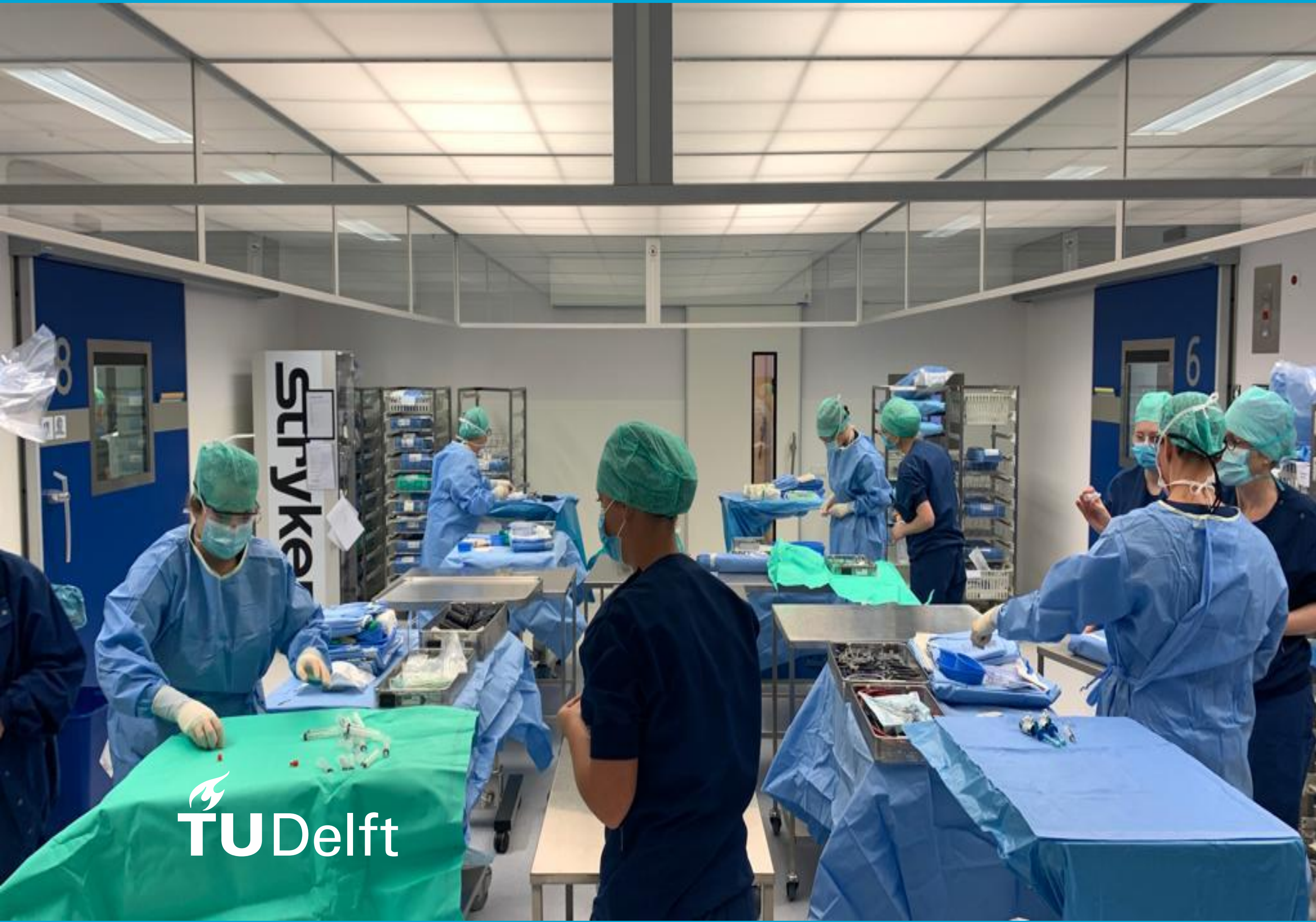
L.M. de Rouw

Design Requirements for Future Technology to Enhance Surgical Instrument Counting

An Observational Study at the Reinier de Graaf Gasthuis



Design Requirements for Future Technology to Enhance Surgical Instrument Counting

By

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TU Delft

Preface

My medical and technical interests could not have come together more perfectly than in this graduation project. This research has proven to me how interdependent the medical and technological domains are. As a Biomedical Engineering student, I am honored to have had the opportunity to closely examine the surgical counting process, even beside the operating table. Spending hours in an operating room environment has been not only educational but also very enjoyable. I always felt very welcome at the Reinier de Graaf Gasthuis.

I want to thank the nurses in the Reinier de Graaf Gasthuis for taking the time to explain the surgical counting process in detail to me, even during the coffee breaks between surgeries. Furthermore, I appreciate my contact with John Verweel, whose valuable insights from the sterilization department contributed to my understanding of the counting process. Lastly, I would like to thank John van den Dobbelsteen, Maarten van der Elst, and Anton Kooijmans for keeping me on track throughout the project when it was challenging to keep an overview due to the numerous observations. A simple action, such as counting, can yet be a very complex issue.

Abstract

INTRODUCTION Surgical counting of instruments forms a crucial part of safety procedures in the operating room (OR). This process has remained primitive without technological support. The manual count process is time-consuming and places heavy cognitive demands on nurses. Current technological approaches fail to detect the exact and detailed usage of surgical instruments under real-life OR conditions. This research aims to enhance surgical instrument counting in the hospital by identifying challenges in the pre-operative, intra-operative, and postoperative phases and formulating design requirements for future technology.

METHODS An observational study was conducted in a large teaching hospital in Delft. The process of surgical instrument counting was assessed in the pre-operative, intra-operative, and postoperative phases of 50 surgeries. Nurses were surveyed to assess the method used, the experienced workload, and the willingness to adopt technology for surgical counting. The sterilization department provided data on the number of additional surgical instruments found on surgical trays after surgery and data on the different types of surgical trays delivered to the hospital.

RESULTS In all surgeries, surgical instrument counting was not performed according to the hospital's protocol due to limited time and resources. Nurses used a technique to memorize the surgical instrument count by placing the surgical instruments in even numbers on the surgical instrument table. Surgical instruments were retrieved from their original surgical tray and placed on a surgical instrument table in case of frequent use or retrieved from their surgical tray and promptly handed to the surgeon in case of infrequent use. The return of surgical instruments to the surgical trays occurred intermittently, mostly when the surgical instrument was not deemed necessary anymore for the remaining surgery. After sterilization, occasionally incomplete surgical trays arrived at the hospital (10,0%), necessitating additional surgical trays to be added to the sterile field. During a 16-week timeframe, 801 additional surgical instruments were found on surgical trays indicating they were not returned to their original surgical tray. All nurses were willing to adopt technology for surgical counting, specifically in the pre-and postoperative phases.

CONCLUSION This study highlighted the challenge of balancing protocol, ensuring patient safety, and working efficiently. A control measure for the initial and final surgical instrument count is necessary for every surgery, as the current technique is insufficient. The design requirements for future technology are monitoring counts in the preparation room (PR) and OR, adjusting to accommodate additional surgical trays, having a focal area on the surgical tray, and identifying incomplete surgical trays. Future technology could enhance surgical instrument counting at the Reinier de Graaf Gasthuis by ensuring the presence and return of used surgical instruments to their original surgical tray.

Keywords *Observational study, surgical instrument counting, operating room, patient safety, efficiency, technological design requirements*

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List of Abbreviations

Abbreviation	Definition
CN	Circulating Nurse
ENT	Ear Nose Throat
ISC	Incorrect Surgical Count
OR	Operating Room
PR	Preparation Room
RFID	Radiofrequency Identification
RSI	Retained Surgical Item
SN	Scrub Nurse

Glossary

Term	Definition
Circulating Nurse	A nurse working outside the sterile field
Incorrect Surgical Count	A surgical count disagreeing with the preceding surgical count
Intra-operative phase	Any action during the surgery (from wound incision to wound closure)
Operating Room	A designated area where the surgery is carried out
Partial Counting	Counting the number of surgical instruments retrieved from and returned to the surgical tray instead of the entire surgical tray
Pre-operative Phase	Any action before surgery (before wound incision)
Preparation Room	A designated area where surgical items are prepared by the scrub nurse before surgery
Postoperative Phase	Any action after surgery (after wound closure)
Retained Surgical Item	Any surgical item found in the patient after surgery
Scrub Nurse	A nurse working within the sterile field
Sterile Field	A designated area in the preparation room and operating room, which is free of microorganisms that can infect someone
Sterilization Department	A department responsible for the hospital's transportation, cleaning, inspection, assembly, packaging, and sterilization processes
Surgical Counting	The counting process of surgical instruments, gauzes, or needles before, during, and after surgery
Surgical Instrument	Tools in the surgical tray for performing specific actions such as dissecting, cutting, retracting, grasping, or suturing
Surgical Instrument Table	A table holding surgical instruments, gauzes, disposables, and needed to perform a surgery
Surgical Item	A surgical instrument, gauze, or needle
Surgical Tray	Containers holding various surgical instruments needed to perform a surgery

1. Introduction

Surgical counting in operating rooms (ORs) is crucial for safe patient care (Al-Quarayshi et al., 2015; Kertesz et al., 2020; Riley et al., 2006). The surgical count process includes counting surgical instruments, gauzes, disposables, and needles throughout surgery to prevent retained surgical items (RSIs) within patients (Freitas et al., 2016; McArthur, 2016; Rowlands, 2012; Stawicki et al., 2013; Steelman & Cullen, 2011).

Although surgical counting is considered a standard and straightforward preventive technique, it can be time-consuming; especially when extensive counting is required. Nurses must keep track of up to 200-500 surgical instruments and hundreds of gauzes and needles throughout a surgery (Gibbs et al., 2007; Hensley, 2010). Nurses must maintain constant focus and situational awareness while balancing time constraints, heavy cognitive demand, and competing priorities in the OR (Fang et al., 2020).

Healthcare systems are shifting from reactive to proactive approaches to medical errors. RSIs are categorized as 'never events', entirely avoidable (Weprin et al., 2021). Despite new regulations and protocols, RSIs continue to arise, proving the complexity and multifactorial problem (Steelman & Cullen, 2011; Hempel et al., 2015; Sengupta et al., 2017; Edel, 2012). While unintentionally leaving behind a surgical item is rare, it is an error that can have significant consequences (McArthur, 2016). Although recounts are performed to avoid RSI, incorrect surgical counts (ISCs) can lead to increased operation times, radiation and anesthesia exposure, and overall costs (Reformat et al., 2017; Fang et al., 2020).

1.1. Problem Statement

The causes and prevention methods for ISCs remain uncertain (Reformat et al., 2017; Weprin et al., 2021). Moreover, the time-intensive process of manual counting results in skipped counts (Corrigan et al., 2018; Berkowitz et al., 2007; Mahran et al., 2013; Fencl, 2016; Steelman, 2014; Inaba et al., 2016). Although technologies have demonstrated effectiveness in reducing the occurrence of soft RSIs (e.g., gauzes and towels), this progress has highlighted a need for more advancements regarding hard RSIs (e.g., surgical instruments, needles, wires) (Weprin et al., 2021). Developing technologies to detect hard surgical items should be prioritized (Hempel et al., 2015; Zaman et al., 2015).

Attempts to enhance or replace manual counting with adjunct technology will necessitate a deeper understanding of its benefits, drawbacks, diagnostic accuracy, clinical factors, and effects on healthcare costs (Freitas et al., 2016; Egorova et al., 2008). Currently, no highly reliable technology can effectively detect the exact usage of surgical instruments across a wide range of surgeries in real-life OR conditions. Consequently, integrating and evaluating future technology is urgently needed.

1.2. Research Question

This research aims to enhance surgical instrument counting by understanding the pre-operative, intra-operative, and postoperative challenges. Additionally, the goal is to formulate design requirements by identifying how future technology can be easily integrated into the counting process of the hospital. Future technology should avoid imposing additional challenges while enhancing patient safety and efficiency. Therefore, this thesis is directed by the following research question:

What are the design requirements for future technology in enhancing surgical instrument counting?

The following research approaches guide the report:

1) Understanding the counting process of surgical instruments in the hospital

2) Identifying challenges in adhering to the hospital's surgical counting protocol

3) Determining the potential benefit of future technology to the surgical count process

1.3. Thesis Structure

In the Reinier de Graaf Gasthuis, an observational study was conducted to investigate the surgical counting of instruments, gauzes, and needles throughout surgeries. Analysis of the measurements revealed that counting gauzes and needles exhibited minimal ISCs, resulted in a limited increase in workload, and was unaffected by the final number of surgical trays. Adding technological applications to the already secure process of handling these materials would not add to a beneficial result. Therefore, the research described in the report focuses on surgical instrument counting. The research on surgical counting of gauzes and needles can be found in Appendix A.

In this report, Chapter One offers background information on RSIs, surgical counting, and technological approaches for surgical instrument counting. To understand the findings of the observational study, Chapter Two first describes the counting protocol of the hospital and sterilization department, followed by the Methods and Results section. After identifying the challenges and how future technology could benefit surgical instrument counting, the design requirements for future technology are determined in Chapter Three. Chapter Four provides a discussion and conclusion of the study.

I

Chapter One – Background

2. Background Information

2.1. Retained Surgical Items

An RSI is ''any item identified within the patient's body cavity, either during the patient's presence in the OR prior to the closure of the incision or in the postoperative period'' (Greenberg et al., 2008). The occurrence of RSIs is estimated to be once in every 1000-18000 surgeries (Al-Quarayshi et al., 2015; Corrigan et al., 2018; Hacivelioglu et al., 2013; Lovrec et al., 2018; Stawicki et al., 2013). The rates of RSIs must be acknowledged as conservative estimates, as the numbers are only based on reported malpractice claims and excluded near-miss events (Birolini et al., 2016; Corrigan et al., 2018; Hacivelioglu et al., 2013; Stawicki et al., 2009; Williams et al., 2014). The rates of RSIs are high in vascular, urologic, gynecologic, and abdominal surgeries (Al-Quarayshi et al., 2015; Jayadrevan et al., 2014; Stawicki et al., 2013; Wang et al., 2015).

Figures 2.1a-c depict images displaying a retained surgical instrument, gauze, and needle (Gibbs et al., 2007). An RSI is nine times more likely to occur during emergency surgeries and surgeries that have unexpected changes (Mahran et al., 2013). The increased likelihood may be explained by safety protocol deviation during acute critical care surgery (Weprin et al., 2021). In most cases (69%-83.33%), reoperation was necessitated to remove the RSI (Freitas et al., 2016; Lincourt et al., 2006; Teixeira et al., 2007).

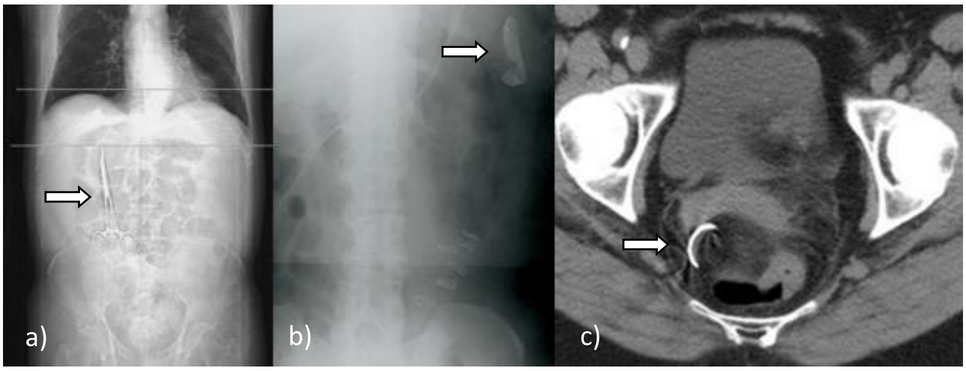

Figure 2.1a-c. (a) Abdominal radiograph with a retained surgical instrument. (b) Abdominal radiograph with retained gauze. (c) CT scan of the pelvis with a retained needle. The arrow indicates the location of the retained surgical item (adapted from Gibbs et al., 2007).

