



Sustainability in Obstetrics: Assessing the Reusability of the vela® Vacuum Extractor

A Study for Design Optimisation and Material Selection
Using Material Testing and Finite Element Analysis

Gloria Micali

Sustainability in Obstetrics: Assessing the Reusability of the Vela® Vacuum Extractor

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by

Gloria Micali

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Thesis committee:	Prof. dr. ir. J. Dankelman,	TU Delft, supervisor
	Ir. D. Drexhage,	LAYCO® Medical Devices
	Dr. S. Pirola,	TU Delft, technical supervisor
	Dr. ir. R.M. Oosting,	TU Delft

LAYCO

 **TU Delft**

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Abstract

INTRODUCTION: The quest for sustainable and effective medical devices in obstetrics has directed attention towards the vela® Vacuum Extractor (VE), a reusable VE currently under development at LAYCO® Medical Devices. This study focuses on the reusability aspects of its critical component—the connection between the tube and the cup, featuring a reinforcement wire within the walls of the tube. This study aimed to optimise the design of this connection and select the most suitable materials for the cup and the other rigid components, as well as evaluating the overall performance of the connection, contributing to the device’s overall efficiency and sustainability in clinical settings.

METHODS: A comprehensive approach was employed, involving the reprocessing of several materials—Grilamid® LKN-5H, Ultem™ HU1010, Radel® R 5500 NT 15, and Udel® GF120 NT as candidates for the cup, Kevlar® 29 for the reinforcement wire and silicone for the tube—under various conditions including glutaraldehyde (2% solution), sodium hypochlorite (0.5% solution), and 134°C steam sterilization, as well as their combinations. These materials underwent rigorous testing before and after 1, 30, and 100 reprocessing cycles to assess their tensile properties, colour stability, weight change, and shore hardness A. The Abaqus/Explicit finite element solver was utilized to simulate the clinical behaviour of the wire and cup using data from tensile tests, to evaluate the performance of different designs and the different materials. Key design parameters—wire diameter, cup thickness, wire length, and location—were varied across different iterations to identify the optimal configuration for the design. The candidate materials were evaluated based on their properties and their performance in the finite element model.

RESULTS: The results of the material testing indicate that silicone and Grilamid® LKN-5H displayed significant discoloration after reprocessing. Silicone also exhibited a notable increase in Shore Hardness A over the reprocessing cycles. Ultem™ HU1010, Radel® R 5500 NT 15 emerged with the most favorable mechanical properties, particularly in terms of yield stress and ultimate deformation values.

The optimization process identified a superior design, featuring a unique arrangement with strategically placed holes for manufacturability, a wire diameter of 1.5 mm, and a disc thickness of 2.6 mm. Ultem™ HU1010 emerged as the most suitable material for the cup based on its performance in the finite element analysis (FEA). Despite the selection of the best performing material, the results revealed that the stresses in the disc under worst-case traction forces (453 N) exceeded the material’s yield stress, indicating potential plastic deformation. However, the stress levels remained within more acceptable values under lower traction forces (225 N), indicated as the safety traction limit by scientific literature [1–4]. However, the reinforcement wire and silicone tube presented challenges—exceeding stress limitations and showing significant property degradation after extensive reprocessing, respectively.

CONCLUSION: This study successfully optimised the design of the vela® VE’s tube-cup connection and identified Ultem™ HU1010 as the optimal material for the cup, aligning with the device’s performance requirements under typical use conditions. The findings underscore the need for further material evaluation to address the limitations identified with the reinforcement wire and the silicone tube.

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List of Abbreviations

A autoclave 134°

C control

FEA finite element analysis

FEM finite element model

G 2% glutaraldehyde

GA 2% glutaraldehyde + autoclave 134°

HIC high-income country

LMIC low- & middle-income country

PA12 polyamide 12

PEI polyetherimide

PPSU polyphenylsulfone

PSU polysulfone

SH 0.5% sodium hypochlorite (bleach)

SHA 0.5% sodium hypochlorite + autoclave 134°

VAD vacuum assisted delivery

VE vacuum extractor

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Introduction

1.1 Vaginal operative delivery

Vaginal operative delivery indicates the employment of forceps or a vacuum extractor (VE) to aid vaginal delivery of the child and it is generally performed in case of prolonged or obstructed second-stage labour [9]. Vacuum extraction offers several advantages over cesarean section (C-section) in certain situations. Firstly, it allows for a quicker and less invasive delivery process, reducing maternal recovery time and the risk of postoperative complications. Additionally, vacuum extraction may promote a more natural birthing experience, as it allows for vaginal delivery in cases where the baby's position or other factors may warrant assistance. This method is also associated with a lower risk of infection and maternal morbidity compared to C-section [10]. Vacuum assisted delivery has a number of benefits over forceps delivery as well, such as reduced maternal discomfort, less genital trauma for the mother, less anaesthesia and shorter delivery times [11]. For these reasons, the proportion of vacuum assisted delivery compared to the use of forceps has been increasing [9].

A vacuum extraction consists of the application of the VE's suction cup to the scalp of the foetus (Figure 1.1). A partial vacuum is created inside the suction cup by operation of the VE's pump to secure adhesion of the device to the scalp. This allows the obstetrician to exert the necessary traction force on the device to guide the baby out of the birth canal. When the head of the baby is crowning, suction is disengaged and the cup is detached.

In low- and middle-income countries (LMICs), the application of vacuum extraction (VE) is significantly less common compared to high-income countries (HICs). In Sub-Saharan Africa, vacuum extractions generally account for less than 1% [12]. Moreover, a considerable number of maternal and perinatal deaths related to childbirth continue to persist in LMICs [13]. When vacuum extraction is performed with proper supervision and care, it can significantly lead to a reduction in maternal and neonatal morbidity and mortality [14]. This underscores the importance of introducing vacuum extraction in LMICs.

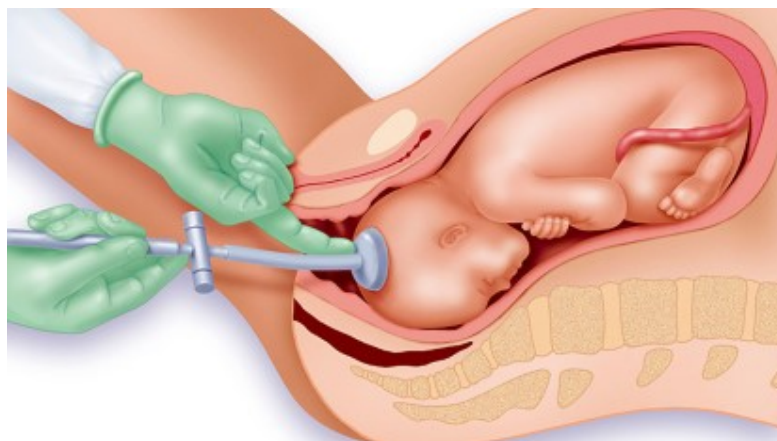


Figure 1.1.: Vacuum extraction. Reproduced from [5].

1.2 A reusable vacuum extractor

The most widely used VE available on the market is the Kiwi OmniCup® (Clinical Innovations, Murray, UT), designed by Aldo Vacca in 2001 [15]. However, the Kiwi OmniCup® is a single-use device, which should get disposed of after its use. In the past decades, disposable devices have become the preferred option over the reusable alternatives thanks to their ease-of-use and safety, since they do not need to be reprocessed and their quality can be guaranteed at every use. However, more recent research has proved them to be overall less financially convenient and have a greater environmental impact compared to reusables [16–19]. Additionally, continuous supply of single-use devices cannot be ensured in rural, low resource settings, for which having a reusable version of a medical device would be preferable over the disposable [20]. For these reasons, the latest trends in the medical devices' field have seen a shift back to reusable devices over single-use.

In 2020, LAYCO® Medical Devices was founded to address the issue of insufficient integration and limited accessibility of medical equipment in low- and middle-income countries (LMICs). This problem stems from the fact that the development of medical devices has predominantly been centred in high-income countries (HICs), despite the urgent need to expand healthcare services in LMICs [21]. LAYCO® Medical Devices is focusing on the development of vela®, a reusable vacuum extractor, aiming to improve the accessibility of vacuum extraction in LMICs and offering a more sustainable solution to all hospitals. While vela® is currently in the prototype phase, it is crucial to perform validations to confirm its reusability.

1.3 Reprocessing methods

To ensure patients' safety, reusable medical devices must be reprocessed between uses. Reprocessing can include cleaning, disinfection and/or sterilisation. The vela® VE is a semi-critical device as it “comes in contact with non-intact skin or mucous membranes but ordinarily does not penetrate them” [22] and as such, it requires to undergo high level disinfection and sterilisation is strongly recommended [23].

According to the EU regulation 2017/745 (Medical Device Regulation, MDR), the manufacturer must provide instructions on the appropriate methods of reprocessing of the device [24]. After preliminary studies on the availability of cleaning, disinfection and sterilisation methods in low-resource settings, the most commonly used practices were identified. These include washing the device with warm water and soap for cleaning, immersion in glutaraldehyde, JIK (sodium hypochlorite, NaOCl or bleach) or glutaraldehyde for disinfection and the use of an autoclave for steam sterilisation. Therefore, these were selected as the recommended reprocessing methods for vela® VE.

1.4 Effects of reprocessing on materials' properties

High level disinfection and sterilisation are processes that create harsh conditions, e.g. corrosive chemicals, elevated temperatures or pressures, to which microorganisms cannot survive. The unwanted consequences of such harsh conditions are the effects which they have on the material properties of the device itself.

The techniques which use high temperatures can be problematic for some classes of materials, such as polymers. Most polymers have low glass transition temperatures (T_g), which makes them extremely heat-sensitive [25]. This implies that they start degrading at temperatures reached in sterilisation methods such as steam sterilisation. They commonly start distorting, melting, softening or expanding due to chain scission or other chemical phenomena, which compromise their structural integrity and physical properties [25].

Another sterilising agent which importantly affects material properties is moisture, which is used in steam sterilisation. Moisture can damage polymers and other materials causing oxidation [26]. Sterilisation carried out through the use of chemical agents can cause damage to the chemical properties of the materials. These sterilising agents exert their antimicrobial abilities by chemically reacting with the microorganisms' cells. However, they can also react with the chemical structure of the material being sterilised, resulting in permanent damage. Moreover, there might be toxic

residues which would be hazardous upon clinical application of the device.

Degradation of the materials can lead to changes in their chemical structure and/or physical properties, resulting in the loss of mechanical properties and surface quality, which could compromise the device's functionality and safety. For instance, reprocessing can affect the ultimate tensile strength of the material. Since a VE must be able to withstand traction forces as high as 453 N [1], a decrease in the ultimate tensile strength of the materials composing it could result in a hazardous situation for the patient. The elastic properties of a material are also essential for maintaining its functionality and reprocessing methods might significantly affect them.

Furthermore, disinfection and/or sterilisation can hinder the dimensional stability of the materials, leading to deformations. These could result in faulty connections between the components of the device, which are crucial for its integrity and performance. Additionally, reprocessing methods can also affect the materials' colour, which does not directly influence its functionality but it is nonetheless a relevant indicator to the medical professionals and patients. Usage of colours can be essential for the usability of the device, especially since the vela® VE uses colour indicators to signal pressure values. Furthermore, it is preferable that the tubing connecting the suction cup to the pump remains transparent throughout its service life to allow for visual inspection of its hollow cavity during reprocessing. Additionally, the patient's perception of the device as "dirty" could induce a feeling of mistrust and distress, which is to be avoided in such a critical situation as delivery. Overall, damage to the materials composing the device can eventually result in its failure, determining the end of its service life and possibly compromise patient safety.

1.5 Scope and research question

This thesis aims to evaluate vela®'s reusability, specifically addressing the research question: "Can the vela® VE endure 100 cycles of reuse?". The project focuses on two crucial aspects that determine the vela® VE's ability to withstand 100 re-uses, material resilience and structural integrity. Therefore, the scope of this research includes design optimisation process for the tube-cup component of the vela® VE, as well as the material selection for its rigid parts. The initial focus is on assessing the materials' capacity to withstand disinfection and sterilisation processes, specifically looking at the deterioration of their properties after undergoing 100 cycles of reprocessing. This investigation has been shown to be necessary as a conclusion of a thorough systematic literature review, which found a significant gap in publicly available data concerning the degradation of the high-performance engineering polymers selected for vela®. Much of this critical information remains undisclosed by polymer-producing companies, making it necessary to carry out an investigation to assess the durability of these materials.

Simultaneously, the research focused on the structural integrity of the device, evaluating its ability to endure the traction forces exerted during the device's repeated use. Carrying out finite element analysis (FEA) is crucial at this stage, especially since the device is still in the prototyping phase. FEA allows for a virtual exploration of various potential designs and materials, simulating real-world conditions and predicting how the device will respond to different loading scenarios. By conducting FEA before physical testing, it is possible to efficiently identify potential weak points, optimise the design for enhanced durability, and select the most suitable materials, ultimately streamlining the prototyping process and ensuring a more informed and successful final product. FEA was carried out with the software Abaqus CAE (Dassault Systemes, 2017), to simulate the effects of 100 uses on a critical component within vela®, the connection between the cup and the tube. The computational approach provides insights into the mechanical performance of the connection under stress conditions. To enhance the comprehensiveness of the study, the outcomes of material property tests post-reprocessing are incorporated into the finite element model.

Ultimately, this thesis aims to tackle the following research questions:

- Which is the most suitable material for the rigid components?
- What is the optimal design for the connection between the cup and the tube?
- Conclusively, can vela® endure 100 cycles of reuse?

Methods

The methodology employed in this study aimed to comprehensively evaluate whether the vela® VE can withstand 100 re-uses through a bilateral approach. Firstly, the study investigated the impact of reprocessing procedures, including disinfection and sterilisation, which can alter material properties and induce failure. To systematically evaluate these effects, various materials underwent rigorous testing after being exposed to steam sterilisation, glutaraldehyde immersion, sodium hypochlorite immersion or a combination of them. Tensile properties, shore hardness A, weight change and colour stability were evaluated to quantify the alterations induced by reprocessing, providing a comprehensive understanding of the device's material stability throughout its intended life cycle.

Furthermore, a finite element analysis (FEA) was carried out to optimise the design of the tube-cup connection, select the optimal material for manufacturing and evaluate overall resistance to traction forces. To comprehensively incorporate these findings, the results obtained from the post-reprocessing material testing were integrated into the computational model. This integration facilitated a comprehensive mechanical analysis, providing insights into the device's structural integrity considering the effects of both repeated use and reprocessing procedures. In the following sections, the procedures for reprocessing and testing will first be explained, followed by the description of the methodology employed to carry out the FEA.

2.1 Material testing after reprocessing

2.1.1 Materials

The material selection process is a fundamental decision in developing a reusable medical device like vela® VE, given its need to withstand demanding reprocessing conditions and endure high traction forces across numerous cycles. Vela® VE comprises three distinct materials: a hard plastic for rigid components, a soft polymer for the tube, and a reinforcement wire within the tube to bare the traction forces.

The requirements for the hard components include resistance to heat up to 134°C, resilience to moisture and high pressures (up to 15 psi), excellent chemical stability in both acidic and alkaline environments, good mechanical properties, medical grade, colour stability, and chemical bonding properties with silicone. Following a thorough analysis and consultations with various polymer distributors, potential candidates were narrowed down to:

- Grilamid® LKN-5H: a polyamide 12 (PA12)
- Radel® R 5500 NT 15: a polyphenylsulfone (PPSU)
- Udel® GF120 NT: a polysulfone (PSU)
- Ultem® HU1010: a polyetherimide resin (PEI).

In this report these materials will be referred to as: Grilamid, Radel, Udel and Ultem.

For the soft plastic, prerequisites involve resistance to heat up to 134°C, durability against moisture and high pressures (up to 15 psi), excellent chemical stability in acidic and alkaline environments, good colour stability to ensure visual inspection of the cleanliness of the tube's hollow lumen, medical grade, sufficiently flexible, airtight, and

with good bonding properties with a hard plastic. LAYCO® Medical Devices selected high-temperature vulcanized (HTV) silicone as the most appropriate material for this application.

Regarding the reinforcement wire, the criteria include resistance to heat up to 134°C and robust mechanical strength in traction, while maintaining high flexibility. LAYCO® Medical Devices deemed Kevlar® 29 as the most suitable material thanks to its unique properties of high strength, high elastic modulus, toughness and thermal stability.

2.1.2 Sample preparation

The selected materials were acquired from reliable material suppliers. In this section, shapes, dimensions and quantities of the samples of each material will be illustrated in detail. Table 2.1 summarises the information described in this section.

Table 2.1.: Materials investigated and available quantities of each of them.

Material	Manufacturer	Quantity (n)	Coding
Grilamid® LKN-5H	EMS Grivory	48	Grilamid
Radel® R 5500 NT 15	Solvay	48	Radel
Udel® GF120 NT	Solvay	41	Udel
Ultem™ HU1010	Sabic	38	Ultem
HTV Silicone	KaraLuna	96	Silicone
Kevlar® 29	DuPont	18	Kevlar

Grilamid® LKN-5H

A total of 48 samples of Grilamid were acquired from EMS Grivory in the shape of tensile bars (Figure 2.2), with dimensions according to the standard ISO 527 tensile specimen type 1A (Figure 2.1) [6].

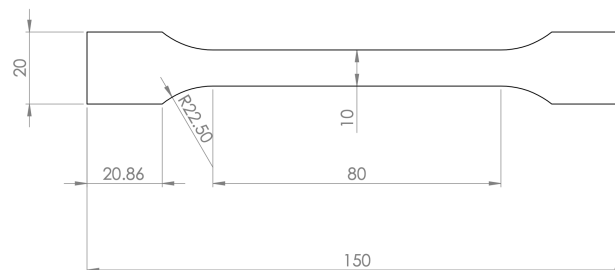


Figure 2.1.: Tensile bar according to ISO 527 tensile specimen type 1A [6]. All dimensions are in mm.



Figure 2.2.: Tensile bars of Grilamid (n=48).

Radel® R 5500 NT 15

Samples of Radel were acquired from Biesterfeld AG, specifically, 8 plates of 6x6 cm with a thickness of 2 mm and a bigger plate of 15x15 cm with a thickness of 5 mm (Figure 2.4). In order to be able to perform tensile tests on the materials, the plates were water jet cut into the shape of tensile bars (Figure 2.4) with dimensions according to the standard ASTM D1708 18 (Figure 2.3) [7]. A total of 48 tensile bars were obtained from the water jet cutting.

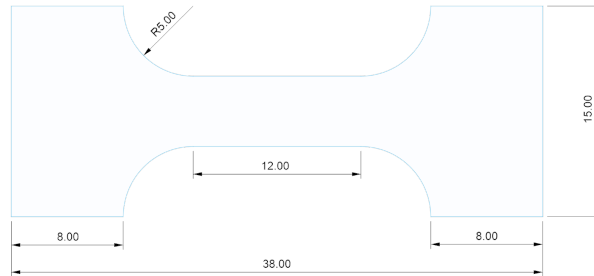


Figure 2.3.: Tensile bar according to ASTM D1708 18 [7]. All dimensions are in mm.



Figure 2.4.: Plates of Radel before and after water jet cutting (n=48).

Udel® GF120 NT

Samples of Udel were acquired from Biesterfeld AG, specifically, 9 plates of 6x6 cm with a thickness of 2 mm and 5 plates of 7.5x5 cm with a thickness of 2 mm (Figure 2.5). In order to be able to perform tensile tests on the materials, the plates were water jet cut into the shape of tensile bars with dimensions according to the standard ASTM D1708 18. A total of 41 tensile bars were obtained from the water jet cutting (Figure 2.5).

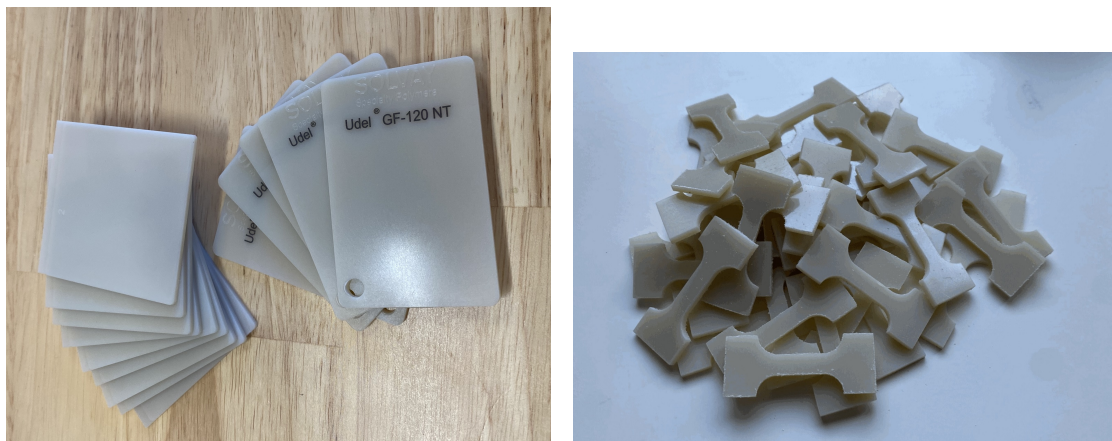


Figure 2.5.: Plates of Udel before and after water jet cutting (n=41).

Ultem® HU1010

A total of 38 samples of Ultem were acquired from Ultrapolymers® in the shape of tensile bars (Figure 2.6), with dimensions according to the standard ISO 527 tensile specimen type 1A (Figure 2.1).



Figure 2.6.: Tensile bars of Ultem (n=38).

HTV Silicone

A silicone sheet with a thickness of 1.2 mm was purchased and cut into regular squares of 3x3 cm (Figure 2.7). Due to the limited thickness of each sample, shore hardness A and weight change measurements were performed on two silicone samples stacked on top one another, yielding a total thickness of 2.4 mm. Furthermore, it was not possible to purchase medical grade silicone, therefore, the sheets of material tested in this study are generic silicone.



Figure 2.7.: Samples of silicone (n=96).

Kevlar® 29

Four and a half metres of Kevlar cord were purchased online. It was cut into 19 specimens each 25 cm long. The reinforcement wires, enclosed within the tube walls, are fully encapsulated by silicone and remain protected from direct contact with disinfectants. Consequently, Kevlar's testing was exclusively conducted after steam sterilisation, as the elevated temperature during this process may potentially impact its properties.

2.1.3 Reprocessing procedures

The material samples underwent different reprocessing methods, including disinfection with sodium hypochlorite, disinfection with glutaraldehyde, steam sterilisation, and a combined disinfection-sterilisation approach. The reprocessing protocols adopted for the procedure are outlined in this section and summarised in Table 2.2. Material properties of the samples were evaluated after 1, 30, and 100 reprocessing cycles. Additionally, a control group was tested without being reprocessed. The experimental setup comprised three samples per condition; however, limited

sample availability prevented having three samples for each material under every condition. Table 2.3 provides an overview of the number of samples tested for each condition.

Table 2.2.: Specifications of each reprocessing method.

Reprocessing condition	Manufacturer	Duration 1 cycle [min]	Coding
Control	-	-	C
Glutaraldehyde 2%	Carl Roth GmbH Co.	40	G
Sodium Hypochlorite 0.5%	Albert Heijn B.V.	20	SH
Autoclave 134°C	MELAG	5 minutes sterilisation time, 25-35 minutes complete cycle	A
Glutaraldehyde 2% + Autoclave 134°C	<i>See above</i>	<i>Duration of each procedure as described above</i>	GA
Sodium Hypochlorite 0,5% + Autoclave 134°C	<i>See above</i>	<i>Duration of each procedure as described above</i>	SHA

Table 2.3.: Conditions table.

Reprocessing method	Cycle	N samples of material, per condition					
		Grilamid	Radel	Udel	Ultem	Silicone	Kevlar
C	0	3	3	3	3	6	3
G	1	3	3	2	1	6	0
	30	3	3	3	3	6	0
	100	3	3	3	3	6	0
SH	1	3	3	2	1	6	0
	30	3	3	3	3	6	0
	100	3	3	3	3	6	0
A	1	3	3	2	1	6	3
	30	3	3	3	3	6	3
	100	3	3	3	3	6	3
GA	1	3	3	1	1	6	0
	30	3	3	3	3	6	0
	100	3	3	3	3	6	3
SHA	1	3	3	1	1	6	0
	30	3	3	3	3	6	0
	100	3	3	3	3	6	3

Glutaraldehyde immersion

Samples were immersed in a 2% glutaraldehyde (Carl Roth GmbH Co.) solution with water. The Center for Disease Control and Prevention (CDC) states that 20 minutes is the minimum recommended exposure time to reliably kill *M. tuberculosis* and nontuberculous mycobacteria with a 2% glutaraldehyde [14].

However, field research conducted in LMICs found that healthcare facilities do not strictly adhere to these guidelines, resulting in much longer immersion times in the disinfectant. Therefore, based on the data collected in Uganda and Kenya by LAYCO® Medical Devices, it is estimated that one disinfection cycle with 2% glutaraldehyde is 40 minutes long. In order to simulate 100 disinfections, the total duration of immersion in the solution is 4000 minutes (67 hours). The 2% glutaraldehyde solution was prepared in a plastic container with a removable lid in a controlled environment at 21° C (Figure 2.8). The samples for each condition were placed in a plastic cup and then immersed in the solution, allowing to identify the individual samples for each condition. After retrieving the samples from the glutaraldehyde

bath, they were rinsed with water and let air dry for 30 minutes. They were then placed in sealed plastic bags in a dark environment and stored at room temperature until transport to the testing facility at the TU Delft.



Figure 2.8.: Immersion of samples in 2% glutaraldehyde aqueous solution.

Sodium hypochlorite immersion

Samples were immersed in a 0.5% sodium hypochlorite aqueous solution. The WHO recommends a 10 minutes immersion in 0.5% sodium hypochlorite aqueous solution to safely decontaminate instruments such as vaginal speculum, vaginal retractors and biopsy forceps [27].

However, to simulate the procedures adopted in LMICs, based on the data collected in Uganda and Kenya by LAYCO® Medical Devices, it is estimated that one disinfection cycle with 0.5% sodium hypochlorite is 20 minutes long. In order to simulate 100 disinfections, the total duration of immersion in the solution is 2000 minutes (34 hours). The 0.5% sodium hypochlorite solution was prepared in a plastic container with a removable lid in a controlled environment at 21° C (Figure 2.9). The samples for each condition were placed in a plastic cup and then immersed in the solution, allowing to identify the individual samples for each condition. After retrieving the samples from the glutaraldehyde bath, they were rinsed with water and let air dry for 30 minutes. They were then placed in sealed plastic bags in a dark environment and stored at room temperature until transport to the testing facility at the TU Delft.



Figure 2.9.: Immersion of samples in 2% sodium hypochlorite aqueous solution.

Steam sterilisation

Samples were sterilised with the tabletop autoclave MELAtronic 17 (© MELAG Medizintechnik GmbH & Co. KG) (Figure 2.10). The sterilisation cycles reached 134°C at 2 bar pressure for 5 minutes. Autoclave tape was used in every sterilisation cycle to confirm that the temperature of 134°C was correctly reached (Figure 2.11). The autoclave is equipped with a pressure gauge with a non-return (slave) pointer which shows the maximum pressure achieved. It was confirmed that for each cycle the pressure reached at least 2 bars. One complete sterilisation cycle took 25-35 minutes from start to end. The samples' location rotated every 15 cycles to ensure that they were equally exposed to all the positions (Figure 2.12). After retrieving the samples from the autoclave they were let cool down and air dry for 30 minutes. They were then placed in sealed plastic bags in a dark environment and stored at room temperature until transport to the testing facility at the TU Delft.



Figure 2.10.: MELAtronic 17 (© MELAG Medizintechnik GmbH & Co. KG) autoclave with pressure gauge and temperature indicator.

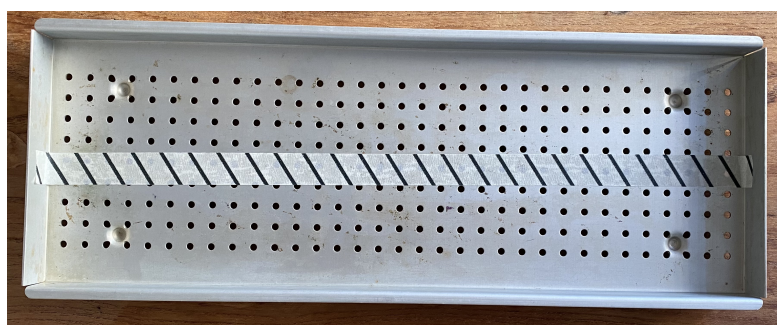


Figure 2.11.: Autoclave tray with autoclave tape applied on its entire length, showing that a temperature of 134°C was reached in every location.

Combination of disinfection and sterilisation

The samples which were selected to undergo both disinfection and sterilisation were first disinfected, according to the procedure previously described in this section. After retrieval, they were rinsed with clean water, let air dry and subsequently placed in the autoclave to be sterilised. After retrieving the samples from the autoclave they were let cool down and air dry for 30 minutes. They were then placed in sealed plastic bags in a dark environment, at room temperature until transport to the testing facility at the TU Delft.



Figure 2.12.: Loaded autoclave tray.

2.1.4 Testing protocols

In this section, the procedures followed for each testing method will be outlined in detail. Specifically, the tensile properties of Grilamid, Radel, Udel, Ultem and Kevlar were assessed with a tensile testing machine. The shore hardness A values of silicone were determined with a durometer. Colour stability of Grilamid, Radel, Udel, Ultem and silicone was qualitatively assessed from photographs of the samples. Finally, the weight change of Grilamid, Radel, Udel, Ultem and silicone was measured with a precision scale.

Tensile properties

For the purpose of this research, the tensile properties of Grilamid, Radel, Udel, Ultem and Kevlar were assessed for each condition. The ZwickRoell Z010 material testing machine was used to perform tests on the samples with 10 kN wedge grips (Figure 2.13). The test was conducted at different speeds for each material, specifically 5 mm/min for Grilamid and Ultem, 4 mm/min for Kevlar, 3 mm/min for the 5 mm thick samples of Radel and 2 mm/min for Udel and the 2 mm thick samples of Radel. The force-deformation data points were exported. The results obtained from the tensile tests of each sample were compared with the data from the control group.

Shore Hardness A

Silicone samples were tested for shore hardness A with a durometer (instrument made and tested in line with the ISO 868-1986 Plastics and rigid rubber) with a resolution of 0.5 HA and a range of 0-100 HA. To obtain more accurate measurements, the durometer was employed to assess the combined thickness of two silicone samples stacked on top one another, yielding a total thickness of 2.4 mm. The shore hardness A measurements recorded from each sample were compared with the values from the control group.

Colour Stability

In a room with no source of natural light, under controlled and consistent lighting conditions (nanlight 60b at 5600k with a soft box and grid at 3890 lumen), a picture of each sample was captured with a mounted camera (Canon R6 Mark II with lens Canon EF 50 mm F1.8) in raw form with consistent camera settings (ISO 400 f2.5 shutter speed 1/100). The images were qualitatively compared with the values from the control group.

Weight change

The weight of each sample was recorded with a precision scale with a resolution of 0.01 g before and after reprocessing. The post-processing weights were recorded 30 minutes after reprocessing, allowing for the samples to air dry. The data was used to calculate the weight change for each sample.

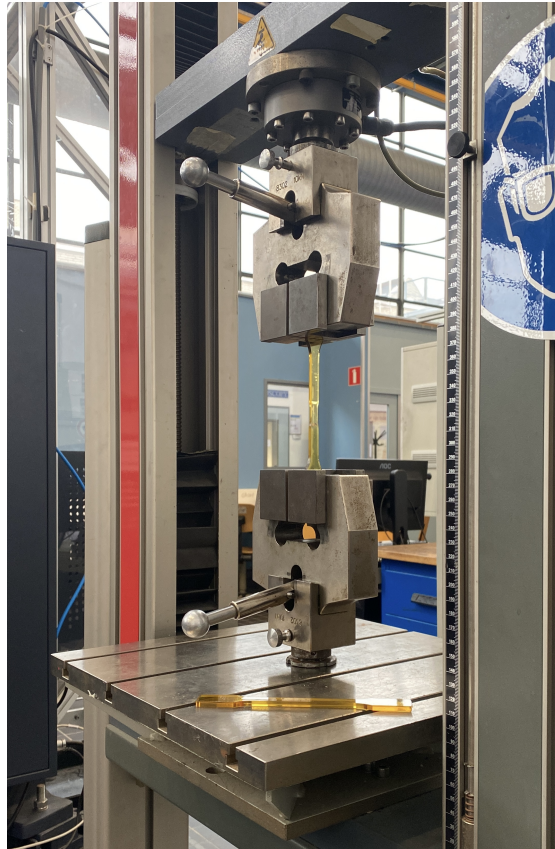


Figure 2.13.: ZwickRoell Z10 testing a sample of Ultem® HU1010.

2.2 Computational Modelling

FEA was carried out with the software Abaqus/Explicit finite element solver (SIMULIA, Dassault Systemes, 2017) to evaluate the effects of the traction forces on the device during its repeated use and to compare different materials and designs and their ability to withstand the forces exerted during delivery. The analysis was carried out for one specific component of the vela® VE, more precisely, the critical connection point between the tube and the cup. The decision to concentrate on this particular component came from an evaluation of the potential weak links in the device. The connection between the tube and the cup was regarded as the most likely to fail due to the high traction forces exerted on the tube. Figure 2.14 shows the vela® VE, drawing attention to the tube and cup components.

The cup is the component which is placed on the baby's head and it is made of a hard plastic. The tube is the component which allows for the partial vacuum to be created inside the cup by pumping with the handle and it is made of silicone. As silicone alone is not suitable for withstanding high traction forces, reinforcement wires are integrated inside the tube to bear the forces exerted during the extraction process. These wires extend along the entire length of the tube, from the cup to the handle. To ensure stability, the wires are securely attached to the cup through an over-molding process during injection moulding of the cup. The cup and wires are then further encapsulated with silicone, not only facilitating the creation of a vacuum within but also preventing the accumulation of dirt in these critical areas, ensuring the safety and effectiveness of the vacuum extraction procedure. Figure 2.15 shows different views of the cup-tube component, including a longitudinal section, showing one reinforcement wire.

The FEA was conducted on three different designs of the tube-cup connection. Each design has specific features which will be detailedly explained in the next sections. The characteristics which are in common to all three designs will only be explained once, showing images from one of the three. In the following paragraphs, the computational model will be described in detail.

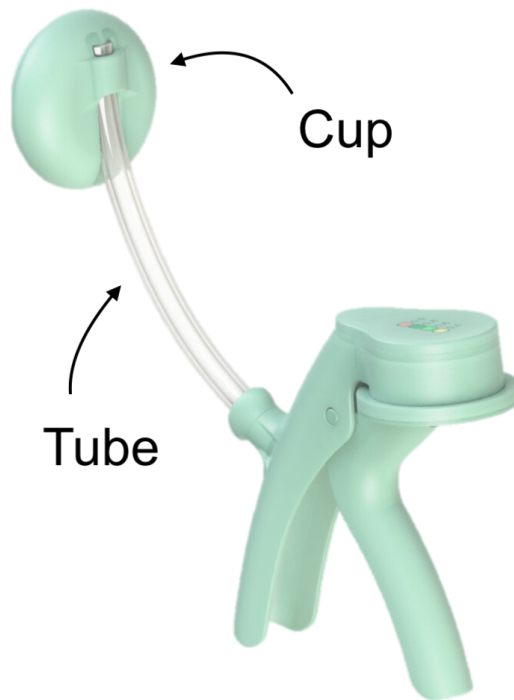


Figure 2.14.: Rendering of the vela® VE highlighting the components of tube and cup (this drawing does not represent the final design of the vela® VE).

2.2.1 Geometry

In the geometric representation of the tube-cup connection, the parts were simplified to enhance computational efficiency. The silicone part of the tube was intentionally excluded from the model, as it was anticipated that all loads would be borne by the reinforcement wire, and the tube itself would not undergo significant stress. Consequently, the model only included two components: the reinforcement wire and the cup. In Figure 2.16 it is possible to see the reinforcement wire overmolded in the cup, without the silicone tubing. To streamline the computational process, only a section of the cup was integrated into the model. This selected portion constituted a disc centred around the entry point of the wire into the cup (Figure 2.17).

Both components, the reinforcement wire and the cup, were modelled as 3-dimensional rigid bodies to capture the interactions within the critical connection point of the vela® VE. The rationale behind modelling the disc as a 3D rigid body was evident, given that the wire traverses through its thickness. The choice of modelling the reinforcement wire as a 3D body instead of as a beam came from the intention to examine stress distribution not only along the length but also throughout the thickness of the wire. The decision to treat it as a 3D body was justified by the nature of its stress conditions, experiencing tension exclusively without any compression forces.

Only half of the geometry was modelled, under the assumption of symmetry. Despite the fact that the applied traction forces would not be entirely perpendicular to the cup, but would also have x and y components, symmetry along the xz-plane was assumed. This is justified by the fact that the x and y components are significantly smaller than the z component. Symmetry along the yz-axis could not be incorporated into the model due to the inherent asymmetry in the geometry itself.

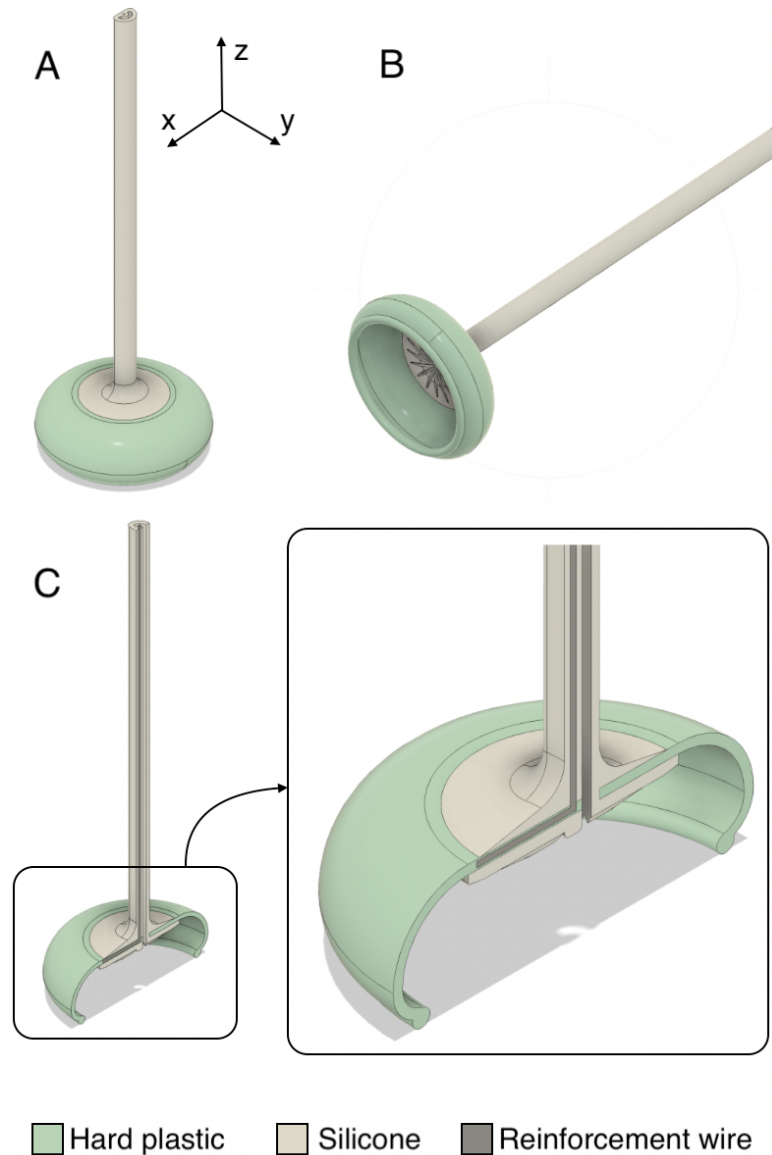


Figure 2.15.: Computer-aided designs (CAD) of the connection between the tube and the cup.

A. Side view of the design.

B. Bottom view of the design.

C. Section of the component and close-up.

The white coloured components represent silicone material, while the light green indicates the hard plastic and the dark grey denotes the reinforcement wire (images from Model 3).

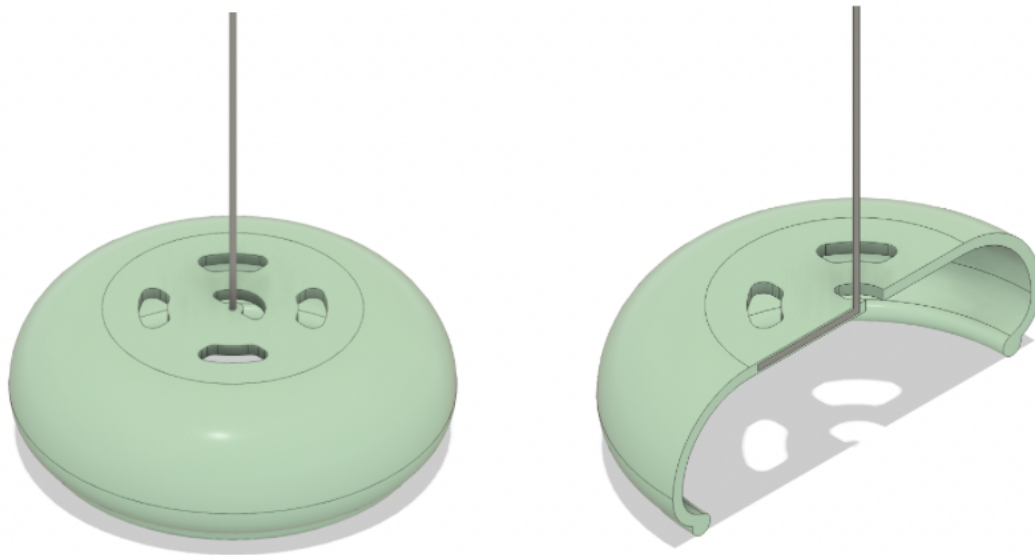


Figure 2.16.: Tube-cup component with only the cup and the reinforcement wire, without the silicone (image from Model 3).

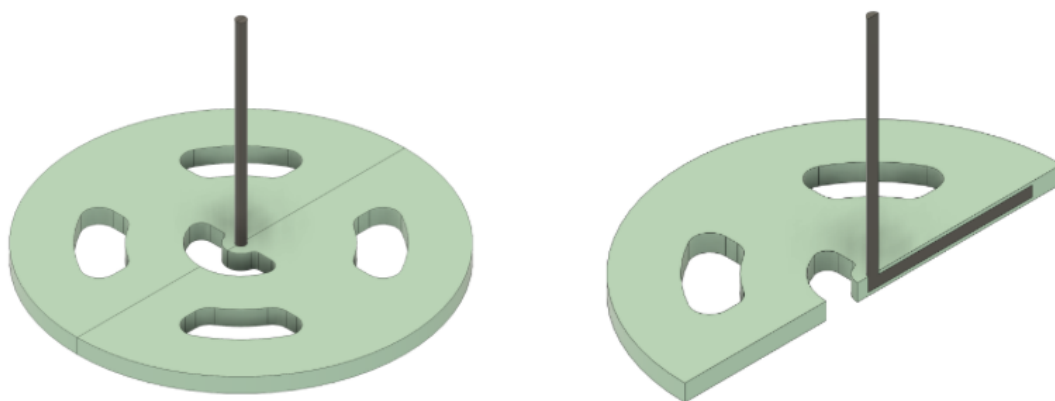


Figure 2.17.: Simplified tube-cup component with only a portion of the cup and the reinforcement wire (image from Model 3).

