From surgical waste to medical products

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From surgical waste to medical products

B.J. van Straten

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‘Man was made to create’
Maurits Jan Alexander van Straten

‘

We are borrowing this world from our children therefore, we need to create technological solutions that minimize waste so that future generations enjoy a more sustainable environment.

From surgical waste to medical products

Dissertation

for the purpose of obtaining the degree of doctor
at Delft University of Technology
by the authority of the Rector Magnificus, Prof.dr.ir. T.H..J.J. van der Hagen,
Chair of the Board for Doctorates
to be defended in publicly on
Tuesday 7 June 2022 at 12:30 o'clock

by

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Motivation and inspiration for my PhD Research. From left to right: Roos van Straten, André Kuipers, Maurits van Straten

‘Vanuit een baan om de aarde voel je duidelijk hoe kwetsbaar onze planeet eigenlijk is, met een heel dunne dampkring en relatief weinig vruchtbare grond. Menselijke activiteit is, zelfs met het blote oog, goed te zien op land en op zee. Onze aarde is een ruimteschip met beperkte voorraden waar we heel zuinig op moeten zijn.’

André Kuipers

“From orbit around the earth you can clearly feel how vulnerable our planet really is, with a very thin atmosphere and relatively little fertile soil. Human activity can be clearly seen, even with the naked eye, on land and at sea. Our Earth is a spaceship with limited supplies that we have to be very careful with”

André Kuipers

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Preface

This foreword is based on a contribution from Bruno Bruins. On June 18, 2018, Bruno, Minister for Health, Welfare and Sports, received an instrument mesh basket from me. We had made this instrument basket, partly from recycled stainless steel. What I couldn't foresee at the time was the impact this handover would bring. In fact, this moment can be seen as the start of my research period. I had known Bruno for some time and I consider that wonderful day in June and his contribution to this preface to be of great value. The preface is written both in Dutch as well as in English.

Dutch
Er zijn van die dagen, en die voorjaarsdag in 2018 was er zo één. Te veel afspraken, te krap gepland en kriskras door Nederland. De oplossing was snel gevonden: als de afspraak met Bart kon worden verzet, was de agenda gered. Anderzijds: de afspraak was in thuishaven Den Haag, meer specifiek bij Societeit De Witte, waar Bart en ik jarenlang schouder-aan-schouder deel uitmaakten van het College van Bestuur. Just in time arriveerden we bij de door Van Straten Medical georganiseerde bijeenkomst over circulair instrumentbeheer.

Geen materialen weggooien, maar hergebruiken. Niet een tweede keus of een 'afdankertje', maar instrumenten reviseren en een nieuwe toepassing geven. Dat was de boodschap van de bijeenkomst. Bij wijze van voorbeeld kreeg ik van Bart een metalen sterilisatie net, gemaakt van gerecycled instrumentarium. Beter: ik kreeg niet alleen een netje, ik kreeg een visie op recycling van medische materialen. In een omgeving waar zoveel materiaal wordt verbruikt, is het creëren van awareness rond het onderwerp hergebruik belangrijk. Zo'n thema krijgt kracht als een variëteit van professionals en betrokkenen ermee aan de slag gaat. Het instrumentennet was afkomstig van Van Straten Medical, maar bij de bijeenkomst waren ook vertegenwoordigers uit de zorg, de patiënten, de wetenschap en de industrie. Het enthousiasme was breed gedragen.

Deze middag leerde ik dat hergebruik een gelijkwaardig alternatief voor ‘nieuw’ kan zijn. Dat het belangrijk is om mogelijkheden voor hergebruik te onderzoeken. Dat we met hergebruik de planeet kunnen dienen en de patiënt op gelijke wijze. Bij mij is die middag dat zaadje geplant; daarvoor dank Bart! En het netje dat ik in ontvangst mocht nemen? Dat heb ik voor vertrek weer teruggegeven aan Bart - over hergebruik gesproken.

Bruno Bruins

Minister voor Medische Zorg en Sport 2017-2020

English
There are those days, and that spring day in 2018 was one of those. Too many appointments, too tight schedule and across the Netherlands. The solution was quickly found: if the appointment with Bart could be rescheduled, the agenda would be rescued. On the other hand: the appointment was in The Hague, home base, more specifically at Societeit De Witte, where Bart and I sat shoulder-to-shoulder on the Executive Board for many years. We arrived

just in time at the meeting about circular instrument management organized by Van Straten Medical.

Do not throw away materials, but reuse them. Not a second choice or a 'cast-off', but overhauling instruments and giving them a new application. That was the message of the meeting. As an example, Bart gave me a metal sterilization mesh basket, made from recycled instruments. Better: I didn't just get a mesh basket, I got a vision on the recycling of medical materials. In an environment where so much material is consumed, it is important to create awareness about reuse. Such a theme gains power when a variety of professionals and stakeholders get to work on it. The instrument set came from Van Straten Medical, but representatives from healthcare, patients, science and industry were also present at the meeting. The enthusiasm was widespread.

This afternoon I learned that reuse can be an equivalent alternative to 'new'. That it is important to investigate possibilities for reuse. That we can serve the planet and the patient by reusing products. That afternoon a seed was planted with me; Thanks for that Bart! And the mesh basket that I was allowed to receive? I gave that back to Bart before departure - talking about reuse.

Bruno Bruins

Minister for Health, Welfare and Sports 2017-2020


TU Delft

General introduction

Partly based on the Letter to the Editor as published in the Journal for Hospital Infection in June 2020:

De Man, P*., van Straten, B*., van den Dobbelsteen, J.J., Van Der Eijk, A.C., Horeman, T. & Koeleman, H. (2020).

Sterilization of disposable face masks by means of standardized dry and steam sterilization processes; an alternative in the fight against mask shortages due to COVID-19. Journal of Hospital Infection, 105(2), 356-357.

* First two authors contributed equally

and partly based on: Steam sterilization of used disposable face masks with respect to COVID-19 shortages:

van Straten, B., van den Dobbelsteen, J.J., Horeman, T. (2020).

Steam sterilization of used disposable face masks with respect to COVID-19 shortages. Delft University of Technology. https://research.tudelft.nl/en/publications/steam-sterilization-of-used-disposable-face-masks-with-respect-to.

Background and relevance

Historical context

The world population has grown from 1 billion persons in 1800 to 7.9 billion in 2021 and is estimated to reach 10 billion in 2057 [1]. A consequence of this growth are the greenhouse gas emissions that may cause a large threat in terms of environmental impact for the coming generations. A legally binding international treaty was signed in Paris by 196 parties on 12 December 2015 [2]. The goal is to limit global warming to well below 2^0C, preferably below 1.5^0C.

The European Commission plans to encourage the European Union to become more circular and more sustainable. The European Green Deal is a set of initiatives and proposals aiming to make the European Union climate neutral in 2050. Furthering this aim, the Green Deal on sustainable healthcare [3] was formulated as an agreement, signed by hospitals, government administrations, medical companies and universities. This agreement aims to foster the healthcare sector to reduce carbon dioxide emissions, stimulating a circular healthcare economy.

The European climate law stipulates that the European Union will be climate neutral by 2050 [4]. To achieve this goal, the climate law aims to reduce CO_2 emissions by 49% in 2030 compared to 1990. In 2021, this objective was further increased to 55% reduction for 2030 [5].

The global growth of hospital waste has a significant impact on the environment and has been the result of a growing population in combination with an increased use of disposables [6]. A circular health care economy could help in reducing hospital waste volumes. The Circular Economy is a system in which waste is prevented, minimized or even completely reused [7].

Although a holistic, universal circular approach or 'state of the art' common practice for reusing specific hospital waste is difficult to achieve, the number of green teams in hospitals and green initiatives in industry are emerging. As the Green Deal [3] was formulated to stimulate the healthcare sector to create these initiatives, these task force teams explore the possibilities to initiate green, circular initiatives. Literature does describe various circular sub-processes. This includes studies describing the reduction of medical waste by means of purchasing different products which produce less waste [8] which could be realized by focusing on reusable products instead of disposable. Some studies analyze recycling potential of plastic medical wastes streams [9-11]. Other studies focus on life cycle assessment investigations, examining the difference in climate change impact between disposable and reusable medical devices where the impacts of the disposable products generally exceed those of reusable medical devices [12,13].

Adopting a circular economy approach to hospital waste streams in a holistic way seems to be an area to be explored further. This includes the development and validation of physical/technical processes to reprocess medical waste including circular designs – product designs that limit raw material extraction and production of waste - of medical devices but also making material and reprocessing data available in an open-source manner.

The Butterfly reference Diagram

The Butterfly Diagram [14] as shown in Figure 1 exemplifies the circular economy. The cycles illustrate the circular strategies including reuse, maintenance, refurbishment, remanufacturing and recycling. These circular strategies help to minimize the generation of waste, reuse waste as raw material, extend product life cycles and therefore, reduce the extraction of natural resources.

The left side of the diagram shows the biological cycle. The right side shows the mechanical cycles as closing loops.

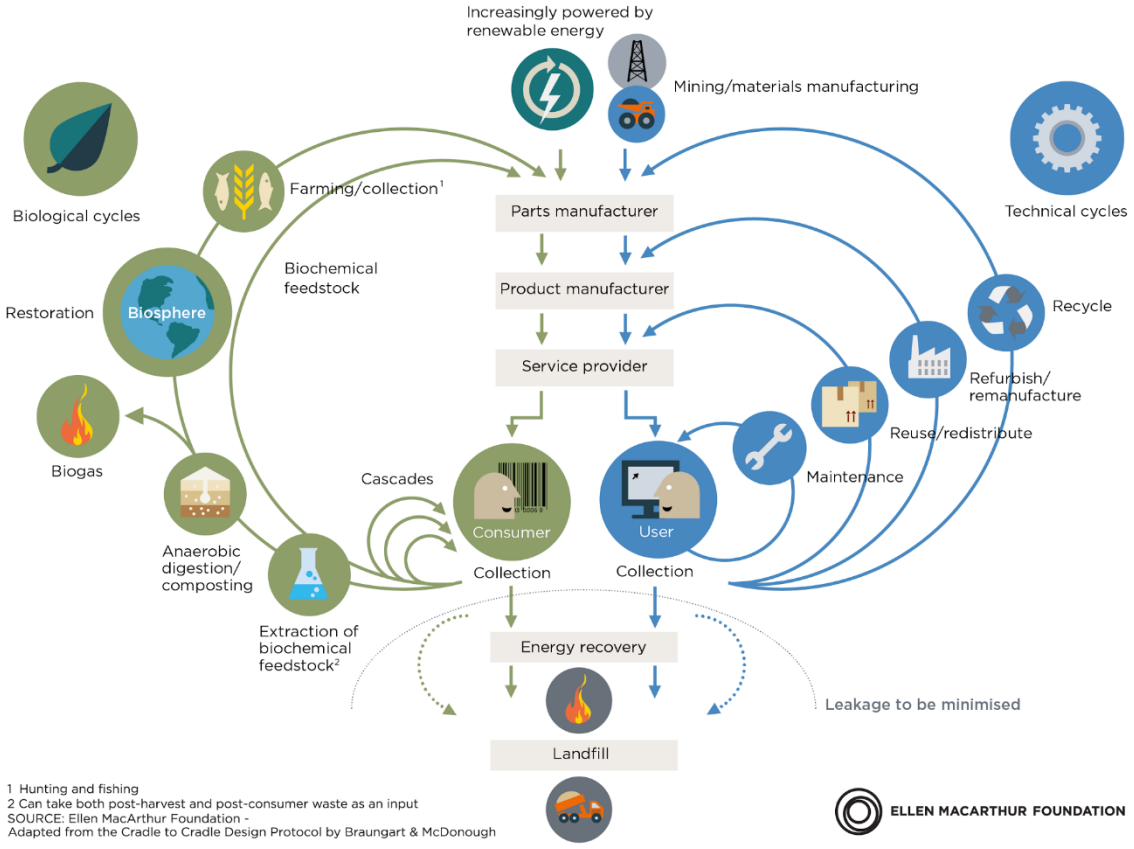

Fig. 1. Butterfly Diagram from the Ellen McArthur Foundation showing the circular strategies [14].

Circular strategies not only protect our natural resources by reducing the use of raw materials and prevent waste but they also contribute to preventing shortages of resources in the supply chain and limit environmental impact. An example of shortages of supply occurred during the Covid-19 pandemic with unexpected, shortages of face masks [15-18]. Circumstances arose that resulted in threatening deficits of personal protective equipment where no care could be given and healthcare professionals were not protected. The chain of events sometimes leads to ad-hoc decisions and uncontrolled response of governments and industries. This demonstrates the importance of using circular strategies with regard to independency on resources and protection of our public health.

On request of several hospitals - to the address of our research team - different methods for the reprocessing of disposable face masks were studied in the period starting at 17 March 2020 [17-19]. Threatening shortages of face masks were expected by the end of the week. As a response, our consortium of industrial partners and universities shifted their focus to setting-up a regular steam sterilization process, to inactivate the coronavirus in order for the face masks to be reused [20,21]. Within a couple of weeks new processes and facilities were created to reprocess different kinds of personal protective equipment (PPE's) like face masks, filters, gowns and other essential parts. New test methods and hardware were developed to ensure the quality of reprocessed materials.

After sterilization the samples were tested and benchmarked with new face masks. The pressure/flow of the face masks were measured and particle tests were conducted. A custom test set-up was built to measure the pressure drop over the masks and outflow with regard to the permeability of the masks. A direct comparison between new and sterilized masks did not show substantial differences.
We openly shared our positive experiences of the steam sterilization process, with other hospitals in the Netherlands that were also preparing for the outbreak. The urgency and relevance of our study regarding the reusability of face masks was conducted in the spirit of the circular economy; preventing shortages of resources, minimizing waste and preventing environmental impact. All being aspects of the scope of this thesis.

Objective of this thesis

The goal of this thesis is to develop and investigate methods for a circular health care economy.

The research questions formulated, are:

1. Can disposable medical devices be reprocessed and brought back into circulation?

2. Can reprocessing of medical waste be feasible for hospitals?

3. Can new medical devices be designed and made from medical waste?

4. What is the climate change impact after reprocessing?

Six dedicated studies were conducted with different research teams in order to answer the research questions. These studies were set-up in cooperation with the Dutch Ministry of Health, Welfare and Sports, Amsterdam University Medical Center, locations AMC and VUmc, Maasstad Hospital, Westeinde Hospital, Bronovo Hospital and Antoniushove Hospital, Leiden University Medical Center, NEN: Royal Netherlands Standardization Institute, staff and students from the Delft University of Technology, departments of Chemical Engineering and BioMechanical Engineering, Department of Process & Energy and Leiden University.

Outline of the thesis

In **part I** we focus on the reusability of face masks by means of steam sterilization as well as the climate change impact of reusing single-use medical devices. In **chapter 2** we investigate if FFP2 face masks can be reprocessed using 121°C steam sterilization. The effect of sterilization on the materials was furthermore, investigated. A total of 74,834 used face masks were processed by the CSSD of CSA services. Nineteen hospitals adopted our sterilization and testing methods in the Netherlands as well as multiple hospitals across the globe. **Chapter 3** evaluates the circular methods of repair, refurbishing, recycling of surgical instruments recovered from different hospitals.

Part II evaluates the circular strategies on a process, product and engineering level.

In **Chapter 4** we study the surgical reprocessing of blue wrapping paper used for wrapping surgical instrument sets. This blue wrap is melted, grinded to flakes and injection molded into new medical products, so-called instrument openers. These instrument openers, designed to keep a hinged instrument open during washing and disinfection, were applied on the CSSD of the same hospital who supplied the wrapping paper waste.

Chapter 5 investigates the experimental reprocessing of disposable laryngoscope blades made from Zamak. These blades were recovered from the operating room, disinfected, melted and casted into new components used in a steerable punch.

Chapter 6 evaluates the climate change impact by means of a Life Cycle Assessment (LCA) where the impact of disposed versus reprocessed face masks are assessed and compared.

A discussion, to conclude the findings of our studies, including the impact of our research on society is provided in **Chapter 7.** In this chapter we formulate the answers to the research questions and make conclusions for the different circular approaches. Reprocessing surgical waste into medical products from this perspective may contribute to a different approach. As part of the future perspectives we look into creating circular processes and potential circular designs. These perspectives may serve as a basis for future research and new technologies that stimulate the circular healthcare economy.

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Part I

Chapter 2

Based on the article as published in PloS One: Open Scientific Library in September 2021

Van Straten, B., Robertson, P. D., Oussoren, H., Pereira Espindola, S., Ghanbari, E., Dankelman, J, Picken, S, Horeman, T. (2021).

Can sterilization of disposable face masks be an alternative for imported face masks? A nationwide field study including 19 sterilization departments and 471 imported brand types during COVID-19 shortages. PloS one, 16(9), e0257468.

https://doi.org/10.1371/journal.pone.0257468


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Can sterilization of disposable face masks be an alternative for imported face masks? A nationwide field study including 19 sterilization departments and 471 imported brand types during COVID-19 shortages.

Abstract

Background

Face masks, also referred to as half masks, are essential to protect healthcare professionals working in close contact with patients with COVID-19-related symptoms. Because of the Corona material shortages, healthcare institutions sought an approach to reuse face masks or to purchase new, imported masks. The filter quality of these masks remained unclear. Therefore, the aim of this study was to assess the quality of sterilized and imported FFP2/KN95 face masks.

Methods

A 48-minute steam sterilization process of single-use FFP2/KN95 face masks with a 15 minute holding time at 121°C was developed, validated and implemented in the Central Sterilization Departments (CSSD) of 19 different hospitals. Masks sterilized by steam and H2O2 plasma as well as new, imported masks were tested for particle filtration efficiency (PFE) and pressure drop in a custom-made test setup.

Results

The results of 84 masks tested on the PFE dry particle test setup showed differences of 2.3±2% (mean±SD). Test data showed that the mean PFE values of 444 sterilized FFP2 face masks from the 19 CSSDs were 90±11% (mean±SD), and those of 474 new, imported KN95/FFP2 face masks were 83±16% (mean±SD). Differences in PFE of masks received from different sterilization departments were found.

Conclusion

Face masks can be reprocessed with 121^0C steam or H_2O_2 plasma sterilization with a minimal reduction in PFE. PFE comparison between filter material of sterilized masks and new, imported masks indicates that the filter material of most reprocessed masks of high quality brands can outperform new, imported face masks of unknown brands. Although the PFE of tested face masks from different sterilization departments remained efficient, using different types of sterilization equipment, can result in different PFE outcomes.

Introduction

After the outbreak of COVID-19, this respiratory disease has spread at a rapid pace [1,2]. Adequate face masks are essential to protect healthcare professionals. In many hospitals shortages of personal protection equipment occurred due to increased demand [3]. In the search for alternative sources, hospitals started to consider reusing their single-use face masks by sterilizing them [4].

Face masks, also referred to as half masks, are used to protect individuals against airborne particles during aerosol generating procedures. Three classes of particle filtering face piece (FFPs) are described in European Norm (EN) 149:2001+ A1:2009 [5]. The most commonly used masks in relation to COVID-19 are the Class 2 FFP2 masks. These are considered to be equivalent to the American N95 mask [6], conforming to the standards of the National Institute for Occupational Safety and Health (NIOSH) 42 CFR 84 mask [7], and the Chinese KN95 mask complying to the Guobiao (GB) 2626–2006 standard [8]. The filter efficiency of smaller particles is a crucial element. The European Norm requires a minimum filter efficiency of 94%, whereas NIOSH [7] and GB [8] require 95%.

Testing filter material of face mask

EN 149:2001+A1:2009 [5] and more specifically NEN-EN 13274–7:2019, part 7 describe a test setup to determine the particle filtration efficiency (PFE) of face masks. It consists of a flow tube, a flow generator, a NaCl particle generator and two particle measurement devices and generates flows up to 120 l/min with NaCl particles of 0.1 to 10 µm. Unfortunately, this setup is costly to build. Therefore, in the first two months of COVID-19 only two systems were operational in the Netherlands that could be used for testing new, imported face masks. The costs at different commercial test laboratories for testing one face mask was approximately 1,500 Euro with a waiting list of up to four weeks. A new quick testing method was needed. Therefore, a single line test set-up was build using only a particle counter with a custom-made and low cost particle chamber which was relative easy to operate within a short lead time.

Potential reprocessing methods

Several studies have shown the effects of different sterilization methods, including gamma sterilization, plasma sterilization, steam and dry heat sterilization, microwaves, washing machines and UV–C light, as methods to decontaminate face masks for reuse [9–13]. These studies suggest that gamma and steam sterilization conducted at 134°C damage the microstructure of the filter material [9].

Washing machines and microwaves have a low capacity, and microwaves do not create a uniform heat distribution and require a steam bag [10–12]. Some studies suggest that the high concentration of liquid H2O2 in plasma sterilization (approx. 60%), and its strongly charged ionized vapor may neutralize the electrostatic charge of the filter media [11, 12]. Moreover, the sterilization efficacy would likely be affected by the presence of moisture (e.g. exhaled breath) in worn masks, as water is a polar molecule. Finally, the capacity per run remains low due to the vacuum-driven process [13]. The evaporation of moisture may restrict the sterilizer's ability to pull deep vacuum. UV treatment of face masks seems to have potential

but requires preparation time as face masks need to be unfolded in such a way that UV light reaches all of the mask material [10–13]. UV-B sterilization was not considered as this method is not yet commonly used and not readily available at hospital sterilization departments. Steam sterilization at 121°C could be an option since studies have shown the effectiveness at 121°C in inactivating the Coronavirus [14, 15].

Pilot studies, that included ATCC 12228 bacterial testing, have been conducted to determine whether 121°C sterilization was a safe and effective method to deactivate the Corona virus. The protocols and results were made available to hospitals via the repository of the Delft University of Technology after demonstrating that sterilization of face masks was possible up to 5 times for high-quality face masks [9, 16]. Although proven efficient, the potential of this new 121°C sterilization method was not explored. Moreover, a study where many different brands of face masks were processed at different CSSD's, with comparisons between new, imported masks and sterilized masks, did not exist. Therefore the aim of this study is to find the best alternative for high quality face masks in times of shortage by assessing the quality of sterilized and imported FFP2/KN95 face mask filter materials.

The following research questions were defined:

1. Can FFP2 masks be reprocessed using 121°C steam or H_2O_2 plasma sterilization?
2. Are reprocessed face masks an alternative for new ones?
3. What effect does sterilization have on the materials?

Methods

A sterilization facility of a Dutch CSSD (ISO 7 validated, Van Straten Medical, De Meern, the Netherlands, operated by CSA services) was set-up for the purpose of reprocessing used (potentially COVID-19 contaminated) FFP2 face masks. New testing methods were developed to test the filter material quality after sterilization [4, 9, 16]. The testing was carried out for any hospital, reseller or manufacturer wanting to check the quality of sterilized or new, imported face masks.

Reprocessing by 121°C steam at CSA services sterilization

Within this new reprocessing approach, decontamination was done solely by steam sterilization. To implement the 121°C sterilization process, a special logistical routing was set-up to collect and process face masks. Upon receipt, the masks were removed from their double wrapping and inspected individually for visual damage. In case of deformations, dirt, lipstick, hairs, black streaks, stains or other deviations, the masks were discarded. The visually approved face masks were marked with a dot and packaged in autoclavable impermeable sterilization laminate bags (type CLFP150X300WI-S20, Halyard, UK) (Fig 1). A mask was disposed after it was marked with a maximum of 5 dots. A maximum of five face masks were packaged per bag to ensure proper sterilization. The autoclaves (GSS6713H-E, Getinge, Sweden) were activated with a 121°C program and re-validated. The autoclave cycle was set

for 48 minutes with a 15 min holding time (high vacuum 121 °C; ≥15 min HT, total CT 48 min). Face masks with a higher class (FFP3/N95) were treated as FFP2/KN95. The PFE for the average FFP2/KN95 mask material has to be 94% or higher for a pass and under 94% for a fail [5]. The performance of the mask material was determined by measuring the PFE and breathing resistance. Fig 2 shows the particle counter with a custom-made particle chamber (Lighthouse Solair 3100, San Francisco, www.golighthouse.com). The machine drew air through the mask into the chamber and to the particle counter. The diameter of the chamber was chosen such that it guaranteed sufficient airflow through the filter material for the particle counter [9, 16, 17]. The PFE was determined by measuring the difference in the number of particles before and after filtration by the mask. First, the particle concentration in a standard volume of room air was determined by measuring the number of particles (sizes 0.3, 0.5, 1.0, and 5.0 μm) in a volume of surrounding air. Second, the mask was installed on the chamber to measure the number of particles after filtration.

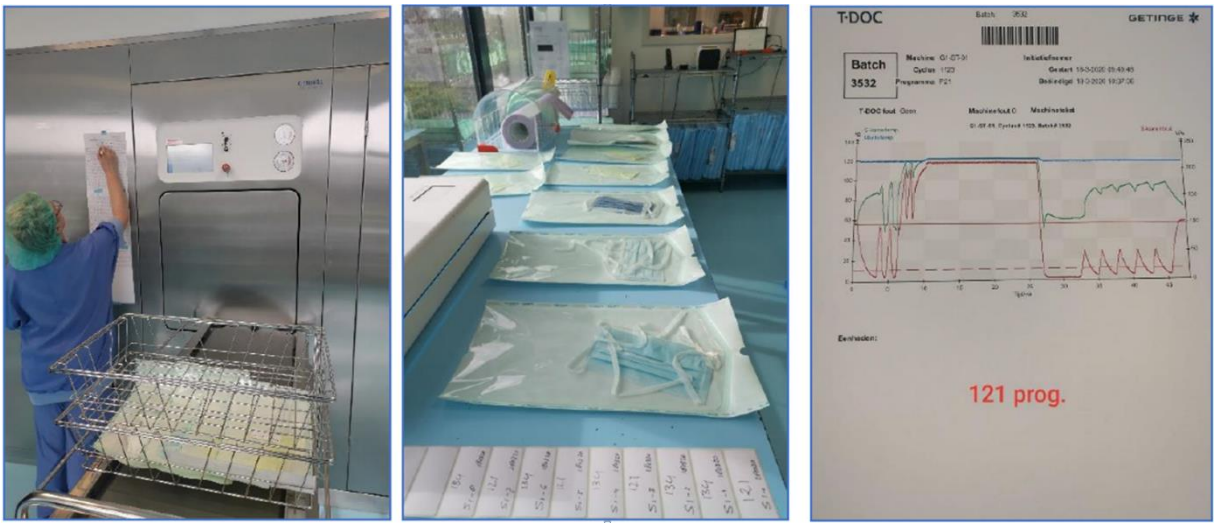

Fig 1. Autoclave procedure with Halyard laminate bags. Left, laminated bags entering the autoclave. Middle, masks are wrapped in laminate. Right, the 121 °C steam sterilization program as used for face mask sterilization.

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Fig 2. Lighthouse Solair 3100 particle counter connected to a particle chamber.

When very dense filter materials are used with a very high PFE for the smallest particles, it causes a breathing resistance for the user [16, 17]. This resistance causes a pressure drop which was measured using an analog differential pressure sensor, type SDP2000-L (Sensirion AG, Staefa ZH, Switzerland) connected to the particle chamber. The pressure sensor is temperature compensated, calibrated and has a resolution of 11 Pa with a repeatability of 0.3% and accuracy of 1% [17]. The breathability requirements for respiratory protective devices are provided in a European standard [18]. The maximum permitted resistance (mbar) differs for the FFP1, FFP2, and FFP3 masks, ranging from 0.6–1.0 for inhalation at 30 l/min, 2.1–3.0 for 95 l/min and 3.0 for exhalation at 160 l/m. The norm for a FFP2-mask at 30 l/min is 0.7 mbar.

https://doi.org/10.1371/journal.pone.0257468.g002

Test setup validation to the European Norm EN 13274–7

The accuracy of the developed particle test setup was evaluated by comparing results from known face masks, tested on (our) particle setup, with the results of the same brand and type masks, tested on a continuous flow system. The continuous flow test system used NaCl particles and was built at the Delft University of Technology according to NEN-EN 13274–7:2019 [19].

Additionally, the standard EN 149:2001+A1:2009 describes experiments to determine if a mask creates a proper fit on the face without leakages. The inward leakage is determined by means of a fit test and strap test [17, 18]. In this study, inspection of the materials were conducted and leakage tests were performed on all reprocessed masks. Although this study focused on the material properties, only masks that showed no change in fit or material properties were included. The types that did deteriorate were registered and disposed after arrival. Although we followed the EN-149 standard as much as possible, we did reference our

outcomes with the NaCl test since we used a custom-made test setup as a non-standard EN-149 methodology.

121 ^{0}C steam sterilization consistency between CSSDs

The consistency of sterilization results, caused by different processes and equipment was compared between 19 CSSDs. Samples of masks representing the most commonly used brands and types were selected and measured with the PFE setup. Only CSSDs were included that provided a minimum of four masks that were sterilized once. Face masks were not cleaned after visual inspection and prior to sterilization. A student's t-test (two tailed, unequal variance, SPSS 17.0) was used for comparison, and a probability of $p<0.05$ was considered to be statistically significant.

Face mask material differences

Differences in mask material were analysed by chemically and thermally comparing the fabric of the two most common types. Therefore, a differential scanning calorimetry (DSC), an X-ray diffraction (XRD) and a transform infrared spectroscopy (FTIR) were conducted (Supplemental file 1.

Testing new masks

To determine how many samples of imported face masks were needed, the variance of the PFE and pressure drop was determined on three imported face masks. Ten measurements conducted on each face mask type (Supplemental 2) showed that the largest variance was found in the 0.3 µm particle size category of 0.6%, 1.1% and 0.3% of the mean values respectively. The pressure drop measurements showed a variance of 0.7%, 1.8% and 1.8% of the mean values respectively. This low variance indicated consistent behavior of the filter materials. Combined with the importance of a short processing time it was determined to measure a minimum of two masks of each type that was provided by the clients. The averaged values are listed in Supplemental file 3. In case a deviation of more than 10% was found in the 0.3 µm category, two additional masks were tested and the supplier was notified. This data was excluded from the study.

Samples were selected for PFE measurement from batches of imported masks. The PFE results of those new face masks were compared to the PFE results of the sterilized face masks from the 19 CSSDs. New imported face masks that scored above 98% PFE in the particle range were further investigated for breathability by measuring the pressure drop.

Results

Reprocessing by 121°C steam sterilization at CSA services

A total of 74,834 masks were processed by the CSSD of CSA services. Of these masks, 56,668 were disposed after incoming inspection due to visual damage, deformities or dirt. The remaining 18,166 face masks were steam sterilized at 121°C. Table 1 shows the top five brands that were sterilized and returned to hospitals for use.

Table 1. Top five reprocessed face masks.

Brand (Type)	Percentage
3M (1862+)	42%
3M (1872+)	21%
My-T-Gear	8%
IMG Europe (R620)	5%
Kimberly Clarc Corp	5%
Rest	19%

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Test setup validation to the European Norm EN 13274–7

Preliminary tests conducted with 84 different masks, tested on the PFE dry particle test setup and a NaCl test setup, following the EN 13274–7:2019 standard, indicated an outcome deviation of 2.3±2% (mean±SD) on average with a max of 7% (Supplemental file 4). A measurement test conducted with another ten different masks indicated that an average of 19 s ±21% (mean±SD) (SD 21) is needed to install and inspect the mask on the particle counter and an additional 15 s ±13% (mean±SD) is needed to take the mask from the system after 1 minute of measurement. None of the masks showed visual signs of deformation or damage after being measured.

121˚C steam sterilization consistency between CSSDs

The reprocessing methods by means of steam sterilization were adopted by 19 hospitals (Amsterdam University Medical Center (VUmc and AMC locations), Holendrecht Medical Center, Franciscus Hospital, CombiSter RDGG & Haga, Spaarne Hospital, Erasmuc MC, University Medical Center Groningen, Leiden University Medical Center, Flevo Hospital, Isala Hospital, Diakonessenhuis Utrecht, VieCuri, Rode Kruis Hospital, Noordwest Hospital Group, Amphia Hospital, and Tweesteden Hospital). The PFE results of 444 reprocessed FFP2/KN95 face masks from the CSSDs of 19 different hospitals in the Netherlands are provided in Fig 3. Of the 444 masks, 371 masks were sterilized with steam sterilization and 73 with H_2O_2 plasma (Supplemental file 5).

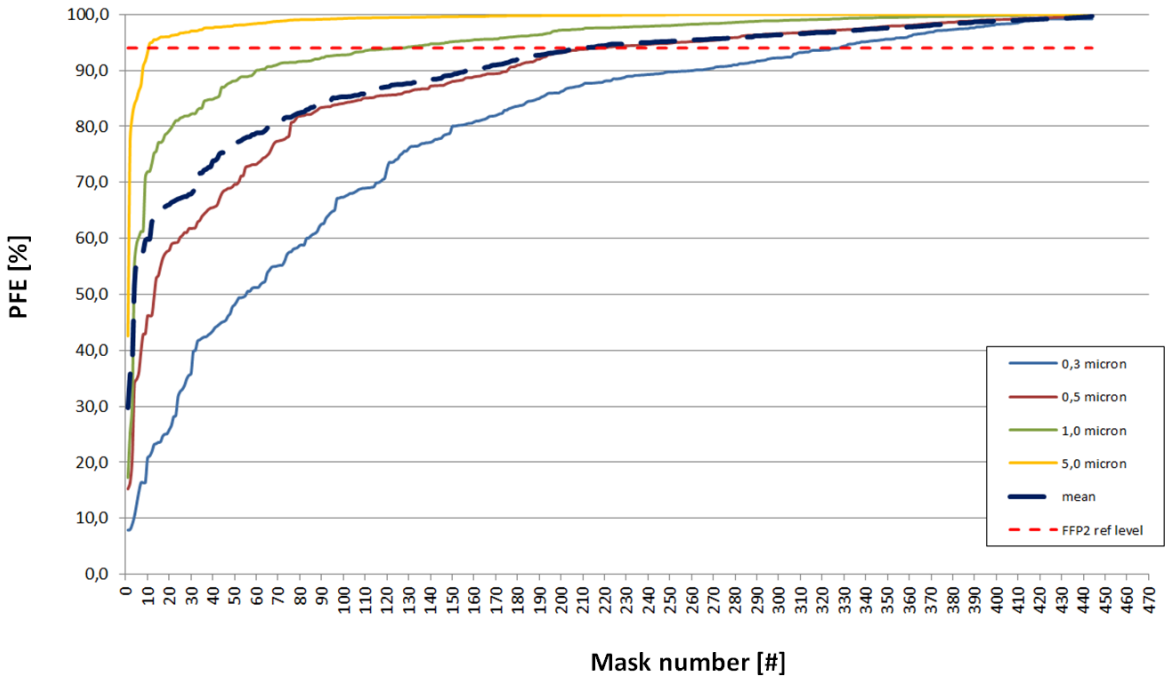

Fig 3. PFE values after sterilization with 121 °C steam or H_2O_2 plasma sterilization in chronological order from worst to best. The red dotted line indicates the FFP2 level at 94% PFE. Each mask number represents a sample of a sterilized batch from one type only.

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From these 444 tested face masks, 58 3M 1862+ face masks were provided by seven CSSDs of four university hospitals, one general hospital and one general practitioner which were only sterilized once at 121°C using steam sterilization (Supplemental file 6). The influence of different installations, protocols or staff on the PFE is shown in Fig 4. The “N” value indicates how many 3M 1862+ face masks were included in the study that were only sterilized once. The statistical tests reveal differences in outcome mainly for the CSSD of University Hospital 2.

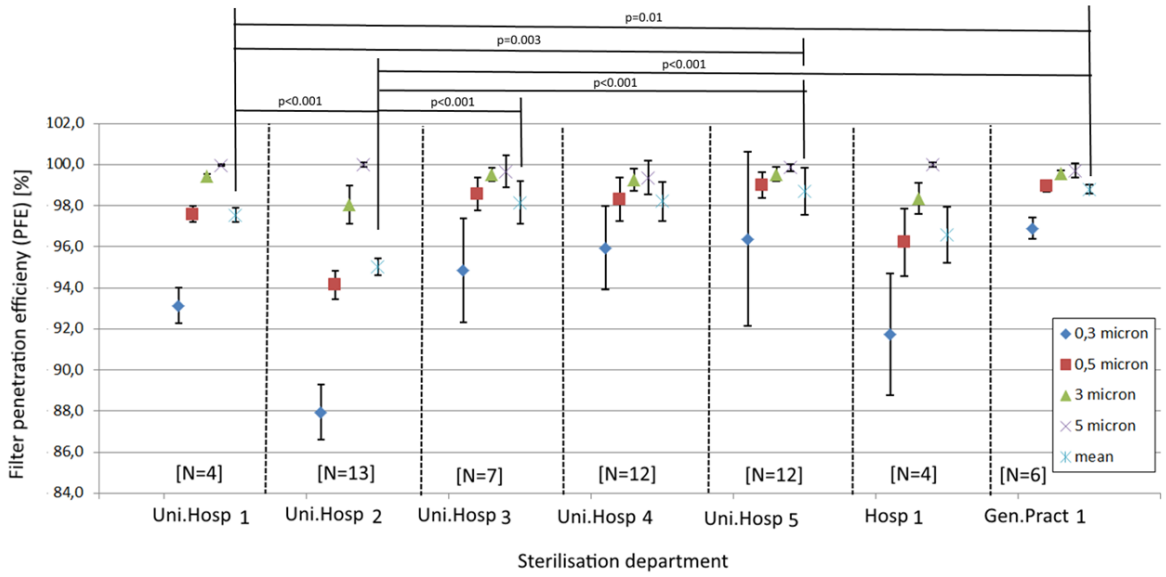

Fig 4. PFE values with standard deviation of different 3M 1862+ coming from 7 different CSSDs. Statistical differences are indicated with P values above the figure.

https://doi.org/10.1371/journal.pone.0257468.g004

Face mask material differences

The 444 face masks consisted of 101 different types. Of the 101 different types, 3M 1862 and Kolmi Op-Air were mostly tested. The PFE results of 89 3M 1862 and 26 Kolmi Op-Air are provided in Table 2 for 0.3, 0.5, 1 and 5 µm particles.

Table 2. Particle filter efficiency of two commonly used mask after either 121°C steam or H2O2 plasma sterilization.