2.2. The Surgical Count

Most ORs have policies in place designed to prevent RSIs. Each facility is responsible for developing and following a legal policy (Gibbs et al., 2007; McArthur, 2016). Most hospitals follow procedures that include two nurses counting every surgical item as it enters the sterile field and, after surgery before the patient leaves the OR (Egorova et al., 2008; McArthur, 2016). Time-outs and checklists are incorporated into protocols for effectively managing surgical items (Macario et al., 2006; McDowell & McComb, 2014; Gibbs et al., 2007).

An ISC occurs when a count disagrees with the preceding count (Egorova et al., 2008). Patient safety cannot be ensured when an ISC occurs (Gawande et al., 2003). ISCs account for 62-88% of RSI events. Despite one individual being aware of an ISC, in 20-50%, the surgeon continued with wound closure (Inaba et al., 2016; Stawicki et al., 2013; Williams et al., 2014). The risk factors for ISCs range from specific factors, such as complexity and duration of the surgery, urgency, and time of day, to more general factors, including communication issues and general chaos (Egorova et al., 2008; Fang et al., 2020; Reformat et al., 2017).

The publication 'Operating Room: Surgical Counts' presents the best practice recommendations for surgical counting (McArthur, 2016). In a study by Gomes et al. (2021), three main barriers to implementing the best practices were identified. These include a lack of awareness among the surgical team regarding the significance and value of surgical counting, the resistance to changing the current counting process, and the absence of suitable digital tools to record the surgical instrument and needle counts effectively. In addition, a new barrier identified was the absence of technology to guarantee the protocol's effectiveness.

With the emergence of technologies designed for surgical counting, the reliance on conventional counting techniques could change. The accuracy of surgical counting could be enhanced by integrating technological approaches with manual counting (Gibbs et al., 2007; MrArthur, 2016; Norton et al., 2012; Reece et al., 2011).

2.3. Technological Approaches for Surgical Instrument Counting

Appendix B considers various technological approaches for surgical instrument counting. The technologies for surgical instrument counting relied on a single sensor type, such as bar- and matrix coding (Freitas et al., 2016; Greenberg et al., 2008) and radiofrequency identification (RFID) technology (Kusada et al., 2016; Norton et al., 2012; Steelman et al., 2011). Moreover, technologies relied on multisensorial approaches, such as vision and weight approaches (Glaser et al., 2015) and computer vision combined with machine learning (Arda et al., 2021; Lee et al., 2021).

The ACRREx method was used to structure the technological approaches for surgical instrument counting. Abstraction, Categorization, Reflection, Reformulation, and Extension were all steps involved in this methodology (Breedveld et al., 2011). The main goal, surgical instrument counting, was divided into two working principles: surgical instrument detection and identification; and surgical instrument tracking. In the next layer, the methods available per working principle were stated. The final layer consists of solutions utilized in technological approaches. The created ACRREx tree is depicted in Figure 2.2.

Applying novel technologies within the OR can improve efficiency and patient safety if deemed appropriate. However, constraints on previously suggested technological approaches for surgical instruments relate to the time-consuming approach (Freitas et al., 2016), modifying all surgical instruments (Egan & Sandberg, 2007; Kusada et al., 2016; Neumuth & Meißner, 2012), and only targeting specific surgical instruments or surgeries (Arda et al., 2021; Glaser et al., 2015). Furthermore, adjunct technologies were tested under laboratory conditions, while real-life OR conditions will likely negatively impact detection rates during procedures (Arda et al., 2021; Glaser et al., 2015).

The technological approaches reveal that no highly reliable technology can effectively detect the exact usage of surgical instruments across a wide range of surgeries. However, when design requirements are formulated based on real-life OR conditions, future technology could potentially enhance surgical instrument counting.

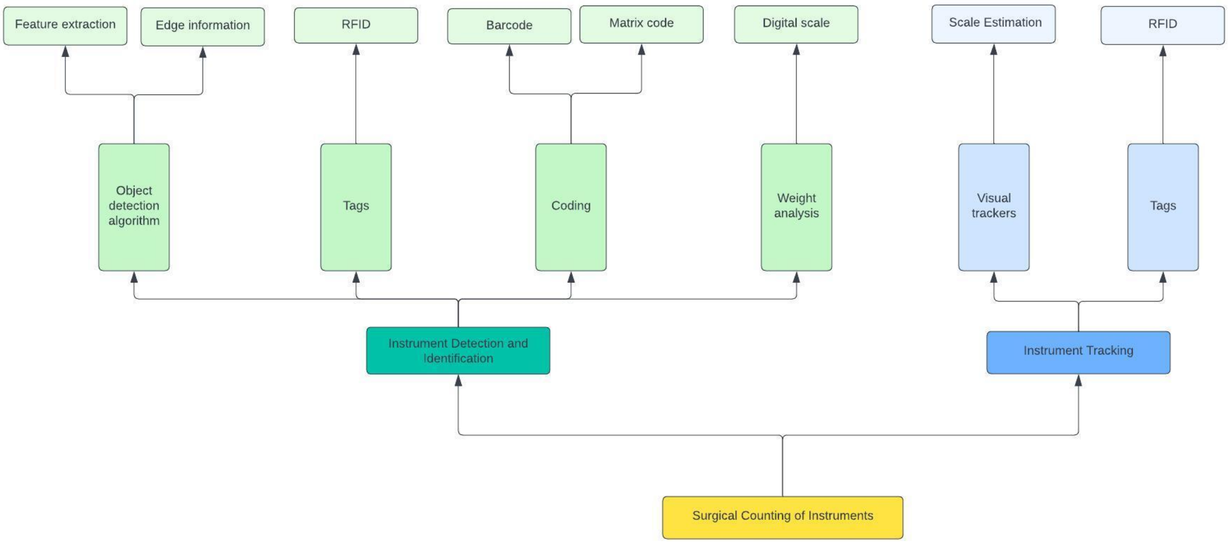

Figure 2.2. The ACRREx tree based on technological approaches for surgical instrument counting.

II

Chapter Two – Observational Study at the Reinier de Graaf Gasthuis

3. The Protocol for Surgical Instrument Counting

The Reinier de Graaf Gasthuis has an external sterilization department, Combister, responsible for the hospital's surgical trays' transportation, cleaning, inspection, assembly, packaging, and sterilization processes. Surgical instrument counting is performed in both the Reinier de Graaf Gasthuis to ensure the completeness of instruments and at Combister for the correct assembly of surgical trays.

3.1. Surgical Instrument Counting at the Reinier de Graaf Gasthuis

Two nurses, a scrub nurse (SN) and a circulating nurse (CN), count surgical instruments in three operative phases. The SN works within the sterile field in the preparation room (PR) and OR, and the CN works outside the sterile field. In the PR, surgery preparation occurs (e.g., putting on sterile clothing, preparing the surgical instrument table, and counting surgical items). In the OR, the surgery takes place. The SN is responsible for estimating how much time they need to prepare the surgical instrument table before surgery. The agreements per operative phase are described below.

Pre-operative counting of instruments

Before surgery, surgical trays are wrapped in sterile packaging and contain a barcode sticker and a Combister guidance list. This document lists every surgical instrument in the surgical tray. According to the Combister guidance list, the SN and CN count the surgical instruments after unwrapping the surgical tray.

The SN identifies the quantity and type of surgical instruments. The Combister guidance list is signed off if the surgical tray is complete. When the surgical tray is incomplete, a report is made on the checklist. The CN scans the barcode of each surgical tray into the electronic health record, HiX, in the OR and reports whether there are any particularities.

Intra-operative counting of instruments

The SN and CN count any additional surgical trays required during surgery, similar to the abovementioned method. The SN keeps all surgical instruments on the table throughout the surgery. If surgical instruments wrapped in laminate are opened, the CN notes it on the whiteboard, and the package should be kept. Once the surgery is complete and upon wound closure, the two nurses must count the surgical instruments again. The SN informs the surgeon if all surgical instruments are present. No garbage bags or surgical instruments may be removed from the OR before the final count. The final count must be completed prior to the patient waking up.

When the surgical instrument number is incomplete, the SN specifies the missing surgical instrument. The CN scans the OR, and if needed, empties trash cans to find the surgical instrument. Once more, the SN examines the surgical site, and if feasible, the surgeon inspects the wound for remaining surgical instruments. If the surgical instrument is still absent, a radiograph of the operated body area must be taken. The patient remains under anesthesia until the surgeon can examine the radiograph. If there is still any uncertainty, the surgical team leader is informed, and a particular incident notification is created in HiX.

Postoperative counting of instruments

After wound closure and ensuring the surgical tray is complete, the CN records the surgical tray's completion in HiX. The nurses' names who performed the final count are noted on the counting sheet.

3.2. Surgical Instrument Counting at Combister

Combister is responsible for the complete assembly of surgical trays. Employees utilize barcode scanning technology on the surgical tray's side. An inventory of the surgical instruments is displayed on the computer to facilitate the assembly. The surgical instruments are checked off the inventory list when placed in the surgical tray. Completion of the checklist indicates that the tray is assembled correctly. The surgical tray is wrapped in blue sterile packaging to indicate that the surgical tray is complete.

In addition, Combister is responsible for recognizing additional or missing surgical instruments on the surgical tray. If additional surgical instruments are identified, the surgical instrument is placed in a container reserved for the Reinier de Graaf Gasthuis purposes. If missing surgical instruments are identified, the surgical tray is temporarily set aside with the expectation that the surgical instrument can be retrieved from the Reinier de Graaf's container. Otherwise, the surgical instrument is retrieved from Combister's inventory.

Suppose the Reinier de Graaf's container and Combister's inventory fail to supplement the surgical tray; Combister contacts the Reinier de Graaf Gasthuis to get approval for sending an incomplete surgical tray. The surgical tray is wrapped in green to indicate an incomplete surgical tray. A label is attached to the green wrapping indicating the missing surgical instrument.

4. Methods

This section presents the methodology for conducting measurements and observations at the hospital and sterilization department. Hence, the section describes how a survey was administered to nurses.

4.1. Design

This research was an observational study evaluating the surgical counting performance of surgical instruments. The aim was to investigate how future technology could easily be integrated into the counting process of surgical instruments without imposing additional challenges and benefitting surgical counting.

Therefore, the surgical instrument counting was assessed in pre-operative, intra-operative, and postoperative phases. The pre-operative phase involves the preparation of surgical instruments before surgery. Hence, the intra-operative phase entails the surgical instrument counting performed during surgery. The postoperative phase encompasses the actions taken after wound closure.

Nurses will have to embrace and utilize future technology to take advantage of technological developments during surgical instrument counting. However, their viewpoints are of great importance for successful implementation. Therefore, their viewpoints must be acknowledged and taken into consideration. Consequently, nurses were surveyed to assess the method used, the experienced workload, and willingness to adopt technology for surgical counting.

4.2. Study Setting and Sample

Structured observations were conducted in the Reinier de Graaf Gasthuis, a large teaching hospital in Delft. The OR complex was the primary site for performing measurements on surgical counting and administrating the survey to nurses. Additionally, the researcher visited the sterilization department to understand the assembly process of surgical trays.

This study documented 50 surgeries, including emergency add-ons (n=3) and excluding weekend cases. Surgical cases were selected based on the OR schedule. Only cases belonging to one OR were attended, taking into consideration the maximum number of 10 individuals allowed in an OR during a procedure. The surgical domains included ear-nose-throat (ENT) (n=14), robot urology (n=5), plastics (n=1), vascular (n=7), gynecology (n=6), trauma surgery (n=11), orthopedic surgery (n=2), and general surgery (n=4). The survey was administered to 22 nurses. Trainee nurses were excluded from the study. Observations occurred in eight ORs, all comparable in size, equipment, work organization, and staffing levels, between 07:30 and 17:00.

4.3. Data Collection Procedure

The researcher received the Reinier de Graaf's surgical instrument counting protocol, described in Section 3.1, from the OR coordinator. Information regarding the surgical instrument counting protocol from Combister, described in Section 3.2, was gathered during a visit to the sterilization department and through conversations with the Head of Logistics.

Before surgery, consent was obtained from the OR staff to research the surgical counting performance, conduct a survey, capture images, and identify opportunities for technological applications. The survey was administered anonymously. Patient consent was not sought due to the absence of patient identities and details. The surgical counting performance was assessed using a tool and a survey, found in Appendix C. Development of the tool involved:

- the examination of policies and standards (the protocol);
- collaborating with the nurses to understand surgical counting activities; and
- research performed on relevant literature.

Two nurses, the SN and CN, were assigned to an OR per day. The measurements concerning the surgical instrument counting were performed on the SN. Simultaneously, the survey was administered to the CN. As the nurses alternated between the SN role and the CN role for every surgery, both nurses underwent the administration of measurements and surveys. Information obtained from observations or conversations with the nurses was recorded in a dedicated notebook. The recorded data encompassed the type and name of the surgery, followed by the findings.

The aim was to minimize disruptions to the SN to understand the counting process and identify real-life OR conditions. As the researcher was not allowed in the sterile area, all measurements and observations were performed from the non-sterile area. Images were taken alongside the measurements whenever feasible, capturing the surgical instrument table in the pre-operative, intra-operative, and postoperative phases. The sections below address the data collection procedure per operative phase.

Due to temporal constraints inherent to this research, the researcher could not measure whether the surgical instruments were returned to their original surgical tray after surgery. However, Combister systematically gathered weekly data on finding an additional surgical instrument within a surgical tray, indicating they were not returned to their original surgical tray after surgery. The data was collected over 16 weeks, from September 2022 to December 2022. Furthermore, Combister provided a document describing the different types of surgical trays delivered to the Reinier de Graaf Gasthuis. The number of surgical instruments per surgical tray is used to understand the number of instruments nurses must count throughout the surgery.

Pre-operative data collection procedure

The OR schedule was determined based on the anticipated duration of the surgery, from incision to wound closure. In the pre-operative phase, surgical instruments were prepared on the surgical instrument table. The researcher was responsible for being present in the PR before the designated start time to perform the surgical instruments' initial measurement.

In the general section of the tool, the researcher recorded information such as:

- the type of surgery;
- the surgery name; and
- whether the surgery was performed on an elective or emergency basis.

In the surgical instrument section of the tool, information was recorded to assess the presence of incomplete surgical trays, such as:

- the wrapping color;
- whether the initial count was conducted in collaboration with the CN and according to the Combister guidance list;
- the prevalence of filling in the Combister guidance list;
- the number of surgical trays used; and
- the necessity to open an additional surgical tray;

The reason for filling in the Combister guidance list and opening an additional surgical tray was documented in the notebook. The additional surgical tray was added to the number of trays used for the surgery. Furthermore, whether an assembly error or unforeseen reason caused the tray addition was noted.

Intra-operative data collection procedure

When the researcher was in the OR, the general information section included the document of the start time of the wound incision.

The return of surgical instruments to the surgical tray took place intermittently. Therefore, the time spent returning surgical instruments is defined as when the SN actively returns surgical instruments to the surgical tray and does not account for actions in between, such as continuing surgical instrument handovers or gathering garbage. These actions indicate the number of interruptions that took place.

In the surgical instrument section, a record was made of:

- the time spent returning surgical instruments to the surgical tray; and
- the occurrence of interruptions while returning surgical instruments to the surgical tray.

The time spent on returning surgical instruments was measured utilizing an XL-009B stopwatch. If additional surgical trays were added during the surgery, this information was recorded and added to the number of surgical trays utilized.

During surgery, the researcher administered the survey to the CN when the nurse was not actively involved in tasks such as counting or passing surgical items to the SN. The responses were not restricted to one option per question. Efforts were made to address all questions to the CN. However, due to the concurrent involvement during surgery, achieving a complete survey was not always feasible.

