An investigation into the sterilisation capabilities of biopolymers and the introduction of an organisational knowledge management methodology for the medical device industry.

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Submitted to Swansea University in fulfilment of the requirements for the Degree of MSc byResearch

2021

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Abstract

The medical device industry is currently under pressure to improve the sustainability of the products that are manufactured and used. Two single use medical device products manufactured from Acrylonitrile Butadiene Styrene (ABS) and PolyCarbonate were chosen to explore whether they could be replaced with biobased or biodegradable alternatives. Seven alternative polymers are selected as candidate materials based on their mechanical properties being desirable for these devices. The first objective of this research is to assess the magnitude of deterioration in mechanical properties of alternative polymers with two sterilisation methods, Gamma and Ethylene Oxide sterilisation. The polymers are pull tested and three-point bend tested to determine their tensile and compressive properties respectively. These tests are completed before sterilisation, after gamma irradiation, and after ethylene oxide sterilisation. The results show that a biodegradable polymer manufactured from starch-based Poly(Lactic Acid) PLA is as a viable option to replace ABS. The tests also concluded polymers with a higher fibre content experience a larger deterioration in properties after sterilisation, however a non-linear variation was in this relationship. Such results provide valuable organisational knowledge. Much of which is difficult to access, reuse and is lost over a period of time. This leads to the second objective of this research i.e. to evaluate the use of Failure Modes and Effects Analysis (FMEA) tables to store and reuse organisational knowledge required for root cause analysis. A bottom up approach is followed wherein business questions were gathered from employees of a medical device manufacturing company to determine the type of information that staff require access for root cause analysis. The data/information stored is either stored in an enterprise resource planning (ERP) system or the FMEA tables. A methodology is proposed that stores information in a graphical database using entity relationship diagrams that are analogous to the terminology used within the FMEA guideline documents. The FMEA data for an industrial partner for the two selected medical devices is populated in a prototype graph date base software. It is suggested that if the data is stored within a graphical database structure within the software, then this data pull can be automated allowing easy access and reuse. This also ensures that the knowledge is not lost over a period of time.

Declarations and Statements

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

Signed C. Haynes .....

Date: 30/09/2021

This thesis is the result of my own investigations, except where otherwise stated. Other sourcesare acknowledged by footnotes giving explicit references. A bibliography is appended.

Signed C. Haynes .....

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I hereby give my consent for my work, if relevant and accepted, to be available for photocopying and for inter-library loans after expiry of a bar on access approved by the University.

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The University's ethical procedures have been followed and, where appropriate, that ethical approval has been granted.

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Acknowledgements

KESS2 – Thank you to everyone involved in KESS2 for providing me with this unique opportunity to complete my MSc by Research whilst gaining industry knowledge.

Dr Rajesh Ransing - Thank you for giving me the opportunity to conduct this MSc by Research,and for your continual support throughout the project. I hope we have the opportunity to worktogether again in the future.

Matthew Franks – Thank you for giving me the opportunity to conduct this research whilst being fully integrated at DTR Medical. Thank you for taking the time to offer support and guidance throughout the last year.

Staff at DTR Medical – Thank you to all staff at DTR Medical for welcoming me and makingme feel like part of the team. You have each taught me valuable skills required to work withinthe industry. Special thanks to NPD for supporting me on a daily basis.

Knowledge Economy Skills Scholarships (KESS 2) is a pan-Wales higher level skills initiative led by BangorUniversity on behalf of the HE sector in Wales. It is part funded by the Welsh Government's European SocialFund (ESF) convergence programme for West Wales and the Valleys

Abbreviations

Abbreviation	Meaning
POM-C	Acetal Copolymer
PMMA	Acrylic
ABS	Acrylonitrile Butadiene Styrene
AP	Action Priority
AI	Artificial Intelligence
ASR	Automatic Speech Recognition
AIAG	Automotive Industry Action Group
BOM	Bill of Materials
CO2	Carbon Dioxide
CO2e	Carbon Dioxide Equivalent
CNT	Carbon Nanotubes
CBR	Cervical Biopsy Punch with Rotation
Cu/Be	Copper/Beryllium
DFMEA	Design FMEA
DEHP	Di(2-ethylhexyl)phthalate
D	Displacement
Ef	Elastic Modulus
ERP	Enterprise Resource Planning
EO	Ethylene Oxide
FMEA	Failure Mode and Effects Analysis
FCAP	Finance and Commercial Assurance Panel
εf	Flexural Strain
σf	Flexural Stress
FAQ	Frequently Asked Questions
VDA	German Automotive Association
Tg	Glass Transition Temperature
Gy	Gray’s
HDPE	High Density Polyethylene
IoT	Internet of Things
F	Load
LDPE	Low-Density Polyethylene

Cpl	Lower Capability
LCL	Lower Capability Limit
LSL	Lower Specification Limit
ML	Machine learning
MRP	Materials Requirement Planning
CH4	Methane
MAP	Mobile Amorphous Phase
NHS	National Health Service
NLG	Natural Language Generation
NLU	Natural Language Understanding
L	Nominal Span
OKM	Organisational Knowledge Management
OEM	Original Equipment Manufacturers
O	Other plastic types
PPE	Personal Protective Equipment
PBS	Poly(Butylene Succinate)
PCL	Poly-(ε-CaproLactone)
PLA	Poly(Lactic Acid)
PVoH	Poly(Vinyl Alcohol)
PVC	Poly(Vinyl Chloride)
PA	PolyAmide
PCL	PolyCaproLactone
PC	PolyCarbonate
PEEK	Polyether Ether Ketone
PET	Polyethylene Terephthalate
PHA	PolyHydroxyAlkanoates
PP	PolyPropylene
PS	PolyStyrene
PTT	PolyTrimethylene Terephthalate
PVC	PolyVinyl Chloride
Cpk	Process Capability Index
PFMEA	Process FMEA
PI	Process Item

PS	Process Step
PWE	Process Work Element
RAF	Rigid Amorphous Fraction
RPN	Risk Priority Number
SUI	Single Use Surgical Instruments
SME	Small/Medium Enterprise
SPC	Statistical Process Control
SAL	Sterility Assurance Level
SQL	Structured Query Language
h	Thickness
t	Time
US	United States
Cpu	Upper Capability
UCL	Upper Capability Limit
USL	Upper Specification Limit

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Chapter 1 - Introduction

The healthcare industry remains a large source of carbon emissions, with the National Health Service (NHS) contributing the 4% of England's total carbon footprint [3]. Consequently, the NHS have announced their aims to become the world's first carbon neutral national health system by 2040. They have recently extended this goal to include the entirety of their emissions (NHS Carbon Footprint Plus) reaching net zero by 2045 [4]. The NHS Carbon Footprint Plus covers the supply chain of the products procured by the NHS. Figure 1 shows that 10% of the NHS carbon footprint is currently generated by the supply chain of medical equipment [3]. The NHS England Delivering Net Zero report states that "While the NHS does not control these emissions directly, it can use its considerable purchasing power to influence change." This suggests that any manufacturing organisations wishing to supply medical devices to the NHS must begin to improve the sustainability of those products [3].

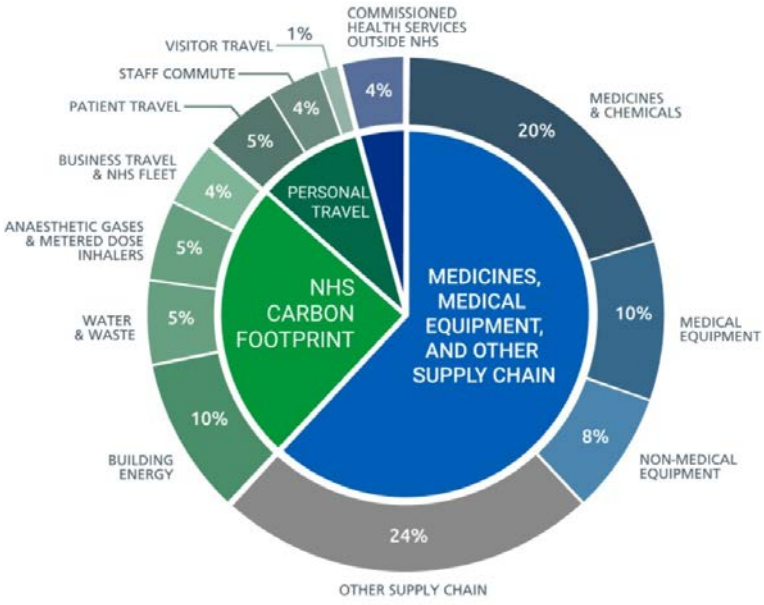

Figure 1. Sources of carbon emissions within the NHS [3]

Many single use medical devices are manufactured from polymers. This is due to the cheap cost, good mechanical properties, and ability to be sterilised. The environmental effect of the disposal of single use plastic is also an increasingly concerning problem that is being faced today. Medical waste is estimated at around 7kg per patient per day, with around 20% (1.4kg) being plastic [1].

One way that this can be combatted is through the repurposing of medical devices. This is where instead of being disposed of after use, the devices are cleaned and sterilised and are then re-used. This comes at a high cost and can often lead to lost or damaged devices, causing delayed surgeries [5]. As well as damage to the devices, reprocessing devices can lead to abnormal proteins called prions remaining on the surface of a device. Prions cause infection within the patient, which can have catastrophic side effects [6]. The medical device directives within the UK "do not explicitly permit re-manufacturing or reprocessing." [7]

Another method of reducing the environmental impact of single use polymers within medical devices is to substitute the petroleum-based polymers which have high carbon dioxide equivalents (CO_2e) with more sustainable polymers that are almost carbon neutral. A more sustainable polymer could be partially or completely biodegradable or biobased.

One of the main risks when changing the polymers used within medical devices is the material's reaction to sterilisation. Sterilisation is reported to alter the Young's modulus and tensile elongation at break properties. The effect on more established polymers is reported in multiple studies, however the effect on newer polymers, especially biobased polymers is not reported within available literature. Therefore, organisations need conduct these investigations themselves during any material change projects.

Sterilisation is the process of killing bacteria that are present on the surface of a product. This can be achieved through many methods, however for plastic medical devices gamma irradiation and ethylene oxide sterilisation are the primary methods due to their low operating temperatures of 22-55ºC. Medical devices must be sterilised to a Sterility Assurance Level (SAL) of 10^{-6}. This ensures that out of every million products, only one product will be unsterile [8].

To implement improvement projects, such as material changes, organisations must firstly recognise which products have the potential to become more sustainable, and secondly recognise how that would be achieved. The information gathered during such projects also

needs to be easily accessible and available to all staff who may need this information. This allows the knowledge gathered to be used in future projects, enabling more informed decision making. Identifying, implementing, and recording these improvement projects requires a high level of Organisational Knowledge Management (OKM). This is where information within an organisation is stored within databases which make accessing and utilising the information straightforward. The potential risks associated with product designs must be assessed, and design parameters should be established to mitigate these risks. DTR Medical (DTR) has a vision to remain at the forefront of using data-centric risk management techniques suitable for the medical device industry. Everything a medical device company does needs to be based on a risk-based decision-making process as proposed by recently changed quality standards (ISO9001:2015). Risk assessments, including Failure Modes and Effects Analysis (FMEA) enable these decisions to be made.

As well as improvement projects, organisations must access product information to determine any root causes following field failures of products. This is extremely challenging and resource intensive. However, improved OKM and risk management will enable these root causes, which will be present within the design or process FMEA forms, to be located quickly and easily.

Currently the FMEA forms are generated as part of a customer requirement, usually after designs or process have already been finalised, and they only require a surface level of information to be completed. In 2019 new FMEA guidelines were introduced which outline the requirements of FMEA to be used as a knowledge base which stores all information relating to a design or process [2]. This improves the level of detail by approaching the process or design in a hierarchical way, where each level zooms in further on an aspect of the subject.

The aim of this project is twofold, firstly to explore more sustainable material options for existing medical devices, and secondly to explore the feasibility of a systematic software-based approach to increase efficiency by reusing organisational knowledge in decision making. In-process data comprises of manufacturing information, market reject information and failure information on all things that go wrong. Currently, for most industries this paperwork is a desk-based exercise that does not proactively influence the risk-based decision making and therefore for static excel based FMEA risk assessments, the decision making could be based on somethings from two years ago.

The objectives of this thesis are as follows:

1) Explore how the polymer matrix, type and quantity of fibre reinforcement affects the magnitude of degradation due to sterilisation.
2) Identify potential tools to enable an SME to remain lean and agile by minimising the time taken for root cause analysis for failures during the prototype or production stages of these products.

To complete objective one, polymers are investigated in Chapter 2, including the environmental problems that arise from their use, as well as their need within the medical industry. Waste management within the medical industry is explored to determine how best to mitigate these effects. Chapter 3 explains how, using this research, seven more sustainable polymers are be identified that have the potential for replacing the current unsustainable polymer within one of two products sold by DTR, the Cervical Biopsy Punch with Rotation (CBR), or the Ear Specula. This chapter also includes the methodology of how the materials are mechanically tested to destruction in accordance with ISO 178 and ISO 527 to determine flexural and tensile properties respectively. The test is completed on unsterilised samples, then after gamma irradiation or ethylene oxide (EO) sterilisation to determine how each sterilisation method effects the performance of the polymer.

The mechanical tests produce stress-strain curves similar to Figure 2, it is expected that after gamma sterilisation the gradient of section A will decrease, point B will occur at a lower stress value, and point D will move closer to point B, as there is less elongation before break. These results are presented in Chapter 4 and discussed in Chapter 5.

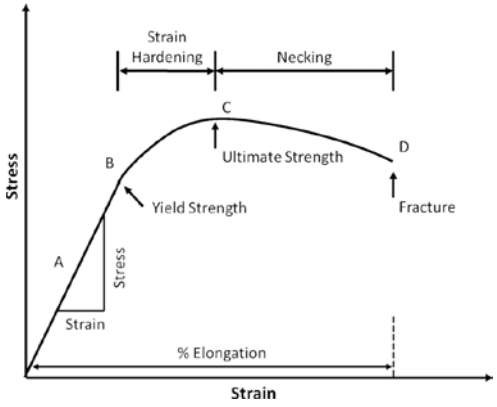

Figure 2. Typical stress-strain curve of a polymer [9]

The outcome of this thesis is novel data on the sterilisation capabilities of a range of biobased polymers for which the literature is currently limited, whilst current materials for which there is sufficient literature is used to ensure that the test methods used produce reliable results. This enables a better understanding of how different polymers are affected by sterilisation and allows manufacturers to make more informed decisions when selecting polymers to use.

The results showed a non-linear relationship between glass fibre percentage and mechanical degradation. Most of the polymers reacted in the same way that the literature suggested, however, the magnitude of these changes varied depending on the type of fibre and fibre percentage.

Objective two is investigated in Chapter 6, where the feasibility of connecting multiple separate data islands and using live document formats to ensure that real time data is utilised in the most effective way is assessed. Root cause analysis is data heavy work requiring full time efforts of data scientists and risk engineers. To help to improve this process live FMEA forms are proposed which enables decision to be smart, present, and accurate at the time of manufacture. This enables the FMEA system to act as a central knowledge pool of an organisation. These forms can be used in conjunction with an ERP system to identify valuable information in an organisation's knowledge base. To continue as a lean and agile company, DTR needs to put greater emphasis on a proactive monitoring and measuring system where feedback mechanisms link all risk assessments with in-process and historical data.

Within this chapter, the transition between the previous FMEA format to the new AIAG-VDA format is be investigated and a compilation of mistakes that are commonly made, and recommendation of how to avoid them is be produced and presented in section 6.1.2.

This section also requires a review of OKM to identify how improvements can enable an organisation to ensure that their data is stored efficiently and correctly to ensure that the connection of these data islands and access to the knowledge stored is possible. One such method of storing all of the organisational knowledge is within a graphical format [10].

Databases can come in many forms. Currently many organisations use relational databases which are not as effective when dealing with big data and cannot be used with incomplete or constantly changing datasets [11]. This is a problem for organisations which aspire to grow drastically in the near future, as their commitment to a relational database could lead to problems when trying to add new data or new systems. One alternative to this is graphical

database. Graphical databases can be represented using entity relationship diagrams, which enables a large amount of data to be stored and quickly searched [12]. Encoding OKM within the entity relationship diagrams of a graphical database is effective in an organisation which performs multiple operations such as sales, production, quality inspection and innovation such as DTR.

This also equips an organisation to move towards a more automated system which can incorporate machine learning when they have large amounts of data stored and easily accessible. A discussion is conducted into how making these changes can improve root cause analysis and regulatory compliance by reducing the resource burden will decrease the time that high level employees spend on root cause analysis tasks, and free up their time to focus on higher level innovative tasks which cannot be automated. This could also enable lower-level employees to complete these tasks, providing jobs for less experienced, skilled graduates. This will ensure that DTR can continue to grow its existing product catalogue of 700 devices and the more stringent regulatory aspect of the industry does not cause the growth to stagnate.

Chapter 2 - Background Information and Literature Review

This chapter provides background information on polymers, and how modification of polymers can influence their mechanical properties. The problems that polymers pose on the environment are then explored, focussing on pollution caused by plastics and the carbon emissions generated by their life cycle. This leads to an investigation of more sustainable polymers that have the potential to be used within medical devices, using two of DTR Medical's products as a case study. Sterilisation is necessary for all medical devices, and is known to affect their mechanical performance, so a literature review is conducted to determine how these materials are expected to react to sterilisation. The literature will also highlight any biopolymers for which the literature detailing its reaction to sterilisation is sparse.

A polymer is a substance that is built up of smaller repeating monomer units. Most have a backbone made of carbon atoms, which have four valent electrons. Therefore, carbon can form a wide variety of covalent bonds, including with other carbon atoms, hydrogen atoms or functional groups such as acid and alcohol groups. The addition of functional groups affects the properties and function of the polymer considerably. The large number of different covalent bonds that carbon can form is the reason why such a vast variety of polymers are available [13].

Plastics are synthetic polymers which are classified as either thermosetting or thermoplastic. Thermosetting polymers can be moulded into a shape, but when reheated they will degrade. Their chains are held together by strong cross links and primary bonds, resulting in high tensile strength and melting point. Unlike thermosetting polymers, thermoplastic polymers can be reheated and remoulded many times. These polymers are bound together by secondary bonds called Van der Waals forces or hydrogen bonds, which can be broken and formed more easily, making them more ductile and easier to deform [14].

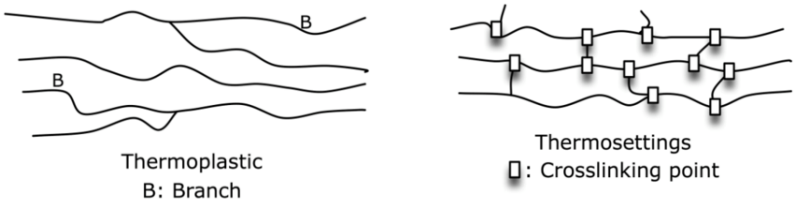

Figure 3. Classification of polymers [15]

Most thermoplastics are semi-crystalline. Semi-crystalline polymers exhibit crystalline regions as well as amorphous regions [15]. Within the crystalline regions the linear chains of the polymer align, or stack, into lamella whereas within the amorphous regions they display a more random, entangled arrangement shown in Figure 4. Polymers that are more branched will be less crystalline, as the main polymer chain cannot align regularly. If these branches are long, then a reasonably high crystallinity can still be achieved. However, multiple short branches limit the degree of crystallinity that will be possible to achieve [14]. Crystallinity can be quantified into a percentage, i.e. percentage of a material that exhibits crystalline arrangement. This property can also be affected by processing parameters such as heating and cooling rates, and the temperature at which the measurement is taken [16].

Within the amorphous phase, some particles contribute to the rigid amorphous fraction (RAF) and others contribute to the mobile amorphous phase (MAP). The RAF is an intermediate phase, between the crystalline phase and the MAP, where there is a lower mobility due to the nearby crystalline region. The MAP will devitrify around the glass transition temperature, Tg, whereas the RAF will need to reach higher temperatures for this to occur [17].

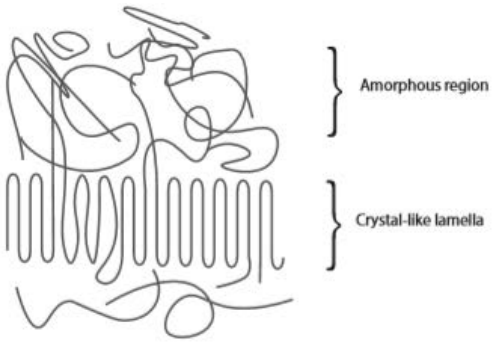

Figure 4. Illustration of polymer chains in the amorphous and crystalline regions [18]

Plastics are incredibly versatile and there are seven main types of plastic, with varying properties and functions. These include polyethylene terephthalate (PET), which is used in drinks bottles, polystyrene (PS), used in Styrofoam cups and plates, and PP, used to make furniture and electronic devices. Other types of plastics are high- and low-density polyethylene (HDPE, LDPE), polyvinyl chloride (PVC) and other types (O), which includes nylon [18]. As well as the versatility of plastics, other attractive features include their strength, ductility, chemical resistance, and thermal resistance. These characteristics are extremely desirable within medical devices.

Polymers such as acetal copolymer (POM-C), acrylic (PMMA), and polyether ether ketone (PEEK), are classified as medical grade polymers due to their biocompatibility and sterilisation compatibility. They also possess characteristics valuable to their function, such as POM-C's resistance to disinfectant agents, PMMA's strength and optical clarity – lens implants, and PEEK's ease of manufacture and resistance to stress cracking [19] [20].

2.1. Modification of Polymers

The versatility of polymers is partially due to their ability to be modified. They can be reinforced with fibres, blended with other polymers, or chemically altered with plasticisers. This will alter the characteristics of the polymer to better suit the application. There are a range of techniques that allow polymers to be optimised, and some of these techniques can be combined. This enables manufacturers to adapt a polymer for a specific function, without synthesising a completely new polymer. This is considerably cheaper, quicker, and poses fewer risks [21].

2.1.1. Physical Blending

Physical blending of polymers is relatively cheap, as it does not require any expensive machinery. This process mixes two or more polymers when they are melted with no chemical reactions taking place. Combining the properties of both materials, can lead to alterations in the cost, mechanical properties, toughness, and water sensitivity of the base material. Materials can be blended in different ratios to alter characteristics, which suggests that predictions of material behaviour can be made prior to mixing [22].

An example of the benefits of physical blending is the cost reduction of blending cheaper starch-based polymers into more expensive Polyhydroxyalkanoates (PHA) polymers. This will

reduce the amount of PHA material that must be used to produce the required volume of polymer, and therefore reduce the cost [23].

2.1.2. Fibre Reinforcement

Polymers can be combined with many different types of fibres to change the physical properties. The fibres are known as the reinforcing phase, whilst the original polymer is known as the matrix. The reinforcing phase is not soluble within the matrix, so when they are combined, they are known as a composite material. There are many different types of fibres which all have different advantages and disadvantages such as cost, strength, and sustainability [24].

2.1.2.1. Glass Fibre

Glass fibre reinforcement uses a polymer matrix, with fibres containing silica woven through. This increases the hardness, strength, flexibility, and stiffness of the base polymer [25]. Glass fibres are introduced to the plastic in varying concentrations depending on the desired mechanical properties of the polymer. There are also different types of glass fibre, with slightly different chemical compositions, which allows more control over the physical properties of the polymer [26].

Glass fibres can be long or short. Long glass fibres align in one direction within the polymer, this increases the improvement that glass fibre reinforcement has on the mechanical properties of polymers. Short glass fibres are often unaligned and do not have as much of an impact on the mechanical properties of the polymer. Glass fibres are often much cheaper than the polymer, and therefore offer a cost benefit, with short fibres being the cheaper of the two options [26].

One disadvantage of glass fibre reinforcement is the wear that it causes to machinery. Injection moulding tools can degrade rapidly when subject to glass fibre reinforced resins. As well as not being biodegradable, glass fibre reinforced polymers cannot be recycled conventionally, however they can be recycled into concrete to increase the compressive strength [27]. Despite this method being available, there is currently only 13% of glass fibre being recycled [28]. Another disposal method for glass fibre reinforced plastic is by incineration for energy. After incineration, the fibres will remain in the ash which can be collected and used in the production of asphalt or cement [29].

2.1.2.2. Natural Fibre Reinforcement

To enable polymers to be strengthened, without the adverse effects of glass fibre, natural fibres can be used. There are many types of natural fibres, with varying mechanical properties. One study showed hemp fibre to have the greatest effect on the tensile and flexural moduli [30]. However, they can be inferior in stiffness, strength and moisture resistance when compared with glass fibre reinforced polymers [24].

Natural fibres are recyclable, biodegradable and carbon neutral, and do not cause damage to tooling or machinery. A life cycle assessment found that natural fibres are environmentally superior to glass fibres in the majority of cases [31]. Examples of these natural fibres are cellulose, wood, and hemp.

Table 1. - *Comparison of natural and glass fibres [32]*

	Natural Fibres	*Glass Fibres*
Density	Low	Twice that of natural fibres
Cost	Low	Low, but higher than NF
Renewability	Yes	No
Recyclability	Yes	No
Energy consumption	Low	High
Distribution	Wide	Wide
CO_2 neutral	Yes	No
Abrasion to machines	No	Yes
Health risk when inhaled	No	Yes
Disposal	Biodegradable	Not biodegradable

2.1.2.3. Carbon Reinforcement

Carbon nanotubes (CNT's) are composed of thin strands of carbon atoms wound together into tubes. These lightweight strands can be used to enhance the mechanical properties of polymers.

They have an extremely high Young's modulus of up to 1 TPa (10^3 higher than that of most polymers), and a tensile strength of up to 60 GPa (10^2-10^3 times higher than most polymers) [33].

Carbon fibres are similar to carbon nanotubes; however, they have much larger diameters, and are more disordered. Therefore, they do not have the same outstanding mechanical properties, however they still strengthen polymers considerably.

Currently only 20% of carbon fibre is recycled in the UK, with over 35% going to landfill. As well as the environmental implications of this, it also has a large economic effect. If all of this carbon fibre was recovered and resold as recycled carbon fibre, it would be worth up to £13 million [28].

A disadvantage of carbon fibre is its cost. Despite dropping considerably in recent years, the cost of carbon fibre is still high. In 2018 it was estimated to be £20-40 per kg [32]. The high cost coupled with its strength and light weight has seen carbon fibre used primarily within the aviation and elite sports industries.

2.1.3. Plasticisation

Plasticisers are the most common type of plastic additive. They are materials that can be added to polymers to increase their plastic properties. Plastic properties include flexibility, distensibility and processability [34]. Plasticiser molecules are of low molecular weight, and are positioned between the polymer chains, disturbing the Van der Waals forces connecting adjacent chains [35]. This increases the impact resistance of polymers due to increased mobility of the polymer chains. When chains are place under stress, they can slide past each other, still connected by the intermediate plasticiser molecule, which reduces the energy concentration in the impacted area [36]. Internal plasticisers form chemical bonds to the polymer chain, which causes a decrease in glass transition temperature. On the other hand, more common external plasticisers only form secondary bonds with the base material, meaning that these plasticisers can later be extracted from the polymer [35].

Plasticisers can also be classified as primary or secondary. Primary plasticisers are completely soluble in the base material and will not exude from the resultant material [34]. Whereas secondary plasticisers will change the surface properties, such as exuding from the surface or causing surface tackiness. This occurs due to the migration of the plasticiser particles to the surface of the material [35].

Plasticisers can be petroleum based or biobased. Using petroleum-based plasticisers will reduce the degradation properties of the resultant polymer and have a larger environmental impact. Therefore, when manufacturing a biobased, biodegradable polymer it is favourable to select a biobased plasticiser. Many biobased plasticisers are oils which originate from agricultural sources such as trees, fruits, vegetables, and cereals, with the main form of biobased plasticisers using vegetable oils [37]. One form of natural plasticiser is palm oil. Palm oil is becoming increasingly popular as a replacement for the currently toxic di(2-ethylhexyl)phthalate (DEHP) which is commonly used to plasticise poly(vinyl chloride) (PVC) used in food packaging, contact lenses and children's toys [38]. However, in 2017 oil palm plantations occupied 18.7 million hectares of land. The deforestation that occurs to adapt this land into plantations is the primary factor affecting biodiversity in these areas. Palm oil plantations also adversely affects the environment, due to lower offset of carbon emissions as a result of deforestation, and fertilizer/pesticide runoff which impacts water quality [39]. This demonstrates how the environmental, social, and economic impacts of the plasticiser material must be considered when selecting polymer additives.

Compatibility of plasticisers and polymers must be adequate to ensure the plasticiser does not migrate to the surface. Migration can reduce the effects of the plasticiser, and lead to the material becoming more brittle than predicted [40]. The general rule that is accepted is that polymers will be compatible with plasticisers of similar solubility. Quantitatively, products are said to be compatible if the difference in their solubility does not exceed 3.7 J/cm^3. Another important factor for compatibility is polarity, where plasticisers will generally only dissolve in polymers of a similar polarity. Therefore, high polarity polymers will dissolve in water, but they will not mix with hydrocarbons since they are nonpolar [34].

Research into the molecular composition of plasticisers has found that an ideal plasticiser consists of aliphatic chains to induce mobility, an ester group to improve cohesion, and an aromatic ring to improve stability and compatibility. The length of the aliphatic chain must be short enough to ensure that formulation can occur, however if they are too short then they may become too volatile. The plasticisation effect will be reduced if the chains are branched, or if the branches are too close to the polar group due to the obstruction of the primary and secondary bonds [34].

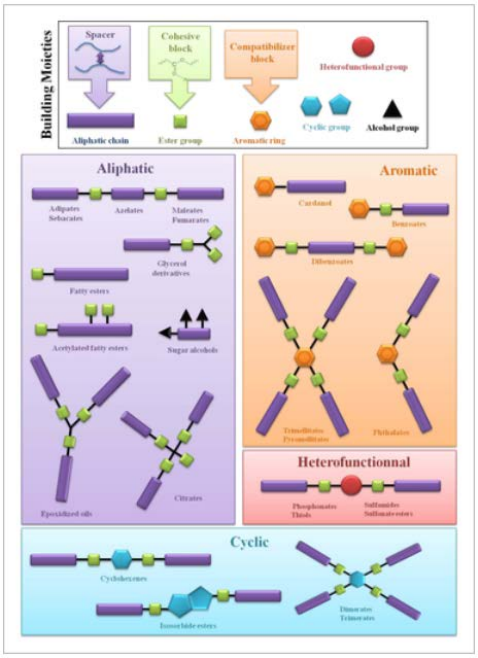

Figure 5. Molecular composition of common plasticisers [36]

2.2. The Plastic Problem

Many plastics are petroleum based, meaning that they are produced through polymerisation of crude oil. Despite the plastic industry only expending 8% of the world's petroleum, it must still be noted that this fossil fuel is a non-renewable resource, which is being consumed at a much faster rate than it is being produced [41]. Petroleum was also used to produce 33% of the energy consumed worldwide in 2019, and is imperative for transportation, therefore its depletion will have detrimental effect [42].

The manufacturing of plastics generates a vast amount of carbon dioxide, (CO_2). In 2018 it was reported that 2.7 million tons of CO_2 was produced in the UK from the production of plastics, this is equivalent to the energy used by 311562 US homes in one year [43]. CO_2 is a greenhouse gas which contributes to global warming [44]. The last decade has seen 9 of the hottest years on record within the UK, which has taken the lives of almost 900 people [3]. As CO_2 levels continue to rise, weather adversity will increase, leading to hotter summers and rising sea levels, as well as increased storms and flooding [3]. It is estimated that each year flooding in

the UK causes £540 million of damage [45]. Therefore, reducing the volume of this gas that is produced is of increasing importance.

In 2018, 359 million tons of plastic was produced globally, over half of which is single use [46] [47]. This raises concern surrounding how plastics are processed after their intended use. Many polymers cannot be recycled due to a number of reasons, including their chemical make-up, their size, colour, or contamination, for example thermosetting polymers cannot be recycled. Some plastics are not recycled due to the economic viability or local infrastructure. In order to be recycled, plastics must be separated into categories, which is time consuming and labour intensive [48]. With each cycle, plastics lose quality, and they are downcycled into products requiring lower mechanical properties, however eventually they will become unsuitable for recycling. For most plastics, this procedure can only be conducted once or twice until the material must be discarded [49].