Brand & type	Number of masks	Sterilization method	0.3 µ % PFE (SD)	0.5 µ % PFE (SD)	1 µ % PFE (SD)	5 µ % PFE (SD)	Mean % PFE
3M 1862	5	H_2O_2 Sterrad	86,4 (12,5)	93,8 (6,2)	97,4 (2,7)	99,5 (0,5)	**94**
3M 1862	72	121 °C steam	93,6 (4,1)	97,3 (2,1)	99,0 (0,8)	99,7 (0,7)	**97**
3M 1862	4	2 x H_2O_2 Sterrad	41,3 (1,7)	66,9 (1,6)	83,9 (1,3)	99,5 (0,4)	**73**
3M 1862	8	2 x 121 °C steam	91,6 (3,2)	96,2 (1,8)	98,3 (0,8)	100 (0,1)	**97**
Kolmi OP-Air M52010	11	H_2O_2 Sterrad	89,8 (1,4)	96,4 (1,4)	98,4 (0,5)	99,8 (0,3)	**96**
Kolmi OP-Air M52010	15	121 °C steam	21,2 (6,8)	56,3 (8,5)	78,4 (8,2)	99,8 (0,5)	**64**

https://doi.org/10.1371/journal.pone.0257468.t002

The results indicate that 3M 1862 shows low PFE values after 2x H_2O_2 plasma processing and that Kolmi Op-Air shows low and inconsistent PFE values after 1x 121°C processing (Supplemental file 3).

Thermal properties of 3M Aura 1862+ and Kolmi Op-Air M52010 face masks using DSC

The three tests, differential scanning calorimetry (DSC), X-ray diffraction (XRD) and transform infrared spectroscopy (FTIR), confirmed that both masks consisted of 5 layers with the profile of Polypropylene (PP) material (Supplemental File 7).

Tests of new, imported masks

The PFE results of 471 different types of new, imported FFP2/KN95 face masks from collaborating hospitals and resellers are shown in Fig 5. Of these, 27 face masks scored above 98% PFE for the 0.3 micron particle size category. These masks were tested for breathability by measuring the pressure drop (Supplemental file 8). Fig 6 shows the breathing potential of the 27 face masks. The material of 27 face masks with high PFE values showed pressure drops between 251 and 3976 Pa on the measurement setup. When calculated for the total mask areas A and B, five out of 27 masks showed a total pressure drop higher than the EU standard of 0.7 mbar [18]. Finally, four masks showed readings at approximately 3.7 mbar, which is very close to the maximum measurable pressure drop of 4500 Pa. In two occasions the PFE data of the two tested masks of the same type deviated more than 10% (i.e. PFE of 67% vs 84% at 0.3 µm). Closer inspection revealed that the two masks had a different appearance as one had an additional logo in the shape of a heart.

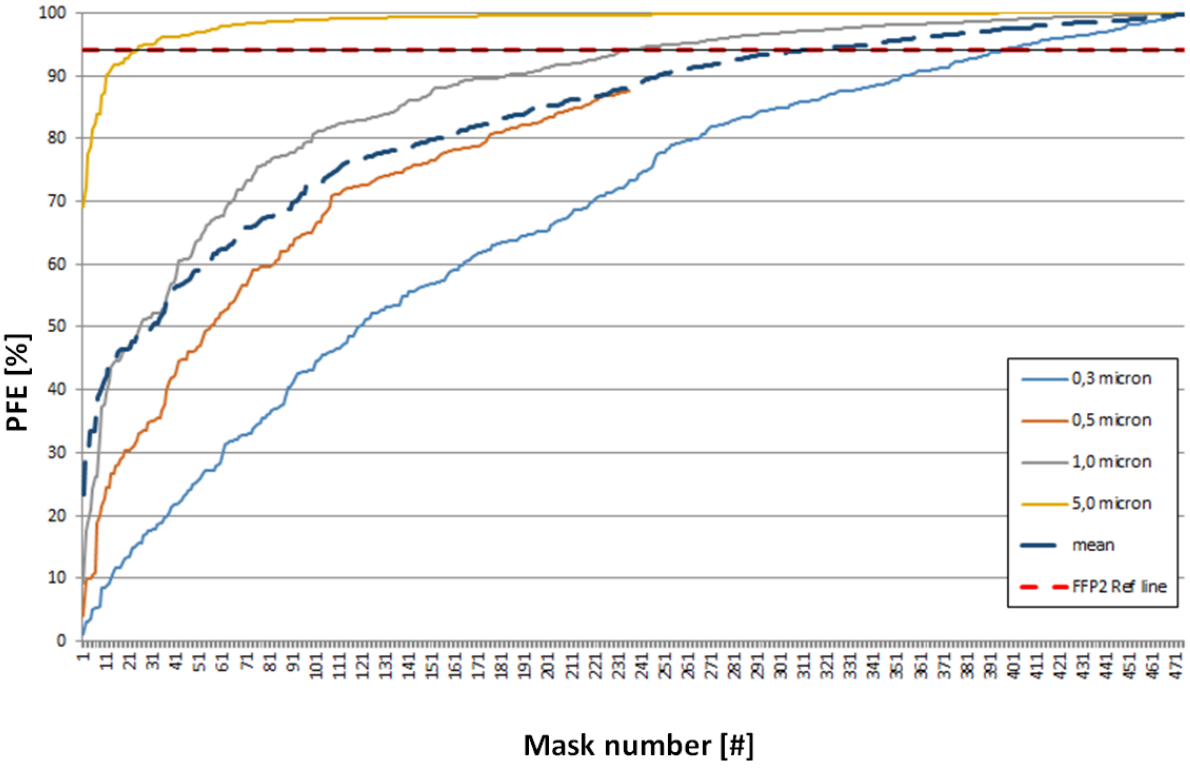

Fig 5. PFE values of new imported FFP2/KN95 face masks in order from worst to best. The red dotted line indicates the FFP2 level at 94% PFE. Each mask number represents a sample of a new batch from one type only.

https://doi.org/10.1371/journal.pone.0257468.g005

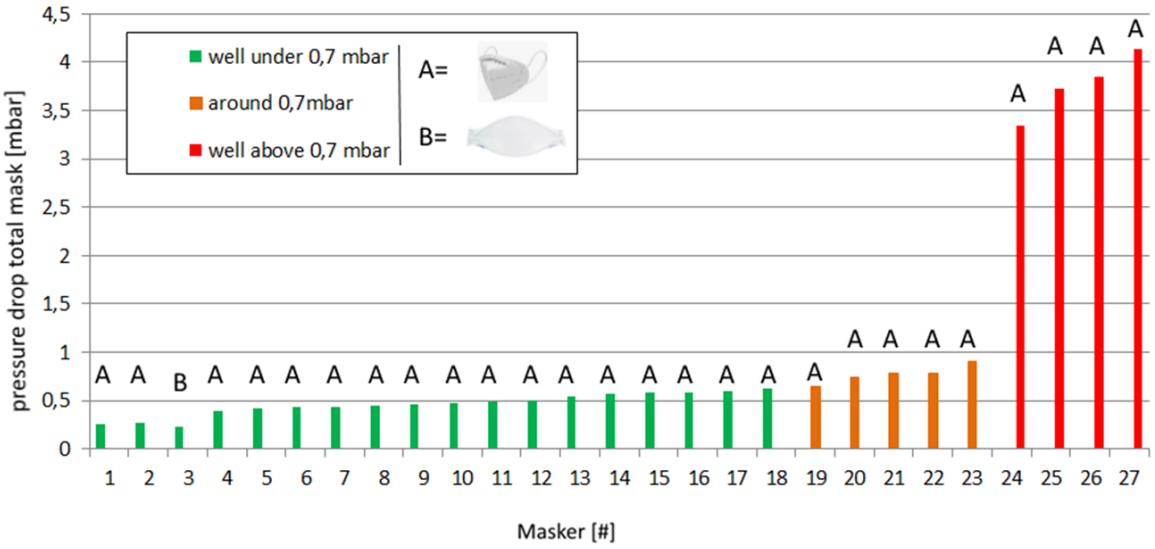

Fig 6. Pressure drop of 27 new face mass with PFE>0,7 mbar. Four masks performed really low (red), 5 performed around the EU norm of 0,7 mbar and 18 performed well according to the EU norm of 0,7 mbar.

https://doi.org/10.1371/journal.pone.0257468.g006

Discussion

Regarding the research questions, it can be confirmed that FFP2 masks can be safely reprocessed with 121°C steam sterilization if appropriate testing facilities are available. The data from Figs 3 and 5 indicate that reprocessed face masks can act as alternatives for new face masks as sterilization of well-known brand often gives better PFE results compared to newly imported masks. Although the base materials are similar, the manufacturing, preparation, and use of coatings have a large effect on the PFE of mainly the smaller particles.

The cross validation with the NaCl continuous flow setup built according to EN 13274–7 standard showed that the most important requirements for determining the filter material properties were met. After nineteen hospitals adopted the steam sterilization process, a nationwide data field experiment was initiated that informed multiple international NGOs, universities, and industry members about the advantages and disadvantages of sterilization of face masks [17–21], which led to a Dutch standard for sterilization of face masks. After the first results were shared by request [22], general practitioners, dental practices and pharmacies claimed to successfully adopt the 121°C sterilization process in their smaller sized autoclaves with sufficient results [16].

Sterilization with the purpose of reusing medical devices is often driven by cost savings [23]. However, some studies also report the reuse of medical devices to realize environmental benefits [24]. In this study, steam sterilization is used to prevent shortages. In 1986, a survey was conducted including Canadian hospitals reusing disposable medical devices [25]. Forty-one percent of the hospitals confirmed that they reused disposable medical devices, with respiratory therapy equipment as the most reused medical device.

Testing by particle counting seems to be essential for both new and sterilized single-use face masks as it indicates the quality of the mask in terms of filtration capacity. This became evident as our data revealed large differences in PFE despite the similar appearance of the mask material. Our results in S6 and S8 Files indicate the presence of coatings that improve the electrostatic behaviour of the mask. As the presence of these kinds of coatings is very difficult to demonstrate, it is advised to test the PFE with a particle counter at all times. To rule out that reprocessed and new face masks do not meet the stated FFP standard, a particle test as a ‘quick and dirty’ test could be applied on every batch, as the test method described in this study can give a quick indication of the quality.

As high quality FFP2 masks react differently to different sterilization methods, it is expected that the electrostatic charge of a mask has a major effect on the PFE especially for smaller lighter particles. Although not part of this study, it would be interesting to investigate how either 121°C sterilization or H2O2 plasma affects the mask’s electrostatic charges and how this is related to the fibre orientation, pore size and openings between the stacked layers.

Face masks sterilized with the intention of reuse could furthermore undergo a “fit test”. This test may be regarded as a fit validation conforming to a proper fit on the face without leakages around the mask. To assure a decreased risk of spreading other diseases, the bio efficacy of a face mask should also be considered. Tests regarding this aspect were conducted previously

and appeared negative for bacteria on steam-sterilized face masks that were tested at the dept. of Microbiology at Franciscus Hospital in the Netherlands [9].

Testing face masks for particles is important in the quality assurance of the sterilization process. Our data shows that despite the implementation of similar 121°C sterilization protocols, mean PFE outcomes can differ up to 6%. As the types of masks and sterilization methods are similar, the only unknown variable is the wearing/processing influence on the mask during use, transport and inspection. University Hospital 2 in Fig 4 seems to show much lower PFE outcomes. It could be that stretching and bending of the mask can influence the integrity. However, it is also expected that the confidence interval would have been larger as the intensity of the stretching and bending is human dependent. As the confidence interval of the mean PFE outcomes of University Hospital 2 seems similar or even smaller than those of other hospitals, it is advisable to perform validation tests at all hospitals.

In the CSSD at De Meern, a 10% tolerance was accepted for sterilized face masks after testing. Therefore, an 84% filtration capacity on a 0.3 μm particle level was the minimum limit. Although not based on any evidence in the literature, this percentage was considered to be sufficient with respect to the shortages of face masks, taking into consideration that the Coronavirus (SARS-CoV-2) is mainly spread through 0.3 μm or larger droplets. However, a consensus needs to be made to actually define the minimal allowable PFE values in times of crisis.

The DSC, XRD and FTIR test results in S6 File conducted on each of the five layers of the 3M Aura 1862+ and Kolmi op-Air M52010 masks reveal that all layers are made of the same Polypropylene material. The differences in behaviour when sterilized cannot be explained by chemical composition. A detailed interpretation of the results can be found in Supplemental file 9.

The data of 410 sterilized and 471 newly imported KN/N95 or FFP2 face masks reveal that, despite the differences in PFE between different sterilization processes, still approximately 75% of the face masks of known brands reach the FFP2 standard after sterilization when compared to only 50% of newly imported, less known brands. Our results suggest that the technology needed to manufacture a good mask is not easy. Manufacturing and quality assurance should be monitored and controlled by the government. During the study period, it was observed two times that within a single batch of imported face masks, the quality and layout of the masks were different, despite being wrapped in the same packaging with the same printed PFE standard. This suggests that multiple factories were supplying to one brand. In other cases, some masks (Fig 6) showed almost complete lack of air penetration due to the use of wrong materials or manufacturing processes.

Although our results indicate that sterilized face masks can be used if the filter material can be properly tested, it might be considered that wearing a used mask can have a psychological impact on healthcare workers. To overcome this issue, masks could be marked with the user's initials so that it can be returned to the same person.

Study limitations

It is of utmost importance that the reprocessing of single-use PPE, as described in this study, is equivalent to existing standards. Each deviation or omission of such standards needs a clear demonstrated equivalence with the applying standards. In our setup, only environmentally dry particles were used in the developed rapid test setup. Although we validated the dry particle setup with an aerosol testing setup (NaCl test, paraffin oil setup) according to the EN 13274–7 standard, it was only possible to compare the PFE for a limited range of particle sizes. Therefore, in-depth knowledge about the PFE related to particle size was not generated. To identify other potential differences between the dry particle and continuous flow setups, a 'gap' analysis should be conducted. Other than testing the basic material of the filter layers, we were not able to indicate the presence of surface active coatings. Therefore, it was not possible to investigate the role of surface active coatings on the melting or oxidation of the fibres. Although the study used a validated reprocessing method based on 121°C sterilization to inactivate the virus in the mask, the retention of the inactivated virus has not been studied and should be investigated further in future studies.

Conclusions

Sterilization of disposable face masks by means of standardized steam sterilization at 121°C could be an alternative during face mask shortages due to COVID-19 as long as the fit does not change and the filter materials are not significantly affected by heat. The varying efficiency after reprocessing amongst different brands shows that only quality masks of particular brands such as 3M Aura 1862, 3M Aura 1873 and My-T-Gear 301 are suitable for limited reuse. The data show that the 121°C sterilization process can be safely implemented as long as proper testing of each batch is possible and the process and logistics is well controlled. The new PFE testing method proved to be accurate enough to determine degeneration of the mask material after sterilization and to determine the material quality of imported face masks. FTIR, XRD and DSC measurements indicate that all layers from both masks are made from Polypropylene. Future testing is needed to determine if differences in PFE outcomes after sterilization with 121 °C steam or H2O2 plasma can be explained by the level of crystallinity, or by the orientation and dimensions of the fibres and potential proprietary treatment in the layers of the face mask. PFE comparison between sterilized masks and imported face masks with varying filter qualities indicates that health care professionals in some cases can better reuse a known reprocessed brand rather than an imported face mask from a reseller with an unknown brand.

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Chapter 3

Based on the article as published in Sustainable Production and Consumption in July 2021

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A Circular Healthcare Economy; a feasibility study to reduce surgical stainless steel waste. Sustainable Production and Consumption, 27, 169-175.

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A Circular Healthcare Economy; a feasibility study

Abstract

The Circular Economy faces a growing interest. The aim of this study is to determine the feasibility of a circular approach towards reusing discarded hospital instruments and stainless steel waste. Secondary, this study aims to identify if any cost savings can be realized by following a circular instrument repair and recycling approach.

During 6 months SS waste from three hospitals was collected. Both repair as well as recycling possibilities were evaluated by analyzing the waste composition and by calculating the percentage of SS that could be recovered and turned into raw material. Cost savings were calculated for three categories: (1) extending the life cycle of instruments by repair instead of disposal, (2) recycling of instruments by means of melting it into raw material, and (3) savings on waste handling costs.

A total of 1,380 kg instrument waste was collected of which 237 kg was refurbished and returned to the hospitals for being put in use, resulting in savings of € 38,868 (1). Of the 1,143 kg SS instruments, sheet material was made to manufacture components for new instrument baskets. The SS revenues of € 1,040 were sufficient, covering logistical and disinfection costs (2). The hospital savings on waste costs were € 316 (3). The total gain for the hospitals were € 39,184.

These results indicate that circularity as a sustainable model could provide a basis for a new approach in surgical waste management, realizing cost savings and environmental benefits on the long run.

1. Introduction

Since health care waste has a negative impact on the environment, medical personnel should take environmental costs as a result of health care into consideration and focus on how to reduce material and energy consumption (Jameton et al., 2001). The use of resources, materials and energy in healthcare have been growing tremendously over the years. Literature has been increasingly reporting the adverse effects on human health as a result of declining environmental conditions and generated waste (Jameton et al., 2001; Leaf, 1990; McMichael, 1993; Haines et al, 2000; Solomon GM and Schettler, 2000; Chivian, 2001).

The global growth of healthcare waste has not only been the result of the growth of the population. Also the number and size of hospitals and growing use of disposable products contributed significantly (Mohee, 2005). Literature described a variety of classifications of health care waste. However, during the recent years studies identified two streams of health care waste: hazardous (mostly infectious waste) and non-hazardous (municipal solid waste) fractions (Minoglou et al, 2017). Non-hazardous waste streams from health care institutions form up to 80% of the total health care waste stream (WHO, 2016).

Several studies showed waste production in hospitals ranging from 0.5 to 2.0 kg per bed per day (Madhukumar & Ramesh, 2012) to 4.89 to 5.4 kg per patient per day depending on the size of the hospital and the activities (Hamoda et al, 2005).

A study conducted in 2010 with collected data from 12 hospitals ranged from 0.25 to 2.77 kg bed per day (Sanida et al, 2010) where Kane reported in 2017 numbers rising from 0.44 kg per patient per day in the republic of Mauritius to 8.4 kg in the US (Kane et al, 2017) with European countries resulting around 3.3 to 3.6 kg per patient per day. Approximately 5.9 million tons of hazardous (15%) and non-hazardous medical waste is disposed in the USA by hospitals every year (85%) (Yazdani et al, 2020). The production of carbon dioxide emissions as a result of this equals 8% (Voudrias, 2018).

Medical instruments being part of hospital waste can be considered as both hazardous and non-hazardous waste streams. Disposable instruments intended for single-use are part of hazardous waste streams and reusable instruments part of non-hazardous waste as they are disinfected and sterilized each time after use. Typically and according to hospital procedures, reusable instruments need to be disinfected first after which they are examined in the CSSD and sterilized thereafter. Hospital instruments are highly critical products since they are required for carrying out surgical procedures. This paper examines the feasibility of reusing medical instruments extracted out of the waste streams from a perspective of the Circular Economy.

The Circular Economy faces a growing interest around the globe as it may generate economic benefits to society (Van Berkel et al, 2019). Already in 2014 the World Economic Forum (World Economic Forum., 2014), reported potential benefits of the Circular Economy regarding the use of less energy and material inputs. Although there are many definitions, the Circular Economy may be best described as being an economic system in which waste is prevented, minimized or even completely reused (Geissdoerfer et al, 2017). Circularity may therefore be considered as an economic model in which, amongst other aspects, waste is being reused again and again.

However, the Circular Economy also requires other aspects than the reuse of waste only. These are e.g., the circular (re) design of products, the use of specific materials, recycling, reselling, repurposing, repair, refurbishment and remanufacturing. These aspects have the objective to prevent the generation of waste and to drastically limit the use of natural resources. The Ellen MacArthur Foundation defined the Circular Economy as “an industrial economy that is restorative or regenerative by intention and design” (MacArthur, 2013). Being restorative by means of circulating resources into the economic system is in contrast to a linear economy which is based on a 'take, make, dispose' model of consumption patterns (World Economic Forum., 2014). The linear economy uses raw material on a single-use basis resulting in putting pressure on the earth's natural resources.

McGain reported in 2010 that in healthcare the use of pharmaceutical materials and medical devices resulted in higher carbon dioxide emissions as compared to the energy consumption and transport together (McGain et al, 2010). McGain also showed that the use of disposables in the medical field have been growing significantly and that the decision to purchase a medical product did often not include environmental impact considerations. As hospitals lose a lot of money by following traditional ways of dealing with Stainless steel waste, the aim of this study was to determine the feasibility of a circular approach towards reusing hospital instrument waste, in particular surplus Stainless Steel instruments and other stainless steel waste. With this study we want to demonstrate the viability of reprocessing surgical instruments as a circular process which may positively contribute to waste prevention, cost savings and environmental impact.

For this study the following research question was formulated:

“Can cost savings be realized when using repair, refurbishing, recycling as methods to reach a concept of closing the circular loop in a hospital environment?”

Most of the discarded instruments and stainless steel (SS) medical waste contain valuable materials that can be reused; having good resistance against corrosion or having titanium alloys and even ceramic and polymeric materials (Mainier and Fernando., 2013). Surgical instruments are typically manufactured out of SS. This material represents iron (Fe)-based alloys containing a percentage of Chromium (Cr) and Nickel (Ni). Furthermore, it typically contains alloying elements such as Molybdenum (Mo), manganese, carbon, nitrogen (N), phosphorus, sulfur, and silicon (Weihong and Paul, 2019). SS has mechanical properties and corrosion resistance which can be enhanced when alloying with Chromium (Cr), Nickel (Ni), Molybdenum (Mo), and nitrogen. Most often SS316 is used for surgical instruments and SS304

for instruments and instrument related accessories such as instrument mesh baskets and stainless steel disposable products. Surgical instruments in general are manufactured out of SS316 and SS304 according to DIN EN ISO 7153-1 (Pezzato et al, 2016).

Both types of SS that are often used within the Operating Room are recyclable by means of melting and reprocessing. According to the Australian Stainless Steel Association (ASSA), SS offers good prospects for recycling (ASSDA, 2019). They state that SS's long service life, 100 percent recyclability and its valuable raw materials make it an excellent environmental performer. Moreover, the ASSA indicates that SS contains valuable raw materials like Cr and Ni which makes recycling SS economically viable (Broadbent, 2016). SS is actively recycled on a large scale whereby it involves re-melting scrap to manufacture new steels without changing the properties of the material, resulting in a closed loop. (recycled SS) (Broadbent, 2016). SS objects should never become waste at the end of their useful life. Instead, recycled SS objects should be systematically separated and recovered and lead back into the production process through recycling.

To demonstrate this feasibility, an experiment was initiated focusing on prevention of SS waste by a combination of repair of the discarded instruments and melting SS waste into new raw materials when they could not be repaired anymore. Three Dutch hospitals, including Westeinde Ziekenhuis, Bronovo in The Hague, Maasstad Hospital in Rotterdam and Amsterdam University Medical Center, location VUmc in Amsterdam, participated to determine the feasibility of this research in a small scale experimental set-up.

2. Methods

During a period of nearly 6 months between 25 September 2018 – 12 February 2019, discarded reusable as well as disposable instruments and SS waste from the Operation Room (OR) of the affiliated hospitals was collected. The waste collection and handling was managed by a Dutch medical supplying and instrument repair company named Van Straten Medical (VSM, De Meern-Utrecht, The Netherlands).

Most instruments were disinfected through standardized disinfection programs at 90°C in disinfectors at the supplying hospital site, except the disposable instruments from Bronovo Hospital, these were disinfected at VSM. After the transport bins were filled, the hospitals contacted VSM and the waste was collected and brought to the storage containers at VSM. In a first step, the waste composition was analyzed by instrument technicians and divided into SS instruments that could be recovered/repaired, and SS that could be recycled and turned into new raw SS material. The collected SS material was separated by indication of material and use (e.g. SS304 used for trays or baskets and SS316 for surgical instruments) in two different containers. In case of doubts a strong Neodium magnet was used for identification as both material types have different attraction to a magnetic field.

The metal recycling company collected the recyclable SS material at VSM when the containers were full and had the materials melted into new sheet metal. The sheet material was acquired from the same metal recycling company that collected the material from VSM and used to manufacture components for instrument mesh baskets and for SS components used in instrument fixation. The sheet metal plates were processed on a water jet cutting machine to

cut components for surgical instrument mesh baskets and components for instrument mesh basket instrument fixation. The leftover machining material was returned to the circular container to be picked up for melting. In this way no material waste would be generated during the process.

The hospital costs with respect to waste disposal varies per hospital and per contract the hospital negotiates with the waste processing company. The costs for waste removal at the hospitals consists out of a price per kg waste removal and costs for using additional accessories such as costs charged for special waste containers, additional transportation costs and other associated and handling costs. Also costs such as electricity, costs for overhead and logistical costs were calculated for the period of this study. The costs for electricity were based on an allocation of the electricity which was assigned to the area where the waste was stored as well as the area for refurbishment of the instruments and part of the overhead associated with the reprocessing of the waste. The stainless steel revenues however is dependent upon the applicable market price for SS.

The routing, disinfection, refurbishment and transport costs were based on the costs as made by VSM. All handling and storage costs, employee costs and process handling fees were calculated over the period and extrapolated over the total amount of collected waste in this study.

In this study we concentrated on three main cost cycles associated with stainless steel waste:

(1) Non-contaminated instruments collected which could be refurbished/repaired. Both the average repair price as well as the price for a new instrument were calculated over all instrument used in the hospitals.

(2) Recycling of contaminated and non-contaminated SS instruments which could not be repaired.

(3) Saving of direct cost for waste handling, because less waste is produced. In general the hospital costs for waste disposal can be divided into two categories: general waste and contaminated waste. Both categories are charged differently by the waste processing companies. The costs are invoiced with build-up expenses per tons of waste, added with rental charges of waste containers, cassettes, handling fee and other expenses.

The numbers to calculate the costs depend on the amount of waste in the specific categories. These results are provided in the results section. To prevent repetition, the method to calculate the costs are therefore provided in the results as well. For ease of calculations, all costs were related to units equivalent to 1,000 kg (ton).

3. Results

A total of 1,380 kg waste was collected from the three participating hospitals. The waste consisted of instruments used for basic surgery like scissors and bone cutters, but also instruments for more specialized surgery such as catheter intervention or minimally invasive surgery (Figure 1). Furthermore, mesh baskets, wire baskets and stainless strays were identified. The first inspection showed that 20 % of the waste consisted of instruments that

were in good enough condition to be repaired. The remaining discarded instruments consisted of older model instruments that were taken out of rotation or instruments that showed corrosion, color changes, partial loosening of its surface layer or pitting.

Fig. 1. Left: Two carts filled with mesh baskets filled with instruments from Maasstad Hospital Right: Circular bin with discarded instruments at Van Straten Medical.

From the 1,380 kg, 50 kg consisted of disposable SS instruments which were collected separately in a closed container. 1,330 kg was found to be surplus SS instruments and surplus mesh baskets (Table 1) of which 20%, approximately 266 kg, seemed to be a potential for refurbishment, pending on final inspection during repair of the instruments. All stainless steel waste, consisting of SS316 and SS304 was melted and recycled into sheet material. The total amount of waste per hospital category are provided in Table 2. The distribution over type of waste (refurbished and recycled) per hospital is provided in Table 3.

Table 1. Collected instruments.

Collected	**Material specification**	**Collected weight (kg)**
Reusable instruments and mesh baskets	Mixed SS304/SS316	1,330
Disposable instruments	SS304	50
Total		**1,380**

Table 2. Collected waste types and distribution per hospital category.

Hospital	Type of hospital	Type of waste	Waste collected (kg)
Maasstad Hospital, Rotterdam	Large peripheral	SS baskets, containers, discarded instruments	717
Haaglanden MC, The Hague	Merged hospital consisting of Westeinde, Bronovo & Antoniushove	SS baskets, discarded instruments, used disposable instruments	209
AUMC, loc. VUmc, Amsterdam	Academic Hospital	SS instruments, baskets	454
Total			**1,380**

Table 3. Circular processed waste.

	Collected (kg)	Refurbished (kg)	Recycled mixed (kg) SS 304/316	Disinfected & Recycled (kg) SS 304
Maasstad	717	71	646	
Haaglanden MC	209	120	39	50
VUmc	454	46	408	
Total	**1,380**	**237**	**1,093**	**50**

A total of 945 instruments were refurbished into new manufacturing's condition. For Maasstad the number of instruments were 282 instruments, for Haaglanden MC 478 instruments and for VUmc 185 instruments. The average weight per instrument was 251 g, totalling 237 kg.

3.1. Costs Calculations

An overview of the costs and savings per kg and per 1,000 kg used in the calculations of costs are provided in Table 4. Shipments were made with a total of 237 kg resulting in an average price of 0.10 €/kg for logistics and transport for Haaglanden Medical Center (HMC) consisting of Westeinde, Bronovo, Antoniushove as well as for VUmc and Maasstad hospital in the study period. These costs were based on a standardized transport pallet price of €50/pallet, independent from the distance in The Netherlands and having an average weight of 500 kg per transport (company, location, date). Although in this pilot study the collected SS waste was in smaller portions, we expect that threshold waste volumes can be easily reached, therefore, the calculations were conducted with the standard transport pallet prices.

Table 4. Conversion of costs and savings for VSM per 1 kg and per 1.000 kg.

Costs	**(€/kg)**	**(€ per 1,000 kg)**
Transportation costs	0.10	100
Collection bins	0.07	70
Handling costs	0.01	10
Disinfection costs	0.15	150
Overhead costs	0.01	10
Total logistical costs	**0.34**	**339**
Savings		
Steel revenue	**0.91**	**910**

The costs of the transport bins in which the instruments and other stainless steel waste were disposed, was calculated on € 25/bin based on its purchasing cost price including other minor costs such as stickers and paper work. For the three hospitals amounting to € 100 which was divided over the total collected batch of 1,380 kg, resulting in € 0.07/kg. The costs for disinfection of contaminated instruments were calculated at € 0.15/kg. The handling costs as well as the overhead (incl. storage) costs at the supplier, Van Straten Medical (VSM), were calculated to be € 10/ton each, consisting of overhead costs calculated to be € 7/ton and allocated electricity and employee costs of € 3/ton.

3.2. Savings by repairing instruments

A total of 237 kg resulted in refurbished instruments. The savings were calculated as compared as shown in Table 5 to replacing them with new instruments. The average costs of refurbishment were € 39 per 250 g. The average sales price of a new instrument of € 80,- was based on the average sales price of a total of 16,912 SS instruments offered by VSM in the market. The average costs price of a new instrument is € 80 resulting in savings of € 41 per instrument equalling 250 g resulting in savings of € 164 per kg. SS prices, prices of refurbishing instruments, price fluctuations of new instruments and possible extra costs may vary per hospital and per country, resulting in potential variations in net gains for hospitals. Both the costs as well as the savings of the 50 kg disposable instruments from Bronovo hospital were higher as this concerned contaminated disposable instruments. These instruments had to be disinfected at VSM, costing 0.15 €/kg. The savings on Bronovo hospital were higher as it resulted in preventing higher medical waste costs of 1 €/kg.

Table 5. Total savings and savings per kg obtained by refurbishment/ repair.

	Refurbished instruments (kg)	Savings from refurbished per instrument kg (€)	Savings from refurbished instruments as compared to new (€)
Maasstad	71	164	11,644
Haaglanden MC	120	164	19,680
VUmc	46	164	7,544
Total	**237**		**38,868**

3.3. Costs for recycling

A total of 1,143 kg mixed SS 304 and SS 316 were collected by a metal recycling company Independent of the grade, an average price of 0.91 €/kg, as calculated from the credit invoices, was paid by the collecting metal recycling company, resulting in a revenue of € 1,040 for VSM.

3.4. Direct hospital savings costs on waste handling

To establish a cost prize for hospital savings on waste, the waste disposal invoices of the affiliated hospital were averaged resulting in € 0.20 per kg general waste and € 1,- per kg contaminated waste. These cost prize indications include all expenses made by the waste processors. Other related costs which were taken into account were transport costs for collecting the waste and costs of transport bins in which the hospitals deposited their discarded instruments and SS waste as well as cleaning and disinfection costs for contaminated waste and handling, storage and overhead costs.

An overview of the savings from refurbished instruments, reduced waste cost and per hospital is provided in Table 6. More details of the calculations and obtained data can be found in Supplemental file 14.

Table 6. Net gain for the participating hospitals.

	Direct hospital savings on waste costs (€)	Savings from refurbished instruments as compared to new (€)	Total gain for hospitals (€)
Maasstad	143	11,644	11,787
Haaglanden MC	82	19,680	19,762
VUmc	91	7,544	7,635
Total	**316**	**38,868**	**39,184**

4. Discussion

The environmental quality may be improved while handling the SS waste. Healthcare waste demonstrated to have a negative impact on the environment which may be reduced by including handling SS waste in a circular way (Viani et al, 2016). Environmental impacts have grown as a result of the use of disposable instruments including stainless steel disposables (Ibbotson et al, 2013). Furthermore, literature has been increasingly reporting the negative effects of medical waste (McGain et al. – 2010). This study examined the feasibility of collecting hospital ss waste, processing it circularly by means of refurbishment or recycling of the material in order to prevent it to become landfill- or incinerated waste. In some countries the ratio of used disposable instruments may vary between plastics and ss versions. The ss instruments which are used in the Netherlands were used as basis for this study and included needle holders, scissors, tweezers, and instruments part of suture sets. In certain studies waste was related to kg per bed or patient (Madhukumar & Ramesh, 2012), (Hamoda et al, 2005), (Sanida et al, 2010), (Kane et al, 2017). However, in our study waste was calculated in kg collected directly from the Operating Rooms or CSSD. Therefore, it is needed to know the number of beds of patients in each hospital for qualitative comparison.

The instrument repair demonstrated that both instruments for general surgery as well as instruments for specialized surgery could be repaired and brought back into circulation. The savings in the refurbishment or repair category were the highest as compared to the other two categories of recycling and waste disposal. The inspection before repair showed that the quality of instruments and its basic materials are of great importance for increasing the life span and therefore, contributing to preventing an instrument being discarded in earlier phase. It should be considered by the hospital buyers that factors such as resistance against pitting and crevice corrosion have an influence on the longevity of the instruments and therefore, on the amount of waste in a certain time period. The costs associated with repair and refurbishment were 49% of the average purchase costs.

Instrument with circular and sustainable designs such as the new modular instruments developed for advanced endoscopic surgery seem to be more sustainable in terms of cost-reduction due to a reduction in repair time (Hardon, 2019). These type of instruments can have a major contribution to surgical circularity as they include in their design, detachable parts which can be replaced in case of malfunctioning.

Due to the complexity of financial flows in hospitals and vulnerability of these flows, especially for teaching hospitals (Liu et al, 2011), it proofed difficult to calculate the exact cost prices of each procedure as well as the exact costs of waste disposal. Differences in Total Cost of Ownership and economic advantages of circular reuse of materials or reusable instruments versus disposable instruments are based on assumptions and need to be studied further. This study used the unit kg/bed/patient and related to the SS instruments' waste cane be measured in-terms of kg/bed/patient

Comparative calculations where reusable instruments are compared to disposable instruments often equal to sterilization costs versus purchase costs of disposable instruments. Advantages such as longevity of the reusable products are often neglected during these

calculations (McGain et al. 2010). McGain argues that “a cause of a trend of using the disposable or single-use products which continues to increase as they are supposedly a more cost-effective option. Many single-use products replaced the conventional long-lasting SS products for daily hospital practices. Subsequently, the environmental consideration is increasingly gauged into one of the criteria of the consumer purchasing decisions due to the rising concerns in resource scarcity, human health and quality of ecosystem”. Since purchasing decisions are complex regarding this matter, knowledge on circular public procurement aspects may improve these decisions (Sönnichsen and Clement, 2019). It will be a challenge to make balanced choices, based on costs comparisons which incorporate all costs. These costs need to include increase of costs due to the price increases of extracting natural resources and converting them into raw materials, increasing shipment and delivery costs, packaging, sharpening medical (MDR) regulations, environmental costs and ecological impacts. Taking these into account, the reuse of waste and materials can have a major positive impact (Herrmann et al, 2015). Circular projects such as this study experienced great enthusiasm among hospital staff and provided insights in the potential reusability of surgical waste.

Although the total of received SS revenues were sufficient to cover the costs for bins, logistical and disinfection costs for VSM, further optimization of the process is needed in order to decrease the costs and to create a sustainable business model.

The cost price to collect and process stainless steel waste was 0.17 € / kg. Compared with the revenues ranging from 164 €/kg repairable clean SS material to € 0.93 / kg for clean SS waste and € 1.42/ kg for contaminated SS. It was therefore, demonstrated that this step in circular instrument management is feasible and even profitable.

4.1. Suggestions for further work

Viani (Viani et al, 2016) reported in 2016 recovering value from used medical instruments however, the reuse and reprocessing of disposable medical devices, faces international issues and difficulties as well as demanding ethical considerations, high standards of reprocessing and factors such as regulations, clinical challenges regarding safety and sterility (Popp et al, 2010).

Further research in recycling, refurbishment, remanufacturing, and reuse of surgical products with a focus on energy consumption during the melting process and CO2 footprint is needed to understand the true impact of this type of circular instrument management. For this a Life Cycle Analysis (LCA) could be conducted. Although out of the scope of this study, such a LCA can be used to quantify the environmental impacts of the different phases in instrument repair, refurbishment, remanufacturing and recycling of SS waste. Such Assessment of environmental impact can be made according to standards such as ISO 14040 and ISO 14044 (ISO/ FDIS, “ISO 14044 2006, ISO/FDIS, “ISO 14040 2006).

Furthermore, focusing on a design for the circular economy, including aspects such as design for recycling as well as design for disassembly, contribute to realizing product sustainability (Kane et al, 2017). Studying the applied materials, their recycling rates and transforming these into new medical devices may contribute to material life extension. These studies should

further identify which alternative processing steps could reduce the energy consumption, processing and transport times and thus CO2 footprint associated with hospital waste when circular reprocessed. These study findings may be incorporated into business modelling methods contributing to an increase of sustainability as they still hardly focus upon (Guzzo, 2019). As a result, the research outcome may lead to successful Circular business models in healthcare which are defined as sustainable business models typically focussing on Circular Economy aspects (Geissdoerfer et al, 2018).