Postoperative data collection procedure

After surgery, information was recorded such as:

- the end time;
- the occurrence of staff turnover; and
- whether the Combister guidance list was utilized to return surgical instruments to the surgical trays and counted with the CN.

This research used the findings of Combister to highlight the incidence of surgical instruments being returned to the incorrect surgical tray after surgery.

4.4. Data Processing and Analysis

The collected measurement data were stored in an Excel Spreadsheet and exported to IBM SPSS Statistics for processing and analysis. One spreadsheet was utilized to record the measurements of the surgical counting performance, and another was dedicated to documenting the survey results. The subsequent section will explain the methods employed to analyze the surgical counting performance, followed by an account of the survey methodology. The received data from Combister did not require further analysis, thus, will not be explained.

Descriptive statistics were analyzed to evaluate the surgical counting performance to obtain information regarding the minimum, maximum, central tendency, and standard deviations for:

- the final number of surgical trays;
- the time spent returning surgical instruments to the surgical trays; and
- the number of interruptions while returning surgical instruments to the surgical trays.

A boxplot was generated for the relationship between the final number of surgical trays and the following two variables: the time spent returning surgical instruments to surgical trays and the number of interruptions while returning surgical instruments to surgical trays.

Furthermore, descriptives were analyzed on the frequency of filling in the Combister guidance list and the addition of surgical trays. The reason for completing the Combister guidance list or opening an additional tray was obtained from notations in the notebook. The survey findings were examined by generating bar graphs per question.

A flowchart addressing the challenges during surgical instrument counting at the Reinier de Graaf Gasthuis was developed based on the measurements, observations, and surveys. The identified challenges were utilized to formulate design requirements for future technology.

5. Results

The final number of surgical trays utilized during a surgery depended on the type of surgery. Table 5.1 depicts the distribution of surgical trays utilized per surgery. Throughout the observations of 50 surgeries, 87 surgical trays were utilized.

Table 5.1.The Distribution of the Total Number of Surgical Trays used per Surgery

		Frequency	Final number of surgical trays
Final number of surgical trays	1	31	31
	2	12	24
	3	1	3
	4	3	12
	5	2	10
	6	0	0
	7	1	7
Total		**50**	**87**

5.1. Surgical trays

Combister delivers up to 642 types of surgical trays to the Reinier de Graaf Gasthuis. The composition of the surgical tray varies. The distribution of the number of surgical instruments per surgical tray can be viewed in Table 5.2.

Table 5.2.The Distribution of the Number of Surgical Instruments on Surgical trays

Number of surgical instruments in tray	Frequency of surgical trays
1-10 surgical instruments	609
10-20 surgical instruments	25
21-30 surgical instruments	2
31-40 surgical instruments	4
101-110 surgical instruments	1
151-160 surgical instruments	1
Total	**642**

Different types of surgical trays were identified during the study:

a. The surgical trays exhibited diverse dimensions.

b. The surgical trays contained either a single layer or multiple layers.

c. The arrangement of surgical instruments within the surgical tray varied. Surgical instruments either contained a specific arrangement or were placed loosely in the surgical tray. The type of arrangement depended on the fragility of the surgical instrument. Fragile surgical instruments require more protection and have a specific arrangement inside the blue clips of the surgical tray.

Figure 5.1a displays a half-sized surgical tray on the left and a standard-sized surgical tray on the right. Both trays contain specific arrangements for all surgical instruments. In addition, the standard-sized surgical tray consists of two layers. The top layer is placed above the corresponding surgical tray. Figure 5.1b displays a single-layer and standard-sized surgical tray. The surgical instruments are placed loosely in the surgical tray.

All surgical instruments had specific arrangements or were placed loosely in the abovementioned surgical trays. However, it is also possible to have specific arrangements for certain surgical instruments while the other surgical instruments are placed loosely in the surgical tray. Figure 5.1c displays a single layer and standard-sized surgical tray. The surgical instrument on the left contains specific arrangements, while the surgical instruments on the right are placed loosely in the surgical tray.

Figure 5.1a-c (a) Half-sized surgical tray (left) and standard-sized surgical tray (right). Both surgical trays contain specific instrument arrangements for all surgical instruments. The standard-sized tray contains multiple layers. (b) Single layer and standard-sized tray. The surgical instruments do not have specific arrangements in the surgical tray. (c) Single-layer standard-sized surgical tray. Surgical instruments on the left contain specific arrangements. Surgical instruments on the right are placed loosely in the surgical tray.

5.2. The Surgical Counting Process of Instruments

Figure 5.2 illustrates the counting process of surgical instruments specific to the Reinier de Graaf Gasthuis. The left side of the flowchart displays identified challenges. Blue represents the pre-operative phase, orange the intra-operative phase, and green the postoperative phase. Below, the challenges per operative phase will be described, corresponding to the numbered challenges in the flowchart.

5.2.1. Pre-operative Surgical Instrument Counting

Table 5.3 includes the percentage of the following:

- the surgical tray wrapping color;
- location of surgical instrument preparation on the surgical instrument table;
- whether the SN counted the surgical instruments with the CN; and
- whether counting the surgical instruments was performed according to the Combister guidance list.

Table 5.3. Percentage of Surgical Instrument Counting Variables in the Pre-operative Phase

		Frequency
Wrapping of surgical trays	Blue wrapping	96,0%
	Green wrapping	4,0%
Location of surgical instrument preparation	PR	72,0%
	OR	28,0%
Counting surgical instruments with CN		0,0%
Counting surgical instruments according to the Combister guidance list		0,0%

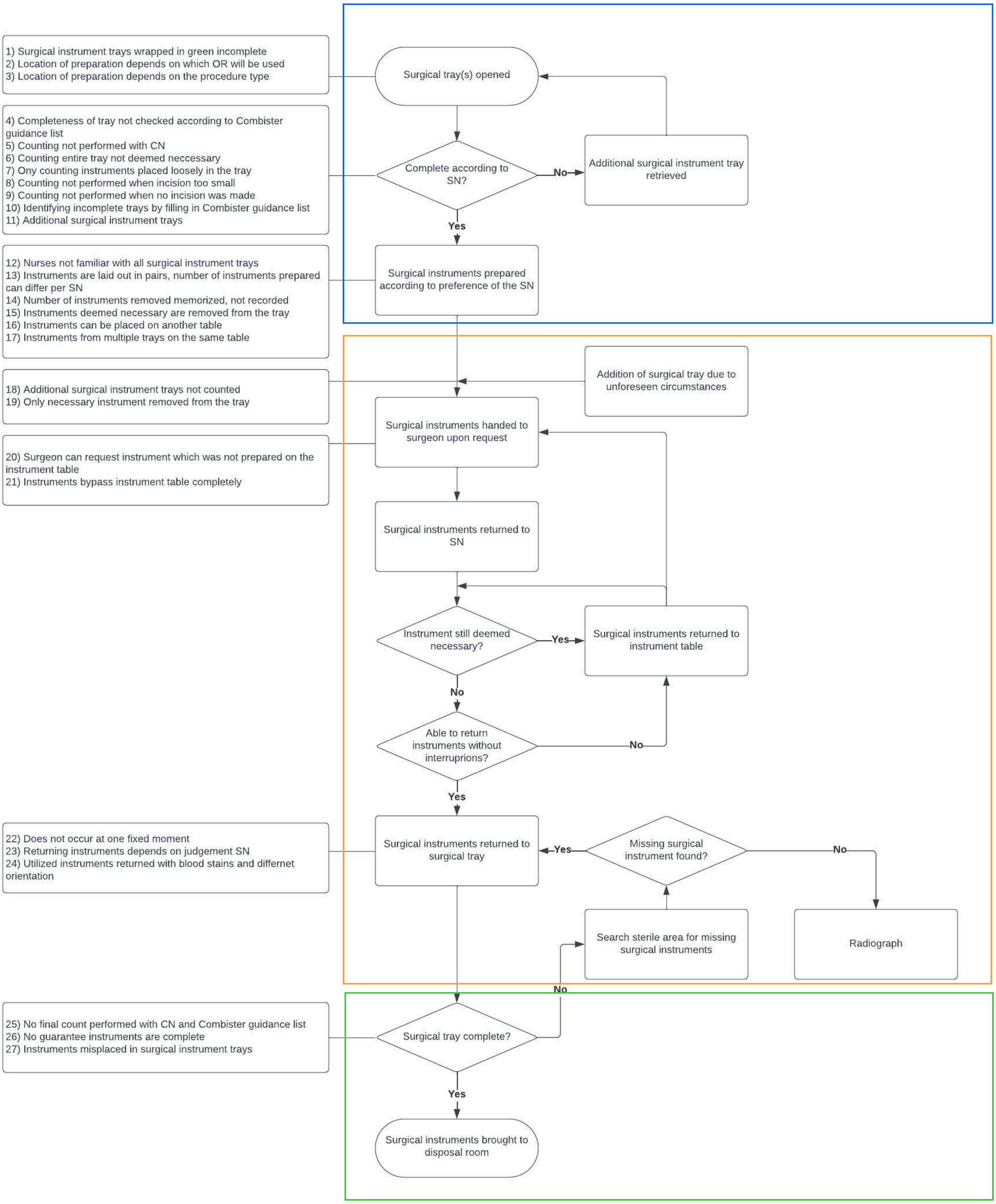

Figure 5.2. The counting process of surgical instruments at the Reinier de Graaf Gasthuis and the corresponding challenges per operative phase. Blue represents counting in the pre-operative phase; orange represents counting activities during the intra-operative phase; green represents counting activities in the postoperative phase.

[1] Surgical trays contained a blue (94,0%) or green wrapping (4,0%). A blue wrapping indicated a complete assembly of surgical instruments by Combister. Hence, a green wrapping indicated an incomplete surgical tray due to a missing instrument. Figure 5.3a displays a rack containing surgical trays wrapped in blue and green in the PR. The nurses indicated that the missing surgical instrument usually concerned a surgical instrument placed loosely in the surgical tray. A label containing the missing surgical instruments in a surgical tray wrapped in green can be viewed in Figure 5.3b.

Figure 5.3ab. (a) Rack in the PR containing surgical trays wrapped in blue and green. Blue indicates complete surgical trays. Green indicates incomplete surgical trays (b) Label on green wrapping indicating the missing surgical instruments in the surgical tray.

[2-3] The Reinier de Graaf Gasthuis has two sterile areas in the PR for the preparation of the surgical instrument table. One sterile area is for the even-numbered ORs, and the other is for the odd-numbered ORs. Multiple SNs prepare the surgical instrument table simultaneously. In most cases, the SN prepared the surgical instruments in the PR (72,0%). Surgical instrument preparation for ENT surgeries was performed in the OR (28,0%). ENT surgeries do not necessitate sterile preparation because the throat is an unhygienic body part.

[4-5] Counting the entire surgical tray according to the Combister guidance list (0,0%) and with the CN (0,0%) was impossible in the pre-operative phase due to time constraints and limited resources in the OR environment.

[6] The nurses deemed a full inspection of every tray was unnecessary. The SN assumed that a blue wrapping denoted the completion of a surgical tray. Exclusively in abdominal procedures, a precise scissors count is conducted before the surgery. The scissor count in abdominal procedures is securely performed as the scissors may be located near the surgical site, on the wrapping surrounding the patient, or, in the case of a cesarean section, in the region of the newborn.

[7-9] The nurses indicated that a count was only performed on surgical instruments placed loosely in a surgical tray. By scanning the surgical instruments with specific arrangements, the nurses could determine if the surgical tray was complete. Furthermore, a count was reckoned unnecessary for some surgeries because the likelihood of losing a surgical instrument was minimal. For instance, the incision was considered too small during thumb fracture surgery to lose a surgical instrument. Moreover, nurses indicated that surgical instruments were not counted during specific gynecological procedures because no incision was made in the first place.

[10] During the preparation of surgical instruments by the SN, the Combister Guidance list was completed in 10,0% of the procedures. Completing the Combister guidance list indicated that five surgical trays were identified as incomplete. A white label was attached to the surgical tray to serve as a visual cue for Combister employees indicating a problem with the surgical tray. The white label is displayed in Figure 5.5ab. The reasons for completing the Combister guidance list, and the cases in which it was necessary to open a new tray, are displayed in Table 5.4.

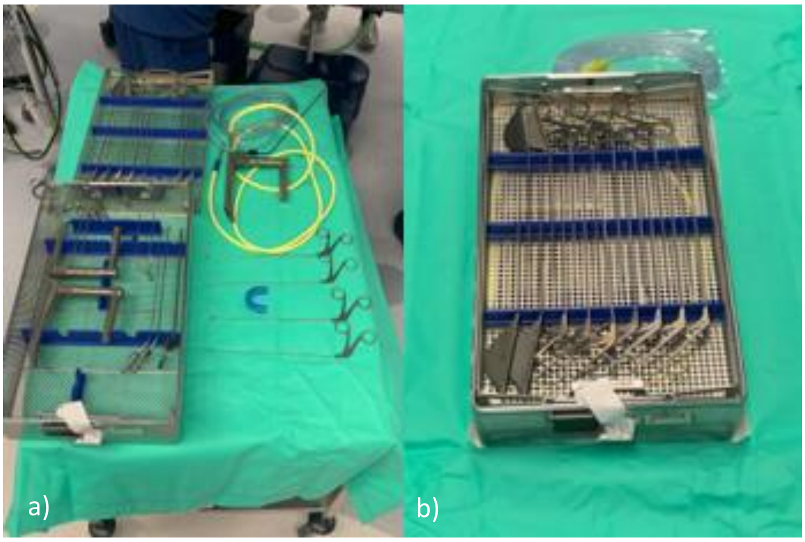

Figure 5.4ab. A white label was attached to surgical trays to serve as a visual cue for Combister employees indicating a problem with the surgical tray.

Table 5.4. Reasons for Completing the Combister Guidance List and the Necessity to Open a New Surgical tray

		Reason for completing the Combister guidance list	Necessary to open a new tray
Combister guidance list	1	Two blunt surgical instruments instead of sharp and blunt	No
	2	Missing a bipolar forceps	Yes
	3	The attachment item did not fit onto a surgical instrument	Yes
	4	Additional surgical instrument	No
	5	Missing surgical instrument	Yes

[11] In 10,0% of the surgeries, an additional surgical tray was opened in the PR, signifying the occurrence of five unintended surgical tray openings before surgery. Table 5.5 presents the reason for opening an additional surgical tray and the number of instances when an assembly error by Combister was found to be the contributory reason.

In current cases, the hospital had excess stock to supplement the missing surgical instrument. However, the nurses also indicated that there were instances of no excess stock being available when they discovered the missing surgical instrument on the tray while the patient was already under anesthesia.

Table 5.5. Reasons for Opening Additional Surgical Trays in the PR and whether an ISC caused this

		Reason for additional surgical tray	Caused by tray assembly error
Additional surgical tray	1	Missing surgical instrument	Yes
	2	Incorrect number of degrees optical instrument	No
	3	Incorrect number of degrees optical instrument	No
	4	Missing bipolar forceps	Yes
	5	The attachment did not fit onto the surgical instrument	Yes

[12] Nurses are expected to be able to assist in any surgery. Due to the experience of nurses, they are familiarized with surgical trays and can memorize particular trays. However, during a robot urology surgery, a nurse indicated she was familiar with robot urology trays as she often prepares the surgical instruments for these surgeries. However, if she were to prepare the surgical instruments for vascular or ENT surgeries, she would not know if the surgical tray is entirely complete by scanning the tray.

[13-14] SNs focused on keeping track of the number of surgical instruments removed from the surgical tray by placing them on the surgical instrument table in even numbers. Placing instruments in even numbers facilitates memorization and easy counting. Another technique to make the surgical instrument count easier is threading them through a particular surgical instrument's ear. The number of surgical instruments prepared on the surgical instrument table can differ per nurse. No formal count or record is made of the number of surgical instruments removed from the tray before surgery.