In 2016, 27.3% of Europe's post-consumer plastic waste was sent to landfill, where they will remain for many years, however this value reduced to 23% the following year, showing that progress is being made in reducing this volume [50]. Figure 6 demonstrates how plastics in landfill undergo four phases:

1. Bacteria within the soil break down the molecular chains within the polymer, consume oxygen and produce CO_2 during respiration.
2. Oxygen is consumed during respiration, bacteria convert compounds into acetic, tatic, and formic acids, and methanol. Acids react with the moisture and cause nutrients to dissolve. This produces nitrogen and phosphorous. This reaction generates hydrogen and CO_2.
3. Bacteria in the soil consume acids and form acetate. Methane producing bacteria consume CO_2 and acetate. This relationship is symbiotic.
4. Concentration of gases remains constant, and decomposition begins. These gases are emitted for around 50 years after the waste is discarded into landfill.

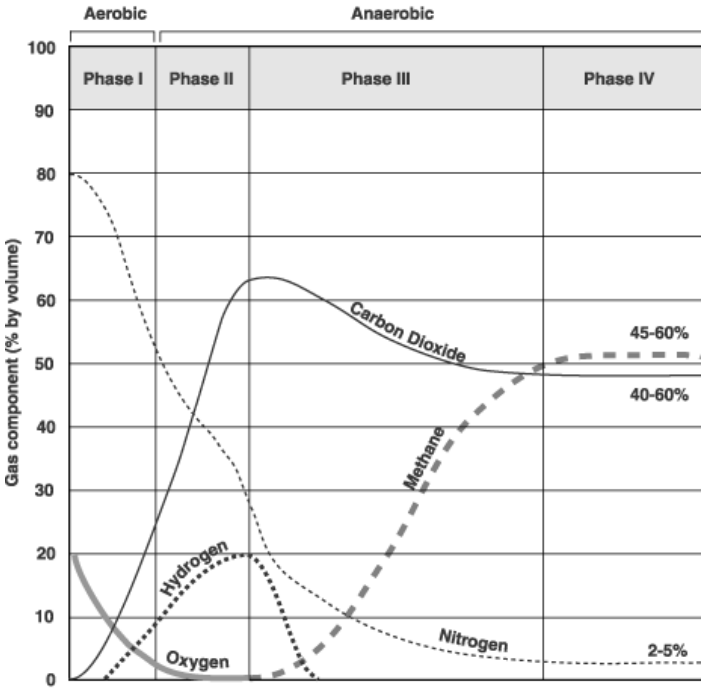

Figure 6. Changes in landfill gas composition across four phases [51]

Another method of polymer disposal is incineration. This method, where the plastics are burned, contributes to global warming, and can release harmful toxins into the surrounding air such as Dioxins, Furans, Mercury, and Polychlorinated Biphenyls [51]. This pollution decreases air quality and increases the risk of respiratory diseases such as asthma. It can also contain carcinogens and increase the risk of heart disease [52]. One benefit of incinerating plastic waste is the energy generated during the process. The heat energy produced during the process is often captured. Plastic is more energy dense than coal, and therefore is an efficient fuel for energy production, which relieves the pressure on fossil fuels as a source of energy production. This process can also use filters to decrease the amount of pollution that is produced. A review shows how incinerating plastic waste for heat recovery is the second-best disposal method, behind recycling separated materials, but ahead of recycling unseparated materials, landfill, and pyrolysis in terms of environmental and resource impact [53].

The mistreatment of plastic waste has resulted in a large accumulation of plastic in the ocean, where 2.41 million tonnes is dumped every year [54]. This vast floating patch spans 1.6 million square kilometres, where 94% of the contents is plastic [55]. This has a detrimental effect on marine life within these areas. Much of the plastic within the ocean has undergone photodegradation (broken down by sunlight) into micro plastics, which contribute to agricultural and marine pollution. Evidence has shown their presence within soil and, through ingestion, within fish consumed by humans [56]. There are, however, some biodegradable petroleum-based polymers, which will decompose in the optimal environment [57]. Examples of this type of polymer are polycaprolactone (PCL) and poly(butylene succinate) (PBS) [58]. This process works when the microorganisms in the environment, such as fungi or bacteria, secrete enzymes such as lipase, proteinase k, and dehydrogenase by hydrolysis. These enzymes degrade the polymer into smaller molecules called oligomers, dimers, and monomers, which can then be mineralized. Mineralisation is the breaking down of the smaller molecules into carbon dioxide, water, and methane [59].

In conclusion plastics generate vast amount of pollution from cradle to grave. In 2010 it was estimated that across England 264,749 years of life were lost as a results of air pollution caused by humans. As well as this, the cost of this pollution is estimated to be £8.5 billion - £18.6 billion per year. This emphasises the need to reduce the pollution generated at any stage in the life cycle of a plastic as much as possible [60].

2.3. Biobased Polymers

An alternative to petroleum-based polymers is biobased polymers. Biobased plastics are currently primarily used in packaging, medicine, and textile applications.

The terms “bioplastic” and “biobased plastic” cannot be used interchangeably. A bioplastic is defined as a plastic which is biobased and/or biodegradable. Biobased materials on the other hand, are manufactured from renewable biomass such as starch, cellulose, and lignin. Therefore, materials can be either biobased or bioplastic, or both. Only 43% of biobased plastics are compostable or biodegradable, highlighting that the assumption that all biobased plastics are biodegradable can have an adverse effect on the movement [61]. EN 13432:2000 defines ultimate biodegradability as “*breakdown of an organic chemical compound by micro-organisms in the presence of oxygen to carbon dioxide, water and mineral salts of any other elements present (mineralization) and new biomass or in the absence of oxygen to carbon*

dioxide, methane, mineral salts and new biomass." The European standard for a packaging material being labelled as compostable states that the packaging must break down under industrial-scale composting conditions within 12 weeks. This must leave no more than 10% of the original material in pieces bigger than 2mm and must do no harm to the soil (EN 13432).

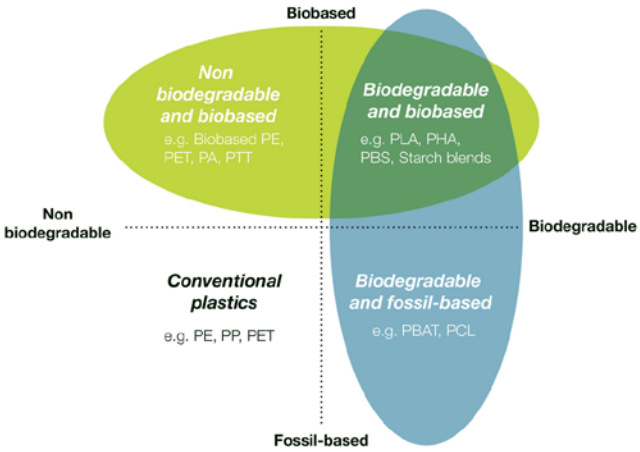

Figure 7. Classification of plastics [62]

The use of biobased materials reduces the dependence on petroleum resources, landfill space, and provides a non-toxic alternative to plastics, which suggests that they are favourable to petroleum-based polymers. However, there is still speculation around their overall sustainability.

Sustainable materials reduce the impact on the environment, as well as occupational and public health over their whole life cycle [62]. Since many are manufactured from plant-based materials, some biobased plastics are carbon neutral. This means that the carbon dioxide that the plants consume during respiration in their lifetime offsets the carbon dioxide that is produced when manufacturing them into a polymer. However, growing crops to produce biobased plastic takes valuable land away from the food production industry. Many plants grown for plastic production are genetically modified. The lack of understanding on their effect on the environment causes concern [63]. There is also concern about the pollution that is caused by the fertilisers used during the growth process, as these can make their way into water

systems causing eutrophication (increased minerals in water leading to excessive algae growth) [64].

Biobased plastics' ability to be composted into CO_2 and H_2O reduces the amount of methane (CH_4) that is released into the atmosphere. Sometimes biobased polymer degradation is facilitated by hydrolysis, oxidation or photodegradation [65]. However, this is reliant on the infrastructure in place to ensure that all biobased plastics are sent to compost sites instead of landfill. In landfill many biobased plastics will release the same emissions as petroleum-based polymers shown in Figure 6.

The main obstacle when trying to replace traditional polymers with biobased polymers is that their mechanical properties are often inferior to petroleum-based polymers [66]. As well as this, they are often less thermally stable and have permeability issues. This is thought to be due to their poor fibre-matrix bonding [67]. The most common biobased plastics used today are PLA, PHAs, starch plastics, cellulose esters, and protein-based plastics [68].

Contamination of biodegradable plastics in recycling streams is also a large issue. In 2018 the UK Parliament rolled out a circular economy system alongside Vegware, where designated collection of their compostable food packaging was implemented. However, the first batch of the waste that was returned to the distributers had to be incinerated due to the high levels of contamination. This is reported to have improved in the following years; however, contamination still remains a problem in many waste streams, and highlights a lack of understanding or compliance among consumers [69].

A recent review of the environmental impact of different polymers found that due to different life cycle assessment techniques it was not possible to conclude that biobased polymers are more 'environmentally friendly'. This is also due to the vast range of polymers, which all have extremely different effects on the environment at different stages of their life cycle, therefore grouping them into bio based and fossil based does not show significant differences. The review also concluded that biobased polymers were superior in terms of climate change and energy use, however they underperformed in eutrophication and acidification (reduces the pH of the ocean). As well as this, within the literature there was extremely varied results for a single polymer type (particularly PLA) under different life cycle assessment methods. This variation was between 200-400%, however it is not known whether this is due to variation in methodology or the processing conditions [64].

2.3.1. Non-Biodegradable Biopolymers

Despite being created from renewable biomass, 57% of all biobased polymer types are non-biodegradable. An example of this is PolyAmide 11 (PA11), which is a semi crystalline polymer produced from castor beans. Another widely used non-biodegradable polymer is bio-PE. It is manufactured using ethanol extracted from various feedstocks such as sugar cane and wheat grain [70].

Although they are non-biodegradable, both of these biobased polymers are widely recyclable, and the carbon dioxide that is offset during the growth of the crop improves the sustainability of these polymers.

2.4. Medical Devices

Within the medical industry, many of the devices used are single use. This is due to the eradication of reprocessing time and contamination problems caused by prions, remaining on the product after decontamination [6]. The medical device directives within the UK “do not explicitly permit re-manufacturing or reprocessing.” [7]

Many fine precision reusable devices will become damaged, or their quality will deplete over time, causing potential failures of instruments or harm to patients - single use instruments decrease this risk considerably [5]. An example of this is the matte black coating on reusable metal ear specula. If the finish becomes scratched or chipped, light from the otoscope can be reflected back toward the outer ear, hindering vision to the centre of the ear. Another factor to consider is multi-part devices. If devices are returned from reprocessing in separate parts, the contamination of the product starts when they are reassembled. Therefore, this product will have a greater bioburden than a single use item which comes readily assembled.

A life cycle assessment on two medical devices (laryngoscope handles and tongue blades) shows that the cost of purchasing single use products is 5-18 times more expensive and produces between 40-50% more greenhouse gases [71]. However, this study assumes that reprocessing will be conducted onsite, whereas within the UK this is often outsourced to third party reprocessing companies. Therefore, time, costs, and emissions from transporting the products to and from the reprocessing plants must be considered.

This transportation also increases the risk of products being damaged or lost, leading to further reprocessing or replacement costs. Many items are reprocessed in bulk, on trays. During the reprocessing procedure the devices can fall from the trays and will not be returned to the

hospital. The cost of replacing these reusable items will be much higher than purchasing single use items. This can also increase patient wait times and cancelled surgeries, since operations cannot be conducted without the correct instruments.

Medical waste is estimated at around 7kg per patient per day, with around 20% being plastic [1]. Therefore, the ability to recycle this waste is imperative. Many single use surgical instruments (SUI) are categorised as clinical waste, and therefore must be treated by specialist companies. If this waste is thought to have come into contact with high or medium risk tissues (outlined in Annex A1 of the Transmissible Spongiform Encephalopathy guidance [72]) then the device must be incinerated. However, if these plastics have only contacted low risk tissues and fluids such as blood and saliva then they can be recycled by a third party. These products must be separated after use, then treated offsite to reduce the risk of cross contamination, before being sent for recycling [73]. There is limited literature surrounding the management of waste within hospitals within the UK, and what proportion of recyclable waste is correctly disposed of.

Waste streams within the NHS categorise waste depending on its risk factors, such as sharps, infectious, clinical, recycling, and municipal. These different categories must be treated differently, and therefore have different costs of disposal. Figure 8 was included within a Freedom of Information report published in 2018, which shows the variation of the costs of waste disposal across different NHS trusts within England in 2015/16 [74]. Further information in this report explains that the higher values of waste removal seen in Figure 8 are only representative of one trust. Generally, the costs are much lower, therefore the median gives a better representation of the costs. This demonstrates that the incorrect disposal of waste within hospitals can have a large financial effect. The report also states that the total cost of waste disposal was £3.3 million. Increasing the amount of waste that can be recycled will reduce this cost considerably [74].

Cost per tonne	Municipal (residual)	Municipal (recycling)	Offensive	Infectious (orange)	Infectious (yellow)
Highest	£2,138	£2,356	£3,625	£5,000	£21,937
Lowest	£0.16	£12.30	£130	£26.30	£32.40
Median	£142	£114	£241	£337	£475

Source: RCN Survey 2017

Figure 8. Range of costs of waste disposal across different NHS England trusts [74]

The NHS Sustainability Annual Report highlights recycling streams being implemented to ensure the correct processing of waste; however, this is primarily focussed on coffee cup disposal rather than medical instruments [4]. The attention to this does, however, suggest that reducing single use plastic in any form is important to the NHS.

Due to the COVID-19 pandemic medical waste has increased considerably, with an increase of 350% and 370% in Catalonia and China respectively [46]. This is likely due to the drastic increase in the use of personal protective equipment (PPE) as well as an increase in single use medical devices.

The NHS have already achieved a 44% carbon reduction in the last six years. In 2018 it was reported by NHS England that by 2050 the NHS aims to reduce its carbon footprint by 80% compared to its 1990 values [60]. However, the NHS Supply Chain website has now been updated to report that the target is to become the first net zero national health system by 2040 [75]. The greatest opportunity and challenge reported as being within its supply chain. Therefore, suppliers acting sustainably, using materials with a low carbon footprint will be viewed favourably by the NHS [3].

Sustainability is now included as a check within the Finance and Commercial Assurance Panel (FCAP). This drives suppliers to increase their sustainability and be more mindful of the life cycle of their products, as this is something that will need to be proven when marketing products to the NHS. They are also developing a Commercial Strategy, which will demand more quantitative data from prospective suppliers about the sustainability of their products [4].

2.5. DTR Medical

DTR Medical manufacture single use surgical instruments, some of which use plastic components. The cervical biopsy punch with rotation (CBR) handle and the ear specula are currently manufactured using plastics, Polycarbonate (PC) and Acrylonitrile Butadiene Styrene (ABS) respectively. Both of these products have a shelf life of 5 years, as this is the maximum allowed shelf life for medical devices due to sterilisation constraints. Another similarity between these devices is that they are both injection moulded. Both polymers are petroleum based and non-biodegradable. Table 1 shows properties of these polymers currently used within the devices.

Table 2. Mechanical properties of current plastics used for the CBR and ear specula manufactured by DTR. The polymer trade name is displayed at the top of the heading row, with the polymer type in parenthesis below.

Property	*UNIT*	*Sorona (PTT)*	*Latilon (PC)*	*MAGNUM (ABS)*
Density	g/cm³	1.44	1.33	1.05
Melt Flow Rate	g/10 min	13		8
Melting Point	ºC	227	280-300	232-249
Stress at Break	MPa	120		35
Strain at Break	%	2.5	3	
Tensile Strength	MPa	120	100	45-48
Young's Modulus	MPa	6500	5500	2340
Flexural Strength	MPa	160		75
Flexural Modulus	MPa	5800		2400
Charpy Impact Strength Notched	kJ/m²	5.5	10	1.9
Charpy Impact Strength Unnotched	kJ/m²	25	40	
Biobased Carbon Content	%	31	0	0
Shelf Life		5 YEARS	5 YEARS	5 YEARS

2.5.1. CBR

The CBR (Figure 9) is a device used to extract tissue from the cervix. The device features a long metal shaft with a jaw at the end. This shaft is secured into the handle currently manufactured using Latilon, PC with 20% glass fibre content, and was previously manufactured using Sorona, containing 15% glass fibre. Sorona is a trade name for DuPont's biobased Polytrimethylene Terephthalate (PTT), which is manufactured using glucose from corn crops. PC is a petroleum-based polymer manufactured from hydrocarbon fuels and Sorona has now been discontinued, therefore there is a need to find another biobased material which delivers suitable mechanical properties.

Figure 9. DTR Medical's CBR

Within this handle there are 3 plastic components which enable the rotation and jaw mechanism, along with a metal spring. When the trigger of the CBR is pulled, the jaw will clamp down and take a biopsy of the patients' tissue. Studies have found that the stiffness of cervical tissue can vary greatly, with the lowest stiffness being in pregnant women at values in the range of 0.013-0.068 bar/mm. Stiffness is higher among non-pregnant women, and increases further in post-menopausal women, to values as high as 0.315 bar/mm [76] [77]. The jaw must clamp down with enough force to overcome this stiffness. If the plastic selected does not have adequate mechanical properties, then the internal plastic components can split, and the jaw will not grip with enough force. This problem does not occur with Latilon, however it does with Sorona, suggesting that properties more similar to Latilon may be preferable. The product DFMEA details how if these lower-level element failures occurred during real life application the failure effects include trauma to the tissue, or loss of parts in the patient. Both of these failure effects will cause trauma to the patient and increase times and cost of operations.

Another failure cause which leads to insufficient bite of the jaw is the trigger being too flexible, and bending when being pulled back, consequently not transferring enough energy to clamp the jaw. Another failure mode of the trigger is it snapping, this occurs when the yield strength of the material is too low to withstand the force. This highlights the strict boundaries that the chosen material must fall within.

2.5.2. Ear Specula

Ear specula enable clear vision of the inner ear by allowing light to be transmitted through the device. There are four variations of the ear specula, which have slightly different shapes. They

have a matte black finish so light does not reflect off the surface. According to the DFMEA, if the lower level element of the ear specula not being matte black occurs, then the product will not absorb adequate light and the failure effect of inadequate user visibility will occur. Despite having a low severity, the product will be unfit for purpose. Therefore, the polymer must be suitable for masterbatch colour mixing or come in a black colour.

Figure 10. DTR Medical's Tumarkin Ear Specula

In contrast to the CBR, the ear specula do not have to withstand high forces, and so the biopolymer selected might not be as similar to the original plastic. The Tumarkin variation of the ear specula, (Figure 10) features a narrow slit from the tip to the base, this should be able to withstand enough stress to force the two edges to meet or overlap without snapping. If the failure mode of the product fracturing occurs, then the failure effect could be fragments entering the inner ear. Inadequate yield stress is the failure cause of this failure mode.

ABS is a thermoplastic polymer which is manufactured, by Magnum, through the polymerization of styrene and acrylonitrile. It is petroleum based, and non-biodegradable, however it is recyclable. Due to the push towards sustainability within the NHS, a biobased alternative to ABS must be found. Plastics Europe reported that in 2015 the 100 year carbon dioxide equivalent (CO_2e) for each kilogram of ABS produced was 3.80 kg, this was reported to have dropped by 18.4% to 3.10 kg in 2018. In 2018, 11.2 million tons of ABS was produced worldwide, therefore the total 100-year CO_2e production was 34.72 million kg [78]. This CO_2e is equivalent to the amount of greenhouse gases produced from running 7551 cars over one year [43]. CO_2e is a measure of the carbon footprint caused by a particular process. This incorporates the mass of CO_2 produced, along with the effects of other greenhouse gases such as methane and nitrous oxide. These gases are converted into equivalent amounts of CO_2 using standard ratios [79].

The tools used to manufacture a range of the ear specula products contain Copper/Beryllium (Cu/Be) cores, which are damaged over time if glass fibre reinforced resin is repeatedly used. Damaged tools can cause defects on the surfaces of products, and eventually break the tool completely. Therefore, it is favourable to select a polymer without such reinforcement, so new tools are not required, and the products maintain a high standard.

2.6. Biobased Alternatives

During this study, an investigation into which biobased polymers can be used to replace the current polymers within the two products of choice will be conducted. With future FMEA and automated software the research required to evaluate these polymers can be performed automatically. A number of more sustainable polymers were investigated and mechanically tested to determine which are suitable for the CBR and the Ear Specula.

2.6.1. CBR

Due to the complex mechanism within the CBR, it is important that the material selected has similar properties to those of Sorona and Latilon. If the stress at break, and flexural and Young's modulus are too low, then the connector pin within the device will snap, and the product will not be able to perform its function. If the strain at break of the material is too high, then the material will deform when the trigger is pulled, insufficient energy will be transmitted through the device, and the jaw will not bite with enough force to extract a sample. Previous testing conducted at DTR Medical has allowed parameters for the mechanical properties to be chosen, in order to narrow down material selection.

Table 3. Boundary Values selected for CRB replacement material

Property	*Unit*	*Minimum Value*	*Maximum Value*
Young's Modulus	MPa	4500	7000
Strength at Break	MPa	80	140
Strain at Break	%	2	4

One material that has similar properties is Polyamide 11 (PA11) with a 30% glass fibre content, manufactured by RTP Company. As well as attractive mechanical properties, this polymer has a biobased carbon content of 68%, meaning that over two thirds of the product is manufactured from a renewable source. PA11 is manufactured from castor beans. These plants offer no

nutritional value to humans and are grown in areas where little else can grow, this is more ethically agreeable than using land which can be used to grow food resources [80].

Another grade of PA11 manufactured by the RTP Company is RTP 203 C. This material has a slightly lower glass fibre content of 20%, which may allow for slightly more ductility and avoid any breakages when the trigger is pulled. This product also has a higher biobased carbon content of 79%.

Rilsan CX1307 is also a glass fibre reinforced PA11 with a shelf life of 2 years. However, at this point this material is only in the experimental stage, and so the datasheet does not have as accurate data and the glass fibre content is not stated.

PA11 is a non-biodegradable polymer, and with the introduction of glass fibres it is no longer widely recycled. However, it is possible for this polymer to be recycled into concrete by specialist companies. Due to the specific and high mechanical properties required it was not possible to find a polymer without a glass fibre content. The reduction in carbon emissions and relief on non-renewable resources still makes this an attractive polymer when finding more sustainable solutions.

Table 4. Mechanical properties of CBR suitable materials.

Property	*Unit*	*Sorona PTT GF15*	*Latilon PC GF20*	*RTP 203 C PA11 GF20*	*RTP 205 C PA11 GF30*	*Rilsan CX1307 PA11 GF?*
Density	g/cm³	1.44	1.33	1.18	1.25	1.7
Melting Point	ºC	227	224-288	224-288	224-288	197
Stress at Break	MPa	120				>180
Strain at Break	%	2.5	3	3-4	2.5-3.5	>2
Tensile Strength	MPa	120	100	83	86.2	
Young's Modulus	MPa	6500	5500	4826	6550	>2000
Flexural Strength	MPa	160		117	124	
Flexural Modulus	MPa	5800		4826	5520	>1800
CIS Notched	kJ/m²	5.5	10			
CIS Unnotched	kJ/m²	25	40			>60
Biobased Carbon Content	%	31	0	79	68	>85

2.7. Ear Specula

In contrast to the CBR, the ear specula devices do not undergo such high impact or force, and therefore the material properties of a suitable biobased material might be further away from that of the current material, ABS. The Tumarkin ear specula must be able to bend without snapping, and the finish must be matte black.

Table 5. Mechanical properties of Ear Specula suitable material.

Property	*Unit*	*Magnum 8391 ABS*	*Switch 25 PLA Hemp fibre*	*Biolite 240 PP Wood fibre*	*Norner PP Cellulose fibre*
Density	g/cm³	1.05	1.26	1.04	1.03
Melt Flow Rate	g/10 min	8		9	9
Melting Point	ºC	232-249		230	166
Stress at Break	MPa	35	30	27	
Strain at Break	%		3.3	13	6.1
Tensile Strength	MPa	45-48		28	40
Young's Modulus	MPa	2340	2300	1680	3300
Flexural Strength	MPa	75			
Flexural Modulus	MPa	2400			
CIS Notched	kJ/m²	1.9	2.95	3.84	3.7
CIS Unnotched	kJ/m²		26	44	
Recyclable		Yes	Yes	Yes	Yes
Biodegradable		No	Yes	No	No

Trifilon is a company that focusses on reducing the impact of their polymers on the environment. They have created a polymer with the brand name Switch. This polymer is a form of starch-based PLA, which uses the starch from sugar cane and beetroot, this polymer is biobased and biodegrades after 39 days at 58ºC and 100% humidity (ISO 20200:2015). The products can be recycled, sent to a industrial composting facility, or returned to Trifilon. The carbon that is offset by the plants that are used to manufacture the polymer during their lifecycle

greatly reduces the impact of this polymer on the environment. This polymer is also available from the supplier in black, which will eradicate the need to add colour later. Their website states that the CO2e is reduced by 75% compared to that of ABS [81].

Another product manufactured by Trifilon is the BioLite brand. These products are manufactured from polypropylene (PP), which is a petroleum-based polymer, however it is reinforced with natural fibres, which in turn uses less plastic within the product and reduces the carbon dioxide equivalent by approximately 60% [82]. This material can also be returned to the suppliers, which can then be used to create their recycled PP, "Revo", therefore reducing the amount of natural resources being used to create new material.

Norner have manufactured an experimental grade of PP filled with 30% cellulose fibre. Using this material as a substitute for ABS will reduce the CO2e by 67.5% based off equation 1. Assuming that the CO2e for ABS and PP is 3.20 [78] and 1.44 [83] respectively, and the CO2e for cellulose fibre is 0 when accounting for the carbon sequestered during its lifetime as a crop.

$$\frac{3.1 - (1.44 * 0.7)}{3.1} \times 100 = 67.5\% \quad (1)$$

2.8. Sterilisation

Bacteria living on the surface of a material is called a bioburden. When present on medical devices this microbiological contamination can cause infection to the patient, therefore, such devices must be sterilised to remove this risk and achieve a SAL of 10^{-6}.

There are many different forms of sterilisation which work to remove a bioburden in different ways, i.e. heat, radiation and gas. The method of sterilisation often depends on the limitations of the materials or the packaging, for example, products using plastics with low melting points might not be suitable for heat sterilisation. The main sterilisation methods used for plastic medical devices are gamma irradiation and ethylene oxide sterilisation.

2.8.1. Ethylene Oxide

In the United States (US), around half of the medical devices used are sterilised using Ethylene Oxide (EO) gas, in a chamber at controlled pressure, temperature and humidity [84]. Low operating temperatures of 22-55ºC mean that EO sterilisation is suitable for medical devices using polymers. This method of sterilisation may also be used when a product is sensitive to

moisture that is present during steam sterilisation [85]. Primarily found in gas form, EO is an alkylating agent, which reacts with amine, hydroxyl, and sulfhydryl groups. During sterilisation, the agent reacts with microorganisms' DNA, forming irreversible cross-links between DNA bases (Figure 11). These cross links prevent the cellular metabolism and cell division processes, leading to cell death, and therefore killing the microbes present on the surface. EO sterilisation procedures can accommodate for large quantities of products at once and can penetrate through the packaging to reach the product inside.

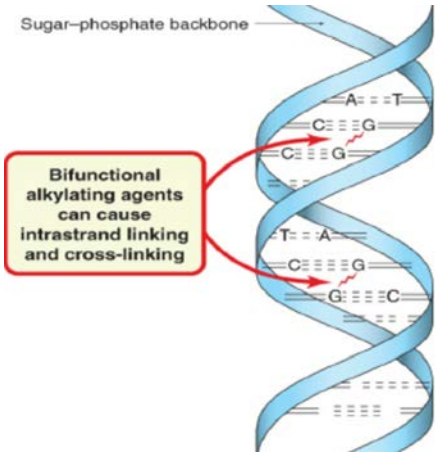

Figure 11. Effect of an alkylating agent on DNA strands [86]

There are three stages to EO sterilisation [8]:

1. Preconditioning:

   This step involves the preparation of the chamber for the sterilisation process. During this stage, the appropriate temperature, pressure, and humidity conditions are established. This is dependent on the material and geometry of the product.

2. Sterilisation:

   In this stage the EO gas enters the chamber, until the desired concentration is reached. The material can absorb the gas, and therefore more gas might need to be pumped into the chamber to maintain the correct concentration. The lower the concentration of EO, the longer the sterilisation process will take. Generally, sterilisation takes around 2.5 hours.

3. Aeration:

   This stage ensures that any EO gas that has been absorbed by the product evaporates back into the surrounding air. For this purpose, filtered air at 30-50ºC is circulated over the products. This can take around 48 hours and requires special ventilation systems to be implemented and checked thoroughly, due to the risk of this gas if inhaled.

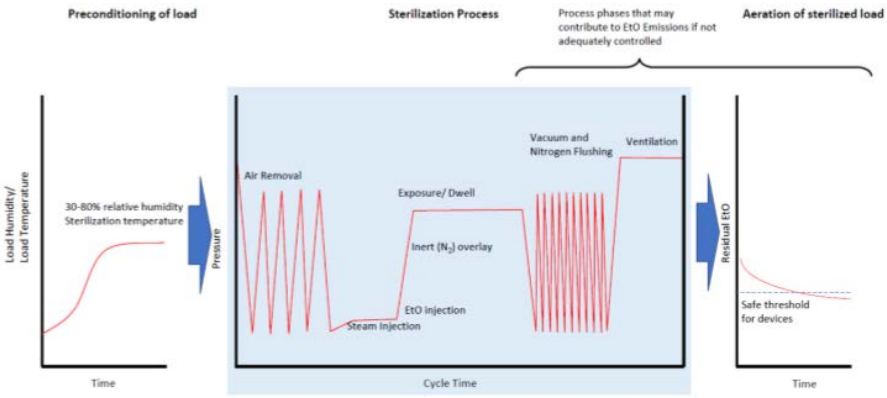

Figure 12. Overview of the Ethylene Oxide sterilisation cycle [84]

Long term exposure to excess levels of EO gas can cause health defects such as eye, skin, nose, throat and lung irritation, as well as increasing the risk of some cancers. An assessment must be conducted to ensure that the material compatibility and biocompatibility will not be affected by the sterilisation method. Therefore, ISO 10993-7 specifies the allowable level for EO residuals that can remain on the surface of a product after sterilisation, and still be considered to be biocompatible [84].

Ethylene oxide sterilisation is compatible with most polymers and will not cause any degradation to the polymer. Sometimes the polymer's geometry and absorptivity impact the amount of toxic residue that is left on the surface of the polymer, but this can be overcome by altering a number of the sterilization conditions such as humidity, EO gas concentration, temperature and aeration [87]. Another method of reducing this is to package the product in a breathable material such as Tyvek, to allow the gas to pass through [85].

ABS, PP, and PA are all reported to be compatible with ethylene oxide sterilisation. However, this method of sterilisation may have a long-term effect on the tensile modulus of PP [88]. EO gas is incompatible with PVoH, PLA and PGLA, due to degradation caused by moisture.

Therefore, it is expected that Trifilon Switch 25 will degrade. EO also poses risks such as high flammability and carcinogenic potential, however these risks can be minimised by adhering to strict regulations [85].

No other literature is available that detail the effects of ethylene oxide sterilisation on the plastics being investigated. Most literature surrounding ethylene oxide sterilisation discusses its safety due to the toxic residue left.

2.8.2. Gamma Irradiation

Gamma irradiation is the emission of high energy photons from the nucleus of a Cobalt-60 atom, through the surface of a material. Non-radioactive Cobalt-60 is a naturally occurring element, however radioactive Cobalt-60 is a synthetically produced atom with a half-life of 5.27 years [89]. This is the length of time required for half of an isotope's radioactive material to decay. The nucleus of Cobalt-60 will spontaneously release the extra energy that is causing it to be unstable, this is in the form of radioactive particles (alpha and beta radiation) or waves (gamma radiation) [90].

This form of sterilisation affects the microbes' DNA by changing the chemical structure, breaking the sugar-phosphate backbone, or breaking the bonds between the bases, leading to cell death [91]. Gamma irradiation can penetrate the products packaging, eradicating the need for breathable packaging, and thus improving the sterility. There is also no requirement to maintain specific temperature, humidity and pressure conditions, and a vacuum is not needed. This method can take minutes or hours to complete depending on the dose administered. Gamma radiation is measured in Gray's (Gy), where one Gy is equivalent to one joule of energy deposited into one kilogram of a material [92]. The reference dose is 25kGy, which guarantees a SAL of 10^{-6}.

