TU DELFT - UNIVERSITY OF TECHNOLOGY

MASTER THESIS

DEPARTMENT OF BIOMEDICAL ENGINEERING

# The development of an objective test method to evaluate the (optical) quality of rigid endoscopes at the CSSD

*Author*
Lisa Denise VAN DER PLAATS
Studentnr: 4088107

*Supervisor TU Delft*
Prof.dr. Jenny DANKELMAN

*Supervisor Zign Medical*
Erik BOCKWEG

TU Delft Delft University of Technology

*In collaboration with:* ZiGN medical

August 12, 2019

# Preface

This report contains the culmination of my final master project: my master thesis. I have completed this project in partial fulfillment of the requirements for the degree of Master of Science in Biomedical Engineering at the Delft University of Technology. This report extensively summarizes the work done and knowledge gained over the last twelve months.

Following my literature review on multiple DoF (Degree of Freedom) control methods for instruments used in minimally invasive surgery and NOTES (Natural Orifices Transluminal Endoscopic Surgery) procedures I was increasingly intrigued by the developments on instruments used during minimally invasive surgery. While I was figuring out how to further develop this interest I met Erik Bockweg from Zign Medical at the MEDICA fair in Dusseldorf in 2017. Our conversations led to an increasing interest into the quality management of reprocessable instruments used during minimally invasive surgery, and between March and August of 2018 I succesfully completed an internship at Zign Medical investigating the possibilities of developing a new test device to examine rigid endoscopes on their quality. During this internship two main things became very clear to me: Firstly, the importance of quality management of these delicate surgical instruments is globally underestimated and needs to be addressed. Secondly, available knowledge on quality management of rigid endoscopes is limited and lacks objective and quantitative measures. This has inspired me to dedicate my master thesis research to increase the available knowledge and further develop a measurement method incorporating this knowledge.

During this past year, I have learned much more then I anticipated at the start of this project. During the many phases I have grown more confident, both in my own capabilities as well as about the importance of this research and the contribution it might be towards increased patient safety during minimally invasive surgery.

The collaboration with Zign Medical has provided me with great support, inspiring people to work with, in-depth knowledge, valuable discussions and critical evaluations of my work that have contributed immensely to this report. I would like to thank Erik Bockweg from Zign Medical in particular for his guidance, trust and support the last year; challenging, encouraging and helping me during every phase of the project.

Finally, I would like to speak out my gratitude to the following people without whose support I would not have been able to finish my master thesis in its current form. First of all, I would like to thank my supervisor prof. dr. Jenny Dankelman for your guidence, reassurance and down-to-earth advice that has given me the confidence and knowledge to be able to lift my thesis to higher level. I would like to thank the three hospitals (Reinier de Graaf Ziekenhuis/Combi-Ster in Delft, Jeroen Bosch Ziekenhuis in Den Bosch, Leiden Universitair Medisch Centrum(LUMC)) I have visited for their hospitality and flexibility to help me investigating the many aspects regarding the quality of endoscopes during the reprocessing cycle in hospitals. I am very grateful for the extensive knowledge shared with me and the opportunity to perform my measurements at ERPA Instruments. Ernst Paar, general director and expert on rigid and flexible endoscopes, you have been vital to the success of this project, and I would be very happy to possibly working together on this topic more in the future. In the development of the test set-up, Rik ter Horst (optical expert and manufacturer of telescopes) has helped me understand how to apply the learned knowledge on optical systems to the specific system of rigid endoscopes. Lastly, I would like to thank my family, boyfriend and friends for their support in every possible way, including accepting my (at the time seemingly empty) promise that I was almost finished with my thesis for the last 6 months!

I feel proud and confident with the result of this thesis as I believe this field shows great potential for further research which I am very interested in pursuing myself as well.

## How to read this report

This report is a complementary document to my paper ”Design and validation of a test set-up to measure the optical quality of rigid endoscopes”. This report can be read as a stand-alone document summarizing the background information and the literature research done prior to performing the experiments with the developed test set-up. The report includes a detailed introduction to rigid endoscopes, the reprocessing cycle and a description of the failure risks of rigid endoscopes within the reprocessing cycle. It also includes a detailed definition and description of all quality indicators for rigid endoscopes. Finally, the report discusses the state of the art in relation to the defined quality indicators and discusses the potential of a new testing method for rigid endoscopes that can be easily integrated in the current workflow at the Central Sterilization Services Departments (CSSD) at clinical facilities such as hospitals.