2.2.2 Designs

Three different designs were evaluated in the early stages of computational modelling. Each has specific features that should be evaluated. Their characteristics and dimensions will be outlined in the following paragraphs.

2.2.2.1 Model 1

The first model is the most simple design, consisting of a disc with a hole in the middle to allow air extraction to create vacuum and 2 reinforcement wires entering in its thickness. The disc has a diameter of 20 mm and a thickness of 2 mm. The central hole has a diameter of 5 mm. The wires each have a diameter of 0.5 mm and their edge closest to the central hole is located at 0.5 mm from it. Figure 2.18 shows the design with its dimensions.

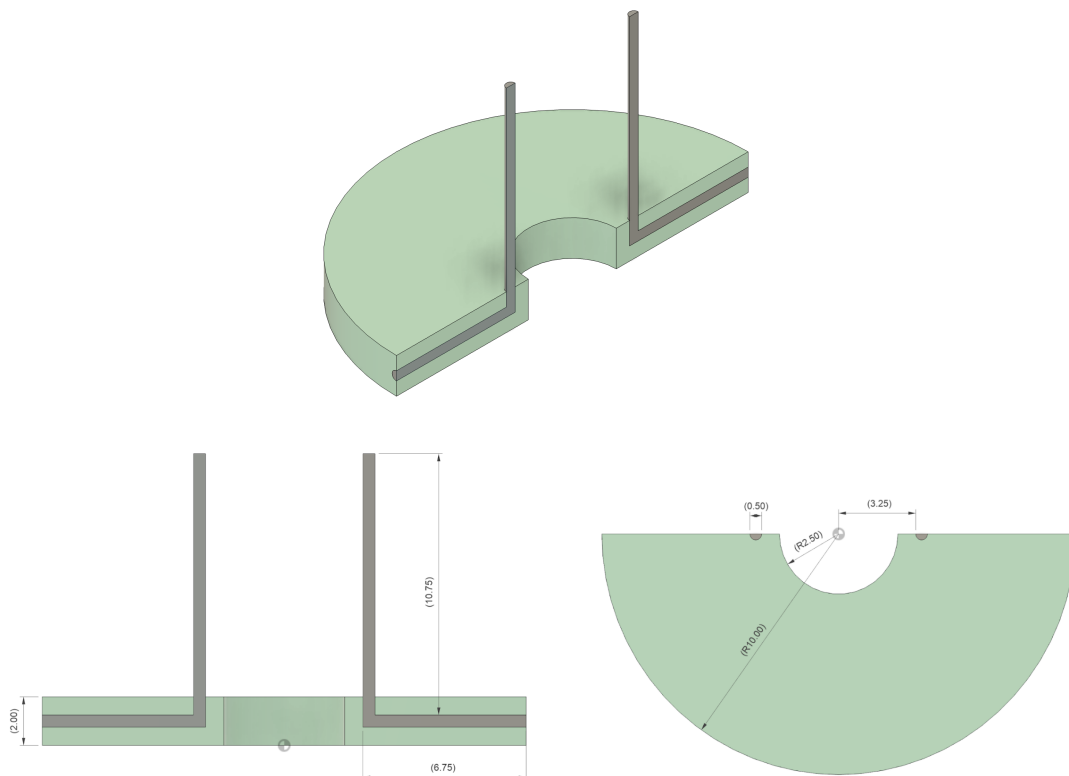


Figure 2.18.: Model 1 (all dimensions are in mm).

2.2.2.2 Model 2

Model 2 is similar to the previous one. However, it has an additional notable feature: an added thickness around the central hole to increase support to the reinforcement wires. The entire disc has a diameter of 22.2 mm and the additional layer around the central aperture has an external diameter of 10 mm. The entire disc is 3 mm thick and the additional layer around the whole is 6 mm thick. Moreover, the central hole is not a circumference, but an ellipse with a minor axis of 3.5 mm and a major axis of 5 mm. There are two reinforcement wires, each with a diameter of 0.5 mm. Figure 2.19 shows the design with its dimensions.

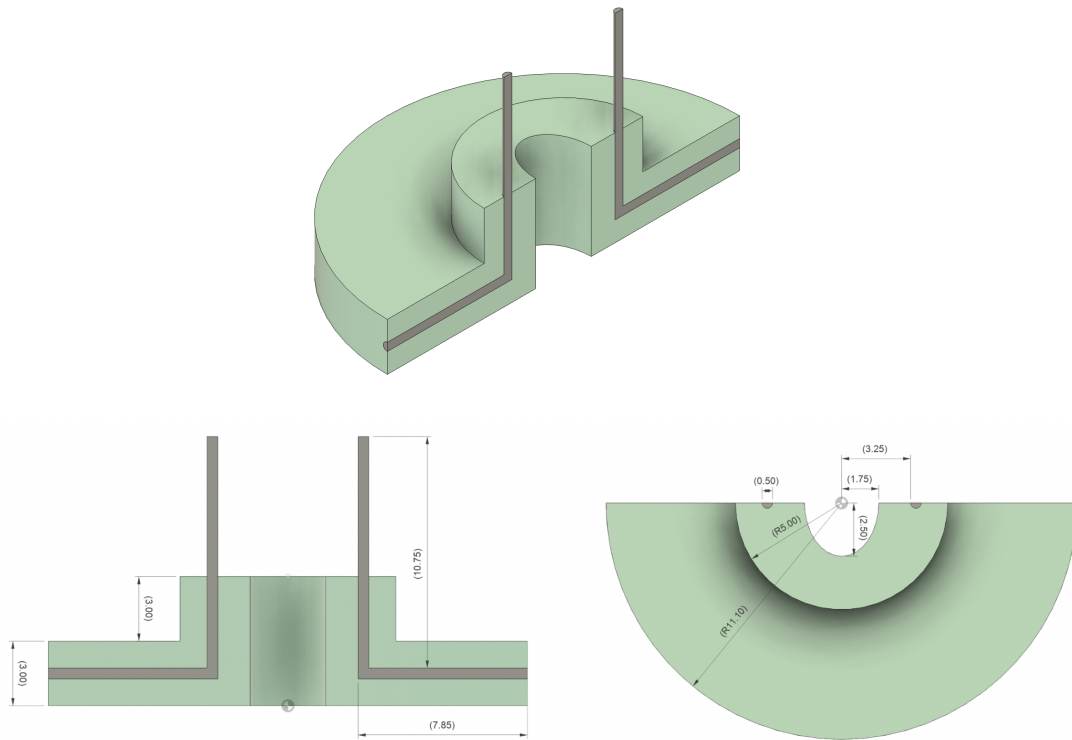
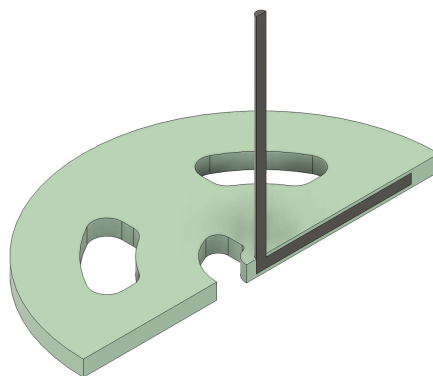


Figure 2.19.: Model 2 (all dimensions are in mm).

2.2.2.3 Model 3

The last design features four additional holes besides the central aperture representing the lumen of the tube. The four holes, located externally on the cup, were incorporated for manufacturing considerations. These perforations facilitate a robust connection between the silicone and the hard plastic cup during the injection moulding pouring process, ensuring structural coherence between the two components. The disc has an external diameter of 36 mm and a 1.6 mm thickness. This design comprises a single reinforcement wire with a diameter of 1 mm, located at the centre of the disc. Figure 2.20 shows the design with its dimensions.



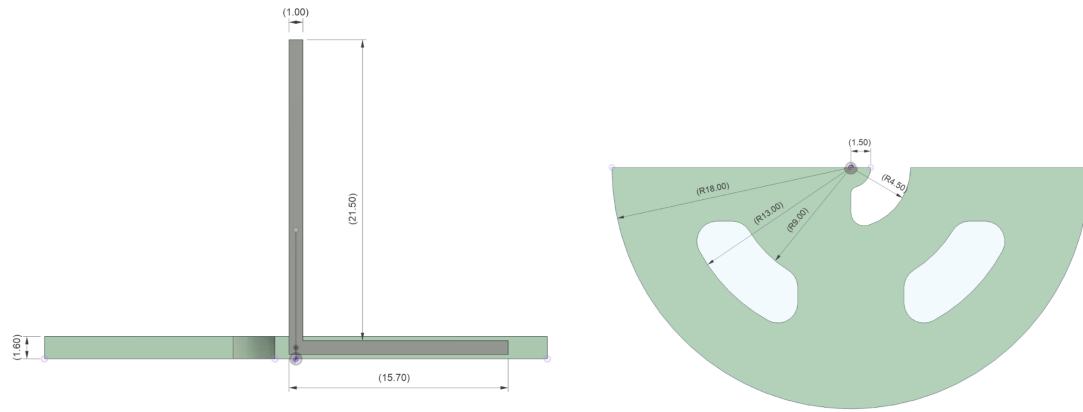


Figure 2.20.: Model 3 (all dimensions are in mm).

2.2.3 Material Properties

Several material models were created based on the results retrieved from tensile testing of the material samples, described in Section 3.1.1. For each material, two models were created: one based on the control group (un-reprocessed) and the other with the properties observed after the most impacting method, specific to each material. More detailed information regarding the materials' modelling can be found in Appendix C.

The force-displacement data points of the control group and of each test group after 100 cycles of reprocessing with a specific method were imported in MATLAB version R2023b (MathWorks Inc.). The stress strain components were calculated from the dimensions of the sample, under the assumption of small deformations for which the true stresses and strains are equal to the engineering stresses and strains. The curves were interpolated and a mean curve for each group was calculated. The first portion of the curve was linearised and the steepness of the linear fit represents the Young's modulus. A 0.2% offset was applied to the line. The intersection point between the offset and the stress-strain curve represents the yield point. The hardening region's data points to model plasticity in Abaqus were calculated by subtracting the elastic values from the yield point onwards. Figure 2.21 shows the linearised portion, the 0.2% offset line and the intersection point found for the control group of Grilamid.

Kevlar and Udel were modelled as a linear elastic material, with Poisson's ratio of 0.4. Grilamid, Radel and Ultem were modelled as elastoplastic materials, with Poisson's ratio of 0.4.

2.2.4 Interactions and Constraints

The interaction between the disc and the reinforcement wire is characterised by a chemical bond, where the wire is over-molded into the disc to establish a robust connection. To accurately represent this bond in the computational model, a tie constraint was implemented. This tie constraint reflects the physical reality of the chemical bond formed during the manufacturing process, ensuring that the disc and the reinforcement wire behave as a single, integrated unit.

Additionally, a reference point was created on the surface at the top of the wire (for Model 1 and 2 with two reinforcement wires, two reference points were created, one for each surface). It was then coupled with that surface so that the loads applied to the reference point would distribute to the top of the wire.

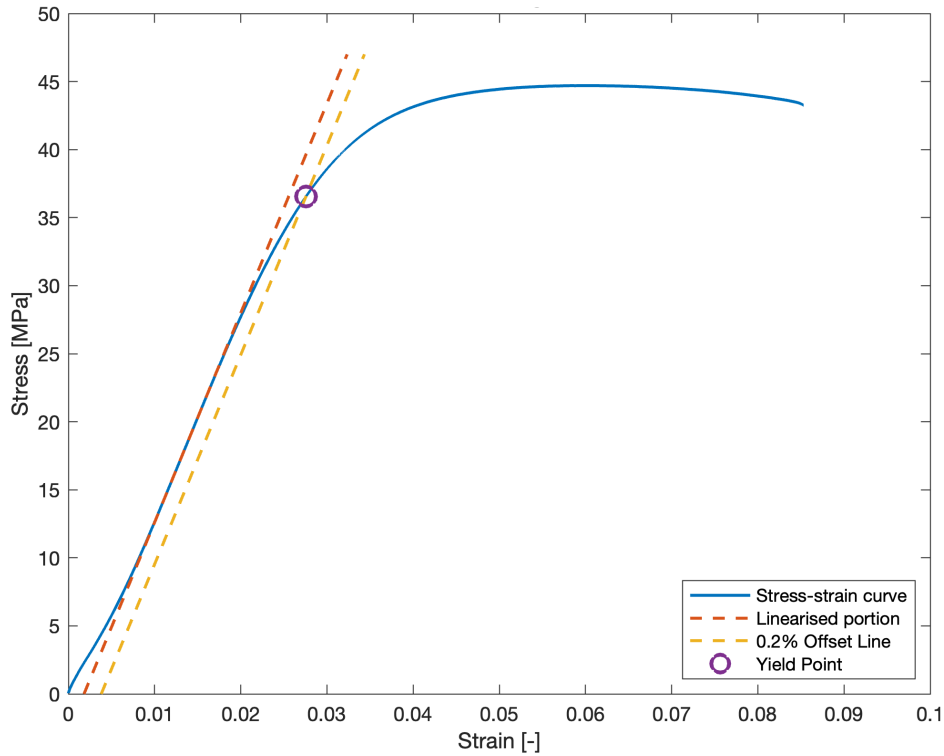


Figure 2.21.: Stress-strain curve of Grilamid, with linearised portion, 0.2% offset line and yield point.

2.2.5 Boundary Conditions

For the computational model's boundary conditions (BCs), two key BCs were implemented to simulate realistic scenarios. Firstly, a symmetry boundary condition along the y-axis was established to apply the assumed symmetry to the model. This condition allowed for modelling only half of the geometry, significantly reducing computational complexity while still capturing the essential mechanical behaviour of the vacuum extractor's critical components.

Secondly, the top surface of the disc (the side oriented towards the tube) was fixed with an encastre boundary condition. This constraint reflected the practical scenario where the cup, anchored to the baby's head by the created vacuum, experiences minimal relative motion. By setting the top surface as encastre, any movement in the radial or axial directions was restricted, aligning with the expected stability of the cup during its intended use.

2.2.6 Loads

After conducting a literature search on traction forces applied during vacuum extraction, it was found that previous studies reported a maximum stress of 453N [1–3, 8, 28–32]. This value was chosen as the basis for applying loads in the finite element analysis (FEA), given the objective of assessing the worst-case scenario. The load, equivalent to 453N, was applied at the reference point, coupled to the surface at the top of the wire, with a ramp amplitude. In Models 1 and 2, where two wires are included in the design, the load was applied entirely to one wire, simulating a clinical scenario where the cup is bent at a 90° angle from the tube axis, and all the load is concentrated on a single wire.

Moreover, various sources in the literature have defined an upper limit for safe traction force during vacuum extraction at 225N, beyond which there is a risk to the baby [1–4, 33]. Therefore, this scenario was also investigated

once the final design and optimal material were defined. For comprehensive information and further details regarding the traction forces observed during vacuum extraction, please refer to Appendix A.

2.2.7 Mesh

Each part of the model was independently meshed. The element type selected for this FEA is a standard, linear element without reduced integration (element type: C3D8). The wire(s) were meshed with hex elements with a structured meshing technique. A global element size was defined for the entire part. The disc was meshed with hex dominated elements to allow some triangular prisms in transition regions. A finer mesh was obtained in the "critical" area of the disc, corresponding to the lumen where the wire runs through, where the highest stresses are to be expected. The rest of the disc was meshed with a single bias going from the finer mesh close to the lumen to a coarser mesh in the rest of the part. The element sizes were selected based on the results of accurate mesh sensitivity tests, run independently for each design and the results are shown in Table 2.4. The detailed results of the mesh sensitivity test can be found in Appendix D.

Table 2.4.: Approximate element size for the parts of each model

Approximate element size	Disc - close to lumen	Disc - non critical	Wire
Model 1	0.20	2	0.27
Model 2	0.27	2	0.27
Model 3	0.32	2	0.27

2.2.8 Step and Analysis

A static general step with the option of non linear geometry was used to carry out the analysis. No automatic stabilisation was selected. The maximum number of increments was set to 10,000 with an initial increment size of 0.01, minimum of 1E-12 and maximum of 0.1.

The primary objective of this finite element analysis is to conduct a comprehensive comparison of diverse designs and materials, focusing on their respective impacts on stress distributions within the tube-cup component of the vela® VE. To facilitate this investigation, an initial design optimization was meticulously structured. Four key design parameters were identified and systematically varied to assess their effects on stress distributions in both the wire and the disc. Particularly, the parameters are:

- Diameter of the wire: the wire's diameter values were varied between 0.5 mm and 1.5 mm. It was not increased above 1.5 mm due to user requirements to maintain the tubing component as thin as possible.
- Thickness of the disc: the disc's total thickness included values between 1.6 mm in the initial design of the third model and up to 6 mm in the reinforcement layer of the second model.
- Positioning of the wire: the location of where the wire enters the disc is described by its relative distance from the inner cavity of the disc. It varied between 0.5 mm and 1 mm.
- Length of the wire: it indicates the distance between the level where the wire enters the disc and the top surface where the load was applied. It was increased by 50% to evaluate its influence on the results of the simulations.

To maintain methodological rigor and isolate the effects of design variations, a composite material model was devised to simulate the elastoplastic behavior observed in the plastics under consideration for the vela® VE. The worst case loading scenario, corresponding to a traction force of 453 N was applied to each model. Due to time constraints, it was unfeasible to execute exhaustive simulations encompassing every possible combination of design variations. Therefore, the lowest amount of design variations was run, while allowing to draw significant conclusions.

Following the analysis of these parameters, a final design was selected, and various material models, based on

the tensile testing results, were assigned to the components. Two simulations were then executed for each material, one with the material model created from the control group and the other simulating the properties recorded after the most damaging reprocessing condition. Based on these findings and the intrinsic material properties, a plastic material was identified as the optimal choice for the vela® VE.

Finally, the stress levels and deformations observed in both the disc and the wire will be meticulously described. This analysis will encompass two loading scenarios: the worst-case scenario, exerting a pulling force of 453N, and the scenario representing the upper limit for safe traction force at 225N. Detailed results will be presented in Section 3.2.3 and discussed in Section 6.

Results

This chapter describes in detail the results obtained from the materials testing and the computational modelling. The first part is focused on the mechanical and physical properties of the materials studied in this project that have been tested before and after reprocessing with different methods. After that, the results obtained from the FEA will be shown, comparing different designs and materials, including the earlier measured post-processing material properties. Table 3.1 summarises the coding used to describe the different material and reprocessing conditions

Table 3.1.: Coding of test groups as combination of material, reprocessing method and number of cycles.

Materials	Coding	Reprocessing method	Coding	N cycles
Grilamid® LKN-5H	Grilamid	Control	C	1
Ultem™ HU1010	Ultem	Glutaraldehyde	G	30
Radel® R 5500 NT 15	Radel	Sodium Hypochlorite	SH	100
Udel® GF120 NT	Udel	Autoclave	A	
Kevlar® 29	K	Glutaraldehyde + Autoclave	GA	
Silicone	S	Sodium Hypochlorite + Autoclave	SHA	

3.1 Materials Testing

As previously described in Section 2, the six materials included in this study were reprocessed under different disinfection and sterilisation methods, or a combination of them, and their properties were assessed. Particularly, the next paragraphs will describe the results of the materials' tensile properties, their weight change, their colour stability and shore hardness A values of silicone.

As previously described in Table 2.3, a maximum of three samples for each material was available per condition. Additionally, due to the limited availability of Udel and Ultem only one or two samples were tested for specific conditions. Furthermore, one sample of Udel was damaged while performing a tensile test and its results were not recorded (specifically, a sample that had been autoclaved for 30 times).

3.1.1 Tensile Properties

Tensile properties of the materials were assessed with a ZwickRoell Z010 material testing machine, which automatically records yield stress, maximum stress and ultimate deformation values. Figure 3.1 shows the mean stress strain curves calculated as described in Appendix C of the control group of the materials considered for the cup of the vela® VE. The following sections will show and describe the results obtained from the tensile tests of Grilamid, Ultem, Radel and Udel, the materials currently under evaluation as candidates to be used to manufacture the cup of the vela® VE. Kevlar's tensile properties were also evaluated with the same procedure as for the previously described materials. However, its properties will be shown and described separately from the others, since Kevlar has a different application than the other materials. It will constitute the reinforcement wire in the tube of the vela® VE and it is currently the only material selected for this application.

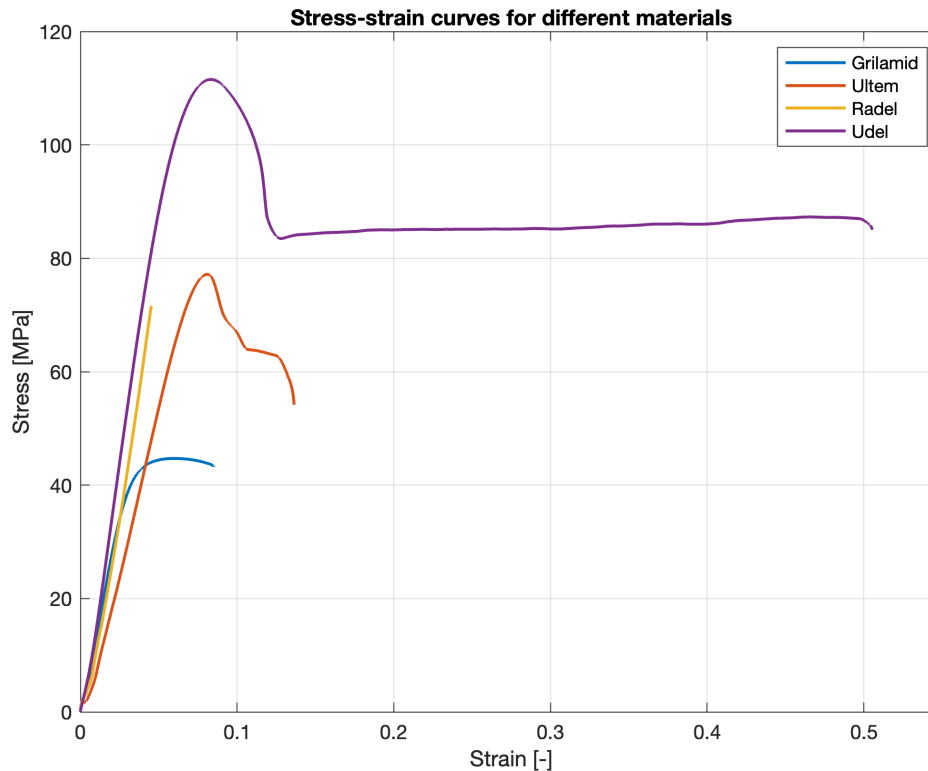


Figure 3.1.: Mean stress strain curves of the control group of every material.

Maximum stress and yield stress values

As previously mentioned (Section 2.2.3), Grilamid, Ultem and Radel are elastoplastic materials, which show an elastic behaviour for small loads and undergo plastic deformation once the loads are increased. Their mean yield stress values, recorded after each of the reprocessing condition, are shown in Figure 3.2. On the other hand, Udel shows a purely elastic behaviour. The maximum stress values of Udel are also shown in Figure 3.2d. Additionally, Figure 3.3 shows the percentage change in yield stress, calculated relative to the control, to assess the impact of reprocessing.

Firstly, observing the results obtained for Grilamid, it is possible to see that its yield stress values range from a maximum of 45.25 MPa (± 0.08) to a minimum of 31.10 MPa (± 0.24). By comparing the values recorded for the control group with the ones after disinfection with glutaraldehyde or bleach, it is noticeable that these reprocessing methods do not have a significant impact on its properties. On the other hand, steam sterilisation (on its own or in combination with a disinfection method) determines a significant change in yield stress, reaching almost a 30% decrease after 100 cycles, going from 43.02 MPa (± 0.35) to 31.10 MPa (± 0.24).

Ultem shows considerably higher yield stress values, with the lowest value recorded at 110.11 MPa and the maximum as high as 116.03 MPa. As for Grilamid, Ultem's yield stresses do not seem to be significantly impacted by disinfection methods. Conversely to the trend observed for Grilamid, where reprocessing methods including autoclaving determined a significant decrease in its yield stress, it can be observed that steam sterilisation determines an increase in the yield stress values of Ultem. Particularly, the highest yield stress recorded among all samples was for obtained after 100 cycles of disinfection with sodium hypochlorite followed by 100 cycles of autoclave.

Yield stress values of Radel range between 77.00 MPa (± 1.64) and 80.40 MPa (± 1.02). These values are considerably lower than the ones recorded for Ultem, but higher than the ones of Grilamid. Looking at the effect of reprocessing methods on its yield stress values, they appear to remain relatively constant throughout the reprocessing cycles, only recording a slight increases after the combination of disinfection methods and steam sterilisation.

Udel's maximum stresses are in a similar range than the ones of Radel, but with a higher variance. Particularly, they go from as low as 61.12 MPa, recorded after 100 cycles of glutaraldehyde disinfection and steam sterilisation, to as high as 95.48 MPa, observed after one cycle of immersion in 2% glutaraldehyde. Studying the effect of reprocessing methods on Udel, it is not possible to identify any specific trend in the maximum stress values of Udel. The standard deviations of the mean maximum stresses have high amplitudes, which indicates a considerable variance.

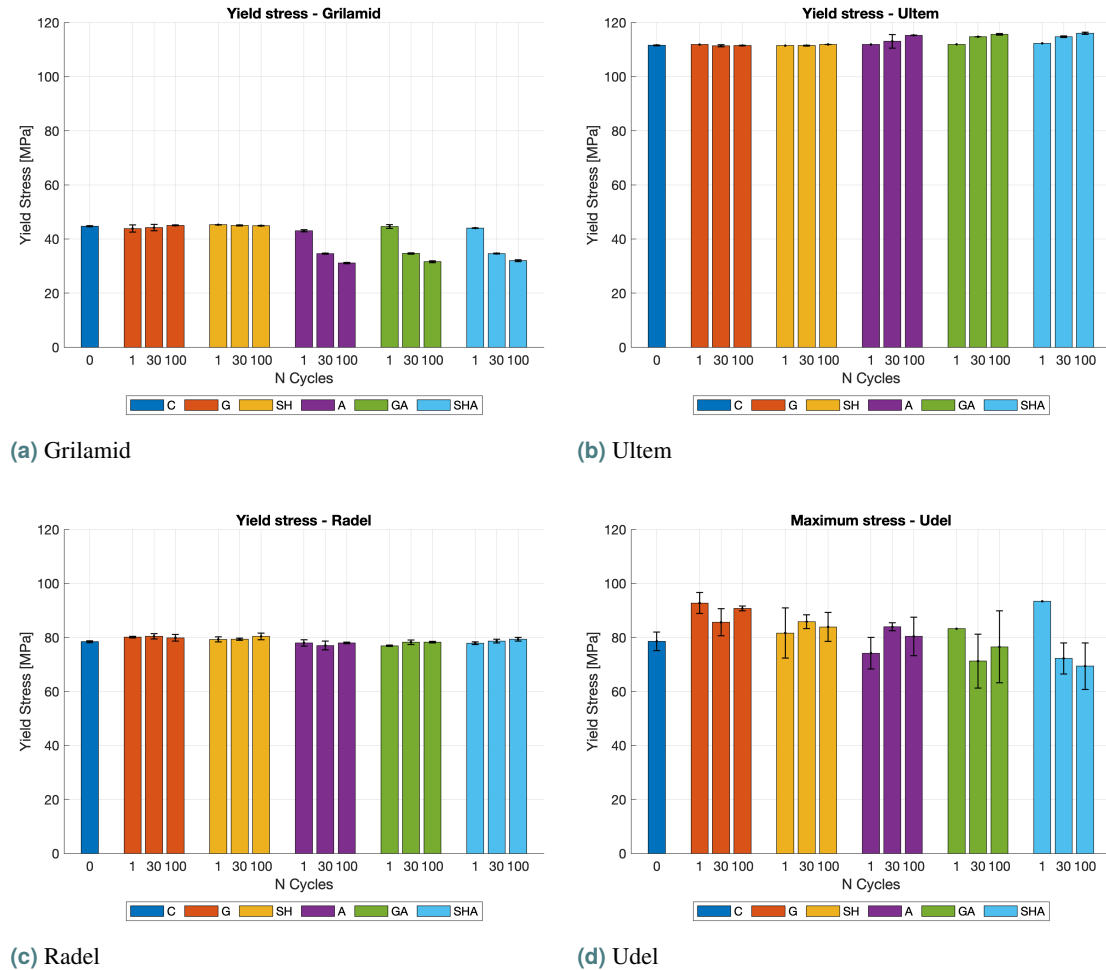
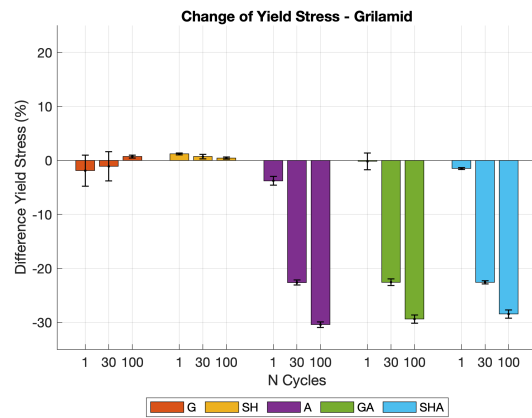
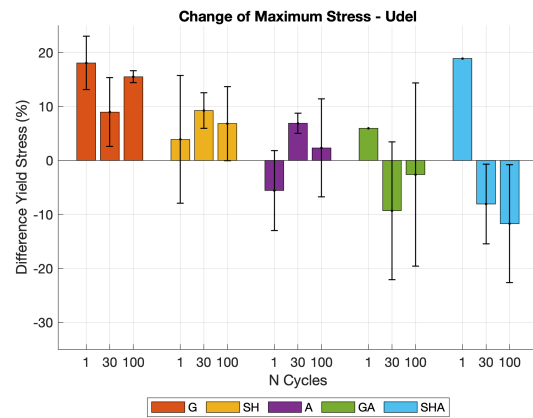


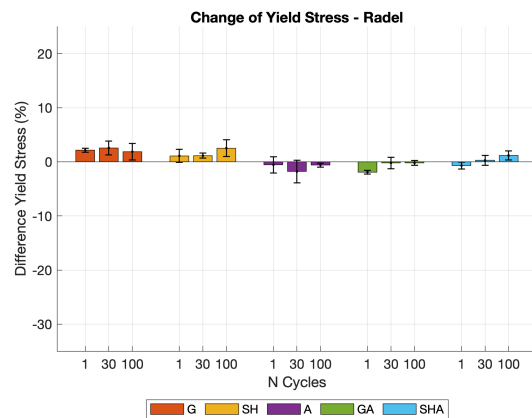
Figure 3.2.: Yield stress values for each material after 1, 30 and 100 cycles of different reprocessing methods.



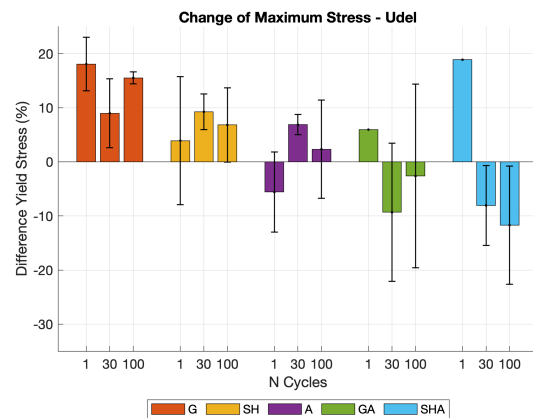
(a) Grilamid



(b) Udel



(c) Radel



(d) Udel

Figure 3.3.: Percentage change in yield stress values for each material after 1, 30 and 100 cycles of different reprocessing methods.

Ultimate deformation values

The ultimate deformation values, referring to the material's capacity to deform under stress before the break, of Grilamid, Ultem, Radel and Udel are shown in Figure 3.4, while Figure 3.5 displays their relative change to the control group.

Ultimate deformation values of Grilamid are in the range of 8.49% (± 0.63). Such a low overall standard deviation also shows that these values remained stable across different reprocessing methods and cycles, with only slight decreases. On the other hand, Ultem shows significantly different values of ultimate deformation, going from as low as 5.65%, observed after 30 cycles of glutaraldehyde disinfection followed by 30 cycles of autoclave, to as high as 72.98%. The standard deviations of these results indicates a considerable variance in the ultimate deformations of Ultem. Overall, it is possible to observe that steam sterilisation seems to determine an important decrease in ultimate deformation values. However, these values have a high variance. It is also impossible to observe a specific trend over the number of cycles. The values of Radel have less variation than the ones of Ultem, going from a minimum recorded value of 9.14% to a maximum of 25.52%. Overall, Radel shows minor changes in its ultimate deformations after disinfection procedures. However, it seems to be significantly affected by steam sterilisation and its combination with disinfecting products. While the mean ultimate deformation of the control group is 15.42% (± 2.87), the values already after one cycle of autoclaving go up to 21.99% (± 1.68). The values of ultimate deformations of Udel seem to be almost unaffected by reprocessing, with insignificant changes over the number of cycles and the different methods, with a total recorded average of 4.81% (± 0.41).

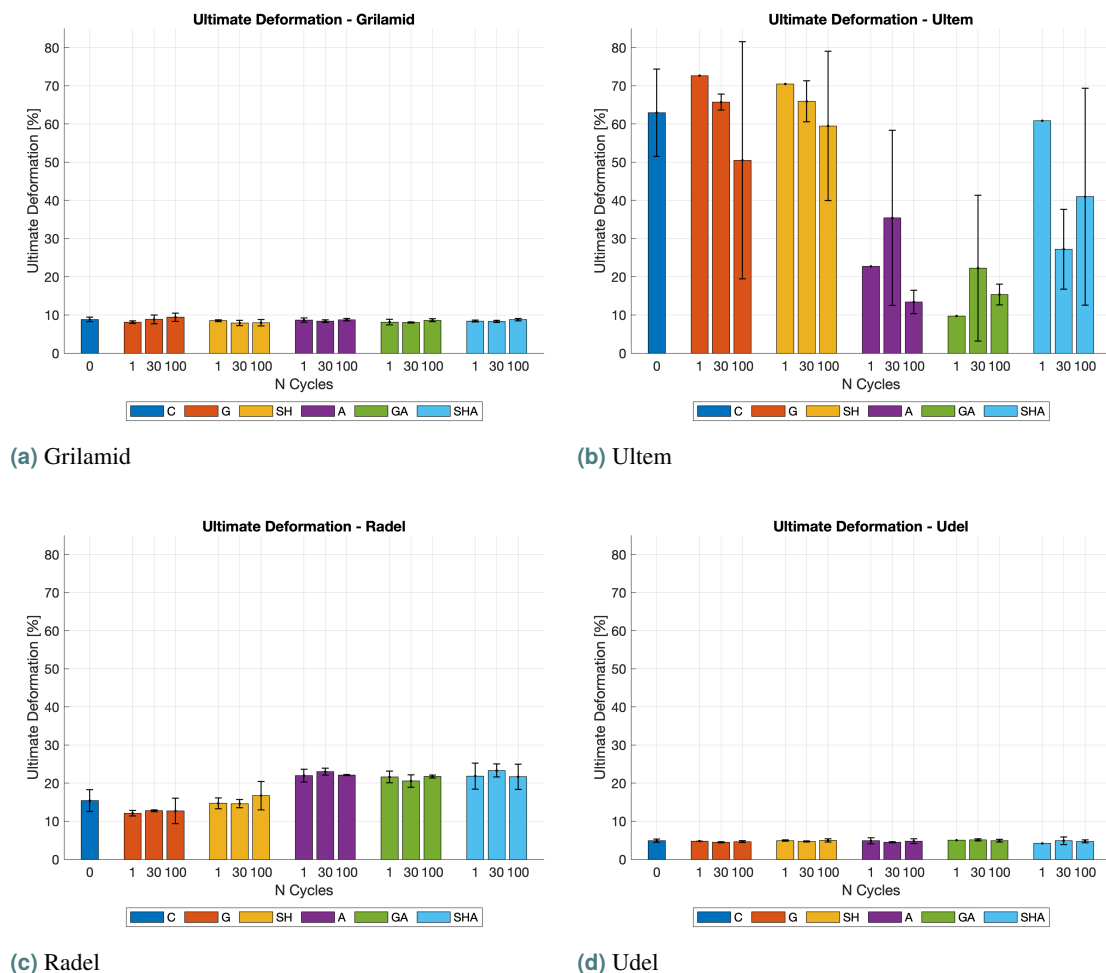
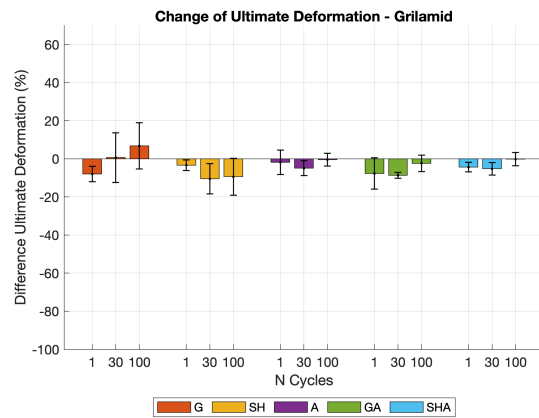
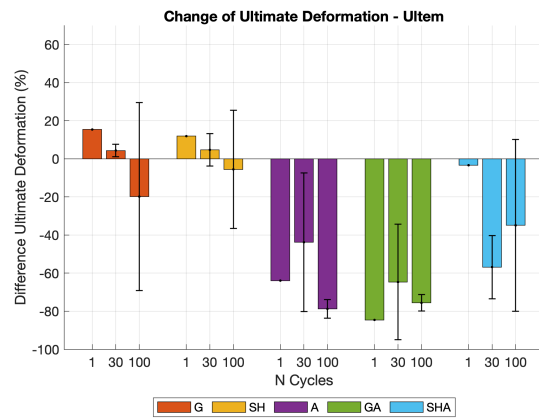


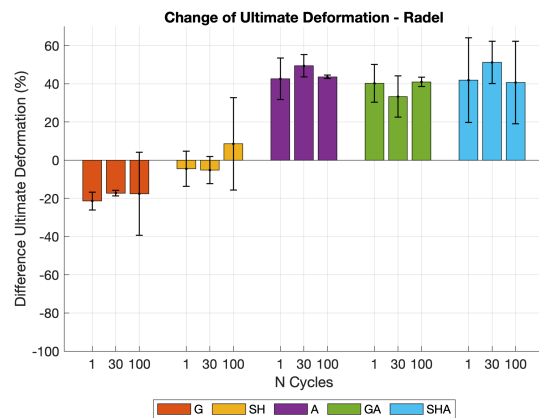
Figure 3.4.: Ultimate deformation values for each material after 1, 30 and 100 cycles of different reprocessing methods.



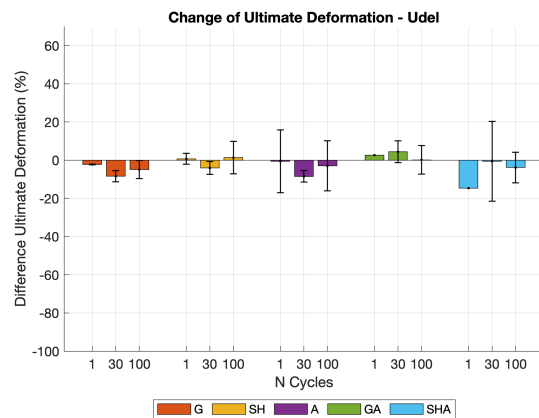
(a) Grilamid



(b) Ultem



(c) Radel



(d) Udel

Figure 3.5.: Percentage change in ultimate deformation values for each material after 1, 30 and 100 cycles of different reprocessing methods.

Kevlar

From the stress strain curve recorded for Kevlar (Figure 3.6), it shows a purely elastic behaviour. It is possible to observe its maximum stress values in Figure 3.7a. The average maximum stress recorded for the control group is 649.36 MPa (± 45.03). This property seems to be significantly affected by reprocessing, considering that Kevlar shows an average decrease in its maximum stress values of up to -15% already after one cycle of steam sterilisation. However, the high standard deviation's amplitude of 203.99 MPa suggests a significant variance in that condition. It is interesting to notice the extremely high decrease in Kevlar's maximum stress after the combination of immersion in bleach and steam sterilisation of up to -95% of its value. The maximum stresses decrease from 649.36 MPa (± 45.03) to 31.5 MPa (± 11.89).

The ultimate deformation values for Kevlar are shown in Figures 3.7c and 3.7d. The control group has a mean ultimate deformation of 10.29% (± 4.53). Studying the effects of reprocessing on Kevlar, it shows an average decrease in its ultimate deformation values of up to -40% already after one cycle of steam sterilisation. However, the control group shows a considerably high standard deviation's amplitude. Despite this, it is possible to notice the significant decrease in Kevlar's ultimate deformation after the combination of immersion in bleach and steam sterilisation of up to -95% of its value, going down from 10.29% (± 4.53) in the control group to 1.60% (± 0.35) after 100 cycles of immersion in bleach followed by 100 cycles of steam sterilisation.

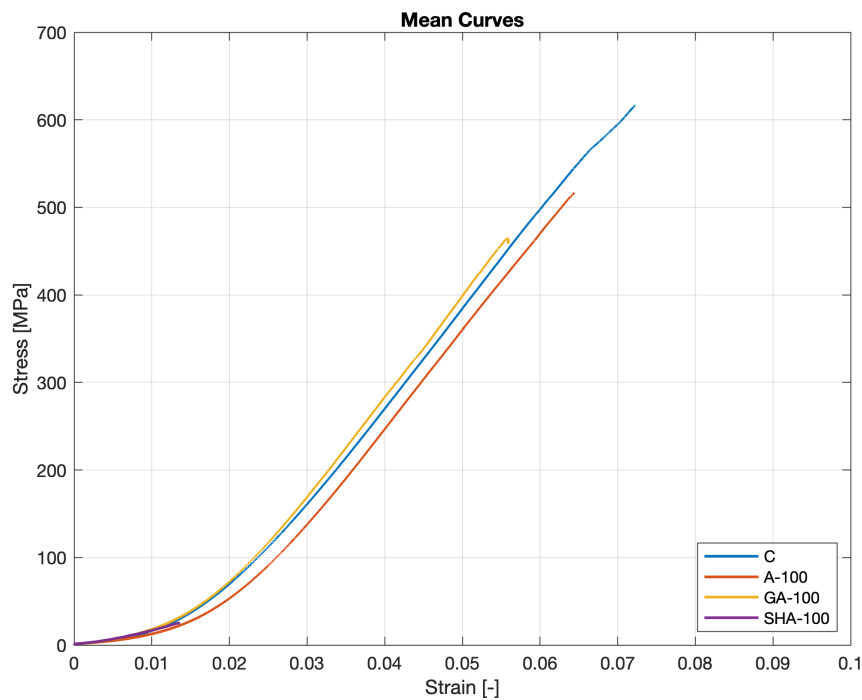
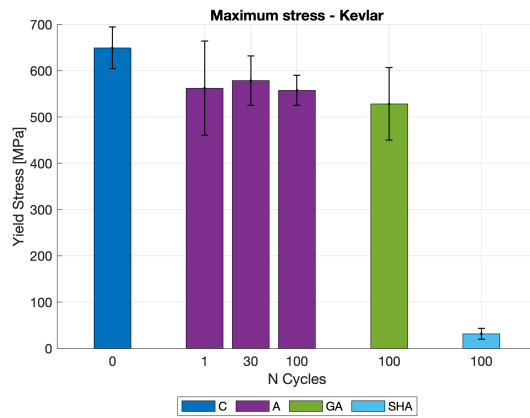
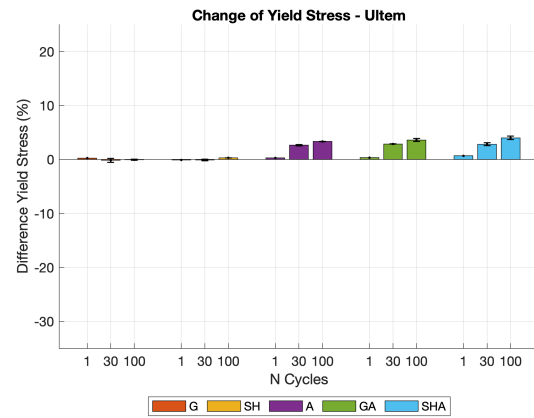


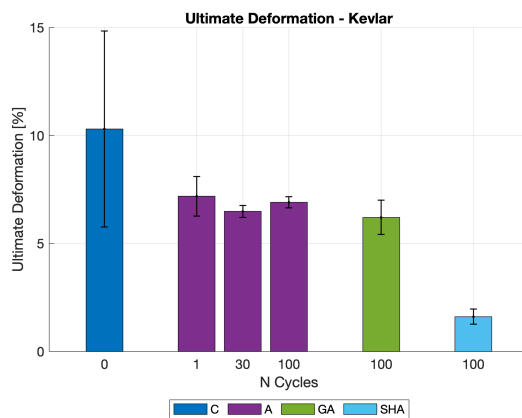
Figure 3.6.: Stress strain curves of for Kevlar after different reprocessing methods.



