Corrosion Susceptibility of Surgical Stainless Steels in Instrument Reprocessing for LMICs: Influencing Factors and Accelerated Testing

by

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Abstract

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Abstract

This study investigates surgical stainless steels 304, 410, and 420 corrosion susceptibility under manual reprocessing conditions typical of low- and middle-income countries (LMICs). Cleaning protocols using sodium hypochlorite and the enzymatic agent Sanizyme were compared alongside an accelerated Salt Mist Test to explore predictive value for corrosion. Results show that sodium hypochlorite causes rapid corrosion across all steel types. In contrast, Sanizyme significantly delays corrosion onset and reduces the affected surface area, with stainless steel 304 demonstrating the most outstanding resilience. Minor differences between 410 and 420 were observed, with no significant performance distinction. Including 2-hour rest periods, intended to activate stainless steel's self-healing properties, did not significantly impact corrosion resistance. Additionally, the Salt Mist Test showed limited correlation with corrosion development observed under manual reprocessing conditions, indicating the need for refined predictive methods. These findings suggest that gentler enzymatic cleaning protocols enhance the longevity of surgical instruments in LMIC contexts, while accelerated corrosion tests may require adjustments to simulate clinical reprocessing better.

Foreword

Throughout my thesis journey, I came to understand the importance of time as a valuable, finite resource. Managing time effectively proved essential for staying organised, maintaining clarity, and achieving my objectives. This experience taught me to set priorities and focus on the path to reaching my goals.

I am especially grateful to my supervisors, Jenny Dankelman, Roos Oosting, and Yaiza Gonzales Garcia, for their generous guidance and dedicated time. I would also like to thank Lia Kondova from the TU Delft Writing Centre for her support in improving my academic writing skills. I am also thankful to the Gynaecology Department at AvL for the opportunity to further develop my clinical understanding through a part-time role alongside my graduation project. To my family and friends, I am deeply grateful for your unwavering support and encouragement.

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Contents

1 Introduction **6**
1.1 Research Questions 7

2 Theoretical Framework **8**
2.1 Instrument reprocessing in LIMCs 9
2.1.1 Reprocessing of surgical instruments 9
2.1.2 Reprocessing protocols for surgical instruments in LMICs 10
2.1.3 Observations of the 4-Bucket System in Uganda 10
2.1.4 Implementation of manual cleaning in this study 11
2.2 Stainless steel for surgical instruments 12
2.2.1 Austenitic, ferritic, and martensitic stainless steel 12
2.2.2 The 300 and 400 series for stainless steel 13
2.2.3 Chemical composition of stainless steel 13
2.2.4 Passivation layer and self-healing properties 14
2.3 Corrosion in Stainless Steel 15
2.4 Fundamentals of Corrosion 15
2.4.1 Forms of corrosion 16
2.4.2 Impact of cleaning agents on corrosion resistance 17
2.4.3 Conclusion 18
2.5 Accelerated corrosion testing 18
2.5.1 Methods for accelerated corrosion testing 18
2.5.2 Salt Mist Test 19

3 Materials and methods **21**
3.1 Reprocessing testing 22
3.1.1 Materials 22
3.1.2 Methods 22
3.2 Accelerated corrosion testing 26
3.2.1 Materials 26
3.2.2 Methods 26
3.3 Summary of test protocols 27
3.4 Data collection 28
3.5 Data processing and analysis 28
3.5.1 Corrosion surface area calculation 28
3.5.2 Data collection and structuring 29
3.5.3 Surface area approximation and comparative metrics 29
3.5.4 Statistical analysis 29
3.5.5 Salt Mist Test data processing 30
3.5.6 Comparative analysis between reprocessing tests and Salt Mist Test 30

4 Results **31**
4.1 Reprocessing tests 31
4.1.1 Test 1: Continuous NaClO Reprocessing 32
4.1.2 Test 2: Continuous Sanizyme Reprocessing 34
4.1.3 Test 3: Intermittent NaClO Reprocessing 36
4.1.4 Test 4: Intermittent Sanizyme Reprocessing 38
4.1.5 Differences in corrosion between stainless steel 304, 410, and 420 . 40
4.1.6 Corrosion comparison between NaClO and Sanizyme 42
4.1.7 Impact of rest periods on corrosion onset and affected area 44

4.2 Accelerated corrosion testing 45
4.2.1 Test 5: Salt Mist Test 45
4.2.2 Comparing corrosion-affected surfaces: Reprocessing versus Salt Mist Test 46
4.2.3 Correlation between Salt Mist Test corrosion area and Sanizyme Reprocessing cycles to corrosion onset 46

5 Discussion **47**
5.1 Summary of key findings 47
5.2 Evaluation of methodological choices 48
5.2.1 Use of the 4-Bucket System 48
5.2.2 Evaluation of the Reprocessing tests 48
5.2.3 Evaluation of the Salt Mist Test for surgical instruments 48
5.2.4 Sample size and test adaptations 49
5.2.5 Documentation of corrosion 49
5.3 Interpretation of results 49
5.3.1 Material susceptibility to corrosion 49
5.3.2 Effect of sodium hypochlorite versus enzymatic cleaning on corrosion susceptibility 50
5.3.3 Impact of rest periods on corrosion susceptibility 50
5.3.4 Evaluating the predictive value of the Salt Mist Test 50
5.3.5 Towards an understanding of the main research question 51
5.4 Limitations of this study 51
5.5 Relevance and implications of this research for LMIC contexts 52
5.6 Future research recommendations 53

6 Conclusion **54**

References **54**

7 Appendix **60**

Appendix A: Equipment and materials used for reprocessing tests **60**

Appendix B: Equipment and materials used for Salt Mist Test **61**

Appendix C: Excelsheets of Reprocessing data **62**

Appendix D: Excelsheet Salt Mist Test **65**

Appendix E: Data Analysis in RStudio **66**

1 Introduction

Yearly, approximately 313 million surgical procedures are performed worldwide. Despite this large volume, only about 6% of these procedures occur in low- and middle-income countries (LMICs), home to over a third of the global population [1]. Access to safe and affordable surgical care remains a significant challenge for LMICs [2]. Five billion people globally lack access to safe, timely, and affordable surgical and anaesthetic care. This lack of access results in an increased risk of complications from surgical procedures, with mortality rates ranging from 5% to 10% and complication rates between 3% and 16%. Many of these complications could have been prevented [1].

Unifix Care's mission is to make surgery safer and more affordable by supplying hospitals in the region with high-quality, cost-effective surgical instruments. Given the limited resources available in many LMICs, selecting materials that can endure frequent use and reprocessing while maintaining quality and safety is crucial [3]. Instrument reprocessing involves several stages, including cleaning, inspection, and sterilisation. If one of these stages is omitted or inadequately implemented, instrument dysfunction or post-operative complications, such as surgical site infections, may occur. In LMICs, the ability to reprocess instruments effectively is often limited due to a lack of resources and specific information on proper reprocessing techniques, such as cleaning, disinfection, sterilisation procedures, and instrument maintenance [3, 4]. A literature review from 2020 highlighted a significant need for more research on sterile processing in LMICs, which is often overlooked in Infection Prevention and Control evaluations [5].

In many hospitals within these countries, automated cleaning machines are unavailable, necessitating manual instruments cleaning. Manual cleaning often involves solutions with enzymatic agents or sodium hypochlorite ($NaClO$) [3]. Inconsistency in manual cleaning practices can lead to considerable variation in cleaning quality, which can affect instrument longevity and patient safety [6]. A frequently observed problem is susceptibility to corrosion on surgical instruments. This is a form of corrosion that not only shortens the lifespan of the instruments but also prevents effective sterilisation providing a site for microorganisms to hide, thus increasing the risk of post-operative infections in patients. Additionally, susceptibility to corrosion can compromise the structural integrity of instruments, which may lead to mechanical failure during use or to release of particles into the surgical site, potentially causing harm to patients and increasing the risk of infection [7].

The susceptibility to corrosion of surgical instruments depends heavily on the chosen material, with stainless steel being most commonly used. However, even stainless steel is susceptible to corrosion depending on the composition and the conditions to which it is exposed [8]. Given sufficient time, stainless steel forms a protective layer on its surface that helps protect against corrosion, reducing its susceptibility. [9].

The aim of this research is to explore surgical instruments' susceptibility to corrosion under various reprocessing and corrosion conditions, explicitly focusing on stainless steel 304, 410, and 420. This can support Unifix Care's mission, as it provides insights into how they can make informed decisions regarding developing durable surgical instruments in their target LMIC.

1.1 Research Questions

In the previous section, the significance of understanding how various factors, such as material composition and cleaning methods, influence the susceptibility to corrosion of surgical instruments under manual reprocessing conditions was discussed. This study aims to address the following main research question:

Main Research Question:
What factors influence the susceptibility to corrosion of surgical instruments during reprocessing containing manual cleaning, and to what extent can an accelerated testing tool adequately indicate this susceptibility?

To answer this question, the following sub-research questions are formulated:

1. How do material differences in stainless steel alloys (304, 410, and 420) impact the susceptibility to corrosion under varying reprocessing conditions?
2. How does using sodium hypochlorite versus an enzymatic cleaning agent affect the susceptibility to corrosion and the number of cycles to corrosion onset of surgical instruments?
3. To what extent does incorporating a rest period between reprocessing cycles influence the susceptibility to corrosion and the number of cycles to corrosion onset?
4. How does the extent of corrosion observed in accelerated testing compare to that observed after multiple instrument reprocessing cycles?
5. Does the surface area affected by corrosion in accelerated testing correlate with the number of cycles to corrosion onset during instrument reprocessing?

2 Theoretical Framework

This chapter presents the foundational theories and concepts essential to understanding factors that influence susceptibility to corrosion in surgical instruments during reprocessing. It begins with an introduction to the theoretical framework of instrument reprocessing and its application in low- and middle-income countries (LMICs), forming a basis for how reprocessing is examined throughout this thesis. The focus then shifts to stainless steel as a commonly used material for surgical instruments, discussing various types and their properties. Next, corrosion mechanisms are explored in more depth to provide essential context. Finally, the chapter presents an overview of accelerated corrosion testing methods, with specific attention given to the Salt Mist Test.

2.1 Instrument reprocessing in LIMCs

Surgical site infections (SSIs) are a common and preventable complication in low- and middle-income countries (LMICs). Due to limited resources and infrastructure, SSI rates in these regions are significantly higher than in high-income countries [10]. Although better cleaning and sterilisation of instruments could reduce SSI risk, LMICs often lack the resources to meet international infection prevention guidelines, such as those from the WHO [5]. The complexity of sterile processing (SP) in LMICs is compounded by conflicting guidelines, resulting in inconsistencies in procedural application [5]. This chapter outlines the main steps in instrument reprocessing, WHO guidelines, and findings from Unifix's fieldwork in Uganda. Finally, the rationale for selecting the 4-bucket system as the reprocessing method for this study is discussed.

2.1.1 Reprocessing of surgical instruments

According to the European Medical Device Regulation (MDR), surgical instruments fall under the Class Ir classification, meaning they are reusable medical devices used invasively during surgery. Therefore, they must be thoroughly cleaned and sterilised after each procedure to ensure patient safety. Instruments such as scalpels and forceps require rigorous cleaning and sterilisation due to direct contact with internal body tissues [11]. Proper cleaning and sterilisation of these instruments is an absolute necessity.

Instrument reprocessing in four steps

The reprocessing of surgical instruments typically involves four fundamental steps: (1) cleaning, (2) inspection and packaging, (3) sterilisation, and (4) storage and transport.

1. **Cleaning** Cleaning is the first and most important step, involving the removal of visible dirt from instruments, such as blood and tissue residues, using water and detergents [12]. There are two types of detergents commonly used:

   - **Regular detergents** ("soap") loosen fats and dirt particles, allowing them to be rinsed off with water. However, they are limited in breaking down complex biological residues [12].
   - **Enzymatic detergents** use enzymes such as proteases to break down proteins in organic contamination. These detergents are essential in medical settings as they effectively target biological residues on surgical instruments [12].

   Cleaning aims to remove all visible contamination, but it does not kill microorganisms [12].

2. **Inspection and packaging** After cleaning, instruments are carefully inspected to ensure all residues are removed. This step is crucial for effective sterilisation. Worn or defective instruments are removed, and clean instruments are correctly packaged using sterilisation wraps or containers to maintain sterility [13].

3. **Sterilisation** Sterilisation ensures that all microorganisms are killed. The most common method is steam sterilisation in an autoclave at 134°C, which typically lasts between 20 and 40 minutes. A lower temperature (121°C) may be used for heat-sensitive instruments requiring longer exposure. After sterilisation, instruments are dried using the vacuum system in the autoclave [12].

4. **Storage and transport** After sterilisation, instruments must be stored in a sterile environment to prevent recontamination. They are packed in special trays or bags and stored in a dry, clean location until transported to the operating room [12].

2.1.2 Reprocessing protocols for surgical instruments in LMICs

In LMICs, the reprocessing of surgical instruments —particularly the cleaning stage— is manual mainly due to the lack of automation in hospitals, leading to inconsistencies in cleaning and variations in quality [14, 15]. The WHO recommends a three-step process for instrument cleaning: soaking in detergent, rinsing with clean water, and a second rinse to remove any residue, followed by drying [16]. However, limited access to essentials like warm water, enzymatic detergents, and reliable sterilisation equipment makes it challenging for many LMICs to consistently adhere to these guidelines [17, 18].

Conflicting guidelines between WHO standards and national recommendations frequently lead to confusion and inconsistency in sterilisation practices. In some instances, healthcare workers adhere to outdated or inadequately adapted national protocols, reducing their willingness to implement WHO guidelines. This issue is further exacerbated by the fact that inspectors and healthcare providers are not always up to date with the latest revisions, which hinders the adoption of uniform, safe procedures [14, 15]. Additionally, healthcare staff often face limitations due to a lack of training in modern infection prevention techniques, with outdated procedures and minimal practical education resulting in inadequate reprocessing methods that increase infection risk and significantly shorten instrument lifespan [19, 18].

These challenges underscore that adherence to WHO guidelines in LMICs is not merely a matter of knowledge transfer but requires structural support and regular adaptation of national protocols to reflect local resources and constraints. Such measures are essential to achieving consistent, safe reprocessing practices and improving patient safety in resource-limited settings [20].

Figure 1: Configuration of a 4 bucket system in Kampala, Uganda

2.1.3 Observations of the 4-Bucket System in Uganda

In 2023, Unifix employees observed the reprocessing of medical instruments in 28 hospitals in Uganda. A notable finding was the widespread use of the "4-bucket system" (see Figure 1). This system is a common adaptation in Uganda, although it deviates from the WHO's recommended three-step cleaning process. Despite a shared foundation, there was considerable variation in how the 4-bucket system was implemented across hospitals. At least two buckets were always filled with clean water, while the other buckets contained

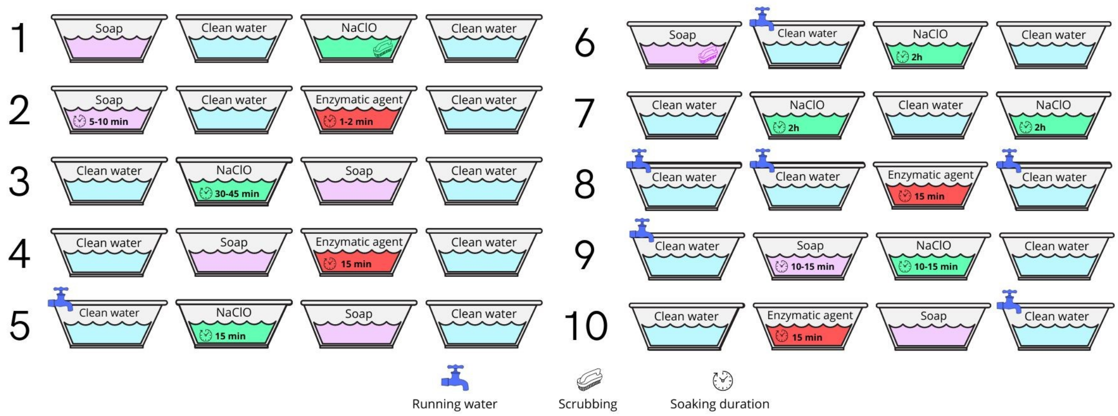


Figure 2: Observed configurations of the 4 bucket system in Uganda and Kenya

different cleaning agents, such as dish soap, sodium hypochlorite, or enzymatic detergents. The sequence, contents, and soaking times varied significantly between hospitals. Figure 2 illustrates ten different configurations of the 4-bucket system observed in hospitals in Uganda, highlighting these variations.

2.1.4 Implementation of manual cleaning in this study

This study adopts the 4-bucket system as the primary method for testing material degradation under different cleaning conditions. The steps in this system are illustrated in Figure 3. While this approach differs from the WHO's recommended three-step process—which includes soaking in detergent followed by two rinses—the 4-bucket system introduces an initial cleaning step using a non-enzymatic soap (Omo), followed by rinsing, soaking in either sodium hypochlorite or Sanizyme, and a final rinse with clean water.

Aside from differences in the sequence, the main deviation from WHO guidelines is the additional Omo step. This step was likely introduced to complement sodium hypochlorite, a disinfectant that, while effective at killing microorganisms, lacks the cleaning properties needed to remove organic material. Organic residues, such as blood or tissue, can inhibit the disinfectant's effectiveness [21, 22]. Using Omo first removes surface contaminants, allowing sodium hypochlorite to focus on disinfection rather than cleaning.

A consistent cleaning protocol is crucial for accurately comparing the effects of various cleaning agents on material degradation. Using Omo as an initial step standardises the cleaning process across tests, ensuring that any differences in material degradation result from the cleaning agents, not variations in the cleaning method. Sterilisation remains an essential step to ensure patient safety. Thus, after cleaning, the instruments in this study will undergo a sterilisation process, reflecting typical healthcare practices.

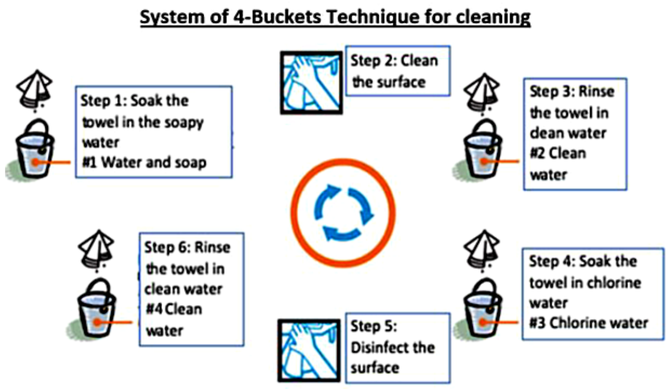


Figure 3: Cleaning and disinfection procedures for healthcare facilities recommended by the Ugandan Ministry of Health in 2022 [23]

2.2 Stainless steel for surgical instruments

Stainless steel is one of the most widely used materials in medical instruments due to its excellent balance between mechanical strength and corrosion resistance [24]. Surgical instruments, in particular, require materials that can withstand repeated exposure to reprocessing processes, moisture, and body fluids while maintaining their functionality over time [25]. The versatility of stainless steel arises from its chemical composition and microstructure, which can be tailored to meet the specific demands of different applications. This section provides an overview of the key types of stainless steel used in medical environments—austenitic, ferritic, and martensitic—with a focus on grades 304, 410, and 420, as well as the role of key alloying elements like chromium, nickel, and carbon in determining their properties [26, 9]. Additionally, this section covers the formation and importance of the passivation layer, essential to the corrosion resistance of stainless steel.

2.2.1 Austenitic, ferritic, and martensitic stainless steel

Stainless steel is divided into three primary types based on its microstructure: austenitic, ferritic, and martensitic. These types have distinct crystal structures and mechanical properties, which impact their strength, corrosion resistance, and magnetic properties [26]. Figure 4 illustrates the crystal structures of these three types of stainless steel.

- **Austenitic stainless steel**:Austenitic steels have a face-centred cubic (fcc) structure, making them non-magnetic with excellent ductility and formability. These steels contain high levels of chromium and nickel, which give them superior corrosion resistance. Their ability to withstand a wide range of temperatures makes them the most commonly used stainless steels for demanding environments, including medical applications [27].
- **Ferritic stainless steel**: Ferritic steels have a body-centred cubic (bcc) structure and contain lower amounts of nickel or none, making them magnetic and more cost-effective. They provide moderate corrosion resistance and strength but are generally less resistant to corrosion than austenitic steels [26, 24].
- **Martensitic stainless steel**: Martensitic steels are known for their body-centred tetragonal (bct) structure and the ability to be hardened by heat treatment, resulting in high strength and wear resistance. While they offer excellent mechanical properties, they are generally less corrosion-resistant than the other types [27, 28].