Our results indicate that hospital cost savings can be realized as a result of lower instrument repair as compared to higher instrument replacement costs and by minimizing waste costs.

4.2. Limitations

Although there seem no major fluctuations in waste production during a year which could not be accounted for during the six-month period of this study, however there might be fluctuations as a result of expanding or decreasing variations in number of surgical procedures. The results of this study are based on the six-month period which might differ when assessing longer period.

This study emphasizes on repair and recycling of medical instruments as selected R strategies. However, when a new component was needed such as a screw the R strategy changes towards remanufacturing of the instrument. To include this type of events, a framework such as described by Morseletto (Morseletto, 2020) can be used to define these activities as circular economy strategies as it includes refuse, rethink, reduce, reuse, repair, refurbish, remanufacture, repurpose, recycle and recover as different R strategies. Although we divided stainless steel waste into 304 and 316, it can be interesting to conduct a contribution/sensitivity analysis for deeper understanding of the type of material waste and how it is liked to different surgical disciplines including possible cost fluctuations.

5. Conclusion

The results of this circular pilot project conducted with 3 hospitals indicated thAt circular reprocessing of SS waste into new raw material and (re) manufacturing of new medical devices from SS hospital waste is feasible. Furthermore, circular reprocessing not only contributes to waste prevention but also saves costs related to contaminated and non-contaminated hospital waste disposal. From the 3 main waste reprocessing methods (repair/refurbishment, recycling and hospital waste disposal), the repair and refurbishment of surgical instruments, instead of replacing with new instruments, show to have the most potential in terms of cost reduction.

Finally, we demonstrated that circularity as a sustainable model could provide a basis for a new approach in surgical instrument and waste management having cost savings and environmental benefits on the long run.

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Part II

Chapter 4

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Surgical waste reprocessing: Injection molding using recycled blue wrapping paper from the operating room

Abstract

Introduction

Hospitals in the Netherlands generate approximately 1.3 million kg of waste from the polypropylene (PP) wrapping paper (WP) used to wrap surgical instruments each year. The aim of this study was to develop a method to recycle WP waste into new medical devices.

Methods

WP was recovered from Maasstad Hospital, Netherlands. The WP was melted into bars, granulated, and mixed with virgin material at different ratios and temperatures. Dog bones were injection-molded from volume (v.%) virgin, mixed (%R), and recycled (100%R) granulate, and a tensile testing machine was used to compare the material properties before and after ten disinfection cycles at the sterilization department. Then, 25 instrument openers were made from the 50%R material and circulated for four weeks.

Results

The data indicated no significant differences in the mechanical properties at different melting temperatures. For dog bones made from the 100%R, 50%R, and virgin granulate, the Young's moduli were 1021 (SD13), 879 (SD13), and 795 (SD14) MPa, and the strains were 8%, 12%, and 14%. Ten disinfection cycles did not significantly change the material properties. After one month, the openers did not show any deterioration or damage other than surface scratches.

Discussion

The results indicated that the initial WP melting temperature did not influence the mechanical properties. Although devices could be produced directly from the recycled WP granulate, increasing the recycled granulate in the mix ratio increased the strength and brittleness.

Conclusions

It is feasible to recycle WP waste into a high-quality raw material for the injection molding of medical devices without using additives. This would allow hospitals to become more compliant with the circular economy enabling economically viable and circular processes that positively contribute to cleaner technical processes, sustainable products, and the reduction of medical waste.

1. Introduction

Urban mining is the process of harvesting materials directly from used products, buildings, or waste, as opposed to geological mining, where virgin materials are extracted from ore that is mined from the earth. The objective of urban mining is to decrease the high environmental impact caused by the extraction and processing of virgin materials in local urban areas (Muller et al., 2019).

Because a hospital is seen as an urban environment, the recovery and recycling of operating room (OR) waste into raw materials is considered to be urban mining (Zhu and Xuan, 2014). From the perspective of urban mining, hospitals could be a good source for raw material extraction because many of the supplies used in hospitals are often made from high-quality materials and are single-use items.

Interest in the reuse or recycling of medical waste is growing globally (Van Straten et al., 2020; Pinjing et al., 2013). There are several motivations for reducing medical waste. First, it may contribute to a decrease in the dependency on natural resources and an increase in the availability of medical products in times of scarcity. Several studies have revealed the benefits of reprocessing medical products in times of scarcity (De Man et al., 2020), as well as using alternative materials (Teesing et al., 2020) and reusing filtering facepiece respirators (Harskamp et al., 2020). Second, there are arguments that waste decreasing and recycling activities may not only have environmental benefits but also generate potential financial gains for hospitals (Van Straten et al., 2020; Voudrias, 2018). Third, medical waste has a negative impact on public health, as well as on the environment. It appears that the public does not sufficiently understand medical waste management (Yong et al., 2009), and hospitals seem to manage their medical waste in different ways (Bokhoree et al., 2014) where protective measures should be taken (Zhang et al., 2013). Medical waste is not only a potential threat to employees and patients, but also to surrounding communities (Mesfin et al., 2020). Therefore, medical waste remains problematic (Çetinkaya et al., 2020). Because medical waste can spread diseases (Irianti and Sri, 2013), there is a need to switch to sustainable alternatives (Patricio Silva et al., 2020). It is important to decrease the volume of medical waste to reduce these hazardous effects. Some studies have reported an increase in medical and plastic waste of up to 30% as a result of the Covid-19 pandemic (Patricio Silva et al., 2020; Sutrisno et al., 2020).

As the volume of medical waste has grown (Razali et al., 2010; Manga et al., 2011; Haque et al., 2020), so has the public concern regarding the disposal of this waste (Pullishery et al., 2016; Chudasama et al., 2014). Awareness among hospital staff is highly important and needed (Pinto et al., 2014), especially in the case of sharp medical waste (Ghodrat et al., 2017). In addition to public concerns, because of increasing waste disposal costs, decreasing medical waste could potentially lead to hospital cost savings (Van Straten et al., 2020; Berwick et al., 2012), which could be substantial (Zimmer et al., 2008). Earlier studies reported the possibility of recycling medical materials such as blue (and green) wrapping paper (WP), which is used to pack surgical instrument trays after sterilization to enable transport and storage (Voudrias, 2018; Babu, 2018). The OR is considered to be a large contributor to medical waste (Chang et al., 2020; Stall et al., 2013), which includes wasted energy, water (Wormer et al., 2013), and

solid materials (Shinn et al., 2017), and in some cases, it is the largest contributor to the total waste of a hospital (Rigante et al., 2017; Albert et al., 2015). Approximately 30% of all hospital waste is plastic, 30% is cardboard and paper (Lee et al., 2002), and approximately 20% comes from ORs.

The use of WP seems to be a large contributor to waste production because it is used in every type of surgical procedure. WP is used to wrap an instrument tray with surgical instruments. The WP forms a sterile barrier around the tray, allowing the instruments to remain sterile.

WP is made from non-woven polypropylene (PP), which is a thermoplastic polymer, and has a high recycling potential [8]. PP is widely used in many products and is found in many industrial applications (Ajorloo et al., 2020). The automotive sector is a large user of PP-based composites because of their suitable mechanical properties such as their low density and chemical resistance (Wang et al., 2019).

Two aspects should be considered when recycling medical grade PP.

1) Additives: The polymeric materials used in injection molding may be combined with additives, fillers, and/or reinforcements to improve the mechanical properties and color of the polymer or to reduce costs (Suplicz et al., 2020). Reinforcements can be used to enhance the strength or rigidity of plastics by mixing the polymer materials with additives or fillers. These materials such as glass fibers are used to create mechanical bonding between the fibers and the polymer matrix. Other additives and fillers help to create a specific melt flow index; however, the addition of these additives can modify the mechanical behavior of the recycled PP (Jmal et al., 2018).

2) Material degradation: The other aspect is the potential degradation of the recycled material. Several studies have reported changes in the material properties as a result of recycling. The elastic modulus and complex viscosity of recycled PP may decrease with the number of reprocessing cycles. Several studies have shown that recycling at high temperatures can lead to thermo-mechanical degradation (Wang et al., 2019; Spicker et al., 2019). Moreover, it has been reported that during recycling, the material properties of PP change as a result of chain scission and an increase in crystallinity (Aurrekoetxea et al., 2001; Hyie et al., 2020).

Although several studies have focused on the recycling of PP (Aurrekoetxea et al., 2001; Hyie et al., 2020), no studies have been conducted on recycling WP waste from the OR into injection-molded products without using additives.

The main objective of this work was to experimentally determine if a standardized approach is possible for the collection, melting, and granulating of WP waste for use in injection molding to produce new medical products. These products are then used in a hospital, creating a circular loop as shown in Fig. 1.

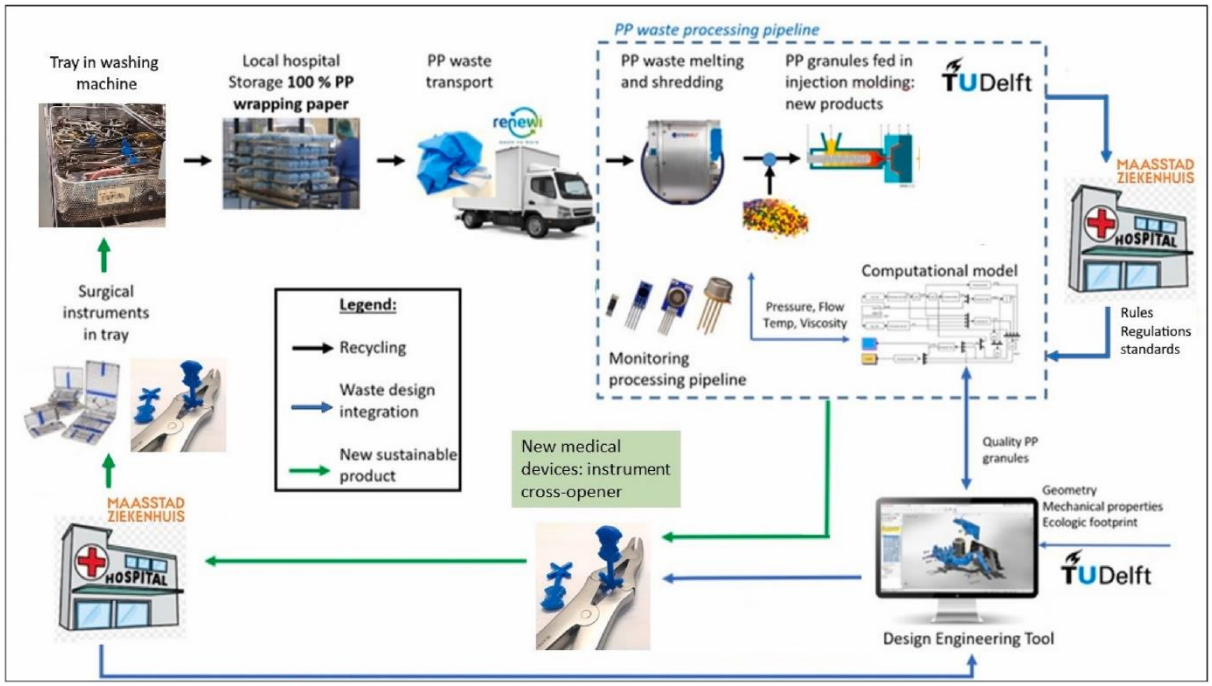

Fig. 1. Potential approach to centralized reprocessing line allowing hospitals to reprocess their waste into new reusable products.

To investigate the versatility of PP WP waste, it was necessary to determine and compare the mechanical properties of the molded WP waste material when mixed with virgin materials, as this is commonly seen in recycled products. Finally, this study investigated how debris like stickers and tape would influence the injection molding process.

The following research questions were formulated for this study:

1. Does the melting temperature influence the properties of reprocessed WP waste material?

2. Does mixing virgin and recycled PP alter the mechanical properties?

3. Does commonly seen debris such as stickers and tape influence the properties of the reprocessed WP waste?

4. Can the material be used to make new reusable medical products without adding additives to the process?

2. Methods

This study involved eight steps to analyze whether WP waste could be used to fabricate a medical device with sufficient mechanical properties to be used again in a hospital environment. Different steps were used to answer the research questions and included setting up a legally approved logistical process, determining the best melting temperature for WP waste, developing a melting process, setting up an injection molding process, analyzing the material properties after molding, analyzing the influence of debris such as stickers and tape embedded in the WP waste, and designing a process for using the new medical device in the hospital.

This research included the collection of three batches of PP surgical WP from an OR where the WP was used to wrap instrument sets. These batches were recovered over three separate days. A procedure was designed to collect the WP after use, after which a melting process was used to recycle the plastic waste at different melting temperatures. Different methods were evaluated to determine whether discarded medical grade WP could be mined using a standardized process and used for the injection molding of new medical products.

2.1. Logistical process

A dedicated logistical process was set up to collect WP waste at the Maasstad Hospital (Rotterdam, the Netherlands). This type of surgical waste is categorized as medical waste and is subject to legislation for hazardous and medical waste when transported and processed. The OR staff was asked to collect WP at the OR in the preoperative preparation area. This is the area where surgical instrument sets are prepared for surgery. Transparent 160 L PP collection bags were used, in which the WP was collected. The bags were transported from the OR to the waste collection center of the hospital. The bags were collected by a waste processing company (Renewi Nederland B.V., Eindhoven, the Netherlands). The WP waste was analyzed and weighed after collection. As required by the permit for the transport of medical waste, the WP waste was first transported to a central sterile services department (CSSD) location (CSA Services, Utrecht, the Netherlands), where it was sorted and checked for potential contamination and the presence of other undesired debris. The WP waste was then brought to the Delft University of Technology (Delft, the Netherlands) to be melted.

2.2. Influence of melting temperature on reprocessed WP waste material

To determine the influence of the melting temperature of the WP waste, the WP was first melted at 200 °C, 250 °C, and 300 °C. A tubular shape was selected because it was easy to manufacture and fit well inside the cylindrical oven. The PP WP waste was melted into bars after placing it into a tubular-shaped cylinder with a diameter of 100 mm, which was capped at each side and placed in the oven (Fig. 2). The melting temperature that produced the best properties was evaluated and used for melting the next batches.

Fig. 2. Overview of different stages of material. From top left to bottom right: collected WP, melted WP formed into bars, granulated WP after melting, filter inside melting tube, and residue removed from filter used to make polluted dog-bones.

2.3. Melting of PP

The WP was collected and melted in a stainless-steel cylinder in an electrical melting oven (KOS, Electric crucible, series 219029). The WP sheets were manually placed into cylinders and melted at 250°C. After the material was melted, the molten material was pulled through the filter by gravity. The melted PP bars were granulated using a Moditec grinding mill (Gplus 2) and used for direct injection molding at 200°C. The virgin granulate was mixed with recycled PP by volume before injection molding (indicated as %R). The dog bones and rectangular bars needed for tensile testing were made from 25%R, 50%R, and 75%R PP. These were compared with each other and with dog bones made from virgin PP and 100%R PP.

2.4. Injection molding

Two different molds were made and used for the injection molding (Babyplast, injection molding machine 6/10P). The mold with the dog bone design shown in Fig. 3 was used to make dog bones with different qualities for tensile testing (Supplemental file 15). A second mold was used for a medical product, an instrument opener. It had the form of a cross and was designed to keep double-hinged instruments open during washing and disinfection in a decontamination machine at the CSSD to ensure that all the parts of the instruments were cleaned during washing. A circular loop could be created by the urban mining, recycling, and injection molding of WP to fabricate new products and bring the material back into circulation in a hospital.

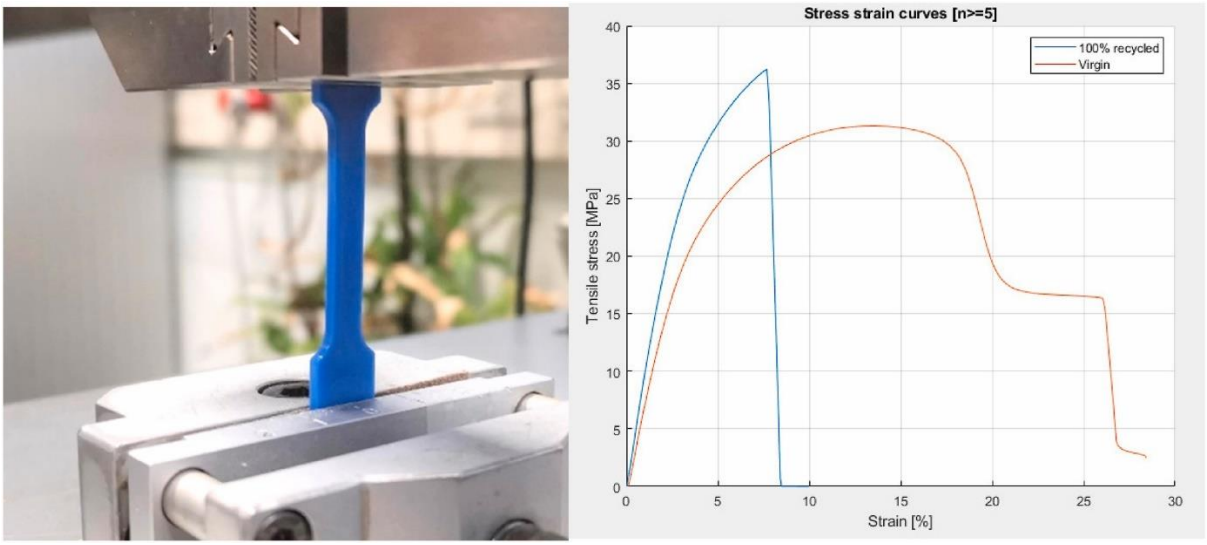

Fig. 3. Tensile testing of dog bones. Left, setup with injection molded dog bone sample installed in hydraulic clamps of test bench. Right, example of stress strain relation of virgin versus 100R material.

2.5. Material properties of 100% reprocessed WP waste and when mixed with virgin material

For analysis and strength comparison purposes, six different sets of five dog bones each were made from PP that was melted at 250 °C and used for injection molding at different mix ratios at 200 °C.

Six sets of five dog bones with various mixing ratios.

1. 100% virgin PP as the benchmark (virgin)

2. 25% recycled PP WP mixed with 75% virgin PP (25%R)

3. 50% recycled PP WP mixed with 50% virgin PP (50%R)

4. 75% recycled PP WP mixed with 25% virgin PP (75%R)

5. 100% recycled PP WP (100%R)

6. 100% recycled PP WP, polluted with stickers and tape (polluted)

The melting and injection molding parameters used with the collected PP WP are shown in Supplemental file 16.

2.6. Influence of stickers and tape on properties of reprocessed WP waste

Paper and other waste such as stickers can enter the WP reprocessing process and pollute the PP end product. This pollution not only influences the material properties but also clogs or damages the melting oven or delicate injection molding machines. A worst-case scenario was included in the experiments by taking the concentrated residue material from the filter after an unsorted batch of WP waste was processed in the melting oven. This residual material, which consisted of approximately of 50 v% pollution, was granulated and used to create five dog bones for tensile and Shore D hardness testing.

2.7. Analysis

Tensile strength tests were conducted to analyze the mechanical properties of the dog bones composed of the recycled PP because obtaining acceptable properties is seen as a challenge when PP waste contains different kinds of plastics such as tape and stickers, or when it is mixed with other types of materials (Hyie et al., 2020). The Young's modulus (E) was analyzed by measuring the elastic behavior (relationship between the tension and axial strain:). The ductility of the material was analyzed by measuring the elongation at break as a percentage by comparing the new length after the breakage of the dog bone and the initial length. The ultimate yield strength was measured to show the maximum tensile stress of the material, and the Shore D test was used to measure the hardness of the dog bone. The combined stress–strain relationships of the dog bones were compared, which were measured using a tensile bench (Delft University of Technology, Faculty of Mechanical Engineering, Zwick Roell, Zwick GmbH & Co.KG, Ulm, Germany), as shown in Fig. 3.

The dog bone bars had shoulders at both ends. These shoulder ends enabled a solid grip when placed in the testing machine. The dog bones were also tested on both shoulder ends with a shore durometer (Sauter, HBD 100–0.HBD 100–0, Durometer, www.sauter.eu), which was used to measure the hardness of the recycled material.

2.8. New products made from WP

To determine whether products made from the WP granulate could withstand a cleaning and disinfection process at the CSSD, additional tests were required. To determine whether multiple CSSD cleaning cycles would influence the material properties, dog bones made from virgin, 50%R, and 100%R were tested before and after being cleaned and disinfected ten times in a Getinge G1-WA-04 thermal disinfector (Getinge. Lindholmspiren 7, SE-417 56 Gothenburg, Sweden) at the CSSD. Thereafter, an instrument opener was designed to keep double-hinged instruments open during washing and disinfection. To determine the maximum load on the instrument opener, multiple double-hinge bone cutters were compared and tested by adding masses to a cable that ran through the opening of the hinge (Fig. 4). The 2 mm cable made contact with the metal of the hinge at the same location as the opener. The load was increased in 0.5 kg steps until the hinge remained open under the applied total load, which was defined as Fmax. A virtual finite element method (FEM) analysis was conducted using Solidworks (2020, Dassault Systèmes). The analysis was performed to relate the ultimate tensile strength (UTS) of the measurement outcomes to the dimensions and shape of the instrument opener when loaded with Fmax. This analysis showed the relationship between the design parameters and the material properties of the chosen granulate. Fig. 8 shows how the CAD model was imported and simplified, with half of the cross used in the analysis.

Fig. 4. Testing bone cutting hinge force. Left, tested bone cutters ordered from low to high hinge force. Right, bone cutter with highest hinge force opens when loaded with 6 Kg mass.

One thousand instrument openers were injection molded using 50%R and 100%R granulate, which should have survived at least ten CSSD disinfection cycles in a thermal disinfector at 90 °C. The Expert Sterile Medical Devices (DSMH) of the hospital was asked to supervise the implementation of 25 instrument openers (50%R) and to inspect each instrument opener before, during, and after the disinfection phase. CSSD user and DSMH feedback was requested four weeks after the introduction of the instrument opener at the CSSD of Maasstad Hospital.

3. Results

The WP was used to package instrument sets after cleaning and sterilization in the CSSD. The WP protected the instruments by creating a sterile barrier after steam sterilization at 134 °C. The collected paper was unwrapped at the OR and did not come into contact with the patients. The Halyard brand WP (12754 Halyard, Kimguard, One Step, H100) was discarded after use in the OR and collected into special PP transparent bags. The OR staff did not report any difficulties while collecting the WP. A total of 8.16 kg, divided over 17 transparent bags, was collected. The majority consisted of H400 114 × 114 WP, with each sheet weighing 160 g and 5–6 sheets in each bag. The bags were transported in a roll container from the OR to the logistical area of the hospital, where they were collected and transported by the waste processor Renewi. After arrival, the WP was manually placed in cylinders and melted into bars, after which it was granulated and used for injection molding.

3.1. Melting and granulating

After melting, the PP bars were removed from the cylinders. The bars were granulated into flakes to form a raw material for injection molding.

Fig. 6 shows pictures of the dog bones that were injection molded. For clarification, the structure of the polluted dog bone was enlarged 5 times, and the contrast was enhanced to better expose the particles.

3.2. Influence of melting temperature on reprocessed WP waste material

During injection molding, when the nozzle temperature was 200 °C, all the input materials flowed well, and no problems were observed during the injection molding with any of the dog bones and instrument openers. The results of the tensile tests are shown in Fig. 5. The dog bones shown from left to right were made out of 100% recycled WP melted at 200, 250, and

300 °C. No significant differences were found between the dog bones produced at different initial temperatures of the melting tube. Because the initial melting temperature of 250 °C seemed to give the best results, the following WP batches of granulate were made from WP melted at 250 °C.

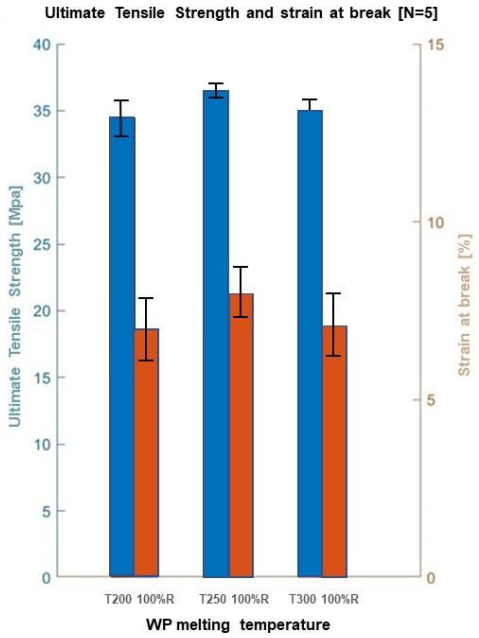

Fig. 5. Ultimate tensile strength and strain of dog bones made from WP melted at different melting temperatures.

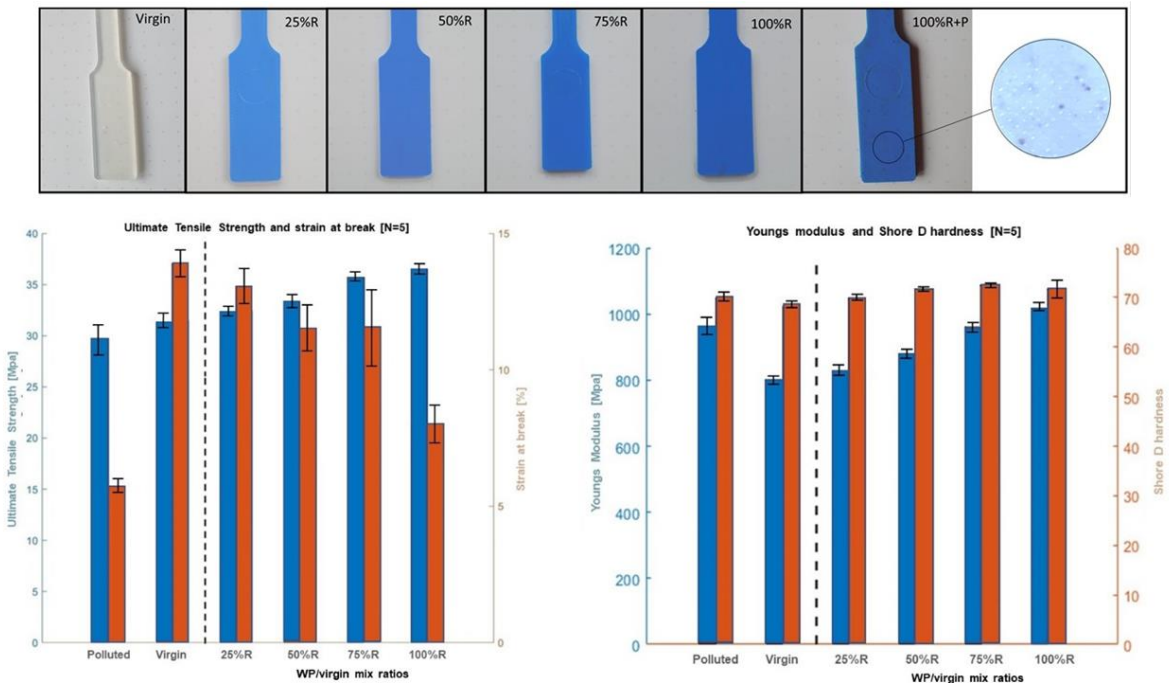

Fig. 6. Dog bones and their material properties. Top: pictures of dog bone. Bottom left, ultimate tensile strength and strain. Bottom right, Young's modulus and hardness measured in Shore D.

3.3. Influence of mixing ratio

Fig. 6 shows the results for the polluted scenario, virgin PP, and different mix ratios. With the exception of the polluted dog bone, the UTS values were all greater than 30 MPa. The UTS increased from 31.5 MPa for the virgin material to 36.5 MPa for 100%R. The dog bones made out of 100%R granulate showed an approximately 6% lower strain than the virgin PP. The strain at break decreased with a decrease in the amount of virgin material in the dog bones. The results showed that mixing recycled PP with virgin PP increased the strain, depending on the mixing ratio, with a maximum of 5%. Fig. 6 (right) shows the material hardness, measured in Shore D values in combination with the Young's modulus. The bars indicate that the tensile stiffness and hardness increased when the material mix contained more recycled PP. The polluted and 100%R dog bones showed similar tensile stiffness and hardness values.

For dog bones made from the 100%R and 50%R mixes, the Young's modulus values were 1021 (SD13) and 879 (SD13) MPa, respectively. The average strains for the 100%R and 50%R mixes were 8% (SD2) and 12% (SD4), respectively. Dog bones made from virgin PP showed an average Young's modulus of 795 MPa (SD14) and strain of 14% (SD0.5). The injection-molded instrument opener was subjected to ten washing and disinfection process cycles, and a visual inspection showed no deterioration.

3.4. Influence of stickers and tape on properties of reprocessed WP waste

The tensile test conducted on the dog bones that were injection molded with particles from the stickers and tape in the granulate, as a worst-case scenario, showed a strain of 6% (SD1) and UTS of 29.8 (SD1.4) MPa.

3.5. Tensile and shore D tests after ten cycles of washing & disinfection

The results of the tensile and Shore D tests of the dog bones made of virgin, 50%R, and 100%R, which were washed and disinfected for ten cycles in the CSSD (Supplemental file 17) are presented in Fig. 7. Compared to the data in Fig. 7, the virgin PP showed an increase in elongation of 0.7%, an increase in UTS of 1.9%, and a decrease in hardness of 2.86%. The 50%R showed a decrease of 1.8% in elongation, an increase in UTS of 0.9%, and a decrease in hardness of 1.85%. The 100%R showed an increase in elongation of 1.7% after ten disinfection cycles, with a decrease in UTS of 0.69% and no change in hardness.

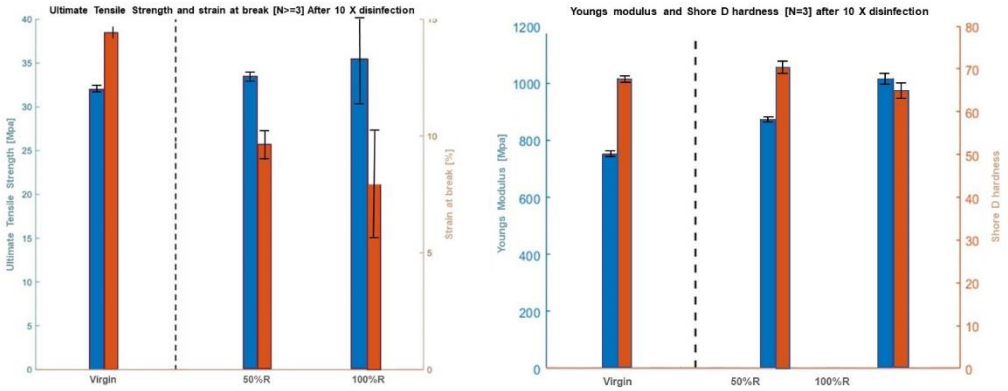

Fig. 7. Ultimate tensile strength, strain, Young's modulus, and hardness after 10 cleaning and disinfection cycles.

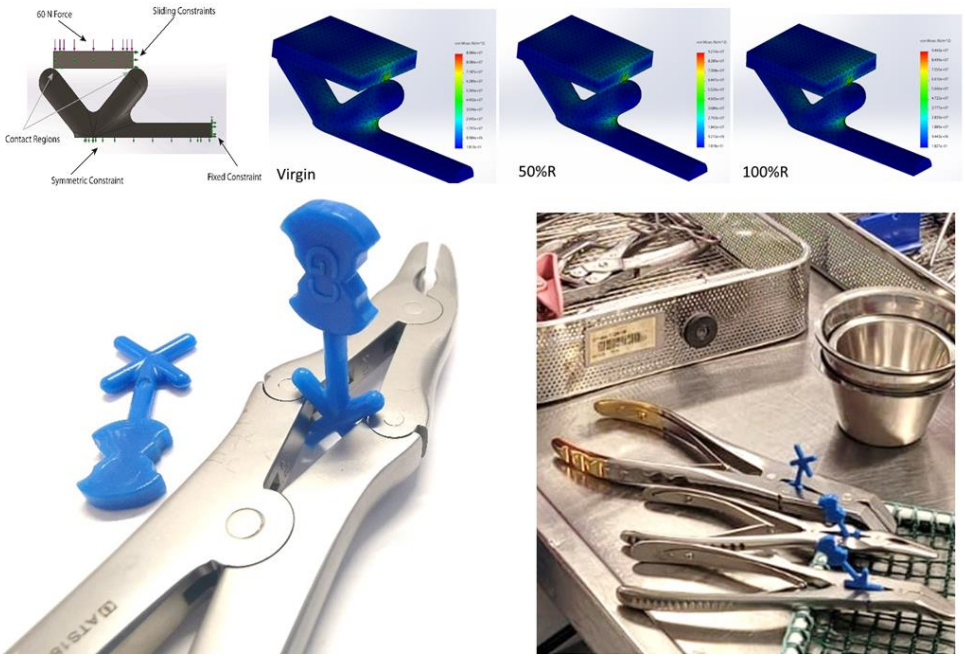

Fig. 8. Design based on WP material properties. Top: screenshots of Finite Element Analysis (FEA) of relevant section of opener/bone cutter hinge interaction indicating area of highest tensile and compression stress around center of cross of model. Bottom: instrument openers made from WP waste and deployed at sterilization department of Maasstad hospital.

3.6. Development and validation of new product made from WP

Experiments indicated that a 6 kg load was sufficient to keep the hinge of the heaviest bone cutter open. As shown in Fig. 8, within the model, the highest stresses were found at the center of the cross of the opener, with a maximum compression stress of 59.8 MPa and tensile stress of 20.4 MPa for virgin material, a maximum compression stress of 59.7 MPa and tensile stress of 20.5 MPa for 50%R, and a maximum compression stress of 59.5 MPa and tensile stress of 20.7 MPa for 100%R. To prevent damage due to high contact forces during insertion, the instrument openers were designed with curved edges to ensure that the forces were distributed more equally.

Fig. 8 shows the molded instrument opener design that was used to open hinged spreaders and bone cutting forceps of different sizes. None of the 25 openers suffered damage during the testing period. The following statements show some of the user feedback from the CSSD staff after one month of repeated use: it is easy to use and straightforward to apply to an instrument; it has an improved design compared to the current openers that are used from a local retail store (these products are not medically validated and appear to leave white debris behind after use in the thermo disinfector); the instrument opener is better to hold in your hands and to place inside the hinge; the instrument holder is made of recycled material, which is perceived as an advantage; it effectively keeps the instrument open during washing.

4. Discussion

For the first time, medical devices made out of recycled PP hospital waste were used in the harsh environment of the sterilization department of that hospital. The results showed that the study aim was reached, and it was possible to process PP waste into new qualitative products that could be used in the same hospital without the use of additives. The initial melting temperatures of 200–300 °C applied to turn the blue WP waste into bars for granulation did not significantly influence the properties of the injection-molded products. An initial melting temperature of 250 °C combined with an injection molding temperature of 200 °C resulted in satisfactory results. Other studies have reported that the melting temperature of recycled PP has a significant negative effect on the stress at break, with the addition of virgin material compensating for this effect (Czichos and Saito, 2006; Da Costa et al., 2007). However, this study found that for the initial melting step before injection molding, temperature differences between 200 °C and 300 °C did not significantly influence the properties of the final product. From Fig. 6, it can be concluded that the mixing ratio of virgin material to recycled granulate had a strong influence on the material properties. Injection-molded products made from 100% recycled WP were stiffer, harder, and more brittle than those made from 100% virgin PP. The degradation of the material could be reduced by adding virgin material to the recycled PP (Gabriel and Tiana, 2020). However, the increased stiffness and hardness could be an advantage for supportive devices at the CSSD where instruments are heavy and sharp, detergents are used, handling is rough, and washing is done with a high water flow at high pressure.

A comparison of the results for the 25%R and 100%R samples showed that with 25%R granulate the strain at break was 5% higher, while the UTS was 11% lower. These results showed that the mixing ratio had a stronger influence on the strain at break than on the UTS.

In the worst-case scenario simulation, melted WP waste contaminated with stickers and labels was granulated into flakes that were immediately used in injection molding to produce dog bone samples. Although highly polluted, it was found that the strain was only 8% lower than that of virgin PP and 2% lower than that of pure 100%R PP, whereas the UTS was 5% lower than that of virgin PP and 18% lower than that of pure 100%R PP. This showed that pollution with tape and stickers had a limited effect on the mechanical properties. In this case, the color of the molded material changed.

4.1. Potential to make new products without adding additives to process

The FEM simulations indicated that despite the different characteristics of the mixed materials, the difference in the maximal allowable stresses remained low under equal loading conditions. This showed that for simple non-constructive designs that are not deformed during use, manufacturers can safely mix virgin and 100%R granulate depending on the availability and wishes of their clients. In practice, it was found that the instrument openers made from 100% PP and 50%R PP both met the specifications for holding hinged instruments in an open position for multiple disinfection cycles. However, the data indicated that extra attention is needed with respect to device designs containing deformable compliant elements (e.g., snap fingers) because the material becomes more brittle (Hyie et al., 2020; Czichos et al., 2006), with the break properties decreasing (Da Costa et al., 2007) leading to a potential decrease in the mechanical properties (Gabriel and Tiana, 2020; Aurrekoetxea et al., 2001) after multiple cycles of recycling. This indicated that in order to increase the circular use of recycled medical plastics, design choices should be linked to the type of waste and mixing ratio. This could be a basis for developing more medical products manufactured from medical plastic waste such as PP trays, mesh basket accessories, and labels, considering the costs and potential environmental impacts of such products. Every medical product needs to undergo CE approval according to the Medical Device Regulation. Testing is mandatory, and material specifications must be demonstrated in technical files. This includes toxicity testing of the material, which may exclude the toxicity of potential pollutants and unknown substances during recycling, demonstrating that products made out of waste can be safely used in hospitals.