One problem with gamma irradiation is its effect on many biobased polymers. Irradiation tends to change the molecular composition of these polymers, as well as altering the mechanical properties. Research suggests that gamma irradiation leads to an increase in crystallinity, which in turn causes an increase in tensile strength but a lower elongation at break and having no effect on the young's modulus, it can also cause a yellow discolouration to occur on the polymer [93]. If a polymer has been blended or plasticised, then it may not follow these trends. Although it is not favourable for the material properties to change during sterilisation, full knowledge of this process could aid in achieving the desired characteristics of a product.

Changes in the mechanical properties of polymers post irradiation are thought to be due to cross linking and chain scission which take place within the polymer. Crosslinking occurs due to the formation of highly reactive, uncharged molecules called free radicals, which react with the polymer to create longer chains of a high molecular weight [94]. These molecules are largely unstable and undergo chain scission, whereby the longer chains break down into smaller polymer chains [95]. This occurs primarily in amorphous regions, due to the weaker bonds in these regions. These shorter chains are more mobile, leading to a decrease in T_g. Shorter chains are also less subject to entanglement and can align more easily into crystalline regions. This greater crystallinity increases the brittleness of the material, due to the amorphous regions decreasing in size [96] [97].

The creation of active radical sites during irradiation can be used to the advantage of the material manufacturer, during radiation grafting. As the free radicals are formed, another monomer is introduced, which bonds to the active sites to create a new polymer [98].

Literature discussing the effect of these methods on polymer properties is limited for some of the polymers selected to be tested.

2.8.2.4. Polypropylene (PP)

A review in 1987 investigated the reported half value doses of gamma radiation vs the dose rate of the irradiation for a range of studies. The caption of this figure states that only the studies labelled ∇ and ◇ used a material of a similar width to the test samples that will be used in this study (Figure 13). The half value dose of gamma for the elongation for these two studies was 100 kGy and approximately 50 kGy, respectively [99].

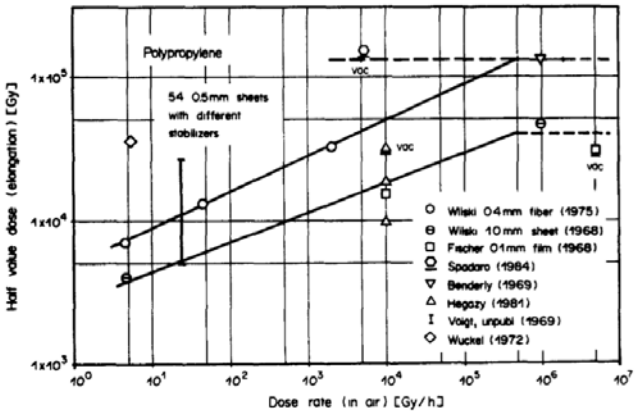

Fig. 12. Polypropylene. ⊖ Hostalen PP 1 mm sheet.[50] □ 0.1 mm film, biaxially drawn, made of Hostalen PPN 1075.[51] I Hostalen PP sheets 0.5 mm thick, with 54 different stabilizer systems in "normal" concentration.[52] ▽ Tenite 4221 injection molded sheet, 3 mm thick.[53] ◇ Daplen rod 4 mm thick.[54] ○ Fibers of 0.4 mm diameter of Hostalen PP.[55] △ Sheets 0.5 mm thick without any stabilizer.[56] ○ Sheets 0.5 mm thick of Moplen D 60 P [57]

Figure 13. Half value doses of elongation vs dose rate of gamma irradiation of polypropylene [99].

The study labelled ∇ shows that polypropylene Tenite 422's tensile strength decreased from 4800 psi to 4100 psi after 25 kGy of gamma radiation. The elongation % of this polymer fell from around 60% to around 20% at this dose. It is suggested that this is due to the crosslinking within the polymer [100].

Another test investigated the effect of melt flow index and radiation dose of PP mixed with wood fibres on the mechanical properties. It found that the flexural (Figure 14) and tensile (Figure 15) strength increases slightly from 54.5 to 55 MPa and 25.5 to 26 MPa respectively, up to 50 kGy, but then decreases slightly at 75 kGy. This study also shows that polymers with a higher melt flow index will have higher mechanical properties. The tensile test used in this study used a dumbbell shape sample of 165 x 19/10 x 3 mm, and a loading rate of 5mm/min. For the flexural test, rectangular samples of 5 x 12 x 100 mm were used. The study suggests that ionic, radical, and peroxide groups are formed by the radiation in the presence of oxygen. The peroxide group reaction causes chain scission which breaks the molecules down into smaller parts. The reactions involving radicals is said to cause the cellulose chain to break down. The free radicals can be created when the irradiation breaks some of the carbon-carbon bonds. The cross linking that occurs between two or more adjacent molecules improves the mechanical properties by creating a larger molecule. [101]

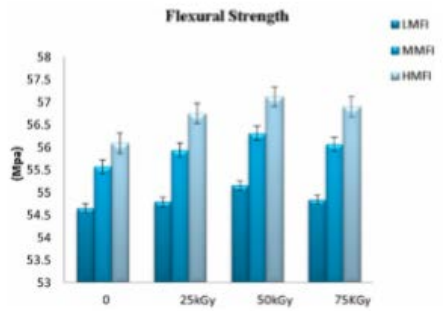

Figure 14 - Flexural strength of samples of different MFIs after doses of gamma radiation. [101]

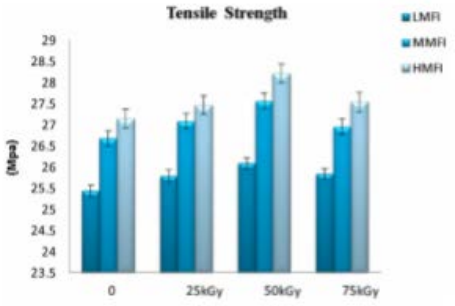

Figure 15 - Tensile strength of samples of different MFIs after doses of gamma radiation. [101]

Another test shows that after 25 kGy the Young's modulus approximately doubled, from around 290 to 580 MPa and the elongation at break decreased from around 25% to 15%, as seen in Figure 16. Figure 17, taken from this study, shows that a PP/HDPE blend that is reinforced with wood flour is much more stable under sterilization, with PP blended high-density polyethylene showing a decrease in tensile strength of around 5MPa up to 25 kGy whilst the same polymer blended with wood increased by around 1 MPa [102]. The tensile strength for PP increased by around 16% after irradiation of 25 kGy. The tensile test used a rate of 25 mm/min, and the mean value from 10 samples was calculated. This test produced a variability of <10%. Again, this is reported to be due to a combination of chain scission and cross linking.

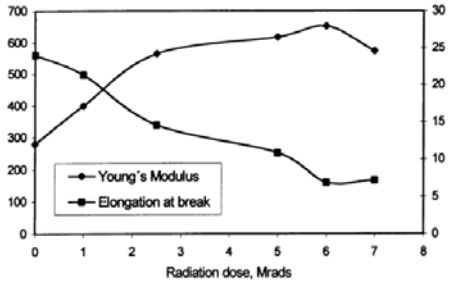

Figure 16. The effect of gamma radiation on Young's Modulus (MPa) and elongation at break (%) of PP. [102]

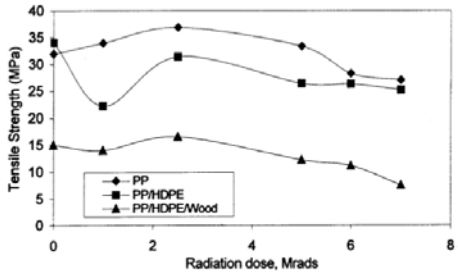

Figure 17. The effect of gamma radiation on Tensile Strength (MPa) of different PP blends. [102]

As shown in Figure 18, a test on a series of PP homopolymers and copolymers saw a very small increase in tensile strength of less than 2%, from approximately 5700 psi to 5800 psi (39.30 MPa to 39.9 MPa) after exposure to 28.1-38.4 kGy of gamma radiation. They also showed a decrease of up to 48.6% in the elongation at break values, from around 37% to 18%. The flexural modulus of the different PP polymers increased slightly up to values of 6%, however exact values are hard to extrapolate from this graph, it is estimated that the flexural modulus rose from around 260000 to 275000 psi (1792.63 to 1896.05 MPa). This report did not provide information about the samples, such as quantity, shape, or size, nor did it explain what test methods were used. [103]

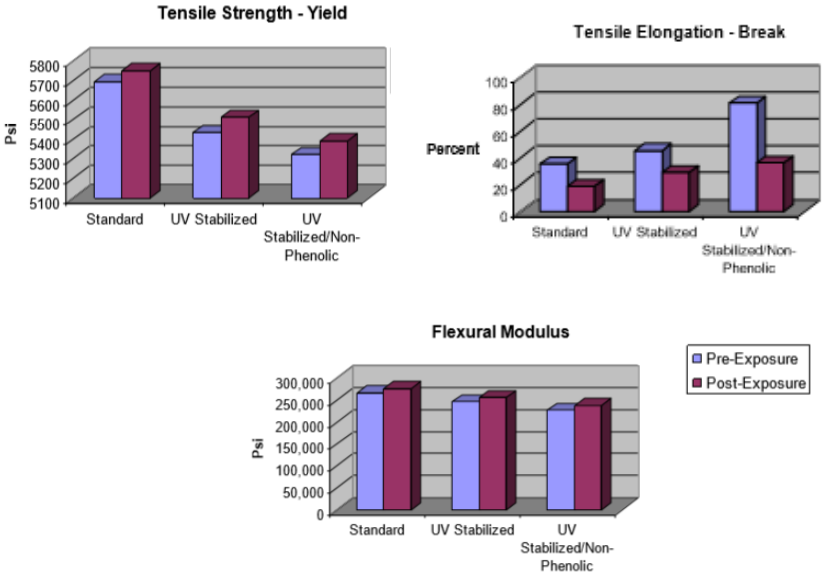

Figure 18 - Results presented in a study comparing the Tensile Strength (Psi), Tensile Elongation (%), and Flexural Modulus (Psi) of PP after different stabilization conditions. The purple bars show the property values before 28.1-38.4kGy of gamma radiation and pink bars are after. [103]

The elongation at break of isotactic polypropylene (iPP) decreased by 87% from approximately 450mm at 0KGy to around 60mm at 21.78KGy. There was also a decrease in tensile stress from 25 MPa to just under 10 MPa (1% decrease). This test used a load rate of 10 mm/min on samples that were only 0.8mm thick, and therefore the results may not be comparable [104].

A test on PP syringes that are mixed with 2% LDPE are sterilised under 30kGy, load at break decreased by 23-62% depending on the diameter of the syringe. The elongation at break decreased by 30-69% as well. At 30kGy the melting temperature decreased by 1.5ºC, but this was statistically insignificant. The crystallinity increased by between 10.81-11.90% depending on the diameter of the syringe. Ten tensile tests for each sample were completed, at a load rate of 100 mm/min [105].

Table 6- Load at break of PP after increasing doses of gamma irradiation under vacuum. [105]

Samples	*Load at break (N)*	
	Gamma radiation	Electron-beam radiation
PP syringe 10 ml/0 kGy	0.584±0.041	0.584±0.041

PP syringe 10 ml/30 kGy	0.350±0.032	0.372±0.033
PP syringe 10 ml/60 kGy	0.140±0.011	0.220±0.022
PP syringe 10 ml/120 kGy	0.090±0.010	0.128±0.023
PP syringe 5 ml/0 kGy	0.352±0.082	0.352±0.082
PP syringe 5 ml/30 kGy	0.150±0.060	0.205±0.071
PP syringe 5 ml/60 kGy	0.110±0.012	0.123±0.023
PP syringe 5 ml/120 kGy	0.080±0.060	0.080±0.090
PP syringe 2.5 ml/0 kGy	0.238±0.010	0.238±0.010
PP syringe 2.5 ml/30 kGy	0.190±0.012	0.234±0.011
PP syringe 2.5 ml/60 kGy	0.180±0.022	0.202±0.021
PP syringe 2.5 ml/120 kGy	0.140±0.010	0.137±0.003

Table 7- The effect of gamma irradiation of thermal properties of PP syringes under vacuum [105]

Samples	T_{melt} *(°C)*	ΔH_{melt} *(J/g)*	*%Variation in degree of crystallinity*
PP syringe 10 ml/0 kGy	1.51.5±0.1	-70.3±9.0	0
PP syringe 10 ml/30 kGy	150.2±0.5	-62.7±7.4	10.81
PP syringe 10 ml/60 kGy	149.5±0.8	-60.7±8.1	13.66
PP syringe 10 ml/120 kGy	148.5±0.2	-60.4±10.3	14.08
PP syringe 5 ml/0 kGy	151.8±0.1	-71.0±3.4	0
PP syringe 5 ml/30 kGy	149.4±0.9	-63.8±6.7	10.14
PP syringe 5 ml/60 kGy	147.7±0.4	-61.6±5.8	13.24
PP syringe 5 ml/120 kGy	145.7±0.5	-60.9±9.7	14.23
PP syringe 2.5 ml/0 kGy	151.8±0.1	-70.6±11.9	0
PP syringe 2.5 ml/30 kGy	149.7±0.2	-62.2±10.2	11.90
PP syringe 2.5 ml/60 kGy	146.8±0.8	-61.8±3.8	12.46
PP syringe 2.5 ml/120 kGy	146.9±0.7	-60.7±14.6	14.02

The tensile strength of a wood fibre reinforced polypropylene increased by around 0.5 MPa after irradiation doses of up to 30kGy but decreased after that. This was tested with load rates of 12.5 mm/min for tensile and 1.35 mm/min for flexural tests. The bending strength also follows the same trend. The paper concludes that the tensile and bending strength decrease

drastically, however this is not true for lower radiation doses of up to 30kGy. This study does use films; however, and therefore the results may not be repeatable with thicker samples [106].

Another test was completed on a range of PP composites, which all had varying starting values for each property. PP syringes elongation at break decrease between 9-25% after 33kGy. While the strength at break decreases by 7-17%. These samples were 2 mm thick and tested at a load rate of 200 mm/min using a load cell with a 907 kg capacity. The mean of five test specimens was reported [107].

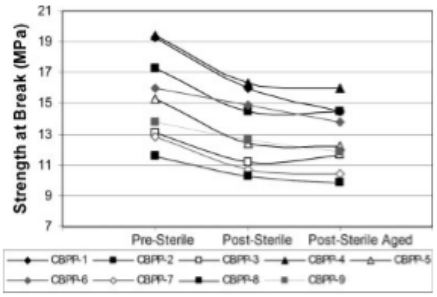

Figure 19. Strength at break (MPa) of PP-based composites before and after gamma sterilisation and aging. [107]

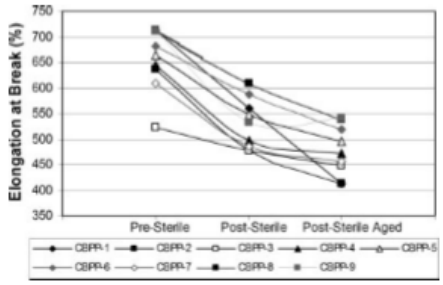

Figure 20 - Elongation at break (%) of PP-based composites before and after gamma sterilisation and aging. [107]

At a dose of 30kGy the tensile yield stress and flexural modulus remained constant [108].

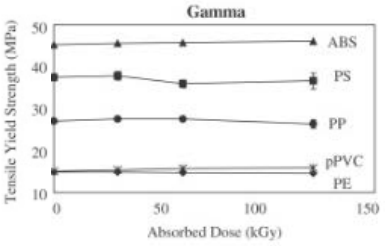

Figure 21 - Tensile yield strength (MPa) of a range of polymers 8 weeks after gamma irradiation. [108]

In summary, it was found that after gamma irradiation the tensile strength of PP saw a maximum increase of 16%, whereas the minimum increase was no significant change (Figure 22). The tensile strength saw a mean increase of 4.4%, although these tests were completed at different dosages of gamma irradiation and on different shaped samples to the ISO527 standards. The elongation at break decreased in each reported case, to a maximum extent of 87% and a minimum of 17%, with a mean decrease of 48.52%, however as with the tensile strength, the testing and irradiation parameters were not consistent. Further conclusions from the literature include the increase of the Young's modulus by 100%, as well as crystallinity increasing by approximately 11% in one study and 2.7% in another. The melting temperature decreased almost 5% from 165.4-157.5 ºC in one study, and 1.97% from 166.45ºC to 157.75ºC in another. Figures 22 and 23 were created to depict how the same polymer can react to different magnitudes, therefore making prediction of exact values difficult.

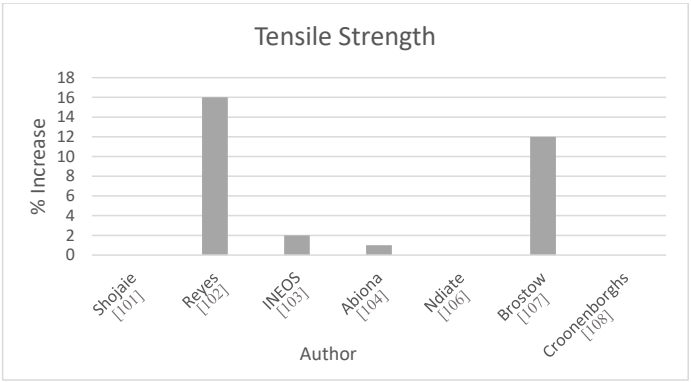

Figure 22 - The increase in tensile strength from the literature above, excluding experiments that used films. Where a range was reported, the midpoint is calculated and plotted.

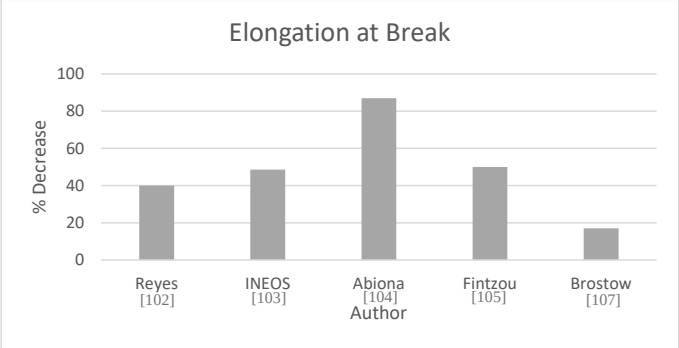

Figure 23 - The decrease in tensile strength from the literature above, excluding experiments that used films. Where a range was reported, the midpoint is calculated and plotted.

It would be reasonable to predict that the Trifilon Biolite 3 and 230 will follow the same trends, i.e. increase in tensile strength and decrease extension at break. However, contrary to the materials discussed in the literature, the BioLite materials are reinforced with natural fibres, which may obstruct any cross linking. This may cause a decrease in tensile strength since chain scission can still take place.

2.8.2.5. Polyamide 11

One test saw a tensile strength increase of <1 MPa from approximately 55.2 MPa to 56MPa after 33kGy of beta radiation, whilst the Young's modulus increases 4.9% to around 70 MPa after this dose (initially 1420 MPa rising to 1490 MPa). This study evaluated the samples at ambient temperature (23ºC) and at 80ºC. The percentage change in tensile strength recorded at 80ºC after the 33kGy dose was found to be 2.6% higher (104.2 %) compared with the same test at ambient temperature (101.5 % increase). The tensile test was conducted at a rate of 50 mm/min. [108]

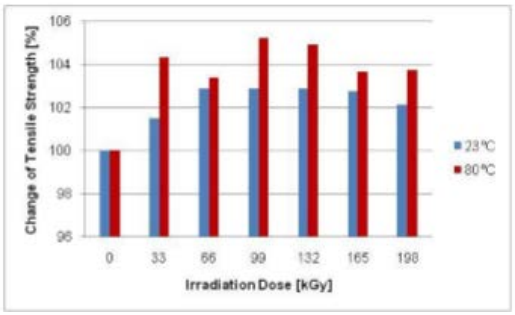

Figure 24 - Change in Tensile strength (%) of PA11 after beta irradiation at different temperatures. [108]

The thermomechanical properties were altered significantly by the 33kGy dose, with an increase in the melting temperature of 130ºC (initially 200ºC). This is reported to be due to cross linking creating longer, more flexible chains [109].

Results are expected to follow similar trends but may not be completely comparable due to the different radiation type (beta not gamma). The amount of energy absorbed by the material will be the same as from gamma radiation of 33kGy, however gamma irradiation penetrates much deeper into the material, so this may affect the material to a different extent. A study on how the effects of bets and gamma irradiation differ was conducted on electrospun poly-(ε-caprolactone) (PCL) fibre mats. Figure 25 shows that gamma and beta radiation affect the polymer in the same way, but to different degrees. The aligned unirradiated mesh has a tensile stress of 6 N/mm^2, the aligned 25 kGy gamma and beta irradiated mesh have a tensile stress of 6.9 N/mm^2 and 6.5 N/mm^2 respectively. The unaligned unsterilized mesh has a tensile stress of 5 N/mm^2, whilst the unaligned 33 kGy gamma and beta irradiated mesh has a tensile stress of 3.2 N/mm^2 and 3.0 N/mm^2 respectively [110].

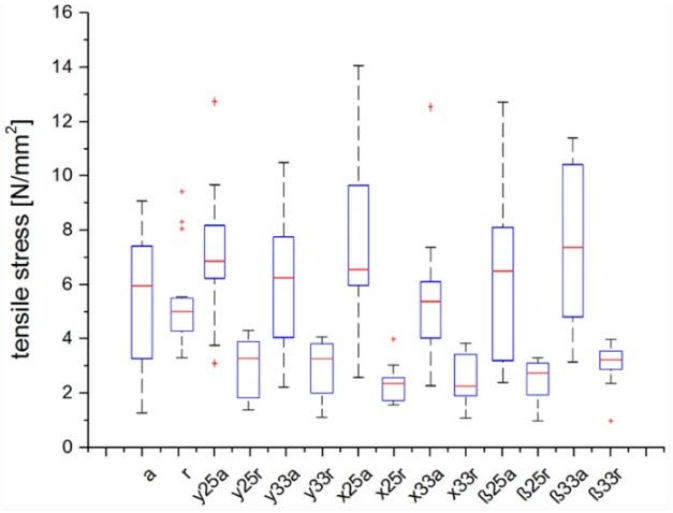

Figure 25 - Tensile stress for PCL scaffolds. a = aligned, r = unaligned, y = gamma radiation, x = x-ray radiation, ß = beta radiation. [110]

No studies were found on the effect of gamma irradiation on the mechanical and thermal properties of polyamide 11.

2.8.2.6. Starch based polymer

A starch-based polymer blended with locust bean gum, polyvinyl alcohol, sucrose, and glycerol was created. The polymer was formed into films and subjected to a maximum of 24kGy of gamma irradiation. The tensile strength decreased by around 6.3%, from 10.04 MPa to 9.41 MPa, whilst the elongation at break decreased by more than 50%, from 53.72 % to 26 %. The testing speed was set to 50 mm/min. This test was completed on film samples so the results may not be repeatable [111].

A starch-based polymer blended with PVoH saw a 12.3% decrease in tensile strength after an irradiation dose of 5kGy, from around 7.3 MPa to 6.5 MPa [112]. This is only an approximation as the data in Figure 26 is hard to interpret, as the data points are all very close together. Whilst the elongation at break decreased by around 12%, from around 89% to 78%. Again, this was performed on films, so the results may not be transferrable to other sample types as different test methods are used and often results are heavily affected by the thickness of the specimen.

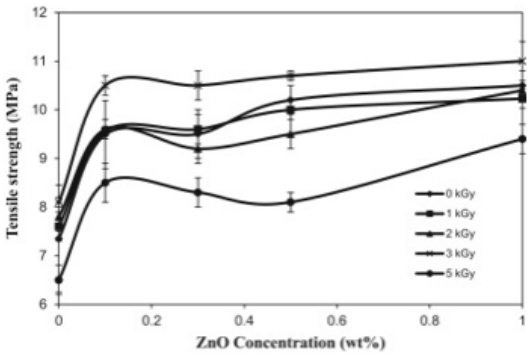

Figure 26 - The effect of gamma irradiation and Zinc Oxide concentration on the tensile strength (MPa) of starch-based films. [112]

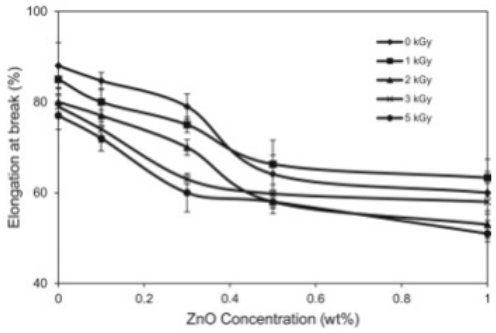

Figure 27 - The effect of gamma irradiation and Zinc Oxide concentration on the elongation at break (%) of starch-based films. [112]

A study on the effect of 25kGy gamma irradiation on extruded potato starch samples showed a 24.76% decrease in elongation at break from 206% to 155%. The tensile stress at break also decreased from 7.1 MPa to 6.4 MPa (-9.86%). The study suggests that this is due to the depolymerisation of the starch molecules, causing fragmentation of the chains and therefore a decrease in mechanical performance [113].

2.8.2.7. ABS

A study shown in Figure 12 took the mean of five identical test samples and subjected them to a dose of gamma radiation of 120 kGy. The test will not exceed 30 kGy, therefore the study

will be evaluated up to this dose. After the dose of 30kGy the tensile yield stress and flexural modulus remained constant [108].

Another study irradiated the ABS specimen to 15 kGy. In this study a gauge length of 20 mm and a load rate of 5 mm/min for tensile tests and 1.3 mm/min for flexural tests. The experiment tested six irradiated solid samples and reported that the results were in "excellent agreement" within the uncertainties. After gamma irradiation the ultimate strength increased by 3.5%, and the Young's modulus increased by 9%. The maximum elongation percentage increased by 6.9%. The flexural strength and flexural modulus increased by 14.3% and 23.5% respectively. While the flexural strain percentage decreased by 0.8%. Despite being statistically significant, the report expressed how these changes in mechanical properties are negligible from an engineering viewpoint. The study states that in irradiated samples cross-linking is dominant [114].

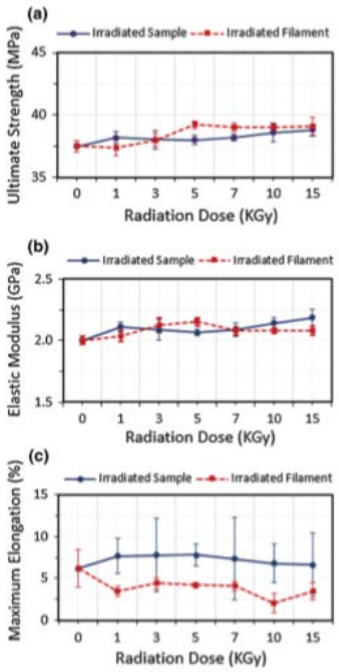

Figure 28 - The effect of varying radiation dose on the mechanical properties of ABS samples and filament. *[114]*

Another study on 3D printed samples investigates the effect of gamma irradiation on ABS, however this report shows data up to 10kGy, then jumps to 1000kGy. There was no statistical difference in the mechanical properties up at 10kGy, but a large differences at 1000kGy, however no more detail about what happens between these values can be inferred due to the large gap in data, as shown in *Figure 29* [115]. The study tested six samples at each dose with a gauge length of 20 mm and a displacement of 5 mm/min for tensile and 1.2 mm/min for flexural testing.

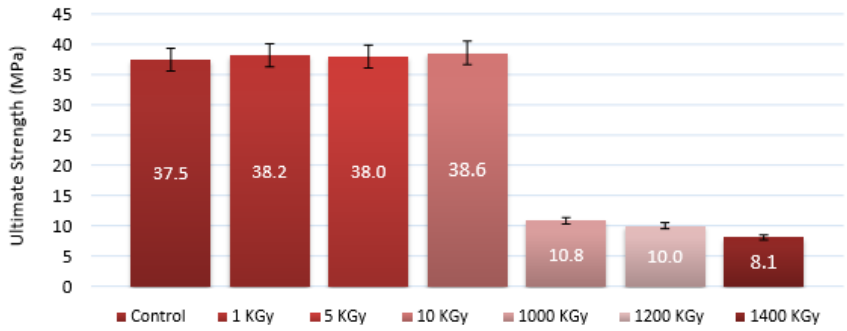

Figure 29 - Ultimate tensile strength after increasing radiation doses of 3D printed samples. [115]

The effect of gamma irradiation on crystallinity was only investigated in one of the studies found for the test polymers. However, there is further literature that discusses the effect of crystallinity on other polymers. In a study on the effects of gamma irradiation on poly(vinylidene fluoride) it was found that a 50kGy dose caused a 6.25% increase in crystallinity, from 40% to 42.25%. This is due to simultaneous cross linking and chain scission. Chain scission breaks the molecular bonds between adjacent chains, which reduces the entanglement of the molecule and relieves the intramolecular stress which is present in the amorphous region. This causes an increase in the mobility of the molecules within the polymer chain. The increased mobility allows the chains to cross-link into a crystalline region, where they are thermodynamically stable [116].

This study also discusses the widely accepted relationship that an increase in crystallinity causes an increase in tensile strength. However, the findings of this study did not support this claim, as the tensile strength encountered no significant change as the crystallinity increased. This is thought that the increase in tensile strength caused by the crosslinking is counteracted

by the decrease in tensile strength caused by the chain scission, and therefore no change is seen. This could enable an insight into whether cross-linking or chain scission is dominant in each polymer [116].

In conclusion, more established polymers such as PP and ABS have a range of literature detailing their reaction to sterilisation. The literature suggests that the tensile strength and elongation at break of PP are likely to increase and decrease respectively after gamma irradiation, however the extent to which is unclear due to a large range of percentage changes within the literature results. ABS is expected to have good sterilisation resistance, and not degrade or improve considerably with either sterilisation method. The extensive literature surrounding these polymers means that confidence will be gained in the methodology if the results follow similar trends.

Starch based PLA is expected to decrease in tensile strength and elongation at break due to the results of studies on films and blended starch-based polymers. There is no current literature on the sterilisation reaction of thermoplastic starch-based PLA or PA11, and so these results will be valuable to the field.

Chapter 3 - Methodology

This chapter discusses how the polymers discovered above were selected from a larger selection of biopolymers. It also details how the test methods were selected and executed. Test methods were selected based on the relevant ISO standards to ensure that the results produced are accurate and repeatable.

3.1. Material Selection

The material selection was first performed manually. Initially the function and design of both products was analysed, along with any forces or impacts that the material of each one would need to withstand. Within the current system this information is not captured quantitatively within the FMEA forms, whereas within the new guidelines, any forces, or environmental conditions that the material might need to withstand will be included.

The plastic selected for the CBR handle must be able to withstand a high impact, so the force of the trigger being pulled does not split the internal components, which has been experienced previously. The material must not be too flexible, otherwise the trigger will bend when pulled backwards instead of converting the force to the jaw to clamp down on the tissue.

Research into biobased materials was conducted. This research started off with internet searches to find the names of many biobased polymers, feedstock for each, their biodegradability capabilities, and current uses. Using this information, journal databases were then searched to find more reliable, scientific research on the positive and negative aspects of each material.

For the Cervical Biopsy Punch with Rotation there is one previously used material, and one currently used material with known mechanical properties. As well as this, material trials on other materials had currently been conducted, so these results were also considered when selecting the constraints of the new biobased material. The mechanical properties were used as an input into MatWeb, an online materials directory, with a slight buffer either side. The material boundaries that were used were Young's Modulus of 5-8 GPa, Density of 1.2-1.6 g/cm3, and a Strain at Break of 2-4%. As well as mechanical properties, the director allows other properties to be selected such as biopolymers. The search was completed both with and

without the biopolymers filter to ensure that none of the materials that has previously been identified in the literature were missed from this filter.

As well as MatWeb, polymer distributers' websites were also a valuable place to find newer polymers which are not yet as widely known. As many biobased polymers are new to the market, it is important not to rely on just one online materials database, as this has more established materials.

The suggested materials were then investigated in further detail. The other mechanical properties, biocompatibility details and feedstock origin were found. All of this information was entered into a spreadsheet. The manufacturers' website was also searched to identify any materials that were excluded from the database, which might be suitable.

After this, the company was contacted directly, either through an information request on their website, or through email, for price information, shipping costs, lead times and sample information, i.e. size, shape, cost of samples.

The same process was followed when selecting materials for the Ear Specula, however these devices do not need as stringent mechanical properties. These materials must be able to flex slightly and have a smooth finish. The material used for the current product was used as a guideline, however there was a much wider buffer for which materials were selected to be tested.

