

Design for Industry 4.0

Reflective Essay

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Lecturer: Graham Howe

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Student ID: 2110656

Student Name: Nathan Darran Gunter

Email: 2110656@student.uwtsd.ac.uk

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Utilising Industry 4.0 technologies and Tools in the Design of Orthopaedic Implants and Creating New Business Models

Abstract

Industry 4.0 technologies offer designers and manufacturers a wide range of data driven tools to aid in the creation and development of ever improving products and processes. Generative design is one such tool which Zimmer Biomet can take advantage of to reduce development times. Improvements in FEA systems can also help reduce real-world testing and help lower the costs of developing new products. By combining the two systems as well as integrating the company's vast amount of product and test data, Zimmer Biomet could create a bespoke generative design tool. This tool could be used to open new servitisation opportunities by putting allowing doctors and surgeons' direct access to custom implants. This could result in

the need for Zimmer Biomet to adopt a circular economy model to deal with the single use fixturing that might occur from custom implant manufacture.

Contents

1. INTRODUCTION	3
2. I4.0 GENERATIVE DESIGN IN THE DEVELOPMENT OF ORTHOPAEDIC IMPLANTS	3
2.1. GENERATIVE DESIGN AND FEA FEEDBACK	3
2.2. CUSTOM IMPLANTS AND SERVICISATION	4
3. IMPACT OF CUSTOM IMPLANTS ON MANUFACTURING.....	4
3.1. CHANGES TO MANUFACTURING FOR ONE-OFF AND CUSTOM IMPLANTS	5
3.2. MANUFACTURING FEEDBACK INTO A DESIGN AI	5
4. UTILISING A CIRCULAR ECONOMY	6
4.1. INTRODUCING A CIRCULAR ECONOMY TO ZIMMER BIOMET UK	6
4.2. SERVICISATION AND CIRCULAR ECONOMY ALREADY IN PLACE AT ZIMMER BIOMET UK	6
5. CONCLUSION	6
6. REFERENCES	8

1. Introduction

Industry 4.0 technologies offer designers and manufacturers a wide range of data driven tools to aid in the creation and development of ever improving products and processes.

Almost the entirety of orthopaedic implants are designed using a 3D CAD system. This not only allows designers to design the final product quickly and easily but are also able to check fits and clearances with other mating components and instrumentation. This functionality greatly reduces development time by eliminating basic design faults without the need for testing. The use of such CAD systems is nothing new and utilising digital mock ups are almost standard practise in many companies and industries.

I4.0 offers tools that can expand a CAD systems capability beyond what would typically be achievable. Utilising cloud computing, large amounts of data together with improvements in FEA and topology optimisation, designers can now confidently create new implants and conduct a series of tests all within a digital environment. This can greatly reduce the time and investment required when conducting any mechanical testing of a new orthopaedic implant. This can be taken advantage of by the design and development teams at Zimmer Biomet which should result in new products released to the market in a greatly reduced time scale and possibly create new business models.

2. I4.0 Generative Design in the Development of Orthopaedic Implants

2.1. Generative Design and FEA Feedback

There is very little distinctiveness between not only Zimmer Biomet hip stem products, but the industry. This is to be expected to a certain degree as human skeletal structures do not differ in ways that provides an opportunity for radically differing products. This has resulted in new implant development being more closely related to continuous improvement than new product development. A predicate device will often be used as part of the implant submissions to regulatory bodies to gain the required approval prior to releasing any new product to the market. This is a common practice and will likely become more common in the future as any new implant now requires substantial clinical data prior to any regulatory approval. It is important to perform analysis of the methodological quality of data obtained from different sources to identify and assess the level of evidence, bias, other inherent weakness or other possible shortcomings (Medical Device Coordination Group, 2020). The use of predicate devices as part of a submission reduces the need for timely and costly clinical studies. With the design of most new implants based on an existing product they inevitably begin to share common features such as stem taper angles, neck offsets and distal profiles.

This leaves very few areas left to redesign and become more distinguishable from competitors' products. One large feature, and perhaps, the most important is the section of the hip stem that sits inside of the femur. This distal part of the hip stem is important as an incorrect fit can result in the implant loosening or possible bone resorption and ultimately, further medical procedures for the patient. A design that results in as little bone removal as possible while maintaining the fixation on par with existing stems would benefit the patient by allowing them to keep more of their femur.

Utilising the vast amounts of data gathered via real-world tests and decades of product performance data, post market surveillance and complaints Zimmer Biomet has at hand, a bespoke generative design algorithm could be used in the design process. Designers and development teams would be able to automate parts of the development process which until now has been labour intensive. Discussion of physical automation often undermines the current and future extent of software automation which is already showing a concerningly similar trend as

that of industry and agriculture before that (Page, 2018). By using a predicate device as a starting geometry before running the design through the algorithm to optimise to a required parameter or feature.