[15-17] The surgical instruments deemed necessary were placed on the surgical instrument table in the anticipated order. The number of surgical instrument tables depended on the number of surgical trays used. In Figure 5.5a, the surgical instruments are placed on one surgical instrument table in front of the surgical tray. Alternatively, the instruments can be placed on a separate surgical instrument table, as seen in Figures 5.5b and 5.5c. The surgical instrument table in Figure 5.5b contains the surgical trays and the disposables. The surgical instrument table in Figure 5.5c contains the surgical instruments. The surgical instrument table contains retrieved surgical instruments from multiple surgical trays.

Figure 5.5a-c. (a) Surgical instruments are placed in front of the surgical tray on the same surgical instrument table. (b-c) Multiple surgical trays are used for a procedure. The surgical instrument table in Figure 5.5b contains the surgical trays and the disposables. The surgical instrument table in Figure 5.5c contains the surgical instruments. Surgical instruments from different surgical trays are placed on the same table.

5.2.2. Intra-operative Surgical Counting of Instruments

[18-19] Additional surgical trays were added during the surgery in 6,0% of the surgeries. Table 5.6 presents the reasons for opening an additional surgical tray. The researcher could not identify the reason for opening the additional surgical tray for one surgery. In all cases, opening additional trays was not caused by an ISC. The additional surgical tray was supposed to be counted with the SN and CN according to the Combister checklist. However, as only the instrument missing from the surgical tray was retrieved from the surgical tray, a count of the entire tray was not performed.

Table 5.6. Reasons for Opening Additional Surgical Trays and whether an ISC caused this

		Reason for Additional Surgical tray	Caused by ISC
Additional Surgical Tray	1	Unsterile surgical instrument	No
	2	Not in accordance with the surgeon’s preference	No
	3	Reason unknown	

[20-21] The surgical instruments used during surgery were not limited to those prepared on the surgical instrument table. Instruments were retrieved from their original surgical tray and placed on a surgical instrument table in case of frequent use or retrieved from their surgical tray and promptly handed to the surgeon in case of infrequent use. When the surgeon requested a surgical instrument from the surgical tray, the surgical instrument bypassed the surgical instrument table completely.

[22-24] After usage by the surgeon, the surgical instrument was either placed directly back in the surgical tray or back on the surgical instrument table. When surgical instruments were no longer deemed necessary, they were returned to the surgical tray. The count of the number of surgical instruments returned to the tray was performed in the same manner as retrieval from the surgical tray. The surgical instruments were returned to the designated clip in the surgical tray for specific surgical instrument arrangements. Figure 5.6a displays a SN returning the surgical instruments into the clips. When all clips are full, the tray is complete. The surgical instruments were returned in pairs when they did not have a specific arrangement in the surgical tray. Figure 5.6b displays a surgical tray with surgical instruments placed loosely in the tray after surgery. Utilized surgical instruments were returned with blood stains and in different orientations compared to surgical instrument retrieval.

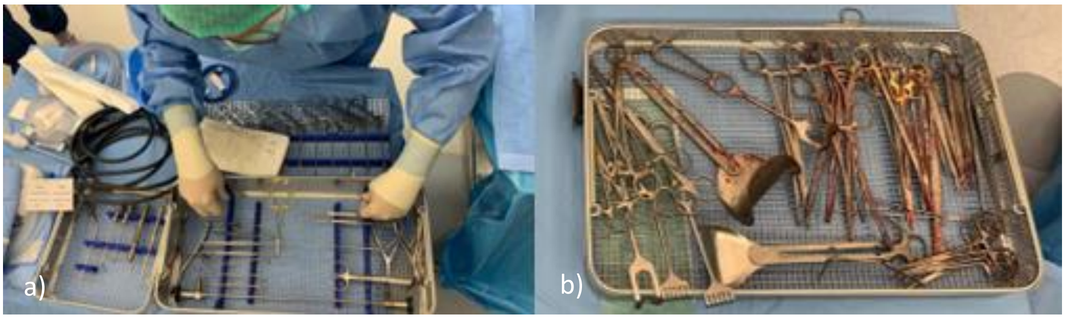

Figure 5.6ab. (a) A SN returning surgical instruments to a surgical tray with specific arrangements. The tray is complete when all surgical instruments are clipped into the blue clips. (b) Surgical instruments were placed loosely in the surgical tray after surgery. Utilized surgical instruments were returned with blood stains and placed in the tray in different orientations than surgical instrument retrieval.

In Table 5.7, the frequency descriptives are depicted for:

- the final number of surgical trays;
- the time spent returning surgical instruments to the surgical trays; and
- the number of interruptions while returning surgical instruments to the surgical tray.

A boxplot analysis in Figures 5.7 and 5.8 is presented to visualize the relationship between the final number of surgical trays and the two variables: time spent returning surgical instruments and the number of interruptions while returning surgical instruments, respectively. In the boxplots, the blue box represents the interquartile range (50%), with the median indicated by the black line inside. The ends of a box measure a quartile mark. The bottom side of the box represents the 25% mark, and the top side of the bar the 75% mark. The whiskers extend to the minimum and maximum values.

Table 5.7. Descriptives of the Final Number of Surgical trays, the Time Spent Returning Surgical Instruments, and the Number of Interruptions while Returning Surgical Instruments.

	Min	Max	Mean	Median	SD
Final number of surgical trays	1	7	1,74	1	1,31
Time spent on returning surgical instruments (s)	5,58	372,91	72,82	29,03	87,65
Number of interruptions while returning instruments	0	6	0,82	0	1,31

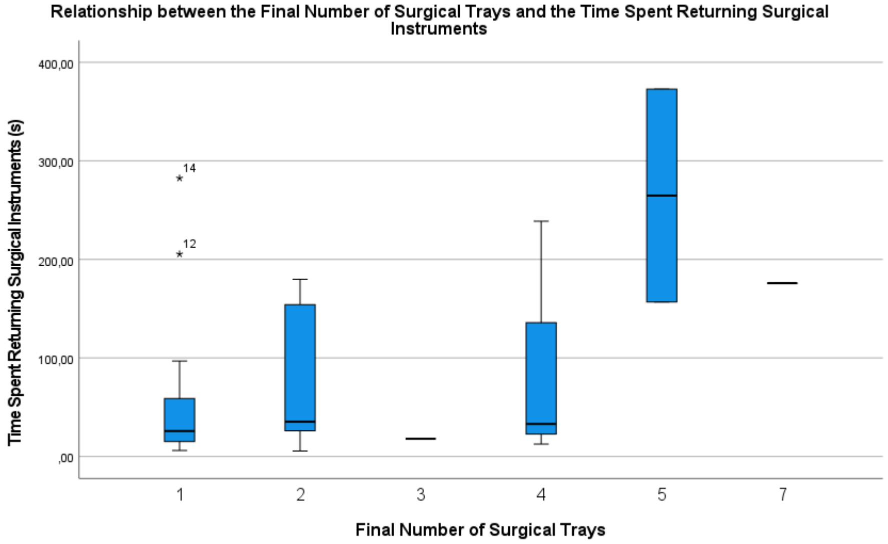

Figure 5.7. A boxplot analysis representing the relationship between the final number of surgical trays the time spent returning surgical instruments.

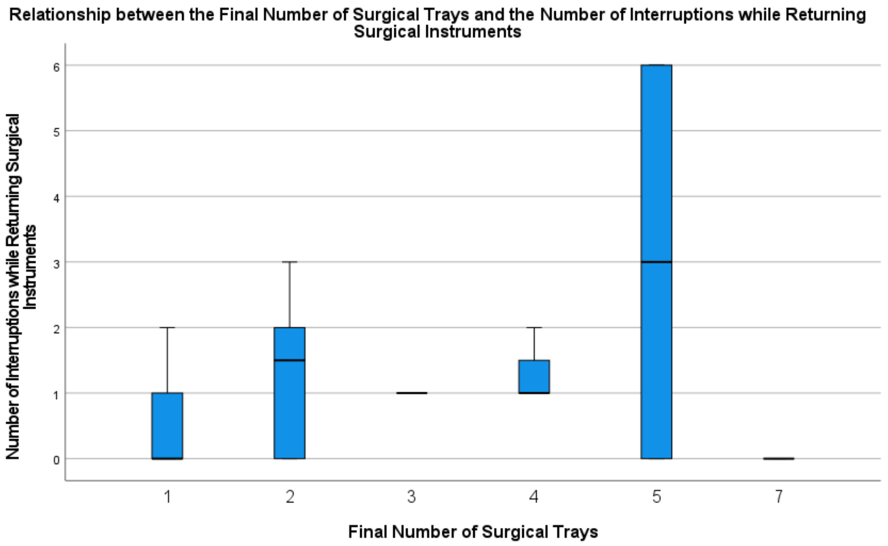

Figure 5.8. A boxplot analysis representing the relationship between the final number of surgical trays and the number of interruptions while returning surgical instruments.

5.2.3. Postoperative Surgical Counting of Instruments

[25-26] In none of the surgeries, the surgical instrument count was performed with the CN or according to the Combister guidance list. No final count was performed after returning the surgical instruments to the surgical trays. All surgical instruments were marked as complete in HiX following the surgery. Table 5.8 displays the frequency percentage of the variables mentioned above.

Table 5.8. Frequency Percentage of Variables Related to the Post-operative Surgical Instrument Counting

		Frequency
Location of count	OR	100,0%
Counting surgical instruments with CN		0,0%
Counting surgical instruments according to the Combister guidance list		0,0%
Surgical instruments marked as complete in HiX		100,0%

[27] The number of surgical instruments which were not returned to their original surgical tray is displayed in Table 5.9. At Combister, 801 additional surgical instruments were identified, indicating that around 200 surgical instruments per month were not returned to their original surgical tray after surgery. The incorrect placement of surgical instruments after surgery results in the hospital being informed of a missing surgical instrument when the surgical tray has arrived at the sterilization department. Consequently, this leads to a discussion between the hospital and the sterilization department regarding the surgical instrument's location.

Table 5.9. Type and Number of Additional Surgical Instruments Found on Surgical trays

Type of surgical instrument	Total number of surgical instruments identified
Scalpels	32
Tweezers	134
Scissors	61
Clamps	154
Pliers	22
Needle holder	46
Fabric clamps	38
Siphons/Spoons/Curettes	27
Wound Spreaders	13
Wound/large hooks	30
Hooks	56
Osteotome	17
Hammers	2
Various items	169
Total	**801**

5.6 Survey Results

Figures 5.9-5.15 display a graphical representation of the survey results.

Question 1: Do you count the entire surgical tray before surgery? (N=18)

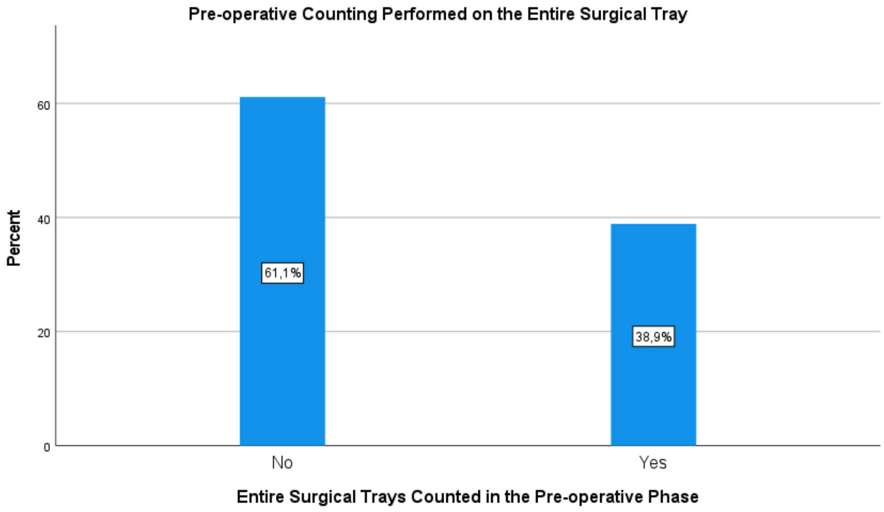

Figure 5.9. The frequency of counting entire surgical trays in the pre-operative phase.

Question 2: Do you experience an increased workload while counting surgical instruments, gauzes, or needles? (N=20)

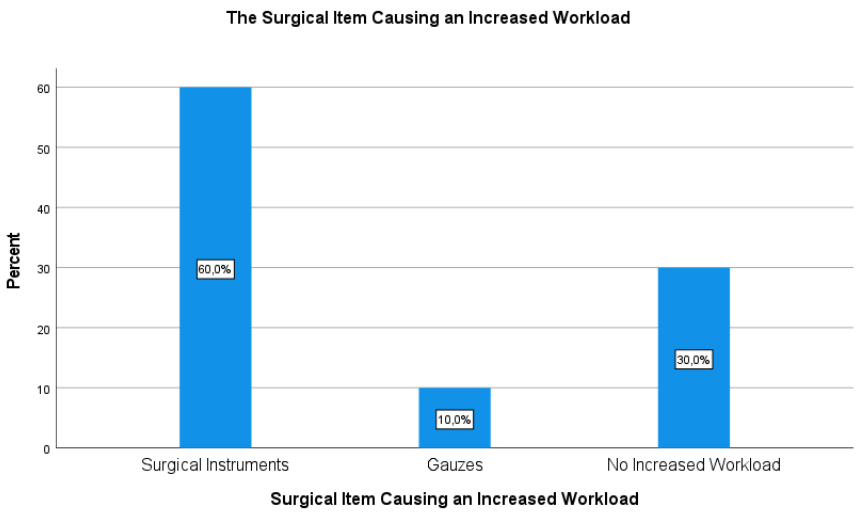

Figure 5.10. The type of surgical item for which an increased workload is experienced.

Question 3: What was the cause of the increased workload during surgical counting? (N=13)

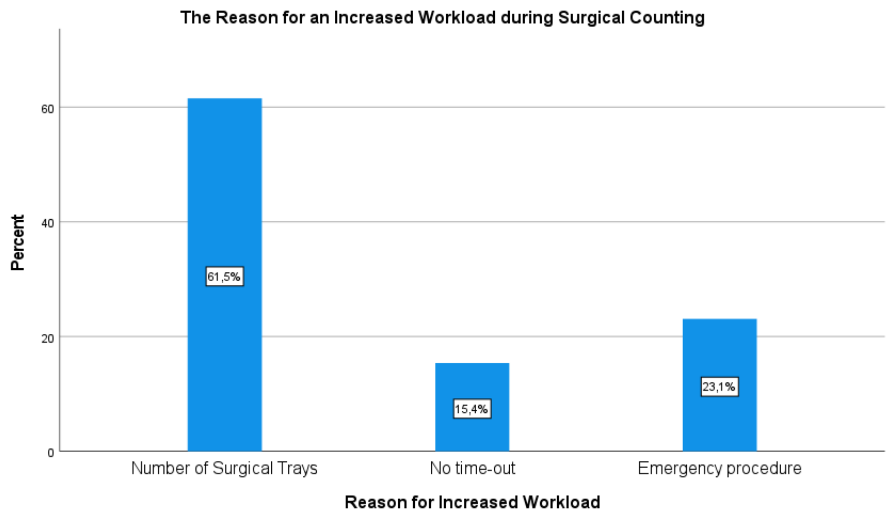

Figure 5.11. The reason for an increased workload during surgical counting.