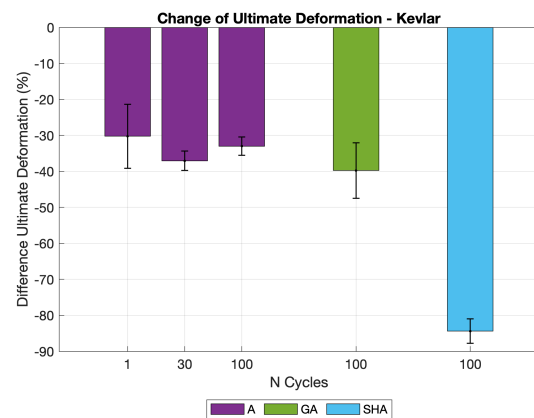
(a) Maximum stress values



(b) Changes in maximum stress



(c) Ultimate deformation values



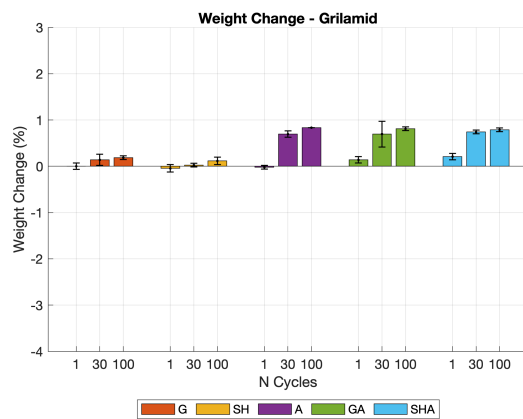
(d) Changes in ultimate deformation

Figure 3.7.: Tensile properties for Kevlar after 1, 30 and 100 cycles of reprocessing.

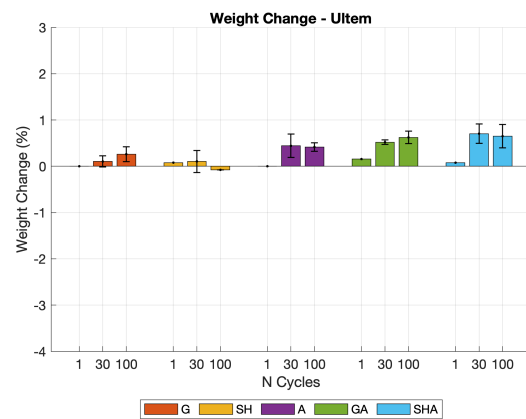
3.1.2 Weight change

The weight of each sample was recorded before and after reprocessing and the percentage change relative to its own weight was calculated. Weight change is indicative of material loss or absorption, which may be significant for the long-term integrity and functionality of medical devices. Figure 3.8 shows the results obtained for Grilamid, Ultem, Radel, Udel and silicone.

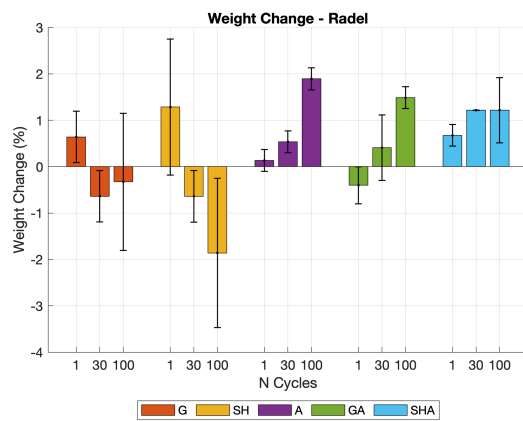
Grilamid's weight seems to remain almost unvaried after disinfection. However, it increases by almost 1% after 30 cycles of steam sterilisation. A similar trend can be observed for Ultem, with a maximum increase of 0.70% (± 0.21) after 100 cycles of steam sterilisation and 100 cycles of disinfection with bleach. Radel seems to also show an increase in its weight after steam sterilisation. However, the variance within tests groups remains relatively high. The variance observed in Udel test samples is even larger and it makes it impossible to observe specific effects of reprocessing on its weight. Silicone samples' weight shows a significant decrease after 100 cycles of disinfection followed by sterilisation. Particularly, it decreases by 1.66% (± 0.70) after 100 cycles of glutaraldehyde immersion and 100 cycles of autoclaving.



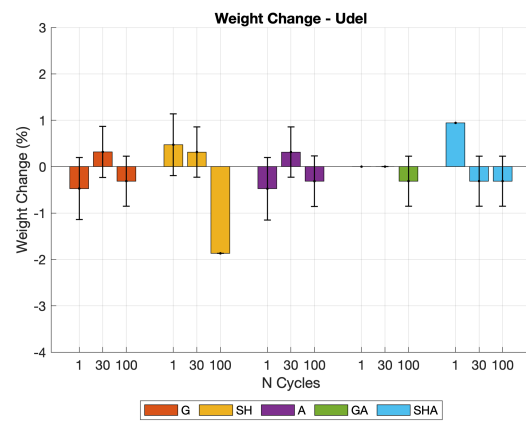
(a) Grilamid



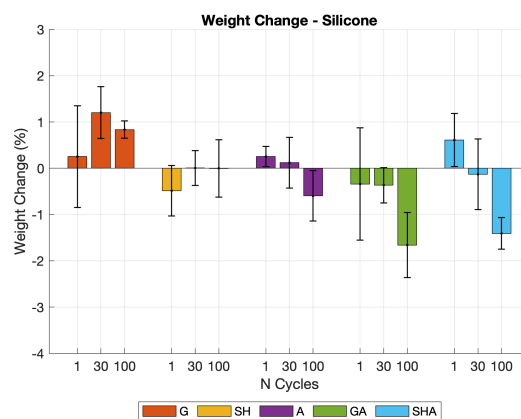
(b) Ultem



(c) Radel



(d) Udel



(e) S

Figure 3.8.: Changes in weight of each material after 1, 30 and 100 cycles of different reprocessing methods.

3.1.3 Shore Hardness A

Shore hardness A values of silicone were assessed with a durometer, placing it over two sheets of material stacked on top of each other to reach a satisfying thickness. The results of the measurements can be observed in Figure 3.9a and Figure 3.9b shows the percentage change in shore hardness A values relative to the control group.

The samples' hardness seems to be almost unaffected by disinfection with bleach or glutaraldehyde. On the other hand, the values increase significantly after steam sterilisation. Noticeably, the biggest change, of 10.09% (± 1.44), appears to be after 100 cycles of immersion in glutaraldehyde followed by 100 cycles of autoclaving, with a final shore hardness A value of 58.16 (± 0.76) against the control group's value of 52.83 (± 0.28).

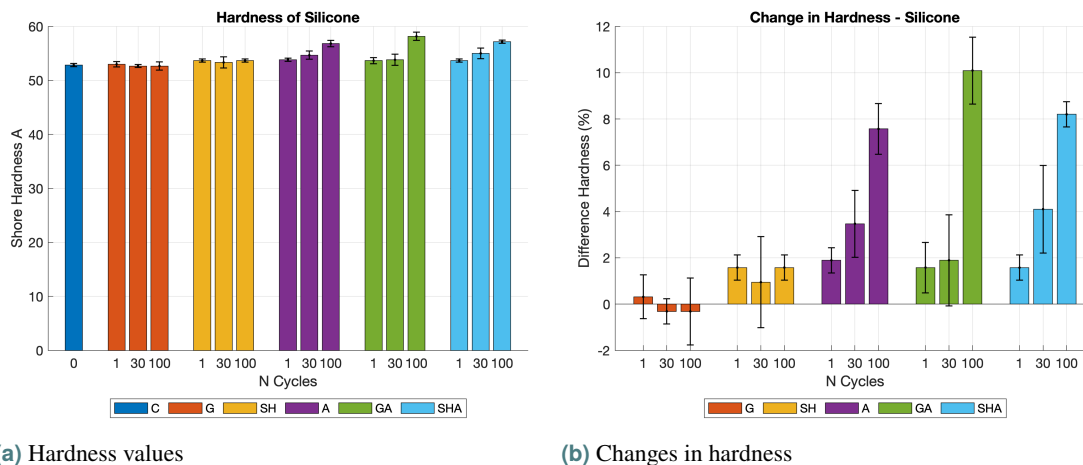


Figure 3.9.: Hardness values for silicone after 1, 30 and 100 cycles of reprocessing.

3.1.4 Colour Stability

The color stability of the material samples was evaluated through visual assessment by capturing images of reprocessed samples alongside those of the control group. The images are shown in Appendix B. Grilamid exhibited minimal changes post disinfection but displayed significant discoloration following steam sterilization or a combination of steam sterilization and disinfection. The degree of discoloration escalated with an increase in the number of cycles. It is possible to observe some dark brown stripes on some of the samples. These were caused by the presence of autoclave tape on the trays where the samples were placed, which discoloured and stained the samples of Grilamid. Conversely, Ultem, Radel, and Udel demonstrated remarkable color stability, with no apparent variation in appearance under any of the reprocessing conditions. On the other hand, silicone samples exhibited notable discoloration after steam sterilization, particularly following 100 cycles of immersion in bleach followed by 100 cycles in the autoclave.

3.2 Computational modelling

This section presents the outcomes derived from the Finite Element Analysis (FEA) conducted on the tube-cup connection of the vela® VE. This analysis is crucial for comprehending the mechanical responses of the device's materials when exposed to simulated forces encountered during clinical use. Utilizing a finite element model enables a cost-effective and swift comparison of designs and materials.

The first section discusses the stress values observed for various designs, leading to the selection of an optimal design. Subsequently, the analysis was performed on the final design with different material models, facilitating a precise evaluation of how material properties influence the stresses observed in this specific component of the vela® VE. Based on the findings, the optimal material is determined and the results of a detailed analyses are reported at the end of this section. The examination scrutinizes structural integrity, deformation patterns, stress distribution, and potential points of failure, ensuring a comprehensive understanding of the device's performance characteristics.

3.2.1 Comparison of design characteristics

For the purpose of this analysis, three distinct designs, provided by LAYCO® Medical Devices, were analysed. The first design is characterized by its simplicity, comprising a flat, homogeneous disc with two wires running through it. The second design, resembling the first in principle, incorporates a reinforcement layer precisely at the points where the wires penetrate the disc, increasing the thickness in those regions. The third design introduces distinctive attributes such as strategically positioned holes within the disc, serving manufacturing purposes, and the use of a single wire. A comprehensive exposition of each design's characteristics is provided within the methods Section 2.2.1, offering an exhaustive delineation of their structural configurations and operational features.

Four design parameters were identified and systematically varied to analyse their respective influences on stress distributions in the wire and the disc, namely: the wire's diameter, the disc's thickness, the wire's length and the location of its entry point in the disc, see Section 2.2.8 for further details. As previously described in Sections 2.2.6 and 2.2.8, these simulations were executed for the worst case scenario, where 453 N of traction force was applied on a single wire. Table 3.2 reports the maximum Von Mises stresses observed in the wire and in the disc for each design variation.

The first result shown in the table is an 'Error' outcome for the simulation of Model 1 with a wire with a diameter of 0.5mm. This implies that the Abaqus/Explicit finite element solver did not complete the simulation and it exited with errors. The message file generated with the outcome of the simulation reports that it could not be completed due to excessive deformations. The same result can be observed for Model 2 with a 0.5mm wire.

Looking at the other results obtained for Model 1, which represents our baseline with its plain disc and two wires, it is possible to note that increasing the wire's diameter from 0.5 mm to 1 mm led to the completion of the simulations. The maximum Von Mises stresses in the wire remained around 3579 MPa for a wire's diameter of 1 mm, dropping to 1810 MPa only when the wire diameter reached 1.5 mm. The stresses in the disc remained around 205 MPa for different disc's thicknesses and wire's lengths. They increased to 222 MPa when the wire was located further away from the central cavity in the disc. When the disc's thickness increased to 4 mm, the stresses increased significantly to 327 MPa. Moving on to Model 2, the wire's diameter was varied from 1mm to 1.5 mm, observing its interaction with an enhanced disc, reinforced at the points of wire entry. Here, a decrease in maximum wire stress is noted, from 3579 MPa down to 1653 MPa as the wire's diameter was increased from 0.5 mm to 1.5 mm. Disc stress similarly decreased from 135 MPa to 113 MPa.

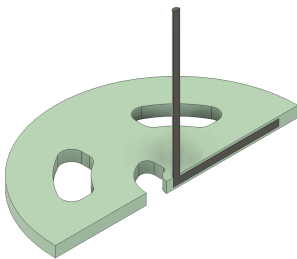
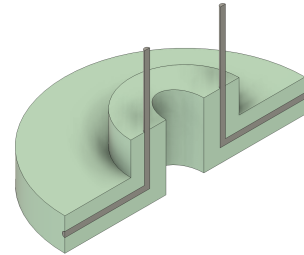
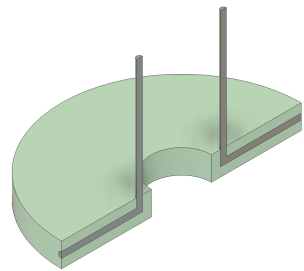
For Model 3, with its strategic holes and a solitary wire, the wire's maximum stress was observed at 6370 MPa for a configuration with a 1.6 mm disc thickness and a wire's diameter of 1 mm. When maintaining the wire's diameter at 1 mm but increasing the disc thickness to 2.6 mm, the wire's stress decreased significantly to 3579 MPa.

Increasing the wire diameter to 1.25 mm, with the disc thickness remaining at 2.6 mm, resulted in a decrease in wire stress to 2331 MPa. A consistent pattern emerged with this variation; as the wire diameter to 1.5 mm, and the disc thickness constant at 2.6 mm, the maximum stress in the wire decreased to 1657 MPa. The stress values in the wire

with a diameter of 1.5 mm then remained constant for different disc's thicknesses.

The stresses in the disc across these configurations showed less fluctuation than in the wire. Starting from a stress of 157 MPa at a disc thickness of 1.6 mm, the increase in thickness to 2.6 mm saw a marginal decrease in stress to 123 MPa. At a disc thickness of 2.5 mm, the stress was slightly higher at 145 MPa, followed by a reduction to 85 MPa as the thickness was adjusted to 2.6 mm. The maximum disc thickness of 3 mm showed a slight increase in stress to 154 MPa.

It is crucial to note that due to structural support considerations, wire diameter and disc thickness changes were not independent. As such, larger wire diameters were accompanied by increased disc thicknesses. These results will be analysed and explained in Chapter 4.

Table 3.2.: Maximum Von Mises stresses recorded in the wire and in the disc for different designs. All model's characteristics are expressed in mm. All stress values are in MPa.

Design	Model's characteristics				Max VM stress [MPa]	
	Wire's diameter	Disc's thickness	Wire's length	Wire's location	Wire	Disc
Model 1	0.5	2	20	0.5	Error	
	1	2	20	0.5	3579	205
	1	2	20	1	3579	222
	1	2	40	0.5	3575	204.5
	1	4	20	0.5	3579	205
	1.5	2.5	20	0.5	1810	327
Model 2	0.5	3	20	0.5	Error	
	1	3	20	0.5	3579	135
	1.5	2.6	20	0.5	1653	113
Model 3	1	1.6	20	0.5	6370	157
	1	2.6	20	0.5	3579	123
	1.25	2.6	20	0.5	2331	119
	1.5	2.5	20	0.5	1657	145
	1.5	2.6	20	0.5	1657	85
	1.5	2.8	20	0.5	1657	113
	1.5	3	20	0.5	1514	154

3.2.2 Comparison between different materials

Based upon the insights gained from the preceding analyses, an optimal design was selected: Model 3 with a wire's diameter of 1.5 mm and a disc 2.6 mm thick. This design was subjected to various simulations to evaluate material performance. Specifically, different rigid plastics: Grilamid, Ultem, Radel, and Udel, were considered for the vela® VE application. For each of them, two distinct material models were generated and integrated into the simulations: one representing the mean curve of the control group, reflecting material properties unaffected by reprocessing, and another simulating properties observed after the most aggressive reprocessing method tailored to each specific material.

To facilitate a comprehensive comparison, the maximum Von Mises stresses of both the wire and the disc were meticulously observed and recorded. These stress values are presented in Table 3.3, alongside the corresponding yield stress of each specific material model, enabling precise evaluation of stress levels specific to each material. Additionally, the last column reports the difference between the maximum Von Mises stress observed in the disc and the yield stress value of the corresponding material, calculated as:

$$\Delta\% = \frac{\sigma_{VMmax} - \sigma_Y}{\sigma_Y} \cdot 100$$

In the case of Kevlar, the material model derived from the control group was implemented when analysing plastics in their original state. Conversely, when assessing reprocessed plastics, the material model derived from properties observed after 100 cycles of autoclave treatment was employed.

Table 3.3.: Maximum Von Mises stresses recorded in the disc and the wire, comparing different materials. All stresses are in MPa.

Material	Condition	Max σ_{VM} wire	Max σ_{VM} disc	σ_Y	$\Delta[\%]$
Grilamid	C	1514	95	44	-114
	A	1514	49	31	-58
Ultem	C	1514	194	111	-73
	SHA	1514	183	116	-57
Radel	C	1514	137	78	-75
	A	1514	118	77	-51
Udel	C	1514	237	78	-201
	GA	1514	226	76	-196

Based on the findings presented in Table 3.3, it becomes evident that the Von Mises stresses in the wire remain consistently at 1514 MPa across all simulations, irrespective of whether the Kevlar material was subjected to reprocessing or remained in its original state. Conversely, notable variations are observed in the stress values within the disc for each material variant.

For Grilamid, stress levels range from 95 MPa in the control group to 49 MPa when utilizing material properties recorded after 100 cycles of steam sterilization, indicating a substantial reduction in stress under the latter condition. Similarly, Ultem exhibits a reduction in stresses, though less pronounced, with values decreasing from 194 MPa to 183 MPa after reprocessing. Comparable trends are observed in Radel, with stress levels declining from 137 MPa in the control group to 118 MPa following reprocessing, and in Udel, where stresses decrease from 237 MPa to 226 MPa after reprocessing. These variations underscore the sensitivity of disc stress to material properties and processing conditions, highlighting the importance of careful material selection and processing optimization in mitigating stress-related concerns within the vela® VE component.

3.2.3 Detailed mechanical behaviour of final design

This section presents the detailed results obtained from the simulation of the final design and the selected material. The primary focus is on analysing stress and deformation distributions to assess the structural performance of the component. Included in this analysis are images of the Finite Element Model (FEM) to visualize areas of elevated stress and deformation.

The results are derived from the simulation of the selected design, namely Model 3, featuring a wire diameter of 1.5mm and a disc thickness of 2.6mm. The chosen material for this simulation is Ultem, selected based on its performance criteria outlined in the materials comparison section, discussed in Chapter 6. To ensure an assessment of the worst conditions, the material models selected for both Kevlar and Ultem are derived from their properties after undergoing 100 cycles of steam sterilization, replicating real-world usage conditions. Furthermore, the results obtained from the simulations implementing the material properties derived from the control groups of Kevlar and Ultem, representing the un-reprocessed materials, showed comparable results to the ones after 100 cycles of steam sterilisation.

The stress and deformation distributions recorded in the disc and the wire will be described in detail for both loading scenarios, namely, the worst case scenario recorded in literature with 453 N load applied to the top of the wire, and the upper limit for safe traction force with 225 N.

3.2.3.1 Worst case scenario - 453 N

Wire

In examining the stress distributions within the Finite Element Model (FEM), the Von Mises stresses in the wire are first analysed. The highest stress value recorded is 1514 MPa, located at the top portion of the wire where the load is applied. This region exhibits the most significant stress concentration, as depicted in Figure 3.10. From this point downwards, the stresses distribute uniformly throughout the length of the wire, maintaining a relatively constant stress level ranging from approximately 700 to 800 MPa. Upon entering the disc, the stress values rapidly decrease. Figures 3.11 and 3.12 illustrate the stress distribution at the point where the wire enters the disc. To enhance clarity, the color scale limit of the stresses has been adjusted to 600 MPa in these images. Figure 3.11 presents stress values along the symmetry cut, revealing the inside of the wire. It illustrates how stresses distribute upon entering the disc, lowering to near-zero within a few millimeters. Conversely, Figure 3.12, depicting the opposite side of the wire entry point into the disc, exhibits higher stresses compared to the inner region of the disc.

Turning to the deformation analysis depicted in Figure 3.13, it is observed that the maximum deformation, reaching 0.986, occurs at the top of the wire where the load is applied. Deformation amplitudes progressively decrease along the length of the wire, nearly approaching zero at the level of the disc.

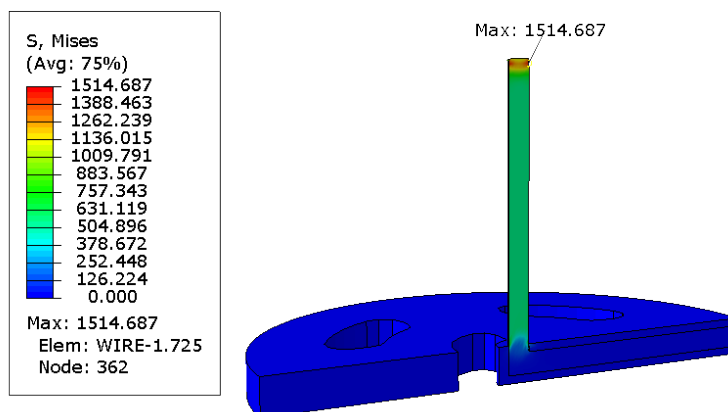


Figure 3.10.: Von Mises stresses recorded in the wire. All values are in MPa.

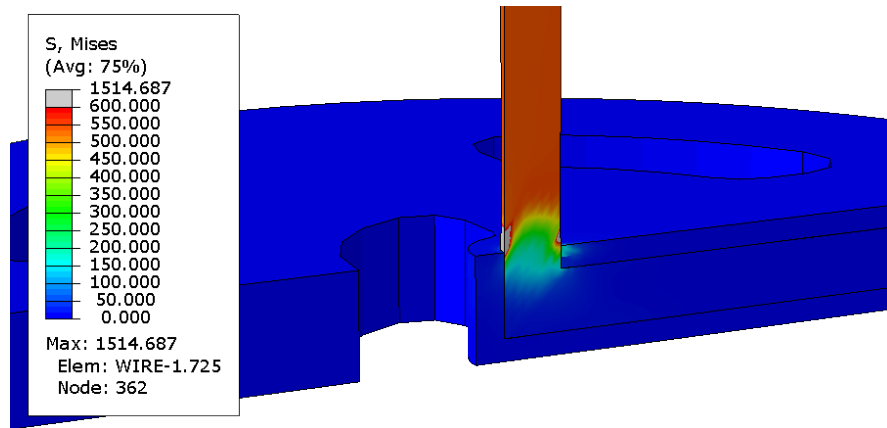


Figure 3.11.: Von Mises stresses recorded in the wire with user-defined upper limit. All values are in MPa.

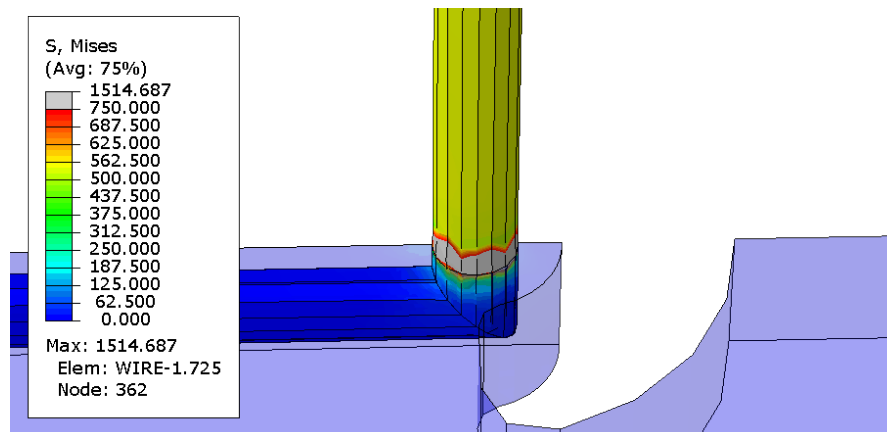


Figure 3.12.: Von Mises stresses recorded in the wire at the entry point in the disc, with user-defined upper limit. All values are in MPa.

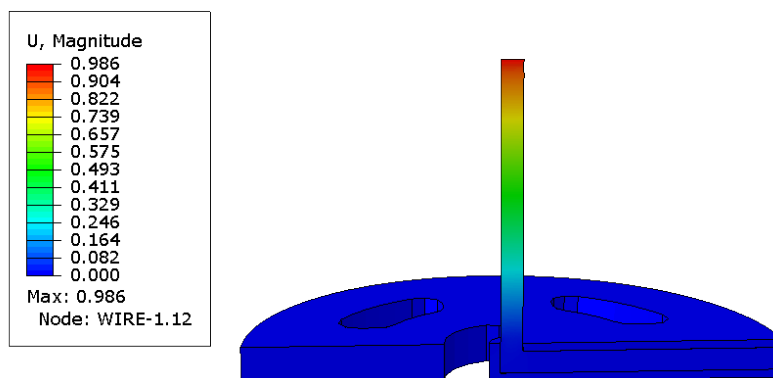


Figure 3.13.: Deformations recorded in the wire.

Disc

In this section, the results of the stress and deformation distributions within the disc are presented. Figure 3.14 illustrates the maximum Von Mises stress recorded in the disc, registering at 183 MPa. This stress peak is localized at the entry point of the wire into the disc, positioned above the section where the wire continues through the disc. In Figure 3.15, depicting the same area but with a color scale limited to a maximum of 50 MPa, the stress distributions are better visualized. Stresses are concentrated in the contact area with the wire and exhibit limited dispersion throughout the rest of the disc. Notably, stress values of approximately 20 MPa are observed within a region of approximately 0.5 mm around the entry circumference. Beyond the 90° angle, stresses propagate along the wire's length before decreasing to almost zero.

Looking at the deformations presented in Figure 3.16, the maximum deformation in the disc is recorded at 0.024, situated near the point where the wire enters the disc, above the 90° angle, coinciding with the region of highest stress concentration. Deformations then propagate along the wire's axis, extending to the tip of this portion of the disc. Figure 3.17 presents the same deformations as Figure 3.16, magnified by a factor of 30 to enhance visibility. This illustration highlights a pronounced shrinkage along the wire's main axis, resulting in the disc being 'pulled' upwards by the wire.

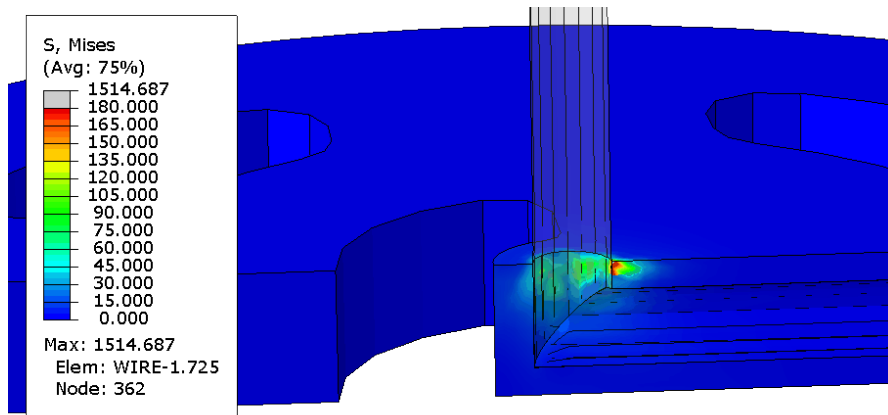


Figure 3.14.: Von Mises stresses recorded in the disc. All values are in MPa.

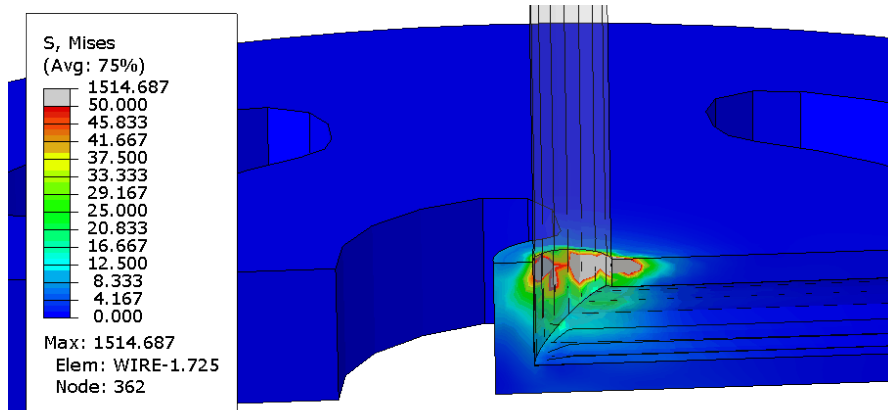


Figure 3.15.: Von Mises stresses recorded in the disc with user-defined upper limit. All values are in MPa.

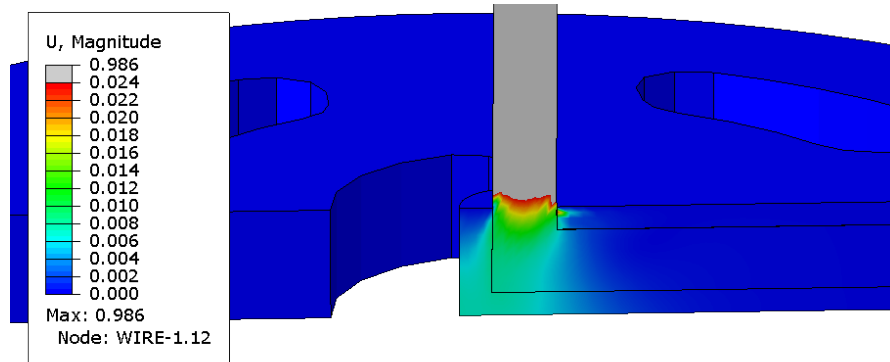


Figure 3.16.: Deformation recorded in the disc with user-defined upper limit.

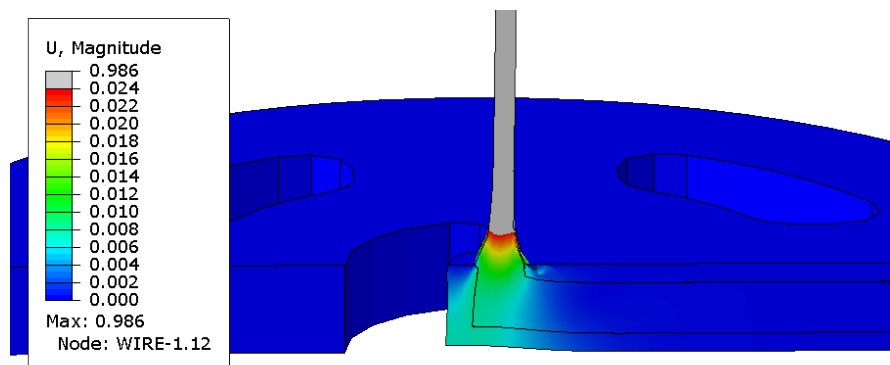


Figure 3.17.: Deformation recorded in the disc, visually increased by 30 times.

3.2.3.2 Upper limit for safe traction force - 225 N

Wire

Examining the stress distributions within the Finite Element Model (FEM) under the loading scenario of 225 N, it is possible to observe comparable patterns in the wire's behavior. The highest stress recorded is notably lower, reaching 776 MPa at the top portion of the wire where the load is applied, as shown in Figure 3.18. This region still exhibits significant stress concentration, though at reduced levels compared to the 453 N scenario. Moving downwards along the wire, stresses distribute uniformly, maintaining levels between 300 and 400 MPa. To enhance clarity, the color scale limit of the stresses in Figures 3.19 and 3.20 has been adjusted to 300 MPa. Figure 3.19 illustrates stress values along the symmetry cut, revealing the inside of the wire and the distribution upon entering the disc. Stress values lower significantly, almost approaching zero within a few millimeters into the disc. Conversely, Figure 3.20, depicting the opposite side of the wire entry point into the disc, exhibits slightly higher stresses compared to the inner region of the disc.

Turning to the deformation analysis, Figure 3.21 illustrates that the maximum deformation, reaching 0.477, occurs at the top of the wire where the load is applied. Deformation amplitudes decrease along the length of the wire, yet to a lesser extent compared to the 453 N scenario, reflecting the reduced loading force.

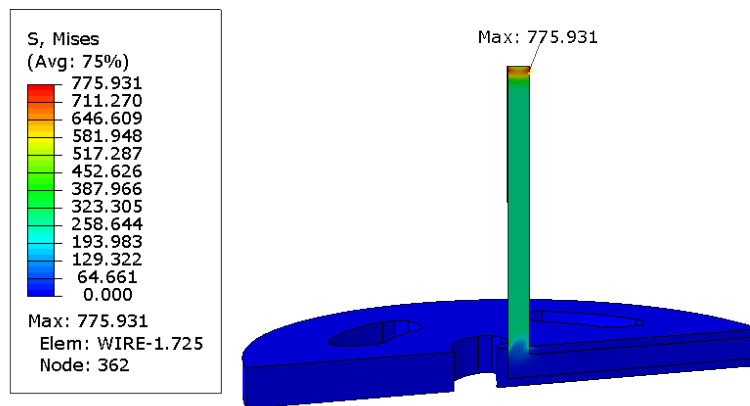


Figure 3.18.: Von Mises stresses recorded in the wire. All values are in MPa.

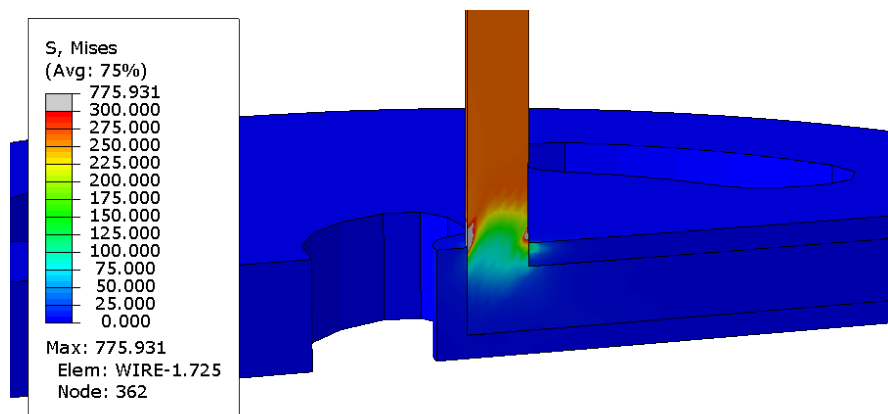


Figure 3.19.: Von Mises stresses recorded in the wire with user-defined upper limit. All values are in MPa.

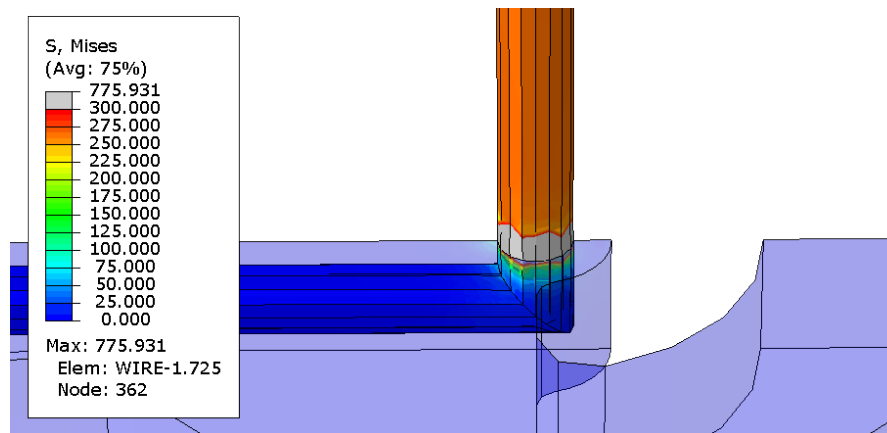


Figure 3.20.: Von Mises stresses recorded in the wire at the entry point in the disc, with user-defined upper limit. All values are in MPa.

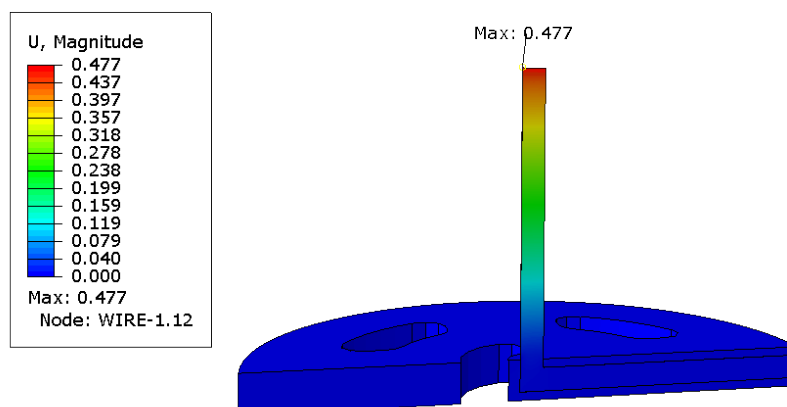


Figure 3.21.: Deformations recorded in the wire.

Disc

In this section, the results of the stress and deformation distributions within the disc under the loading scenario of 225 N are presented. Figure 3.22 illustrates the maximum Von Mises stress recorded in the disc, registering at 127 MPa. Similar to the 453 N scenario, this stress peak is localized at the entry point of the wire into the disc, positioned above the section where the wire continues through the disc. In Figure 3.23, which depicts the same area with a color scale limited to a maximum of 50 MPa, the stress distributions are clearly visualized. Stress concentrations are observed in the contact area with the wire, with limited dispersion throughout the rest of the disc. Beyond the 90° angle, stresses propagate along the wire's length before decreasing to lower levels compared to the 453 N scenario, yet remaining significant.

Turning to the deformation analysis, Figure 3.24 illustrates the maximum deformation in the disc, recorded at 0.011. This deformation occurs near the point where the wire enters the disc, above the 90° angle, coinciding with the region of highest stress concentration. Deformations then propagate along the wire's axis, extending to the tip of this portion of the disc, as observed in the magnified illustration presented in Figure 3.25. Despite the lower loading force, the deformations exhibit a similar pattern to the 453 N scenario, indicating a consistent mechanical response of the disc. Overall, the stresses in the disc are lower compared to the worst-case loading scenario and show a similar distribution.

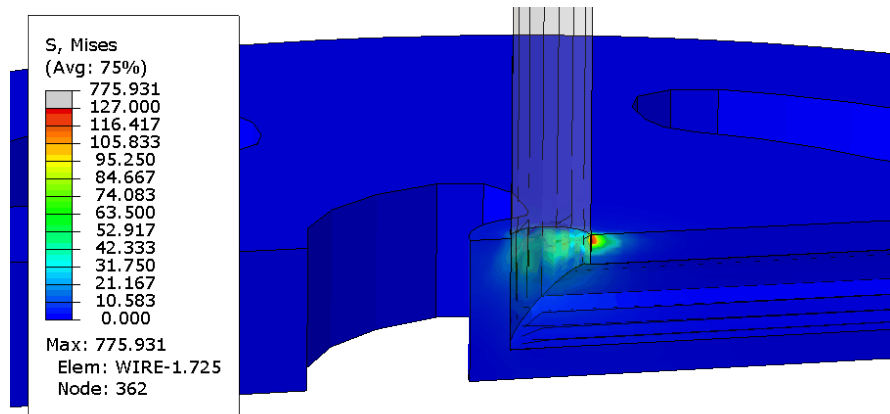


Figure 3.22.: Von Mises stresses recorded in the disc. All values are in MPa.

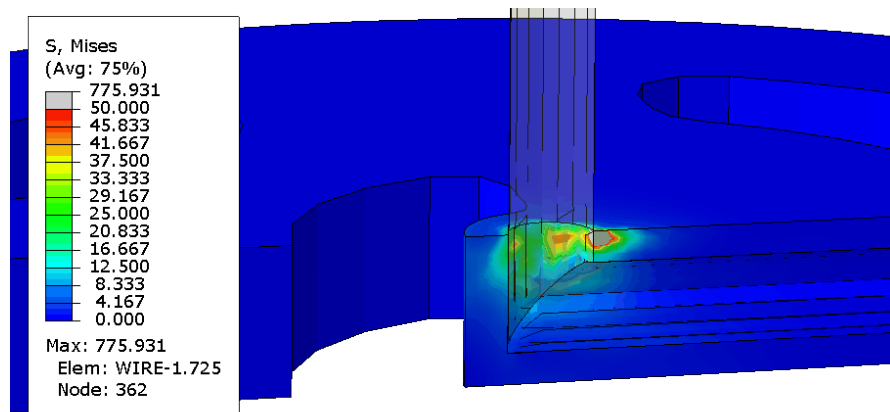


Figure 3.23.: Von Mises stresses recorded in the disc with user-defined upper limit. All values are in MPa.

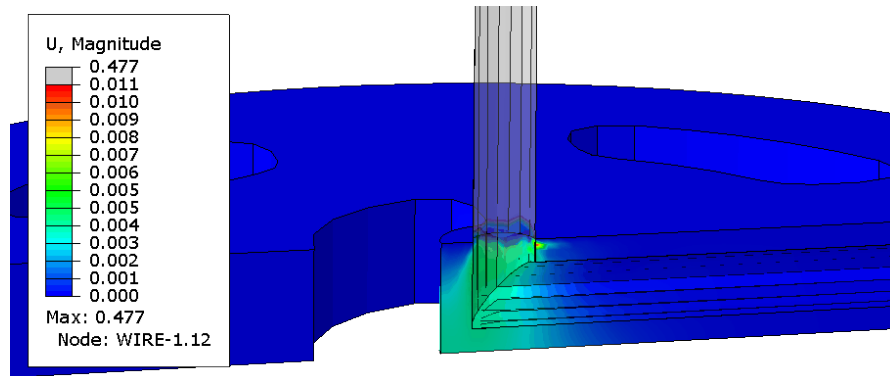


Figure 3.24.: Deformation recorded in the disc with user-defined upper limit.