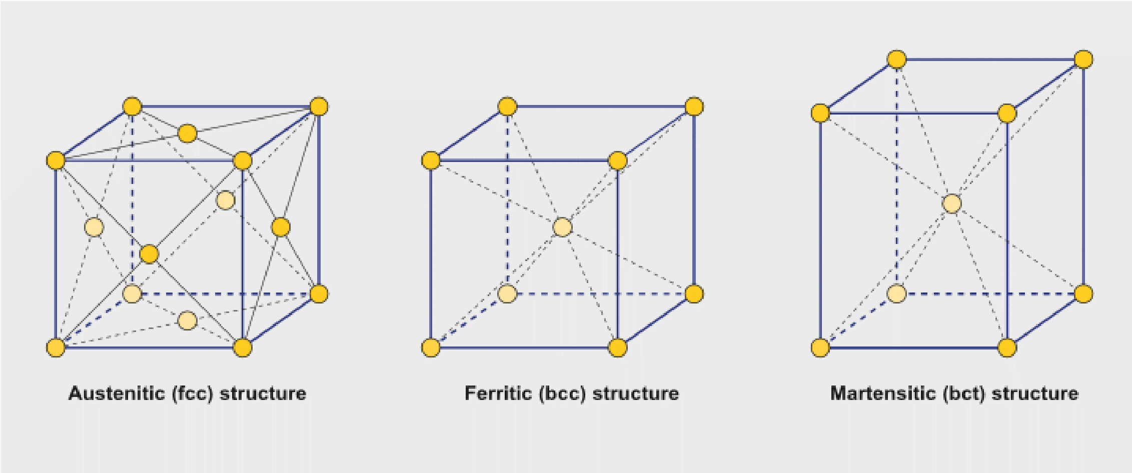


Figure 4: Crystal structures of Austenitic, Ferritic, and Martensitic stainless steels [29]

2.2.2 The 300 and 400 series for stainless steel

The diversity of stainless steel arises from the many possible combinations of crystal structures and alloying elements. Numerous stainless steel grades have been developed by varying the amounts of elements like chromium, nickel, and carbon, each with specific properties suited to different applications [23]. There are over 150 different grades of stainless steel, many of which are classified into series based on their composition and characteristics [24].

The 300 and 400 series are the most widely used, especially in medical applications where corrosion resistance and mechanical strength are essential. The 300 series, such as type 304, includes austenitic steels, while the 400 series, including types 410 and 420, comprises ferritic and martensitic steels [24, 26].

2.2.3 Chemical composition of stainless steel

Stainless steel's corrosion resistance and mechanical properties are determined mainly by the chemical composition of its alloying elements, primarily chromium, nickel, and carbon. These elements interact to form a protective layer and enhance the steel's performance in different environments [26].

Key alloying elements:

- **Chromium (Cr):** Chromium is an essential component of stainless steel, usually found in concentrations of 10.5% or higher. It forms a thin passivation layer of chromium oxide on the steel's surface, which prevents further oxidation and protects the steel from corrosion. This self-healing layer is crucial when corrosion resistance is required [26, 30].
- **Nickel (Ni):** Nickel enhances corrosion resistance and mechanical strength by stabilising the austenitic structure in steels like 304. It also improves resistance to chloride-induced pitting and stress corrosion cracking [23, 31].
- **Carbon (C):** Carbon increases the hardness and strength of stainless steel but can also make it more susceptible to intergranular corrosion if not adequately controlled. In martensitic steels like 410 and 420, a higher carbon content allows for heat treatment,

significantly increasing hardness, making it ideal for cutting instruments, though at the cost of lower corrosion resistance [28, 9].

2.2.4 Passivation layer and self-healing properties

One of the essential reasons stainless steel is corrosion-resistant is due to the formation of a passivation layer. This layer is a thin film, typically made of chromium oxide (Cr_2O_3), that forms on the surface of stainless steel when exposed to oxygen. The passivation layer acts as a barrier, protecting the underlying steel from further oxidation and corrosion. This process occurs naturally in any stainless steel containing at least 10.5% chromium, which is necessary to form and maintain the protective layer [26].

The passivation layer is not a one-time formation but dynamic and self-healing. If the layer is damaged, chromium in the stainless steel will react with oxygen in the environment to reform the protective film. This self-healing ability is essential for medical instruments exposed to harsh conditions, such as sterilisation, chemical cleaning agents, and bodily fluids [30]. See Figure 5 for a visual representation of this process. Although the initial passivation begins within seconds to minutes, research indicates that the layer requires several hours to reach complete stability and maximum protective strength, which is especially relevant in repeated-use environments where the passive film may be frequently disrupted [26].

The formation and stability of the passivation layer depend on the chemical environment, pH, and presence of chloride ions. High chloride concentrations, for example, can weaken the passivation layer, increasing the steel's susceptibility to localised corrosion. Therefore, maintaining optimal conditions is crucial for the long-term durability of stainless steel in medical settings, where exposure to such environments is frequent [30].

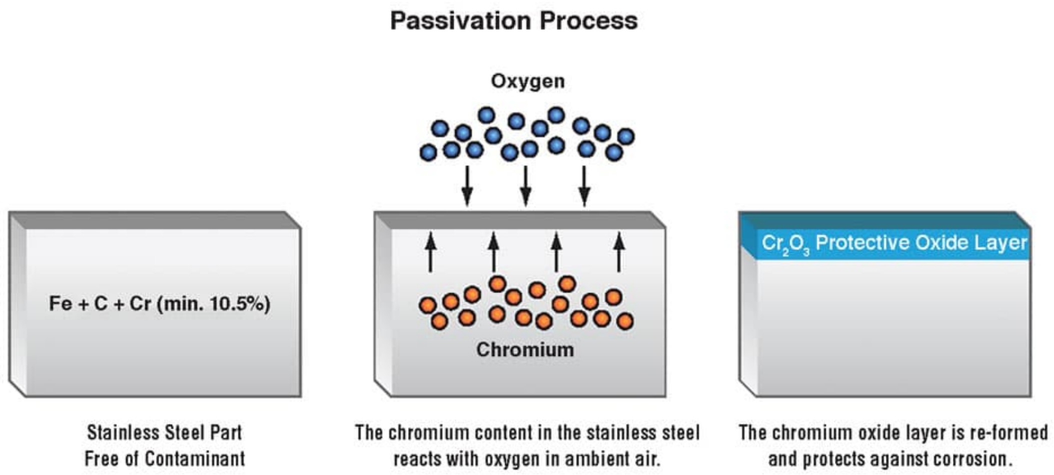


Figure 5: Illustration of the passivation process in stainless steel. Chromium in the stainless steel reacts with oxygen in ambient air to form a protective chromium oxide layer, which protects against corrosion [32].

Importance of the passivation layer

The passivation layer is essential for ensuring the long-term durability of stainless steel, especially in environments prone to moisture and chemical exposure, such as medical devices. Surgical instruments undergo repeated sterilisation cycles involving moisture, and cleaning agents that could lead to corrosion [9]. The passivation layer's self-healing ability ensures that the steel remains protected from corrosion as long as oxygen is present. However, completely stabilising this protective layer can take several hours, crucial in medical applications where instruments undergo frequent cycles that may disrupt the layer. This protective mechanism is a critical factor in surgical instruments' extended service life and reliability, making stainless steel an ideal material for such applications [26, 30].

Conclusion

Stainless steel is the material of choice for medical instruments due to its strength, corrosion resistance, and versatility [30]. The 304 austenitic stainless steel stands out for its superior corrosion resistance, primarily due to its higher chromium and nickel content. It is ideal for surgical instruments exposed to aggressive environments [9]. In contrast, 410 and 420 martensitic stainless steels offer greater mechanical strength and hardness but are more susceptible to corrosion, particularly in chloride-rich environments [31]. This highlights the trade-off between corrosion resistance and mechanical strength in choosing the suitable material for specific medical applications. Ultimately, the passivation layer plays a crucial role in extending the life and functionality of these instruments by providing a self-healing barrier against corrosion, ensuring that stainless steel remains a reliable and durable material in the demanding context of healthcare [26, 30].

2.3 Corrosion in Stainless Steel

Stainless steel is valued in medical applications for its corrosion resistance, yet it can still degrade under specific conditions, particularly in chloride-rich environments. This section examines the primary corrosion forms affecting 304, 410, and 420 stainless steels. It explores the role of cleaning agents and passive layer maintenance in supporting their long-term durability [9, 30].

2.4 Fundamentals of Corrosion

Corrosion is an electrochemical process that leads to the degradation of metals through reactions with their environment. It involves anodic and cathodic reactions, as Figure 6 illustrates. When stainless steel is exposed to a corrosive environment, such as water or air containing moisture, oxidation can occur on specific metal surface areas, creating anodic and cathodic regions [33].

In the anodic area, iron atoms lose electrons (oxidation) and form iron ions (Fe^{2+}), as shown in the reaction:

$$Fe \rightarrow Fe^{2+} + 2e^-$$

The released electrons then travel through the metal to the cathodic area, where they reduce oxygen in the presence of water, producing hydroxide ions (OH^-) in the following reactions:

$$O_2 + 4H^+ + 4e^- \rightarrow 2H_2O$$

$$O_2 + 2H_2O + 4e^- \rightarrow 4OH^-$$

These hydroxide ions can then react with iron ions to form iron oxide, commonly known as rust (Fe_2O_3). This oxide accumulates on the surface and weakens the metal.

This process is accelerated in environments rich in chloride ions, such as saline solutions, as chlorides disrupt the passivation layer, leading to localized corrosion [9].

This electrochemical process is fundamental to understanding the susceptibility of stainless steel to corrosion, especially in medical environments where exposure to moisture, cleaning agents, and chloride ions is frequent [33, 9].

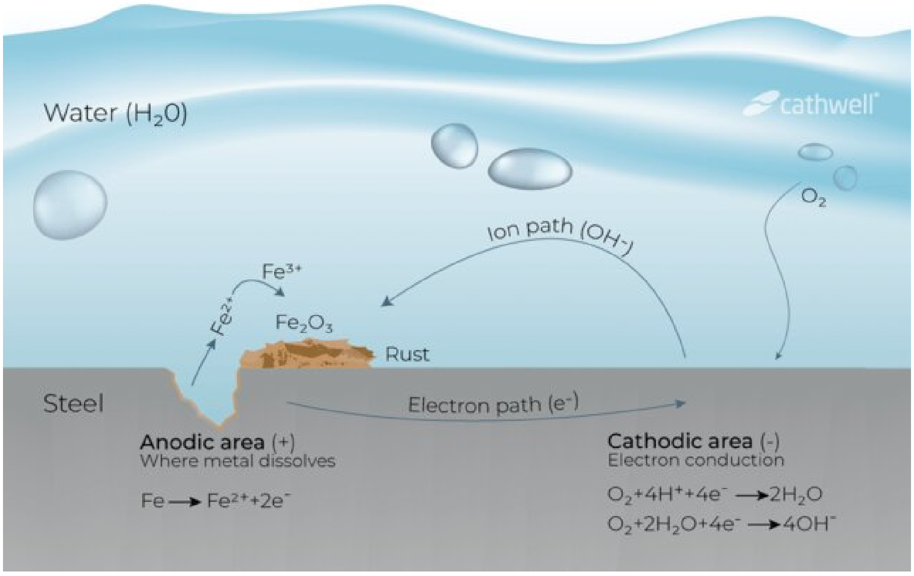


Figure 6: Electrochemical corrosion process in stainless steel, showing anodic and cathodic reactions that lead to rust formation [34].

2.4.1 Forms of corrosion

Corrosion in stainless steel can occur in various forms, each influenced by specific environmental conditions (see Figure 7). The most critical types affecting 304, 410, and 420 stainless steels in medical applications are:

- **Uniform Corrosion**: This form of corrosion occurs evenly across the exposed surface. Although less severe than localised corrosion, it reduces the overall thickness and strength of the material over time. Stainless steels such as 304 and 410 are susceptible to uniform attack under acidic conditions, which can be mitigated by maintaining a stable passivation layer [35].
- **Pitting Corrosion**: A highly localised form of corrosion that develops when the passive layer is compromised, particularly in chloride-rich environments. 410 and 420 martensitic steels, with their lower chromium content, are more vulnerable to pitting than 304 austenitic steel, which has higher chromium and nickel levels that improve resistance [9].
- **Intergranular Corrosion**: This form occurs when chromium depletion at grain boundaries leads to localised attack, often due to improper heat treatment. This form of corrosion particularly affects 410 and 420 martensitic steels with higher carbon content, commonly arising in heat-affected zones during welding, where chromium carbides precipitate and reduce the surrounding chromium levels, compromising corrosion resistance [28].
- **Crevice Corrosion**: Found in confined spaces where oxygen is restricted, such as in joints or underseals, leading to a breakdown of the passive layer. This form of corrosion is especially problematic in narrow gaps, where an aggressive local

environment can develop. All stainless steels are susceptible to crevice corrosion, but the high corrosion resistance of 304 provides better protection in such environments [35].

- **Transgranular Cracking**: A form of stress-corrosion cracking in which cracks spread directly through the metal grains rather than along the boundaries between them. Transgranular cracking usually occurs under tensile stress in the presence of specific corrosive agents, such as chlorides, and can significantly impact the mechanical integrity of medical instruments [33].
- **Intergranular Cracking**: Similar to intergranular corrosion, this form involves the propagation of cracks along grain boundaries, often due to residual tensile stresses. Improper heat treatment can increase the susceptibility of martensitic steels, like 410 and 420, to this form of corrosion [36].
- **Selective Leaching**: This corrosion type involves the selective removal of one element from an alloy, leaving behind a weakened, porous structure. In stainless steel, chromium or nickel may be selectively leached under specific conditions, although this is less common in medical applications [37].

These corrosion forms highlight the challenges stainless steels faces, particularly in medical settings where exposure to aggressive agents like moisture and chlorides is common. A comprehensive understanding of these types can guide the selection of appropriate stainless steel grades and help establish effective corrosion mitigation strategies for medical instruments.

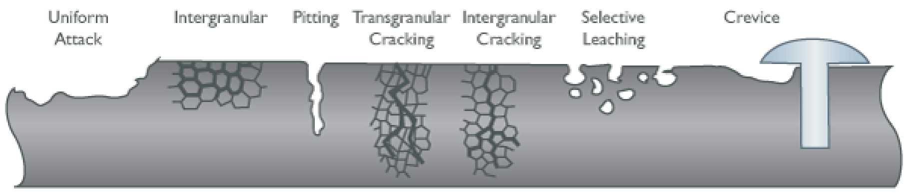


Figure 7: Forms of corrosion that affect stainless steels used in surgical instruments [9].

2.4.2 Impact of cleaning agents on corrosion resistance

Proper cleaning is essential to maintain the corrosion resistance of stainless steel surgical instruments. While not all cleaning agents directly restore the passive layer, they remove contaminants like dirt and organic matter from the surface. This process re-exposes the steel to oxygen, which is necessary for the natural self-healing of the passive layer [9]. By allowing oxygen contact, stainless steel can reform its protective chromium oxide film, reducing its susceptibility to further corrosion.

However, aggressive cleaning agents or improper protocols can damage this protective layer, leading to localised corrosion. For example, exposure to chloride-rich solutions disrupts the passivation layer and increases vulnerability to localised corrosion, such as pitting [35].

In contrast, specific cleaning agents help preserve or even strengthen the passive layer, especially when used at the correct concentrations. Studies on stainless steel in synthetic hard water show that specific products can maintain the passive layer without leaving harmful residues. This indicates that the right cleaning agents can protect against corrosion, even in challenging water conditions typical of medical settings [9].

Electrochemical studies further demonstrate that well-diluted cleaning solutions do not alter the passive layer's thickness or composition, preventing corrosion initiation. This finding is especially relevant for martensitic steels like 410 and 420, which are more prone to chloride-induced corrosion due to their lower chromium content compared to 304 austenitic steel [35].

2.4.3 Conclusion

Corrosion in stainless steel remains a concern for medical instruments, especially those made from 410 and 420 martensitic steels, which offer higher mechanical strength but lower corrosion resistance compared to 304 austenitic steel. Understanding the different forms of corrosion and how they affect these materials is crucial for ensuring the longevity and functionality of surgical instruments. Proper cleaning protocols and maintaining the integrity of the passive layer are essential steps in minimizing corrosion risk and extending the life of stainless steel instruments in medical environments [9, 30].

2.5 Accelerated corrosion testing

2.5.1 Methods for accelerated corrosion testing

Accelerated corrosion testing methods are essential for simulating and expediting natural degradation processes, providing valuable insights into material durability. Each method offers unique benefits and limitations, especially regarding geometric stress and practical feasibility, making a thorough evaluation critical for selecting the most suitable approach.

- **Salt Mist Test (SMT)**: The SMT involves exposure to a continuous saline mist at elevated temperatures, effectively simulating saline-rich environments [38]. This method is straightforward and cost-effective, allowing uniform exposure across the sample surface. It is particularly beneficial for assessing corrosion behaviour in areas with complex geometries and stress points[39]. While the SMT is often discussed in specific field applications, its simplicity and controlled saline conditions make it widely adopted as a practical tool for surface durability evaluation in laboratory settings [40].
- **Cyclic Corrosion Testing (CCT)**: This test cycles samples through controlled wetting and drying phases, often incorporating temperature changes to better mimic fluctuating environmental conditions [41]. CCT effectively captures corrosion across the entire sample, including areas of high geometric stress, making it suitable for materials with complex shapes like surgical instruments [39]. However, CCT requires advanced equipment to maintain precise cycling conditions, impacting feasibility and cost for routine studies [42].
- **Immersion Testing**: This method submerges samples in a corrosive solution, providing insights into long-term stability by maintaining consistent exposure. However, immersion testing lacks environmental variability, potentially limiting its applicability for real-world scenarios where conditions fluctuate [43]. While effective for observing corrosion across large surfaces, it may not adequately simulate corrosion patterns in stress-concentrated areas due to its static setup [44].
- **Electrochemical Behaviour Testing**: Techniques like potentiodynamic polarisation and electrochemical impedance spectroscopy measure corrosion at specific points on the material surface, offering rapid insights into corrosion mechanisms [43]. However, electrochemical methods focus on isolated points rather than the entire geometry of a sample, thus failing to capture geometric stresses comprehensively

[44]. This method also requires specialized equipment and expertise, making it less feasible to assess complex samples.

Given these considerations, the Salt Mist Test was selected as the accelerated testing tool for this study due to its balance of simplicity, full-surface exposure, and practical feasibility. Its straightforward approach and lower equipment requirements make it suitable for assessing corrosion resistance under controlled saline and humid conditions.

2.5.2 Salt Mist Test

The Salt Mist Test (SMT), also known as the Salt Fog or Salt Spray Test, is an accelerated corrosion test performed in a salt mist chamber. It simulates and speeds up the corrosion process that metals and alloys might undergo in real-world conditions. There are several variations of this test: Neutral Salt Spray (NSS), Acetic Acid Salt Spray (AASS), and Copper-Accelerated Acetic Acid Salt Spray (CASS). This thesis focuses on the NSS test, particularly relevant for metals and alloys. AASS and CASS are more suited for decorative coatings, making them less applicable for testing surgical instruments.[45].

The SMT has been used for over 100 years and has evolved to improve reproducibility and reliability. It is based on "oxygen concentration cell corrosion". When a droplet of water rests on a metal surface, oxygen from the droplet and air creates a gradient, resulting in an oxidation potential of about 0.3 volts. This causes the metal in the droplet's centre to dissolve and become positively charged. Electrons move to the droplet's edge, reacting with hydrogen ions to form hydrogen gas. This reaction increases the pH, making the edge of the droplet less acidic, which causes dissolved metal ions to form solid particles. [40]. Figure 8 presents the visual presentation of this process.

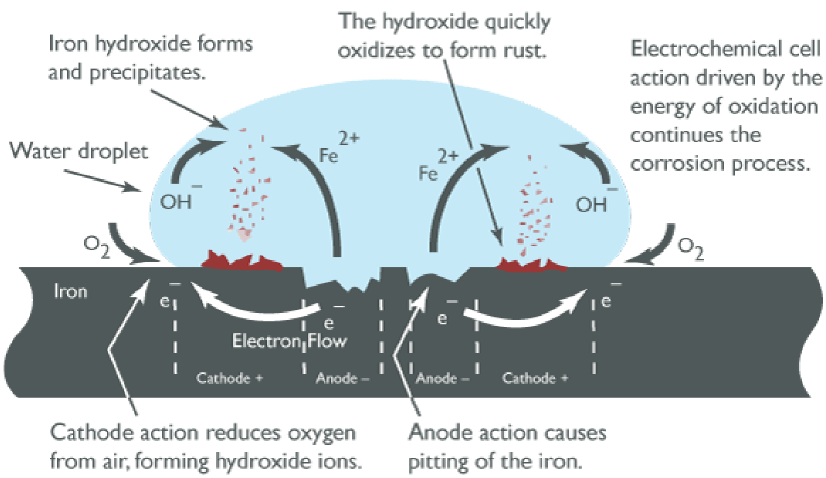


Figure 8: Oxygen concentration cell corrosion [46]

The SMT accelerates corrosion through several mechanisms:

- **Salt solution:** Salt (sodium chloride) is incorporated into the water mist sprayed onto the metal surface. The presence of salt increases the solubility of metal ions in the droplets, extending the duration of the corrosion reaction as the reaction cells remain active.
- **Increased temperature:** The test is often conducted at elevated temperatures. Heat accelerates chemical reactions, thus speeding up the corrosion process.