Question 4: Can the current counting process be reconfigured to be more efficient? If yes, during which operative phase? (N=20)

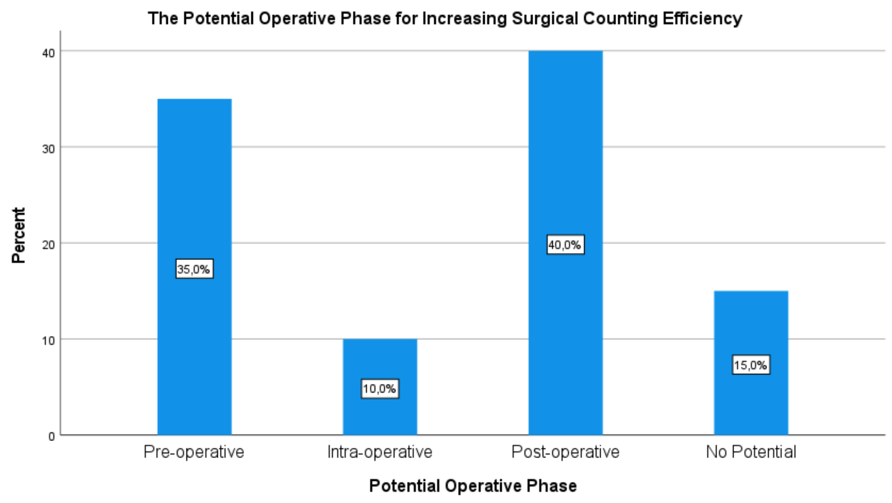

Figure 5.12. The potential operative phase for increasing surgical counting efficiency.

Question 5: Would you be open to the use of adjunct technology during the counting process? (N=15)

All operation assistants demonstrate a willingness to accept technology as an adjunct tool for surgical counting.

Question 6: During which operative phase would you be willing to use technology? (N=13)

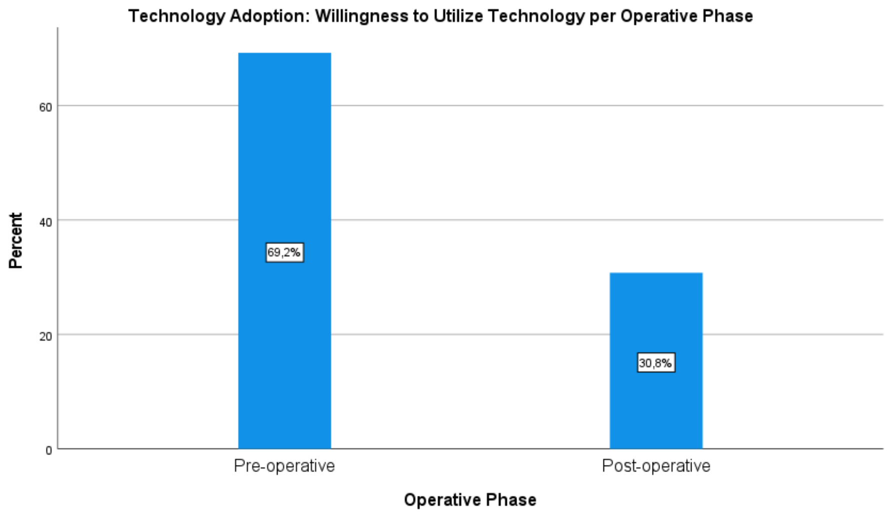

Figure 5.13. Willingness to utilize technology per operative phase.

Question 7: For which surgical item would you be willing to use technology? (N=15)

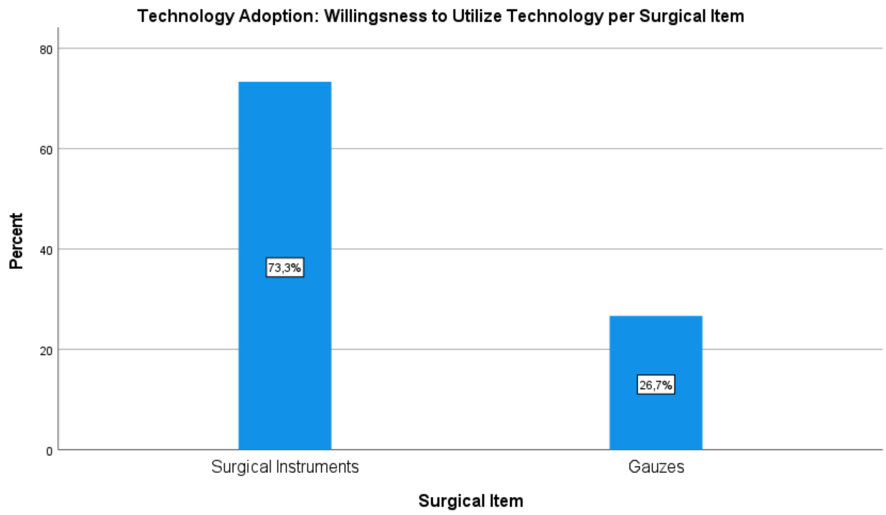

Figure 5.14. Willingness to utilize technology per type of surgical item.

Question 8: What should the requirements for technology be, according to your perspective? (N=12)

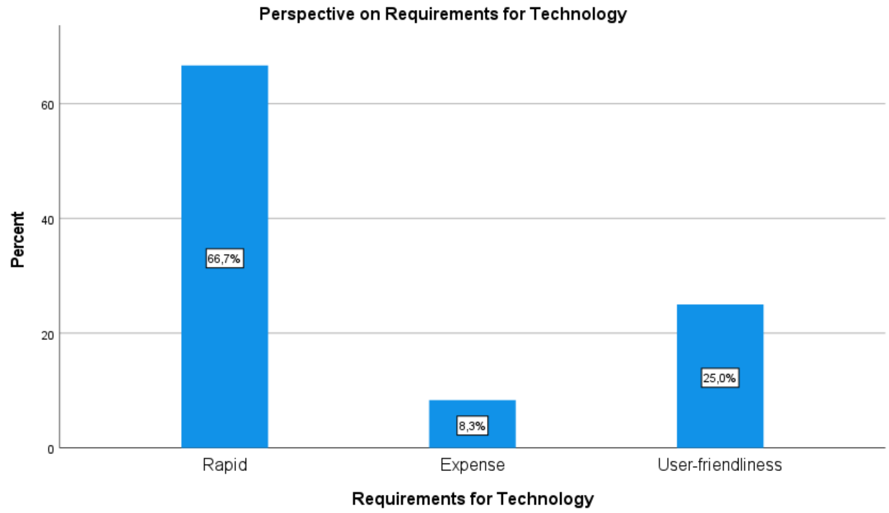

Figure 5.15. Perspective on requirements for technology.

III

Chapter Three – Design Requirements for Future Technology

6. Design Requirements

Before formulating the design requirements for future technology, the challenge intended to be solved must be clear. The defined challenge in Section 6.1 summarizes the 27 challenges identified during surgical instrument counting at the Reinier de Graaf Gasthuis. Counting the number of surgical instruments retrieved from and returned to the tray is considered 'partial counting' in this study.

6.1. Defining the Challenge

Due to limited time and resources, nurses do not count entire surgical trays before and after surgery but rely on partial counting. Nurses use a technique to memorize the surgical instrument count by placing the surgical instruments in even numbers on the surgical instrument table and returning them to the surgical tray similarly. As the entire surgical tray is not counted, and no record is made of the number of surgical instruments retrieved from the surgical tray, there is no control measure to guarantee that all surgical instruments are complete after surgery. Moreover, the incorrect placement of surgical instruments results in the hospital being informed of missing surgical instruments after the patient leaves the OR. Consequently, this leads to a discussion between the hospital and the sterilization department regarding the missing instruments' location.

6.2. Design Requirements per Methodology

Future technology should perform an initial and final count to ensure that the surgical instruments are complete and returned to their original surgical tray. The design requirements for future technology are based on two methodologies:

1) Counting the entire surgical tray
2) Partially counting the surgical tray

Figure 6.1 provides an overview of the design requirements for future technology to enhance surgical instrument counting. The sub-requirements for the two methodologies, corresponding to each design requirement, are detailed below. At the end of this section, Table 6.1 summarizes the sub-requirements per methodology.

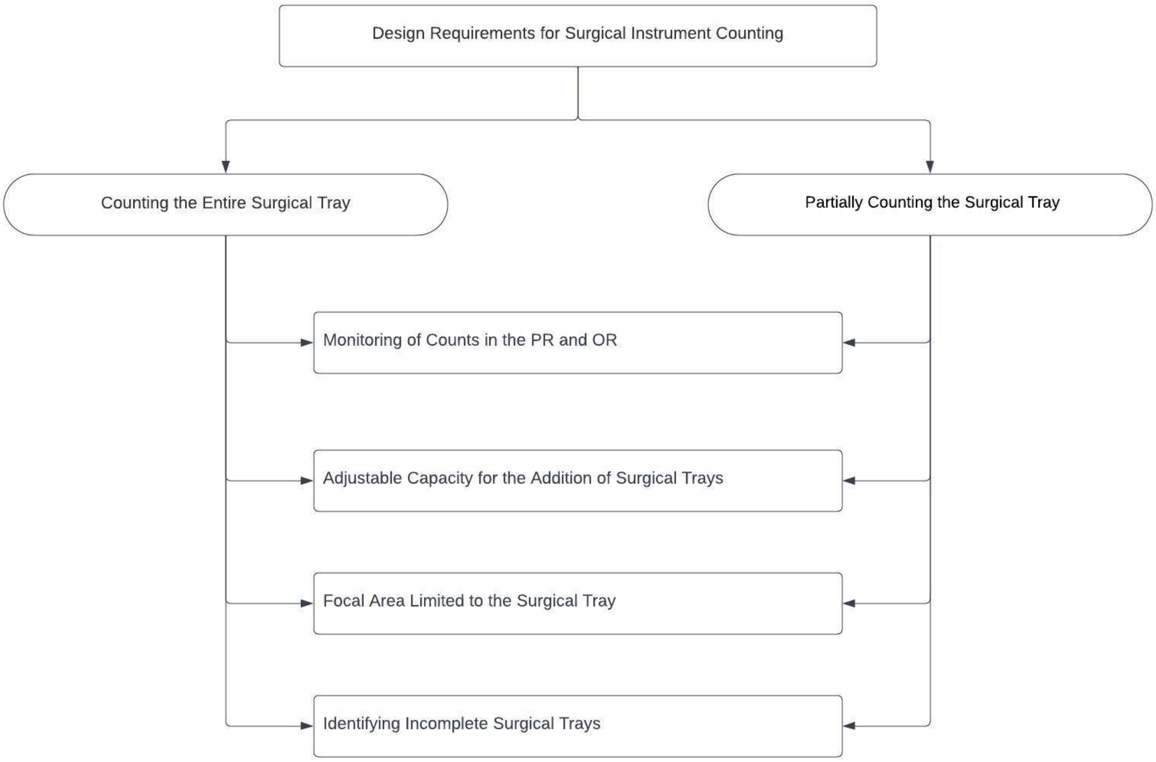

Figure 6.1. Design requirements for future technology are based on two methodologies. An initial and final count can be performed by counting the entire surgical tray or partially counting the surgical tray.

Monitoring of counts in the PR and OR

The initial surgical instrument counts were performed in the PR and the OR, and the final counts were in the OR. Therefore, future technology should monitor surgical instrument counts in both locations for a complete surgical instrument count.

In the PR, surgical instrument tables were simultaneously prepared for every OR. An example of the preparation of surgical instruments by four SNs is depicted in Figure 6.2a. Future technology should be able to count the entire surgical tray or the retrieved surgical instruments belonging to one SN and OR.

In the OR, the location of the surgical instrument table depended on the location of the surgical site. Figure 6.2b displays the surgeon on the left, the SN on the right, and two surgical instrument tables to the left of the SN. Therefore, within the OR, future technology should be able to count the entire surgical tray or the retrieved and returned surgical instruments regardless of the location of the surgical instrument tables.

Figure 6.2ab. (a) Multiple SNs preparing a surgical instrument table in the PR. (b) The surgeon (left) and SN (right) in the OR, with two surgical instrument tables on the left of the SN.

Adjustable capacity for the addition of surgical trays

The number and type of surgical trays were predetermined for every surgery. However, the observations revealed that surgical trays were added to the sterile field in the PR and OR. The instrument missing from a surgical tray was retrieved from the additional surgical tray.

Therefore, future technology must have an adjustable capacity for additional surgical trays. The additional surgical tray or the retrieved surgical instruments from the additional surgical tray, must be added to the initial count. The final count consists of the entire original and additional tray or the surgical instruments returned to the original and additional surgical tray.

Focal area limited to the surgical tray

Surgical instruments were continuously handled between the surgical tray, surgical instrument table, SN, and surgeon. Some surgical instruments bypassed the surgical instrument table completely. Thus, the focal area of future technology should be on the surgical tray as every surgical instrument crosses its trajectory.

For partial surgical instrument counting, future technology would have to record the count throughout the surgery instead of before and after the procedure. The surgical instruments utilized throughout surgery were not limited to those prepared on the surgical instrument table before surgery. Therefore, the count of surgical instruments prepared on the surgical instrument table is not a correct indication of the initial count. Furthermore, surgical instruments were returned to the surgical tray intermittently. Thus, performing a final count of the surgical instruments on the surgical instrument table at the end of the procedure would be an incorrect count. For instance, in Figure 6.3a, the four surgical instruments in the top right were deemed necessary for the remaining procedure. In Figure 6.4b, the two surgical instruments in the top right were deemed necessary for the remaining surgery.

Therefore, the initial and final count should be the number of surgical instruments retrieved from and returned to the surgical tray throughout the surgery instead of a surgical instrument count before and after surgery of the surgical instruments on the surgical instrument table.

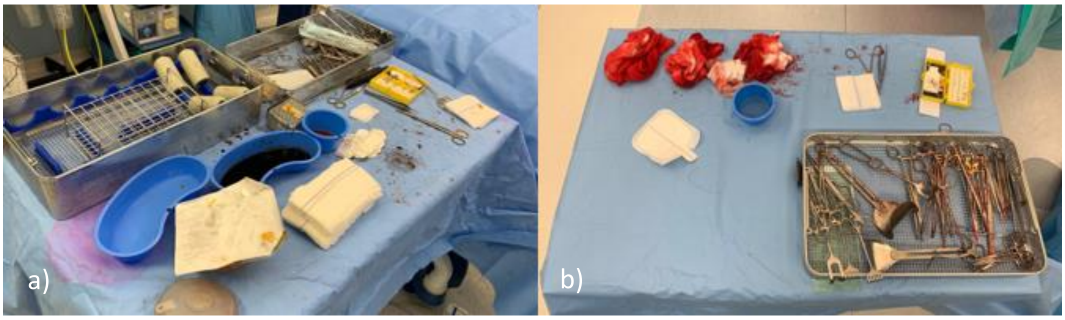

Figure 6.3ab. The surgical instruments on a surgical instrument table would not provide an accurate surgical instrument count. (a) Four surgical instruments (top right) were deemed necessary for the remaining surgery. (b) Two surgical instruments (top right) were deemed necessary for the remaining surgery.

When comparing the initial and final count of entire surgical trays, the counts of each surgical tray should be feasible regardless of the number of surgical trays on one surgical instrument table (Figure 6.3a), the orientations of surgical trays (Figure 6.3b) and the dimensions of surgical trays (Figure 6.3c). Moreover, surgical trays can be placed on each other (Figure 6.3d), or disposables can be placed in the surgical tray (Figure 6.3e). Before performing a final count, items that do not belong to a surgical tray must be removed to ensure the surgical instruments counted before the procedure align with those counted after the surgery.

Figure 6.4a-e. (a) Four surgical trays placed on one surgical instrument table. (b) Surgical trays placed in horizontal and vertical directions. (c) Small-sized and standard-sized surgical trays placed next to each other. (d) Surgical instrument are placed on each other. (e) Disposables placed in the surgical tray.

Identifying incomplete surgical trays

Surgical trays were not always delivered complete to the hospital. The blue wrapping indicated a complete tray, and the green wrapping indicated a missing surgical instrument. However, it was identified that surgical trays with blue wrapping could also contain a missing or additional surgical instrument. During one surgery, the surgical tray contained an instrument with two blunt tips instead of one blunt and sharp tip. Therefore, future technology must identify the type of missing surgical instrument besides performing a count of the instruments, as the number of surgical instruments can remain unchanged.