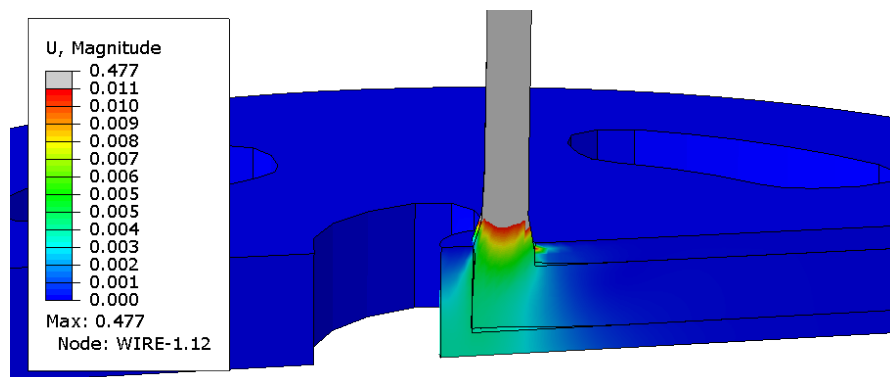


Figure 3.25.: Deformation recorded in the disc, visually increased by 30 times.

Design optimisation

With the results obtained from the material testing, illustrated in Section 3.1, the finite element model (FEM) was implemented to optimise the design of the tube-cup connection of the vela® VE. Beginning with the three distinct design models outlined in Section 2.2.2, four key design parameters were systematically varied: wire diameter, disc thickness, wire location, and length, with the aim of understanding how each parameter influenced stress levels and select the most effective design. Identical simulations were conducted for each design variation. To ensure impartiality, a fictitious material model was created by averaging stress-strain curves from Grilamid, Radel, Udel, and Ultem control groups. Using the worst-case loading scenario—applying 453 N of force—the maximum Von Mises stresses for both the disc and the wire were recorded and are shown in Table 3.2.

This chapter delves into a comprehensive comparison of these diverse design iterations. Three crucial selection criteria were identified to rigorously compare the designs and select the optimal one. Through a detailed evaluation, a Harris profile provides a graded assessment of each design's performance across these criteria, ranging from – to - to + to ++. Furthermore, a detailed discussion of the influence of each design parameter on the stress levels observed within the disc is described. Finally, the optimal design will be selected.

4.1 Design criteria

These evaluation metrics were meticulously defined to include factors crucial for ensuring the functionality, integrity, safety, manufacturability, and user experience of the vela® VE. Each design was evaluated based on its performance on each criteria and assigned a score in the Harris profile in Table 4.1.

Stress levels

The first criterion involves examining the maximum stress values observed in both the wire and the disc across each design. This is possibly the most important parameter, since excessive stress values can determine the structural failure of the device. The objective here is to maintain stress levels at the minimum possible. Designs demonstrating lower stress levels will be deemed superior and, hence, awarded a better score.

Manufacturability

The manufacturing process for this component is intricate, involving several steps. Initially, the bonding between the plastic cup and the reinforcement wire is critical. This integration is achieved through injection molding, wherein the cup is formed over the wires. Subsequently, the component is overpoured with silicone for the tubing component. See Figure 2.15 to clearly understand the shape and placement of the silicone component. The manufacturability of this part is directly influenced by the shape and geometry of the cup.

User Experience

Enhancing user experience, both for the physician and the mother, is imperative. It is desirable for the cup's height to be minimised to facilitate insertion into the vagina (refer to Figure 4.1). A bulkier cup would make it more difficult for the doctor and less comfortable for the patient. Additionally, reducing the total diameter of the tube and thinning its walls is preferable. This reduces the stiffness of the tube, making insertion easier for the physician and more comfortable for the patient.

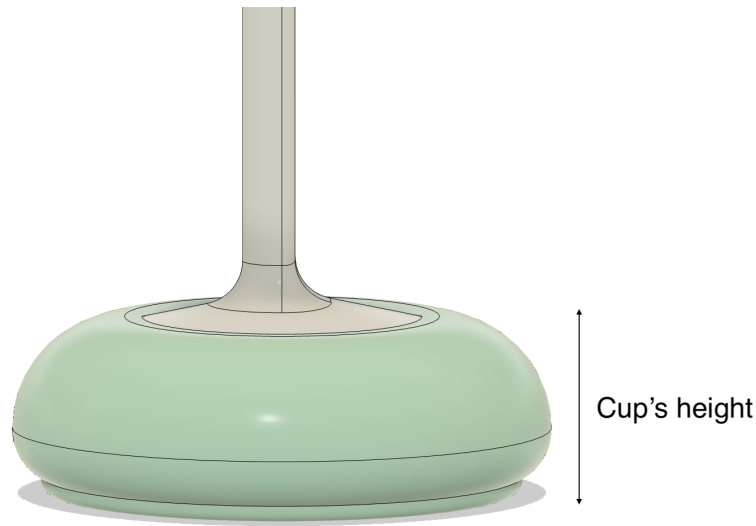


Figure 4.1.: Vela® VE's cup's height

4.2 Influence of design variables on criteria

In this section, the results obtained in Table 3.2 will be analysed. The design optimisation process identified four parameters that might influence the stress levels recorded in the disc: wire diameter, disc thickness, wire length, and its location. The following paragraphs will break down the influence of each of these parameters on the results, and evaluate their impact on the selection criteria. Table 4.1 shows the score assigned to each design variation for each selection criteria.

Inherent characteristics of each design

The design optimisation process started with three distinct models, each with specific characteristics. The first model is the most simple, featuring two reinforcement wires. The second model is similar to the first but includes a reinforcement layer encircling the entry points of the wires into the disc. The third model is distinguished by a single reinforcement wire and incorporates holes on the disc's surface, intended for manufacturing purposes. The preference leans towards the third design due to the manufacturing advantage provided by the disc holes for silicone pouring over the hard plastic. The holes facilitate the pouring process and ensure better connection between the silicone and the cup. Additionally, a single wire is favored to maintain the tube's minimal thickness. Conversely, the second design is the least desirable due to the reinforcement layer potentially increasing the cup's overall height (see Figure 4.1), which is desirable to minimise for improved insertion experience for both the physician and the mother. For this reason, more design iterations were simulated for Model 3 and fewer for Model 2.

The influence of inherent design characteristics on stress values can be studied by comparing three specific design iterations. For Model 1, featuring a wire diameter of 1.5 mm and a disc thickness of 2.6 mm, the maximum von Mises stress values recorded in the wire are 1810 MPa and 327 MPa in the disc. In contrast, for Model 2, with the same wire diameter but a disc thickness of 2.5 mm, the maximum von Mises stress values in the wire are 1653 MPa, with 113 MPa in the disc. Similarly, for Model 3, also with a wire diameter of 1.5 mm and a disc thickness of 2.5 mm, the maximum von Mises stress values in the wire are 1657 MPa and 85 MPa in the disc. These findings illustrate that under similar design parameters, Model 3 exhibits the lowest stresses, while Model 1 records the highest. Overall, Model 2 is the least preferred choice due to its less favorable user experience. Model 1 is deemed the least preferred option in terms of stress values. On the other hand, Model 3 stands out as the optimal choice.

Diameter of the wire

The wire's diameter was varied between 0.5 mm and 1.5 mm. A smaller diameter is preferable as it directly influences the tube's thickness. Since the reinforcement wires are embedded within the tube walls, a thicker wire necessitates an increase in wall thickness, leading to a larger tube diameter and increased stiffness—both of which are undesirable for

user experience. In examining the influence of wire diameter on the stress levels, it was observed that with a diameter of 0.5 mm, the FEA failed to complete and exited with errors. This occurrence typically arises when the deformations induced by applied loads exceed computational limits, implying that a wire with a diameter of 0.5 mm would not be structurally safe. An increase in the diameter of the wire, allowed for the completion of the FEA and allowed retrieval of results. From the results in Table 3.2 it is possible to observe that varying the wire's diameter directly impacted the stress levels, aligning with the fundamental stress equation:

$$\sigma = \frac{F}{A}$$

Increasing the wire's cross-sectional area leads to proportionate reductions in stress. This phenomenon was particularly evident in Model 3, where maintaining a constant disc thickness highlighted a clear decrease in stress levels as wire diameter increased from 1 mm (3579 MPa) to 1.25 mm (2331 MPa), and further to 1.5 mm (1657 MPa). Notably, in cases where wire diameter increased, stresses within the disc also decreased. This correlation stems from stress propagation mechanisms, wherein lower stresses in the wire translate to lower stresses in the disc.

In summary, increasing the wire diameter positively impacts the stress levels of the components, resulting in significantly lower stresses in the wire and decreased stresses in the disc. However, the larger diameter negatively affects user experience. Consequently, this parameter positively influences one criterion while negatively impacting another. Therefore, it is necessary to discuss the relevance of each criterion. In this case, structural integrity of the device outweighs user experience. It is crucial to prioritise safety over comfort. Ensuring that neither the wire nor the disc breaks during the use of the vela® VE is paramount. Ultimately, it is preferable to have a thicker wire diameter to reduce stresses and enhance the overall safety of the device.

Thickness of the disc

The thickness of the disc varied from 1.6 mm to 4 mm across the designs. It would be preferable to keep this values as low as possible. A higher thickness leads to an overall increased cup height, negatively impacting the experience for both obstetricians and mothers. Therefore, based on the "user experience" criterion, the disc should ideally be as thin as possible.

Upon examining the stress levels recorded in Table 3.2, an interesting correlation between the disc's thickness and stress values emerges. This correlation is particularly evident in the last four design variations of model 3, where only the disc's thickness varies while other parameters remain constant. Notably, the stress levels exhibit a distinct trend: starting at 145 MPa for a thickness of 2.5 mm, decreasing to 85 MPa at 2.6 mm thickness, and then increasing again to 113 MPa at 2.8 mm thickness, and finally reaching 145 MPa at 3 mm thickness. This trend suggests an optimal thickness at which the lowest stresses are attained. With a thinner disc, the stresses are higher due to the reduced surface area available for stress distribution, resulting in higher maximums. Conversely, a thicker disc offers more resistance to the traction of the wire in the z-direction, leading to higher stresses. Thus, while the "user experience" criterion favors a thinner disc, the stress analysis highlights the importance of finding a balance to ensure optimal structural integrity while minimising stress levels.

Wire's location

To assess the impact of the wire's entry point location on the disc, two different positions were analysed for their effect on stress levels of Model 1, the computationally fastest option. It is advantageous to position the wire's entry point as close to the disc's inner diameter as possible. Positioning the wire further away would necessitate an increase in the tube's diameter, which houses the wires within its walls, which is undesirable for the user's experience.

Looking at the results in Table 3.2, it possible to observe that the wire's location has no direct effect on the maximum Von Mises stress values recorded in the disc or in the wire. They stay constant at 3579 MPa and 205 MPa. Therefore, the preferable option is to locate the wire's entry point 0.5 mm from the disc's inner diameter.

Wire's length

The total length of the wires is actually fixed parameter and not a design criteria, since it must be equal to the length of the tubing component of the vela® VE. For computational modeling simplification, this length was initially reduced to

20 mm to decrease the number of elements and thus the computational time. During the design process, the length was extended to 40 mm to confirm that this parameter does not significantly influence the stress levels in the wire and the disc. A significant influence would otherwise challenge the validity of our geometric simplification in the FEM. The results show that this parameter has barely any impact on the stresses recorded, therefore proving the robustness of the model.

4.3 Design selection

Looking at the inherent design considerations of the three models and their influence on the decision criteria, it is apparent that the inherent design characteristics have minimal impact on stress levels. However, Model 3 emerges as highly preferable due to its favorable manufacturing characteristics and user preferences over Model 2, making it the chosen design option. The wire's location does not directly influence stress levels but significantly affects user experience. Therefore, it is advisable to position the entry point 0.5 mm from the disc's inner diameter to minimise discomfort for both obstetricians and mothers. Regarding wire diameter, it directly affects stress levels, with larger diameters leading to proportional decreases in stress. Despite the potential decrease in user experience due to a larger tube, it is preferable to prioritise minimising stresses. Thus, a wire diameter of 1.5 mm is deemed the optimal choice. Finally, disc thickness reveals an ideal balance between added resistance and increased surface area for stress distribution. This balance ensures optimal structural integrity while minimising stress levels. In conclusion, Model 3 with a wire diameter of 1.5 mm and a disc thickness of 2.6 mm emerges as the selected design option, offering the best compromise between stress reduction and user experience. Figure 4.2 shows the selected optimised design.

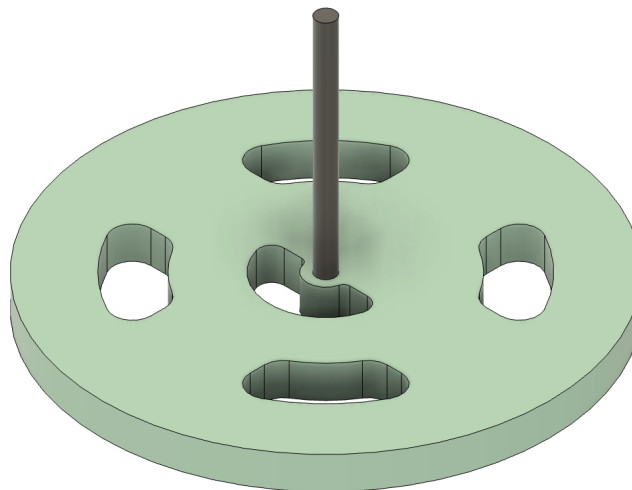
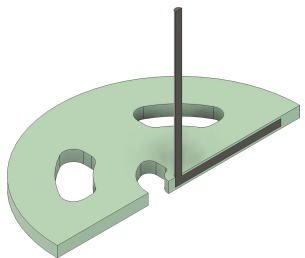
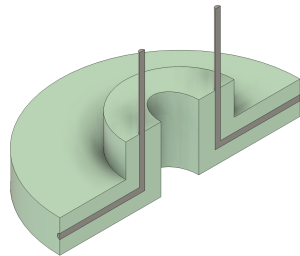
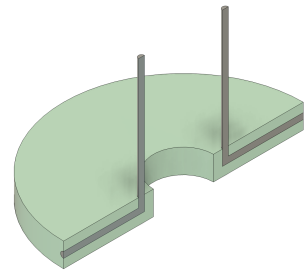


Figure 4.2.: Final design: Model 3 with 1.5 mm wire's diameter and 2.6 mm thick disc.

Table 4.1.: Harris profile for optimal design selection.



Model's characteristics					Criteria			
Design	Wire's diameter	Disc's thickness	Wire's length	Wire's location	Stress wire	Stress disc	Manufacturability	User's experience
Model 1	0.5	2	20	0.5	Error			
	1	2	20	0.5	-	-	-	++
	1	2	20	1	-	-	-	--
	1	2	40	0.5	-	-	-	++
	1	4	20	0.5	-	-	-	--
	1.5	2.5	20	0.5	++	--	-	+
Model 2	0.5	3	20	0.5	Error			
	1	3	20	0.5	-	+	--	-
	1.5	2.6	20	0.5	++	+	--	+
Model 3	1	1.6	20	0.5	--	+	++	++
	1	2.6	20	0.5	-	+	++	+
	1.25	2.8	20	0.5	+	+	++	+
	1.5	2.5	20	0.5	++	+	++	+
	1.5	2.6	20	0.5	++	++	++	+
	1.5	2.8	20	0.5	++	+	++	-
	1.5	3	20	0.5	++	+	++	--

Material selection for optimised design

This chapter focuses on the critical task of selecting the most suitable material for the rigid plastic components of the vela® VE. Building upon the foundation established in the preceding chapter, where the optimal design was identified – Model 3, featuring a wire diameter of 1.5 mm and a disc thickness of 2.6 mm – this chapter focuses on the comparison between different materials and their performance under loading. Through a series of rigorous simulations, the aim is to determine the ideal material that meets the performance requirements of the vela® VE.

Grilamid, Radel, Udel, and Ultem are the candidate materials for the rigid plastic components of the vela® VE. To comprehensively evaluate these materials, their tensile properties underwent meticulous examination using a ZwickRoell Z010 tensile tester. Detailed results from these tests are discussed in Section 3.1.1. For each material, two models were developed: one reflecting the original, un-reprocessed state, derived from stress-strain curves of control group samples; the other representing the material post-100 cycles of reprocessing. For each material, the reprocessing condition that altered the tensile properties of the materials the most from its original state was selected.

Within this chapter, the outcomes of simulations conducted with different material models are systematically compared. A set of predefined criteria serves as the basis for evaluating the performance of each material under consideration. Employing a Harris profile, a qualitative assessment is conducted to compare the materials' performances under loading. Ultimately, this chapter provides the selection of the optimal material that best aligns with the specifications of vela® VE.

5.1 Selection criteria

In this section, the criteria established for the material selection process will be delineated, providing a systematic framework for evaluating candidate materials. These criteria are essential to ensure that the chosen material aligns with the functional requirements, manufacturing constraints, and performance expectations of the vela® VE.

Stress Values

The most important criterion in material selection is the stress values observed from the FEA. This criterion is paramount as it directly correlates with the structural integrity and performance of the vela® VE component under operational loads. By comparing the maximum Von Mises stress values recorded in the disc with the yield stress or maximum stress of each material, we can assess the material's ability to withstand applied loads without failure. A smaller difference between the recorded stress and the material's yield stress indicates better performance. Separate scores will be assigned for un-reprocessed (control) and reprocessed materials, providing insights into their suitability under varying conditions.

Ultimate Deformation Values

Ultimate deformation, or the maximum strain a material can endure before failure, is another crucial parameter in material selection. This criterion evaluates the material's ability to withstand deformation without permanent damage. Higher ultimate deformation values indicate greater resilience and durability, making such materials preferable for use in the vela® VE component. Evaluation will be conducted separately for un-reprocessed and reprocessed material properties, offering insights into their mechanical robustness under different conditions.

Weight Change

Changes in material weight over reprocessing cycles serve as a proxy for potential absorption of disinfectant chemicals or water, material loss, or alterations in chemical structure. Minimising weight change is imperative to maintain material integrity and performance over time. Materials exhibiting lower weight changes over reprocessing cycles are deemed more desirable, as they signify greater resistance to environmental factors and ensure long-term reliability of the vela® VE component.

Colour Stability

The aesthetic appearance of the vela® VE device plays a crucial role in its acceptance and perception by both physicians and patients. Colour stability is therefore a vital criterion in material selection, as any discolouration or fading over time can compromise the device's visual appeal and professionalism. Materials with higher colour stability will be assigned higher scores, as they maintain their original appearance even after multiple reprocessing cycles, ensuring a consistent aesthetic throughout the device's lifecycle.

Chemical bonding with silicone

An additional crucial criterion in the selection of the optimal material for the rigid components of vela® VE is its capability to form a robust chemical bond with silicone. This characteristic is remarkably important, particularly considering that the cup will undergo overmolding with silicone. Ensuring a strong bond between the materials is imperative to maintain the integrity of the tube-cup connection, thereby preserving an airtight seal. Such a seal is essential to prevent the infiltration of dirt or debris between the tube and the cup, safeguarding the safety and reliability of the device. While all the selected materials exhibit the ability to bond with silicone, the efficacy of this bond may vary across different material options. Therefore, meticulous assessment of each material's performance in this regard is indispensable for informed decision-making in material selection.

5.2 Comparison and final decision

Now that the material selection criteria have been elaborated upon, they will be employed to assess the performance of materials specifically for the vela® VE device. Following the selection of the final design (see section 4.3), simulations were conducted with different material properties assigned to the disc. These simulations utilised material models representing stress-strain curves obtained for the four materials included in this study: Grilamid, Ultem, Radel, and Udel. For each material, two models were utilised — one representing properties from the control group and another simulating properties after 100 cycles of the most damaging reprocessing method, specific to each material. The results of these simulations were presented in Table 3.3, featuring the maximum Von Mises stress recorded in the wire and disc, along with the yield stress value of each material model. Based on these findings, materials were evaluated and assigned a score ranging from + + to - - on their stress values. Considering that stresses recorded in the disc exceeded respective yield stresses for all materials, the score was determined based on the difference between these values, with smaller differences receiving higher scores. Evaluation was conducted separately for the control and reprocessed groups. Additionally, materials were assessed with the same grading system on the other criteria, e.g. ultimate deformation, weight change, and colour stability, based on results outlined in Section 3.1. The scores assigned to each material for each criteria are shown in Table 5.1.

Table 5.1.: Harris profile for material selection.

		Grilamid	Ultem	Radel	Udel
Stress	control	- -	-	-	- -
	reprocessed	+	+	+	- -
Ultimate deformation	control	- -	+ +	-	- -
	reprocessed	- -	-	+	- -
Weight change		+	+	- -	-
Colour stability		- -	+ +	+ +	+ +
Bonding with silicone		- -	+ +	-	-

In assessing stress levels, it emerges that none of the materials were able to withstand the traction force of 453 N, representing the worst case loading scenario for vacuum extraction, as the maximum Von Mises stress recorded in the disc exceeded the yield stress of the material. Notably, Ultem and Radel displayed the smallest percentage differences between their yield stress and maximum Von Mises stress in the disc, indicating favorable performance and designating them as top performers among the investigated materials. Conversely, Udel exhibited the highest stress values in the disc, suggesting potential shortcomings in structural integrity.

Looking at ultimate deformation levels, Ultem demonstrated exceptional performance in the control group, having significantly higher deformation values compared to other materials. However, its performance post-reprocessing exhibited considerable variability, raising concerns about the predictability of its tensile properties under such conditions. Conversely, Radel exhibited improved ultimate deformation values after reprocessing, while Grilamid and Udel displayed consistency with their control group performance.

In terms of weight change, Grilamid and Ultem demonstrated minimal weight fluctuations after reprocessing. However, Radel and Udel exhibited more pronounced weight changes, particularly after disinfection with bleach. It's important to note that the recorded weight changes are subject to limitations in measurement accuracy, especially given the smaller initial weights of some samples. Regarding colour stability assessments, Ultem, Radel, and Udel maintained consistent colouration throughout reprocessing cycles, indicating excellent colour stability. In contrast, Grilamid exhibited significant discolouration, suggesting potential concerns regarding long-term aesthetic appearance.

Radel, Udel, Ultem, and Grilamid exhibit diverse chemical bonding capabilities with silicone rubber, heavily dependent on their surface properties and compatibility. Among these, Ultem stands out as the most promising candidate for effective bonding with silicone rubber, especially after undergoing surface treatments aimed at enhancing adhesion. Radel and Udel require similar treatments to bond well with silicone, but would not achieve the same robustness as Ultem would. Conversely, Grilamid, with its flexibility and toughness, shows poor bonding potential.

In summary, Grilamid and Udel fail to meet the performance criteria due to their inadequate mechanical properties. Ultem and Radel both exhibit good performance in stress levels and colour stability. However, Ultem stands out as the preferred material for the vela® VE due to its superior stability in weight, notably high initial ultimate deformation values and best chemical bonding properties with silicone.

Discussion

The primary objective of this study was to comprehensively evaluate the reusability of the vela® VE, with particular emphasis on the integrity of its tube-cup connection. Initially, the study concentrated on optimising the design of this critical component. Through FEA, three distinct design models were compared under simulated traction loading conditions resembling those encountered during vacuum extraction. Key design parameters, including wire diameter, disc thickness, wire location, and length, were systematically varied to discern their impact on stress distribution within the disc and wire. Following meticulous evaluation, Model 3, featuring a wire diameter of 1.5 mm and disc thickness of 2.6 mm, emerged as the optimal design choice. Subsequently, the focus was on the selection of material for the rigid components of the vela® VE. Four polymers, Grilamid, Radel, Udel, and Ultem, underwent comprehensive comparison. The groups of samples were exposed to different reprocessing methods, namely: disinfection in 2% glutaraldehyde, disinfection in 0.5% sodium hypochlorite, steam sterilisation at 134°C or a combination of steam sterilisation and a disinfection method. Properties such as weight change, colour stability, and tensile strength were assessed before and after 1, 30 and 100 cycles of reprocessing. Their stress-strain curves were used to create material models on the finite element solver Abaqus/Explicit and their properties were assigned to the model of the tube-cup connection. Different simulations were run and the maximum Von Mises stresses in the cup and the reinforcement wire were recorded. Based on the evaluation of the material properties and their performance under simulated loading conditions, Ultem emerged as the optimal choice due to its robust mechanical characteristics and favorable chemical bonding affinity with silicone.

This chapter delves into the discussion surrounding the overall durability of the vela® VE, particularly concerning its ability to withstand 100 cycles of use. The analysis focuses on different components of the connection between the tube and the cup, including the cup itself, the reinforcement wire, and the tubing component. To begin, the results obtained from tests conducted on the materials before and after reprocessing are examined. These results serve as a foundational understanding for interpreting the outcomes of the Finite Element Analysis (FEA) conducted on the vela® VE. By scrutinising the mechanical properties of the materials under varying conditions, it is possible to gain insights regarding their performance and resilience over repeated use. Subsequently, the discussion extends to the interpretation of FEA results in light of the material tests. This analysis allows for a comprehensive evaluation of the device's structural integrity and durability under simulated loading conditions. Two loading scenarios were considered, including the most extreme case documented in literature, with a traction force of 453 N [1–3, 8, 28–32], as well as the upper safety limit identified in scientific literature, set at 225 N [1–4, 33]. By correlating the stress and deformation distributions observed in the FEA with the material properties, conclusions can be drawn regarding the vela® VE's capacity to endure the traction forces exerted during vacuum extraction. Furthermore, potential points of failure and areas of concern within the device's design and material selection are identified and discussed. The last section focuses on the limitations inherent in this study and the recommendations for future research, aimed at refining the design and material selection for the vela® VE.

6.1 Cup

In Chapter 5, the outcomes of the material selection were illustrated, supporting the conclusion that Ultem is the most suitable material for the cup of the vela® VE. This material showed remarkable performance in all the tested properties. Starting from exceptional colour stability, evidenced by its lack of discolouration after undergoing various reprocessing methods, as previously described in Section 3.3. This characteristic ensures the device's aesthetic appeal

remains consistent over its operational lifespan, improving the user's experience of the vela® VE.

Looking at the weight change, a maximum increase of 0.7% (± 0.2) in sample weight after 30 cycles of steam sterilisation is observed, which is comparable or below the values recorded for the other materials considered in this study. Weight change is indicative of potential water absorption by the material. This absorption likely influences the material's mechanical properties, as evidenced by a noticeable increase of up to 3.98% (± 0.3) in yield stress values for Ultem. The alteration in the yield stress values of Ultem is, however, desirable, as a higher yield stress signifies the material's enhanced ability to withstand greater stresses before reaching plastic deformation. Surprisingly, the reprocessing of Ultem unexpectedly improves its properties. Additionally, the consistency of these values, as indicated by low standard deviations, underscores the reliability of these measurements. On the other hand, ultimate deformation values exhibit higher variability, particularly following reprocessing, potentially due to changes in material structure or composition.

In order to assess the mechanical behaviour of the cup under simulated use, it is crucial to look at the outcomes of the FEA. The detailed results have been described in Section 3.2.3 and they show the stresses and strains recorded using Ultem's properties after 100 cycles of sodium hypochlorite disinfection and steam sterilisation. The results obtained from using the control group's material properties are deemed comparable and it was therefore decided to focus on the worst case scenario of the reprocessed material.

For the worst case loading scenario of 453 N of traction force, a maximum Von Mises stress of 183 MPa is observed in the disc. This value is higher than the yield stress of reprocessed Ultem at 116 MPa. Notably, this stress concentration occurs at the entry point of the reinforcement wire, near the inner portion of the 90° angle formed by the wire. The location of this maximum stress arises from a combination of induced stresses in the area, particularly:

- the stresses propagated at the contact area with the wire caused by the traction forces along the z direction
- the stresses caused by the compression of that portion of the disc. The surface above the disc is fixed by the encastre boundary condition, whilst the portion of the wire along the x direction compresses it.

The fact that the maximum Von Mises stress in the disc exceeds the yield stress value of the material, indicates that that portion of the disc is most likely to fail. However, it is relevant to note that the location of such elevated stress values are limited to a small portion of the disc, as described above. In the rest of the contact area with the wire, the stresses are significantly lower, between 20 to 90 MPa, below the yield stress values of Ultem, indicating that they are not likely to undergo plastic deformation.

Furthermore, it is crucial to contextualise these findings within real-world usage scenarios. Literature suggests vacuum extraction forces typically fall well below the worst-case scenario analysed. In Appendix A, the results of a literature search show that various sources suggest an upper limit for safe traction force during vacuum extraction at 225 N [1–4, 33]. Under such conditions, the maximum Von Mises stress in the disc is at 127 MPa, only 17 MPa above the lowest yield stress value recorded among all of the Ultem samples, observed after 30 cycles of steam sterilisation. This suggests that with further design adjustments, such as adding a second reinforcement wire to the selected design, the stresses in the disc would likely remain within acceptable limits, ensuring device safety. LAYCO® Medical Devices may consider listing the device's failure above the safety traction force limit as a safety feature inherent to vela® VE's design.

Looking at the ultimate deformation values observed from the tensile testing results, Ultem exhibits ultimate deformation values as high as 62.97% ($\pm 11.42\%$) for the control group. The lowest ultimate deformation value recorded, obtained from a sample undergoing 30 cycles of disinfection in glutaraldehyde and 30 cycles in the autoclave, is 5.65%, or 0.05. The maximum deformation recorded in the disc after a load of 453 N was applied is 0.024, which is half of the lowest ultimate deformation recorded. This suggests that when the stresses recorded in the disc exceed the yield stress, the device will not break, but it would undergo plastic deformation. While this constitutes the device's failure, given the assumption that device failure above safety traction force limits is acceptable as a safety design feature, such deformation ensures no pieces break off, maintaining safety. In summary, while concerns regarding mechanical failure exist under extreme loading conditions, safe traction scenarios suggest the vela® VE constructed from Ultem would operate within safe limits, with any failure likely manifesting as plastic deformation rather than structural fragmentation.

6.2 Reinforcement wire

Kevlar was chosen by LAYCO® Medical Devices as the material for the reinforcement wire. This study meticulously examined its tensile properties before and after reprocessing, with a particular emphasis on the maximum stresses it could withstand. In the control group, the maximum stress observed was 650 MPa (± 45). Remarkably, after undergoing immersion in bleach and autoclaving, the maximum stress dropped substantially to a mere 24 MPa, a 96% decrease compared to the control. However, the reinforcement wire will be fully encapsulated by the silicone of the tubing component and it will not come in contact with sodium hypochlorite. Therefore, such drastic changes in the tensile properties of kevlar should not be observed in clinical practice. This result highlights the importance of proper encapsulation of the reinforcement wire. Excluding the maximum stress values recorded after disinfection with bleach, the lowest maximum stress for kevlar after steam sterilisation was recorded at 448 MPa. Looking at the results obtained from the worst case loading scenario of the FEA, the stresses in the wire reach 1514 MPa. Therefore failure of the reinforcement wire appears inevitable. With lower traction forces at 225 N, the maximum Von Mises stresses in the wire reach 776 MPa, once again exceeding the maximum stress values recorded for kevlar. Consequently, it is strongly recommended that LAYCO® Medical Devices explore alternative materials capable of withstanding higher traction forces. Alternatively, adjusting the wire's diameter presents a potential solution, as it is inversely proportional to stress. However, such an adjustment may adversely affect the user experience aspect, as it could lead to an increase in tube wall thickness, overall diameter, and stiffness. Thus, while increasing wire diameter may mitigate stress-related concerns, it necessitates a careful balance between structural integrity and user satisfaction.

6.3 Tube

The performance evaluation of the tubing component, constructed from silicone, is crucial for ensuring its effectiveness in medical applications. This study delved into analysing the properties of silicone, with a focus on various aspects. In terms of colour stability, important for maintaining transparency to enable visual inspection of the tube's hollow lumen during cleaning, silicone exhibited commendable colour stability after reprocessing with glutaraldehyde, sodium hypochlorite and even autoclaving. However, when subjected to a combination of disinfection and sterilisation methods, significant discolouration occurred, which could compromise user perception and experience due to the perceived uncleanliness.

Additionally, examining the weight change in silicone revealed a noteworthy trend. After 100 cycles of autoclaving, the material tended to experience a decrease in weight, reaching a maximum of -2.43%. This likely contributes to the significant increase in the shore hardness A of the material, going from an average of 52.83 (± 0.29) to 58.17 (± 0.76) after 100 cycles of disinfection with 2% glutaraldehyde and disinfection in the autoclave. This increase in Shore hardness A would result in a stiffer tube, potentially compromising user experience by reducing flexibility. As the silicone component of the tube is not responsible for bearing traction forces, its tensile properties were not studied in this analysis.

Overall, silicone demonstrated sensitivity to reprocessing methods, particularly when subjected to a combination of disinfection and sterilisation. Consequently, it is advisable for LAYCO® Medical Devices to explore alternative materials with improved chemical resistance to mitigate these issues and ensure optimal performance of the tubing component in medical applications.

6.4 Limitations

This research has a number of limitations, which extend from the material testing phase to the FEA that was carried out on the vela® VE component. Hence, some considerations have to be discussed to comprehensively understand the conclusions of this research.

Materials testing

Starting with the material tests, one notable limitation arises from the limited number of material samples available for testing. This sample size was insufficient to perform statistical analyses to demonstrate significance between different designs and materials. However, in this initial research phase statistical tests' results are not needed yet and indicative data should be sufficient. Another limitation of this study is that the number of samples for each condition was not constant and, in some cases, it even minimised to one or two samples, reducing the possibility for confident calculations of both average and standard deviation. In addition to this, the material samples were not uniform in their size and weight. Grilamid and Ultem were dumbbell shaped according to the standard ISO 527, shape 1A [6], encompassing a total length of 150 mm, whilst Radel and Udel were water jet cut with a total length of 30 mm, according to the standard ASTM D1708 18 [7]. Furthermore, the thickness of Radel's samples varied between 2 and 5 mm. This variabilities may have influenced the observed weight changes and could have subtly impacted the measured tensile properties of the materials under investigation.

Furthermore, the variation in sample colouration between different materials introduced a potential source of bias in the assessments of colour stability. Inconsistencies in colour may have derived from differences in material composition or colouration methods, potentially compromising the accuracy of colour stability evaluations.

Moreover, in clinical practice it is common to observe longer immersion times than the standard disinfection protocols, particularly in LMICs. This limits the applicability of the results obtained in this study to the cases where disinfection times do not exceed 20 minutes for 0.5% bleach immersion and 40 minutes for 2% glutaraldehyde immersion. However, as described in Section 2.1.3, the disinfection times defined for this study are based on an observational study conducted in LMICs by LAYCO® Medical Devices and take into account a 100% safety margin over the official recommended times [14, 27]. Furthermore, the selected disinfection and sterilisation methods are based on the instructions for use of the vela® VE, including methods typically used in LMICs. However, the inclusion of only two disinfection methods and steam sterilisation, further restricts the generalisability of the findings.

Moreover, the silicone samples investigated in this study are not medical grade but generic silicone. Medical grade materials typically have better performances, especially regarding resistance to reprocessing methods. Additionally, it is possible to notice that the levels of discolouration observed in distinct samples that underwent exactly the same reprocessing conditions, are variable (Figure B.5e). This is likely attributed to the immersion process in the disinfectant, where the silicone sheets may have adhered to each other, resulting in uneven penetration of chemicals across all samples. Moreover, during steam sterilisation, the samples positioned on the outer edges of the autoclave trays were closer to the metal walls of the chamber, which tend to retain more heat, potentially subjecting them to slightly different temperatures. However, this difference in the exposition of the materials to the reprocessing methods reflects the variability observed in a real-life clinical scenario. Furthermore, despite the efforts to maintain a controlled reprocessing environment, environmental factors such as temperature, humidity, and airborne contaminants could have influenced the material properties during reprocessing and testing. These factors introduce a level of uncertainty that should be acknowledged when interpreting the results.

Computational modelling

Turning to the FEA conducted on the vela® VE tube-cup component, several noteworthy limitations must be addressed. Firstly, the assumption of perfectly elastic material behaviour in the material models overlooks potential non-linearities in the stress-strain relationship, which may impact the accuracy of the stress analysis. However, this simplification was uniformly applied across all materials. Therefore, while it may introduce a limitation, its consistent application ensures comparability among the materials, thereby minimising its impact on material selection comparisons. Another limitation of the material modelling is that manual calculations were performed to determine the Young's modulus and yield points, which introduces subjectivity into the material characterisation process, potentially compromising the reliability of the FEA results.

Additionally, the exclusion of the silicone part in the FEM overlooks the potential mechanical role of silicone in the tube-cup connection, which may influence stress distribution, potentially absorbing stresses propagated from the wire and lowering the stress levels in the wire itself and in the cup. However, it is important to note that while silicone may have a mechanical role to some extent, its influence should not be too significant, thus maintaining model accuracy. Additionally, if silicone does indeed contribute to the mechanical behaviour, it could potentially alleviate stresses in both the disc and wire, further enhancing the model's reliability.

The symmetry assumption in the FEA, modelling only half of the component, may oversimplify the structural behaviour

of the vela® VE, but with the unidirectional loads applied in this study, this simplification does not have any impact on the results. Additionally, modelling the wire as a rigid body disregards its flexible behaviour as a wire, potentially affecting the accuracy of the stress analysis. Furthermore, the simplified sharp 90° angle at the wire's entry point into the disc may not accurately represent the actual manufacturing process, potentially affecting stress distribution in the vicinity of the wire entry point. The tie constraint used to model the chemical bond between the wire and the cup assumes a static, unyielding connection, disregarding the potential for bond failure under loading conditions. However, in this initial research phase the information provided by this simplified FEM are deemed to be sufficient.

Moreover, due to a lack of data on time-dependent properties, fatigue analysis and repeated loading simulations were not conducted, limiting the comprehensive assessment of device durability and long-term performance. Furthermore, the study only considered static loading scenarios in a single direction, which may not fully capture the complex loading conditions experienced during clinical use. In summary, while this study provides valuable insights into the mechanical behaviour of the vela® VE components, these limitations underscore the need for further research to comprehensively evaluate device reusability and performance. Addressing these limitations in future studies could enhance the reliability and applicability of findings in real-world clinical settings.

6.5 Future recommendations

There are several recommendations for future research aimed at improving the design and materials of the vela® VE. This study has identified limitations and areas for further exploration essential for enhancing the device's functionality, safety, and reusability. Firstly, an essential aspect to explore is the investigation of alternative materials for the reinforcement wire. While Kevlar® 29 has demonstrated favorable properties, such as heat resistance, the results of the FEA proved it is necessary to explore higher-grade variants, such as Kevlar® 49. This material grade offers superior load-bearing capabilities, addressing one of the critical requirements for the device's structural integrity. Moreover, attention should be directed towards enhancing the resilience of silicone to reprocessing methods, since it was found that its colour stability and hardness were significantly impacted. Plasma treatment, coating techniques, or alternative curing methods, like peroxide or platinum curing, could improve silicone's chemical properties. Additionally, the utilisation of additives in silicone formulations could further optimise its performance. Furthermore, minor adjustments to the device's design might also bring improvements to the tube-cup connection. The results of the FEA showed that under 225 N of traction force the stresses recorded in the disc still exceed the yield stress of Ultem by 17 MPa. Considerations such as incorporating a second wire could enhance the device's mechanical performance and longevity. By further refining the design through modelling and simulation studies, novel configurations may emerge that optimise functionality and durability.

To comprehensively evaluate device performance, it is imperative to investigate the time-dependent material properties of the selected materials. Conducting cyclic loading simulations based on these properties can offer insights into the device's long-term durability under repeated use, a critical aspect in clinical settings. Exploring diverse loading scenarios is crucial for capturing the range of conditions encountered during clinical use. Conducting simulations with different loading directions and amplitudes can provide a comprehensive understanding of device behaviour, providing additional information for the identification of potential failure modes and weak points. Lastly, integrating fatigue analysis into future studies would be essential for assessing device durability and predicting potential failure mechanisms. Incorporating fatigue testing protocols can validate simulation results and guide design improvements to enhance device longevity. Following these further tests and computational simulations, it is recommended that the device's performance is assessed in a test set-up mimicking usage conditions. By addressing these recommendations, LAYCO® Medical Devices can advance the understanding of the vela® VE's mechanical behaviour, optimise its design and materials selection, and ultimately enhance its performance, safety, and reusability in clinical settings.

Conclusions

This thesis is a comprehensive study focusing on the reusability of the vacuum extractor vela® VE, with a particular emphasis on optimizing one of its pivotal components: the connection between the tube and the cup. This investigation was not only aimed at optimizing the design through the evaluation of three distinct initial models but also at selecting the most suitable material for the cup among the candidates: Grilamid, Ultem, Radel, and Udel. Additionally, the study aimed to assess the performance of Kevlar as the reinforcement wire and silicone for the tube. To achieve these objectives, the materials were reprocessed under different conditions, specifically: 2% glutaraldehyde immersion, 0.5% sodium hypochlorite immersion, 134°C steam sterilisation, and a combination of them. They were tested before reprocessing and after 1, 30, and 100 cycles of each reprocessing method to assess their mechanical and physical properties, including tensile properties, colour stability, weight change, and shore hardness A. The properties found from the tensile tests were used to create material models on the finite element solver Abaqus/Explicit to simulate the behaviour of the wire and cup during clinical use.

During the design optimisation process, four key parameters were identified and varied in different design iterations, namely, wire's diameter, cup's thickness, wire's length, and wire's location. It was found that the wire's diameter has a direct impact on the stress levels; the bigger its cross-sectional area, the lower the stresses. The disc's thickness has an ideal value, for which the lowest stresses are reached, and they increase with lower or higher thickness values. Wire's length and its position don't significantly influence the overall stress distribution within the model. Criteria were established to evaluate the results: stress levels to be as low as possible, easiness of manufacturability, and enhanced user experience. Based on these criteria, the different designs were evaluated, and the optimal one was selected: Model 3, with holes positioned on top for better manufacturability, with a wire of 1.5 mm and disc thickness of 2.6 mm. Then, the different materials were evaluated. Based on their properties before and after reprocessing and their mechanical behaviour in simulated loading conditions, it was concluded that the most suitable one for the application in vela® VE was Ultem™ HU1010.

Finally, the performance of the optimised design with the selected material was evaluated. The results of the finite element analysis of the worst-case scenario (453 N of traction force) and the upper limit for safe traction (225 N) were studied. The stresses recorded in the disc in the worst-case scenario exceed the yield stress of the material, indicating that the material will likely undergo plastic deformation with this high traction force but will not break. However, for lower traction forces, the maximum stress recorded in the disc is only 17 MPa above the lowest yield stress of Ultem recorded in this study. With minor design adjustments it is deemed likely that the component will be able to withstand 225 N of loading. LAYCO® Medical Devices may consider deliberately listing the device's failure above the safety traction force limit as a safety feature inherent to vela® VE's design. Regarding the wire, the maximum Von Mises stresses are at 1514 MPa, exceeding the maximum stress of the material by approximately 3 times as much. Therefore, it is advised to find an alternative material, specifically a better grade of kevlar, such as Kevlar® 49. Alternatively, the stresses in the wire could be lowered by increasing its diameter. However, this would compromise the user experience. Looking at the tubing component in silicone, 100 cycles of reprocessing seem to hinder its properties, particularly increasing its hardness and causing discolourations. This is an unwanted outcome, and it is therefore advisable to look for an alternative material or look into material treatments such as plasma treatment, coating techniques, alternative curing methods, like peroxide or platinum curing, or the utilization of additives in silicone.

However, this study has limitations, particularly regarding the limited sample sizes for the material tests and the simplifications operated for the FEA. Regarding the recommendations for the future research, it is advisable to consider alternative materials or surface treatments for the reinforcement wire and the tube. Furthermore, it is also recommended that more advanced FEA is carried out to refine the understanding of the vela® VE's mechanical behaviour, particularly, including time-dependent material properties and cyclic loading scenarios.