Within the Netherlands, an estimated 1.3 million kg of WP is used each year. Potentially, 8,320,000 cross-shaped openers could be manufactured when collecting WP waste for only one year (Supplemental file 18). Hypothetically, 70,000 instruments with a (double) hinge are circulate in 90 hospitals in the Netherlands. To put this into context, this means that recovering WP waste during a single year would ensure a raw material supply for the manufacturing of instrument openers for the next 119 years in the Netherlands. The urban mining of WP waste could be the answer to the circular manufacturing of a wide range of medical devices. These could include medical products such as cleaning nozzles, tubes, holders, and containers to be used in CSSDs or ORs and manufactured from recycled PP.

4.2. Theoretical and practical implications

This study demonstrated that an OR waste reprocessing method could be conducted locally with potential environmental benefits. The theoretical implications are that the material properties of processed waste could be examined in a standardized manner with dog bones before using the obtained material properties to conduct loading simulations on a new instrument design. The linear relationship between the percentage of recycled material used and the hardness or strength could be used to calculate the mechanical properties of the final product. This characterization of waste material properties would allow designers in practical applications to optimize their products based on the “green” wishes of customers. They would not only need to design future medical products to facilitate easier reprocessing but would also need to consider the fact that recycled materials are used in the design.

4.2.1. Future work

As this study demonstrated the feasibility of reprocessing PP waste from hospitals into new medical products, future studies should investigate the reprocessing options for other types of plastic hospital waste, as well as calculating the environmental and financial impacts from a more holistic point of view.

4.2.2. Study limitations

Although not included in the scope of this study, a Life Cycle Assessment (LCA) study could be conducted to calculate the benefits of the environmental impact, in particular the CO2 and water impacts, when recycling WP into new products, as compared to its disposal or incineration. In addition, a cost analysis of the urban mining, recycling, manufacturing, and reuse of PP from medical devices, as opposed to disposal after a single use, would be an area of interest for further investigation. However, consideration should be given to the fact that a special logistical routing is needed for this type of waste because it is potentially contaminated, generating extra costs for comparison. In the pilot study, some openers were reused more than 10 times without damage. Because the exact number is unknown, a future study should relate the impact on the material properties of more than ten disinfection cycles, as well as the effect of autoclave sterilization.

5. Conclusions

In this study, Maasstad Hospital became the raw material supplier for its products. The results of this study demonstrated that recycling WP waste into new medical products is feasible. Despite becoming more brittle, the strength and hardness of the recycled PP WP increased, making it even more suitable for use in the specific harsh environment of the CSSD. It was demonstrated that the proposed WP reprocessing method could be conducted locally, reducing waste generation, with potential environmental benefits. This would allow hospitals to become more compliant with the circular economy using circular product lines.

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Chapter 5

Reprocessing Zamak laryngoscope blades into new instrument parts; an ‘all-in-one’ experimental study

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WERKLAST

Reprocessing Zamak laryngoscope blades into new instrument parts; an ‘all-in-one’ experimental study

Abstract

Introduction
Disposable instruments in healthcare have led to a significant increase of medical waste. The aim of this study is to validate the recycling of disposable Zamak laryngoscope blades into new medical products by using a new 'all-in-one' affordable reprocessing setup as alternative for die-casting.

Methods
An "all-in-one" casting set-up was designed and built. Laryngoscope blades, recovered from two hospitals, were disinfected, melted and casted into dog-bones and into new instrument parts. The quality of the casted material was evaluated using X-ray fluorescence spectrometry. The mechanical properties were obtained by assessing the Ultimate Tensile Strength (UTS) and tensile tests.

Results
A recovery of 93% Zamak was obtained using a melting temperature of 420 ^{0}C for three hours. The XRF Spectro data showed higher Zinc and silicon concentrations when compared with Virgin Zamak. The dog-bones tests resulted in an average UTS, Yield Strength (YS) and Young's Modulus (YM) of 236 ±61 (MPa), 70 ±43 and 9 ±3, respectively, representing 82%, 103% and 64% of the UTS, YS and YM of standard Zamak. Functional instrument parts with extensions and inner chambers were casted with a maximal shrinkage percentage of 1±1%.

Discussion
This study demonstrates that the created "all-in-one" reprocessing method can process contaminated disposable Zamak laryngoscope blades into new raw base material and new instrument parts. Although material and surface properties can deteriorate, reprocessed Zamak still has sufficient mechanical properties and can be used to cast complex parts with sufficient dimensional tolerances and minimal shrinkage.

Conclusion
A circular micro reprocessing method was designed and used to turn disposed laryngoscope blades into new basis material and semi-finished products. Follow up studies are needed to scale and optimize this process towards a functional alternative for die casting. It should be further investigated how this process can contribute to further medical waste reduction and a circular healthcare economy**.**

1. Introduction

Health care waste has been growing significantly as a result of the growing population and the use of disposable products [1,2]. Operating rooms are among the largest contributors of medical waste produced in hospitals as a result of disposable surgical supplies [3] creating huge amounts of waste [4].

In line with the circular economy (CE) philosophy, waste should be minimized and seen as a valuable input material for the manufacturing of raw base materials for new products. Waste can be prevented by conducting proper maintenance, repair or refurbishment to extend the product's life cycle. Recycling is preferred when the previous is not possible [5]. By reusing medical waste, the valuable materials are preserved, greenhouse gas (GHG) emissions are lowered and the environmental impact is reduced [6,7,1].

The European Green Deal stimulates sectors to participate in achieving a circular economy [8]. The aim is to become climate neutral by 2050 [9,10]. Healthcare waste in high income countries vary between 1.7 kg and 8.4 kg per bed per day [11]. Similar to the USA (7.9%), Japan (7.6%), Belgium (7.7%), Denmark (6.4%) to Germany (6.7%) [13], hospitals in the Netherlands are also responsible for around 7% of the total carbon footprint [12] meaning that improvements can be made with regard to waste processing and CO_2 emissions.

An analysis of the environmental impact when using disposable metal instruments indicated that disposable stainless-steel scissors have the highest negative environmental impact and appeared to have higher total cost of ownership than reusable scissors [14]. In line with these findings it is of interest to investigate other metal disposable instruments that are used in high quantities in the Operating Room (OR). During endotracheal intubation, laryngoscope blades are used in high quantities every day as either a disposable or reusable product. Due to the combination of the complex shaped blade with disposable parts such as an optical fibers and locking members, cleaning becomes difficult and sterilization costs are increased. Therefore, there is a trend towards the manufacturing of the disposable versions of these blades. Disposable metal blades such as the laryngoscope blades from Teleflex are made from a non-ferrous metal alloy named Zamak. Zamak allows for rapid casting of disposable complex shapes [15]. Figure 1 shows an image of the disposable Rüsch Polaris Fiber Optic Laryngoscope Blade (Teleflex, Dublin Road Westmeath, Ireland).

Figure 1. Zamak Laryngoscope blades. Left, the Rüsch Polaris Miller and Mackintosh type Laryngoscope Blade. Right, Laryngoscope blades disposed after use.

Zamak Laryngoscope blades

Zamak consists of Zinc, Aluminum, Magnesium and Copper [16]. The laryngoscope blades as shown in Figure 1 are disposed after use on the OR. Zamak 3 is the most common type of material and used for casting of medical products. The standard composition is 3.5-4.3% aluminum, 0.02-0.06% magnesium, a maximum of 0.25% copper with the remainder being zinc (≈ 95%) [17]. The function of aluminum and copper is to increase the strength. The function of magnesium is to prevent corrosion [18]. Table 1 shows the standard and mechanical properties of Zamak 3. The main body of the Teleflex laryngoscope blade is made from Zamak that is covered by an epoxy-polyester coating and contains three inserts with a diameter of 4 mm made of both stainless steel and brass. The influence of metal impurities and presence of other alloys may influence the occurrence of defects and diminish material properties [19,20] after casting. To ensure a high quality end-product, the influence of the melting, casting and presence of undesired plastics or metals should be investigated.

Table 1. Standard thermal and mechanical properties of Zamak 3

Zamak 3 [11]	Value
Melting Temperature – Liquidus (Celsius)	390 ^{0}C
Melting Temperature – Solidus (Celsius)	380 ^{0}C
Viscosity [12] (Pa s)	≈ 3.5 mPa*s @ 400^{o}C
Solidification shrinkage (%)	1.2 %
Ultimate Tensile Strength (Mpa)	280 MPa
Yield strength (0.2% offset)	210 MPa
Young's modulus	86 GPa
Elongation at Break	11 %

The casting of Zamak is commonly done through die-casting, a metal casting process where molten metal is forced under high pressure through a system into a mold [21]. This specific casting process is often used to produce geometrically complex shaped metal parts and requires expensive die-casting machines and processes [22]. Besides the need for dedicated machinery, the die-casting process involves critical optimization of injection parameters and mold configurations to prevent that gas is entrapped in the cast resulting in the formation of pores in the casted material [23]. Therefore, a need exists to develop an alternative and a less complex 'all-in-one' set-up in which disposed medical instruments can be disinfected, melted and directly molded into new end-products.

Aim

The aim of this study is to validate the recycling of disposable Zamak laryngoscope blades into new medical products by using a new 'all-in-one' affordable reprocessing setup as alternative for die-casting.

2. Methods

For this study, two batches of disposable Teleflex laryngoscope blade waste with a total mass of 48kg were separated from the material flow of Spaarne Hospital, Hoofddorp, the Netherlands and Amsterdam University Medical Center, Amsterdam, the Netherlands. The OR staff deposited the waste in special containers with a lockable lid. The containers were opened after receipt, disinfected at 90^0C and the blades were put in a larger collection bin until they were further processed.

Figure 2 shows how the blades were disinfected in a modified G7782 CD Miele medical thermo disinfector at 90^0C (Miele Nederland, Vianen, the Netherlands).

Figure 2. Thermal disinfection with customized insert rack for disinfection of blades in larger quantities.

The blades were manually put in the stainless steel bowl and funnel and placed in the melting oven. The blades were melted into ingots and cleaned ultrasonically. The melting and casting is done in a single production line, based on a single location at the Sustainable Surgery Lab of Delft University of Technology (Supplemental file 19). An induction furnace (electric melting oven, KOS, series 219029) was used for melting the laryngoscope blades (Figure 3). The melting oven contains a cylindrical crucible with a diameter of 395mm and a height of 345mm as maximal space for the "all-in-one" melting process.

Figure 3. Melting Oven. A: The induction furnace for melting of the Zamak laryngoscope blades. B: All-in-one casting setup, a bowl with grate placed in the melting oven. C: Top bowl with filter allows only the Zamak to pass. D: Cast with riser. E: Exploded view cast with riser.

After melting, the flow of the liquid Zamak is propagated into a mold using the principle of gravity casting. The adhesion of the epoxy-polyester coating is reduced with the bake-off method [24]. Earlier studies show that the bake-off requires heating of a coated item to 340°C - 400°C to turn the coating starts turning to ashes while keeping the inserts made from stainless steel and brass intact [25,26]. At these temperatures, the coating starts flaking and forming cracks. Once the coating has been degraded enough, the Zamak flows into the mold. This process usually takes between three to six hours. During oxidation, gases and debris can be absorbed by the Zamak, while in its liquid form it may create defects in the form of porosity during casting. To reduce the oxidation rate, a melting temperature of 420°C is chosen for the experiments as this lies within the margin of the Zamak recommended melting temperature (395°C and 425°C) [27]. The used Zamak blades also contains a tube made of a shielded transparent fiber held in place by a polyvinylchloride part.

2.1 Melting setup

The melting setup consists of a flat bottom stainless steel bowl with a grate on the bottom and a stainless-steel ingot mold (Figure 3). The grate acts as a filter to prevent the coating residue, inserts and the particles from plastic parts to flow along into the mold. The funnel is held up by a stand and has the 3 x 3mm hole grate. The mold was placed below the bottom funnel hole. The conical shape of the funnel is used to have all of the liquid converging towards the funnel opening supported by gravity, contributing to a higher Zamak recovery.

During solidification, the melted material decreases its volume and the casting shrinks. The particles are pulled in the direction where the solidification starts, tending to start at the walls of the mold. This causes cavities to appear if not enough melt is available to compensate for the lost volume named shrinkage porosity [28]. To prevent this shrinkage porosity, the ingot mold was designed with a riser, a reservoir for casting. The melted material in the riser solidifies last. Therefore, the mold can pull from the riser towards areas where cavities would otherwise emerge. The design of the riser follows Chvorinov's rule, stating that the

solidification time of a casting depends on the relation between the volume and surface area according to [29]:

$$t = B\left(\frac{V}{A}\right)^2 \quad (1)$$

t = Solidification time in [s]
B = Mold constant in [s·m^{-2}]
V = Volume in [m^3]
A = Surface area in [m^2]

According to DeGarmo [30], a 25% difference between the solidification time of the casting and the riser is sufficient. Because the riser and the rest of the casting use the same mold, the mold constant B would be equal to each other. When applying the 25% difference, the equation can be simplified to:

$$\left(\frac{V}{A}\right)^2_{Riser} = 1.25\left(\frac{V}{A}\right)^2_{Casting} \quad (2)$$

The riser has a cylinder shape with a volume of 10.75 cm^3 and a surface area of 33.13 cm^2. Following Equation 2, the riser has a solidification time 26% slower than that of the casting. Because the mold and the casting both have to cool down from the same temperature when removed from the furnace, the riser and casting solidification process starts once the mold walls have cooled down to the solidification temperature. Assuming that every part of the mold wall cools down equally, the shrinkage cavities start occurring in the middle. Therefore, the riser is positioned above the middle part of the casting so gravity forces the melting material into the casting in an efficient way (Figure 3). The setup is used to cast two ingots at 420^{o}C, that are machined into dog-bones and 2 cylinders. The cylinders with a diameter between 30 and 50mm are used for material analysis. The dog-bone samples were designed in accordance with the ASTM E8 standard [36] and are used to carry out the tensile tests (Supplemental file 20). Furthermore, an ingot made from virgin Zamak was made and used to machine dog-bones. These ingots were made using laryngoscope blades from which the coating is removed by means of a chemical dissolving agent (Superafbijt 507645, Pearl Paint Holland BV, Lelystad – the Netherlands).

2.2 Material validation experiments

To determine the purity of all of the casted ingots, they are compared with samples made from virgin Zamak 3. All of the cylindrical samples are analyzed using X-ray fluorescence (XRF) spectroscopy (Panalytical Axios Max WD-XRF, Malvern, United Kingdom) [31-35]. The purity is calculated with SuperQ5.0i/Omnian software. Based on the concentrations of zinc, aluminum, magnesium and copper.

The dog-bones and tested material properties were used to determine the stress-strain curves. The Ultimate Tensile Strength (UTS) was defined as the highest measured tensile strength before breakage. The Yield Strength (YS) is defined as the first point in the graph the stress remains constant during elongation. The Young's Modulus is defined in this study as YS/strain.

2.3 Part manufacturing, a test case

To investigate whether the “all-in-one” process can be used to manufacture functional quality products, a stainless steel casting mold for a steering wheel is made. The steering wheel is part of the handle of the SATA instrument, a medical instrument used for laparoscopy [37]. This specific wheel has a complex shape with multiple cutouts and an inner chamber making this medical part the ideal test subject. The mold shown in Figure 4, consists of 3 slabs, each 10 x 55 x 55 mm in size, held to together by nuts and bolts. The wheel ingot is casted with the same melting setup after heating the laryngoscope blades for an hour on 420^{o}C. To determine the level of shrinkage, the most relevant steering wheel dimensions are measured and compared to the dimensions of the original shape. Measurements are conducted with a Mitutoyo digimatic caliper. The dimensions of the four extremities shown in Figure 4 are measured in an alternating way. Protrusion and indentation are measured on four locations on 0, 45, 90 and 135 degrees (Figure 4-Left). The shrinkage is determined by calculating the percentage the steering wheel dimensions deviated from the cast shape dimensions.

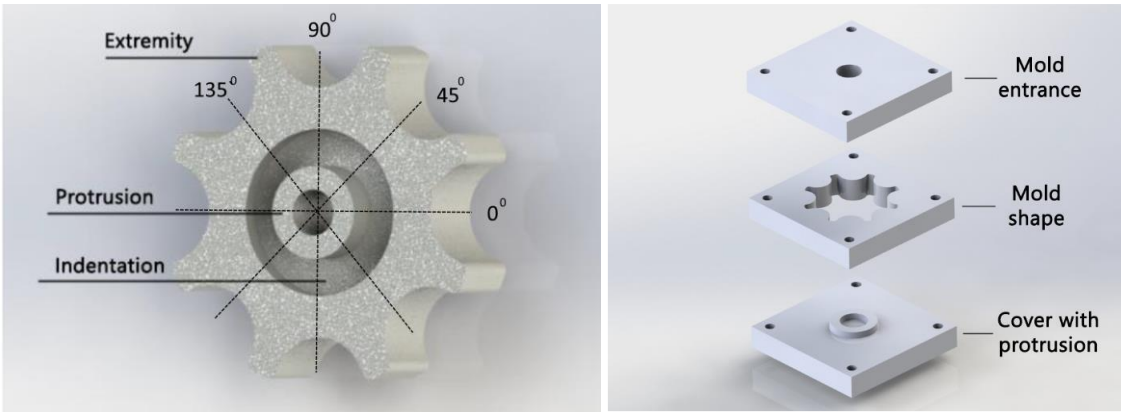

Figure 4. Steering wheel casting. Left, the simplified cast. Right, mold design.

The edges of the inner shape of the steering wheel cast are not rounded to investigate the potential of the Zamak to form uniform sharp edges within the process. An electric microscope system with zoom capability up to 10.000x (MF measuring microscope, Mitutoyo, Kanagawa, Japan) is used to determine the roughness of the edges on four locations on a pair of opposing extremities in order to quality assure the casted parts. Finally the wheel surfaced is machined to match the exact properties of a functional wheel by machining the rims and surfaces on a Lathe. A hole is drilled and a thread cut inside the hole for a fixation screw. The wheel is placed on an instrument for functional testing of the thread during and after assembly and the thread was optically inspected after disassembly.

3. Results

Two batches of laryngoscope blades were collected from the Spaarne Hospital (Hoofddorp, the Netherlands) and the Amsterdam University Medical Center (Amsterdam, the Netherlands) and melted and casted. An example of a produced ingot is given in Figure 5.

Figure 5. Ingot after ultrasonic cleaning.

The amount of Zamak extracted from the blades per melting setup is provided in Table 2. The melting setup resulted in approximately 93% recovered Zamak over a time span of three hours.

Table 2. Results of the weighing test for the melting setup

Temp	number of blades used	Zamak mass before casting	Zamak mass after casting	Zamak recovery %
420 °C	10	750 g	680 g	91.9%
420°C	10	742 g	700 g	94.4%

The results from the XRF tests show that although impurities are present in the castings, they mainly contain Zinc. The tested ingots S2-C and S2-D had a purity of 99.7% (Table 3). The full material composition data from the XRF tests can be found in Supplemental file 21.

Table 3. Chemical composition of the casted ingots.

Element Concentration	Ingot A	Ingot B	Coating removed	Virgin Zamak
Zinc (Zn)	94.97%	95.65%	96.36%	91.55%
Aluminum (Al)	4.28%	3.78%	3.3%	4.5%
Magnesium (Mg)	0.42%	0.25%	0.17%	0.8%
Copper (Cu)	0.04%	0.04%	0.02%	2.8%
Iron (Fe)	0.04%	0.05%	0.01%	0.01%
Nickel (Ni)	0.01%	0.02%	-	0.01%
Silicon (Si)	0.12%	0.1%	0.05%	0.05%
Chloride (Cl)	0.08%	0.04%	0.17%	0.17%
Sulfur (S)	0.03%	0.02%	0.04%	0.01%
Phosphorus (P)	0.01%	0.01%	-	0.01%
Potassium (K)	-	0.01%	0.04%	0.03%
Calcium (Ca)	-	0.02%	0.02%	0.02%
Fluorine (F)	-	-	-	-
Chromium (Cr)	-	0.02%	-	-
Total Purity %	99.7%	99.7%	99.85%	99.7%

Examples of machined dog-bone samples for tensile testing, according to ASTM E8, are shown in Figure 6.

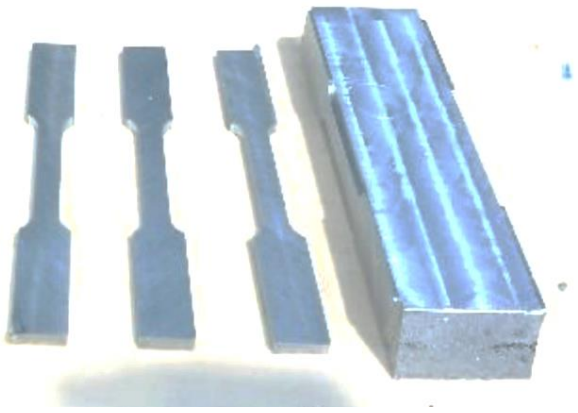

Figure 6. Dog-bone samples machined from the casted ingots.

3.1 Mechanical properties

The results of the tensile tests are shown in Table 4. Figure 7 shows the stress-strain curves of two dog-bones from each cylinders (A1, A2, B1, B2), and two virgin dob-bones (IPS 1, IPS2). The individual stress-strain curves of each sample are shown in Supplemental file 22. The average UTS of reprocessed Zamak was 236 ±61 (MPa), being 82% of the averaged UTS of standard Zamak (287 MPa). The average YS of the reprocessed Zamak was 103% or 70±43 MPa when comparing to standard (virgin) Zamak (68 MPa).The average Young's Modulus of the reprocessed Zamak was 64% or 9±3 GPa of the standard Zamak (14 Gpa).

Table 4. Results of the tensile tests.

Zamak Properties Tensile Test	**Ultimate Tensile Strength [MPa]**	**Yield Strength [MPa]**	**Young's Modulus [GPa]**
Standard Properties Literature	*280 MPa*	*210*	*86*
Ingot Virgin IPS			
Sample IPS-1	293	67	*14,6*
Sample IPS-2	280	68	*14,3*
Ingot A			
Sample A-1	220	43	6.8
Sample A-2	161	28	8,3
Ingot B			
Sample B-1	304	124	12,3
Sample B-2	260	86	10
Ingot average, SD/±	236 ±61	70 ±43	9 ±3

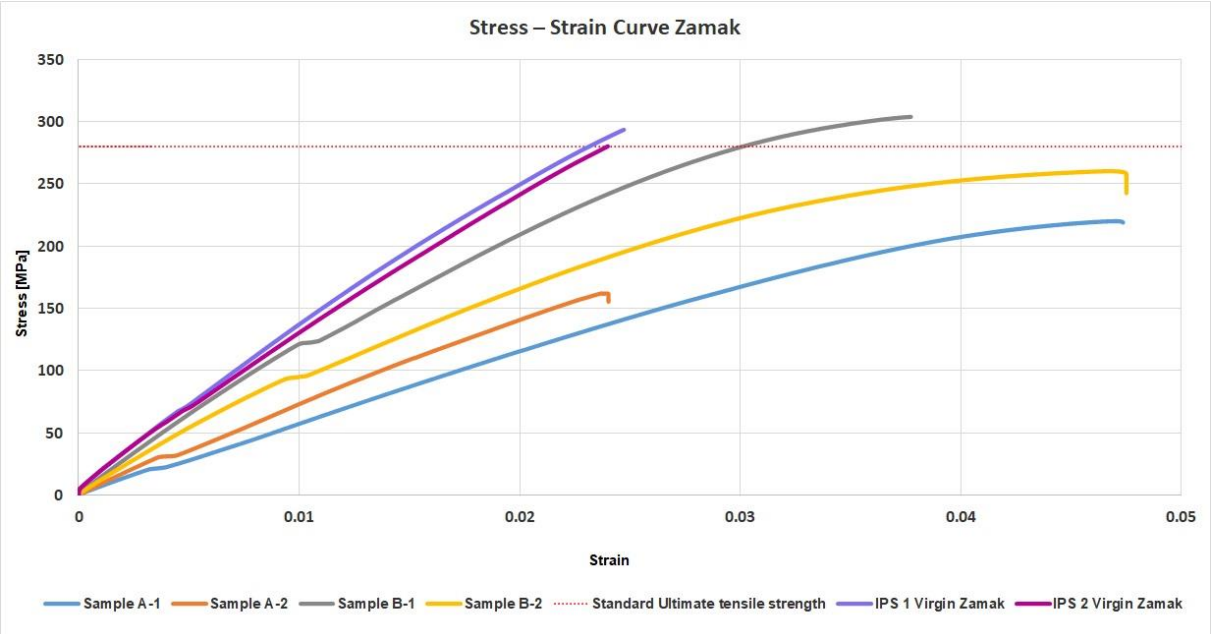

Figure 7. Stress-strain curve of the tensile tests with dog-bones.

3.2 Part manufacturing, a test case

Casting turned successful (Figure 8) and only three undesired surface faults were detected with a maximal depth of 0.6 mm along the edges of the protrusion. It was possible to remove the product from the cast within 10 minutes by pressing the wheel from its cast with a 0.5 tonnage rack and pinion press. The casts did not show any damage after removal. Table 5 shows the measured dimensions of both cast and steering wheel.

Table 5. Pattern shrink percentages of different sections of the rotation knob (averaged over 4 measurements)

Description	Outer diameter indentation [mm]	Inner diameter protrusion [mm]	Most outer diameter wheel [mm]	Outer diameter minus cutout [mm]	thickness rims [mm]	with rims [mm]	height cutout [mm]	sharpness corner side 1 [mm]	sharpness corner side 2 [mm]
Location									
Product meaurements	17,95	9,90	37,96	27,08	10,22	3,62	3,03	0,02	0,02
	17,80	9,89	37,92	27,03	10,24	3,60	3,09	0,02	0,05
	17,84	9,87	37,94	27,07	10,19	3,58	3,07	0,04	0,03
	17,79	9,90	37,92	26,98	10,23	3,62	3,02	0,04	0,06
Mean	***17,85***	***9,89***	***37,94***	***27,04***	***10,22***	***3,61***	***3,05***	***0,03***	***0,04***
SD	***0,07***	***0,01***	***0,02***	***0,05***	***0,02***	***0,02***	***0,03***	***0,01***	***0,02***
Cast measurements	17,96	9,89	37,98	27,03	10,19	3,73	3,12	0,02	0,04
	17,92	9,90	38,02	27,23	10,25	3,61	3,08	0,03	0,03
	17,97	9,92	37,91	27,00	10,23	3,62	3,09	0,03	0,04
	17,99	9,89	38,24	27,01	10,21	3,63	3,07	0,04	0,03
Mean	***17,96***	***9,90***	***38,04***	***27,07***	***10,22***	***3,65***	***3,09***	***0,03***	***0,04***
SD	***0,03***	***0,01***	***0,14***	***0,11***	***0,03***	***0,06***	***0,02***	***0,01***	***0,01***
avaraged difference	0,12	0,01	0,10	0,03	0,00	0,04	0,04	0,00	-0,01
Difference in % (shrinkage	0,64	0,10	0,27	0,10	0,00	1,17	1,21		

The shrink varied between 0.0% and 1.2% and varied over the individual extremities. The shrink for the thickness of the steering wheel was around 0.0%, whereas the shrink for the height of the cutout was around 1.2%. The sharpness of the corners was measured to be around 0.01 mm.

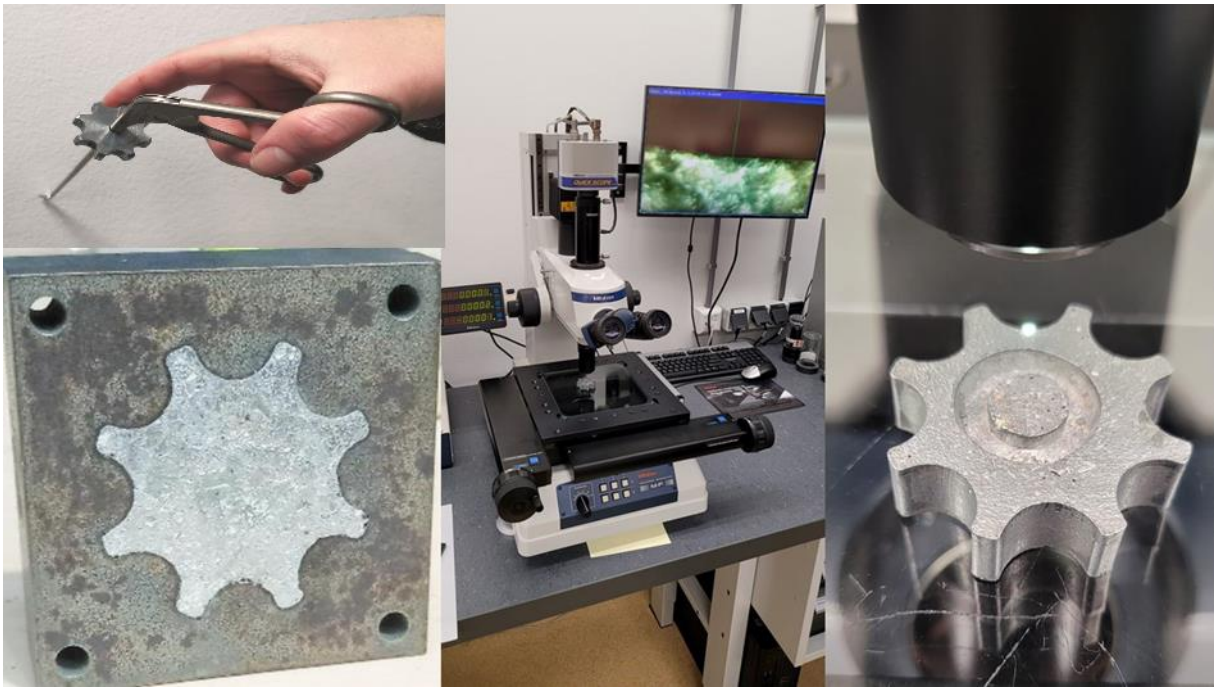

Figure 8. Assessment of the final product. Top left: a finalized wheel fixed on the instrument to test the fixation strength. Below Left: a very tight fit established between product and casted half fabricate. Middle and Right, measuring microscope with casted steering wheel close up.

4. Discussion

4.1 Mechanical properties

The results of this study show that melting Zamak disposable blades into raw material to make new products and components is feasible. The melting, having a temperature of 420^0C, was implemented for three hours, resulted in 93% Zamak extracted from the blades. The tensile tests revealed that the mechanical properties of the reprocessed laryngoscope blades are lower compared to the standard Zamak properties from the literature. Nevertheless, they are in line with the tested virgin Zamak (IPS). The averaged UTS, yield strength and Young's modulus were 82%, 103% and 64% of virgin Zamak (IPS). Within our "all-in-one" processing method, gravity casting was used. The most noticeable results of the mechanical tests are the values of the YS of all tested samples in relation to the theoretical YS of 280 MPa. In all cases, the values remained much lower, indicating a significant difference in the location of the yield point. In case of pure Zamak, the stress strain curve is more linear compared to the tested samples. Therefore, it is likely that the theoretical YS is based on the 0.2% offset method [38] instead of using the true Yield point. Another factor which may affect the mechanical qualities are the impurities [39]. Although it is likely that most observed impurities on the surface of the ingots came from the coating and the other plastic parts of the laryngoscope blades, the XRF data show that removal of the coating did not result in significant differences in composition regarding impurities.

4.2 Ingot Porosities

The concentrations of Zinc and silicon found in the ingots after casting were higher than in virgin Zamak. The silicon is likely coming from the plastic parts of the laryngoscope blades. No significant porosities were observed in the ingots. Therefore, it is likely that gas porosity is prevented due to the use of the Zamak recommended casting temperature of 420^0C and the presence of a riser that prevented shrinkage porosity. This is supported by the lack of visual signs of shrinkage porosity. The observed contaminants and inclusions most likely come from entrainment of liquid/gas that is sucked out of the surrounding material as the pressure in the flowing medium is lower compared to its environment [40].

4.3 Gravity casting process

The results show that it is feasible to create an "all-in-one" Zamak casting process for functional new parts with a minimal production setup as alternative for die-casting. Although it demonstrated to be possible to incorporate specific details into the stainless cast-design, some minor flaws were detected along the edges of the wheel part. Therefore, it is suggested to investigate if the inflow of material in the indentations and protrusions of the cast can be improved by adjusting the height of the setup or by controlling the cooling down of the setup. The used molds were manufactured from 10 mm thick stainless steel plate with multiple sections. It is likely that the segments with differing surface areas and volumes have different cooling rates. As this can lead to non-uniform shrinkage as observed in de indentation cut-out, the segments in the mold design should compensate for this by removal or adding material around the wall of the mold to create a more uniform wall thickness. A more uniform wall thickness and controlled cooling can result in less material tension in the product leading to better tolerances.

4.4 Circular economy

Despite the observed limitations, the results indicate that is feasible to use medical waste, such as laryngoscope blades, as source of raw material and semi-finished products. After this process is further matured and scaled, it can contribute to reduce medical waste. Reducing waste within the Circular Economy is growing in significance due to its benefits to society [41,42]. Reusing and reprocessing of disposable medical devices after sterilization have been reported earlier [43]. The reuse of Zamak laryngoscope disposables in their current design may significantly contribute to CO_2 reductions but is legally restricted [44]. Melting, as a second option, will require more energy than (re)sterilizing but is more sustainable than incineration. Before environmental claims can be made about the benefits of using disposed Zamak as input material for new products, a Life Cycle Assessment (LCA) study needs to be conducted to calculate other environmental impacts categories as water- and land use, fine particulate matter and eco-toxicity. To investigate the costs of reprocessing versus the manufacturing of components made out of virgin and reprocessed Zamak, an in-depth cost study, such as a Life Cycle Costing (LCC) should be conducted.

4.5 Study limitations

Although not included in the scope of this study, a cost analysis of the logistical process of the urban mined laryngoscope blades, melting and casting would be an area of interest for further investigation as this has not been explored in this study. Special logistical set-up is needed, as these blades have been used with patients on the Operating Room, meaning that they are potentially contaminated, generating more costs. These costs include safe-handling of the waste, use of validated and special containers with closable lids and the costs of the process of thermo-disinfection. These costs should be compared with the standard current costs for hospitals when disposing medical waste. With regard to the casting procedure, additional research is needed to determine whether the Zamak quality remains constant with gravity casting as compared to die-casting. Furthermore, the material use and quality consistency of molds, used during the casting, is an area to be explored additionally.

5. Conclusion

A circular “all-in-one” process was designed using disposed Zamak laryngoscope blades that were successfully reprocessed into raw material and directly molded into a surgical instrument component. After being optimized, a gravity driven “all-in-one” reprocessing setup for Zamak disposables can be an affordable alternative for expensive die casting methods. Despite the changing mechanical properties as compared to standard Zamak, reprocessing Zamak laryngoscope blades demonstrated to have potential for making new (medical) parts. The casted Zamak parts still require post-processing, and is not yet an ‘as-ready’ product when the part is released from the mold. However, this study demonstrated the feasibility of reprocessing Zamak medical waste into new product components contributing to a circular health care economy.

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Chapter 6

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A life cycle assessment of reprocessing face masks during the Covid-19 pandemic

Abstract

Introduction

The Covid-19 pandemic led to threatening shortages in healthcare of medical products such as face masks. Due to this major impact on our healthcare society an initiative was conducted between March and July 2020 for reprocessing of face masks from 19 different hospitals. This exceptional opportunity was used to study the costs impact and the carbon footprint of reprocessed face masks relative to new disposable face masks. The aim of this study is to conduct a Life Cycle Assessment (LCA) to assess and compare the climate change impact of disposed versus reprocessed face masks.

Methods

In total 18.166 high quality medical FFP2 face masks were reprocessed through steam sterilization between March and July 2020. Greenhouse gas emissions during production, transport, sterilization and end-of-life processes were assessed. The background life cycle inventory data were retrieved from the ecoinvent database. The life cycle impact assessment method ReCiPe was used to translate emissions into climate change impact. The cost analysis is based on actual sterilization as well as associated costs compared to the prices of new disposable face masks. A Monte Carlo sampling was used to propagate the uncertainty of different inputs to the LCA results.

Results

The carbon footprint appears to be 58% lower for face masks which were reused for five times compared to new face masks which were used for one time only. The sensitivity analysis indicated that the loading capacity of the autoclave and rejection rate of face masks has a large influence on the carbon footprint. The estimated cost price of a reprocessed mask was €1.40 against €1.55.

Discussion

The Life Cycle Assessment demonstrates that reprocessed FFP2 face masks from a circular economy perspective have a lower climate change impact on the carbon footprint than new face masks. For policymakers it is important to realize that the carbon footprint of medical products such as face masks may be reduced by means of circular economy strategies.

Conclusion

This study demonstrated a lower climate change impact and lower costs when reprocessing and reusing disposable face masks for five times. Therefore, this study may serve as an inspiration for investigating reprocessing of other medical products that may become scarce. Finally, this study advocates that circular design engineering principles should be taken into account when designing medical devices. This will lead to more sustainable products that have a lower carbon footprint and may be manufactured at lower costs.

Introduction

According to the European Commission, the European recovery plan for the economy after Covid-19 aims to make the European economy more circular and more sustainable. The Green Deal on Sustainable Healthcare [1], as set out in The Netherlands, consists of a formal contract signed by hospitals, government organisations, industrials and universities, and will be used in the European's recovery strategy by stimulating a circular economy [2] by building a more resilient European Union. One of the goals as seen from the Dutch Green Deal on Sustainable Healthcare is to reduce waste. By 2030, the CO_2 emissions from healthcare should be reduced by 49% compared to the 1990 levels, and by 2050 realise a climate neutral situation [1].

Hospital waste production in high income countries varies between 1.7 and 8.4 kg per bed per day depending on hospital size and activities [3]. For hospitals in Europe ranging from 1.7 kg in the Netherlands to 3.6 kg in Germany, between 3.6 and 4.0 in Middle East countries such as Kuwait [4]. and in the US these numbers are rising to 8.4 kg [5]. In total 5.9 million tons of medical waste is disposed in the USA by hospitals annually and healthcare produces 8% of the total CO2 emissions in the US [6]. Subsequently, severe health risks associated with medical waste disposal by hospitals have been reported [7].

The Covid-19 pandemic led to severe shortages of medical products in particular with personal protective equipment (PPE) [8]. These local shortages of PPE included face masks, aprons and isolation gowns. This period led to an emergency scenario in which reprocessing was devised as an alternative. This resulted in situations in which either no care could be given or in situations where health care professionals were not fully protected. The authorities decided to temporarily exempt these medical products from CE registration [9]. Meaning that manufacturers and suppliers were able to supply non-CE-marked medical equipment, such as face masks, at the explicit request of hospitals or other healthcare institutions, when shortages occurred as a result of the coronavirus.

Upon request of several hospitals, a variety of methods for reprocessing were investigated of single use face masks in the period starting at 17 March 2020 [10]. The quality of reprocessed as well as new face masks were tested with a custom test set-up which was built to measure the filter penetration of particles with different size and pressure drop over the face masks. With this system the filter capacity and filter material pressure drop of, commonly used, sterilized masks were evaluated between 17 March and 1 July 2020 [11].

In total 18,166 FFP2 face masks were steam sterilized at 121 °C and 88 different masks brands were evaluated, showing that the Particle Filtration Efficiency (PFE) in the particles range of 0.3, 0.5 and 5 microns did not change significantly for the commonly used 3M 1862+ masks with and without a valve. The study indicates that for reuse up to five times after multiple heat sterilization procedures the PFE remained, with an averaged minimum of 96,8% for the smallest particle size, well above the FFP2 standard of 94% for particles larger than 0,3 micron10,12. In addition, the pressure drop measured for 3M 1862+ masks that were used and reprocessed up to 3 times showed that the pressure drop remained well below the 0,7 Mbar standard as defined in the EN-149 with values around 0.2 Mbar [11,12]. As leakage is a very relevant aspect, all masks seals were visually and tactilely inspected for damages and

changes in elasticity before the masks were placed on the face and used [11]. Reprocessing by means of steam sterilization of disposable face masks at 121 °C showed acceptable PFE results, maintaining its filtration material quality, and can be done if the fit does not change [10]. Our suggestion that 3M 1862+ masks can be reprocessed was later confirmed in a technical bulletin by the manufacturer of the masks, 3M [13] and by the National Institute for Public Health and the Environment [14]. These studies demonstrated that a circular approach for certain face masks is feasible.

The Corona crisis period appeared to provide a potential motive to investigate the effects of reprocessing medical equipment. Since the circular reprocessing involved steam sterilization, it was of equal importance to determine whether this approach is sustainable. This study was therefore conducted to demonstrate the environmental sustainability by means of a Life Cycle Assessment (LCA) and to investigate economic feasibility. The carbon footprint (expressed in kg CO2 eq) and costs of reprocessed face masks and new ones will be studied from a circular economy perspective.

Several studies assessed the impact of facemasks or other PPE from different perspectives. Allisson et al. [15], performed a Life Cycle Assessment as well as a cost comparison to demonstrate that reusable face masks have a lower environmental and economic impact when compared to single-use face masks. Kumar et al. [16] conducted a Life Cycle Assessment of Personal Protective Equipment (PPE) where cycles during end-of-life PPE to landfill and incineration were investigated. Schmutz et al. [17] investigated the ecological factors by comparing surgical masks with cotton masks. However, the perspective of our study is to identify the differences in climate change impact when reusing the same single-use face mask five times.

The aim of this study is to conduct a Life Cycle Assessment (LCA) to assess and compare the climate change impact of disposed versus reprocessed face masks. The following research questions were formulated:

1. What is the climate change impact of reprocessed versus disposable FFP2 face masks?

2. What are the financial differences of reprocessed versus disposable face masks?

Methods

Scope

We compared disposable face masks that were used once with face masks that were sterilized and used five more times (six times in total). Sterilisation and PFE test data of the Aura 1862+ (3M, Saint Paul, Minnesota, USA) face mask indicate that this type of face mask shows good performance after multiple sterilisation cycles [10,11,12]. In a previous pilot study, the company CSA Services (Utrecht, the Netherlands), a sterilization facility for cleaning, disinfection and sterilization of medical instruments, was rebuild to process FFP2 face masks. In total, 18,166 single use FFP2 masks were sterilised after use in a medical autoclave. As the majority (n = 7993) were Aura 1862+ (3M, Saint Paul, Minnesota, USA), this particular type of face mask was chosen for the LCA.

The total weight of the face masks and packaging together during end-of-life consists of incineration for the face masks (97%) and landfill for the carton box packaging of new face masks (3%). There is no recycling potential used in our model since the materials coming from the operating room and its packaging is commonly disposed as medical waste. In the Netherlands, no energy recovery takes place at the incineration of regulated medical waste. Therefore, no co-function was applicable for the end-of-life scenario.

Recycling is often a multi-functional process that produces two or more goods. To deal with the multi-functionality in the background processes, the cut-off approach was applied to exclude the allocation of the greenhouse gas emissions to additional goods. This means that potential rest materials such as energy gained during incineration are cut-off and that the greenhouse gas emissions are fully allocated to the waste treatment processes itself.

In the LCA, the 'functional unit' defines the primary function that is fulfilled by the investigational products and indicates how much of this function is considered [18]. In this study, we pragmatically chose as a definition for the protection of 100 healthcare workers against airborne viruses, using one FFP2 certified face mask, each during one working shift of an average of 2 h in a hospital in the Netherlands.

Table 1 shows the differences between the two scenarios:

1. 100 masks including packaging, transported from production to the hospital, used and disposed.
2. 100 times use of reprocessed masks. We calculated that 27.1 masks are being produced and transported from production to the hospital. The 27.1 are being reprocessed five times, taking into account that 20% of the batch cannot be reprocessed. Therefore 80% of the batch could be used for reprocessing after each step resulting in: 27.1 (new) + 21.7 (repro 1) + 17.3 (repro 2) + 13.9 (repro 3) + 11.1 (repro 4) + 8.9 (repro 5) = 100 times of use. For each time of reprocessing the batch is transported from the hospital to the (hospital) Central Sterilization Services Department (CSSD) and disposed after five times of reprocessing.

Table 1 Comparison between reference flow 1 and 2

	times (re)sterilized	purchased masks	reprocessed	disposal	times protection
Reference flow 1	0	100	0	100.0	100.0
Reference Flow 2	0	27.1	27.1	0.0	27.1
	1	0.0	21.7	5.4	48.8
	2	0.0	17.3	4.3	66.1
	3	0.0	13.9	3.5	80.0
	4	0.0	11.1	2.8	91.1
	5	0.0	8.9	2.2	100.0

Combining the functional unit with the two alternative scenarios results in the reference flows for the protection of 100 health care workers against airborne viruses, either using a face mask one single time (100 virgin masks produced for the 1st scenario), or reusing a face mask for five additional times (27.1 virgin masks produced for the 2nd scenario). For both reference flows, only FFP2 certified face masks are considered. For the calculations each mask is used for a single two hours working shift in an average hospital in the Netherlands.

Life cycle inventory (LCI) analysis

The inventory data includes all phases from production (including material production and part production), transport, sterilisation to end-of-life of the life cycle of the single use and reprocessed face masks. We disassembled one face mask to obtain the weight of each individual component on a precision scale (Fit Evolve, Bangosa Digital, Groningen, the Netherlands) with a calibrated inaccuracy of 1.5%. Component information and materials were obtained from the data fact sheet provided by the manufacturer. We conducted a separate validation experiment to establish the material composition in the filtering fabric (Supplement file 10).

This LCA with the Aura 3M masks was based on steam sterilization by means of a hospital autoclave and therefore part of this study. Therefore, face masks were placed in a sterilization bag that contained up to five masks. A total of 1000 masks were placed into an autoclave (Getinge, GSS6713H-E, Sweden) per cycle. After sterilization, the masks were transported to the hospital. Masks were reprocessed for a maximum of five times before final disposal [10,11].

The assessment of climate change impact is done following as closely as possible the internationally accepted Life Cycle Assessment (LCA) method following the ISO 14040 and 14044 standards [19,20]. The LCA examines all the phases of the product's life cycle from raw material extraction to production, packaging, transport, use and reprocessing until final disposal [19]. The LCA was modelled using SimaPro 9.1.0.7 (PRé Sustainability, Amersfoort, The Netherlands). The background life cycle inventory data were retrieved from the ecoinvent database (Ecoinvent version 3.6, Zürich, Switzerland) [21].

To make a valid comparison between the disposable and reprocessing face masks, the system boundaries should be equal in both scenarios. The system boundaries in this study consisted of the production, the use and the disposal and waste treatment of the masks. For the reprocessed face masks, the lifecycle is extended due to the sterilisation process (Fig. 1). Therefore, the additional PPE’s and materials needed to safely process the masks (e.q. masks, gloves and protective sheets) are included in the production phase. The production of machinery for the manufacturing of the face masks and the autoclave were not included in this study.

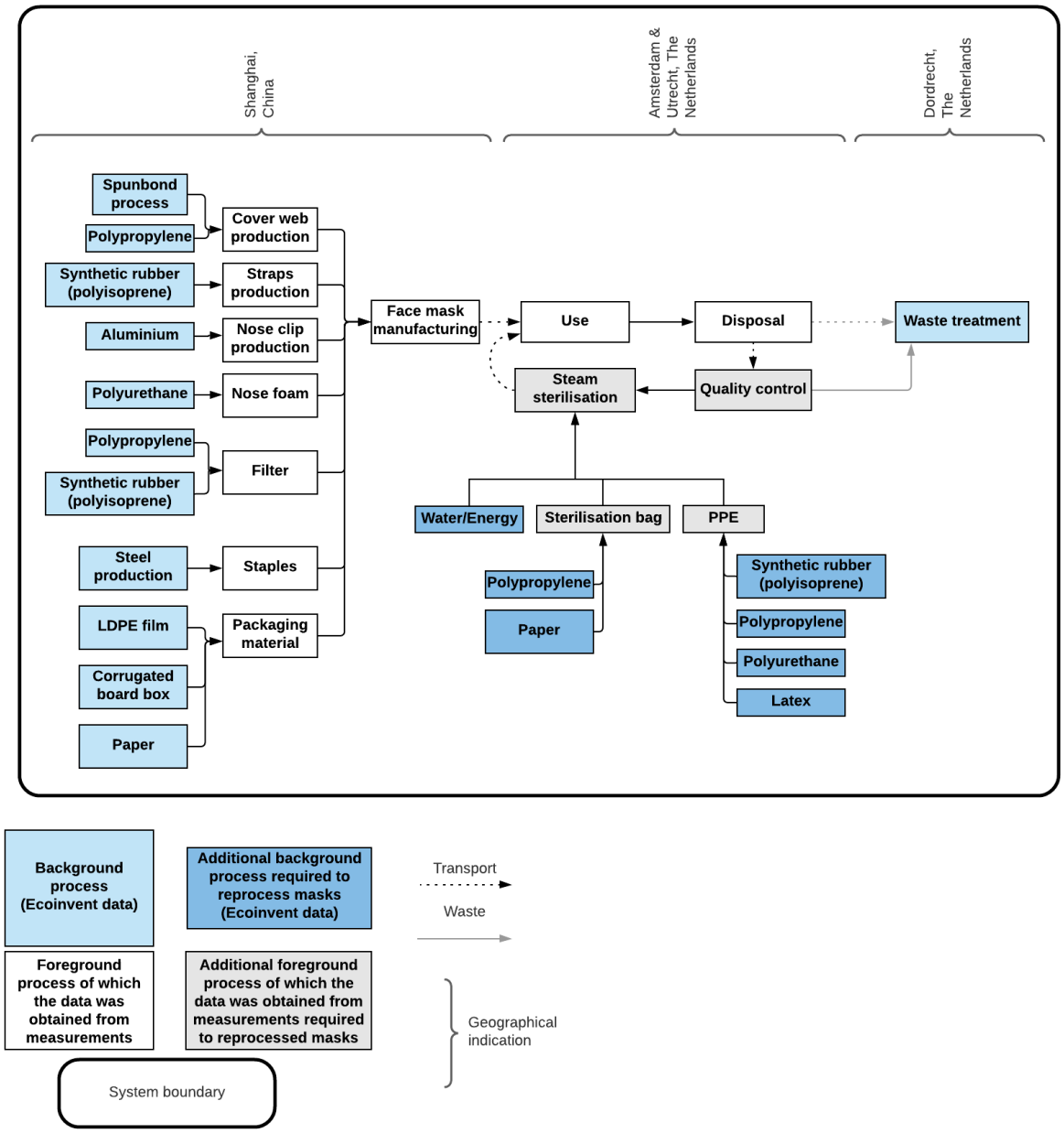

Figure 1. System boundary overview of new and reprocessed face masks including waste treatment by incineration.

The production facility for the face masks is located in Shanghai, China [22,23]. Further distribution took place from Bracknell, UK to Neuss, Germany and the final destination was set in Rotterdam, the Netherlands.

The packaging materials were disposed in the hospital where the face masks are used primarily. After first use, face masks were transported to the sterilisation department. All masks were manually checked before reprocessing by personnel wearing PPE. Of all used Aura 1862+ facemasks that entered the CSA, approximately 10% was discarded. To remain conservative, the LCA was conducted based on a 20% rejection rate as a result of face masks which could not be reused anymore due to deformities, lipstick, and broken elastic bands.

A full overview of the life cycle inventory table for the two scenarios and details on model assumptions are added in the Supplemental file (Supplemental file 11).

Life cycle impact assessment

The carbon footprint (kg CO2 eq) was chosen as the primary unit in the impact category. ReCiPe was applied at midpoint level and used to translate greenhouse gas emissions into climate change impact [16].

Uncertainty analysis

The final LCA model contains several uncertainties based on assumptions and measurement inaccuracies [24]. The included uncertainties were based on weighted components of the masks as well as the packaging which were measured with 1.5% inaccuracy of the precision scale apparatus. A Monte Carlo sampling [25] was conducted for both alternatives (disposable and reprocessing) where input parameters for the LCA were sampled randomly from their respective statistical distributions in for 10,000 'runs'. Because input parameters between scenarios were partly overlapping, we compared these two scenarios directly using a discernibility analysis. This technique, establishes which scenario is beneficial for each of 10,000 Monte Carlo runs. We report the percentage of instances where the reprocessing scenario has a lower carbon footprint than the disposable scenario.

Sensitivity analysis

A sensitivity analysis was conducted to check the sensitivity of the outcome measures to variation in the input parameters. To determine which parameters are interesting to investigate, three aspects were considered: the variations in number of face masks per sterilization cycle (autoclave capacity), rejection rate (number of losses per cycle) and transport distance to the CSSD. Finally, we included the relative contribution of these variations. The following three parameter variations were chosen for the sensitivity analysis:

1. Rejection percentage. The rejection rate was defined based on experiences from the participating sterilisation department and studies that show that sterilisation of the face masks up to 5 times is possible. Masks were re-used for 5 times, approximately 10% was discarded during the total life cycle. Out of this experience and to remain conservative, the total rejection rate was set on 20%. Therefore it is interesting to investigate whether variation in PFE testing outcomes or differences in user protocols influence the outcomes. This should indicate if masks from higher or lower quality can also be suitable candidates for reprocessing.

2. Autoclave capacity, which largely depends on the loading of the autoclave. To mimic different loads of the autoclave, it is interesting to know the influence of sterilizing fewer masks per run on the model.

3. Transport. As it is likely that many hospitals have a Central Sterilisation Services Department (CSSD) it is interesting to know the effect of having zero transportation. Moreover, in case hospitals are not willing to change the routing in their CSSD it is interesting to observe how outcomes are influenced if transportation is set on the maximal realistic value of 200 km.

The parameters have been varied with 250 and 500 face masks per sterilisation batch. A rate varying with 10% and 30% of the face masks being rejected due to quality reasons and variation in transport kilometres of 0–200 km.

There is a small difference between the baselines of the sensitivity, LCIA and contribution analyses because all these are performed using separate Monte-Carlo simulations. The output of the different simulations may show minor differences due to statistical distribution.

Cost price comparison

A cost analysis was made to give insight in costing from a procurement perspective. The cost analysis is conducted with five face masks that were steam sterilized per batch in a permeable laminate bag, Halyard type CLFP150X300WI-S20 and includes the expenses of energy, depreciation, water consumption, cost of personnel, overhead and compared to the prices for a new disposable 3M Aura face mask during the first and second Corona waves. Five pieces per bag were chosen in order to have enough space between the masks to sterilise each mask properly. The cost analysis is based on actual sterilization as well as associated costs compared to the prices of new disposable face masks. The costs were then related to the functional unit of protecting 100 health care workers by calculating the difference in the amount of Euros per 100 face masks.

Results

The impact category outcomes of new versus reprocessed face masks over a functional unit of 100 times use with Standard Deviation (SD) for carbon footprint are:

- 6.55E+00 (SD 3.11E−01) kg CO_2 eq for new face masks.
- 2.77E+00 (SD 1.21E−01) kg CO_2 eq for reprocessed face masks.

The carbon footprint is approximately 3 kg CO2 eq for 100 times of protection with a face mask which is (re)sterilized and reused for an additional five times.

The relative difference on carbon footprint is 58% lower for (re)sterilised face masks compared to face masks that are disposed after one time of use.

Figure 2 shows the normalized contribution expressed in percentages of the total carbon footprint of a disposable mask.

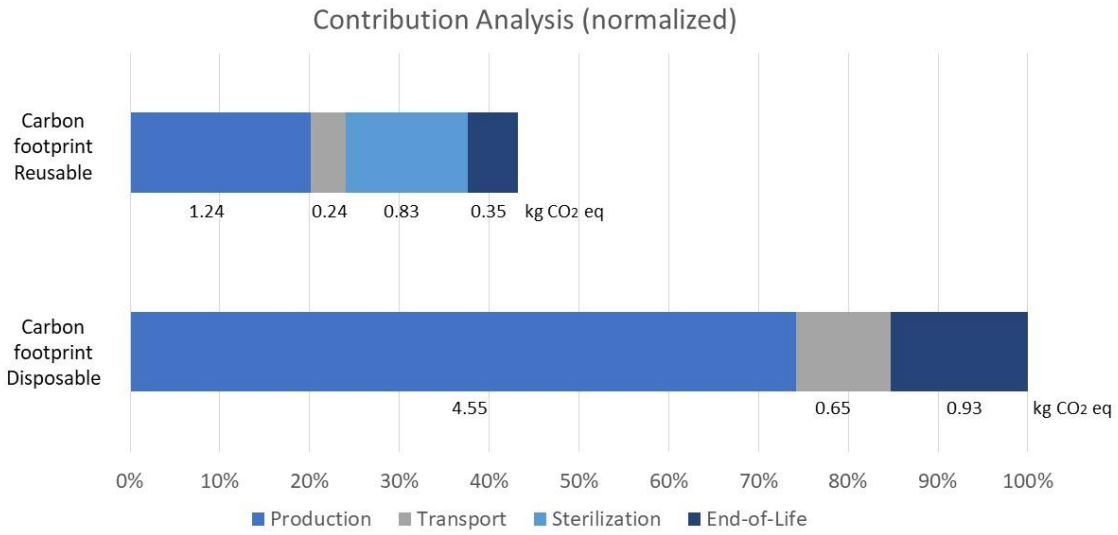

Figure 2. Sources of impact relative to the impact category carbon footprint

Compared to disposal, reprocessing of face masks showed a lower climate change impact.

The contribution analysis shows that the highest reduction in climate change is caused by the production phase of the face masks. The production phase is reduced from 4.55 kg CO2 eq to 1.24 kg CO2 eq. Moreover, the impact caused by transport reduces from 0.65 to 0.24 kg CO2 eq and the end-of-life impact decreases from 0.93 to 0.35 kg CO2 eq.

Sterilization however, has a significant impact on the total results of reprocessed face masks. This phase contributes with 0.83 kg CO2 eq. When comparing to disposable masks, reprocessed face masks even when including sterilization, remains the alternative with a lower impact on climate change.

The discernibility analysis indicated that the reprocessing scenario had a lower climate change impact.

Sensitivity analysis

Figure 3 shows the sensitivity analysis outcomes, including the baseline results and results using different autoclave loading capacity, rejection rate after inspection and transport differences.

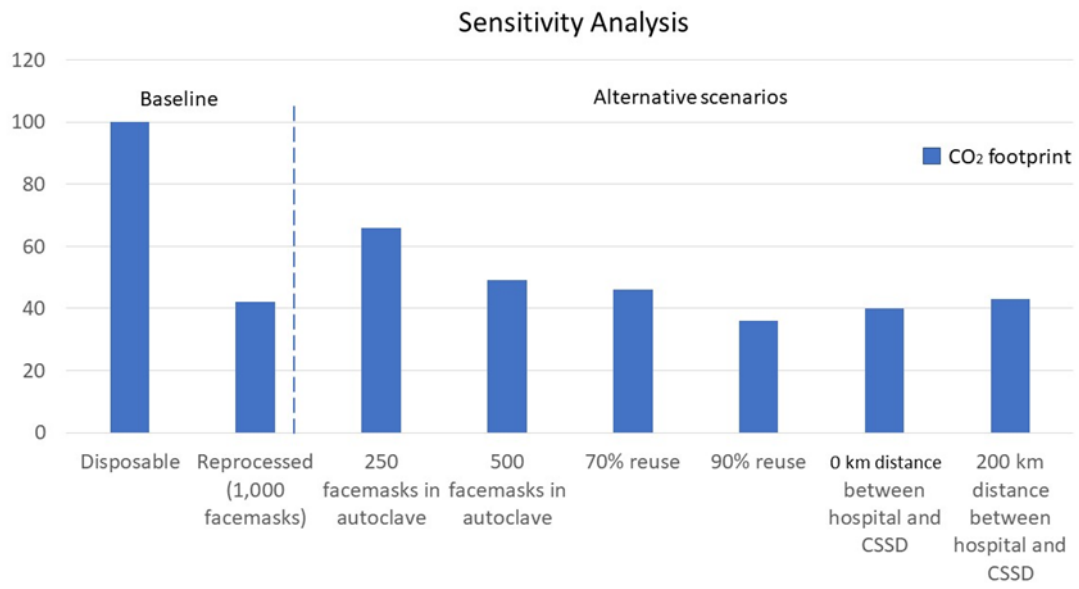

Figure 3. Sensitivity analysis. Left of dotted line, baseline disposable (masks used only one time) versus reprocessed face masks with benchmark autoclave loading capacity of 1000 masks, rejection rate of 20% and transport distance of 46.1 km. Right of dotted line, effect on carbon footprint of different autoclave loading capacity, different rejection rates and different transport distances from hospital to sterilisation site.

The baseline characteristics for the autoclave capacity was determined for 1000 face masks per cycle and a transport distance from the hospital to the CSSD of 46.1 km. We assumed that 80% of the masks were reused each time the mask came back into the CSSD for reprocessing. When the autoclave capacity drops to 250 or 500, the CO2 emissions increases by 57% and 17% respectively. If 70% of the face masks are reused, the CO2 emissions increase with 8%. If 90% of the face masks are reused, the emissions decrease with 14%. If the travel distance changes to 200 km as a max feasible distance, the CO2 emissions increases with 2%. Reducing the distance to 0 when the CSSD is inside the hospital decreases the emissions with 7%.

The results of the sensitivity analysis show that even with relatively large variations in changing parameters, the reprocessed face masks continue to have a lower impact in all categories when compared to using new disposable masks (Supplemental file 12). The uncertainty and discernibility analysis were performed (solely) over the weight of the mask. The results demonstrate that the inaccuracy of the scale does not affect the fact that reprocessed mask has a lower score in terms of climate change as compared to disposable masks.

Cost price comparison

The cost price of a reprocessed mask by means of steam sterilization in a permeable laminate bag is €1.40. The purchase price of a new, disposable face mask was €7 during the peak time of shortages in the hospital Haaglanden MC. The prices after the first Corona wave dropped to €186.06 per 120, having an average price of €1.55 per Aura 1862 face mask. Saving 560

Euro per 100 protected healthcare workers in the first wave and 15 Euro in the second Corona wave when using reprocessed masks.

Discussion and interpretation

The main finding in this study, when looking back at the research questions, demonstrate that there is a significant environmental benefit if FFP2 face masks are reprocessed. Therefore, reprocessing may contribute to achieving a circular economy as the Life Cycle Assessment indicates a 58% reduction in carbon footprint.

Furthermore, there is a price benefit when reprocessing face masks as compared to using new disposable masks. Although the prices after the first Corona wave dropped to €186.06 per 120, having an average price of €1.55 per Aura 1862 face mask for Haaglanden MC, this was still higher than the cost price of the reprocessed masks.

The sensitivity analysis conducted in this study indicates that both loading fewer face masks into an autoclave as well as variation in the rejection rate have a significant impact on the end result. The relative high impact of the sterilization process is in line with other studies that showed that the sterilization process is a critical process for the environmental footprint of sterile products [26]. Therefore, a hospital should take into consideration to optimally load an autoclave since the volume has a significant effect on the cost price and the climate change impact per product.

Next to steam sterilization, other methods of sterilization of face masks are available such as H_2O_2 plasma sterilization, Gamma radiation or UV irradiation sterilization [27]. However, Steam sterilization seems an attractive method as studies indicate better PFE results compared to H_2O_2 and gamma radiation [10]. Although steam sterilization is readily available at hospitals and because of the larger loading capacity, most autoclaves can handle much more face masks per cycle compared to most alternatives. However, it is interesting to perform an LCA based on those alternatives for comparison.

Disposable 3M 1862+ masks that were sterilized up to five times by means of steam sterilization at 121 °C showed good PFE results above 94% while maintaining their breathability and shape. However, other masks with similar FFP2 standard showed varying quality after sterilization [10]. Therefore, unknown masks should be tested after sterilization for PFE, pressure drop and facial fit before brought back into circulation. This should be taken into account when hospitals decide to reprocess different types or brands of face masks in times of shortage.

The LCA was conducted on the basis of a 20% rejection rate as a result of face masks which could not be reused anymore due to deformities, lipstick, and broken elastic bands. However, If better care would be taken for used face mask such as instructions on how to wear, store and treat masks properly, it is likely that the rejection percentage drops even further. This will result in a better outcome in number of masks to be reprocessed and therefore, further improving carbon footprint values.

When considering that hypothetically 200 million disposable face masks are used per year in the Netherlands in all healthcare institutions during the Corona period, an increase in carbon

footprint is expected. Based on the outcome of this study we can conclude that reprocessing 200 million disposal face masks will lead to a reduction of 7.56 million kg CO_2 eq (Supplemental file 13).

Many face masks that cannot be used anymore and need to be discarded were made of high-quality polypropylene material (Supplemental file 7) and can still contribute to the transition towards a circular economy for medical devices. Therefore, repurposing products at the end of their life cycle to be reused or to become raw material for new medical devices should be included in the design of these products. Then, modular design of masks could decrease the disassembly effort and therefore, reduce the climate change impact as well28.

This study focuses on the Life Cycle Assessment of disposed versus reprocessed face masks and may form a basis for further studies. These studies in the medical field can focus on instrument blue wrapping paper, drapes also made out of the Polypropylene material6 as well as anaesthetic and oxygen masks and oxygen tubing made out of other types of thermoplastic materials. These further studies should determine if they have similar environmental benefits. Reuse and reprocessing of medical products is possible such as with surgical instruments, especially when modular designed [29,30].

Facing the climate challenges and following the EU's 2020 climate goals it seems evident that the carbon footprint needs to be reduced. For policymakers it is important to realize that reducing the carbon footprint of medical devices such as face masks may have relevant positive effects on climate change. The insights from this study could help to reach the goals of the Green Deal [31] by reducing the CO_2 emissions by 49% in 2030.

Limitations

Although it is likely that CSSD employees use a maximum autoclave loading, the LCA sensitivity analysis included variations in holding capacity. However, it remains more interesting to know the impact on the LCA if different types and sizes of autoclave are used that require different energy and water consumption. In order to better relate the model and study results to different CSSD setups (e.g. general practitioner, larger academic hospital etc.) a study expansion is needed that includes autoclave type in addition to holding capacity. The uncertainty analysis was only performed on the inaccuracy of the scale, weighing the masks. To improve the Monte Carlo analysis accuracy in further studies, it is advised to investigate the influence of all potential uncertainties, of foreground and background data.

Amongst other factors, the production of machinery for the manufacturing of the face masks and the autoclave are not included in this study since this data was not readily available, and therefore, outside the system boundary. Furthermore, the Global Inventory Data (GLO), representing the average global situation, and the data from the Rest of the World (RoW), average inventory data for all geographical areas not covered in ecoinvent, were combined in our study as not all data was available in the GLO dataset. Although not expected, further studies should identify if this may cause small deviations in outcome.

A Life Cycle Costing (LCC) has not been conducted in this study. An LCC would be recommendable in further studies in order to analyse the cost of each phase. Furthermore, it may be helpful for designers when designing new (circular) products.

The fit of the mask on the face of the users was determined by means of tactile and visual inspection. To ensure that masks remain fully functional and without damage after five reprocessing cycles it is advisable to check besides pressure drop and filter efficiency for inwards leakage with commercially available systems like the ACCUFIT system (AccuFIT 9000 Respirator Fit Test apparatus (https://accutec-ihs.com/accufit-9000) before reprocessing of face masks is implemented in any hospital.

Conclusion

The results of this study showed clear benefits of reprocessing face masks. The LCA demonstrated a significantly lower climate change impact for reprocessed medical face masks compared to new. Furthermore, reprocessing results in lower costs. This study may serve as an inspiration for investigating the reprocessing of other medical devices due to the potential large climate change impact and cost reductions. Therefore, this study advocates that circular design engineering principles should be taken into account when designing medical devices. This will lead to more sustainable products that have a lower carbon footprint and may be manufactured at lower costs. A circular economy for medical devices may serve therefore, as potential to execute the goals of the Green Deal and the global sustainable development goals of the United Nations.

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SCIENCE IN WASTE

Chapter 7

Discussion and future perspectives

A holistic approach, following all of the circular branches from the Butterfly Diagram, is needed, starting with the first loop of reuse and ending with recycling if all of the previous loops are not feasible. This dissertation evaluates surgical waste reprocessing, in particular methods to reuse or reprocess medical waste into new products. Multiple circular strategies of the Butterfly Diagram [1] were used as inspiration for finding new processes to transform disposed waste into new or reprocessed products. These circular strategies include reuse, maintenance, refurbishment, remanufacturing and recycling of single-use medical devices which would otherwise have been disposed.

During the previous years the Climate Agreement and the Green Deal shifted the Dutch political and industrial agenda towards circularity and sustainability. During the Corona pandemic it became evident that reuse, refurbishment, remanufacturing and recycling are strong methods not only with respect to circularity but also to prevent shortages of resources. Our studies showed that hospital waste of different origins can be processed on the level of reuse, remanufacturing and recycling [2-7]. The results impacted not only the international health care community but also influenced the social debate.

The aim of this thesis was to design and evaluate methods to reduce medical waste and to reprocess this waste into new medical products. In the following section we address the research questions as formulated in the introduction.

Research question 1: Can disposable medical devices be reprocessed and brought back into circulation?

In Chapter 2 we showed that disposable face masks can be safely reprocessed with 121^0C steam sterilization with a minimal reduction in particle filtration efficiency (PFE). PFE comparison between filter material of sterilized masks and new, imported masks showed that the filter material of most reprocessed masks of high quality brands even outperformed new, imported face masks of unknown brands.

The nationwide field experiment, that included nineteen hospitals, international NGO's and multiple industrial partners, generated data that revealed that reprocessing is feasible.The reprocessing methods by means of steam sterilization were adopted by 19 hospitals and multiple health institutions around the world. The test methods were used to test the safety of millions of FFP2 masks that entered the Netherlands in 2020.

The measurement method for face masks revealed that imported face masks offered less protection than claimed by several manufacturers. A resolution was submitted in the Dutch parliament, finding that the use of qualitatively unsound masks may lead to a false safety. The Dutch government was asked to monitor these face masks (appendix - Impact from the research on society, motion Azarkan - F. (2020). Tweede Kamer der Staten-Generaal).

New bulletins were published after we shared our results of the steam sterilization process with the National Institute for Public Health and the Environment, RIVM and with hospitals that were preparing for the outbreak. As shown in appendix C - Impact from the research on society - RIVM updated and published their bulletin with the information of our measurements for the reprocessing of FFP2 face masks after steam sterilization.

With the input of our findings the medical industry updated their information regarding the reprocessing of PPE as well. As shown in appendix D – Impact from the research on society – a white paper was published by Belimed. This white paper provides details of medical device reprocessing as a result of our shared research and the implementation of our methods.

Our findings furthermore, contributed in co-authoring the national NEN guideline (NEN, the Royal Netherlands Standardization Institute, Delft), NEN-Spec 3 [7], describing the steps that must be followed when reprocessing single-use medical devices in times of crisis. This NEN-Spec, based on EU directives [8,9,10], is developed in the Netherlands and may serve as a guideline for other countries wishing to reuse single-use medical devices such as face masks during times of crisis.

To answer the research question, it can be confirmed that disposable medical devices can be reprocessed and safely brought back into circulation after testing the basic functionalities.

Research question 2: Can reprocessing of medical waste be feasible for hospitals?

We studied the impact in three hospitals of three main SS waste reprocessing methods: Repair/refurbishment, recycling and hospital waste disposal. Our works demonstrated that both instruments used for general surgery as well as instruments for specialized surgery could be repaired and brought back into circulation. The savings on refurbishment or repair were the highest comparing to the other two categories, recycling and waste disposal. Cost savings were calculated for three categories: (1) extending the life cycle of instruments by repair instead of disposal, (2) recycling of instruments by means of melting it into raw material, and (3) savings on waste handling costs.

Savings were realized from the instrument waste collected over all categories repair/refurbishment, recycling and waste disposal. Instrument with circular and sustainable designs that foster repair may further contribute to increased sustainability and cost-reduction.

If we want to increase the volume of reusing SS waste streams, not only the hospitals have a responsibility to focus on repair/refurbishment and (preventive) maintenance programs. Also the medical manufacturers and suppliers of surgical instruments have responsibilities as they should embrace circular economy principles in their product designs and in their processes. Combined, hospitals and manufacturers may have significant climate change impacts and may be considered part of their corporate social responsibilities.

To answer Research question 3, the repair and refurbishment of surgical instruments, instead of replacing them with new instruments show to have the highest potential for both environmental footprint as cost reduction. The results demonstrate that reprocessing of SS

medical waste is feasible for hospitals, realizing long term cost savings and environmental benefits.

Research question 3: Can new medical devices be designed from medical waste?

For the first time, medical devices were made out of recycled blue wrap (WP) hospital waste and used in the same hospital who supplied the waste. In Chapter five we described how we processed Polypropylene (PP) WP waste into new medical products that were used during washing and disinfection. Dog-bones were injection-moulded from virgin, mixed and 100% recycled granulate without using of additives.

A comparison of the mechanical test data showed that the elasticity was less and the UTS was higher for fully recycled PP as compared to lower mix ratios. This means that the material becomes more brittle and harder when recycled. Multiple batches of surgical instrument openers were made from the recycled material and circulated for four weeks at the Central Sterilization and Services Department of Maasstad hospital. The disinfection cycles did not significantly change the material properties of this device.

Based on our study [2], member of Parliament Eva van Esch submitted a resolution to the Minister of Health, Welfare and Sports on 28 October 2021 (appendix Impact from the research on society, motion Van Esch, 2021. Tweede Kamer der Staten-Generaal). This resolution refers to our innovative recycling method in which waste from hospitals is melted and processed into new medical instruments. Parliament member Van Esch calls on the government to recycle a mandatory percentage of hospital waste each year.

In our Zamak study (Chapter 5), we designed a Zamak instrument part made from disposable laryngoscope blades recovered from two hospitals after use on the operating room. With a new “all-in-one” melt and casting setup, specifically build to fit within an oven, blades were melted and casted into a steering wheel. Thereafter, the steering wheels were mounted in two surgical instruments and successfully tested on functionality. In response to Research question 3, we demonstrated that it is feasible to design medical devices and components for medical devices made out of hospital waste.

Research question 4: What is the climate change impact after reprocessing?

We showed that there is a significant environmental benefit when reprocessing disposable medical devices. The carbon emissions can be lowered when PPE’s such as face masks are reused for multiple times compared to buying new ones that are only used once. As the calculated cost price of the reprocessed face masks was lower, a financial benefit was detected. The sensitivity analysis however, did show that the volume of loading of an autoclave as well as the rejection rate of the products does have a large impact on the end result. Therefore, it is important that efficient processes by means of optimal autoclave loading and processing are taken into consideration.

Potential and additional environmental and cost benefits may be further increased when other categories of disposable medical devices such as instruments, blue wrap, laryngoscope blades are reprocessed. Prevention of using disposable devices at first, followed by reuse, repair, refurbishment and recycling help to increase environmental benefits and cost

reductions. Applying this on a large scale will lead to greater CO_2 reductions in healthcare. Extending this to other waste types will significantly reduce waste volumes and climate change impacts.

For policymakers it is important to realize that the carbon footprint of medical products such as face masks may be reduced by means of circular economy strategies. The large number of citations indicated that our research contributed for investigating the reprocessing of other medical products. Our studies, as presented in this thesis, advocates that circular design engineering principles should be taken into account when designing new medical devices. This will lead to more sustainable products having a lower carbon footprint and lower manufacturing costs.

To answer Research question 4, the impact on climate change after reprocessing can contribute to achieving a circular economy as the Life Cycle Assessment indicates a 58% reduction in carbon footprint.

Future perspectives

This thesis showed that reprocessing medical waste is feasible. Our works fulfilled the goals of our studies however, additional research is necessary. For the future it is important to explore multiple applications for reprocessing hospital waste. From this perspective we designed and built a production/recycling line in a field lab to facilitate circular (future) experimental research. This field lab will be used to further explore the possibilities of urban mining and a circular health care economy. Reprocessing by means of reuse, refurbishment, remanufacturing and recycling of complex surgical devices but also the recycling of face mask material are further explored.

A process is designed in which reprocessing is realized on a single location and with as little energy consumption as possible. Figure 1 shows a how we developed such a dynamic waste engineering process.

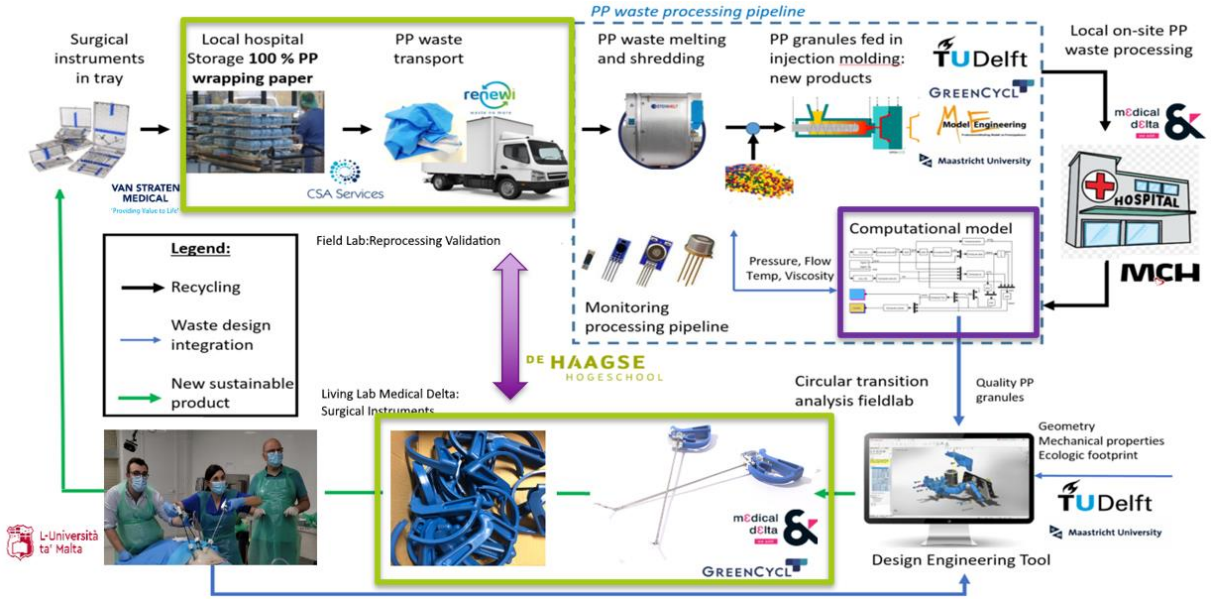

Figure 1. Dynamic waste engineering process (Illustration by T. Horeman [11]).

Furthermore, we believe that it is important to generate data regarding recycled materials. Therefore, we want to create a knowledge-based catalogue of recycled material. The objective is to create database for engineers on which they can base their design strategies and fundamental choices. In our studies we determined the mechanical behavior based on individual measurements. If we want to create a more structural method, we need to create a model with all common types of reprocessed surgical waste materials. This future database should provide open source information and include statistics such as material strength, elongation and other behavioral characteristics of recycled materials. As a result of our studies we started to build such a model. Figure 2 shows the contours of the database which is being build.

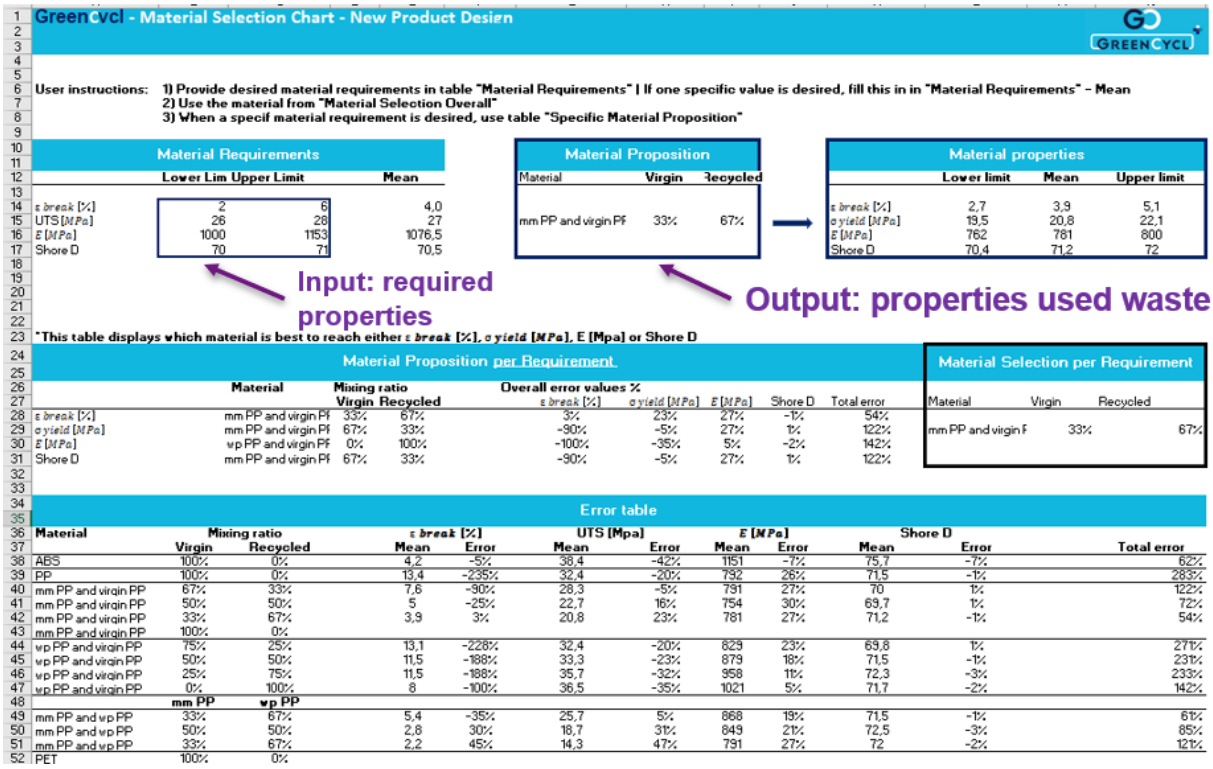

Figure 2. Example Database built as an engineering plugin (illustration by T. Horeman [11]).

Finally, our future perspective is to create more components and products made out of different types of surgical waste. As part of our upcoming research we aim to explore the design of more products made out of 100% recycled blue wrap, face mask material and other plastic waste.

Figure 3, shows the original and redesigned handle of the SATA grasper technology from Surge-On medical [12]. The redesigned handle is made out of recycled PP blue wrap, recovered from Maasstad Hospital. The handle was optimized so that it can be made completely from recycled PP waste and with 32% less material.

Figure 3. Redesign of SATA handle made completely from PP WP waste and with less material (illustration by T. Horeman [11]).

As a result of our findings a subsidy trajectory was awarded to our field lab as part of the Circular Chain Projects named ‘Rethinking Medical Waste’. This circular chain project focuses on the residual flow chain of surgical face masks. Due to COVID-19, the consumption of face masks has increased exorbitantly and there is a growing need to reduce these waste streams.

Next to face mask polypropylene, it can be seen that all hospital waste streams and material flows, ranging from stainless steel to blue wrap polypropylene as well as Zamak have significant impact. On the one hand the waste streams have increased and on the other hand the raw material supply of these resources is under pressure.

Our collaboration with universities, hospitals, the medical industry, governmental organizations is aimed at scaling-up our works to national and international levels. New circular product design inputs are investigated to develop future products made out of sustainable materials. These circular products with modular designs are aimed to facilitate easier reuse, maintenance, refurbishment, remanufacturing and recycling.

Sustainable development and circular engineering is possible with the common goal of minimizing waste and reducing greenhouse gas emissions. We will continue to investigate and scale-up the circular reprocessing of medical waste and expand to other waste categories. With respect to future generations, it is our goal to minimize surgical waste streams and to design new medical devices based on the circular strategies of the Butterfly Diagram. In addition to raising public awareness and developing new sustainable technologies we aim at creating evidence-based data and support the anchoring of circular engineering in our educational system. In this way we can serve the next generations to make the world more sustainable.

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Chapter 8

Summary

Hospital waste has a major impact on the environment. The worldwide growth of hospital waste is the result of the growing world population and the increase in use of disposables. A circular healthcare economy may contribute to the reduction of hospital waste. The circular economy is a system in which waste is prevented and where waste is reused.

This thesis reports the findings of circular methods and strategies.

The introduction in Chapter 1 provides an outline according to the Butterfly Diagram of the Ellen McArthur Foundation. The circular strategies include reuse (reuse), repair, refurbishment, maintenance and recycling of products and materials. Circular strategies not only protect our natural resources by reducing the use of raw materials and avoiding waste, they also contribute to the prevention of shortages of resource and reduce environmental impact. The Covid-19 pandemic resulted in such unexpected shortages. Circumstances arose that led to impending shortages of personal protective equipment where care could not be provided and health care professionals were not protected.

The aim of this thesis is to develop and investigate methods for a circular health care economy.

In Chapter 1 the research questions are formulated:

1. Can disposable medical devices be reprocessed and brought back into circulation

2. Can reprocessing of medical waste be feasible for hospitals?

3. Can new medical devices be designed from medical waste?

4. What is the climate change impact after reprocessing?

Chapter 2 describes a nation-wide field study in which 74,834 used face masks were processed. Of these masks, 56,668 masks were discarded upon entry inspection due to visual damage and deformities. 18,166 face masks were steam sterilized at 121°C. This field experiment with 19 hospitals, international NGOs and the industry provided data showing that reprocessing is feasible, with satisfactory results for quality after sterilization. It therefore, has been demonstrated that disposable medical devices such as face masks can be reprocessed and brought back into circulation.

In Chapter 3 we describe the study investigating the impact in three hospitals of three major processing methods for SS waste: repair/refurbishment, recycling and disposal of hospital waste. We showed that both instruments for general surgery as well as instruments for specialized surgery could be repaired and brought back into circulation. The savings with refurbishment and repair were the highest compared to the other two categories, recycling and waste disposal. Cost savings were calculated for three categories: (1) prolonging the life

of instruments through repair as compared to disposal, (2) recycling of instruments by melting them into raw material, and (3) savings on waste disposal costs.

A total of 1,380 kg of instrument waste was collected, of which 237 kg was refurbished and returned to the hospitals, resulting in a saving of € 38,868 (1). Sheet material was made from the 1,143 kg SS instruments to manufacture components for new instrument baskets. The SS profit of €1,040 as recycling revenue was sufficient to cover the logistical and disinfection costs (2). The hospital savings on waste costs amounted to € 316 (3). The total financial benefits for the hospitals was € 39,184.

Chapter 4 investigates how blue instruments wrapping paper waste, collected as waste from the Maasstad Hospital, was processed into new raw material and products. The waste was melted into bars, granulated and mixed with virgin material in various proportions and temperatures. Tensile bars were injection molded from volume (v.%) virgin, blended (%R) and recycled (100%R) granulate. Tensile testing was used to analyze the material properties before and after ten disinfection cycles in the sterilization department. Subsequently, 25 instrument openers were made from the 50%R material and used for four weeks in Maasstad Hospital. Ten disinfection cycles have not significantly changed the material properties of this device. After a month, the openers showed no deterioration.

In addition, we injection moulded a handle for a surgical instrument. The SATA steerable grasper was made from recycled Polypropylene blue wrapping paper.

In Chapter 5 we describe how we designed a rotation knob made from the waste of Zamak laryngoscope blades. The knob is designed for a medical instrument, the steerable punch. The laryngoscope blades were collected from two hospitals. About 93% Zamak was withdrawn from the blades using a custom made melting set-up and at melting temperatures of 420^0C for three hours. After melting, the Zamak was casted into a mold. It can be concluded that reprocessed Zamak can be used for applications requiring a UTS strength of 223 MPa or lower. With these results we showed that it is feasible to design medical devices made from hospital Zamak waste.

Chapter 6 discusses the climate impact of reprocessing face masks. We showed that there is a significant environmental benefit from reprocessing face masks. The carbon footprint is 58% lower for FFP2 face masks that were reused five times compared to new face masks that were used only once. The estimated costs of a reprocessed mask was €1.40 in comparison to new mask which was €1.55, showing that there is a financial benefit. The impact on climate change after reprocessing can contribute to achieving a circular economy, as the life cycle assessment indicates a significant reduction in the carbon footprint.

In Chapter 7 we answer the research questions, describe the impact of our research on the social debate and look ahead with a future perspective and vision.

Chapter 9

Dutch translation and summary

Ziekenhuis afval heeft een grote invloed op het milieu. De wereldwijde groei van ziekenhuisafval is het gevolg van de groeiende wereldbevolking en de toename in gebruik van disposables. Een circulaire zorgeconomie kan bijdragen aan de reductie van ziekenhuisafval in een circulair systeem. De circulaire economie is een systeem waarin wordt voorkomen dat afval ontstaat en afval wordt hergebruikt als grondstof.

Dit proefschrift presenteert de circulaire methoden en strategieën zoals hergebruik, reparatie, revisie en recycling.

De inleiding in hoofdstuk 1 geeft een introductie van de Butterfly Diagram van de Ellen McArthur Foundation. Dit zijn circulaire strategieën zoals hergebruik (reuse), repair, refurbishment, maintenance en recycling. Circulaire strategieën beschermen niet alleen onze natuurlijke hulpbronnen door het gebruik van grondstoffen te verminderen en verspilling te voorkomen, maar ze dragen ook bij aan het voorkomen van tekorten aan hulpbronnen en het voorkomen van een negatieve impact op het milieu. De Covid-19-pandemie resulteerde in zulke onverwachte tekorten. Er deden zich omstandigheden voor die leidden tot dreigende tekorten aan persoonlijke beschermingsmiddelen waar geen zorg kon worden gegeven en beroepsbeoefenaren in de gezondheidszorg niet werden beschermd.

Het doel van dit proefschrift is het ontwikkelen en onderzoeken van methoden voor een circulaire gezondheidszorg.

In hoofdstuk 1 worden de onderzoeksvragen geformuleerd:

1. Kunnen medische hulpmiddelen voor éénmalig gebruik worden herverwerkt en terug in circulatie worden gebracht?

2. Is herverwerking van medisch afval haalbaar voor ziekenhuizen?

3. Kunnen nieuwe medische producten worden ontworpen uit medisch afval?

4. Wat is de impact op klimaatverandering na herverwerking?

In hoofdstuk 2 wordt een landelijke veldstudie beschreven waarin 74.834 gebruikte mondmaskers worden verwerkt. Van deze maskers werden 56.668 maskers weggegooid na inspectie bij binnenkomst vanwege visuele schade en misvormingen. 18.166 gezichtsmaskers werden met stoom gesteriliseerd op 121°C. Een landelijk veldexperiment met negentien ziekenhuizen en internationale NGO's en met de industrie leverde data op waaruit blijkt dat herverwerking haalbaar is, met voldoende filterkwaliteit na stoomsterilisatie. Er is daarmee aangetoond dat medische wegwerphulpmiddelen opnieuw kunnen worden verwerkt en weer in omloop kunnen worden gebracht.

Hoofdstuk 3 beschrijft de studie die wij uitvoerden om de impact in drie ziekenhuizen van drie belangrijke verwerkingsmethoden voor SS-afval in kaart te brengen: reparatie/renovatie, recycling en verwijdering van ziekenhuisafval. Met onze studie toonden wij aan dat zowel instrumenten voor algemene chirurgie als instrumenten voor gespecialiseerde chirurgie weer hersteld en in omloop kon worden gebracht. De besparingen in de renovatie en reparatie van de instrumenten waren het hoogst in vergelijking met de andere twee categorieën, recycling en afvalverwerking. Kostenbesparingen werden berekend voor drie categorieën: (1) verlenging van de levensduur van instrumenten door reparatie in plaats van weg te gooien, (2) recycling van instrumenten door deze om te smelten tot grondstof, en (3) besparingen op afvalverwerkingskosten.

In totaal werd 1.380 kg instrumentenafval ingezameld, waarvan 237 kg opgeknapt werd en teruggebracht naar de ziekenhuizen, wat een besparing opleverde van € 38.868 (1). Van de 1.143 kg SS-instrumenten werd plaatmateriaal gemaakt om componenten voor nieuwe instrumentenmanden te vervaardigen. De RVS opbrengst van € 1.040 bleek voldoende om de logistieke en desinfectiekosten te dekken (2). De ziekenhuisbesparing op afvalkosten bedroeg € 316 (3). De totale financiële baten voor de ziekenhuizen bedroeg € 39.184.

Hoofdstuk 4 onderzoekt hoe blauw instrumenteninpakpapier als afval, opgehaald uit het Maasstad Ziekenhuis, kon worden verwerkt tot nieuwe grondstof en nieuwe producten. Het afval werd tot staven gesmolten, gegranuleerd en gemengd met nieuw materiaal in verschillende mengverhoudingen op verschillende smelttemperaturen. Trekstaven werden via spuitgieten gemaakt uit volume (v.%) virgin, gemengd (%R) en gerecycled (100%R) granulaat. Een trekbank werd gebruikt om de materiaaleigenschappen te analyseren voor en na tien desinfectiecycli op de sterilisatie afdeling. Vervolgens werden 25 instrumentopeners gemaakt van het 50%R materiaal en gedurende vier weken ingezet in het Maasstad Ziekenhuis. Tien desinfectiecycli hebben de materiaaleigenschappen van het materiaal van de instrumentopeners niet significant veranderd. Na een maand vertoonden de openers geen materiaal degradatie.

Daarnaast hebben we een handvat voor een chirurgisch instrument, de SATA stuurbare grasper, gemaakt uit gerecyclede Polypropyleen inpakpapier.

In hoofdstuk 5 beschrijven we hoe we in een Zamak-studie een draaiknop ontworpen, gemaakt van het afval van Zamak disposable laryngoscoopbladen. Een draaiknop is ontworpen voor een medisch instrument, de Steerable punch. De laryngoscoopbladen zijn na gebruik op de operatiekamer opgehaald uit twee ziekenhuizen. Ongeveer 93% Zamak werd uit de bladen onttrokken met behulp van een smeltopstelling en op een smelttemperatuur van 420^0C gedurende drie uur. Na het smelten werd het Zamak in een mal gegoten. Geconcludeerd kan worden dat opgewerkt Zamak materiaal kan worden gebruikt voor toepassingen die een sterkte van 223 MPa of lager vereisen. Hiermee hebben we aangetoond dat het haalbaar is om medische hulpmiddelen te ontwerpen die gemaakt zijn van Zamak ziekenhuisafval.

Hoofdstuk 6 gaat in op de klimaatimpact van herverwerking. We tonen aan dat er een aanzienlijk milieuvoordeel is bij het verwerken en opnieuw inzetten van medische

wegwerphulpmiddelen zoals mondmaskers. De CO_2-voetafdruk is 58% lager voor FFP2-gezichtsmaskers die vijf keer werden hergebruikt in vergelijking met nieuwe gezichtsmaskers die slechts één keer werden gebruikt en daarna weggegooid. De geschatte kostprijs van een herverwerkt masker was € 1,40 tegen € 1,55 voor een nieuw masker, waaruit blijkt dat er ook een financieel voordeel ontstond bij herverwerking ten tijde van de Coronacrisis. De impact op klimaatverandering na herverwerking kan bijdragen aan het bereiken van een circulaire economie aangezien de levenscyclusanalyse een significante vermindering van 58% van de CO_2-voetafdruk laat zien.

In Hoofdstuk 7 beantwoorden we de onderzoeksvragen, beschrijven wij de impact van ons onderzoek op het maatschappelijk debat en kijken in een toekomstperspectief vooruit.

Appendices

Supplemental files

Supplemental file 1: DSC, XRD and FTIR tests on face mask materials.

Differences in mask material was analysed by chemically and thermally comparing the fabric of the two most common types of face masks, showing different PFE after being sterilised once or twice with 121 ^{o}C or H_2O_2 plasma sterilisation methods. A Differential Scanning Calorimetry (DSC), X-Ray Diffraction (XRD) and Transform InfraRed spectroscopy (FTIR) were conducted.

The chemical characterization test was conducted with a Fourier Transform InfraRed spectroscopy (FTIR) (Nicolet 6700 from ThermoFisher Inc., USA) to narrow down the potential polymer types that were used. Spectra was collected from 650 to 4000 cm^{-1} at a resolution of 2 cm^{-1} and averaged over 128 scans.

Thermal analysis of the sample material was conducted using Differential Scanning Calorimetry (DSC) calorimeter (PerkinElmer Diamond, https://www.perkinelmer.com), Figure 1, to investigate the thermal properties of the polymer layers. The method is based on the characteristic melting and crystallization transitions T_m, which reflect the physical and chemical changes, endothermic and exothermic processes, or changes in heat capacity [20]. Samples of approximately 5 mg (figure 2) were cut and heated with a heating rate of 10 ^{o}C/min. The temperature scan was set to -25 to 180 and 250 ^{o}C and the cooling was conducted by nitrogen gas purge.

Additionally, the materials were tested with X-Ray Diffraction (XRD). XRD is a non-destructive test method used to analyse the structure of crystalline materials by identifying the crystalline phases present in a material and therefore reveals the chemical composition information. The experiments were conducted with a Bruker D8 Advance diffractometer (2theta-theta scan, often called Bragg-Brentano or focusing geometry) with Co Kα source (λ = 1.7889 Å, 35 kV and 40 mA) with Lynxeye position sensitive detector. The measurement range on a motorised varied divergent slit was set from 5 to 50 degrees with step size of 0.02 mm. A measuring time of 0.1 second per step was employed. Bruker software (DiffracSuite.EVA version 5.1, Bruker, USA) was used to interpret the data.

Furthermore an Infrared spectroscopy (FTIR) was conducted.

Figure 1. Measurement setups. Left, Differential Scanning Calorimetry (DSC). Right,samples of 5 mg are accurately prepared for XRD measurements.

Supplemental file 2: Measurement reports.

Online Supplemental file: https://doi.org/10.1371/journal.pone.0257468.s002

Supplemental file 3: Validation PFE outcome of particle counter setup against continues flow system of Delft.

Online Supplemental file: https://doi.org/10.1371/journal.pone.0257468.s003

Supplemental file 4: Particle counter, MISIT.

Online Supplemental file: https://doi.org/10.1371/journal.pone.0257468.s004

Supplemental file 5: Comparison between CSSD's.

Online Supplemental file: https://doi.org/10.1371/journal.pone.0257468.s005

Supplemental file 6: New foreign masks tested on particle counter setup.

Online Supplemental File: https://doi.org/10.1371/journal.pone.0257468.s006

Supplemental file 7: Material analysis.

Differential Scanning Calorimetry (DSC), X-Ray Diffraction (XRD) and Transform InfraRed spectroscopy (FTIR) were conducted to determine the material properties in both the 3M Aura and Kolmi-Op-Air M52010. Figure 1 shows that 5 different polymeric layers of each mask consisting of different texture, fiber size and orientation as macroscopically observable.

Figure 1. Dissection of 5 constituent layers of 3M Aura 1862+ mask filter.

They have individually undergone controlled thermal ramp for Differential Scanning Calorimetry. The first heating traces of each constituent layers are shown in Figure 2.

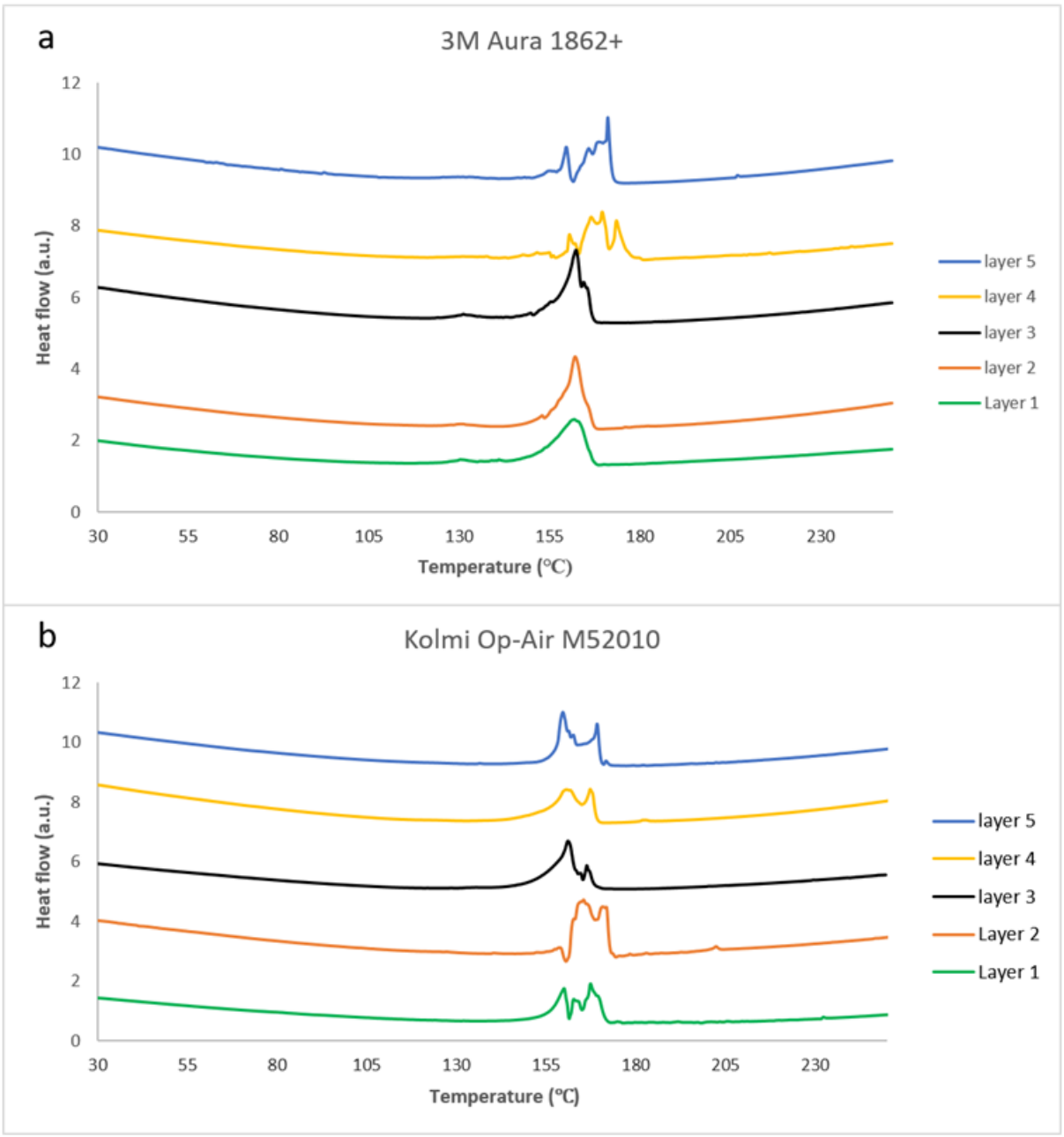


Figure 2. DSC plots showing melting transitions of layers upon heating 10 degrees/min (endo up), a: 3M mask, b: Kolmi mask.

Upon heating of each layer, broad endothermic melting transition occurred over a larger temperature range. In the 3M Aura 1862+ mask filter (Figure 2a), the melting transition of the three first layers occurred over 130-168 °C while the endpoints of layer 4 and 5 shift to 174°C and 180°C respectively. The melting transition peaks of the layers of Kolmi Op-Air M52010 masks varied in shape, and the melting occurred over 161-167 °C (Figure 2b). The enthalpy varied between 69 J/g for Layer 1 and 100 J/g for Layer 2 which indicate that these layers hold the same polymer composition or have a different fibre morphology, as the level of crystallinity is dependent on the polymer processing.

In order to eliminate the effect of fibre morphology and history of the samples, layer 1 has undergone a second heating following a cooling ramp after first heating. As shown in Figure 3 the serrated shape of the melting transition has switched to a smooth melting peak which occurs at exactly the same temperature.

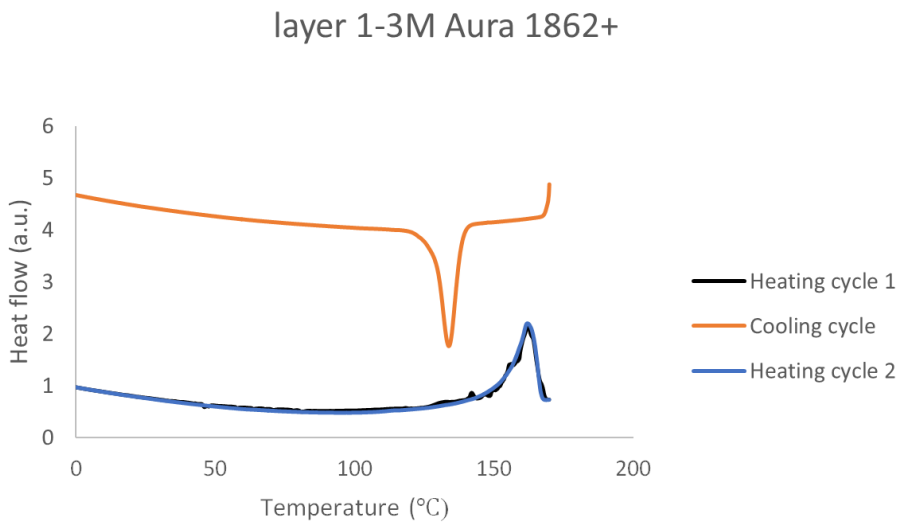


Figure 3. DSC traces (heat-cool- heat cycles under 10 ℃/min) on layer 1 of 3M Aura 1862+ mask filter.

This suggests that some of the DSC features in the first heating scan are due to (history dependent) artefacts, such as surface moisture, absorption of volatile substances. It is worth noting that normally DSC results on organic substances and polymers rely on using the second heating curve, as the first heating curve very frequently shows these artefacts. In the case of facemasks, and the actual use of the surface structure on the fibres in the mask material, we considered it useful to also show the first DSC heating curves.

XRD measurements

The Bruker D8 X-Ray Diffraction test results (Figure 4) for the 3M Aura 1862+ mask reveal 4 peaks for the 3M mask layers 1,2,3 and Kolmi 1,3,4 peaks at 16, 20, 22 and 25 degrees and 16, 20, 22 and 25 degrees.

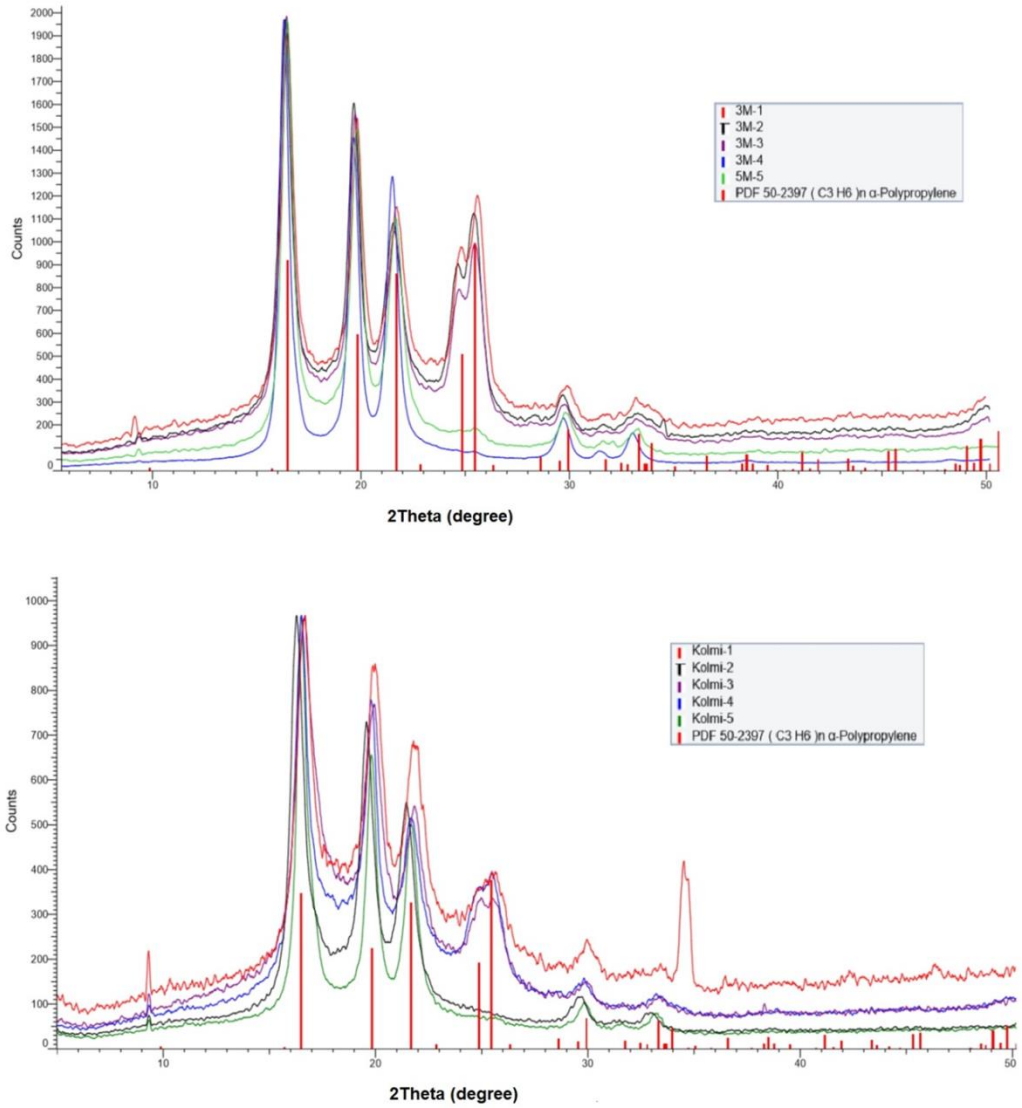


Figure 4. The Bruker D8 X-Ray Diffraction test results with Polypropylene reference data for 3M (top) and Kolmi (bottom).

For the layers 4 and 5 of the 3M mask, peaks were found at 16, 20 and 22 degree. For layers 2 and 5 of the Kolmi mask, peaks were also found at 16, 20 and 22 degrees. It was observed that the amplitude expressed in counts was higher for all layers of the 3M masks compared to the Kolmi.

Infrared Spectroscopy (FTIR)

Test results from the Infrared Spectroscopy confirmed a match of all 5 layers of both masks with the profile of the material PP. Figure 5 shows the comparison between layer 1 from 3M, layer 2 from Kolmi.

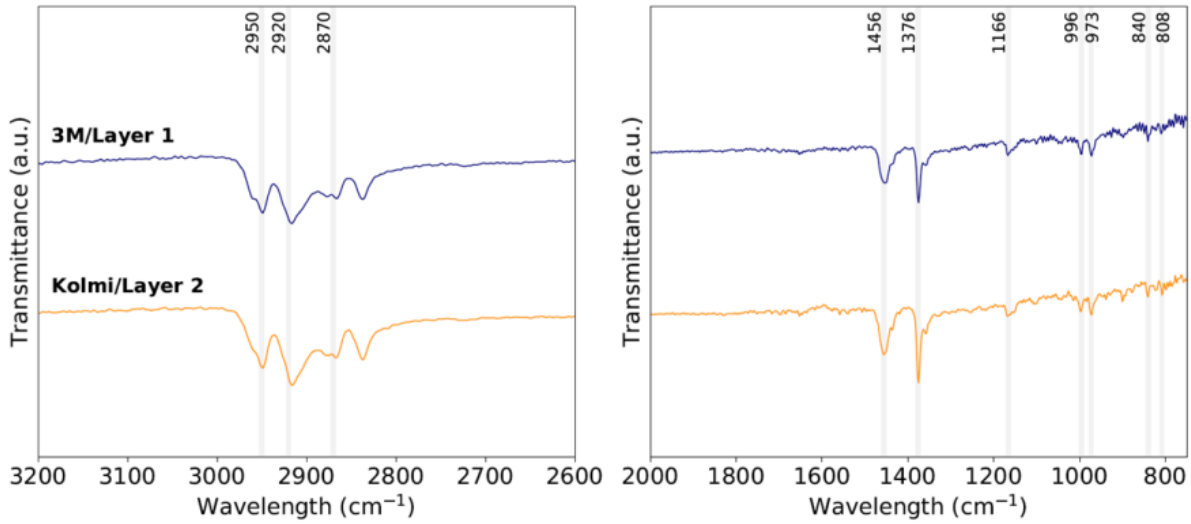


Figure 5. The FTIR spectra of layer 1 from 3M mask (Top), and layer 2 from Kolmi mask (Bottom). Characteristics peaks of polypropylene are indicated by grey lines. The functional group assignment and vibration type of each PP peak can be found at Fang et al. (2012).

Supplemental file 8: Testing pressure drop over filter material.

Online supplemental file: https://doi.org/10.1371/journal.pone.0257468.s008

Supplemental file 9: Discussion material test results.

The XRD tests reveal that for 3M 1862+ face mask, the main peak positions are in good agreement with known PP data [1,2] as PP crystallizes in a monoclinic unit cell with a = 6.630, b = 20.780, c = 6.500 Å and β = 99.0 degrees, it shows 2teta (miller indices, hkl) peaks at 16.5 (110), 19.8 (040), 21.7 (130), 24.9 (111), 25.5 (131), 30.0 (060) and 33.3 (220) degrees. Layer 1,2,3 can be defined as PP, which is the commonly used non-woven fabric material for face masks. The peak positions of Layer 4 are also in line with the PP data. However, the peaks at 24.9 (111) and 25.5 (131) are not clearly observed. 3M-4 and 3M-5 layers are considered as PP and the missed peaks maybe caused by orientation during fiber spinning. For Kolmi Op-Air face masks, Layer 1, 3 and 4 are consistent with PP, and Layer 2 and 5 are mostly consistent with PP by different manufacturing process. However the small peak at 9.3 and 34.7 degrees cannot be explained and may are caused by additional substances that give the mask its color, polarization properties or are needed in the manufacturing process. The measurements show that both face masks are made of the same material whether they come from a different company and have different colors. When comparing the layers of each graph in Figure 4 of supplemental file 7, it is obvious that the fourth peak is missing in 2 of the layers of each mask. This can be caused by differences in the manufacture process.

The three tests indicate that all 10 layers of each mask are made from the base material PP. Differences in melting temperature can be explained by the presence of a coating as indicated by the unexpected peaks as indicated in supplemental file 7, Figure 2a (Layer 4 and 5) and supplemental file 7, Figure 2b in the first DSC and in the XRD measurement. Also the differences in structure, shape, length and how fibers are interconnected, influence how fast the overheated steam penetrates the fibers and molecule structures [3]. Moreover, the glass transition temperature of fibrous PP is somewhere between 0 and -20 ^{0}C depending on the ratio between atactic, syndiotactic and isotactic components [4,5]. Therefore, during the transitional state of 121 ^{o}C, the level of crystallinity of the PP fiber as determined during fabrication in combination with internal material tension will result in differences in deformation resistance during sterilization.

Regarding H_2O_2 plasma sterilization it is likely that the low temperatures do not influence the properties of the PP filter material. However, the oxidation process most likely effect any surface ionization coatings on the fibers and therefore reducing the attraction of small particles during use.

References

[1] Immirzi A, & Iannelli P. Whole-pattern approach to structure refinement problems of fibrous materials: application to isotactic polypropylene. Macromolecules 1988; 21(3), 768-773.

[2] Cho D, Zhou H, Cho Y, Audus, D, & Joo Y. L. Structural properties and superhydrophobicity of electrospun polypropylene fibers from solution and melt. Polymer 2010; 51(25), 6005-6012.).

[3] Mark H F. Encyclopedia of polymer science and technology, concise. John Wiley & Sons 2013.

[4] Rodriguez-Arnold J, Zhang A, Cheng S.Z., Lovinger A. J., Hsieh E. T., Chu P., & Hawley, G.R. Crystallization, melting and morphology of syndiotactic polypropylene fractions: 1. Thermodynamic properties, overall crystallization and melting. Polymer 1994; 35(9), 1884-1895.

[5] Janevski A, Bogoeva-Gaceva G, & Mäder E. DSC analysis of crystallization and melting behavior of polypropylene in model composites with glass and poly (ethylene terephthalate) fibers. Journal of applied polymer science 1999; 74(2), 239-246.

Supplemental file 10: Face mask material

The 444 masks consisted of 101 different types of masks. From the 101 different types, the 3M 1862 and Kolmi Op-Air were tested the most on the test setup. The PFE results of 89 3M 1862 and 26 Kolmi Op-Air are provided in Table S1 for 0.3, 0.5, 1 and 5 µm particles. The results indicate that the 3M 1862 shows low PFE values after 2x Sterrad (H_2O_2 plasma) processing and Kolmi Op-Air shows low and inconsistant PFE values after 1x 121 ^oC processing. Measurements conducted at Delft University of Technology, Department of Chemical Engineering (Supplemental file 7).

Table S1
Particle Filter Efficiency of two commonly used mask after either 121 ^0C steam or H_2O_2 Plasma sterilisation

Brand type	Number of masks	Sterilization method	0.3 µ % PFE (SD)	0.5 µ % PFE (SD)	1 µ % PFE (SD)	5 µ % PFE (SD)	Mean % PFE
3M 1862	5	H_2O_2 Sterrad	86,4 (12,5)	93,8 (6,2)	97,4 (2,7)	99,5 (0,5)	**94**
3M 1862	72	121 ^oC steam	93,6 (4,1)	97,3 (2,1)	99,0 (0,8)	99,7 (0,7)	**97**
3M 1862	4	2 x H_2O_2 Sterrad	41,3 (1,7)	66,9 (1,6)	83,9 (1,3)	99,5 (0,4)	**73**
3M 1862	8	2 x 121 ^oC steam	91,6 (3,2)	96,2 (1,8)	98,3 (0,8)	100 (0,1)	**97**
Kolmi OP-Air M52010	11	H_2O_2 Sterrad	89,8 (1,4)	96,4 (1,4)	98,4 (0,5)	99,8 (0,3)	**96**
Kolmi OP-Air M52010	15	121 ^oC steam	21,2 (6,8)	56,3 (8,5)	78,4 (8,2)	99,8 (0,5)	**64**

See Supplemental file 7 for further details on the identification of characteristics of polypropylene material of the face mask material.

Supplemental file 11: Inventory Data

Table S2, Alternative 1 single use of face mask

Production of 3M Aura Face Mask			
Economic inputs			
Product		**Amount**	**Ecoinvent name**
1	Fabric face mask	5.82 gram	Textile, non-woven polypropylene {RoW}| textile production, non woven polypropylene, spun bond | Cut-off, S
2	Elastic straps	0.97 gram	Synthetic rubber {GLO}| market for | Cut-off, S
3	Nose guard	0.61 gram	Polyurethane, flexible foam {RoW}| market for polyurethane, flexible foam | Cut-off, S
4	Staples	0.48 gram	Steel, chromium steel 18/8 {GLO}| market for | Cut-off, S
5	Nose clip	0.72 gram	Aluminium, wrought alloy {GLO}| market for | Cut-off, S
6	Plastic wrap around single mask	1.22 gram	Extrusion of plastic sheets and thermoforming, inline {GLO}| market for | Cut-off, S
7	Manual	0.45 gram	Printed paper {GLO}| market for | Cut-off, S
8	Small cardboard box	3.91 gram	Corrugated board box {RoW}| production | Cut-off, S
9	Large cardboard box	2.36 gram	Corrugated board box {RoW}| production | Cut-off, S
10	Plastic wrap around large cardboard box	1.39 gram	Packaging film, low density polyethylene {GLO}| market for | Cut-off, S
11	Transport from factory to port Shanghai	0.00032 TKM	Transport, freight, lorry 16-32 metric ton, euro5 {RER}| market for transport, freight, lorry 16-32 metric ton, EURO5 | Cut-off, S
12	Transport from port Shanghai to port Southampton	0.389 TKM	Transport, freight, sea, container ship {GLO}| market for transport, freight, sea, container ship | Cut-off, S
13	Transport to port Southampton to end-user	0.0167 TKM	Transport, freight, lorry 16-32 metric ton, euro4 {RoW}| market for transport, freight, lorry 16-32 metric ton, EURO4 | Cut-off, S
Environmental inputs			
Product		**Amount**	**Ecoinvent name**
	N/A		
Economic outputs			
Product		**Amount**	**Ecoinvent name**
	3M Aura Facemask	1 piece	
14	Disposal of plastic wrap	1.22 gram	Municipal solid waste {NL}| market for municipal solid waste | Cut-off, S
15	Disposal of manual	0.45 gram	Waste graphical paper {NL}| market for waste graphical paper | Cut-off, S
16	Disposal of small cardboard box	3.91 gram	Waste paperboard {NL}| market for waste paperboard | Cut-off, S
17	Disposal of large cardboard box	2.36 gram	Waste paperboard {NL}| market for waste paperboard | Cut-off, S
18	Disposal of plastic wrap carboard box	1.39 gram	Waste plastic, mixture {NL}| market for waste plastic, mixture | Cut-off, S
19	Disposal of face mask	8.57 gram	Municipal solid waste {NL}| market for municipal solid waste | Cut-off, S
Environmental outputs			
Product		**Amount**	**Ecoinvent name**

	N/A		

1 – 5: The facemask was disassembled and each part was weighted with a precision scale (Fit Evolve, Bangosa Digital, Groningen, the Netherlands) with a calibrated inaccuracy of 1.5%. Based on the technical data sheet provided by the manufacturer, the main material of each component was determined.

6 – 10: The packaging material was weighted with a precision scale (Fit Evolve, Bangosa Digital, Groningen, the Netherlands) with a calibrated inaccuracy of 1.5%. Based on the technical data sheet provided by the manufacturer, the main material of each component was determined.

11: 3M masks are produced in Shanghai, China. The distance between the production location of 3M in Shanghai and the industrial port is estimated on 15.9 km. The weight of the facemask and packaging is 17.93 gram. Hence, the transport between the factory and port is 0.00032 TKM per face mask.

12: 3M masks are transported from Shanghai, China to Southampton, United Kingdom. The distance between the two ports is estimated on 21694.33 km. The weight of the facemask and packaging is 17.93 gram. Hence, the transport between the factory and port is 0.38898 TKM per face mask.

13: From the port in Southampton, the masks are transported to Bracknell, United Kingdom, Neuss, Germany and finally, the end-user is assumed to be located in Rotterdam, The Netherlands. This results in a total distance of 932.77 KM. With a weight of 17.93 gram, the total transport was 0.0167 TKM per facemask.

14 – 18: The disposal is based on the weight and the traditional waste treatment scenarios. The manual of 9.33 gram is divided over the 20 facemasks in which box it is included. The small cardboard box of 77.09 is divided over the 20 facemasks that are transported in the box and finally the large cardboard box of 150.3 grams is divided over the total 120 facemasks that are stored in the box.

Table S3, Alternative 2 reprocessing of face mask

Production of Personal Protection Equipment (PPE)			
Economic inputs			
Product		**Amount**	**Ecoinvent name**
1	Single use 3M Aura face mask	1 piece	N/A (see alternative 1)
2	Protective suit	133.04 gram	Textile, non-woven polypropylene {GLO}| market for textile, non woven polypropylene | Cut-off, S
3	Packaging of protective suit	5.04 gram	Packaging film, low density polyethylene {GLO}| market for | Cut-off, S
4	drape	102.51 gram	Textile, non-woven polypropylene {GLO}| market for textile, non woven polypropylene | Cut-off, S
5	Hair cover	2.22 gram	Textile, non-woven polypropylene {GLO}| market for textile, non woven polypropylene | Cut-off, S
6	Pair of gloves	16.71 gram	Latex {RER}| market for latex | Cut-off, S
7	Goggles (main part)	23.44 gram	Polyethylene terephthalate, granulate, amorphous {GLO}| market for | Cut-off, S
8	PUR foam (goggles)	6.5 gram	Polyurethane, flexible foam {RoW}| market for polyurethane, flexible foam | Cut-off, S
9	Elastics straps (goggles)	1.34 gram	Synthetic rubber {GLO}| market for | Cut-off, S
Environmental inputs			
Product		**Amount**	**Ecoinvent name**
	N/A		
Economic outputs			
Product		**Amount**	**Ecoinvent name**
	Set of PPE	1 set	
10	Disposal of PPE	299 gram	Municipal solid waste {NL}| market for municipal solid waste | Cut-off, S
Environmental outputs			
Product		**Amount**	**Ecoinvent name**
	N/A		

1: A set of Personal Protection Equipment includes a single use face mask, such as the 3M aura

2 – 9: Each component of a set of Personal Protection Equipment was weighted using a precision scale (Fit Evolve, Bangosa Digital, Groningen, the Netherlands) with a calibrated inaccuracy of 1.5%. The main material of each component was determined by using declarations on the website of a manufacturer of a similar product.

10: The disposal is based on the weight of the total set of Personal Protection Equipment and a traditional waste treatment process in the Netherlands.

Table S4, production of sterilisation bag for alternative 2 reprocessing of face mask

Production of a sterilization bag			
Economic inputs			
Product		**Amount**	**Ecoinvent name**
1	Lower part of the sterilization bag	5.85 gram	Kraft paper, bleached {GLO}| market for | Cut-off, S
2	Upper part of the sterilization bag	4.37 gram	Polyethylene, high density, granulate {GLO}| market for | Cut-off, S
Environmental inputs			
Product		**Amount**	**Ecoinvent name**
	N/A		
Economic outputs			
Product		**Amount**	**Ecoinvent name**
	Sterilization bag	1 piece	
3	Disposal of sterilization bag	10.22 gram	Municipal solid waste {NL}| market for municipal solid waste | Cut-off, S
Environmental outputs			
Product		**Amount**	**Ecoinvent name**
	N/A		

1 & 2: Each part of a set of sterilization bag was weighted using a precision scale (Fit Evolve, Bangosa Digital, Groningen, the Netherlands) with a calibrated inaccuracy of 1.5%. The main material of each component was determined by using declarations on the website of a manufacturer of a similar product.

3: The disposal is based on the weight of the total set of Personal Protection Equipment and a traditional waste treatment process in the Netherlands.

Table S5, meta data reprocessing of face mask

Reprocessing of facemask			
Economic inputs			
Product		**Amount**	**Ecoinvent name**
1	Set of PPE	0.0005 piece	N/A
2	Sterilization bag	0.2 piece	N/A
3	Tap water	0.228 liter	Tap water {Europe without Switzerland}| market for | Cut-off, S
4	Electricity	0.0109 kWh	Electricity, low voltage {NL}| market for | Cut-off, S
5	Transport between hospital and sterilization site	0.00084 TKM	Transport, freight, lorry 16-32 metric ton, euro5 {RER}| market for transport, freight, lorry 16-32 metric ton, EURO5 | Cut-off, S
Environmental inputs			
Product		**Amount**	**Ecoinvent name**
	N/A		
Economic outputs			
Product		**Amount**	**Ecoinvent name**
6	Quality control, rejection rate	0.2 piece	Municipal solid waste {NL}| market for municipal solid waste | Cut-off, S
7	Sterilized face mask	1 piece	
8	Waste water	0.228 kg	Wastewater, unpolluted {RoW}| treatment of, capacity 5E9l/year | Cut-off, S
Environmental outputs			
Product		**Amount**	**Ecoinvent name**
	N/A		

1: Two autoclaves with a capacity of 1000 facemasks and a cycle of 1 hour are operated by two persons using a set of PPE each for two hours. Hence, the input of PPE is $\frac{2}{(1000 \times 2 \times 2)} = 0.0005$ piece.
2: Each sterilization bag can be used to sterilize 5 facemask. Subsequently, the input of a sterilization is 0.2 piece.
3: Per cycle, the autoclave uses 228 liter tap water. This means that, with a capacity of 1000 face masks for each cycle, a total amount of 0.228 liter can be accounted to each sterilized mask.
4: Per cycle, the autoclave uses 10.9 kWh electricity. This means that, with a capacity of 1000 face masks for each cycle, a total amount of 0.0109 kWh can be accounted to each sterilized mask.
5: The transport between the hospital in Rotterdam and the sterilization site was estimated on 49.1 km. Each sterilization cycle, the face masks were transported to and from the sterilization site. With a weight of 8.57 gram, the total transport was 0.00084 TKM.
6: During quality control the rejection rate was 20% so 0.2 piece was disposed as municipal waste.
7: The output of the sterilization process is 1 sterilized facemasks.
8: The input of tap water is disposed to the waste water treatment system.

Supplemental file 12: LCIA Results

Project	3M-Aura_Reprocessing
Calculation:	Compare
Results:	Impact assessment
Product 1:	1 p LCA mask reprocessing (of project 3M-Aura_Reprocessing)
Method:	ReCiPe 2016 Midpoint (H) V1.04 / World (2010) H
Indicator:	Characterization
Skip categories:	Never
processes:	No
Exclude long-term emissions:	No
Sorted on item:	Impact category

Table S6, Output of the different simulations show minor differences due to statistical spread and differences due to multiple simulations of the same datasets. Raw data output:

LCIA results	Impact		Unit	Mean for new face masks		Mean for reprocessed masks		Difference
	Global warming		kg CO2 eq	6,55E+00 (SD 3,11E-01)		2,77E+00 (SD 1,21E-01)		58%

Sensitivity reprocessed								
Impact category	**Unit**	**Original Scenario**	**Autoclave 250st**	**Autoclave 500st**	**Reuse 70%**	**Reuse 90%**	**Transport 0 km**	**Transport 200 km**
Global warming (carbon foorprint)	kg CO2 eq	2.6494	4.3533	3.2174	2.9815	2.3719	2.5897	2.8329
Uncertainty reprocessed								
Impact category	**Unit**	**Mean**	**Median**	**SD**	**CV**	**2,5%**	**97,5%**	**SEM**
Global warming (carbon foorprint)	kg CO2 eq	2.7668	2.7646	0.1209	4.3712	2.5414	3.0109	0.0012
Uncertainty disposable								
Global warming (carbon foorprint)	kg CO2 eq	6.5544	6.5536	0.3110	4.7454	5.9932	7.1503	0.0031
Contribution reprocessed								
Impact category	**Unit**	**Total**	**Top**	**Mask production**	**Transport**	**Waste**	**Packaging**	**Sterilization**
Global warming (carbon foorprint)	kg CO2 eq	2.6494	0.0000	0.9399	0.2354	0.3470	0.2963	0.8309
Contribution disposable								
Global warming (carbon foorprint)	kg CO2 eq	6.1275	0.0000	3.4573	0.6472	0.9333	1.0896	

Impact category	A >= B	Mean	Median	SD	CV	25%	75%	SEM
Global warming	100	3.79402	3.79074	0.236035	6.221236	3.615896	3.966964	0.00236

Supplemental file 13: Reduction of carbon emissions

Reduction of 7.56 million kg CO_2 eq which could be achieved when reprocessing 200 million face masks:

6.55 – 2.77 kg CO2 eq / 100 * 200 million = 7.56 million kg CO_2 eq.

Supplemental file 14: Calculation for table 6

Collected from hospital

HMC: 208.8791 kg of which 50 kg contaminated used disposable instruments collected from the Operating Room.

158 kg non-contaminated X €0,2 general waste = €31,6 + 50 X €1 = €81,6 waste cost

VUmc: 454.1758 kg non-contaminated X €0,2 general waste = €90,84 waste costs

Maasstad: 716.9451 kg non-contaminated X €0,2 general waste = €143,39 waste costs

Savings from refurbished instruments as compared to new:

HMC: 120 kg refurbished/repaired/remanufactured X €41 savings per 250 g instrument X 4 = €19,680,- savings

VUmc: 46 kg refurbished/repaired/remanufactured X €41 savings per 250 g instrument X 4 = €7,544,- savings

Maasstad: 71 kg refurbished/repaired/remanufactured X €41 savings per 250 g instrument X 4 = €11,644,- savings

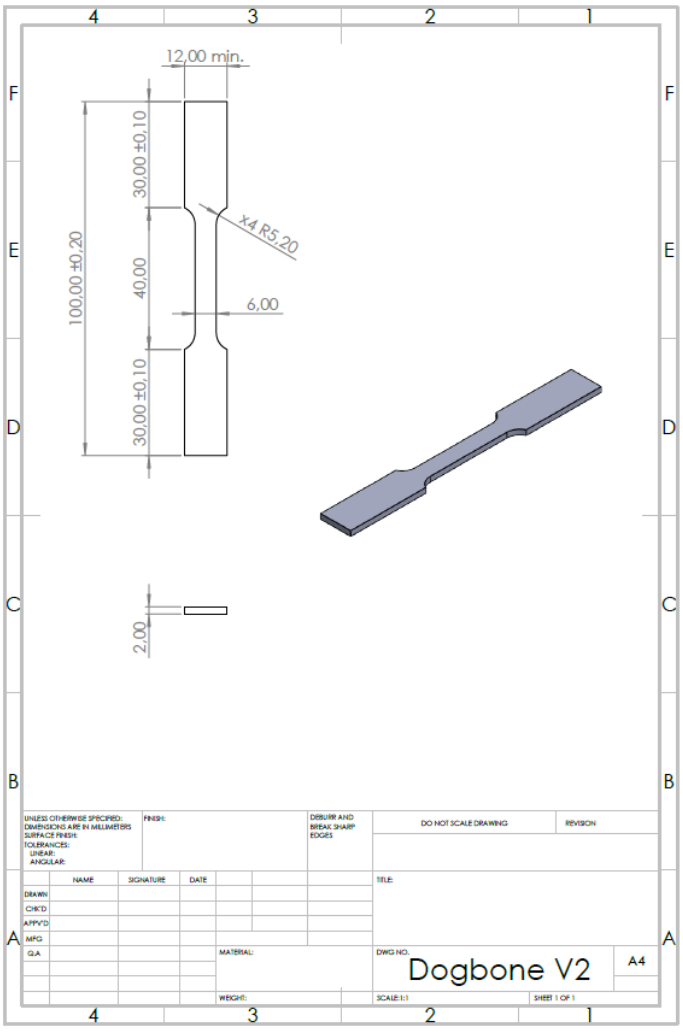
Total: €38,686*

* The data was collected and categorized by activity during the period of this study. Logistical costs: calculated at 50 km using a caddy for transport (the prices were benchmarked with another courier). Costs for storage included Electricity, Rental space ,Employee cost, Administration costs and expressed in Euro per kg instruments. The amount received “Steel revenue” for the SS material was derived and taken from the of the credit note invoices as received by the metal recycling company. The prices of waste disposal costs were derived from the invoices as calculated by the waste processor to the hospitals. The instruments were weighed and repair/refurbishment/remanufacturing costs were derived from the invoices made to the hospitals.

Supplemental file 15: Dog bones from different qualities for tensile testing purposes

Dog bones as shown in Figure 1 were designed and injection moulded for the purpose of testing the material. The injection moulding was done on a Babyplast, injection molding machine 6/10P.

The dog bone tensile test sample is shown in figure 1.



The dog bones were moulded as tensile test samples for use in a tensile test set-up. The design has a shoulder at each end and a smaller part in the middle (Figure 2). The shoulders are wider than the middle part, resulting in a stress concentration in the middle when applying tensile force.

Fig. 2. Dog bone made for tensile testing of PP.

This stress concentration is aimed at realizing a higher probability that the sample will rupture away from the ends when tested on tensile. When the rupture of a sample occurs in the middle, the PP dog bone is getting its maximum tensile strength on that area. If the dog bone would rupture at one of the shoulder ends or in the grip itself, the failure may be attributed to improper loading or a pre-existing defect in the material. The design of the dog bone is to ensure the highest probability that the sample will fail due to maximum tensile loading. The objective is to have the sample rupture in the middle section as a result of reaching its maximal tensile strength.

The injection moulding of the dog bones, as show in Figure 3, were done in different mixing ratios, varying from 100% recycled to 50%R, 75%R and 100% virgin PP. An important process parameter is the process injection temperature. This temperature may have the most significant negative effect on the stress at break and energy to break [1].

Fig. 3. Injection moulding of dog bones in various mixing ratios.

Six types of injection molded products were analysed as shown in table I.

Table I. Outcomes with different ratios of mixed PP including hardness in Shore D.

Type	$\epsilon_{break}[\%]$	$\boldsymbol{\sigma_{yield}[Mpa]}$	$\boldsymbol{E\ [MPa]}$	$\boldsymbol{Shore\ D}$
100%R with Pollution	5.7±1	29.8±1.4	959±25	69.8±0.9
100% V	13.9±0.5	31.5±0.7	795±14	68.3±0.5
75%V/25%R	13.1±0.7	32.4±0.5	829±15	69.8±0.4
50%V/50%R	11.5±0.9	33.3±0.7	879±13	71.5±0.5
25%V/75%R	11.5±1.4	35.7±0.4	958±16	72.3±0.5
100% R	8.0±0.7	36.5±0.5	1021±13	71.7±1.7

Changes in Youngs modulus and strain:

Youngs Modulus for 100R: 1021 MPa compared to MPa after 10 X disinfection (1014 MPa) = -1%.

- Yield Strength for 100R: 36,5 MPa to MPa after 10 X disinfection (35,5 MPa) = -3%.
- Youngs Modulus for Virgin: 795 MPa to MPa after 10 X disinfection (748 MPa) = -6%.
- Yield Strength for Virgin: 31.5 MPa to MPa after 10 X disinfection (32,1 MPa) = 2%.

References

1. Da Costa, H., Ramos, V., De Oliveira, M., 2007. Degradation of polypropylene (PP) during multiple extrusions: Thermal analysis, mechanical properties and analysis of variance. Polymer Testing. 26, 676–684.

Supplemental file 16: Moulding parameters of collected recycled blue wrap waste

The melting and injection moulding parameters used with the collected PP blue WP are summarized in Table I.

Table I

Melting and moulding parameters.

Parameter	Unit	Value
Melting temperature of the waste	^{0}C	200, 250, 300
Melting temperature used for following batches	^{0}C	250
Processing temperature molding, 3 heat zones ascending towards the nose/exit	^{0}C	185,190,200
Injection molding temperature used for following batches	^{0}C	200
Mould temperature	^{0}C	30
Injection pressure	bar	40
Holding pressure	bar	10
Injection rate	cm^3/s	135

Supplemental file 17: Dog bones tested before and after 10 times of washing and disinfection

Three times three sets of dog bones were measured and evaluated before and after ten times of washing & disinfection cycles.

The batches were divided over sets of 100% recycled PP waste, 50% recycled PP and 100% Virgin PP.

Batches processed
PP dog bones 3 X 100%R
PP dog bones 3 X 50%R
PP dog bones 3 X 100%V

The dog bones were cleaned and disinfected for ten cycles in a thermal disinfector on the Central Sterilization and Services Department using a fine mesh stainless steel mesh basket as shown in Figure 1.

Fig. 1. Dog bones cleaned & disinfected during ten cycles.

Type of washing & disinfection program

Washing and rinsing program. 90 ^{0}C, Schulke “P1” program was selected which is also used for cleaning and disinfecting surgical instruments.

The following parameters and data were applicable.

Type of machine
Getinge G1-WA-04, thermal disinfector (Getinge. Visiting address. Lindholmspiren 7, SE-417 56 Gothenburg, Sweden).

Cycles of washing & disinfection
10 times

Dates of washing & disinfection
Friday 07 May, 2021
Monday 10 May, 2021

Type of cleaning agent
Thermosept X-tra was used (Schülke & Mayr, Robert-Koch-Str. 2, 22851 Norderstedt I Deutschland).

Type of rinsing agent
Thermosept BSK, 1526527 rinsing agent was used (Schülke & Mayr, Robert-Koch-Str. 2, 22851 Norderstedt I Deutschland).

A Shore D hardness test was conducted on all samples of the dog bones, before and after the cleaning & disinfection cycles as shown in Table I. The Dog bones were measured on two (end) places of the dog bone.

Table I
Hardness measurements in Shore D values with decreased hardness of recycled and increase of virgin PP.

	Dog bones 10 times cleaned and disinfected. Program: Getinge 90 degrees instrument disinfection.							
	Before cleaning & Disinfection		**After 10 X**			**% difference**		**%**
50%V/50%R	measuring point 1	measuring point 2	50%V/50%R	measuring point 1	measuring point 2	measuring point 1	measuring point 2	
	Shore D	Shore D		Shore D	Shore D			
7	70	70		65	69	-7.14%	-1.43%	
8	71	69		68	68	-4.23%	-1.45%	
9	69	70		68	69	-1.45%	-1.43%	
Average	70	69.67	Average	67	68.67	-4.29%	-1.44%	-2.86%
100%R			100%R					
10	72	74		69	70	-4.17%	-5.41%	
11	72	73		75	70	4.17%	-4.11%	
12	72	70		70	71	-2.78%	1.43%	
Average	72	72.33	Average	71.33	70.33	-0.93%	-2.76%	-1.85%
100%V			100%V					
13	65	67		65	65	0.00%	-2.99%	
14	64	66		67	65	4.69%	-1.52%	
15	64	66		65	65	1.56%	-1.52%	
Average	64.33	66.33	Average	65.67	65	2.07%	-2.01%	0.03%

Table II
Table with comparable results of tensile strength before and after ten times of thermo disinfection and hardness in Shore D.

	$\epsilon_{break}[\%]$			$\boldsymbol{\sigma_{yield}[Mpa]}$			$\boldsymbol{E\ [MPa]}$			$\boldsymbol{Shore\ D}$		
Type	Before	After 10X	Diff [%]	Before	After 10X	Diff [%]	Before	After 10X	Diff [%]	Before	After 10 X	Diff [%]
100% V	13.9±0.5	14.6±0.4	0.7	31.5±0.7	32.1±0.3	1.9	795±14	748±6.8	-5.91	69.8	67.8	-2.86
50%V/50%R	11.5±0.9	9.7±0.8	-1.8	33.3±0.7	33.6±0.5	0.9	879±13	849±7.6	-3.41	72.2	70.8	-1.85
100% R	5.9±0.7	7.6±2.4	1.7	36.5±0.5	35.5±4.7	-2.7	1021±13	1014±12	-0.69	65.3	65.3	0

Supplemental file 18: Blue wrapping paper waste and total volume in the Netherlands

The PP blue wrapping paper sheets are used to wrap instrument trays after washing in a thermo disinfector at the Central Sterilization Services Department (CSSD) clean room. Every day the Operation Room (OR) of Maasstad hospital in Rotterdam produces about 20 bags of blue wrapping paper. Per year this would result in 7.3 tons of blue wrapping paper.

This blue wrapping paper is used to ensure that medical instruments stay sterile after being sterilized in the autoclave. The only other materials on the wrapping paper are; tape, which ensures the wrapping paper stays around the instruments, and a sticker naming what the instrument net contains. Unfortunately, these sheets of blue wrapping paper cannot be used multiple times as structural integrity of the sheets is of great importance. The structural integrity is so important because of cross contamination. This blue wrapping paper is made from virgin polypropylene (PP). The PP sheets come out of the OR in the hospital, this means it is regarded as medical grade waste. Consequently, it is send to the incinerator in Dordrecht to be burned.

Blue wrap in Maasstad hospital: Halyard PP blue wrap 114 X 114. H400. Weight: 160 gr.

The details of the recovered of blue wrap waste are shown in Table II.

Table II
Collected blue wrap (3 batches in 3 shifts).

Collected	Unit
Transparent bags	17
Av. number of sheets per bag	5-6
Weight per blue wrap sheet	160 gr
Total weight	2,720 kg per batch
Total 3 batches collected	**8,16 kg**

Blue wrapping is used in order to create a sterile barrier after sterilization in the autoclave.

The 114 X 114 with a weight of 160 grams was the most used in Maasstad hospital. The sheets are sorted in the hospital with the PP blue wrap sheets in one transparent bag (60L bag made out of PP). With each full bag weighing a little more than 1 kg, resulting in about 7.3 tons of blue wrapping paper used per year in Maasstad hospital

It is estimated that on average a smaller sized hospital produces 5,000 kg of blue wrap waste up to 14,720 kg for large hospitals (Haga hospital using 92,000 sheets per year averages 160 gr). Maasstad hospital produces 20 kg of blue wrap per day resulting including the weekends, resulting 7,300 kg per year. On average this would lead to 9,860 kg per hospital in the Netherlands.

In 2019, the Netherlands counted 69 hospital organizations of which 8 university medical centers having a total of 116 hospital locations and 129 outpatient (poli) clinics [1]. Furthermore, in total 136 private clinics were registered [2] of which 74% aims at a specific specialism. Of these 100 private clinics it is assumed that they use 30 kg of blue wrap per week (on average 4 kg per day). This results in another additional 144,000 kg of blue wrap waste generated by private clinics.

In total in the Netherlands this would sum op to 1,143,760 kg generated by hospitals, 144,000 kg generated by private clinics, in total 1,287,760 kg per year. This total could deviate when numbers of

surgery are delayed due to circumstances such as Corona or when hospitals initiate special programs to shorten waiting lists and make up for interventions.

References

1. Volksgezondheidenzorg.info. 2021. RIVM – National Institute for Public Health and the Environment, Ministry of Health, Welfare and Sport. www.volksgezondheidenzorg.info. Accessed 19 January 2021.

2. Zelfstandige Klinieken in Nederland. 2021. ZKN. https://www.zkn.nl/cijfers-zkn. Accessed on 19 January 2021.

Supplemental file 19: "All-in-one" process.

The extraction, casting and manufacturing of Zamak will occur in a single system without the user needing to continuously interact with it. By applying this concept to the laryngoscope blades, the recovery of Zamak and manufacturing of new products can sequentially be achieved. An "All-in-one" process for melting of Zamak in conjunction with casting it without additional manual steps in between is shown in Figure 1.

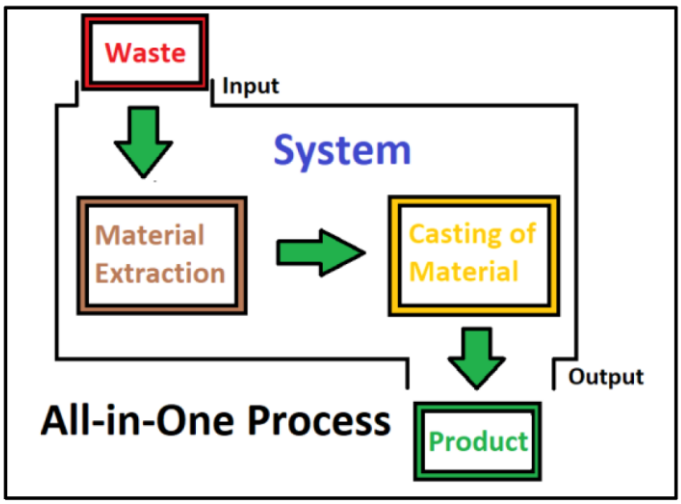


Figure 1. Schematic of the "all-in-one" process with recovered laryngoscope blades, melting and casting of new products in a single production line.

The melting, in an electric melting oven, KOS, series 219029, as well as the casting is done in a single production line, based on one location. Disinfection, melting, casting in one production line as shown in Figure 2.

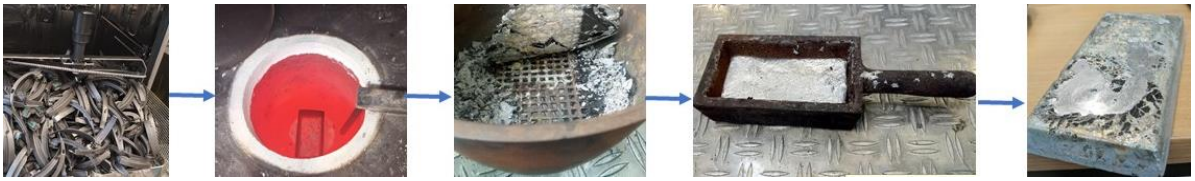


Figure 2. "All in One" process on one location.

Supplemental file 20: Dog-bones

Dog bone samples were used to carry out the tests. Figure 1 shows the size and dimensions. The dog bone samples were designed in accordance with the ASTM E8 standard [1]. They were created by first milling the Zamak ingots according to the designed dog bone and afterwards sawing them in slices.