When counting the entire surgical tray, technology must count the number of surgical instruments before and after surgery and identify the missing or additional surgical instruments. In addition, the surgical instruments were returned with blood stains and different orientations compared to the surgical tray before surgical instrument retrieval. Thus, future technology should identify the surgical instruments irrespective of the blood stains and different orientations after surgery.

Moreover, surgical instruments were occasionally returned to the incorrect surgical tray. Future technology should recognize when a surgical tray is incomplete by identifying the instrument to be returned to the surgical tray. The return of surgical instruments can occur in a different configuration than how they were retrieved from the surgical tray. Future technology must be capable of performing the initial and final count, regardless of the configuration in which it occurs. Finally, future technology should identify the surgical instruments in the tray irrespective of the blood stains and different orientations when returning surgical instruments to the surgical tray.

Table 6.1. An Overview of the Sub-Requirements per Methodology

	Counting the entire surgical tray	Partially counting the surgical tray
Monitoring of counts in the PR and OR	1. Counting surgical trays belonging to one SN and OR in the PR 2. Counting surgical trays regardless of placement of surgical instrument table in OR	1. Counting surgical instruments belonging to one SN and OR in the PR 2. Counting surgical instruments regardless of placement of surgical instrument table in OR
Adjustable capacity for the addition of surgical trays	3. Adjustable capacity for counting entire additional surgical trays 4. Additional surgical tray should be added to initial count	3. Adjustable capacity for counting the surgical instruments retrieved from and returned to the additional surgical tray 4. Additional retrieved surgical instrument should be added to initial count
Focal area limited to the surgical tray	5. Counting surgical trays irrespective of the number of trays on one surgical instrument table 6. Counting trays irrespective of their orientation on the surgical instrument table 7. Counting trays irrespective of their dimensions 8. Surgical items that do not belong to the tray must be removed before performing a count	5. Count throughout the entire surgery instead of before and after surgery 6. Counts should not focus on the surgical instruments placed on the surgical instrument table but on the retrieved and returned surgical instruments from the surgical tray
Identifying incomplete surgical trays	9. Counting the missing or additional surgical instruments in the surgical tray before surgery 10. Counting the missing or additional surgical instruments in surgical tray after surgery 11. Acknowledging that surgical instruments are returned with blood and other orientations during the final count of surgical trays	7. Counting the surgical instruments which need to be returned to surgical trays throughout the surgery 8. Counting surgical instruments regardless of the configuration of retrieval and return to the surgical tray 9. Acknowledging that surgical instruments are returned with blood other orientations during the final count of surgical instruments

IV

Chapter Four – Discussion and Conclusion

7. Discussion

This section will discuss the surgical instrument counting at the Reinier de Graaf Gasthuis. In addition, the challenges of adhering to the counting protocol will be addressed, followed by the potential benefit of future technology to the surgical count process. Finally, the study's limitations and future research will be elaborated.

7.1. Discussion on Surgical Instrument Counting at the Reinier de Graaf Gasthuis

The survey results indicated that a higher number of surgical trays was the primary cause of an increased workload during surgical counting, as this necessitates more skill, knowledge, and time to identify the surgical instruments belonging to each surgical tray. Although 15,0% of the nurses deemed the surgical count process could not be reconfigured more efficiently, and 30,0% indicated no perceived increase in workload during surgical counting, all nurses expressed their willingness to adopt technology for surgical counting. In addition, nurses were expected to be able to assist in any surgery, meaning they should be familiar with 642 different types of trays and count up to 160 surgical instruments per surgical tray. Being familiar with surgical trays from every domain is a significant demand for nurses.

The time spent returning surgical instruments to the surgical tray increased as the final number of surgical trays increased. The increased time spent returning surgical instruments may be attributed to more surgical instruments being returned to surgical trays. The presence of outliers in the surgeries utilizing one surgical tray can be accounted for by the surgical tray containing specific surgical instrument arrangements. The surgical instruments had to be returned to the designated clips instead of placed loosely in the surgical tray, which likely took more time.

While returning surgical instruments to surgical trays, the interruptions varied from zero to six. An interruption indicated that the SN was engaged in multiple tasks simultaneously. Bubric et al. (2021) concluded that resuming a task when a nurse was interrupted became challenging and necessitated additional working memory to recommence the suspended task. Furthermore, according to Edel (2012) and Fencl (2016), the counting accuracy could be improved when surgical team members are not performing multiple tasks simultaneously. Although the Reinier de Graaf Gasthuis nurses choose to return the surgical instruments while engaged in other tasks, interruptions could impede their ability to focus on placing them into their original surgical trays. Moreover, interruptions could hinder their ability to keep track of the number of surgical instruments returned. At the end of the surgeries, no final count was conducted to verify if the surgical instruments were returned to their original surgical tray. Consequently, this study could not examine whether interruptions contributed to incorrectly placed surgical instruments in surgical trays.

In 16,0% of the surgeries, an additional surgical tray had to be added to the sterile field. Unforeseen circumstances, such as a surgical instrument becoming unsterile or not aligning with the surgeon's preference, pose difficulty preventing challenges. Nevertheless, it was observed that 37,5% of the added surgical trays could have been avoided if the tray assembly had been correct. Sevdalis et al. (2013) reported that inefficiencies during the surgical counting resulted in time wastage and OR revenue loss. Moreover, Guédon et al. (2021) acknowledged that surgical instrument unavailability could cause delays and stress in the OR. Lastly, Wubben et al. (2010) measured that each unavailable surgical instrument led to an average of twelve minutes of extra work and a delay of five minutes. In the Reinier de Graaf Gasthuis, requesting a new surgical tray from the logistics department and preparing the surgical instruments of the additional surgical tray did not directly harm the patient as there was excess stock available. However, it imposed extra work on nurses and could result in operational delays. Consequently, when no excess stock is available, it could impact patient safety.

7.2. Discussion on the Challenges in Adhering to the Counting Protocol

The observations revealed that performing counts of the entire surgical tray before and after surgery was not feasible due to limited time and resources in the OR environment. According to the hospital's counting protocol, all surgical instruments must be counted accurately for every surgery. However, it should be argued whether counting the entire surgical tray to evaluate the completeness of surgical trays is the hospital's responsibility. A hospital is responsible for counting surgical instruments to prevent the occurrence of RSIs. The surgical instruments which have a possibility of being retained are the surgical instruments utilized during surgeries. In addition, the surgical instruments which were incorrectly returned to surgical trays after surgery are the retrieved surgical instruments, not the unused ones in the surgical tray. Therefore, partial surgical instrument counting may suffice to ensure no surgical instruments are lost during surgery or left in the patient.

Counting surgical instruments for every surgery was not deemed necessary, as the likelihood of losing a surgical instrument was minimal. Although the counting process has little influence on patient safety when retaining a surgical instrument is impossible, implementing a control measure can prevent discussions if any arise regarding a missing surgical instrument between the hospital and sterilization department. Therefore, a control measure for the initial and final surgical instrument count is necessary to guarantee completeness of surgical instruments.

7.3. Discussion on Future Technology for Surgical Instrument Counting

Nurses indicated they would benefit from future technology capable of indicating the completeness of surgical instrument trays. Two methodologies for future technology were proposed to enhance surgical instrument counting by performing an initial and final count. The first methodology focused on counting the entire surgical tray, and the second focused on partially counting the surgical tray. Both approaches shift the focus of future technology to surgical instruments within the surgical tray to ensure a complete surgical instrument count.

Counting the entire surgical tray would follow the Reinier de Graaf Gasthuis protocol. An initial count of the surgical instruments would occur before retrieving surgical instruments from the tray and the final count when all surgical instruments are returned to the surgical tray. However, as mentioned above, partial surgical instrument counting may suffice. For partial surgical instrument counting, future technology would have to record the count throughout the whole surgery instead of before and after the surgery. The initial count would be the number of surgical instruments retrieved from the surgical tray, and the final count would be the number of surgical instruments returned to the surgical tray.

Future technology aims to enhance surgical instrument counting without decreasing the effectiveness of the process. Therefore, it should be investigated whether it is necessary to use technology for every surgical tray. For instance, the additional surgical instruments discovered on surgical trays primarily consisted of clamps, tweezers, and other unspecified 'various items' as recorded in the Combister dataset. These surgical instruments are recognized as general surgical instruments for surgeries, so they are likely to be the surgical instruments placed loosely in the surgical tray. In addition, when surgical instruments containing specific arrangements are placed into the clips before and after surgery, the nurse can determine whether the tray is complete by viewing the tray. Therefore, a technological control measure might only benefit the surgical trays where surgical instruments are placed loosely in the surgical tray.

7.4. Limitations

This study used an observational design to capture the surgical counting process in the OR. Structured observations have been proven beneficial in numerous hospital settings (Kertesz et al., 2020). However, limitations include the absence of subjective or qualitative interference (Shouhed et al., 2012). Although a survey aimed to understand the experienced workload and attitude towards technology, individual coping strategies used to manage distractions and interruptions during surgical counting could not be assessed. Furthermore, the Hawthorne effect is possible, as the nurses knew they were being observed. The prevalence of examining surgical trays before surgery and filling in the Combister guidance list may have been influenced by potential observer effects.

Data extraction was time-consuming, and human error was possible as one researcher completed the measurements manually. A measurement in the PR could be missed when the researcher was on a break between surgeries. In the breakroom, only the start of the surgery was broadcasted; however, this implies that the preparation of surgical instruments was already completed.

7.5. Future Research

Outsourcing surgical instrument sterilizations can reduce costs if the process is well-designed and optimized. However, inadequate supply chain management can result in surgical instrument unavailability, posing risks to patient safety (Van de Klundert et al., 2007). The Reinier de Graaf Gasthuis outsources the sterilization of surgical instruments to Combister. The delivery of incomplete trays influences the surgical count process of the hospital. Therefore, future research should extend the analysis to the sterilization department. After identifying the challenges in both stages, a cost-benefit analysis should be conducted to investigate the returns of delivering complete surgical trays to the hospital and sterilization department.

The design requirements for future technology were based on the surgical counting process at the Reinier de Graaf Gasthuis. Future research must analyze the OR procedures in other hospitals to identify if the same methodologies are applicable or if a variation of the method must be used. For instance, if surgical instruments are not returned to the trays throughout the procedure, a final count could be performed at the end of the procedure. Hospitals must analyze their OR procedures to identify how future technology would benefit them.

Finally, current research identified different types of surgical trays. Future research should focus on a deeper investigation of the composition of surgical trays to identify which ones require a technological approach or whether a manual control measure will suffice.

8. Conclusion

The aim was to enhance surgical instrument counting at the Reinier de Graaf Gasthuis by understanding the challenges in the pre-operative, intra-operative, and postoperative phases and formulating design requirements for future technology. This study highlighted the challenge of balancing protocol, ensuring patient safety, and working efficiently. Due to limited time and resources, nurses do not count entire surgical trays but rely on partial counting. However, as no record is made of the number of surgical instruments retrieved from and returned to the surgical tray, the hospital cannot guarantee that all surgical instruments are complete. In addition, surgical instruments were occasionally returned to the incorrect surgical tray. A control measure for the initial and final surgical instrument count is necessary for every surgery, as the current technique is insufficient.

The design requirements for future technology are monitoring counts in the PR and OR, being adjustable to accommodate additional surgical trays, having a focal area on the surgical tray, and identifying incomplete surgical trays. Future technology could enhance surgical instrument counting at the Reinier de Graaf Gasthuis by ensuring the presence and return of used surgical instruments to their original surgical tray.

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Appendix A

Research performed on Gauzes and Needles at the Reinier de Graaf Gasthuis

I Background information: Gauzes

In this section, the types of gauzes and the agreements stated in the counting protocol of the Reinier de Graaf is described.

Types of gauzes

In the Reinier de Graaf Gasthuis, several types of gauzes are used, such as ‘halve gazen’, ’deppers’, ‘hartjes’, and ‘patties’. The selection of gauzes depended on the type of procedure. Figure A.1a shows the surgical instrument table, including ‘halve gazen’ and ‘deppers’. Figure A.1b represents the surgical instrument table containing ‘patties’.

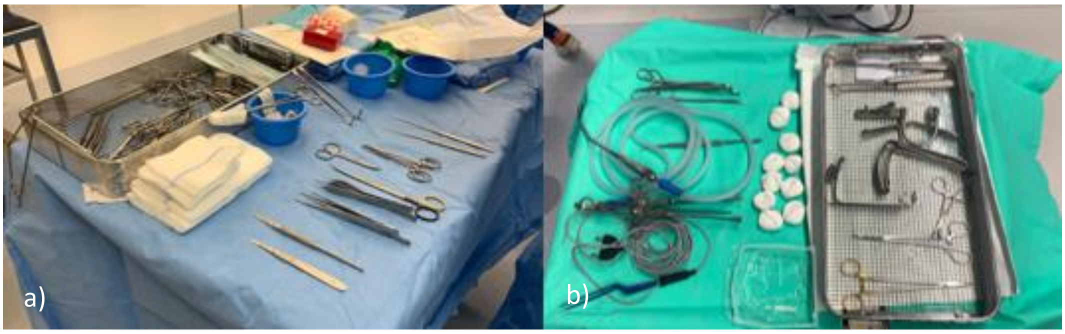

Figure A.1ab. (a) Surgical instrument table containing ‘halve gazen’ and ‘deppers’. (b) Surgical instrument table containing ‘patties’.

Agreements regarding the surgical counting of gauzes

Gauze counts are performed before, during, and after every surgery. The count should always be conducted with at least two nurses. The gauze materials have a lead wire and counting cards to provide tracking. The lead wires must be visible during the counting procedure to ensure that all gauze components are counted.

Pre-operative counting of gauzes

The initial gauze count occurs when the SN prepares their surgical instrument table. Previously, an employee would work exclusively in the PR to assist with these counts. However, this is no longer viable due to a staff shortage. Any individual in the PR can be asked to perform the count with the SN.

Intra-operative counting of gauzes

During surgery, the SN either places the gauzes on the surgical instrument table or disposes of them in the appropriate waste bin. The CN gathers the gauzes, unfolds them, and arranges them on the surgical instrument table in order of size. Figures A.2a and A.2b represent unsorted gauzes on the table. Figure A.2c-e represent sorted gauzes on the surgical instrument table. When gauzes are added during the procedure, the SN and CN must count together again. The number of gauzes added to the sterile field is noted on the whiteboard. For the SN and CN to clearly understand the quantity of gauzes used in the surgical field, it is crucial to update the count on the whiteboard.