- **Continuous refreshing of corrosion Cells:** The salt solution continuously flows over the surface by tilting the test sample. This prevents the accumulation of reaction by-products (such as metal ions and hydroxides) that could otherwise slow down the corrosion. Instead, the cells are refreshed with new electrolytes, ensuring uninterrupted reaction.
- **Fine mist:** The fine mist creates numerous tiny droplets on the metal surface, continuously forming new corrosion cells and ensuring constant exposure.

The SMT accelerates natural corrosion using salt, heat, sample tilting, and a continuous fine mist. This approach provides a rapid assessment of material durability and performance in practical conditions [47, 48].

Commercial SMT setups can be costly and are generally designed for large-scale use. Consequently, there is a need for affordable, reliable methods for smaller-scale testing. Various solutions are available online, including informal sources like blogs and videos, as well as academic research on adapting the method for smaller-scale applications [38].

Smaller-scale test designs vary in objectives and methods. Academic research typically uses well-documented procedures, while informal tests prioritise convenience and accept a broader range of results. Guidelines for the SMT are provided by the American Society for Testing and Materials (ASTM) in the document "Standard Practice for Operating Salt Spray (Fog) Apparatus" and by ISO 9227:2022.

Key points include:

- For NSS, use a neutral, approximately 5% sodium chloride solution in a controlled environment.
- The solution must reach 35 °C ± 2 °C before atomisation.

3 Materials and methods

This chapter comprehensively presents the materials and methodologies applied to analyse surgical instrument degradation under various reprocessing conditions. It starts by describing the materials used and focusing on the types of stainless steel selected for their relevance in medical applications. The chapter then details the experimental protocols, including reprocessing and accelerated corrosion testing, to assess material performance and susceptibility to degradation systematically. In addition, methods for data collection, processing, and statistical analysis are outlined to ensure a rigorous evaluation framework.

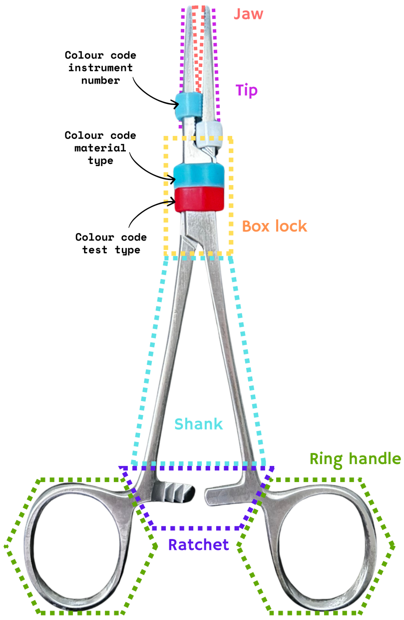


Figure 9: *Components of the Dunhill Artery Forceps*

3.1 Reprocessing testing

This section describes the reprocessing tests conducted to replicate the repetitive cleaning cycles that surgical instruments undergo in LMICs. Each test involves different cleaning agents and reprocessing frequencies, including intermittent and continuous exposure to sodium hypochlorite and enzymatic detergents. Standardising the protocols and conditions establishes a basis for comparing the effects of various reprocessing methods on material degradation.

3.1.1 Materials

For this study, three types of stainless steel (SS) were selected: 410, 420, and 304. These SS types are commonly used materials for medical instruments due to their corrosion resistance and mechanical properties [24]. The chemical composition of each SS type was confirmed using a Direct Emission Spectrometer. Table 1 provides an overview of the composition of the different steel types. A total of 180 surgical instruments were used, with each SS type comprising 60 instruments. In the first two tests, continuous NaClO reprocessing and continuous Sanizyme reprocessing, 60 instruments were used per test. This included 20 instruments of each SS type. The third and fourth tests, intermittent NaClO reprocessing and intermittent Sanizyme reprocessing used 30 instruments per test. Each test included ten instruments of each SS type. Table 2 provides a summary of this distribution. The surgical instruments tested were 130-mm Dunhills Artery forceps provided by a manufacturer in Pakistan. These forceps are characterised by their box lock, ring handle, ratchet, shank, tip, and jaw, as depicted in Figure 1. An image of the instrument, including the naming of each part, will be inserted for further clarification. A complete list of materials and equipment used in this study can be found in Appendix A.

3.1.2 Methods

Sample preparation

The surgical instruments were used directly in the experiments upon receipt, without further adjustment or treatment. They were colour-coded with sterilisable silicone rings to

Element	Stainless steel 304 (%)	Stainless steel 410 (%)	Stainless steel 420 (%)
Chromium (Cr)	18.293	12.021	13.102
Nickel (Ni)	8.391	0.239	0.101
Carbon (C)	0.067	0.139	0.181
Manganese (Mn)	1.625	0.315	0.613
Silicon (Si)	0.275	0.269	0.271
Phosphorus (P)	0.015	0.023	0.021
Sulfur (S)	0.009	0.017	0.016
Iron (Fe)	71	87	86

Table 1: *Composition of stainless steel grades 304, 410, and 420 determined using Direct Emission Spectroscopy*

Reprocessing tests	304	410	420	Total instruments
1. Continuous NaClO	20	20	20	60
2. Continuous Sanizyme	20	20	20	60
3. Intermittent NaClO	10	10	10	30
4. Intermittent Sanizyme	10	10	10	30
Total instruments	60	60	60	**180**

Table 2: *Distribution of stainless steel instruments across reprocessing tests*

identify individual instruments throughout the various test cycles, as shown in Figure 9. All instruments were photographed before testing to document any pre-existing damage, stains, or other anomalies. These photographs served as a reference for evaluating any changes in the condition of the instruments after the cleaning cycles.

A blood simulant was used in each test to replicate real-world surgical conditions. The instruments were first immersed in a salt solution with a chloride concentration of 103 mmol/L, corresponding to the chloride content found in human blood [49]. This solution was prepared by dissolving 60.18 grams of pure NaCl (sodium chloride) from Labshop.nl into 10 litres of deionised water. This step simulated the instruments' exposure to blood during surgery.

This process was consistently applied for each SS type and cleaning agent. All steps were strictly timed using a stopwatch to ensure consistency.

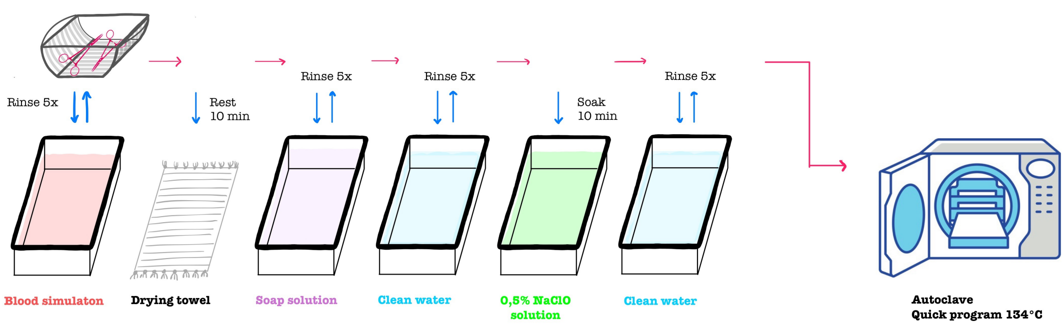


Figure 10: *Setup of Continuous NaClO Reprocessing*

Test 1: Continuous NaClO Reprocessing

Test 1 used sodium hypochlorite (NaClO) as cleaning agent. The procedure followed these steps, with each cycle lasting approximately 60 minutes. A total of 60 instruments were processed simultaneously in each cycle. Eight consecutive cycles were completed each day. Figure 10 shows a schematic representation of all steps.

Step 1 - Blood Simulation: A colander containing the instruments was rinsed five times through a blood simulant solution.

Step 2 - Dryer Towel: The colander was placed on a towel. The instruments rested for 10 minutes next to the tub, allowing them to dry while still covered in the simulation fluid.

Step 3 - Soap Solution: As the first cleaning step, the instruments were rinsed five times with 30 grams of OMO detergent dissolved in 10 litres of tap water.

Step 4 - Rinsing in Clean Water: The instruments were thoroughly rinsed in clean tap water five times.

Step 5 - NaClO: The instruments were then soaked for 10 minutes in a 0.5% NaClO solution.

Step 6 - Rinsing in Clean Water: The instruments were again rinsed five times in clean tap water.

Step 7 - Autoclaving: The cleaned instruments were placed in racks and sterilised using a MELAtronic 15 EN+ autoclave. The autoclave process involved 14 minutes of sterilisation at 134°C, followed by 2 minutes of pressure adjustment and 10 minutes of drying, for a total autoclave time of 26 minutes per cycle.

Step 8 - End of Cycle: Finally, the instruments were removed from the autoclave and placed back in the colander. After each testing day, they were placed in a clean, dry area to air dry.

During these cycles, the instruments were arranged in a colander to ensure that they were all fully immersed in the solutions simultaneously. The tubs containing the various solutions were covered at the end of each testing day. The solutions and rinse water were refreshed after every three days of testing.

At the end of the first 8 cycles, the instruments were inspected for any signs of corrosion. All observed corrosion was documented in an Excel sheet, and photographs were taken. Instruments were excluded from further testing if corrosion was detected, except in the case of corrosion on the box lock. Corrosion on the box lock was recorded and photographed, but it was not considered a criterion for exclusion.

This procedure was repeated for three consecutive days, meaning instruments were subjected to a maximum of 24 reprocessing cycles.

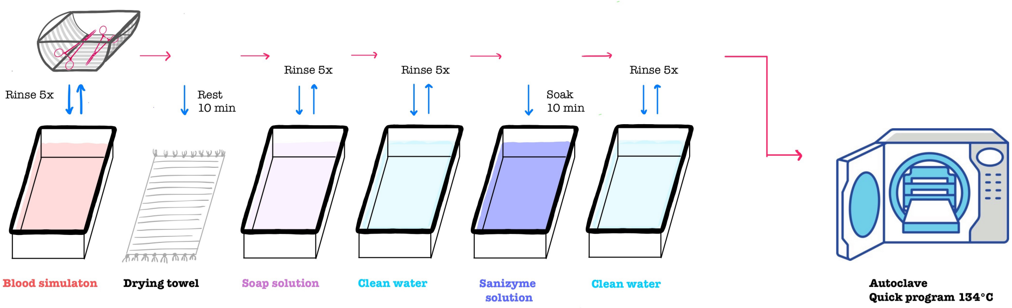


Figure 11: *Setup of Continuous Sanizyme Reprocessing*

Test 2: Continuous Sanizyme Reprocessing

Test 2 followed the same procedure as described in Test 1 (Steps 1 through 8), with the only change being the use of Sanizyme instead of NaClO. A concentration of 160 grams of Sanizyme, an enzymatic detergent, was dissolved in 10 litres of tap water, as recommended by the supplier. A schematic representation of the steps is shown in Figure 11.

As in Test 1, 60 instruments were processed simultaneously, with 8 consecutive cycles per day, each lasting approximately 60 minutes. Instruments were inspected at the start of each day. Corrosion was documented in an Excel sheet, and photographs were taken. Instruments showing corrosion, except those with corrosion on the box lock, were excluded from further testing.

This test was conducted over 19 days, with instruments undergoing up to 150 reprocessing cycles.

Test 3: Intermittent NaClO Reprocessing

Test 3 followed the same procedure as Test 1 (Steps 1 through 7), using NaClO as the cleaning agent. The key difference was introducing a minimum 2-hour rest period between each cycle, allowing for 4 cycles per day.

In Step 8, instead of being placed back in the colander, the instruments were transferred to a clean, dry area to air dry for at least 2 hours between cycles.

A total of 30 instruments were tested over 2 days, with each instrument undergoing 8 cycles. After the final cycle, all instruments were inspected and photographed to document any corrosion.

Test 4: Intermittent Sanizyme Reprocessing

Test 4 followed the same procedure as Test 1 (Steps 1 through 7), with two key differences: Sanizyme was used as the cleaning agent instead of NaClO, and a minimum 2-hour rest period was applied between each cycle, allowing 4 cycles per day.

In Step 8, the instruments were placed in a clean, dry area to air dry for at least 2 hours between cycles. After every 8 cycles (typically after two days of testing), the instruments were thoroughly inspected and photographed. Corrosion was documented in an Excel sheet, and photographs were taken. Instruments showing corrosion, except those with corrosion on the box lock, were excluded from further testing.

A total of 30 instruments were tested over 16 days, with each instrument undergoing up to 64 cycles.

3.2 Accelerated corrosion testing

This section details the Salt Mist Test as an accelerated method for examining the corrosion resistance of stainless steel surgical instruments. The test is conducted in a controlled, saline-rich environment that intensifies corrosive conditions, allowing corrosion effects to develop more rapidly. This setup enables the systematic observation and documentation of material degradation under standardised conditions.

3.2.1 Materials

In order to assess the corrosion susceptibility of surgical instruments under accelerated conditions, the Salt Mist Test was selected as the specific accelerated corrosion test for this study. This choice builds on the theoretical foundation provided in the previous chapter, where the Salt Mist Test was introduced as a relevant method for simulating corrosive conditions over a compressed timeframe. This section details the setup and procedures of this Salt Mist Test implementation, designed to evaluate the performance of SS types 304, 410, and 420 in a controlled corrosive environment. The exact composition of these materials is provided in Table 1. A total of 30 instruments, with 10 from each SS type, were tested. Each instrument was marked with sterilisable silicone rings to enable consistent identification throughout the test cycles. Additional details regarding the specific materials and equipment used for this setup can be found in Appendix B.

3.2.2 Methods

Figure 12: *Image of the Salt Mist Test setup*

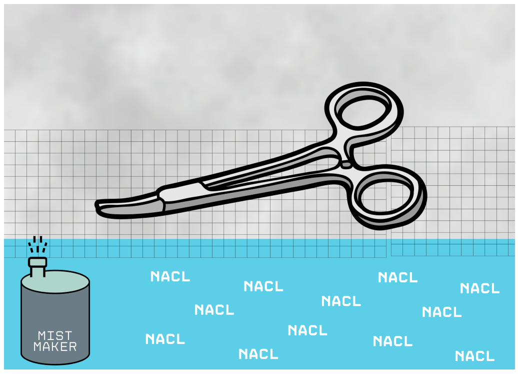


Figure 13: *Schematic representation of the Salt Mist Test setup*

Test 5: Salt Mist Test

The preparation for the test began by filling the container with 7 litres of demineralised water. The sous vide stick was set to heat the water to 35°C. Once the water reached the desired temperature, 368 grams of pure NaCl were added to create a 5% salt solution. A plastic spatula was used to stir the solution until all NaCl particles were fully dissolved.

A small plastic rack was placed about 8 cm below the water's surface, and the mist maker was positioned on it, with its top approximately 4 cm submerged. Another plastic rack was placed above the mist maker, on which 4 instruments of the same material were carefully arranged, ensuring they did not touch each other. The container was then sealed with a transparent plexiglass sheet with an opening for the sous vide stick. To start the test, the mist maker was switched on, and the timer was set for 4 hours. During this period, the setup was not disturbed. After 4 hours, the mist maker was turned off, and the plexiglass sheet was removed. The instruments were taken out and rinsed under running water to remove the salt. The equipment was thoroughly cleaned to eliminate any salt residue. The instruments were air-dried, and once dry, they were wiped with a damp cloth to remove the rust film, making any corrosion spots clearly visible. This process was repeated 8 times, ensuring that only instruments of the same material were tested together. After testing, the instruments were stored in a clean, dry area.

Figure 12 shows a photo of the setup before the plexiglass cover was placed on the container. Figure 13 provides a schematic representation of the setup inside the container.

3.3 Summary of test protocols

This section provides an overview of the five test protocols used in this study, summarising the key differences between each reprocessing and accelerated corrosion test. As shown in Figure 14, the graphic highlights the number of instruments per test, the number of cycles per day, the inclusion of rest periods, and the maximum number of cycles performed. This overview serves as a reference for the methodologies applied, clarifying the distinct approaches used to evaluate corrosion susceptibility across different testing conditions.

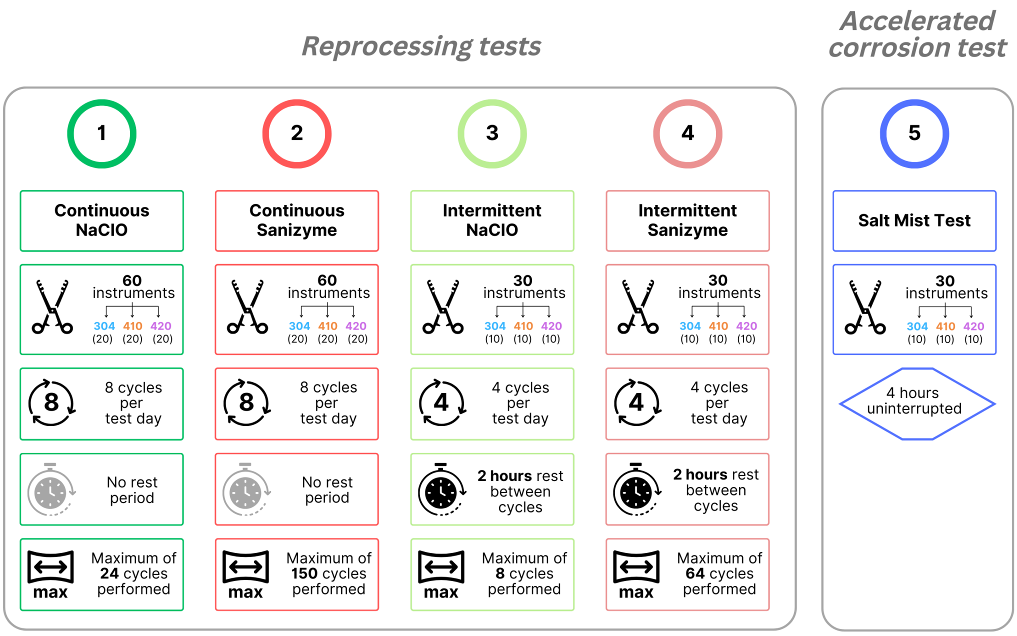


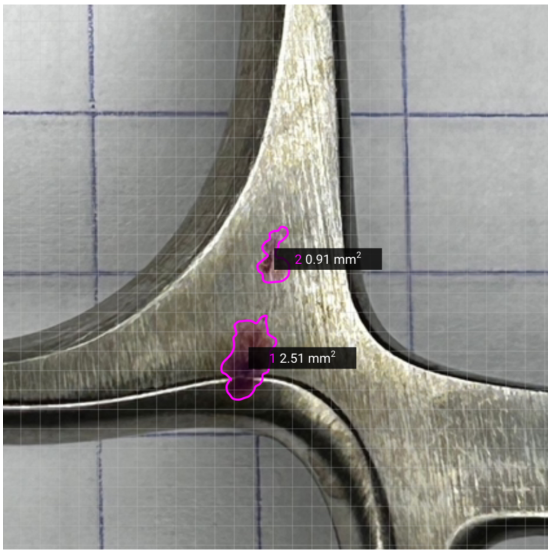
Figure 14: *Overview of reprocessing and accelerated corrosion test protocols. The diagram summarises key parameters for each test.*

3.4 Data collection

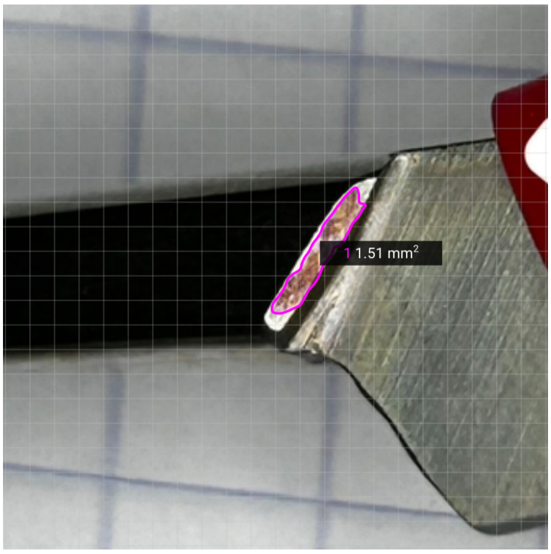
During the reprocessing tests, data were systematically logged in an Excel sheet. Each instrument was thoroughly inspected every eight cycles, and daily observations were recorded. These included instances where no corrosion was detected or corrosion spots were challenging to assess. The number of cycles completed by each instrument and any detected corrosion were documented. Instruments exhibiting corrosion, with the exception of corrosion on the box lock, were excluded from further testing and set aside.

Photographic documentation of each corrosion spot was conducted with a standardised setup designed to capture detailed images. This setup included a controlled lighting environment with a wireless ring light, a tripod for stability, and a dark background to enhance image clarity. A 5 mm grid paper was placed behind the instruments to provide a scale for measurements.

Each image was manually labelled with the test type, material type, instrument identification number, and the specific photo number (e.g., 2/4). This setup ensured consistent lighting and clarity, allowing for an accurate assessment of the corrosion spots.