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Appendix

Traction forces during vacuum extraction

A literature review was conducted to explore the range of traction forces exerted during vacuum extraction, consolidating findings from various studies to gain insights into the forces typically encountered in clinical practice. The aim of this review is to provide a comparative analysis of the reported values of pulling forces and to draw conclusions regarding the typical forces involved in vacuum-assisted delivery.

Vacuum extraction is a medical procedure whose duration typically varies, but it usually lasts less than 20 minutes to minimize the risk of injury or stress to the baby. The force exerted during vacuum traction can range widely depending on various factors such as the clinical scenario, the baby's position, and the specific circumstances of the labor. A physician will typically apply several pulls, synchronizing with the mother's contractions to maximize the effectiveness of the assistance and reduce the duration of the procedure. In Figure A.1 it is possible to see a force-time profile graph from a vacuum traction procedure providing a visual representation of the forces applied over time. The x-axis measures the time in minutes, while the y-axis measures the force in newtons. As seen in the graph, there are multiple peaks indicating the moments when traction force is applied. These peaks are not uniform, illustrating the variability in the force applied with each pull. Between the peaks, the force returns to near-zero, reflecting the release of traction between contractions. The force range is quite wide, as evidenced by the varying heights of the peaks, demonstrating the dynamic nature of the procedure. Each peak correlates to a single pull, with the number of peaks indicating the total number of pulls applied throughout the process.

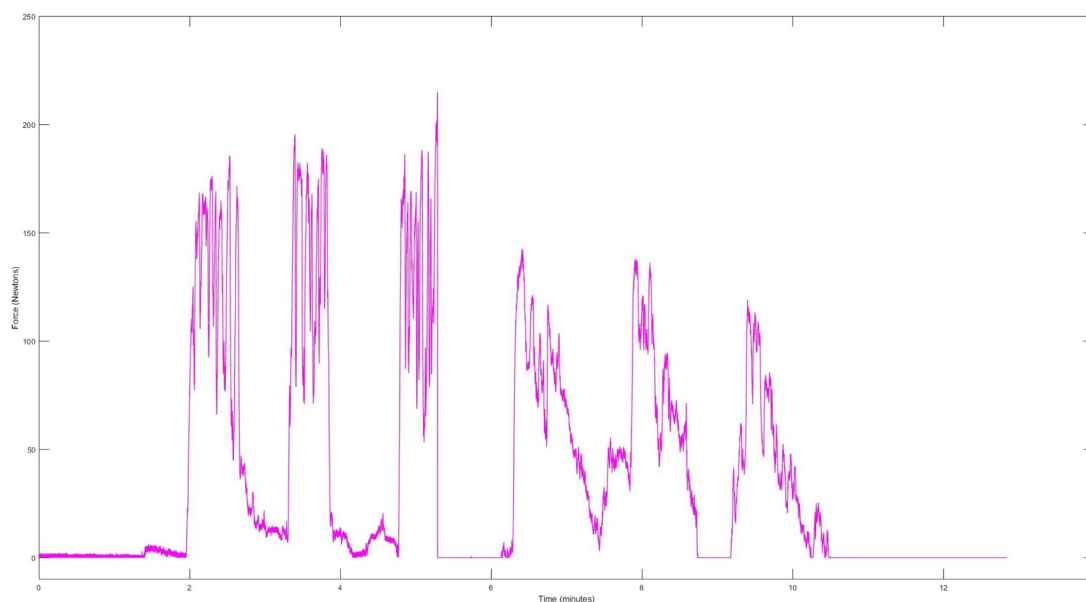


Figure A.1.: Traction force profile from Romero et al. [8].

A.1 Main findings

Goordyal et al. observed that the vacuum extraction procedure typically spans around 10 minutes over 2 to 3 pulls, with each pull exerting forces up to 115N [29]. Vacca et al. suggested that a traction force of 115N could lead to successful delivery in 80% of cases, emphasizing that traction should not exceed 135N to avoid maternal sphincter damage and scalp injury to the baby [28]. Saling's investigation into traction forces recorded during clinical use of the Malmstroem device reported a maximum force of 125N for successful delivery. It was also found that traction forces exceeding 196N resulted in cup detachment in almost 50% of the cases [3]. Lapeer et al. conducted a finite element analysis on the effect of vacuum extraction on the baby's skull, using data from previous studies to suggest that the maximum applicable force is 131N [32]. In recent studies by Pettersson et al., traction forces during vacuum extraction were meticulously recorded using a force-measuring handle [1]. In their 2015 investigation, patients were stratified into three distinct groups based on force amplitudes. Group A, comprising cases with minimum extraction forces (n=114), exhibited an average force of 176N, ranging from 5N to 360N. Group B, representing instances of average extraction forces (n=37), demonstrated a mean force of 225N, with a range spanning from 115N to 436N. Conversely, Group C, characterised by excessive extraction forces (n=42), displayed an average force of 241N, fluctuating between 164N and 452N. Notably, Pettersson et al. observed that failed vacuum extractions all had significantly higher total traction forces compared to successful cases, with all unsuccessful extractions categorised as excessive [1]. In their subsequent 2017 study, Pettersson et al. expanded their research cohort and recorded the peak forces for the first three pulls [30]. They divided the participants into two distinct groups: strong and non-strong. The strong group, comprising cases with excessive traction forces (n=70), exhibited peak pull forces averaging 195N in the first pull, ranging from 89N to 404N, 199N in the second pull, ranging from 76N to 371N, and 195N in the third pull, ranging from 91N to 453N. Conversely, the non-strong group, consisting of cases with lower traction forces (n=201), demonstrated peak pull forces averaging 162N in the first pull, ranging from 5N to 361N, 131N in the second pull, ranging from 28N to 436N, and 120N in the third pull, ranging from 15N to 369N [30]. Additionally, Romero et al. conducted a similar study design, categorising participants into two groups: case and control [8]. The case group, representing instances of severe perinatal outcomes (n=13), exhibited peak pull forces averaging 203N in the first pull, ranging from 142N to 299N, 210N in the second pull, ranging from 86N to 311N, and 200N in the third pull, ranging from 75N to 332N. Conversely, the control group, comprising cases with no severe perinatal outcomes (n=39), displayed peak pull forces averaging 173N in the first pull, ranging from 110N to 306N, 163N in the second pull, ranging from 48N to 290N, and 155N in the third pull, ranging from 53N to 245N [8].

A.2 Upper limit of safe traction

A first relevant conclusion that can be drawn from these findings is the association between unsuccessful deliveries or those with severe perinatal outcomes and higher traction forces. Consequently, this Appendix focuses also on the literature that tries to define an upper limit of safe traction for VE. This upper limit represents a value slightly above the force required to affect delivery but just below the threshold needed to overcome the adhesive force of the cup, as cup detachment due to excessive traction is recognized as the primary cause of serious foetal injury.

Prior investigations by Baskett et al. and Vacca et al. on traction forces exerted on vacuum extractors with rigid plastic cups have suggested that peak traction forces less than 113 N would be sufficient in 80–86% of vacuum extractions, indicating that most extractions should not necessitate more force than this [15, 28]. Perone et al. delineated different limits for various types of cups [2]. For a rigid (metal) cup with a 5 cm diameter, such as the Bird modified Malmström, detachment occurred when 125 N of traction is applied, affecting delivery, whereas with a similar rigid (plastic) cup, detachment occurs with 100 N of traction. Consequently, for a rigid cup with a 5 cm diameter, such as the vela® VE's cup, the traction safety limit could be defined between 100 and 125 N [2]. Moolgaoker et al. proposed a safe traction force of up to 216 N using the 50 mm Malmstrom metal cup with 80 kPa negative pressure [33]. Issel et al. discovered that, with the same type of cup, up to a traction force of 200 N, the compression effect on the foetal head amounts to only 10–40 N, but this increases rapidly if the applied traction force exceeds 200 N [34]. Hence, while

there are reasonable models for understanding how excessive traction forces could be harmful, these mechanisms are still poorly understood. Noticeably, most studies suggest a traction force of 225 N (equivalent to a mass of 23 kg) as an upper limit for safe vacuum assisted delivery [3, 4, 35].

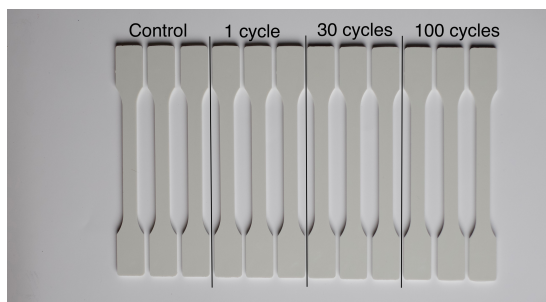
A.3 Conclusions

This review of literature on traction forces during vacuum extraction offers valuable insights into the range of forces typically encountered in clinical practice. The data collected from various studies reveal a broad spectrum of force amplitudes, from the minimum required for successful delivery to excessive forces associated with unsuccessful outcomes. Notably, the worst-case scenario recorded in this literature reports a traction force of 453N, whilst underscoring the potential risks associated with excessive force application during vacuum extraction procedures. However, despite the wide variability in force magnitudes, the average peak forces observed in most studies tend to range much lower than the extreme cases.

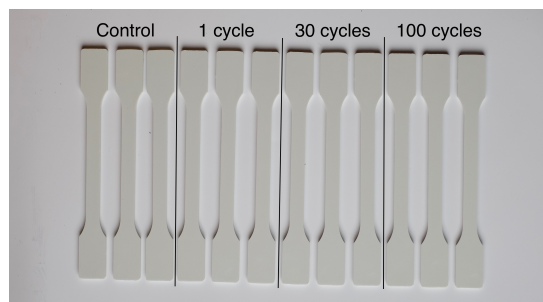
In light of the literature's findings and the imperative to prioritise maternal and foetal safety, multiple sources suggest the establishment of an upper safety limit for traction forces during vacuum extraction. The literature commonly proposes a traction force of 225N as the upper safety threshold, with some studies advocating for even lower limits. Therefore, for the purposes of this research, it was decided to adhere to the recommended upper limit of 225N.

Colour stability assessments

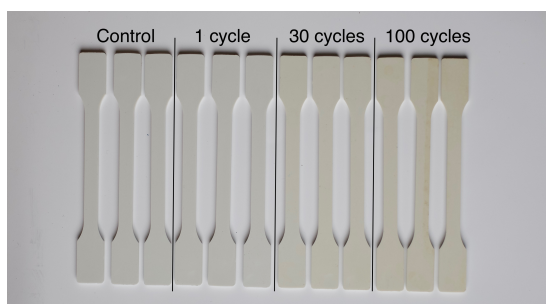
In this Appendix, it is possible to view the images taken of each sample included in this study after each reprocessing condition. They are extremely valuable to assess colour stability of the samples.



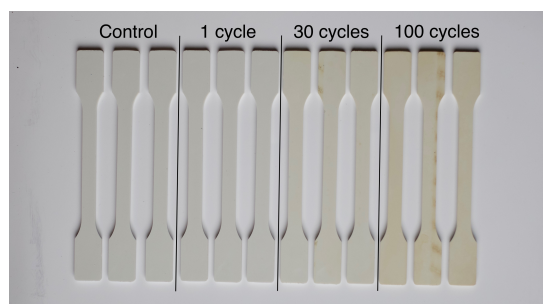
(a) Grilamid-G



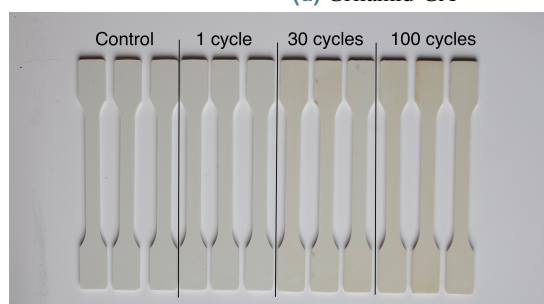
(b) Grilamid-SH



(c) Grilamid-A

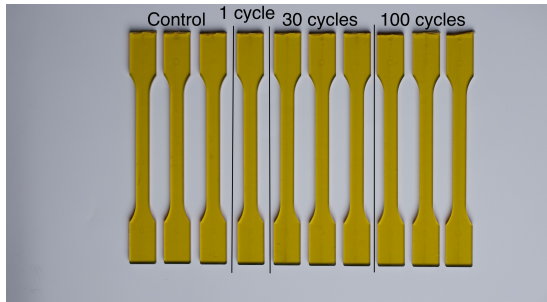


(d) Grilamid-GA

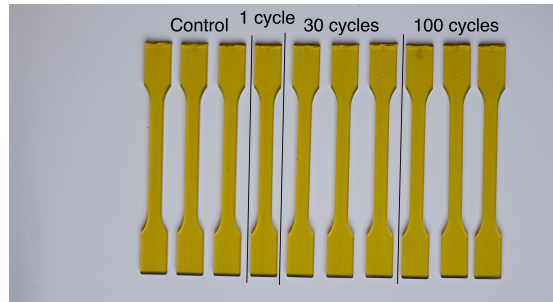


(e) Grilamid-SHA

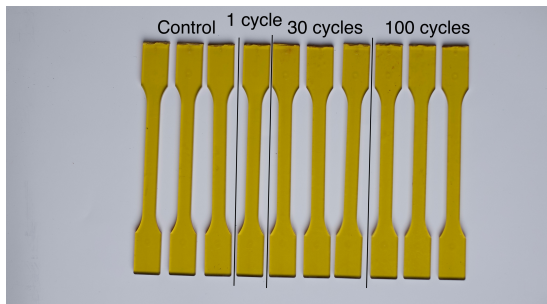
Figure B.1.: Pictures of Grilamid® LKN-5H samples before and after 1, 30 and 100 cycles of different reprocessing methods



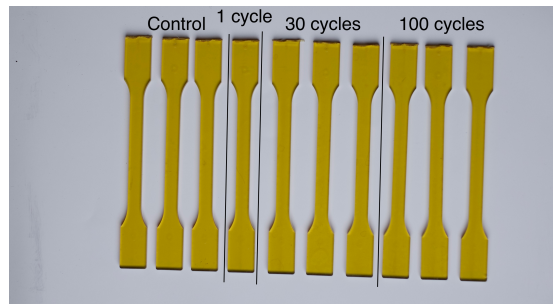
(a) Ultem-G



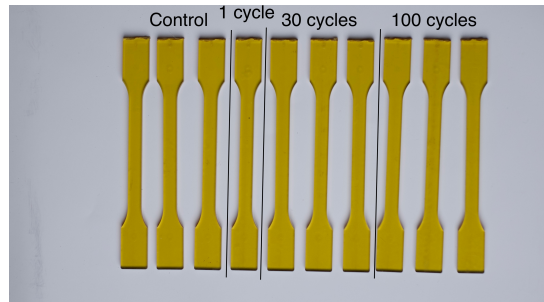
(b) Ultem-SH



(c) Ultem-A



(d) Ultem-GA



(e) Ultem-SHA

Figure B.2.: Pictures of Ultem™ HU1010 samples before and after 1, 30 and 100 cycles of different reprocessing methods

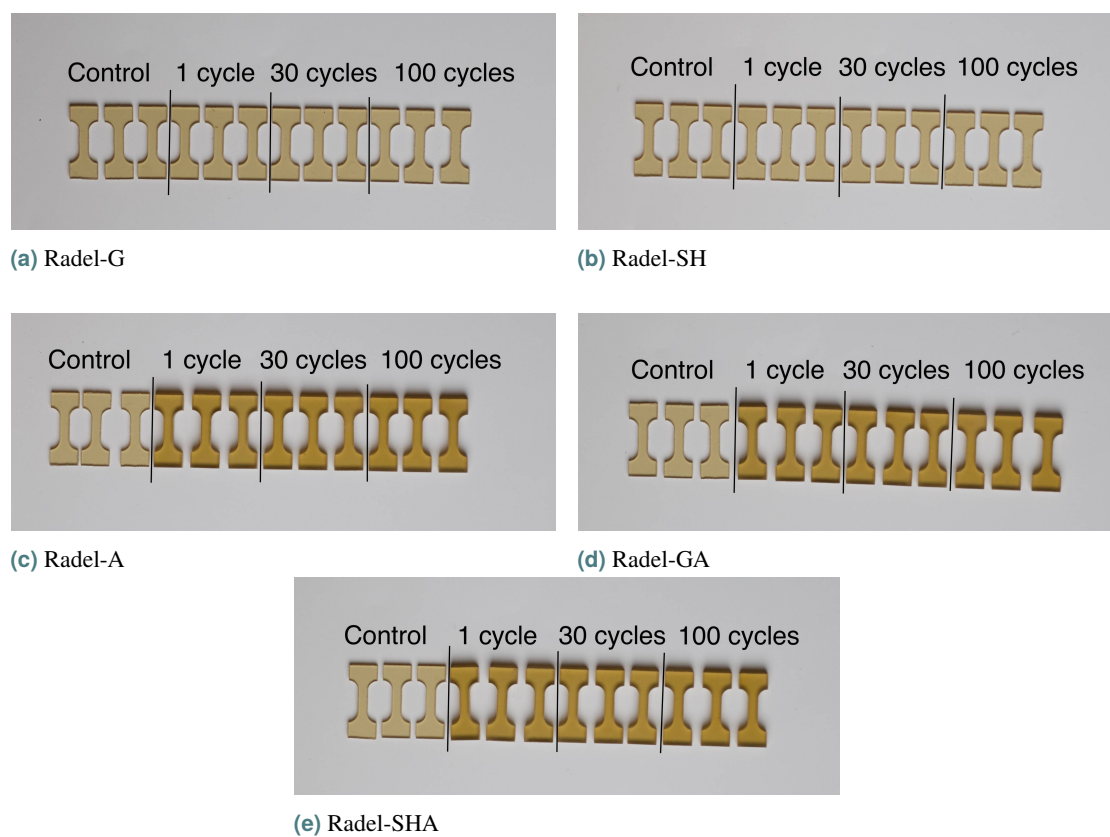


Figure B.3.: Pictures of Radel® R 5500 NT 15 samples before and after 1, 30 and 100 cycles of different reprocessing methods

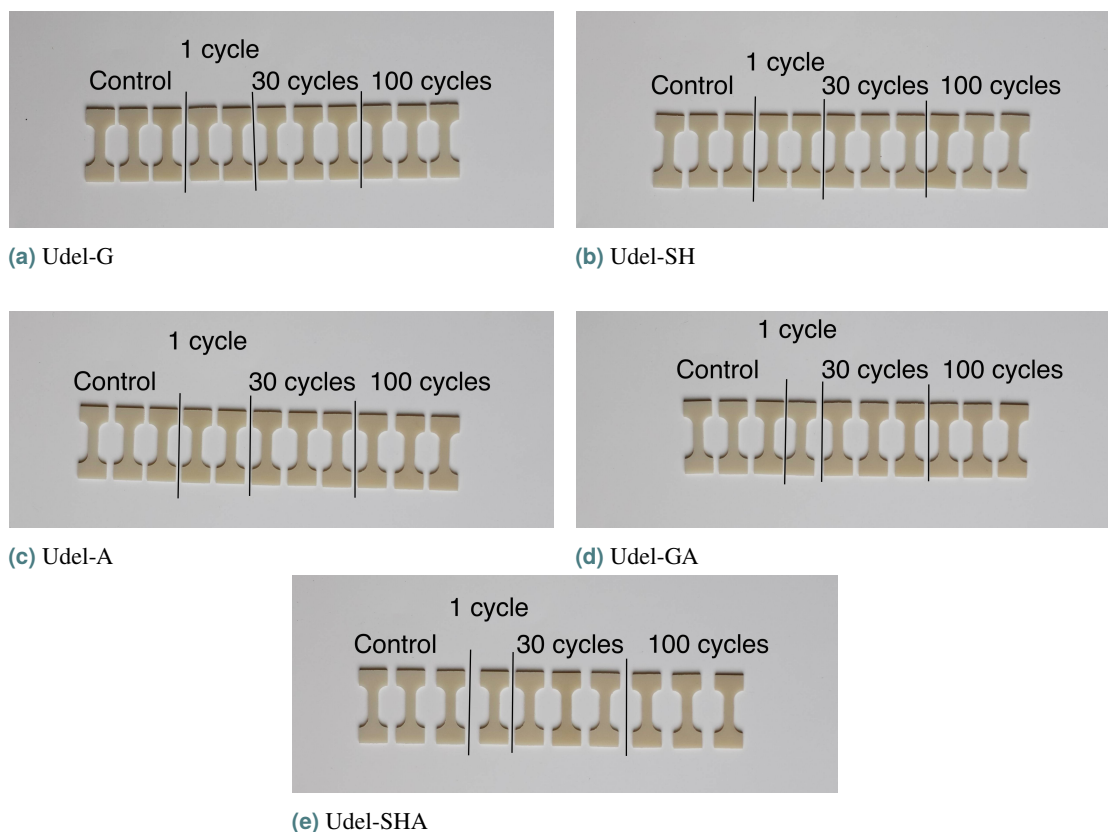


Figure B.4.: Pictures of Udel® GF120 NT samples before and after 1, 30 and 100 cycles of different reprocessing methods

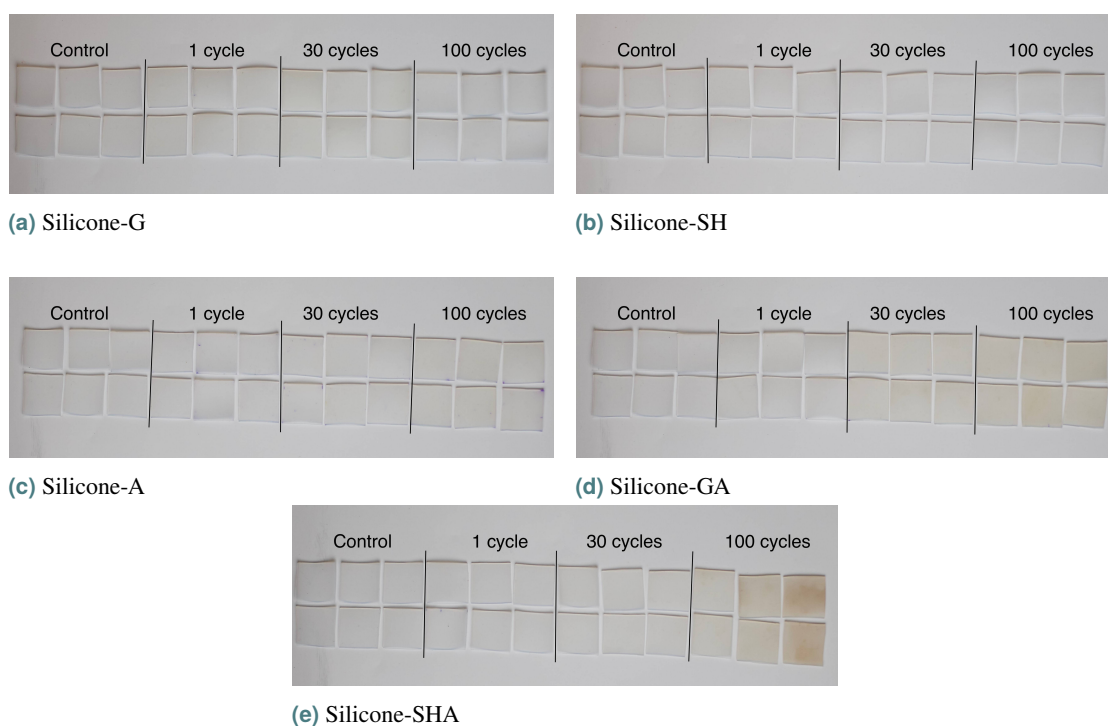


Figure B.5.: Pictures of silicone samples before and after 1, 30 and 100 cycles of different reprocessing methods

Material models

This chapter describes in detail the methodology followed to create each material model based on the force displacement values exported from the tensile tester.

The material models were meticulously constructed for each material, both for the control group and for every reprocessing conditions after 100 cycles. Force-displacement data points were imported into MATLAB and stress values were calculated by dividing the force by the transversal area of the samples to generate the stress-strain curves. They were then interpolated. Subsequently, the curves corresponding to each condition were averaged to obtain a representative mean curve. Following this, two distinct points along the curve were manually selected, defining a segment to be linearised. A linear regression analysis was performed on this segment, and a 0.2% offset was applied to the resulting line. The intersection point between the offset line and the stress-strain curve was identified as the yield point. Tables C.1, C.2, C.3, C.4, and C.5 show the elastic modulus, yield stress and yield strain values calculated for each material for each test group. Figures C.1, C.2, C.3, C.4, and C.5 visually represent all available curves, showcasing the variations observed under different conditions and providing insights into material behavior across various reprocessing states.

Grilamid	E [MPa]	σ_Y [MPa]	ϵ_Y [-]
C	1539,12	36,54	0,028
G	1558,42	36,77	0,028
SH	1570,65	36,64	0,026
A	989,66	21,56	0,025
GA	1028,76	22,16	0,024
SHA	1047,92	22,57	0,023

Table C.1.: Elastic modulus, yield stress and yield strain values calculated from the stress strain curves for Grilamid® LKN-5H.

Ultem	E [MPa]	σ_Y [MPa]	ϵ_Y [-]
C	1967,16	87,09	0,049
G	1937,94	87,27	0,051
SH	1960,84	87,53	0,049
A	1994,70	93,83	0,053
GA	1959,89	93,19	0,054
SHA	1982,71	94,16	0,054

Table C.2.: Elastic modulus, yield stress and yield strain values calculated from the stress strain curves for Ultem™ HU1010.

Radel	E [MPa]	σ_Y [MPa]	ϵ_Y [-]
C	1180,05	70,44	0,066
G	1300,10	69,61	0,056
SH	1177,25	71,00	0,063
A	690,31	67,17	0,114
GA	718,09	66,60	0,102
SHA	710,4401805	65,55	0,099

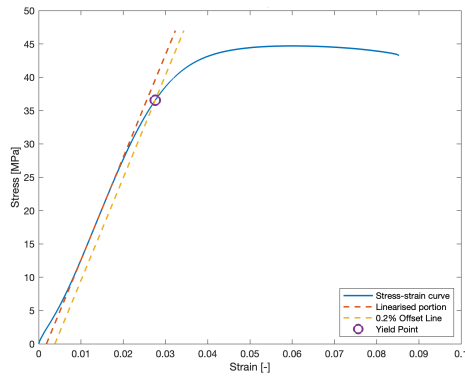
Table C.3.: Elastic modulus, yield stress and yield strain values calculated from the stress strain curves for Radel® R 5500 NT 15.

Udel	E [MPa]	σ_{max} [MPa]	ϵ_{max} [-]
C	1719,38	71,60	0,045
G	2032,24	87,81	0,045
SH	1771,77	75,12	0,045
A	1796,12	68,02	0,042
GA	1607,87	69,12	0,045
SHA	1664,16	65,35	0,045

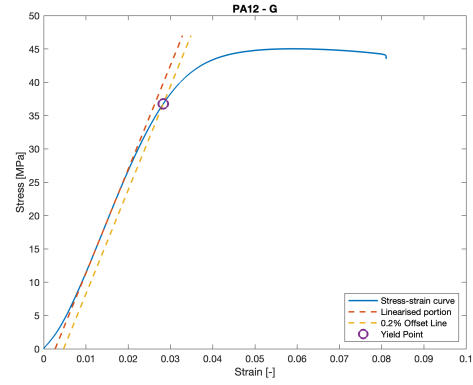
Table C.4.: Elastic modulus, yield stress and yield strain values calculated from the stress strain curves for Udel® GF120 NT.

Kevlar	E [MPa]	σ_{max} [MPa]	ϵ_{max} [-]
C	10912,33	616,40	0,072
A	10900,20	516,01	0,064
GA	11423,65	465,03	0,056
SHA	2396,74	25,31	0,014

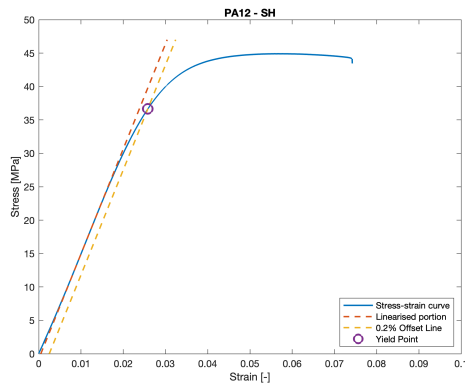
Table C.5.: Elastic modulus, yield stress and yield strain values calculated from the stress strain curves for Kevlar® 29.



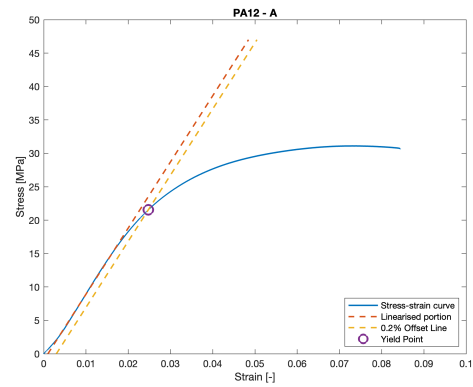
(a) Grilamid-C



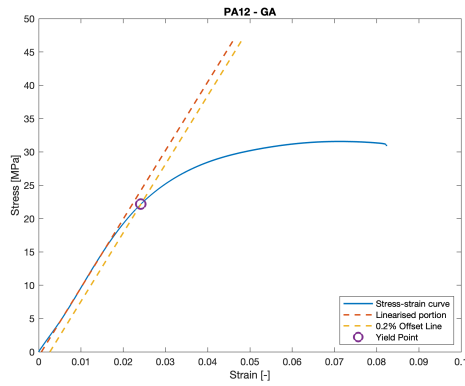
(b) Grilamid-G



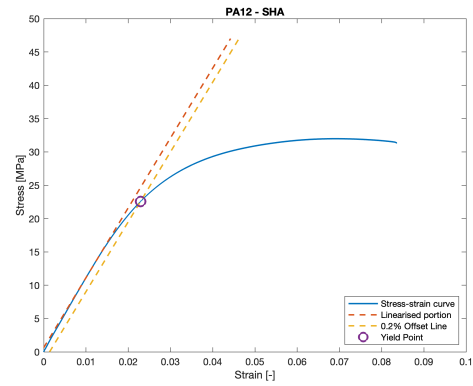
(c) Grilamid-SH



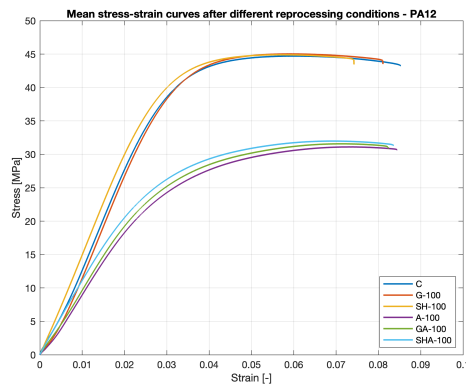
(d) Grilamid-A



(e) Grilamid-GA



(f) Grilamid-SHA



(g) All conditions

Figure C.1.: Stress-strain curves of Grilamid® LKN-5H for every condition.

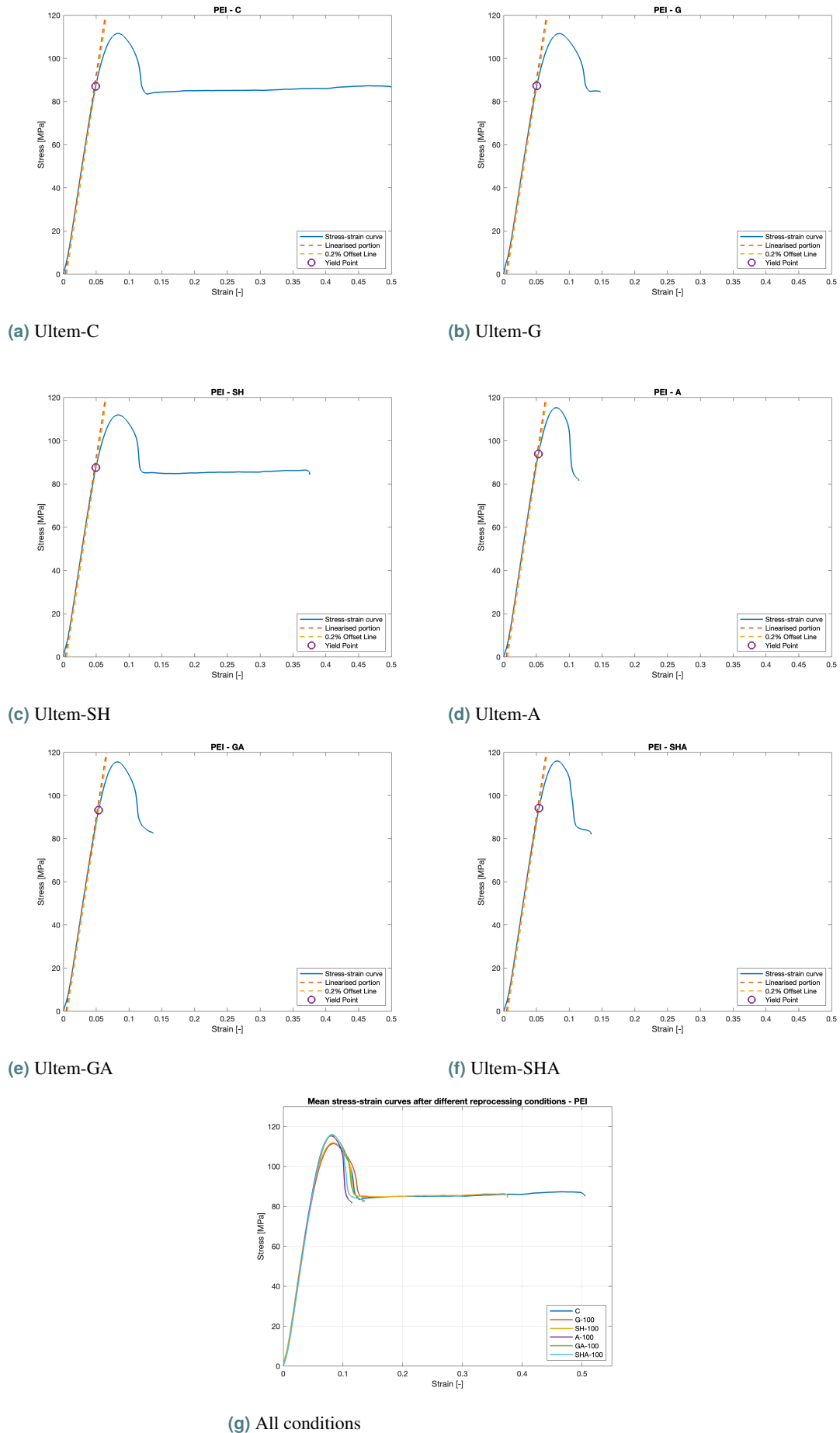
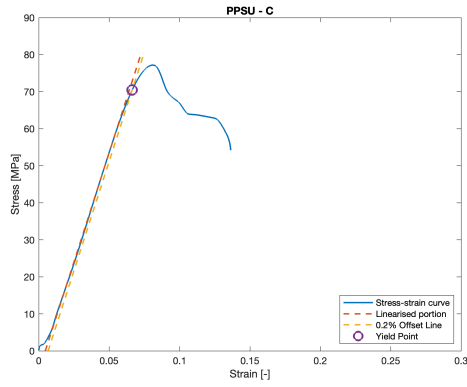
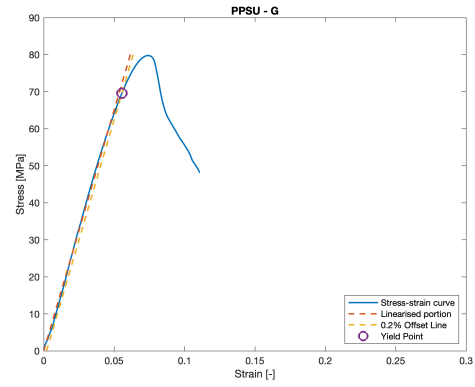


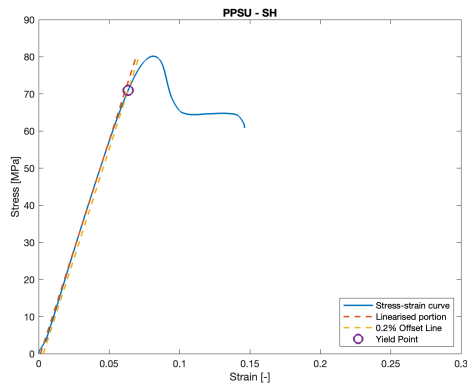
Figure C.2.: Stress-strain curves of Ultem™ HU1010 for every condition.



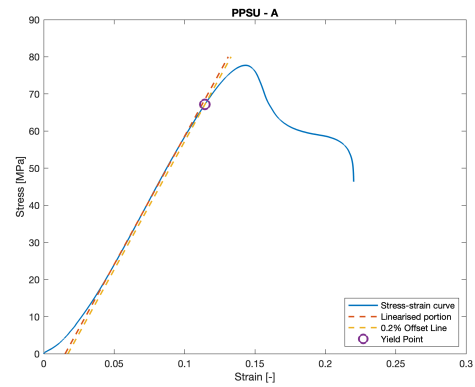
(a) Radel-C



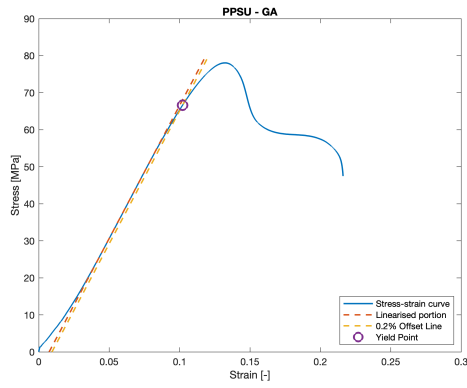
(b) Radel-G



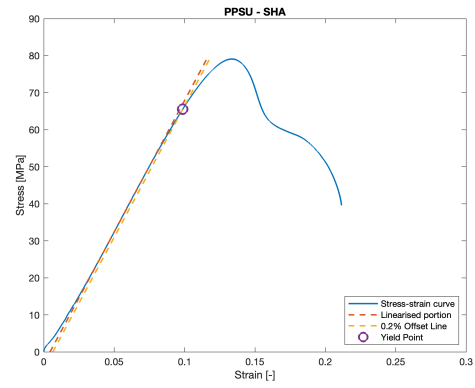
(c) Radel-SH



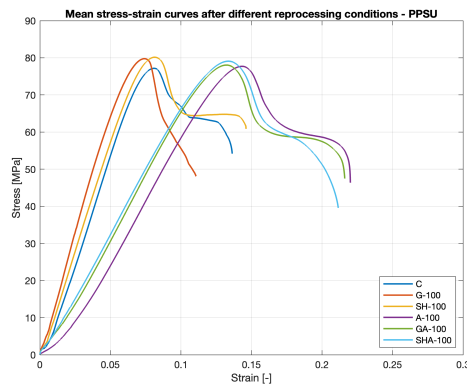
(d) Radel-A



(e) Radel-GA

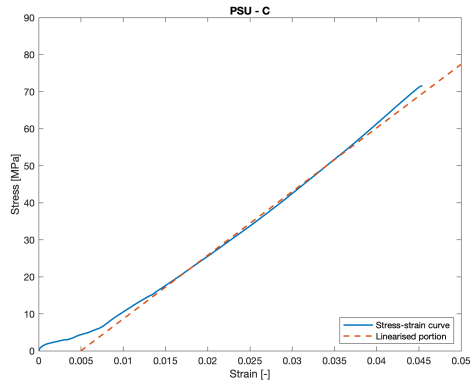


(f) Radel-SHA

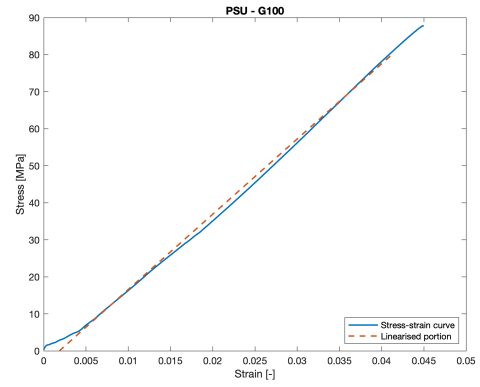


(g) All conditions

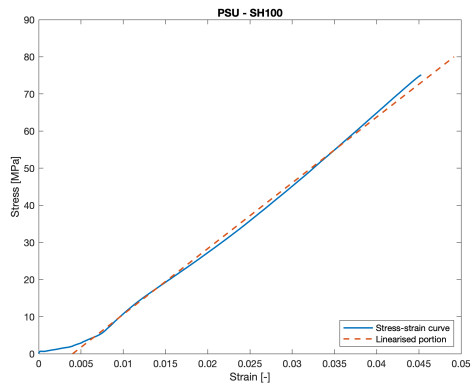
Figure C.3.: Stress-strain curves of Radel® R 5500 NT 15 for every condition.



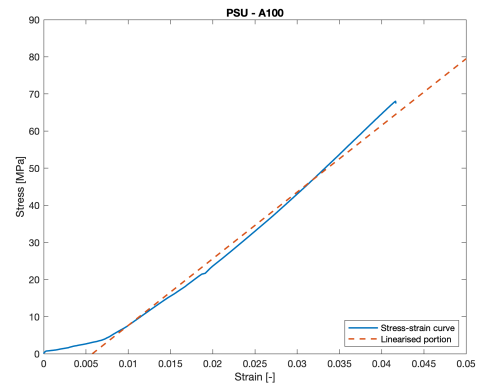
(a) Udel-C



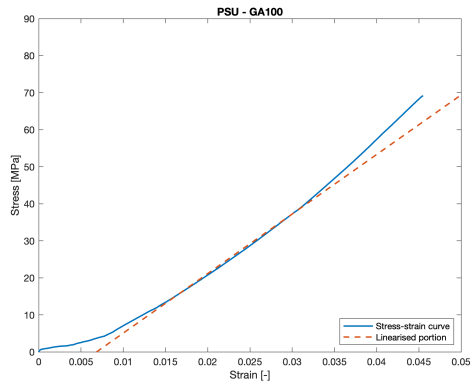
(b) Udel-G



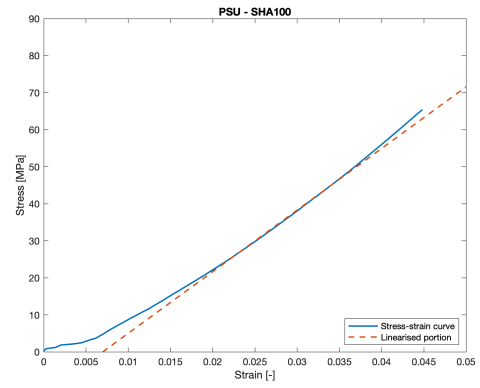
(c) Udel-SH



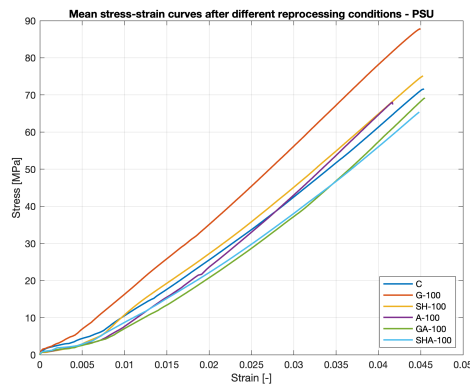
(d) Udel-A



(e) Udel-GA

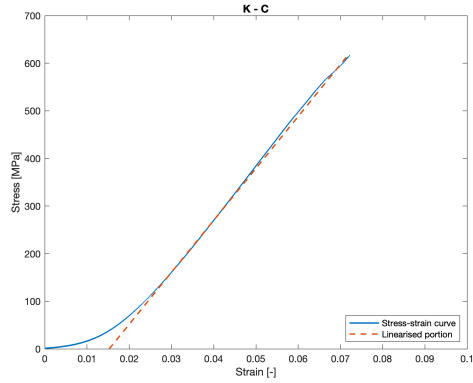


(f) Udel-SHA

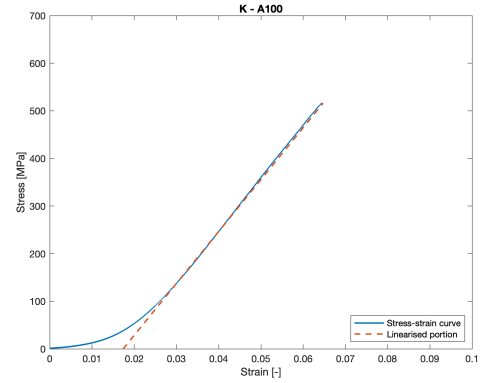


(g) All conditions

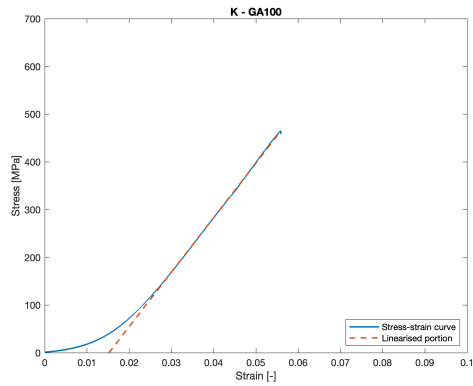
Figure C.4.: Stress-strain curves of Udel® GF120 NT for every condition.