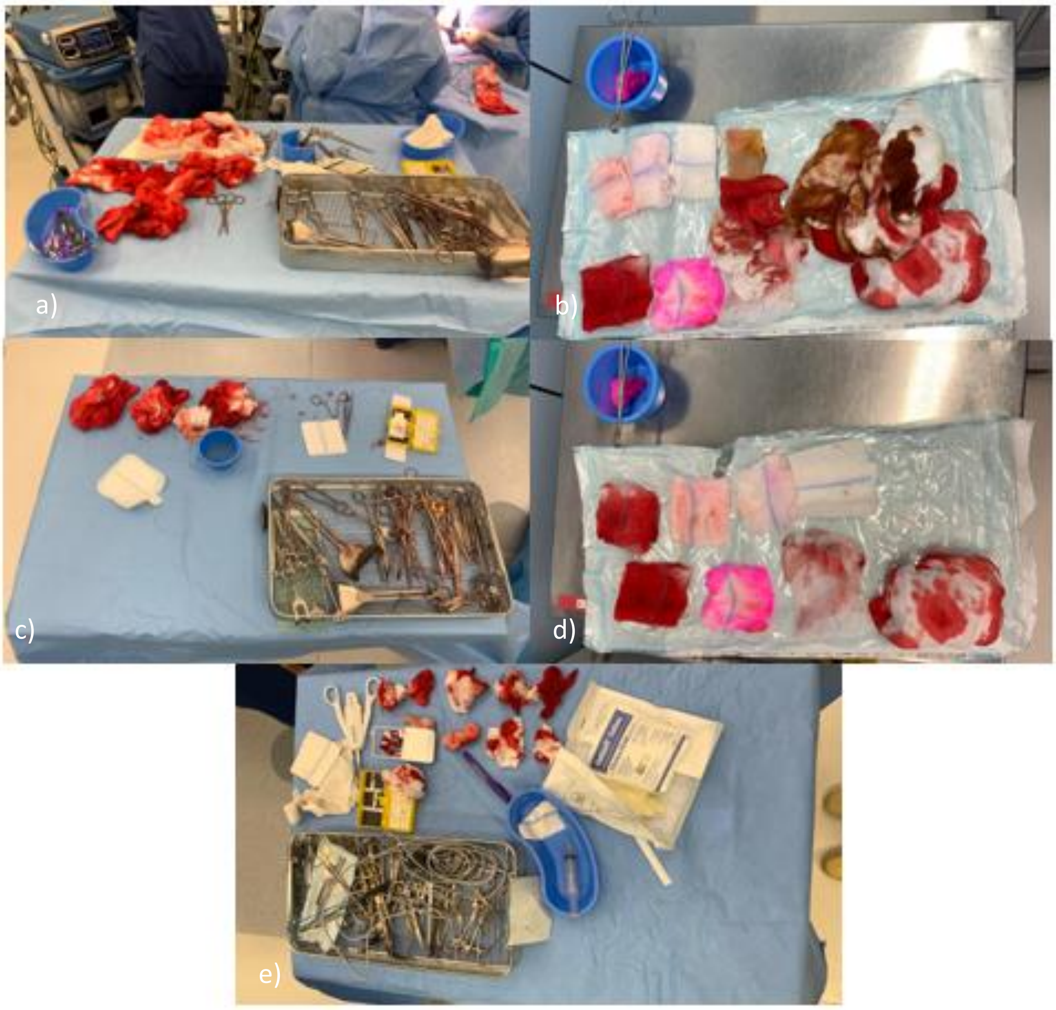

Figure A.2a-e. (a-b) Surgical instrument table containing unfolded 'halve gazen' and 'deppers.' (c-e) Surgical instrument table containing sorted halve gazen' and 'deppers.'

The gauzes should be weighed when multiple gauzes are used and the patient loses a significant blood volume. The gauzes are placed in a plastic bag with the same quantity as how they were packed, for example, ten 'deppers' and five 'halve gazen' in each bag.

In this study, ‘interim counts’ describe the counts that occur during the process but before the wound is closed. The count after wound closure will be called the ‘final count.’ Interim gauze counts occur when there is a personnel change in the SN or CN, at the SN or surgeon’s request, or during the closure of the peritoneum, fascia, and cavities.

The SN is responsible for selecting an appropriate time for the final gauze count. The final count usually happens as the surgeon is suturing since the SN knows that they will have uninterrupted time to complete the count at this point. The SN notifies the surgeon that the material is complete.

In the case of missing gauze, the CN searches the sterile area while the SN checks the operative site. The surgeon inspects the wound cavity for any remaining gauze. When the count remains incomplete, an X-ray is made. The radiograph will show the lead wire in the gauze.

Postoperative counting of gauzes

The CN must complete the gauze counting form in HiX for each surgery. Depending on the nurse's preference, some update the form throughout the surgery and others at the end. The form requires information regarding the nurses' names, how much gauze was provided and received, and whether the gauze was complete.

II Background information: Needles

In this section, the types of needles and the agreements stated in the counting protocol of the Reinier de Graaf is described.

Types of needles

Suture, injection, and diathermy needles are several types used in surgery. Hence, blades and saws are the types of sharp objects employed during the procedures. The suture needles are prepared in the PR on the surgical instrument table. The number of needles in a package can vary from one to eight. Every surgery requires a needle box for counting and a collecting bin for the outer package. Figure A.3a shows an surgical instrument table with a needle box and prepared suture needles, and in Figure A.3b needle box containing needles and sharps after a procedure is depicted.

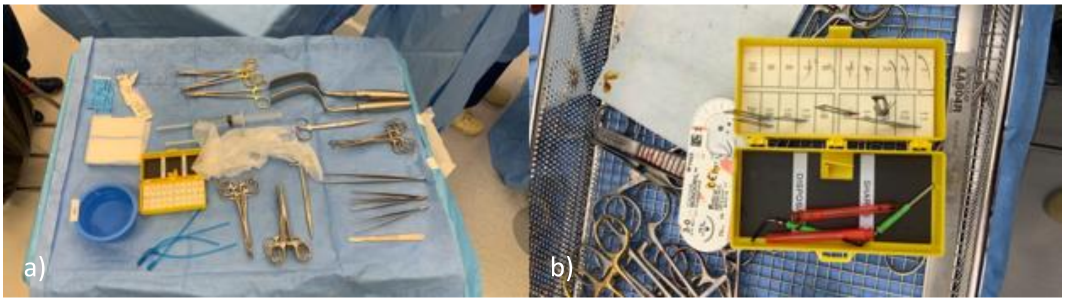

Figure A.3a-b. (a) Surgical instrument table containing a needle box and prepared suture needles. (b) Needle box with numbered spaces to accommodate needles and sharps.

Agreements regarding the counting protocol of needles

For each surgery, the counting of needles and sharps should be performed. The SN and CN should inspect and count the contents after opening the sterile package of needles and sharp objects and verify that no sharp items are present before sealing the wound.

Pre-operative counting of needles

When removing them from their sterile wrapping, the SN and CN must verify and count the number of needles and sharps. The CN is responsible for keeping the packaging of sharp objects.

Intra-operative counting of needles

The counting occurs before, during, and after the wound is closed, whenever the SN or CN changes, and upon the surgeon's request. The number of additional needles added during surgeries is noted on the whiteboard.

The SN and CN count the needles and sharps before wound closure. The count is often carried out immediately following the gauze count. The SN notifies the surgeon when all needles and sharps have been identified. Each of the needle box's numbered spaces accommodates a needle, allowing all utilized needles to be viewed simultaneously. When the SN does not have time to place the needle directly in a numbered location, the needles can be placed on the right side of the box, with a magnet to secure the needles.

In the occasion of missing material, the same steps as for gauze are taken.

Postoperative counting of needles

The CN registers that the number of needles and sharps is complete by checking the corresponding boxes in Hix.

III Methods: Gauzes and Needles

This section presents the methods for assessing the surgical counting performance of gauzes and needles.

Data collection procedure

Pre-operative phase

Within the gauze and needle section of the tool information was recorded such as:

- the initial count location;
- the time taken for counting;
- whether the count was performed with the CN; and
- the occurrence of distractions during the count.

Intra-operative phase

During the interim and final counts the following was recorded in the gauze and needle section:

- the duration;
- whether the count was performed with the CN;
- and any distractions during the count.

The duration of gauze and needle counts was measured utilizing an XL-009B stopwatch. The final count recorded whether the surgical items were complete, misplaced, or retained. A misplaced or retained surgical item indicated an ISC. After the surgery the number of counts and distractions were added and recorded. Additionally, in the gauze section, it was noted whether the measurement of blood loss was performed by weighing gauzes as this affected the counting process. Due to the researcher's simultaneous measurement of multiple variables, it was not feasible to document the exact quantities of gauzes and needles counted.

Data processing and analysis

The Shapiro-Wilk test was utilized to determine the normality of the scale variables. The data had a normal distribution when $p>0,05$. When a variable is compared in the non-normal distribution analysis, non-parametric tests should be utilized to compare variables (Mishra et al., 2019). For data analysis, variables were compared to the final number of surgical trays. Due to the non-normal distribution of this variable ($p<0,05$), the non-parametric Spearman correlation and

Mann-Whitney U-test were utilized to assess the relationship between the surgical counting performance of gauzes and needles and the final number of surgical trays.

The frequency descriptives calculated for the surgical counting performance of gauze and needles included:

- the occurrence of an initial, interim and final count;
- whether a distraction took place during the count
- whether the count was performed with a CN; and
- the count's location.

As it was not always possible to measure all variables during a procedure, or the measurement did not occur, the dataset contains missing values. Therefore, the decision was made to use valid percentage frequencies when analyzing the frequency descriptives. This approach ensures a more precise data representation by excluding missing values.

Descriptive statistics were analyzed to evaluate the surgical counting performance to obtain information regarding the minimum, maximum, central tendency, and standard deviations for the:

- initial count;
- interim count;
- final count;
- number of counts per surgery; and
- number of distractions per surgery.

The Spearman correlation coefficient assessed the direction and strength of a monotonic relationship between all scale variables. The correlation can range between -1 and +1, a positive score indicating that as one variable increases, the other also tends to increase. A correlation coefficient greater than 0,70 is interpreted as a high correlation, between 0,5 and 0,7 a moderate correlation, and below 0,50 a low correlation. The significance score indicates whether the observed relationship was likely to be attributed to chance or represents a valid association. A significance level of $p<0{,}05$ indicates that the correlation is improbable to have happened by chance (Artusi et al., 2002; Mukaka, 2012).

The Mann-Whitney U-test is appropriate for assessing whether there is a significant difference in value distribution between two variables on a single scale variable. A significance level of $p>0{,}05$ indicates that the distribution of the two variables does not differ (Nachar, 2008).

IV Results: Gauzes and Needles

The results obtained on the surgical counting performance of gauzes and needles is presented in this section.

Normality of data testing: Gauzes and Needles

The duration of the initial gauze count and interim gauze and needle counts exhibited a normal distribution, as indicated by the Shapiro-Wilk test ($p>0,05$). However, the duration of the closing counts, the number of counts per procedure, and the number of distractions for gauze and needle counting did not follow a normal distribution ($p<0,05$).

Descriptive Statistics: Gauzes and Needles

Surgical gauze counting included an initial, one or two interim counts, and a final count. Furthermore, the needle counts included one or two interim counts and a final count. Tables A.1 and A.2 represent the frequencies of:

- the occurrence;
- distractions;
- whether the count was performed with a second individual;
- the location of the count; and
- whether an incorrect count occurred.

Table A.1. Descriptives on the nominal variables related to the surgical counting performance of gauze

		Occurrence of count	Distractions	Counting performed with another individual	Location of count		Incorrect surgical count (misplaced)
					PR	OR	
Initial count		80,0%	0,0%	91,7%	94,4%	5,6%	
Interim count	(1)	18,0%	11,1%	77,8%		100,0%	
	(2)	4,0%	0,0%	66,7%		100,0%	
Final count		82,0%	5,1%	87,2%		100,0%	4,0%

Table A.2. Descriptives on the nominal variables related to the surgical counting performance of needles

	Occurrence of count	Distractions	Counting performed with another nurse	Location of count		Incorrect surgical count (misplaced)
				PR	OR	
Interim count (1)	12,0%	16,7%	83,3%		100,0%	
(2)	2,0%	0,0%	100,0%		100,0%	
Final count	69,6%	0,0%	92,3%		100,0%	2,0%

In Table A.3 displays the frequency descriptives of the:

- initial gauze and needle count;
- interim gauze and needle counts;
- final gauze and needle count;
- number of gauze and needle counts; and
- number of distractions during the gauze and needle counts.

Table A 3. Descriptives on the scale variables related to the surgical counting performance of gauze and needles

		Min	Max	Mean	Median	SD
Gauze	Initial count	1,63	9,21	3,78	3,81	1,64
	Interim count	1,53	24,31	9,31	10,80	7,17
	Final count	1,44	30,54	8,54	6,28	5,85
	Number of counts	1,00	4,00	2,28	2,00	0,64
	Number of distractions	0,00	1,00	0,08	0,00	0,27
Needle	Interim count	0,56	9,84	5,84	5,53	4,01
	Final count	1,09	75,10	10,25	4,25	17,99
	Number of counts	1,00	3,00	1,22	1,00	0,49
	Number of distractions	0,00	1,00	0,03	0,00	0,18

Statistical Analyses: Gauzes and Needles

No statistically significant relationships were found when identifying the relationship between the final number of surgical trays and the surgical counting performance of gauze and needles. The Spearman correlation coefficient, Mann-Whitney U-score, and individual levels of significance are presented in Table A.4.

Table A 4. The Spearman correlation coefficient, Mann-Whitney U-score, and respective levels of significance between the final number of trays and variables related to the surgical counting performance of gauze and needles.

	Gauze				Needles			
	Shearman's Rho		Mann-Whitney U-test		Spearman's Rho		Mann-Whitney U-test	
	Correlation coefficient	Sig. (2-tailed)	Mann-Whitney U	Sig. (2-tailed)	Correlation coefficient	Sig. (2-tailed)	Mann-Whitney U	Sig. (2-tailed)
Number of counts	-0,26	0,10			-0,14	0,46		
Time Spent on the initial count	-0,03	0,85						
Time Spent on interim counts	0,55	0,13			0,80	0,18		
Time Spent on the final count	0,09	0,61			0,17	0,54		
Number of distractions	0,01	0,96			0,30	0,10		
Incorrect Surgical Count			22,0	0,25			7,50	0,35

V. Discussion and conclusion: Gauzes and Needles

The surgical counting of gauze and needles occurred in nearly every surgery. No initial needle count occurred as only two suture needles were prepared in the pre-operative phase. Furthermore, gauzes were unpacked in the pre-operative phase, facilitating a fast, facile, and accurate count. The counting was performed with a second individual as instructed by the protocol.

The frequency of interim counts varied depending on the SN's preference. Therefore, the counts occurred irregularly, making the measurement difficult to complete. The duration of the highest interim count was 20,76 and 5,92 seconds for gauze and needles, respectively. The material was sorted on the surgical instrument table during gauze interim counts. Following use, needles were immediately placed in the needle container with pre-numbered slots, enabling the SN to determine whether all needles and sharps were present rapidly.

During a final gauze count, a distraction occurred because the surgeon requested a surgical instrument while the SN performed the count. After the disturbance, the count was resumed. The final needle count was conducted without any distractions. Needle counting without distractions could arise because needles are frequently counted after gauzes during the final count. .

In none of the surgeries, an RSI occurred. However, in 4,0% of the surgeries, gauzes were misplaced during the final count, and in 2,0%, needles were misplaced during the final count. The duration of gauze counts where an ISC occurred was 15,16 and 19,03 seconds. The duration was comparable to those where no ISC occurred. The count duration during an ISC was 75,10 seconds for the needle count. The radiology department was to be called to ensure the needle was not inside the patient, but the CN eventually found the needle on the floor.

It was assumed that the workload associated with surgical counting would increase as the final number of surgical trays increased, leading to decreased counting performances of gauze and needles. However, the nurses indicated that counting gauze and needles did not considerably influence their workload. Furthermore, the final number of surgical trays did not influence the surgical counting performance of gauzes and needles. Regarding the willingness to adopt technology, none of the operation assistants wanted to use it for needles, and only a minority wanted to use it for gauzes.

To conclude, counting gauzes and needles exhibited minimal ISCs, resulted in a limited increase in workload, and was unaffected by the final number of surgical trays. Adding technological applications to the already secure process of handling these materials would not add to a beneficial result.

Appendix B

Technological approaches for surgical instrument counting

VI Technological approaches for surgical instrument counting

Two-dimensional (2D) bar and matrix coding

A device approved by the Food and Drug Administration (FDA) is the thermally applied bar codes or matrix labels for counting gauzes and instruments. An electronic bar code scanning counter is employed to scan the unique labels when gauzes and instruments are passed beneath the scanning mechanism (Gibbs, 2007). A data matrix code secured to an instrument can be seen in Figure 4.1 (Bohler et al., 2016).

