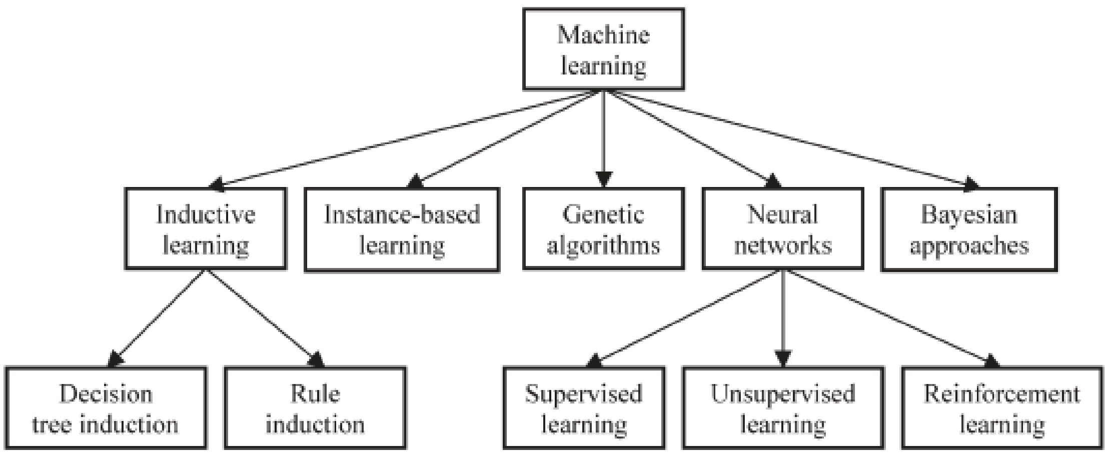

Figure 3-7: Classification of Major Machine Learning Techniques [42]

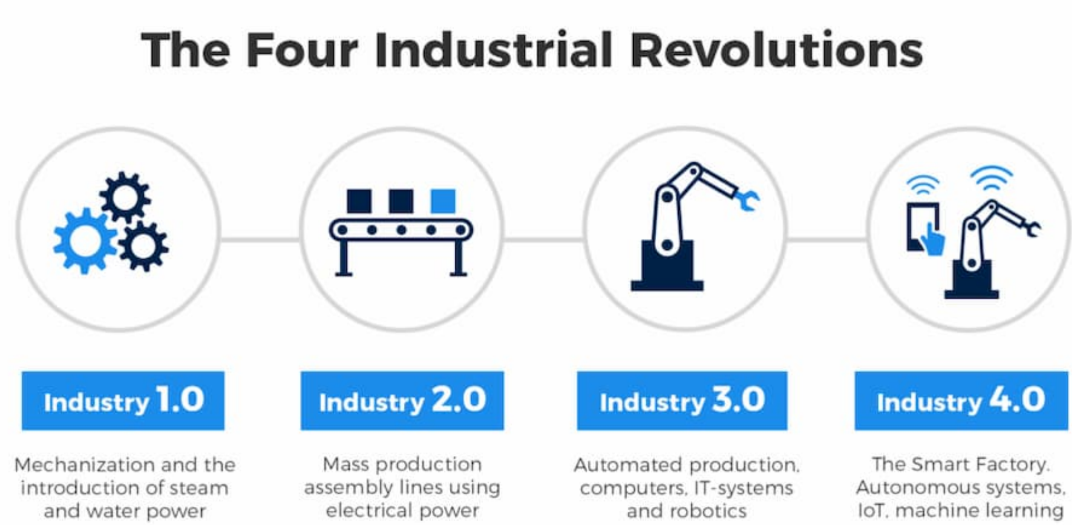

Figure 3-8: The Four Industrial Revolutions [8]

General Electric (GE), one of the largest companies in the world, has made large investments into making their factories "smart." The technology behind their Brilliant Factories is GE's Brilliant Manufacturing Suite, a software suite powered by Predix, GE Digital's in house IoT edge-to-cloud data connectivity, processing, analytics, and services to support industrial applications.

According to GE, the Brilliant Manufacturing Software Suite enables organizations to predict, adapt, and react more quickly and effectively across design, engineering, manufacturing, supply chain, and distribution to create one globally scalable intelligent system [23]. The platform uses sensors to monitor all aspects of manufacturing in order to detect all possible problems and failures before they occur. Predix also has deep-learning capabilities that processes the raw data and transforms it into actionable insights [8].

In 2014, GE's Brilliant Factory has been estimated to contribute to a 20% faster product development cycle and 20% improvement in manufacturing and supply chain efficiency [3]. In 2016, factories that implemented the Brilliant Factory Reference Architecture, which GE also mentions is all about a digital thread, saw an increase in on time delivery by 58%, decreased lead time of 60%, decreased downtime of 10-15%, and the list goes on [23]. As GE's former CFO Jamie Miller puts it, *"By connecting and listening to machines we're able to recognize they're going to fail and move to fix them faster – resulting in higher availability, lower costs, and improved quality as we can see critical machine data and make proactive adjustments."*

Finally, in the Medical Devices industry, artificial intelligence and machine learning is also being increasingly adopted and incorporated into medical devices to build better products and assist healthcare providers and improve patient experience. An article on the FDA's website highlights the increasing importance of AI and ML in medical devices, plans for regulation in the future [7], as well as a list of AI/ML-enabled medical devices that is currently in the market [6].

3.3 Machine Learning Algorithms

There is a plethora of machine learning algorithms out in the world made to address different classes of problems. The three main categories of ML are: supervised learning, unsupervised learning, and reinforcement learning. Before diving deeper into the various algorithms, *labeled data, classification*, and *regressions* are terms that will be referred to frequently so we will define it first. *Labeled data* is data that also contains a tag with the desired output, or the target value your machine learning algorithm is trying to predict. *Classification* refers to predicting the label of a new data point by inferring from a labeled training set where the label is a discrete value, e.g. spam vs. not spam, true vs. false, and hand-written digit classification. *Regression* refers to predicting the value of a continuous variable rather than a categorical variable as in the case of classifications, e.g. housing prices, or in our case, FTF in surgical staplers.

This project uses primarily supervised machine learning techniques, so we will dive deeper into the specifics of the algorithms used in this thesis.

3.3.1 Supervised machine learning

As defined by Singh, Thakur, and Sharma, "Supervised machine learning is the construction of algorithms that are able to produce general patterns and hypotheses by using externally supplied instances to predict the fate of future instances [48]." On a high level, supervised machine learning algorithms are provided with labeled data they can use as examples for figuring out how to classify or what value to assign to a newly introduced random variable. Common supervised machine learning algorithms include linear regression, decision trees, random forests, k-nearest neighbor, support vector machines (SVM), neural networks, etc. Here, we will go over some of the supervised machine learning algorithms used in the thesis.

Linear Regression

Linear regression is a type of linear model that attempts to fit a linear equation to the observed data [61]. Therefore, linear regression models inherently assume a linear relationship exists between a target variable (y) and one or more predictors.

Ordinary Least Squares (OLS) is one of the oldest and most simple regression models. Ordinary Least Squares Regression works by fitting a line and computing the distance from the predicted to the actual point. The Least Squares model is the model that minimizes the squared distance between the prediction and the observation [49]. In this form, models are not penalized for its choice of weights, so if a particular feature seems especially important, the model can place a large weight on the feature. This could result in overfitting, especially on small data sets [60]. Over time, variants have been invented to address some of the weaknesses of OLS.

Lasso stands for Least Absolute Shrinkage and Selection Operation and is a modification of OLS designed to penalize models with large weights. It adds a penalty term to the cost function which is the sum of the absolute value of the weights. As a result, the number of features that end up in the regression model could be significantly reduced as many weights become zero during the minimization process [60]. Lasso tends to perform well when there are a few features that have significant impact on the output while other features have almost no impact. Similarly, if the number of predictors (p) is greater than the number of observations (n), Lasso will allow at most n predictors to be non-zero, even if all predictors are relevant. Furthermore, if there are multiple variables that suffer from multicollinearity[1], then Lasso selects one of them randomly, which does not contribute to the interpretability of data [16].

Ridge regression takes it a step further and penalizes the model for the sum of squared value of the weights [60]. As a result, weights not only have small absolute values but also remain penalized for large weights. Compared to Lasso, however, Ridge does not reduce the number of independent variables in the model, it simply

[1]Multicollinearity, or collinearity, is the existence of near-linear relationships among the independent variables. Multicollinearity can create inaccurate estimates of the regression coefficients, inflate the standard errors, and degrade the predictability of the model, among others effects [41].

ensures the weights of the features are more even. Therefore, Ridge models are particularly useful when most predictors impact the dependent variable and for dealing with multicolinearity issues, but are not helpful in feature reduction [16] [41].

Random Forests

Random forest (RF) is a type of ensemble learning method for classification and regression tasks. Ensemble learning is a ML technique that combines multiple base models to produce one optimal predictive model that outperforms the results obtained from any constituent learning model alone [36]. In the case of random forests, it combines the output of multiple decision trees (into a forest) to reach a single result. In an article by IBM, random forest is described as "an extension of the bagging method as it utilizes both bagging and feature randomness to create uncorrelated forest of decision trees [19]." The main idea here is through generating random subsets of features to build decision trees, the correlation between individual decision trees is low, which reduces the risk of bias, overfitting, and produces a more accurate result.

Additional benefits offered by RFs are that it provides a tremendous amount of flexibility and it is easy to determine feature importance. RFs are flexible in that they can perform both classification tasks and regression tasks. Compared to linear regression models, RFs also do not make any assumptions about existing relationships amongst the input data. On the flip side, they tend to consume more resources and are more complex than a single decision tree [19].

3.3.2 Unsupervised machine learning

Unsupervised machine learning algorithms get provided with unlabeled data sets, i.e. no correct answer is provided, and the algorithms self-organize to identify hidden patterns within the data set. The term "unsupervised" refers to the ability to learn and organize information without providing an error signal to evaluate the potential solution [45]. Popular unsupervised algorithms include clustering algorithms such as k-means clustering and hierarchical clustering. Common applications of unsupervised learning include customer segmentation or recommendation services on e-commerce websites or video-streaming platforms such as Netflix and Hulu.

3.3.3 Reinforcement Learning

Reinforcement learning methods aim at using observations gathered through interactions with the environment and feedback attained from performing various actions to maximize rewards and minimize risk [13]. Similar to how humans learn, sometimes through trial and error, we associate certain actions with a positive outcome and therefore should be pursued and some actions with a negative consequence hence should be avoided. Markov Decision Process describes the process of an agent repeatedly receiving input, performing an action based on its current state, and updating its understanding about the world around it. Applications of reinforcement learning include AlphaGo, robotics, and autonomous driving tasks [35].