(a) *Measurements around the ring handle*



(b) *Measurements around the box lock.*

Figure 15: *Measurements of surface area affected by corrosion using SketchAndCalc*

3.5 Data processing and analysis

3.5.1 Corrosion surface area calculation

Each photograph was carefully analysed to determine the surface area of each corrosion spot. The app SketchAndCalc, running on an iPad Pro, was used for this purpose, allowing for precise measurements with the Apple Pencil. First, the scale was set using the 5 mm grid paper visible in the background of each photograph. The perimeter of each corrosion spot was then traced, allowing the software to calculate the surface area.
The surface areas of all spots were summed for each instrument component. Figure 15 visually represents the corrosion surface area analysis conducted in the SketchAndCalc app.

The data collected from the photographs were combined with the logged test data for the instruments that underwent the reprocessing tests. A new Excel sheet was created to document the number of corrosion spots, the total surface area affected by corrosion, and the number of cycles completed before corrosion was observed for each component. Only the total surface area affected by corrosion and the number of spots per instrument component were recorded for the instruments that underwent the Salt Mist Test, as all instruments were subjected to the same 4-hour exposure period. The Excel sheets containing all data for the four reprocessing tests can be found in Appendix C.

3.5.2 Data collection and structuring

Data from each reprocessing test were initially collected and organised in Excel. For the reprocessing tests, data were structured by cycles and categorised into "number of cycles to corrosion onset." Corrosion onset was defined as the first appearance of corrosion around the box lock, which was considered the initial failure point. Since inspections occurred in 8-cycle intervals, the midpoint of each cycle range was used as the approximate onset.

Additionally, the number of cycles to initial corrosion (excluding box lock corrosion) was recorded for each instrument. The box lock was not an exclusion criterion for further testing, so all instruments were tested beyond the onset of box lock corrosion. This allowed for a comparative bar chart illustrating corrosion onset with and without the box lock as a criterion across Test 1 (Continuous NaClO Reprocessing), Test 2 (Continuous Sanizyme Reprocessing), and Test 3 (Intermittent Sanizyme Reprocessing). Test 4 (Intermittent NaClO Reprocessing) was excluded from this analysis because instruments completed only eight cycles with no interim checks.

For surface area analysis, the surface area affected by corrosion was recorded for each instrument, along with the number of cycles completed. Scatterplots were created to visualise the affected area against the number of cycles. Normalised corrosion surfaces per cycle were also calculated for each test and displayed in box plots by material in Excel.

3.5.3 Surface area approximation and comparative metrics

A simplified CAD model of the forceps was created in Autodesk Fusion 3D to contextualise the surface area affected by corrosion relative to the total instrument area (see Figure 16). This model estimated a total surface area of approximately 40 cm^2, which facilitated calculations of the proportion of affected surface area per instrument. For each test and material, metrics such as mean corrosion-affected area, mean affected area as a percentage of total surface area, average number of corrosion spots, and average spot size were computed.

3.5.4 Statistical analysis

All statistical analyses were conducted in RStudio. Shapiro-Wilk tests were first applied to check for normality in each dataset, and none displayed a normal distribution. To address research questions regarding the number of cycles to corrosion onset, a Kaplan-Meier survival analysis was applied [50]. This method accounts for censored data, such as instruments that did not exhibit corrosion within the maximum cycle count. Differences between groups were tested using the Log-Rank test, which is appropriate for survival data [51].

To ensure comparability, data from Continuous Sanizyme Reprocessing were censored at 64 cycles to align with the maximum cycles in Intermittent Sanizyme Reprocessing. Instruments that exceeded 64 cycles in Continuous Sanizyme Reprocessing were marked as “no corrosion” after that point.

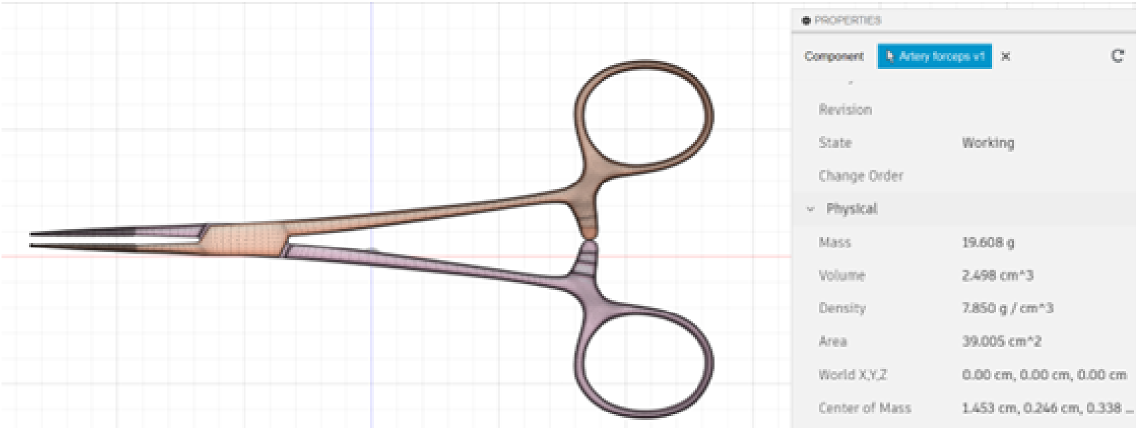


Figure 16: *Simplified CAD model of the forceps used to estimate total surface area (approx. 40 cm*^{2}*) for comparative analysis of corrosion-affected regions.*

For surface area affected by corrosion, normalised corrosion areas were compared using the Wilcoxon test, a non-parametric test suitable for data that is not normally distributed and for comparisons between groups [52].

3.5.5 Salt Mist Test data processing

Salt Mist Test data were organised in Excel by stainless steel type. The total corrosion-affected areas were visualised in a box plot. Due to the extensive corrosion coverage, a bar chart by component was not informative. Instead, the data were summarised in a table that includes component-specific corrosion areas as percentages of the total area, mean spot count, and mean spot size.

3.5.6 Comparative analysis between reprocessing tests and Salt Mist Test

A Spearman correlation analysis was conducted to assess the relationship between the normalised surface area affected by corrosion in reprocessing tests and the surface area from the Salt Mist Test [53]. This non-parametric test was chosen because it does not assume normality in the data. Results were compiled in a table.

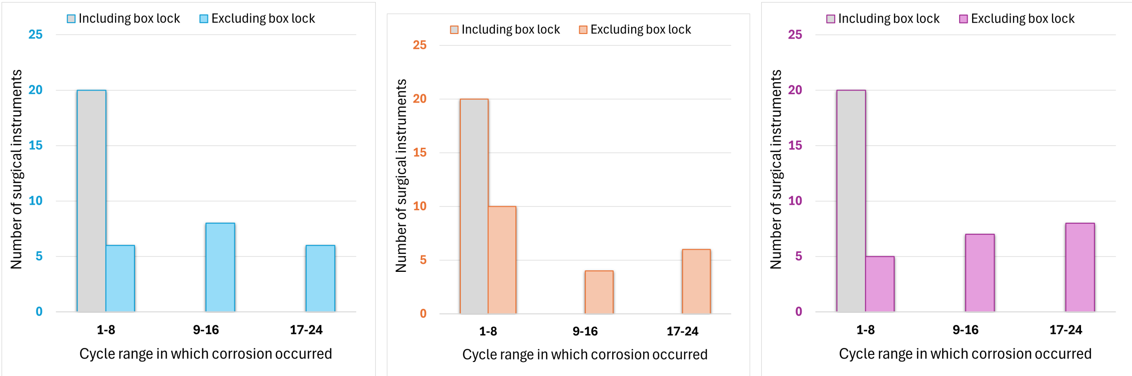
Finally, another Spearman correlation analysis was performed to compare the normalised surface area per cycle and the number of cycles to corrosion onset in Sanizyme Reprocessing with the Salt Mist Test results. These findings were summarised in an additional table. The RStudio scripts used for all statistical analyses can be found in Appendix D .

4 Results

This chapter presents the experimental findings on corrosion onset, affected surface area, and component-specific corrosion patterns for each stainless steel type. The chapter begins with an overview of the results from each reprocessing test, followed by a deeper examination of the effects of the material, cleaning agent, and rest period. This section uses comparisons and statistical analyses to assess variations in corrosion susceptibility across materials and test conditions. The subsequent section details the outcomes of the accelerated Salt Mist Test, focusing on corrosion patterns observed under these conditions. Finally, results from the reprocessing tests are compared with those from the Salt Mist Test to investigate potential correlations between these methods.

4.1 Reprocessing tests

This section presents the outcomes of the reprocessing tests, including data on the number of cycles to corrosion onset and the surface areas affected by corrosion for each stainless steel type. The results are grouped by test type, highlighting differences in material behaviour under continuous and intermittent exposure to sodium hypochlorite (NaClO) and Sanizyme.nou heb



(a) Stainless steel 304 (b) Stainless steel 410 (c) Stainless steel 420

Figure 17: *Number of surgical instruments exhibiting corrosion across cycle intervals (1-8, 9-16, 17-24), comparing results with and without the box lock. Results indicate an earlier onset of corrosion when the box lock is included for all stainless steel types, underscoring the susceptibility of the box lock region to early-stage corrosion.*

4.1.1 Test 1: Continuous NaClO Reprocessing

This section presents the results of the Continuous NaClO Reprocessing test, in which 60 instruments (20 of each stainless steel type: 304, 410, and 420) were subjected to 24 reprocessing cycles over three days. The test evaluated the number of cycles to corrosion onset and the surface area affected by corrosion.

Number of cycles to corrosion onset

The analysis of the number of cycles to corrosion onset demonstrates a clear distinction between the different stainless steel types and the impact of the box lock component. Figure 17 presents the number of instruments that exhibited signs of corrosion at various cycle intervals (1-8, 9-16, and 17-24), with a breakdown per material type and an additional comparison of data including and excluding the box lock. When the box lock is included, all instruments across all stainless steel types began to show corrosion within the first eight cycles. When the box lock is excluded from the data, a delay in corrosion onset is observed across all materials, highlighting the box lock's significant influence on early corrosion. However, signs of corrosion were still detected relatively early elsewhere on the instruments, and by 24 cycles, each instrument exhibited corrosion on other components as well.

Surface area affected by corrosion

The extent of corrosion, measured by the surface area affected, further emphasises the susceptibility differences between the materials. Figure 18 highlights that certain instrument components, notably the box lock, ratchet, and ring handle, are more prone to corrosion, regardless of the material. Scatterplot analysis in Figure 19 illustrates the relationship between the total surface area affected by corrosion and the number of cycles undergone before corrosion onset. Furthermore, normalised surface area data in Figure 20 allows for a more direct comparison of corrosion severity across instruments subjected to varying cycle counts. Material 420 consistently shows the highest median affected area per cycle, underlining its susceptibility in Continuous NaClO Reprocessing. These findings are corroborated by Table 1, which summarises key corrosion metrics, showing that material 420 had the largest mean area affected and the most numerous corrosion spots.

	304	410	420
Mean area affected by corrosion (mm²)	24	30	39
Mean proportion of total surface affected by corrosion (%)	0,60	0,75	0,98
Mean number of corrosive spots	7,6	8,2	13,3
Mean area of corrosive spots (mm²)	3	4	3

Table 3: *Summary of corrosion metrics under Continuous NaClO Reprocessing, showing that type 420 has the largest affected area and highest number of corrosive spots.*

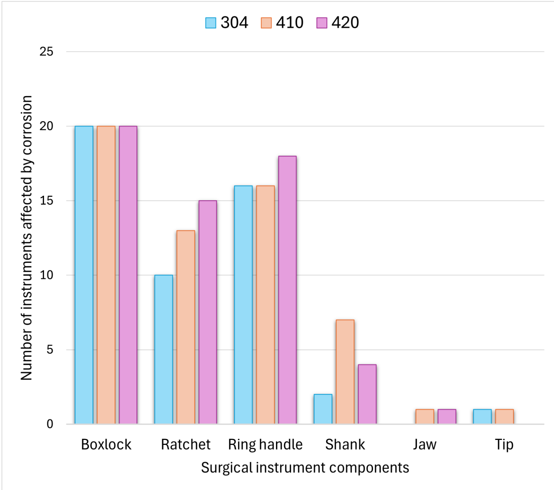


Figure 18: *Distribution of corrosion across specific instrument components, with type 420 exhibiting the highest overall susceptibility. The box lock demonstrates the greatest vulnerability across all materials.*

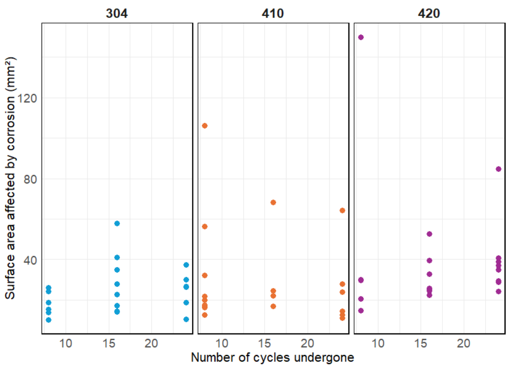


Figure 19: *Scatter plot illustrating the relationship between total surface area affected by corrosion and cycles completed. Data points for type 420 show a general increase in affected areas with higher cycle counts, reflecting trends in corrosion progression over time.*

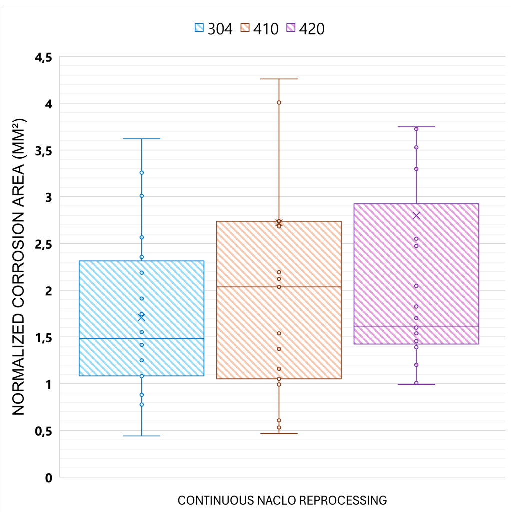
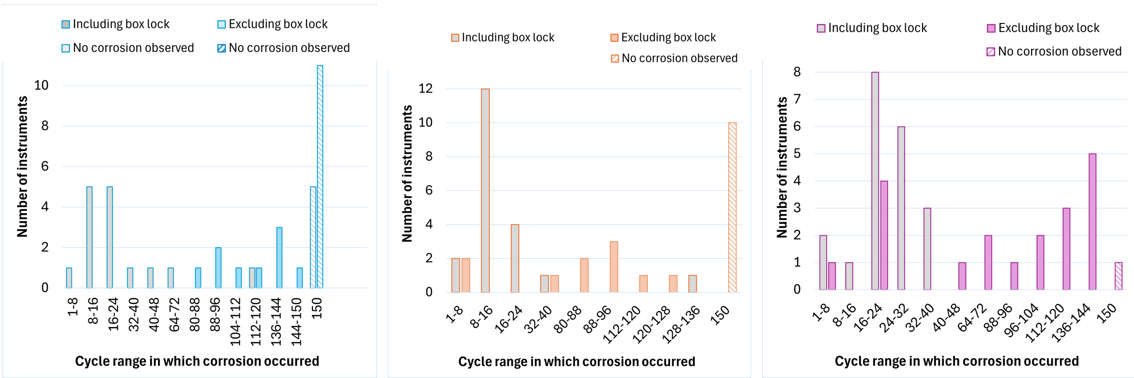


Figure 20: *Box plot of normalised surface area affected per cycle, revealing that type 420 has the highest median affected area per cycle, indicative of heightened susceptibility under Continuous NaClO reprocessing.*



(a) Stainless steel 304 (b) Stainless steel 410 (c) Stainless steel 420

Figure 21: *Corrosion onset in cycles during Continuous Sanizyme Reprocessing, comparing instruments with and without the box lock. Including the box lock significantly lowers the corrosion onset threshold across all materials, with type 410 exhibiting the most substantial effect.*

4.1.2 Test 2: Continuous Sanizyme Reprocessing

In Test 2, 60 instruments underwent Continuous Sanizyme Reprocessing over 150 cycles across nineteen days, evenly distributed among stainless steel types 304, 410, and 420. The test evaluated the number of cycles to corrosion onset and the surface area affected by corrosion.

Number of cycles to corrosion onset

The results show that including the box lock significantly accelerated corrosion onset for all materials. Figure 21 illustrates the number of instruments showing signs of corrosion across various cycle ranges (1-8, 9-16, and beyond), with data presented including and excluding the box lock. For stainless steel type 410 (Figure 21b), the majority of instruments began corroding within the first 16 cycles when the box lock was present. This pattern is also observed for types 304 (Figure 21a) and 420 (Figure 21c), though to a lesser degree. When the box lock is excluded, the onset of corrosion occurs much later, with some instruments lasting up to 144 cycles before showing signs of degradation. This highlights the box lock's susceptibility to corrosion.

Surface area affected by corrosion

The surface area affected by corrosion paints a detailed picture of each material and component's susceptibility to Sanizyme Reprocessing. Figure 22 shows the distribution of corrosion across key instrument components, such as the box lock, ratchet, and ring handle. The box lock again emerges as the most corrosion-prone part across all materials, with material 420 displaying the highest incidence of affected areas. Table 4 further summarises these trends, with material 420 exhibiting the largest mean affected area and the highest proportion of surface affected.

The scatterplot in Figure 23 demonstrates the relationship between the total surface area affected and the number of cycles completed before corrosion onset. Material 420 suffers more extensive corrosion at earlier stages than 304 and 410, especially in the later cycle ranges. In Figure 24 the normalised surface area affected per cycle is given for each stainless steel type. Material 420 exhibits the highest median surface area affected per cycle.

	304	410	420
Mean area affected by corrosion (mm²)	5	6	7
Mean proportion of total surface affected by corrosion (%)	0,13	0,15	0,18
Mean number of corrosive spots	6,5	6,0	12,2
Mean area of corrosive spots (mm²)	1	1	1

Table 4: *Corrosion metrics for Continuous Sanizyme Reprocessing, showing type 420 with a higher mean affected area and frequency of corrosive spots, indicative of significantly greater susceptibility.*

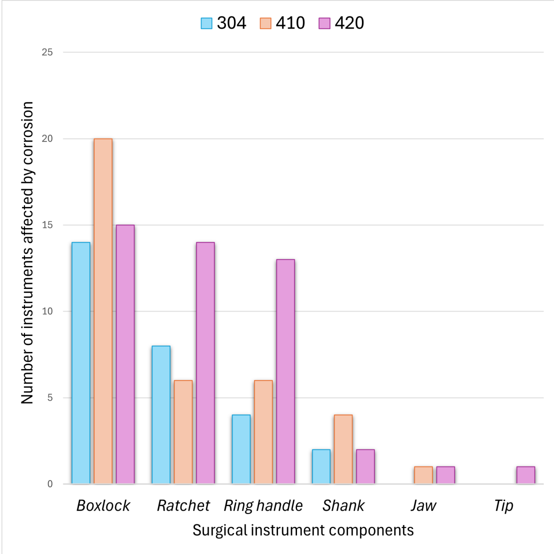


Figure 22: *Component-specific corrosion distribution under Continuous Sanizyme Reprocessing, showing that the box lock remains the most corrosion-prone part, while type 420 demonstrates the highest incidence of affected areas.*

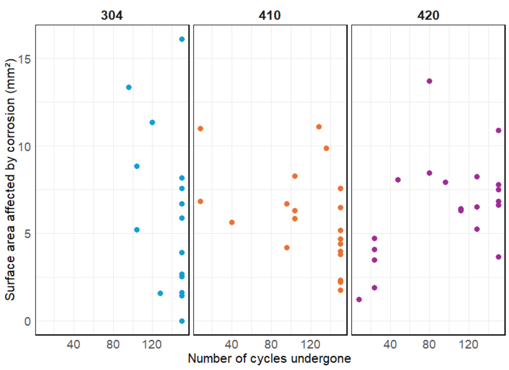


Figure 23: *Scatter plot of surface area affected by corrosion against cycles completed under Continuous Sanizyme Reprocessing, with type 420 consistently exhibiting larger affected areas, particularly in earlier cycles, reinforcing its increased susceptibility.*

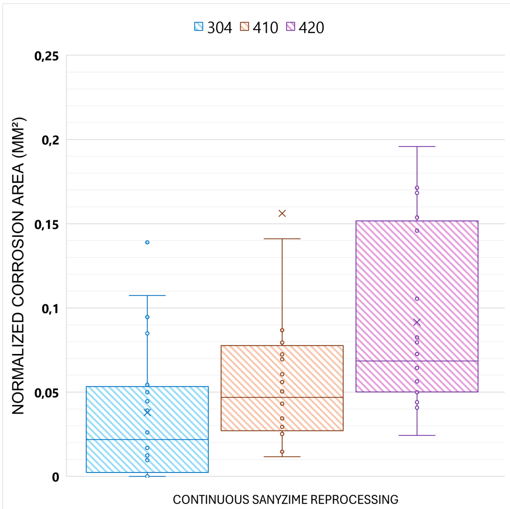


Figure 24: *Box plot showing the normalised surface area affected per cycle under Continuous Sanizyme Reprocessing. Type 420 shows the highest median affected area, indicating a greater susceptibility than types 304 and 410.*

4.1.3 Test 3: Intermittent NaClO Reprocessing

The Intermittent NaClO Test investigated corrosion susceptibility during reprocessing with a 0.5% NaClO solution. Instruments were given a minimum 2-hour rest after each cycle. A total of 8 cycles were performed, and after completion, each instrument was assessed for signs of corrosion. Since all instruments showed corrosion after eight cycles, no further insights were gained regarding the number of cycles to corrosion onset. Therefore, we compare the surface areas affected by corrosion after eight cycles across the different materials.