According to preliminary research, barcode technology outperformed manual counting in detecting count discrepancies, encompassing miscounted and misplaced surgical gauze (Greenberg et al., 2008). However, because the barcode reader can only process one instrument at a time, this technology adds extra stages to the process and extends the surgical counting time (Freitas et al., 2016; Greenberg et al., 2008; Kusada et al., 2016; Margie et al., 2021). The inability of the barcode system to read blood-stained barcodes, which requires repeated marking processes, is a severe restriction (Kusada et al., 2016).

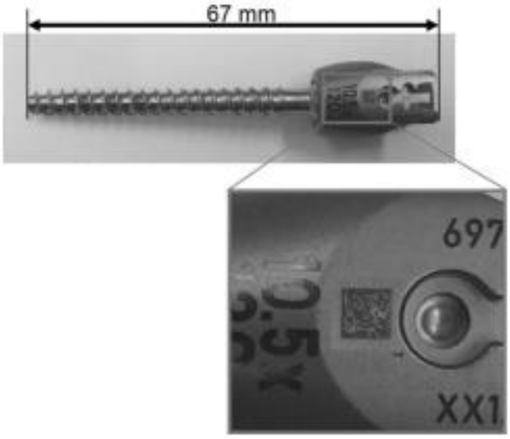

Figure B.1. Data matrix code affixed to a medical screw (Bohler et al., 2016).

Radiofrequency Identification Systems

The application of radiofrequency identification (RFID) tags has the potential for detecting and tracking gauzes and instruments. The system has two fundamental components: a reader-writer unit and an RFID tag. The reader-writer unit has a controller and an antenna. When surgical items with an RFID-equipped tag are brought close to the antenna, the antenna extracts data from the object. Each tag contains an integrated circuit that contains detailed item-level data The broadcast signals can be read within a few inches to several feet depending on the antenna's size, dimensions, and power. A computer that sends and receives signal data is attached to this reader-writer unit. Figure 4.2a-c displays an RFID tag, the tag attached to an instrument, and the reader-writer unit. The block diagram of the management system is depicted in Figure 4.2d. The system can register multiple items simultaneously.

Factors like tracking, usability, and sterility are essential when considering RFID. The RFID tags necessitate durability against washing and sterilization when applied to instruments. In the long run, this technology might be extensively used to track all surgical items inside the OR and across the hospital (Gibbs et al., 2007; Kusada et al., 2016; Yamashita et al., 2008). Besides the encouraging outcomes of RFID technology, the requirement for additional tags creates new challenges ranging from detection to battery issues (Egan & Sandberg, 2007; Neumuth & Meißner, 2012). Furthermore, applying a tag on very slim instruments is often impossible. Considering the substantial number of instruments, which can reach several thousand items due to manufacturers' diverse range of instruments, concerns about the cost-effectiveness and feasibility of integrating RFID strategies into the current clinical workflow (Glaser et al., 2015).

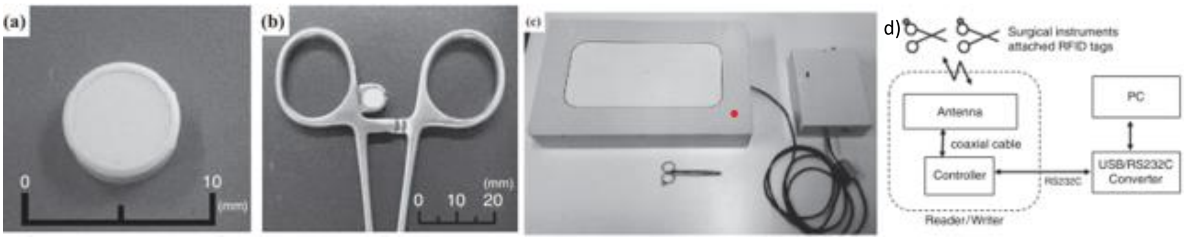

Figure B.2.a-d. (a) RFID tag, (b) surgical instrument equipped with RFID tag, (c) Reader/writer unit with antenna circuit, (d) block diagram of the management system (adapted from Kusada et al., 2016).

Video and Weight-Based Approach

A novel design developed for instrument detection in real-time eliminates the requirement for instrument modification. This system combines a multisensorial approach, Specifically a 2D camera, digital scale, and infrared (IR) camera, combining video and weight information. The 2D camera is placed above the surgical instrument table, supported by an IR camera located at the side of the table, and a digital scale placed under the surgical instrument table. Additionally, specialized software was developed to efficiently recognize and record the sequential changes occurring on the surgical instrument table throughout a surgical procedure. The video and weight sensors are connected to a computer system, the analyzer central unit. The automated system can be viewed in Figure 4.3. The analyzer central unit is divided into a builder and an analyzer. The builder gathers information on the surgical instruments by weighing and obtaining images of the instrument in different positions to build a reference container. The reference container holds all information on the surgical trays used for a specific procedure. It thus serves as a repository for all relevant a priori information known to the system. Hence, the analyzer's primary function is to detect and identify objects placed on the surgical instrument table accurately. The 2D camera takes snapshots of images, known as frames. By looking at the accompanying thermal pictures captured by the IR camera, any frame with a recognizable hand or finger is disqualified from further analysis.

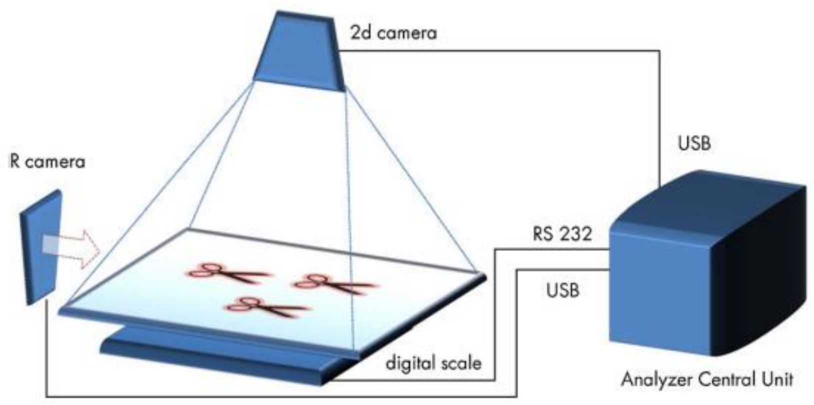

Figure B.3. Schematic representation of the video and weight-based approach (Glaser et al., 2015)

In controlled laboratory settings, the detection rates were evaluated by monitoring the use of instruments during 27 functional endoscopic sinus surgeries (FESS). Including the weight information improved the accuracy of instrument detection, as evidenced by the higher detection rates. The detection rate was 84,9% when video-based detection was used exclusively. The overall detection rate rose to 90,3% when a combination strategy of weight-based data and video-based detection was utilized. However, it is essential to note that the system monitors the surgical instrument table and cannot detect instruments used by the surgeon or SP. Furthermore, solid shadows and superposed instruments present difficulty for the vision algorithm as they negatively impact the detection. When instruments overlap, the visual process creates a single blob, making distinguishing between the different instruments challenging. Supplementary algorithms would be required for these limitations (Glaser et al., 2015).

Computer Vision with Machine Learning

Another technological application eliminating the need for handheld scanners and surgical item modification is a vision-based approach combining computer vision and machine learning to detect gauzes and instruments. The application consists of a detection phase and the tracking phase. The object detector is trained to identify surgical items and output detections with accompanying bounding boxes and labels. Subsequently, the object tracker receives the bounding boxes and tracks the identified objects in consecutive frames. The computational load was significantly reduced by implementing a periodic execution of the object detector and using a faster and more effective object tracker. Combining object detection and tracking enabled the possibility of processing more frames per second while maintaining the accuracy of visually tracking surgical items. Specifically, the hybrid approach increased the speed by up to 200% (Arda et al., 2021).

The trained dataset in Arda et al. (2021) consisted of images of instruments taken in various orientations, lighting conditions, situations where the surgical instrument was held by hands wearing surgical gloves, and the handling of instruments. The collection included six commonly used surgical instruments: a scalpel, curved hemostat, tissue forceps, surgical scissors, and needle holder. The Single Shot Multibox Detector (SSD) model using the MobileNet feature extractor was utilized in the study. The SSD design combines the predictions from various feature maps with varied resolutions to address the detection of instruments in different sizes. Bounding boxes were connected with each cell in the feature maps utilized during predictions. Subsequently, a non-maximum suppression approach filtered and retained the most significant detections (Liu et al., 2016). The six feature map layers present in the network can be seen in Figure 4.4. The object tracker uses scale estimation methods to increase the accuracy of visual tracking (Danelljan et al., 2014).

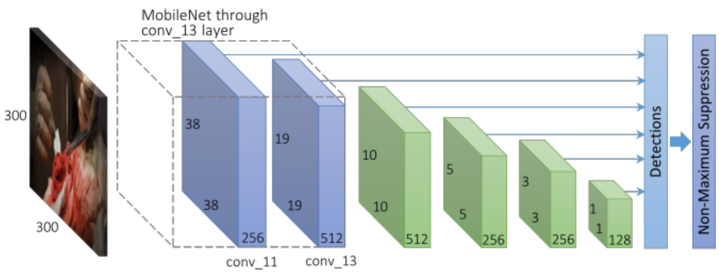

Figure B.4. SSD Mobile Net Architecture using six feature caps. Two existing Mobile Net convolution layers are used, namely 11 and 13, and four additional convolution layers with a decreasing resolution of 512, 256, 256, and 128 depths (Arda et al., 2021).

To capture a top view of the surgical site, the ideal setup in the OR involved mounting a camera near the OR table on the lights. The instrument count and annotations were shown on a monitor. The system labels the instrument based on its classification, such as forceps or scalpel. Regardless of the scale, posture, camera view, occlusions, or lighting conditions, the object detection task tries to determine the locations of a given instrument in all instances. The accuracy of detection might be jeopardized during real-time utilization because of the handling and moving of instruments. In these situations, tracking techniques are used as a preventive measure in missed detection cases.

The application lists every surgical instrument present in the frame. A yellow rectangular box in the center of the frame simulates the region of operation. The count increases when a surgical instrument enters the region and decreases when an instrument leaves the yellow region. Outside of this area, surgical items are not counted. The outcomes of using a surgical counter application on a video sequence can be viewed in Figure 4.5.

It was essential to note that the occlusions and motion blurs presented difficulties for the effect object tracker and that there needed to be more clarification in classifying similar instruments. In these situations, detections during the object detection phase may fail, providing an inaccurate count. Results showed that the object detectors have difficulty locating small surgical instruments. Future enhancements were required before this surgical counterapplication could effectively support the manual counting process during surgery (Arda et al., 2021).

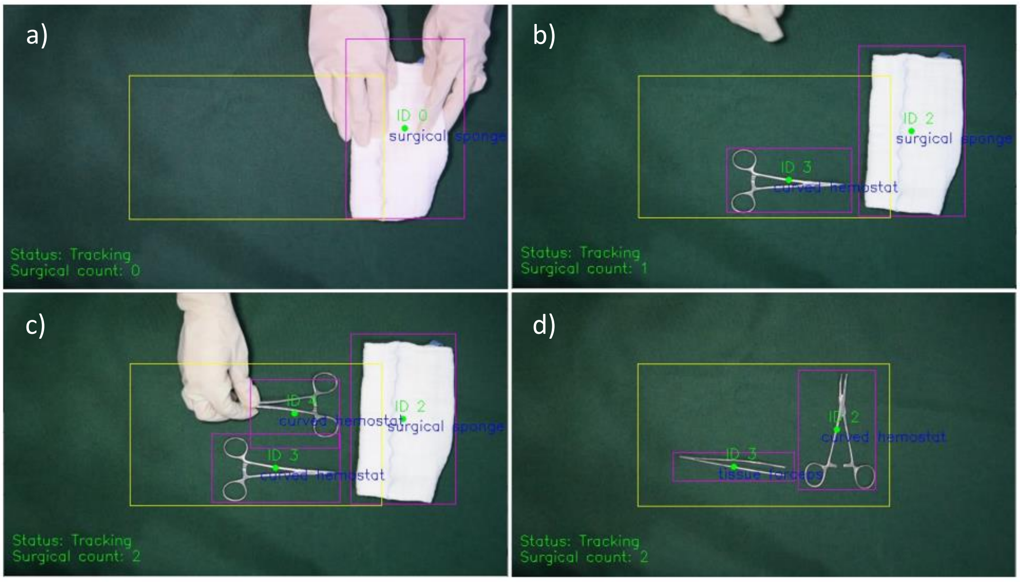

Figure B.5. Evaluation of the surgical counter application on a video sequence. (a) Surgical gauze was detected. However, the item is outside the yellow region, therefore, not counted. (b) Hemostat detected inside the yellow region, thus counted; surgical gauze detected outside the yellow region, therefore not counted. (c) Two hemostats were detected in the yellow region and thus counted. Surgical gauze was detected outside the yellow region, so not included in the count. (d) Tissue forceps and hemostats were detected and included in the count (Arda et al., 2021).

Appendix C

Generated Tool to Assess Surgical Counting at the Reinier de Graaf Gasthuis

General	
Type of surgery: Name according to planning sheet RdGG:	ENT / Urology / Plastics / Robot/ Vascular / Gynecology / Surgery
Elective/emergency:	Elective / Emergency
Start & End incision time	Start: End: Duration:
Staff turnover during procedure?	

Surgical Instruments	
Wrapping color	Blue wrapping / Green wrapping
Initial count performed with 2nd nurse and Combister list:	Yes / No
Combister guidance list filled in by nurse:	Yes / No
Number of surgical trays:	
Addition of surgical trays during procedure?	
Time spent on returning instruments in correct tray (s):	
Number of interruptions:	
Instruments returned 2nd nurse and Combister list:	Yes / No

Counting of needles				
Needles counted in PR / OR Initial (I) / Interim (CU) / Final (F) count	1	2	3	4
Time spent on counting (sec)?	1	2	3	4
Counted with 2nd person Distraction (Yes/No) Final count complete (Yes/Misplaced/Retained)	1 2 3 4			
Total number of counts and distractions				

Counting of gauzes								
Blood loss measured by weighing gauzes?	Yes / no							
Gauzes counted in PR / OR Initial (I) / Interim (CU) / Final (F) count	1.	2.	3.	4.	5.	6.	7.	8.
Time spent on counting (sec)?	1.	2.	3.	4.	5.	6.	7.	8.
Counted with 2nd person Distraction (Yes/No) Final count complete (Yes/Misplaced/Retained)	1. 2. 3. 4. 5. 6. 7.							
Total number of counts and distractions								

Vragenlijsten voor de operatieassistenten in het Reinier de Graaf Gasthuis

Telling instrumenten

1. Controleer jij een net in zijn geheel op de compleetheid van instrumenten?
   - ○ Ja
   - ○ Nee

Ervaring & werkdruk

2. Ervaar jij een verhoging van de werkdruk tijdens het tellen?

Naalden	Gazen	Instrumenten	Geen verhoging

3. Redenen:
   - ○ Spoedoperatie
   - ○ Duur van de operatie
   - ○ Aantal instrumentnetten
   - ○ Geen time-out
   - ○ Anders:

4. Vind jij dat het huidige telproces efficiënter kan worden ingericht?
   - ○ Bij de opdek (preoperatief):
   - ○ Gedurende de operatie (intra-operatief):
   - ○ Aan het einde van de operatie (Postoperatief):

Technologie

5. Zou jij openstaan voor technologie als hulpmiddel tijdens het telproces?
   - ○ Ja
   - ○ Nee

Indien ze openstaan voor technologie:

6. Gedurende welke fase zou de technologie het meeste van toepassing zijn?
   - ○ Preoperatief
   - ○ Intra-operatief
   - ○ Postoperatief

7. Is er een specifiek materiaal waarbij je technologie als hulpmiddel zou willen gebruiken?
   - ○ Gazen
   - ○ Naalden
   - ○ Instrumenten

8. Voorwaarden: