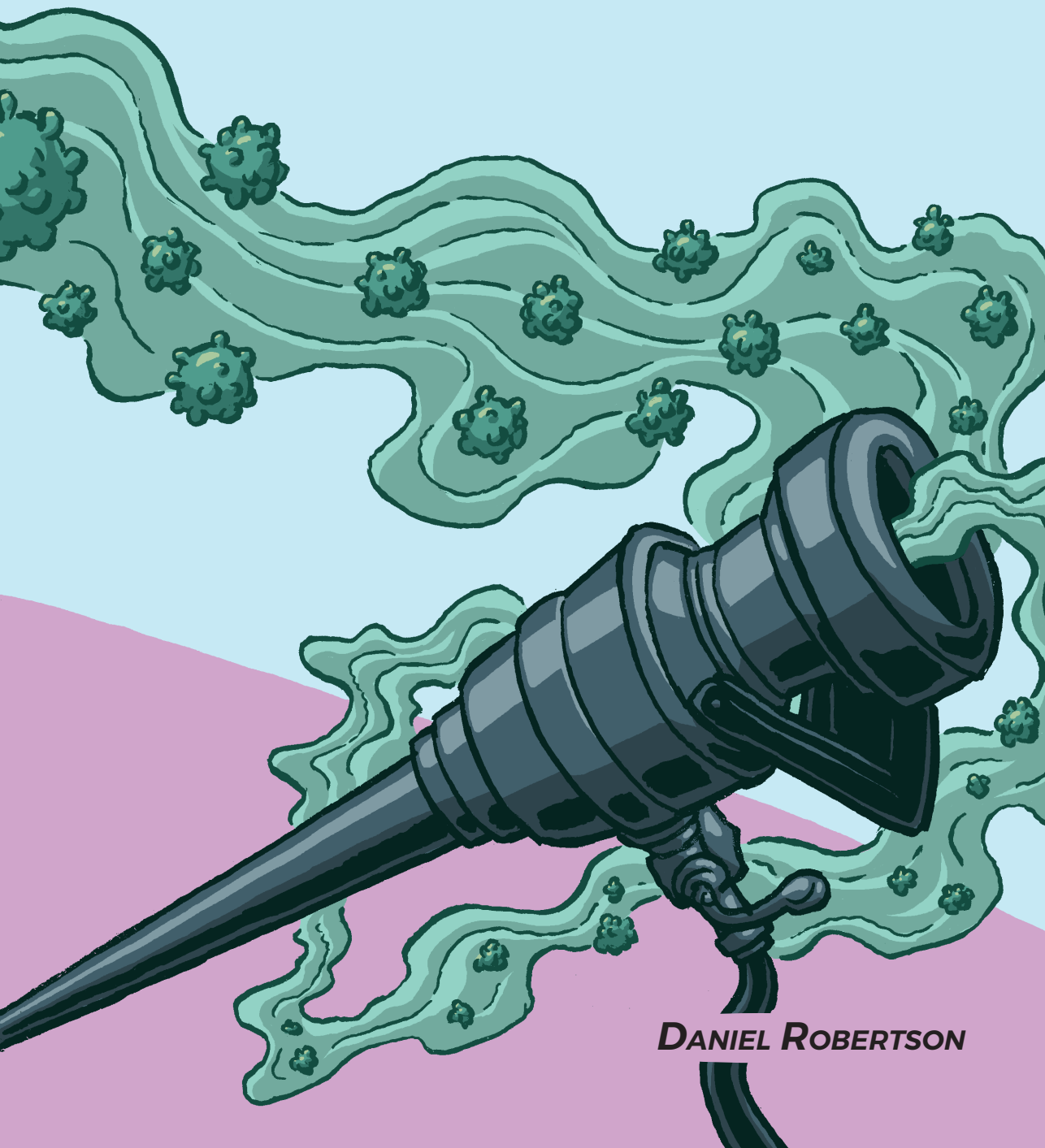
Preventing Contamination by Laparoscopic Instruments

In Low-Middle and High Income Countries



Daniel Robertson

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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. H. Bijl,

chair of the Board for Doctorates

to be defended publicly on

Monday, 13 April 2026 at 12:30

by

Peter Daniel ROBERTSON

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Keywords: laparoscopy, low-middle income countries, gas leakage, surgical instrument reprocessing
Printed by: Gildeprint
Cover by: Niek van Ooijen

ISBN 978-94-6384-935-7

An electronic copy of this dissertation is available at
https://repository.tudelft.nl/.

To Hannah and Sam

Contents

Summary

Laparoscopic surgery has become a standard technique in modern medicine, offering numerous advantages over open surgery, including reduced recovery time, lower infection rates, and decreased blood loss. However, despite these benefits, contamination risks persist, particularly in two key areas: the sterilization and reprocessing of laparoscopic instruments and the leakage of insufflation gas, which can carry contaminants into the operating room.

This thesis investigates these risks in both low-resource and high-income surgical environments. The research is divided into two main parts: **Part I** examines the challenges associated with sterilization and reprocessing of laparoscopic instruments in rural hospitals in India, while **Part II** focuses on the measurement and characterization of gas leakage through trocars. The goal of this work is to identify the main risks and propose solutions that enhance the safety and accessibility of laparoscopic surgery worldwide.

Part I: Clean Laparoscopic Instruments in Rural India

Assessment of Laparoscopic Instrument Reprocessing in Rural India

The first study assesses the reprocessing of laparoscopic instruments in four rural hospitals in India. Observations and interviews revealed that sterilization practices were often inconsistent and did not adhere to international guidelines. Nurses responsible for instrument cleaning frequently relied on household detergents and improvised tools, such as toothbrushes and needles, instead of specialized cleaning equipment.

Laparoscopic instruments were not autoclaved, as recommended by organisations like the World Health Organisation, but instead disinfected with glutaraldehyde or formaldehyde. However, soaking times and the concentration levels of these disinfectants were not routinely monitored, potentially reducing their effectiveness. Additionally, autoclaves present in these hospitals lacked proper

vacuum cycles, rendering them unsuitable for sterilizing the complex internal channels of laparoscopic instruments. The lack of formal training among nurses and the absence of written protocols further contributed to the inconsistent re-processing practices.

These findings underscore the urgent need for context specific solutions tailored to the constraints of rural hospitals. Simply transferring high-income country sterilization methods is impractical, and instead, efforts should focus on designing equipment and training programs that address the unique challenges faced by hospitals in low-resource settings.

Context-Driven Design of a Laparoscopic Instrument Cleaner

Building on the findings from the first study, a laparoscopic instrument cleaner was designed to improve reprocessing reliability in resource-limited settings. The device aimed to be intuitive and easy to operate, even with minimal training, and to reduce the time required for instrument reprocessing. This would allow the staff to spend more time on their many other tasks around the operating theatre The design process incorporated insights from previous observations, emphasizing simplicity, affordability, and ease of use, while basing the cleaning cycle on high-income country processes.

The initial evaluation of this cleaner among hospital staff revealed that it was not directly intuitive to use. The nurses struggled to understand the workings of the device and how to load the instruments. This difficulty was likely due to their unfamiliarity with comparable machinery, which is common in high-income countries but not widely available in low-resource hospitals.

Based on these findings, the study proposed a redesigned laparoscopic instrument cleaner to enhance its ease of use. Adjustments were made to improve the clarity of operation and usability, ensuring that hospital staff could confidently incorporate the device into their workflow. These improvements not only enhance sterilization effectiveness but also optimize workflow efficiency within hospitals where time and resources are limited.

The development and evaluation of this cleaner demonstrate that low-cost, tailored medical devices can bridge the gap between high-income sterilization standards and the practical constraints of rural hospitals. By integrating such solutions into surgical workflows, the safety of laparoscopic procedures in low-income countries can be markedly improved.

Part II: Trocar Gas Leakages

Characterization of Trocar-Associated Gas Leaks

While the first part of the thesis focuses on the contamination risks associated with instrument reprocessing, the second part addresses the issue of CO_2 gas leakage from trocars during laparoscopic surgery. To quantify the extent of leakage, experimental studies were conducted using different trocar designs under various surgical conditions and manipulations.

The results demonstrated that all trocars exhibited some degree of leakage, with significant variation based on their design and sealing mechanism. Additionally, gas leakage increased whenever an instrument was inserted or removed, highlighting the importance of the interaction between the trocar and the surgical instruments in maintaining insufflation pressure.

These findings indicate that trocar selection can have a direct impact on gas containment and should be carefully considered when planning laparoscopic procedures. Future trocar designs should prioritize reducing leakage while maintaining ease of instrument exchange.

Influence of Prolonged Instrument Manipulation on Gas Leakage

To better understand the dynamics of gas leakage during laparoscopic surgery, this study investigated the effects of prolonged instrument manipulation on trocar sealing performance. Measurements were taken to assess whether leakage rates changed over time as instruments were repeatedly inserted, rotated, and moved within the trocar.

The results showed that, contrary to initial expectations, gas leakage did not progressively increase with prolonged instrument use. Instead, leakage rates remained relatively stable throughout the duration of the tests. However, the amount of leakage was influenced by the type of instrument used and the degree of instrument motion. Instruments with larger diameters and those that required extensive movement within the trocar tended to generate slightly higher leakage rates compared to smaller, less frequently manipulated instruments.

These findings suggest that trocar seals generally maintain their integrity over time although some trocars can be sensitive to mechanical wear. While prolonged use alone does not appear to worsen leakage, efforts to improve sealing performance should focus on optimizing trocar designs to accommodate a wide range of instrument movements with minimal gas escape.

Escape of Surgical Smoke Particles in valveless trocars

Another significant concern addressed in this thesis is the contamination risk posed by surgical smoke. During laparoscopic procedures, the use of electrosurgical devices produces smoke that contains ultrafine particles, including carcinogens and viral fragments. This study compared the particle escape rates between conventional and valveless trocars.

The findings showed that valveless trocars allowed a greater number of surgical smoke particles to escape into the operating room, increasing the potential exposure of surgical staff. These results highlight the need for improved smoke evacuation strategies and stronger guidelines on personal protective equipment (PPE) use in laparoscopic surgery. Ensuring better containment of surgical smoke can contribute to a safer working environment for operating room staff.

Sterilization of Disposable Face Masks

The final study in this thesis investigates whether disposable face masks can be resterilized and reused as an emergency measure, particularly during supply shortages such as those experienced during the COVID-19 pandemic.

The study found that while sterilization was effective for some mask types, repeated processing led to a gradual degradation of filtration efficiency and material integrity. After multiple sterilization cycles, certain masks no longer provided an adequate seal, reducing their protective effectiveness. These findings suggest that while mask sterilization may serve as a short-term solution in crisis situations, it is not a viable long-term strategy for maintaining respiratory protection in healthcare settings.

Final Recommendations

This thesis identifies and addresses key contamination risks associated with laparoscopic surgery, focusing on both instrument sterilization challenges in low-resource settings and gas leakage risks in high-income surgical environments.

- For LMICs: Implement cost-effective sterilization technologies and enhance training programs for hospital staff.

- For trocar design: Improve sealing mechanisms to reduce gas leakage, with a particular focus on instrument-trocar interaction.
- For surgical safety: Strengthen smoke evacuation protocols and refine PPE guidelines to protect surgical staff.

By addressing these issues, laparoscopic surgery can become safer and more accessible worldwide, improving patient outcomes and enhancing occupational safety for healthcare professionals.

Samenvatting

Laparoscopische chirurgie is een standaardtechniek geworden in de moderne geneeskunde en biedt talrijke voordelen ten opzichte van open chirurgie, waaronder een kortere hersteltijd, een lager infectierisico en minder bloedverlies. Ondanks deze voordelen blijven er echter besmettingsrisico's bestaan, met name op twee belangrijke gebieden: de reiniging en sterilisatie van laparoscopische instrumenten en het lekken van insufflatiegas, dat micro-organismen in de operatiekamer kan verspreiden.

Dit proefschrift onderzoekt deze risico's in zowel omgevingen met beperkte middelen als in hoogontwikkelde chirurgische omgevingen. Het onderzoek is opgedeeld in twee hoofdonderdelen: **Deel I** onderzoekt de uitdagingen met betrekking tot reiniging en sterilisatie van laparoscopische instrumenten in rurale ziekenhuizen in India, terwijl **Deel II** zich richt op de meting en karakterisering van gaslekken via laparoscopische trocars. Het doel van dit werk is om de belangrijkste risico's te identificeren en oplossingen te bieden die de veiligheid en toegankelijkheid van laparoscopische chirurgie wereldwijd verbeteren.

Deel I: Schone laparoscopische instrumenten in rurale ziekenhuizen in India

Evaluatie van de sterilisatie van laparoscopische instrumenten in rurale ziekenhuizen in India

De eerste studie beoordeelt het sterilisatieproces van laparoscopische instrumenten in vier rurale ziekenhuizen in India. Observaties en interviews toonden aan dat de sterilisatiepraktijken vaak inconsistent waren en niet voldeden aan internationale richtlijnen. Verpleegkundigen die verantwoordelijk waren voor de reiniging van instrumenten vertrouwden regelmatig op geïmproviseerde schoonmaakmiddelen en huishoudelijke hulpmiddelen, zoals tandenborstels en naalden, in plaats van gespecialiseerde reinigingsapparatuur.

Laparoscopische instrumenten werden niet geautoclaveerd, zoals aanbevolen door organisaties zoals de Wereldgezondheidsorganisatie, maar gedesinfecteerd met glutaraldehyde of formaldehyde. De inweektijden en de concentratieniveaus van deze desinfectiemiddelen werden echter niet routinematig gecontroleerd, wat de effectiviteit ervan mogelijk verminderde. Bovendien ontbrak bij de aanwezige autoclaven een geschikte vacuümcyclus, waardoor ze ongeschikt waren voor het steriliseren van de complexe interne kanalen van laparoscopische instrumenten. Het gebrek aan specifieke training onder verpleegkundigen en het ontbreken van schriftelijke protocollen droegen verder bij aan de inconsistente sterilisatiepraktijken.

Deze bevindingen onderstrepen de behoefte aan contextspecifieke oplossingen die zijn afgestemd op de beschikbare middelen van rurale ziekenhuizen. Het direct overnemen van sterilisatiemethoden uit landen met een hoog inkomen is onhaalbaar; in plaats daarvan apparatuur en trainingsprogramma's ontworpen worden die aansluiten bij de specifieke uitdagingen van ziekenhuizen in omgevingen met beperkte middelen.

Contextgestuurde ontwikkeling van een laparoscopische instrumentenreiniger

Op basis van de bevindingen uit de eerste studie werd een laparoscopische instrumentenreiniger ontworpen om de betrouwbaarheid en effectiviteit van de sterilisatie in ziekenhuizen met beperkte middelen te verbeteren. Het apparaat had als doel intuïtief en eenvoudig te bedienen te zijn, zelfs met minimale training, en de tijd om de instrumenten te reinigen te verkorten. Dit zou het personeel in staat stellen om zich meer te richten op andere taken rondom de operatiekamer. Het ontwerpproces, gebaseerd op de bevindingen van Hoofdstuk 1, benadrukte eenvoud, betaalbaarheid en gebruiksgemak, terwijl de reinigingscyclus was gebaseerd op processen die gangbaar zijn in hoge-inkomenslanden.

De eerste evaluatie van deze reiniger onder ziekenhuispersoneel toonde aan dat het apparaat niet direct intuïtief in gebruik was. De verpleegkundigen hadden moeite met het begrijpen van de werking van het apparaat en hoe de instrumenten correct moesten worden geladen. Dit probleem werd waarschijnlijk veroorzaakt door het gebrek aan bekendheid met vergelijkbare machines, die in hoge-inkomenslanden veel gebruikelijker zijn.

Op basis van deze bevindingen werd een verbeterd ontwerp voorgesteld om de gebruiksvriendelijkheid van de instrumentenreiniger te vergroten. Aanpas-

singen werden doorgevoerd om de bediening en het gebruiksgemak te verbeteren, zodat ziekenhuispersoneel het apparaat gemakkelijker in hun werkprocessen kon integreren. Deze verbeteringen vergroten niet alleen de effectiviteit van sterilisatie, maar optimaliseren ook de efficiëntie van de werkprocessen in ziekenhuizen met beperkte middelen.

De ontwikkeling en evaluatie van deze reiniger tonen aan dat op maat gemaakte medische apparaten tegen lage kosten een brug kunnen slaan tussen de sterilisatiestandaarden in hoogontwikkelde landen en de praktische beperkingen van rurale ziekenhuizen. Door dergelijke oplossingen in chirurgische werkstromen te integreren, kan de veiligheid van laparoscopische procedures in lage-inkomenslanden aanzienlijk worden verbeterd.

Deel II: Gaslekken via trocars

Karakterisering van gaslekken bij trocars

Terwijl het eerste deel van het proefschrift zich richt op besmettingsrisico's bij de sterilisatie van laparoscopische instrumenten, behandelt het tweede deel het probleem van CO_2 gaslekken via trocars tijdens laparoscopische chirurgie. Om de omvang van de lekkage te kwantificeren, werden experimentele studies uitgevoerd met verschillende trocarontwerpen onder diverse chirurgische omstandigheden en manipulaties.

De resultaten toonden aan dat alle trocars in zekere mate gaslekken vertoonden, met aanzienlijke variatie afhankelijk van het ontwerp en het afdichtingsmechanisme. Bovendien was er een verhoogde lekkage telkens wanneer een instrument werd ingebracht of verwijderd, wat het belang benadrukt van de interactie tussen de trocar en de chirurgische instrumenten bij het handhaven van de intraabdominale druk.

Deze bevindingen geven aan dat de keuze van de trocar een directe invloed kan hebben op gasverbruik. Toekomstige trocarontwerpen moeten prioriteit geven aan het verminderen van lekkage, terwijl de eenvoudige instrumentuitwisseling behouden blijft.

Invloed van langdurige instrumentmanipulatie op gaslekken

Om een beter inzicht te krijgen in de dynamiek van gaslekkage tijdens laparoscopische chirurgie, onderzocht deze studie het effect van langdurige instrumentmanipulatie op de afdichting van trocars. Er werden metingen uitgevoerd

om te bepalen of de lekkagesnelheden veranderden naarmate instrumenten herhaaldelijk werden ingebracht, gedraaid en bewogen binnen de trocar.

De resultaten toonden aan dat, in tegenstelling tot eerdere verwachtingen, gaslekkage niet geleidelijk toenam bij langdurig instrumentgebruik. In plaats daarvan bleven de lekkagesnelheden relatief stabiel gedurende de duur van de tests. Wel werd vastgesteld dat de hoeveelheid lekkage werd beïnvloed door het type instrument en de mate van beweging. Instrumenten met een grotere diameter en instrumenten die intensieve bewegingen vereisten, genereerden iets hogere lekkagesnelheden dan kleinere, minder vaak gemanipuleerde instrumenten.

Deze bevindingen suggereren dat de afdichting van trocars over het algemeen intact blijft, hoewel sommige trocars toch gevoelig zijn voor mechanische slijtage. Al lijkt langdurig gebruik geen verslechtering van de lekkage te veroorzaken, moeten toekomstige ontwerpen zich richten op het verbeteren van de afdichtingsmechanismen om gasverlies bij verschillende instrumentbewegingen te minimaliseren.

Verspreiding van chirurgische rookdeeltjes bij trocars zonder klep

Een andere belangrijke zorg die in dit proefschrift wordt behandeld, is het besmettingsrisico dat wordt veroorzaakt door chirurgische rook. Tijdens laparoscopische ingrepen produceert het gebruik van elektrochirurgische instrumenten rook die ultrafijne deeltjes bevat, waaronder kankerverwekkende stoffen en virale fragmenten. In deze studie werden de hoeveelheden ontsnapte deeltjes vergeleken tussen conventionele en ventielloze trocars.

De bevindingen toonden aan dat trocars zonder mechanische kleppen een groter aantal chirurgische rookdeeltjes lieten ontsnappen naar de operatiekamer, waardoor het zorgpersoneel werd blootgesteld aan een verhoogd risico. Deze resultaten onderstrepen de noodzaak van betere rookafzuiging en strengere richtlijnen voor het gebruik van persoonlijke beschermingsmiddelen (PBM) bij laparoscopische chirurgie. Een betere beheersing van chirurgische rook kan bijdragen aan een veiligere werkomgeving voor personeel in de operatiekamer.

Sterilisatie van wegwerpmondmaskers

De laatste studie in dit proefschrift onderzoekt of wegwerpmaskers kunnen worden gesteriliseerd en hergebruikt als een noodmaatregel, met name tijdens

tekorten aan persoonlijke beschermingsmiddelen, zoals die zich voordeden tijdens de COVID-19 pandemie.

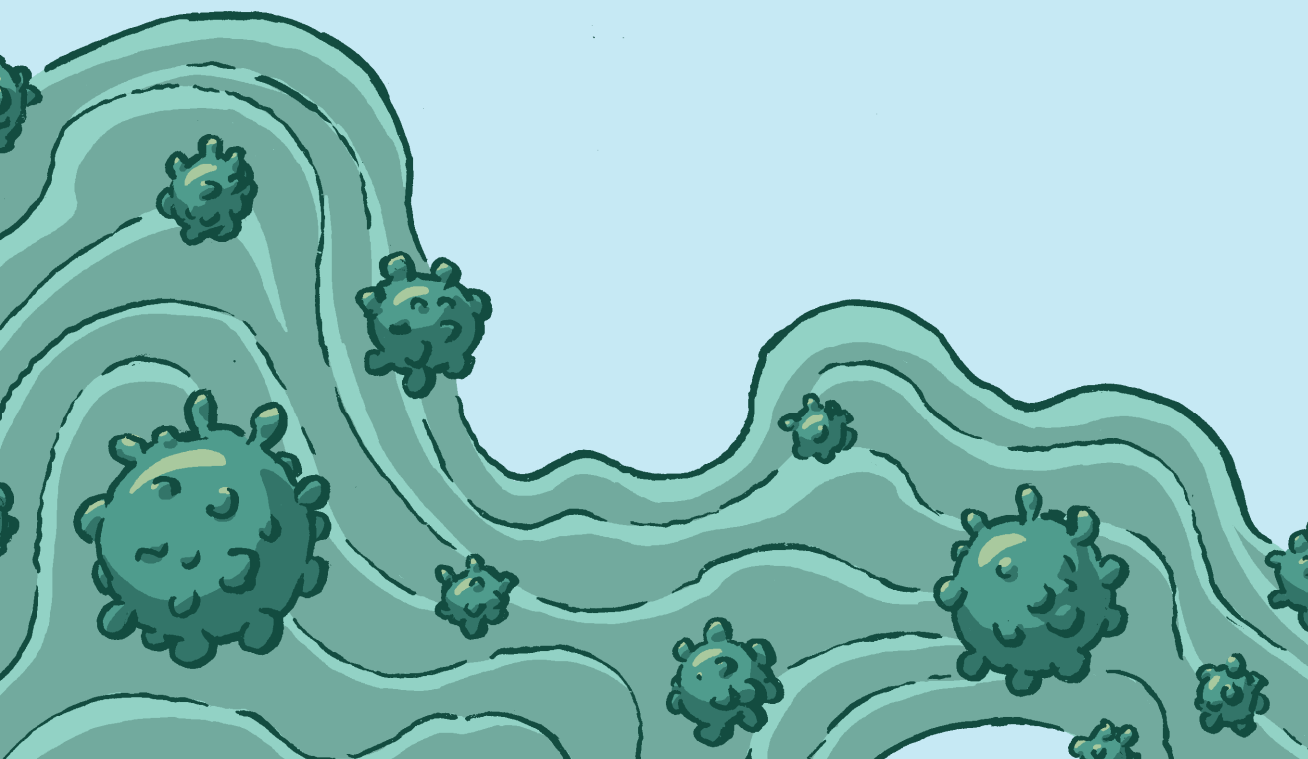
Uit het onderzoek bleek dat, hoewel sterilisatie effectief was voor bepaalde maskertypen, herhaaldelijke sterilisatie leidde tot een geleidelijke achteruitgang van de filtratie efficiëntie en de materiaalkwaliteit. Na meerdere sterilisatiecycli boden sommige maskers geen adequate afdichting meer, waardoor hun beschermende werking afnam. Deze bevindingen suggereren dat, hoewel sterilisatie van mondmaskers een tijdelijke oplossing kan zijn in crisissituaties, het geen haalbare langetermijnstrategie is om ademhalingsbescherming in zorgomgevingen te garanderen.

Aanbevelingen

Dit proefschrift identificeert en behandelt belangrijke besmettingsrisico's die gepaard gaan met laparoscopische chirurgie, met een focus op zowel de uitdagingen rondom instrumentsterilisatie in ziekenhuizen met beperkte middelen als de risico's van gaslekkage in chirurgische omgevingen met een hoog welvaartsniveau.

- Voor lage- en middelinkomenslanden: Implementeer kosteneffectieve sterilisatietechnologieën en verbeter trainingsprogramma's voor ziekenhuispersoneel.
- Voor trocarontwerp: Verbeter de afdichtingsmechanismen om gaslekkage te verminderen, met bijzondere aandacht voor de interactie tussen instrument en trocar.
- Voor chirurgische veiligheid: Versterk rookafzuigprotocollen en verfijn richtlijnen voor persoonlijke beschermingsmiddelen (PBM) om chirurgisch personeel te beschermen.

Door deze kwesties aan te pakken, kan laparoscopische chirurgie wereldwijd veiliger en toegankelijker worden, wat leidt tot betere patiëntresultaten en een verbeterde veiligheid van zorgpersoneel.



1

Introduction

1.1 Introduction

For the largest part of medical history, surgeons used relatively simple tools to operate on patients. These tools, such as scalpels and forceps, required a large exposed area around the target site to give the surgeon enough visibility and manoeuvrability to operate. The surgeon would start by making a large incision in the skin and then dissecting the underlying tissues until they reached the area of interest. The larger incision exposes more sterile tissue which increases the risk of infection, even after advances in antisepsis in surgery since the 19th century [1]. Besides this, the patient needs a long time to recover from the trauma of surgery, there is a high risk of blood loss, and it causes a large amount of stress on the body.

Surgeons and engineers have sought ways to achieve the same results as open surgery, but with less trauma to the human body. The development of a scope with a light source allowed surgeons to see inside the patient with only small incisions [2]. This development was the beginning of Minimally invasive surgery (MIS): The surgeon uses a scope, thin and slender instruments, and small incisions to reach the spot that needs treatment. This method of operation also reduces the risk of infection, while also lowering blood loss, causing less pain, improving cosmetic results, and resulting in faster patient recovery [3]. A common form of minimally invasive surgery is laparoscopic surgery, where surgeons perform the procedure in

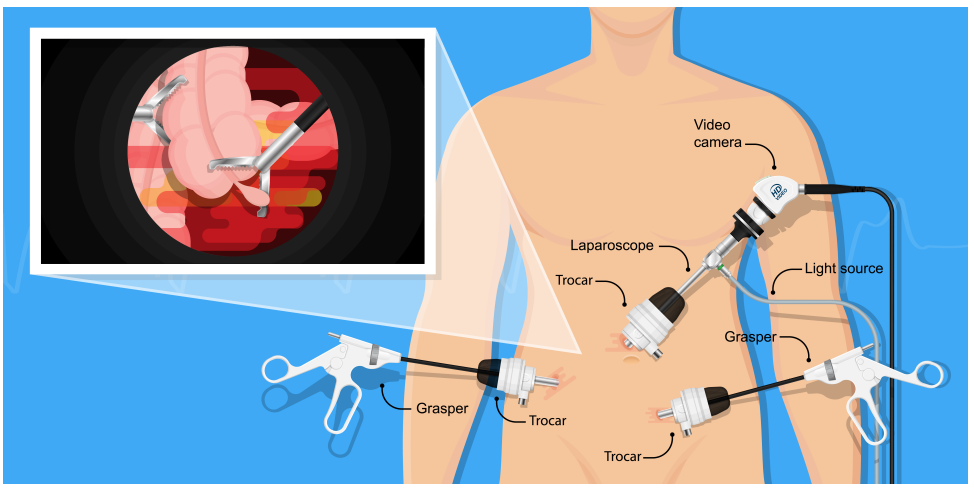


Figure 1.1: Arrangement of a laparoscopic surgery (Image source: Shutterstock image ID: 1041363958)

the abdominal cavity. During laparoscopy, the surgeon inflates the abdomen with carbon dioxide (CO_2) gas, which creates space in the abdominal cavity. The surgeon then uses long, slender laparoscopic instruments to reach the target site. A camera, attached to a laparoscope, is used to visualise the surgical workspace. Because the abdominal cavity is at a higher pressure than the operating room, a device called a trocar is needed to allow instruments to pass through the abdominal wall while containing the gas inside.

While minimally invasive surgery leads to a lower infection rate, it still carries a risk of contamination due to factors related to the procedure. This thesis will address two contamination risks related to laparoscopic surgery. The first relates to the cleaning and sterilisation of laparoscopic equipment. Because the instruments that are used in laparoscopic surgery are more complex than those used in open surgery, they are expensive and difficult to sterilise and maintain, especially for resource-constrained hospitals. The other contamination risk stems from pressurised CO_2 in the patient's abdomen which causes contaminated gas to leak into the operating room.

Laparoscopy in Low and Middle Income Countries

Worldwide, about two billion people do not have access to surgical care, who are largely concentrated in Low or Middle Income Countries (LMICs) [4]. To advocate this issue, The Lancet Commission on Global Surgery put forth a report in 2015 about the state of global surgery and the barriers that prevent access to safe, affordable, high-quality surgical care [5]. As there is an increasing global attention for non-communicable diseases, there a high demand to offer patients in LMICs the same advanced surgical procedures as in high income countries (HICs). LMIC patients could disproportionately benefit from the advantages of laparoscopy such as a faster recovery time, less pain, and lower infection rate. However, even though laparoscopy has become widely practiced in high income countries, it is not as widespread in LMICs.

Despite the benefits, many consider laparoscopy too expensive and unsafe for LMIC settings, and some argue that it distracts from the development of other essential surgical care [6]. The complexity and cost of laparoscopic equipment, hierarchy in the surgical team, and limited access to training, proved to be barriers to the uptake of laparoscopic surgery in LMICs [7]. Furthermore, other major concerns are the shortage of suitable equipment

and supplies, and operating procedures in the sterilisation procedure of laparoscopic instruments [8]. Reliable cleaning and sterilisation of devices and instruments is often not possible in LMICs [5].

Nevertheless, it has been shown that the smaller incisions used in minimally invasive surgery do lead to a lower infection rate. Several comparative studies in India state that the surgical infection rate after laparoscopy is much lower compared to open surgery [9–11]. Although it is often difficult to trace the causes of the higher infection rate, some case reports could relate infection outbreaks to difficulties in the reprocessing cycle. Vijayaraghavan et al. published the case of an outbreak of bacterial infection of laparoscopic port sites (PSIs) in India over a period of six weeks and found 145 PSIs in 35 patients. This was traced back to a biofilm formation at the bottom of disinfection trays [12]. Other infection outbreaks were also linked to the unsafe processing of laparoscopic equipment [13, 14].

To fit through the small incisions, laparoscopic instruments are thin and slender although they require complex mechanisms needed to execute a broad range of surgical actions such as cutting, manipulation, coagulation or diagnostics. The relation between instrument size and complex internal mechanics often result in delicate and small components. To remove blood, proteins and other bioburden is a challenge in even a well utilised sterilisation departments. To prevent microorganisms contaminating patients by unsterile instruments, modern hospitals have access to elaborate facilities, called central sterilisation departments (CSDs) where the surgical instruments are processed. To prevent the spread of microorganisms, a reprocessing cycle considers all steps the instruments go through. This includes use in surgery, collection and transport to the CSD, cleaning, disinfection, inspection, sterilisation, and storage. Specialised staff reprocesses the contaminated instruments using specific tools and machines that give consistent results. Because of the geometry and delicate mechanisms of laparoscopic instruments, these automated cleaning methods have been shown to be more effective than manual techniques[15].

As laparoscopy is an advanced surgical technique, it requires a higher standard of sterile reprocessing than conventional surgery. In one study by Fast et al., the sterile processing capabilities of hospitals in three LMICs were assessed. None of the evaluated facilities complied with the WHO-recommended standards due to lack of training and supplies, incorrect storage, and broken equipment [16]). Household items such as toothbrushes and fingernail brushes were used to clean the surgical instruments and

laundry soap and bleach was the detergent. When debris is not adequately removed from the surface of surgical instruments, it reduces the effectivity of later reprocessing stages like sterilisation and disinfection. However, the assessed hospitals did not offer laparoscopy [16], so it is unclear to what degree hospitals in LMICs that practice laparoscopy have been able to enforce these higher reprocessing standards.

Although the technology to reprocess laparoscopic equipment exists in high-income settings, it is insufficient to transplant it into a low-income context. LMIC hospitals are able to acquire medical equipment either by buying it or receiving it through to a donation when they do not have the financial means. Medical equipment designed for high income countries (HICs) often fails prematurely in LMICs because the equipment is designed to operate in the conditions of high income country hospitals. The conditions in LMIC hospitals are harsher on equipment due to factors such as a less reliable infrastructure, including power fluctuations and poor water quality, lower availability of technical staff for maintenance and repair, and unavailability of spare parts [17, 18].

For successful deployment of medical devices in a low resource settings, it is crucial to consider these contextual factors early in the design process of medical devices. The conditions in LMIC hospitals, under which medical instruments are used, form the context of use. The context in LMIC hospitals often contrasts with HIC hospital contexts. Incorporating the context into the design requirements leads to a more successful implementation [19, 20]. Furthermore, this approach not only facilitates easier adoption of the technology by the local workforce, but also extends the lifespan of the devices, thereby reducing waste. Furthermore, innovations tailored for frugal contexts in LMICs have the potential to lead to more efficient technologies that could benefit HIC hospitals as well.

Because of the increased demand for laparoscopic surgery in LMICs, this surgery will become more prevalent. However, because of the variable reprocessing standards in low resource settings, there is a significant risk of contamination because of unsterile equipment. By studying the local context under which laparoscopy is performed, context-specific equipment can be designed that will improve its safe deployment. Therefore, the first contamination risk in laparoscopy that is studied in this thesis is related to the cleaning and sterilisation of laparoscopic instruments in LMICs.

Laparoscopic Gas Leakage

Inadequate cleaning and sterilisation cause contaminants to be carried on the surgical instruments which can infect patients and staff at a later stage. However, contaminants can also migrate during laparoscopic procedures which poses a direct risk to surrounding staff. During the SARS-CoV-2 pandemic, surgical staff was concerned of being infected by the abdominal gas which continuously leaks in surgery and could carry the virus into the operating room. Consequentially, during the Covid-19 pandemic, surgeons in certain countries refused to perform laparoscopic surgeries because of this escaping gas.

During laparoscopic surgery, the abdominal cavity is inflated with CO_2 gas to separate the abdominal wall from the organs to give the surgeon space to work. Because there is a higher pressure in the abdominal cavity than the operating room, CO_2 gas leaks into the breathing space of the surgeon. Before the Covid-19 pandemic, surgical teams were less concerned about the health hazards of breathing surgical smoke. The risks related to the nature of these leakage, such as the amount of gas and the influence of equipment, was not a matter of interest and was therefore rarely recorded.

Abdominal gas becomes contaminated with surgical smoke produced by electrosurgical devices. The surgeon uses these techniques to dissect tissue and to stop bleeding by applying high-frequency, high voltage electricity to cut and burn tissue, which vaporises the material. Several studies have been performed that measured the composition of surgical smoke which contained ultrafine particles of carcinogenic compounds and viruses. Moreover, the inhalation of surgical smoke during a single procedure has been compared to smoking multiple cigarettes [21, 22]. As the dangers of inhaling surgical smoke are known, exposure to surgical smoke has to be avoided.

The hazard of surgical staff breathing surgical smoke particles during laparoscopy depends on the nature of the exposure. This is determined by characteristics such as amount leakage, e.g. type of trocar, and by the equipment in the operating room such as the personal protection equipment used by operating room personnel and the type of ventilation that is used in the operating room. During the Covid-19 pandemic, a shortage of face masks with high filtration capacity reinforced the concerns of surgeons to a point that the Technology Committee of the European Association of Endoscopic Surgery actively started to develop solutions and guidelines [23]. In face of this, other options to supplement the supply of masks had to be explored.

During laparoscopy, the main device that prevents CO_2 leakage is the trocar which maintains the pressure inside of the patient's abdomen. It consists of a hollow tube and one or multiple valves. The tube passes through the abdominal wall of the patient and the valves seal the gas inside when the trocar is either empty or while an instrument is inserted, as shown in Figure 1.2. There are many types and brands of trocars and instruments that the surgeon could choose from that each have a different configuration of valve types, materials and dimensions. The specific combination of trocar and instrument used by the surgeon could therefore influence the amount of gas leakage. Thus far, one study has measured the flow of gas through the trocar and instrument, although the contribution of either the trocar or instrument was not quantified.

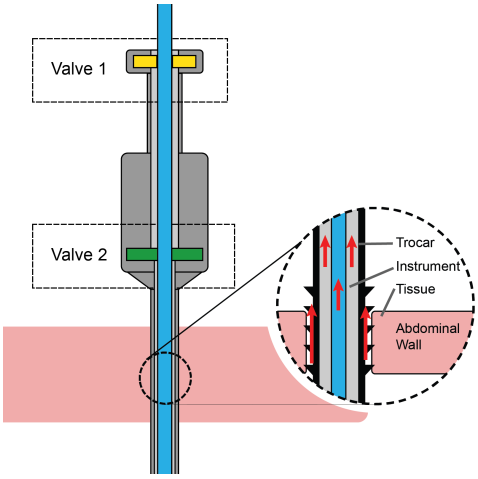


Figure 1.2: Typical arrangement of a trocar. The arrows indicate the possible leakage pathways. Figure adapted from [24].

There are three possible pathways through which gas leakage could occur: through the incision, through the trocar, and through the instrument, the contribution of each of these is not yet understood. Also, whether this leakage increases over prolonged use during surgery, for instance because of wear, has not yet been studied. Therefore, the second contamination method that is studied in this thesis relates to the escape of contaminated gas through laparoscopic equipment.

Overall Aim of this Thesis

Laparoscopic surgery has many advantages over conventional surgery. However, it still poses challenges with regards to preventing the risk of contamination. Therefore, the main aim of this thesis is to identify risk of contamination around laparoscopic surgery, and to design ways to overcome these.

Part 1 is concerned with finding a viable solution to improve the sterility of laparoscopic instruments in rural hospitals in India.

Part 2 investigates the influencing factors of gas leakage during laparoscopic surgery.

Outline

Part 1 In Chapter 2, the methods that are used to reprocess laparoscopic instruments in rural hospitals in India are assessed. Chapter 3 presents the context-specific design methods that were applied to create a new design for a device that cleans laparoscopic instruments in rural hospitals.

Part 2 In Chapter 4, the gas leakage through laparoscopic trocars is characterised. Whether this gas leakage through laparoscopic trocars increases over prolonged use is studied in Chapter 5. Chapter 6 compares the leakage of particles of a novel trocar type to a conventional trocar. Chapter 7 discusses how reprocessing mouth-masks affects the efficiency of their ability to filter airborne particles.

Finally, the results of this thesis are evaluated in the Discussion.

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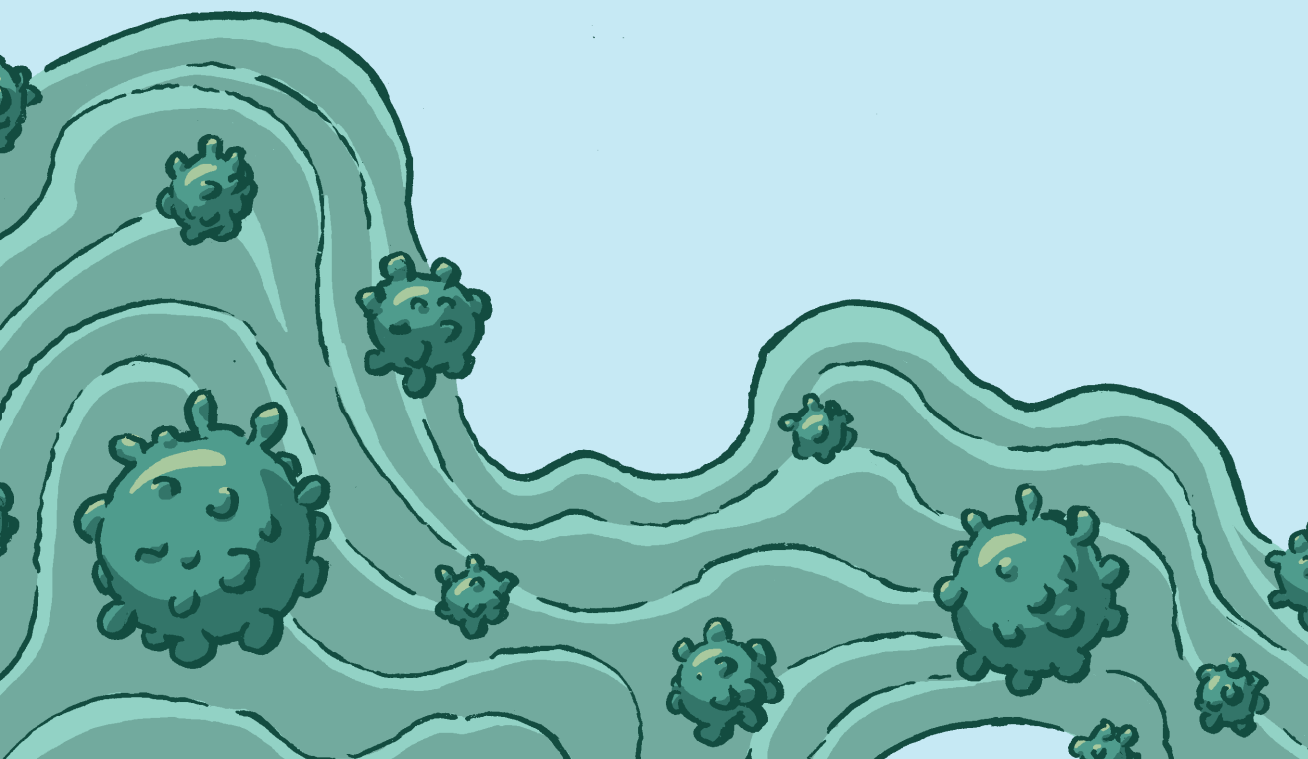
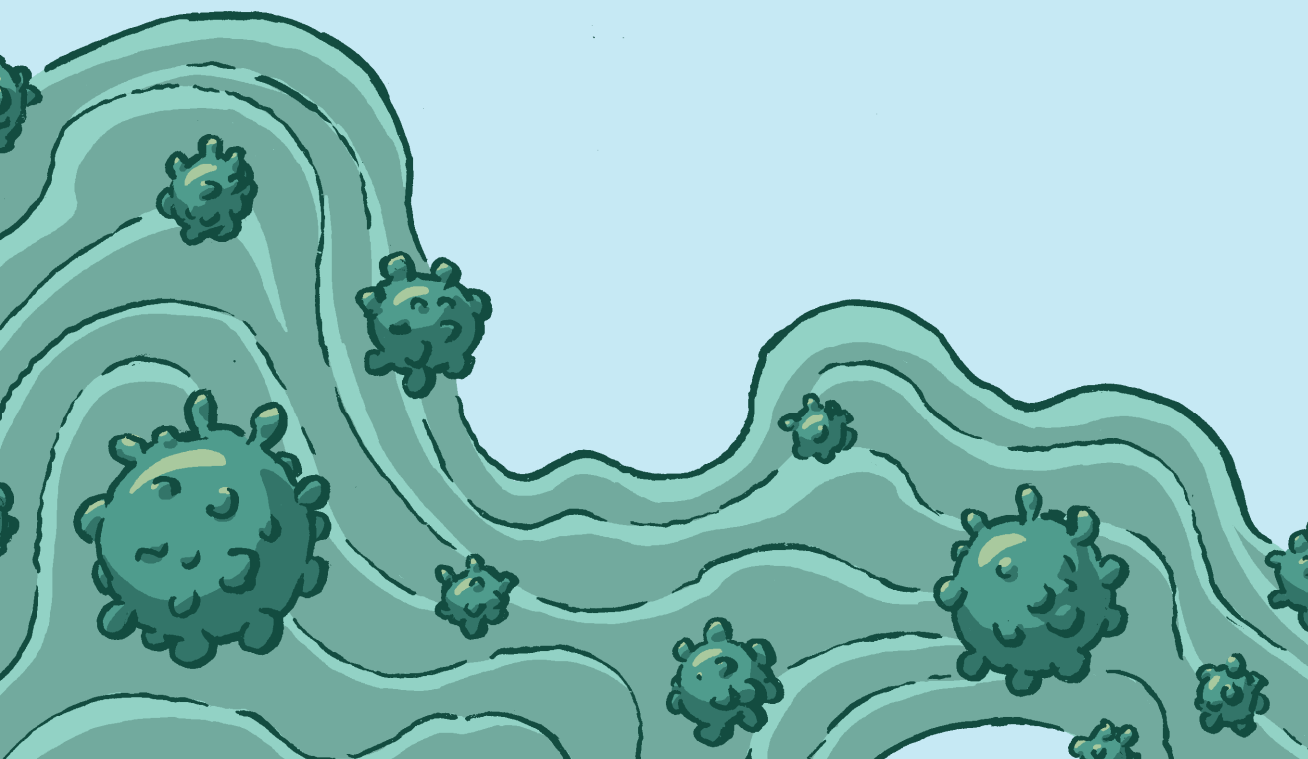


Part 1: Clean Laparoscopic Instruments in Rural India



2

Assessment of Laparoscopic Instrument Reprocessing in Rural India

Daniel Robertson, Jesudian Gnanaraj, Linda Wauben, Jan Huijs, Vasanth Mark Samuel, Jenny Dankelman, Tim Horeman-Franse

Parts of this chapter have been published in Antimicrobial Resistance and Infection Control **10**, 109 (2021) [1].

2.1 Introduction

India is a low-income to middle-income country (LMIC) with a very diverse healthcare landscape. Many urban centres have world-class private facilities, but there are also public urban and rural hospitals that serve the uninsured low-income population [2]. Some of the these public centres are investing in laparoscopy to enable patients to benefit from this form of minimally invasive surgery (MIS).

Laparoscopy requires far smaller incisions than conventional surgery leading to faster recovery times, less pain, and less blood loss. Additionally, the smaller incisions used in MIS lead to a lower infection rate compared with open surgery. These advantages could greatly benefit patients in low to middle income countries as it could result in a faster return to work and a lower bed occupation in hospital wards [3]. Several studies conducted in India have compared post-surgical site infections rates of laparoscopic versus open surgery, these studies showed an infection reduction of 9.6%, 16%, and 21% in [4],[5],and [6] respectively.

However, laparoscopy is often considered too expensive and unsafe for LMIC settings [3, 7], particularly when taking into account the complex reprocessing procedures that the instruments require. Minimally invasive surgery relies on long, slender instruments containing fragile tubular components that require specialised reprocessing methods [8]. Updated training of staff and specific equipment is needed such as long brushes to remove debris from lumen and more advanced autoclaves that sterilise by ensuring steam penetration into all of the components. When instruments are not reprocessed according to manufacturer's instructions, the advantages of laparoscopic surgery are negated by higher instrument wear and higher patient infection rates and the operating cost increases [9]. Insufficient sterilisation has led to several infection outbreaks after laparoscopic procedures [10–13].

Numerous authors have assessed the sterile processing of surgical instruments in LMIC hospitals by carrying out a checklist survey [14–16]. However, no studies exist that document the current laparoscopic reprocessing methods in LMICs. Therefore, it is unknown whether hospitals, that currently perform laparoscopic surgeries, have the updated their facilities, standard operating procedures (SOP) and training to safely reprocess laparoscopic instruments.

Therefore, the aim of this study was to assess the capacity for sterile reprocessing of laparoscopic instruments in rural India in terms of

procedures, infrastructure and effectiveness of sterilisation equipment. We developed a checklist, performed measurements on the autoclaves in the hospital, and conducted interviews. By documenting the sterilisation process, we were able to determine whether the processes in these Indian rural hospitals are suitable to safely reprocess laparoscopic instruments and discover the underlying causes for these current methods.

2.2 Methods

In March 2020, four rural hospitals in India were visited to assess the sterile reprocessing processes for laparoscopic instruments. This study used a mixed methods approach to determine the current status of the techniques used in sterile reprocessing [17]. These methods included qualitative observations and interviews and quantitative autoclave measurements. Ethical permission to perform the study was granted by the Delft University of Technology Human Research Ethics Committee (document number 1063) and written clearance was provided by each of the hospitals visited.

2.2.1 Observations

The variations in reprocessing methods in the hospitals were studied by performing observations using a checklist. This developed checklist was based on (inter)national guidelines, expert recommendations and previous experiences [18–22]. An initial pilot study was run over a six day period to find missing entries in the checklist, before the final version was used for three other hospitals. After the third hospital, the checklist was updated to add missing entries and re-ordered to follow the common sterile reprocessing procedures.

The checklist was filled by conducting direct observations by one observer who visited the reprocessing departments in each hospital. The observations in the hospitals were performed during a single day, except for the pilot study. When a direct observation of an entry could not be made, the item was completed by asking the responsible person in the hospital. The final version of the checklist is added as a supplemental file.

2.2.2 Measurements

Measurements were performed on the autoclaves to determine the capabilities of the autoclaves for sterilising laparoscopic instruments. The temperature and pressure within the autoclave chamber was monitored during a sterilisation cycle, using EBRO EBI sensors: EBI 10-T22x, EBI 10-TP230, and EBI16 [Xylem Analytics Germany Sales GmbH & Co. KG Ebro, Ingolstadt Germany]. The EBI 16 has a process challenge built-in which provides an indication of air removal during the vacuum stage. The data collected by the sensors were processed with WinlogMed software [V3.64 2017, Xylem Analytics Germany Sales GmbH & Co. KG Ebro, Ingolstadt Germany].

2.2.3 Interviews

Semi-structured interviews were conducted with surgeons and staff to gain understanding of the motives and interpretations of reprocessing methods that were used in their hospital. Three different interview guides were made for surgeons, nurses and SSD staff respectively. Surgeons were queried on the incidence of infections, nurses about their training and access to new information, and the SSD staff on failure, maintenance and repair of laparoscopic equipment. During the interviews, the subjects were presented with the methods of reprocessing the laparoscopic instruments observed in their hospital. Then they were asked to indicate the motivation for using the practiced methods, and how their reprocessing methods could be improved.

The interviews were recorded and manually transcribed and coded in ATLAS.TI [8.4.24.0, ATLAS.ti Scientific Software Development GmbH, Berlin, Germany] with one author generating the codes and coding the interviews. These codes were then used by another author who independently coded the interviews. Both authors discussed the coding of the interviews until a consensus was reached.

2.3 Results

We received permission to assess eight hospitals, however, because of the Covid-19 pandemic, not all could be visited. We were able to conduct the checklist, in total of four hospitals. The hospitals included in the study are

shown in Table 2.1. They were all rural, secondary district hospitals in the states: Jharkhand, Tamil Nadu and Assam.

2.3.1 Sterile Processing Capacity and Facilities

Table 2.2 shows information on the hospitals' infrastructure, record keeping and procedures and available equipment. Of the four hospitals evaluated, two had an area available that was designated as a Sterile Supply Department, (SSD). These were areas that are constructed such that a clear workflow could be maintained with separate areas for dirty, clean and sterile instruments. However, in neither hospital did staff follow this workflow, and only in one hospital the SSD was used as the main sterile reprocessing location.

None of the hospitals had dedicated tools and equipment for reprocessing surgical instruments. One hospital had an automated washer-disinfector, but it was not in use because not enough instruments were used during the day to fill the machine to full capacity. Also, none of the hospitals had any personal protective equipment (PPE) for staff, like waterproof gowns, thick elbow gloves or face shields. In all cases standard surgical gloves were used as the only protection.

2.3.2 Laparoscopic Instrument Reprocessing Method

The basic steps of the reprocessing cycles along with the details observed in the hospitals are shown in Figure 2.1. These steps are based on WHO and CDC sterile reprocessing manuals [18, 20]. All of the hospitals operate the same steps in the sterile reprocessing cycle, with some variations which can be seen in the details in Figure 2.1.

Table 2.1: Facility size and surgical capacity

Type of hospital	Total number of beds	Operating theatres	Surgeries per year	Laparoscopic surgeries / year	Operating theatre nurses	Sterile supply dept. staff	Biomedical technicians
Secondary district	100	4	300	80–100	6	2	0
Secondary district	35	2	800	40–50	28	0	0
Secondary district	50	2	600	40–50	6	0	0
Secondary district	25	1	360	100–110	4	0	0

Table 2.2: SSD information and available equipment in 4 rural hospitals

General	Hospitals n=
Record keeping of sterile processing	3
Hospitals with a SSD	2
Area with dirty to clean processing	2
instruments are processed in the SSD	1
Periodic review of sterile processing	0
Product documentation are available	0
There is a procedure for new materials/instruments	0
Disassembly instructions for instruments are available	0
There is a written protocol for manual cleaning	0
There is a protocol for repair of instruments	0
Laparoscopic instruments are processed in the SSD	0

Cleaning

In all four hospitals, the nurses reprocessed all the instruments during the time between surgeries. Laparoscopic and regular surgical instruments were collected together into uncovered stainless steel basins (n=4) where they were soaked in tap water. The collected instruments were transported to a sink in rooms adjacent to the operating room (n=3). In one hospital, the sink used to rinse the instruments was also used by the surgeons for washing hands.

All of the instruments were manually cleaned. No specific brushes for brushing long lumens on laparoscopic instruments were available, only toothbrushes and puncture devices like needles were used for cleaning. Instead, the lumens were held under running water to rinse. None of the hospitals used a dedicated detergent for instrument cleaning, instead, soap or clothes-washing powder was used. The detergent was applied where necessary and not used as a soaking agent. The instruments were soaked in bleach if the patient was known to be infected (n=2).

Table 2.3: Description of available equipment in the SSDs and OT areas in the 4 rural hospitals

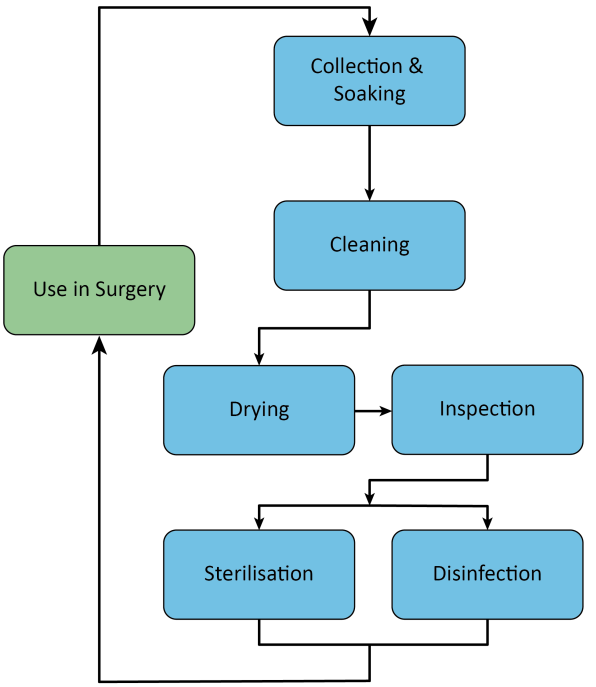
Description of SSD / OT cleaning facilities	Hospitals n=
Washer-disinfector	1
Drying machine	1
Water gun	0
Hand shower	0
Brushes for internal and external cleaning	0
Ultrasonic cleaner	0
Compressed air	0
Personal protection equipment	0
Clean Area/Sterilisation equipment	**Hospitals n=**
Manual steam autoclave	3
Pressure cooker	1
Ethylene oxide steriliser	1
Insulation tester	0
Microscope	0
Instrument composition baskets	0
Set Composition reference	0
Heat sealer	0

Drying and Inspecting

While preparing for sterilisation or disinfection, the laparoscopic instruments were separated from the regular instruments. In only one of the hospitals, the laparoscopic instruments were actively dried between cases by using a hairdryer. In the other facilities, the laparoscopic instruments were not dried before placing in the disinfectant and left to air dry at the end of the day.

Disinfecting/Sterilising

Only the regular steel surgical instruments were steam sterilised, the laparoscopic instruments were high-level disinfected. The main disinfection method for laparoscopic instruments was soaking in trays with a high level disinfectant. In all of the hospitals this was glutaraldehyde (Cidex). No



	Hospitals n =
Collection in steel basins	4
Instruments soaked in tap water	4
Instruments brought to SSD	1

Instruments are manually cleaned	4
Toothbrush used as only cleaning tools	4
Soap powder is used for cleaning	4
Bleach used on instruments	2
PPE is available during cleaning	0

Instruments are actively dried	1
Instruments are air dried	3
Cleanliness is inspected after cleaning	0
Instrument functions are tested	0
Instrument insulation is inspected	0

Regular and lap instruments are separated	3
Lap instruments are disinfected	4
Regular instruments are steam sterilised	3
Glutaraldehyde disinfection is performed	4
Glutaraldehyde test strips are used	0
Formalin disinfection is performed	4

Figure 2.1: Summary of the instrument reprocessing cycles in the four hospitals. The data was collected using an observational checklist. The flow chart shows the steps in the reprocessing cycle and the table highlights details of the process.

hospital tested the minimal level of concentration of the disinfectant with Cidex indicator strips.

The other disinfection method used was formaldehyde gas, also known as formalin. The formalin chambers are chambers where instruments are sterilised by exposure to formaldehyde gas. The gas is released by formalin tablets that are placed in the chamber. In three hospitals, the chambers were used as a storage for cleaned instruments for surgery the following day. In one of hospitals the chambers were used as intermediate disinfection method in between surgeries. Only in one of the hospitals was the date of placement of the formalin tablets noted.

2.3.3 Steam Sterilisation

At the end of the day, the steel instruments that were used during the day were sterilised in the autoclave. In three out of four hospitals, there were manual autoclaves present. In one hospital, only a pressure cooker was available, which only sterilised textiles, like surgical gowns. One hospital used an ethylene-oxide (ETO) steriliser to sterilise all instruments with plastic or electric components like electrosurgical knives and disposable bipolar instruments.

In two hospitals, we performed measurements on the autoclave to assess whether the autoclave was suitable for sterilising laparoscopic equipment. Both autoclaves were manually controlled, horizontal autoclaves. The results of these measurements can be seen in Figure 2.2. It shows the graphs of the pressure and lowest temperature measured in the autoclaves. Autoclave 1 sterilised at 134 °C and had a very shallow vacuum phase (red dashed line), the other sterilised at 121 °C and lacked a vacuum phase. Based on the readout of the sensors, the autoclaves failed to sterilise the load.

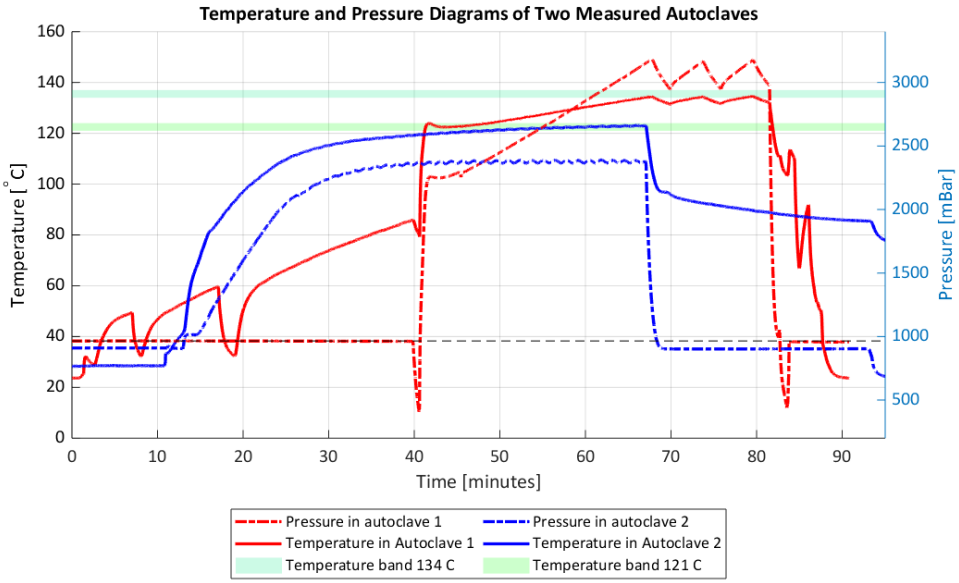


Figure 2.2: Temperature and pressure diagrams of the two measured autoclaves. The graphs show the readout of pressure and temperature sensors placed into the autoclave chamber during one cycle.

2.3.4 Interview Results

Interviews with 2 surgeons and 2 nurses from three different hospitals were conducted. The interview codes were categorised in three main topics, these were then further subdivided into sub-categories, this can be seen in Table 2.4.

Table 2.4: Categories of interview codes

Categories	Codes in category	Frequency mentioned	Mentioned by participants
Current Methods	Explanation of Current Reprocessing methods	25	4/4
	Suggested improvements in sterilisation process	10	4/4
	Incidence of Infections and contamination	4	3/4
	Availability of written procedures for instrument cleaning	4	3/4
Financial Constraints	Availability Surgical Instruments	12	4/4
	Availability of cleaning equipment	11	4/4
Training and Education	Education of Rural Nurses	18	3/4
	Access to new information	14	4/4
	Surgeons Knowledge of Cleaning Process	12	3/4
	Education of Nurses in Developed Centres	5	2/4

Current Methods

After presenting the observed reprocessing cycle, all respondents confirmed that the process presented by the interviewer was correct. When asked about why this process was used, two nurses confirmed that this method was taught in school and was a standard method in India.

Suggested Improvements Two respondents recommended more detailed training for nurses in handling the instruments.

> *"We need to train trainers.[...] a month training program, something that helps them acquire knowledge in particular areas, [..]that nurse's knowledge will then spread to other areas."* [Nurse 2]

One surgeon did not recommend any specific improvements, but rather asked what improvements could reduce reprocessing time and costs. The other surgeon suggested the rural hospitals to have checklists for the cleaning process.

Infections Three respondents (two surgeons and one nurse), indicated that they did not see any problems with the current methods because they have not had any problems with infections during laparoscopy.

> *"We've not had what we have identified as infections [...] So I think they're doing a good job. But. I need to study it to further understand and see if there are any flaws in their system."* [Surgeon 1]

Written procedures Both nurses said that there were no written procedures for them to follow. One surgeon mentioned that in the large urban tertiary centres, there are procedures and audits in place.

Financial Constraints

Availability of instruments and cleaning equipment The financial limitation of the hospitals are reflected by the surgical instruments that are available and the means the nurses have available to clean them. The shortage of laparoscopic instruments is confirmed by all respondents and influences the procedure in different ways. Two nurses indicated that there were no replacements available when instruments break.

There is a large degree of reuse of disposable instruments and tools. Two respondents confirmed that ports, hand instruments, electrosurgical tools and even sutures were reused. The shortage of surgical equipment also puts pressure on the time available to properly clean the instruments because the same instruments are needed in the next operation. This is confirmed by two respondents.

> *"Speed, that's important because we need to wait between the cases so that since we only have one scope, that actually would be useful if it could to some degree be shortened."*[Surgeon 2]

All respondents mentioned pieces of equipment or solutions that were financially out of reach e.g. ultrasonic cleaners, personal protection equipment, and cleaning solutions.

Training and education

According to a surgeon and nurses, the training given to rural nurses is a general nursing course. All respondents mention that this general nursing course is inadequate for learning how to reprocess laparoscopic instruments. The rural nurse is required to be a *"Jack of all trades"* [Surgeon 1], they have to assist in surgery, prepare the patient, clean the operating room and reprocess the instruments. There are no specific roles given to the nurses in the hospitals where the respondents work.

Access to new information Nurses also have trouble acquiring new information about new sterilisation practices and learning how to clean specific pieces of equipment. Nurses rely on the training they have received and adopt the process that is taught to them by the senior staff. If they are uncertain of something, the surgeon is the only person available to them for new information.

> *"So if you ask a particular staff member about how to use a new handle or a new instrument, it, they don't know. [...] Also, they don't know how to handle the chemical combinations they use. They are using it because they have been told."*[Nurse 2]

Rural nurses would not independently change the process they already use. When asked about who should suggest changes to the sterilisation process:

> *" It's not the surgeons task at all. He could question it, but he can't comment on it because it's taken care of by the nurses. You know, the sensible thing, if I have a problem I could always question and maybe audit it and to see if there's something going wrong with the process. A surgeon can do that. But the accountability of the process lies with the nurses."*[Surgeon 1]

This surgeon also mentioned that they only get a basic level of information about reprocessing in their surgical training and that there are no courses available to update their knowledge.

2.4 Discussion

The aim of this study was to assess whether the reprocessing facilities in rural hospitals in India were suitable to process minimally invasive surgical equipment. After evaluating the reprocessing methods in these rural hospitals, we found deficiencies in available equipment and training of staff. Although India is an ISO member, neither the ISO standards nor reprocessing procedures recommended by either WHO, CDC or other governing bodies were enforced in the rural hospitals [22]. The diversity of Indian healthcare is reflected by the presence of word class high tech hospitals as well as clinics that have to serve low income, uninsured population. Therefore, the results of this study are not representative of the whole Indian healthcare. Due to the Covid-19 pandemic, we were limited in the number of hospitals we were able to visit.

However, because of the uniformity of the results, a similar status of SSDs can be expected in many rural Indian hospitals. Similar deficiencies in training of staff and equipment have been found by several authors studying sterile reprocessing in other LMICs [15, 16, 23]. A survey of the sterile processing capacity of 59 facilities in 3 African countries by Fast et al. showed similar lack of training, PPE, detergents and reprocessing tools as found in this study [14].

Laparoscopic equipment is expensive due to the complexity of the components, therefore hospitals generally own one laparoscopic instrument set. Staff in the hospitals tried to reduce operative costs by maximising the lifespan of all pieces of equipment. Therefore, gentler reprocessing procedures, like high level disinfection, are preferred over more effective methods such as steam sterilisation. Many of the limitations of high level disinfection were not known to hospital staff. The availability of one laparoscopic instrument set meant that the instruments had to be reprocessed in between surgeries. This severely limited the time nurses had to clean the instruments and lead to inspection and validation not being actively performed.

The nurses had 30-45 minutes in between cases to prepare the operating room for the next patient, and clean and sterilise the instruments. The lack

of inspection after cleaning resulted in many of the instrument surfaces to still contain visual contamination. In addition, damages to components, such as the electrical insulation, might be overlooked as a result of limited inspection tools. Burns caused by insulation failure is one of the most common and severe complications during laparoscopy [24]. The lack of replacement instruments were also a cause for converting the surgery from laparoscopic to an open procedure, as indicated by one of the nurses. This increases the risk of infection.

In the peripheral hospitals, strong preconceptions exist in sterile reprocessing, because new knowledge, such as scientific literature and manufacturer's instructions, does not reach the nurses. This impacts patient and staff safety, but is also detrimental to equipment. For instance, instruments were commonly disinfected using bleach, which has long been known to corrode surgical instruments [14].

The concentration of glutaraldehyde has to be periodically verified by using indicator strips, even within the manufacturers' recommended expiry time of 14 days [21]. The effectivity of disinfectants is reduced by inserting wet instruments that dilute the disinfectant or by the presence of large amounts of bioburden [25]. However, none of the hospitals were familiar with this method of testing the glutaraldehyde. Glutaraldehyde also impedes cleaning as it binds proteins onto instruments which have not been sufficiently cleaned. This causes a build-up of bioburden, giving microbes a higher chance of surviving the disinfection or sterilisation process [20, 26].

The other main form of disinfection was using formaldehyde gas. This sterilant is unreliable as it is difficult to maintain the exact conditions needed for sterilisation such as the correct room humidity [27]. In the hospitals, it was impossible to maintain these conditions because of the lack of monitoring and the wide variety of containers used for formaldehyde disinfection.

Staff seemed unaware towards the risks they faced when handling soiled instruments or chemicals. The use of PPE was thought to be too cumbersome, which put staff at risk of cross contamination. Additionally, no precautions were taken to minimise contact with disinfectant chemicals. Formaldehyde and ethylene oxide are known to be carcinogenic, and glutaraldehyde has been reported to cause asthma and allergic reactions [28, 29].

2.4.1 Ensuring sterile laparoscopic equipment

Laparoscopic equipment contains long narrow tubes and is considered a porous load. Hence, to successfully autoclave these long tubes, an autoclave is needed that performs vacuum air removal before injecting steam for sterilisation, according to standard EN 285 [30] . Neither of the autoclaves measured during this study was suitable for sterilising laparoscopic instruments due to a lack of deep, pulsed, vacuum cycles.

Without active air removal by steam-pulsing in deep vacuum, air remains trapped in the middle of the tube and sterilisation cannot be guaranteed. Active air removal is not only required to sterilise surgical equipment. In India, surgical gowns are reused by laundering and sterilising them in textile packs. Active air removal by means of steam-pulsing (above-atmospheric or in combination with a vacuum) is required for the steam to penetrate to the centre of a bundle of gowns, to ensure sterilisation [31, 32].

Both autoclaves measured during this study, showed a lack of adequate air removal or underpowered steam generation. Mainly because the lack of an adequate vacuum, these autoclaves are not suitable for the sterilisation of laparoscopic equipment. Textile packs require least above-atmospheric steam pulsing; performance can be yet improve with steam pulsing in combination with vacuum. There are currently many methods to validate autoclave cycles, however, most of these tests are unsuitable for rural LMIC hospitals. The existing methods are currently financially out of reach, or the tests are not critical for the manual autoclaves that are used in these hospitals. This raises the need for adequate low-cost process challenge devices for batch sterilisation monitoring in rural hospitals.

2.4.2 Recommendations

Today, pre and post-operative broad spectrum antibiotics are used to reduce the risk of post-surgical wound infection. However the combination of intensive use and poor confirmation to protocols, as provided in the Instructions For Use (IFU), can lead to a high incidence of multidrug resistant bacteria such as MRSA [33], which influences surgical safety on a national level. Training programmes in sterile reprocessing for rural healthcare workers have to be compiled that take into account the wide range of responsibilities they carry. However, this will only become a priority when policy is installed at the local hospital levels up to the upper levels of government.

Naturally, the financial limitations have a severe impact on the reprocessing methods. With more financial means, hospitals can afford more of the necessary machinery, tools, and chemicals which are optimised for cleaning delicate instruments like laparoscopic instruments. However, because of the limited size of many of these hospitals, installing the internationally recommended processes and equipment will never be financially viable. Many international standards are written to ensure the highest levels in reprocessing safety for hospitals dealing with a large patient turnover. A minimum viable safety standard is needed so that it is clear up to what level processes have to be improved.

In support of this, redesign of both surgical equipment and reprocessing tools is needed such that the reliability of the reprocessing is less dependent on local knowledge and practices. Surgical instruments should be robust, repairable and easy to inspect so that the lifespan is maximised and procedures become more economical because of an increased availability of instruments [34, 35]. Reprocessing equipment is needed that can operate with a small batch of surgical instruments and that takes resource consumption, like water, into account.

2.5 Conclusion

During this study, we investigated whether the reprocessing methods performed in rural hospitals in India were suitable for laparoscopic equipment. By using a checklist based on various established standards and recommendation, we were able to collect data that allowed us to assess the methods used in reprocessing laparoscopic equipment. Based on our observations, and measurements of the autoclaves, we can conclude that the current methods pose serious risks to patient and staff safety. Interviews revealed that the issues facing the sterile processing of laparoscopic surgical instruments are a multi-faceted problem that cannot be easily solved with one strategy. It is evident that the lack of knowledge, training and equipment has a severe impact on how complex laparoscopic instruments are reprocessed. Since laparoscopy is becoming more widespread in many nations, we recommend that handling of complex instruments is incorporated into basic nursing training, and that specific surgical instruments and reprocessing equipment is designed that takes the local context into account.

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3

Context-Driven Design of a Laparoscopic Instrument Cleaner for Rural Low-Resource Hospitals

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Parts of this chapter have been published in ASME Journal of Medical Devices **19**, 1:015001 (2025) [1]

3.1 Introduction

The 2015 the Lancet Commission Global Surgery Report brought to light the limited access to safe surgery faced by 5 billion people, particularly in Low- and Middle- Income Countries (LMICs). The report emphasizes the importance of investing in surgical services, as it is not only affordable but also saves lives and promotes economic growth [2]. So far, we have seen various initiatives emerging from this call for action, often in the form of surgical training programs in LMICs [3–5]. However, the introduction of modern surgical techniques, such as laparoscopic surgery has been slow [6].

Laparoscopy is a widely used surgical treatment in High-Income Countries (HICs), in which the surgeon uses long, slender instruments inserted through tiny incisions in the skin to perform surgery in the abdominal cavity. Patients treated laparoscopically can be discharged from the hospital sooner thanks to advantages such as lower mortality, lower pain rates and a lower infection rate compared to conventional open surgery [7–9]. These benefits might even have a greater impact in LMICs than in HICs, where workers often rely on day wages as their main form of income.

However, it is believed that this type of surgery is inaccessible to patients in LMICs [10]. A review by Chao et al. uncovered systemic barriers to laparoscopic surgery in LMICs, including a limited availability of trained staff, training opportunities, limited resources, and equipment [11]. Many LMIC hospitals do not have facilities available to adequately sterilise surgical equipment [12, 13]. Fast et al. found that none of the reprocessing facilities of hospitals in three different LMICs complied with the WHO-recommended standards for surgical instrument reprocessing because of untrained staff, missing supplies, incorrect storage, and broken equipment [14].

These barriers hamper the safe introduction of laparoscopy and contribute to a higher post-surgical infection in LMIC hospitals that have managed to introduce laparoscopy compared to HIC hospitals [8, 15]. One cause for the higher infection rate in LMICs is related to the reprocessing of laparoscopic equipment [16–18]. To combat complications due to unsafe reprocessing, surgeons administer perioperative antibiotics. However, because of a global increase in antibiotics use, there is a growing concern for resistant organisms [19].

There are initiatives focusing on the development of innovative laparoscopic equipment that fits the context of use in LMICs [20, 21]. Although specific

devices intended to clean laparoscopic instruments exist, they are designed to operate within the conditions of a HIC central sterilisation department. For LMIC hospitals, the requirements relating to the context, such as unavailable spare parts, absence of maintenance programs and a harsher operating climate, must be considered [2, 22, 23]. Hence, to ensure that laparoscopic surgery can be safely practiced in LMIC hospitals, the issue of reliable reprocessing must be addressed.

Therefore, the goal of this paper is to present the design method of a laparoscopic instrument cleaner, specifically for LMIC hospitals. The applied context-driven design approach is based on the Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide [21], extended with structured interviews, observations and surveys [24]. The design method resulted in a detailed description of the setting in rural hospitals in India which was used as the basis for a set of context-specific design requirements. A non-functional prototype was developed to show the proof of concept. Finally, a usability evaluation with Indian nurses was performed to test the early prototype and receive valuable feedback for a following design iteration.

3.2 Methods

The roadmap for the design of safe surgical devices for low-resource settings, which was used as a template for the design process [25], consists of four phases (Phase 0-3). Over a period of 4 years, four studies were conducted to gather the data to fulfil the phases. Three studies were conducted in urban and rural hospitals which are peripheral hospitals, in areas with low population densities in India. Table 3.1 shows an overview of the field studies that were performed (Study A-D).

Ethical clearance for the field visits was given by the Human Research Ethics Committee (HREC) of the Delft University of Technology (Delft, The Netherlands, reference numbers: 679, 1063, 2499) and the Institutional Ethics Committee (IEC) of Maulana Azad Medical College (New Delhi, India, reference number: F.1/IEC/MAMC/73/01/2020/No48).

Table 3.1: Overview of the field studies performed.

Study #	Year	Phase #	Study Type	Number of Participants	Visited Hospitals	Location
A	2019	0	Survey, observations of laparoscopic surgeries in India	10 laparoscopic surgeons*, 2 general surgeons*	1 Urban Tertiary, 1 Rural District	Karnataka, West-Bengal, India
B+	2020	1, 2	Survey, semi-structured interviews, and observations in rural Indian Hospitals	2 nurses [NB1-2], 2 laparoscopic surgeons [LB1-2]	4 Rural District	Jharkhand, TN, Assam, India
C	2023	2	Semi-structured interviews with experts	1 LMIC reprocessing expert [ELC1], 1 HIC reprocessing expert [ELC1], 1 laparoscopic surgeon [LC1]*	–	Netherlands
D	2023	2, 3	User evaluation and semi-structured interviews with Indian nurses	5 Urban nurses [NUD1-5], 4 Rural nurses [NRD1-4], 3 nursing students [SD1-3]	3 Rural District, 1 Urban Tertiary	Assam, Tripura, Delhi, India

* A laparoscopic surgeon is trained to perform laparoscopy, as opposed to a general surgeon who is not. + Study B was published by Robertson at al. in 2021 [26].

3.2.1 Phase 0: Evaluation of the needs around laparoscopy in rural India

Phase 0 assessed the need for a surgical device. During Study A, two researchers, DR and TL (see acknowledgements), evaluated the needs of Indian hospitals relating to laparoscopic surgery by conducting a survey in two locations in 2019. These were the general council meeting of

the Association of Rural Surgeons of India in Bagalkot, Karnataka, and a training session of gasless laparoscopic surgery for rural surgeons in Kolkata, West-Bengal, India. The on-paper survey consisted of 40 multiple-choice and open questions about the type of hospitals, available equipment, barriers that surgeons face when introducing laparoscopic surgery in rural and urban hospitals, and methods they used to reprocess the laparoscopic instruments.

The survey was completed by twelve rural surgeons, of which ten had experience in laparoscopy. Besides this survey, the two researchers observed four surgeries performed by rural surgeons during two days of the training session in Kolkata. These observations were recorded by means of photographs and notes of conversations with surgeons.

3.2.2 Phase 1: Context of Laparoscopic Instrument Reprocessing

Phase 0 established the need for a device that improves laparoscopic instrument reprocessing in India. After this, Phase 1 of the roadmap, studied the context under which the device was to be used by determining the barriers to safe surgery, and recording specific aspects of safe surgery. In this project, it concerned the context in relation to the reprocessing of laparoscopic instruments in India, which was studied in Study B and C.

Study B identified the barriers related to current reprocessing methods in four rural hospitals in three different states in India: Jharkhand, Tamil Nadu, and Assam. Data was collected by DR using semi-structured interviews with two surgeons and two nurses, and checklist observations to identify the reprocessing methods. The items of the checklist were based on (inter)national guidelines, expert recommendations and previous experiences [27–31]. One outcome of Study B, published by Robertson et al. in 2021 [26] was a detailed description of the reprocessing methods used in the rural hospitals. Moreover, relevant barriers were related to issues local healthcare workers encounter in the sterile supply of surgical instruments, and to methods used in reprocessing laparoscopic instruments.

In Study C, observations were performed of the methods used in the reprocessing cycle of laparoscopic instruments in two hospitals in the Netherlands. Data was collected by DR and AK by taking photographs and making notes. The data was used to make a comparison with the reprocessing methods recorded in India in Study B.

3.2.3 Phase 2: Design Requirements for a Laparoscopic Instrument Cleaner

Findings from Phase 0 and 1 were projected into a product journey of laparoscopic instruments to provide a visual representation of the reprocessing cycles of Indian and Dutch hospitals. This visual representation was used to determine the critical stages in which the device was intended to operate.

To find the design requirements in Study C, AK and DR conducted semi-structured interviews with experts in the field of reprocessing surgical instruments. The design team spoke with an expert in reprocessing in a Dutch hospital, an expert in reprocessing in LMIC hospitals, and an Indian rural surgeon in a period between 2021 and 2022. Requirements that were mentioned during the interviews in Phase 0 and 1 were also included. The results of the studies in this Phase 2 led to a set of context-specific design requirements. Besides these, a review of scientific literature on the cleaning of surgical devices [27–31] and ISO standards including ISO 15883-5 formed a set of technical design requirements [32].

3.2.4 Phase 3: Act

Translating insight into design solutions

During Phase 3, the synthesis stage of the design process of a laparoscopic instrument cleaner was started based on a waterfall design method [24]. First, a function analysis of the laparoscopic instrument cleaner was performed to meet the full set of design requirements. Then, three concepts were created using morphological charts, which were turned into three physical mock-ups that were evaluated by the experts of Study C. Their feedback was incorporated into a final concept, consisting of several sub-systems such as the mechanical cleaning system and the loading system of the laparoscopic instruments. The loading system should save time and be intuitive to use with limited additional training of staff. Therefore, evaluating the design of the loading system was the focus of the evaluation during Phase 3. To do this, a non-functional prototype was made based on the final concept of the loading system. The prototype consisted of two parts: a non-functional housing that contained a simulated washing chamber with a non-functioning control panel, and two loading baskets designed to contain the laparoscopic instruments (Figure 3.6). After the evaluation, another iteration of the design was made.

Usability Evaluation Study

To evaluate the loading system, Study D evaluated whether it was intuitive for nurses in India to load laparoscopic instruments into the loading baskets of the prototype, without any prior explanation. The study was conducted in one urban and three rural hospitals in the states Delhi, Tripura, and Assam. The participant groups included in the study are shown in Table 3.1, and Figure 3.1. All of the participants had experience in handling laparoscopic instruments (Urban nurses: 11-27 years, Rural nurses: 3-25 years, Nursing students: 2 years), but none had previous experience using automatic cleaners or washer disinfectors.

Protocol

The evaluation started with a short verbal introduction of the aim of the study and a general explanation of the prototype. After this, informed consent from the participant was obtained. The participant was then given a leaflet explaining the laparoscopic instrument cleaner and its functions. The hands-on tasks during the tests were recorded with a camera, and the audio of the interviews was recorded. An overview of the protocol is provided in Figure 3.1.

A task analysis, performed prior to the study, identified three main tasks as most critical to load laparoscopic instruments into the instruments. These were: unloading the baskets from the cleaner, loading the instruments into the baskets, and loading the baskets back into the cleaner. The main part of the study consisted of two parts: Test 1, and Test 2 (see Figure 3.1), where the participants were asked to perform the three tasks. During Test 1, the participants were asked to load one set of laparoscopic instruments (which was the same for all participants) into the baskets without any explanation about where to place them. Before Test 2, the participants were informed which instruments belonged to which baskets, but no additional information was provided where and how to place them in the basket. Then, the participants performed the three main tasks again. Each test was followed by an interview to debrief about behind the participant's actions. Finally, participants were asked questions about what their overall perception was of the device. The nursing students only participated in Test 1 because the large amount of time needed for them to complete the first test.

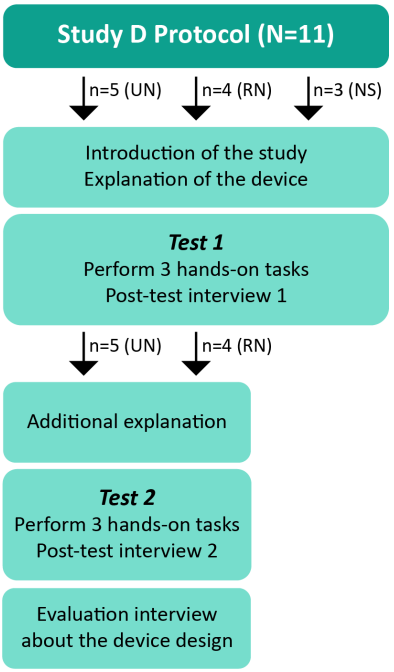

Figure 3.1: Protocol of the usability evaluation study.

3.2.5 Data collection & analysis

All interviews, study notes and photographs were transcribed and coded using ATLAS.TI (23.1.1.0, ATLAS.ti Scientific Software Development GmbH, Berlin, Germany) by DR and AK. The barriers to safe reprocessing were determined by coding the interviews conducted in all phases. The codes were grouped into cultural barriers, financial barriers, and structural barriers, according to the design for safe surgery roadmap [25]. The interviews conducted in Phase 3 were analysed to determine recommendations and further design requirements.

Study A involved a questionnaire with 40 questions to assess the general needs concerning laparoscopy in India. Only the questions concerning the reprocessing of laparoscopic instruments were included in this paper. The data of Study D was analysed to determine which type of use error occurred. The participant comments from the interviews and observations from the camera recordings were used to perform a root cause analysis. The type of use error was categorised according to IEC 62366-1:2015/Annex D (International Electrotechnical Commission, 2015), and were divided into

three categories: Perception errors, Cognition errors, and Action errors [33, 34].

3.3 Results

During the four-year period, with three field studies in India (Table 3.1), 18 semi-structured interviews were conducted with 17 healthcare workers.

3.3.1 Phase 0: Needs Assessment In Reprocessing Laparoscopic Instruments

The survey (Study A, Surgeons 1-12) in which the surgeons were asked to indicate the methods that their hospital used in the reprocessing of laparoscopic instruments, revealed mixed results. All surgeons indicated that an autoclave was available in their hospital, however, only 8 out of 12 indicated that the laparoscopic instruments were always sterilised in between procedures. Only 5 out of 12 surgeons indicated that the instruments were also disassembled, and 4 out of 12 indicated that they were visually inspected.

Because of their complexity, laparoscopic instruments need a rigorous reprocessing procedure to sufficiently sterilise them. The observations performed during the surgical training session in West-Bengal (Study A) and survey confirmed that manual cleaning and chemical disinfection was the default method to reprocess laparoscopic and general surgical instruments (see Figure 3.2). Soaking instruments in high-level disinfectant was considered a form of sterilisation which replaced conventional steam sterilisation, which was confirmed after consulting one nurse and one surgeon. This explains the high response to the question whether the laparoscopic instruments are always sterilised between procedures. The current methods posed a challenge for nurses that reprocess the instruments, and were a hazard to patient and staff safety. Therefore, the issues uncovered during Study A showed the need for a solution to aid nurses to reprocess laparoscopic instruments. Table 3.2 shows the type of hospitals the rural surgeons of Study A worked in. The nine surgeons that operated laparoscopically worked in secondary (6 out of 9), community (1), private (1), and tertiary hospitals (1). Primary, secondary, and tertiary hospitals in India are public hospitals, as opposed to private hospitals. Community

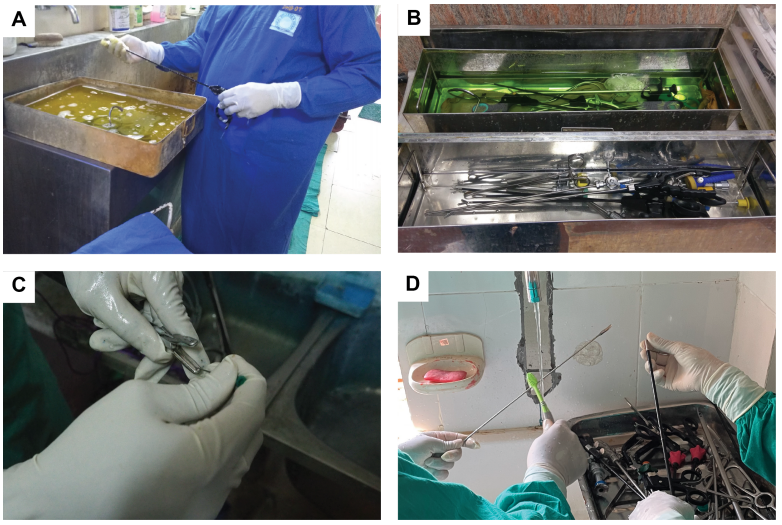

Figure 3.2: Observation examples of cleaning. 2A) C) D) Nurses manually cleaning the laparoscopic instruments after surgery. B) Laparoscopic instruments being disinfected in CIDEX and rinsed in saline solution.

hospitals are similar to secondary hospitals but do not receive government funding.

Table 3.2: Type of hospitals of the rural surgeons of Study A (N=12)

Type of facility		Number of beds		Number of surgeons		Surgeries performed per day	
Primary	1	**0-10**	1	**1**	5	**1-5**	9
Secondary	6	**10-50**	7	**2-5**	4	**5-10**	2
Tertiary	1	**50-200**	2	**5-10**	1	**10-30**	1
Community	2	**200-500**	1	**>10**	1	**30+**	0
Private	2	**500+**	1				

3.3.2 Phase 1: Context of Reprocessing Surgical Instruments

Phase 1.1: Barriers to Safe Reprocessing of Laparoscopic Instruments

We collected information on perceived barriers for laparoscopic surgery in rural Indian hospitals in the interviews conducted in all phases (N=17;

Laparoscopic surgeons: n=3, Experts: n=3, Nurses: n=11). Table 3.3 lists the identified barriers, which are further elaborated below.

Table 3.3: Barriers identified by 17 healthcare professionals during all studies.

Barrier Group	Barrier	Frequency Mentioned
Cultural	Education of Nurses	35
	Role of the Surgeon	15
	Role of the Nurse	7
Financial	Cost of Equipment	12
	Cost of Staffing and Training	5
Structural	Access to information	24
	Time	18
	Availability of surgical instruments	17
	Availability of equipment	16
	Availability of staff	3

Cultural Barriers With regards to surgical instrument reprocessing, the cultural barriers exist mainly in the form of the roles of the nurses and the surgeons, and the education that the nurses receive.

Education of Rural Nurses - The education of nurses is a barrier in reprocessing laparoscopic instruments. Cleaning and sterilisation of surgical instruments is part of their general nursing education, but none of these nurses were taught how to handle laparoscopic instruments. Newly employed nurses in the hospital are taught the reprocessing methods by the more senior nurses in the hospital:

> *[I have not received] "special training for laparoscopic instruments. [...] So laparoscopic surgery, I have not seen many times. But open I have."* [ND6]

Role of the Surgeon - Another barrier is that nurses are dependent on the surgeon for guidance, although the surgeons do not have detailed knowledge or official responsibility over the reprocessing of surgical instruments:

> *[Responsibility of reprocessing surgical instruments is] "not the surgeons task at all. He could question it, but he can't comment on it because it's taken care of by the nurses. You know, the sensible thing, if I have a problem I could always question and maybe audit it and to see if there's something going wrong with the process. A surgeon can do that. But the accountability of the process lies with the nurses."* [LB1]

Role of the Nurse - In rural hospitals, there was one team of nurses that execute all the tasks surrounding surgery. Besides reprocessing the surgical instruments, the nurses had many tasks, such as pre-, and post-operative care of the patient, assisting in surgery, and cleaning the operating room:

> *"So it's a multi role model system that at the moment in rural India we follow. So it's not just a scrub nurse or not as a circulating nurse, it's all the roles will be melted together. So there are no specific cleaning staffs, particularly in rural setups"* [NB2]

Financial Barriers Two financial barriers were identified during the interviews: The cost of equipment which refers to either new surgical instrument, or equipment that staff could use in reprocessing, and the cost of staffing and training.

Cost of Equipment - Both nurses and surgeons indicate that there is a financial barrier against buying better reprocessing equipment:

> *"And bio enzymes at the moment we are not using in the rural setup till now. It's because it's not affordable by them."* [NB2]

Cost of Staffing and Training - Training and staffing are not a financial priority to hospitals:

> *"People don't want to spend money on maintenance. The hospital management often considers it unnecessary to reserve a budget for training of nurses and engineers."* [ELC1]

Structural Barriers Five structural barriers were identified.

Access to information - Although the responsibility of the reprocessing cycle lies with the nurses, they have difficulty in finding new information to research new techniques or when they encountered instruments they have not worked with before. Additionally, India has many languages and not

everyone is proficient in the official languages. This makes information even harder to find in some regions:

> *Researcher: "If you have new instruments that you don't know how to clean. Do you know where to find extra information to clean it?" Nurse: "No". Researcher: "So who do you ask if you don't know how to clean something?" Nurse: "The surgeon". Researcher: "Do you have instructions for cleaning the instrument. Like on paper?" Nurse: "No, nothing"* [NB1]

Time - There is time pressure on the operating room nurses and helpers, while reprocessing the laparoscopic instruments. The nurses described they need between 15 and 30 minutes to clean the laparoscopic instruments and about one hour to fully reprocess them. Because of all the other tasks, they indicated that they do not have enough time to properly reprocess the laparoscopic instruments:

> *"We have lots of work. We have to see other patients. We need to arrange the patient, we need clean everything. And sometimes we also have no time to rest."* [NRD4]

Availability of surgical instruments - Many of the hospitals have one set of laparoscopic instruments:

> *"Speed, that's important because we need to wait between the cases so that, since we only have one scope, that actually would be useful if it could to some degree be shortened."* [LB2]

Availability of equipment – Hospitals do not have reprocessing equipment specific to laparoscopic instruments.

> *"Secondly, again, as I mentioned, maybe it's to do with a little bit of financial crunch, also. That they have [not] been able to afford the correct instrument and the correct methods."* [LB1]

Availability of staff - Staff shortages were mentioned as a barrier, and hospitals often have one team of nurses:

> *"We don't have that much staff. The staff shortage is also there sometimes.* "[NB2]

3.3.3 Phase 1.2: Aspects of Reprocessing

Reprocessing Journey

Based on the observations in four rural hospitals (Study B) we constructed an instrument journey, showing the differences in reprocessing of laparoscopic instruments between HIC hospitals and rural LMIC hospitals (Figure 3.3).

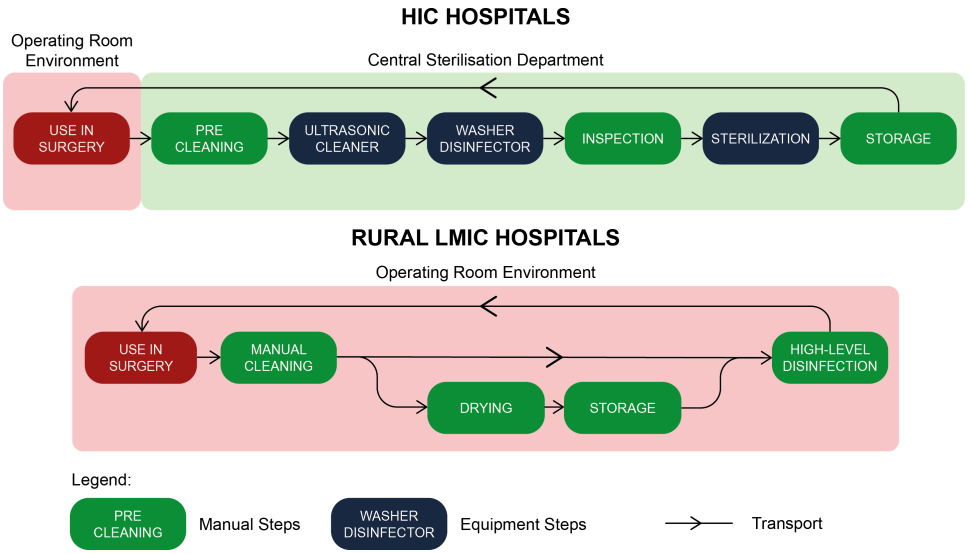

Figure 3.3: Instrument journey describing schematic the reprocessing cycles in LMICs and HICs

Aspect: HIC CSD

In HIC hospitals, surgical instruments are transported to the Central Sterilisation Department (CSD) where they are reprocessed by dedicated staff that are trained in sterile reprocessing. Instrument reprocessing at a CSD is a continuous process which gives staff enough time to execute all reprocessing steps resulting in a consistent outcome. Multiple instrument sets are needed when working with a central setup, allowing for sets to be reprocessed while others are used in surgery.

When instruments are brushed and rinsed, droplets of water containing microorganisms are aerosolised, which can contaminate surrounding surfaces and infect people. A CSD is designed to have a floorplan which separates

the processing of dirty, clean and sterilised instruments. The floor plan prevents cross-contamination between instruments that have just been used and those that have already been sterilised. Furthermore, staff handling the dirty instruments wear personal protecting equipment (PPE) like masks, water-proof gowns and gloves.

Aspect: HIC Reprocessing Methods

Because of the geometry of laparoscopic instruments, several cleaning steps are performed to ensure all bioburden is removed. Debris is first removed in pre-cleaning in sinks with water guns and ultrasonic cleaners. After this, they are automatically cleaned in a washer-disinfectors, which also dries the instruments. Then, the cleaning of the instruments is manually inspected before the instruments are wrapped and sterilised.

Aspect: Indian Infrastructure

None of the four hospitals reprocessed the laparoscopic instruments in the CSD. Most of these hospitals lack a CSD. Only one has a CSD, but it was not actively used. Instead, the laparoscopic instruments are collected after surgery and transported to a sink, either in the operating room or in an adjacent room in the operating room environment. These areas lack the facilities of a CSD such as treated water or PPE and do not have a layout to prevent cross contamination.

Aspect: Indian Equipment

The Indian hospitals in this study own only one set of laparoscopic instruments, and this set has to be reprocessed between each surgery. Specific reprocessing equipment is unavailable: toothbrushes are used to clean the instruments' surfaces, and hypodermic needles and scalpels to remove debris from difficult to reach areas of the laparoscopic mechanisms (Figure 3.2). Only one hospital has an automated cleaner available which is not in use. Three of the four hospitals are equipped with manual steam sterilisers of different types. However, the laparoscopic instruments are not steam sterilised because of concerns that the heat damages the components.

Aspect: Indian Reprocessing Methods

All steps of the reprocessing cycle are performed manually by the nurses. After cleaning, the instruments are rinsed under tap water and deposited into a container with the high level disinfectant Glutaraldehyde or Formalin gas. In one hospital, the instruments are dried before being disinfected, in other hospitals the instruments are only air-dried at the end of the day to store them. Glutaraldehyde fixates unremoved bioburden on the instruments' surface, making them even more difficult to clean over time. This means that disinfection cannot be guaranteed when the cleaning methods are unreliable.

3.3.4 Phase 2: Design Direction and Design Requirements

Key Challenges

The analysis of the context shows that there are many factors that contribute to insufficiently processed laparoscopic instruments. Table 3.4 shows a summary of the key challenges that are identified during Phases 0 and 1, which are divided into three groups: Staff, Infrastructure, and Instruments.

Table 3.4: Key challenges to reprocessing laparoscopic instruments in Indian hospitals

Infrastructure	Lack of a CSD	Construction of a CSD is financially unfeasible. Cleaning instruments near operating room is a contamination hazard.
	Reprocessing Equipment	Reprocessing equipment such as detergent and suitable brushes are unavailable
Instruments	Complex cleaning of laparoscopic Instruments	Cleaning of laparoscopic instruments involves multiple time-consuming steps. Quality of cleaning affects disinfection or sterilisation.
	One laparoscopic instrument set	The laparoscopic instrument set must be reprocessed in between surgery which limits time that can be spent on reprocessing.
Staff	Education and training	Nursing education does not incorporate laparoscopy and finding new information is difficult.
	Staff safety	The needles and scalpels used for cleaning can injure nurses and transfer contaminants.

3.3.5 Design Direction

Based on the Key Challenges, the design direction was to develop an automated laparoscopic instrument cleaner which is designed to operate in the context of an operating room environment of an LMIC hospital. The proposed solution resulted in a new reprocessing journey (see Figure 3.4). Because the cleaner is kept in the same environment, the journey does not greatly differ from the current journey (Figure 3.3). However, the proposed journey includes an inspection step which is crucial to the reliability of the process, and steam sterilisation which is the preferred method for laparoscopic instruments.

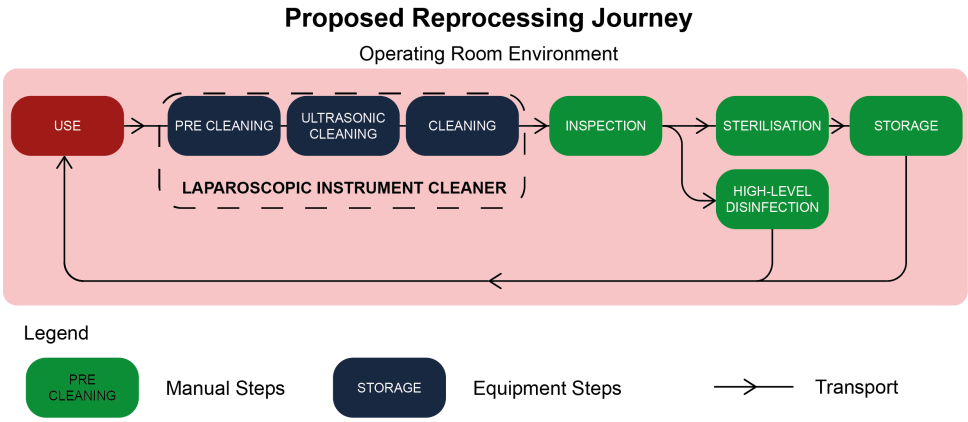

Figure 3.4: New reprocessing journey with the steps that the new device is intended to automate

3.3.6 Design Requirements

As a result of Studies A-C, and the review of ISO 15883-1, design requirements were established and are presented in Table 3.5.

3.3.7 Phase 3: Act

Translating insight into design solutions

The laparoscopic instrument cleaner was developed during Phase 3. Three iterations of the waterfall design method resulted in a final concept design

Table 3.5: Context-specific design requirements for the laparoscopic instrument cleaner

ID	General Requirements	Reference
G1	The cleaner should operate in the operating room environment	Aspects: Indian Infrastructure
G2	The cleaner must have a small footprint area	Aspects: Indian Infrastructure
G3	The design of the instrument cleaner must minimize the use of consumables.	Barriers: Financial and Barriers: Availability of equipment
G4	The device shall have a pre-cleaning phase	Aspects: HIC Methods, Literature: ISO 15883-1
G5	The device shall have a cleaning phase	Aspects: HIC Methods
G6	The device shall have a rinsing phase	Literature: ISO 15883-1
G7	The device will not have a disinfection phase	Aspects: Equipment
Operational Requirements		
O1	The instrument cleaner must be able to be filled with water automatically as well as manually.	Aspects: Infrastructure
O2	The loading system must be able to be correctly loaded by nurses who have no experience loading instrument cleaners.	Barriers: Cultural
O3	The instrument cleaner must be quick to load	Expert Requirement: Rural Surgeon, Barriers: Time
O4	The device must clean one set of laparoscopic instruments	Barriers: Availability of Surgical Instruments
Cleaning Requirements		
C1	The device shall provide ultrasonic cleaning to the instrument inserts	Aspects: HIC reprocessing
C2	The device must internally flush the instruments with enough pressure to overcome blockages cause by bioburden	Literature: ISO 15883, Sterilisation Expert
C3	The device should finish the cycle in 15 minutes (time between surgeries)	Barriers: Time
C4	The device should process the water to a quality that will not impair the cleanliness of the load	Expert Requirement: LMIC Trainer, Literature: ISO 15883-1
Maintenance Requirements		
M1	The instrument cleaner must be easily repairable with locally available and affordable parts.	Expert Requirement: LMIC Reprocessing Expert, Aspects: Equipment
M2	The instrument cleaner must not depend on frequent maintenance.	Expert Requirement: LMIC Reprocessing Expert, Aspects: Equipment

(Figure 3.5). The laparoscopic instrument cleaner, intended to operate in the operating room environment (Requirement G1), can be filled either by connection to a water main or manually. The device cleans only laparoscopic instruments, this way, the wash chamber can be kept compact to limit its footprint (Requirement G2). Washer-disinfector machines in CSDs

have a disinfection cycle after washing the instruments which makes the instruments safe to handle by healthcare workers. Because in LMIC hospitals the instruments are directly disinfected after cleaning, it was chosen not include a thermal disinfection phase which also shortens the cycle time (Requirement G7).

The cleaner was designed to clean one set of instruments per cycle as per Requirement O4. The disassembled instruments are loaded into two baskets by the nurses. The design of the baskets are based on what is currently used in industry. Basket 1 carries the handles, inserts and other small parts, and basket 2 carries the hollow components. This allows for flushing of the hollow components and exposes enough surface area for cleaning. Baskets are loaded vertically to allow for the hollow components to drain fluids. Surface cleaning is done by spray jets inside the wash chamber, the lumens are cleaned by forcing water forced through the lumen by an alternating flow mechanism (Requirement C2). The cleaning programme includes a pre-cleaning with water of surfaces and lumens, cleaning with water and detergent of surfaces and lumens, ultrasonic cleaning of mechanism tips, rinse with water (Requirement G4-7, C1).

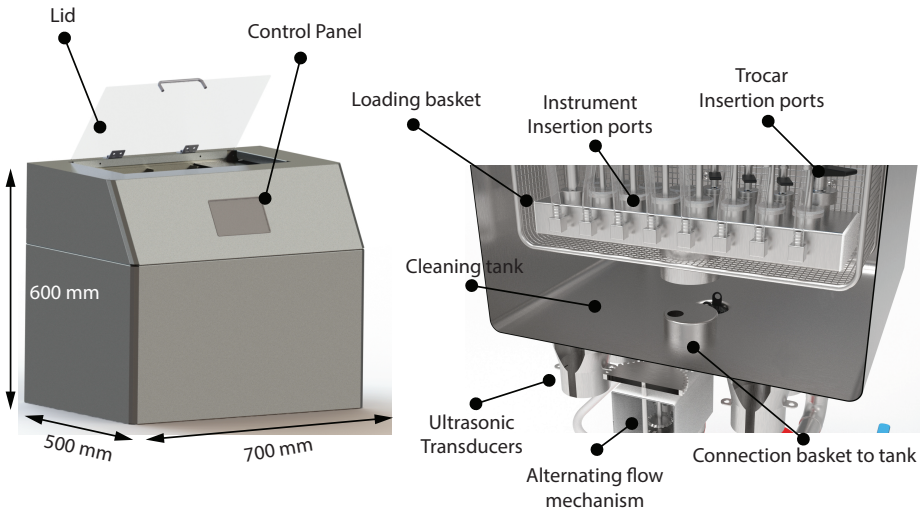

Figure 3.5: Renders of the casing of the laparoscopic instrument cleaner (left) and a detail of the connection between the basket and the wash chamber (right).

Usability Evaluation Study

Figure 3.6 shows the prototype that was made based on the final concept and used for the usability evaluation in Study C. Table 3.6 shows the tasks the nurses performed, the use errors (according to IEC62366-1:2020 Annex D), the root causes for the errors, and the time the nurses spent per test. The results show that no participant was able to perform all tasks correctly. During the first and second tests, the nurses made 4.4 and 2.4 use errors on average respectively. On average, urban and rural nurses made a similar number of errors in the first test (4.6 and 5.4 respectively. Only one of the tasks (A6) was performed without any errors. The urban nurses on average took 7:11 minutes (ranged between 02:49 – 09:45 minutes), the rural nurses 06:46 minutes (ranged between 02:55 – 14:30 minutes), and the nursing students 15:58 minutes (ranged between 12:20 – 21:05 minutes).

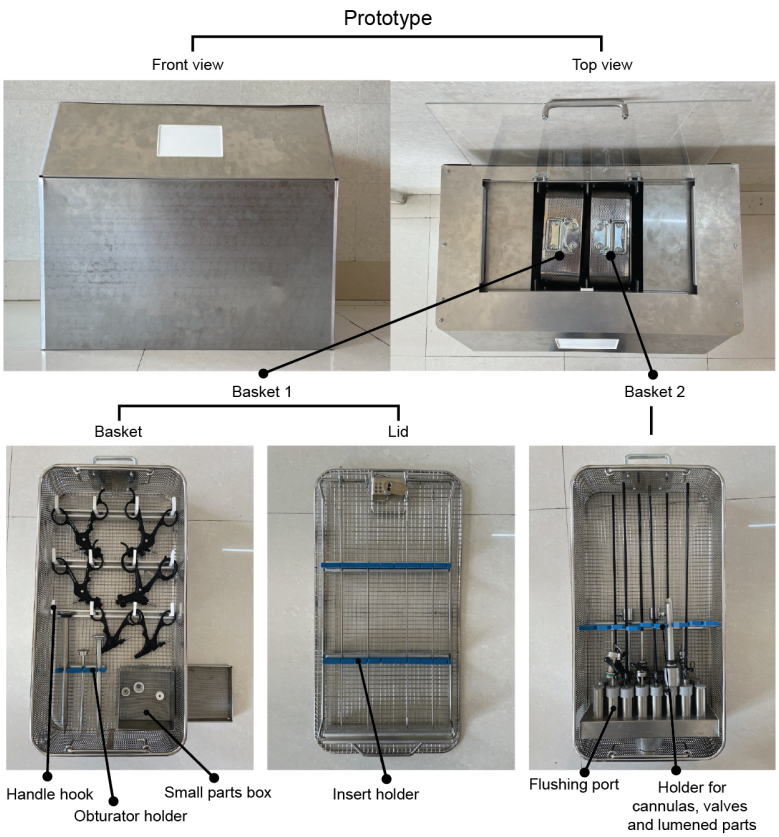

Figure 3.6: The prototype used for the usability evaluation(top) with the two loading baskets containing laparoscopic instruments (bottom).

Use Errors Tasks A2-A5 and B1-B3 were placing items in the correct location in the baskets. None of these seven tasks were performed without errors in either test. In the debrief interviews the nurses mentioned that the baskets did not convey enough information where to place an item causing cognition errors. The nurses placed items in other locations, for instance, placing the obturators loose in the basket and commented: *"I am not sure where I should put it"* [NUD1]. Another reason for placing items in another locations than intended was to prevent damage to the parts. The nurses tried to prevent this by either ensuring that parts would not fall down in the vertical baskets, or that the plastic parts would not contact sharp metal edges: *"I put the inserts and the black sheaths in a different box from the trocars. As the inserts and black sheaths get damaged more easily"* [NUD2]*" It is fixed which means it will not be broken"* [NRD2]. When nurses were unsure where to put a certain item they looked for a location based on geometry: *"I think it is okay. The length is appropriate for this one"* [NUD1]. The nurses also tried to prevent damage to the baskets themselves. In one of the ports, the nurse was unable to fit the black tubes into the hole of the port, leading to an action error: *"I put the black sheaths there because rubber stand it. It is designed for black sheath. The flush port has a very small hole to install it"* [NUD5].

Correct Uses The nurses who correctly executed a task did this for different reasons. The nurses correctly placed items if they could securely fasten it. *"It is designed in such a way. It clamps it."* [NRD1]. For other parts, the correct location provided information where to place it, for instance with the handles: *"For the handles the hooks are meant there"* [NUD1]. With only one task (B2: Load lumens of trocars on the rods on the manifold), two of the nurses gave a rationale related to the cleaning of the part: *"The trocar is more contaminated so in this location it has more space to be cleaned"* [NUD2]. *"The aluminium fixes the instrument and trocars are hollow, the inside will be [cleaned]."* [NRD4]

Evaluation interviews

Nine nurses participated in the evaluation interviews [NUD1-5, NRD1-4] and provided general feedback on the device design and its (potential) value within the reprocessing cycle. The nurses mentioned that the cleaner could save time during the reprocessing cycle and decrease the work pressure currently put on them (9x), loading the baskets is comfortable (5x), although

Table 3.6: Results of the usability Study. The table shows the required task, the observed result, the use error type (according to IEC62366-1:2020 Annex) and the root cause of the error.

Test Number	Urban (n=5) 1	2	Rural (n=4) 1	2	Student (n=3) 1	Observation	Use Error Type	Root Cause
Task	Number of errors							
U1. Unload baskets from cleaner	2	0	0	0	0	Only one basket is unloaded	Cognition	Unclear information from device
A. Loading tasks for basket 1								
A0. Instruments are not assembled before loading	1	1	0	0	0	Assembles instruments	Cognition	Unclear instruction from device
A1. Remove lid from basket	1	0	0	0	0	Unable to open mechanism	Cognition	Unclear information on how to perform action
A2. Load the obturators in the silicone holders	5	2	2	2	3	Puts object in wrong location	Cognition	Unclear information where to place item
A3. Load handles on the hooks	4	0	2	2	3	Puts object in wrong location	Cognition	Unclear information where to place item
A4. Load the inserts in the silicone holders	4	2	3	3	3	Puts object in wrong location	Perception	Correct location is not noticed
A5. Load small parts in the box	1	0	2	1	0	Puts object in wrong location/ Assembles instrument	Cognition	Unclear information where to place item
A6. Attach lid on basket	0	0	0	0	0			
B. Loading tasks for basket 2								
B1. Load black sheaths in the ports	4	4	2	2	2	Puts object in wrong location/ Puts object in right location incorrectly	Action / Cognition	The mounting points are too small. Unclear information where to place item
B2. Load trocar cannulas on the rods	4	1	4	2	2	Puts object in wrong location	Cognition	Unclear instruction from device. Unclear information where to place item
B3. Load trocar valves on the rods	5	4	4	4	3	Puts object in wrong location/Assembles instrument	Cognition	Unclear instruction from device. Unclear information where to place item
L1. Load baskets in cleaner	2	0	1	0	0	Puts object in right location incorrectly	Cognition	Unclear instruction from device
Time [minutes: seconds]	06:34	07:48	07:37	05:54	15:58			

the baskets is a little heavy and needs to get habituated to the mechanism (1x), the cleaner is a more reliable system for cleaning the laparoscopic instruments compared to the current system of manual cleaning (5x), expect less damage to laparoscopic instruments when using the instrument cleaner (3x), working with the cleaner would increase the work safety during the cleaning process by decreasing the amount of physical contact with the contaminated instruments (3x), and expect the laparoscopic instrument cleaner to use less water than when the instruments are manually cleaned under continually running tap water (2x).

Prototype iteration 2: Redesign based on usability study

Based on the results of the user evaluation, we developed a redesign of the laparoscopic instrument cleaner (Figure 3.7). Most of the errors made during the instrument loading tasks had root causes relating to cognition. Therefore, instruction diagrams were added to the surface of the washer (see Figure 3.7C) to support nurses with varying levels of experience in loading washer-disinfectors in properly positioning the instruments into the trays.

3.4 Discussion

This paper outlines the approach taken to develop a device aimed at enhancing the sterility of laparoscopic instruments in Low- and Middle-Income Country hospitals, by focussing on the design of the laparoscopic instrument cleaner. Based on the Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide, Phase 0 uncovered the need for such a device. Then, studies of the context in Indian hospitals produced a set of context-specific design requirements which led to a concept. Finally, the loading system of the concept was evaluated in a the usability study of its loading system with local nurses which updated the concept into the final design of the laparoscopic instrument cleaner.

An automated cleaner has the main benefit of providing a reliable level of cleaning without being dependent on the time that the nurses have to spend on reprocessing or what their training level is. Lower levels of bioburden improves the outcome of the sterilisation or disinfection steps. Contamination due to aerosolization is reduced because cleaning is contained within the device. Additionally, nurses' safety and longevity of the

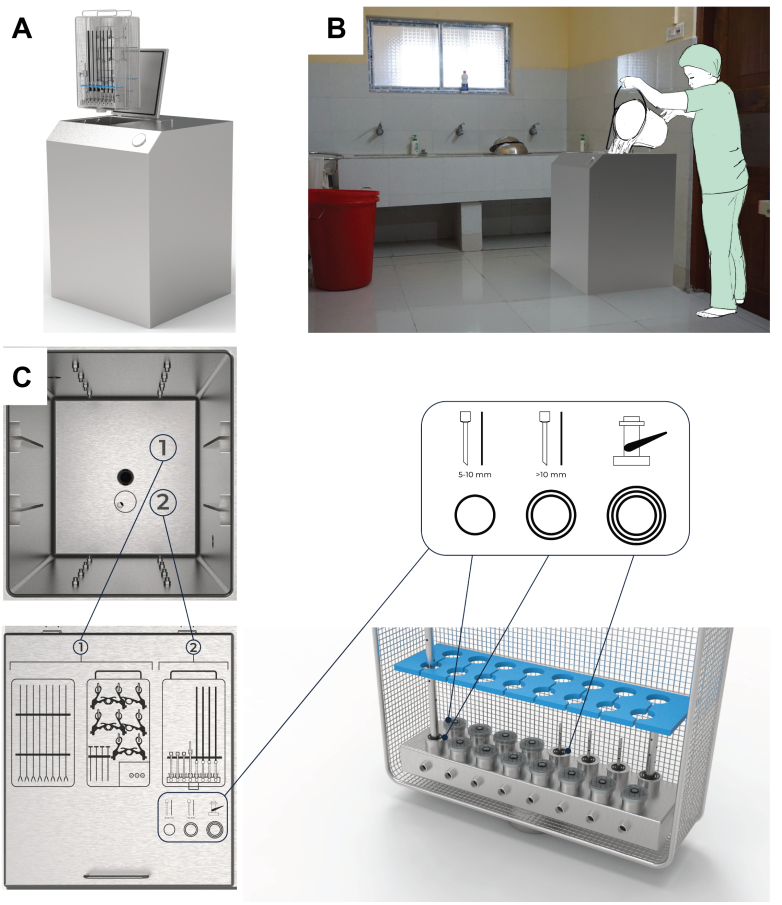

Figure 3.7: A) Rendered image of the redesigned laparoscopic instrument cleaner. B) Render of the cleaner in an operating room environment. C) Redesign with instructions diagrams based on outcomes of the user study.

laparoscopic instruments is expected to improve because manual cleaning is no longer performed with toothbrushes, needles and scalpels.

Especially for complex equipment such as laparoscopic instruments, automatic cleaning has been proven to be more effective than manual cleaning [35]. This is because it ensures that all surfaces of the instruments are washed with water and detergent. One study compared manual and automatic reprocessing of endoscopes in emerging economies, it showed that automated cleaning saves cost, labour time and improves the lifespan

of the endoscopes [36], although the manufacturer instructions were not always followed.

3.4.1 Design Process

A significant portion of the project focused on the design and evaluation of the loading system of the laparoscopic instrument cleaner. This component was chosen due to its prominence in the user interaction with the device. The design of the loading system was initially influenced by systems used in industry, with the assumption that nurses, experienced in handling surgical instruments, would intuitively adapt to these systems. However, the user evaluation revealed that this was not the case. Notably, the root cause analysis showed that only one of the nurses mentioned cleaning efficacy as an argument for placing an instrument in the basket. This exposed a gap in understanding among nurses regarding the requirements to correctly clean laparoscopic instruments, such as the need to flush hollow parts to remove bioburden. The study illustrated challenges for nurses in this context associated with limited training opportunities, and a difficulty in finding reliable information and manuals. Knowledge transfer relied on word of mouth as there was no system for keeping device related manuals and documents. Therefore, the redesign of the loading system primarily focused on providing clear instructions on the device such that it can be operated by all users. However, the effectiveness of these proposed solutions is yet to be fully evaluated.

The Roadmap for the Design of Surgical Equipment for Safe Surgery Worldwide stimulates mapping the context of use of a surgical device and translating this into a set of design requirements [25]. For this project, the context were the factors relating to the reprocessing of laparoscopic instruments: the reprocessing methods were studied, as well as the barriers that workers faced during reprocessing. As Phase 1 showed, there are many barriers that inhibit a reliable sterilisation process of laparoscopic instruments, one design would not be able to overcome all of these barriers. It was therefore, necessary to define the scope of the key barriers that this design was going to act upon. Phase 0 of the roadmap identifies a need to solve a certain problem. Especially in topics related to healthcare and surgery, this problem is often multi-faceted which means that several solution directions can be a result of this phase. We suggest an addition to the roadmap where the scope of the project is defined. This should be a

problem analysis, after Phase 0. This would make the context study phase, and the design requirements more specific.

This study made clear that hospitals in LMICs needed tailored solutions to enhance the efficacy and safety of sterile processing in smaller settings. The current focus in improving sterilisation in LMIC hospitals has been on the development of training programmes, which have demonstrated success [37]. However, no other initiatives were found that aim to improve the reprocessing facilities in low-resource settings.

3.4.2 Limitations and future work

The user evaluation was limited by the fidelity of the prototype. The prototype was a non-functional device that the nurses could not see in operation. Even though the nurses received information of the method of operation, it could be difficult to imagine for people who had little experience with automated medical cleaners. Future work should include a re-evaluation of the loading system to gauge the effectiveness of the proposed solutions. Other solutions in the supply of sterile laparoscopic instruments could be through the use of disposable instruments. Previous economic analyses suggest financial advantages in reusing surgical instruments [38–42]. Furthermore, during our studies we observed many hospitals reprocessing disposable instruments as a cost-cutting measure. However, novel cost-effective and biodegradable materials could be a solution to these issues.

During the design process for a device such as the laparoscopic instrument cleaner, there are many opportunities to validate design choices. In this approach, the design requirements were translated from the observational studies performed in design Phases 1 and 2. Although additional requirements were suggested by experts, a direct validation of the design requirements by surgeons and nurses in Indian hospitals was not performed.

This study recorded the contextual factors relating to the reprocessing of laparoscopic instruments and the end-users, and resulted in a prototype of a laparoscopic instrument cleaner. Further technical development of the device should account for contextual factors such as manufacturability, physical setting, distribution, and how to organise maintenance. These factors will expand the current list of design requirements.

A potential business model is that hospitals will pay for the device per operation cycle, and licence the machine (medical device as a service). In

these schemes, the manufacturer is incentivised to design a robust machine that can easily be maintained.
In later stages of the cleaner's development, training programs have to be created that explain the operation, maintenance, and troubleshooting of the machine. To ensure adoption and comprehension, these instructions should be designed so that prior experience, education, and language do not pose barriers.

3.5 Conclusion

In conclusion, this project followed a structured design approach to develop a device for overcoming the challenges in reprocessing laparoscopic instruments in LMIC hospitals. This approach involved comprehensive context mapping, which led to the design of a potential concept. The user evaluation underscored the importance of considering local users' specific needs in designing medical technology, as existing designs may not always align with expectations. This project serves as a stepping stone towards addressing the critical issue of sterile supply in resource-constrained environments, with broader implications for the design of medical devices worldwide.

3.6 Acknowledgements

We would like to thank J.C. Diehl for his help in drafting this article and advising during the organisation of Study C. Also, we thank T.A. Lenssen for his help in organising Study A. Special appreciation is given to all the hospitals who hosted our study and the nurses and surgeons who took part.

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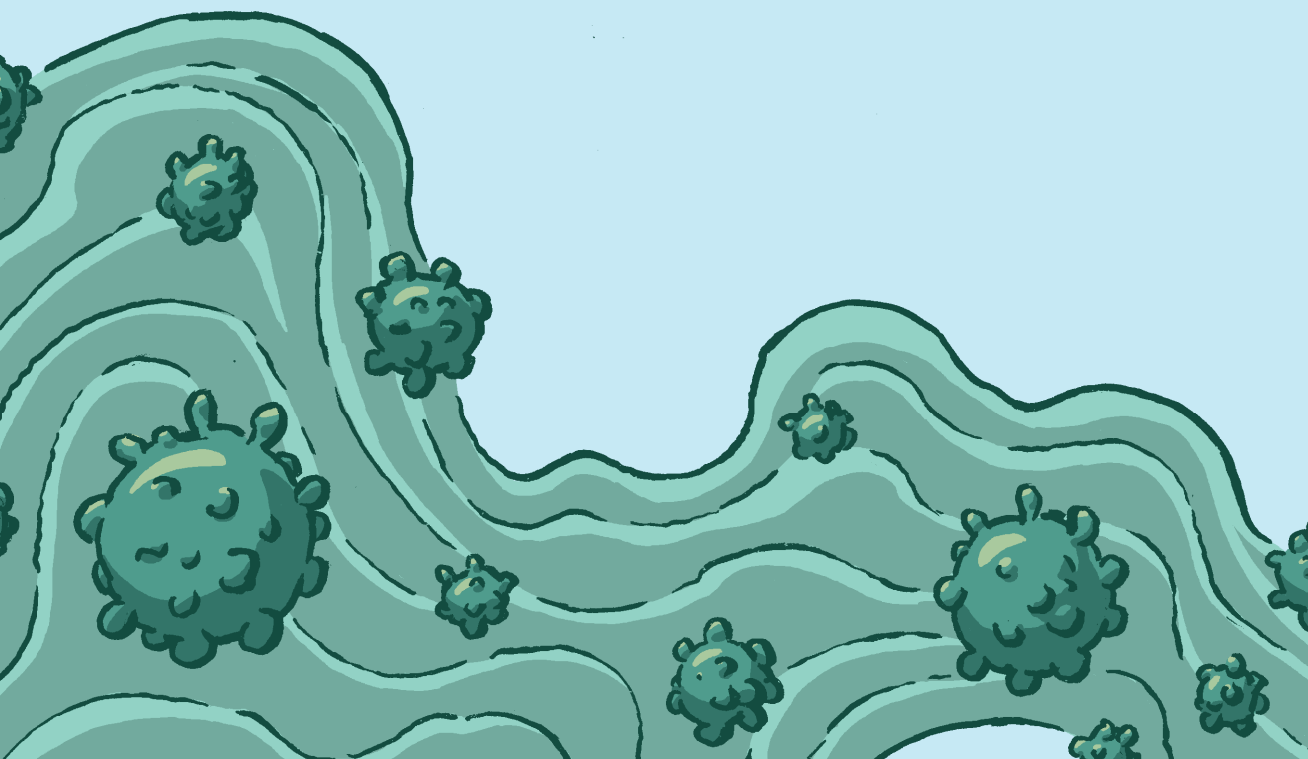
II

Part 2: Trocar Gas Leakages



4

Characterisation of Trocar Associated Gas Leaks During Laparoscopic Surgery

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Parts of this chapter have been published in Surgical Endoscopy **36**, (2022) [1].

4.1 Introduction

In minimal access surgery, the surgical field is exposed by insufflation of pressurized carbon dioxide gas (CO_2). Trocars provide access to the body cavity for both gas insufflation and insertion of a scope and instruments. In clinical practice, a perfect gas seal is difficult to achieve, with minor leaks of carbon dioxide gas through the incision, the trocars and the surgical instruments. In certain procedures with higher pressures, longer operating times, or frequent instrument changes this can result in the leakage of several hundred litres of gas into the operating theatre [2].

One of the main concerns is the exposure of operating theatre personnel to surgical smoke and other aerosols. There have been studies measuring the composition of smoke in laparoscopy, in which carcinogenic compounds were found [3, 4]. It has been proven that peritoneal fluids can contain pathogens such as viral particles [5] that can be carried into the operating theatre through insufflation gas leakage. There have been rare documented cases where surgical smoke containing viruses like the human papilloma virus (HPV), have led to human transmission [6–8].

Covid-19 has revived the concerns over peritoneal gas leakage potentially containing harmful substances. Recently, a number of studies have been published on the safety of performing laparoscopic surgery on Covid-19 positive patients [9, 10]. Considering the current knowledge on the transmission and virulence of Covid-19 the spread through insufflation gases cannot be ruled out [11].

Cross contaminations in the OR can be prevented by a number of different measures. These range from improved airflow to specific smoke evacuation devices. Although laminar airflow reduced the number of smoke particles near the OR personnel, these systems cannot counteract a strong influx of contaminated gas [12]. Smoke evacuation devices aim to prevent particles escaping into the OR entirely. However, leakages through laparoscopic equipment could undercut both protective measures.

Thus far, one study has measured the flow of gas through a cannula and instrument. However, the contribution of either the cannula or instrument was not quantified [13, 14]. The use of different combinations of trocars and instruments will likely result in varying leakage performances. The choice of equipment might cause OR personnel to be exposed to contaminated gas. Therefore, this study aims to investigate gas leakage through representative and commonly used trocars and instruments. A model was developed to

measure gas leak due to trocar-instrument interactions that occur during a laparoscopic procedure.

4.2 Materials and Methods

4.2.1 Trocars and instruments

To quantify the problems related to trocar and instrument leakage during laparoscopy, surgeons from hospitals throughout Europe were asked to provide trocars and instruments that are used in their hospitals. As this study was a technical equipment evaluation, no IRB permission was required. All materials were checked for defects and categorized before testing. Only trocars with a nominal size of 5 mm and 12 mm were included, duplicate trocars were excluded. No scopes were included in the instrument measurements. The trocars and instruments were categorised based on size and reusability: reusable, disposable or reposable (partially-reusable). Before performing the measurements, relevant trocar properties such as: the number of valves; valve type; valve lumen diameters and distances between valves were noted, which are shown in Figure 4.1.

4.2.2 Model

Three potential leak pathways were identified: 1) through the trocar; 2) through the instrument; 3) through the incision between the tissue and trocar. For this study only pathways 1 and 2 were of interest. To avoid the third 'tissue leak' pathway, two custom nozzles were designed to provide an airtight seal for 5 and 12 mm trocars. These nozzles were made from silicone and had an inner diameter that was smaller than the smallest outer diameter of a trocar. The shape of these nozzles is shown in Figure 4.2.The airtight seal was verified with a soap bubble test.

To investigate pathways 1 and 2, a rigid container was used as a model for trocar leak during a laparoscopic procedure. A schematic of the model is shown in Figure 4.1. The rate of gas leakage is mainly dependent on variables such as the intra-abdominal pressure and the resistance to gas flow by the trocar and instrument. In practice, gas leak and CO_2 absorption cannot be distinguished from each other. Abdominal compliance can also affect the incision leak around the trocar. Therefore, this model isolates the leakage through trocars and instruments. The model was insufflated using

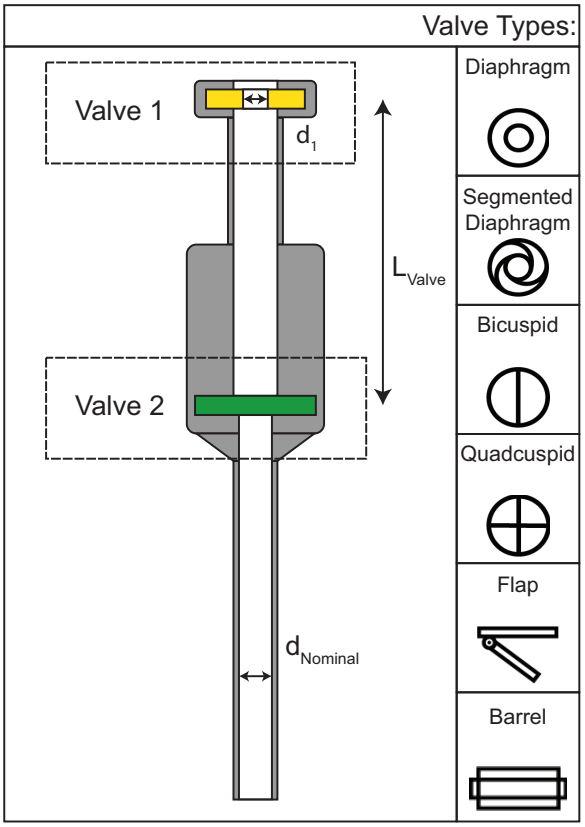

Figure 4.1: Trocar dimensions and valve types, dNominal was used for categorization. The distances between the valves and the lumen diameters were measured. Six different types of valves could be distinguished: diaphragm, segmented diaphragm, flap, barrel, bicuspid and quadcuspid valve.

an external pressure source which pressurized room air to 15 mm Hg to comply with standard intra-abdominal operating pressures.

4.2.3 Protocol

The effects of trocar-instrument interaction were studied by performing a series of manipulations and an instrument insertion. The different tests represent conditions that could occur during surgery. These test are designed to investigate performance aspects of the specific valves of the

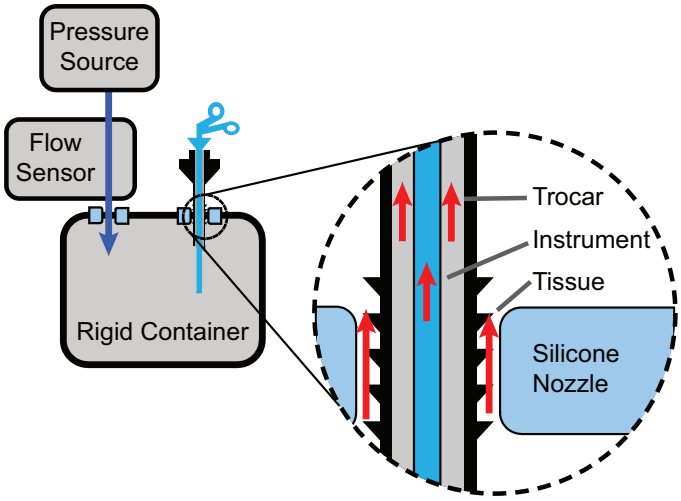

Figure 4.2: The leak measurement setup and leak pathways: A rigid container that was pressurized using an external pressure source. The flow needed to keep the rigid container pressurized was measured at the inlet, the inlet flow equalling the leak through the trocar and/or instrument. In an OR setting, CO_2 can leak through three pathways: through the instrument, through the trocar and between the trocar and tissue. In this setup a silicone membrane was used to prevent leak through the tissue pathway

trocar. All trocars underwent baseline measurements, manipulations and an insertion test.

Baseline During the baseline measurement, the trocar was empty, and valve 2 prevented gas from escaping. The instruments were measured when directly inserted into the silicone nozzle, without trocar.

1. **Baseline**: only empty trocar or individual instrument.

Manipulation When manipulating tissue, the instrument is inserted into the cannula with the shaft protruding all valves. During manipulation, valve 1 creates a seal around the shaft of the instrument, while valve 2 is kept open by the instrument. Manipulations on all trocars were performed manually with two solid steel rods to mimic the use of a surgical instrument. By using a solid rod, the leakage was isolated through the trocar. The rods used had a

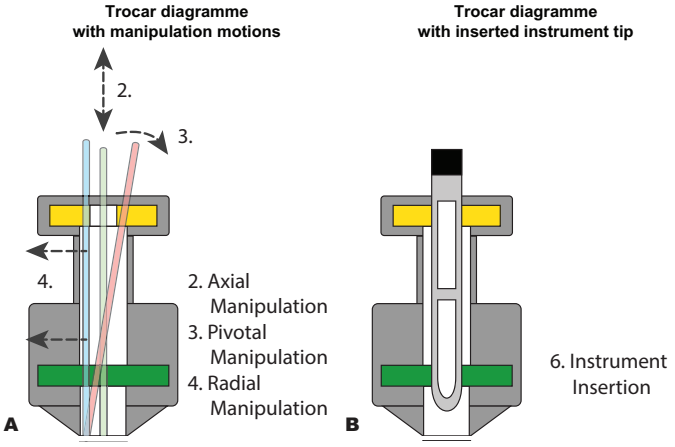

Figure 4.3: A) Manipulations of the rod within the trocar, in axial (2), pivotal (3) and radial (4) directions. Axial manipulation oscillation are performed with a 5 cm amplitude. During the pivotal and radial manipulation the rod is maximally displaced. B) During the instrument insertion test, a grasper with a fenestrated structure was inserted into the trocar and kept in contact with both valves to allow for an open passage of gas

diameter of 5±0.02 mm and 12±0.02 mm for the respective size of trocar and a length of 350 mm, providing sufficient length to manipulate the rods on both ends protruding from the trocar. The 12 mm trocars with diaphragms that were smaller than 5 mm, were tested with the 5 mm and 12 mm tools In total four different manipulations were manually performed as shown in Figure 4.3A. The manipulations were:

2. **No manipulation**: placing the rod through all valves in the trocar and held in an upright position by an instrument holding arm by which no forces or displacements were exerted on the rod or trocar.

3. **Axial manipulation**: five oscillations of the rod with a 5 cm amplitude axial to the trocar.

4. **Pivotal manipulation**: pivoted placement of the rod within the trocar until the maximum angle allowed by the trocar entry.

5. **Radial manipulation**: moving the rod within the trocar parallel to the trocar axis until maximum displacement.

Insertion During instrument insertion, both valves determine the leakage performance. When a fenestrated instrument tip is longer than the distance between two valves, it opens both valves simultaneously and could allow leak through the instrument tip as seen in Figure 4.3B. The insertion test was performed with a 5 mm fenestrated atraumatic grasper with a 4.9 mm diameter and a 28 mm tip length, and with a 12 mm stapler with a 12.2 mm diameter and a 70 mm tip length. The inter-valve distance was related to the leakage resulting from instrument insertion.

6. **Instrument insertion**: holding the instrument tip between both valves of a 5 mm atraumatic grasper and a 12 mm stapler in the respective trocar sizes.

To verify that the manipulations and insertion test did not cause significant degradation in trocar leak performance, the no manipulation test was repeated after the manipulation and insertion tests.

4.2.4 Data collection and Processing

The container used for this model was rigid, the inlet flow needed to maintain the pressure equalled the leak through the trocar and/or instrument. The insufflation pressure and trocar leak were measured using a pneumotachograph (Hans Rudolph, series 8410A) combined with differential pressure sensors. These sensors sampled at 200 Hz. Before every experiment the flow measurement was calibrated to room air using a 100 mL syringe (Hans Rudolph 5510 Series). Pressure and leak measurements were recorded using LabVIEW 2019 (National instruments, Austin, Texas, U.S.). For each baseline, manipulation or insertion measurement a separate recording was made. Data processing was performed using Matlab (R2020a, Mathworks, Natic, Massachusetts, U.S.).

The manipulations during the measurements initially caused disturbances in the flow data, after which the flow stabilised to a steady-state leakage. Before visual inspection of the recording, a low-pass filter was applied with a cut-off frequency of 20 Hz. From every recording a sample was visually selected that contained this steady-state leak. In the axial manipulation test the sample was visually selected to contain 5 oscillation. The minimal sample length for all selected samples was 0.5 second. After selection, samples were averaged.

Since the 12 mm trocars were tested with 5 mm and 12 mm rods and instruments, two baseline measurement were available. Therefore, an

additional comparison was made to verify that the manipulations and insertion test did not damage the trocar.

4.3 Results

4.3.1 Included trocars and instruments

The inquiry for trocars under EAES members resulted in the inclusion of 22 trocars which are listed in Table 4.1. Regarding the valves inside the trocars, the following observations were made: Most of the 5 mm trocars had 2 valves. Trocars f and k appeared to have one valve, however after disassembling those two trocars, f turned out to have two different valves stacked on top of one another. Trocar k had a single component valve in which a diaphragm valve was combined with a cross flap valve, so this was categorized as single valve. Trocar I was the only trocar which had three valves, with an additional valve after valve 2. Valve 2 in trocar I serves the same purpose as in the other trocars. Some of the 12 mm trocars came with a removable diaphragm adapter for use with a 5 mm instrument, in that case, its diameter is shown in the table.
First valve diameters ranged from 0 - 4 mm in the 5 mm category and 0.5 - 9.5 mm in the 12 mm category. For the first valve the most common (18/22) choice was a diaphragm valve, the other (4/22) were a variation of the diaphragm valve. For the second valve a broader variety of valves was present. The most common (11/22) choice was a bicuspid valve, other (9/22) valves used were flap (5); quadcuspid (3); barrel (1) and bicuspid diaphragm (1) type valves. Internal valve distance ranged from 0 – 35 mm for 5 mm trocars and 7 – 32 mm for 12 mm trocars.

The consistency of the trocars' performance was verified after comparing the 'No Manipulation' results at the start and end of the measurement series. The degradation over a measurement series was found to be less than 0.1 L/min, with the exception of G, which was only tested with a 5 mm instrument due to failure during the 12 mm instrument test. The 5 mm results of trocar G were still included as the baseline measurement differed by 0.01 L/min. J and K were only tested with a 12 mm instrument because the first valve diameter was too large for use with a 5 mm instrument.

In total, 26 instruments were tested for leakage: 5 mm disposable instruments (14/26), 5 mm reusable instruments (6/26). Six instruments had diameters larger than 5 mm: 10 mm (2/26) and 12 mm (4/26), grouped as

10/12 mm instruments. No reusable instruments with a large diameter were available.

Table 4.1: Properties of the included trocars, every trocar was labelled. The trocars are indicated with a letter; lower-case letters indicate a 5 mm trocar, upper-case letter represent the 12 mm trocars. The 12 mm trocars were tested using both a 5 mm instrument and 12 mm instrument. The colours in the table represent if a trocar is disposable, reusable or reposable. The recorded details were: number of valves, type of valves 1 and 2, diameter of valve 1, internal valve distance and adapter valve diameter.

Label	Size	Use type	No. of valves	Valve 1		Valve 2	Internal valve distance	Adapter valve diameter
				Type	Diameter	Type		
[-]	[mm]	[-]	[-]	[-]	[mm]	[-]	[mm]	[mm]
a	5	Reusable	2	Diaphragm	3.5	Flap	30	
b	5	Reusable	2	Diaphragm	2.8	Barrel	30	
c	5	Reusable	2	Diaphragm	3.5	Flap	35	
d	5	Reposable	2	Integrated Diaphragm	4	Bicuspid	15	
e	5	Disposable	2	Diaphragm	2.8	Bicuspid	15	
f	5	Disposable	2	Diaphragm	4	Quadcuspid	0	
g	5	Disposable	2	Diaphragm	2.5	Bicuspid	19	
h	5	Disposable	2	Diaphragm	2.5	Bicuspid	19	
i*	5/10	Disposable	2	Diaphragm	2	Quadcuspid	10	
j	5	Disposable	2	Diaphragm	3.4	Bicuspid	4	
k	5	Disposable	1*	Diaphragm/cross flap	0	NA	NA	
A	12	Reposable	2	Segmented Diaphragm	1.5	Bicuspid	18	
B	12	Disposable	2	Diaphragm	3.5	Bicuspid	15	
C	12	Disposable	2	Diaphragm	3.8	Bicuspid	19	2.4
D	12	Disposable	2	Diaphragm	3.3	Bicuspid	20	
E	12	Disposable	2	Diaphragm	5	Flap	7	2.2
F	12	Disposable	2	Diaphragm	4	Quadcuspid	17	
G	12	Disposable	2	Diaphragm		Bicuspid	32	
H	12	Disposable	2	Diaphragm	3.5	Bicuspid	22	4
I	12	Disposable	3+	Segmented Diaphragm	0.5	Bicuspid+Diaphragm	16	
J	12	Reusable	2	Diaphragm	9.5	Flap	49	
K	12	Disposable	2	Diaphragm	6.5	Flap	18	

* This valve was a combination of a diaphragm and cross flap valve, it was considered to have a single valve since it was a single component with zero distance in between. +Behind the bicuspid valve another diaphragm valve was placed. This is considered an extra valve with xx distance between valve 2 and 3.

4.3.2 Baseline leak

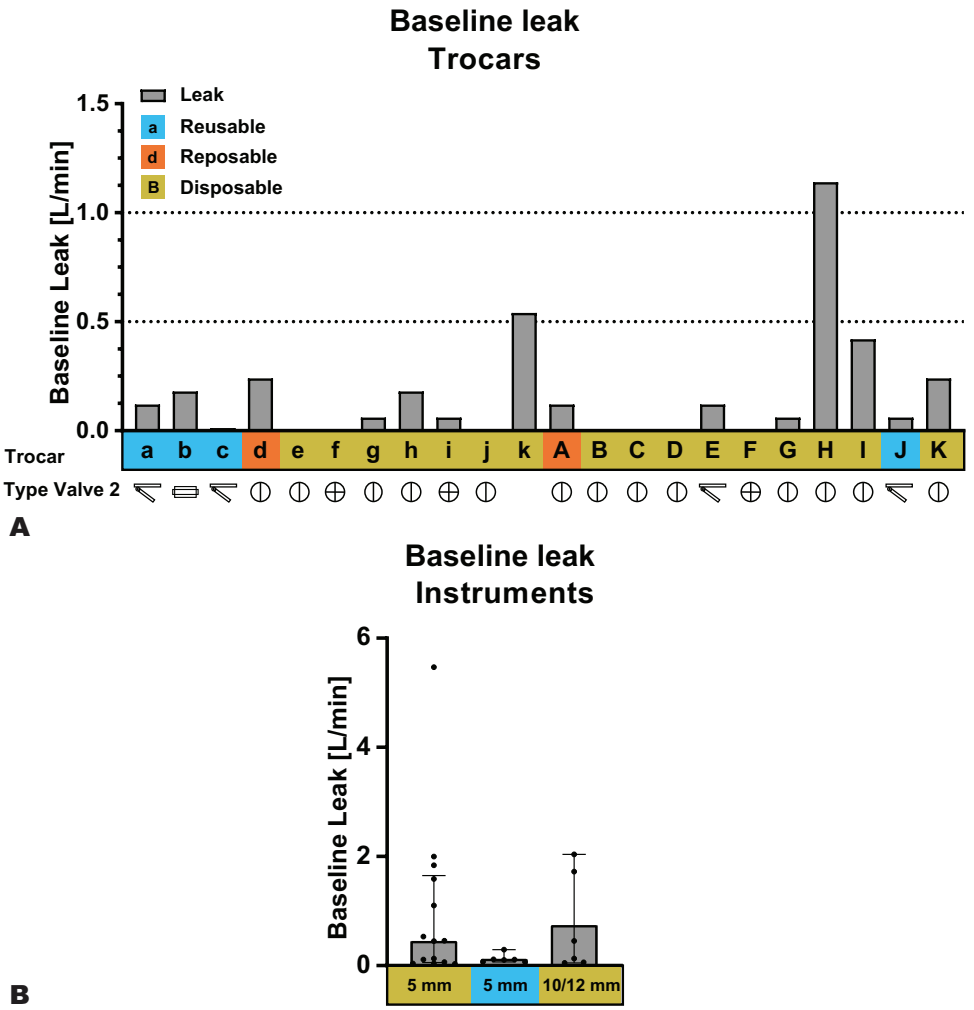

Figure 4.4: A) Baseline flow measurements in trocars at 15 mm Hg. Along the x-axis the trocar names are noted, the colours correspond to the trocar type. The type of valve 2 is denoted by a symbol under the result of each trocar and is detailed in table 1. As trocar k only had one valve, it does not have a symbol.
B) Flow through measured instruments. The bar height indicates the median leak for each group, the crosses shows the inter-quartile range and the dots represent the result of each individual instrument.

The results of the baseline leak measurements for the trocars and instruments can be seen in Figure 4.4. Figure 4.4A shows the measured leak in the individual trocars. The median leaks were 0.06 L/min with an interquartile range (IQR) of 0 to 0.18 and 0.06 L/min (IQR 0 to 0.24) for 5 and 12 mm trocars respectively. In an empty trocar, valve 2 blocks the airflow through the trocar. Therefore, the results of this measurement are related to the performance of valve 2.

Figure 4.4B shows measured leak through instruments. The results were grouped by instrument size and reusability. The 5 mm disposable instruments had a median of 0.45 L/min (IQR 0.06 to 1.7), the 5 mm reusables the median was 0.11 (IQR 0.07 to 0.16), 10/12 mm disposables had a median of 0.29 L/min (IQR 0.06 to 1.8). This meant that the 5 mm reusable instruments had the lowest median and IQR in leak.

4.3.3 Manipulations

4.3.4 Baseline leak

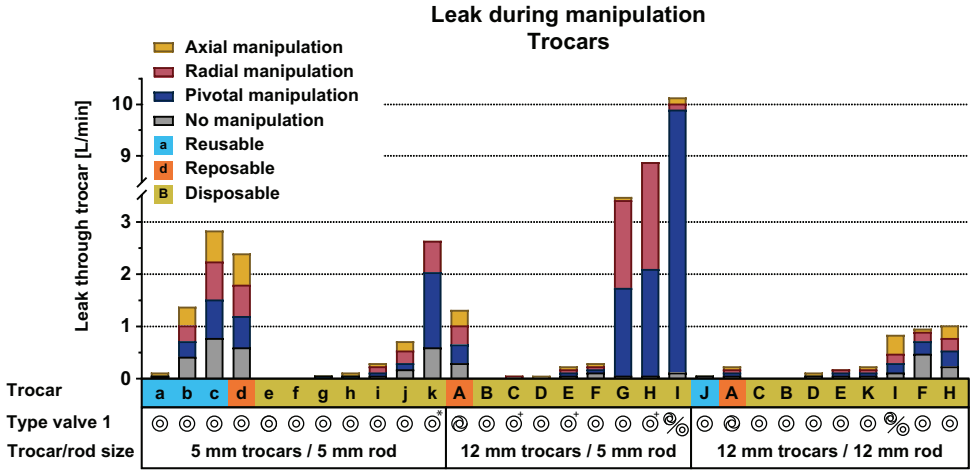

Figure 4.5: Leak through trocar caused by different manipulations with a solid shaft. The symbols below the bars indicate the type of valve 1 that was used on each trocar. The shaft size, number of valves and adapter valve are also indicated below the graph. Trocar I was equipped with a third valve. *single valve. +removable diaphragm 5 mm adapter valve.

Figure 4.5 shows the leak through the trocar when the trocar is manipulated with a solid shaft. The results are stacked to show the leak results of each manipulation that is related to valve 1. In the figure we see that there is a large variation in leak between trocars caused by different manipulations. Even within their respective groups, trocars differ in the amount of leakage caused by the individual manipulations.

4.3.5 Instrument insertion and Valve Distance

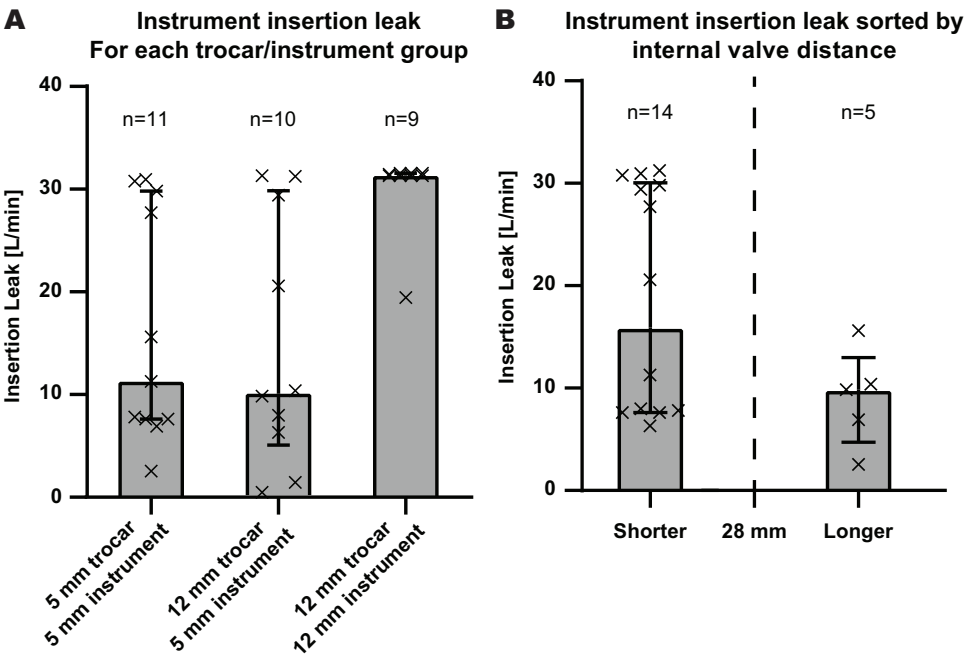

Figure 4.6: A) Leak during instrument insertion trocars grouped per trocar size and used instrument size, median and inter-quartile range per group. B) The effect of valve distance compared to the tool tip length of the surgical instrument, in this case longer or shorter than 28 mm. The height of the boxes is the median value, the crosses represent the inter-quartile range and the crosses are each individual trocar.

In Figure 4.6A the flow through the trocars during instrument insertion can be seen. Both the 5 mm and 12 mm trocars achieved varying results when tested with the 5 mm instrument. The 5 mm trocars with 5 mm instrument had a median of 11.3 L/min (IQR of 7.6 to 29.8), the 12 mm trocar with 5

mm instrument had 10.1 (IQR of 5.1 to 29.9), the 12 mm trocars with 12 mm instrument had a median of 31.3 (IQR 31.3 to 31.6). In the 12 mm trocars with 12 mm instrument group, the measurement results do not reflect the actual leak as it was outside the saturation limit of the sensor.

Figure 4.6B shows a plot of the instrument insertion test, in which all trocars are divided into two groups: trocars with an inter-valve distance larger and shorter than the instrument tip. The figure shows that the trocars with a larger inter-valve distance had a smaller variation in leakage, than trocars with a smaller distance between the valves.

4.4 Discussion

The results of this study show the potential of gas leakage pathways through laparoscopic trocars and instruments. A wide range of leakages through trocars and instruments was found under varying conditions by utilising a protocol of different interactions. These findings show that the choice of equipment as well as the circumstances under which the equipment is used determine the exposure level of OR personnel.

4.4.1 Interpretation of results

Baseline In trocars, valve 2 prevents gas from escaping the peritoneum, therefore the results of the baseline measurement are related to the properties of this valve. However, no clear relation was found between valve type and performance which becomes apparent when observing the large variance in performance of the most used valve: the bicuspid valve.

The median baseline leak of instruments is higher than that of trocars. The results do show a great variation within comparable instrument types. For example, a tenfold difference in leakage was measured between two 5 mm tissue sealing devices of different brands. The choice of instrument type and reusability has a large influence on the total gas leakage. This becomes apparent when comparing the medians and IQR of the 5 mm instrument types. Between these categories, reusable 5 mm instruments perform better than the disposable 5 mm instruments. Upon inspection, the reusable 5 mm instruments were fitted with a rubber seal at the proximal end. Testing the effect of removing this seal could not be tested, yet this seal is expected to have prevented a large portion of the gas flow through the instrument. It

is unclear why other manufacturers have not included similar measures for their disposable instruments.

Manipulation Trocars that perform well during baseline measurements, do not always perform well during manipulation. During the largest portion of a surgical procedure, trocars will be manipulated by an inserted instrument. Therefore, the performance of trocars during surgical manipulation will significantly determine the overall performance in gas leakage of the trocars. The results in Figure 4.5 show the rate of leakage during each manipulation and, therefore, does not represent leakage during surgery.

There are several additional factors that need further research before the results above can be used to predict actual leakage during surgery. Firstly, the frequency and duration of the manipulations during surgery is unknown. These are needed to determine the ratio at which the leakage during each respective manipulation occurs.

Secondly, the manipulations in this study were performed to their maximum effect. For instance, the pivotal manipulation was performed with external stabilisation such that the instrument insertion leakage was reached. In reality, the pivot angle of the trocar is limited by the compliance of the abdominal wall. Therefore, leakage caused by pivoting the trocar will be less during surgery than in this study and will depend on the mechanical properties of the trocar valves and the patient.

Lastly, the steel rods used in this study were selected to match the marketed standard diameters of 5 and 12 mm instruments. In reality, these dimensions vary and could result in higher or lower leakages depending on the interaction between the trocar and instrument.

From the measurements it seems that the 12 mm trocars with 5 mm instruments maintain a less reliable seal when compared to 5 mm instruments in 5 mm ports, especially during pivotal and radial manipulation. Some 12 mm trocars are more successful in accommodating smaller size instruments than others. Some trocars have measures for this, such as trocar C, E, and H yet the apparent measures, such as an adapting valve, do not guarantee a good seal, as can be seen in Figure 4.5. The additional valve in trocar I, does also not increase the performance under manipulations.

Insertion As seen in Figure 4.6, many of the trocars were susceptible to leaks during instrument insertion, especially in trocars that have a small inter-valve distance. The tip length of the 12 mm instrument was much larger than the inter-valve distance of the 12 mm trocars. Despite reaching the sensor saturation limit, Figure 4.6 shows that none of the 12 mm trocars were able to successfully prevent leakage caused by the 12 mm instrument.

4.4.2 Limitations

A total of 11 5-mm trocars were tested and 12 12-mm and 5/12-mm trocars were tested. Each trocar was tested once. The authors were aware that single trocars might not always be representative for a larger sample. Even after careful inspection of trocars, defects might have gone unnoticed.

Not all trocar and instrument manufacturers were represented in this study. The authors were limited to the equipment that was provided, which could therefore be a source of bias. Because of the large variation in trocar valve types and geometries, it was not possible to directly show a statistical relation with the leakage results. For instance, we cannot make claims of the performance of reusable over disposable trocars.

This study did not investigate the incision leak pathway and had only one sample of most trocars and instruments available. The results of this study should therefore not be considered as a recommendation of specific trocars, but should provide information on the leak performance in relation to specific design properties.

4.4.3 Contamination and leakages

The work by Stotz et al. [2] describes type and usage of instruments and trocars during a median of 103 gynaecological laparoscopic interventions. This data can be used to estimate leakage during a hypothetical intervention to add perspective to the individual measurement results of this study.

During the interventions, a four-trocar arrangement was used: one 12 mm trocar for the endoscope, two 5 mm trocars for 5 mm hand instruments, and one 12 mm trocar used for 12 mm surgical instruments. On average 20 instrument changes take place per hour per trocar. The results of the instruments and trocars are used to extrapolate this data. The 25th and 75th percentiles are taken to indicate the spread in leak that was observed.

During surgery, the trocars had no instruments inserted for 16.4 minutes per hour. This situation was measured during the trocar baseline measurements and results in leakages of 0.2 L/hr and 8.8 L/hr for the 25% worst and 25% best performing trocars.

For 43.6 minutes per hour, an instrument is inserted into a trocar. When an instrument is inserted, gas escapes past the trocar valves and through the instrument. These were measured during the instrument baseline measurement, which showed that leakage through the instruments contributes most to the total leakage. Because more data is needed to incorporate each manipulation, only the 'no manipulation' condition is included in the calculation. Combining the leakage of the 25% best and 25% worst performing trocars (8.5 L/hr and 54.4 L/hr) and instruments (8.3 L/hr and 79.4 L/hr), results in 16.9 L/hr and 133.8 L/hr respectively.

Each of the twenty times per hour the instruments are switched, there is an increase in leakage that is assumed to last one second. The level of increase was measured and presented in Figure 4.6. For the two 5 mm and one 12 mm working trocars, the instrument switches contribute 15.5 L/hr and 29.7 L/hr for the 25% best and 25% worst performing trocars.

The choice of equipment can result in a difference of 140 L/hr of escaping CO_2.This example shows that a large variation can be expected between different combinations of trocars and instruments. The impact of this leakage on surgical safety is part of the ongoing debate on the risks of contaminated gas and air in the surgical environment.

Although large volumes of gas seem to have a large influence on the exposure of OR staff to insufflation gas, the method of leakage is equally important. When inserting an instrument a small burst of gas leaks from the trocar. This higher speed might have more severe consequences for the safety of operating theatre personnel as it is released directly into the surgical workspace.

The OR ventilation system will have a major influence on how long gas remains present in the surgical workspace. Operating room airflows are difficult to predict because of the dynamic nature of this workplace. Limiting CO_2 leakage at the source of the equipment, by means of a redesign, could be an alternative way to minimise exposure. The results of this study stress the importance of leak performance indicators for careful equipment selection.

4.4.4 Recommendations

For healthcare personnel concerned about gas leakage, there is no method for choosing equipment based on leakage requirements, as manufacturers do not readily provide this information. As there is currently no universal leakage testing standard for trocars and instruments, such a standard would allow comparison of leakage performance between manufacturers. Additionally, a standardized testing method could also detect equipment failures in reusable trocars after routine maintenance. Wear and damage to the valves during sterile reprocessing of equipment are easily overlooked. For example, two reusable trocars were excluded from the results because they showed much higher leakage during baseline testing. After close inspection, we discovered that the seals under the flap valve were torn or missing. Investigation of wear over time requires comparison of leak performance between multiple trocars of an identical brand and type to exclude the effect of individual samples.

Levels of exposure can be minimised in many ways. One safety measure to prevent insertion leakage that can easily be applied, is to pair instruments and trocars based on tip length and inter-valve distance. However, none of the 12 mm trocars had sufficient inter-valve distance to prevent leakage during instrument insertion. An adapted design with a large valve distance would be an option that substantially increases the size of the trocar. An alternative could be an adapter specifically for use with large-tip instruments such as surgical staplers.

The experiments showed that none of the trocars were able to prevent leakage in all of the tests. More research is needed into the influence of aspects such as: valve material, valve compliance or thickness, valve diameters and manufacturing method. This can be used in the design process of trocars with improved gas leak performance.

4.5 Conclusion

This study quantified gas leaks of equipment in situations related to laparoscopic surgical settings. Not only the individual contribution of trocars and instruments was measured but also the effect of specific trocar-instrument interactions was studied. The results show a large variation between trocars of the same size and type. Additionally, large differences

were observed between instruments of different types meant for the same functionality.

Peritoneal gas possibly carries harmful substances into the OR through the identified leakage pathways. For surgical teams willing to select equipment based on their leak performance, it is difficult to make the selection based on geometric properties and appearance. Therefore, manufacturers should standardise reporting on the leakage performance and incorporate leakage in the design process of laparoscopic equipment.

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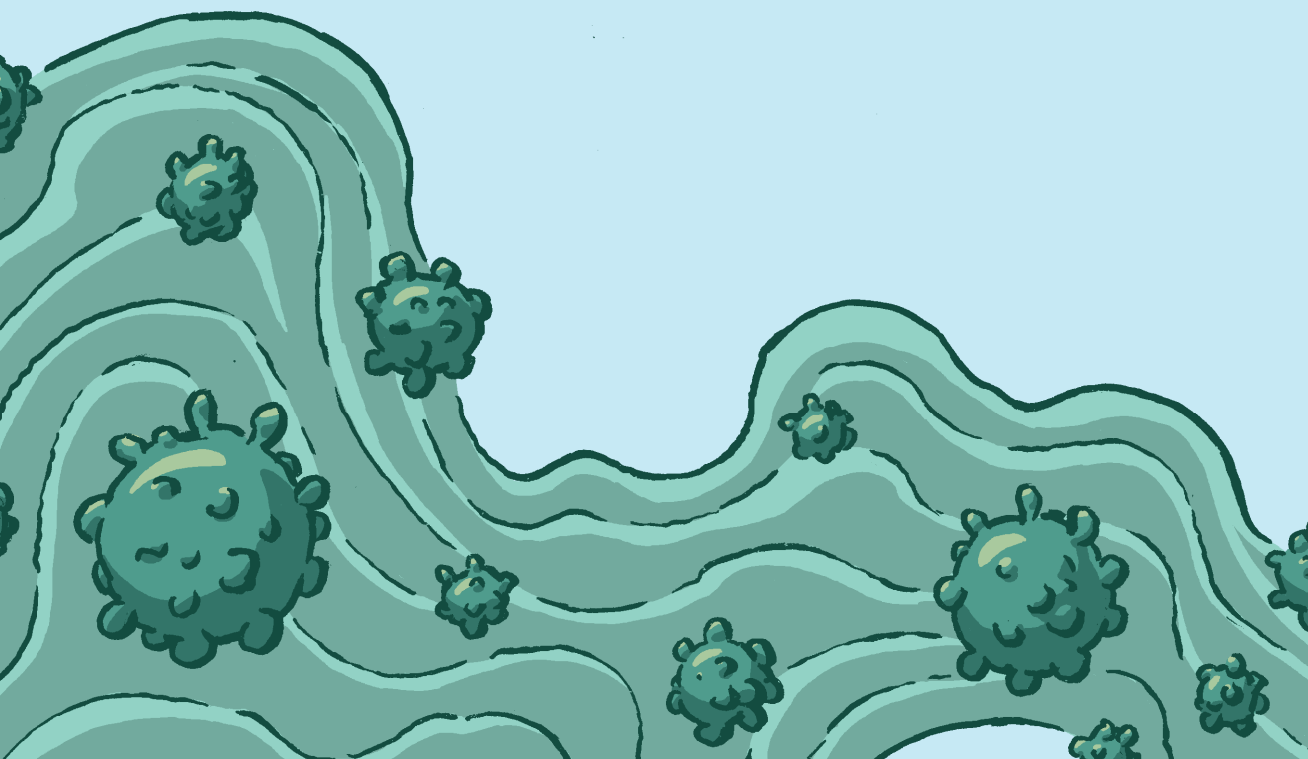


5

The Influence of Prolonged Instrument Manipulation on Gas Leakage through Laparoscopic Trocars

Daniel Robertson, Matthijs van Duijn, Alberto Arezzo, Yoav Mintz, Technology Committee of the EAES, Tim Horeman

Parts of this chapter have been published in Surgical Endoscopy **37** (2023) [1].

5.1 Introduction

During minimally invasive surgery (MIS) like laparoscopic surgery, the surgical site is inflated with carbon dioxide (CO_2) to create sufficient space for tissue manipulation. An insufflator inflates CO_2 gas to differential pressures, commonly between 8-12 mmHg [2, 3]. Trocars act as the access port between the operating room and intra-abdominal environments. Valves inside the trocar prevent CO_2 from escaping the intra-abdominal cavity. Despite the presence of trocar valves, recent studies show that gas leakage could still occur [4, 5].

Leaked gas could contain carcinogenic particles, viruses, and other ultrafine particles, exposing operating personnel [6–10]. Aerosolized human papillomavirus (HPV) and Hepatitis B virus have already been detected in surgical smoke [11]. Additionally, SARS-CoV-2 is known to be viable in aerosols for multiple hours, creating a theoretical risk of transmission [12]. Surgeons expressed concern about contracting COVID-19 during surgery, stressing the risks in clinical practice [13], resulting in a growing need for research clarifying the safety of gas leakage during MIS. Previous research addressing gas leakage has mainly focused on investigating the composition of intra-abdominal gas and its harmful effects [6, 14–16].

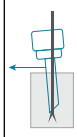
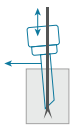
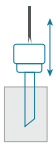
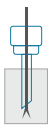
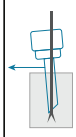
Literature describes three different leakage methods how contaminated gas can leak into the operating room: leakage through the instrument shaft, between the trocar and the incision, and through the trocar [4]. Leakage through the instrument's shaft depends on the individual instrument design and can be considered constant during surgery. Leakage between the trocar and the incision is associated with incision size, abdominal wall composition, and entry technique, making leakage quantities partly subject to the personal skill level of the surgeon. Finally, trocar leakage is influenced by the interaction between the trocar and the instrument [5].

There have been studies that investigated this interaction between the trocar and instrument, however, these do not evaluate whether leakage increases over the longer period of a surgical procedure. Literature has shown that especially trocars that can facilitate instruments with diameters of 10 mm and above show significant gas leakage [4, 5, 17]. Therefore, this study investigates the influence of prolonged instrument manipulation on gas leakage through trocars with internal diameters of 10 mm and above. Since such loading is representative of clinical practice, insight into the trocars' performance under these circumstances is paramount in illuminating gas leakage during surgery.

5.2 Methods

5.2.1 Protocol

Table 5.1: Schematic overview of the measurements

Step number	1	2	3	4	5	6	7	8	9
Action	Empty trocar	Static insertion unloaded	Static insertion loaded	Axial manipulation unloaded	Axial manipulation loaded	Insertion and retraction	Static insertion unloaded	Static insertion loaded	Empty trocar
Duration	1 minute	1 minute	1 minute	20 minutes	20 minutes	18 times	1 minute	1 minute	1 minute
Schematic view									

The instrument manipulations performed during laparoscopic surgery combine axial, pivotal, and radial displacements. To simulate the influence of instrument manipulation during clinical practice on gas leakage through trocars, a protocol was developed to measure the difference in gas leakage before and after manipulation. As the study did not involve human participants or animals, no approval of the Institutional Review Board (IRB) was required.

Static measurements were taken before (steps 1, 2, 3) dynamic measurements as a baseline and after as control measurements (steps 7,8,9) to measure the difference in gas leakage after manipulation. The steps of the protocol are described in Table 5.1. The order of the steps was chosen to increase wear over time. Per trocar, two test rounds of 9 steps were performed, first using a 5 mm instrument and then using a 10 mm instrument. During the first and last steps of the protocol, the trocar was empty where step 9 of the 5 mm instrument sequence doubled as step 1 of the 10 mm instrument sequence. The inserted instrument in the trocar was either moving in the axial direction or static and was either loaded or unloaded.

When the instrument was used, it was inserted so that the tip passed all trocar valves and protruded from the cannula. The loaded steps were performed with a radial load connected to the trocar to mimic the force between the instrument and the trocar. A static weight of 1100 grams was

attached to the trocar using a wire and pulley, resulting in a moment of 0.54 nm, this is in line with loads applied during laparoscopic surgery [18, 19].

The dynamic steps included unloaded and loaded axial manipulation for 20 minutes, with a stroke length of 30 mm and a velocity of 25 mm/s. This is a common velocity during instrument manipulation by experienced laparoscopic surgeons [20]. Step 6 simulates instrument exchanges by consecutively inserting and entirely removing the instrument past all trocar valves 18 times. The removal and insertion velocity was set to 40 mm/s. This is the average instrument exchange rate calculated during 40 minutes of surgery [21–31].

Before the measurement of every trocar, the container was flushed with 35 litres of CO_2 to ensure saturation with CO_2. Subsequently, the silicone nozzle was sealed, and the container was pressurized to 15 mmHg with a flow of 15 L/min to obtain a zero leakage flow measurement for 30 seconds to calibrate the offset of the flow sensor. The test sequence was initiated with the obturator inside the trocar to mimic clinical practice. Measurements were timed, started, and stopped manually using a custom interface on the computer.

All trocar valves were inspected for visual damage after the final measurement. If leakage was suspected, a soap bubble test was performed to locate the leakage. Additionally, trocar-specific testing was conducted based on observations during testing (e.g., peaks in the flow curve, audible gas leakage, visible valve damage) to determine the cause of the leakage.

5.3 Materials

5.3.1 Trocars

Surgeons associated with the European Association for Endoscopic Surgery (EAES) were asked to send in trocars they would use in clinical practice. Trocars with a nominal inner diameter of 10 mm or larger were included. Both new disposable, and reusable trocars with new valves were included. All trocars were inspected for defects and categorized prior to testing.

5.3.2 Experimental Setup

A schematic overview of the experimental setup is presented in Figure 5.1. An airtight, transparent, rigid acrylic container (200x200x250mm) with a wall

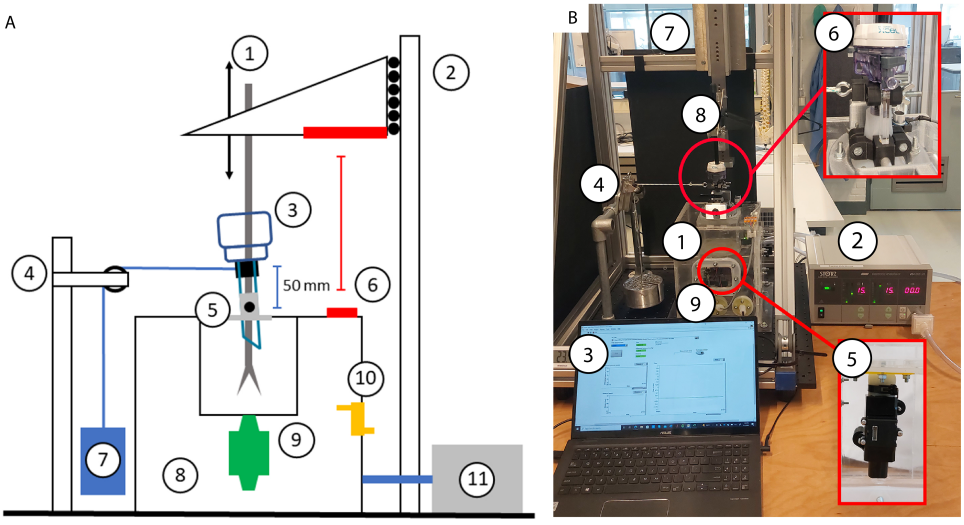


Figure 5.1: A) Schematic of the experimental setup. 1: Laparoscopic instrument, 2: Linear stage, 3: Trocar, 4: Pulley frame, 5: Trocar Mount, 6: Distance sensor, 7: Weight, 8: Airtight container, 9: Flow sensor, 10: Differential pressure sensor, 11: Insufflator. B) Overview test setup. 1: Acrylic container, 2: Insufflator, 3: Laptop running LabView, 4: Static load, 5: Flow sensor, 6: Trocar mount, 7: Linear stage, 8: Laparoscopic instrument, 9: Arduino UNO R3 microcontroller

thickness of 5 mm was manufactured, with multiple through holes for the trocar, insufflation hose, pressure sensor outlet, and wiring. The through holes were air tightened with custom silicone nozzles. The silicone nozzle for the trocar had a smaller diameter than the trocar to prevent leakage. The trocar's pivot point was fixed, and a second clamp was connected to the trocar 50 mm above the pivot point to attach the weight for the loaded steps. Two lids allowed access to the electronics.

Laparoscopic instruments were used to ensure realistic friction between the instrument and the trocar valve. The instrument handle was removed, and the proximal end of the shaft was capped to prevent leakage through the instrument shaft. All tests were conducted with a 5 mm LigaSure Blunt Tip Laparoscopic Sealer (Covidien, Dublin, Ireland) and a 10 mm Endo Babcock instrument (Covidien, Dublin, Ireland). No additional lubrication was added during testing, following the instructions for use provided with new trocars.

The instrument was connected to a linear stage (Festo EGSL-BS-55- 250-12.7P, Festo, Esslingen am Neckar, Germany) that ensures only axial displacement of the instrument. The Festo Configuration Tool (Festo, Esslingen am Neckar, Germany) was used to pre-program the displacements and velocities.

During the experiment, the container was pressurised using an insufflator (Electronic Endoflator Model 26 4305 20, Karl Storz, Tuttlingen, Germany) connected to a CO_2 bottle. To prevent the insufflation flow from distorting the opposing leakage flow, the insufflation hose was connected to a dedicated nozzle at the bottom of the container, instead of to the trocar.

5.3.3 Data Acquisition and Processing

A flow sensor (Honeywell Zephyr, HAFUHH0050L4AXT , Honeywell International Inc., Charlotte, North Carolina, USA) was located collinearly to the trocar to measure gas leakage. The flow sensor was calibrated with CO_2 using a 3 litre calibration syringe (Hans Rudolph series 5530, Hans Rudolph Inc., Shawnee, Kansas, USA). The differential pressure between the lab environment and the inside of the container was measured using a pressure sensor (Honeywell ABPMRRN060MGAA5, Honeywell International Inc., Charlotte, North Carolina, USA). The distance between the instrument mount and container was measured using an ultrasonic distance sensor (HC-SR04, SparkFun Electronics, Niwot, Colorado, USA) to track instrument displacement during instrument manipulation. CO_2 concentration levels were monitored using a thermal conductivity sensor (Sensirion STC31, Sensirion AG, Stäfa, Switzerland), and were displayed using an Arduino Uno R3.

Sensor data was retrieved with an Arduino Uno R3 microcontroller with a sampling frequency of 40Hz. Flow, pressure, and distance data from the microcontroller were recorded in LabVIEW (Version 18.0f2, National Instruments, Austin, Texas, USA).

Diadem (Version 22.0.0f8498, National Instruments, Austin, Texas, USA) was used for data processing, and OriginPro (Version 9.8.0.200, OriginLab Corporation, Northampton, Massachusetts, USA) was used for visualisations. The flow data per step was summarised as the median value. The difference between the control and baseline measurement was presented by subtracting the baseline from the control measurement. Also, the difference between leakage at the start and end of a dynamic measurement was compared. Absolute leakages larger than 0.25 L/min were reported, and

leakages larger than 0.1 L/min were reported for the difference between the control and baseline.

5.4 Results

5.4.1 Included Trocars

Table 5.2: Overview of included trocars. D = Disposable, R = Reusable.

Label	Group	Brand	Type	Use Type	Diameter [mm]	Reference
1-3	1	Sejong Medical	Laport Disposable Trocar	D	12	T11-1210
4-6	2	Applied Medical	Kii Fios First Entry	D	12	CFF73
7-9	3	Applied Medical	Kii Optical Access System	D	15	C0R37
10-12	4	Covidien	VersaStep Plus	D	12	VS101012P
13-15	5	Karl Storz	HICAP w/ multifunctional valve	R	12	30107
16-17	6	Ethicon	Endopath Excel	D	12	B12LT
18-19	7	Ethicon	Endopath Excel	D	11	B11LT
20-21	8	Ethicon	Endopath Excel	D	12	D12LT
22	9	Covidien	VersaOne	D	12	NONB12STF
23	10	Covidien	VersaPort Plus V2	D	12	179096PF
24	11	Covidien	Auto Suture	D	10	OMS-T10BT
25	12	Mölnlycke	Bladeless Dilating Tip	D	12	899312

A total of 25 trocars from six different brands were included. Twelve unique trocar types were available, with diameters ranging from 10-15 mm, 22 trocars were disposable. Equal trocar types were grouped. An overview of all included trocars is presented in Table 5.2. One reusable trocar type was included with a reusable lower valve and a disposable upper valve. This was listed as three separate trocars as the top valve was replaced after each use. This reusable trocar was only compatible with 10 mm instruments. Therefore, the three trocars from group 5 were tested with 10 mm instruments, and the 22 other trocars were tested with both 5 mm and 10 mm instruments. None of the trocars showed visible defects before testing.

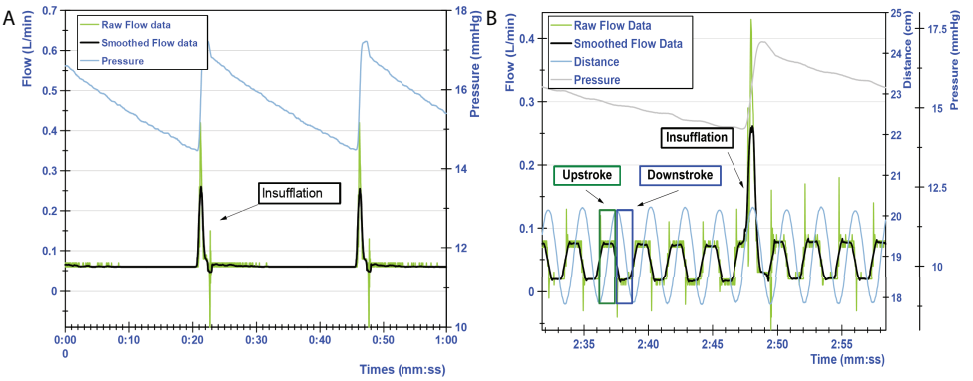


Figure 5.2: Visualisation of the raw, smoothed flows and pressure inside the trocar. A) Example of static flow measurement. B) Dynamic flow measurement

5

5.4.2 Raw Data

Figure 5.2A shows an example of a one-minute unloaded static measurement with a 5 mm instrument. The flow remains steady at around 0.06 L/min. The two peaks in the flow data occur are caused by insufflation and correspond to peaks in the pressure curve. Figure 5.2B shows a 30-second sample of a 20-minute dynamic unloaded measurement with a 5 mm instrument. The distance curve oscillates corresponding to the up and down stroke of the instrument. One additional peak around 0.4 L/min occurs during insufflation.

5.4.3 Manipulation Trocar Leakage

The rate of gas leakage from the trocars during manipulation (steps 4 and 5) is shown in Figure 5.3. The 25 trocars underwent four measurements, except in group 5, as they could only be tested with a 10 mm instrument. Only group 6 showed leakage rates higher than 0.25 L/min which occurred during loaded manipulation. For trocar 17, leakage rates were 5.58 L/min and 5.85 L/min for loaded manipulation with a 5 mm and 10 mm instrument, respectively. Median leakage rates after manipulation (steps 7, 8, 9) per trocar are shown in Figure 5.4. Six measurements are presented for all trocars, while only three are for group 5. Of 141 measurements, 9 (7%) had a median leakage greater than 0.25 L/min. Trocars in group 3 showed a median leakage ranging from 0.30 - 0.41 L/min for loaded measurements

with a 5 mm instrument. Trocars in group 6 showed the highest leakage rates, where trocar 17 had a median leakage for the loaded measurements at step 8 of 5.58 L/min and 5.17 L/min for the 5 and 10 mm instruments, respectively. Trocar 24 showed median empty trocar leakage after the 5 mm and 10 mm instruments, respectively, of 0.29 and 0.36 L/min. Figure 5.5 shows the differences between the static measurement after and before. Positive values indicate that median leakage was higher after manipulation. An increase in median leakage larger than 0.1 L/min was seen in trocars 7,8,9,14, and 24.

All trocars from group 3 (trocars 7,8,9) showed an increase in leakage after manipulation ranging from 0.17-0.22 L/min for the loaded trocar inserted with a 5 mm instrument, increasing from 0.19 L/min to 0.39 L/min.

Trocar 14 from group 5 showed an increase in leakage for both unloaded and loaded measurements with a 10 mm instrument. Baseline leakage for the unloaded and loaded control measurements was -0.01 L/min and 0.0 L/min

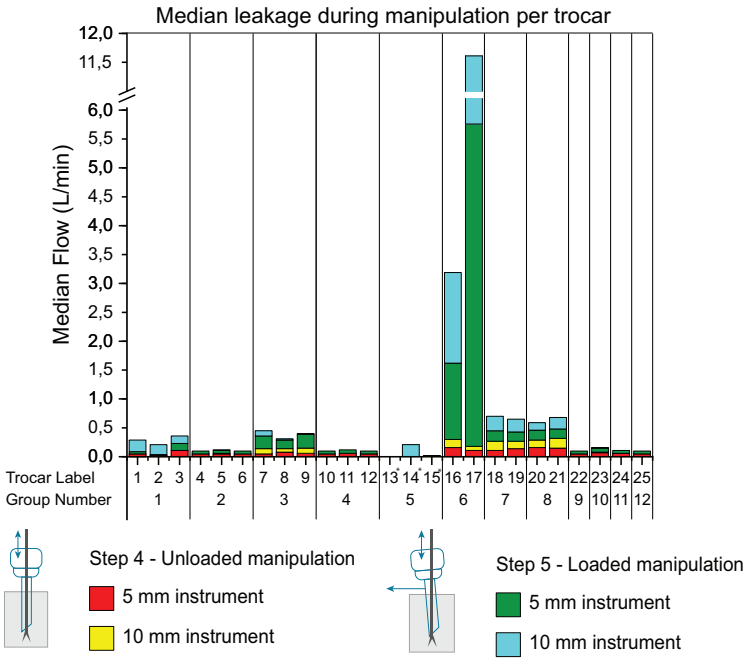


Figure 5.3: Median leakage during manipulation per trocar. Trocar numbers indicated with * were only tested with a 10 mm instrument.

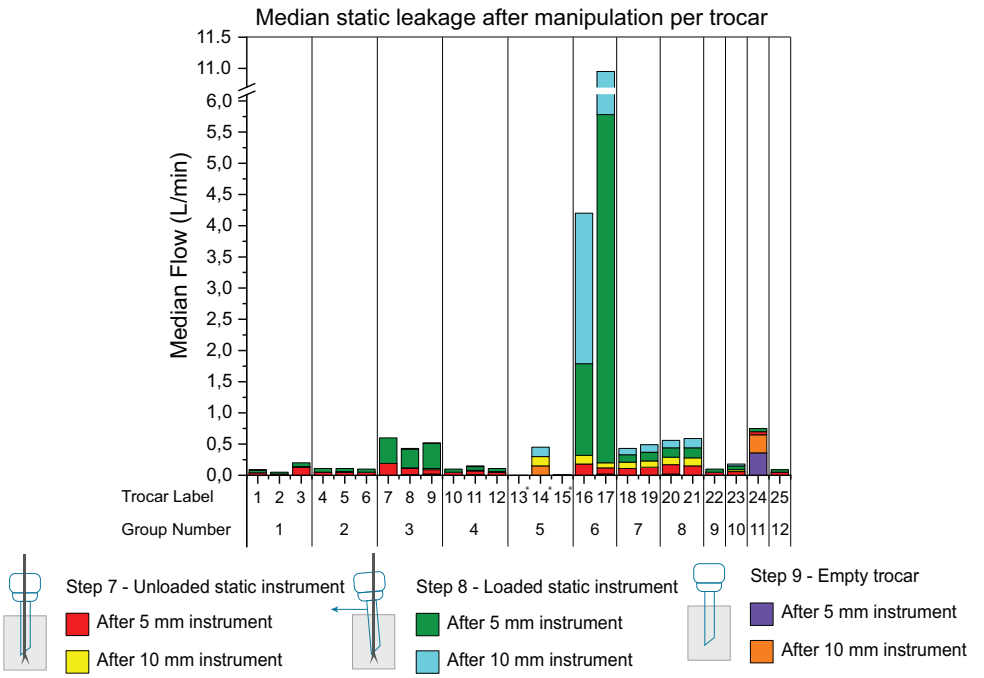


Figure 5.4: Median leakage during manipulation per trocar. Trocar numbers indicated with * were only tested with a 10 mm instrument.

compared to 0.15 L/min and 0.15 L/min for the 5 and 10 mm instruments respectively. Leakage of the empty trocar measurement also increased after manipulation from 0.0 L/min to 0.15 L/min.

Trocars 15, 16, and 17 show a reduction in leakage greater than 0.1 L/min after manipulation. Trocar 15 showed a reduction of 0.14 L/min in median leakage at step 9 with a 10 mm instrument. Trocars 16 and 17 of group 6 showed reduced leakage rates ranging from 0.25-0.56 L/min after manipulation in loaded measurements. Lastly, trocar 24 showed an increased median leakage of 0.36 L/min in the empty trocar measurement after manipulation with a 5 mm instrument. Additionally, trocar 17 also showed a reduction at step 8 for the 10 mm instrument of 0.29 L/min.

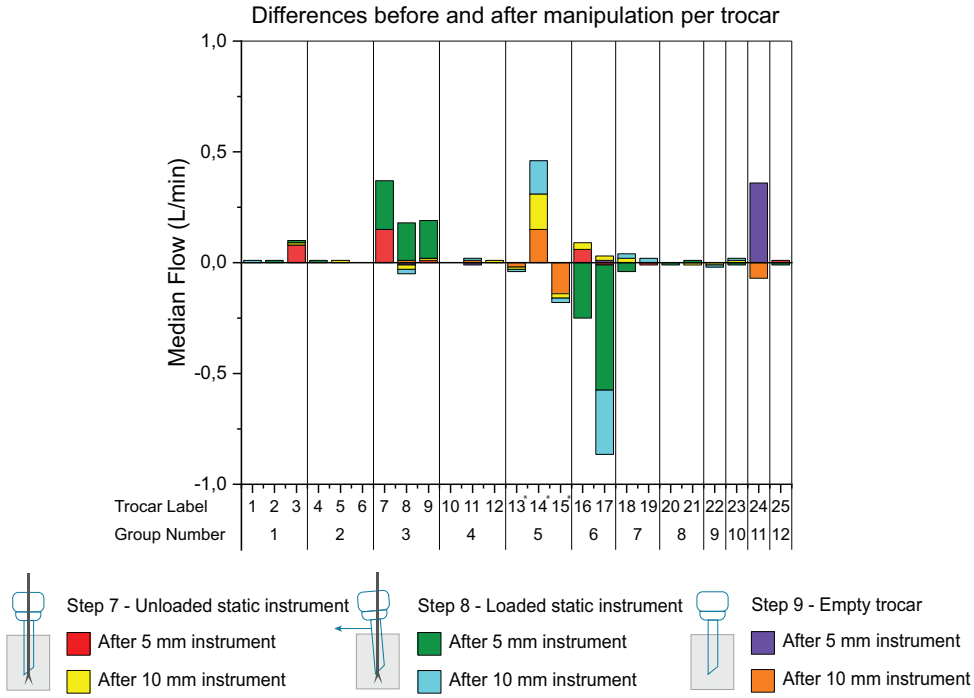


Figure 5.5: Median differences before and after manipulation per trocar calculated by subtracting the static baseline measurement from the static control measurement. Trocar numbers with * indication were only tested with a 10 mm instrument.

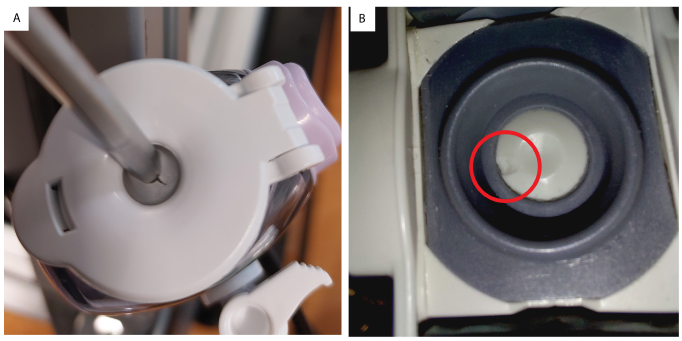


Figure 5.6: Observed damage to trocars after inspection A) Tear in the upper valve of trocar 1. B) Visible damage to the lower valve of trocar 24

5.4.4 Trocar Inspection

Of all 25 trocars, trocars 1 and 24 showed visible damage after the measurements. In trocar 1, a tear was found in the upper valve (Figure 5.6A). This was caused by the upper trocar valve being clamped between the instrument and the trocar during loaded manipulation with a 5 mm instrument. A video of the soap bubble test performed on trocar 1 was added as a supplemental file.

Trocar 24 showed valve damage to the lower valve after manipulation (Figure 5.6B). Before valve damage, the empty trocar leakage was 0.0 L/min. After manipulation, the damaged valve caused a median leakage of 0.36 L/min.

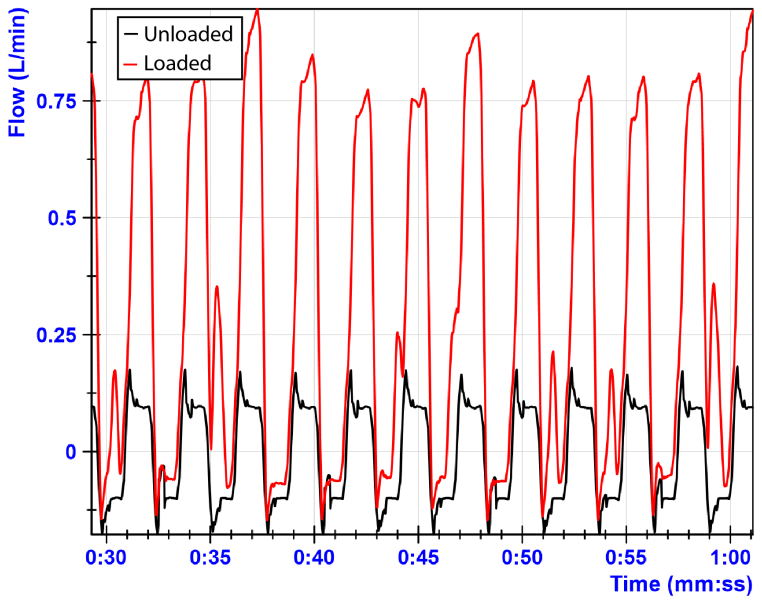


Figure 5.7: Comparison of unloaded versus loaded manipulation of trocar 1

All trocars from group 1 had audible leakage during the upstroke of the loaded dynamic measurement with a 10 mm instrument and were further investigated. Figure 5.7 shows a sample of both the unloaded and loaded leakage curve for manipulation with a 10 mm instrument. This pattern was consistent during the full 20 minutes of measurement data. The figure shows that leakage rates of the loaded measurement are larger during the upstroke than the unloaded measurement. For the down stroke, both curves show similar leakage rates.

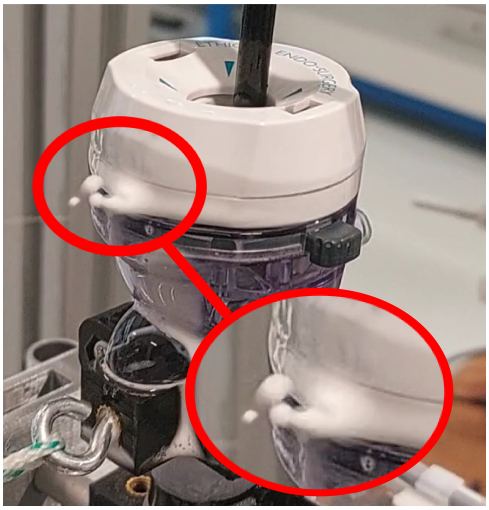


Figure 5.8: Expelled soap bubbles showing leakage between the head and body of trocar 17

Trocars of group 6 showed the highest leakage rates of all trocars and required further investigation. A soap test showed leakage from the connection between the head and body of the trocar (Figure 5.8), a video of this test is provided in supplemental file 2.

The influence of the orientation of the connector orientation was tested by repeating step 8 of the protocol twice: first with the connectors were oriented perpendicular to the load; then with connectors being oriented collinear with the trocar load. In the collinear condition, leakage rates were 0.11 L/min and 0.13 L/min for the 5 mm and 10 mm instruments, respectively. In the perpendicular condition, leakage rates were 4.39 L/min with a 5 mm instrument and 5.42 L/min with a 10 mm instrument.

5.5 Discussion

This study evaluated 25 individual trocars to find the influence of prolonged trocar manipulation on trocar leakage. After applying a series of manipulations on the trocars, it was found that for 20 out of 25 trocars, the leakage rates after manipulation did not differ from leakage rates before manipulation. Six trocars showed leakages larger than 0.25 L/min during one or more of the measurement steps. Two trocars showed damage caused by

manipulation. Additionally, investigation of two trocars revealed undesirable leakage pathways.

5.5.1 Trocar wear mechanisms and recommendations

The valve of trocar 1 developed a tear during loaded instrument manipulation. This trocar was designed such that the upper valve was mounted at the proximal end of the trocar. Therefore, forces applied to the instrument are directly transferred to the trocar valve, causing wear. In other trocars, the upper valve is located deeper in the trocar so that the instrument contacts the trocar body when the instrument is loaded. This configuration is recommended as it limits the friction force on the valve when the instrument is manipulated.

All 15 mm trocars of group 3 showed increased leakage after manipulation with a 5 mm instrument. Although inspection did not reveal any valve damage, the use of the 5 mm instrument in the 15 mm trocar potentially accelerated the wear of the valves. A 5 mm instrument in a 15 mm trocar is generally not recommended, although it could be required during specific procedures.

The reusable trocar in group 5 was tested three times, replacing the upper valve after every set. Despite the newly replaced valve, the second measurement with this trocar showed increased leakage, which could not be explained after inspection for damage. Results from this trocar group suggest that trocars can show varying leakage rates even within a specific trocar type. Robertson et al. [5] also reported significant variations between similar trocars.

Some trocar groups had leakage pathways while still in their new state, such as trocar group 6. These trocars leaked from a seal between the top and bottom part of the trocar, which could be caused by mechanical play in the connection. Trocars from groups 7 and 8 were of the same brand and similar design and did not show this behaviour. A design or manufacturing flaw that can cause a very high increase in gas leakage that can cause a relevant clinical risk to the surgical staff should be detected within the Quality Assurance process of the manufacturer. It is unclear whether manufacturers' testing and inspection protocols include any relevant loading conditions that simulate leakage during normal use of surgical instruments. These testing protocols could be included in the Medical Device Regulations [32].

Trocar 24 developed wear on the lower trocar valve during instrument manipulation. While the instrument was inserted, the spring of the flap valve pushed the valve against the instrument shaft, causing wear on the valve and instrument. Loss of valve material prevented a tight seal which causes leakage. If the manufacturer performed a similar wear test as this study, this leakage could have been prevented by selecting more durable materials.

5.5.2 Limitations and Further research

The study was performed with trocars that were sent to the researchers by surgeon. This meant that group sample sizes were too small to provide a statistical comparison between different trocar groups. Furthermore, four individual trocars were tested and might not represent all trocars of the same type. Additionally, different instruments, than the ones used in this study, might cause more damage to trocar valves during instrument insertions.

Instrument manipulation, during laparoscopic surgery, consists of a combination of pivotal, axial, and radial displacements. Currently, studies presenting detailed information about the interacting force between laparoscopic instruments and trocars are lacking. Accurate force/torque measurements during surgical procedures would enable more accurate load cases in future experimental research.

Using a static trocar load in combination with axial manipulation was chosen for reproducibility, although it is a simplification of clinical practice. The setup resulted in loading a specific part of the trocar valve for a prolonged time, which is more severe than surgical practice. Despite this, leakage did not increase after manipulation. However, other peak loads that might occur in clinical practice might still cause damage to trocar valves.

The median leakage rates of empty trocars found in this study were in line with findings in previous research [17, 33, 34]. In general, most leakage measurements were below 0.1 L/min. However, this leakage would occur continuously during surgery. A surgical procedure of two hours would still result in 12 litres of gas leakage per trocar with a leakage rate of 0.1 L/min potentially resulting in higher costs, more bottle changes, exposure to carcinogens [6] and, in case of outflow of particles, an increased risk to the surgical staff [35].

The leakages measured in this study are small compared to other leakages found in literature. For instance, opening the trocar stopcock results in more

than four litres of leakage per minute [4], which is considered common practice during laparoscopic surgery [6, 36, 37]. During instrument insertions, leakage values up to 17 L/min and 31.3 L/min have been reported by Cahill et al. [4] and Robertson et al. [5], respectively.

Gas leakage through trocars is part of particle escape, along with leakage between the incision and the trocar and through instrument shafts. Several studies have quantified leakage through the trocar and the instrument shaft [4, 5, 17, 33, 38]. However, studies quantifying leakage between the incision and the trocars are still lacking. Therefore future research should focus on this leakage mechanism and influencing factors.

The hazard of these gas leakages is caused by particles present in the abdomen that patients and staff could inhale. These risks can be mitigated by elements such as OR ventilation and smoke evacuation systems. Modern operating theatres use air ventilation above 3000 m3/hour [39]. Nevertheless, Hardy et al. stated that modern operating rooms could not prevent particle spread sufficiently [14]. Studies comparing different types and ventilation properties concerning particle exposure of the operating personnel are needed. The use of smoke removal systems during laparoscopy is an effective tool for removing smoke from the abdomen, improving visibility during surgery.

Whether these systems completely prevent particles from reaching the breathing space of operating room staff has not yet been studied. Therefore, until risks related to gas leakage are clarified, operating personnel should be aware of the potential hazard and adhere to current existing guidelines to mitigate exposure as much as possible.

5.6 Conclusion

During this study, a protocol for prolonged instrument manipulation was developed and applied on 25 individual trocars. The results show that, for most trocars, prolonged instrument manipulation did not influence gas leakage rates in dynamic and static measurements. Nevertheless, the study did show that instrument manipulation caused damage to some trocars and revealed new unintended leakage pathways in individual trocars. These failure mechanisms, presented in this study, could guide new trocar development, design guidelines, and testing protocols and as a possible starting point for future research.

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6

Escape of surgical smoke particles, comparing conventional and valveless trocar systems

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Parts of this chapter have been published in Surgical Endoscopy **37** (2023) [1].

6.1 Introduction

During minimal access surgery, a trocar system is used to insufflate the abdominal cavity with carbon dioxide (CO_2) gas to provide the surgeon with surgical workspace. This system is a combination of an insufflator, which regulates the flow and pressure of gas, and a trocar. Trocars are ports for surgical instruments to enter to the abdominal cavity, and seal the pressurised gas inside. Conventional trocar systems, also known as closed trocar systems, utilize valved trocars to prevent the outflow of insufflated CO_2 gas.

In recent years, valveless trocar systems, also known as open, flow-through, constant-pressure barrier, gasketless, or valve-free systems have been developed. These use a pressure barrier within the trocar to maintain pneumoperitoneum pressure. This system was developed to overcome problems with conventional trocars, such as difficulty with the removal of specimens and needles, and soiling of the telescope lens [2–4]. Valveless systems inject CO_2 at high flows through the working channel of the trocar to form the pressure barrier that maintains the pneumoperitoneum. The pneumoperiteum pressure is measured at the distal trocar tip, while gas taken up at the proximal side is taken up, filtered and re-injected through the working channel [5].

Benefits of valveless trocars compared to conventional trocars include: a more constant insufflation pressure, less friction between the trocar and surgical instruments, and improved smoke removal [4, 6]. However, some controversy exists on the use of valveless trocar systems. Previous studies have shown that their use can lead to the entrainment of air [7, 8] which might affect peritoneal pressure, humidity, carbon dioxide concentration, and temperature [9].

During surgery, tissue is cut or coagulated using electrosurgical devices. This produces surgical smoke, which contains a mixture of water vapour, ultrafine particles, and vaporized biological materials [10]. Smoke can obscure the surgical field, leading to surgical errors, and longer operative times [11]. When smoke escapes from the abdominal cavity, it is prone to inhalation by the surgical team. A growing body of evidence on the health risks of exposure to surgical smoke includes respiratory and systemic infections, allergic reactions, and cancer [11]. Especially in times of Covid-19, surgeons became more aware of the risks related to surgical smoke as a potential carrier of harmful particles [12].

Various laparoscopic surgical smoke removal solutions have been developed to mitigate these risks and improve the overall surgical experience. These systems use filters, suction devices, and other methods to remove smoke generated during surgery. Conventional trocar systems commonly use a separate suction line to remove smoke. The valveless trocar systems adopt a more integrated solution to prevent surgical smoke particles from escaping into the operating room, which actively suctions and filters the abdominal gas before reinsufflating it.

Some studies characterised the particle interaction of trocar systems. No studies were found that quantified the number of particles that escape conventional trocar systems. For valveless trocar systems, Dalli et al. evaluated user safety and reported the escape of particle-rich aerosols through an AirSeal Access Port (CONMED Corporation, Largo, USA) during transanal surgery [13]. Lathers et al. compared the intra-abdominal surgical smoke distribution between conventional and valveless trocar systems in a benchtop setup [14]. This study found a higher smoke evacuation rate when using valveless trocars, although a higher percentage of particles escape from the trocar port. However, these studies do not allow for a direct comparison of the number of particles that escape these trocar systems.

This study investigates the difference in particle escape between a conventional and a valveless trocar system in an in-vitro model. The model facilitates different pressure settings, and differently-sized laparoscopic instruments, and contains a moving mechanical diaphragm to closely mimic the effect of ventilation on the pneumoperitoneum.

6.2 Materials and Methods

During this experiment, a conventional and a valveless trocar set were selected for comparison in an in vitro model. A protocol was defined to determine the influence of instrument diameter, pressure and ventilation on particle leakage. An overview of the experimental setup is shown in Figure 6.1. As the study did not involve human participants or animals, no approval of the Institutional Review Board (IRB) was required.

6.2.1 Trocar Systems

The conventional trocar system was a combination of an insufflator (ELECTRONIC ENDOFLATOR model 26 4305 20, Karl-Storz GmbH & Co. KG,

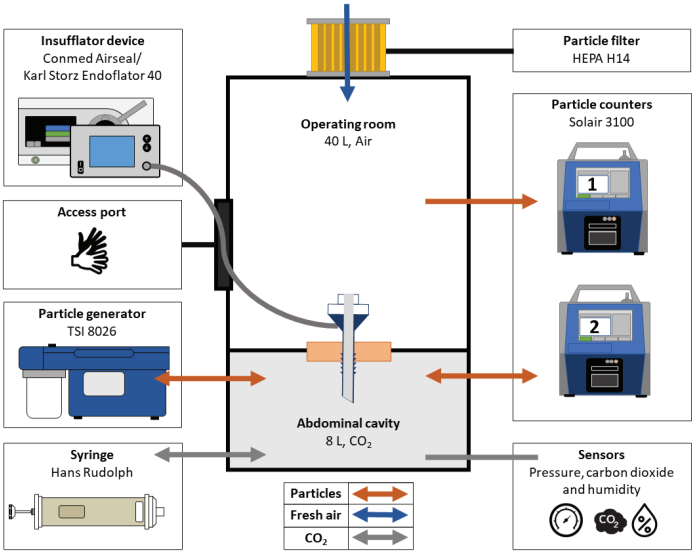

Figure 6.1: A schematic overview of the in vitro model for measuring particle leaks during laparoscopic surgery. The insufflator, access port, particle generator and syringe are on the left side. On the right, filters and measurement equipment and HEPA filter.

Tuttlingen, Germany) connected to a 12 mm trocar (Kii Optical Acces System, Applied Medical Resources Corporation, Rancho Santa Margarita, CA, USA) using a 300 cm filtered insufflation tube (Insufflation tubing set with gas filter, model 031200-01, Karl Storz GmbH & Co. KG, Tuttlingen, Germany). The conventional trocar had an internal diameter of 13.4 mm at the proximal end and 13.1 at the distal end. The valveless trocar system included an AirSeal iFS insufflator (CONMED Corporation, Largo, USA), connected via a tri-lumen filtered tube set to the AirSeal Access port (ASM-EVAC1, CONMED Corporation, Largo, USA). The valveless trocar had an internal diameter of 13.4 mm proximally and 13.2 distally. The wall separating the reservoirs, holds a silicone nozzle through which the trocar can be inserted. To ensure repeatable measurement condition, the silicone nozzle was designed to create an airtight seal between the trocar and abdomen. The airtightness of the seal was verified through a soap bubble test.

During surgery, mechanical ventilation influences the mechanics of the abdominal cavity through movement of the diaphragm. This is simulated

with a 3 L syringe (Hans Rudolph Inc., Shawnee, USA) driven by a linear actuator (EGSL-BS-55-250-12.7P, Festo, Esslingen, Germany). The syringe was placed outside the abdominal cavity and could push gas back and forth to mimic the volume displacement of the diaphragm. As the model in this study has a stiffness different from the abdominal wall, the displacement of the syringe was chosen such that the pressure in the model mimics the abdominal pressure variations that occur during laparoscopic surgery. During this study, the total volume displacement was 30 mL at a simulated respiratory frequency of 15 breaths per minute. The diaphragm distortion in the model was similar to the pressure pattern described by Perretta et al.[8]. The actual displacements used for the study are added as a supplemental file to the original article [1].

To simulate surgical smoke, a particle generator (model 8026, TSI Incorporated, Shoreview, USA) was used to saturate the simulated abdominal cavity with particles. The particle generator was placed inside of the abdominal cavity. This generator produces particles by evaporating a sodium chloride solution by pumping air through the solution at a rate of 1.5 L/min. The particles measured in this study ranged between 0.3 µm and 1.0 µm, which falls within the particle size range of surgical smoke [10, 15, 16].

6.2.2 Protocol

6.2.3 In vitro model

The model consists of two circular acrylic reservoirs with a wall thickness of 4 mm, as can be seen in Figure 6.1. The lower, 8-litre, reservoir simulates the abdominal cavity and the upper, 40-litre, reservoir serves as the operating room environment. The sensor equipment and smoke generator were placed within the abdominal cavity. This equipment occupies 2.5 litres within the 8-litre reservoir, resulting in an effective volume of 5.5 litres, which is consistent with abdominal volumes found in literature [17]. The size of the operating room environment was chosen such that it represents the breathing space of the surgeon. A 0.2 µm HEPA H14 filter prevents background particles from moving in or out of the operating room environment. The filter also allows the pressure in the operating room environment to equalize to ambient pressure. The insufflator setting determines the pressure in the abdominal cavity.

1. **Baseline**: Start with the obturator inserted. For the valveless trocar system, the instructions for use indicate that the obturator should stay

in during startup [18], the same was done when using the conventional insufflator system.

2. **Remove Obturator**: The obturator is removed such that an instrument can be inserted into the trocar.
3. **Diaphragm movement**: The effect of diaphragm movement was investigated by activating the linear actuator and syringe.
4. **Insert instrument**: For investigation of particle leak during normal use, an instrument was inserted through the entire trocar.
5. **Remove instrument**: The instrument is removed to investigate the difference with phase four.
6. **Diaphragm movement off**: Ventilation is turned off to investigate the difference with phase three.
7. **Baseline**: The obturator is inserted to confirm the influence of the trocar on particle escape.

As the insufflation pressure and instrument diameter are known to affect gas leakage [18], the measurements were performed at three different insufflation pressures: 5, 10 and 15 mmHg, each with two instrument diameters. Therefore, four cases were defined: 1) conventional insufflation with a 5 mm instrument; 2) conventional insufflation with a 10 mm instrument; 3) valveless insufflation with a 5 mm instrument; and 4) valveless insufflation with a 10 mm instrument. Solid rods with the corresponding diameters were used as instruments. The conventional insufflator flow setting used for all cases was 5.0 L/min. The valveless insufflator was used in AirSeal mode, at 5.0 L/min insufflation flow, and low smoke evacuation.

Each recording was repeated three times to ensure repeatable conditions, for atmospheric changes due to the weather and conditions in the lab could affect the results. The pressure, humidity, carbon dioxide concentration and temperature were monitored and recorded to verify the conditions within the abdominal cavity. In total, the combinations of pressures, instruments and repetitions led to 18 recordings for each type of trocar system.

6.2.4 Data collection and processing

Two laser particle counters were installed that measured particles ranging from 0.3 µm to 10 µm (Solair 3100, Lighthouse Worldwide Solutions, Medford,

OR, USA). The first particle counter counted the particles in the operating room environment. The second particle counter was used to quantify the particles created within the abdominal cavity. A closed measurement system was required to allow pressure build-up in the abdominal cavity. To this end, the outlet of the particle counter fed back into the abdominal cavity. These devices count the number of particles that pass the sample port in three seconds at a flow rate of 28.3 litres/minute. Flow rates of all particle sizes were summed. By dividing the counted number of particles by three, the total number of particles per second were obtained.

The pressure sensor (ABPMRRN060MGAA5, Honeywell International Inc., Charlotte, NC, USA) measured pressure within the abdominal cavity relative to the ambient air. Humidity and temperature were measured using one sensor in the abdominal cavity (Asair AHT10, Guangzhou Aosong Electronic Co., Ltd., Guangzhou, China). Another sensor, placed inside the abdominal cavity, was used to record the carbon dioxide concentration, (STC31, Sensirion AG, Stäfa, Switzerland).

The data from the particle counters was retrieved over a serial connection. A custom data acquisition program was created in LabVIEW (NI Instruments Corp., Austin, TX, USA) to retrieve sensor data at a 1 Hz sampling frequency. The other sensors were read out through a LabJack T7 (LabJack Corporation, Lakewood, CO, USA), which was then recorded by the same data acquisition program. All data was automatically labelled and stored in tab-separated columned files.

The recordings were analysed using MATLAB (MathWorks, Inc., Natick, MA, USA). The analysis was limited by a small sample size. Therefore, instead of taking the mean, the median recording was calculated and presented. The spread between the measurements was reported by calculating the interquartile range (IQR).

All of the recordings were visually inspected to verify similar experimental conditions. Then, the variation of the experimental conditions between recordings of the valveless and conventional insufflation system was verified, by calculating the median and IQR of humidity, temperature, and carbon dioxide concentration for the combined 18 recordings, per phase. This verification of the experimental conditions was also performed for the combined three recordings of each pressure level, per trocar system. The effect of pressure, instrument diameter, and surgical phase on particle leakage was calculated by taking the median, minimum and maximum particle leakage of three recordings. The average leakage per phase was

calculated by taking the average over the three pressure levels, for each instrument diameter.

6.3 Results

During the measurements, the valveless trocar and the conventional trocar showed different responses to the protocol. To illustrate this, two recordings are shown in Figure 6.2: one repetition for the valveless and conventional trocar systems at 15 mmHg with a 10 mm instrument. Figure 6.2A shows the pressure measured in the abdominal cavity using each of the trocar systems, and in Figure 6.2B the number of particles in the operating room environment and in the abdominal cavity can be seen.

The first phase started with the obturator still inserted in the trocar. While the obturator was inserted, the pressure maintained by the valveless trocar was higher than the set pressure, whereas the conventional trocar showed no pressure difference. The variation seen in the first phase for both graphs was caused by the insufflation of gas to maintain the set abdominal pressure.

In phase two, after the obturator was removed, both trocars show a drop in abdominal pressure. The systems drop to 3.8 and 10.4 mmHg and recover to the set pressure in approximately 2.5 and 8 seconds, for respectively the conventional and valveless trocar system. After recovering the abdominal pressure, the pressure with the conventional trocar varied more (IQR of 1.2) than with the valveless trocar (IQR of 0.4) due to insufflation peaks. These peaks were not seen with the valveless system.

Diaphragm movement was started after the second phase. This can be seen in the graph of the conventional system, which varies in conjunction with the applied diaphragm movement. The valveless trocar did not respond as much to the diaphragm movement and maintained a more stable pressure (IQR of 0.4) than the conventional trocar (IQR of 2.2). The pressure maintained by the valveless trocar was consistently lower than the set pressure. During the last phase, the obturator was re-inserted, which can be seen in the pressure graphs for both systems.

The pressure response of each trocar system, as seen in Figure 6.2A, can be related to the values in Table 6.1. The table shows the median and IQR pressures of six combined recordings of two instrument diameters. The median values and IQR per trocar system and phase were consistent

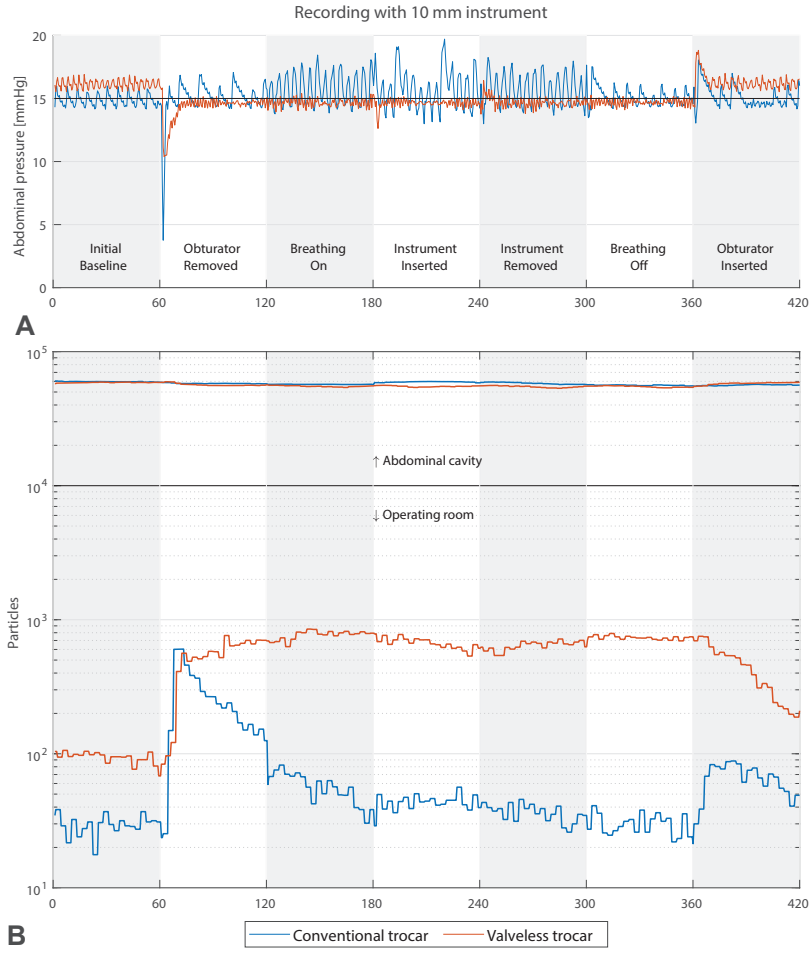

Figure 6.2: An example of two recorded samples in the conventional trocar system (blue) and the valveless trocar system (orange), both recordings were obtained using a 10 mm instrument while the insufflation pressure was set to 15 mmHg. A) Pressure setting (black) and pressures measured within the abdominal cavity. B) On the logarithmic y-axis, the counted number of particles, with a size ranging between 0.3 – 1 µm, within the operating room environment during every protocol phase.

throughout all recordings. During the phase in which the obturator was removed the valveless system had a lower median pressure when compared

to the conventional system. During the diaphragm movement phases the pressure IQR was higher for the conventional system when compared to the valveless system.

Table 6.1: Pressures recorded in mmHg within the abdominal cavity. Median and IQR for both trocar systems pressure for each phase.

per pressure n = 6	Pressure (mmHg)	Baseline	Obturator removed	Breathing on	Instrument inserted	Instrument removed	Breathing off	Obturator inserted
Conventional	5	4.6 (1.0)	5.2 (0.9)	5.9 (1.5)	4.9 (1.4)	5.5 (1.0)	5.5 (0.2)	4.7 (0.2)
	10	9.8 (0.9)	10.0 (1.0)	11.7 (1.5)	10.0 (2.4)	10.9 (1.8)	9.9 (0.7)	9.8 (0.4)
	15	14.9 (0.8)	15.0 (0.7)	16.8 (1.6)	14.1 (1.6)	14.7 (1.2)	15.2 (0.7)	15.0 (1.0)
Valveless	5	6.2 (0.7)	4.6 (0.2)	4.6 (0.2)	4.7 (0.1)	4.6 (0.3)	4.7 (0.1)	5.8 (0.3)
	10	11.2 (0.8)	9.7 (0.4)	9.6 (0.3)	9.7 (0.3)	9.7 (0.2)	9.6 (0.2)	11.0 (0.5)
	15	16.1 (0.6)	14.7 (0.4)	14.9 (0.4)	14.7 (0.6)	14.5 (0.5)	14.8 (0.5)	16.0 (0.6)

6.3.1 Measurement conditions

Figure 6.2 is exemplary for all measurement conditions. To verify for consistency between measurement conditions, the humidity, temperature, particle number in the abdominal cavity, and CO_2 level were monitored. Table 6.2 shows the medians and IQR's of these values for the 18 recordings per trocar system, and similarity between the conditions that both trocar systems underwent.

Within the abdominal cavity approximately 6×10^4 particles were measured for the conventional and valueless trocar at 15 mmHg. The measurement conditions when using the conventional system remained constant. During recordings with the valveless system, the humidity level dropped slightly and the CO_2 level increased slightly, which can be seen in Table 6.2.

Table 6.2: Medians and IQR for temperature, humidity and CO_2 recorded during each phase.

per system n = 18	Condition	Baseline	Obturator removed	Breathing on	Instrument inserted	Instrument removed	Breathing off	Obturator inserted
Conventional	Temp. (°C)	33.7 (2.3)	33.8 (2.2)	33.9 (2.1)	33.9 (2.0)	34.0 (2.0)	34.0 (2.1)	34.1 (2.0)
	Hum. (%)	26.1 (6.3)	26.1 (6.1)	26.2 (5.9)	26.1 (5.7)	26.2 (5.8)	26.4 (5.8)	26.5 (5.7)
	CO2 (%)	94.6 (0.8)	94.6 (0.7)	94.6 (0.8)	94.6 (0.7)	94.5 (0.7)	94.6 (0.7)	94.6 (0.6)
	Particles (1×10^4)	6.2 (1.4)	6.3 (1.4)	6.3 (1.5)	6.2 (1.6)	6.2 (1.7)	6.3 (1.8)	6.2 (1.4)
Valveless	Temp. (°C)	33.0 (4.7)	33.0 (4.7)	33.0 (4.7)	33.1 (4.7)	33.2 (4.6)	33.4 (4.6)	33.6 (4.4)
	Hum. (%)	22.0 (2.8)	19.1 (2.2)	18.2 (2.2)	17.7 (2.1)	17.5 (2.2)	17.3 (2.2)	19.9 (2.3)
	CO2 (%)	96.5 (0.8)	96.9 (0.6)	97.0 (0.6)	97.0 (0.6)	97.0 (0.5)	97.1 (0.5)	96.8 (0.7)
	Particles (1×10^4)	6.6 (0.9)	6.3 (1.0)	6.2 (1.1)	6.1 (1.0)	6.1 (1.2)	6.0 (1.2)	6.5 (1.3)

6.3.2 Particles

Figure 6.3 shows the particles that escape into the surgical workspace. Each Subfigure shows a combination of a trocar system and instrument diameter. The median of three recordings for each pressure level is shown within each Figure. The number of particles that escaped the trocar systems per second is shown in Table 6.3, the average per phase was calculated over the three pressure levels. When using the conventional trocar, a release of particles was seen after inserting or removing the obturator, corresponding with the pressure drop in Figure 6.2A. The level of particles then decreased as the number of particles leaking into the surgical workspace was less than those removed by the particle counter. Figure 6.3A shows that after inserting the 5 mm instrument, the leakage of particles increased, which can be seen in the 'instrument inserted' phase. During the insertion phase of the 5 mm instrument, the average measurement for all pressure levels was 211 particles per second. Figure 6.3C shows that this leakage was absent when the 10

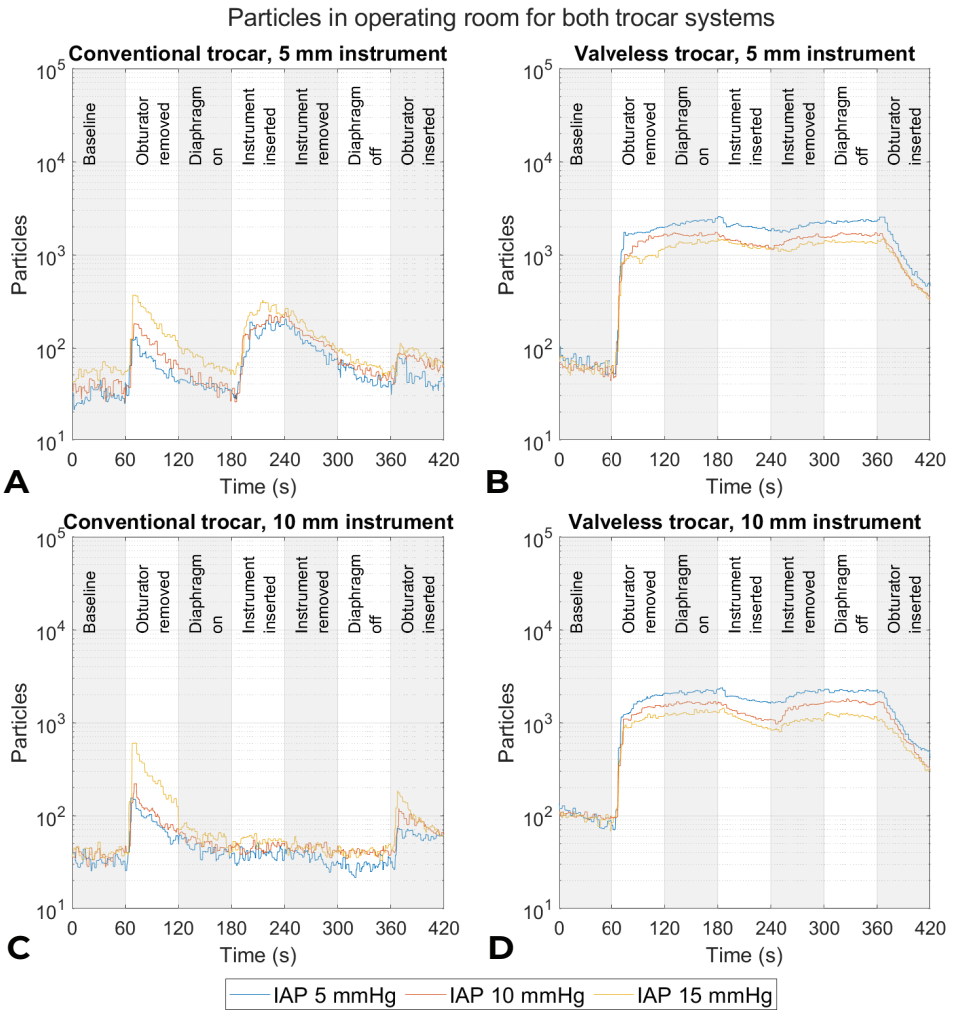

Figure 6.3: Four panels, with a logarithmic y-scale, showing the number of counted particles over time. Three different pressure conditions per panel: 5 mmHg (blue), 10 mmHg (orange) and 15mmHg (yellow). Included particle sizes, 0.3 – 1 µm. A) Conventional insufflation and a 5 mm instrument. B) Valveless insufflation and a 5 mm instrument. C) Conventional insufflation and a 10 mm instrument. D) Valveless insufflation and a 10 mm instrument.

mm instrument was used, which had an average of 50 particles per second. When using the conventional trocar, a higher abdominal pressure led to a higher leakage of particles.

Table 6.3: Averaged exposure to particles for each phase and instrument, in particles per second.

per size n = 9	Instrument size (mm)	Baseline	Obturator removed	Breathing on	Instrument inserted	Instrument removed	Breathing off	Obturator inserted
Conventional	5	44 (27)	68 (50)	48 (33)	211 (111)	89 (21)	46 (17)	64 (22)
	10	40 (27)	73 (35)	38 (17)	50 (13)	35 (15)	39 (17)	61 (16)
Valveless	5	54 (70)	1716 (770)	1745 (700)	1276 (580)	1531 (640)	1722 (573)	396 (114)
	10	86 (44)	1508 (660)	1598 (670)	1084 (630)	1610 (771)	1637 (714)	358 (150)

Figure 6.3B and 6.3D show the release of particles when the valveless system was in use. A sharp increase in particle leakage was seen when the obturator was removed from the valveless trocar, this also coincided with the pressure drop seen in Figure 6.2A. The level of particles increased to a higher level, which remained relatively constant until the obturator was re-inserted. A slight decrease in particle release was seen when an instrument was inserted. The decrease was more substantial for the 10 mm instrument. During the instrument insertion phase, the average number of particles across the three pressure levels was 1276 and 1084 particles per second for the 5 mm and 10 mm instruments, respectively. A lower escape rate of particles was found when higher insufflation pressures were in use.

6.4 Discussion

This study investigated particle escape when using two different trocar systems in a benchtop setup. Each trocar system releases particles differently, depending on the set pressure and instrument diameter. This study shows that a higher number of particles is released into the surgical workspace when using a valveless trocar when compared to a conventional trocar.

The conventional trocar system releases particles at two distinct situations during surgery. The first concerns the insertion of a 5 mm instrument into a

12 mm trocar, which can be explained by the incomplete seal. This leakage is in line with a previous study by Robertson et al. that evaluated leakages in laparoscopic trocars [19]. The second moment of leakage occurs when the obturator is handled. The obturator provided with the conventional trocar has a hollow shaft with holes, providing a direct pathway for the abdominal gas to leak into the operating room environment.

The valveless trocar system has a tubeset which is designed to filter the abdominal gas before it is released into the surgical workspace. Similar to the study by Lathers et al. [14], this study shows that particles from the abdominal cavity are released from the trocar into the operating theatre, despite the presence of filters.

Lower abdominal pressures in the valveless system caused more particles to escape into the operating room environment, which is also in line with the study by Lathers et al. [14]. This could be explained by the pressure barrier inside the trocar, providing a less efficient separation at lower pressures, causing more leak into the operating room environment.

During use of the valveless trocar, the humidity and CO_2 values deviate from their initial values. These variations are not observed when using the conventional trocar, and are likely due to the higher gas flow in the abdominal cavity of the valveless trocar. The humidity level within the in vitro model was not representative of a clinical setting. Therefore, the influence of the drop in humidity should be further investigated clinically. Although not the primary aim of this study, the valveless trocar system was observed to be better suited to mitigate pressure fluctuations in the abdomen due to mechanical ventilation than the conventional trocar system.

6.4.1 Limitations and outlook

The in vitro model in this study was developed to create controllable conditions for comparison between the trocars, however, the influence of some factors will require further investigation. The influence of different steps of the protocol was different per trocar, per phase. Because these results were pronounced enough for a comparison between the trocars, the duration of the steps was not long enough for the conditions to return to baseline. In future, by choosing a longer duration of the steps, it could give more insight into the behaviour of each system.

The number of detected particles in the upper volume is influenced by the placement of components, the extraction rate of the particle counters and

the size of the model. For this reason more studies are needed to determine the actual number of particles that a surgeon would breathe in to allow for a direct comparison. For example, such studies should include the effect of the ventilation systems within an OR.

Only one trocar of each type was used in the study to enhance reproducibility. Noteworthy is that not all conventional trocars follow the same design concept, leading to substantial differences in leak performance [19].

The model also differs from an in vivo setting as the stiffness of the model is different than the stiffness of an abdominal cavity. This might have altered the pressure effects. Additionally, the humidity level in the model was lower than in an in vivo situation. The influence of these factors on trocar performance still needs to be investigated.

When using the valveless trocar, the pressure in the abdomen showed significant fluctuations in several measurements when the obturator was inserted, which disappeared after obturator removal. The cause of these pressure variations could unfortunately not be determined. These conditions did not result in differing initial conditions between the two trocar systems.

Whether the particles that escape during laparoscopy enter the breathing air of operating room staff is not yet clearly understood. The actual exposure of surgery room staff to smoke particles has sparsely been studied [20], and should therefore be further investigated. Many studies have linked the inhalation of ultrafine particles, which are smaller than 0.1 µm, to neurological and psychiatric disorders [16]. These fine particles penetrate medical masks such as the standard N95 mask. This emphasizes the need to for adequate smoke removal during minimal access surgery, to prevent detrimental effects to either the patient or the surgical team.

6.5 Conclusion

This study shows that valveless trocar systems release more particles into the operating room environment than conventional trocars for commonly used abdominal pressures. During instrument insertion, the leakage through the valveless trocar is 6 to 20 times higher than with a conventional trocar. Furthermore, the degree of this leakage depends on the set pressure and instrument size. For higher set pressures, the conventional trocar system shows a higher degree of leakage. The leakage from the valveless trocar is smaller with higher set pressures. Leakage also depends on instrument

diameter, depending on the seal. Therefore, the choice for the surgeon to use the valveless trocar system has the advantage of having better pneumoperitoneal stability at the risk of increased exposure to potentially harmful smoke.

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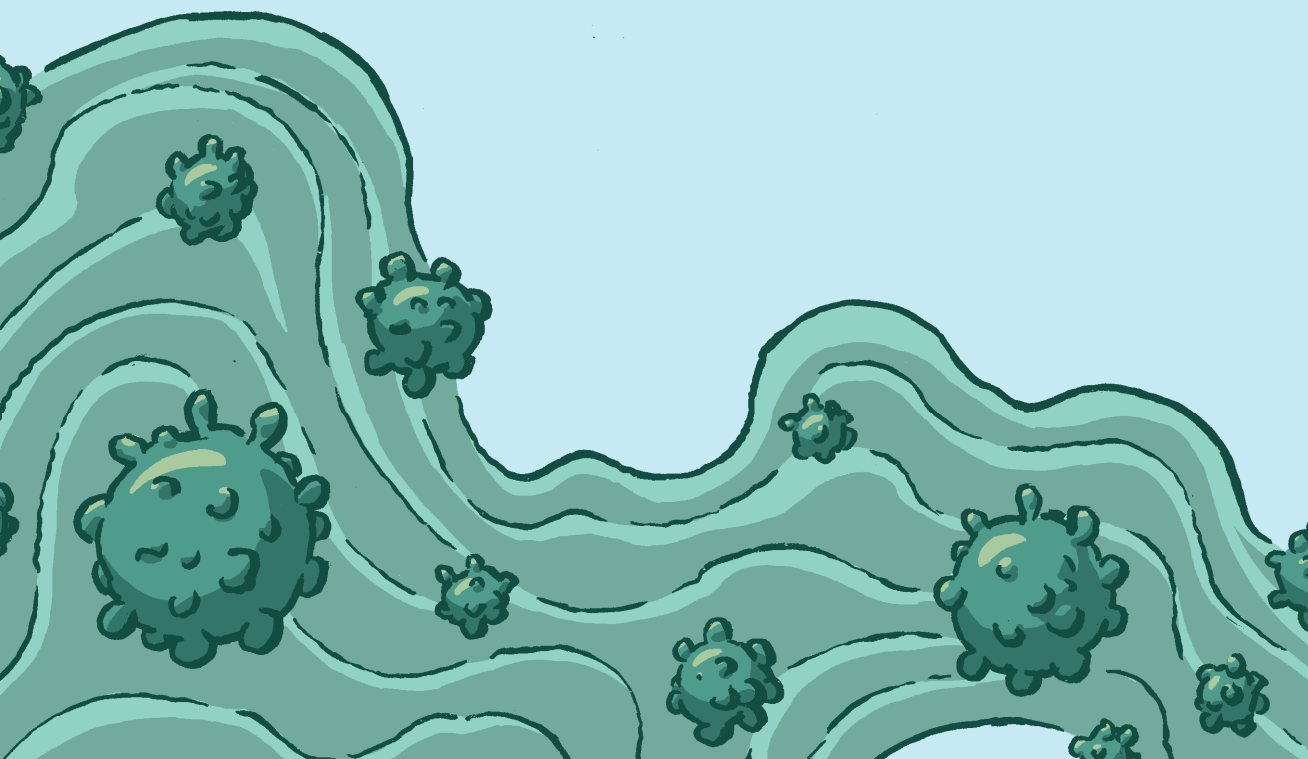

7

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

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Parts of this chapter have been published in PlosOne (2021) [1].

7.1 Introduction

After the outbreak of Covid-19, this respiratory disease has been spreading at a highly rapid pace [2, 3]. Adequate face masks are essential to protect healthcare professionals. In many hospitals shortages of personal protection equipment occurred due to increased demands [4]. In the search for alternative sources, hospitals started to consider reusing their face masks by sterilizing the single-use masks [5].

Face masks, also referred to as half masks, are used during aerosol generating procedures to protect individuals against airborne particles. Three classes of filtering face piece particles (FFPs) are described in European Norm (EN) 149:2001+ A1:2009 [6]. The most commonly used masks in relation to Covid-19 are the Class 2 FFP2 masks, which are considered to be equivalent to the American N95 mask [7], conforming to the standards of the National Institute for Occupational Safety and Health (NIOSH) 42 CFR 84 mask [8] and the Chinese KN95 mask complying to the Guobiao (GB) 2626-2006 standard [9]. The filter efficiency of smaller particles is a crucial element. The European Norm requires a minimum filter efficiency of 94%, whereas NIOSH [8] and GB [9] require 95%.

7.1.1 Testing filter material of face mask

EN 149:2001+A1:2009 [6] and more specifically NEN-EN 13274-7:2019, part 7 describe a test setup that consists of a flow tube, a flow generator, a NaCl particle generator and two particle measurement devices to determine the particle filtration efficiency (PFE) of face masks with different flows up to 120 l/min and NaCl particles of 0.1 to 10 µm. Unfortunately, this setup is costly to build. Therefore, in the first 2 months of Covid-19 only 2 systems were operational in the Netherlands and used for testing new, imported face masks. The costs of tests of one face mask were approximately 1,500 Euro with a waiting list of up to 4 weeks. A new quick testing method was needed.

7.1.2 Potential reprocessing methods

Multiple studies have shown the effect 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 [10–14]. These studies suggest

that gamma and steam sterilization conducted at 134°C damage the microstructure of the filter material [10].

Washing machines and microwaves have a low capacity, and microwaves do not create a uniform heat distribution and require a steam bag [11, 13]. Some studies suggest that the high concentration of liquid H_2O_2 in plasma sterilization (approx. 60%), and its strongly charged ionized vapor may neutralize the electrostatic charge of the filter media [12, 13]. 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 [14]. 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 [11, 13, 14]. 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 to inactivate the coronavirus [15, 16].

Pilot studies were conducted that included ATCC 12228 bacterial testing since hospitals needed to know if the 121°C sterilization method was safe and effective to inactivate 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 [10, 17]. Although proven efficient, the potential of this new 121°C sterilization method was not explored. Moreover, a study of many different brands processed at different CSSD's with comparisons between new, imported masks and sterilised 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?

7.2 Methods

A sterilization facility of a Dutch CSSD (ISO 7 validated, Van Straten Medical, De Meern, the Netherlands, operated by CSA services) was rebuilt for the purpose of reprocessing used (potential Covid-19 contaminated) FFP2 face masks. New testing methods were built to test the filter material quality after sterilization [5, 10, 17]. The testing facility was open for any hospital, reseller or manufacturer to check the quality of sterilized or new, imported face masks.

7.2.1 Reprocessing by 121°C steam at CSA Services Sterilization

Within this new reprocessing approach, decontamination was done solely by sterilization. To implement the 121°C sterilization process, a special logistical routing was set-up for collecting and processing face masks. Upon receipt, the masks were removed from their double wrapping and inspected individually on visual damage. In case of deformities, dirt, lipstick, hairs, black streaks, stains and 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) (Figure 7.1). The mask was disposed after it was marked with a maximum of 5 dots. A maximum of five face masks were packaged per bag to sterilize them properly. 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 should be 94 % or higher for a pass and under 94 % for a fail [6]. The performance of the mask material was determined by measuring the PFE and breathing potential. Figure 7.2 shows the particle counter with a custom-made particle chamber (Lighthouse Solair 3100, San Francisco, www.golighthouse.com). The machine pulls air through the mask into the chamber and to the particle counter. The diameter of the chamber is chosen such that it guarantees sufficient airflow through the filter material in order for the particle counter device to count the particles [10, 17, 18]. The PFE is 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 is 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 is installed on the chamber to measure the number of particles after

filtration. When very dense filter materials are used with a very high PFE

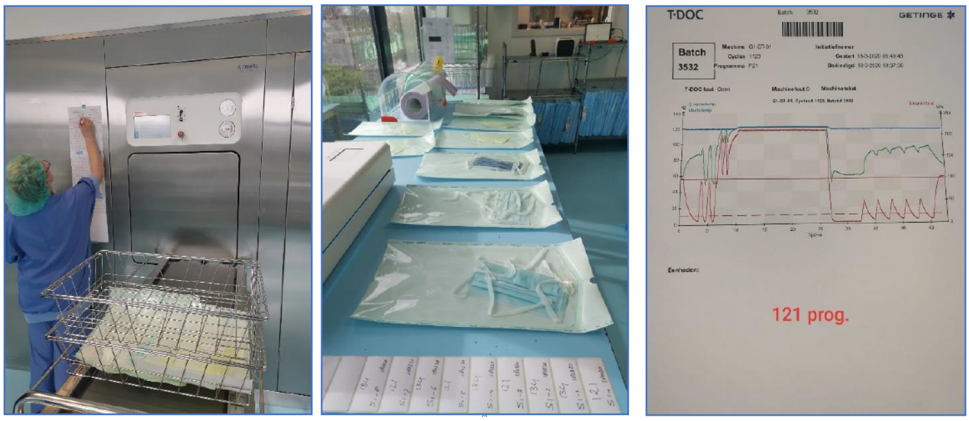

Figure 7.1: Autoclave procedure with Halyard laminate bags. Left, laminated bags entering the autoclave. Middle, masks are wrapped in laminate. Right, the 121 °C steam sterilisation program as used for face mask sterilisation.

for the smallest particles, it causes a breathing resistance for the user [17, 18]. This breathing potential was determined by measuring the pressure drop 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% [18]. The breathability requirements for respiratory protective devices are provided in a European standard [19]. The maximum permitted resistance (mbar) differs for the FF1, 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.

7.2.2 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 [20] that describes how a continues flow test setup should be build. However, the EN 149:2001+A1:2009 standard also includes experiments to determine

Figure 7.2: Lighthouse Solair 3100 particle counter connected to a particle chamber.

inward leakage. Therefore, a fit test and strap test may be conducted, conforming to a proper fit on the face without leakages around the mask [18, 19]. In this study, inspection of the materials and leakage tests were conducted on all reprocessed masks. Although we focused on the material properties in this study, 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.

7.2.3 121 °C STEAM STERILISATION CONSISTENCY BETWEEN CSSDs

The consistency of sterilization results caused by different processes and equipment was compared between 19 CSSD's. 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 minimal of four masks that were sterilized only 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.

7.2.4 Face mask material differences

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

7.2.5 Testing new masks

To determine how many samples are needed per tested important imported face mask type, the variance was determined on three imported face masks. Ten measurements conducted on each face mask type (Supplemental File 2 of the original article) 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 indicates 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 to us by the clients. The averaged values are listed in Supplemental File 3 of the original article. 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.

7.3 Results

7.3.1 Reprocessing by 121°C steam sterilization at CSA services

A total of 74,834 masks from hospitals 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 7.1 shows the top five brands that were sterilized and returned to hospitals for use. Test Setup validation to the European Norm EN 13274-7

Table 7.1: 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%

Preliminary tests conducted with 84 different masks, tested on the PFE dry particle test setup and a NaCl test setup built according to 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 of the original article). A measurement test conducted with another ten different masks indicated that an average of 19±21% (mean±SD) is needed to install and inspect the mask on the particle counter and an additional 15±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.

7.3.2 121 °C STEAM STERILISATION CONSISTENCY BETWEEN CSSDs

The reprocessing method by means of steam sterilization was adopted by 19 hospitals (Amsterdam University Medical Center (VUmc and AMC locations), Holendrecht Medical Center, Franciscus Hospital, CombiSter RDGG and 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 CSSD's of 19 different hospitals in the Netherlands are provided in Figure 7.3. From these 444 masks, 371 masks were reprocessed by means of steam sterilization and 73 were processed by means of H_2O_2 plasma (Supplemental File 5 of the original article). From the 444 tested face masks, 58 3M 1862+ face masks were provided by

seven CSSD's from four university hospitals, one general hospital and one general practitioner which were only sterilised once at 121 °C using steam sterilization (Supplemental File 6 of the original article). The influence of different installations, protocols or staff on the PFE is shown in Figure 7.4. 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.

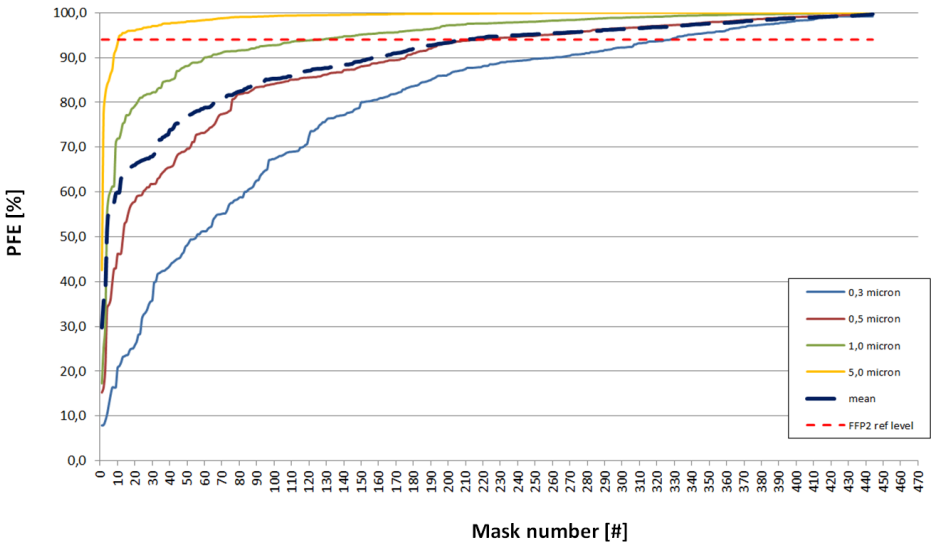

Figure 7.3: PFE values after sterilization with 121 °C steam or H_2O_2 plasma sterilisation in chronological order from worst to best. The red dotted line indicates the FFP2 level at 94% PFE. Each mask number represents a sample of a sterilised batch from one type only.

7.3.3 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 7.2 for 0.3, 0.5, 1 and 5 µm particles. The results indicate that 3M 1862 shows low PFE values after 2 times H_2O_2 plasma processing and that Kolmi Op-Air shows low and inconsistent PFE values after 1x 121 °C processing (Supplemental File 3 of the original article).

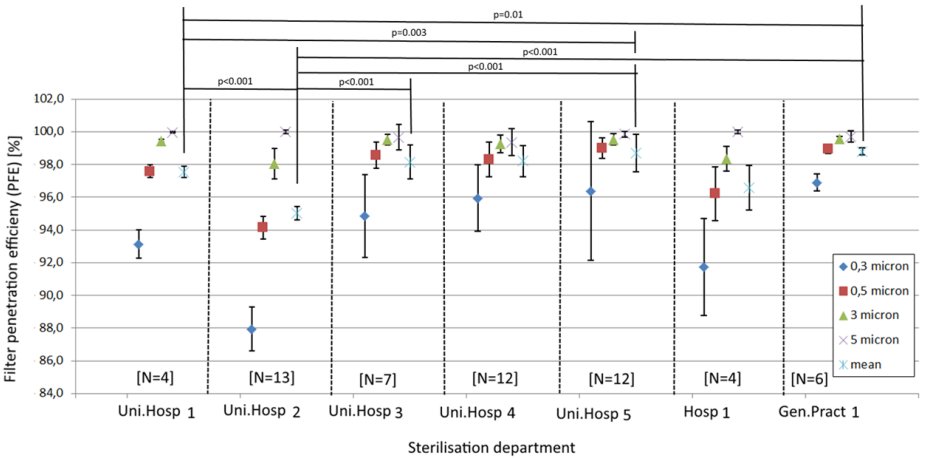

Figure 7.4: PFE values with Standard Deviation of different 3M 1862+ coming from 7 different CSSDs. Statistical differences are indicated with P values above the figure.

Table 7.2: Particle Filter Efficiency of two commonly used mask after either 121 °C 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
	72	121 °C steam	93,6 (4,1)	97,3 (2,1)	99,0 (0,8)	99,7 (0,7)	97
	4	2 x H_2O_2 Sterrad	41,3 (1,7)	66,9 (1,6)	83,9 (1,3)	99,5 (0,4)	73
	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
	15	121 °C steam	21,2 (6,8)	56,3 (8,5)	78,4 (8,2)	99,8 (0,5)	64

7.3.4 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 a match of all 5 layers of both masks with the profile of Polypropylene (PP) material (Supplemental File 7 of the original article).

7.3.5 Tests of new, imported masks

The PFE results of 471 different types of new FFP2/KN95 imported face masks from collaborating hospitals and resellers are shown in Figure 7.5. From these 471 face masks, 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 of the original article). Figure 7.6 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 [19]. 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.

7.4 Discussion

Regarding the research questions, it can be confirmed that FFP2 masks can be safely reprocessed with 121 °C steam sterilization if testing facilities are available. The data from Figures 7.3 and 7.5 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 are met. After nineteen hospitals

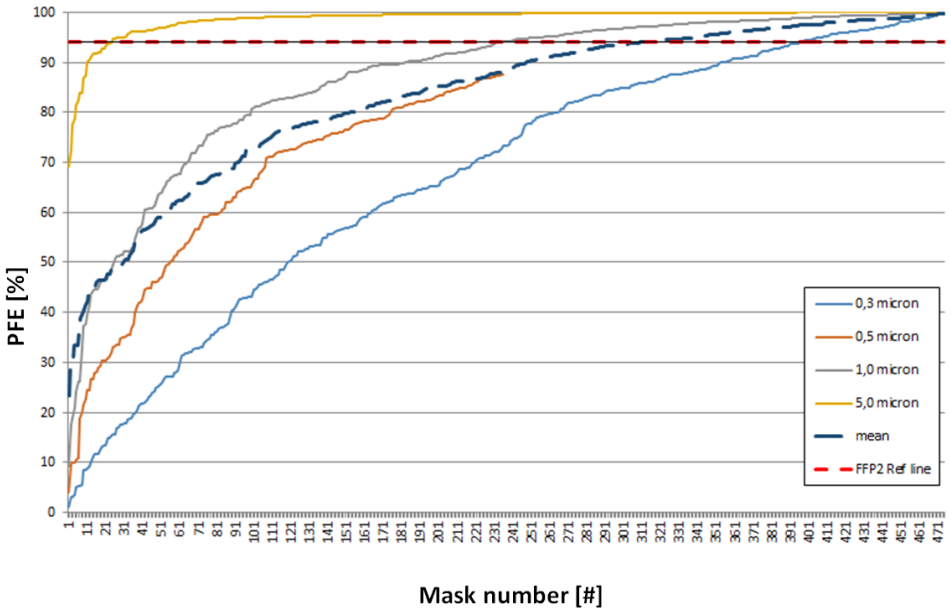

Figure 7.5: PFE values of new imported FFP2/KN95 face masks in order from worst to best. The red dotted line indicates the FFP2 level at 94% PFE. Each mask number represents a sample of a new batch from one type only.

adapted the steam sterilization process, a nationwide data field experiment was initiated that informed multiple international NGOs, universities and industry members about the pros and cons of sterilisation of face masks [18–22], setting a Dutch standard for sterilization of face masks. After the first results were shared on request [23], general practitioners, dental practices and pharmacies claimed to successfully adopt the 121 °C sterilization process in their smaller sized autoclaves with sufficient results [17]. Sterilization with the purpose of reusing medical devices is often driven by cost savings [24]. However, some studies also report the reuse of medical devices to realize environmental benefits [25]. In this study, steam sterilization is used to prevent shortages. In 1986, a survey was conducted including Canadian hospitals reusing disposable medical devices [26]. 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

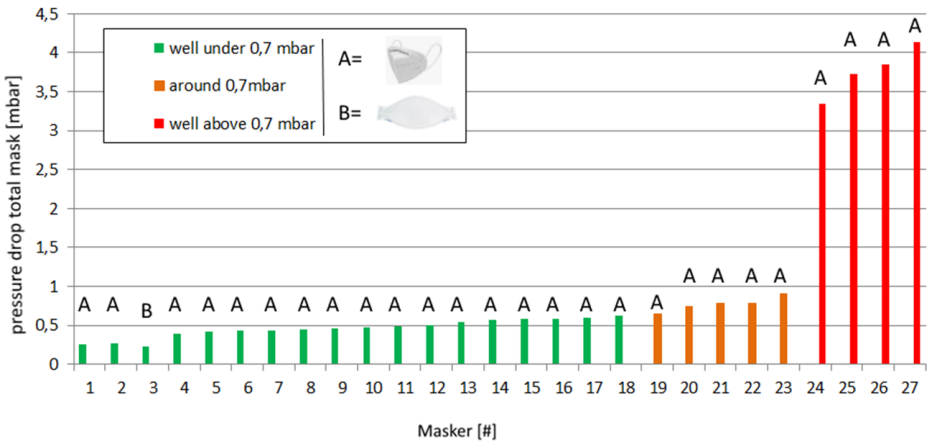

Figure 7.6: Pressure drop of 27 new face mass with PFE>0,7 mbar. Four masks performed really low (red), 5 performed around the EU norm of 0,7 mbar and 18 performed well according to the EU norm of 0,7 mbar.

filtration capacity. This is shown as our data reveals large differences in PFE despite the similar appearance of the mask material. Our results in Supplement files 6 and 8 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. Therefore, the test method described in this study will lead to a quick indication of the quality.

As high quality FFP2 masks do react differently on different sterilisation 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 is very interesting to investigate how either 121 °C sterilization or H_2O_2 plasma affects the mask's electrostatic charges and how this is related to the fiber 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-sterilised face masks that were tested at the dept. of Microbiology at Franciscus Hospital in the Netherlands [10].

Testing face masks on particles is important to quality assure the sterilization process. As our data show that despite the implementation of similar 121 °C sterilization protocols, mean PFE outcomes can differ up to 6%. As the types of mask and sterilisation methods are similar, the only unknown variable is the wearing/processing influence on the mask during use, transport and inspection. University Hospital 2 in Figure 7.4 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.

With 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 Supplemental File 6 of the original article conducted on each of the five layers of the 3M Aura 1862+ and Kolmi op-Air M52010 masks reveal that all layers are made from the same Polypropylene material. The differences in behavior when sterilized cannot be explained from a chemical composition perspective. A detailed interpretation of the results can be found in Supplemental File 9 of the original article.

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 sterilisation 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 plants were working for a single manufacturing label. In other cases, some masks (Figure 7.6) showed almost complete lack of air penetration due to the use of wrong materials or manufacturing processes.

Although our results suggest to use sterilized known face masks over poorly functioning unknown new masks if the filter material can be properly tested, it might be considered that expecting healthcare workers to wear masks of others, can have a psychological impact. To overcome this issue, masks can be marked with the initials of the user so that it can be returned to the same person.

7.4.1 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) built 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 a 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.

7.5 Conclusions

Sterilization of disposable face masks by means of standardized steam sterilization at 121°C could be an alternative against face mask shortages due to Covid-19 if the fit does not change and the filter materials are not significantly affected by the heat. The difference in efficiency after

reprocessing among the different brands concludes that only quality masks of a particular brands such as 3M Aura 1862, 3M Aura 1873 and My-T-Gear 301 are suitable for limited reuse. The data from the six different installations 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 H_2O_2 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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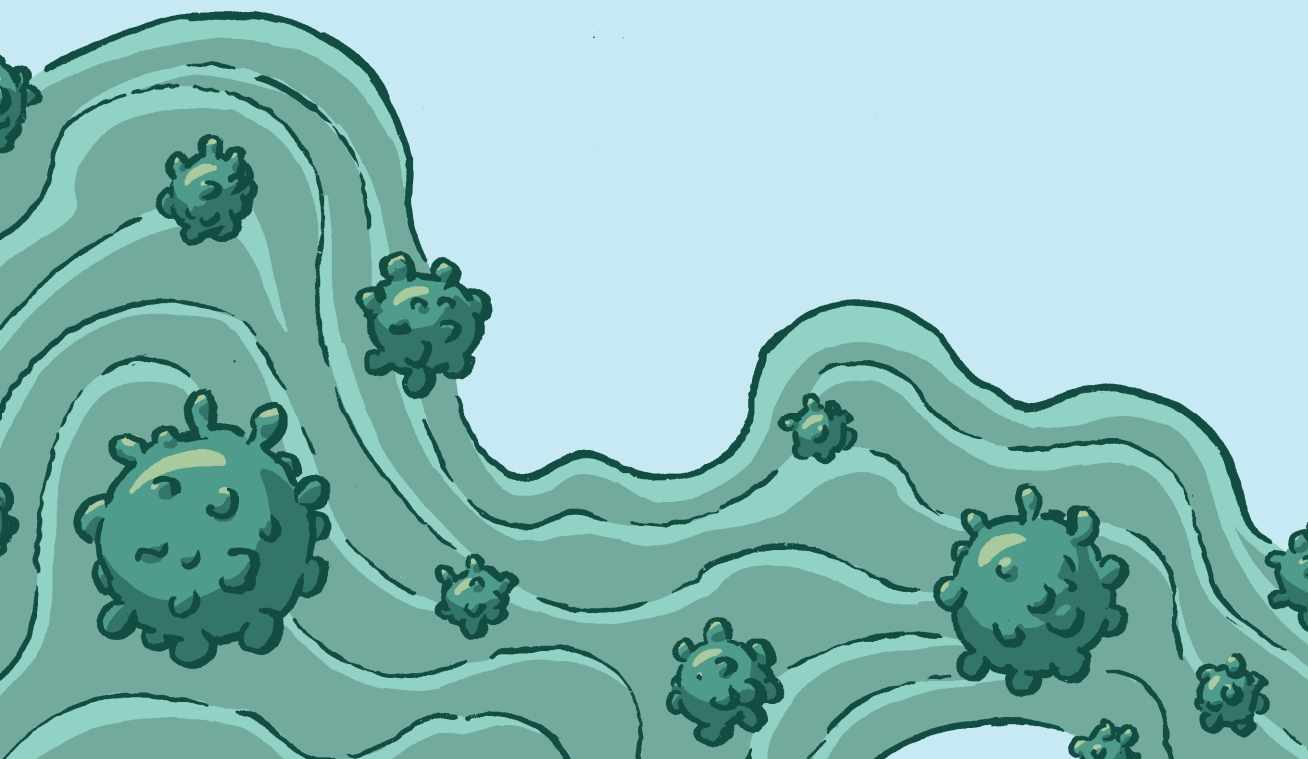


8

Discussion

In this thesis, two contamination risks were explored that occur during laparoscopic surgery: insufficient cleaning and sterilisation of the surgical instruments in low resource hospitals, and the leakage of abdominal gas from laparoscopic trocars.

Part 1 : Clean Laparoscopic Instruments in Rural India

Main Findings

Part 1 of this thesis was concerned with identifying and addressing one of the barriers regarding the introduction of safe laparoscopic surgery in low-resource settings.

The first field study, conducted at two low-resource hospitals in India, aimed to uncover what laparoscopic equipment was available, issues regarding infections and contamination, and the methods that their hospital used to reprocess the laparoscopic instruments. As laparoscopy is an advanced form of surgery, we expected these hospitals were also able to implement the infrastructure required to reprocess and maintain the laparoscopic equipment. However, the reprocessing procedures that followed from the survey and observations differed greatly from the procedures recommended by organisations such as the WHO [1]. Therefore, this first field study concluded that it was evident that inadequate cleaning and sterilisation of laparoscopic instruments in low-resource hospitals in India was a main barrier to safe laparoscopy.

Therefore, we started a process to design a device to overcome some of the issues in the reprocessing of laparoscopic instruments. During this process, the Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide was followed, to design a context-specific solution tailored to these low-resource hospitals. [2]. As part of the research of the context of use, we conducted a second field study in which four rural hospitals were visited in three states in India to assess the current reprocessing methods that are used to clean laparoscopic instruments.

This study uncovered that staff in these hospitals did not reprocess surgical instruments in a central sterilisation department, but instead reprocessed them near the operating room. In these locations, there was no adequate layout, equipment or supplies to effectively and safely reprocess the instruments. Because of the manual cleaning methods that were used, there was not enough time to ensure a reliable sterilisation. One team of operating

theatre nurses was responsible for performing all of the supporting tasks during a day of surgery, such as reprocessing the laparoscopic instruments, cleaning the operating room, caring for the patient and assisting in surgery. The surgeries were planned to maximise the number of procedures during the availability of a visiting surgeon. This put pressure on the nurses to have the equipment ready before the next surgery. On top of this, the nurses had not received additional training in sterile reprocessing since their hospital had started laparoscopic surgery.

Based on these field studies, supplemented by expert interviews, a design direction and requirements was formulated. The proposed solution was a laparoscopic instrument cleaner which could be placed near the operating room where the surgical instruments are currently cleaned, and would be easy to use for the local nurses. After we completed three design iterations, a final prototype was made. As intuitiveness was a key design requirement, the loading system for the laparoscopic instruments was a key feature of the prototype. The loading system's design was based on loading baskets that already exist in industry. Around this, a cleaning system was designed using proven cleaning techniques. To improve the cleaning reliability, we designed a novel mechanism that cleans internal surfaces of instruments, even while some channels are blocked.

As an evaluation of the ease of use of the loading system of the instrument cleaner, we conducted a usability study. During which, we visited four hospitals to evaluate the design with eleven nurses. The evaluation showed that the design was not yet intuitive to use for the Indian nurses. During the interviews and observations, we found that this was because the nurses did not understand what was required to clean the instruments, e.g. that the internal surfaces of the tubes should be cleaned. Based on the evaluation we incorporated the design with clear instructions that should improve the intuitiveness in future designs.

Laparoscopic Instrument Cleaner

The proposed laparoscopic instrument cleaner could solve a major issue for low-resource hospitals wanting to introduce laparoscopy. It gives hospitals a solution that can be implemented into their current practice, without the need for a new sterilisation department. As finding trained staff is another major barrier for these hospitals, the automated nature of the cleaner should ensure reproducible results independent of the user.

During the second field study, we found that the cleaning of the laparoscopic instruments was the most intensive step of reprocessing. It requires many manual manipulations such as disassembly of the instruments, cleaning each separate component with difficult geometry and re-assembly. Automating this cleaning process would give the greatest time benefit. Additionally, cleaning has the greatest impact on sterility in these hospitals. This is due to their preferred method of disinfection with glutaraldehyde which fixates proteins onto the instruments' surface [3]. Therefore, automated cleaning of laparoscopic instruments would significantly improve the reprocessing outcome.

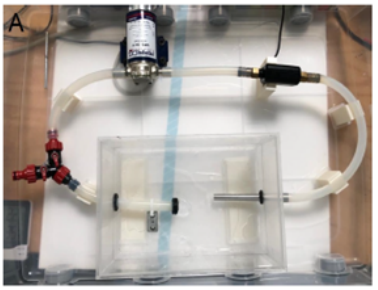
During these studies, we were not able to technically validate the cleaning efficacy of the cleaner. The design does incorporate many of the same cleaning principles found in existing cleaning devices in industry and would therefore be expected to provide the same benefits as other automated cleaning devices. During the formulation of the design requirements, we consulted literature and standards to research requirements on the mechanical removal of bioburden. The leading standard for automated cleaning is the ISO 15883 – Washer Disinfectors which stipulates the requirements that commercial washer-disinfectors should conform to. This standard only dictates that a washer-disinfector should provide the cleaning conditions as specified by the manufacturer of the device that requires cleaning. Conversely, the Instructions For Use (IFU) of the items to be cleaned only state that they are able to be cleaned by washer-disinfectors that comply to the ISO 15883-5 standard [4, 5]. Minimum requirements for the mechanical cleaning action remain unclear.

Up to the latest version of ISO 15883-5:2021, there were no direct requirements for the level and methods of cleaning that a device should achieve. Only since this latest release, a maximum allowable level of bioburden contamination has been specified of 3 µg/cm^2. As stipulated by the standard, residual protein is to be extracted from the surgical instrument by immersing it in a residual protein is to be extracted from the surgical instrument by immersing it in a 1% sodium dedecyl sulfate (SDS) solution. The residual protein is quantified by determining the concentration of protein in the SDS solution. Although the standard provides an objective benchmark, specifying contamination levels as a fraction of overall surface area makes it an unreliable indicator of contamination risk. As bioburden often remains in hard-to-reach areas, a small area with bioburden can have large consequences while the overall instrument cleanliness complies with the standard.

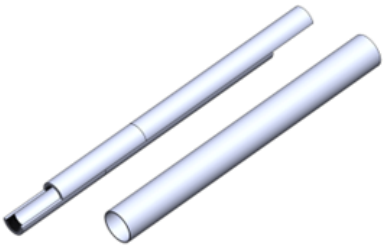
Many washer-disinfectors intended to clean a load with hollow instruments, the lumens are loaded in a manifold that divides the fluid flow across all the exit ports. This arrangement is suitable in cases where the inner diameters of the lumens are equal. When this is not the case, or when there is a blockage of bioburden in one of the lumens, the fluid takes the path of least-resistance and flows through the larger diameters. More importantly, no pressure builds up behind the blockage, leaving the bioburden in the lumen. Another issue with the manifold arrangement, is when most of the exit ports are open. In many washer-disinfectors, the manufacturer provides seals to block ports that are not in use. However, the reprocessing experts in Dutch hospitals indicated during the interviews that these seals are not always used when needed and are easily lost. When all the ports are open, only a small flow of fluid exits the manifold ports. Because there is no minimum cleaning requirement, it is unclear whether these situations still ensure adequate cleaning action. To answer this question, we performed a series of experiments to determine the minimum fluid flow to remove debris from the inside of hollow tubes. In this experiment, the influence of fluid flow speed and soak time on the removal of the test soil on smooth stainless steel tubes was studied. We designed a test setup which consisted of a surgical instrument model mounted in a reservoir. This was connected with silicone tubing to a pump and a flow sensor. The instrument model was a stainless steel tube with an internal diameter of 9 mm that was split lengthwise so that the internal surfaces can be inspected. A test soil consisting of egg yolk prepared according to the guidelines of ISO 15883-5, was deposited on a portion of the model using a mask. The test soil was dried and then weighed before and after cleaning to find the removed mass fraction.

We applied flow rates of between 0 and 8 L/m and varied pre-soaking times between 0 and 10 minutes. The results of this study showed that the removed mass fraction increases significantly for flow rates up to 7 L/min, above this, the removed mass fraction stagnates. The removed mass fraction increased when comparing no soaking time to 5 minutes soaking, however between 5 minutes and 10 minutes soaking no significant difference was found.

This study showed that for adequate cleaning of hollow medical instruments the shear stress induced by the flow rate should be taken into account. The results in this study can be used as a benchmark for follow-up studies where other effects in the cleaning process such as the influence of instrument geometries, and other properties such as oscillating flows, and detergents could be investigated.

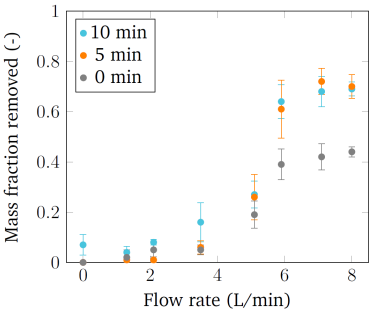


(a) Setup used to study removal of a test soil from representative test pieces.

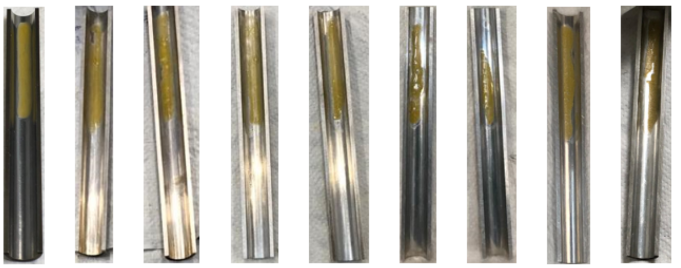


(b) A render of the test pieces used in the experiments.

Figure 8.1: Equipment used for the debris removal experiment.



(a) Removed mass fraction of test soil against a varied flow speed. Three different soaking times were measured.



(b) Photographs of different levels of removed test soil.

Figure 8.2: Results of the debris removal experiment.

In our design of the laparoscopic instrument cleaner, we aimed to solve this by introducing a mechanisms that alternates the flow of fluid over four

groups of manifold ports. This has two advantages: it reduces the number of ports that are cleaned at one time and it oscillates the fluid flow through the ports. Oscillating flow has been shown increase fluid shear stress, and thus enhance the removal of debris [6].

Design Methods

The roadmap that we used in this design process encourages designers to uncover the surgical context in which the device is to be used [2]. This surgical context consists of the "barriers encountered by patients seeking surgical care", "the structure of the healthcare system and the type of surgeries performed", and the "aspects of safe surgery". During our design process, a large focus was placed on studying the surgical context which was used as a basis for the design. This gave insights such as that instruments are locally reprocessed at the operating room, instead of a central location, that there is a preference for chemical disinfection over steam sterilisation and the difficulty for nurses to get additional training in handling minimally invasive instruments. Based on this context, the design requirements are formulated. As such, context-based design was crucial in creating the concept.

As shown in Chapter 3, context-driven design did not immediately lead to a successful design. It is apparent that another design iteration has to be made before our requirements are fulfilled. Mapping the whole context from the outset is an elaborate and time-consuming process with unclear boundaries as to when more contextual information is needed, or that a design cycle should be started. Many of the details that will be collected will turn out to be irrelevant after choosing a more specific design direction. In our design process, we found that context-driven design should be cyclic in nature.

Now that a first concept has been established, a new round of design cycles has to be initiated, with a higher resolution. The success of the device depends on many more contextual factors such as manufacturability, infrastructure, distribution of spare parts and consumables, and economics [7]. The design requirements from these cycles will determine its long-term performance by incorporating what consumables cannot be included or what local facilities are available to make repairs. Contextual information has to be collected on each of these factors. Therefore, we consider the roadmap to be an addition to other methods that map the context.

Reprocessing Methods and Working Culture

The reprocessing methods observed in the sampled hospitals were a direct consequence of their limited financial resources. However, the significance attributed to reprocessing practices is also rooted in the working culture of these healthcare environments. The lower emphasis placed on reprocessing may be caused by surgeons resorting to prophylactic antibiotics to prevent healthcare-associated infections instead of addressing the prevailing challenges in maintaining optimal sterile conditions. However, this practice shields them from confronting the repercussions of inadequate sterility, reducing their incentive to address the issue. This cultural perspective makes the willingness of these hospitals to invest in reprocessing technologies uncertain.

The limited financial resources were also a barrier in purchasing laparoscopic equipment. Despite the benefits of reusable equipment over the long term, including reduced environmental impact and cost-effectiveness [8, 9], low-resource hospitals struggle with the initial high costs associated with reusable instruments. As a consequence, disposable instruments such as trocars and vessel sealers are commonly repurposed through cleaning and sterilisation after use. The re-sterilization of disposable equipment remains a contentious issue, with diverse findings across studies [10–12]. Moreover, the validation of reprocessing methods and the monitoring of outcomes, essential components in ensuring the safety of reused disposable equipment, are frequently unattainable in the resource-constrained settings. This creates a dilemma wherein financial constraints drive hospitals to adopt less sustainable practices, potentially compromising patient safety.

A potential solution could be to redesign commonly used disposable equipment into reusable versions, maintaining its original functionality, but suitable to be reprocessed by the methods found in LMIC hospitals [13]. One of the projects we undertook was the redesign of a bipolar vessel sealer. During our visits to Indian hospitals, we observed that the Ligasure devices were the most common bipolar vessel sealers, which were reprocessed after use. Because nurses were not able to disassemble the instruments, the complex features filled with bioburden that had to be removed with items such as scalpels and needles. The redesign that we made was based on the SATA instrument platform [14]. This allowed the instrument to be fully disassembled to be cleaned and sterilised with basic equipment. By redesigning for use in LMIC we found that a modular design helps us to improve accessibility during cleaning. However, this approach also

leads to many small fragile and loose parts that can go missing or get damaged during (dis)-assembly. We found that the SATA-based design gives instruments more functionality at the cost of more complexity which influences the instruments' lifetime, ease of maintenance and availability of parts.

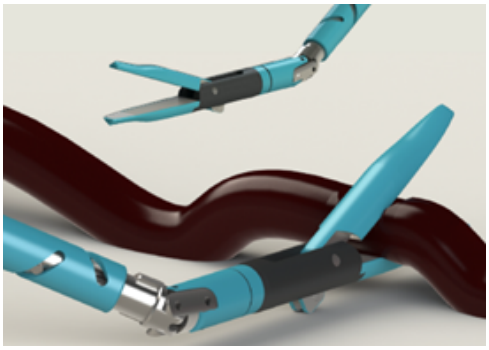


Figure 8.3: Design of a reusable vessel sealer based on the SATA platform

Limitations

During the evaluation study of the laparoscopic instrument cleaner, we were only able to validate a limited number of design requirements within the context of use, such as the ease of loading and the loading time. Many of the technical requirements still have to be evaluated, although these are not influenced by the local setting and can be tested in an external lab setting. However, many of these technical design choices will influence the cleaners' long-term performance, need for maintenance and repairability and pricing. The study participants were positive about the overall concept, yet these results have to be regarded in light of the limited resolution of the final concept.

During the design process, we discussed the design requirements with experts in reprocessing, and LMIC reprocessing to triangulate them. Due to time limitations during the evaluation study, and because of the travel restrictions during the Covid pandemic, this triangulation was not expanded with other experts from the field such as nurses, surgeons and hospital administrators. Therefore whether hospitals are actually willing to invest in reprocessing technology is uncertain and depends on each hospitals' finances together with its working culture. Therefore, further validation of

the requirements and concept as a whole will help us to finalise the design and more accurately determine the target hospitals for such a device.

Future Prospects

Successfully implementing laparoscopy in low-resource requires devices that match the settings where they will be used. The laparoscopic instrument cleaner and the other projects like the reusable vessel sealer could be part of a robust assembly of laparoscopic tools that facilitate the introduction of laparoscopic in low-resource hospitals such as the laparoscopic gasless lift and laptop cystoscope [15, 16]. Such a system of robust laparoscopic devices would increase the availability and safety of laparoscopy to patients worldwide.

Part 2: Laparoscopic Gas Leakage

Main Findings

Part 2 of this thesis identified factors relating to gas leakage through laparoscopic trocars where the source of the contaminations were particles that the gas, meant to inflate the abdomen, carried into the operating room. During the Covid-19 pandemic, it became essential for healthcare workers to prevent contamination with the virus. Because of its airborne nature, the face mask became the most important line of defence for healthcare workers to prevent inhalation of coronavirus particles. Due to the enormous demand for personal protective equipment, a shortage of FFP2/KN95 masks was created. Besides this, laparoscopic surgeons were concerned of being exposed to a higher contamination risk during laparoscopy. It was suspected that the coronavirus was present in abdominal gasses and could leak into the surgeons' breathing space. Therefore, in Part 2 of this thesis, we studied the escape of particles during laparoscopic surgery.

We investigated several ways to prevent that particles are inhaled by people present in the operating room. The most direct method to prevent this, is by wearing a mouth mask. In the face of mask shortages, an alternative method to supply healthcare workers with masks was sought by re-sterilising mouth masks. The study of Chapter 7 developed, validated and implemented a 48-minute steam sterilization process of single-use FFP2/KN95 face masks with a 15 minute holding time at 121 °C [17]. We then developed a test setup to test the particle filtration efficiency and pressure drop of these reprocessed

masks. The results showed that certain masks that were sterilised showed a minimal reduction in particle filtration efficiency depending on the type of filter materials being used.

We addressed the issue of particle escape during laparoscopic surgery. We identified three possible routes that gas can escape from the abdominal cavity: through trocar valves, through the instruments and through the incision. The first two of these routes where characterised using a model of the surgical environment and a protocol of several manipulations. Our study included 23 trocars and 26 instruments, and showed that trocar leakages could vary between 0 and 30 L/min and the leakage through the instruments was between 0 and 5.5 L/min. These leakages could result in hundreds of litres of CO_2 being released into the operating room.

The model in the previous study used a protocol of static forces that were exerted on the trocar. However, surgeons suspected that CO_2 leakage trough trocars increases because of wear during surgery. To assess this, we developed a new model to measure trocar leakage under dynamic loading. We found no large differences in leakage rates before and after manipulation. The dynamic manipulation did damage two different trocars and revealed leakages caused by production flaws.

In the face of Covid exposure, we evaluated the claim that valveless trocar systems increase smoke evacuation from the abdominal cavity and filter the gas that is released into the operating room. To test this, we compared particles escaping from a conventional and valveless trocar system. This study compared the number of particles that escape from conventional and valveless trocar systems by applying different pressures, different instruments, and peritoneal ventilation. We revealed that the conventional trocar showed leakage in two phases: during instrument insertion and removal of the obturator. The valveless trocar system showed a continuous leakage while it was empty or when an instrument was inserted and caused a much larger number of particles to escape into the operating room.

In Covid times, some suggested that a specific type of valveless trocars could further reduce the exposure to particles from the patient during laparoscopy. The claim was that Valveless trocar systems increase smoke evacuation from the abdominal cavity and filter the gas that is released into the operating room. Our study executed with the Technology committee of the EAES compared the number of particles that escape from conventional and valveless trocar systems by applying different pressures, different instruments, and peritoneal ventilation. We identified that the conventional

trocar showed leakage in two phases: during instrument insertion and removal of the obturator. The valveless trocar system showed a continuous leakage while it was empty or when an instrument was inserted and caused a much larger number of particles to escape into the operating room.

Impact of Laparoscopic Gas Leakages

The studies we performed revealed that laparoscopic gas leakages can greatly vary in both volume, frequency and velocity. The largest volume of leakages were observed when gas is able to leak constantly through trocars or instruments over the duration of a whole procedure. High velocity leakages were observed in situations when a direct pathway is created past trocar valves. These occurred during instrument insertion and during the removal of the obturator.

During laparoscopic gas leakage, surgical smoke containing harmful particles are released into the operating room and into the breathing space of the surgeon. The dispersion of the particles into the room depends on the nature of the leakage such as pressure differences at the source, gravity and air movements [18], but also the characteristics of the operating room, such as the ventilation present and the placement of objects around the surgical table [19]. Most literature on the exposure of surgical staff to smoke has focused on open surgeries. One study assessed the airborne particle doses from surgical smoke in 37 open surgeries in several operating rooms. The doses of particles measured in this study were comparable to those present in indoor environments in Western Countries [20]. However, the risk associated with these doses is strongly associated with the hazardous compounds present in the particulate matter. However, as the type of operation and the equipment that is used directly determines the exposure of staff to smoke particles, these studies cannot be used to predict smoke exposure during laparoscopic surgery.

There have been studies that compare the spread of particles in the operating room during open and laparoscopic surgery [21–23]. These studies measured particulate matter in different locations in the operating room, and showed mixed results whether smoke exposure was higher during laparoscopy or laparotomy. Furthermore, no literature could be found that evaluate whether the high-velocity leakage of abdominal gas from laparoscopic equipment increases the exposure of surgical staff.

Trocar Redesign

Chapter 5 showed trocar leakages under different conditions. Although the trocars showed different responses to the protocol, there was one part of the assessment that none of the trocars were able to overcome. This was the situation when an instrument with a long tip was inserted into the trocars. If the length of the tip was greater than the distance between the two trocar valves, the abdominal gas would have a direct pathway and cause a fast leakage. This problem formed the basis for the redesign of a trocar, conducted with the University of Pavia, that was able to vary the inter-valve distance. Although this trocar was effective in preventing leakage during the insertion of long instrument tips, it still has to be further evaluated whether the added complexity offsets the benefits.

Figure 8.4: The redesigned trocar with the extendable bellows

Limitations

Although the studies we performed were only a limited representation of the surgical environment, the in-vitro experiments allowed us to reproducibly evaluate laparoscopic equipment. The tests that we performed could form the basis for leakage testing protocols that can be used to overcome equipment based leakages during the design of laparoscopic equipment.

Surgical Implications

The Covid-19 pandemic increased awareness of surgeons to the hazards of inhaling particles released during surgery. Since then, no transmission of SARS-CoV-2 by surgical smoke has been reported [18, 24]. However, workplace exposure to surgical smoke has remained an active topic. Industry has provided surgeons with many options to prevent smoke leaking into the operating room such as smoke evacuation devices. Other causes of gas leakages during laparoscopy could be prevented by stricter adherence to surgical guidelines such as venting the trocar stopcock, removal of specimen bags and final removal of the trocar [25]. The results of this thesis have shown that surgeons can reduce instrument and trocar related leakages by being aware of the combinations of equipment they choose.

In light of the difficulty of simulating the exposure to smoke, the associated health hazards for all surgeons in all hospitals will likely have to be studied on an individual basis. However, thanks to the already available solutions and protocols, limiting smoke exposure seems to be mainly a matter of personal choice.

Contamination Risks During Laparoscopic Surgery

The two parts of this thesis studied contaminations in vastly different settings. In Part 1, we identified issues in cleaning and sterilisation in Indian low-resource hospitals that perform laparoscopic surgery. Based on these issues, we suggested a solution in the form of a laparoscopic instrument cleaner. A concept of this cleaner was designed in a context-driven design process and was evaluated in a usability study. The evaluation showed that the loading system, which was based on an industry-standard design, was not intuitive for rural nurses to use. Finally, a redesign of the cleaner was presented that should enhance its ease of use.

Part 2 identified and quantified gas leakages in laparoscopic trocars. Long-term operative use of trocars had little effect on the trocars' leakage performance. Large leakage differences were shown between different trocar types and instruments which the surgical team can use for future equipment selection. Our testing protocols could form the basis for leakage testing during the design of laparoscopic equipment.

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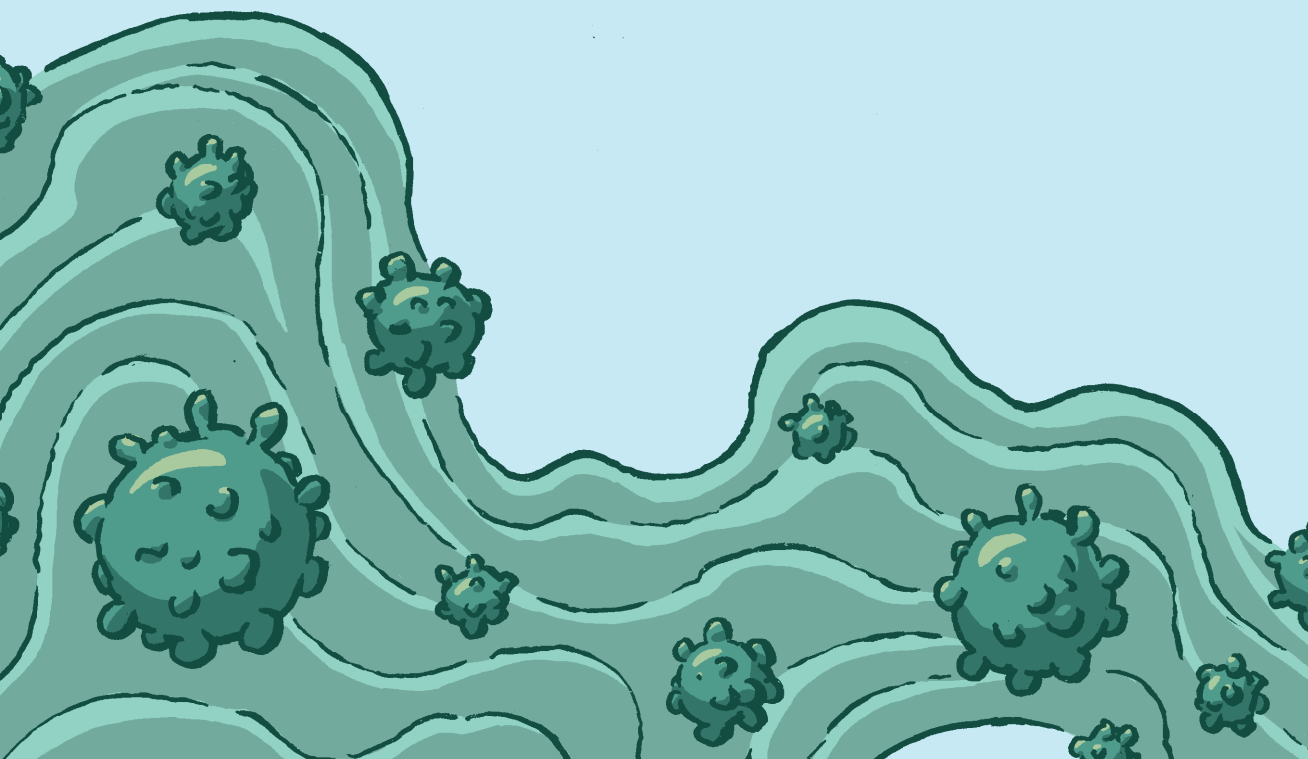

Acknowledgements

Voordat ik aan mijn promotie begon kreeg ik van de meeste ervaringsdeskundigen de waarschuwing dat het vier jaar lang een eenzaam traject zou zijn. De ervaring die ik heb gehad was echter dat iedereen die ik binnen academia heb ontmoet in de afgelopen jaren een enorme bereidwilligheid toonde voor samenwerking en hulp: Of het nou een openstaande kantoordeur was waar je kon aankloppen om een kop koffie te drinken, een expert op een vakgebied die stond te popelen om zijn kennis te delen, of een chirurg aan de andere kant van de wereld die je na een mailtje uitnodigde om op bezoek te komen. In dit hoofdstuk wil ik graag deze mensen bedanken, zonder wie dit werk niet was gelukt.

First of all, I would like thank the members of my defence committee: **Prof. dr. ir. J.C. Diehl, Prof. dr. M.C. Vos, Prof. dr. R. Cahill, Dr. J.A. Sánchez Margallo, Dr. ir. A.C. van der Eijk**, for taking the time to read my thesis and for your questions during the defence.

Beste **Jenny**, naast het inhoudelijke, leerde je me twee essentiële zaken. De eerste was, maak een planning, maar wees niet bang als die vervolgens niet uitkomt. De tweede was de piepjesmethode om niet overal meteen op in te gaan. Je was vaak de nuchtere kracht op de momenten dat ik vast zat. Helaas dat tijdens COVID onze reis naar India samen niet doorging, maar jouw snelle interventie heeft wel mijn laatste reis naar India gered.

Beste **Tim**, tijdens onze contactmomenten liep je altijd over van inspiratie, problemen lijken voor jou soms niet te bestaan, alleen oplossingen. Van technische ideeën tot extra projecten, jouw creativiteit is aanstekelijk! De COVID pandemie was voor jou geen lockdown maar een onuitputtelijke bron aan kansen die je maar al te graag met anderen deelde.

My favorite part of being in academia was the low barrier to collaboration. All of the visits to India would not have been possible without the help and hospitality of **dr. Gnanaraj**. I emailed you in the first weeks of my PhD and you immediately invited me to India and gave me access to a network of hospitals and surgeons which would have been much more difficult to form without you. Since then, I

feel that our academic collaboration has grown into a lasting friendship, and I value remaining involved in your work going forward.

Jan Huijs, jij was de eerste externe persoon buiten de TU Delft die ik ontmoette tijdens mijn promotie en sindsdien bleef je altijd betrokken. Met je enthousiasme voor sterilisatie van medische hulpmiddelen stak je niet alleen mij maar ook vele afstudeerders en studentengroepen aan. **Joost van Doornmalen**, dank voor je hulp in het uitleggen van de principes van sterilisaties en het uitpluizen van het web van ISO-standaarden.

JC Diehl en **Sonja Paus-Buzink**, ik heb veel genoten van het samen begeleiden van afstudeerders en heeft ook mijn onderzoeken in India verbeterd. **Sonja**, bij het schrijven van mijn laatste paper hielp je deze werktuigbouwer niet te verdwalen in de wereld van design theorie.

Veel dank aan iedereen van **Delft Global**: **Roel Kamerling, Sophie Oostelbos, Claire Hallewas**, jullie bijdrage heeft blijvende samenwerking mogelijk gemaakt met chirurgen in India.

Frank, wat begon met onze eerste-eerstejaars WB project (in 2008!) is geresulteerd in een paar mooie wetenschappelijke artikelen. Ik heb toch genoten van de vele uren blazen door plastic buizen. Volgens mij hebben we wel nog een biertje tegoed na onze laatste paper!

Thank you to all the **Graduate students** that helped at different moments of my studies: **Abe, Girish, James, Jessica, Maite, Matthijs, Nabil, Philip, Shivani**. You gave me many great insightsm and I am grateful for your enthusiasm, hard work, and the trust you placed in me as a supervisor.

Arjo, Bart, Francoise, Jan-Willem, Jinne, Julie, Kim, Marit, Nick, Nick, Robin, Sara, Tomas, Tonke en Vera, onder de lichtkoepels van het MISIT lab zetten jullie een geweldige sfeer neer wat het lange promoveren een stuk leuker maakte. Bedankt voor alle koffie, biertjes, feestjes, diners, kraamvisites, suppen, klimmen en pubquizzen! **Roos**, je ontfermde je toch een beetje over me als mede onderzoeker op LMIC gebied, dank voor al je hulp, met name met mijn laatste paper!

Vincent en Sjoerd, dank dat ik jullie op deze dag aan mijn zijde mag hebben. Ook al zie ik jullie minder dan ik zou willen, de ervaringen die we deelden gaven me de afleiding die ik vaak nodig had!

Kim, Jori, John, Audrey, Gerard dank voor alle jaren aan betrokkenheid en alle mooie momenten samen met onze gezinnen.

Mum and Dad, thank you for all the years of support, without it I would not have done this PhD. Literally, mum, you forwarded me the job. You have always motivated me to push myself, which I can only be grateful for.

Lieve **Ilse**, Tijdens de voorbereiding van mijn reis naar India zag ik door de bomen het bos niet meer van alle dingen die ik nog moest doen om de reis te laten slagen. Door samen 's avonds de deur vol met post-its te hangen met to-do's, bracht je de kalmte die ik nodig had. Kalmte die later ver te zoeken was na de geboorte van Hannah wanneer je me toch de vrijheid gaf om reizen naar India te laten maken. Zonder jou was het niet gelukt.

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List of Publications

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