In total, eighteen materials were selected from the initial mechanical properties search to be looked at in further detail. Of these, eight materials were selected for the CBR and six for the ear specula. The remaining four materials were disregarded due to no response from the supplier when inquiring about the materials. Two of the materials selected for the CBR were no longer being manufactured (PA6.10 GF15 and PA6.10 GF30), and so they were disregarded. One of the remaining materials only had a six-month shelf life (PLA 30%GF), which is not plausible for the medical device industry. A sample plaque of one material (PLA 30%GF) was received, and on first inspection the material was clearly too brittle, as it snapped under minimal force, so this material was disregarded too. There were two materials from one supplier that were selected (PA11 GF20, PA11 GF30), one of which was recommended not to select by the supplier as it could not be guaranteed to be safe for medical devices, however a similar alternative with the same base polymer and glass fibre content was suggested. This left three

materials to test for the CBR (PA11 GF20, PA11 GF30, PA11 with unknown glass fibre content).

Of the six materials found for the ear specula, one was disregarded due to lack of response from the supplier (bio-PC). Two of the materials had been discontinued by the supplier (HDPE Cellulose Fibre and Cellulose Acetate), and so they were also not included. Three of the material suppliers (2x PLA, bio-HDPE) responded to initial enquiries, but then did not provide any further information when samples were requested. This left no materials from the initial material database search. Therefore, a range of UK based polymer distributers' websites were investigated, from which one suitable material was found (PLA with natural fibre). This company then recommended two further materials of theirs to investigate (2x PP with natural fibre). Three other materials (3x PVoH) were recommended for testing by a supplier, however due to a lack of information about this material and sparse data sheets it was decided not to test these materials at this time. However, this material still remains as one of interest for future research.

3.2. Materials

The materials outlined in *Table 8* were selected for testing based on their pre sterilisation mechanical properties as well as their sustainability.

Table 8. CBR Test materials

Sample Number	*Polymer Name*	*Polymer Number*	*Polymer Type*	*Reinforcement Fibre*	*Manufacturer*
1	RTP	205 C	PA11	30% Glass	RTP Company
2	RTP	203 C	PA11	20% Glass	RTP Company
3	Latilon	28D G/20 FG	PC	20% Glass	Lati
4	Rilsan	CX1307	PA11	Glass	Arkema

Table 9. Ear Specula Test materials

Sample Number	*Polymer Name*	*Polymer Number*	*Polymer Type*	*Reinforcement Fibre*	*Manufacturer*
5	BioLite	240	PP	Hemp	Trifilon
6	Magnum	8391 MED	ABS	N/A	Trinseo

7	Switch	25	Starch based	Hemp	Trifilon
8	BioLite	3	PP	Wood Cellulose	Trifilon
9	Norner	Experimental	PP	30% Cellulose	Norner

Polymers 1-2 were supplied in tensile test specimen form by the RTP Company. Polymers 5, 7, and 8 were supplied in pellet form from Trifilon and injection moulded by St Davids Assemblies into tensile test specimens, (Figure 30). Materials 3 and 4 were supplied in tensile test sample form by St Davids Assemblies via their suppliers in the form of Figure 30 test samples. Material 6 was purchased in moulded form directly from St Davids Assemblies who moulded the pellets that they received from their suppliers. Material 9 was supplied in the same test sample form by the material manufacturer Norner. This test sample was chosen as it is type 1A in ISO 527-1.

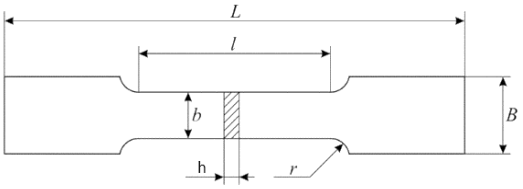

Figure 30. Tensile test sample where L = 150 ± 2, l = 80 ± 2, B = 20 ± 0.2, b = 10 ± 0.2, h = 4 ± 0.2, r = 20 ± 0.2 mm (ISO 527-1)

The tensile test samples will be cut using a milling machine into flexural test samples (Figure 31).

Figure 31. Flexural test sample where l = 80 ± 2, b = 10 ± 0.2, h = 4 ± 0.2 mm

For each of the following tests, five tests were conducted for each material before sterilisation (U), after gamma irradiation (G) and after Ethylene Oxide sterilisation (E). Any tests where the specimen slipped or where the force was not uniform were discarded, and not counted in the

five reported tests. Only three tests were conducted on Norner, as this was the maximum number of test samples available from the supplier.

3.3. Tensile Test

A tensile test in line with ISO 527-2:2012 was completed using a Hounsfield 312 Family Electromechanical UNIVERSAL Test Machine which is calibrated in tension to ISO 7500 – 1 to a lower limit of <1% (Appendix 1). The machine was set up with a 25 kN load cell was conducted at ambient room temperature (approximately 21ºC) at Swansea University. The sample was loaded vertically into the machine (Figure 32), each shoulder was placed into one of the clamps (top or bottom) and tightened, ensuring that the clamp did not cover the fillet radius.

Figure 32. Tensile test set up with extensometer

The extensometer (Epsilon 3542) was connected to the system by clamping the device onto the centre of the device ensuring that the contact did not cause the test sample to bend. A test speed of 5 mm/min and gauge length, L_0, of 5 mm were selected.

When the machine was turned on, the top clamp moved upwards, pulling the top shoulder of the test sample until it breaks. The time, t (seconds), force, F (N), and displacement, D (µm) and strain were recorded, and automatically exported to a Microsoft Excel file.

Using this data, stress σ, strain ε, Young's modulus E, and Poisson's ratio, µ, can be calculated using the following equations:

$$\sigma = \frac{F}{A} \quad (3)$$

$$\varepsilon = \frac{\Delta L_0}{L_0} \quad (4)$$

$$E = \frac{\sigma_2 - \sigma_1}{\varepsilon_2 - \varepsilon_1} \quad (5)$$

Where σ_1 = stress (MPa) measured at strain ε_1 = 0.05% and σ_2 = stress (MPa) measured at strain ε_2 = 0.25%.

The strain at break (ε_b) was calculated by identifying the strain at the last recorded point at which the stress was reduced to 10% of the maximum stress (σ_m). The maximum stress is also known as the strength.

$$\mu = -\frac{L_0}{n_0}\frac{\Delta n}{\Delta L} \quad (6)$$

Where L_0 = gauge/test length in longitudinal direction, (mm), n_0 = gauge/test length in transverse direction, (mm), Δn = decrease of length in transverse direction, (mm) and ΔL = increase of length in longitudinal direction, (mm).

3.4. Flexural Test

A three-point bend test using the same machine (Hounsfield 312 Family Electromechanical UNIVERSAL Test Machine which is calibrated in compression to ISO 7500 – 1 to a lower limit of <1% (Appendix 2)) was conducted at ambient room temperature (approximately 21ºC) at Swansea University. The samples were placed onto the supports (Figure 33) with a nominal span, L, of 64mm, calculated from L = (16+1)h, where h is the thickness. The load cell selected was a 25 kN cell.

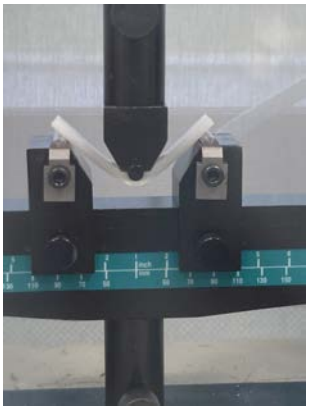

Figure 33. Flexural test set up

Method B from ISO 178:2019 was selected, which meant that the load rate was 2mm/min for the first part of the test in order to calculate E_f. After this the speed was increased to 10mm/min without unloading the test sample. The load was lowered onto the top surface (b x l) of the test specimen at this rate and continued until the test sample snapped or until the flexural strain was 5% or 8.53 mm from the original position.

The results were presented in a table of, time, t (seconds), displacement, D (µm) and load, F (N). These tables were plotted into force-displacement graphs. The gradient of the tangent of the first straight line portion of the graph, m, and the maximum value after this region, flexural strength, were extrapolated.

The following equations were used to calculate flexural stress, σ_f, flexural strain, ε_f, and elastic modulus, E_f.

$$\sigma_f = \frac{3Fl}{2bh^2} \quad (7)$$

$$\varepsilon_f = \frac{6Dh}{l^2} \quad (8)$$

$$E_f = \frac{l^3 m}{4bh^3} \quad (9)$$

3.5. Statistical Significance

A t-test was then used to assess the data for statistical significance. Should this generate a p value less than 0.05 then the null hypothesis will be rejected, concluding that the standard deviations between the groups has differed, and the difference between the means (if any) is not due to natural variation within the test method. This was calculated using:

$$p = \frac{\overline{x_1} - \overline{x_2}}{\sqrt{s^2\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}} \quad (10$$

Where $s^2 = \frac{\sum_{i=1}^{n_1}(x_i - \overline{x_1})^2 + \sum_{j=1}^{n_2}(x_j - \overline{x_2})^2}{n_1 + n_1 - 2}$ (11

3.6. Sterilisation

3.6.1. Gamma irradiation

Ten test samples, five tensile, five flexural, of each polymer type were sterilised by Cobalt-60 gamma irradiation by a third party to a value of 25-35 kGy to a SAL of 10^{-6} as this is the level that their routine medical devices are sterilised to.

3.6.2. Ethylene Oxide

Ten test samples, five tensile, five flexural, of each polymer type were sterilised by Cobalt-60 gamma irradiation by a third party to a SAL of 10^{-6}.

Chapter 4 - Results

The results of each test are displayed within this chapter. They are grouped within two categories, CBR and Ear Specula. This is to allow a comparison between polymers with more similar properties. The tensile and flexural stress-strain curves are taken from one sample test that was most similar to the mean values. The graphs in each section use the same axis to allow a comparison, however if this obscures the detail of the graph, a magnified version of the graph is shown below.

4.1. CBR Results

4.1.1. RTP 205 C

Table 10. Experimental results for RTP 205 C

	Unsterilised		*EO*			*Gamma*		
	Value	SD	Value	%Δ	SD	Value	%Δ	SD
Tensile Modulus (MPa)	5337	159	4884	-8.48	468	5421	1.57	159
Tensile Strength (MPa)	52.21	2.76	48.25	-7.60	0.84	50.53	-3.22	2.30
Tensile Strain at Break (%)	1.38	0.13	1.43	6.24	0.42	1.59	-10.7	0.76
Flexural Modulus (MPa)	5289	89	4139	-21.7	145	4437	-16.1	168
Flexural Strength (MPa)	84.80	2.06	80.30	-5.31	3.09	85.30	0.59	1.63
Flexural Strain at Strength (%)	2.60	0.31	3.38	29.84	0.49	3.59	8.21	0.31

RTP 205 C experienced a significant change in flexural modulus, which decreased by 16.11% from 5289.72 MPa to 4437.33 MPa after gamma radiation. However, the polymer saw no significant change in the tensile modulus, strain at break or ultimate tensile strength ($p = 0.7141, 0.05606, 0.379$ respectively), after exposure to gamma radiation. There was also no significant difference in the maximum flexural stress or strain.

Ethylene oxide sterilisation caused a statistically significant change in the tensile modulus and ultimate tensile strength. The tensile modulus decreased by 8.48% to 4884.48 MPa ($p= 0.0102$). The tensile strength decreased by 7.60% from 52.21 MPa to 48.25 MPa ($p=0.0152$). Ethylene

oxide sterilisation also had a significant effect on the flexural strength of RTP 205 C, causing a 5.31% decrease from 84.80 MPa to 80.30 MPa. The was also a 21.74% decrease in flexural modulus after exposure to EO. The tensile strain at break did not change with statistical significance ($p = 0.8541$).

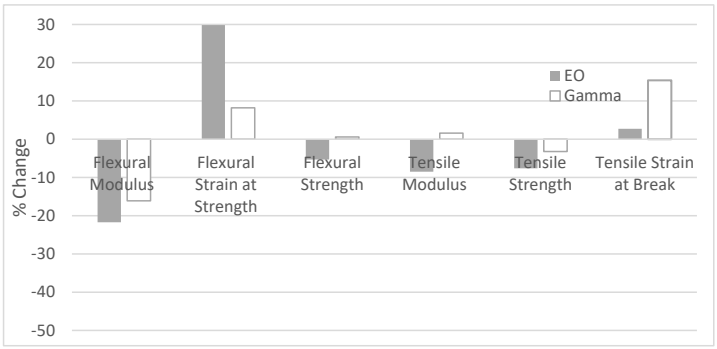

Figure 34. % change in mechanical properties of RTP 205 C after sterilisation

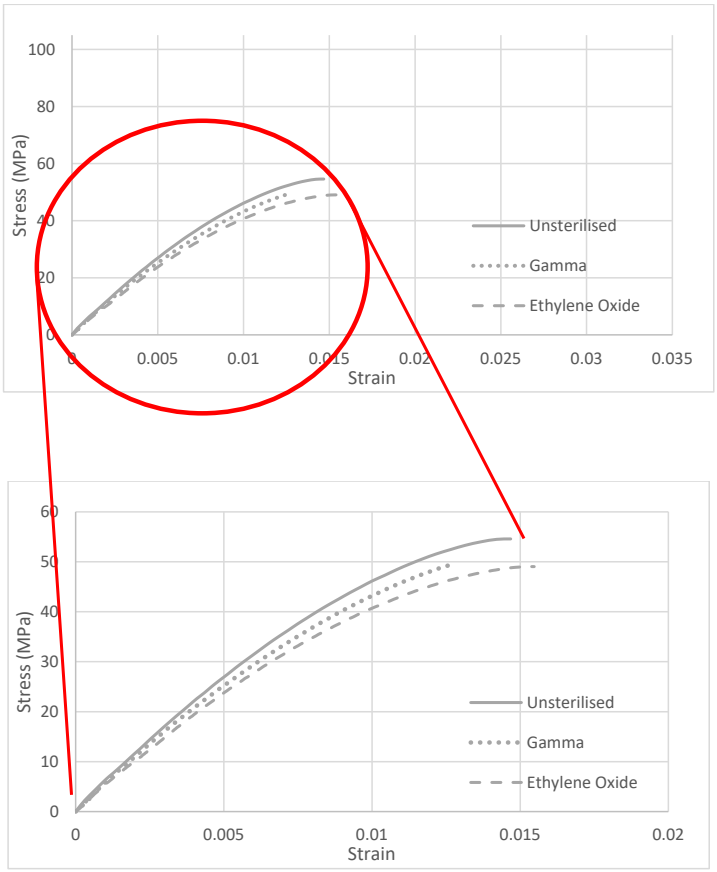

Figure 35. Tensile test results of RTP 205 C under different sterilisation methods

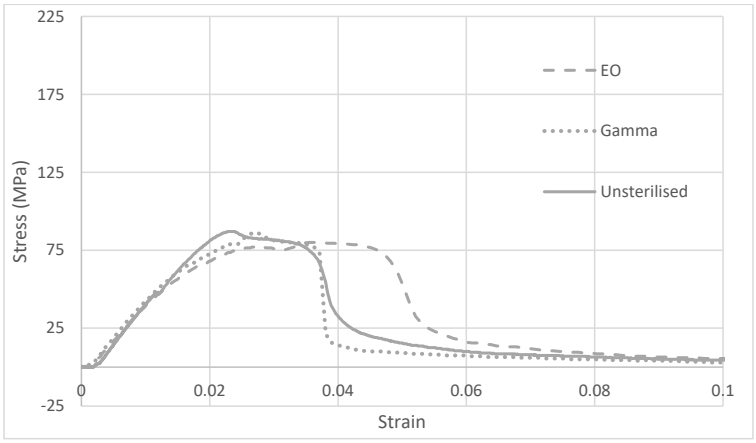

Figure 36. Flexural test results of RTP 205 C under different sterilisation methods

4.1.2. RTP 203 C

Table 11. Experimental results for RTP 203 C

	Unsterilised		*EO*			*Gamma*		
	Value	SD	Value	%Δ	SD	Value	%Δ	SD
Tensile Modulus (MPa)	4351	125	4275	-1.75	283	4293	-1.35	258
Tensile Strength (MPa)	64.85	0.76	62.27	-3.97	1.51	66.80	3.01	0.62
Tensile Strain at Break (%)	2.92	0.87	2.29	-21.35	0.21	2.69	-7.95	0.31
Flexural Modulus (MPa)	4259	152	4100	-3.73	54.32	4141	-2.78	51.48
Flexural Strength (MPa)	107.4	2.69	100.5	-6.42	0.63	102.9	-4.19	1.15
Flexural Strain at Strength (%)	3.47	0.1	3.65	5.17	0.14	3.59	3.63	0.11

The tensile strength was the only statistically significant result after ethylene oxide sterilisation. This decreased by 3.97% from 64.85 MPa to 62.27 MPa (p=0.0094). The flexural strength decreased by 6.42% from 107 MPa to 100.5 MPa. The flexural modulus was almost statistically significant. There was no statistical significance in the change in flexural strain at break (p=0.5625).

RTP 203 C did not experience any statistically significant changes in tensile or flexural properties after being exposed to gamma radiation.

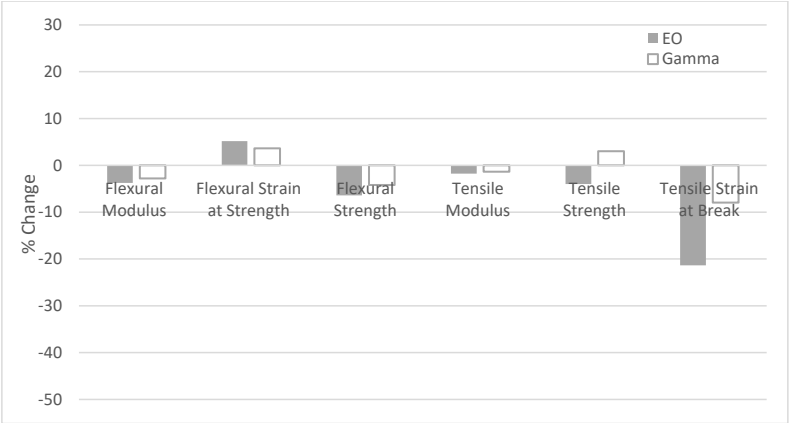

Figure 37. % change in mechanical properties of RTP 203 C after sterilisation

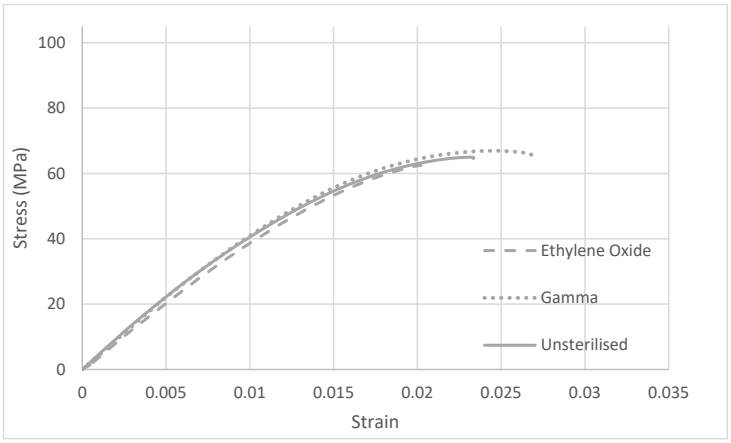

Figure 38. Tensile test results of RTP 203 C under different sterilisation methods

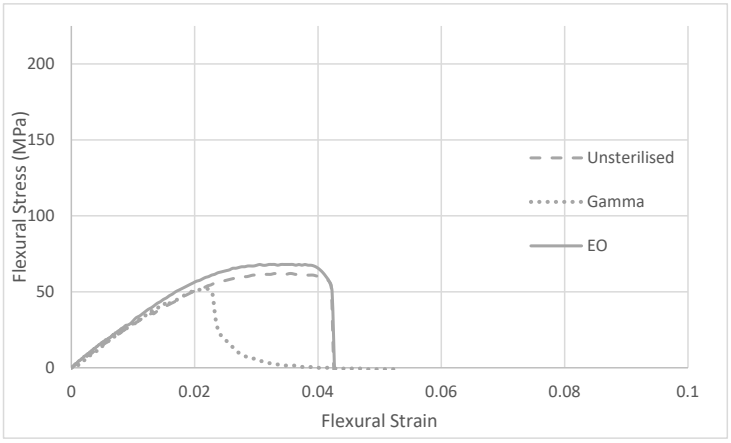

Figure 39. Flexural test results of RTP 203 C under different sterilisation methods

4.1.3. Latilon

Table 12. Experimental results for Latilon

	Unsterilised		*EO*			*Gamma*		
	Value	SD	Value	%Δ	SD	Value	%Δ	SD
Tensile Modulus (MPa)	6203	159	6008	-3.15	468	6301	1.57	159
Tensile Strength (MPa)	104.85	2.76	103.61	-1.18	0.84	104.10	-0.72	2.30

Tensile Strain at Break (%)	3.02	0.13	2.65	-12.1	0.42	2.55	-15.60	0.76
Flexural Modulus (MPa)	5712	89	5830	2.07	145	5830	2.07	168
Flexural Strength (MPa)	147.30	2.06	151.80	3.05	3.09	155.30	5.43	1.63
Flexural Strain at Strength (%)	3.79	0.31	3.59	-5.29	0.49	3.89	2.76	0.31

The tensile strain at break was the only statistically significant change in the tensile properties of Latilon after gamma irradiation. This decreased by 15.60% from 3.02% to 2.55%. The changes to flexural properties after gamma irradiation were not statistically significant.

The only statistically significant result after EO sterilisation was the Young's Modulus which decreased from 6203.82 MPa to 6008.42 MPa (3.15%). The other tensile values were not quite statistically significant.

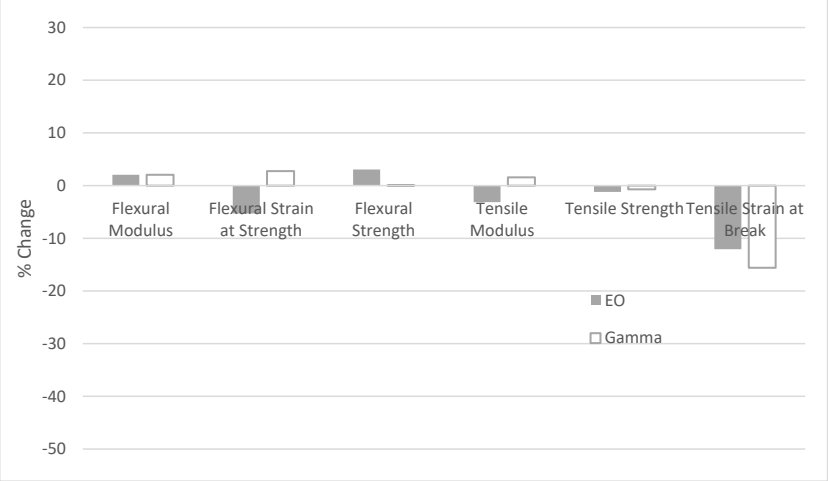

Figure 40. % change in mechanical properties of Latilon after sterilisation

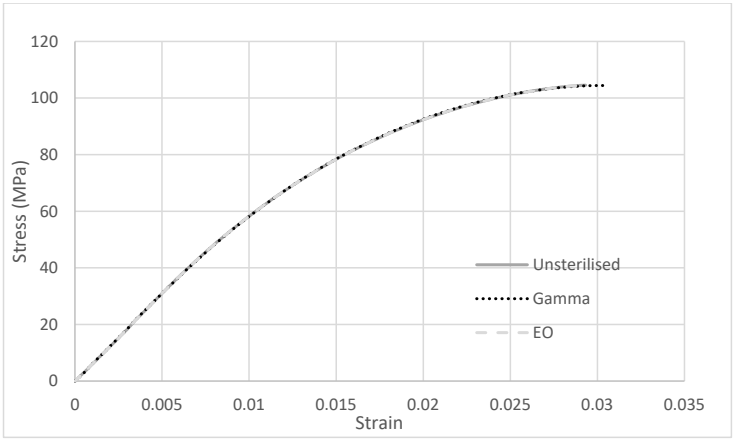

Figure 41. Tensile test results of Latilon after different sterilisation methods

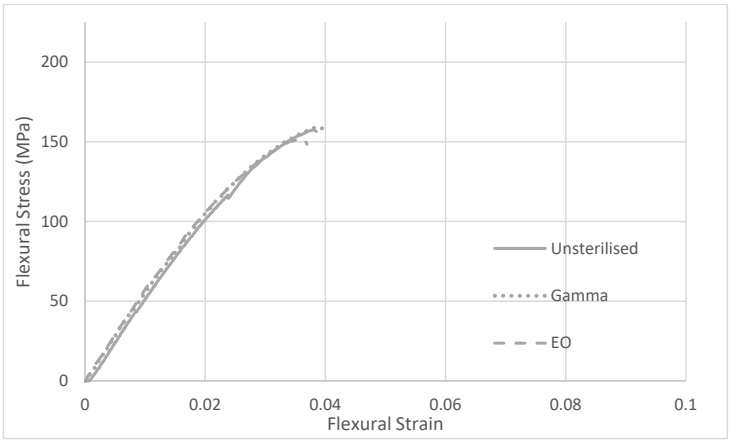

Figure 42. Flexural test results of Latilon under different sterilisation methods

4.1.4. Rilsan

Table 13. Experimental results for Rilsan

	Unsterilised		*EO*			*Gamma*		
	Value	SD	Value	%Δ	SD	Value	%Δ	SD
Tensile Modulus (MPa)	12731	902	13354	4.89	922	13443	5.59	592

Tensile Strength (MPa)	98.41	11.15	90.79	-7.74	9.99	97.43	-0.99	11.94
Tensile Strain at Break (%)	0.87	0.25	0.69	-20.9	0.15	0.72	-17.68	0.14
Flexural Modulus (MPa)	13001	1209	13149	1.14	678	12725	-2.13	873
Flexural Strength (MPa)	209.30	23.16	220.30	5.26	18.54	218.80	4.54	17.15
Flexural Strain at Strength (%)	2.56	0.50	2.44	-4.40	2.16	2.71	5.92	2.04

None of the results for Rilsan showed as being statistically significant. This is due to the large amount of variability within the results. The tensile test samples of this polymer all broke on the grip section of the specimen; therefore, the tensile stress-strain graph has not been included.

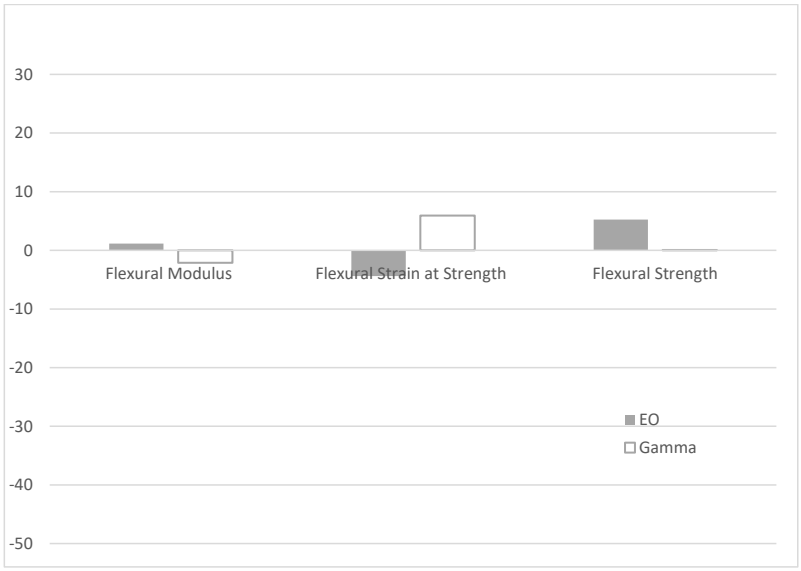

Figure 43. % change in mechanical properties of Rilsan after sterilisation

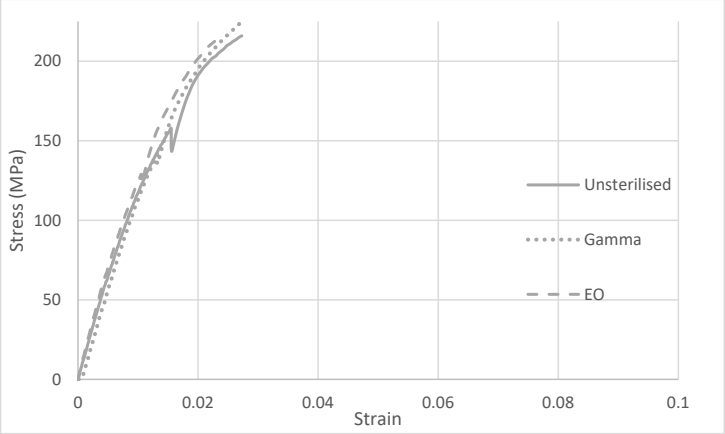

Figure 44. Flexural test results of Rilsan under different sterilisation methods

4.2. Ear Specula Results

4.2.1. BioLite 240

Table 14. Experimental results for BioLite 240

	Unsterilised		*EO*			*Gamma*		
	Value	SD	Value	%Δ	SD	Value	%Δ	SD
Tensile Modulus (MPa)	1704	39.3	1850	8.59	76.5	1823	6.98	43.6
Tensile Strength (MPa)	29.57	0.66	31.65	7.02	0.12	30.42	2.89	0.25
Tensile Strain at Break (%)	9.57	0.22	12.30	28.57	0.18	9.67	1.00	0.06
Flexural Modulus (MPa)	1487	208	1654	11.25	157	1615	8.60	79.2
Flexural Strength (MPa)	39.30	2.82	40.80	3.82	2.46	40.70	3.56	1.36
Flexural Strain at Strength (%)	6.70	0.37	6.27	-6.39	0.32	6.42	-4.18	0.18

All of BioLite 240's tensile properties increased after gamma irradiation, however the <1% increase in tensile strain at break was not considered to be statistically significant. The tensile modulus increased by 6.98% from 1704.38 MPa to 1823.35 MPa (p=0.0019) and the tensile strength increased by 2.89% from 29.57 MPa to 30.43 MPa (p=0.026). Despite these small

changes being statistically significant, they are unlikely to have a considerable effect on the mechanical behaviour of a product made from BioLite 240.

Despite showing the largest percentage change, the flexural modulus was not considered statistically significant due to a larger variance between the results. The flexural strength and strain at strength also showed p values > 0.05.

After EO sterilisation BioLite 240's tensile modulus increased 8.59% from 1704.38 MPa to 1850.78 MPa (p = 0.0052). The tensile strength increased by 7.02% from 29.57 MPa to 31.65 MPa (p = 0.0095).