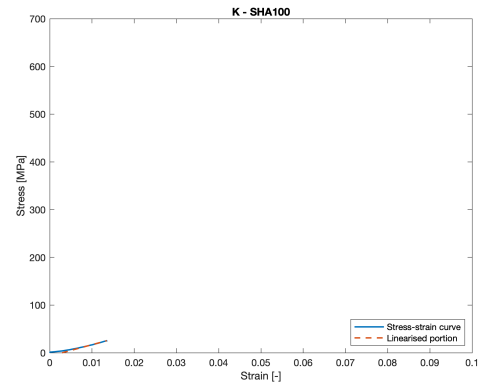
(a) Kevlar-C



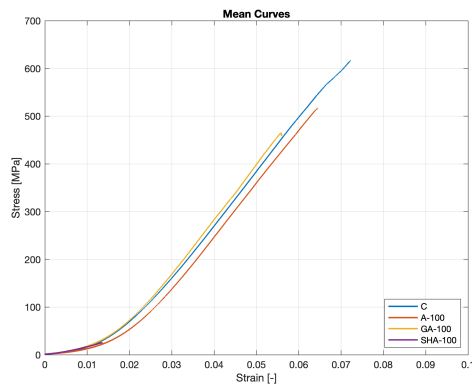
(b) Kevlar-A



(c) Kevlar-GA



(d) Kevlar-SHA



(e) All conditions

Figure C.5.: Stress-strain curves of Kevlar® 29 for every condition.

Mesh sensitivity tests

Mesh sensitivity tests were conducted for each of the three models to ensure accurate and reliable results. However, due to excessive deformations caused by the initial specified wire diameter of 0.5 mm in models 1 and 2, leading to analysis failure with errors, mesh sensitivity tests for these models were conducted using a wire diameter of 1 mm. All other geometric specifications remained consistent with those outlined in Section 2.2.1.

To simulate real-world loading conditions, the mesh sensitivity tests employed a worst-case loading scenario of 453 N, applied to only one of the two wires. Material properties were assigned accordingly, with the wire utilizing the material model derived from tensile testing of the control group of Kevlar® 29, while a composite material model was devised for the disc to emulate the elastoplastic behavior observed in the materials under consideration for the vela® VE: Grilamid® LKN-5H, Ultem™ HU1010, Radel® R 5500 NT 15, and Udel® GF120 NT.

The mesh sensitivity tests were conducted separately for the wire and the disc. The disc underwent analysis first, with local seeds assigned to the critical area around the disc's lumen where the wire is situated. Mesh element sizes were progressively increased further away from the lumen to optimize computational efficiency. The element size of the coarser mesh distant from the lumen was kept constant at 2, after observing that it did not influence the stress values, whilst the mesh size of the elements in proximity of the lumen was progressively decreased. The mesh element size in the wire was kept constant at 0.5.

After selecting the ideal elements size in the disc, mesh sensitivity tests were performed for the wires, progressively decreasing their elements' size, while keeping the number of elements in the disc constant. Tables D.1, D.2, D.3, D.4, D.5 and D.6 show the specific values of the elements' sizes and while graphs D.1, D.3 and D.5 show their converging trend.

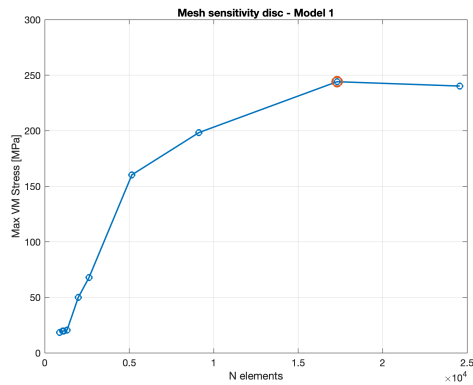
Visual representations of stress distributions observed with the selected mesh size in both the disc and the wire for each design are provided in Figures D.2, D.4 and D.6, offering insights into stress patterns and ensuring robustness in the analysis process.

Table D.1.: Mesh sensitivity test's results disc - Model 1

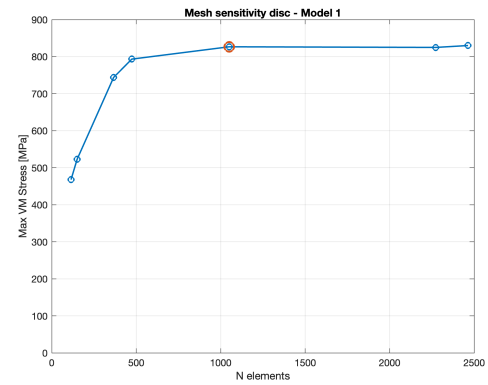
Approximate element size (disc, critical area)	N elements (disc)	Max VM stress (disc) [MPa]
2,00	876	18,417
1,50	1056	19,628
1,13	1132	19,668
0,84	1320	20,616
0,63	1982	49,885
0,47	2620	67,890
0,36	5157	160,299
0,27	9124	198,334
0,20	17300	244,108
0,18	24564	240,196

Table D.2.: Mesh sensitivity test's results wire - Model 1

Approximate global element size (wire)	N elements (wire)	Max VM stress (wire) [MPa]
1,50	114	467,939
1,13	150	522,857
0,47	366	743,881
0,36	474	793,377
0,27	1050	826,624
0,20	2272	824,885
0,18	2464,00	830,00

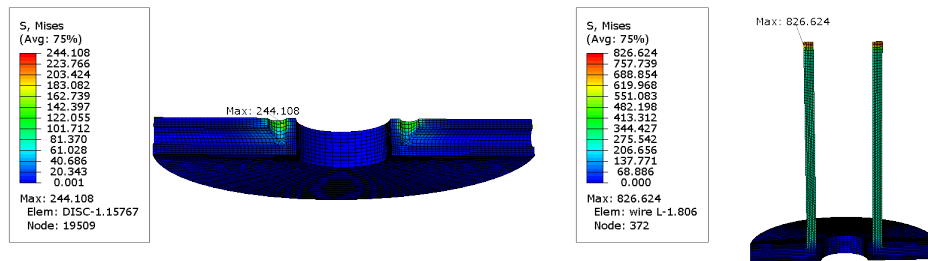


(a) Disc.



(b) Wire.

Figure D.1.: Mesh sensitivity convergency - Model 1



(a) Disc.

(b) Wire.

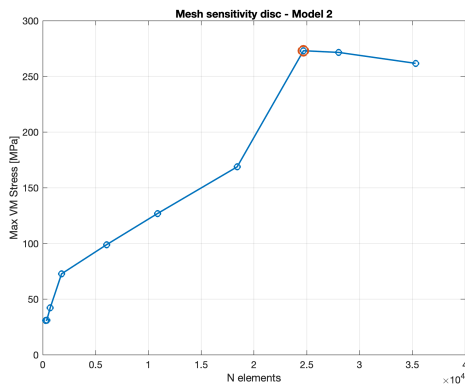
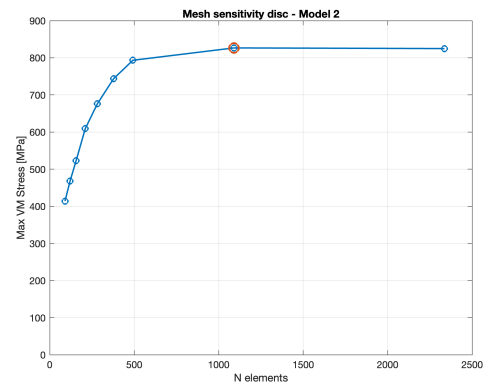
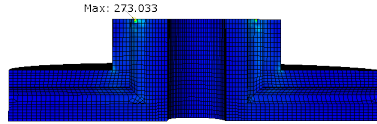
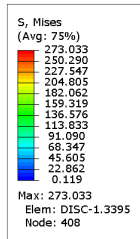
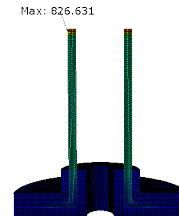
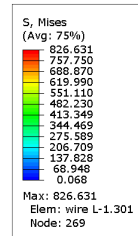
Figure D.2.: Stress distributions for ideal mesh size - Model 1

Table D.3.: Mesh sensitivity test's results disc - Model 2

Approximate element size (disc, crtial area)	N elements (disc)	Max VM stress (disc) [MPa]
2,00	280	30,867
1,50	382	31,112
1,13	700	42,096
0,84	1780	72,702
0,47	6044	98,874
0,35	10868	126,843
0,30	18410	168,772
0,27	24688	273,033
0,26	28028	271,507
0,23	35310	261,699

Table D.4.: Mesh sensitivity test's results wire - Model 2

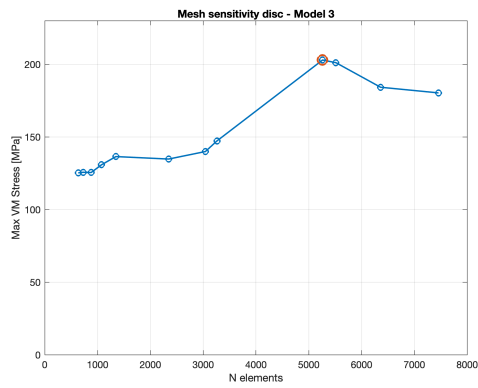
Approximate global element size (wire)	N elements (wire)	Max VM stress (wire) [MPa]
2,00	90,00	413,928
1,50	120	467,812
1,13	156	523,015
0,84	210	609,102
0,63	282	676,511
0,47	378	743,869
0,36	492	793,390
0,27	1090	826,631
0,20	2336	824,886

**(a)** Disc.**(b)** Wire.**Figure D.3.:** Mesh sensitivity convergency - Model 2**(a)** Disc.**(b)** Wire.**Figure D.4.:** Stress distributions for ideal mesh size - Model 2**Table D.5.:** Mesh sensitivity test's results disc - Model 3

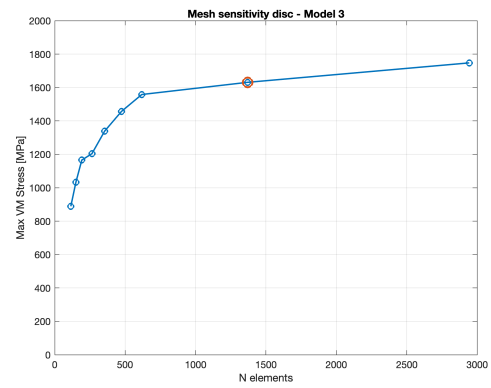
Approximate element size (disc, critical area)	N elements (disc)	Max VM stress (disc) [MPa]
2,00	634	125,23
1,50	726	125,624
1,13	879	125,486
0,84	1075	130,814
0,63	1347	136,455
0,47	2346	134,753
0,36	3042	139,915
0,33	3262	147,253
0,32	5261	202,905
0,30	5512	201,127
0,27	6361	184,176
0,23	7458	180,297

Table D.6.: Mesh sensitivity test's results wire - Model 3

Approximate global element size (wire)	N elements (wire)	Max VM stress (wire) [MPa]
2,00	114,00	888,970
1,50	150	1033,079
1,13	192	1165,702
0,84	264	1204,004
0,63	354	1338,679
0,47	474	1457,051
0,36	618	1558,144
0,27	1370	1631,070
0,20	2944	1747,382

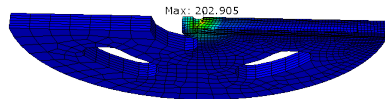
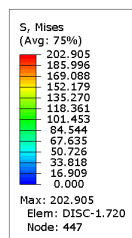


(a) Disc.

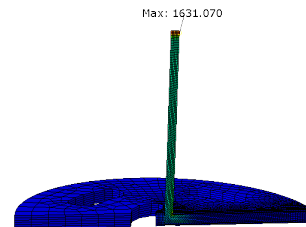
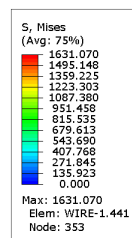


(b) Wire.

Figure D.5.: Mesh sensitivity convergency - Model 3



(a) Disc.



(b) Wire.

Figure D.6.: Stress distributions for ideal mesh size - Model 3

Results design optimisation

This Appendix includes the results of the design optimisation process described in Section 3.2.1. The results are summarised in Table 3.2, while here it is possible to visually observe the detailed stress distributions and deformations in the disc and the wire for all the different design variations.

E.1 Model 1

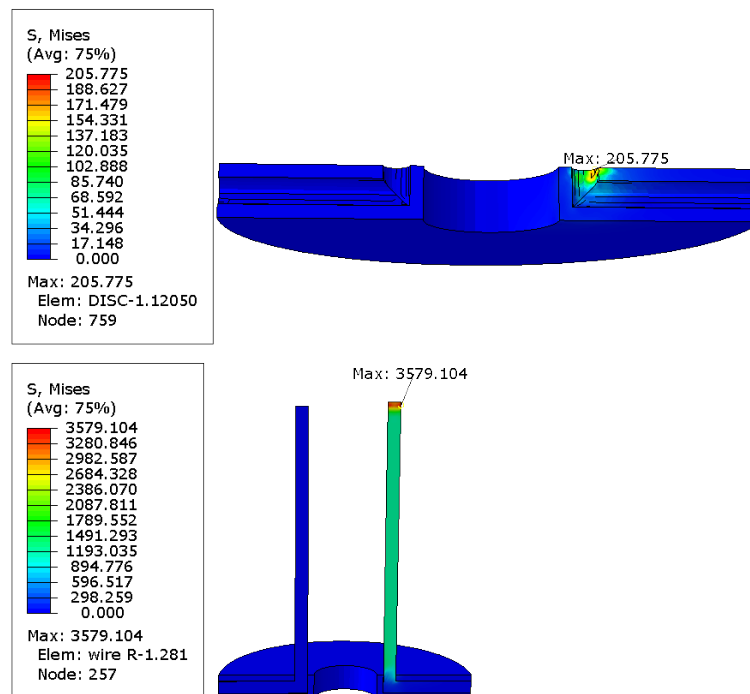


Figure E.1.: Von Mises stresses in Model 1 with 1 mm wire's diameter and 2 mm thick disc.

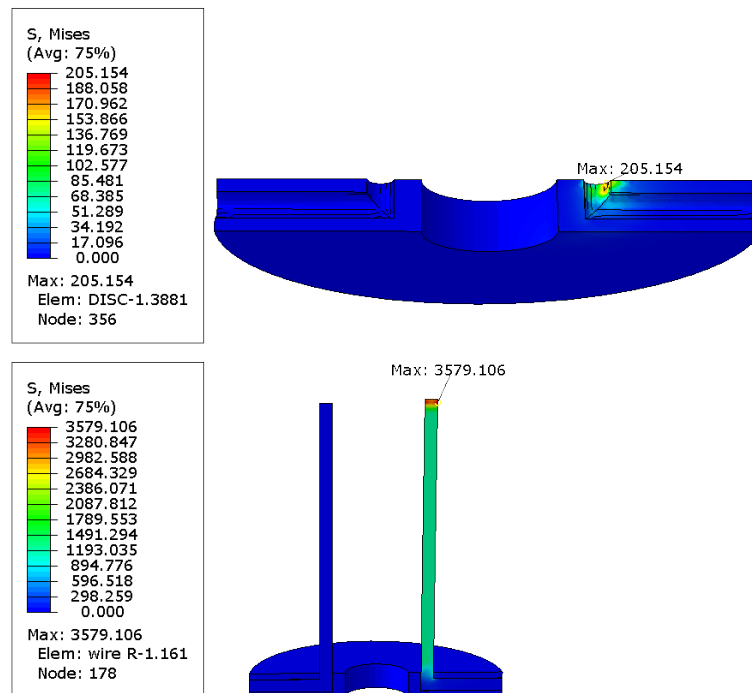


Figure E.2.: Von Mises stresses in Model 1 with 1 mm wire's diameter, 2 mm thick disc and wire located at 1 mm from the central lumen.

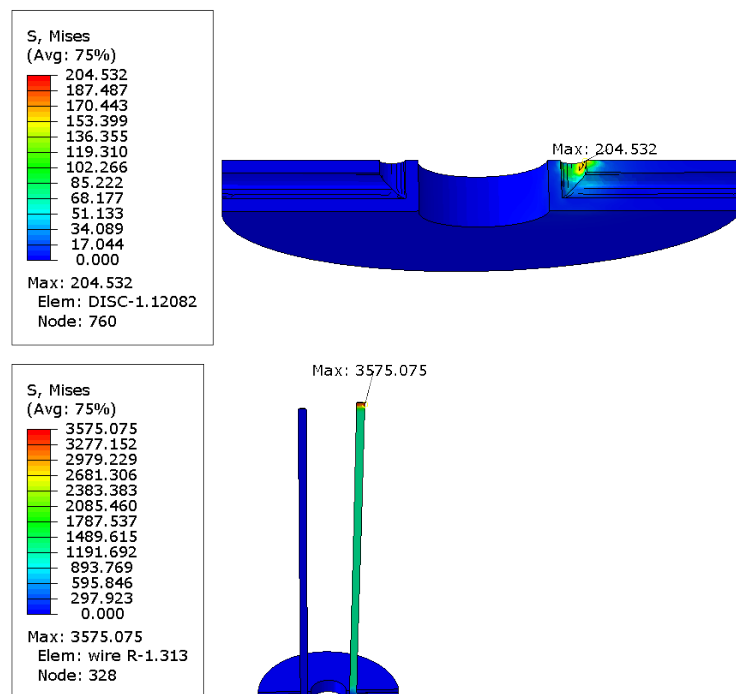


Figure E.3.: Von Mises stresses in Model 1 with 1 mm wire's diameter, 2 mm thick disc and 40 mm long wire.

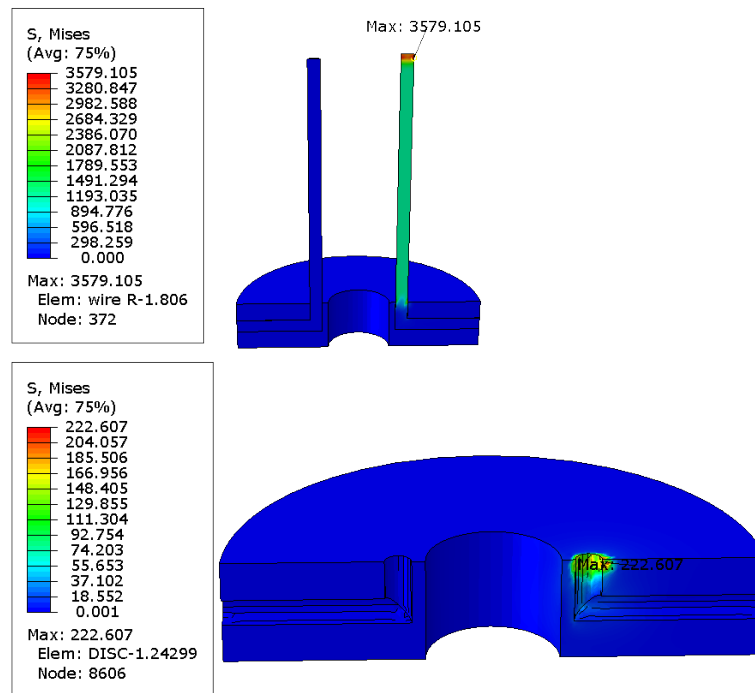


Figure E.4.: Von Mises stresses in Model 1 with 1 mm wire's diameter and 4 mm thick disc.

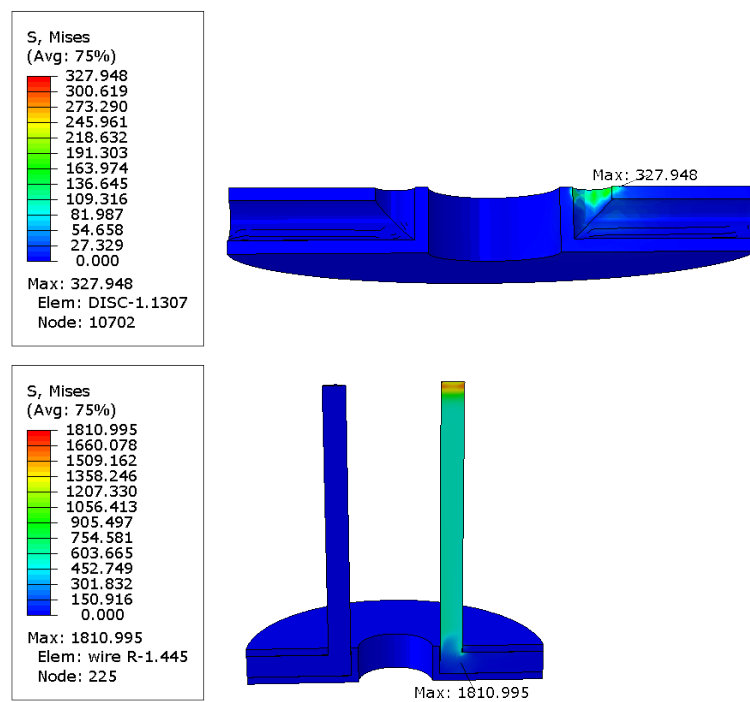


Figure E.5.: Von Mises stresses in Model 1 with 1.5 mm wire's diameter and 2.5 mm thick disc.

E.2 Model 2

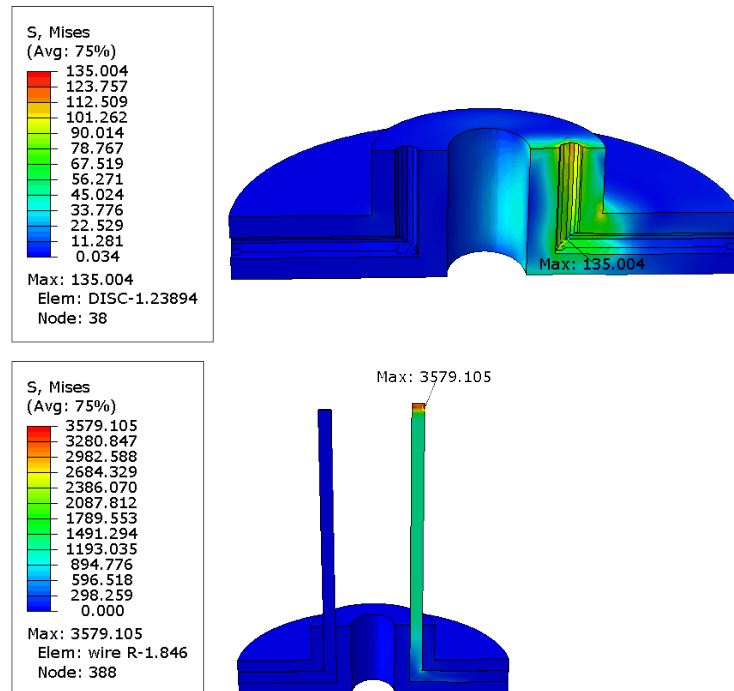


Figure E.6.: Von Mises stresses in Model 2 with 1.5 mm wire's diameter and 2.6 mm thick disc.

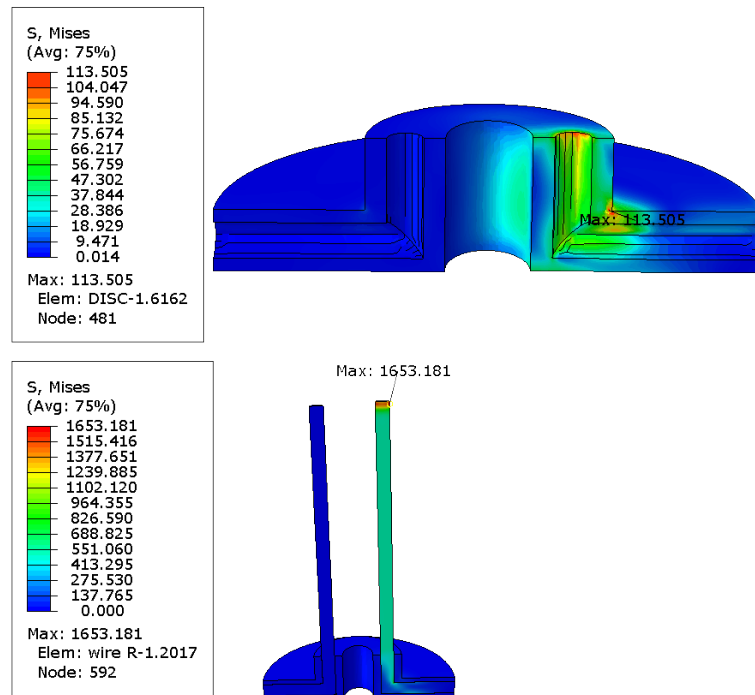


Figure E.7.: Von Mises stresses in Model 2 with 1.5 mm wire's diameter and 2.6 mm thick disc.

E.3 Model 3

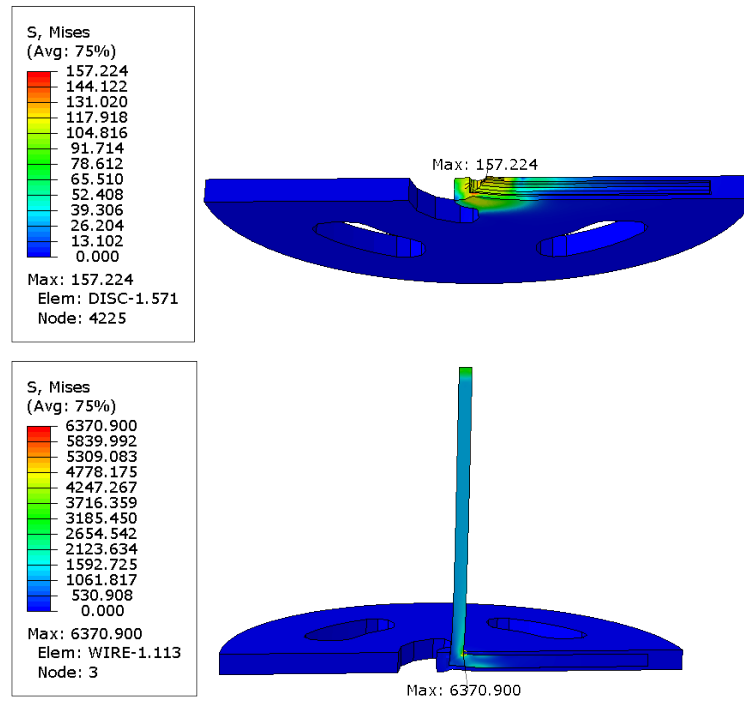


Figure E.8.: Von Mises stresses in Model 3 with 1 mm wire's diameter and 1.6 mm thick disc.

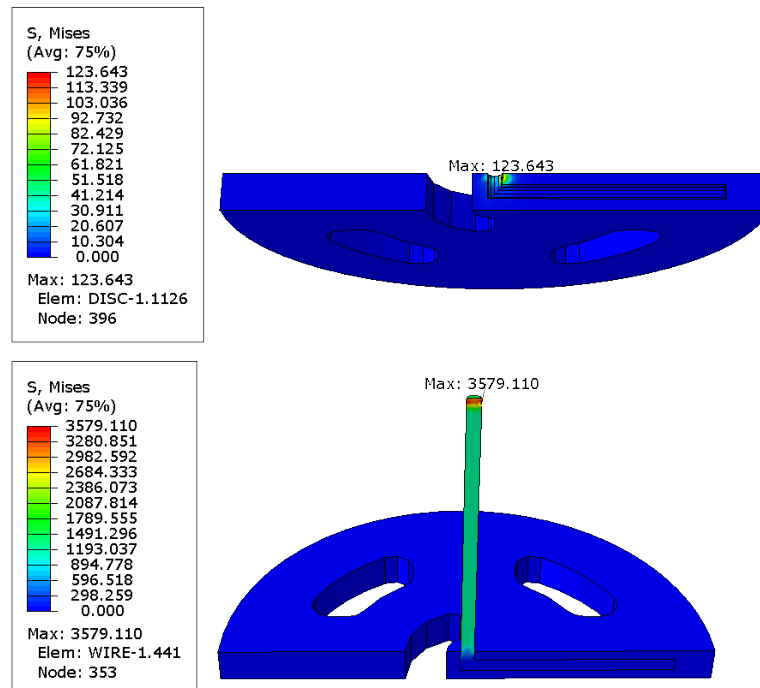


Figure E.9.: Von Mises stresses in Model 3 with 1 mm wire's diameter and 2.6 mm thick disc.

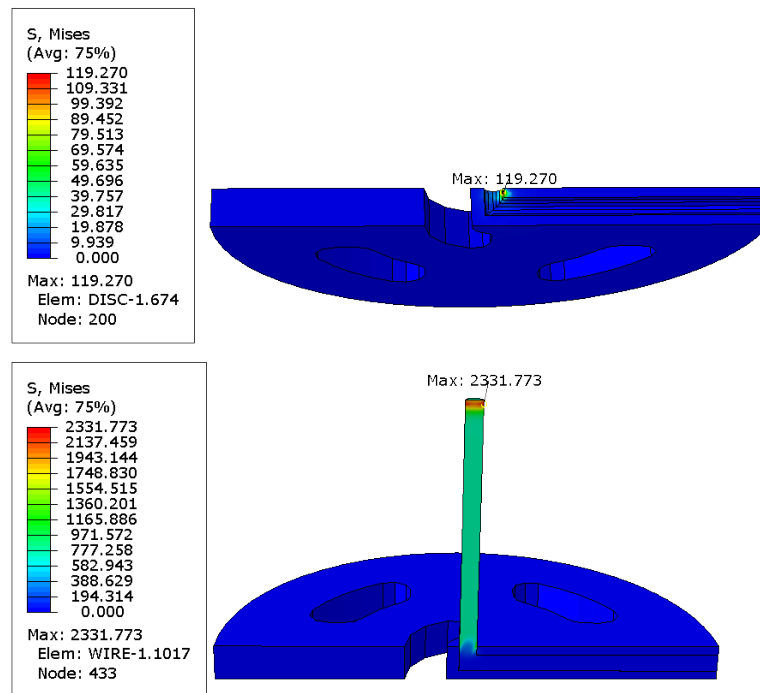


Figure E.10.: Von Mises stresses in Model 3 with 1.25 mm wire's diameter and 2.8 mm thick disc.

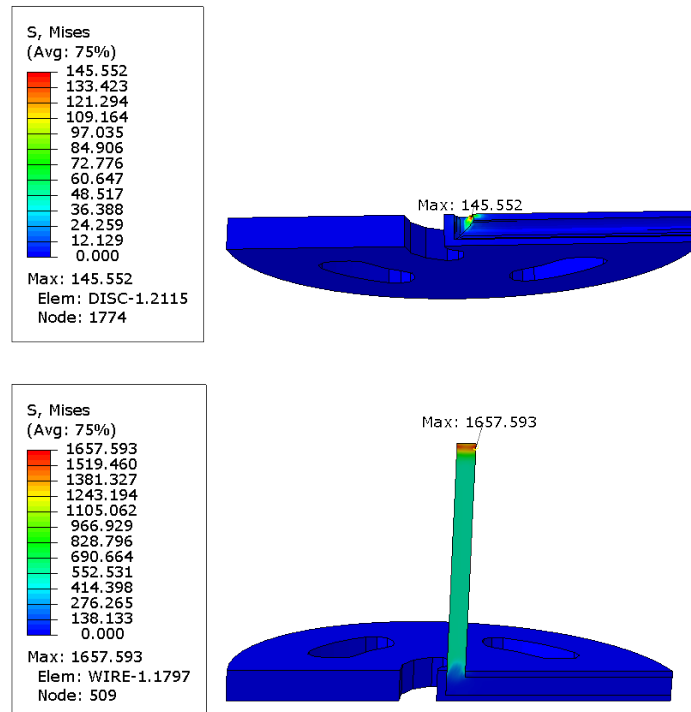


Figure E.11.: Von Mises stresses in Model 3 with 1.5 mm wire's diameter and 2.5 mm thick disc.

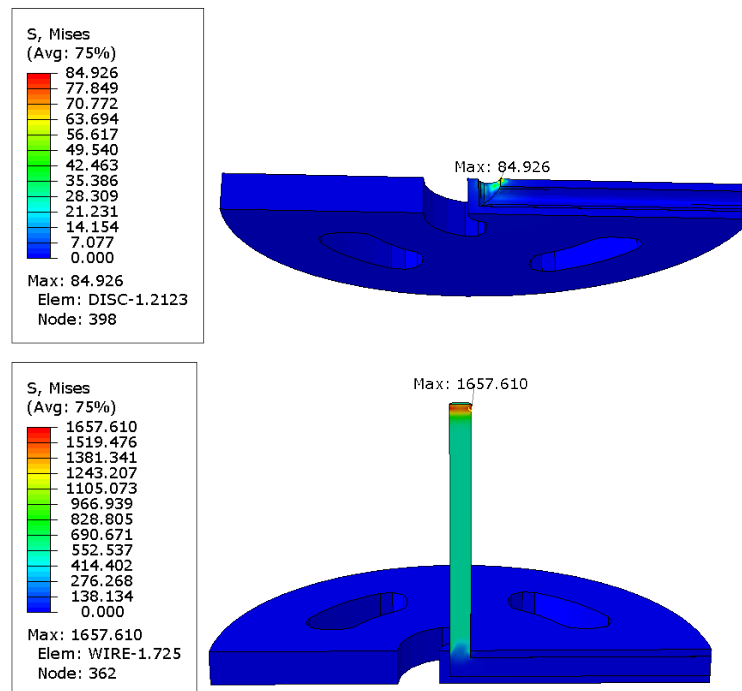


Figure E.12.: Von Mises stresses in Model 3 with 1.5 mm wire's diameter and 2.6 mm thick disc.

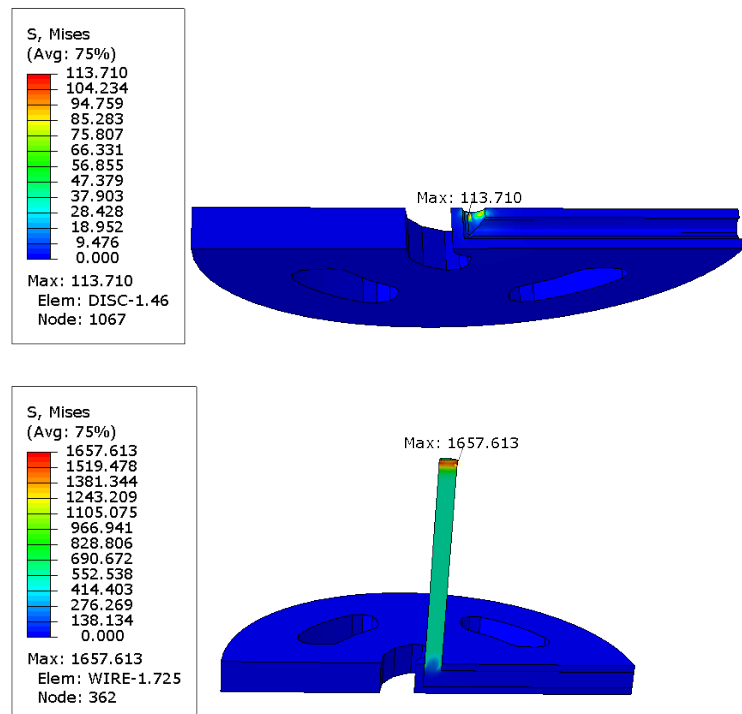


Figure E.13.: Von Mises stresses in Model 3 with 1.5 mm wire's diameter and 2.8 mm thick disc.

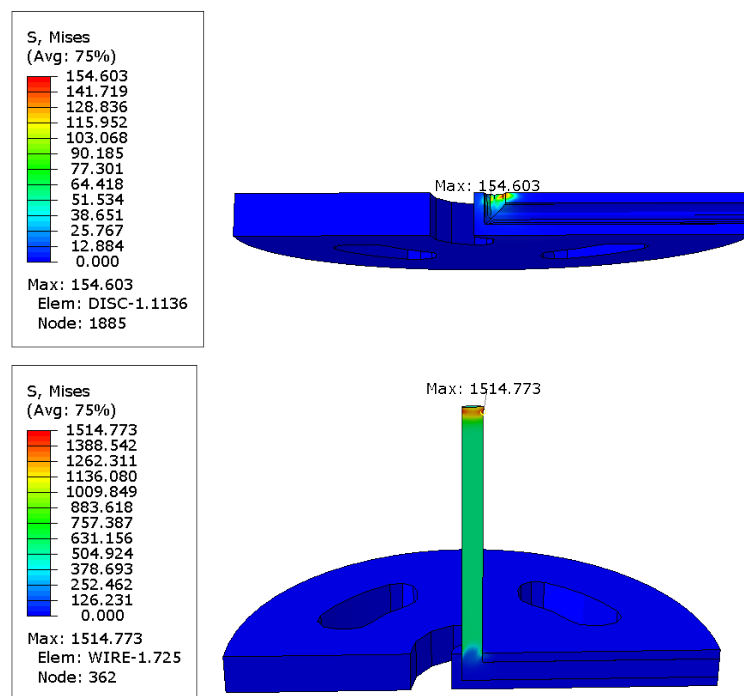


Figure E.14.: Von Mises stresses in Model 3 with 1.5 mm wire's diameter and 3 mm thick disc.

Results material selection

This Appendix includes the results of the material selection process described in Section 3.2.2. The results are summarised in Table 3.3, while here it is possible to visually observe the detailed stress distributions and deformations in the disc for the different material models.

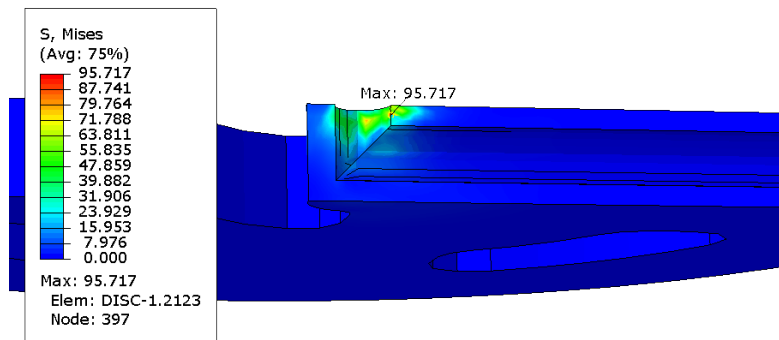


Figure F.1.: Von Mises stresses in the disc with un-reprocessed Grilamid.

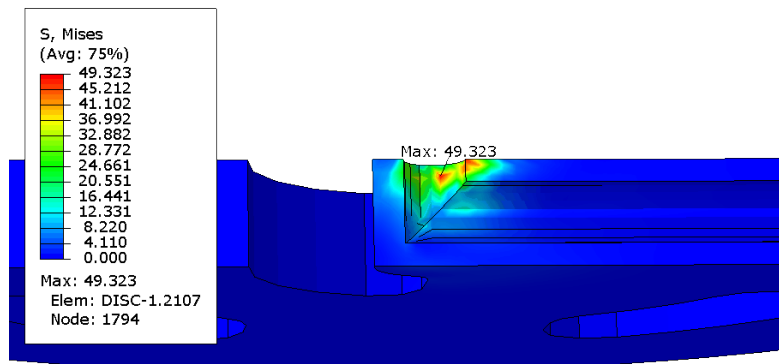


Figure F.2.: Von Mises stresses in the disc with Grilamid after 100 cycles of steam sterilisation at 134°C.

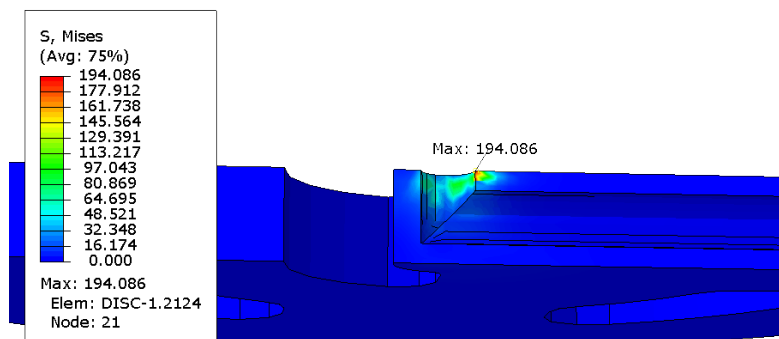


Figure F.3.: Von Mises stresses in the disc with un-reprocessed Ultem.

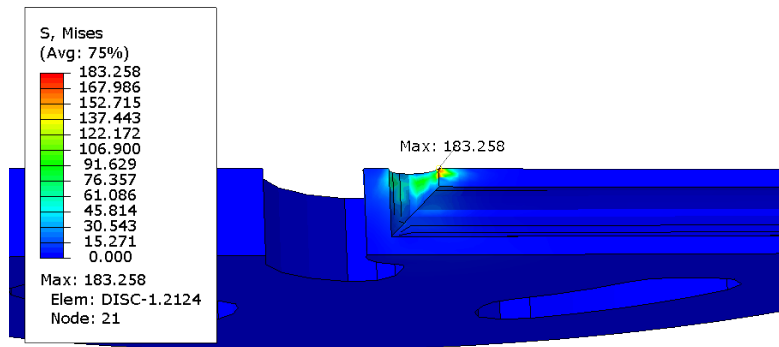


Figure F.4.: Von Mises stresses in the disc with Ultem after 100 cycles of disinfection in 0.5% sodium hypochlorite followed by 100 cycles of steam sterilisation at 134°C.

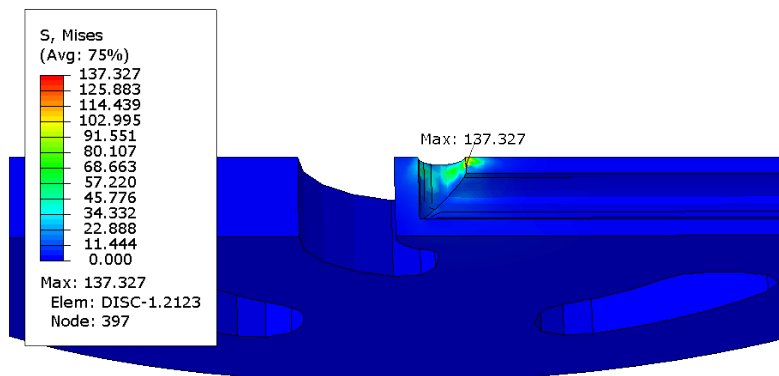


Figure F.5.: Von Mises stresses in the disc with un-reprocessed Radel.

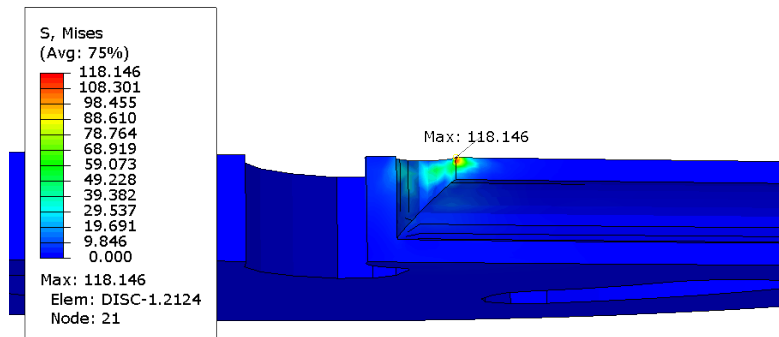


Figure F.6.: Von Mises stresses in the disc with Radel after 100 cycles of steam sterilisation at 134°C.

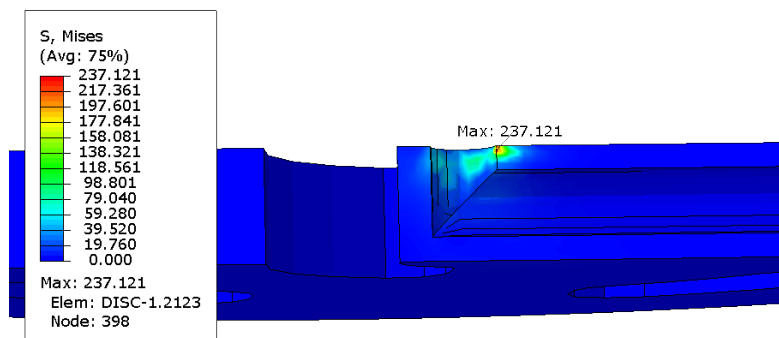


Figure F.7.: Von Mises stresses in the disc with un-reprocessed Udel.

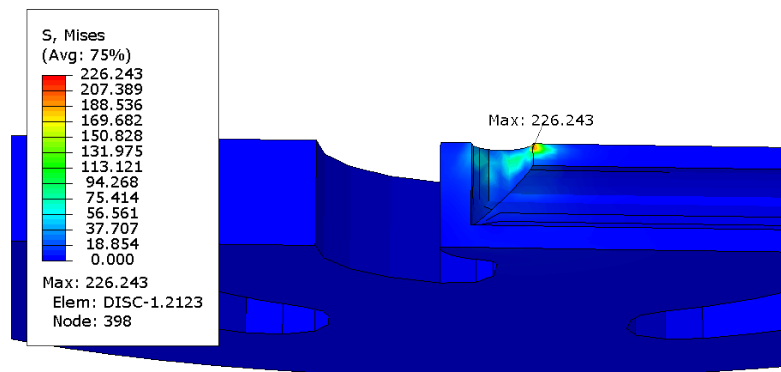


Figure F.8.: Von Mises stresses in the disc with Udel after 100 cycles of disinfection in 2% glutaraldehyde followed by 100 cycles of steam sterilisation at 134°C.



Literature review

This literature review has already been graded by the supervisors.

The following pages contain the literature review 'Effects of Reprocessing Methods on Materials for the Vela® Vacuum Extractor: a Systematic Literature Review'.

Effects of Reprocessing Methods on Materials for the Vela® Vacuum Extractor: a Systematic Literature Review

Gloria Micali

Technical University of Delft - MSc Biomedical Engineering

LAYCO® Medical Devices

Supervisors: Prof. dr. J. Dankelman & D. Drexhage

June 15, 2023

Abstract—The most commonly used vacuum extractors available on the market are disposable devices, which are less financially convenient and have a greater environmental impact than reusable options. For such reasons, LAYCO® is currently developing the vela® vacuum extractor (VE), a reusable device. All reusable medical devices need to be reprocessed between uses, which can include cleaning, disinfection and sterilisation. Particularly, the recommended reprocessing methods for the vela® VE are steam sterilisation and conventional disinfectants, such as glutaraldehyde, ethanol and sodium hypochlorite. However, reprocessing can negatively impact the material properties of the device. For this reason, LAYCO® is considering manufacturing the vela® with four optional materials which are all considered to have high thermal and chemical resistance: PPSU, PEEK, PA12 and silicone. However, they can be affected by reprocessing. The aim of this literature review is to investigate the effects of specific reprocessing methods on the materials selected for the vela® VE. **Methods:** PubMed and Scopus were searched with the defined key terms.

Results: A total of 1057 results were obtained, of which 61 articles were considered eligible to be included in this review. A large data-set was created from the retrieved results, reporting statistical significant or insignificant changes in the material property for the specific testing condition.

Conclusions: The main finding of this review is that there is a gap in the scientific literature regarding the effects of reprocessing on material properties of PA12, PPSU, PEEK and silicone. No or almost no results were obtained for PPSU and PA12, highlighting a relevant knowledge gap. For the other materials, a lack of results was observed for specific reprocessing methods and their effects on a particular material property. From the available literature autoclave seems to be the most damaging reprocessing method among the included ones. Commercial disinfecting solutions, glutaraldehyde and sodium hypochlorite resulted to be almost equivalently detrimental to the materials' properties.

Index Terms—reprocessing, autoclave, disinfectant, silicone, PVS, PDS, PEEK, vacuum extractor

I. INTRODUCTION

A. Vaginal operative delivery

Vaginal operative delivery indicates the employment of forceps or a vacuum extractor (VE) to aid vaginal delivery of the child and it is generally performed in case of prolonged or obstructed second-stage labour [1]. Vacuum assisted delivery

has a number of benefits over forceps delivery, such as reduced maternal discomfort, less genital trauma for the mother, less anaesthesia and shorter delivery times [2]. For these reasons, the proportion of vacuum assisted delivery compared to the use of forceps has been increasing [1]. A vacuum extraction consists of the application of the VE's suction cup to the scalp of the foetus (Figure 1). A partial vacuum inside the suction cup is achieved by operation of the VE's pump to secure adhesion of the device to the scalp. This allows the obstetrician to exert the necessary traction force on the device to guide the baby out of the birth canal.

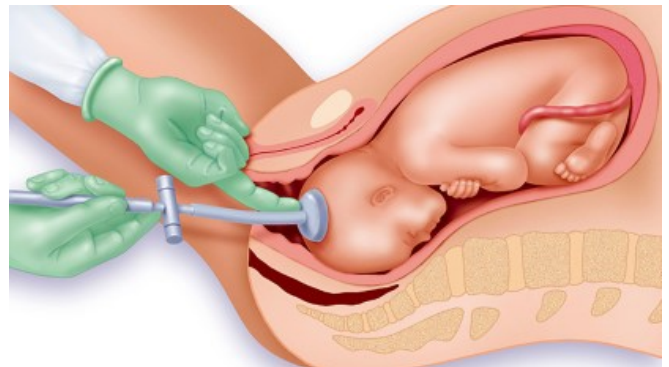


Figure 1: Vacuum extraction. Reproduced from [3].

B. A reusable vacuum extractor

The most widely used VE available on the market is the Kiwi OmniCup® (Clinical Innovations, Murray, UT), designed by Aldo Vacca in 2001 [4]. The Kiwi OmniCup® is a single-use device, which should get disposed of after its use. In the past decades, disposable devices have become the preferred option over the reusable alternatives thanks to their easiness-of-use and safety, since they do not need to be reprocessed and their quality can be guaranteed at every use. However, more recent research has proved them to be overall less financially convenient and have a greater environmental impact compared to reusables [5]–[8]. Additionally, continuous supply of single-use devices cannot be ensured in low resource settings, for

which having a reusable version of a medical device would be preferable over the disposable [9]. For these reasons, the latest trends in the medical devices' field have seen a shift back to reusable devices over single-use. A reusable VE, the vela® VE, is currently under development at LAYCO®.

C. Reprocessing methods

To ensure patients' safety, reusable medical devices must be reprocessed between uses. Reprocessing can include cleaning, disinfection and/or sterilisation. The vela® is a semi-critical device as it "comes in contact with non-intact skin or mucous membranes but ordinarily does not penetrate them" [10] and as such, it requires to undergo high level disinfection and sterilisation is strongly recommended [11]. According to the EU regulation 2017/745 (Medical Device Regulation, MDR), the manufacturer must provide instructions on the appropriate methods of reprocessing of the device [12]. After preliminary studies on the availability of cleaning, disinfection and sterilisation methods in low-resource settings, the most commonly used practices were identified. These include washing the device with warm water and soap for cleaning, the use of a washer disinfectant or immersion in CIDEX™ OPA (0.55 % ortho-phthalaldehyde), JIK (sodium hypochlorite, NaOCl or bleach), glutaraldehyde or alcohol (ethanol) for disinfection and the use of an autoclave for steam sterilisation. Therefore, these were selected as the recommended reprocessing methods for the vela® VE.

D. Effects of reprocessing on materials' properties

High level disinfection and sterilisation are processes that create harsh conditions, e.g. corrosive chemicals, elevated temperatures or pressures, to which microorganisms cannot survive. The unwanted consequences of such harsh conditions are the effects which they have on the material properties of the device itself.

The techniques which use high temperatures can be problematic for some classes of materials, such as polymers. Most polymers have low glass transition temperatures (T_g), which makes them extremely heat-sensitive [13]. This implies that they start degrading at temperatures reached in sterilisation methods such as steam sterilisation. They commonly start distorting, melting, softening or expanding due to chain scission or other phenomena, which compromise their structural integrity and physical properties [13].

Another sterilising agent which importantly affects material properties is moisture, which is used in steam sterilisation. Moisture can damage polymers and other materials causing oxidation [14].

Sterilisation carried out through the use of chemical agents can cause damage to the chemical properties of the materials. These sterilising agents exert their antimicrobial abilities by chemically reacting with the microorganisms' cells. However, they can also react with the chemical structure of the material being sterilised, resulting in permanent damage. Moreover, there might be toxic residues which would be hazardous upon clinical application of the device.

Degradation of the materials can lead to changes in their chemical structure and/or physical properties, resulting in the loss of mechanical properties and surface quality, which could compromise the device's functionality and safety.

For instance, reprocessing can affect the ultimate tensile strength of the material. Since a VE must be able to withstand traction forces as high as 452 N [15], a decrease in the ultimate tensile strength of the materials composing it could result in a hazardous situation for the patient. The elastic properties of a material are also essential for maintaining its functionality and reprocessing methods might significantly affect them. Furthermore, disinfection and/or sterilisation can hinder the dimensional stability of the materials, leading to deformations. These could result in faulty connections between the components of the device, which are crucial for its integrity and performance. Additionally, reprocessing methods can also affect the materials' colour, which does not directly influence its functionality but it is nonetheless a relevant indicator to the medical professionals and patients. Usage of colours can be essential for the usability of the device, especially since the vela® VE uses colour indicators to signal pressure values. Furthermore, it is preferable that the tubing connecting the suction cup to the pump remains transparent throughout its service life to allow for visual inspection of its hollow cavity during reprocessing. Additionally, the patient's perception of the device as "dirty" could induce a feeling of mistrust and distress, which is to be avoided in such a critical situation as delivery.

Overall, damage to the materials composing the device can eventually result in its failure, determining the end of its service life and possibly compromise patient safety.

E. Material selection

Therefore, the material selection process is extremely important for a reusable device. LAYCO® performed a study to evaluate possible candidates for the material of the vela® VE. The requirements included heat resistance and steam resistance to ensure autoclave suitability, transparency to allow visual inspection of the hollow components for cleanability, and suitable mechanical properties. Four materials were identified as possible candidates, which are polyphenylsulfone (PPSU), polyether-ether-ketone (PEEK) or polyamide 12 (PA12) for the rigid components of the device and silicone for the flexible ones. These materials all have a high temperature and chemical resistance. However, the reprocessing methods still have a certain level of impact on the materials' properties.

Therefore, the purpose of this review is to investigate the effects of specific reprocessing methods on the materials selected for the vela® vacuum extractor. This will provide better understanding of the influence of reprocessing on the device's overall lifetime.

This review was carried out to gain a better understanding of the effects of steam sterilisation, multiple disinfectants and cleaning methods on PA12, PPSU, PEEK and silicone, by identifying relevant literature.

II. METHODS

A. Data source and search strategy

To investigate the effects of the specific reprocessing methods on the materials selected for the vela® vacuum extractor, a systematic literature review was conducted using the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) method [16]. Two databases, Scopus and PubMed, were searched to identify potentially relevant studies.

Terms and synonyms were identified to obtain relevant results for the research question "What are the effects of specific reprocessing methods on the materials selected for the vela® vacuum extractor?". Firstly, a list of synonyms of the word "effect" was selected. Secondly, terms referring to the specific reprocessing methods, i.e. washer disinfectant, bleach, CIDEX/OPA, glutaraldehyde and autoclaving, and their alternative names were included. After that, the application for these methods was specified by including the words cleaning, disinfection and sterilisation, since the same methods can also have uses other than reprocessing. Finally, the materials on which this literature review was conducted were specified. Boolean operators "AND" and "OR" were used to create a search string. Its different components, grouped by topic, can be seen in Table 1. Scopus and PubMed were searched with these terms including all the results until April 17, 2023. The results obtained from the research were exported in EndNote and the duplicates were removed by the automated EndNote tool.

B. Eligibility criteria

The imported articles were screened by reading title and abstract. They were considered eligible to be included in the systematic review if they met certain criteria:

- 1) testing of one of the searched materials: silicone, PEEK, PA12 or PPSU;
- 2) testing the material for conventional reprocessing methods;
- 3) relevant mechanical or physical properties are assessed;
- 4) the effect of the sterilisation/disinfection method is assessed separately;
- 5) statistical significance when compared to control group is reported.

Additionally, the studies which satisfied one of the following exclusion criteria were excluded from the review:

- 1) duplicates which were not detected by EndNote;
- 2) written in a language other than English;
- 3) studies with no control group;
- 4) testing of materials other than the searched ones (or an experimental version of the searched materials, i.e. with fillers, composites, ...);
- 5) related to assessing the effectiveness of the disinfection/sterilisation method;
- 6) related to assessing the biocompatibility of the disinfection/sterilisation method;

- 7) testing conditions out of the scope of the review, e.g. testing the effect of window cleaners or acidic rain or food staining;
- 8) testing the effect of reprocessing methods which are specific for applications that are not relevant to this literature review, e.g. disinfectant for dental impressions;
- 9) measured parameters out of the scope of the review, e.g. marginal stability, drug content after sterilisation, bond strength with specific other materials.

The articles remaining after the screening were sought for retrieval and the available full-texts were screened for eligibility. If they satisfied all the inclusion requirements and did not meet any of the exclusion requirements they were included in the literature review.

C. Data extraction

Articles were imported in Microsoft Excel and data from each of them was manually retrieved. The information extracted from the studies includes:

- Material tested, including its application if considered relevant;
- Reprocessing method, with the concentration of disinfectant or temperature, and method of application of the disinfectant if applicable (immersion or spray);
- Duration of exposure and/or number of cycles;
- Mechanical or physical properties evaluated.

It was found that 54% of the articles did not clearly report the initial values and the post-processing values of the tested parameters. Mostly, they either did not report the initial values or only focused on the statistical tests' results.

The raw numerical values of the post-processing parameters, without comparison with the initial values, would not give a significant indication of the change in the material properties. Moreover, the aim of this literature review was to search the effects of various reprocessing methods on multiple material properties of four different materials. Therefore, the obtained results were very heterogeneous, focusing on numerous combinations of methods and materials. This entails that the raw numerical data would be impossible to compare with each other, since the results were recorded for multiple materials, reprocessing methods and measured material properties.

For this reason, this literature review reports the results extracted from the articles in terms of statistically significant (S) or statistically insignificant (NS) difference when compared to the control group. When available, the relative change was also recorded.

Some articles investigated multiple conditions: different reprocessing methods on various materials, with different different exposure times and/or concentration of disinfectant/temperature of autoclave. In these cases, all the results obtained in the study were reported in the data extraction table. Therefore, there are multiple results from the same article.

D. Data interpretation and analysis

A graph was created for each material comparing the number of results reporting S or NS changes in any of the

Table 1: Search terms used in PubMed and Scopus.

Research question: "What are the effects of specific reprocessing methods on the materials composing the vela® vacuum extractor?"			
Effects	Specific	Reprocessing Methods	Materials
(effect OR consequence OR damage OR response OR repercussion OR deteriorat* OR ruin OR degrad* OR degenerat* OR decay OR worsening OR change OR alter* OR modif*)	("washer disinfectant" OR "MediClean forte" OR Mediklar OR "Endo Sept GA" OR jik OR bleach OR "sodium hypochlorite" OR cidex OR opa OR orthophthalaldehyde OR glutaraldehyde OR alcohol OR presept OR "disinfect* solution" OR "disinfect* agent*" OR "disinfect* method" OR disinfectant* OR autoclav* OR "steam sterili*" OR "clean* solution" OR "clean* agent*" OR "clean* method" OR)	(reproces* OR clean* OR disinfect* OR sterili*)	(PPSU OR polyphenylsulfone OR grilamid OR PA12 OR "PA 12" OR "polyamide 12" OR silicone OR peek OR polyetheretherketone)

tested material properties for each reprocessing method.

Another graph was created for each material comparing the number of results reporting S or NS changes in each of the tested material properties for any of the included reprocessing method.

Additionally, two graphs were created with the data from all the materials together. One considering the number of results reporting S or NS changes in any of the tested material properties for each reprocessing method and another one with the number of results reporting S or NS changes in each of the tested material properties for any of the researched reprocessing method.

Lastly, a figure shows the amount of results obtained for the specific combination of reprocessing method and tested material, for all the materials altogether.

III. RESULTS

A. Search results

On 17th April 2023, the databases Scopus and PubMed were searched with the previously discussed key terms. 470 results were obtained from PubMed and 587 from Scopus, resulting in a total of 1057 results. Of these, 200 were duplicates, which were automatically removed by the tool offered on EndNote. After reading titles and abstracts of the articles, a selection was carried out by applying the eligibility criteria described in the methods. It was found that 713 articles did not meet the eligibility criteria and were therefore excluded. The remaining 144 were sought for retrieval, however, 35 did not have a full text available. Thus, 109 articles were read to assess eligibility. Of these, 60 were excluded because they did not meet the eligibility criteria. Two of the articles which were considered eligible are systematic literature reviews and the studies mentioned in these two articles were included as well, if they were not already, which consists of 12 additional articles. In the end, 61 articles were included in this literature review. The PRISMA flowchart summarising the process followed can be seen in Figure 2.

B. Reprocessing methods

From the results obtained from the literature search, 8 different reprocessing methods were considered eligible for

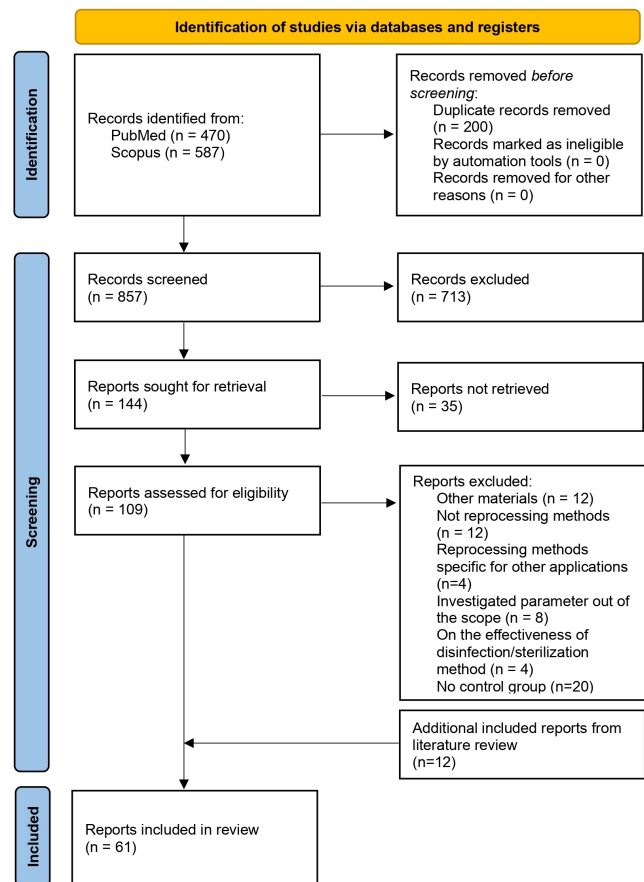


Figure 2: PRISMA flowchart.

this review. As a sterilisation method, only autoclaving was included, which was investigated in 20 of the included studies. A majority of them ran the autoclave at 134°C, only a few at 121°C. Sodium hypochlorite (NaOCl), commonly known as bleach, was the most investigated method, with 54 results. The concentrations of NaOCl in aqueous solutions differed among studies, ranging from 0.5% w/v to 10% w/v. Disinfection with 2% glutaraldehyde was the reprocessing method in 30

results. Aqueous solutions with 3% hydrogen peroxide (H_2O_2) were the subject of study in only 6 articles. Multiple studies ($n=19$), investigated the effects of disinfectant solutions from specific brands and were therefore categorised as “commercial disinfecting solutions” in this review. There was only one result for isopropyl alcohol and one for ethanol. Finally, cleaning with neutral soap, which was studied in 3 articles, was included as a reprocessing method.

Figure 3 shows the number of articles which reported statistically significant (S) or insignificant (NS) changes in any of the material properties of any of the searched materials, caused by each specific reprocessing method.

Tables 2-6 report all the extracted data. There is a separate table for each material included in this review. They show which articles reported S or NS changes for the analysed material property, for the specific reprocessing method. When available, the relative change is also recorded in brackets. For the results where the relative change was not available, the reason for this was indicated with a symbol in the cell of the result. In the table’s legend, the meaning of each symbol is indicated, e.g. the article did not report the initial values, or they did not report raw numeric data at all, or other.

In Tables 2-6 it is also possible to see the exact concentrations of the disinfecting solutions and the temperature for autoclaving, complete with all information regarding the methods of reprocessing, such as if the disinfectant was applied by immersion or spraying.

Additionally, they report the time of exposure to the reprocessing method, including the overall amount of minutes that the material was exposed for, and the details of the methods of exposure. Some studies investigated the effects of reprocessing over a short period of time, such as 10 to 60 minutes, whilst others conducted their research over an extended period of time (up to 6 months in Pahuja et al. [17]), exposing the material to the reprocessing method every day for a few minutes a day.

Furthermore, Figure 7 graphically shows how many results were recorded per condition, i.e. the specific combination of material properties investigated after a certain reprocessing method.

C. Material properties

The articles included in this review investigated the effects of reprocessing on the materials by testing different material properties, according to the subject of interest of each study. Figure 4 shows the number of articles reporting statistically significant or insignificant changes in each of the material properties caused by any reprocessing method in any of the included materials.

The properties tested in the articles included in this review are:

- Dimensional stability: it is the most frequently investigated property, with 88 results for it. It was found to be mostly analysed for PVS and PDS used as dental impression materials. The dimensions are measured as

the distances between specific reference points of the reprocessed material compared to the control.

- Colour stability: it measures the ability of the material to maintain its original pigment after reprocessing. It is generally calculated in the CIE $L^*a^*b^*$ system which gives the colour difference between the original colour value and the one after testing (ΔE). It is most often studied for silicone elastomers used for maxillofacial prostheses or dental liners.
- Surface quality: it was generally assessed by inspection with a scanning electron microscope (SEM) or a stereomicroscope.
- Roughness: it was expressed by measuring the contact angles of the material’s surface. It is usually measured with a stereomicroscope and a goniometer or a profilometer.
- Hardness: it was measured either by nanoindentation and nanoscratch or with a hardness tester.
- Elastic modulus: it is an important indicator of the mechanical properties of the material. In this review, it is expressed in mega Pascals (MPa).
- Ultimate tensile strength: it is measured with tensile testing and it indicates the maximum load that a material can withstand before its failure. It was only studied in one article for PDS [18].
- Elongation at break: it is expressed as a percentage of the original dimensions, indicating how much a material can be elongated before it breaks. It was only studied in one article for PDS [18].
- Viscoelastic parameter: it is a dimensionless parameter that represents the exponential part of the stress-strain curve. It is only measured in one study for PDS [18].
- Flexural strength: it is the value of stress at failure in bending. It is generally equal or slightly larger than the ultimate tensile strength.
- Wettability: it indicates the ability of a liquid to maintain contact with a solid surface. It is quantified by the contact angle’s value, which is usually measured with a stereomicroscope and a goniometer or a profilometer.
- Tensile strength: it was measured in one study for silicone, where the authors stretched the material samples to 200% of their original length and recorded the value of the tensile strength [19].
- Compression force: it represents the capacity of the material to withstand loads that tend to reduce its size. It was evaluated for PEEK in one study where the samples were subjected to $1 \text{ kgf} \pm 20\%$ of compression.

D. Materials

The materials searched in this review are PA12, PEEK, PPSU and silicone. Among the articles considered eligible, none of them studied PPSU and only one was about PA12. Ten articles studied the effects of different reprocessing methods on material properties of PEEK. Silicone was the most researched material, including: 35 results on polyvinyl siloxane (PVS), an addition silicone, 18 results for polydimethylsiloxane (PDS), a condensation silicone, and 8 that did not specify which specific

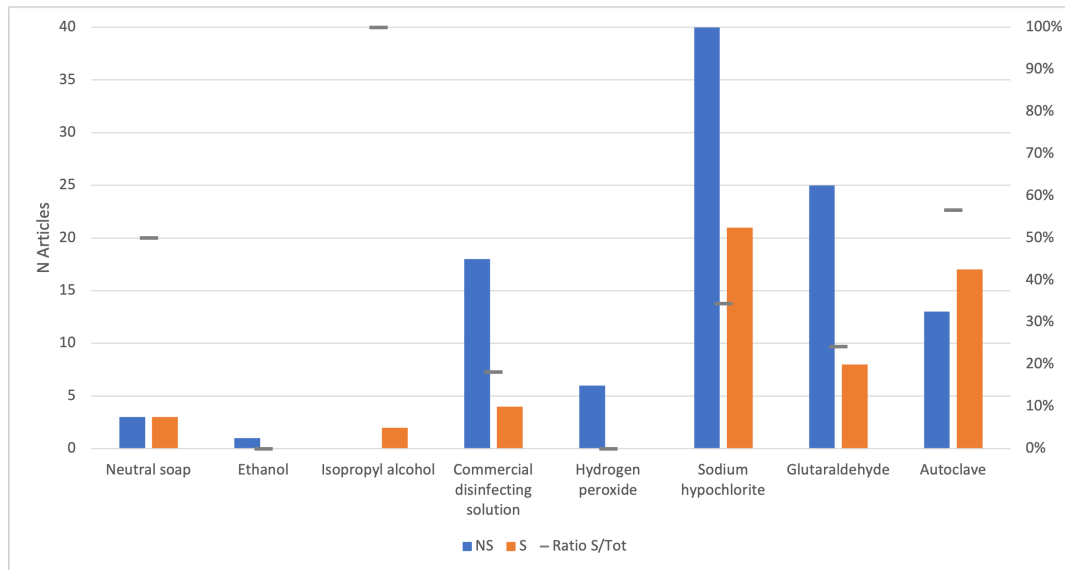


Figure 3: Number of articles reporting S or NS changes caused by each reprocessing method in any material properties of all materials.

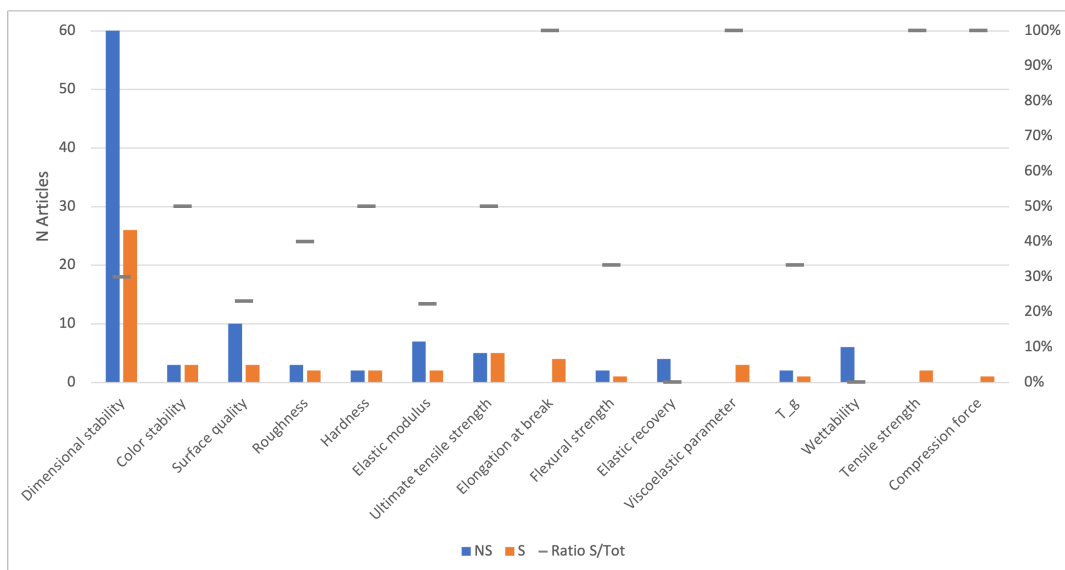


Figure 4: Number of articles reporting S or NS changes caused by any reprocessing method in each material properties of all materials.

type of silicone and were categorised as generic “silicone”, . Tables 2-6 show all the results for each material. They report whether the post-processing value of the analysed material property is statistically significant (S) or non-significant (NS) different. When the information was available in the articles, the accurate relative change was also reported in the tables. Additionally, the details of the processing conditions, such as the method, concentration of disinfectant, temperature of the autoclave, application and time of exposure can be observed. From this data, graphs were created for each material to show the number of results reporting S and NS changes, which can

be seen in Figures 3-6.

Figure 5 focuses on the effect of each reprocessing method and Figure 6 focuses on the material properties affected by reprocessing. Figure 3 shows the changes caused by every reprocessing method in each material, while Figure 4 focuses on the changes in material properties of every material. All graphs include the ratio of articles reporting statistically significant changes over all the articles that investigated it.

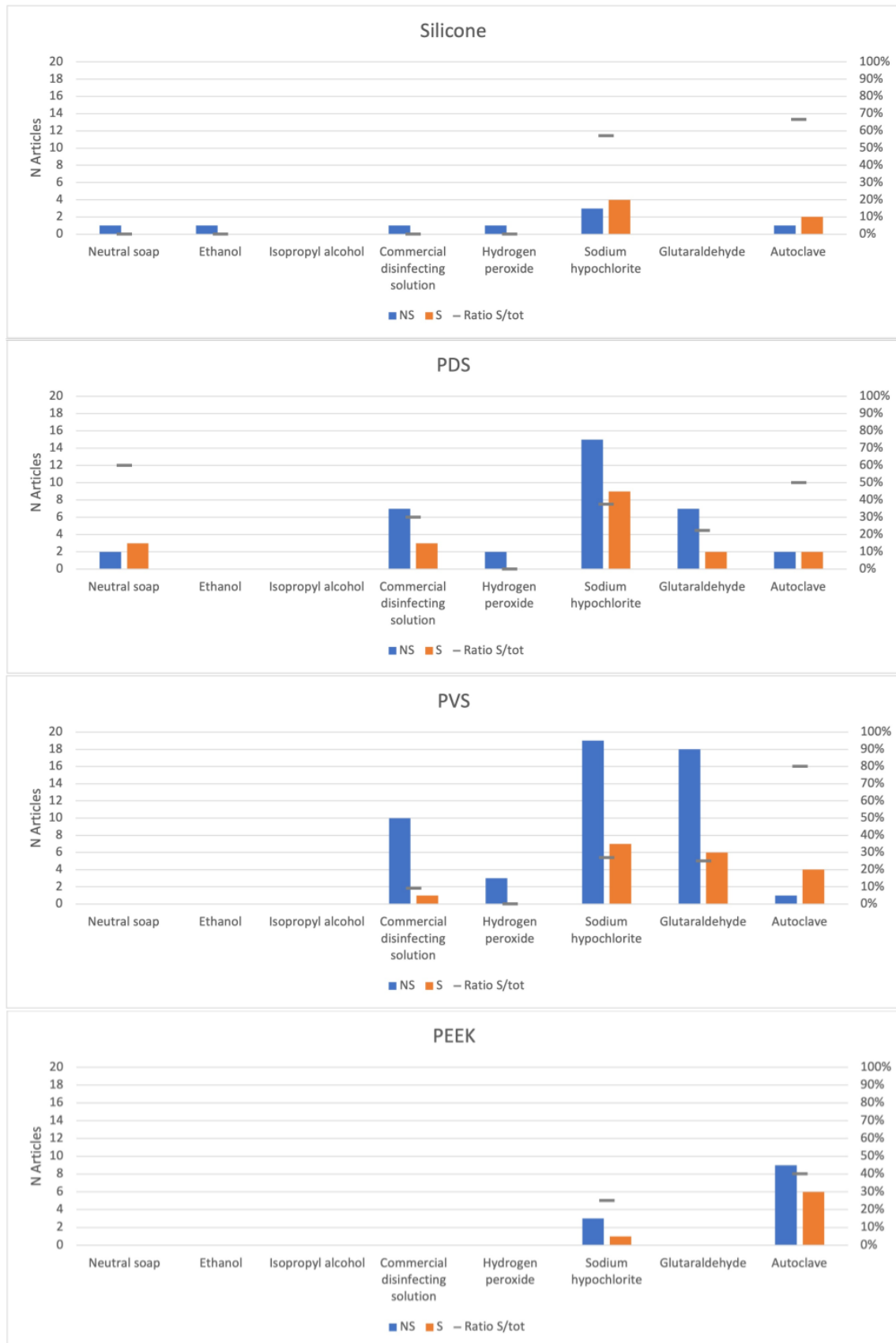


Figure 5: Number of articles reporting S or NS changes caused by each reprocessing method in any of the material properties.

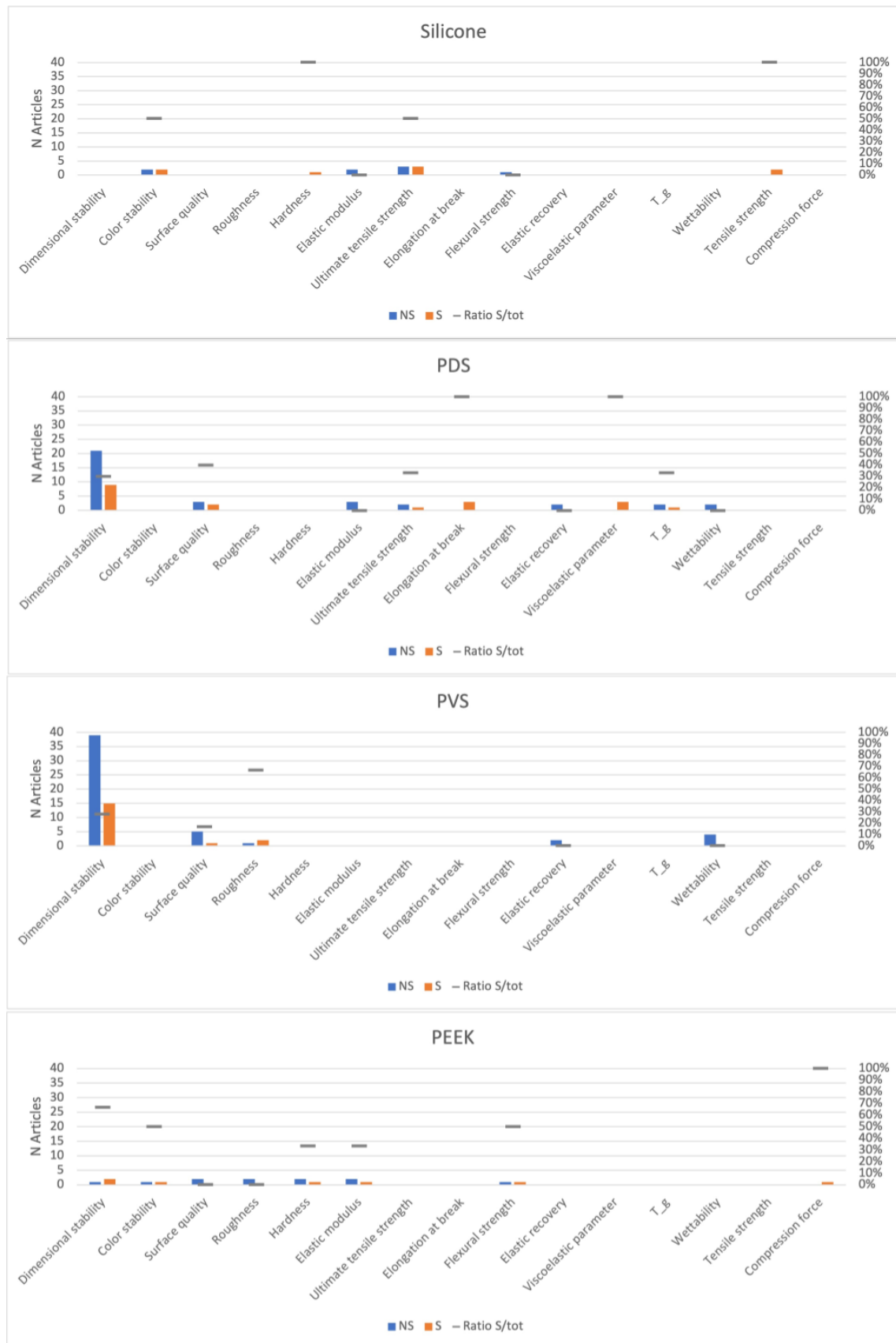


Figure 6: Number of articles reporting S or NS changes in each material property caused by any reprocessing method.

Table 2: Results for PA12.

Author	Reprocessing method	w/v / temp.	Reprocessing conditions	Time [min]	Elastic modulus	Ultimate tensile strength	Elongation at break
Wingham et al. [20]	Autoclave	121°	121° for 20 min	20	S (39% decrease)	S (13 % decrease)	S (64% increase)

Table 3: Results for silicone.

Author	Reprocessing method	w/v / temp.	Reprocessing conditions	Time [min]	Colour stability	Hardness	Elastic modulus	Ultimate tensile strength	Flexural strength	Tensile strength
Stolov et al. [21]	Autoclave	132°	132° for 8 min - 20 cycles	150					NS †	
Terheyden et al. [19]	Autoclave	121°	121° for 20 min	20				S (20% decrease)		S (5% decrease)
Brown et al. [22]	Commercial disinfecting solution	1% - 55°	30 min immersion - 5 times	150				NS *		
Griniari et al. [23]	Ethanol	95°	1 week immersion at 95°	10080	NS ($\Delta E=0.72$)					
Brozek et al. [24]	Hydrogen peroxide	3%	15 min/day immersion - 28 days	420			NS §			
Terheyden et al. [19]	Isopropyl alcohol	70%	24 hours immersion	1440				S (45% decrease)		S (10% decrease)
Griniari et al. [23]	Neutral soap	-	1 week immersion	10080	NS ($\Delta E=0.963$)					
Brown et al. [22]	Sodium hypochlorite	10%	1 hour immersion - 5 times	300				NS *		
Brown et al. [22]	Sodium hypochlorite	10%	16 hour immersion - 5 times	4800				NS *		
Brown et al. [22]	Sodium hypochlorite	10%	1 week immersion	10080				S *		
Brozek et al. [24]	Sodium hypochlorite	2%	15 min/day immersion - 28 days	420			NS §			
Pahuja et al. [17]	Sodium hypochlorite	0.50%	10 min/day immersion - 6 months	1800		S *				
Palasuk et al. [25]	Sodium hypochlorite	0.1%	10 min/day immersion - 14 days	150	S ($\Delta E=4.5$)					
Salloum et al. [26]	Sodium hypochlorite	5.25%	1 week immersion	10080	S ($\Delta E=9.554$)					

* No initial values were available, only post-processing values were reported

† Did not report complete numerical values (e.g. only reported results of statistical tests or incomplete data or qualitative measurement)

§ Results reported in graphs where it was impossible to read the exact number

¶ Too many dimensions were recorded, it was impossible to get a mean relative change

Table 4: Results for PDS.

Author	Reprocessing method	w/v / temp.	Reprocessing conditions	Time [min]	Dim. stability	Surface quality	Elastic modulus	Ultimate tensile strength	Elong. at break	Elastic recovery	Viscoelastic parameter	T _g	Wettability
Dikicier et al. [27]	Autoclave	134°	134° for 50 min	40	S (0.11% change)								
Dikicier et al. [27]	Autoclave	134°	134° for 50 min	50	S (0.07% change)								
Gothwal et al. [28]	Autoclave	134°	134° for 30 min	30						NS *			
Thota et al. [29]	Autoclave	-	-	-	NS †								
Eleni et al. (2013) [18]	Commercial disinfecting solution	-	30 hours immersion	1800			NS *	NS *	S *		S *		
Eleni et al. (2014) [30]	Commercial disinfecting solution	-	30 hours immersion	1800								S *	
Gothwal et al. [28]	Commercial disinfecting solution		10 min immersion	10						NS *			
Martin et al. [31]	Commercial disinfecting solution	-	10 min immersion	10	NS (0.6% change)								
Matyas et al. [32]	Commercial disinfecting solution	-	10 min immersion	10	NS *								
Matyas et al. [32]	Commercial disinfecting solution	-	10 min immersion	10	NS *								
Matyas et al. [32]	Commercial disinfecting solution	-	10 min immersion	10	NS *								
Abinaya et al. [33]	Glutaraldehyde	2%	10 min immersion	10		S †							
Adabo et al. [34]	Glutaraldehyde	2%	30 min immersion	30	NS †								
Amin et al. [35]	Glutaraldehyde	2%	5 min immersion	5	NS (1x10 ⁻³ % change)	NS †							
Carvalho et al. [36]	Glutaraldehyde	2%	60 min immersion	60	S (0.46% change)								
Lad et al. [37]	Glutaraldehyde	2%	10 min immersion	10									NS *
Matyas et al. [32]	Glutaraldehyde	-	10 min immersion	10	NS *								
Salem et al. [38]	Glutaraldehyde	2%	6 hours immersion	3600	NS *								
Silva et al. [39]	Glutaraldehyde	2%	20 min immersion	20	NS (0.07% change)								
Dikicier et al. [27]	Hydrogen peroxide	3%	20 min immersion	10	NS (0.08% change)								
Dikicier et al. [27]	Hydrogen peroxide	3%	20 min immersion	20	NS (0.06% change)								
Eleni et al. (2013) [18]	Neutral soap	-	30 hours immersion	1800			NS *	S *	S *		S *		
Eleni et al. (2014) [30]	Neutral soap	-	30 hours immersion	1800								NS *	
Abinaya et al. [33]	Sodium hypochlorite	5.25%	10 min immersion	10		S †							

* No initial values were available, only post-processing values were reported

† Did not report complete numerical values (e.g. only reported results of statistical tests or incomplete data or qualitative measurement)

§ Results reported in graphs where it was impossible to read the exact number

¶ Too many dimensions were recorded, it was impossible to get a mean relative change

Author	Reprocessing method	w/v / Reprocessing temp. conditions	Time [min]	Dim. stability	Surface quality	Elastic modulus	Ultimate tensile strength	Elong. at break	Elastic recovery	Viscoelastic parameter	T _g	Wettability
Adabo et al. [34]	Sodium hypochlorite	5.25% 10 min immersion	10	NS †								
Amin et al. [35]	Sodium hypochlorite	0.50% 10 min immersion	10	NS change	NS †							
Amin et al. [35]	Sodium hypochlorite	1% 10 min immersion	5	NS (-2x10 ⁻³ % change)	NS †							
Carvalho et al.	Sodium hypochlorite	0.50% 60 min immersion	60	S (-0.46% change)								
Dikicier et al. [27]	Sodium hypochlorite	5.25% 10 min immersion	10	NS (0.09% change)								
Dikicier et al. [27]	Sodium hypochlorite	5.25% 20 min immersion	20	S (0.07% change)								
Eleni et al. (2013) [18]	Sodium hypochlorite	1% 30 hours immersion	1800			NS *	NS *	S *				
Eleni et al. (2014) [30]	Sodium hypochlorite	1% 30 hours immersion	1800								NS *	
Guiraldo et al. [40]	Sodium hypochlorite	2% 15 min immersion	15	S †								
Kalantari et al. [41]	Sodium hypochlorite	0.50% 20 min immersion	20	NS (0.46% change)								
Lad et al. [37]	Sodium hypochlorite	4% 10 min immersion	10									NS *
Martin et al. [31]	Sodium hypochlorite	5.25% 10 min immersion	10	NS (0.75% change)								
Matyas et al. [32]	Sodium hypochlorite	- 10 min immersion	10	NS *								
Saleh Saber et al. [42]	Sodium hypochlorite	5.25% 10 min spray	10	S *								
Salem et al. [38]	Sodium hypochlorite	1% 6 hours immersion	3600	NS *								
Silva et al. [39]	Sodium hypochlorite	1% 20 min immersion	20	NS (0.075% change)								
Sinobad et al. [43]	Sodium hypochlorite	5.25% 10 min immersion	20	S (1.795% change)								
Thouati et al. [44]	Sodium hypochlorite	5.25% 30 min immersion	30	S (0.45% change)								

* No initial values were available, only post-processing values were reported

† Did not report complete numerical values (e.g. only reported results of statistical tests or incomplete data or qualitative measurement)

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Table 5: Results for PVS.

Author	Reprocessing method	w/v temp.	/ Reprocessing conditions	Time [min]	Dimensional stability	Surface quality	Roughness	Elastic recovery	Wettability
Dikicier et al. [27]	Autoclave	134°	134° for 40 min	40	S (0.1% change)				
Dikicier et al. [27]	Autoclave	134°	134° for 40 min	50	S (0.09% change)				
Gothwal et al. [28]	Autoclave	134°	134° for 30 min	30				NS *	
So et al. [45]	Autoclave	134°	134°	-	S †				
Thota et al. [29]	Autoclave	-	-	-	S †				
Alam et al. [46]	Commercial disinfecting solution	1%	30 seconds spray	0.5	NS *				
Alam et al. [46]	Commercial disinfecting solution	2%	30 seconds spray	0.5	NS *				
Gothwal et al. [28]	Commercial disinfecting solution	-	10 min immersion	10				NS *	
Hiraguchi et al. [47]	Commercial disinfecting solution	0.55%	30 min immersion	30	NS ¶				
Hiraguchi et al. [47]	Commercial disinfecting solution	0.55%	24 hours immersion	1440	S ¶				
Jagger et al. [48]	Commercial disinfecting solution	-	5 min immersion	5	NS *†				
Martin et al. [31]	Commercial disinfecting solution	-	10 min immersion	10	NS (0.117% change)				
Matyas et al. [32]	Commercial disinfecting solution	-	10 min immersion	10	NS *				
Matyas et al. [32]	Commercial disinfecting solution	-	10 min immersion	10	NS *				
Matyas et al. [32]	Commercial disinfecting solution	-	10 min immersion	10	NS *				
Milward et al. [49]	Commercial disinfecting solution	-	10 min immersion	10					NS *
Abdelaziz et al. [50]	Glutaraldehyde	2%	8 hours immersion	480	S *		S *		
Abinaya et al. [33]	Glutaraldehyde	2%	10 min immersion	10		NS †			
Adabo et al. [34]	Glutaraldehyde	2%	30 min immersion	30	NS †				
Al Zain et al. [51]	Glutaraldehyde	0.50%	10 min spray	10			NS *		
Amin et al. [35]	Glutaraldehyde	2%	5 min immersion	5	NS (8x10 ⁻³ % change)	NS †			
Carvalho et al. [36]	Glutaraldehyde	2%	60 min immersion	60	S (0.035% change)				
Drennon et al. [52]	Glutaraldehyde	0.25%	10 min spray	10	S (0.025% change)				
Gounder et al. [53]	Glutaraldehyde	2%	60 min immersion	60	NS (0.04% change)				
Hiraguchi et al. [47]	Glutaraldehyde	2%	30 min immersion	30	NS ¶				
Hiraguchi et al. [47]	Glutaraldehyde	2%	24 hours immersion	1440	S ¶				
Khatri et al. [54]	Glutaraldehyde	2.45%	10 min immersion	10	NS †				
Khinnavar et al. [55]	Glutaraldehyde	2%	16 hours immersion	960	S (0.43% change)				
Lad et al. [37]	Glutaraldehyde	2%	10 min immersion	10					NS *

* No initial values were available, only post-processing values were reported

† Did not report complete numerical values (e.g. only reported results of statistical tests or incomplete data or qualitative measurement)

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Author	Reprocessing method	w/v temp.	/ Reprocessing conditions	Time [min]	Dimensional stability	Surface quality	Roughness	Elastic recovery	Wettability
Langenwaller et al. [56]	Glutaraldehyde	2%	10 min immersion	10	NS (0.16% change)				
Lepe et al. [57]	Glutaraldehyde	2%	18 hours immersion	1080					NS (7.25% change)
Matyas et al. [32]	Glutaraldehyde	-	10 min immersion	10	NS *				
Nimonkar et al. [58]	Glutaraldehyde	2%	20 min immersion	20	S *¶				
Piva et al. [59]	Glutaraldehyde	2%	10 min immersion	10	NS (1.61% change)				
Queiroz et al. [60]	Glutaraldehyde	2%	10 min immersion	10	NS *				
Salem et al. [38]	Glutaraldehyde	2%	6 hours immersion	3600	NS *				
Soganci et al. [61]	Glutaraldehyde	2%	10 min immersion	10	NS *				
Walker et al. [62]	Glutaraldehyde	0.50%	1 hour immersion	60	NS (0.31% change)				
Azevedo et al. [63]	Hydrogen peroxide	3%	10 min immersion	10	NS (0.8% change)				
Dikicier et al. [27]	Hydrogen peroxide	3%	10 min immersion	10	NS (0.06% change)				
Dikicier et al. [27]	Hydrogen peroxide	3%	10 min immersion	20	NS (0.03% change)				
Abinaya et al. [33]	Sodium hypochlorite	5.25%	10 min immersion	10		NS †			
Adabo et al. [34]	Sodium hypochlorite	5.25%	10 min immersion	10	NS †				
Amin et al. [35]	Sodium hypochlorite	0.50%	5 min immersion	10	NS (2x10 ⁻³ % change)	NS †			
Amin et al. [35]	Sodium hypochlorite	1%	5 min immersion	5	NS (6x10 ⁻³ % change)	NS †			
Azevedo et al. [63]	Sodium hypochlorite	1%	10 min immersion	10	NS (0.81% change)				
Azevedo et al. [63]	Sodium hypochlorite	5.25%	10 min immersion	10	NS (0.6% change)				
Carvalho [36]	Sodium hypochlorite	0.50%	60 min immersion	60	S (0.04% change)				
Dikicier et al. [27]	Sodium hypochlorite	5.25%	10 min immersion	10	NS (0.04% change)				
Dikicier et al. [27]	Sodium hypochlorite	5.25%	10 min immersion	20	NS (0.03% change)				
Gounder et al. [53]	Sodium hypochlorite	1%	60 min immersion	60	NS (0.05% change)				
Guiraldo et al. [40]	Sodium hypochlorite	2%	15 min immersion	15	S †				
Khatri et al. [54]	Sodium hypochlorite	3%	10 min immersion	10	NS †				
Khinnavar et al. [55]	Sodium hypochlorite	0.25%	16 hours immersion	960	S (0.13% change)				
Kim et al. [64]	Sodium hypochlorite	6%	30 min immersion	30		S *			
Lad et al. [37]	Sodium hypochlorite	4%	10 min immersion	10					NS *
Langenwaller et al. [56]	Sodium hypochlorite	0.05%	10 min immersion	10	NS (0.152% change)				
Martin et al. [31]	Sodium hypochlorite	5.25%	10 min immersion	10	NS (0.01% change)				
Matyas et al. [32]	Sodium hypochlorite	-	10 min immersion	10	NS *				
Nimonkar et al. [58]	Sodium hypochlorite	1%	20 min immersion	20	S *¶				

* No initial values were available, only post-processing values were reported

† Did not report complete numerical values (e.g. only reported results of statistical tests or incomplete data or qualitative measurement)

§ Results reported in graphs where it was impossible to read the exact number

¶ Too many dimensions were recorded, it was impossible to get a mean relative change

Author	Reprocessing method	w/v temp.	/ Reprocessing conditions	Time [min]	Dimensional stability	Surface quality	Roughness	Elastic recovery	Wettability
Poulis et al. [65]	Sodium hypochlorite	0.53%	10 min immersion	10		S †			
Salem et al. [38]	Sodium hypochlorite	1%	6 hours immersion	3600	NS *				
Sinobad et al. [43]	Sodium hypochlorite	5.25%	10 min immersion	10	S (1.215% change)				
Soganci et al. [61]	Sodium hypochlorite	5.25%	10 min immersion	10	NS *				
Thouati et al. [44]	Sodium hypochlorite	5.25%	30 min immersion	30	S (0.2% change)				

Table 6: Results for PEEK.

Author	Reprocessing method	w/v temp.	/ Reprocessing conditions	Time [min]	Dim. stability	Colour stability	Surface quality	Roughness	Hardness	Elastic modulus	Flexural strength	Compression force
Godara et al. [66]	Autoclave	134°	134° for 50 min - 3 cycles	150					NS † §			
Ji et al. [67]	Autoclave	120°	120° for 20 min - 3 cycles	60			NS *					
Kato et al. [68]	Autoclave	135°	135° for 3 min	3	S ¶							
Kumar et al. [69]	Autoclave	121°	121° for 30 min - 100 times	3000	S (8% change)				S (~15% increase)			S (~20% decrease)
Salimon et al. [70]	Autoclave	134°	134° for 18 min - 10 cycles	180			NS †	NS †		NS †		
Sharma et al. [71]	Autoclave	134°	134° for 18 min	18	NS *							
Stolov et al. [21]	Autoclave	132°	132° for 8 min - 20 cycles	160							NS †	
Suchy et al. [72]	Autoclave	134°	134° for 10 min - 100 cycles	1000						S (10% decrease)	S (13% decrease)	
Tekin et al. [73]	Sodium hypochlorite	0.50%	8 hours/day immersion - 120 days	576000		S *						
Erdag et al. [74]	Sodium hypochlorite	5%	8 hours - 3 times	1440		NS *		NS (10% change)				

* No initial values were available, only post-processing values were reported

† Did not report complete numerical values (e.g. only reported results of statistical tests or incomplete data or qualitative measurement)

§ Results reported in graphs where it was impossible to read the exact number

¶ Too many dimensions were recorded, it was impossible to get a mean relative change

E. PA12

Only Wingham et al. investigated the effects of reprocessing on PA12. They autoclaved the samples for 20 minutes at 121°C and recorded statistically significant changes in its material properties [20]. Particularly, the elastic modulus decreased by 39%, its ultimate tensile strength had a reduction of 13% and the elongation at break increased by 64% [20].

F. Silicone

According to the literature included in this review, no statistically significant changes were recorded in generic silicone, i.e. unspecified silicone type, after reprocessing with commercial disinfecting solutions, ethanol, hydrogen peroxide or neutral soap [22]–[24].

Sodium hypochlorite, on the other hand, has 7 results concerning its effects on silicone. Brown et al. measured the changes in silicone's tensile strength. They reported no statistically significant changes for lower exposure times (300 and 4800 minutes in total), but they observed a 5% decrease when compared to the control for a higher exposure time (7 consecutive days of immersion, corresponding to a total of 10080 minutes) [22]. Brozek et al. and Pahuja et al. reported non statistically significant changes in silicone's hardness and elastic modulus [17], [24]. On the other hand, Palasuk et al. and Salloum et al. measured statistically significant differences in the silicone's colour, respectively a ΔE of 4.5 and 9.5 [25], [26].

Regarding steam sterilisation, 2 results reported statistically significant changes, over the 3 total results obtained. Terheyden et al. autoclaved the samples at 121°C for 20 minutes and recorded significant changes in ultimate tensile strength, with a reduction of 20%, and tensile strength, decreased by 5% [19]. Whilst Stolov et al. did not show any significant changes in flexural strength after 20 cycles at 134°C [21].

Terheyden et al. also immersed silicone samples for 24 hours in isopropyl alcohol and recorded statistically significant changes in its properties [19]. Particularly, they found a 45% decrease in its ultimate tensile strength and a 10% reduction of its tensile strength [19].

G. PDS

The most frequently studied material property for PDS is dimensional stability, with 30 results out of the 54 total results recorded for PDS.

Dimensional stability was measured after reprocessing with most of the included methods: autoclave, commercial disinfecting solution glutaraldehyde, hydrogen peroxide and sodium hypochlorite.

The articles report discordant results. 21 recorded no statistically significant changes in PDS' dimensional stability, whilst 9 did.

The statistically non-significant changes range from $0.5 \times 10^{-3}\%$ [35] to 0.75% [31], and the statistically significant range from 0.07% [27] to 1.795% [43] (among the ones where the relative percentage change was available).

It was not possible to identify a correlation between time of exposure and number of recorded statistically significant

changes, nor between concentration of the disinfectant and number of recorded statistically significant changes.

Five results were retrieved for PDS' surface quality. Abinaya et al. reported significant changes after disinfection with 5.25% sodium hypochlorite or a commercial disinfecting solution [33]. On the other hand, Amin et al. did not record statistically significant changes in PDS' surface quality after disinfection with glutaraldehyde, 0.5% sodium hypochlorite or 1% sodium hypochlorite [35].

Eleni et al. tested PDS' elastic modulus, ultimate tensile strength, elongation at break and viscoelastic parameter after immersion for 30 hours in either a commercial disinfecting solution, neutral soap or 1% sodium hypochlorite [18]. They recorded no statistically significant changes, compared to the control group, in the elastic modulus after any of the reprocessing conditions.

They also reported non-significant changes, compared to the control group, after immersion in the commercial disinfecting solution or sodium hypochlorite, but noted significant changes after cleaning with soap.

However, they recorded statistically significant changes, compared to the control group, in the elongation at break and viscoelastic parameter for all conditions [18].

Elastic recovery and wettability of PDS do not have any statistically significant alteration being reported in the included articles.

Dikicier et al. was the only study which investigated the effects of disinfection with hydrogen peroxide on PDS and did not report any statistically significant alteration in the two analysed material properties [27].

Regarding disinfection with glutaraldehyde, 7 results show no statistically significant changes, against only 2 which do. Particularly, Salem et al. studied the effect of the highest immersion time, 60 minutes, and did not record statistically significant alterations [38]. All reported results investigated the effects of 2% glutaraldehyde.

With similar results, commercial disinfecting solutions have been reported to cause statistically significant changes in only 3 results out of the 10 total results. It is relevant to note that Eleni et al. reported all the 3 significant alterations and they immersed PDS in a commercial disinfecting solution for 30 hours, corresponding to a total of 1.800 minutes [18]. The recommended immersion time for this solution is indicated to be 5 minutes, thus they simulated approximately 360 reprocessing cycles.

Reprocessing with sodium hypochlorite gave 24 results, with a ratio of statistically significant changes over the total results of 0.375. Particularly, all the statistically significant alterations in PDS' material properties were recorded by studies investigating the effects over a longer exposition time or with a higher concentration of NaOCl. Eleni et al. observed 2 significant alterations after 30 hours immersion [18] and Carvalhal et al. after 60 minutes immersion [36], which are the highest exposure times studied for sodium hypochlorite on PDS. Regarding concentration, a similar pattern can be

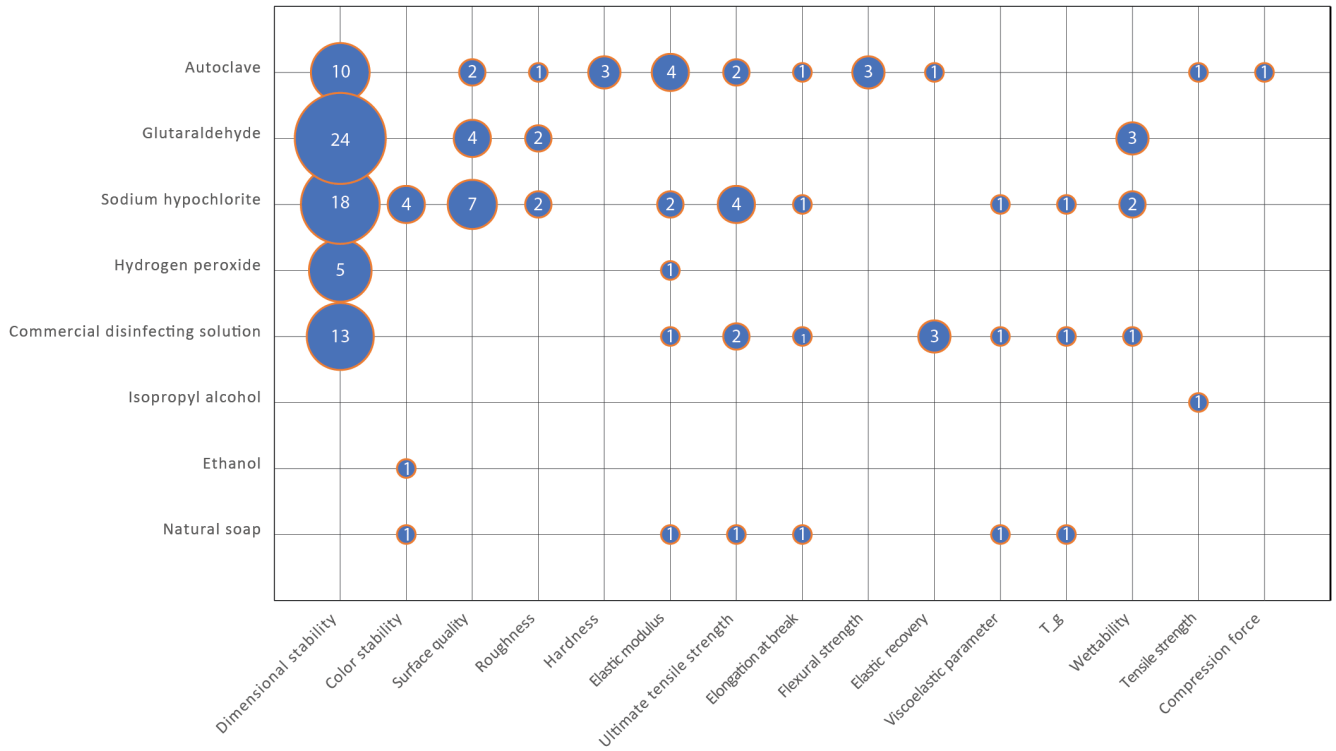


Figure 7: Number of results per condition. The number in each circle is the amount of results obtained for the specific combination of reprocessing method on material property.

observed. The studies which immersed the samples in 5.25% w/v sodium hypochlorite (the highest used concentration), reported all the other statistically significant changes [27], [33], [42]–[44].

Autoclaving and cleaning with neutral soap seem to have the worst effects on PDS. Dikicier et al. reported two statistically significant changes after 50 minutes of autoclaving at 134°C, whilst Thota et al. and Gothwal et al. observed non significant changes.

H. PVS

As for PDS, the most frequently studied material property for PVS is dimensional stability, with 54 results out of the 69 total recorded results.

Dikicier et al., So et al. and Thota et al. all reported statistically significant changes in PVS' dimensional stability after sterilisation with an autoclave [27], [29], [45].

When looking at the dimensional stability after reprocessing with a commercial disinfecting solution, 9 out of 10 values are statistically non-significant different.

The recorded dimensions of PVS after disinfection with 2% glutaraldehyde are statistically insignificantly different in 13 measurements, out of 18. And 15 dimensional changes out of 20 are statistically non-significant after reprocessing with sodium hypochlorite.

The statistically non-significant changes range from $2 \times 10^{-3}\%$ [35] to 1.61% [59], and the statistically significant range

from 0.025% [52] to 1.215% [43] (among the ones where the relative percentage change was available).

It was not possible to identify a correlation between time of exposure and number of recorded statistically significant changes, nor between concentration of the disinfectant and number of recorded statistically significant changes.

Abdelaziz et al., Al Zain et al. and Kim et al. tested PVS' roughness after reprocessing with glutaraldehyde for the first two and sodium hypochlorite for the latter. Abdelaziz et al. and Kim et al. reported no statistically significant changes, while Al Zain et al. did [50], [51], [64].

Wettability, elastic recovery and surface quality of PVS were not affected by any of the included reprocessing methods.

Dikicier et al. investigated the effects of hydrogen peroxide on PVS and they reported two non statistically significant changes. Azevdo et al. also reported non significant changes for PVS being disinfected with hydrogen peroxide.

Commercial disinfecting solutions have the lowest ratio of recorded statistically significant changes over all the recorded changes (0.09), besides hydrogen peroxide. Indeed, 10 results from 7 different studies report NS [28], [31], [32], [46]–[49], whilst only Hiraguchi et al. observed statistically significant changes [47]. However, it is important to remark that all the non-significant changes resulted for an exposure of 30 minutes or less, whereas the significant changes were registered after 24 hours immersion.

Glutaraldehyde's effects on PVS were investigated in 21 articles, from which a total of 24 results were extracted. Of these, 17 were non-significant changes and 7 were significant. For these results it is not possible to find a correlation between time of exposure to the disinfectant or its concentration and a higher number recorded significant changes. Almost all of the studies used solutions with 2% glutaraldehyde, but while some of the studies report S for low immersion times (10 minutes) [52], others which recorded NS tested the samples for as long as 6 hours [38]. Despite the relatively low ratio of significant recorded alterations (0.29), glutaraldehyde can have significant effects on PVS even for short exposure times. Regarding the interaction of sodium hypochlorite on PVS, it has a similar S/total ratio as glutaraldehyde (0.3), with 18 results reporting NS against 8 S. All non-significant changes were observed after immersion in the solution for 10 minutes or less, besides Gounder et al. which exposed the PVS for 60 minutes and recorded significant changes [53], and Salem et al. that immersed it for 6 hours [38]. On the other hand, most of the statistically significant changes were observed for either longer exposure times [36], [55] or higher concentration of sodium hypochlorite [43], [44], [64].

Steam sterilisation resulted to be the reprocessing method which caused the most deterioration in PVS. Dikicier et al. observed significant changes in PVS after autoclaving it at 134°C for 40 and 50 minutes [27]. Similarly, Thota et al. and So et al. recorded significant alterations after steam sterilisation [29], [45], whilst Gothwal et al. were the only ones to register non significant changes [28]. It can be assumed that autoclaving has a serious negative effect on PVS already after one cycle of sterilisation.

IV. DISCUSSION

This literature search was carried out to investigate the effects of specific reprocessing methods on the possible materials for the production of the vela® VE and it produced a high amount of results. Of all the articles found, 61 were considered eligible to be included. Many of the included studies investigated the effects of multiple testing conditions, such as different reprocessing methods or different materials, therefore, multiple results were extracted from these, coming to a total of 132 results.

A data extraction table was compiled reporting whether the changes observed in the material properties after reprocessing were statistically significant or not. When available, the relative change was also recorded. Additionally, the tables contain information regarding the reprocessing method and its conditions, such as exposure time, concentration or temperature. In this section the results obtained in this review will be discussed.

A. Low number of results

The first finding of this literature review is that, despite the abundance of articles included, none of them studied the effects of PPSU. It was not possible to identify even one paper with a focus on studying the effects of reprocessing on PPSU.

Moreover, only one article describes the effects of reprocessing on PA12 [20]. Furthermore, PEEK has 10 articles studying its properties, which is significantly less than silicone, that, including PVS and PDS, was researched in 50 studies.

This highlights a great disparity in the number of results obtained for each material, from zero for PPSU to 50 for silicone. It could be explained by the wide applicability of silicone, which makes it a highly researched material, opposite to PPSU, PA12 and PEEK, more recent and less commonly used materials. Therefore, it can be concluded that further research is needed to fill this knowledge gap and gain more information on the effects of cleaning, disinfection and sterilisation on these materials.

Additionally, looking at the number of results obtained for each condition, intended as the study of the effects of a specific reprocessing method on one material property, a considerably low number of results was reported. Figure 7 graphically shows how many results were recorded per condition. It is possible to see that the great majority of specific combinations of reprocessing method on material property have zero or one result each. The only material property which had a satisfying number of results describing the effects of reprocessing on it, is dimensional stability.

This clearly shows a knowledge gap in the literature studying the effects of reprocessing on materials' properties.

A possible explanation for this is that most of the data regarding testing of materials' properties are privately owned by the plastics' manufacturing companies and they are not accessible by the public.

Most companies do not disclose the specific results of the tests performed on the materials they produce. The technical data sheets only report the conclusions, labelling their product as "heat resistant", or "autoclavable", or "compatible with acidic disinfectants". However, despite being considered resistant to a certain reprocessing method, materials can nonetheless undergo a certain extent of damage. It is extremely important to have publicly available information regarding the effects of reprocessing on materials, in order to be able to clearly quantify the damage that can be expected when sterilising and/or disinfecting a material for a certain number of cycles. Particularly for reusable devices such as the vela® VE, having precise and clear data on the effects of reprocessing would be extremely valuable information in the development process. It is essential that innovative reusable devices are proven to be safe to use after a specific amount of reprocessing cycles. In order to do so, it is necessary to collect detailed information regarding the materials' properties, which is a time and resource consuming process. Thus, if this information were already available to all, it would be remarkably convenient in terms of material and financial resources.

B. Quality of results

The second main finding of this literature review is that, in addition to the fact that there is a general lack of literature quantifying the effects of reprocessing methods on certain material, the available data is hardly comparable with each

other.

Firstly, because a large number of papers did not clearly quantify the relative percentage change of the measured material property (54% of all articles). This happened because of one of the following reasons:

- No initial values were available, only post-processing values were reported (60% of the articles from which the relative change was not available)
- Did not report complete numerical values, e.g. only reported results of statistical tests or incomplete data (28% of the articles from which the relative change was not available)
- Results reported in graphs where it was impossible to read the exact number (6% of the articles from which the relative change was not available)
- Too many dimensions were recorded, it was impossible to get a mean relative change (6% of the articles from which the relative change was not available)

Tables 2-6 show for which articles it was impossible to retrieve or calculate the relative change in material properties and for which reason.

Because of the unavailability of quantifiable percentage change, a numerical comparison of the values was not possible. Therefore, results were mostly reported in terms of S and NS to allow for a comparison among them.

Furthermore, the studies included in this review tested the materials in very different conditions. Exposure times went from as short as 30 seconds to as long as 960 hours, disinfectant concentration ranged from 0.1% to 10% depending on the disinfectant and autoclave temperatures were either 121°C or 134°C. The initial material properties were also different within the same category of material, and very often not reported in the paper. Thus, an all comprehensive data analysis was impossible due to the high amount of variables considered in this review. Particularly, the variables included are: material, reprocessing method, analysed material property, exposure time and concentration of disinfectant or temperature of the autoclave. Since it is impossible to consider all of them at the same time, it was decided to focus on the material, reprocessing method and analysed material property. This simplification entails that the exposure time and concentration of disinfectant or temperature of the autoclave were neglected. Thus, results obtained from studies with considerably different exposure times were compared to each other. However, the influence of time and concentration/temperature will partially be discussed in the following sections.

It is important to have more standardised research, providing data with the same testing conditions, in order to make it more comparable to each other.

C. Comparison with other literature reviews

Two literature reviews were included in this one. However, their scope was considerably more limited.

Qiu et al. focused on studying the effects of sodium hypochlorite and glutaraldehyde on the dimensional stability and surface properties of PVS and PDS for dental impression applications. Although their research question had a very specific focus, they still reported their results in terms of statistical significant changes in the material properties. This supports the methodology followed in this review.

Grasdal et al. reviewed literature pertaining the effect of reprocessing on catheters for intermittent catheterization. In this case, the application of the materials was really specific to a certain application, which limited the number of articles included in the review to 12, which simplifies the data analysis. Furthermore, they did not numerically quantify the changes recorded in the catheters. The assessments were in all cases limited to gross visual inspections of the catheters' surface. In conclusion, the only other found literature reviews which focus on the effects of reprocessing have really narrow scopes and they also do not carry out a data analysis which includes relative changes in the material properties.

D. Effects on materials

In this section the results obtained from the literature search will be discussed for each material.

1) *PA12*: Only one article studied the effects of reprocessing on silicone, which found that steam sterilisation has a very critical impact on the mechanical properties of PA12 after only one cycle. However, one study does not give enough information to draw any definitive conclusions on this regard. More research is needed to provide additional evidence to support this claim.

2) *Silicone*: Looking at the results for silicone, it could be assumed that commercial disinfecting solutions, ethanol, hydrogen peroxide and neutral soap do not negatively impact silicone [22]–[24]. However, only one result for each of these reprocessing methods was retrieved, which is not enough evidence to be able to affirm that these methods do not have significant effects on silicone.

Furthermore, it can also be assumed that even though sodium hypochlorite negatively affects silicone's material properties, statistically significant changes are only recorded for high concentrations and long exposure times.

Finally, isopropyl alcohol appears to be the most impactful reprocessing method on generic silicone, since both the results obtained by Terheyden et al. after 24 hours immersion indicate significant changes [19].

The most heavily impacted material properties, among the measured ones in the articles included in this review, result to be dimensional stability, colour stability, ultimate tensile strength and tensile strength. Silicone's colour stability is crucial to be maintained, since this material would be used for the tubing component of the vela® VE, which should be transparent to facilitate visual inspection after cleaning. It is troublesome that such a relevant material property seems to be heavily affected by reprocessing. Appropriate testing should be performed on the vela® VE's ability to maintain sufficient levels of colour stability.

E. PDS

The results show that glutaraldehyde can be generally considered a safe disinfectant for PDS, however, the effects of reprocessing over a longer period of time should be investigated before indicating it as the appropriate reprocessing method for a reusable device such as the vela® vacuum extractor. Furthermore, most studies investigated the dimensional stability and/or surface quality of the material, which are less critical properties for the vela®'s functionality. Therefore, it would be relevant to carry out additional research on the mechanical properties of PDS, such as elastic modulus, ultimate tensile strength and elongation at break.

When looking at the effects of sodium hypochlorite on PDS, it can be noticed that all the statistically significant alterations in PDS' material properties were recorded by studies investigating the effects over a longer exposition time or with a higher concentration of NaOCl. Therefore, it could be concluded that disinfection with sodium hypochlorite at lower concentrations, like 0.5%-0.1%, as recommended by the WHO [75], and for a limited number of cycles does not affect PDS' material properties greatly.

Autoclaving and cleaning with neutral soap appear to have the worst effects on PDS.

Elastic recovery, wettability and elastic modulus of PDS do not have any statistically significant alteration being reported in the included articles. Dimensional stability was significantly altered in 30% of the results, which were either autoclaved [27], immersed in disinfectant for a longer time (60 minutes) [36] or tested with a high concentration of sodium hypochlorite (5.25%) [27], [40], [42]–[44]. On the other hand Salem et al. immersed the samples in 1% NaOCl for 6 hours and recorded no significant changes in their dimensional stability. Therefore, it can be assumed that PDS' dimensional stability is not greatly affected by the included reprocessing methods, particularly for lower exposition times or concentrations.

The glass transition temperature seems to be relatively stable for PDS, as Eleni et al. reported 2 NS (after reprocessing with neutral soap and sodium hypochlorite) and only 1 S (after reprocessing with a commercial disinfecting solution) [18]. It is important that the T_g does not greatly decrease, as this would make the material more susceptible to deterioration from the high temperatures reached in steam sterilisation.

Eleni et al. also measured ultimate tensile strength, reporting 2 NS and 1 S with different reprocessing methods. Additionally, they measured elongation at break and viscoelastic parameter, both with 3 statistically significant alterations [18], [30]. This suggests that reprocessing highly affects the mechanical properties of PDS. However, such a definite conclusion cannot be drawn from two articles from the same author. Further investigation on the effect of all reprocessing methods on the mechanical properties of PDS should be conducted.

1) *PVS*: Dikicier et al. and Azevdo et al. also reported non significant changes for PVS after disinfection with hydrogen peroxide, which might suggest that it is a safe reprocessing method for PVS [27]. However, both studies only tested

dimensional stability of the samples, which does not give relevant information on the effects of hydrogen peroxide on the mechanical properties of PVS. More evidence should be gathered to consider hydrogen peroxide a safe reprocessing method for PVS.

Commercial disinfecting solutions have the lowest ratio of recorded statistically significant changes over all the recorded changes (0.09), besides hydrogen peroxide. However, it is important to remark that all the non-significant changes resulted for an exposure of 30 minutes or less, whereas the significant changes were registered after 24 hours immersion. Therefore, it can be concluded that commercial disinfecting solutions are highly compatible with PVS for short exposure times, however, their long term effects on the material should be further researched.

Steam sterilisation resulted to be the reprocessing method which caused the most deterioration in PVS' dimensional stability, already after one cycle of sterilisation.

Wettability, elastic recovery and surface quality of PVS seem to not be affected by reprocessing. However, only 2 to 6 results are available for each of these properties, thus more data would be needed to be able to state it.

54 results are available for PVS' dimensional stability and more than 70% of them show non significant changes, which indicates a relatively good resistance to reprocessing for this material property.

Roughness seems to be the most affected material property, which might constitute an issue as PVS would be used for the tubing component of the vela® VE and higher levels of roughness might compromise the ability to effectively clean the hollow cavity of the tube. However, only 3 results are available, with a S/total ratio of 67%.

2) *PEEK*: The results suggest that repeated disinfection with sodium hypochlorite causes alterations in PEEK's material properties.

Steam sterilisation was the most researched reprocessing method for PEEK. All the studies which autoclaved the samples 20 times or less reported non significant changes in the material properties [21], [66], [67], [70], [71], besides Kato et al. which found statistically significant alteration after just one cycle [68]. Suchy et al. and Kumar et al. autoclaved PEEK 100 times and both studies observed statistically significant changes. The evidence from the literature suggests that PEEK is able to withstand a limited number of autoclave cycles with no significant deterioration.

The number of results available for PEEK is limited and it is therefore hard to draw conclusions on the effects of reprocessing on each analysed material property. However, it is possible to say that physical properties such as surface quality, roughness, colour stability and dimensional stability are generally less affected than mechanical properties, such as hardness, elastic modulus, flexural strength and compression force.

Looking at the literature available on the impact of each reprocessing method on the searched materials, the results

suggest that steam sterilisation is the most damaging method. Autoclaving has the highest ratio of significant changes over the total amount of recorded changes. Specifically, out of the 30 results reporting the effects of autoclaving, 17 were considered significant alterations (57%).

Moreover, looking at the available numerical relative changes in the data extraction tables, the highest values are all recorded after autoclaving. Kumar et al., Suchy et al., Terheyden et al. and Wingham et al. all studied the effects of autoclaving on physical and mechanical properties of different materials and reported changes as high as 64% and 39%. Oppositely, the other reprocessing methods have considerably lower relative changes in the analysed material properties, even when considered statistically significant.

The precise extent of steam sterilisation's effects on the materials' properties should be carefully researched.

Only isopropyl alcohol has a higher ratio of S/total than autoclaving, however, only two results were available for this reprocessing method.

Commercial disinfecting solutions, glutaraldehyde and sodium hypochlorite were found to have a similar impact on material properties and their effects on the materials are neglectable compared to the ones caused by steam sterilisation. However, most studies investigated the effects of these disinfectants for relatively low exposure times. Since the vela® vacuum extractor is a reusable device, the long term interaction of the disinfectants with the materials should be further researched. The effects of ethanol, hydrogen peroxide, neutral soap and isopropyl alcohol have not been extensively studied for these materials yet, thus, additional research should be conducted.

Numerous different material properties were investigated in the included studies, however, each study focused only on a limited number of them, most commonly one. Due to this, it is hard to make an overall assessment on the impact of reprocessing on each of the material properties, as there are only a limited number of results available for each of them. Furthermore, some material properties were more commonly tested after specific reprocessing methods. Since the reprocessing methods cause different extents of damage, autoclave being the most damaging one, it is more likely that the material properties more often tested after it will result as being more greatly affected. Specifically, mechanical properties were more likely to be assessed after steam sterilisation, whilst physical properties after disinfection. Therefore, it is not possible to draw conclusions on the effects of reprocessing on each material property.

Dimensional stability was the most researched parameter with 88 results, 70% of which are non significant changes, which is a good indication of the materials' general stability in their dimensions.

F. Limitations

This literature review offers a comprehensive overview of the effects caused by specific reprocessing methods on PA12, PPSU, PEEK and silicone. The information collected from

the literature allowed some relevant conclusions to be drawn, such as the evidence that steam sterilisation is the most damaging reprocessing method out of the ones included in this study. However, there are limitations to this review, some of which might have affected the results and conclusions. The limitations will be discussed in this section.

1) Literature search and data extraction: The literature search was carried out from only two databases, namely Scopus and PubMed. Other databases might have given further content for the review.

This literature review was entirely carried out by one reviewer, the author. The formulation of the search terms, the definition of the eligibility criteria, the articles' screening and further selection were human decisions, dictated by personal judgement and interpretation, and are therefore responsible for risk of bias. Relevant articles might have not been included in this review either because they did not show as results in the literature search or they were excluded through the selection process.

Furthermore, the conclusions are based on the scientific literature. Because most of the data pertaining material properties are commonly owned by private companies, there may be a bias in this study's findings. Additionally, all articles were considered equally relevant, in spite of the fact that the articles' quality might have differed among them. A quality assessment index would ideally provide this review additional support. Furthermore, the sample sizes of each study were ignored, which signifies that studies with little sample sizes were considered equal to studies with considerably bigger sample sizes. This contributes to the risk of bias.

The data was manually extracted from the articles and then imported in Excel for analysis and interpretation, therefore, mistakes or oversights might have been committed due to human error.

2) Data analysis and interpretation: The main limitation of this literature review is that the produced data set is highly inhomogeneous and includes five different variables, i.e. material, studied material property, reprocessing method, exposure time and concentration or temperature.

Due to the heterogeneity of the data, it was possible to compare the effects of different sterilisation methods on different material properties only by quantifying the number of articles reporting the statistically significant or insignificant changes, neglecting the numerical measurement of the deteriorations. This implies that any statistical significant change was regarded the same, independently from the actual extent of the material degradation. However, some numerical values were reported in the results section of this review to give a better understanding of the extent of the changes in the materials. Because of the amount of variables being considered in this review, it was impossible to examine the influence of each one of them on every other one. Therefore, a selection had to be made and it was decided to neglect the exposure times and the concentration or temperature. This entails that results with greatly different times of exposure (from as short as 30 seconds to as long as 960 hours) or disinfectant concentration

(from 0.1% to 10% depending on the disinfectant) or autoclave temperature (121°C or 134°C) were compared with each other. However, these factors were discussed in the previous section when interpreting the results.

As previously explained, when one of the included studies tested for multiple conditions, e.g. different reprocessing methods or exposure times, all results were retrieved. Therefore, in some cases, multiple results were extracted from the same article. This increases the risk of bias since articles that report statistical significant changes for one testing condition are more likely to report it also for other testing conditions. Furthermore, the number of results obtained for each testing condition, i.e. the effect of one reprocessing method on one material property of one material, are greatly uneven. For instance, 88 results were retrieved on dimensional stability, whilst only 1 was obtained for compression force. Therefore, the conclusions drawn from the information collected are biased due to disproportions in the number of results.

Furthermore, some studies indicated the statistical significance or non-significance of the comparison between the post-processing value of the test group and the initial values of the same group. However, other studies compared the post-processing value of the test group with the post-processing value of the control group.

In addition, some materials were more likely to be tested for certain material properties and reprocessing methods, whilst other materials for other testing conditions. For example, PEEK was generally tested for harsher reprocessing methods, i.e. autoclaving, which leads to biased conclusions on the susceptibility of the materials.

All materials within material groups were considered equivalent. Differences such as carbon fiber reinforcements in PEEK, or pigmentation in PVS and PDS were neglected.

Lastly, all commercial disinfection solutions were categorised as the same and no distinctions were made among them, ignoring the differences between types of commercial disinfectants.

G. Future recommendations

The conclusions collected in this literature review allow for recommendations on future research. Firstly, important knowledge gaps have been identified. No or almost no information regarding the effects of reprocessing are available for PPSU and PA12, and PEEK has considerably less data available than silicone. Therefore, it is necessary to conduct further research to examine the interactions between these materials and the reprocessing methods. Moreover, relatively little data was available when looking at the effect of one reprocessing method on a specific material property of each material. Additionally, studies focused on different material properties depending on the researched material. For instance, most of the data available for PVS and PDS regarded the effects of reprocessing on dimensional stability. Thus, it is recommended to gather more data on the insufficiently studied material properties.

Furthermore, it would be relevant to research the overall effects of a combination of reprocessing methods, i.e. cleaning, dis-

infection and sterilisation, as it would be executed in clinical practice.

V. CONCLUSIONS

The purpose of this literature review was to investigate the effects of specific reprocessing methods on the materials used for manufacturing of the vela® vacuum extractor, currently under development at LAYCO®. The databases Scopus and PubMed were searched with the selected key terms, and a total of 1057 results were obtained. After selection, 61 articles were considered eligible to be included in this review.

The data was manually extracted from the articles and recorded on Excel. The obtained dataset included a great number of variables: material, reprocessing method, time of exposure to reprocessing, concentration of the disinfectant or temperature of the autoclave's cycle and the tested material property. The data was particularly heterogeneous, thus, a numerical comparison of the values of the material properties was not feasible. Therefore, the results were reported in terms of recorded statistically significant changes.

The first findings highlight important knowledge gaps in the currently available literature. Studies investigating the effects of reprocessing on PPSU could not be found and only one study researching PA12 was included in this review. Furthermore, the number of articles studying each testing condition (the effects of a specific reprocessing method on one material by testing for a precise material property), was relatively low for almost all of the combinations. Therefore, further research on this topic is needed. It is important to have more standardised research, enabling researchers to better compare different findings.

Disinfection solutions, including commercial disinfecting solutions, glutaraldehyde and sodium hypochlorite, were found to be almost equivalently detrimental to the materials' properties. Therefore, no disinfection solution was proven to perform remarkably better than the others. However, most of the included studies focused on investigating the effects of relatively short exposure times. The future steps in the development of the vela® vacuum extractor should include longer disinfection times.

Steam sterilisation resulted to be the most damaging reprocessing method and it is recommended that precise quantifications of the extent of its effects on the materials are determined to evaluate the service life of the vela® VE. On the other hand, the effects of ethanol, hydrogen peroxide, neutral soap and isopropyl alcohol have not been extensively studied for the searched materials yet, thus, additional research should be conducted.

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