# Contents

# Chapter 1

# Introduction

The current design of rigid endoscopes used in Minimally Invasive Surgery (MIS) all over the world was introduced in 1966 by Karl Storz after Harold Hopkins developed the rod-lens optical technique for transferring images. [25] Since the endoscope represents the eyes of the surgeon, they are essential to the success of any procedure in MIS.

New developments in the medical industry are often technology driven and the speed of innovation is only accelerating. [30] Increasing awareness of medical injuries has gone hand in hand with an increasingly complex industry of medical devices. These newly developed medical devices have led to improved health care efficiency, quality, safety, and cost. However, these same devices also introduce a complex clinical environment which may lead to errors and adverse events. Currently, with the global medical industry using almost 5000 different types of medical devices, problems related to medical devices are inevitable. [27].

Consequently, the medical device industry is a highly regulated industry. Adequate measures for medical devices are required to minimize the issues which users of medical equipment could encounter during their work, especially when dealing with a life or death situation. [24] Governments globally demand insights and transparency from hospitals with regard to the usage and reprocessing of medical devices, and hospital risk management remains a priority for the healthcare industry. [6] [11]

Although the medical industry heavily depends on high quality rigid endoscopes for MIS procedures, there are hardly any minimum requirements or standards available to ensure the quality of these instruments. Moreover, the test-methods for certain aspects of the quality of rigid endoscopes that áre described in an ISO standard are time-consuming, require expert knowledge on optics and/or are not always objective measurements. [19] According to a number of studies, defective rigid endoscopes are still reaching the operating room. [35] [31] [22]

The goal of this thesis is to propose a new test method to ensure the quality of rigid endoscopes during surgery, complementary to the current clinical practices and procedures involving these instruments. More specifically, this thesis will cover the risks and quality indicators for rigid endoscopes, and investigates whether combining existing approaches for each quality indicator results in a promising approach of testing rigid endoscopes objectively at the Central Sterile Services Department (CSSD).

## 1.1 Introduction to Endoscopy

Endoscopy is a medical technique using optical instruments that allow enhancement of the visualization of internal tissue and organs from a distance through natural orifices or small incisions in the patient's skin. Surgical procedures using the technique of endoscopy are more commonly known as Minimally Invasive Surgery (MIS). These MIS procedures have replaced many open surgical procedures with equal or better results, shorter patient recovery times due to smaller incisions, lower patient morbidity and shorter hospital stays. [12]

Surgical fields inside the human body can range from tubular structures, commonly found when entering the body through natural orifices, to hollow cavities, accessed through small incisions in the skin. Tubular structures require flexible instruments with a small diameter to be able to follow a 3D pathway, hollow cavities require more rigid instruments to reach a target area with precision. [12] The different requirements for each target area inside the human body have resulted in the developments of specialized instruments, commonly divided into two main groups: rigid endoscopes and flexible endoscopes.

Figure 1.1: Flexible Endoscope

Flexible endoscopes are a relatively new development in MIS, and provide the ability to follow a 3D pathway often accessed through a natural orifice. Inside a flexible endoscope there are channels with optical fibers to transport light; one transports light from an external light source to the target area, the other transports light back to a camera sensor to project the image. Flexible endoscopes can also include additional channels for the insertion of additional instruments. An example of a flexible endoscope is shown in figure 1.1.

Figure 1.2: Example of a rigid endoscope: two types of laparoscopes

Rigid endoscopes are instruments that can be compared to a small telescope, entering the human body through a natural orifice or a small incision in the skin. As with flexible endoscopes, a bundle of optical fibers transport light from an external light