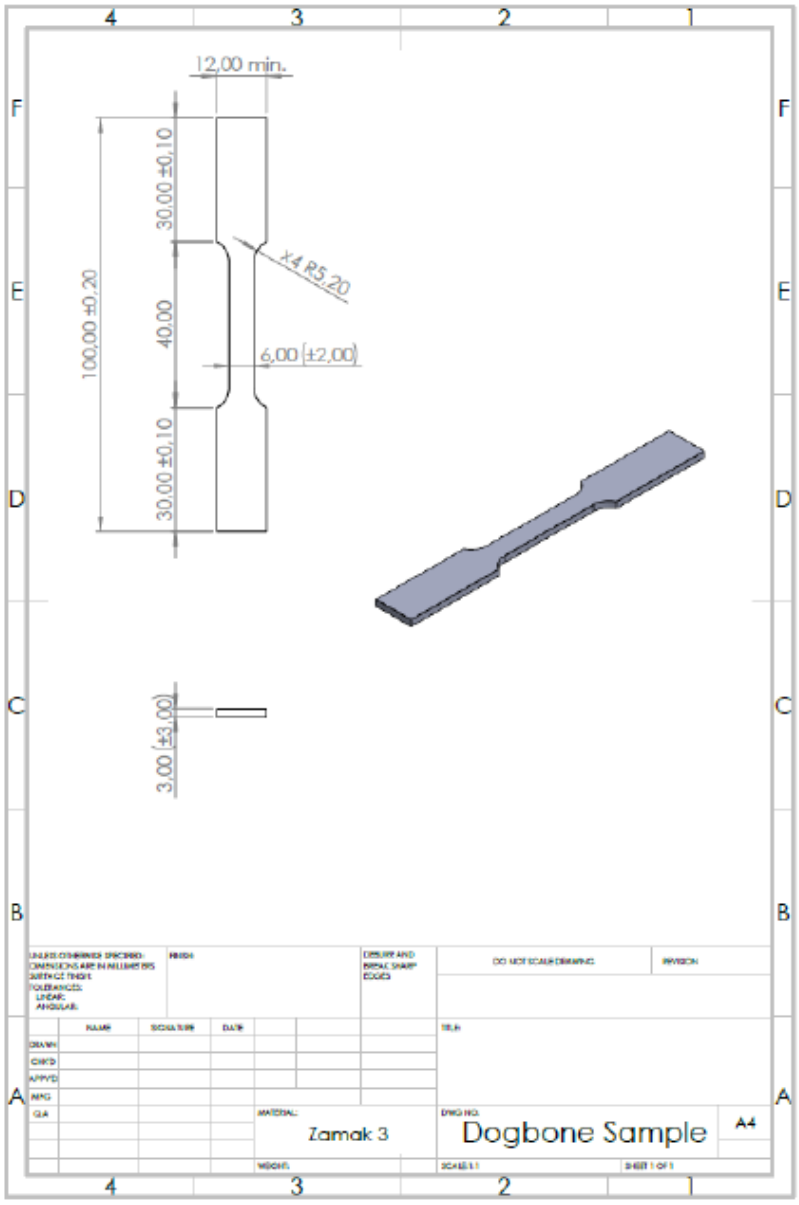


Figure 1. Dog bone Sample

References

1. Davis, J. R. (Ed.). (2004). Tensile testing. ASM international. p. 52

Supplemental file 21: XRF spectroscopy test results

Ingot A*

Material composition

Compound Name	Conc. (wt%)	Absolute Error (wt%)
1 Zn	94.972	0.07
2 Al	4.279	0.06
3 Mg	0.417	0.02
4 Si	0.121	0.01
5 Cl	0.078	0.008
6 Fe	0.042	0.006
7 Cu	0.036	0.006
8 S	0.034	0.006
9 Ni	0.013	0.003
10 P	0.007	0.003

Ingot B*

Material composition

Compound Name	Conc. (wt%)	Absolute Error (wt%)
1 Zn	95.651	0.07
2 Al	3.775	0.06
3 Mg	0.254	0.02
4 Si	0.11	0.01
5 Fe	0.045	0.006
6 Cl	0.039	0.006
7 Cu	0.036	0.006
8 Ca	0.021	0.004
9 S	0.02	0.004
10 Ni	0.015	0.004
11 Cr	0.015	0.004
12 K	0.014	0.004
13 P	0.006	0.002

Zamak with coating removed before melting*

	Compound Name	Conc. (wt%)	Absolute Error (wt%)
1	Zn	96.355	0.07
2	Al	3.296	0.05
3	Cl	0.165	0.01
4	Si	0.053	0.007
5	S	0.04	0.006
6	K	0.036	0.006
7	Cu	0.021	0.004
8	Ca	0.015	0.004
9	Fe	0.011	0.003
10	P	0.007	0.003

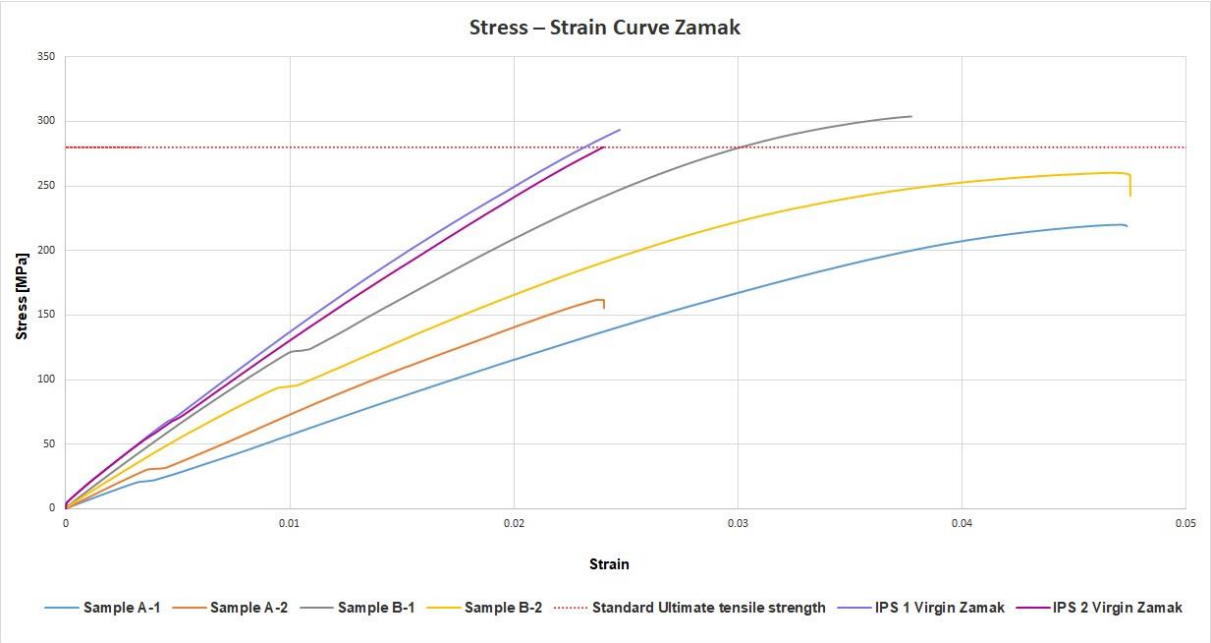
Virgin Zamak*

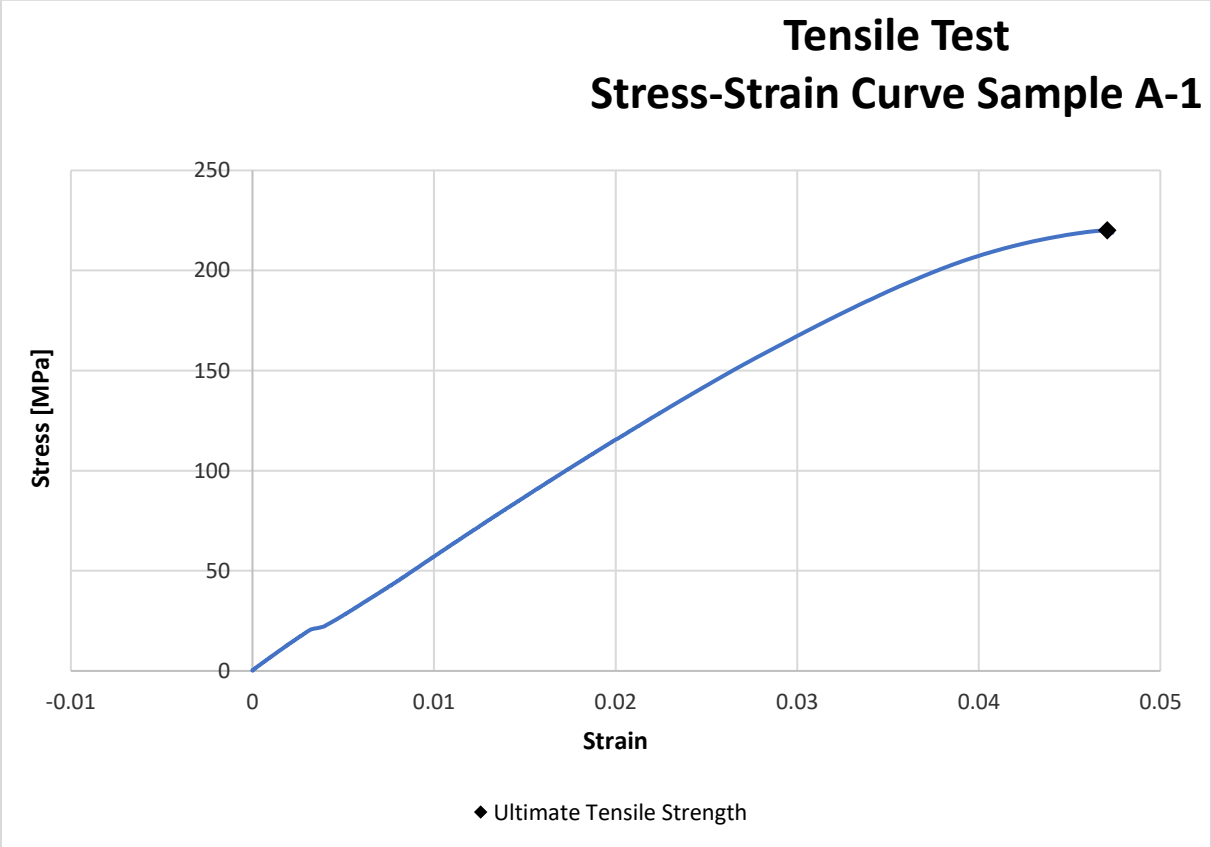
	Compound Name	Conc. (wt%)	Absolute Error (wt%)
1	Zn	91.552	0.08
2	Al	4.503	0.06
3	Cu	2.832	0.05
4	Mg	0.809	0.03
5	Cl	0.168	0.01
6	Si	0.052	0.007
7	K	0.034	0.006
8	Ca	0.016	0.004
9	Ni	0.011	0.003
10	Fe	0.008	0.003
11	P	0.007	0.003
12	S	0.006	0.002

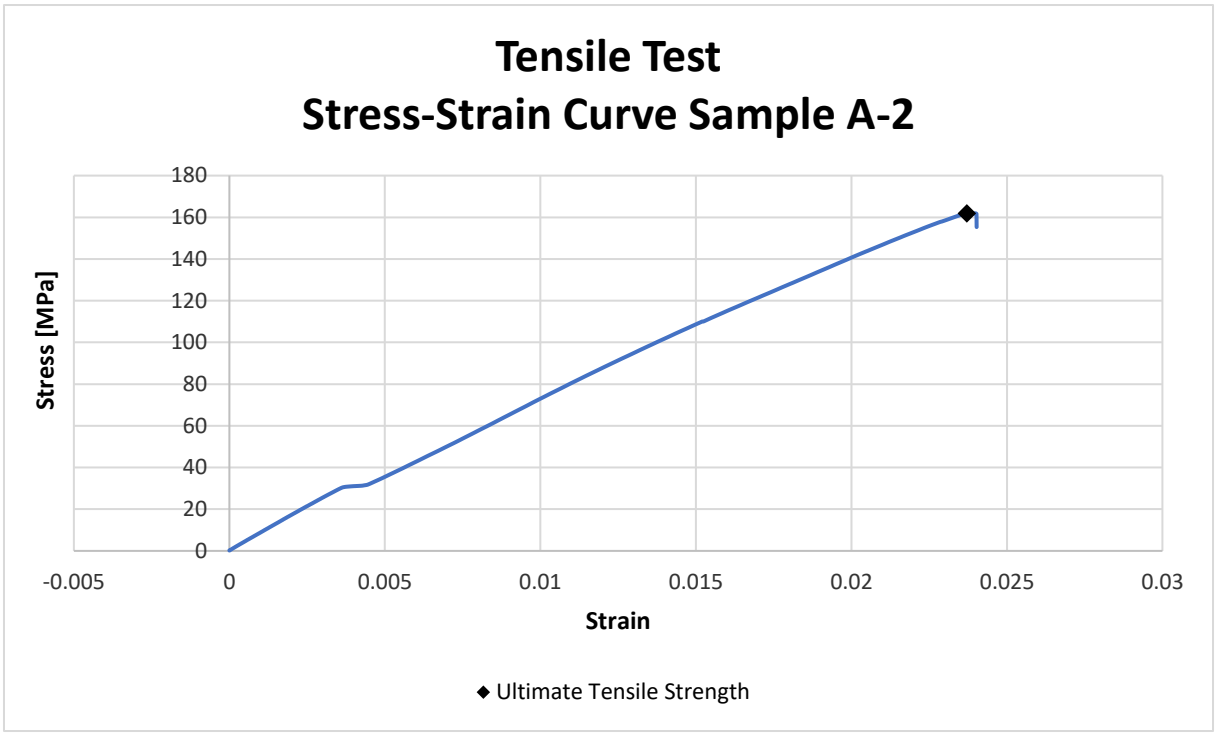
* Ruud Hendrikx at the Department of Materials Science and Engineering of the Delft University of Technology is acknowledged for the X-ray analysis.

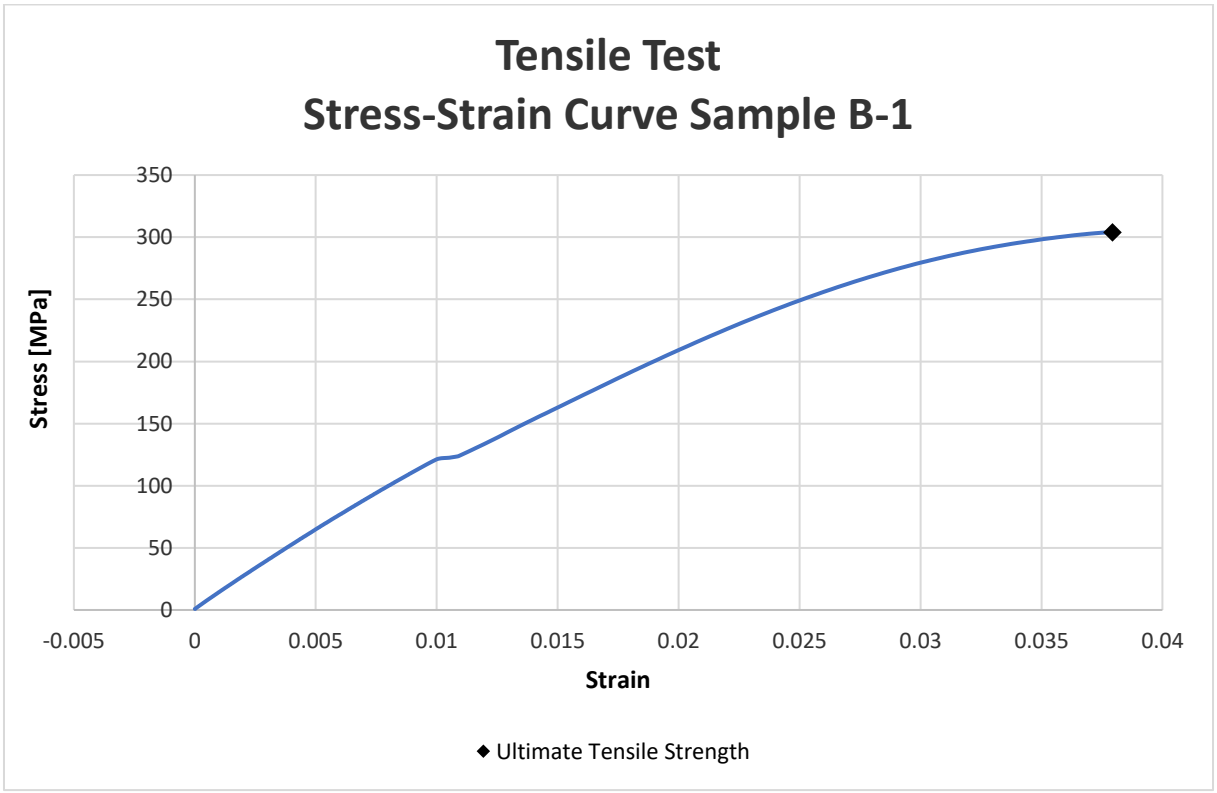
Supplemental file 22: Stress-strain

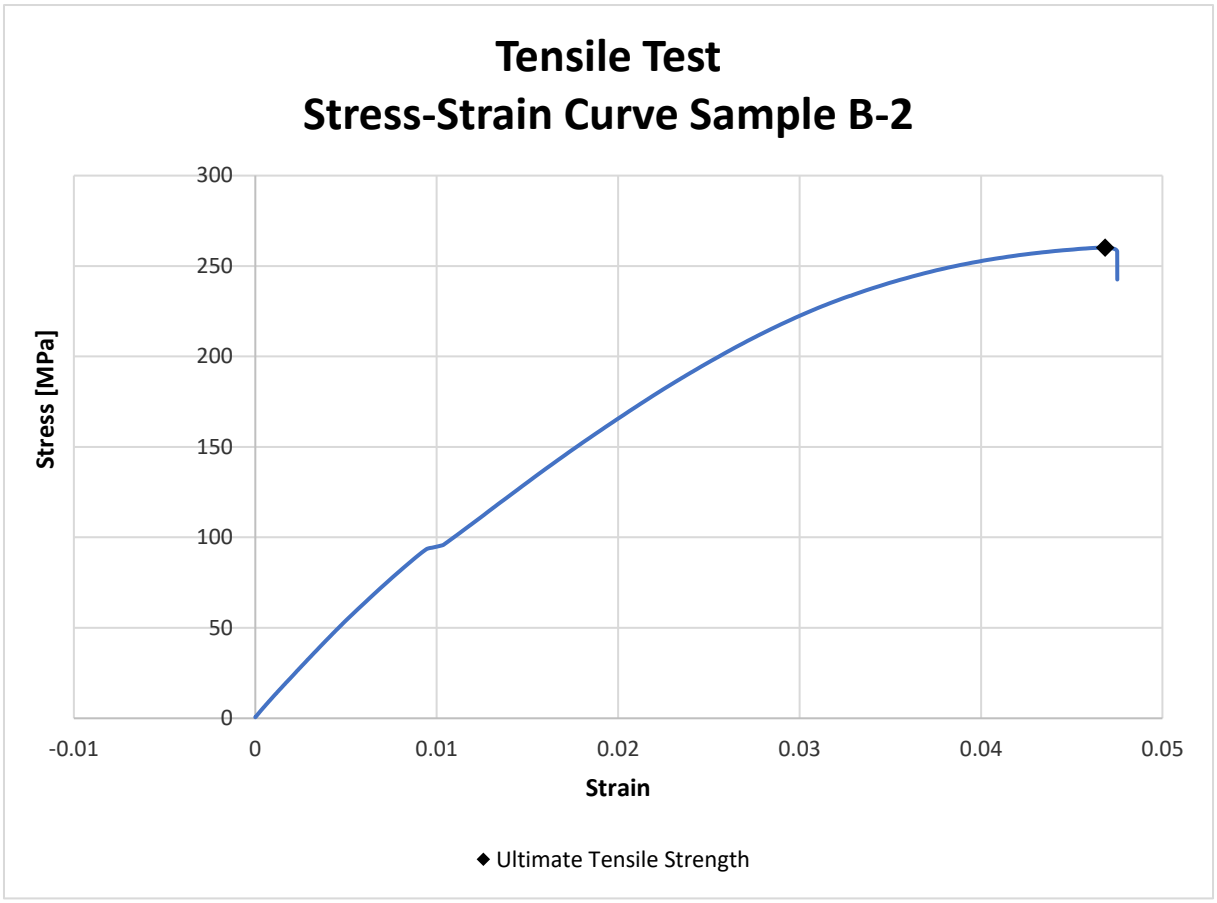
Samples were made from Ingots A (A1 and A2) and B (B1 and B2) and from virgin Zamak-3 (IPS1 and IPS2). This supplemental file shows the combined stress-strain relationships as well as each individual curve per sample.

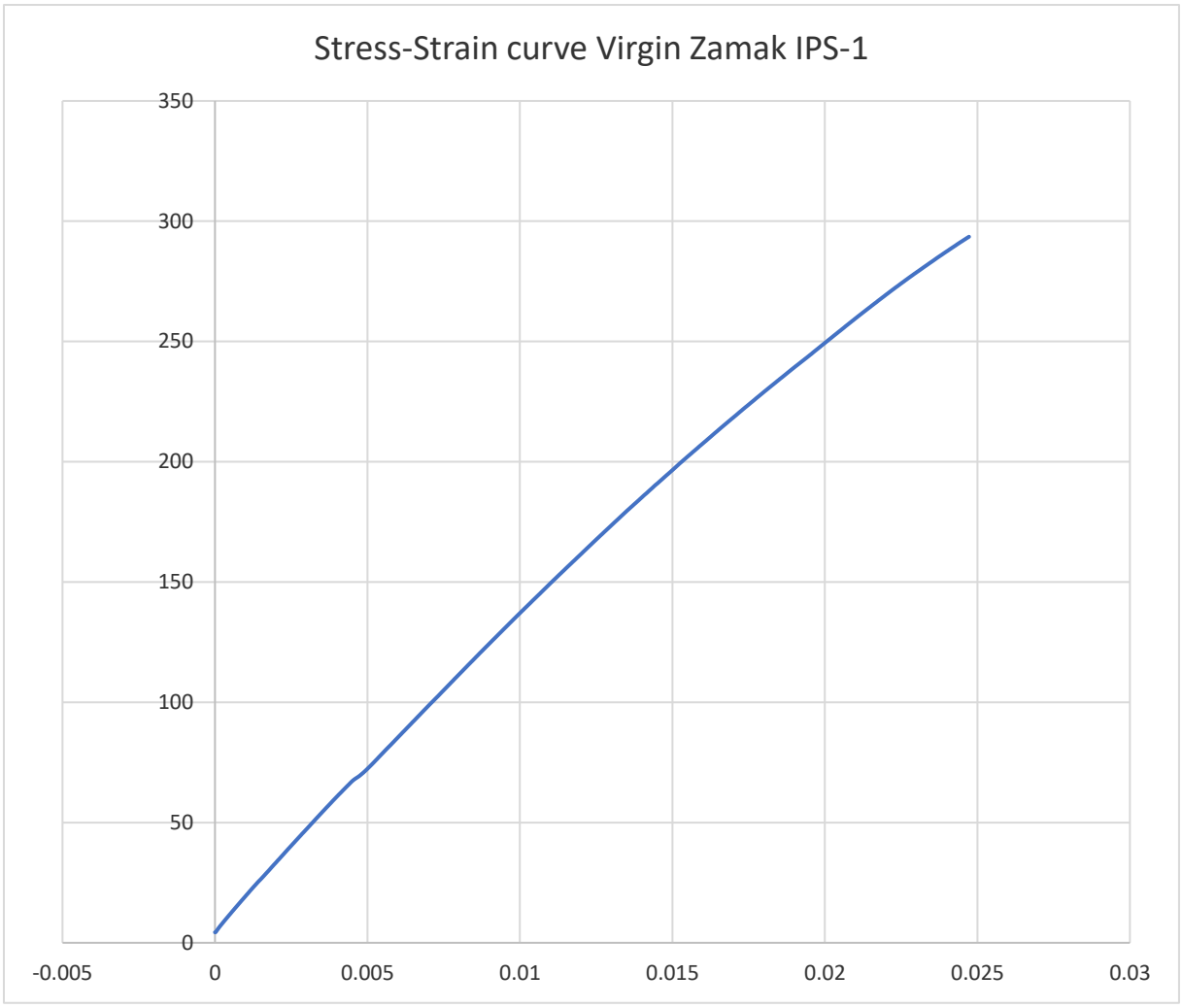


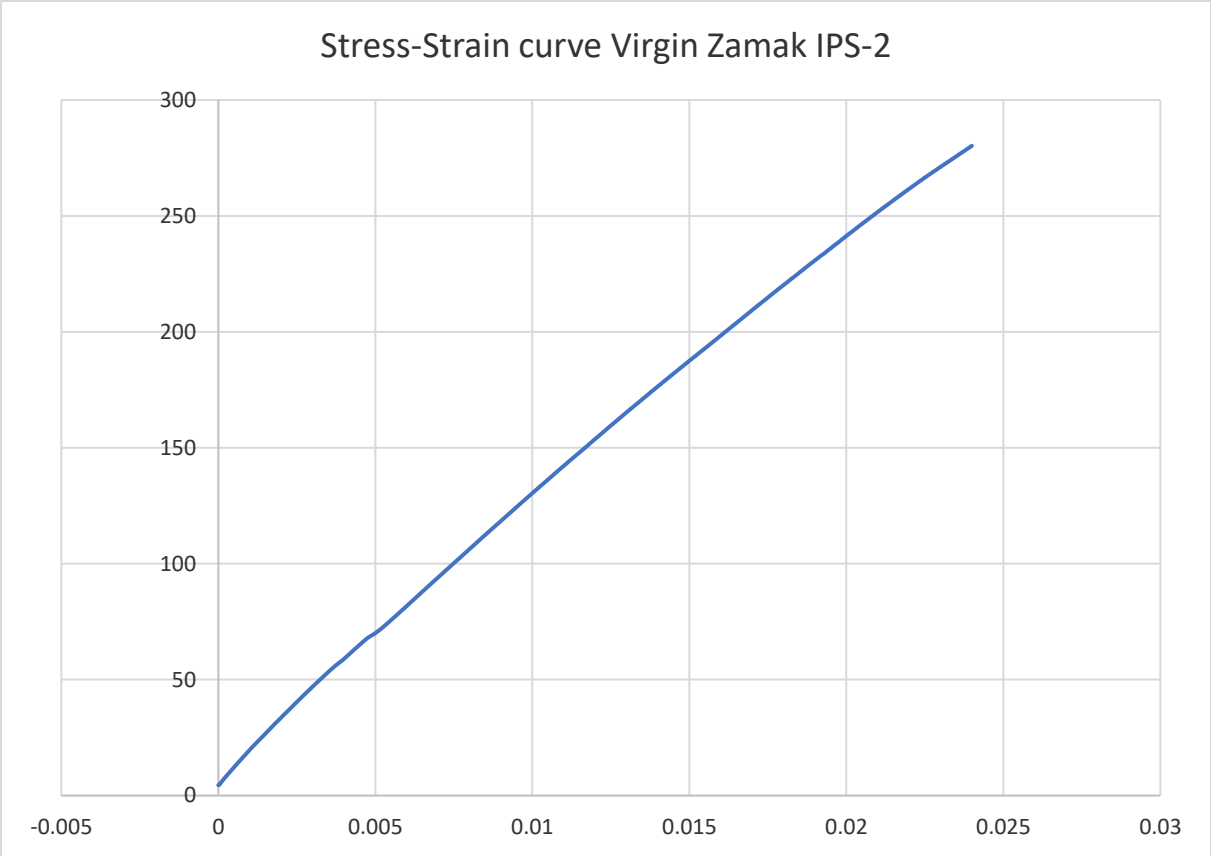



Tensile Test
Stress-Strain Curve Sample A-2
Stress [MPa]
180
160
140
120
100
80
60
40
20
0
-0.005
0
0.005
0.01
0.015
0.02
0.025
0.03
Strain
Ultimate Tensile Strength


Tensile Test
Stress-Strain Curve Sample B-1
Stress [MPa]
350
300
250
200
150
100
50
0
-0.005
0
0.005
0.01
0.015
0.02
0.025
0.03
0.035
0.04
Strain
Ultimate Tensile Strength


Tensile Test
Stress-Strain Curve Sample B-2
Stress [MPa]
300
250
200
150
100
50
0
-0.01
0
0.01
0.02
0.03
0.04
0.05
Strain
Ultimate Tensile Strength


Stress-Strain curve Virgin Zamak IPS-1
350
300
250
200
150
100
50
0
-0.005
0
0.005
0.01
0.015
0.02
0.025
0.03



	UTS	YP	Strain
A1	220	20.25	4.70%
A2	161.63	29.96	2.40%
B1	303.87	121.8	3.77%
B2	258	93.8	4.70%
IPS 1 V	293.22	67	2.50%
IPS 2 V	280.2	67	2.40%

	Strain @ YP	YM
A1	0.3	6.75
A2	0.36	8.322222
B1	0.99	12.30303
B2	0.94	9.978723
IPS 1 V	0.46	14.56522
IPS 2 V	0.47	14.25532

Impact from our research on society: Resolutions Dutch Parliament, RIVM and manufacturers' data

Appendix A

Based on the research of Van Straten et al. Motion Van Esch, E., Ellemeet, C., Simons, S. (2021). Tweede Kamer der Staten-Generaal. Motie van het lid Van Esch c.s. over een jaarlijks groeiend recyclingpercentage voor ziekenhuisafval . Vaststelling van de begrotingsstaten van het Ministerie van Volksgezondheid, Welzijn en Sport voor het jaar 2022. 35 925 https://www.tweedekamer.nl/kamerstukken/moties/detail?id=2021Z18876&did=2021D40547

Tweede Kamer der Staten-Generaal **2**

Vergaderjaar 2021–2022

35 925 XVI **Vaststelling van de begrotingsstaten van het Ministerie van Volksgezondheid, Welzijn en Sport (XVI) voor het jaar 2022**

Nr. 62 **MOTIE VAN HET LID VAN ESCH C.S.**
Voorgesteld 28 oktober 2021

De Kamer,

gehoord de beraadslaging,

constaterende dat de zorg verantwoordelijk is voor 7% van de totale Nederlandse $C0_2$-uitstoot;

constaterende dat een aanzienlijk deel van de CO_2-uitstoot van ziekenhuizen veroorzaakt wordt door het verbranden van medisch afval;

constaterende dat een innovatieve recyclingmethode waarbij medisch afval wordt omgesmolten tot nieuwe medische instrumenten reeds succesvol door acht ziekenhuizen wordt gebruikt;

verzoekt de regering voor medisch afval uit de ziekenhuissector een percentage verplichte recycling vast te stellen dat jaarlijks sneller groeit,

en gaat over tot de orde van de dag.

Van Esch
Ellemeet
Simons

kst-35925-XVI-62
ISSN 0921 - 7371
's-Gravenhage 2021

Appendix B

Based on testing methods for face masks. Azarkan, F. (2020). Tweede Kamer der Staten-Generaal. Motie van het lid Azarkan over het gebruik van mondkapjes monitoren. 25 295 Infectieziektenbestrijding. 7 mei 2020. https://www.tweedekamer.nl/kamerstukken/moties/detail?id=2020Z08185&did=2020D17467

Tweede Kamer der Staten-Generaal **2**

Vergaderjaar 2019–2020

25 295 **Infectieziektenbestrijding**

Nr. 336

MOTIE VAN HET LID AZARKAN
Voorgesteld 7 mei 2020

De Kamer,

gehoord de beraadslaging,

constaterende dat het OMT stelt dat gebruik van niet-medische mondkapjes overwogen kan worden in die omstandigheden waar het niet mogelijk is om 1,5 meter afstand te houden en triage toe te passen;

constaterende dat op basis van de inzichten vanuit het OMT en het RIVM het kabinet heeft besloten in het openbaar vervoer mondkapjes te dragen per 1 juni en dat verplicht stelt;

constaterende dat mondkapjes soms tegen woekerprijzen worden verhandeld en soms enorme schaarste ontstaat;

constaterende dat het gebruiken van kwalitatief niet-deugdelijke mondkapjes leidt tot schijnveiligheid;

constaterende dat in verschillende landen mondkapjes aan de bevolking worden verstrekt;

verzoekt de regering, om het gebruik van mondkapjes te monitoren en indien nodig te bezien of het mogelijk is om bij schaarste en prijsopdrijving Nederlanders collectief te voorzien van kwalitatief goede mondkapjes,

en gaat over tot de orde van de dag.

Azarkan

kst-25295-336
ISSN 0921 - 7371
's-Gravenhage 2020

Appendix C

The National Institute for Public Health and the Environment, RIVM. (2020). Ministry of Health, Welfare and Sports. Updated and published their bulleting with research results from our works after 121^{0}C steam sterilization of FFP2 face masks.

Rijksinstituut voor Volksgezondheid
en Milieu
Ministerie van Volksgezondheid,
Welzijn en Sport

Stand van zaken 30 maart 2020

RIVM

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info@rivm.nl

Het RIVM heeft in eerste instantie ongebruikte mondmaskers van het type 3M 8822 herverwerkt met verschillende reinigingsprocessen en sterilisatieprocessen waaronder stoom en waterstofperoxide, zie processen 1-5.
Vervolgens heeft het RIVM mondmaskers ontvangen van het type 3M 1862+ die veel gebruikt worden in ziekenhuizen. Deze mondmaskers waren gesteriliseerd met verschillende stoomsterilisatieprocessen, waterstofperoxide en gammastraling.

Resultaten
De resultaten zijn in onderstaande tabellen weergegeven.

Proces	**Mondmasker vervormd Ja/Nee**	**Resultaat fittest +/-**
Type masker: **3M FFP2 NR D maskers (type 8822)**		
Controle	Nee	+
1. 60 °C reiniging zonder reinigingsmiddel en desinfectans	Nee	-
2. 90 °C reiniging zonder reinigingsmiddel	Ja	n.v.t.
3. 90 °C reiniging met reinigingsmiddel	Ja	n.v.t.
4. Waterstofperoxide sterilisatie **1x**	Nee	+
Waterstofperoxide sterilisatie **2x**	Nee	+
Waterstofperoxide sterilisatie **3x**	Nee	-
5. Stoomsterilisatie 134 °C	Ja	n.v.t.

Proces	**Mondmasker vervormd Ja/Nee**	**Resultaat fittest +/-**
Type masker: **3M Aura 1862+ FFP2 NR D**		
Controle	-	+
6. Gamma sterilisatie > 25kGy	Nee	-
7. Stoomsterilisatie 121 °C	Nee	+
8. Stoomsterilisatie 121 °C **2x**	Nee	+
9. Stoomsterilisatie 134 °C	Nee	wisselend
10. Stoomsterilisatie 134 °C **2x**	Nee	-
11. 121 °C, droge hitte **1x 3x en 5x**	Nee	Wisselend
12. Waterstofperoxide sterilisatie	Nee	+

Tijdens het meten bleek dat de fittest zoals deze werd uitgevoerd wisselende resultaten opleverde, zo liepen de waarden voor de controle maskers uiteen. De resultaten laten echter wel consequent goede waarden zien na stoomsterilisatie bij 121 graden. Daarmee lijkt dit, evenals de in onze eerdere rapportage genoemde waterstofperoxide sterilisatie, een methode die op basis van de beschikbare gegevens tot een acceptabele kwaliteit leidt.
De mondkapjes 3M 1862+ FFP2 zijn niet voorgevormd en zien er na sterilisatie in alle gevallen goed uit, in tegenstelling tot de eerdere geteste mondmaskers 3M 8822 FFP2. Het niet vervormd zijn betekent echter niet dat het masker nog volledig functioneel is.

Verdere details over de toegepaste werkwijze zijn opgenomen in het document "hergebruik FFP2 mondmaskers" zoals ge-update op 18 maart 2020 (https://www.rivm.nl/documenten/hergebruik-ffp2-mondmaskers).

Appendix D

Belimed. (2020). Contingency Reprocessing of Single-Use Personal Protective Equipment (PPE). White Paper. Belimed AG, Zug, Switzerland. Issue 1, April 2020.
https://www.belimed.com/en-us/corona/reprocessing-ppe

Belimed
Infection Control

Contingency Reprocessing of Single-Use Personal Protective Equipment (PPE)

White Paper
Belimed AG, Zug, Switzerland
Issue 1, April 2020

Workflow Examples

In terms of equipment, some hospitals are sterilising masks in **separate batches** or as a temporary measure **dedicating a steriliser** specifically for this purpose.

Other sites with an existing 121°C / 250°F sterilisation program in place for other goods, have decided to sterilise **mixed loads in the same cycle**, where it is deemed advantageous for the CSSD workflow. From a regulatory perspective, there are no clear rules in place, however as long as the masks are packed correctly there should be no concerns for cross-contamination (see Picture 2).

Example for reprocessing of FFP respirator masks

- Collection of used masks in a container in the ward
- Transport to the CSSD
- Inspection of masks by trained and PPE-protected sterilisation technician. Masks that are dirty, damaged or have already been reprocessed the maximum number of times are disposed
- Mark of the mask with an "X" with a suitable pen, for every reprocessing cycle
- Packaging in pouches for sterilisation
    - Individually
    - In packs of four (4) or five (5) units

  (Individual packing is preferred since it allows that every HCW received a previously untouched mask)
- Where the hospital has decided to reprocess different categories of mask, then each type must be packed into a suitable sterilisation pouch:
    - Masks suitable for steam sterilisation
    - Masks that are only suitable for H2O2 sterilisation
- Sterilisation at 121°C / 250°F with 15-20 minutes holding time
- Delivery of the reprocessed masks in their closed packaging to the respective point of use
- Healthcare workers control the fitting of their mask (as with a new mask). Where the HCW notices a compromised fit, the mask is thrown away

Some minor physical changes of the reprocessed mask were reported by HCWs, but they also stated that new masks do not always have a perfect fit for all faces. HCWs are generally free to ask for a new mask if they are uncomfortable with the feel or fit of the decontaminated mask.

Some small hospitals have personalised this one-time reuse procedure:

- Every second day a HCW is instructed to place his/her mask into a sterilisation pouch at the end of the working day, and to write their name on it.
- On the following day, the HCW can recollect the mask from the previous day, having been sterilised (in the pouch).

In larger hospitals or when the logistics are difficult, HCWs can also receive reprocessed masks without any personalisation.

Picture 2: Steriliser batch with FFP2 masks for decontamination together with other loads suitable for this sterilisation process

Picture 3: Tray pouch packed with FFP2 masks

Picture 4: Individually packed FFP2 mask with name of the HCW written on it.

Additional Stock

Many hospitals have decided to install the steam sterilisation process for reprocessing FFP2 masks as a risk-reduction procedure (for potential out of stock situations within the next 4-6 weeks). The reprocessed masks are kept on stock in the event that no new masks are available.

Some hospitals (NL) have tested the filtration capacities of newly sourced masks (lower quality) and found that some new masks actually had worse filtration properties than steam sterilised high quality masks. This has resulted in the decision to first issue reprocessed (high quality) masks to employees before giving newly sourced (lower quality) masks.

References:

ECDC - TECHNICAL REPORT Cloth masks and mask sterilisation as options in case of shortage of surgical masks and respirators 26 March 2020
https://www.ecdc.europa.eu/en/publications-data/cloth-masks-sterilisation-options-shortage-surgical-masks-respirators

CDC -Decontamination and Reuse of Filtering Facepiece Respirators (April 9th 2020)
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html

A scientific consortium for data-driven study of N95 filtering facepiece respirator decontamination
https://www.n95decon.org/

Website of ProjectMask from the Technical University Delft, including test protocols and test data on specific masks and including an illustrative video (Dutch language with English subtitles)
https://projectmask.nl/

TU Delft website article about the "projectmask" including illustrative video
https://www.tudelft.nl/en/stories/articles/recycling-mouth-masks/

TU Delf Internal publication of the "projectmask" research team
Steam sterilisation of used disposable face masks with respect to COVID-19 shortages
https://pure.tudelft.nl/portal/en/publications/steam-sterilisation-of-used-disposable-face-masks-with-respect-to-covid19-shortages(078a3733-84d6-4d4a-81e6-74210c7fed78).html

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Circular Economy: Urban Mining
MINING
NEW VALUE
from the circular economy
TU Delft
Department of BioMechanical Engineering
of Technology

Publications

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Curriculum Vitae

Bart van Straten was born on 14 January 1971 in Zaandam, the Netherlands. He obtained his Bachelor Degree in Business Administration at the European University/EU Business School. During his studies he participated in a EU exchange program with the State University of New York, College at Brockport. After his Bachelor degree he completed two Master degrees. A Master in Business Administration at European University/EU Business School, followed by Master degree at Institut Cooremans & EU Business School, Académie d'administration publique in Brussels.

During his studies he founded Center Evenementen Organisaties followed by a start-up, VSW Intermediaires, a consultancy practice with two fellow students. During this period he obtained his private pilot license and completed the theory courses at Schiphol-Oost to attain his Airline Transport License. After following professional airline training at Flight Safety Academy, USA he started a part-time flying career as first officer at North Sea Airways.

During this period he attended political learning programs at Haya van Someren Stichting/Volkspartij voor Vrijheid en Democratie 2008 – 2010 and joined the family company Van Straten Medical together with his brother Niels. Van Straten Medical was founded in 1975 with a production facility Medinorm, co-founded by Jaap van Straten in Saarbrücken, Germany in 1984. From the year 2000, he and his brother started slowly transforming the company into a fully circular production company. After having acquired the company medical repairs, they changed the mission of Van Straten Medical with aim of only developing circular designed products. Bart started to experiment with medical devices made out of waste. His professional mission became a personal mission.

Striving for a cleaner world after his children Roos and Maurits made him realize that we have to serve the generations to come. Based on a statement that we did not inherit the world from our parents but that we borrow the world from our children, he started to dedicate his efforts to minimize waste. After he handed over the first instrument mesh basket, made from recycled materials, to the Minister for Health, Welfare and Sports, Bruno Bruins, he dedicated himself to research and a PhD. He co-founded GreenCycl, an organization for making healthcare more sustainable. After attending Graduate School (Faculty Graduate School through Mechanical Engineering) at Delft University of Technology and starting-up his first research, he joined the research-line of Tim Horeman. Under supervision of Tim Horeman and Jenny Dankelman several initiatives were started. Tim and Bart started to set up a melting process at TU Delft for experiments with Zamak Laryngoscope blades and Polypropylene wrapping paper waste recovered from hospitals. Bart and Tim developed a sterilization and testing method for the reprocessing of disposable face masks in March 2020 which was adopted by many hospitals around the world. As co-authors, they were involved in writing the national NEN-Spec 3 guideline for reusing single-use medical devices in times of crisis which was published by NEN on 1 June 2020. Additionally, they are engaged in helping the medical industry to design sustainable devices and to set-up pilots for reprocessing medical waste into new raw material. After completing the University Teaching Qualification (BKO/UTQ) at TU Delft Teaching Academy in 2021, they focused on integrating sustainability engineering and circular design in education.

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