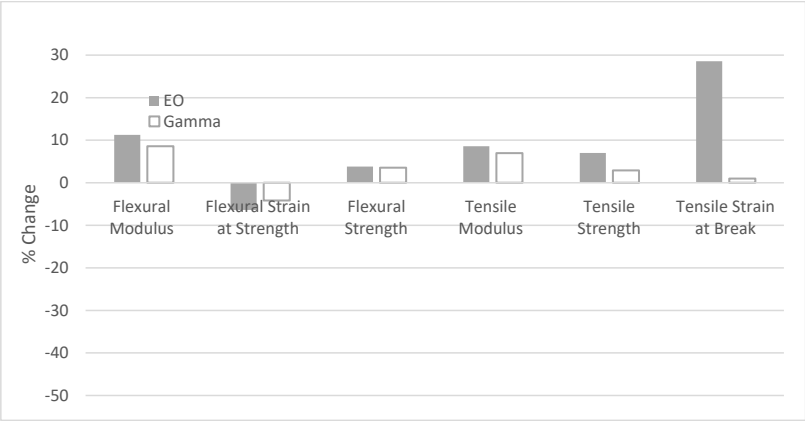

Figure 45. % change in mechanical properties of BioLite 240 after sterilisation

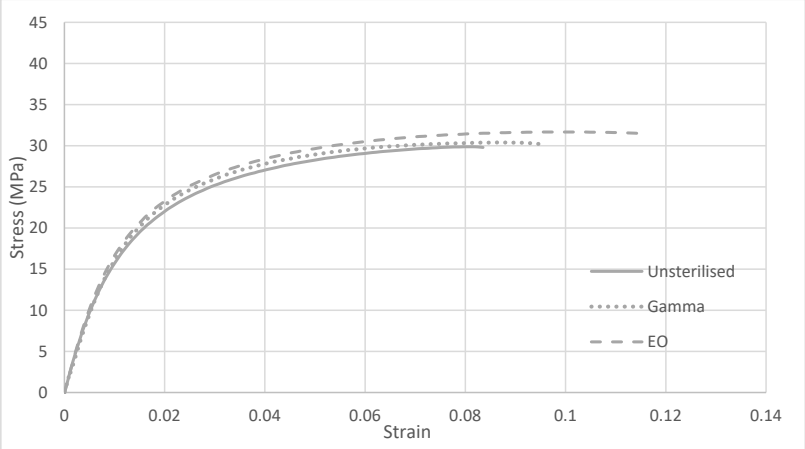

Figure 46. Tensile test results of BioLite 240 under different sterilisation methods

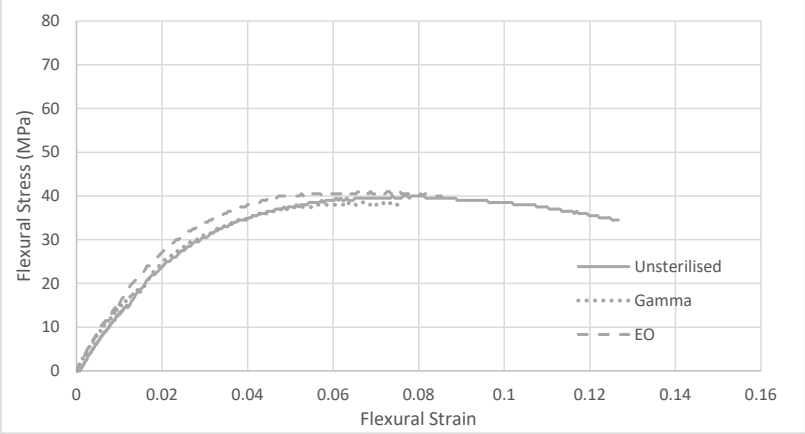

Figure 47. Flexural test results of BioLite 240 under different sterilisation methods

4.2.2. Magnum

Table 15. Experimental results for Magnum

	Unsterilised		*EO*			*Gamma*		
	Value	SD	Value	%Δ	SD	Value	%Δ	SD
Tensile Modulus (MPa)	2218	57.4	2246	1.27	43.9	2207	-0.51	117.7
Tensile Strength (MPa)	40.30	1.06	39.89	-1.03	1.15	40.40	0.23	1.03

Tensile Strain at Break (%)	6.31	2.36	7.70	21.92	2.82	5.07	-19.78	2.31
Flexural Modulus (MPa)	2726	91.6	2610	-4.26	59.1	2705	-0.79	29.4
Flexural Strength (MPa)	76.60	1.11	75.80	-1.04	1.08	76.00	-0.78	0.71
Flexural Strain at Strength (%)	4.61	0.31	4.52	-1.96	0.04	4.00	-14.13	0.02

After gamma radiation the flexural strength of Magnum decreased by 14.13% from 4.52% to 3.96% (p= 0.0077). The only other statistically significant change came after exposure to ethylene oxide sterilisation, which was a 4.26% decrease in the flexural modulus from 2726.76 MPa to 2610.67 MPa (p= 0.0445). The tensile strain at break properties changed by a high percentage, after both gamma (-19.78 %) and ethylene oxide (+21.92 %) although due to high variability within the results this was not considered statistically significant; the p vales were 0.5606 and 0.8541, respectively. The tensile properties of Magnum experienced no statistically significant results after either method of sterilisation.

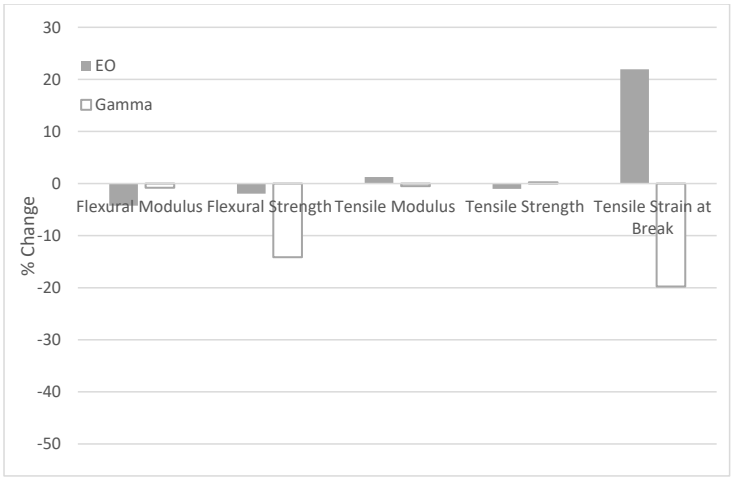

Figure 48. % change in mechanical properties of Magnum after sterilisation

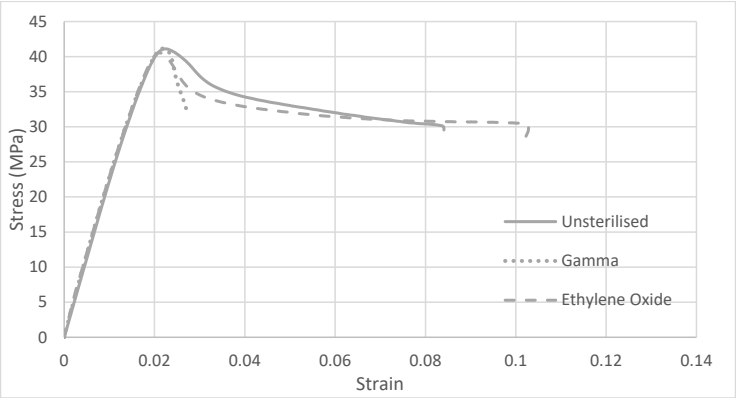

Figure 49. Tensile test results of Magnum under different sterilisation methods

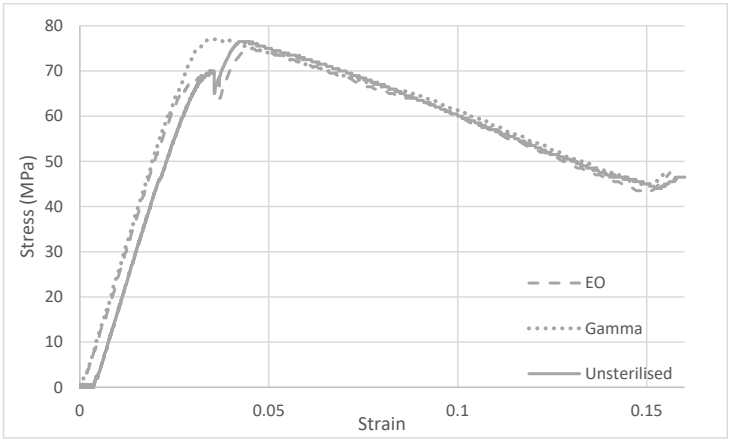

Figure 50. Flexural results of Magnum under different sterilisation methods

4.2.1. Switch 25

Table 16. Experimental results for Switch 25

	Unsterilised		*EO*			*Gamma*		
	Value	SD	Value	%Δ	SD	Value	%Δ	SD
Tensile Modulus (MPa)	2911	92	3017	3.65	124	3061	5.18	109
Tensile Strength (MPa)	37.09	0.36	36.10	-2.65	2.40	32.85	-11.41	1.09
Tensile Strain at Break (%)	2.35	0.30	1.85	-21.43	0.51	1.67	-29.35	0.43

Flexural Modulus (MPa)	2995	79	3195	6.68	187	3206	7.05	78
Flexural Strength (MPa)	64.80	5.10	66.40	2.47	1.39	54.70	-15.59	3.23
Flexural Strain at Strength (%)	3.25	0.28	3.35	3.08	0.24	2.26	-30.45	0.13

This polymer experienced extremely significant results in the change in tensile strength from 37.09 MPa to 32.85 MPa ($p = 0.0001$), as well as in the tensile strain at break and flexural strain at strength, which decreased by 29.35 % from 2.06 % to 1.67 %, and by 30.45% from 3.26 % to 2.26% respectively.

The 5.18% increase in tensile strength from 2911.17 MPa to 3061.92 MPa was almost statistically significant ($p = 0.0583$).

The flexural modulus increased by 7.05% from 2995.54 MPa to 3206.69 MPa ($p = 0.0028$), whilst the flexural strength decreased by 15.58% from 64.8 MPa to 54.7 MPa ($p = 0.0057$).

Ethylene oxide sterilisation did not cause any statistically significant change in the mechanical properties of Switch 25. The tensile strain at break was, however, almost statistically significant with a p value of 0.0942. The flexural modulus was also almost statistically significant

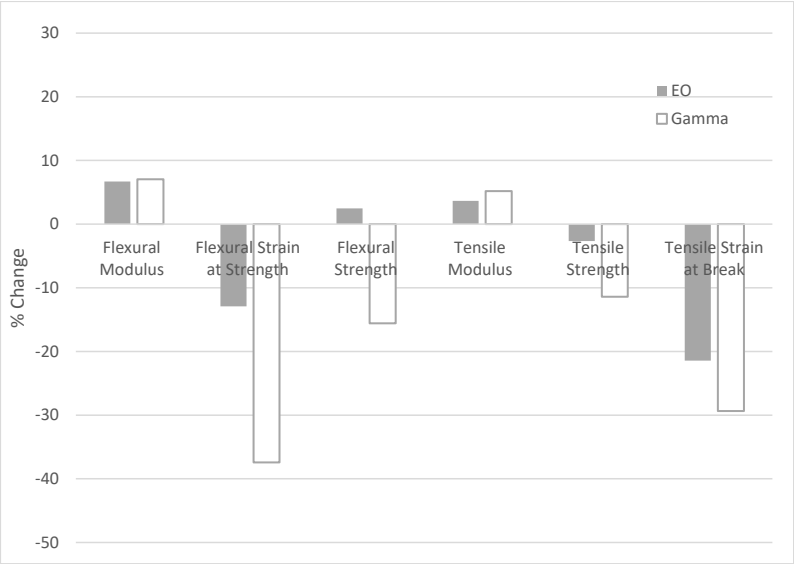

Figure 51. % change in mechanical properties of Switch 25 after sterilisation

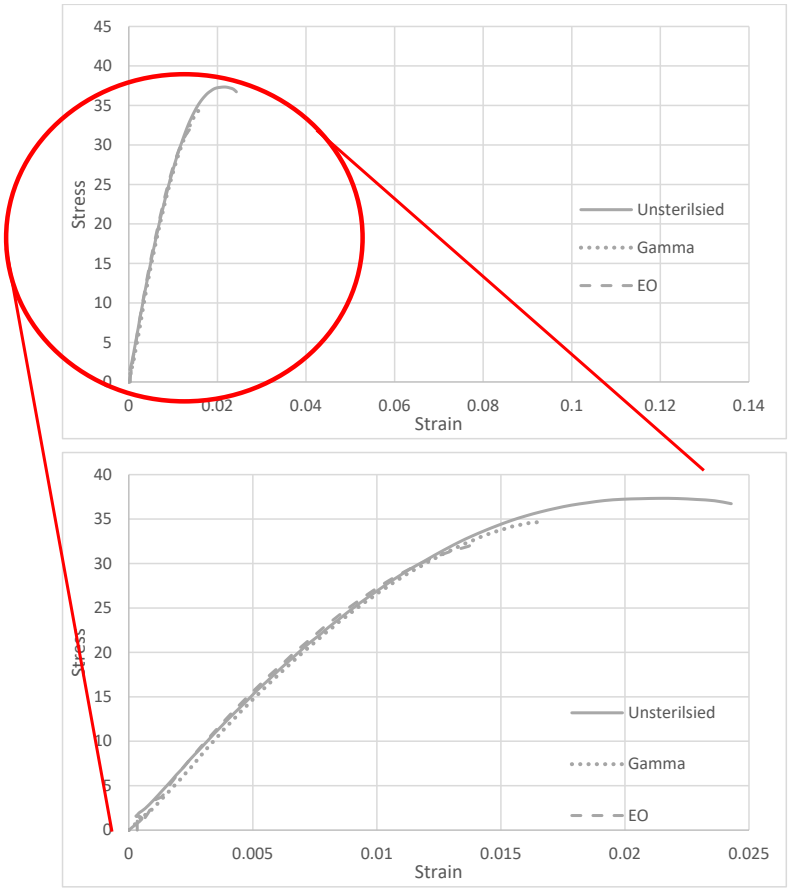

Figure 52. Tensile test results of Switch 25 under different sterilisation methods

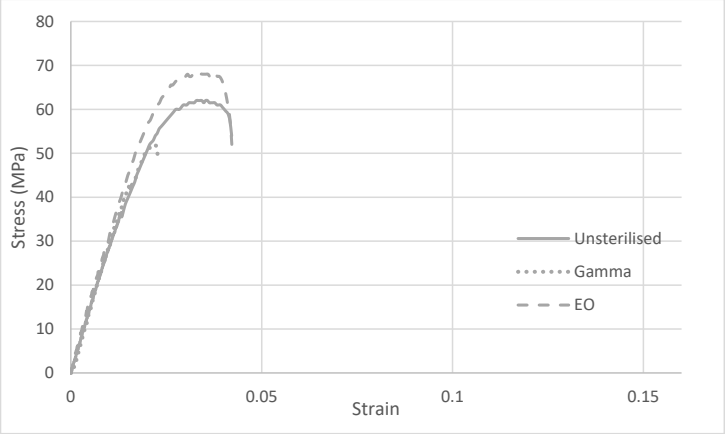

Figure 53. Flexural test results of Switch 25 under different sterilisation methods

4.2.2. Biolite 3

Table 17. Experimental results for Biolite 3

	Unsterilised		*EO*			*Gamma*		
	Value	SD	Value	%Δ	SD	Value	%Δ	SD
Tensile Modulus (MPa)	2189	149	2443	11.60	132	2400	9.60	94.1
Tensile Strength (MPa)	23.84	1.42	24.24	1.67	1.70	25.58	7.29	1.41
Tensile Strain at Break (%)	2.69	0.42	2.58	-4.16	0.79	3.41	26.85	0.14
Flexural Modulus (MPa)	2443	96.5	2483	1.61	267	2481	1.56	199
Flexural Strength (MPa)	43.90	0.66	38.10	-13.21	2.96	41.90	-4.56	1.59
Flexural Strain at Strength (%)	3.71	0.4	3.32	-10.39	0.53	3.28	-11.60	0.19

Biolite 3 experienced a 9.6% increase in tensile modulus from 2189.76 MPa to 2400.06 MPa ($p = 0.0285$) after gamma radiation. The tensile strain at break increased by 26.85% to reach 3.4% ($p = 0.0249$).

The flexural properties of Biolite 3 were also affected by gamma irradiation. The flexural strain at strength decreased by 11.60% from 3.71% % to 3.28% (p = 0.0052). The flexural strength only decreased by 4.56% from 43.9 MPa to 41.9 MPa (p = 0.0321).

Ethylene oxide sterilisation affected the tensile modulus of Biolite 3 and caused a 11.60% change from 2189.76 MPa to 2443.66 MPa (p = 0.0438). The flexural strength decreased 13.21% from 43.9 MPa to 39.1 MPa (p = 0.0027).

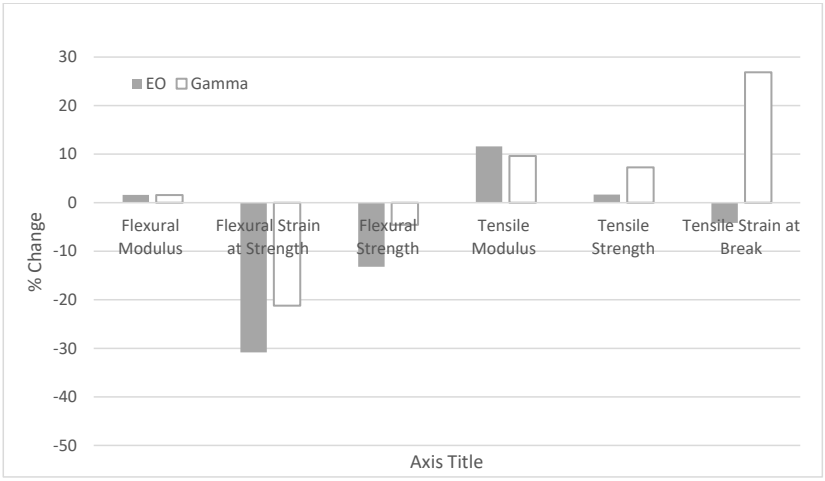

Figure 54. % change in mechanical properties of Biolite 3 after sterilisation

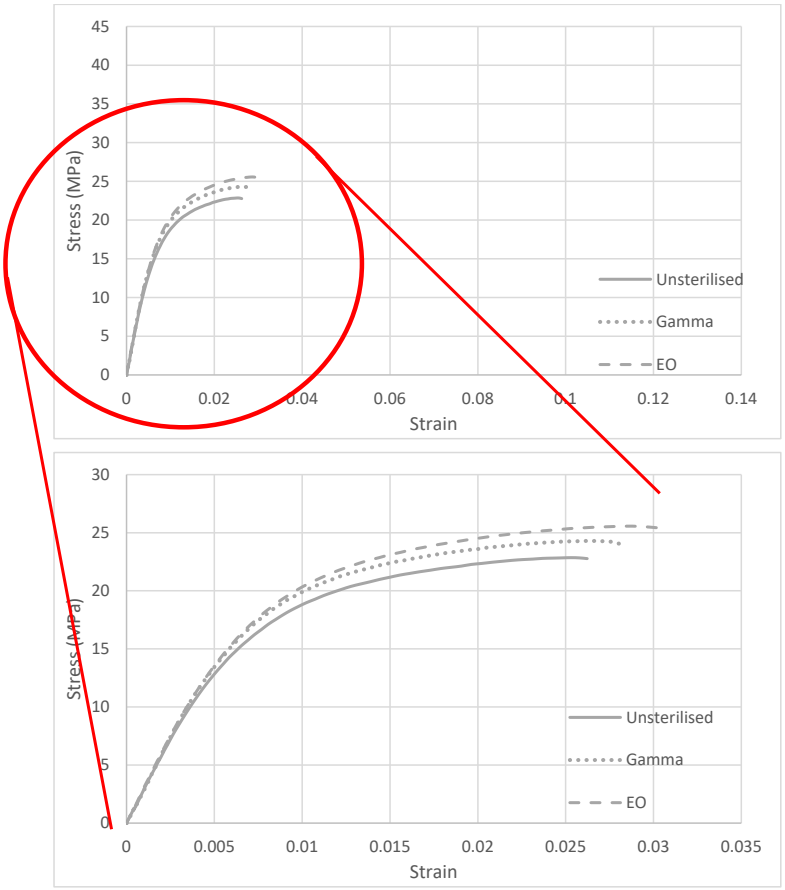

Figure 55. Tensile test results of Biolite 3 under different sterilisation methods

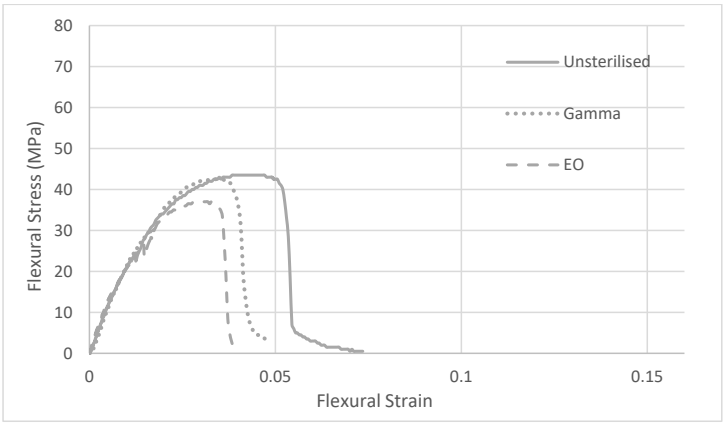

Figure 56. Flexural test results of Biolite 3 under different sterilisation methods

4.2.2.8. *Norner*

Table 18. Experimental results for Norner

	Unsterilised		*EO*			*Gamma*		
	Value	SD	Value	%Δ	SD	Value	%Δ	SD
Tensile Modulus (MPa)	2665	129	2751	3.21	62.65	2943	10.44	86.73
Tensile Strength (MPa)	34.54	1.26	35.10	1.61	0.73	34.58	0.10	1.03
Tensile Strain at Break (%)	6.12	0.46	5.08	-17.11	0.26	3.17	-48.15	0.009
Flexural Modulus (MPa)	2494	118	2561	2.70	160	2558	2.54	2.78
Flexural Strength (MPa)	56.25	0.83	52.83	-6.07	2.46	52.67	-6.37	0.24
Flexural Strain at Strength (%)	7.62	0.15	4.85	-36.39	0.09	4.98	-34.68	0.12

The tensile modulus of Norner increased by 10% from 2665.36 MPa to 2943.67 MPa (p = 0.0366) after gamma irradiation. The tensile strain at break decreased by 48.15% from 6.12% to 3.17% (p= 0.0004). There was a -6.37% decrease in flexural strength from 56.25 MPa to 52.67 MPa. The flexural strain at break also decreased by 34.68% from 7.62% to 4.98%.

After EO sterilisation the tensile strain at break decreased from 6.12% to 5.08% (p= 0.0153). The flexural strain at strength also decreased from 5.38% to 4.85% (p=0.0255). There were no other statistically significant changes after EO sterilisation.

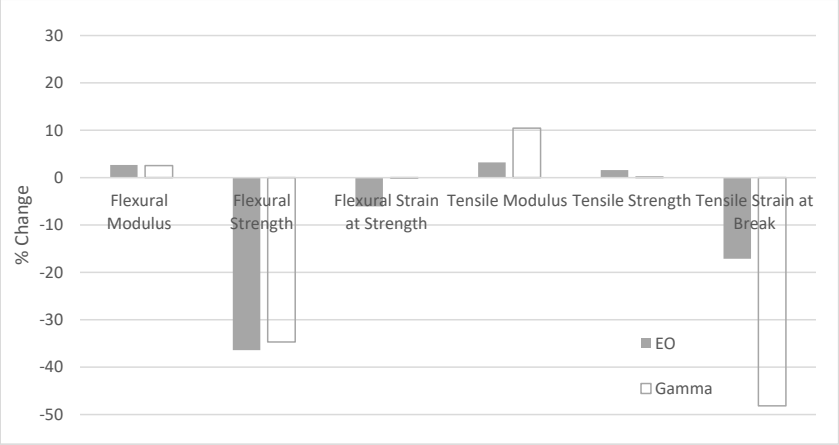

Figure 57. % change in mechanical properties of Norner after sterilisation

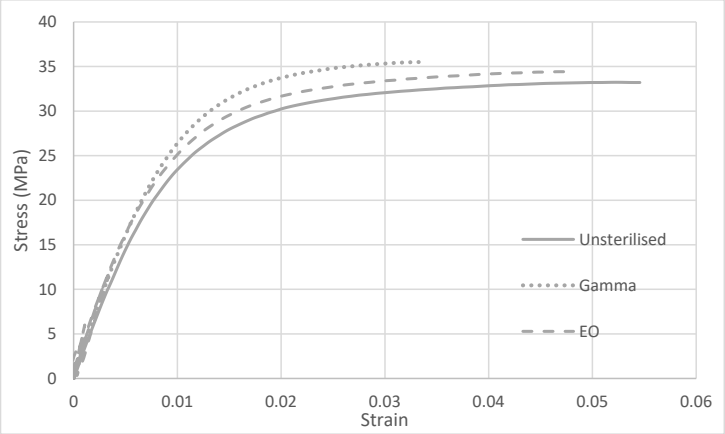

Figure 58. Tensile test results of Norner under different sterilisation methods

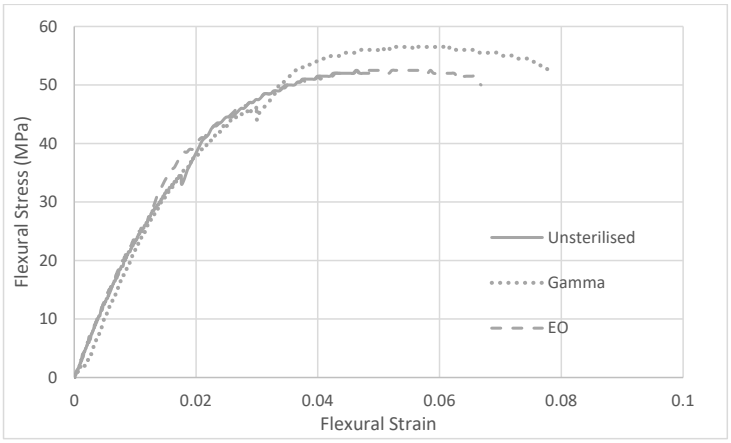

Figure 59. Flexural test results of Norner under different sterilisation methods

4.3. Datasheet Variance

The agreeance between the experimental data and the information provided on the material data sheets varied between different polymers *Figure 62*. The results for Rilsan are not displayed due to the very limited information on the datasheet.

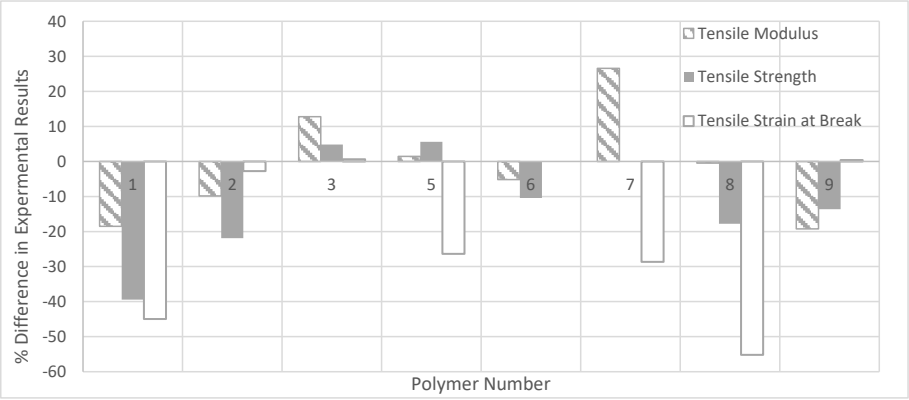

Figure 60. % difference between experimental and datasheet results for tensile properties. (Rilsan datasheet was incomplete and therefore excluded from the figure)

The mean percentage of the absolute values of the variance between the data sheet and experimental values are displayed in *Table 19*.

Table 19. Mean of the absolute values of the variance percentage between experimental and data sheet results

Property	*Mean of Absolute Variance (%)*
Tensile Modulus	11.76
Tensile Strength	14.20
Tensile Strain at Break	19.87
Flexural Modulus	9.85
Flexural Strength	13.98

4.4. Conclusion

All of the polymers chosen as a substitute for the Ear Specula showed good resistance to sterilisation. This is evident by the small change in mechanical properties of these polymers. This resilience coupled with its already desirable mechanical properties suggest that Trifilon Switch 25 is most suitable to replace Magnum in the Ear Specula. The Norner polymer also appears to be a suitable polymer for the manufacture of this product for the same reasons.

Rilsan cannot be recommended to replace Latilon at this stage, due to its high variability leading to statistically insignificant results. Further testing on moulded parts would need to be completed before a conclusion can be drawn about this product. Due to the RTP 205 C polymers significant change in mechanical properties after sterilisation, further testing on moulded parts would need to be conducted to ensure that the product does not break during use.

Chapter 5 - Discussion

A discussion of the findings of the research is presented within this section, this includes possible explanations for any results shown. This chapter also recommends suitable polymers to replace the current petroleum based polymers use within the two devices.

5.1. PA11

Ethylene Oxide sterilisation had a larger effect on RTP 205 C and 203 C than gamma sterilisation did. This was not expected, as the literature previously found reported that PA11 polymers are compatible with EO sterilisation. Both polymers RTP polymers are PA11 plastic. One explanation for this unexpected result is that the ethylene oxide, an alkylating agent, reacted with the OH bonds between adjacent chains of PA11 (Figure 63), which reduced the crystallinity of the polymer. This will allow the chains to move past each other more easily in the x direction, whilst the Van der Waals forces between the hydrogen atoms can maintain the polymer's structure causing an increase in flexural strength. However, this also causes a decrease in tensile strength, as the forces that are holding the chains together in the y direction have been interrupted by the Ethylene Oxide molecules. The Van der Waals forces between the hydrogen atoms are also weaker in the y direction.

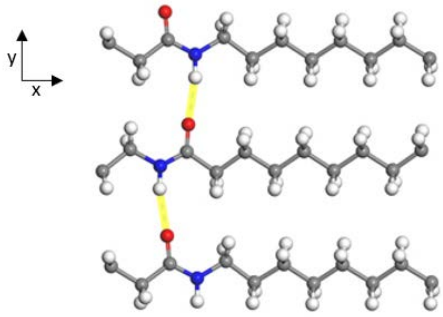

Figure 61. Crystalline structure of PA11. White = Hydrogen atoms, grey = Carbon atoms, Blue = Nitrogen atoms, Red = Oxygen atoms. Yellow line represents O-H bonds. [117]

The results also suggest that the higher the glass fibre content of the polymer, the more severely the Young's modulus will be affected by ethylene oxide sterilisation (Figure 64). The change in RTP 205 C after EO sterilisation was statistically significant. This may be due to the

polymers inability to rebuild secondary bonds between the chains due to the presence of the glass fibres between the molecules. This will inhibit the polymer's ability to reform crystalline regions, which in turn will decrease the Young's modulus. These changes were, however, non-linear making a prediction of the magnitude of polymer degradation due to sterilisation extremely difficult.

The main finding to note in Figure 65 is the large difference in the flexural strain at maximum stress of RTP 205 C after EO sterilisation. This increased from 2.58% to 3.23%. This is likely due to the broken OH bonds allowing the polymer chains to slide past each other more easily in the x direction (Figure 63) whilst maintaining the integrity of the polymer through Van der Waals forces. The higher glass content will increase this by interrupting the hydrogen bonds to allow even more movement of the chains past each other. The same trends were followed with the flexural properties as the tensile properties, for example, EO having a larger effect on the modulus of material with the higher glass content as the molecules are sparser and therefore the bonds are harder to form.

Despite EO having an effect on the properties of the RTP polymers, the effect was small. The largest change in the properties of RTP 203 C was <10% which may not have a large impact on the mechanical performance of the polymer.

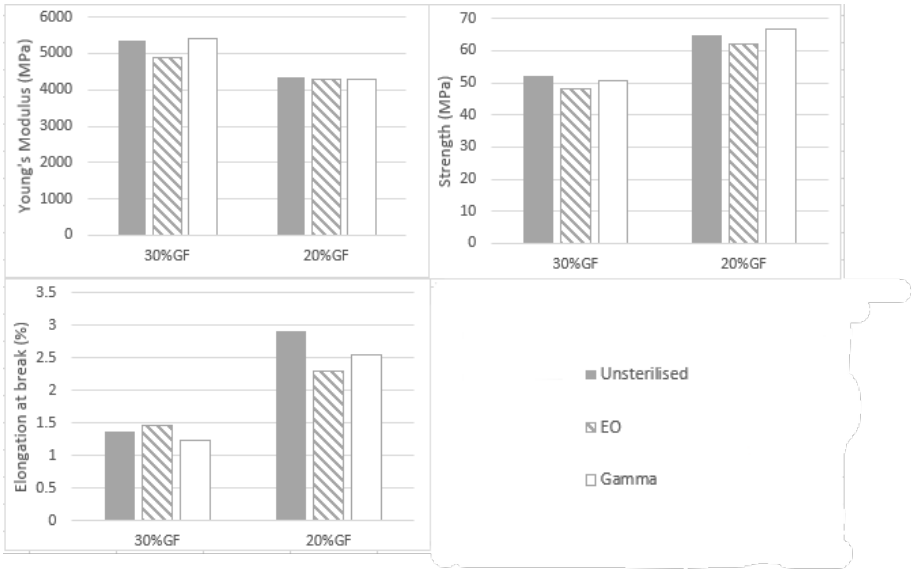

Figure 62. Effect of glass fibre content on Young's Modulus (top left), Tensile Strength (top right), and Tensile strain at break (bottom left) of Polyamide 11 after different sterilisation methods.