This optimised design can then be tested using FEA systems to test any resulting design. This step would either confirm that the generative design phase created an acceptable design or show possible failure methods which would require remodelling on the algorithms part. This feedback from FEA would be vital in the generative design tool improving over time. Should a design pass FEA testing the next step would be real world testing. There are limitations in accuracy when testing digital twins, so generative design and FEA should only be considered a tool. Real world testing will still need to take place, but this also offers another avenue for further improving the generative design and FEA tools by feeding real world data back into these systems. This process would only become increasingly refined as further testing and product performance data is used to further improve and refine the generative design process.

The likely outcome of utilising an FEA-feedback generative design tool would be an optimised implant design that utilises less material but maintains the same product performance. All designed digitally in less time and with less cost. These costs can be reduced further thanks to the efforts undertaken in refining and improving the accuracy of the FEA tools resulting in reduced, but not completely removed, real world testing.

2.2. Custom Implants and Servitisation

Utilising I4.0 tools as part of the design stage and creating a closed-loop system where testing results are used to optimise an FEA-feedback generative design tool, can potentially create a new marketing strategy for Zimmer Biomet. Continuing development and improvement of the generative design tool mentioned above may ultimately result in an AI design process where an optimised patient specific implant could be produced without the need for a large development team.

With the use of cloud computing, Zimmer Biomet would be able to offer a web based design service for bespoke custom implants. Rather than offering a wide range of products to a surgeon or hospital, Zimmer Biomet could instead offer a subscription to their AI design tool. A doctor or surgeon with access to the AI design tool could input patient height, weight, age and if available, CT bone scan data via a web portal. This would then call on the design tool to generate a one-off implant in a matter of hours and conduct FEA based on patient data before getting final approval.

While patient specific implant's is currently a service Zimmer Biomet provides, it does not generate any profit with the design and manufacturing of the implants conducted at a loss for the company. This service is offered mainly as a marketing ploy to introduce new surgeons and hospitals to the wider Zimmer Biomet portfolio, and it is hoped that future sales will eventually cover the cost. This can be changed by instead offering access to Zimmer Biomet's wealth of data and design AI while opening other avenues of revenue such as offering subscriptions to the Zimmer Biomet design service. This service would also help hospitals by reducing the amount of stock to be held onsite to cover the varying sizes of patients. This would help smaller hospitals with less available cashflow.

3. Impact of Custom Implants on Manufacturing

Using traditional subtractive manufacturing methods would require relatively complex fixtures and work holding to accommodate the organic geometries generated by topology optimisation. Formative methods such as casting or forging a near-net can be used to generate most of the geometry required

and in the long run, may work out cheaper than simply cutting the unneeded material away or even 3D printing.

Despite the complexity of a topology optimised geometry, parts of this nature can still be manufactured using conventional manufacturing methods providing that the volumes are high enough. This high volume allows manufacturing sites to spread the potentially higher work holding costs over many more products. One hip stem currently in production at Zimmer Biomet UK, has over 1,600 variants with differing neck lengths and offsets as well as differing distal profiles. What each variant does share is the same 4° taper and surface roughness specifications. This has resulted in a high number of individual fixtures which in turn resulted in a high capital investment. This investment was negated thanks to the volume of product required. Zimmer Biomet UK manufactures over 200,000 of this product range each year and has done so for the last 12 years and planned to do so for at least the next decade.

A common feature on all Zimmer Biomet stems and one that is common throughout the industry is the design and tolerancing of a 4° taper on the proximal end of the implant. Though the number of fixtures is remarkably high, the manufacturing method is identical for each individual stem. The fixturing is a modular part of the CNC machines currently used in manufacturing and helped control the amount of capital required. This may not be the case in other industries such as automotive but thanks to the long product lifespan of orthopaedic implants, higher manufacturing investment can be tolerated. While this would be useful for mass produced products, it does not lend itself to one-off or custom implants.

3.1. Changes to Manufacturing for One-off and Custom Implants

Additive manufacturing or 3D printing is now a common I4.0 technology and offers many advantages over traditional manufacturing methods. One-off or custom products or items can be produced cheaper and quicker using additive manufacturing rather than subtractive methods and is better suited to objects that has undergone topology optimisation during the design process. This is partly due to the way in which the algorithms functions and results in features that looks very similar to natural bone growth. These optimised designs can offer improved performance over traditional designs but can lead to many problems when it comes to manufacturing.

A common feature on all Zimmer Biomet stems and one that is common throughout the industry is the design and tolerancing of a 4° taper on the proximal end of the implant. This allows doctors to interchange components from various manufacturers to get the best result possible for the patient. The tolerance of this 4° taper has a resulting diameter tolerance band of 0.017mm and a surface roughness specification of no more than 0.1Ra. These two requirements are currently beyond the capability of additive manufacturing but can be easily achieved with a well-maintained CNC lathe, which is the preferred method for generating this feature at Zimmer Biomet UK.

To accommodate one-off and custom products in manufacturing so that standard production is unaffected, work holding and fixturing would need to be printed at the same time as the implant. These fixtures can be designed automatically once the implant has been designed and a similar process is already in use at Zimmer Biomet Bridgend. By adopting this method of additive and subtractive manufacturing, Zimmer Biomet would be able to integrate its servitisation model into manufacturing with negligible impact on standard and existing production. The manufacturing industry has to move from mass production to mass customization, which stands for offering a high quantity of goods that are different from each other and customized for the single consumer (Ciccarelli, et al., 2022). A downside of mass customisation such as this however would be the waste caused by the required fixturing that would not be suitable for any other product.

3.2. Manufacturing Feedback into a Design AI

Every manufacturing process has a limit to what specifications can be achieved. Knowing these limits, or floors, is vital to running a successful manufacturing facility by creating feedback to key management positions and departments within the manufacturing site. An often-overlooked department that would benefit from manufacturing feedback is the design and development teams at Zimmer Biomet. This feedback would prevent the Design AI from creating designs that cannot be achieved by current validated manufacturing process. There is also a potential side effect of this feedback. If a company's design capability is linked to the performance of its manufacturing processes there could be increased focus on optimising and maintaining the machines and processes. This would be vital as the capabilities of a manufacturing facility would directly impact the performance of a design AI and any drop in performance could have a direct effect on Zimmer Biomet's servitisation model. A feedback loop such as this could force companies to invest more heavily in their manufacturing systems.

4. Utilising a Circular Economy

Regarding manufacturing, the circular economy changes the traditional model of take-make-dispose, to a closed-loop model where materials and resources are kept in use for as long as possible before being reclaimed or recycled into new products. This often results in the design of products with added durability and recyclability in mind. In some cases, recovered or recycled materials can be used to manufacture a product. Planet Earth cannot sustain the current ways of human development. The negative side-effects of human activity include climate change, destruction of natural ecosystems, and depletion of critical resources on a global scale, jeopardizing the survival of our species (Rockström, et al., 2009). The circular economy aims to reduce the impact of mining and processing new raw materials by recycling and reusing the materials already mined and processed.

4.1. Introducing a Circular Economy to Zimmer Biomet UK

Should Zimmer Biomet offer custom and one-off implants and print the required work holding as stated above, there will be an increase in waste material at the site. The required fixturing would not be suitable for existing product and it would be very unlikely that it would suit another custom implant. These fixtures could be recycled and reprocessed into new raw material for one of the company's 3D printers. This allows Zimmer Biomet to not only operate a closed-loop digital design and test system, but also a closed-loop material system by introducing waste back into the manufacturing process. Scrap transformation is a vital process for future recycling procedures as it enables the fabrication of new and sophisticated products or prototypes from old materials (Nascimento, et al., 2022).

4.2. Servitisation and Circular Economy Already in Place at Zimmer Biomet UK

Zimmer Biomet already has limited servitisation and circular economy models in place. Zimmer Biomet offers their instrument kits on a loan basis. This allows hospitals to only pay for instruments when required and reduces the need for a hospital to hold and maintain stocks of surgical instruments. There is also a scheme where should a hospital purchase a full surgical instrument kit; Zimmer Biomet will continually refurbish used instruments and replace or upgrade parts of the kit as required. The items that are no longer needed are then recycled. 10 of Zimmer Biomet's manufacturing sites are now zero to landfill and the company as a global entity recycles 61% of all materials used with only 25% going to landfill. Zimmer Biomet has an A- rating from the Carbon Disclosure Project (CDP) as of January 2023. The implementation of its current servitisation and circular economy models have help increase this from an "E" grade since CDP first graded the company.

5. Conclusion

The adoption of I4.0 technologies will also allow Zimmer Biomet to consider new business models such as servitisation. By combining the vast amount of test and product data into a bespoke FEA-feedback generative design tool, Zimmer Biomet can not only cut development times by generating optimised designs and digitally test them, but also reduce testing times to the point where real-world testing is done to confirm the results of the digital model.

Manufacturing data would be key to a successful design AI. Having production and manufacturing process limitations clearly defined would prevent the design AI from potentially generating models that cannot be manufactured with either additive or subtractive manufacturing methods.

A design AI can open a new servitisation model that will allow surgeons to create custom implants for their patients. However, this would potentially have a large impact on manufacturing and a circular economy approach to what would be single use fixturing would have to be undertaken to limit the environmental impact of the increase in waste.

This would initially be a large undertaking by Zimmer Biomet. It would require time and knowledge in programming a design AI to consider and factor in the data Zimmer Biomet has. However, this work would be hugely beneficial future development and may result in Zimmer Biomet placing distinctive and better performing products on to the market and help secure the company's position as an industry leader.

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