Chapter 4

Research Methodology

The research methodology taken for this project follows five main steps:

1. **Define** the scope of the problem
2. **Retrieve** the relevant data
3. **Innovate** by analyzing the data and building analytics models
4. **Visualize** the data collected, as well as the results of the analysis
5. **Effectivity**, handing-off to the team that will be continuing the work

Together, the five steps produce the DRIVE methodology, a way of working that J&J has been piloting in recent digital projects and was the methodology followed in this project, along with managing the project through the agile methodology.

More specifically, the approach taken in this project was the following seven steps:

1. Problem definition and scoping
2. Data source identification
3. Data retrieval
4. Construct the digital thread
5. Visualize the data generated from the digital thread
6. Build models to identify trends
7. Provide recommendations for next steps

This section will focus on some of the steps in more detail, namely the data identification and retrieval process, building the digital thread, visualizing the data, and building models.

4.1 Data Preparation

4.1.1 Data Source Identification

Approximately 50 components go into making a surgical stapler. For the purposes of this project and the goal of focusing on one end-of-line quality test - Force to Fire (FTF), key components that influence FTF had to identified and the data collection process centers around collecting data on key components that influence FTF, namely the stapler's knife, washer, and driver/ guide sub assembly. Identifying the key components to focus on for Force to Fire in a surgical stapler was the first step in data collection as it narrows down the data sources and measurements that will be required to build the proof-of-concept digital thread.

In the initial phases of the project, SMEs (subject matter experts) such as research design engineers and manufacturing engineers provided insights into components that influence cut force based on the design of the product and their experiences working with the product. Based on the conversations, the knife, washer, and washer/ driver sub-assembly were identified as key components as shown in the Ishikawa diagram[1] in Figure 4-1.

Knowing the components to focus on, the next steps were to identify which systems the data is stored in, whether the data is available digitally anywhere, and point of contacts for retrieving data that is not available digitally. For the digital thread to be end-to-end, it had to encapsulate more than just Ethicon's data. We needed to also include supplier data and data that can serve as some form of feedback after the products have been manufactured, which in our case, was customer complaints data. There are many more steps in the supply chain that can also be incorporated into the digital thread, as shown in Figure 2-2, but for the POC, we chose to focus on supplier data, assembly data, and customer complaints data.

[1] Also called fish bone diagrams or cause-and-effect diagrams. They are causal diagrams created by Kaoru Ishikawa to show the causes of a specific event. They resemble a fish skeleton, with the "ribs" representing the causes of an event and the final outcome appearing at the head of the skeleton [22]. They represent a simple way to communicate hypotheses to team members, customers, and management [2].

Since our goal is to include supplier data, supplier cooperation and willingness to share their data became an important part of the project's success. Therefore, as soon as the key components and their respective suppliers were identified, I connected with the supplier quality engineers for an introduction with the suppliers. For the three key components, the knife was manufactured by one supplier and the washer as well as the driver/ guide sub-assembly manufactured by another supplier. Figure 4-2 shows the types of data and on a high level, how they will be connected in the digital thread.

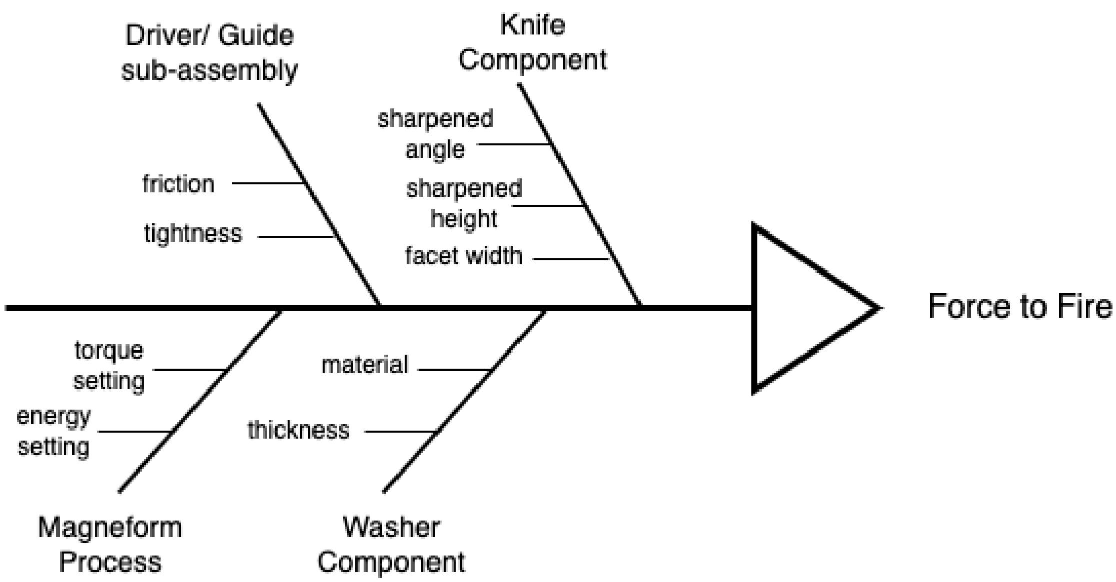

Figure 4-1: Ishikawa Diagram for Force to Fire

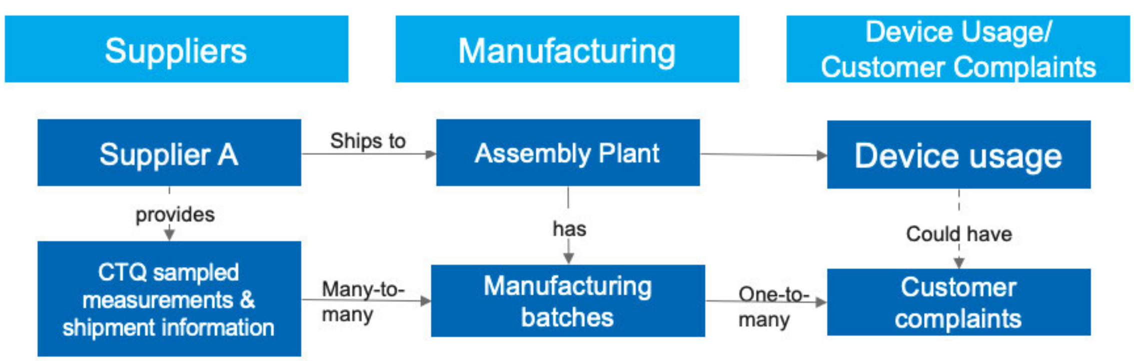

Figure 4-2: Relationships Between Data Sources in the Digital Thread

4.1.2 Data extract, transform, load (ETL)

The data retrieved included data for all sizes offered for the surgical stapler, each corresponding to the diameter of the stapler. The data received were primarily in the form of Excel spreadsheets and therefore had to be transformed and loaded into a database. For this project, we chose to use a relational SQL database running on an Azure instance and executed on Microsoft SQL Server Studio because of the existing infrastructure support and SQL's relational nature made connecting data sources relatively straightforward once the links have been identified. Figure 4-3 shows the high level database design including tables and their respective linkage to one another identified.

The data extraction process began with an attempt to retrieve data stored digitally in a database. However, due to Ethicon outsourcing most of its manufacturing nowadays, we no longer have direct access to the systems. Thankfully, the plant that assembles the product is still the same plant, just sold to a long-time partner of J&J, so many of the employees are former J&J employees that already have established rapport with us. Data needed from the Manufacturing Execution System (MES) and Enterprise Resource Planning (ERP) systems were ultimately shared with us either through Excel spreadsheet or PDFs as email attachments or dropped into a shared OneDrive folder.

With regards to the suppliers, there were many discussions back and forth explaining the rationale behind the project and the collaborative attitude J&J is taking on through building the digital thread, hoping that an end-to-end digital thread can not only help Ethicon reduce costs and customer complaints, but also provide suppliers insight into their existing processes and visibility into where the parts they ship to Ethicon end up. With the E2E digital thread and a digital twin enabled down the road, there could be a reduction in scrap rate that benefits both suppliers and Ethicon. Given the long and complex process of on-boarding and getting another supplier approved for manufacturing a particular part, Ethicon is also not looking to use this as a way to evaluate supplier performance. The discussions with suppliers were truly a trust building exercise. In the end, we were able to get the knife supplier excited about the potential information the digital thread can provide and share their data with us.

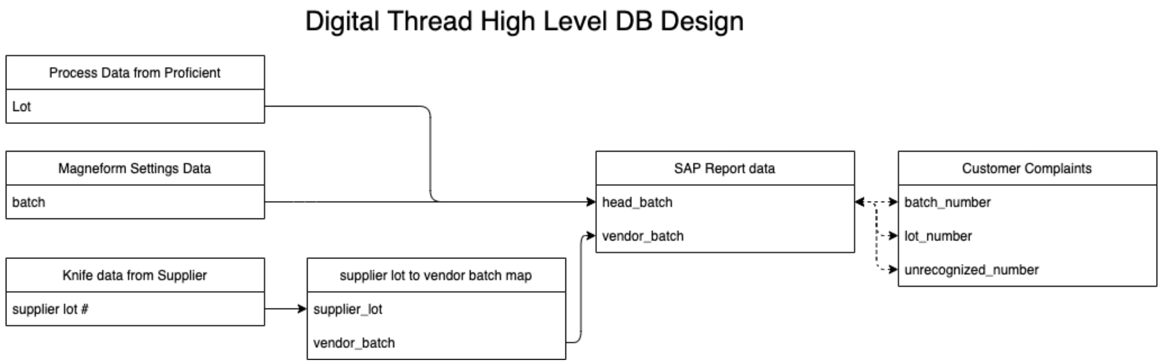

Figure 4-3: Database Design - Data Source Connections in the Digital Thread

4.2 Building the Digital Thread

Data retrieved for the digital thread included the supplier's knife sampled measurement data (Figure 4-4), process data for one of the key processes called magneform, quality data including staple height measurements and force to fire at the end of the assembly process, data from the ERP system with information about supplier part to manufacturing batch mappings, among other information, and finally customer complaints data. Upon receiving the data, the datasets were studied closely to understand how various data sources linked with one another, making it possible to create a digital thread. This proved to be more challenging than originally imagined. The terminology used to describe the same data was different across systems, so conversations with SMEs were crucial in understanding the underlying data.

Furthermore, the datasets differed in granularity across data sources as well. For example, the suppliers had a lot size of 3,000 parts sampled at 50 parts per lot. The magneform process setting is typically calibrated at the beginning of the shift, noted every lot, and only adjusted if the end-of-line quality tests have not been performing at an acceptable level. According to current practice recorded in the control plan, staple heights are measured at the beginning of each batch (3 at the beginning) and sampled at a rate of one in every 20 devices for the remainder of the batch, and the FTF test is performed on every device that is assembled. With the wide range of data granularity across data sources, it was decided that the proof-of-concept digital thread would be on the batch level and the MVP digital thread would include data from one supplier, process and quality data from the assembly plant, and customer complaints data.

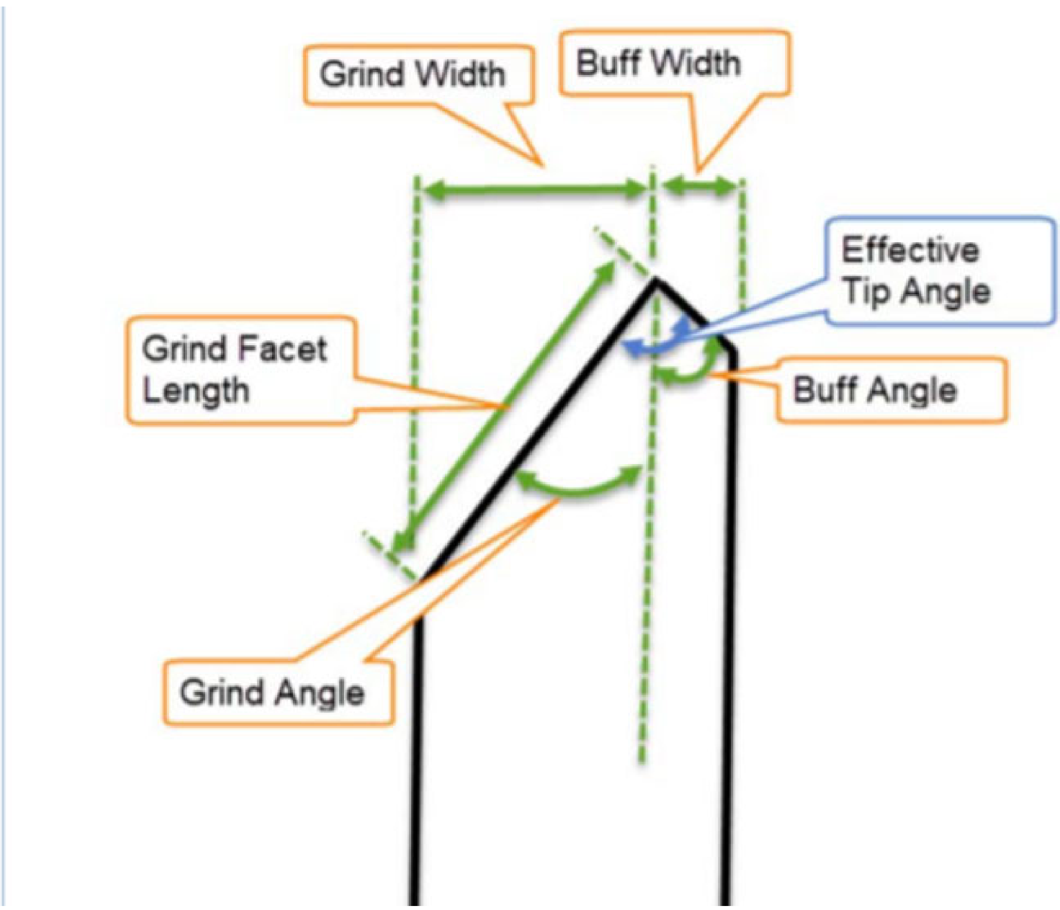

Figure 4-4: Knife Component Measurements

Once the data has been understood, extracted from Excel spreadsheets, transformed, and loaded into the SQL database with the database design in Figure 4-3 in mind, building the digital thread meant writing the SQL query that would connect all of the data sources together and provide a table view of how the materials flow through the system. Appendix B shows the query for the digital thread. It is a SQL view[2] of the stored query found to return the relevant data that make up the digital thread.

4.3 Analytics Model

4.3.1 Exploratory Data Analysis

With the digital thread built, aggregations and visualizations can be created using the merged dataset that is generated across 6 data sources. Exploratory data analysis on supplier data only, assembly data only, and data generated from the digital thread were all used to generate models that help identify correlations in the data.

Within the supplier measurements, there were two pairs of variables that were highly correlated, namely Feature 1 and Feature 2 with Feature 3 and the three buff width measurements (Features 6-8) with Feature 9. As shown in Figure 4-5, before removing variables with multicollinearity, the variables in the top left hand corner measuring the similarities between Feature 1, Feature 2, and Feature 3 are positively correlated with each other. On the bottom right hand corner, the similarities between Features 6-9 are even more apparent. This is due to the fact that Feature 3 is the average of Feature 1 and Feature 2, and Feature 9 is the average of three measurements taken on the same location on the knife (Features 6-8), labeled as "Buff Width" in Figure 4-4. Feature 1 and Feature 2 correspond to the top and bottom tips of the Grind Facet Length in Figure 4-4.

Visualizations were created to understand the current state of the data before any modeling. Figure 4-7 shows the unfiltered data on key measurements gathered from the assembly plant – end of stroke force, Feature 12, Feature 14, and Feature 25. End of stroke force is the force recorded at the end of a staple's firing stroke. Feature 14 is the force recorded during the staple's firing process where the washer breaks. Feature 12 is the percentage of the firing stroke at which the washer broke (i.e. the beginning of the stroke is 0%, end of stroke is 100%, if the washer breaks at

[2] A SQL view is the result set of a stored query, which a database user can query directly just as they would query a database table.

exactly half way through the stroke, then the washer break position is 50%). Feature 25 is the staple height measured after firing the stapler, the height being measured is shown in Figure 4-6.

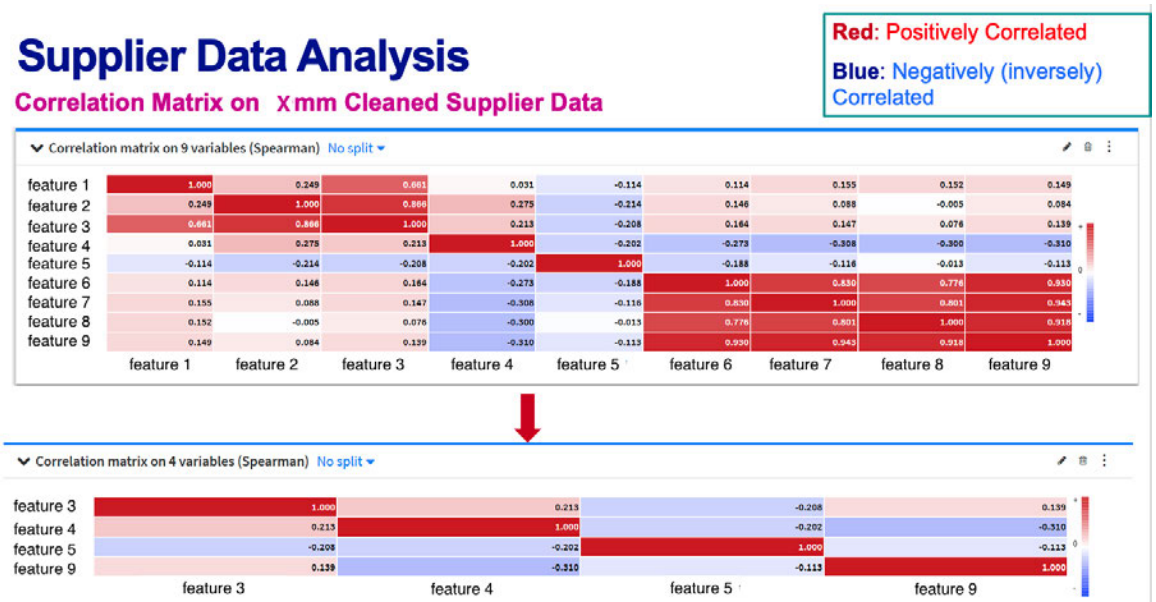

Figure 4-5: Correlation Matrix of Variables in Supplier Data

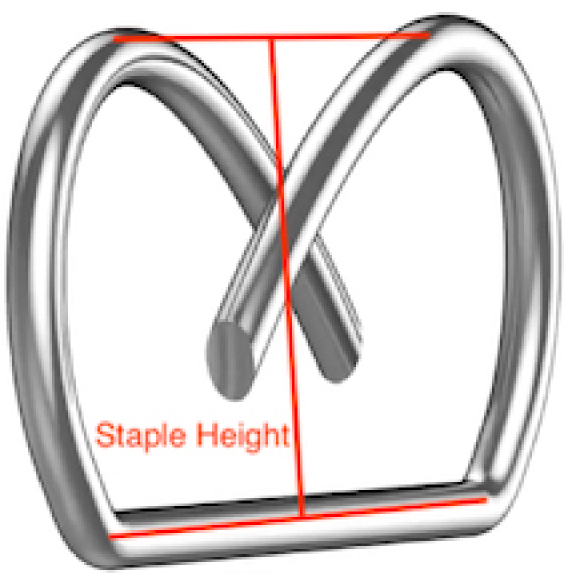

Figure 4-6: Circular Stapler Staple

Figure 4-8 shows key measurements taken during the assembly process after filtering out data points that do not have staple height measurements associated with them. Recall the staple height measurement is sampled whereas Force to Fire test is performed on every device made. End of stroke force, Feature 14, and Feature 12 are measurements recorded during the Force to Fire test, so there will be a data entry for every row in the database for these measurements. However, since staple height is sampled at a rate of 3 at the beginning of the batch and one in every 20 devices thereafter, most of the devices will not have a staple height measurement. Furthermore, when a stapler gets fired, it is either fired at the "high B" or "low B" setting, meaning the high staple height setting (typically ranging from 0.075mm to 0.095mm) or the low staple height setting (typically ranging from 0.045mm to 0.065mm), which in practice is determined by the surgeon based on the patient. The reason the settings are referred to as high or low "B" is because the formed staple after firing makes a "B" shape (Figure 4-6). The two distributions of firing at high B or low B can be seen in the Average Staple Height graph in both Figure 4-7 and Figure 4-8.

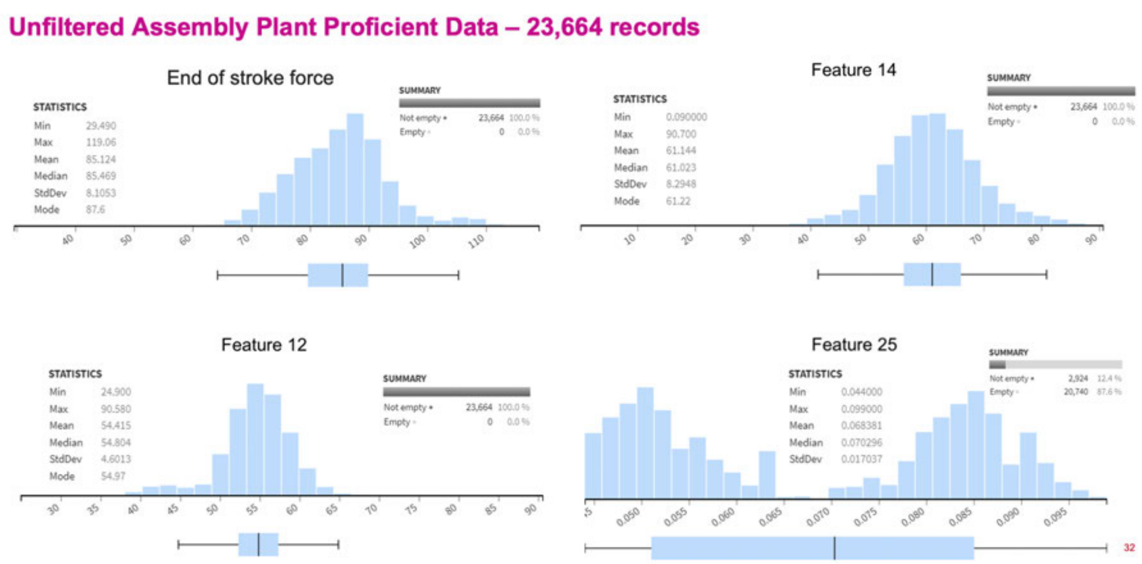

Figure 4-7: Key Measurements during Assembly (Unfiltered)

For every device that gets fired, the device can only be fired at one of the two staple height settings, so the sampled staple height data is further divided into those that were sampled at the high B setting vs. those sampled at the low B setting. To better understand how various measurements impact FTF, the rows that did not contain any staple height data were filtered out and only rows with complete information were used in the analysis, which resulted in data distributions in Figure 4-8. Note that the distribution for Feature 12 changes from a unimodal distribution with a median of 55 to a bimodal distribution with peaks at 43 and 55. This bimodal distribution was initially surprising and alarming. However, upon diving deeper into the data and talking to SMEs, it was discovered that the bimodal distribution corresponds to the effects of firing the stapler at the low B setting or the high B setting.

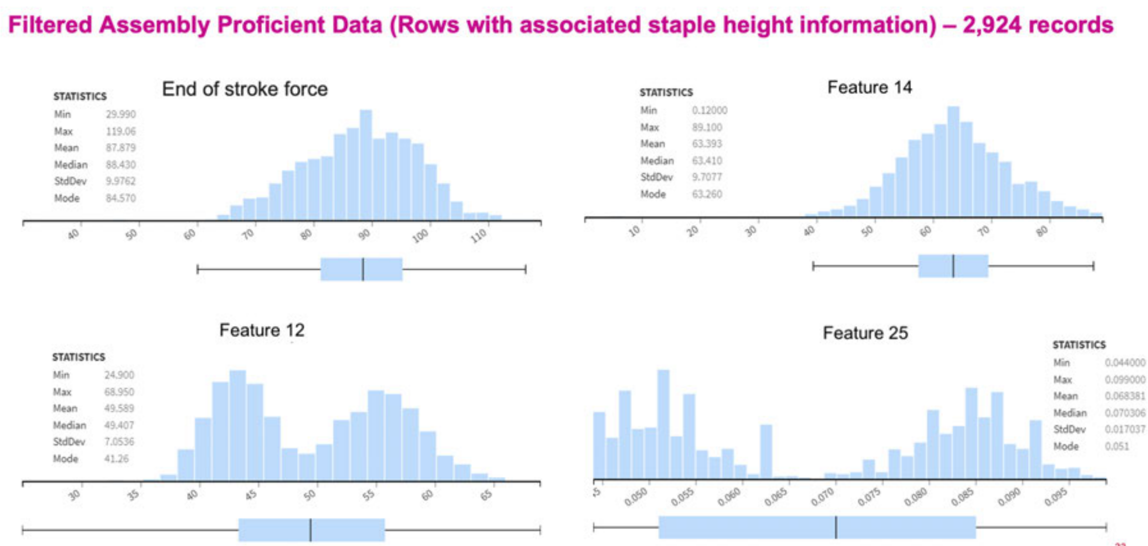

Figure 4-8: Key Measurements during Assembly (Filtered)

Through splitting and visualizing the data in different ways, Figure 4-9 was created to show the difference in Feature 12 and whether the stapler was fired at high B or low B (Feature 28 in the correlation matrix). As shown in the charts, the median of Feature 12 for a stapler that was fired at low B and high B are 43.22 and 55.1, respectively, which corresponds closely to the Feature 12 graph in Figure 4-8. Figure 4-10 provides a closer view of the distribution of Feature 12 where the two peaks appear roughly at 43% and 55% of the firing stroke. Figure 4-9 also shows the disparity between the number of data points measured at high B vs. low B. During the quality control steps, high B is more frequently measured than low B due the higher possibility of having a malformed staple in the staple formation when firing at high B. The number of data points sampled at high B vs. low B is around 14:1. Figure 4-11 illustrates possible staple formations.

It is also worth examining the correlation between all numeric variables in the dataset (Table 4.1), which shows a positive correlation (0.64) between Feature 28 and Feature 12 and a negative correlation (-0.51) between Feature 12 and end of stroke force. Feature 28 is a binary flag that indicates whether the stapler was fired at the high B setting or the low B setting. If the stapler was fired at high B, the feature would have a value of 1, and 0 if the stapler was fired at low B.

	Feature 28	Feature 14	Feature 12	end of stroke force	Feature 13
Feature 28	1	-0.18	0.64	-0.29	0
Feature 14	-0.18	1	0.22	0.16	0
Feature 12	**0.64**	0.22	1	-0.51	0.03
end of stroke force	-0.29	0.16	**-0.51**	1	0.01
Feature 13	0	0	0.03	0.01	1

Table 4.1: Correlation Matrix of Numeric Variables in Assembly Data

There is always more to explore with the raw data such as applying more filters to the data and aggregating it in different ways to continue to find possible correlations, given the time constraint most of the exploratory data analysis were the ones shared in the thesis. After some exploratory analysis, regression and ensemble learning models were built to further attempt to identify correlations that exist in the data. In summary, the goal of performing exploratory data analysis here is to gain an understanding of the shape of the data, distributions, and summary statistics. From there, perform any necessary cleaning to prepare the data for modeling, where the current goal is to further identify and understand correlations in the data.

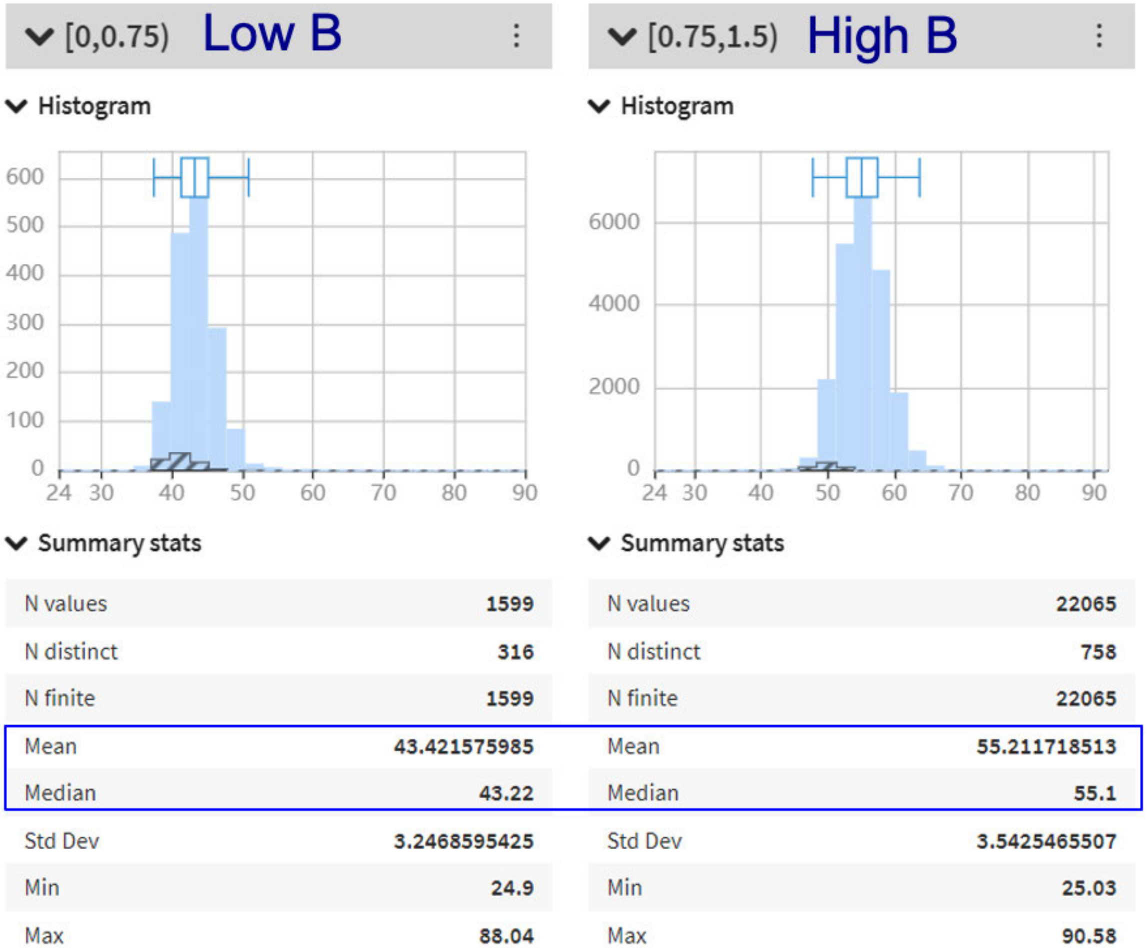

Figure 4-9: Feature 12 Split by Firing at High B vs. Low B

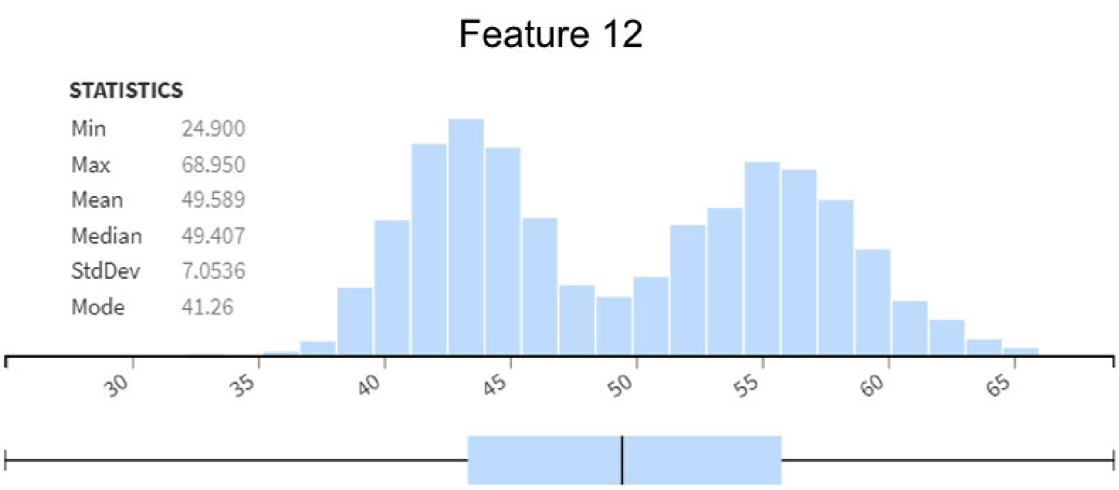

Figure 4-10: Feature 12 from Filtered Assembly Data

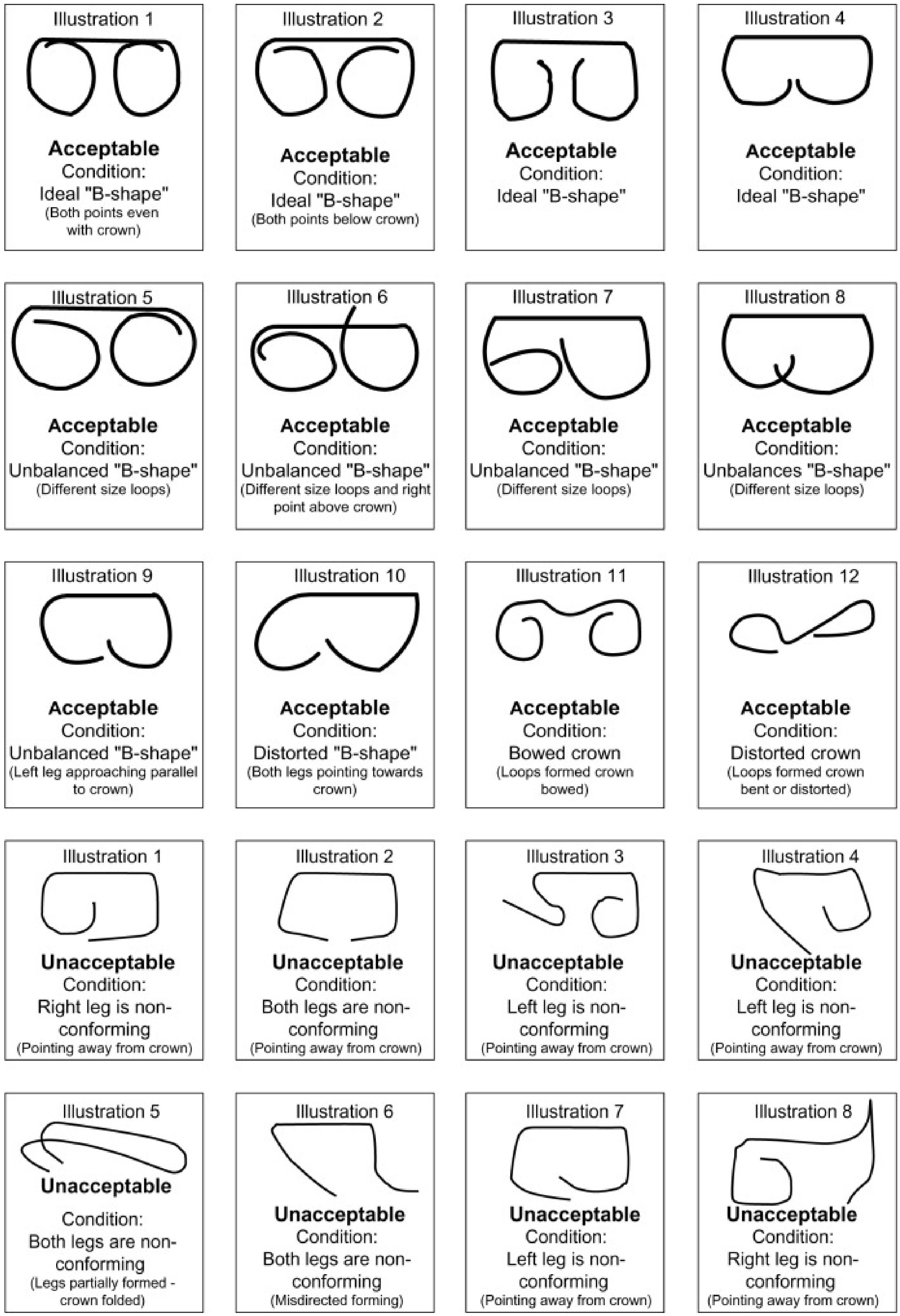

Figure 4-11: Acceptable and Unacceptable Staple Forms After Staples Fire into Tissue to Create an Anastomosis [50]

4.3.2 Modeling

One of the initial goals of modeling is to create a model that returns an equation that can not only help understand the magnitude of the effects various components or measurements have on the Force to Fire (FTF), i.e. end of stroke force, but also provide a way to easily calculate a potential FTF of the device given its measurements. Since the task is to predict FTF given device component measurements, a regression model is needed. Explainability remains important, so in the model selection process, interpretable models were preferred because being able to explain how the model produced the results it did to SMEs and other stakeholders that may not be as familiar with data science is a key piece in continuing to make progress in the digital transformation journey.

First of all, it is worth noting that although one of the goals of creating the digital thread is to use the connected data from the digital thread to predict FTF, particularly using both supplier data and assembly data, but the data funneling effect forced the POC digital thread to be on the batch level, so the data collected over this period did not contain enough batches and detailed information about the batches to use the digital thread data for models (i.e. after all of the data sources were connected, we were left with 66 batches of data. Given we also cannot reliably connect samples taken at the supplier level with samples measured during assembly, building a model based on data from the digital thread did not make sense).

Before building models, since there are many data sources for this project, we shall first outline the various sources used as inputs to models. Since all of the data sources were sampled independently, i.e. components that were sampled at the supplier are not necessarily the components that were sampled during assembly, models had to be created at individual steps. This means models were built for predicting cut force on the supplier level and models were built for predicting cut force after the product has been assembled. Models were also built for considering all stapler sizes together and one specific stapler size, which we will refer to as "X"mm for the remainder of the thesis, to isolate the effect size has on cut force.

Model Selection and Training

Two classes of models were chosen to be part of the initial evaluation – linear regression models and random forest (RF) models. Both models are regression models since the dependent variable in this case is continuous (FTF). The models were chosen because of their interpretability and the importance of the models produced to be explainable.

Linear regression models such as ordinary least squares (OLS), Lasso, and Ridge regressions (introduced in Section 3.3) where built to check the feasibility of getting an equation that predicts and explains the effects various features have on the output variable – FTF (end of stroke force in the data), accurately and reliably. Table 4.2 shows the list of models that were built.

Data Source	**Stapler Sizes**
Supplier	All
Supplier	Filtered to one size
Assembly Plant	All
Assembly Plant	Filtered to one size
Digital Thread (Supplier + Assembly Plant)	All

Table 4.2: Input Data for Models

Individual decision trees (CART models) and random forest models were built as they do not make assumptions about existing relationships in the input data. Hyperparameters outlined in Table 4.3 were tuned empirically. CART models are substantially more interpretable than linear regression models because CART models generate decision trees that can be used to understand how predictions are made. Figure 4-12 shows a partial decision tree outputted from one of the models built.

Parameters	**Definition**	**Sample Value**
`n_estimators`	Number of trees in the forest	100
`criterion`	Metric used to determine the quality of a split	squared_error, absolute_error
`max_depth`	Maximum allowable depth of the tree	10, None
`min_samples_split`	Minimum number of samples required to split a node	2
`min_samples_leaf`	Minimum number of samples required to be a leaf node	1, 2
`max_features`	Number of features to consider when looking for best split	int, log2, None
`max_leaf_nodes`	Maximum number of leaf nodes allowed in the tree	100, None (unlimited)
`min_impurity_decrease`	Minimum improvement in impurity splitting the node brings	0.0

Table 4.3: Parameters for CART and Random Forest Regressors

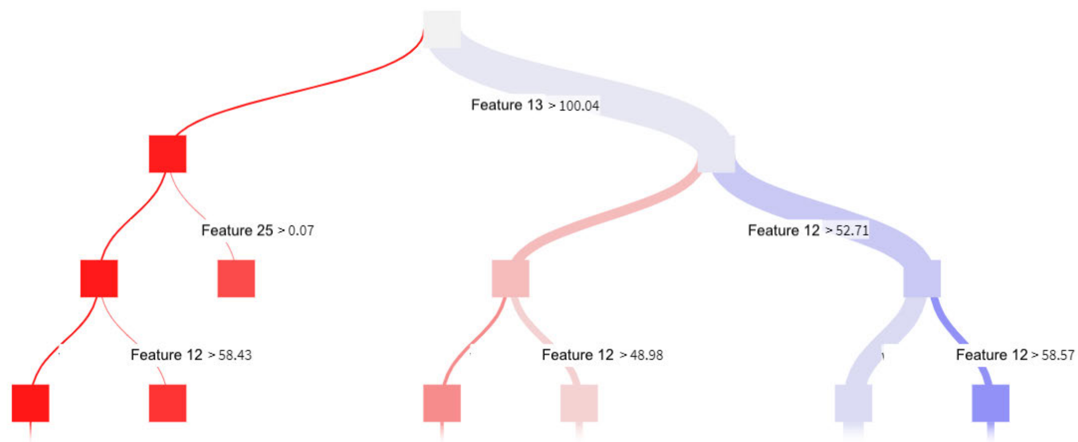

Figure 4-12: Sample Output Decision Tree (Partial)

All of the models built also included k-fold cross-validation, where k=5. K-fold cross-validation is a model evaluation method that performs the "holdout method" k times. Each time, the data set into k subsets and holds one of the subsets as a "testing set" and the remaining k-1 subsets as the training set. The model gets trained on the training set and asked to predict the output values for the data in the testing set. This process is repeated k times, holding out a different subset each time. In the end, the average error across all k trials is computed [46]. Figure 4-13 provides a visual of how k-fold cross-validation works.

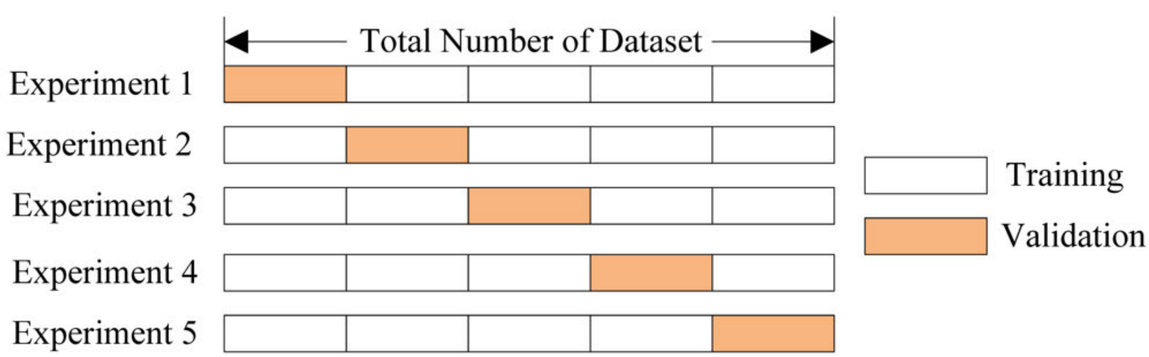

Figure 4-13: 5-Fold Cross Validation [30]

Model Evaluation Metrics

For regression models, there are three metrics commonly used to determine model quality: $\mathbf{R^2}$, **root mean squared error (RMSE)**, and **mean average error (MAE)**. R^2 is a measure of the model's goodness of fit, while RMSE and MAE are measures of error.

$\mathbf{R^2}$, the "coefficient of determination," measures the proportion of the variation in the dependent variable is explained by the independent variables. Its values fall between 0 and 1. The closer the R^2 value is to 1, the more variance is explained by the model. Therefore, a higher R^2 indicates better performances. It works by comparing the regression model with the baseline model where the baseline model predicts simplistically using the average of the dependent variable, without using any information or data from independent variables. R^2 can be expressed as:

$$R^2 = 1 - \frac{sum\, of\, squared\, residuals\, of\, regression\, model}{sum\, of\, squared\, deviations\, of\, baseline\, model} \tag{4.1}$$

The residual sum of squared errors (SSR) in the numerator of Equation 4.1 is:

$$SSR = \sum_{i=1}^{n}(error_i)^2 = \sum_{i=1}^{n}(y_i - \hat{y}_i)^2 \tag{4.2}$$

The total sum of squares (SST), i.e. sum of squared deviations from the mean, which is the denominator of Equation 4.1, is expressed as:

$$SST = \sum_{i=1}^{n}(y_i - \bar{y}_i)^2 \tag{4.3}$$

$$Where,$$

$$\hat{y}\, represents\, the\, predicted\, value\, of\, y$$

$$\bar{y}\, represents\, the\, mean\, value\, of\, y$$

Putting the pieces together, R^2 can be calculated as:

$$R^2 = \frac{SST - SSR}{SST} = 1 - \frac{SSR}{SST} \tag{4.4}$$

Root mean squared error (RMSE) is the square root of mean squared error, which is the average residual squared errors. Equation 4.2 is the sum of squared error, so the equation of RMSE is:

$$RMSE = \sqrt{\frac{1}{n}SSR} = \sqrt{\frac{1}{n}\sum_{i=1}^{n}(y_i - \hat{y}_i)^2} \tag{4.5}$$

RMSE as a model evaluation metric penalizes large errors. It is very common but is hard to interpret. Although the numbers might seem familiar, the metric is calculated by squaring differences so it is not as straightforward as an RMSE of 10 means you are off by 10 units on average [17]. Values for RMSE can range from 0 to ∞. Since it is a measurement of error, the lower the error the better.

Mean absolute error (MAE) is the average of the absolute value of the errors (Equation 4.6). It measures the magnitude of the error on average. Since this is a measure of error, the smaller the value, the better the model is. Unlike RMSE, a MAE of 10 means the model is off by 10, on average. MAE is very easy to understand and unlike RMSE that heavily penalizes large errors, MAE weighs all of the errors equally [17].

$$MAE = \frac{1}{n}\sum_{i=1}^{n}|y_i - \hat{y}_i| \tag{4.6}$$

R^2 was used as the primary measurement of accuracy in this project because given the limited data points, we wanted to get an understanding of how much the model is actually contributing towards the predictions and whether the data set provided to the models were performing better than chance. Between the in-sample and out-of-sample R^2 calculations, the difference is whether we are comparing the results of the training set (in-sample) or the testing set (out-of-sample) with the baseline model. More specifically, SSR is calculated with the training set labels as y_i for in-sample R^2 and testing set labels as y_i for out-of-sample R^2.

Chapter 5

Results and Discussion

5.1 Overview

The digital thread, exploratory analysis, and visualizations built in this project laid the groundwork for more data sources to be incorporated into the digital thread for better end-to-end visibility. It also provided insights into correlations between certain component measurements and quality control outcomes. Through the data gathering and model building steps in the project, however, it was made clear that the level of granularity the data is currently being measured at is not at a level that will enable predictive modeling capabilities on the component level, which is the vision Ethicon wants to achieve in the future. However, the work done in this project using the data available was able to produce random forest models with accuracies in the low 70s for all assembly data and assembly data filtered to Xmm staplers. For the supplier data, only a model on all of the sizes of the knife was able to produce a decent result of in-sample R^2 of 0.640 ($\pm$0.033) with an out of sample R^2 of 0.61. When the data was filtered to just the Xmm knives, there was not sufficient data to produce a model with good results.

5.2 Data Availability

Figure 5-1 shows the funneling effect on data collected in two sources. Although the original raw data collected from the manufacturing plant over a 7-month period contained over 23,000 rows of data, after filtering to only the Xmm staplers that have staple height measurements, the available data points dropped to just under 2,000 points. Similarly, customer complaints for the stapler started with over 11,000 rows of data, but after filtering by the specific product codes I am working with and matching them with the batches that occurred in the 7-month period of manufacturing data, only 5 complaints remained that connected with a known batch. This is not solely due to the fact that complaint levels are low though. This is often because the customer complaint data collection process is somewhat flexible, resulting in most of the complaints often not having an associated batch. As a result, after connecting 6 data sources: supplier knife measurements, magneform process data during assembly, two measurements of quality control (FTF and staple height), ERP, and customer complaints, the proof-of-concept digital thread only contained 66 rows of data, meaning over a 7-month period, we have E2E data on 66 batches.

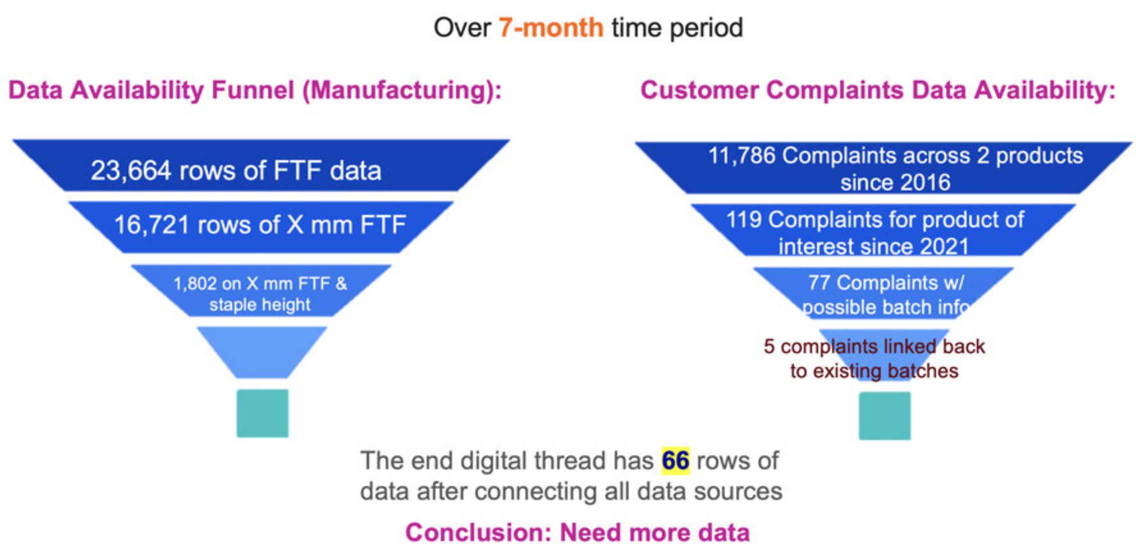

Figure 5-1: Data Funnels Down as Data Sources get Connected Shows Low Data Availability in the Current State

5.3 Digital Thread

The digital thread was built using SQL and manifests as a SQL view with an excerpt of the results in Figure 5-2. The current digital thread shows the mapping between supplier shipments and manufacturing/ assembly batches, and whether any of the batches had any customer complaints associated with them or not. The figure walks through two examples, one of them showing an assembly batch and the lots of the knives used from the knife supplier, as well as customer complaints associated with it and what the complaint was, which in this case was a removal issue while using the stapler during surgery.

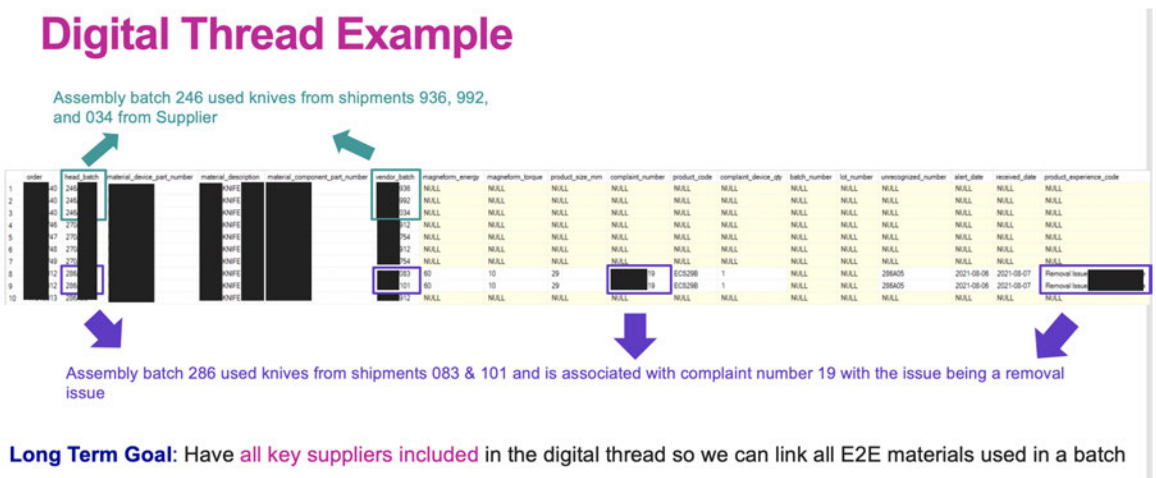

Figure 5-2: Example of Data in the Digital Thread

5.4 Models

Table 5.1 contains a summary of some of the models that were built. Most of the well-performing models were random forest models, likely due to the fact that relationships between dependent and independent variables were non-linear. RF models provide the additional benefit of producing a variable importance ranking (Figure 5-3 and Figure 5-4), which is a result that is interpretable. RF models are also less subjective to bias and overfitting because it takes an average vote of all of its decision trees (hence forest). For example, the RF model built for the supplier data only predicting the washer cut force of just the knife cutting through a washer measured at the supplier came out with an R^2 of 0.64 with the 95% confidence intervals being 0.640 ($\pm$0.033). It produced the results by using 100 trees with a depth of 6 on the training set of size 701 using 5-fold cross-validation. The outcome of the model showed the diameter of the knife being the most important factor in predicting cut force, followed by Feature 5 and Feature 7 (Figure 5-3).

Model	**Data Set**	**In-sample R^2**	**Out-of-sample R^2**
Ridge (L2) Regression	All supplier data	0.629 ($\pm$0.030)	0.6242
Random Forest	All supplier data	0.640 ($\pm$0.033)	0.6096
Ridge (L2) Regression	Supplier data one size only	0.213 ($\pm$0.069)	-
Random Forest	Supplier data one size only	0.221 ($\pm$0.125)	-
Ridge (L2) Regression	All assembly plant data	0.576 ($\pm$0.150)	0.6252
Random Forest	All assembly plant data	0.702 ($\pm$0.096)	0.7237
Ridge (L2) Regression	Assembly plant data one size only	0.198 ($\pm$0.491)	-
Random Forest	Assembly plant data one size only	0.688 ($\pm$0.035)	0.7012

Table 5.1: Model Results Summary

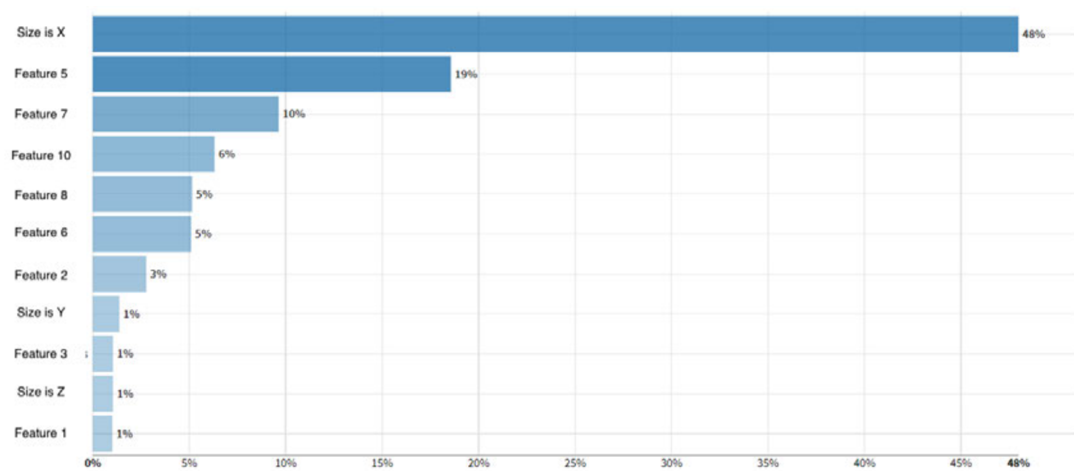

Figure 5-3: Feature Importance Ranking for Random Forest Model on Supplier Data for All Sizes

Since size turned out to be an important factor in influencing the knife cut force, a follow-up model was built to further evaluate other factors that influenced cut force, keeping size constant. This RF model built with supplier data on Xmm knives only had an in-sample R^2 of 0.221 ($\pm$0.125), showing the challenge with making predictions with limited data points and a small sample size from a batch of 3,000.

In the subsequent model with size kept constant, facet width, sharpened height, and sharpened angle continue to be the most important variables.

The random forest model built for the assembly data on Xmm staplers with the dependent variable being end of stroke force identified Feature 12, Feature 13, and Feature 14 as the three most important features in predicting the end of stroke force (Figure 5-4). The three features combined made up 87% of the overall variable importance. The model had a R^2 of 0.688 (± 0.035) and was built with 100 trees, achieved a maximum tree depth of 14 with 5-fold cross-validation.

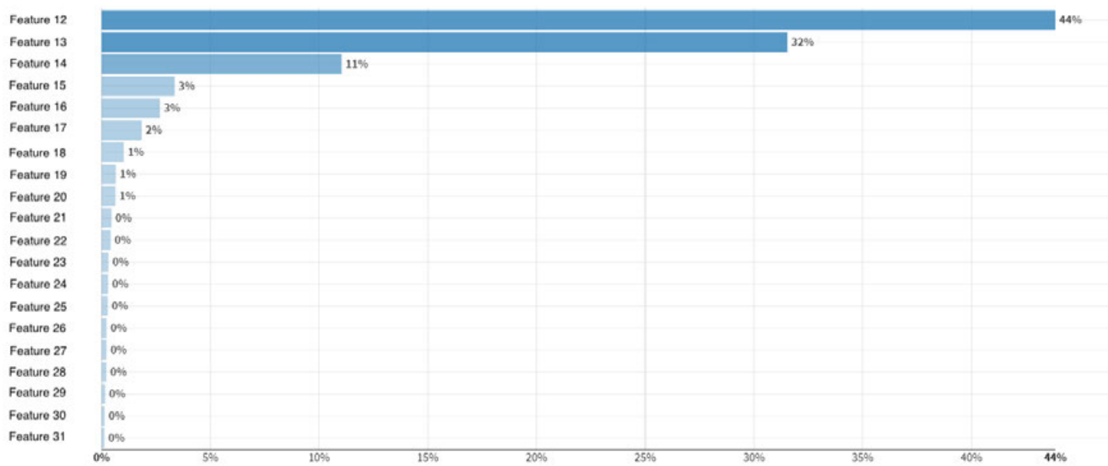

Figure 5-4: Variable Importance for Model Built on Xmm Assembly Data

Finally, an attempt to create a model to predict the end of stroke force by using the average knife cut force measured at the supplier on the lot level, average of Feature 12, average of Feature 13, and average of Feature 14 on the batch level proved to be challenging. The challenge came from the sparse data that only exists on a lot or batch level, rendering it impossible to understand the true effects assembling a device can have on the cut force of the knife and end of stroke force of the finished stapler.

The preliminary results show some promise in predicting end of stroke cut force in the assembly plant. However, since the data set provided does not contain many failures, I opted for attempting to predict the cut force itself instead of predicting whether a given device would fail the Force to Fire test or not. Furthermore, more granular detail and consistency in sampled device across data sources has the potential of dramatically improving the accuracy of future models built.

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Chapter 6

Conclusion and Future Work

6.1 Project Summary

The digital thread developed laid the groundwork for digitizing a vast end-to-end value chain of one of Ethicon's many medical device products and provides an initial working data source SMEs can go to trace material flow from the suppliers to the assembly plant. Once the digital thread is connected with live data flowing through, it can save weeks of time spent tracing material flow for multiple stakeholders, which is a required task for any customer complaint investigation. The exploratory data analysis reaffirmed some of the beliefs SMEs had learned through experience working with the product, which now can be visualized and explained. The data analysis also provided additional insights and raised questions that once answered, will enable deeper understanding of a legacy surgical stapler product that has been in production for more than 30 years.

The analysis conducted in this project is based on data that is collected on the knife as well as the knife's interaction with the washer both pre-assembly and post assembly of the product. The hypothesis of the overall project is that there may be other dimensions or measurements that are not currently being collected that could also influence Force to Fire. After the analysis performed in this project on existing data, additional work can be done in the future through running experimental engineering builds that will serialize each of the important components and take measurements on each of them, which will enable the creation of a digital twin. By using information in the digital twin, models can be built to help prove the hypothesis.

6.2 AI Ethics

With the increase in adoption of artificial intelligence (AI) in industries across the board, ethical dilemmas in the application of AI are also being frequently discussed. For example, when an AI makes a mistake, who is held responsible? If a self-driving car gets into an accident, how do we determine which system caused the accident? We often think of AI as an arbiter of neutrality that can take potentially biased human judgement out of the equation. However, multiple instances have shown that if we feed the system biased data, we get biased results. An example of such system is Amazon's AI recruiting tool that was being used from 2014 to 2018 to screen applicants and hire applicants. The system used Amazon's hiring data such as applicant resumes from the past 10 years to inform hiring decisions for the future. It turns out the system was biased against women due to the high proportion of male software developers that were hired in the past 10 years because of the gender disparity in the field. The AI learned from the resume data from the past 10 years that male candidates were preferable. Through examples like this, we learn that AI systems are very good at picking up patterns from data even if they are not specified, so we must be very thoughtful about the applications we utilize AI for and the data we use to train the systems because if not implemented carefully, they can – at best, not live up to their expectations but at worst, they can cause harm.

As the applications of AI increasingly expands from industry to industry, often to increase productivity and efficiency or personalization and improve customer experience, more and more data get collected about individuals as well. This raises concerns about data privacy. Particularly in the healthcare industry, as AI is being incorporated into processes, decision making, and wearable technology that tracks health statistics of people, the question about whether regulation can keep up with the usage has been a prominent one with many.

In 2016, the European Union (EU) passed the General Data Protection Regulation (GDPR) that set guidelines for the collection and processing of personal information from individuals who live in the EU and the European Economic Area. In 2021, the World Health Organization (WHO) released a guidance document outlining 6 key principles for the ethical use of artificial intelligence in health. The six principles are: protecting autonomy; promoting human safety and well-being; ensuring transparency; fostering accountability; ensuring equity; and promoting tools that are responsive and sustainable [59]. A summary of the six ethical principles and why they matter can be found in Wetsman's article [55]. In September of 2021, the FDA also released an action plan that outlines steps the government aims to take in addressing artificial intelligence at the FDA [7].

In the various regulations and frameworks that have been released over the last few years, many overlap in the basic principles of responsible AI, which include data privacy, data governance, accountability and auditability, robustness and security, transparency and explainability, fairness and non-discrimination, human oversight, and promotion of human values from organizations such as UNESCO's Recommendation on the Ethics of AI, the Ethics Guidelines for trustworthy AI by the the European Commission, the OECD AI Principles, and China's ethical guidelines for the use of AI, to name a few [31].

There are countless applications for AI in healthcare. Through the fight with the COVID-19 pandemic, we have seen examples of countries and institutions scrambling to rapidly deploy AI tools as solutions. Many of the tools, however, contained features that the WHO warned against. In Singapore, officials have admitted data from its COVID contract tracing program TraceTogether can be accessed by the police and used for criminal investigations [20], which is an example of "function creep" where data collected for health reasons were repurposed beyond its original goal without the users' consent. In the United States, hospitals have also used a ML algorithm to predict whether patients experiencing COVID-19 symptoms might need intensive care before the program was tested [29]. The WHO report states – "An emergency does not justify deployment of unproven technologies." The report also recognizes the misalignment of incentives that exist between large technology firms that develop the AI technologies and the actual users of the technology. The companies have the resources and data to build the tools, but the incentive to ensure their products align with the ethical frameworks of AI may often be outweighed by profitability. Finally, the WHO report also warns, "The appeal of technological solutions and the promise of technology can lead to overestimation of the benefits and dismissal of the challenges and problems that new technologies such as AI may introduce," so we must be thoughtful and measured in the way we build and adapt AI systems.

In the medical devices manufacturing industry, perhaps some of the AI being developed do not seem immediately connected with consumer data privacy or ethical decision making. However, in developing any AI or ML algorithms, we have seen that the data quality that goes into training a system gets reflected in the quality of the model it produces. Models developed to automate tasks or flag potential errors upstream have the potential of saving time and cost, but this should not be a complete substitute of end-of-line quality tests currently performed on every device. Perhaps a middle ground could be to conduct sampled end-of-line quality tests as an additional validation because these products are medical devices. At the end of the day, any medical device that gets manufactured can influence a person's life, so the explainability of the model should be prioritized as much as accuracy often is in any ML algorithm.

6.3 Future Work and Recommendations

In this project, the models built were built to identify correlations that exist in the current data on batch level. However, opportunities remain for two class classification models to be built to predict the likelihood of certain components assembled together producing a stapler that passes or fails the Force to Fire and simply return {True, False} on whether the device is likely to pass the FTF test. The vision for these models is that they can not only inform whether components can pass tests or not, but can also provide recommendations on which components assembled together has the highest likelihood of producing a finished product that pasts the FTF test. Of course, all of this relies on the assumption that there is serialized component-level data informing the models.

Moving forward, the next steps include running a serialized engineering build on the product to measure the dimensions of components in a serialized manner such that there exists clear measurements for each component that end up in a finished product. In other words, given a finished good, we would be able to identify the exact parts that went into the product and what their respective dimension measurements were during the supplier manufacturing step and the assembly process. The serialized engineering build will be helpful because although the digital thread connected the data sources together, the insights it provides are still on a high level, on the batch level. It will also enable the design engineers and process engineers to analyze the data more concretely, on features that were not marked as a critical to quality or critical to process component during the product's initial design more than thirty years ago. With the understanding of key dimensions, digital twins can then be built to enable additional capabilities such as simulation.

As important as having serialized component level data is having a centralized source of truth for the data. Although the digital thread can connect different data sources together, it would be beneficial to have a centralized source of truth different systems or different digital threads and digital twins can trust. The centralized data warehouse or data lake can also have capabilities to link with supplier data. There are various ways to ingest third party data. One way could be to have a shared file system the suppliers drop their data into on a regular basis and have automated processes read from the directory and insert the new data into the centralized location. Data sharing in the centralized source of truth will likely need to be a two way street though. Suppliers share their data with Ethicon and in return Ethicon provides supplier access to the digital threads or dashboards summarizing insights generated from the E2E value chain. Having a centralized source of truth for the data along with a digital thread can enable users visibility into the current state of the supply chain in near real-time.

With a completed digital thread, digital twin, and analytics models, the hope is that the system can facilitate process shift detection and flag potential failures before they happen.

Benefits & Challenges

The overall benefits and challenges a digital thread can provide are discussed in Section 3.1.3. This digital thread built in this project is a Minimum Viable Product proof-of-concept focused on Force to Fire as the output. Since this is a MVP, there are many more steps in the value chain that can be added (e.g. more suppliers of key components, the distribution step, etc.) to the digital thread to make it more robust and informative. A completed digital thread can then act as the basis for a digital twin, which can then unlock capabilities such as simulation on design changes without influencing production volume. The digital twin can also help identify additional components that perhaps were not initially identified as a *key component*, but through experimentation and data collected from the digital thread and digital twin, can show that they are key components or key measurements.

Some non-quantifiable benefits of the project include increased suppliers openness to be included in the end-to-end visibility project, being willing to provide their data, motivation to serialize the data, having a better understanding of the current data landscape of the legacy product, and the creation of a digital thread using the data that is currently available.

Appendix A

40 Key Digital Capabilities for Operations [4]

Figure 1: The 40 key digital capabilities for operations

Domain	Capability	Q4	Q3	Q2	Q1
1 Design & Innovation	1.1 AI for product portfolio optimization			●	
	1.2 Feedback 360 across the product lifecycle				●
	1.3 Rapid prototyping (e.g. 3D printing)	●			
	1.4 AI based design tools (e.g. generative design)	●			
	1.5 AI/Analytics to identify design quality risks (e.g. DFMEA)			●	
	1.6 Smart costing tools with AI for design to cost		●		
	1.7 Smart project management tools	●			
	1.8 Smart learning tools to capitalize lessons learned		●		
2 Asset	**2.1 Analytics to assess quality problems/non-conformity**				●
	2.2 Analytics for predictive and/or prescriptive maintenance			●	
	2.3 Analytics to perform conditional maintenance			●	
	2.4 Analytics to self-optimize machine parameter and auto correct/smart guidance		●		
	2.5 Analytics to self-optimize utilization of available assets		●		
3 Workforce	3.1 Paper-less shop floor with wearables, tablets and devices		●		
	3.2 Use **digital workstations, instruction, alerts & poka-yoke**				●
	3.3 Support operators with cobots		●		
	3.4 Dynamic task allocation and activity planning		●		
	3.5 Use of AR/VR for training	●			
	3.6 Remote expert supporting using AR	●			
	3.7 Quality inspection automation using vision and AI		●		
	3.8 Use digital and collaborative dashboard for daily shop floor management			●	
4 Planning	4.1 Digital twins to simulate industrialization scenarios	●			
	4.2 Dynamic & digital **production planning and scheduling**				●
	4.3 Extended supply chain control tower			●	
5 Supply Chain	5.1 Flow and warehouse automation based on AGV and cobots	●			
	5.2 Digital tracking flows and inventories				●
	5.3 Goods track and trace of quality and conformity			●	
	5.4 Inventory optimization based on AI			●	
6 Collaborative Platform	6.1 Use connected product/asset solutions to detect in-services issues		●		
	6.2 Adjacent **digital services** around the products				●
	6.3 Use of blockchain to accelerate admin flows between customers and supplies		●		
	6.4 Collaborative platforms to share data with clients and suppliers				●
	6.5 Voice of Customers analytics to drive product decisions			●	
7 Foundation	**7.1 Digital platform**				●
	7.2 Data lake solutions (incl. cloud)			●	
	7.3 Digital Continuity Maturity				●
	7.4 Readiness for 5G	●			
	7.5 Digital roadmap governance	●			
	7.6 Digital acculturation programs	●			
	7.7 Data quality maturity	●			
	7.8 Data management governance				●
	7.9 Cybersecurity solutions				●

Q4 = quartile 4—least mature; Q1 = quartile 1—most mature. The capabilities in bold are the 11 that are being deployed most rapidly.

The race for digital operations transformation: the time for experimenting is over 5

Figure A-1: Accenture Report - The 40 Key Digital Capabilities for Operations

Appendix B

SQL for Creating the Digital Thread

```
CREATE VIEW viewBatchLevelDigitalThreadReno AS
 SELECT
        [order],
        head_batch,
        material_device_part_number,
        material_description,
        material_component_part_number,
        vendor_batch ,
        mag.energy AS magneform_energy,
        mag.torque AS magneform_torque,
        mag.product_size_mm,
        complaints.complaint_number,
        complaints.product_code,
        complaints.quantity_of_product AS complaint_device_qty,
        complaints.batch_number,
        complaints.lot_number,
        complaints.unrecognized_number,
        complaints.alert_date,
        complaints.received_date,
        product_experience_code
```

```
FROM sap sap
INNER JOIN supplierlotvendorbatchmap map ON map.vendorbatch = sap.vendor_batch
INNER JOIN renoKnife knife ON knife.work_order = map.supplierlot
LEFT JOIN magneformSettings mag ON sap.head_batch = mag.batch
OUTER APPLY (
       SELECT
               primary_product,
               complaint_number,
               product_code,
               quantity_of_product,
               batch_number,
               lot_number,
               serial_number,
               unrecognized_number,
               alert_date,
               received_date,
               created_date,
               closed_date,
               investigation_completion_date,
               patient_consequence,
               product_experience_code,
               analysis_code,
               potential_cause,
               litigation
       FROM circularStaplerCustomerComplaints
       WHERE (PRODUCT_CODE LIKE '[redacted]' OR PRODUCT_CODE LIKE '[redacted]')
       AND (sap.head_batch = batch_number
           OR sap.head_batch = lot_number
           OR sap.head_batch = unrecognized_number
       )
```

```
) complaints
 /* Filtering for the knives */
 WHERE material_device_part_number IN (
 '[redacted]', /* [redacted] 21mm */
 '[redacted]', /* [redacted] 21mm */
 '[redacted]', /* [redacted] 25mm */
 '[redacted]', /* [redacted] 25mm */
 '[redacted]', /* [redacted] 29mm */
 '[redacted]', /* [redacted] 29mm */
 '[redacted]', /* [redacted] 33mm */
 '[redacted]', /* [redacted] 33mm */
 '[redacted]' /* [redacted] 33mm */
 )
GROUP BY  [order], head_batch, material_device_part_number,
   material_description, material_component_part_number, vendor_batch,
       mag.energy, mag.torque, mag.product_size_mm,
       complaints.product_experience_code,
       complaints.complaint_number, complaints.product_code,
       complaints.quantity_of_product, complaints.batch_number,
       complaints.lot_number, complaints.unrecognized_number,
       complaints.alert_date, complaints.received_date
```

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