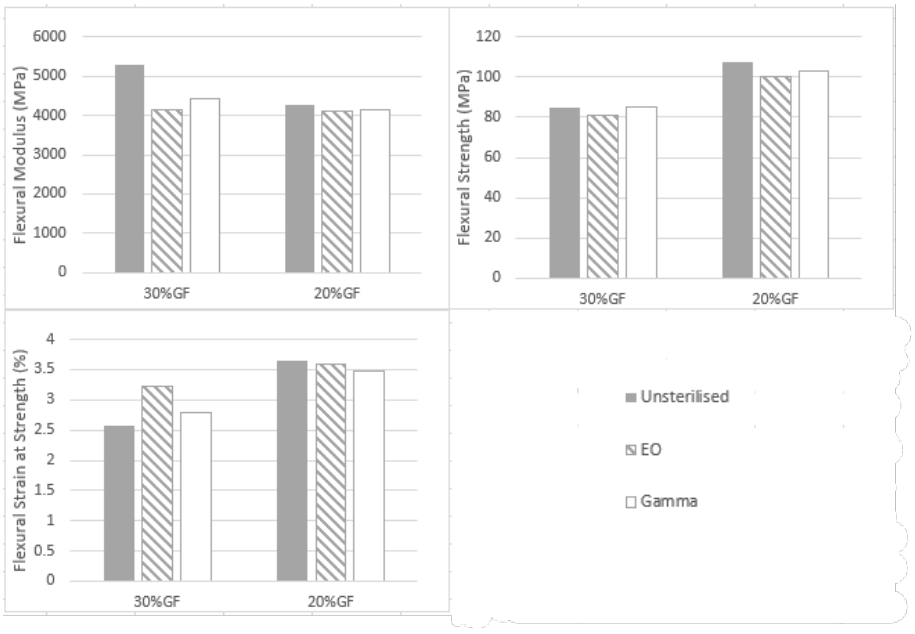

Figure 63. Effect of glass fibre content on Flexural Modulus (top left), Flexural Strength (top right), and Flexural strain at strength (bottom left) of Polyamide 11 after different sterilisation methods.

The tensile results of Rilsan cannot be discussed with confidence as they broke midway through the grip section of the specimen. According to ISO 527 these results should be disregarded as they did not break within the gauge length. One reason for this could have been due to this being the weakest spot on the specimen due to its extremely high tensile strength. This error was not due to the test procedure as all of the polymers were testing with the same parameters, or the moulding process as this polymer was moulded in the same way as polymers 5, 7 and 8 which all broke within the gauge length. The flexural properties of Rilsan remained fairly constant with the largest change being a 5.92% increase in flexural strain at strength after gamma irradiation.

The flexural properties of each of the PA11 polymers were affected in the same way, but to a different magnitude. They all experienced a decrease in tensile modulus, an increase in flexural strain at strength, and the flexural strength remained generally unaffected, with the biggest decrease being -4.18%. The magnitude differences were likely due to different amounts of

glass fibre and other additives such as plasticisers which give these polymers their different mechanical properties despite having the same polymer matrix.

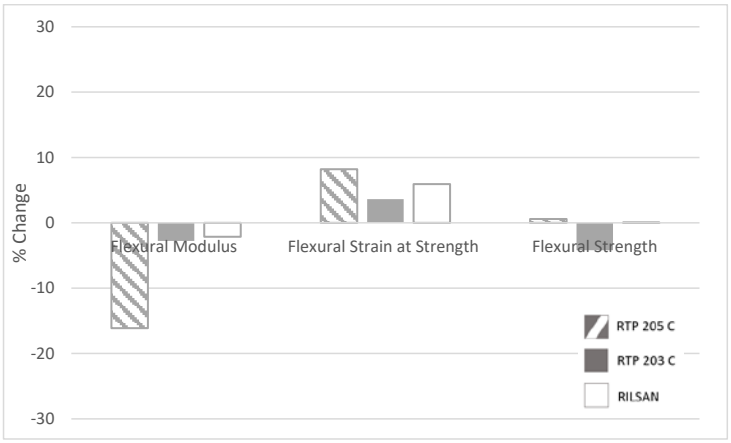

Figure 64. % Change in flexural properties of PA11 polymers after gamma irradiation

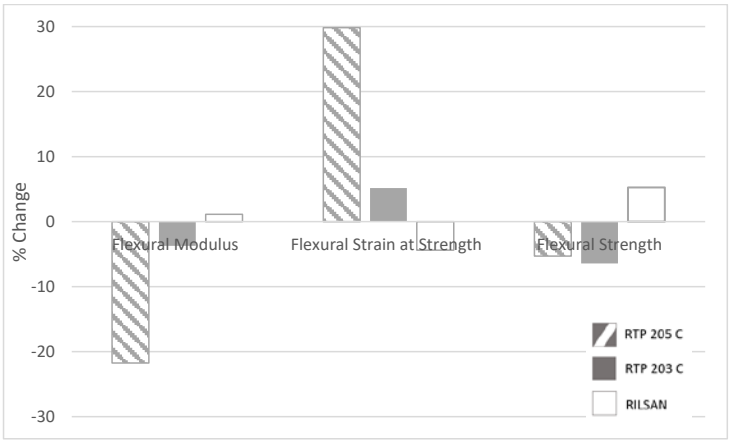

Figure 65. % Change in flexural properties of PA11 polymers after EO sterilisation

5.2. PP

Polymers 5, 8, and 9 are all manufactured from PP; however, they have different types and amounts of fibre. The flexural strain at strength decreased for all three polymers after gamma irradiation but by varying magnitudes. The flexural modulus of all 3 polymers increased by less than 10% and the tensile modulus increased by around 10% for each polymer. However, the tensile strain at break changed considerably and in different ways for each polymer, i.e.

small change, large increase, and large decrease for polymers 5, 8, and 9, respectively. All of the literature surrounding PP suggested that the tensile strain at break would decrease (Figure 23). These results suggest that the fibre type has a larger effect on the tensile strain at break than the other properties.

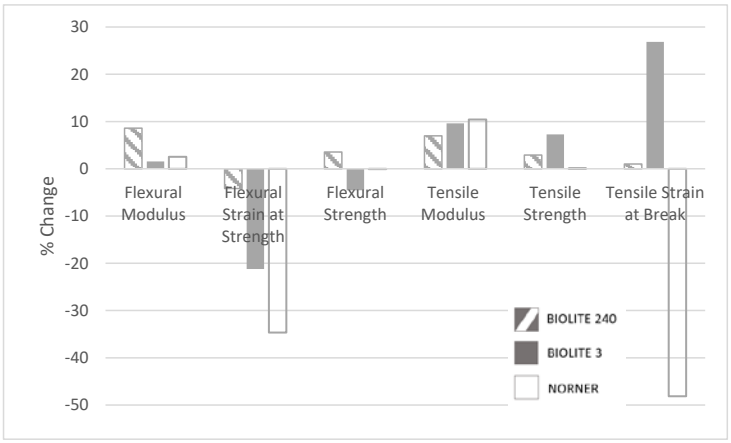

Figure 66. % Change in the mechanical properties of the PP polymers after gamma irradiation

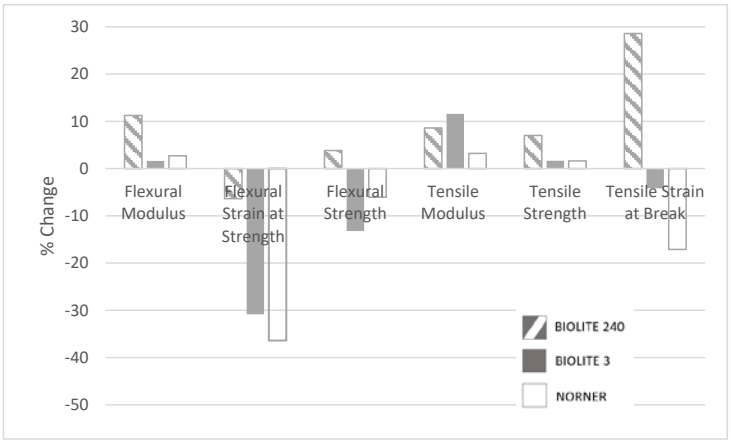

Figure 67. % Change in the mechanical properties of the PP polymers after EO sterilisation

BioLite 240 and Biolite 3 experienced a very similar effect and became more ductile and showed a greater elongation at break during the tensile test. This suggests that a small amount of cross linking occurred – enough to cause the polymer to become more elastic, however, not enough to promote embrittlement.

Norner reacted in accordance with the literature, which suggests that cellulose fibres have little effect on a polymer's resistance to gamma irradiation. The increase in tensile strength and decrease in elasticity suggests that chain scission has occurred, followed by cross linking. The chain scission causes the polymer chains to become shorter, which reduces the flexibility within the chains, and the cross-linking joins adjacent chains, limiting the amount of lateral movement that is possible.

5.3. Other polymers

Magnum showed no statistically significant results, despite a large difference in tensile strain at break, this is due to relatively large standard deviation values of between 2 and 3% for all sterilisation methods. This shows that the polymer has good resistance to both sterilisation methods. Latilon also showed good sterilisation resistance, there was a 3.15% decrease in Youngs Modulus after EO sterilisation however this would not cause a large effect on the polymer's overall performance.

The data sheets suggested that RTP 205 C has a higher tensile strength than RTP 203 C, however this is not what the experimental results showed. Neither polymer achieved the tensile strength value that was provided in the data sheet, (Table 4). This may have affected the agreeance with the material specification could be due to the test speed. The test speed was set at 10mm/min; however, ISO 527 allows a speed between 0.125 and 500 mm/min depending on the material. Therefore, the material specification could have been based off testing at different speeds, however this information is not present on the material specification. Another factor which may have impacted the results is varying fibre orientations, the moulding process causes sheer and elongational flow in the test sample causing the polymer fibres to align, which decreases the effects of the reinforcement [118]. Magnum contains no fibres and produced results most similar to the datasheet (Figure 62) which supports this theory.

There were no consistent trends that could be seen between different polymers, even between those with the same base polymer. This shows that different amounts and types of fibre will react differently to sterilisation. This shows that the reaction cannot be predicted based off of data sheets and material type and therefore testing will need to be completed with future material changes.

5.4. Polymer Replacements

5.4.1. CBR

The material used to manufacture the CBR requires precise mechanical properties, as the material undergoes a large range and magnitude of stresses under its normal operating conditions. It cannot be suggested with confidence that any of the materials tested should replace the current CBR material (Latilon). This is due to a large difference in the flexural and tensile properties in comparison. Figure 72 shows that none of the polymers achieved the same tensile strain at break as Latilon. When the trigger is pulled it exhibits flexural stress onto the inner pin. The flexural strain of RTP 203 C and Latilon are very similar (Figure 73), however the maximum flexural stress is more than 50 N lower. This may affect the polymer's ability to withstand the force of the trigger being pulled. This does not mean that the materials are unsuitable, however more testing will need to be performed on moulded samples.

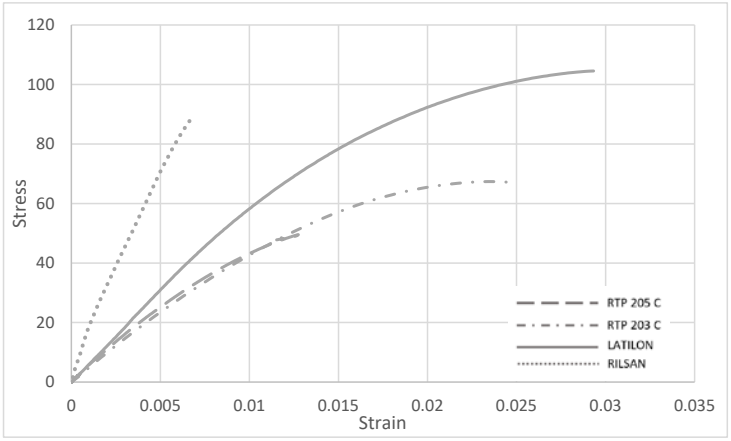

Figure 68. Tensile properties of 3 potential CBR material replacement polymers compared with the current material (Latilon) after gamma irradiation.

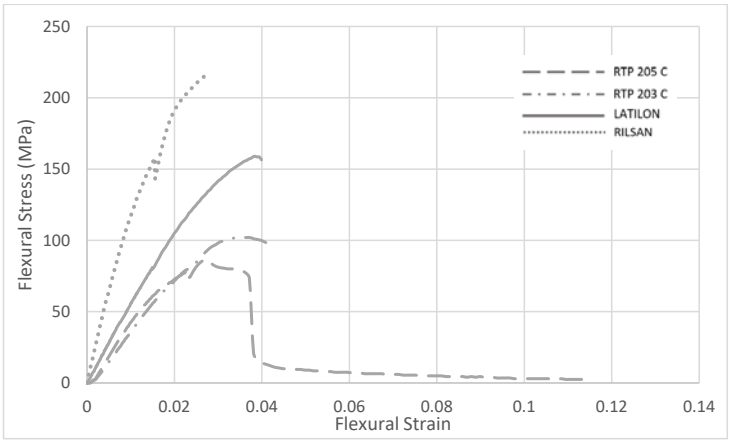

Figure 69. Flexural properties of 3 potential CBR material replacement polymers compared with the current material (Latilon) after gamma irradiation

5.4.2. Ear Specula

The flexural properties are more important when selecting a replacement polymer for the ear specula. This is due to the ear specula needing to withstand enough force not to snap when the slit (Figure 10) is squeezed closed. The ear specula do not undergo any tensile strain under normal operating conditions. Figure 71 shows how the flexural properties of two materials, 7 and 9, compared against the current material, Magnum. The results show that Switch 25 is more similar to the benchmark polymer, as they have very similar yield stress values as well as similar maximum strain values. The tensile properties of Switch 25 also look good, despite the strain at break being much lower, the yield strength is similar, and under normal operating conditions the polymer should not be subjected to forces near to the yield strength. Therefore, Switch 25 is recommended to replace Magnum.

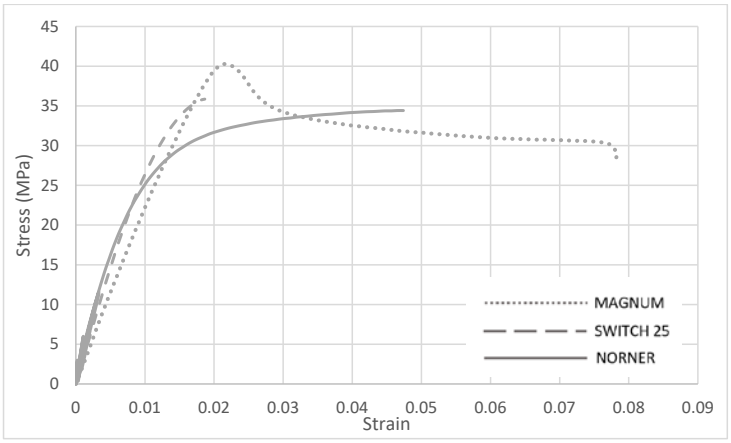

Figure 70. Tensile properties of 2 potential ear specula material replacement polymers compared with the current material (Magnum) after EO sterilisation.

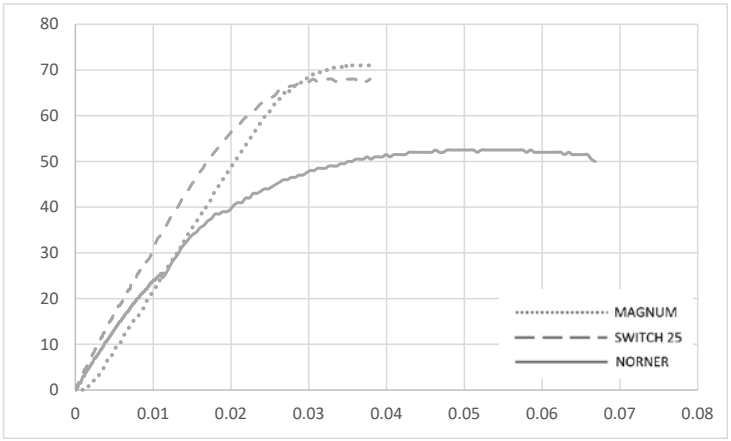

Figure 71. Flexural properties of 2 potential ear specula material replacement polymers compared with the current material (Magnum) after EO sterilisation.

Switch 25 is an environmentally friendly starch based industrial compostable polymer manufactured from renewable resources which has a 75% carbon reduction in comparison to ABS. The plants grown to supply the starch are carbon sequestering throughout their lifetime, and are also a renewable resource, as unlike fossil fuels, they can be replanted after harvesting.

Many of the polymers that were tested were affected in the predicted manner, however the extent of this effect was harder to predict.

This product improvement project was identified manually by stakeholders within DTR Medical and Swansea University. As the mechanical requirements of the products were not stored within the FMEA forms this data had to be pulled from multiple offline data sources i.e. a range of shared and personal drives, and using tacit knowledge from current employees at DTR Medical. The next section explores how this Organisational Knowledge can be better stored to be manipulated automatically, and whether this can streamline similar improvement projects in the future.

Chapter 6 - Organisational Knowledge Management

This section explores the importance of organisational knowledge management within companies, and the time and cost savings that can be made if this is improved. A list of business questions was gathered from current employees of DTR Medical, during the candidate's industry placement, to identify areas where the current OKM within an SME could be improved to increase the day-to-day productivity and satisfaction of these staff members. An overview and appraisal of the recently released AIAG-VDA Failure Mode and Effects Analysis (FMEA) format is also included. Using these business questions and the new FMEA format, entity relationship diagrams using a graphical database methodology were produces for operations that are conducted within this SME. This process led to the creation of an article which describes the mistakes that are commonly made when transitioning between the old and new FMEA format and how these mistakes can be avoided.

The results and lessons learned from the research conducted must be easily accessible to DTR staff. This requires the knowledge gained to be stored in an organised manner in a location where every staff member can locate it. If the information is stored on a local drive (a disconnected data island) then this information will be lost when an employee leaves the organisation or forgotten about over time. Therefore, it is imperative that there are systems and processes in place to ensure effective organisational knowledge management (OKM).

"Organisational knowledge is knowledge specific to the organisation: it is generally gained by experience. It is information that is used and shared to achieve the organisation's objectives." (ISO 9001:2015 7.1.6). The inclusion of organisational knowledge within ISO 9001 highlights how integral organisational knowledge is to a company. The standard goes on to explain how organisational knowledge must be stored, kept up to date and be accessible to anyone who needs access. The primary purpose for the inclusion of organisational knowledge management in the ISO standard is due to the detrimental effect that loss of knowledge has on a company. Companies accrue knowledge over long periods of time, using a range of methods. The loss of organisational knowledge can occur when an experienced employee leaves, or when organisations do not have efficient knowledge management systems in place to enable employees to store and share their personal knowledge effectively [119].

There are three different types of knowledge that are necessary for an organisation to operate effectively.

1. Tacit Knowledge

   Tacit knowledge is gained through experience. It is often intuitive, and difficult to explain to somebody else. Tacit knowledge is the result of having long term knowledgeable employees and would be extremely hard to recover if these employees left the company. An example of this is a person's ability to interpret facial expressions. This skill is personal, developed over time and not easily trained [120]. The most effective method of translating tacit knowledge from one employee to another is through working alongside an expert, such as in apprenticeships or introductory training. These training methods achieve the knowledge transfer through many hours of close contact. However, not all of the expert's tacit knowledge will be transferred [121].

2. Explicit Knowledge

   This is knowledge that is found in documents or databases. Explicit knowledge can be recalled by a large number of employees and remains unaffected by a change in personnel. The primary issue with this type of information is its accessibility. Many organisations have access to far more information than their employees access day to day, primarily because they are not aware that it is being stored, or it cannot be found amongst poorly managed systems [122].

3. Embedded Knowledge

   Embedded knowledge encapsulates implicit, procedural, declarative, and strategic knowledge. The term defines knowledge that embedded into processes, routines, systems, and products. This is the knowledge of when to perform a certain action or the codes of conduct of an organisation.

The main obstacle for companies is enabling as many of their employees as possible to have access to as much information as possible, as quickly as possible. Therefore, documents and data must be organised and managed with clear updates and revisions and be easy to find. This is why organisational knowledge management (OKM) is imperative. A survey conducted in 2004 found that "62% of skilled employees spent a lot of time sifting through irrelevant information to find what they need." This highlights the potential increase in productivity if a

system was implemented in which this information can be easily located [123]. Another study found that over a five-day week poor knowledge management causes a 20% decrease in productivity [123]. This study also found that 69% of people felt frustrated and disappointed by being unable to find relevant information. Improving this by creating an organised, simplified document database would increase job satisfaction levels considerably, and raise morale within the workplace, as well as improving productivity considerably. The improved productivity of highly knowledgeable staff enables innovation and creativity, leading to the creation of high quality, novel products [124].

Another way in which OKM can aid in increasing productivity is in reducing customer support costs. In an unmanaged system, a customer support employee might go through several streams to find out how to deal with a situation. This can be cut significantly with an OKM system where typical complaints and relevant procedures are documented and can be followed easily. This can also be in the form of Frequently Asked Questions (FAQ's) which reduces the time that employees spend answering simple and common questions, which frees up their time to deal with more complex problems. OKM systems can also provide quick access to a customer's history with the company, a customer service operative knowing this information will make the customer feel more valued by a company and which improves the relationship between the customer and organisation. It also allows the organisation to track customer needs as they change, in order to generate maximum profit [125].

These advantages show how the tacit, explicit, and embedded knowledge stored within a company have the ability create a competitive advantage for organisations. If this knowledge is efficiently organised and managed this will enable customers to receive more efficient service and are perceive an organisation as being more knowledgeable which will drive sales [126].

An effective knowledge management system should [119]:

1) Ensure that all of the knowledge necessary for the everyday operations of a business can be stored. This should be based on customer requirements and expectations as well as identifying the information, training, and knowledge that employees must have access to in order to perform their jobs efficiently.

2) Maintain and update knowledge. This is best achieved in a culture where employees are encouraged and willing to share their own tacit knowledge with their colleagues.

This also requires an easily navigated database where data is accessible and easy to locate.

3) Identify knowledge gaps. The changing needs and trends of knowledge should be identified, if there has been any new training then this will need to be documented and shared with those who it will benefit. This should also include how information will be translated from training or procedures to documented information e.g. interviews, audits.

One tool that requires good organisational knowledge management is Enterprise Resource Planning (ERP). ERP systems allow organisations to oversee their purchasing, accounts, manufacturing, and logistics functions [127]. This system aids in decision making and planning. ERP is able to forecast the resources required to meet demand. This improves customer relationships as an organisation can be sure to be able to fulfil an order [128]. It also improves inventory costs by 20-30% as an organisation is not having to hold large quantities of material in case a large order comes in, or through over ordering [129].

ERP systems are very costly and take a large degree of expertise to implement. These systems need to have access to all of the relevant information to make the best business decisions. If a company's organisational knowledge management is poor then they may not get the most out of the ERP system, which will decrease the return on investment considerably [129].

To ensure that the ERP system is as effective as possible it requires continual maintenance. Documents and data need to be written in a specific format, with old documents being converted into the new format. The chosen ERP system must also be suitable for the organisation. There are many different types of ERP system, and organisations selecting the incorrect one for their needs is the primary reason why many ERP systems fail [129].

ERP systems evolved from Materials Requirement Planning (MRP) systems. MRP systems focus on the materials required for production to meet demand, this reduces product lead times as there is no delay before production whilst waiting for materials. MRP systems bring the same benefits as ERP systems do regarding inventory and raw materials, such as reducing the inventory costs and reducing the risk of human error when ordering raw material for production, which could ordinarily lead to ordering too much, not enough or forgetting to order raw material altogether. This makes it easier for SME's to produce a larger range of products whilst keeping customers satisfied with short delivery times [130].

ERP and MRP systems also aid in risk management by automating some of the processes and data gathering that occurs within an organisation.

6.1.1. Implementation within DTR Medical

The following sections report on the candidate's experiences when implementing various OKM techniques within DTR Medical. Information was collected from employees within the company over a yearlong work placement such as the business questions in section 6.1.2. Examples are created using scenarios that are realistic for the organisation to enable stakeholders to visualise the benefits of the work. The FMEA system discussed later in the chapter was implemented within the organisation by the candidate as a proof of concept, which can be continued and improved using more advanced systems, eventually enabling automation in the future. The candidate populated multiple FMEAs for DTR Medical in the new format discussed in 6.3.1, to assess the ability to automate such processes. This experience enabled the five mistakes of writing FMEA's to be developed.

6.1.2. Business Questions

A list of 50 business questions (Table 24.) were gathered by the candidate, from current staff at DTR Medical during industry placement, which will each help to improve the productivity of at least one department. These questions can currently be answered by staff members manually; however, it is often extremely time consuming and difficult to find the information. A study found that employees spent an average of more than one working day (9 hours 40 minutes) looking for information per week [123]. Therefore, having a system that can identify where this information is stored and provide staff with this information is extremely valuable to the company.

If an ERP system is implemented and FMEA forms are completed in line with the new guidelines discussed in section 6.3, and in as much detail as possible, then the information system will be able to answer a wide range of business questions, including the following:

Table 20. Table showing business questions (black) and possible answers (blue). The left-hand side column shows questions answerable by the FMEA system. The right-hand side column shows questions answerable using the ERP system.

OT - FMEA (Knowledge Pool)	IT - ERP (Connected Data Islands)

- When will machine A need maintenance? Generates a date or possibly past maintenance records - What are the possible reasons for the rejection percentage of Product A? - How many units of product A have been reworked? List of number of products and reason for reworking - When was product A last rejected for reason X? Number of products rejected for that reason with dates and supplier info. - What are the design specifications for tolerances/dimensions of product B? Drawing of product, upper and lower limits for key dimensions - What was the percentage of rejects from supplier X for reason A in the last year? Number with option to create report of all reject reasons with percentages from one supplier over the last year - Has fault A ever occurred before with product B? Reasons for the fault. Report detailing previous faults with highlighted similar defects to the one in the question - What are possible root causes for customer complaint A? Report of relevant Process/Design FMEA fields including detection failures - What are the possible risks associated with defect X? Report of relevant Design FMEA fields - What information do we have on material A? Document with relevant information is presented, possibly with relevant lines reported too - What is the description/function of product A? Product description is generated	- How many units of ZMED1234 are in incoming goods? Generates a number - How many of product A were delivered yesterday? Number generated - What is the rejection percentage of product A? Graph/chart of products rejected/accepted, breakdown of reasons for rejection - How many boxes of product B are in finished goods? Number and locations - Which products are currently being sterilized? List/report of all products current at sterilization and which method, with their expected return date - What ZMED's of material A are currently in the clean room? How many of each? List of GRN's and quantities of units - Is product B currently in stock? Stock quantities and locations - What is the current location of product A? Shelf number and quantity present - Which products are in shelf location X? All products listed that are in given location - Does order X need 1st or 2nd class delivery? Delivery details, 1st or 2nd class - How many units of product X are expected to be delivered today? Number of units/boxes - How many units of product X are on back order? Number of units, cost of units, time on back order in a report/table, how long it's been there, reason for shortage - When is product B likely to be ordered? Date and likely customer and quantity that they ordered last time, report/table

- What is the product code (ZMED) of product A? ZMED generated - What stage is project A in? Current status and person responsible. Report of previous stages and who completed them - How effective was a change to process/design? Statistical data for before and after change occurs. Taking into account all changes that occur simultaneously. - Where can information on bioburden for material X be found? Document with relevant information is presented, possibly with relevant lines reported too	- When is customer A likely to place another order? Date and past order information - How many orders have customer B placed in the last 3 years? What did they order? Report/spreadsheet of past orders from one customer and price/dates/product details - How many of product A were sold last year? Table with number of units, customers, month by month breakdown - What is the forecast of sales for product A over the next year? Table with number of units, customers, month by month breakdown - What is the total number of deliveries from supplier X last year? Total number presented first, option to create report of all deliveries and dates - When can customer A expect their order? Date and order details - What is the current wait time for product X? Wait time for products, any reasons for hold up - What is the price of product X? Pricing information (Number from price list) - What is the price difference between products A and B? Price of product A and price of product B are shown - When was customer B last approached about ordering? Report of last contact and any notes recorded from meeting about potential purchase times.

These questions can increase the safety and productivity of an organisation, such as eradicating or significantly reducing machine downtime, as maintenance will be conducted before a machine fails. This is considerably more efficient than waiting for a machine to fail, identifying the problem, then waiting for the repairs to be conducted. This system will also enable a faster

investigation process if the product fails in the field. The user can identify any history and then find possible root causes for a defect quickly and address these problems. This will decrease the amount of time a customer is waiting, as well as the time that the product production/distribution is paused for. This will also increase the safety aspects, as all risks can be assessed immediately. The design/improvement process will also be accelerated, where similar materials can be selected with full knowledge of the details. This also improves the efficiency of writing reports for biocompatibility and ensures that products are being stored in correct conditions.

Some of the questions are likely to be asked by a warehouse operative, as they will save a large amount of time looking for items which may or may not be in the last recorded location on a paper-based system. They will instantly be able to check where a product is located, the quantity of products there and the status of that product. This also improves product traceability in case of any customer complaints. They can also instantly find delivery details to ensure each product is sent to the right place in the correct number of days. This will maintain and improve positive customer relationships.

A sales staff member might want to ask the system whether a product is in stock before they recommend it to a customer, or to recommend likely wait times. Production staff might want to ask these questions so they know how many more of this product must be manufactured to satisfy current orders or the monthly forecast of orders. This will decrease customer wait times and create a more transparent working environment where all staff can identify the status of products and there is no confusion.

Production staff will benefit from this system as they are able to ensure that they have material or products in stock to fulfil likely orders. It also enables sales representatives to contact customers in the most efficient way i.e. when they are likely to order. The system will also improve customer relationships as they will receive accurate wait times and can make informed decisions on whether to place an order or not. This will reduce customer frustration with long wait times and decrease the number of cancelled orders.

As well as creating a more productive and therefore satisfying environment for staff members, this system will also enhance the customers' experience of dealing with an organisation. Having quick, concise answers to questions will improve their impression of an organisation and make them more likely to deal with them again in the future.

A system is proposed in which an organisation can utilise the FMEA software discussed previously alongside their existing ERP system to aid staff in their everyday working lives. The ERP system will organise and oversee the operations at the company, including sales, finance, business insights, material inventory management costs and more. Meanwhile the FMEA system discussed will assist with access to product specifications, processes, and storage conditions, as well as process work elements and their failures.

Together these databases will pool all of the organisation knowledge management together to create an information hub. This information hub will enable a more transparent working environment where staff can answer important business questions rapidly. The data to answer any of these questions can be found in either the ERP system or the FMEA system.

In the early stages of the hybrid system, the user interface will have click buttons and drop-down menus to enable the information to be accessed. However, in the future this proof-of-concept system will be able to be adapted and built upon. This can incorporate machine learning and automation. This software will be capable of scanning an FMEA form to identify any processes or design features that can be improved upon. This information can also be extracted from emails and published articles to keep up to date with all information as it emerges. The system will suggest areas for improvement, such as a high-risk process, or a new material emerging within scholarly articles which meets the requirements for the device. This eradicates the need for an employee to identify areas of research and spending time on these without knowledge that new research or regulations have emerged.

6.2. Graphical vs Relational Databases

A database is a structure that is used to store data in an organised manner. Modern databases are electronic. The purpose of a database is to allow data within a large data set to be located and used for modelling and design and decision-making purposes [147].

Flat-file databases are in a tabular format, which are comprised of rows and columns. Each column represents a ‘field’. These fields are a piece of information about one entity. An entity can be a person, process, product etc. One row of the database is known as a record [147]. The order of the records within the table are not relevant and can be re-ordered without impacting the data [11]. This is because the data is located by the value, not the location of the entry. The same is true for the order of the fields within the database [148].

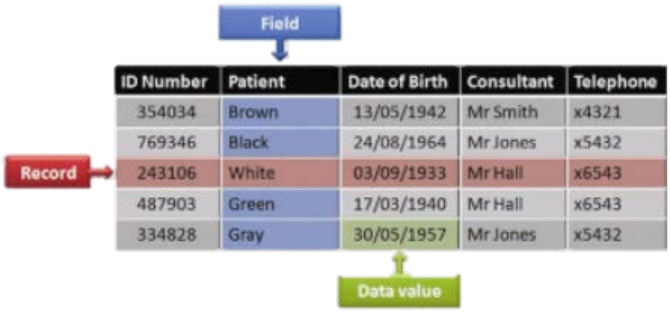

Figure 72. Structure of a table within a flat-file database [147]

More commonly data is gathered and stored within relational databases. A relational database consists of multiple different flat-file databases which are connected by relationships. While one table will hold information about one type of entity, having multiple related tables allows many different types of entity to be related. This type of database allows a vast array of knowledge to be stored within them. [147]

One advantage of relational databases is the ease of which they can be converted into forms. As the data is all clearly labelled and the relationships are linear, programs can extract the information from a form and insert it into a template with ease. This is often accomplished using Structured Query Language (SQL) [147].

SQL is a method of using a series of hierarchical commands to create a complex query using a simple process. It is currently the industry standard method of manipulating relational databases [149]. SQL uses three components: keywords, identifiers, and literals. Traditionally represented in upper case, keywords use verb commands such as SELECT, UPDATE, and DELETE. An identifier is the name of one of the tables, entities, or records that make up the database. An identifier can also be a specific cell. Finally, literals are the specific values that the keyword is trying to act upon. This could be the specific value that the operator wishes to find or delete [10]. This allows the operator to easily manipulate the dataset in a large variety of different ways using combinations of keywords, identifiers, and literals. They can also be compounded using keywords such as AND and OR [150].

A restriction of relational databases is that each field in the database, the information must be presented as a single datatype. This cannot be mixed, otherwise an error will occur [10]. This includes missing values. If a dataset is incomplete, then an error may occur. Similarly, the table

size must be set when constructing the database, therefore if a dataset exceeds the designated length, then an error will occur, or data will be lost. They have been observed to perform well with up to 1000 records [151]. This inhibits its use in many real-life situations as commonly organisations do not have complete data sets. Another drawback is that relational databases often cannot process complex images.

One way to overcome the hurdle of storing big data is to use an alternate form of data storage - a graphical database. Graphs contain edges, which represent the relationship between two nodes. The relationship can be in one direction or in both directions [152]. Nodes in a graph represent the entity that is being described. This format is ideal to visualise complex structured with many different relationships and entities. These graphs can quickly become extremely large and can often be three dimensional [12].

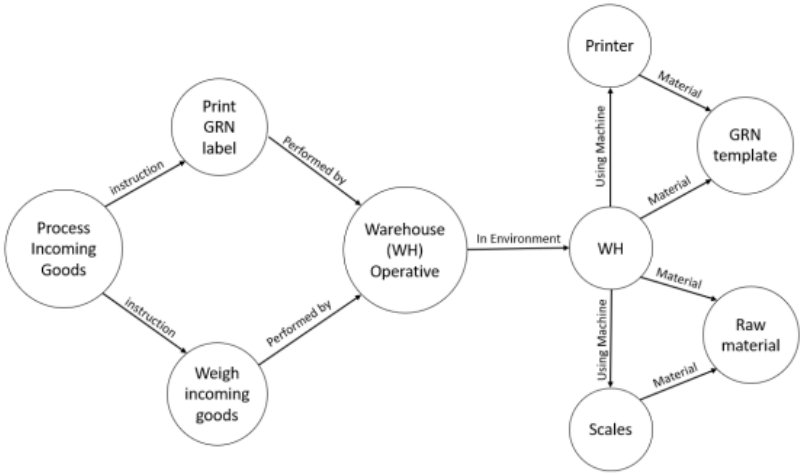

Figure 73. Structure of a graph database (Circles are nodes/entities, lines/arrows are edges/relationships) using process steps from DTR Medical [152]

Graphical databases are more efficient at answering queries when dealing with big data. This is because the system does not need to interpret all of the data, just the localised selection of nodes that are required to answer the specific query [152]. Another advantage is the ability to add data and relationships during and at the later stages of the construction process. To adapt a

relational database, the system must often be taken offline and the whole database must be restructured to accommodate a new relationship or record [152].

Figure 73 was created by the candidate to demonstrate how the processes and work instructions within an organisation can be represented as entities and relationships. This allows this knowledge to be stored on a graph database. Storing information in this way allows specific queries to be answered quickly. Hence, using a graphical database to encode organisational knowledge within entity relationship diagrams will enable the business questions (*Table 24*) to be answered.

6.3. Risk Management

Risk management systems are tools used to evaluate risks associated with health, safety, environment, security, and ethics, and assess ways in which to reduce these risks. Risk management systems often must adhere to international standards, such as ISO 9001 [131].

As technology becomes more advanced, customers' expectations increase. With many customers no longer willing to accept and rework faulty goods it is imperative that as many potential causes of failure are mitigated [132]. Another reason that risk management tools are of extreme importance is that should a product fail, the liability is with the manufacturer. This can incur large costs, both financially, legally and on an organisation's reputation. This strict liability is due to four policy considerations: [133]

- Risk Spreading: If losses are incurred, a manufacturer will need to increase the price of all of the products.
- Cost Incentive: Higher prices caused by risk spreading must be reduced so that an organisation can maintain competitive pricing. This drives the motivation of creating safer products and more stable processes.
- Customer Protection: Customers purchasing products should be protected from risks even if they are unaware of them.
- Proof Problems: The difficulties in proving whether a fault was caused by an operator, or a product defect previously led to many manufacturers avoiding responsibility. This is overcome by stricter laws surrounding liability – placing it on the manufacturer.

A business model centred around risk management not only improves on the health and safety within the organisation but can also drive profits through continuous process improvement. One such model is the Six Sigma methodology.

Six Sigma is a term used within the manufacturing industry to describe the model of using process performance data and statistics to drive process improvement with the goal of moving towards a six-sigma process. The name six-sigma comes from the standard deviation symbol 'sigma' (σ). The standard deviation quantifies how much the values in a dataset vary from the mean. A lower standard deviation signifies that the values within the dataset are closer to the mean. The number preceding σ signifies that system will operate within that many multiplications from the mean in the maximum and minimum directions.

In manufacturing, the sigma level can be equated to a number of defects within a million products for any operation. In a six-sigma process, out of every million products produced, 3.4 will be defective. The sigma capability of a six-sigma process is 99.99966%, if this were to drop below this level, to 99.9% this would mean that 5000 incorrect surgical procedures are taking place each week. This highlights the importance of achieving a six-sigma process and adopting this model for process improvement [134].

Benefits of applying Six-Sigma are [134]:

- Improved employee satisfaction
- Process efficiency (decreased cycle time)
- Less waste (fewer defective products due to improves process capability)
- Statistical indications and justifications for business decisions
- Decrease health and safety risks within the workplace

Each of these benefits will lead to an increase in profit margin, creating a return on investment on any expenditure caused when transitioning to the Six Sigma methodology. *Table 20* shows the 12-step process of Six Sigma.

Table 21. 12 Step process of Six Sigma recreated from [134]

Phase	*Step*
Define and Measure	1) Select product or process critical to quality characteristics

	2) Define performance standard
	3) Validate measurement system
	4) Establish process capability
Analyse	5) Define improvement objectives
	6) Identify variation sources
	7) Screen potential causes for change and identify the vital few
Improve	8) Discover variable relationships between vital few
	9) Establish operating tolerances on vital few
	10) Validate measurement system for vital few
Control	11) Determine ability to control vital few
	12) Implement process control system on vital few

The term Six Sigma was taken from the description of a process that is believes to have adequate process stability. This can be calculated using Statistical Process Control (SPC) [134].

An SPC determines the likelihood of a product conformity from a given process. Variability within a process is unavoidable, some variation is a natural part of a system and is generally repetitive and stable, these are known as ‘common causes’ and are generally accepted by the SPC as they are expected. On the other hand, ‘special causes’ are unforeseen events that occur outside of the common causes. They are an indication of a process or system fault which must be corrected, as they often cause non-conformities within a product/process [2]. It is important that the causes are correctly defined so that the process can be correctly and effectively controlled and improved. If the system begins to move towards the boundaries of the specification and the product is at risk of no longer conforming, then the SPC will recognise this and should give a signal. This system works continuously to reduce the amount of variation that is found in a process or design using two phases [135]. The first phase in SPC is focussed on gaining a better understanding of a specific process and evaluating how stable that process is. The second phase involves identifying any possible causes of the variation so that these can be eradicated, minimised, or controlled to increase the stability of the process [136]. A stable process is a process that is in statistical control, meaning that the variation due to special causes have been eradicated. Visually this is represented by no points being outside of the control limits on a control chart [137].

To achieve a detection rating of ≤3 then the SPC must provide a Process Capability Index (Cpk) value of ≥1.33. The Cp compares the actual spread of data generated by a process and the allowed spread of data generated by process. The lower that the Cp value is, the more variation there is present within a process and therefore it is less stable, and the process capability is lower [136]. The Cpk is the Cp centred on the mean. This value is determined by:

$$Cpk = \min(Cpu, Cpl) \tag{10}$$

$$Cpu = \frac{USL - \bar{\bar{X}}}{3\sigma} \tag{11}$$

$$Cpl = \frac{\bar{\bar{X}} - LSL}{3\sigma} \tag{12}$$

Where USL is the upper specification limit, LSL is the lower specification limit, $\bar{\bar{X}}$ is the mean and σ is the standard deviation. Cpu and Cpl represent the upper and lower capabilities, respectively. The standard deviation is estimated from a control chart, and not calculated using the traditional formula. The upper and lower specification limits are set by the customer requirement, an example of this is the tolerances that are allowed regarding specific dimensions [137]. A larger Cpk value is more desirable, with an index of 1-1.33 being adequate for most customers, as a variability of ±4σ is allowed without causing a non-conformity (Figure 74) [138]. A Cpk of <1 is considered inadequate whilst a Cpk of > 1.67 is considered to be excellent [136]. Process with a Cpk of 1 is known as a six-sigma process. This is where there are 6 standard deviations between the Upper Capability Limit (UCL) and Lower Capability Limit (LCL) Figure 74. The UCL and LCL are the actual upper and limits achieved by a process [136].

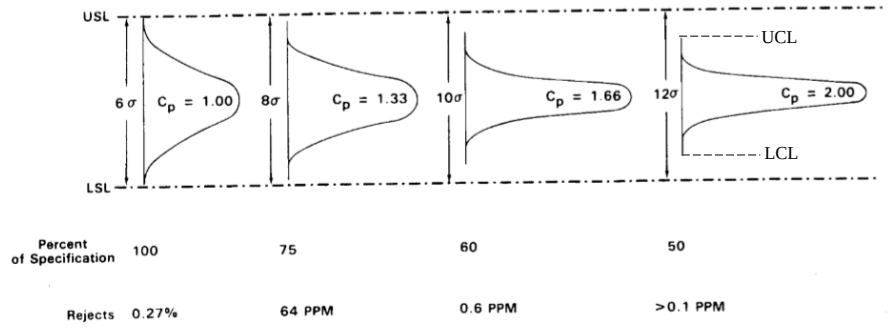

Figure 74. Cp Indices for Varying Widths of the Process Distribution [138]

To evaluate the risks associated with a process which may lead to statistically unstable or unsafe processes organisations use a risk management technique originating from the military industry, then expanding across a wide range of industries, called Failure Mode and Effect Analysis (FMEA). FMEA is used to identify and assess potential risks within a system, process, or design, and to identify methods to prevent or detect these risks. This analysis technique became commonly used within most manufacturing industries, particularly the automotive industry [139]. This tool can be utilised to aid an organisation in achieving six-sigma by storing detailed information about a product or process and the potential risks associated with them. Process or design improvements can then be made to reduce any risks where possible and increase the Cpk value.

6.3.1. FMEA

In 1993 the Automotive Industry Action Group (AIAG) published an FMEA process, and a supporting manual which can be followed during use. This was the most widely accepted method in most of the world until 2019. The AIAG FMEA method uses a failure cause, failure mode, and failure effect. Failure mode describes how a system can fail, the failure cause describes why the system failed, and the failure effect describes the pain that is felt as a result of a failure mode [132]. The German Automotive Association (VDA) also created an FMEA system which was generally used by suppliers to Germany. This method uses a hierarchical model of system, function, and failure. The contrast between the two methods caused confusion within companies supplying to both sectors, and so a harmonized version was created.

6.3.1.9. AIAG-VDA Format

In 2019 the AIAG and VDA fused their FMEA systems to create a universal standard [2]. The result was a seven-step process:

1. Scope
2. Structure Analysis
3. Function Analysis
4. Failure Analysis
5. Risk Analysis
6. Optimisation
7. Documentation

This chapter discusses the process FMEA's (PFMEA) and design FMEA (DFMEA) reports. They both have the same seven step process, and three tier structures, however the contents of the tiers differ between the two types of FMEA.

Current FMEA's are time-consuming documents to complete and are often composed after the design or process has already been implemented. They are also typically treated solely as a customer requirement, rather than a useful tool in the design process. Generally, faults are found with designs and process when they are trialled such as a sample being created. This is much less cost effective than if the FMEA tool is used to evaluate a design before this stage and usually leads to product launch delays [140]. Documents using the AIAG-VDA format are intended to be treated as live documents which are constantly being updated. Being completed alongside the design process, FMEA forms should be continuously running alongside the project, being revisited with any design changes.

The initial FMEA process should be completed early in the product timeline, before large scale production commences. This allows a development team to assess any risks with the design and adapt the design accordingly before any physical products or tools have been manufactured. FMEA documents also allow full transparency of the design and manufacturing process to enable the cause of any failures which lead to customer complaints to be identified and addressed. This negates the need for trial and error, which increases efficiency as a money and time saving tool [140].

1. **Scope**

This is the project planning step, which involves five T's. It allows the team to plan each aspect of the project comprehensively, determine roles and deadlines, and ensure all necessary tools/resources are available.

Table 22. Five T's in the Scope of the AIAG-VDA FMEA.

InTent	*Task*	*Team*	*Time*	*Tools*
The objective or favourable outcome of the project using measurable terms where possible.	Tasks that need to be completed during the project.	The personnel involved with completing each task.	Target start and completion dates for the project and each task.	Tools and resources that will be used throughout the project.

These five steps ensure that each member of the team is aware of their own responsibilities and targets, as well as their colleagues. This also enables accountability after the process, so each part can be tracked back to an individual if any further work is required. [2]

2. **Structure Analysis**

Process FMEA

This involves a Process Item (PI), Process Step (PS) and a Process Work Element (PWE).

The PI is the name of the overall process, this is the highest in the hierarchical system. This is often a broad description which encapsulates many other tasks. An example is "product assembly". This item will incorporate many other steps to achieve its aim.

PS is the next constituent which is the name of each process within the PI. These will often have an operation number. This step will generally include each department or area within an organisation as each department will typically complete one process step at a time.

The lowest tier is the PWE, which describes how a PS is completed. This step must be described using the 4 M's (Person (Man), Environment (Milieu), Material, Machine), and they must be a single action. Since many PS's involve multiple steps, there can be multiple PWE's for each PS. This creates a branch like structure. Each PWE should be described using an active verb-noun combination.

Table 23. Structure Analysis of an AIAG-VDA PFMEA using process items, steps and work elements from DTR Medical, adapted into AIAG-VDA format using the manual. OP signifies the operation number that is currently used at DTR Medical.

Process Item	*Process Step*	*Process Work Element*
Product Assembly	OP-50 Production	Place products in pouch Person – Clean room operative Env – Clean room Material – Product Pouch Machine – Manual Operation
		Seal pouch Person – Clean room operative Env – Clean room Material – Product Pouch Machine – Heat Sealer
		Place pouch in box Person – Clean room operative Env – Clean room Material – Product Pouch, Cardboard box Machine – Manual Operation

Design FMEA

Similar to the process FMEA, the design FMEA (DFMEA) uses the three-tiered approach where instead of process item, process step and process work element, the tiers are the next higher element, the focus element, and the next lower element.

The next higher element describes the customer requirement, without focussing on the specific components of the device. This will tell the design team what the general product is that they will be designing from a top-level point of view. The focus element is each component or part of the device. In the vast majority of devices there are multiple focus elements which are assembled to complete the next higher element. The next lower element states the specific details of the focus element. There are four categories of next lower elements: dimensions, material, surface, appearance. Each next lower element should detail each of these categories

in order for the FMEA form to be complete. These next lower element characteristics lead to the root causes of the device failure. [2]

3. Function Analysis

PFMEA

This step describes the function of the three elements from the structure analysis. The process item function should be categorised as: In Plant, Ship to Plant, and End User. The In Plant stage describes the function of the process item in the company that are creatin the FMEA. Ship to Plant is the function of a process item at any plants further downstream. Many products pass through multiple plants before they reach the end user and are used and adapted each time. The end user is the final customer who will be using the completed product for its intended purpose. An example of this is the driver of a car. The process step function should describe how the process step is completed, as well as the specification and conditions for the process step. The process work element function should incorporate all of the work instructions and safety instructions.

DFMEA

The next higher element function describes the function of the whole device, from a customer point of view, and explains what problem the device is being designed to solve.

The focus element function describes the function of the specific component, from a design point of view. It explains why that component has been chosen and what its purpose within the assembled device is.

The next lower-level element function describes the why the specific characteristics of the focus element have been chosen, and why that makes it appropriate for its function. For example, why a tube needs to be 4 mm diameter instead of 6 mm. [2]

4. Failure Analysis

PFMEA

This step describes how each of the process functions can fail. Similar to the process item function, the process item function failure is categorised as In Plant, Ship to Plant, and End User. This step describes what happens when the failure reaches further downstream. A failure

in plant could cause a line shutdown, however a failure at the end user could cause serious injury to the customer.

The failure of the process step function describes how the process step failed whilst the failure of the process work element function explains why the process work element function failed. Therefore, the PWE function failure is the root cause of the failure of the process.

DFMEA

Similarly, the failure steps in the DFMEA describe how each tier can fail. The higher-level element failure describes how the whole device can fail, and how the customer need has not been met. The focus element function describes how a single component can fail, and what might happen if the specific dimensions, material, appearance, and surface finish criteria are not met. [2]

5. Risk Analysis

PFMEA

Risk analysis assesses the severity of a process item function failure. It is assigned a value between 1 and 10, with 1 representing that there will be no discernible effect, and 10 showing that the failure of the process can cause harm to an operator or will breach regulations.

The prevention actions explain how the failure occurring can be prevented. The occurrence rating grades the effectiveness of this prevention method, from 1-10 where 1 is a highly effective technical prevention method, and 10 is no prevention method in place. As well as technical prevention methods, behavioural ones can also be put in place, these have a higher occurrence rating as there is a higher likelihood of error.

The detection step includes any type of inspection where defects on a product are found, these can be visual, sensory, or functionality tests. Using a machine based automated detection can improve the detection rating to as low as 2, from the lowest human inspection rating of 6. This is due to human inspectors often working for many hours, performing repetitive tasks, this can cause fatigue and general human error to allow a defective product to progress along the supply chain. Differences in the opinions of staff regarding whether a particular defect would cause a product to fail, or whether the defect is severe enough, can also cause discrepancies within batches [141]. In the medical device industry, this can have an extremely high severity or serious harm to the user or patient.

Detection techniques are systems that are in place to detect any errors such as inspection. These are also numerically rated from 1-10 with 1 being a 100% automatic inspection system and 10 being a system where there is no inspection system. To enable the detection rating to be lowered to a 5 or below, a SPC system must be in place.

These scores are combined using a matrix to give the action priority (AP) rating. The matrix first considers the severity, this has the most weighting on the final AP. A risk that is classified as a 9 or 10 can only be assigned a low action priority is the occurrence and detection ratings are extremely lol (1-3). It then takes into account the likelihood of occurrence, and then the detection rating is considered last and has the least impact. The AP is classified as high, medium, or low. High AP states that there must be further steps taken to reduce the risk, or the lack of action must be justified using relevant supporting documents. The medium AP states that action should be taken or justified, and low action priority shows that action to reduce risk could be taken. The reason for the AP rating is to allow the team to identify which risks to focus on first, due to resourcing and time constraints making it difficult to evaluate all of the possible risks [2].

DFMEA

The risks associated with the DFMEA assess the severity of the failure of the focus element. This explains what the pain felt by the customer would be, this is also graded from 1-10 with 10 being that the failure affects the safe function of the device, 5 meaning that there is a degradation of convenience function and 1 being no discernible effect.

The prevention action explains how the failure can be prevented, and this is graded with an occurrence rating, also from 1-10. With 10 showing that there are no preventative controls, this is the first application of the technology, and that standards and best practices do not exist. 1 represents that there is no possibility of failure due to preventative control and failure free history, the design is identical to another that has a failure free production, and the design is proven to conform to standards and best practices.

Detection methods are those in place to find the failures when they are not prevented. This is graded from 1-10 where 10 is that there is no test procedure, or the procedure is not capable of detecting a failure prior to design delivery, and 1 represents detection causes that have previously been validated. [2]

The action priority rating for the DFMEA forms is identical to that of the PFMEA forms.

6. Optimisation

The optimisation stage is where any investigations or improvement actions are logged. This section logs the status of the report, any target start and completion dates for improvement actions, and the person responsible for those improvements which provides full clarity on the process.

The status can be open, decision pending, implementation pending, completed, or not implemented. These actions can only be closed once they have been reviewed and the action priority has been reduced as much as possible.

Improvement actions take place to suggest new detection or prevention actions, therefore lowering the detection or prevention ratings. The severity rating should not change, as the failure remains the same. There should be evidence of any actions taken which is logged in this section.

After the improvement actions the revised severity occurrence and detection rating are rated, and the process step function is given a second action priority rating. At this point there is also a section to justify any actions taken, and detail any remarks or lessons learnt. This enables colleagues to have full clarity when updating the report. [2]

7. Documentation

This step is the documentation of the results from any investigation, any relevant reports, or standards, and the FMEA's themselves.

An FMEA report must then be generated which will include a summary of the scope of the project and whether the procedure differed from the planned scope. This should comment on the accuracy of the 5 T's, for example, if the project overran, if any additional colleagues participated. The report should also provide a summary of how functions were determined and show the rating justification tables for each of the severity, occurrence, detection, and action priority. A summary of high priority failures and actions that have been taken or planned to mitigate them should be included, as well as the status of all actions. Finally, the report should

include a plan for ongoing FMEA improvements, including anything that has gone wrong in the FMEA writing process so that future risk management is a smoother process. [2]

AIAG-VDA Appraisal

Table 24. Advantages and disadvantages of AIAG-VDA FMEA format

Advantages	*Disadvantages*
AP number prioritises severity then occurrence then detection	60% longer to create [142]
More rigid S, O, D ratings	More complex
More robust system (4 M's)	Not suitable for Excel format
Optimisation is documented and traceable	Primarily used for automotive industry

Advantages

The AIAG method uses a risk priority number (RPN) to grade the risk of a particular feature. This is calculated using S*O*D. The way that this number is calculated means that there is equal weighting on the severity occurrence and detection. Therefore, a risk with a low severity, but high occurrence and detection could be weighed equally to a risk with high severity and occurrence but lower detection. In contrast the AIAG-VDA method classifies the failure using an AP, which uses a matrix that treats the severity with the most impact, followed by the occurrence, and finally the detection rating with the lowest impact. This is due to the fact that if a failure is extremely severe, but it is not very likely to occur and will be detected 100% of the time is less of a problem than a failure which is not as severe but is very likely and impossible to detect. Using this matrix, it is easier to prioritise which risks should be mitigated first. The AP classifies the need for action, rather than whether the risk is high, medium, or low.

The severity, occurrence, and detection ratings in the AIAG format are easily manipulated and open to interpretation. The new guidelines offer a must more rigid scoring justification, so that numbers cannot be reduced to enable a failure to be accepted.

The AIAG-VDA system uses a system with 6 M's. These are the environment (milieu), person (man), machine, material, measurement, and method. All of these 6 M's for each product and

process are discussed in either the DFMEA or PFMEA. This enables the failures associated with each of these aspects to be identified, which creates a much more robust system. One disadvantage of this system is that the root cause might not be found, however it is recommended to find the root cause of any errors/defects which might arise from failures relating to any of these 6 M's [142]. This creates a much larger list of potential errors and root causes.

The optimisation section is more detailed in the new system, the status enables anybody viewing the document to identify which stage it is in and recognise who is responsible for any investigations or improvements. The documentation section requires a summarising report to be completed. Together these documents improve the transparency and traceability of the whole FMEA process. It also enables constant improvement of the FMEA process using the lessons learnt feature.

Disadvantages

The new format reportedly takes 60% longer to complete than the previous format. Partly due to the larger number of steps involved and the report writing process at the end. The complexity of the forms also contributes to this, as initially the AIAG-VDA format is hard to complete without making mistakes and takes time to form a habit of writing in the correct language. Therefore, this 60% extra time may be decreased when this format is more commonly used. Another consideration should be that despite the extra time being spent on the FMEA, if this ensures that the process and design are evaluated fully, the time spent correcting/investigating errors after the technical release will be eradicated.

The AIAG format can be completed comprehensively using Microsoft Excel, as the item, mode, cause, and effect can be followed linearly from left to right. However, as discussed, the AIAG-VDA format is comprised of hierarchical tiers, (higher level element, focus element, and lower level element) and linear sections (item, function, failure). This format is more easily represented and understood using a graphical format. This cannot be achieved using simple computer programs like Excel, and therefore specialised software must be used.

Another shortcoming with this FMEA format is that it was designed with the automotive industry as the primary focus. Within the medical device industry in particular there are User Risk Evaluations which take place, for which there is not a template or scoring criteria in this format.

6.3.2. FMEA Software

Due to the more complex structure of the AIAG-VDA discussed above, software must be used to complete the FMEA in a comprehensive way. It is not vital, however, without software the forms can be extremely difficult to follow and interpret. Using software for the FMEA system also allows it to be updated and maintained more easily, and the forms can be more collaborative documents amongst all team members. There are multiple different brands of FMEA software, with differing user interfaces but all with an identical aim, to simplify risk management and increase its effectiveness.

One such software is APIS IQ – Software, which is an FMEA software which was developed over 20 years ago and has been updated with the new guidelines as they have evolved. The software is downloaded onto a PC and has limited licenses. Similarly, you can purchase additional modules depending on your company's needs. With IQ FMEA providing 21 out of 29 functions, and IQ-RM PRO offering all 29. There are 3 more types of APIS software which offer a varying number of modules. Previous to the introduction of the AIAG-VDA method, APIS used the VDA format. The tree structure of this format better suits this type of software, as Microsoft Excel is adequate for the AIAG format [143]. The VDA format is more easily transferrable to the new format as these graphical tree structures are already in place. Benefits of this software include more efficient data management which increases productivity level. However, its limitations include the high cost of implementation and compatibility issues [144].

6.3.2.10. AIAG-CTS Software Review

Another software is the Core Tools Support software released by AIAG was trialled to be compared to the bespoke software that was created for DTR Medical. This software has a very attractive and coherent home page (Figure 75), which shows each person's assigned tasks, schedule, projects, and personal information such as urgent actions and last activities. This system also shows and records which staff member makes certain changes, which enables accountability and traceability of any changes that are made. The "Parts" tab (Figure 76is also extremely simple to use and contains all the data that would be desired, including the part number, name, location, type, and stage. Another attractive feature on this page is keywords, these can be associated with the part for later searches. The parts can be classified as

subsystems, components, or systems. The subsystems can then be added to the Bill of Materials (BOM) for a system. This tab also allows revisions of the form to be updated. When the form is updated another revision number must be assigned. This allows a clear history of the form to be seen to ensure the revision history complies with ISO standard. However, each revision of a form saves as a separate part which may become confusing once hundreds of parts are loaded with many revisions each (Figure 77).

Figure 75. AIAG-CTS Home page

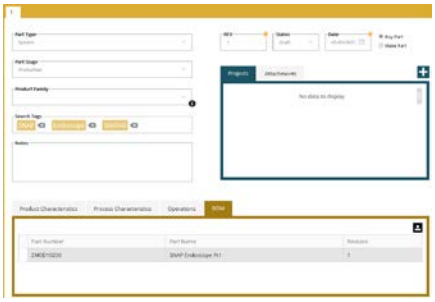

Figure 76. AIAG-CTS Part Page

Parts that you have access to:

Part Number	Name	Revision	Location	Status
SNAP40	SNAP Endoscope	1	Goods In W...	Active
SNAP40	SNAP Endoscope	*	Goods In W...	Active
SNAP40	SNAP Endoscope	2	Goods In W...	Active

Figure 77. Revisions of one product saved as separate parts

The first disadvantage found with this program is that the processes are difficult to input. The form allows the selection of one of the 4M's at a time, to then input the PWE function this applies to. Commonly, one PS will have multiple PWE's, however this format requires the PS and PS function to be inputted again every time. This is repetitive and causes the forms to be difficult to follow. Another difficulty faced when filling in these forms is identifying where to input the severity occurrence and detection ratings. This makes composing a PFMEA extremely difficult.

The software launch presentation explains how the software is only "a little better than spreadsheets." This is due to the ability to collaborate and see your own targets and deadlines on the form. The presentation also states that the software is only aimed at tier 2 and smaller enterprises [145]. Tier 2 enterprises are generally the first link in the supply chain, they have simple products and processes and often supply to tier 1 enterprises or original equipment manufacturers (OEM) [146]. OEM's are the final stage in the supply chain before the customers, they may assemble or manufacture the final parts, or may just distribute the final product to customers. DTR Medical is an OEM, which may explain why this software does not appear to be advanced enough for their FMEA forms. The usability of this software appears to be good at first, however, when trying to apply ratings and add failures, the software quickly becomes a lot more difficult to navigate and use.

6.3.2.11. 7Epsilon Software Review

The home page is less sleek than the AIAG CTS program, however this product is only in the prototype stage, and work on its user interface appearance has not yet had a lot of attention. Despite this, the home page and menu are still very simple to navigate and read. The tabs include 'Products' where you can enter a product name, specification document number, linked flow chart numbers, part number, product family, technical filename, and any tools/equipment that might be needed for this product. These are all fields which are currently found on the specification document. The next tab is the 'Structure and Function' tab. This is where you enter the process name, process step and process work element, and the function for each. Within the process work element, you can enter the area where this takes place, add a diagram and any related documents (Figure 78). This software would be improved if there were four

fields for the 4M's to be entered separately, this would make assigning a failure to each M more straightforward.

The next tab is the 'Failure and Risk' tab. This is where the failures and prevention of each function are documented. This currently described the failures as failure effect, cause, and mode. Transferring old FMEA onto this software will be more straightforward if they are labelled process failure, PS failure, and PWE failure, as the author is less likely to fall back into old habits. The failure modes are linked to severity where the author can enter the defect and severity. However, if the severity explanation was in the form of a dropdown with the severity rating automatically assigned then this would ensure the rating is less open to manipulation. The linking of the tiers and steps on this system is very straightforward and easy to use.

One aspect of this software which is not clear from this prototype is how the reports are formed. This software uses a graphical database (Figure 79) so exporting the structure of them would not be as simple as exporting them into a table format as is done traditionally. This also raises the concern of the software's ability to enable DTR Medical to comply with BS EN ISO 9001:1015 which states documentation of any design and development changes, review results, change authorisation and prevention and detection actions must be kept.

Figure 78. Process Work Element page in the Structure and Function tab

Figure 79. Graphical format of a PFMEA form. Only OP10 is extended fully. The orange circle is the process name and therefore the centre of the graph.

The DFMEA reports have not yet been added onto this software, so a comparison cannot be made regarding this.

In conclusion, the AIAG-CTS software has a sleeker front end, and the feature of assigning each colleague their own actions and tasks, and logging who has made which changes is extremely valuable. Currently, somebody could edit a field in the bespoke software and there would be no traceability of who had made those changes. However, the tabular format is rigid and navigating where to input information is difficult. This is where the bespoke software excels in comparison as the process is much more fluid and the software takes you through the process tab by tab. The AIAG-CTS is more of a finished product at this stage; however, the bespoke software has the potential to excel once the aforementioned changes have been made and concerns on report format and revision history are addressed.

6.3.3. FMEA Mistakes

Since the new format was only introduced in 2019, many organisations are still in the transition period from either the AIAG 4th Edition or the VDA version. During this project, a list of common mistakes was created. These mistakes can make the transition to the new format much more difficult.

The first mistake that people often make is attempting to translate one of the previous types of form directly into the new form. Despite this appearing to be a desirable shortcut, this often results in the forms taking longer, being incomplete, or completed incorrectly. It is recommended instead that the process or design is evaluated again from a starting point, as if

the previous FMEA forms were not created. This avoids confusion between terms and prevents the author from falling back into old habits of the AIAG 4th edition forms. It also enables the team to re-evaluate the potential risks, and not to be bound by the risks detailed on the old form, which may exclude some risks. Furthermore, this approach brings an opportunity to encode organizational knowledge as defined in the ISO9001:2015 quality standard.

FMEA reports are often treated as standalone offline documents. All of an organization's Process and Design FMEA's should be treated as linked, live documents. It is a vital organizational knowledge pool that has potential to power the next generation of automated software for your organization. It is recommended that software is used which can drive and manage all improvement projects. An improvement in the manufacturing process of one product could impact the risks associated with another process, this should be considered continuously when updating forms. Updating these forms should then lead to tracked revisions of all linked documents simultaneously.

Top 5 mistakes to avoid:

1. The most important mistake is categorizing a design and/or process failure either as a failure mode, failure cause, and failure effect at the onset. This makes it difficult to recognise which function in the hierarchical system a failure is related to. Instead of using words 'cause', 'mode', and 'effect', failures should be referred to as the Process function failure, Process Step (PS) function failures, Process Work Element (PWE) function failure in PFMEA forms, and the Focus Element, Next Higher Element, and Next Lower Element in DFMEA forms, as this is easier to visualise.

2. Inputting a preventable failure as a process step function failure is a second common mistake. It should not be possible to directly prevent a process step function failure. If a failure is directly preventable then it should be redefined as a process work element function failure. This is because each PS failure can be caused by multiple PWE failures, the PWE failures are specific actions that are taken to fulfil the PS function. A PS function failure must be due to a PWE failure which can then be prevented.

3. The third mistake that is often made is in the description of the PS and PWE function failures. The process step function failure should describe "how" a process step function has failed or the conditions under which the failure has occurred. The PS function should consist of a verb-noun combination, and the failure of this describes how this function has not been fulfilled.

Similarly, the PWE function failure should describe “why” the PWE function has failed, not how or under what conditions. The name of the PWE function should be described using a verb-noun combination, and the failure of this should describe the reason why this action has not been completed. Meanwhile, the process function failure should describe the severity of the failure in one of four ways: (i) product non-conformance to customer specifications (defects, dimensions, properties etc.) (ii) product not delivered to the customer as per the delivery schedule, (iii) one or more persons are injured during the process, (iv) regulatory non-compliance. Together with these classifications and the tables within the handbook, an appropriate severity rating can be determined.

4. The fourth common mistake is that the 4M’s are often compounded together into one PWE function failure. The process work element should be described using one of the four M’s (Person (Man), Environment (Milieu), Material, Machine). These should be separated into different entries, so each one can be assigned a separate prevention or detection action. This will lead to multiple PWE’s per PS, which is why an Excel based relational database is not advised, as this can become difficult to follow. The prevention and detection actions should correspond to only one of the 4M’s.

5. The final mistake is that an FMEA form does not map onto the 6M’s involved in a process. This includes the four from above as well as the Method, which is captured within the process steps, and finally Measurement, which is captured within the PWE or PS, and within the DFMEA this is often related to inspection. These 6M’s are generally used in Ishikawa or Cause and Effect diagrams. Therefore, detailing these in the FMEA writing process will enable each aspect of these fault-finding tools to be considered ahead of time. This will reduce the possibility of oversight of a risk dramatically. This will also aid in the use of these forms as investigation and improvement tools should any failures arise.

Avoiding these top 5 mistakes will benefit an organization considerably, as it allows a large portion of the organizational knowledge to be stored within these forms, containing an in depth, accurate data pool. This knowledge can then be utilised effectively to aid in design and process improvement and also to maintain regulatory compliance.

6.4. Automation of FMEA

The AIAG-VDA FMEA writing process is 60% more time consuming than the previous format. However, using software to create FMEA's can speed up the process considerably after the initial set up time. Using software and machine learning FMEA's can be automated.

Within this FMEA software, ontology can be used to learn the language patterns used in each field, and identify failures associated with a component, what the functions, failures and severity ratings are. Therefore, the FMEA tables will be filled automatically.

Ontology is the ability of a person or computer to interpret what sentences mean, and how they are related to other topics. A person can interpret sentences despite differences in structure and vocabulary, whereas a computer may struggle with this. Therefore, building a system that incorporates ontology is valuable within the engineering world, as this allows links between information to be made.

The main hurdle, however, is that the language used in these documents varies greatly depending on the person creating the documents, and the customers and company's expectations. Some forms are completed in great depth, whilst others do not explain processes, functions, and corrections fully. Therefore, the language used in these forms must be standardised, and the level of detail must be constant, so that the patterns can be learnt by the technology.

Standardising this language will make a more transparent file which can be understood to the same extent by a person who created it and a person who did not. The current format of FMEA can be interpreted differently by different people, and often can only be fully understood by the person who compiled them.

Another restriction when automating these tables is that they can differ slightly between companies and products, and reforming that to the necessary standards is time consuming and redundant to companies who have already completed tables to their standards.

This technology can lead to an increase in productivity, as repetitive failures can be detected and flagged up, then the cause can be identified. Knowing the cause of the continual failures can allow the company to correct this by making changes to their process, materials, personnel, or environment to increase the number of accepted products, and therefore drive profits.

Productivity increase is imperative in order to maintain profits and prepare companies for growth. The production of products must be accelerated. One way to achieve this is to reduce the time spent on FMEA writing, fault finding and improvement projects by using automation and machine learning.

In summary, automation of FMEA using knowledge management is feasible, however standardising the use of language is imperative to obtaining accurate and desired results. This transition will take increased time and effort initially due to the nature of the forms, but the outcome of an automated system will increase efficiency in the future.

Chapter 7 - Conclusion

In conclusion, the effect of sterilisation on PA11 and PP can generally be predicted, however the extent of this effect was not linearly affected by the type and quantity of fibres. It was found that the fibre type has a larger effect on the tensile strain at break properties. However other additives such as plasticisers will also have a large effect on the reaction to sterilisation which suggests why Rilsan did not follow the same trends as RTP 205 C and 203 C.

The material that appears to be most suitable for the CBR is RTP 203 C, due to its good reaction to both EO and gamma sterilisation. This polymer does not produce identical results to the current polymer (Latilon); therefore, the polymer should still be modelled using FEA on the product geometry to ensure that the material is adequate.

Switch 25 appears to be the most suitable for the more sustainable alternative to the ear speculum. This is due to its good reaction with EO sterilisation. However, due to its low operating stresses, Norner also has adequate properties.

It is feasible to suggest that the FMEA software can become automated to complete the theoretical aspect of this work if the system was developed much further than the stage it is currently in. The properly completed AIAG-VDA 1st edition FMEA forms hold data that will be valuable when selecting new materials, such as the current material's mechanical properties and product storage conditions. These mechanical properties were used when manually selecting polymers, so this could be replicated with a semi-automated process.

The experimental data differed by varying amounts compared to the data given on the datasheets, and the different sterilisation methods affected different polymers to different extents. Because of this, the manual mechanical tests will need to be completed, as it would not be possible to predict a polymers reaction to sterilisation. Therefore, the automated system will be effective in researching and suggesting polymers to perform the mechanical tests on. This will save a large amount of time of high skilled employees which will free up their time and enable them to focus on design and innovation challenges that cannot be automated.

It appears that software which uses a graphical database format will be more equipped to enable companies to transition towards better knowledge management and will make using automating this process more efficient, due to faster search times and a more dynamic format,

as well as the ability to function using incomplete datasets. This makes this format much more suitable for a real-life environment where not all datasets are complete. However, the key area for consideration is how the report writing and audit trail will be achieved with this database format.

Chapter 8 - Future Recommendations

The FMEA software proof of concept can be extended in two stages. The first step should be to continue the development of the system to an offline demonstration with all the required features to use information from selected documents including FMEA, ERP data and locally stored files to locate and present the data required to compile reports such as innovation recommendations and regulatory reports for up to three products.

The next step would be to further develop this demonstration into an online system which can be used as a central information hub for all of an organisation's knowledge and consistently provide suggestions for product innovation, and aid in maintaining regulatory compliance by automatically compiling regulatory reports and improve productivity by answering the business questions suggested.

To further build on this, the FMEA software can be used as a knowledge base to collect data to input into a deep learning algorithm to train a conversational AI system. A conversational AI system will need a large amount of training data, if the FMEA system runs within an organisation alongside the ERP system then this will provide the necessary data. This will increase productivity and innovation across multiple sectors by providing rapid responses to business questions such as the ones discussed.

The next stages of this materials research should be to investigate the re-sterilisation capabilities of each material. This will enable the feasibility of a circular economy to be investigated. The regulation and restrictions regarding recycling of clinical waste will need to be investigated in more detail, and permissions from governing bodies will need to be obtained. Once the framework of this system is established, then a pilot study involving one product in one hospital. This can then be rolled out to other products, materials, and hospitals. This will drastically decrease the amount of raw material that is being used to create polymers, as well as the carbon emissions generated from the incineration of polymers.

Another test that could be carried out is a differential scanning calorimetry test to investigate the crystallinity of the polymers. This would allow the hypotheses of the crystallinity altering due to radiation to be proven.

The investigation into a water-soluble material, PVoH, was beyond the scope of this study. However, future research should investigate the sterilisation capabilities of this polymer in thermoplastic form. This material is soluble in municipal waste streams. Therefore, if the material was found to be suitable for use in medical devices, then this would reduce a large amount of waste plastic being incinerated and in turn drastically reduce the carbon emissions generated by the medical industry. If this material is found to be capable, then the waste restrictions will need to be investigated.

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Appendix 1 - Automated Product Inspection

Another way in which software can be used in the quality monitoring process is in fault detection of products. Types of inspection include: the observation of processes to identify any process deviations; inspecting a product for physical defects; measuring items to identify whether dimensions are acceptable; and patrolling, where the work of other employees is monitored by a supervisor [153].

Currently many products are inspected for defects manually by inspection staff. These staff members will use magnifying lenses, callipers, and other apparatus to ensure that product dimensions and surface finish is compliant with the product specification, as well as performing other functional tests such as electrical conductivity and pull tests. Quality staff can perform slight reworks at this time, if, for example, the product needs to be wiped, but no major reworking is done. Products can be accepted or rejected, and a report detailing the quantity of rejects for each reason will be sent to the supplier. Common defects include orange discolouration similar to rust, out of dimension products, and screw threads that do not function correctly (thread will continue to turn and not tighten effectively).

The number of products in one batch that are inspected varies based on the confidence in that product. A product that is commonly rejected will be 100% inspected – all of the devices/material within that batch will be inspected, whereas only a proportion of devices will be inspected if the product is proven to rarely show defects. A product transitioning to and from more stringent inspection procedures is dependent on a number of consecutive batches being either acceptable or unacceptable. This is based off a sampling plan which is based on the process control plan.

Manual inspection conducted by staff can be inaccurate and lead to a large amount of variability. A defect on a product may be considered acceptable to one staff member, but unacceptable to another. Another disadvantage of human inspection is that staff have been proven to tire when performing repetitive tasks which can lead to mistakes. There is also a high cost implication of employing many highly trained visual quality inspectors [154].

Automated inspection systems are intended to identify any defects within a product, which will then either alert the operator to manually separate the defective product or the machine will separate it automatically. The inspection system will then need to log the reason for rejection so this can be fed back to the supplier to try to prevent these defects from occurring in future

batches. The intention of machine inspection is to improve the accuracy and cost of the detection stage [154].

The advantages of a digital inspection system are:

- Time savings = cost savings
- High accuracy
- Traceability (photos are stored)
- Operators do not need to be skilled
- No human bias/variability
- No human error
- Easier statistical analysis of results

Images must first be pre-processed to optimize the inspection. This stage will remove all unnecessary pixels such as the background of an image. If this stage is not complete, then the inspection time will significantly increase [155]. Firstly, the image of the product must be adapted to increase the visibility of any surface defects. This can be achieved by increasing the contrast of the image. The sharpness of the image can also be increased to allow the edges to be identified more easily Figure 82.

Images can be binary, greyscale, colour, or range. Binary images are black and white images. This type of image can be used to measure dimensions, component presence, decoding and product shape. This type of image is not capable of identifying surface defects [156].

Grey scale images are capable of identifying surface defects; however, this is not achieved to the same level of accuracy as colour images. Range images can inspect 3 dimensional objects.

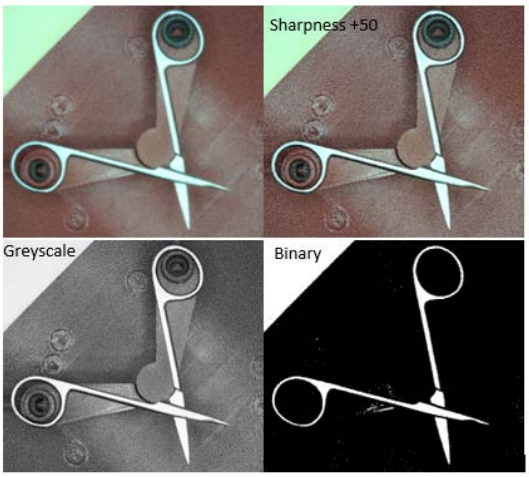


Figure 80. Image captured by inspection system (top left) and image after processing has taken place.

8.1. Considerations

The automated inspection system must be accurate enough to identify any defects. These defects can sometimes be extremely difficult to identify visually, as they can be less than 1 mm in size. Therefore, the cameras used in a visual inspection system must be adequate. Callipers are often used by inspection staff to measure the dimensions of products, these have an accuracy of 0.02 mm, as stated in BS 887:2008, a camera inspection system should have a similar or better accuracy to make the system comparable.

Another consideration is whether operators will still be needed. In some systems the process is fully automated, and staff are not required, however it is more common that visual inspection systems will use human inspectors as well as automated systems. This is called hybrid inspection [153]. Hybrid inspection allows any products that the system may not be able to classify with confidence to be inspected more closely by a human inspector. This will still reduce the cost of overheads as the number of borderline products will be far lower than the total number of products being inspected. However, if staff are still needed to load the products into a fixture, then to be economically viable, the system must either inspect much faster than a human inspector or have extra capabilities, such as identifying microscopic defects that a human would not be able to [156].

The most expensive step within a manufacturing industry tends to be the inspection process [154]. Although these systems can be expensive as a one-time cost, they can drastically decrease the amount of skilled staff that are needed to inspect the products. This hourly cost, as well as fewer production line disturbances downstream can lead to a relatively short payback time [154].

The cost of maintaining such systems should also be considered before an organisation invests in an automated visual inspection system. The more complex the inspection system is, the more components it will have to break down. It must be considered how the break down or routine maintenance of the system will affect the production line. With some systems, the production line may need to stop completely, in which case the cost effect of this will be large [157]. Therefore, it is important that an organisation implements a plan for when this will occur. Although these systems can be expensive as a one-time cost, they can drastically decrease the amount of skilled staff that are needed to inspect the products. This hourly cost, as well as fewer production line disturbances downstream can lead to a relatively short payback time [153].

The capabilities of a system should also be considered. With simple devices that only require top and side inspection then a conveyor belt design can be used which passes items into bins depending on their reject reason or an ‘accepted product’ bin. These systems generally have top and side mounted cameras. For static products that must be inspected over 360° mirrors can be inserted into gaps between the conveyor belts to allow a bottom view [158]. This method is more effective on spherical objects and will not be effective on objects which lie flat on the surface. For devices which lie flat on a surface or must be inspected over a range of motion (i.e. scissor blades) then robotic arms can be used. Robotic arms are extremely complex and costly and are beyond the scope of many SME’s. In this case, operators can be used to move the device to the desired position. Despite still using operators, this still has benefits over an entirely manual inspection, as the operator does not need to be trained, they will save time that would otherwise be spent measuring a device, as well as this, there is a record of the images captured [158]. If products must be tested for their functionality, this must be done by the operator. However, the overall process will still be improved.

Another consideration is whether operators will still be needed. In some systems the process is fully automated, and staff are not required, however it is more common that visual inspection

systems will use human inspectors as well as automated systems. This allows any products that the system may not be able to classify with confidence to be inspected more closely by a human inspector. This will still reduce the cost of overheads as the number of borderline products will be far lower than the total number of products being inspected. However, if staff are still needed to load the products into a fixture, then to be economically viable, the system must either inspect much faster than a human inspector or have extra capabilities, such as identifying microscopic defects that a human would not be able to [156].

Implementing an inspection system at the site of a supplier will ensure that each product that is distributed by them is within the specification. This will drastically decrease the number of products that are being inspected at the secondary organisation and therefore decrease the inspection time and costs considerably.

There are two ways in which an inspection system can fail. This can occur by missing a defect that is present within a device (false-negative) or failing a device for a defect that is not present or within tolerance (false-positive) [156].

8.2. Dimensions

The dimensional analysis can identify the measurements of a product, as well as any distances between certain objects, which may be required when inspecting an assembly. To achieve this a reference object must be used. This reference object must be clearly identifiable, either by always being located in a fixed position (e.g., top left corner of the image) or by being visually unique (e.g., certain colour, shape). The reference object must also always be of known dimensions. The pixels per metric of the reference object are calculated by identifying how many pixels there are per unit of measurement. This is achieved using equation (13)

$$\boldsymbol{pixels\ per\ metric} = \frac{\boldsymbol{reference\ object\ image\ width}\ (\boldsymbol{pixels})}{\boldsymbol{reference\ object\ known\ width}\ (\boldsymbol{mm})} \qquad (13)$$

The system will then identify how many pixels are in the product image, and multiply this by the pixels per metric to calculate the size of the product in mm.

This method requires the camera to be perfectly perpendicular to the objects, and for the objects to be completely flat, otherwise the image can distort the measurements due to perception and

the result will be incorrect. The camera must also be calibrated to ensure that the images are accurate [159].

8.3. Surface finish

Surface defects and blemishes can also be identified automatically. To achieve this, the contrast of the image is increased, and the hue, hue saturation and hue intensity are used to identify any surface defects on coloured images [160]. This can also be used to identify whether an image is the correct colour. On greyscale images the pixel intensity is evaluated, a blemish/surface defect will appear to be a different intensity than the surface of the object.

Automated inspection systems can also identify the presence of logos and marks. This can include company logos, regulatory details, and measurements such as the size of a screwdriver head. As well as the presence of these details, the system will also ensure that the etchings are clear and correct. This step is imperative, as without certain logos, an organisation could be in breach of medical device regulations.

8.4. Decoding

Decoding is another feature that is available with machine inspection. This can include barcodes and QR codes. This allows for product traceability as individual products can be assigned a code. Using this feature, field failures can be returned with the corresponding barcode, and the images from the inspection stage can be viewed to identify whether the fault was present at this stage. This can then lead to inspection system improvement or other process improvements along the production line. Another benefit of using barcodes is that scanning a barcode is 100 times faster than manually entering the same information. This method is also far less likely to lead to errors when inputting the data manually [161].

8.5. Inspection Systems and Machine Learning

Dynamic machine learning can be used to ensure that the inspection system is constantly developing. These models are trained online while the inspection system is in use and is constantly updating and training. On the other hand, a static model is shown labelled (rejected or accepted) examples before the system is live and will then learn how to classify different devices [162]. For an automated inspection system on known products, a static model is adequate. New models would have to be created and trained each time a new product is introduced. However, a dynamic model is more likely to be able to adapt to a new product

using the data from previous products. For an organisation which is constantly inspecting new products, a dynamic model may be optimal.

In conclusion, the suitability of an automated inspection system is dependent on the current manual system capabilities. Studies have shown that the accuracy and efficiency of inspection does not always increase with automation [154]. The cost of installing and personalising these types of systems if often very high for a SME, and the risk is often too high. Many successful introductions of these systems are seen primarily in high volume applications. Kopardekar states that “if the rate of production is low then automated inspection is not economically justifiable.” [153]

8.6. Review

The inspection system that was designed for DTR Medical was able to generate the top left image in Figure 82. Image captured by inspection system (top left) and image after processing has taken place., of Iris scissors. The device uses a 3D printed structure held together by metal bolts. This structure supports a ring light, a side light, a top view camera and identical side view camera to capture images. The structure also supports a web camera which can film the process. The products are placed onto a fixture at the base of the system. The fixtures have moving parts which can manipulate the products to allow images of all the surfaces to be captured, such as the inside of the blades at different opening angles.

Figure 81. Inspection system. Product central to camera (left). Base fixture fixed in place (right).

The inspection system was a good proof of concept for a more advanced system to be implemented later. The system was able to capture images of a fair quality, which, with the aid of specialised software will be able to measure the dimensions of the products being inspected.

This may require an image processing step to increase the sharpness of the image as seen in Figure 83.

One of the primary concerns with these images is the red fixture colour. This may affect the contrast of the image and make the perimeter of the object more difficult to distinguish. Another option is to use an illuminated white board underneath, such as a lightbox to improve the contrast and ensure a clearer outline of the object.

Using the current cameras, only the larger surface defects are clearly displayed. This may be possible with a higher resolution camera; however, the magnification of the images may also be a factor in this, which is hard to combat when only capturing one image of the whole device. A way to combat this may be to have a remote controlled automatically focussing camera to capture an image of the areas where defects are often found. For example, the images of the iris scissors will magnify the blade surfaces, specifically near to the hinge.

Unfortunately, the surface plate does not align the product centrally beneath the camera (Figure 83). The red bar along the bottom is also not long enough to reach the bottom plate to secure it in place. If the system is set up as it is in Figure 83 left, then the base is free to move which may cause the camera to lose focus and may cause the images to not be uniform. This could easily be rectified by creating an extension piece from the left-hand side base support to the base plate.

A positive aspect of the current cameras is that the focus, contrast, and magnification of the cameras is difficult to tamper with once the system is set up. This does not allow the operator to alter the camera, as this may lead to images differing in quality and position which may affect the acceptance rates.

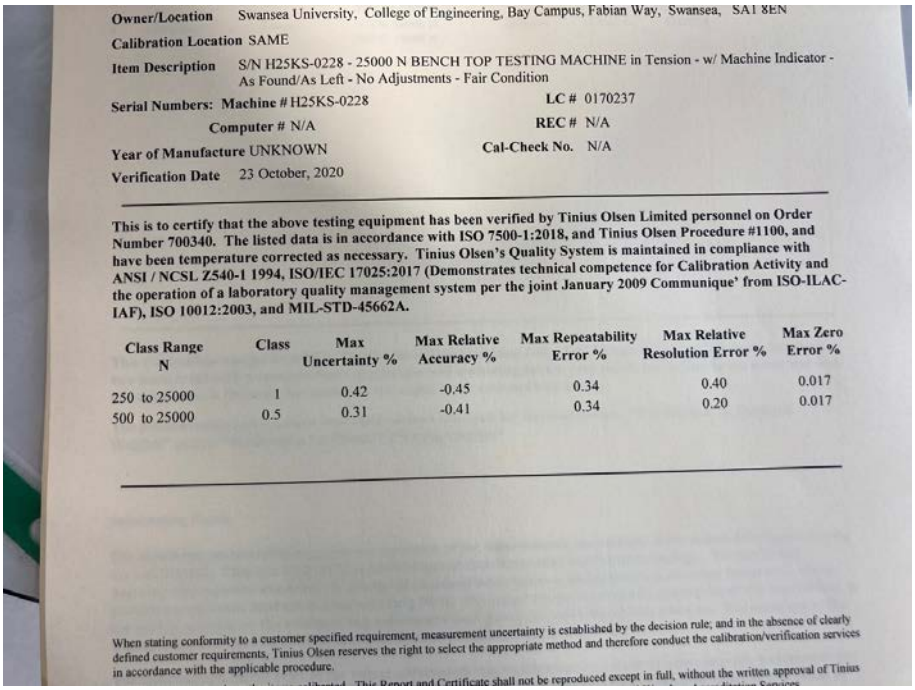
The system is a desk top system, which also allows use of the computer, it is also lightweight and easy to assemble and use. These are all good qualities for the inspection system being used in a modern office, as it can be moved out of the way when not required, and easily moved from desk to desk.

Another positive is that the base fixtures can be interchanged simply, as well as new fixtures being 3D printed to fit new products and slide onto the base. The rest of the system being 3D printed keeps the price low and allows replacement parts to be created quickly and easily.

DTR Medical can use this proof of concept to design and create an inspection system that meets all of their requirements. Within the proof of concept, the computer software that inspects the parts was not investigated or trialled. Therefore, this must be evaluated before a fully working inspection system can be created.

Another method of decreasing inspection costs using this device is to implement the device as a photo capture system at the supplier end. The system would capture the images as they are being manually inspected to ensure that suppliers are inspecting 100% of the products. Then in plant only a sample of product would need to be inspected to ensure that the photos taken correspond to the images captured. This would reduce the inspection costs considerably.

Appendix 2 – Calibration Certificates



Owner/Location Swansea University, College of Engineering, Bay Campus, Fabian Way, Swansea, SA1 8EN

Calibration Location SAME

Item Description S/N H25KS-0228 - 25000 N BENCH TOP TESTING MACHINE in Tension - w/ Machine Indicator - As Found/As Left - No Adjustments - Fair Condition

Serial Numbers: **Machine #** H25KS-0228 **LC #** 0170237

Computer # N/A **REC #** N/A

Year of Manufacture UNKNOWN **Cal-Check No.** N/A

Verification Date 23 October, 2020

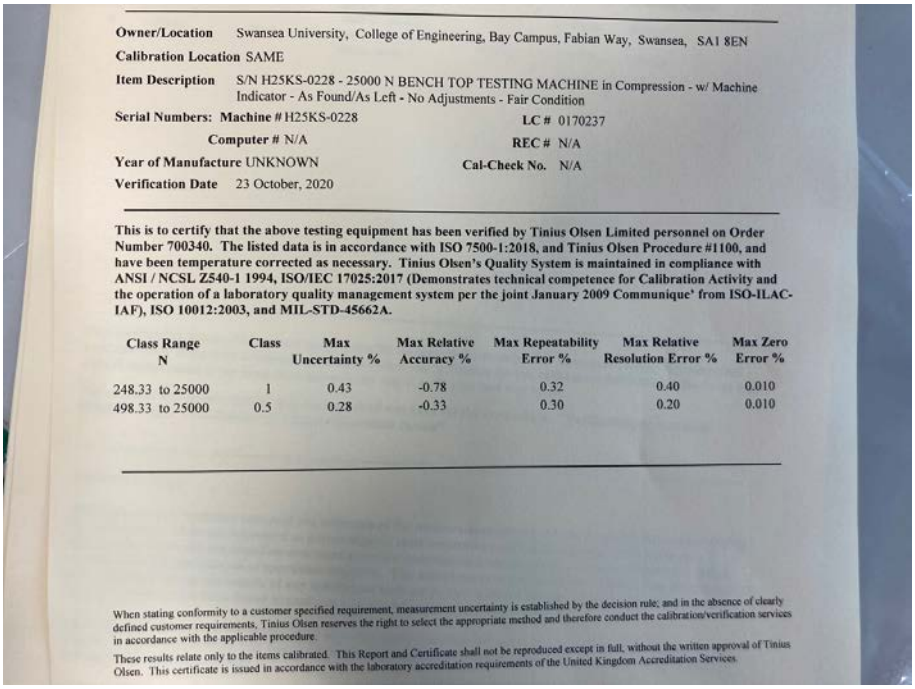
This is to certify that the above testing equipment has been verified by Tinius Olsen Limited personnel on Order Number 700340. The listed data is in accordance with ISO 7500-1:2018, and Tinius Olsen Procedure #1100, and have been temperature corrected as necessary. Tinius Olsen's Quality System is maintained in compliance with ANSI / NCSL Z540-1 1994, ISO/IEC 17025:2017 (Demonstrates technical competence for Calibration Activity and the operation of a laboratory quality management system per the joint January 2009 Communique' from ISO-ILAC-IAF), ISO 10012:2003, and MIL-STD-45662A.

Class Range N	Class	Max Uncertainty %	Max Relative Accuracy %	Max Repeatability Error %	Max Relative Resolution Error %	Max Zero Error %
250 to 25000	1	0.42	-0.45	0.34	0.40	0.017
500 to 25000	0.5	0.31	-0.41	0.34	0.20	0.017

When stating conformity to a customer specified requirement, measurement uncertainty is established by the decision rule; and in the absence of clearly defined customer requirements, Tinius Olsen reserves the right to select the appropriate method and therefore conduct the calibration/verification services in accordance with the applicable procedure.

This Report and Certificate shall not be reproduced except in full, without the written approval of Tinius

Figure 82. Calibration certificate for Hounsfield machine in tension



Owner/Location Swansea University, College of Engineering, Bay Campus, Fabian Way, Swansea, SA1 8EN

Calibration Location SAME

Item Description S/N H25KS-0228 - 25000 N BENCH TOP TESTING MACHINE in Compression - w/ Machine Indicator - As Found/As Left - No Adjustments - Fair Condition

Serial Numbers: Machine # H25KS-0228 **LC #** 0170237

Computer # N/A **REC #** N/A

Year of Manufacture UNKNOWN **Cal-Check No.** N/A

Verification Date 23 October, 2020

This is to certify that the above testing equipment has been verified by Tinius Olsen Limited personnel on Order Number 700340. The listed data is in accordance with ISO 7500-1:2018, and Tinius Olsen Procedure #1100, and have been temperature corrected as necessary. Tinius Olsen's Quality System is maintained in compliance with ANSI / NCSL Z540-1 1994, ISO/IEC 17025:2017 (Demonstrates technical competence for Calibration Activity and the operation of a laboratory quality management system per the joint January 2009 Communique' from ISO-ILAC-IAF), ISO 10012:2003, and MIL-STD-45662A.

Class Range N	Class	Max Uncertainty %	Max Relative Accuracy %	Max Repeatability Error %	Max Relative Resolution Error %	Max Zero Error %
248.33 to 25000	1	0.43	-0.78	0.32	0.40	0.010
498.33 to 25000	0.5	0.28	-0.33	0.30	0.20	0.010

When stating conformity to a customer specified requirement, measurement uncertainty is established by the decision rule; and in the absence of clearly defined customer requirements, Tinius Olsen reserves the right to select the appropriate method and therefore conduct the calibration/verification services in accordance with the applicable procedure.

These results relate only to the items calibrated. This Report and Certificate shall not be reproduced except in full, without the written approval of Tinius Olsen. This certificate is issued in accordance with the laboratory accreditation requirements of the United Kingdom Accreditation Services.

Figure 83. Calibration certificate for Hounsfield machine in compression

Appendix 3 – Materials Researched

Property		Density	Melt Flow Rate	Melting Point	Stress at Break	Strain at Break	Tensile Strength	Young's Modulus	Flexural Stress at 3.5% strain	Flexural Strain at Break	Flexural Strength	Flexural Modulus	Charpy Impact Strength Notched	Charpy Impact Strength Unnotched
	Unit	g/cm³	g/10min	°C	MPa	%	Mpa	MPa	MPa	%	MPa	MPa	kJ/m²	kJ/m²
Sorona	Polytrimethylene terephthalate (PTT) 15% GF	1.44	13	227	120	2.5	120	6500			160	5800	5.5	25
Latilon 28D	PC 20% GF	1.33		280-300		3	100	5500					10	40
MAGNUM™ 8391	ABS	1.05	8	232-249	35		45-48	2340			75	2400	1.9	
Biomer I900	PLIA	1.25	3.00-6.00			2.4	70	3600			98		3.3	16.5
Rilsan CX1307	Polyamide 11	1.7		197	>180	>2		>2000				>1800		>60
Biomer P304	PHB	1.2				8.0-15.0	25-28	1300-1500			31			5.0-6.0
Terralene HD 4527	Bio HDPE	1.07	13.0-15.0	130-140	24	16	26	1845	25	No Break		1745	2.2	36
Bio-Flex® F 7510	PLA	1.25	2.0-4.0	155		16.3	20.9	3000	73			3075	2.4	64.5
Fibrolon S 7530	PLA	1.27	9.0-11.0	140-160	36.5	3	37	3850	-	2.8		3650	3.7	8
Biograde C 9550	Cellulose Acetate	1.67	11.0-15.0	>180	41	6.5	41	4200	63	7		4050	2	37
Bio-Flex® GF30	PLA 30% GF	1.46		>155	56	2	57	7250	-				6	21
Zytel	PA610-GF33	1.34		225		3.3	180	10000			270	9000	13	90
Akro plastic	Nylon610 15%GF	1.18		220	120	4		5500			180	4800	6	65
Durabio	bio-PC	1.36	10			72	79	2700	116			2700	7	
PA410 EcoPaxx	Polyamide410 (GF +MD)30	1.34		250	95	2.5	65/95	8000			175	6650	4	35
RTP 203 C FR	PA11 GF20	1.5		224-288		2.0-3.0	83	5861			103	5516		
RTP 203 C	PA11 GF20	1.18		224-288		3.0-4.0	83	4826			117	4826		
RTP 205 C	PA11 GF30	1.25		224-288		2.5-3.5	86.2	6550			124	5520		
Akromid	PA6.10 GF30	1.31		220	160	4.5		8600			230	7700	17	100
RTP 799 X 140537	HDPE - Cellulose Fibre	1.1		193-232	26.9	2.0-3.0		2760			51.7	2.76		
Trifilon Switch 25	Starch based with hemp fibre	1.26			30	3.3		2300					2.95	26
BioFlex S 5630 WH	PLA	1.55	6.5-10	140-160	29	9	32	2160	46	no break		2400	3	51