Surface area affected by corosion

The comparison of surface areas affected by corrosion shows a clear trend of material susceptibility. Figure 25 presents a boxplot that illustrates the surface area of each stainless steel type affected by corrosion after the eight cycles. Material 420 exhibits the highest median affected surface area, with a more comprehensive interquartile range, indicating greater corrosion susceptibility than 304 and 410. Figure 26 further analyses specific instrument components and highlights the areas most prone to corrosion. The box lock is identified as the component with the highest incidence of corrosion across all materials, followed by the ratchet. Material 420 again shows the most extensive corrosion across all components. Finally, Table 5 provides a quantitative summary of these results.

	304	**410**	**420**
Mean area affected by corrosion (mm²)	10	13	15
Mean proportion of total surface affected by corrosion (%)	0,25	0,33	0,38
Mean number of corrosive spots	6,0	6,7	5,7
Mean area of corrosive spots (mm²)	2	2	3

Table 5: *Corrosion metrics after eight cycles of Intermittent NaClO Reprocessing, with type 420 showing the greatest affected area, demonstrating increased vulnerability to NaClO-induced corrosion.*

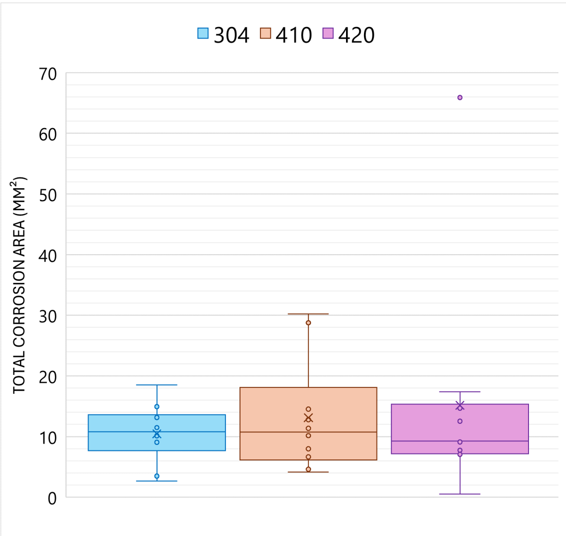


Figure 25: *Surface area affected by corrosion following eight cycles of Intermittent NaClO Reprocessing, with type 420 demonstrating the greatest affected area, highlighting higher susceptibility to NaClO-induced corrosion.*

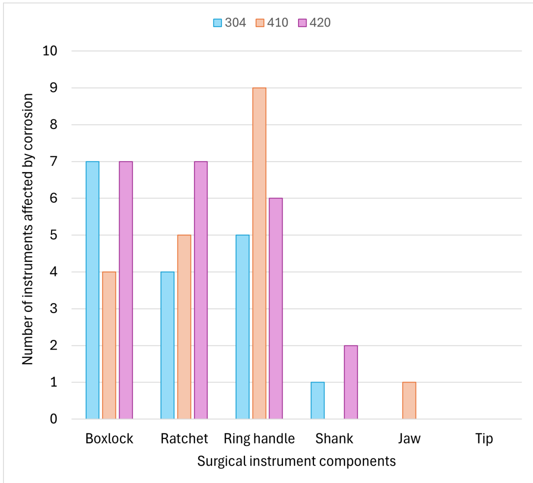
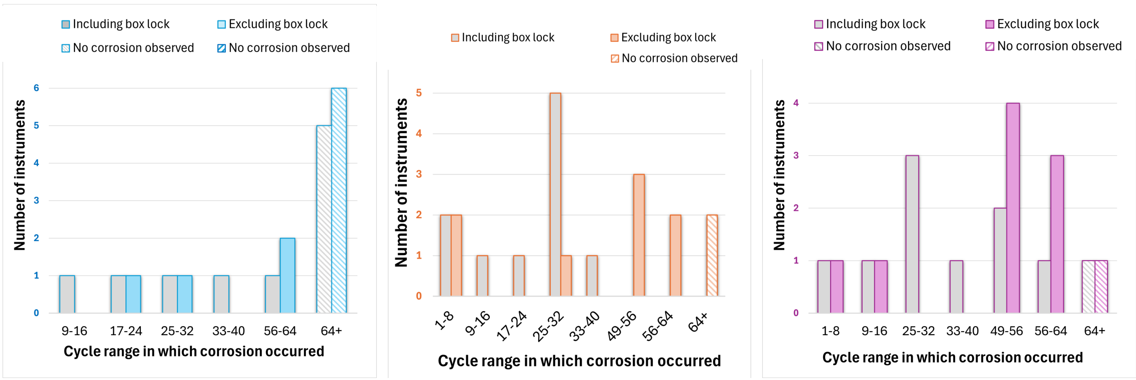


Figure 26: *Corrosion distribution across instrument components under Intermittent NaClO Reprocessing, with the box lock and ratchet displaying the highest incidence of corrosion, particularly in type 420.*



(a) Stainless steel 304 (b) Stainless steel 410 (c) Stainless steel 420

Figure 27: *Number of cycles to corrosion onset across cycle intervals during Intermittent Sanizyme Reprocessing, comparing data with and without the box lock. Results indicate an earlier onset of corrosion in type 420, particularly when the box lock is included, highlighting increased susceptibility in this material.*

4.1.4 Test 4: Intermittent Sanizyme Reprocessing

Test 4 examined how instruments responded to Intermittent Sanizyme Reprocessing, with a minimum two-hour rest period between cycles. The test lasted 16 days, and each instrument underwent up to 64 cycles.

The data reveal that the inclusion of the box lock continues to accelerate corrosion onset, similar to previous tests. Figures 27a, 27b and 27c display the number of instruments showing corrosion across different cycle ranges. In materials 410 and 420, the highest incidence of corrosion occurred between 25-32 and 49-56 cycles when the box lock was included. More instruments reached 64 cycles without visible corrosion without the box lock, particularly in material 304.

Surface area affected by corosion

After Intermittent Sanizyme Reprocessing, the surface area affected by corrosion reinforces the trends observed in previous tests. Figure 28 presents the distribution of corrosion across key instrument components, with the box lock emerging again as the most corrosion-prone area. Material 420 shows higher affected areas across all components, followed by 410, while 304 remains the least affected. Table 6 further summarises these findings, showing that material 420 has the highest mean area affected by corrosion (6 mm^2) and the most significant number of corrosive spots. Both materials 410 and 420 have a mean proportion of total surface area affected of 0.15%, further underscoring their greater susceptibility in Intermittent Sanizyme Reprocessing conditions compared to material 304. Figure 29 further explores the relationship between the number of cycles and the total surface area affected by corrosion. Material 420 shows larger affected areas at earlier cycle ranges than materials 304 and 410, confirming its greater susceptibility under Intermittent Sanizyme Reprocessing conditions. Finally, Figure 30 presents each material's normalised surface area affected per cycle. Material 420 exhibits the highest median affected surface area, particularly when compared to 304, demonstrating minimal corrosion even after 64 cycles.

	304	410	420
Mean area affected by corrosion (mm²)	2	6	6
Mean proportion of total surface affected by corrosion (%)	0,05	0,15	0,15
Mean number of corrosive spots	1,4	7,1	7,8
Mean area of corrosive spots (mm²)	1	1	1

Table 6: *Corrosion metrics for Intermittent Sanizyme Reprocessing, with type 420 consistently showing the highest affected area and number of corrosion spots, indicating heightened susceptibility relative to types 304 and 410.*

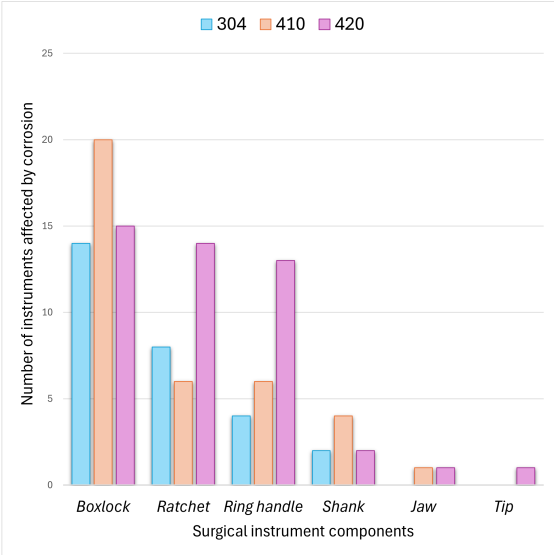


Figure 28: *Distribution of corrosion across critical instrument components under Intermittent Sanizyme Reprocessing, with the box lock consistently showing the most vulnerability across materials. Type 420 exhibits the highest corrosion incidence across multiple components.*

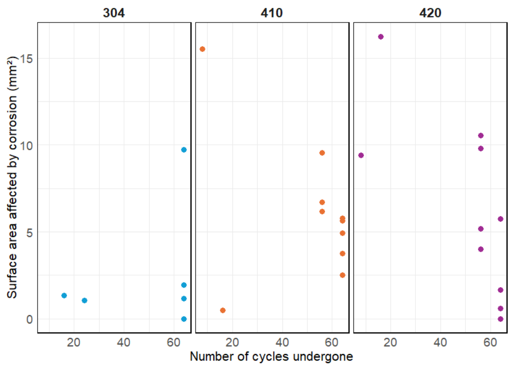


Figure 29: *Scatter plot of surface area affected by corrosion against cycles completed under Intermittent Sanizyme Reprocessing, where type 420 demonstrates larger affected areas in earlier cycle stages, underscoring its increased susceptibility.*

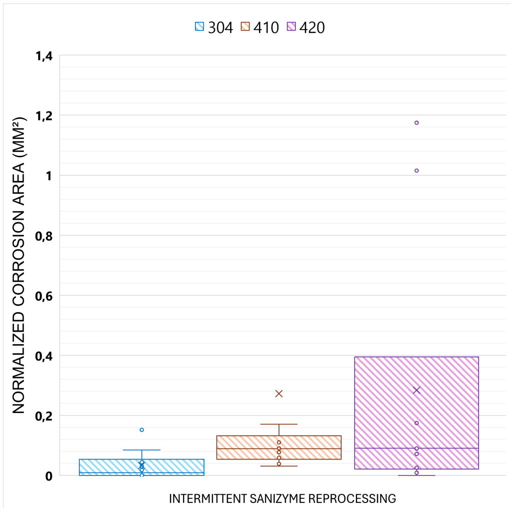


Figure 30: *Box plot of normalised surface area affected per cycle under Intermittent Sanizyme Reprocessing, with type 420 exhibiting a larger median affected area per cycle, highlighting its heightened susceptibility.*

Comparison	**Continuous Sanizyme (Chi-square)**	**Continuous Sanizyme (p-value)**	**Intermittent Sanizyme (Chi-square)**	**Intermittent Sanizyme (p-value)**
304 vs 410	7.8	0.005 (**)	9.2	0.002 (**)
304 vs 420	2.9	0.09 (ns)	8.5	0.004 (**)
410 vs 420	4.4	0.04 (*)	0.4	0.5 (ns)

Table 7: *Log-rank test results comparing cycles to corrosion onset across materials under Continuous and Intermittent Sanizyme Reprocessing, with statistically significant differences indicated.*

4.1.5 Differences in corrosion between stainless steel 304, 410, and 420

This section explores how material differences in stainless steel alloys (304, 410, and 420) affect corrosion susceptibility under various reprocessing conditions, focusing on the number of cycles to corrosion onset and the surface area affected by corrosion.

Number of cycles to corrosion onset

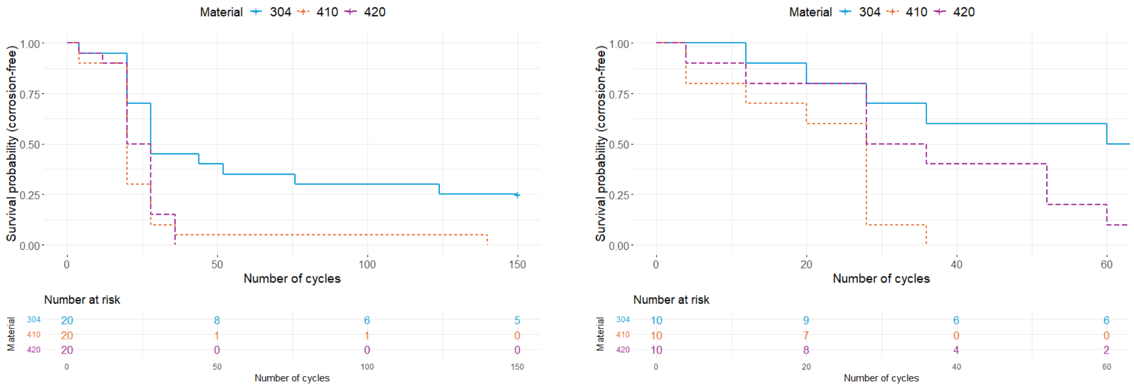
Significant differences in corrosion onset between materials were observed only during the Sanizyme reprocessing tests, with no differences seen in the NaClO tests. Kaplan-Meier survival analysis was used for Continuous and Intermittent Sanizyme tests, accounting for instruments that remained corrosion-free at the end of 150 or 64 cycles. Data include the box lock, which significantly influences early corrosion onset. Midpoints of the cycle ranges were used for the Kaplan-Meier analysis, resulting in a 60-cycle mark rather than 64 cycles.

Figure 31a shows the Kaplan-Meier survival curves for Continuous Sanizyme reprocessing. Material 304 demonstrates the highest corrosion resistance, with approximately 25% of instruments remaining corrosion-free after 150 cycles. In contrast, material 410 exhibits a rapid decline in survival probability within the first 50 cycles, and material 420 follows a similar, slightly better trajectory. By 50 cycles, all 420 instruments had corroded.

The "numbers at risk" below the plot indicate the number of instruments still considered in the analysis at different cycle points. As instruments corrode, they are excluded from the survival probability calculations, reducing the number of instruments still at risk of corrosion.

Figure 31b presents the Kaplan-Meier survival curves for Intermittent Sanizyme reprocessing. Similar trends are observed, though fewer instruments remained corrosion-free by 60 cycles compared to the Continuous test. The numbers at risk confirm that all 410 and 420 instruments had corroded by the end of the test.

The log-rank test, summarised in Table 7, indicates significant differences ($p < 0.05$) between materials 304 and 410, as well as between 410 and 420, under both Continuous and Intermittent Sanizyme conditions. Higher chi-square values indicate a more significant difference in corrosion susceptibility between the materials, with a chi-square of 7.8 showing a substantial difference between 304 and 410 under Continuous Sanizyme conditions. An even greater difference, with a chi-square value of 8.5, was found between 304 and 420 under Intermittent Sanizyme conditions ($p = 0.004$).



(a) *Kaplan-Meier survival curves during Continuous Sanizyme Reprocessing.*

(b) *Kaplan-Meier survival curves during Intermittent Sanizyme Reprocessing.*

Figure 31: *Kaplan-Meier survival curves for Continuous and Intermittent Sanizyme Reprocessing, showing the probability of remaining corrosion-free across cycles completed. The 'numbers at risk' indicate instruments included in the analysis at each interval.*

Comparison	**Continuous NaClO (p-value)**	**Continuous Sanizyme (p-value)**	**Intermittent NaClO (p-value)**	**Intermittent Sanizyme (p-value)**
304 vs 410	1.0 (ns)	0.1586 (ns)	1.0 (ns)	0.021 (*)
304 vs 420	0.36 (ns)	0.0025 (**)	1.0 (ns)	0.079 (ns)
410 vs 420	1.0 (ns)	0.1572 (ns)	1.0 (ns)	1.0 (ns)

Table 8: *Wilcoxon test results for surface area affected by corrosion across reprocessing conditions, with significant variations identified for each material.*

Surface area affected by corrosion

The surface area affected by corrosion was compared between materials using the Wilcoxon test, as the data did not meet normality assumptions. The tests were performed separately for each reprocessing condition. For Continuous NaClO, Continuous Sanizyme, and Intermittent Sanizyme tests, normalised surface areas were used; for Intermittent NaClO, total surface areas were compared since all instruments underwent the same number of cycles.

Table 8 summarises the Wilcoxon test results. No significant differences were found under Continuous NaClO conditions. However, under Continuous Sanizyme reprocessing, significant differences were observed between materials 304 and 420 (p = 0.0025), with 420 showing a larger affected surface area. Under Intermittent Sanizyme reprocessing, material 410 exhibited greater susceptibility than 304 (p = 0.021).

	Continuous Sanizyme versus Continuous NaClO		Intermittent Sanizyme versus Intermittent NaClO	
Material	Chi-square	p-value	Chi-square	p-value
304	35.3	3.00e09 (***)	19.0	1.00e-05(***)
410	31.9	2.00e-08 (***)	12.7	4.00e-04 (***)
420	35.3	3.00e-09(***)	15.5	8.00e-05(***)

Table 9: *Log-rank test results comparing cycles to corrosion onset under Continuous and Intermittent reprocessing with NaClO and Sanizyme, with significant differences indicated for each material.*

	Continuous Sanizyme versus Continuous NaClO	Intermittent Sanizyme versus Intermittent NaClO
Material	p-value	p-value
304	6.60e-08 (***)	1.60e-04 (***)
410	2.00e-09 (***)	7.30e-04 (***)
420	1.50e-11 (***)	6.80e-03 (**)

Table 10: *Wilcoxon test results for the surface area affected by corrosion under Continuous and Intermittent NaClO and Sanizyme reprocessing, with statistically significant differences highlighted.*

4.1.6 Corrosion comparison between NaClO and Sanizyme

This section examines how NaClO and Sanizyme affect corrosion susceptibility in surgical instruments, focusing on two factors: the number of cycles to corrosion onset and the surface area affected by corrosion.

Number of cycles to corrosion onset

Kaplan-Meier survival analyses compared the number of cycles to corrosion onset between Continuous and Intermittent reprocessing using NaClO and Sanizyme for stainless steel types 304, 410, and 420. Figures 32, 33 and 34 show the survival curves for each material.

Unlike the gradual decline in the Sanizyme tests, NaClO caused a more abrupt corrosion onset. In both Continuous and Intermittent NaClO Reprocessing, all instruments experienced corrosion onset very early in the test, as shown by the sharp drop in survival probabilities. For example, under Continuous Sanizyme reprocessing, approximately 25% of 304 instruments remained corrosion-free after 150 cycles. However, with Continuous NaClO, all 304 instruments failed after just a few cycles. Similar patterns were observed for materials 410 and 420, where NaClO reprocessing led to significantly faster corrosion onset than Sanizyme.

Log-rank test results in Table 9 confirmed significant differences in corrosion onset between NaClO and Sanizyme for all materials ($p < 0.05$), with chi-square values highlighting the magnitude of these differences. For instance, the comparison for material 410 under Continuous reprocessing showed a chi-square value of 31.9 ($p < 0.0001$), indicating a strong divergence between NaClO and Sanizyme regarding corrosion onset.

Surface area affected by corrosion

The Wilcoxon test was used to compare the normalised surface areas affected by corrosion during NaClO and Sanizyme reprocessing for each material. The Wilcoxon test results in Table 5 show that both Continuous and Intermittent reprocessing conditions showed significant differences ($p < 0.05$), with NaClO leading to larger affected areas across all materials.

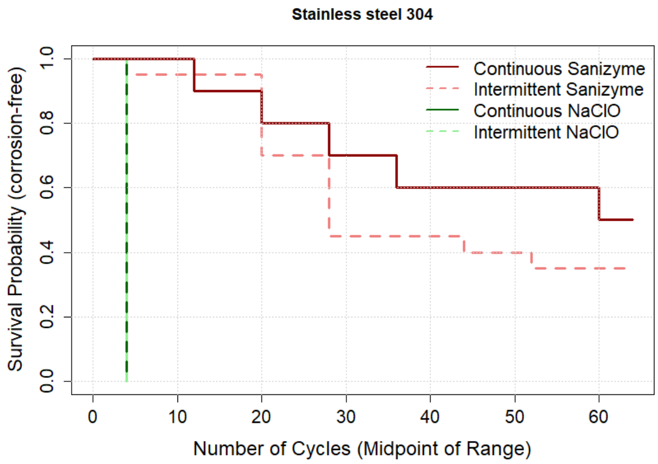


Figure 32: *Kaplan-Meier survival curves for stainless steel type 304 comparing Continuous and Intermittent NaClO and Sanizyme reprocessing.*

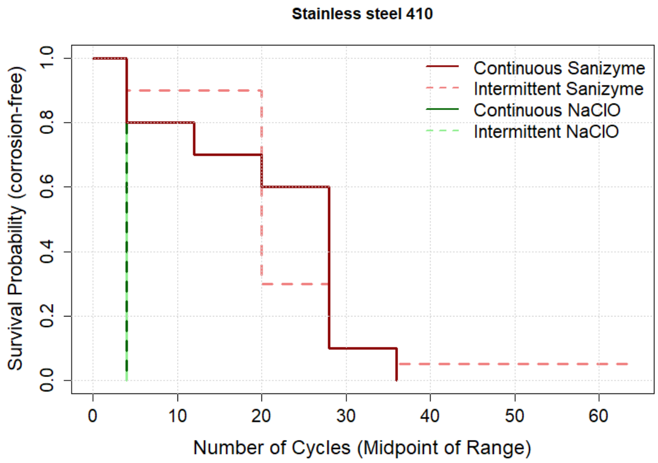


Figure 33: *Kaplan-Meier survival curves for stainless steel type 410 comparing Continuous and Intermittent NaClO and Sanizyme reprocessing.*

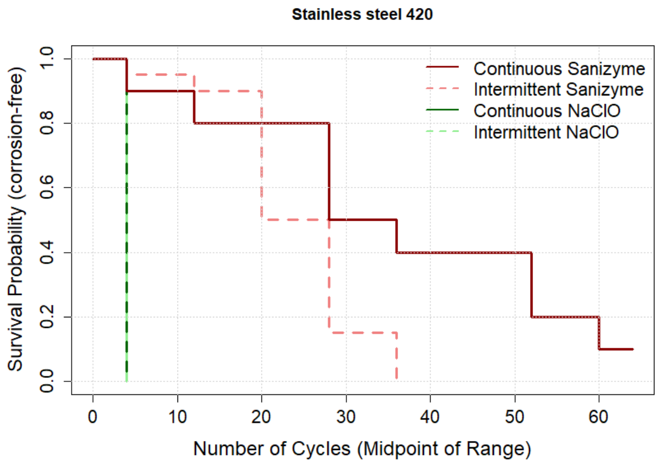


Figure 34: *Kaplan-Meier survival curves for stainless steel type 420 comparing Continuous and Intermittent NaClO and Sanizyme reprocessing.*

4.1.7 Impact of rest periods on corrosion onset and affected area

This section examines the impact of incorporating rest periods between reprocessing cycles on corrosion susceptibility and the number of cycles to corrosion onset. This was investigated by comparing Intermittent Reprocessing tests, which included rest periods, with Continuous Reprocessing tests, in which eight cycles were performed without rest periods.

Number of cycles to corrosion onset

Kaplan-Meier survival analysis compared the corrosion onset for Continuous and Intermittent Sanizyme Reprocessing across the three stainless steel types. Figures 32, 33 and 34 display the survival curves for materials 304, 410, and 420, showing how many instruments remained corrosion-free throughout the tests. For stainless steel 304 (Figure 32), the Continuous and Intermittent reprocessing curves were similar, with no significant differences observed in the number of cycles to corrosion onset, confirmed by the log-rank test with a p-value of 0.40, as can be seen in Table 11. In contrast, the survival curves for stainless steel 420 (Figure 34) show a more pronounced difference. Continuous reprocessing leads to earlier corrosion onset compared to Intermittent reprocessing. This is supported by the log-rank test, which found a significant difference between the two conditions ($p = 0.02$). For stainless steel 410, no significant difference was detected between the two reprocessing conditions ($p = 0.80$).

Surface area affected by corrosion

The surface area affected by corrosion was compared using the Wilcoxon test, normalised by the number of cycles completed. Table 12 summarises the results. For material 410, Continuous Sanizyme led to significantly larger affected areas than Intermittent ($p = 0.04$). No significant differences were found for materials 304 and 420 under Sanizyme reprocessing. For NaClO reprocessing, material 420 showed significantly larger affected areas under Continuous reprocessing than Intermittent ($p = 0.04$), indicating that rest periods reduced corrosion progression.

In summary, rest periods significantly impacted corrosion onset and surface area for material 420 but not for materials 304 and 410.

Material	Chi-square	p-value
304	0.6	4.00e-01 (ns)
410	0.1	8.00e-01 (ns)
420	5.9	2.00e-02 (*)

Table 11: *Log-rank test results comparing cycles to corrosion onset under Continuous and Intermittent Sanizyme Reprocessing, with significant differences noted for type 420.*

	Continuous Sanizyme versus Intermittent Sanizyme	Continuous NaClO versus Intermittent NaClO
Material	p-value	p-value
304	4.46e-01 (ns)	4.22e-01 (ns)
410	3.50e-02 (*)	2.48e-01 (ns)
420	5.30e-01 (ns)	4.39e-02 (*)

Table 12: *Wilcoxon test results comparing Continuous and Intermittent Sanizyme and NaClO reprocessing, with statistically significant differences identified for each material.*

4.2 Accelerated corrosion testing

This section summarises the findings from the Salt Mist Test, focusing on corrosion extent across stainless steel types 304, 410, and 420. The results offer a comparative view of material susceptibility under accelerated conditions, documenting the surface areas affected and corrosion patterns specific to each material.

4.2.1 Test 5: Salt Mist Test

The results of the Salt Mist Test reveal distinct differences in the susceptibility to corrosion of the three stainless steel materials tested: 304, 410, and 420. As shown in Figure 35, the average area affected by corrosion is smallest for 304, followed by 410 and 420.

Table 36 presents the average number of corrosive spots and the corresponding affected areas for each material. The data indicate that material 304 exhibited fewer corrosive spots and had a smaller average area per spot compared to 410 and 420. In contrast, 410 and 420 displayed a marked increase in the number of corrosive spots and the total affected area, with 420 showing the highest average values for both parameters.

Table 36 also shows the distribution of corrosion among components. The ring handle was the most affected of all materials, particularly in 420, which accounted for 4.75% of the total surface corrosion. The box lock and ratchet also showed increased susceptibility, with smaller but significant affected areas, underscoring the varying vulnerability of different instrument components.

Material comparison using the Wilcoxon test

A Shapiro-Wilk test indicated that the data were not normally distributed. Therefore, a post hoc Wilcoxon test was performed to compare the corrosion susceptibility between the materials. The results suggest that material 304 exhibited significantly lower corrosion susceptibility compared to both 410 ($p = 0.00118$) and 420 ($p = 0.00025$). However, no significant differences were found between 410 and 420 ($p = 0.24281$), indicating that these two materials showed similar corrosion susceptibility under the conditions of the Salt Mist Test.

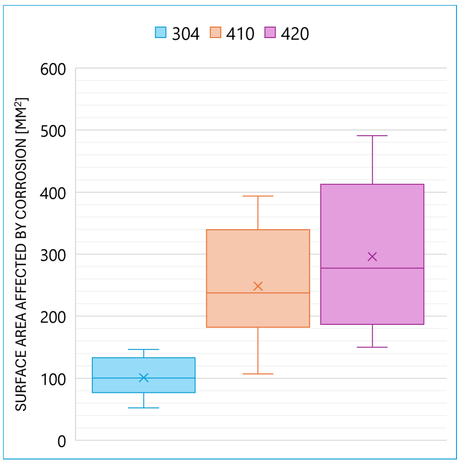


Figure 35: *Box plot of surface area affected by corrosion following the Salt Mist Test, with type 420 showing the highest median affected area, underscoring its increased susceptibility relative to types 304 and 410.*

304	Mean area affected by corrosion (mm²)	Mean proportion of total surface affected by corrosion (%)	Mean number of corrosive spots	Mean area of corrosive spots (mm²)
Total instrument	101	2,53	27,7	4
Box lock	14	0,35	4,6	3
Ratchet	21	0,53	9,6	2
Ring handle	66	1,65	12,9	5
Shank	1	0,03	0,6	1
Jaw	0	0,00	0,0	0
Tip	0	0,00	0,0	0
410	Mean area affected by corrosion (mm²)	Mean proportion of total surface affected by corrosion (%)	Mean number of corrosive spots	Mean area of corrosive spots (mm²)
Total Instrument	248	6,20	38,2	7
Box lock	24	0,60	4,8	5
Ratchet	54	1,35	9,6	6
Ring handle	168	4,20	22,6	7
Shank	1	0,03	1,2	1
Jaw	0	0,00	0,0	0
Tip	0	0,00	0,0	0
420	Mean area affected by corrosion (mm²)	Mean proportion of total surface affected by corrosion (%)	Mean number of corrosive spots	Mean area of corrosive spots (mm²)
Total Instrument	296	7,40	39,8	7
Box lock	42	1,05	22,6	2
Ratchet	58	1,45	13,1	4
Ring handle	190	4,75	16,3	12
Shank	2	0,05	1,2	1
Jaw	2	0,05	0,3	7
Tip	2	0,05	0,5	3

Figure 36: *Corrosion metrics from the Salt Mist Test, including mean area affected by corrosion and number of corrosive spots. Results are presented both overall and per component, indicating material-specific susceptibility differences.*

4.2.2 Comparing corrosion-affected surfaces: Reprocessing versus Salt Mist Test

In this section, we examine the correlation between the extent of corrosion observed in the Salt Mist Test and that observed after varying reprocessing cycles. Using the normalised surface areas affected by corrosion from reprocessing tests, these values were compared with the total surface areas affected by the Salt Mist Test across materials 304, 410, and 420 using a Spearman correlation analysis.

Table 13 summarises the correlation coefficients and corresponding p-values. Stainless steel 304 shows a significant negative correlation between the corrosion observed in the Salt Mist Test and Continuous NaClO reprocessing, with a Spearman correlation of -0.66 (p = 0.03). Stainless steel 420 also shows a weak but statistically significant positive correlation with Intermittent Sanizyme reprocessing (r = 0.72, p = 0.02).

In contrast, no significant correlations were found for all three stainless steel types across the various reprocessing conditions.

	Continuous NaClO versus Salt Mist Test		Continuous Sanizyme versus Salt Mist Test		Intermittent NaClO versus Salt Mist Test		Intermittent Sanizyme versus Salt Mist Test	
Material	**Correlation**	**p-value**	**Correlation**	**p-value**	**Correlation**	**p-value**	**Correlation**	**p-value**
304	-0.66	0.03 (*)	0.46	0.16	0.08	0.84	0.03	0.93
410	0.62	0.06	-0.04	0.92	-0.54	0.11	0.72	0.02 (*)
420	0.02	0.98	-0.05	0.91	0.58	0.11	-0.35	0.36

Table 13: *Spearman correlation analysis between the Salt Mist Test and reprocessing cycles, highlighting a range of positive and negative correlations observed across materials.*

4.2.3 Correlation between Salt Mist Test corrosion area and Sanizyme Reprocessing cycles to corrosion onset

This section examines the correlation between the corrosion-affected surface area in the Salt Mist Test and cycles to corrosion onset during manual Sanizyme reprocessing. Due to uniform failure within eight cycles in Continuous and Intermittent NaClO reprocessing, these conditions lacked variability for correlation analysis.

For Continuous and Intermittent Sanizyme reprocessing, the midpoint of the cycle range at corrosion onset was correlated with Salt Mist Test surface areas using Spearman correlation per material (Table 14). Results show a significant positive correlation for material 410 in Intermittent Sanizyme (r = 0.72, p = 0.02), suggesting Salt Mist Test corrosion extent may predict earlier onset under this condition. No significant correlations were found for materials 304 and 420, suggesting the Salt Mist Test may not consistently predict cycles to corrosion onset in Sanizyme reprocessing for these materials. presents these results with correlation coefficients and corresponding p-values.

	Continuous Sanizyme versus Salt Mist Test		Intermittent Sanizyme versus Salt Mist Test	
Material	**Correlation**	**p-value**	**Correlation**	**p-value**
304	0.23	0.5	0.1	0.79
410	-0.04	0.92	0.72	0.02 (*)
420	-0.07	0.85	0.2	0.6

Table 14: *Spearman correlation between the Salt Mist Test and cycles to corrosion onset during Sanizyme reprocessing, highlighting a range of positive and negative correlations across materials. Stainless steel 410 shows a significant positive correlation under Intermittent Sanizyme conditions.*

5 Discussion

5.1 Summary of key findings

Main research question

What factors influence the susceptibility to corrosion of surgical instruments during reprocessing containing manual cleaning, and to what extent can an accelerated testing tool adequately indicate this susceptibility?

Corrosion susceptibility in surgical instruments was primarily influenced by material type and the choice of cleaning agent. Stainless steel 420 exhibited the highest susceptibility, showing rapid onset and extensive surface degradation, while type 304 demonstrated the most significant resistance. NaClO exposure proved highly destructive across all materials, meaning the influence of material type was most evident in tests with Sanizyme. Although two-hour rest periods were included in intermittent tests, their effect on corrosion progression was inconsistent and did not significantly impact the outcomes. The Salt Mist Test results largely failed to correlate with outcomes from manual reprocessing. This indicates that, in its current implementation, the accelerated test does not reliably predict corrosion onset or extent for stainless steel types 304, 410, and 420 under manual reprocessing conditions.

Sub-research questions

1. *How do material differences in stainless steel alloys (304, 410, and 420) impact the susceptibility to corrosion under varying reprocessing conditions?*
   No significant differences were found between the materials under NaClO reprocessing. In Sanizyme reprocessing, however, type 420 showed the highest susceptibility, followed by type 410, with type 304 demonstrating the most significant resistance across continuous and intermittent conditions.
2. *How does using sodium hypochlorite versus an enzymatic cleaning agent affect the susceptibility to corrosion and the number of cycles to corrosion onset of surgical instruments?*
   NaClO exposure induced rapid corrosion across all materials, whereas Sanizyme reprocessing delayed corrosion, particularly in type 304.
3. *To what extent does incorporating a rest period between reprocessing cycles influence the susceptibility to corrosion and the number of cycles to corrosion onset?*
   The inclusion of two-hour rest periods, tested in the intermittent reprocessing test and compared to continuous reprocessing, did not show consistent significance in reducing corrosion progression across materials. However, type 420 showed some indications of delayed onset.
4. *How does the extent of corrosion observed in accelerated testing compare to that observed after multiple instrument reprocessing cycles?*
   A minimal correlation was found between reprocessing outcomes and Salt Mist Test results regarding surface area affected by corrosion, suggesting that the Salt Mist Test does not reliably reflect corrosion susceptibility under reprocessing conditions.
5. *Does the surface area affected by corrosion in accelerated testing correlate with the number of cycles to corrosion onset during instrument reprocessing?*
   Insignificant correlations across most materials suggest that the Salt Mist Test lacks predictive value for estimating the number of cycles to corrosion onset under reprocessing conditions, including manual cleaning with NaClO or Sanizyme.

5.2 Evaluation of methodological choices

5.2.1 Use of the 4-Bucket System

Reflecting on the choice of the 4-bucket cleaning system, adhering to WHO guidelines may have been more valuable. As discussed in Section 2.1.2, discrepancies between national and WHO recommendations create confusion and inconsistency in cleaning practices across LMICs. Despite WHO's advisement for safer enzymatic alternatives, corrosive agents like chlorine remain widely used [15]. By deviating from WHO protocols, this study may not fully support the broader need for harmonised, standardised guidelines that healthcare providers can implement consistently. In retrospect, aligning more closely with WHO standards might have contributed more effectively to the call for evident, unified cleaning practices that enhance infection control and instrument longevity across diverse settings.

5.2.2 Evaluation of the Reprocessing tests

Impact of the blood simulation

To approximate the chloride exposure that surgical instruments face in real use, instruments were briefly dried after rinsing. This approach aimed to balance clinical realism with practical testing limitations, avoiding extended cycle times. Future studies might investigate prolonged blood exposure to enhance clinical relevance.

Accelerated corrosion observations around the box lock

Corrosion developed quickly around the box lock in this study, unlike observations in pilot studies with other instrument types. One likely factor is the limited oxygen accessibility within the box lock area, which increases susceptibility to crevice corrosion. Low oxygen levels create anodic regions where metal ions dissolve into the solution [35]. Although crevice corrosion is known to occur in these confined spaces, the specific areas where corrosion was most prominent were not in the narrowest parts of the hinge itself. As shown in Figure 15 in Section 3.5.1, the corrosion-prone sites were somewhat exposed but had notably rough surface finishes, which could indicate a manufacturing defect. Poor surface finishes can compromise the material's resistance to corrosion by disrupting the passive layer, making the metal more vulnerable in aggressive environments [9, 28].

The possible influence of such manufacturing imperfections on the corrosion outcomes led to a decision not to use these specific sites as exclusion criteria for further testing. Intermittent Reprocessing Tests were included to investigate whether introducing rest intervals could mitigate corrosion onset, allowing the surface time for passive layer recovery between cycles [26].

Normalising corrosion surface area across test cycles

Instruments were excluded from testing once corrosion outside the box lock was observed to prevent contact corrosion. This normalisation per cycle enabled more consistent comparisons across instruments despite the non-linear nature of corrosion [54]. Although this approach does not track precise progression, it allows for a fairer comparison of corrosion-affected surface areas across materials with differing cycle counts. This helps to mitigate potential biases resulting from varied exposure levels. Future studies could maintain uniform cycle numbers across instruments to enhance comparability.

5.2.3 Evaluation of the Salt Mist Test for surgical instruments

The Salt Mist Test proved valuable for assessing corrosion susceptibility but presented challenges due to its constant conditions, which differ from the fluctuating environments in clinical settings [55]. The aim was not to replicate clinical conditions but to evaluate if insights from the Salt Mist Test could inform manual reprocessing outcomes. Pilot studies helped refine parameters like salt concentration and temperature based on ASTM standards [56]. A four-hour exposure was selected; however, it may have been excessive, amplifying corrosion beyond expected levels and potentially reducing the test's predictive accuracy for clinical applications. Shorter exposure times in future studies could capture early-stage corrosion more effectively.

5.2.4 Sample size and test adaptations

An initial power analysis suggested 60 instruments per test to ensure statistical reliability. However, rapid corrosion, especially in the continuous NaClO tests, led to adaptations, including the addition of intermittent tests. Redistributing instruments resulted in 30 instruments per intermittent test and Salt Mist Test, with 10 per stainless steel type (304, 410, and 420). Although uneven, this distribution provided extra valuable insights within the constraints of available resources.

5.2.5 Documentation of corrosion

The 2D images often lacked depth and boundary clarity, particularly around curved areas. Variations in lighting and contrast across the instruments further complicated the accuracy of surface area measurements. Additionally, most corrosion spots were very small (<1 mm), making precise documentation challenging. While these factors may have affected measurement precision, they were consistent across all instruments, minimising any impact on the overall findings.

5.3 Interpretation of results

5.3.1 Material susceptibility to corrosion

Based on the literature in Section 2.2, corrosion resistance was expected to correlate with chromium content, with type 304 performing best, followed by 420 and 410. However, results from the Sanizyme tests showed type 420 as the most susceptible to corrosion, even more so than 410, suggesting chromium content alone does not determine corrosion resistance.

This discrepancy may stem from the microstructural properties of 410 and 420, both martensitic stainless steels known for their hardness. These can create vulnerabilities such as internal stresses and microcracks that make these materials more prone to corrosion under aggressive conditions. Additionally, the higher carbon content in 420 may lead to carbide formation at grain boundaries, weakening the passive layer and increasing susceptibility to intergranular corrosion [57]. Studies also indicate that carbide formation and internal stresses in the martensitic matrix of 420 significantly reduce corrosion resistance, particularly after heat treatment [58, 59].

In summary, the unexpected performance of type 420 highlights that chromium content alone is not a reliable predictor of corrosion resistance. Further research could focus on the balance between hardness and corrosion resistance to guide material choices for surgical instruments in LMICs.

5.3.2 Effect of sodium hypochlorite versus enzymatic cleaning on corrosion susceptibility

Sodium hypochlorite (NaClO) significantly increases corrosion susceptibility in stainless steels due to its highly oxidative nature, which disrupts the passive layer and exposes the material to further corrosion [60]. This effect is particularly severe in martensitic stainless steels (types 410 and 420), where the protective oxide layer is less stable than in austenitic steel (type 304) [61]. In contrast, the enzymatic agent Sanizyme lacks oxidative action, resulting in a gentler impact on surface integrity and delaying the onset of corrosion [60].

These findings underscore the importance of selecting less aggressive cleaning agents, especially for materials prone to corrosion under oxidative conditions. Such agents could be particularly valuable in resource-limited settings where instrument longevity is crucial [60].

5.3.3 Impact of rest periods on corrosion susceptibility

Given stainless steel's longer recovery time, short rest intervals were anticipated to have a limited impact on corrosion onset. However, distinct responses were observed among types 304, 410, and 420, primarily due to their differing compositions and reactivity.

Type 420 showed substantial corrosion under NaClO but not under Sanizyme, likely because NaClO rapidly degrades the chromium oxide passive layer, while intermittent exposure allows partial passivation, limiting corrosion [59, 62]. In contrast, Sanizyme's enzymatic action does not harm the passive layer, resulting in no significant impact on corrosion surface area [57]. Type 410 displayed notable differences only under Sanizyme, likely due to its lower chromium content and less stable passive layer, which offers minimal protection against NaClO even with rest periods [63].

Type 304 showed no significant differences between continuous and intermittent exposure. This may reflect 304's strong self-repairing passive layer, supported by high chromium and nickel, which provides notable resistance to corrosion in NaClO and Sanizyme Reprocessing, even without rest periods. Rest intervals in this timeframe did not lead to substantial improvements in susceptibility to corrosion. More extended rest periods may be necessary to observe more pronounced effects [64].

5.3.4 Evaluating the predictive value of the Salt Mist Test

Correlation of surface area affected by corrosion

The limited correlation between the Salt Mist Test and reprocessing tests likely stems from methodological differences. The Salt Mist Test is conducted in a controlled environment with consistent variables, such as salt concentration, humidity, and temperature, minimising data variability. In contrast, reprocessing methods simulate real-world conditions, which are more challenging to standardise and introduce more variability in results [65]. Normalising the affected surface area per cycle in reprocessing tests also implies a linear corrosion progression, which does not align with the typically non-linear nature of corrosion [54]. Variable sample sizes and non-normal data further reduce statistical power, impacting correlation reliability.

Additionally, the inconsistent correlation direction—positive for some materials and negative for others—suggests an absence of a meaningful relationship between the affected surface areas in the Salt Mist Test and those observed during reprocessing. An accurate correlation would likely show a consistent direction across all materials. This lack of uniformity reinforces the conclusion that the Salt Mist Test does not reliably predict corrosion behaviour under reprocessing conditions.

Predictive value for corrosion onset
The correlation analysis between the affected surface area in the Salt Mist Test and the number of cycles to corrosion onset during reprocessing is similarly impacted by differences in metrics and methodological constraints, such as variable sample sizes and non-normal data distributions, which increase the risk of Type II errors [66].

Moreover, the mixed positive and negative correlations further indicate a lack of consistent relationship between the two tests. If an accurate correlation existed, one would expect uniform correlation directions (e.g., all negative), suggesting that larger affected areas in the Salt Mist Test correspond to fewer cycles to corrosion onset in reprocessing tests. The observed inconsistency implies no coherent relationship, limiting the Salt Mist Test's predictive value for corrosion onset in reprocessing conditions.

5.3.5 Towards an understanding of the main research question

This study underscores how various cleaning protocols and material factors significantly impact the corrosion susceptibility of surgical instruments, reinforcing the need for a standardised manual cleaning protocol. A clear protocol could reduce confusion around guideline adherence and enhance instrument longevity, particularly in LMIC contexts where resources may be limited [67, 68]. Developing best practices to optimise instrument durability may be essential in reducing corrosion-related wear and extending the functional lifespan of these tools [7].

Findings suggest that factors such as chromium content, carbon structure, and the aggressiveness of agents like NaClO versus enzymatic cleaners impact corrosion susceptibility [7, 67]. Additional variables, such as sterilisation techniques and mechanical handling, were standardised in this study but could warrant further investigation due to their potential impact on corrosion [7]. This study's use of enzymatic agents under similar soaking protocols to NaClO highlights the need to tailor cleaning techniques to each agent's properties to maximise efficacy while preserving material integrity [68].

Regarding the Salt Mist Test, this study revealed limitations in its predictive value under manual reprocessing conditions. The controlled test conditions, including stable temperature and humidity, contrast with the variable settings in clinical environments, likely explaining the observed lack of correlation with real-world corrosion patterns [65]. The findings of this study do not conclusively rule out the Salt Mist Test as a potential indicator of corrosion susceptibility in reprocessing contexts that include manual cleaning. Although the test in its current form did not correlate well with reprocessing outcomes, this should not be taken as definitive evidence of its inadequacy. Instead, the findings highlight several methodological limitations, suggesting further research.

5.4 Limitations of this study

This study has several limitations that may influence the interpretation and generalisability of the findings.

Time and budget constraints
This research was conducted within the framework of a master's thesis, with limited

time and budget. These constraints restricted sample sizes per test, which may reduce statistical power and increase the risk of Type II errors, potentially missing accurate correlation [66]. Additionally, the limited timeframe restricted the simulation of prolonged blood exposure. It limited the rest period in the intermittent reprocessing protocol to two hours, which may be insufficient to capture optimal corrosion recovery intervals.

Methodological limitations
Challenges in documenting corrosion on reflective, complex instrument surfaces may have led to slight underestimations in corrosion extent. 2D images often lacked boundary clarity and depth, especially for small corrosion spots, and variations in lighting and contrast may have impacted measurement accuracy. Furthermore, normalising corrosion surface area per cycle assumes a linear progression, potentially oversimplifying the non-linear corrosion progression observed in clinical settings [54]. While this normalisation facilitated comparison, it may only partially represent the complex nature of corrosion in practical applications.

Limitations in selected testing methods
The study's scope was limited to testing a single enzymatic cleaning agent despite the availability of other formulations with diverse compositions and efficacies. This narrow focus may limit the applicability of findings to reprocessing protocols involving other enzymatic agents. In addition, a single, standardised sterilisation method was used, which, while ensuring consistency, may overlook variations in corrosion susceptibility linked to different sterilisation practices. Certain aspects of manual reprocessing—such as mechanical handling and scrubbing—were also not included, though these may impact corrosion susceptibility. Finally, this study relied solely on the Salt Mist Test as an accelerated corrosion method and did not explore alternative tests that might provide complementary insights. The Salt Mist Test relies on highly standardised settings which may not entirely capture the variability of clinical environments [65]. While the Salt Mist Test provided valuable data, future studies could investigate complementary accelerated testing methods to better reflect corrosion behaviours under simulated clinical conditions.

Addressing these limitations in future research could improve understanding of corrosion susceptibility and enhance the predictive value of accelerated testing methods under clinical reprocessing conditions.

5.5 Relevance and implications of this research for LMIC contexts

This study offers valuable insights into improving surgical instrument management in LMICs. Limited resources make corrosion control essential for extending instrument lifespan and ensuring patient safety [7]. The findings highlight the need for a clear, standardised cleaning protocol in LMICs that addresses cleaning efficacy and long-term instrument durability. Such a protocol could mitigate current inconsistencies in reprocessing practices, providing healthcare workers with reliable guidance that reduces corrosion risk and supports instrument longevity [2].

Furthermore, this research raises important considerations for material selection. While 400 series stainless steel is commonly chosen for its hardness, its susceptibility to corrosion may challenge its suitability in LMICs, where corrosion can more directly impact sterility [67]. Exploring materials that better balance strength with corrosion resistance could enable more durable instrument use in these settings [9]. By focusing on sustainable, cost-effective reprocessing methods, this research contributes to safer and more resilient surgical instrument management practices suited to the unique needs of LMICs.

5.6 Future research recommendations

This study suggests several directions for future research to further enhance our understanding of corrosion susceptibility in surgical instruments, particularly in low—and middle-income countries (LMICs).

Material properties and investment considerations for LMICs

Significant price differences exist between stainless steel types 410, 420, and 304, making it essential to explore which material properties are most critical for surgical instruments in LMIC settings. While the 400 series is commonly chosen for its hardness, its corrosion susceptibility raises concerns for LMIC applications, where corrosion poses a higher risk to instrument sterility and contributes to surgical site infections. Examining the balance between material strength and corrosion resistance in LMIC contexts would provide insights into which materials offer the best long-term value for healthcare facilities in these regions.

Extended rest periods in reprocessing cycles

Testing the effect of longer rest periods between reprocessing cycles, with inspection after each cycle, could help determine if extended intervals promote more robust passivation and greater corrosion resistance, especially in materials that are otherwise prone to rapid corrosion.

Investigation into contact corrosion

Assessing the influence of contact corrosion would allow for more comprehensive testing beyond the initial signs of corrosion onset. Such analysis may reveal how contact between corroded and non-corroded areas accelerates degradation and could inform strategies to mitigate this effect.

Salt Mist Test protocol optimisation

Adjusting salt concentration and exposure duration to refine the salt mist test could improve its predictive accuracy for real-world corrosion patterns, making it a more effective accelerated testing tool for clinical reprocessing scenarios.

Component-specific corrosion analysis

Future studies could benefit from a detailed analysis of corrosion patterns in individual instrument components. This may uncover vulnerabilities in specific areas, such as hinges or serrations, allowing for targeted improvements in design and maintenance.

Additional recommendations

Further research might also include testing alternative enzymatic cleaning agents, exploring diverse sterilisation protocols, and investigating the effects of mechanical handling, such as scrubbing, on corrosion progression. Addressing these areas would provide a more comprehensive foundation for optimising reprocessing practices and material choices.

6 Conclusion

This study assessed the corrosion susceptibility of surgical stainless steels 304, 410, and 420 under reprocessing conditions representative of low—and middle-income countries (LMICs). The research utilised both reprocessing tests with sodium hypochlorite and the enzymatic agent Sanizyme and an accelerated Salt Mist Test to evaluate potential predictive correlations.

The reprocessing tests demonstrated that sodium hypochlorite is highly corrosive, leading to rapid degradation across all tested stainless steels, which could compromise the integrity and safety of surgical instruments. In contrast, using Sanizyme significantly delayed corrosion onset, reducing the affected surface areas across all materials. This suggests that milder enzymatic agents could extend instrument lifespans in LMICs, where repeated reprocessing is essential.

Among the materials, stainless steel 410 and 420 are known for their strength and hardness, which is essential for the functionality of surgical instruments, while 304 is valued for its corrosion resistance. This study highlights a trade-off between mechanical durability and corrosion resistance that warrants further exploration in LMIC settings, where balancing these properties could impact both instrument longevity and patient safety.

The Salt Mist Test was employed as an accelerated method to simulate corrosion patterns, but outcomes did not correlate closely with the manual reprocessing behaviours observed. This finding suggests that while the Salt Mist Test holds potential for accelerated corrosion assessment, refinements are necessary for predictive accuracy in clinical contexts.

Overall, these findings underscore the importance of enzymatic agents as a viable, less corrosive alternative to sodium hypochlorite, with implications for enhancing the longevity and safety of surgical instruments in LMICs. Further studies are recommended to refine accelerated testing methods and explore materials that balance strength and corrosion resistance, tailored to the resource limitations in LMICs.

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7 Appendix

Appendix A: Equipment and materials used for reprocessing tests

To supplement the materials and methods section for the reprocessing tests, the following equipment and materials were used to carry out the tests:

- Five plastic containers, each with a capacity of at least 10 litres.
- Pure sodium chloride (NaCl) from Labshop.nl.
- Sanizyme solution (enzymatic detergent) from SIRMAXO CHEMICALS.
- Sodium hypochlorite diluted to 0.5% by adding 0.4167 litres of NaClO (12.5%) to 10 litres of water.
- OMO detergent powder.
- Demineralised water.
- Clean tap water.
- A towel.
- A MELAtronic 15 EN+ autoclave.
- A plastic colander for holding the instruments during cleaning cycles.
- Rubber gloves to prevent skin contact with cleaning agents.
- Plastic spatulas for mixing the solutions.
- A precision scale for accurate measurements.

Figure 37: Overview of the setup.

Figure 38: MELAtronic 15 EN+ autoclave used for sterilization.

Figure 39: Materials used during the tests

Figure 40: Timer setup to accurately measure cleaning cycle times.

Figure 41: Photo booth setup used for documenting corrosion spots.

Appendix B: Equipment and materials used for Salt Mist Test

To supplement the materials and methods section for the Salt Mist Test, the following equipment and materials were used to carry out Test 5:

- A large container with a capacity of 10 litres, filled with demineralised water.
- A Kitchenbrothers sous vide stick for temperature control.
- A plexiglass cover with a cut-out for the sous vide stick.
- Pure sodium chloride (NaCl) from Labshop.nl to create the saline solution.
- A plastic rack to suspend the instruments above the water level.
- A Tbest 12-LED ultrasound mist maker for generating the salt mist.
- Plastic spatulas for mixing the solutions.
- A precision scale for accurate measurements.

Appendix C: Excelsheets of Reprocessing data

Data Continuous NaClO Reprocessing

Continuous NaClO	BOX LOCK			RATCHET			RING HANDLE			SHANK			JAW			TIP			SPOTS	TOTAL AREA	#Cycles till failure	
Type instrument	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	TOTAL	ALL PARTS	Including box lock	Excluding box lock
304_1	8	1	7.27		0	0	24	2	22.73		0	0		0	0		0	0	3	30	8	24
304_2	8	4	15.81		0	0	8	1	8.27		0	0		0	0		0	0	5	24.08	8	8
304_3	8	1	4.63		0	0	16	8	36.41		0	0		0	0		0	0	9	41.04	8	16
304_4	8	2	9.78		0	0	16	3	48.14		0	0		0	0		0	0	5	57.92	8	16
304_5	8	1	7.99		0	0	16	1	0.89	16	1	0.84		0	0	16	3	4.4	6	14.12	8	16
304_6	8	3	14.14	16	2	6.58	16	1	7.28		0	0		0	0		0	0	6	28	8	16
304_7	8	1	5.93	24	1	0.82	24	2	11.92		0	0		0	0		0	0	4	18.67	8	24
304_8	8	3	12.69	16	2	1.83		0	0		0	0		0	0		0	0	5	14.52	8	16
304_9	8	1	4.26		0	0	16	1	30.73		0	0		0	0		0	0	2	34.99	8	16
304_10	8	3	11.29	16	1	1.26	16	6	4.75		0	0		0	0		0	0	10	17.3	8	16
304_11	8	2	9.46		0	0	24	3	1.1		0	0		0	0		0	0	5	10.56	8	24
304_12	8	1	7.64		0	0	16	4	15.01		0	0		0	0		0	0	5	22.65	8	16
304_13	8	3	11.42		0	0	8	6	7.43		0	0		0	0		0	0	9	18.85	8	8
304_14	8	1	5.78	8	3	4.45		0	0		0	0		0	0		0	0	4	10.23	8	8
304_15	8	2	11.35	8	3	3.94		0	0		0	0		0	0		0	0	5	15.29	8	8
304_16	8	2	8.23		0	0	8	2	5.73		0	0		0	0		0	0	4	13.96	8	8
304_17	8	1	5.71	24	8	11.8	24	2	8.74		0	0		0	0		0	0	11	26.25	8	24
304_18	8	1	7.13	24	21	18.61	24	8	11.51		0	0		0	0		0	0	30	37.25	8	24
304_19	8	3	14.53	8	3	11.53		0	0		0	0		0	0		0	0	6	26.06	8	8
304_20	8	1	6.84	24	14	15.41	24	1	0.94	24	2	3.54		0	0		0	0	18	26.73	8	24
410_1	8	3	14.97		0	0	8	1	1.84	8	2	3.01		0	0		0	0	6	19.82	8	8
410_2	8	1	3.67		0	0	8	3	13.87		0	0		0	0		0	0	4	17.54	8	8
410_3	8	1	6.14	16	2	1.63	16	3	59.03	16	2	1.36		0	0		0	0	8	68.16	8	16
410_4	8	1	6.25	24	3	5.87	24	2	2.07	24	2	0.4		0	0		0	0	8	14.59	8	24
410_5	8	2	10.11		0	0	16	3	4.86	24	4	1.87		0	0		0	0	9	16.84	8	16
410_6	8	1	5.57		0	0	16	3	19.05		0	0		0	0		0	0	4	24.62	8	16
410_7	8	4	14.35	8	2	37.62	8	1	4.45		0	0		0	0		0	0	7	56.42	8	8
410_8	8	2	9.54	8	1	90.24	8	4	6.29		0	0		0	0		0	0	7	106.07	8	8
410_9	8	3	16.28	8	1	0.69		0	0		0	0		0	0		0	0	4	16.97	8	8
410_10	8	2	9.86	24	1	0.42	24	1	0.13	24	2	0.35	24	1	0.43		0	0	7	11.19	8	24
410_11	8	3	11.58	24	12	25.12	24	2	23.77	24	2	3.94		0	0		0	0	19	64.41	8	24
410_12	8	2	9.2	24	5	3.56		0	0		0	0		0	0		0	0	7	12.76	8	24
410_13	8	2	10.44	24	8	9.45	24	14	7.94		0	0		0	0		0	0	24	27.83	8	24
410_14	8	3	14.3	8	4	2.25		0	0		0	0		0	0		0	0	7	16.55	8	8
410_15	8	2	9.85	8	4	2.11	8	4	20.1		0	0		0	0		0	0	10	32.06	8	8
410_16	8	2	13.5		0	0	16	1	2.78		0	0		0	0		0	0	3	16.28	8	8
410_17	8	1	5.73		0	0	16	4	16.08	16	1	0.1		0	0		0	0	6	21.91	8	8
410_18	8	2	9.37	8	2	3.11		0	0		0	0		0	0		0	0	4	12.48	8	8
410_19	8	2	10.57		0	0	16	4	11.39		0	0		0	0		0	0	6	21.96	8	16
410_20	8	2	12.92	24	8	8.38	24	3	2.3		0	0		0	0	24	1	0.21	14	23.81	8	24
420_1	8	2	12.86	8	9	7.88	8	4	9.05		0	0		0	0		0	0	15	29.79	8	8
420_2	8	2	10.86	8	5	9.55		0	0		0	0		0	0		0	0	7	20.41	8	8
420_3	8	3	16.66	24	14	4.68	24	29	17.45		0	0		0	0		0	0	46	38.79	8	24
420_4	8	3	14.6	8	5	7.05	8	2	8.33		0	0		0	0		0	0	10	29.98	8	8
420_5	8	3	18.2	24	15	16.78	24	1	2		0	0		0	0		0	0	19	36.98	8	24
420_6	8	2	9.97		0	0	16	4	15.63		0	0		0	0		0	0	6	25.6	8	16
420_7	8	3	13.25	16	5	3.18	16	3	8.5		0	0		0	0		0	0	11	24.93	8	16
420_8	8	2	13.41		0	0	16	9	8.85		0	0		0	0		0	0	11	22.26	8	16
420_9	8	1	4.53	24	4	19.06	24	12	61.09		0	0		0	0		0	0	17	84.68	8	24
420_10	8	3	14.67	16	1	6.96	16	3	31.11		0	0		0	0		0	0	7	52.74	8	16
420_11	8	2	10.98	8	1	3.63		0	0		0	0		0	0		0	0	3	14.61	8	8
420_12	8	2	12.69		0	0	24	7	16.65		0	0		0	0		0	0	9	29.34	8	24
420_13	8	1	4.2	24	17	11.6	24	2	19.14		0	0		0	0		0	0	20	34.94	8	24
420_14	8	2	9.86		0	0	24	7	14.34		0	0		0	0		0	0	9	24.2	8	24
420_15	8	3	17.5		0	0	16	4	22.07		0	0		0	0		0	0	7	39.57	8	16
420_16	8	1	5.32	24	2	20.1	24	4	8.45	24	2	1.78	24	4	5.18		0	0	13	40.83	8	24
420_17	8	2	8.9	8	4	35.3	8	2	11.03	8	3	94.75		0	0		0	0	11	149.98	8	8
420_18	8	4	16.55	16	7	8.56	16	1	6.46	16	2	1.18		0	0		0	0	14	32.75	8	16
420_19	8	2	11.8	24	12	8.93	24	3	6.73	24	5	1.37		0	0		0	0	22	28.83	8	24
420_20	8	2	10.83	16	2	1.01	16	4	12.78		0	0		0	0		0	0	8	24.62	8	16

Data Continuous Sanizyme Reprocessing

Continuous Sanizyme	BOX LOCK			RATCHET			RING HANDLE			SHANK			JAW			TIP			SPOTS	TOTAL AREA	#Cycles till failure	
Materiaal	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	TOTAL	ALL PARTS	Including box lock	Excluding box lock
304_1	32	1	2.66		0	0		0	0		0	0		0	0		0	0	1	2.66	32	>150
304_2	8	16	12.06		0	0		0	0	8	1	4.06		0	0		0	0	17	16.12	8	>150
304_3	32	2	2.54		0	0		0	0		0	0		0	0		0	0	2	2.54	32	>150
304_4		0	0	128	13	1.59		0	0		0	0		0	0		0	0	13	1.59	128	128
304_5		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>150	>150
304_6		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>150	>150
304_7	48	1	2.87	150	3	1.04		0	0		0	0		0	0		0	0	4	3.91	48	150
304_8	32	2	4.17	150	1	2.58	150	1	0.78	150	1	0.63		0	0		0	0	5	8.16	32	150
304_9	32	2	3.72	104	10	5.11		0	0		0	0		0	0		0	0	12	8.83	32	104
304_10	24	2	3.62	120	24	7.73		0	0		0	0		0	0		0	0	26	11.35	24	120
304_11	32	4	6.32	96	13	6.79	96	1	0.23		0	0		0	0		0	0	18	13.34	32	96
304_12	24	3	6.7		0	0		0	0		0	0		0	0		0	0	3	6.7	24	>150
304_13	24	2	4.63	150	14	2.16	150	2	0.48	150	2	0.3		0	0		0	0	20	7.57	24	150
304_14	80	1	1.45		0	0		0	0		0	0		0	0		0	0	1	1.45	80	>150
304_15	24	1	1.6		0	0		0	0		0	0		0	0		0	0	1	1.6	24	>150
304_16		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>150	>150
304_17		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>150	>150
304_18	24	3	5.87		0	0		0	0		0	0		0	0		0	0	3	5.87	24	>150
304_19		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>150	>150
304_20	56	1	2.76	104	2	2.18	104	1	0.26		0	0		0	0		0	0	4	5.2	56	104
410_1	24	5	2.2		0	0		0	0		0	0		0	0		0	0	5	2.2	24	>150
410_2	24	4	6.48		0	0		0	0		0	0		0	0		0	0	4	6.48	24	>150
410_3	24	2	4.17	8	1	0.31	24	3	2.16	24	1	0.2		0	0		0	0	7	6.84	8	8
410_4	24	1	2.31		0	0		0	0		0	0		0	0		0	0	1	2.31	24	>150
410_5	32	2	5.17		0	0		0	0		0	0		0	0		0	0	2	5.17	32	>150
410_6	24	2	3.28	24	1	0.16		0	0	8	4	6.1	24	2	1.47		0	0	9	11.01	8	8
410_7	32	1	1.76		0	0		0	0		0	0		0	0		0	0	1	1.76	32	>150
410_8	32	4	4.72		0	0	40	1	0.92		0	0		0	0		0	0	5	5.64	32	40
410_9	24	2	4.41		0	0		0	0		0	0		0	0		0	0	2	4.41	24	>150
410_10	24	3	7.21	128	19	3.9		0	0		0	0		0	0		0	0	22	11.11	24	128
410_11	24	4	7.42	136	11	2.04	136	3	0.4		0	0		0	0		0	0	18	9.86	24	136
410_12	24	1	4.68		0	0		0	0		0	0		0	0		0	0	1	4.68	24	>150
410_13	24	2	3.96		0	0		0	0		0	0		0	0		0	0	2	3.96	24	>150
410_14	40	1	2.55	96	11	1.41	96	1	0.23		0	0		0	0		0	0	13	4.19	40	96
410_15	24	1	4.46	96	2	1	96	2	1.22		0	0		0	0		0	0	5	6.68	24	96
410_16	32	2	5.39		0	0	104	6	0.44		0	0		0	0		0	0	8	5.83	32	104
410_17	144	4	3.79		0	0		0	0		0	0		0	0		0	0	4	3.79	144	>150
410_18	24	2	7.56		0	0		0	0		0	0		0	0		0	0	2	7.56	24	>150
410_19	24	2	7.19		0	0		0	0	104	2	1.07		0	0		0	0	4	8.26	24	104
410_20	24	4	5.8		0	0		0	0	104	1	0.51		0	0		0	0	5	6.31	24	104
420_1	16	4	12.66		0	0	80	5	0.98	80	1	0.07		0	0		0	0	10	13.71	16	80
420_2		0	0		0	0	24	3	4.08		0	0		0	0		0	0	3	4.08	24	24
420_3	32	1	3.02		0	0	128	1	3.49		0	0		0	0		0	0	2	6.51	32	128
420_4	24	2	6.97	48	3	1.11		0	0		0	0		0	0		0	0	5	8.08	24	48
420_5		0	0		0	0	24	3	1.91		0	0		0	0		0	0	3	1.91	24	24
420_6		0	0		0	0	24	3	4.58	24	1	0.12		0	0		0	0	4	4.7	24	24
420_7	40	6	2.88	112	1	0.16	112	10	0.8		0	0		0	0	112	1	2.56	18	6.4	40	112
420_8	32	2	5.58	150	10	1.03		0	0		0	0		0	0		0	0	12	6.61	32	150
420_9	24	2	5.33	150	1	1.49		0	0		0	0		0	0		0	0	3	6.82	24	150
420_10	24	2	3.78	150	37	7.12		0	0		0	0		0	0		0	0	39	10.9	24	150
420_11		0	0	24	4	0.69	24	3	1.67		0	0	24	1	1.14		0	0	8	3.5	24	24
420_12	32	1	3.1	128	18	1.92	128	2	0.21		0	0		0	0		0	0	21	5.23	32	128
420_13	32	2	5.88	150	17	1.91		0	0		0	0		0	0		0	0	19	7.79	32	150
420_14	32	3	3.66		0	0		0	0		0	0		0	0		0	0	3	3.66	32	>150
420_15	24	3	2.38	112	20	1.43	112	1	2.51		0	0		0	0		0	0	24	6.32	24	112
420_16	40	2	5.11	96	7	1.32	96	3	1.49		0	0		0	0		0	0	12	7.92	40	96
420_17	32	2	4.81	80	22	2.07	80	3	1.56		0	0		0	0		0	0	27	8.44	32	80
420_18	32	5	7.01	150	4	0.48		0	0		0	0		0	0		0	0	9	7.49	32	150
420_19		0	0	8	3	0.89	24	1	0.34		0	0		0	0		0	0	4	1.23	8	8
420_20	40	2	2.31	128	13	5.34	128	3	0.6		0	0		0	0		0	0	18	8.25	40	128

Data Intermittent NaClO Reprocessing

Intermittent NaClO	BOX LOCK			RATCHET			RING HANDLE			SHANK			JAW			TIP			SPOTS	TOTAL AREA
Type instrument	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	TOTAL	ALL PARTS
304_1		0	0		0	0	8	1	3.47		0	0		0	0		0	0	1	3.47
304_2		0	0		0	0	8	3	6.3	8	3	3.82		0	0		0	0	6	10.12
304_3	8	7	3.26	8	4	5.81		0	0		0	0		0	0		0	0	11	9.07
304_4	8	7	6.1	8	3	5.3	8	2	3.55		0	0		0	0		0	0	12	14.95
304_5	8	1	2.66		0	0		0	0		0	0		0	0		0	0	1	2.66
304_6	8	5	6.19	8	3	2.89		0	0		0	0		0	0		0	0	8	9.08
304_7		0	0	8	2	18.5		0	0		0	0		0	0		0	0	2	18.5
304_8	8	1	3	8	1	4.93	8	2	4.09		0	0		0	0		0	0	4	12.02
304_9	8	2	1.58	8	6	7.76	8	1	3.81		0	0		0	0		0	0	9	13.15
304_10	8	2	3.66	8	3	4.52	8	1	3.31		0	0		0	0		0	0	6	11.49
410_1	8	2	10.19		0	0	8	1	4.35		0	0		0	0		0	0	3	14.54
410_2		0	0		0	0	8	3	6.65		0	0		0	0		0	0	3	6.65
410_3		0	0		0	0	8	3	4.16		0	0		0	0		0	0	3	4.16
410_4	8	1	3.11	8	2	2.16	8	4	4.89		0	0		0	0		0	0	7	10.16
410_5		0	0		0	0	8	2	4.6		0	0		0	0		0	0	2	4.6
410_6	8	1	1.84	8	8	21.92	8	1	2.43		0	0	8	2	2.57		0	0	12	28.76
410_7	8	1	1.66	8	4	10.03	8	9	18.51		0	0		0	0		0	0	14	30.2
410_8		0	0		8	7.97		0	0		0	0		0	0		0	0	8	7.97
410_9		0	0	8	7	10.29	8	2	2.5		0	0		0	0		0	0	9	12.79
410_10		0	0	8	5	2.56	8	1	8.8		0	0		0	0		0	0	6	11.36
420_1		0	0	8	4	2.87	8	9	63.03		0	0		0	0		0	0	13	65.9
420_2	8	1	1.45	8	1	3.63	8	1	2.68		0	0		0	0		0	0	3	7.76
420_3	8	1	3.33	8	5	9.22		0	0		0	0		0	0		0	0	6	12.55
420_4		0	0		0	0	8	3	3.24	8	1	6.15		0	0		0	0	4	9.39
420_5	8	2	7.05		0	0		0	0		0	0		0	0		0	0	2	7.05
420_6		0	0		0	0	8	1	0.53		0	0		0	0		0	0	1	0.53
420_7	8	1	4.17	8	2	4.82	8	1	8.39		0	0		0	0		0	0	4	17.38
420_8	8	2	3.47	8	6	4.97		0	0	8	2	0.67		0	0		0	0	10	9.11
420_9	8	3	7.97	8	3	6.47	8	1	0.23		0	0		0	0		0	0	7	14.67
420_10	8	2	4.04	8	5	3.16		0	0		0	0		0	0		0	0	7	7.2

Data Intermittent Sanizyme Reprocessing

Intermittent Sanizyme	BOX LOCK			RATCHET			RING HANDLE			SHANK			JAW			TIP			SPOTS	TOTAL AREA	#Cycles till failure	
Type instrument	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	#Cycli	#Spots	Total A	TOTAL	ALL PARTS	Including box lock	Excluding box lock
304_1		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>64	>64
304_2		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>64	>64
304_3		0	0		0	0	16	1	1.36		0	0		0	0		0	0	1	1.36	16	16
304_4		0	0		0	0		0	0	24	1	1.06		0	0		0	0	1	1.06	24	24
304_5		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>64	>64
304_6		0	0	64	4	1.18		0	0		0	0		0	0		0	0	4	1.18	64	64
304_7	40	1	1.94		0	0		0	0		0	0		0	0		0	0	1	1.94	40	>64
304_8	32	1	2.05	64	3	4.6	64	3	3.09		0	0		0	0		0	0	7	9.74	32	64
304_9		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>64	>64
304_10		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>64	>64
410_1	32	3	4.5	56	5	1.33	56	2	0.88		0	0		0	0		0	0	10	6.71	32	56
410_2		0	0	8	4	2.81		0	0	8	2	12.73		0	0		0	0	6	15.54	8	8
410_3	32	1	3.74	56	11	2.79	56	2	3.03		0	0		0	0		0	0	14	9.56	32	56
410_4	40	3	3.09	64	6	0.54		0	0	64	3	2.02		0	0		0	0	12	5.65	40	64
410_5	32	2	3.77		0	0		0	0		0	0		0	0		0	0	2	3.77	32	>64
410_6		0	0	8	3	0.22	16	1	0.28		0	0		0	0		0	0	4	0.5	8	16
410_7	24	2	4.95		0	0		0	0		0	0		0	0		0	0	2	4.95	24	>64
410_8	32	1	1.83	56	13	3.08	56	1	1.26		0	0		0	0		0	0	15	6.17	32	56
410_9	32	2	2.5		0	0		0	0		0	0		0	0		0	0	2	2.5	32	>64
410_10	16	2	5.28		0	0		0	0	64	1	0.51		0	0		0	0	3	5.79	16	64
420_1	32	1	3.28	56	2	0.34	56	5	1.55		0	0		0	0		0	0	8	5.17	32	56
420_2	56	1	3.17	56	4	0.28	56	11	6.35		0	0		0	0		0	0	16	9.8	56	56
420_3	16	2	4.7		0	0	16	6	11.55		0	0		0	0		0	0	8	16.25	16	16
420_4	8	1	1.94	8	1	0.66	8	2	6.8		0	0		0	0		0	0	4	9.4	8	8
420_5		0	0		0	0	64	4	0.59		0	0		0	0		0	0	4	0.59	64	64
420_6	32	1	2.06	56	7	1.95		0	0		0	0		0	0		0	0	8	4.01	32	56
420_7		0	0		0	0		0	0		0	0		0	0		0	0	0	0	>64	>64
420_8	40	2	0.92		0	0	64	3	0.74		0	0		0	0		0	0	5	1.66	40	64
420_9	32	1	2.67	64	5	3.08		0	0		0	0		0	0		0	0	6	5.75	32	64
420_10	56	3	4.04	56	16	6.52		0	0		0	0		0	0		0	0	19	10.56	56	56

Appendix D: Excelsheet Salt Mist Test

304	BOX LOCK		RATCHET		RING HANDLE		SHANK		JAW		TIP		TOTAL		
	Spots	Area	Spots	Area	Spots	Area	Spots	Area	Spots	Area	Spots	Area	**Spots**	**Area**	
1	4	24.62	6	11.54	11	41.16	3	5.13	0	0	0	0	**24**	**82.45**	
2	4	11.24	18	44.56	9	49.29	0	0	0	0	0	0	**31**	**105.09**	
3	6	18.68	12	13.97	26	47.54	0	0	0	0	0	0	**44**	**80.19**	
4	7	9.34	10	17.73	7	68.72	0	0	0	0	0	0	**24**	**95.79**	
5	4	11.11	5	15.17	5	104.35	0	0	0	0	0	0	**14**	**130.63**	
6	6	25.87	8	22.76	15	16.97	2	0.21	0	0	0	0	**31**	**65.81**	
7	3	7.92	12	28.66	17	76.58	0	0	0	0	0	0	**32**	**113.16**	
8	4	11.88	9	12.33	11	115.88	0	0	0	0	0	0	**24**	**140.09**	
9	7	15.15	6	11.42	22	25.52	0	0	0	0	0	0	**35**	**52.09**	
10	1	2.81	10	32.3	6	110.35	1	0.75	0	0	0	0	**18**	**146.21**	
													27.7	101.151	*Average*

410	BOX LOCK		RATCHET		RING HANDLE		SHANK		JAW		TIP		TOTAL		
	Spots	Area	Spots	Area	Spots	Area	Spots	Area	Spots	Area	Spots	Area	**Spots**	**Area**	
1	5	27.55	10	56.08	13	123.95	1	4.8	0	0	0	0	**29**	**212.38**	
2	5	8.67	10	30.17	47	181.73	0	0	0	0	0	0	**62**	**220.57**	
3	2	5.68	6	48.7	24	301.41	0	0	0	0	0	0	**32**	**355.79**	
4	4	21.36	13	87.87	27	284.28	0	0	0	0	0	0	**44**	**393.51**	
5	6	34.21	12	50.29	22	114.29	0	0	0	0	0	0	**40**	**198.79**	
6	2	17.3	9	37.1	14	199.67	0	0	0	0	0	0	**25**	**254.07**	
7	7	40.86	4	10.96	21	52.43	6	2.64	0	0	0	0	**38**	**106.89**	
8	11	29.59	13	103.77	28	200.23	2	0.38	0	0	0	0	**54**	**333.97**	
9	3	49.51	10	83.35	11	139.51	2	4.54	0	0	0	0	**26**	**276.91**	
10	3	8.73	9	36.41	19	86.7	1	0.09	0	0	0	0	**32**	**131.93**	
													38.2	248.481	*Average*

420	BOX LOCK		RATCHET		RING HANDLE		SHANK		JAW		TIP		TOTAL		
	Spots	Area	Spots	Area	Spots	Area	Spots	Area	Spots	Area	Spots	Area	**Spots**	**Area**	
1	10	51.83	16	17.15	15	68.73	1	1.17	1	10.97	0	0	**43**	**149.85**	
2	8	38.98	12	41.33	27	410.55	0	0	0	0	0	0	**47**	**490.86**	
3	13	27.31	16	62.95	11	69.32	2	1.77	1	4.24	5	16.82	**48**	**182.41**	
4	5	75.79	10	14.05	24	105.55	0	0	0	0	0	0	**39**	**195.39**	
5	19	137.42	19	56.19	15	172.94	0	0	0	0	0	0	**53**	**366.55**	
6	4	6.04	11	151.85	9	249.98	1	0.46	0	0	0	0	**25**	**408.33**	
7	4	7.77	7	47.32	17	133.5	0	0	0	0	0	0	**28**	**188.59**	
8	5	10.29	17	86.7	20	316.31	1	7.14	1	5.05	0	0	**44**	**425.49**	
9	9	44.19	14	68.69	10	218.51	6	5.52	0	0	0	0	**39**	**336.91**	
10	7	25.37	9	33.69	15	157.52	1	1.04	0	0	0	0	**32**	**217.62**	
													39.8	296.2	*Average*

Appendix E: Data Analysis in RStudio

Load Libraries and Data

```
# Load necessary libraries
library(survival)
library(ggplot2)
library(dplyr)
library(ggsignif)

# Load datasets
survival_data <- read.csv("C:/Users/annev/OneDrive/Documenten/Excel final results/SurvivalAnalysis.csv")
smt_data <- read.csv("C:/Users/annev/OneDrive/Documenten/Excel final results/SMT.csv")
area_data <- read.csv("C:/Users/annev/OneDrive/Documenten/Excel final results/AreaAnalysis.csv")
```

Data Filtering

```
# Filter the data for Stainless Steel types (304, 410, 420)
survival_data <- survival_data %>% filter(Material %in% c("304", "410", "420"))
smt_data <- smt_data %>% filter(Material %in% c("304", "410", "420"))
area_data <- area_data %>% filter(Material %in% c("304", "410", "420"))
```

Kaplan-Meier Analysis

```
# Kaplan-Meier Analysis and plotting for each Material
perform_kaplan_meier <- function(material) {
  data <- survival_data %>% filter(Material == material)
  surv_obj <- Surv(time = data$MidpointRange, event = data$Event)
  fit <- survfit(surv_obj ~ Test, data = data)

  print(fit) # Print survival fit summary for documentation
}

# Run Kaplan-Meier Analysis for each material and filter by test type
perform_kaplan_meier("304")
perform_kaplan_meier("410")
perform_kaplan_meier("420")
```

Log-Rank test for survival analysis

```
# Perform Log-Rank Test for comparing different tests within each material
log_rank_test <- function(material, test_pairs) {
  data <- survival_data %>% filter(Material == material)

  results <- lapply(test_pairs, function(pair) {
    subset_data <- data %>% filter(Test %in% pair)
    surv_obj <- Surv(time = subset_data$MidpointRange, event = subset_data$Event)
    test_result <- survdiff(surv_obj ~ Test, data = subset_data)
    return(list(pair = paste(pair, collapse = " vs "), result = test_result))
  })

  return(results)
}

# Define test pairs and run tests for each material
test_pairs <- list(c("ContinuousNaClO", "ContinuousSanizyme"), c("IntermittentNaClO", "IntermittentSanizyme"), c("Continuous
NaClO", "IntermittentSanizyme"), c("ContinuousSanizyme", "IntermittentNaClO"))
log_rank_results_304 <- log_rank_test("304", test_pairs)
log_rank_results_410 <- log_rank_test("410", test_pairs)
log_rank_results_420 <- log_rank_test("420", test_pairs)

# Print Log-Rank Test results for each material
print("Log-Rank Test Results for Material 304")
lapply(log_rank_results_304, print)
print("Log-Rank Test Results for Material 410")
lapply(log_rank_results_410, print)
print("Log-Rank Test Results for Material 420")
lapply(log_rank_results_420, print)
```

Additional survival analyses for different reprocessing tests

```
# Additional survival analysis for specific reprocessing protocols within each material
perform_additional_analysis <- function(material, reprocessing_type) {
  data <- survival_data %>% filter(Material == material, Test == reprocessing_type)
  surv_obj <- Surv(time = data$MidpointRange, event = data$Event)
  fit <- survfit(surv_obj ~ 1, data = data)

  print(fit) # Print survival fit summary for documentation
}

# Perform survival analysis for specific reprocessing types for each material
perform_additional_analysis("304", "ContinuousNaClO")
perform_additional_analysis("410", "IntermittentSanizyme")
```

Wilcoxon Test for corrosion area comparison

```
# Wilcoxon test to compare normalized corrosion area between reprocessing methods within each material
wilcoxon_test_area <- function(material) {
  data <- area_data %>% filter(Material == material)
  results <- pairwise.wilcox.test(data$NormalizedArea, data$Test, p.adjust.method = "bonferroni")
  return(list(material = material, results = results))
}

# Perform Wilcoxon tests for each material
wilcoxon_results_304 <- wilcoxon_test_area("304")
wilcoxon_results_410 <- wilcoxon_test_area("410")
wilcoxon_results_420 <- wilcoxon_test_area("420")

# Print Wilcoxon test results for each material
print("Wilcoxon Test Results for Material 304")
print(wilcoxon_results_304$results)
print("Wilcoxon Test Results for Material 410")
print(wilcoxon_results_410$results)
print("Wilcoxon Test Results for Material 420")
print(wilcoxon_results_420$results)
```

Spearman correlation analysis

```
# Perform Spearman correlation between number of cycles to corrosion and the corrosion area for each material
correlation_analysis <- function(material) {
  survival_subset <- survival_data %>% filter(Material == material)
  smt_subset <- smt_data %>% filter(Material == material)

  min_length <- min(nrow(survival_subset), nrow(smt_subset))
  truncated_cycles <- survival_subset$MidpointRange[1:min_length]
  truncated_smt_area <- smt_subset$TotalArea[1:min_length]

  correlation_result <- cor.test(truncated_cycles, truncated_smt_area, method = "spearman")
  return(list(material = material, correlation = correlation_result$estimate, p_value = correlation_result$p.value))
}

# Perform correlation analysis for each material
correlation_304 <- correlation_analysis("304")
correlation_410 <- correlation_analysis("410")
correlation_420 <- correlation_analysis("420")

# Print correlation results for each material
print("Spearman Correlation Results for Material 304")
print(correlation_304)
print("Spearman Correlation Results for Material 410")
print(correlation_410)
print("Spearman Correlation Results for Material 420")
print(correlation_420)
```