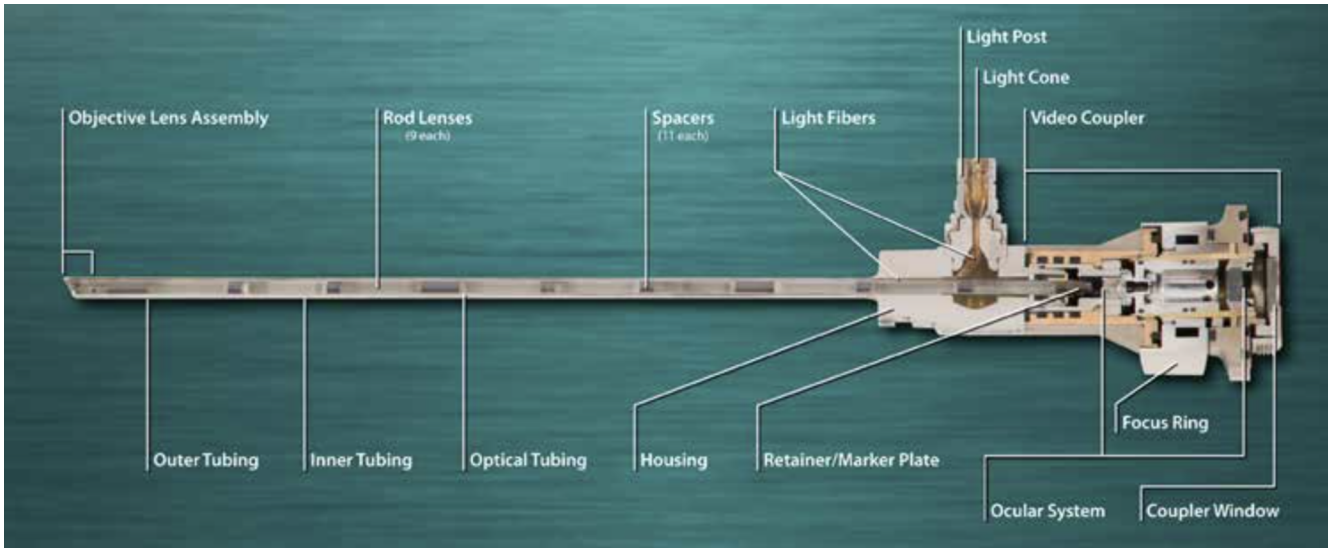


Figure 1.3: Anatomy of a Rigid Endoscope

source towards the distal end of the endoscope. A series of glass rod lenses then transfer the light back to the eyepiece of the endoscope. An example of rigid endoscopes is shown in figure 1.2. The use of glass rod lenses make these instruments the high quality, but fragile, instruments that they are. This thesis will be focusing on developing a testing method to ensure the required quality of rigid endoscopes.

## 1.2 Anatomy of a rigid endoscope

A rigid endoscope, as is shown in figure 1.3, is an instrument with an extensive lens-system used clinically to look into the human body and examine hollow cavities and organs. Flexible glass fibers transmit light from the light post through the tubing towards the distal end of the endoscope and project the light often in an angle onto the target area without transmitting damaging heat. The light reflecting on the target area travels back through the rod-lens-system towards the ocular system. A video camera is usually attached to the coupler window of the endoscope to transmit the image to a video monitor. [23]

Apart from the above described system of transporting light as the core element of a rigid endoscope, the rest of their individual design is specified by the requirements of the medical field it is used for. They can be diagnostic or operative, some include channels for irrigation and/or suction and channels to insert accessory instruments. Rigid endoscopes are available in a variety of lengths and a variety of diameters, depending on the requirements of different procedures and sometimes even the specific requirements of a surgeon.

Each rigid endoscope is also specified with a viewing angle. The viewing angle of a rigid endoscope depends on the position of the target area to be inspected during the procedure. Most commonly seen angles are:

- $0^\circ$ for forward viewing
- $12^\circ$ for forward oblique views
- $30^\circ$
- $45^\circ$
- $90^\circ$ and $70^\circ$ for lateral viewing
- $110^\circ$ or retrograde, for viewing backward

Other standard parts of a rigid endoscope are:

- **Eyepiece** - The eyepiece is located at the proximal end of the rigid endoscope. The eyepiece is used to attach a camera coupler to connect to a video monitor, or can be looked through directly with the human eye.
- **Ocular Lens Assembly** - This lens assembly including the focusing lens of the endoscope is located near the proximal end of the rigid endoscope. This lens assembly focuses the light/image transmitted through the rod lenses onto the camera coupler or the human eye.
- **Light Post** - A light source needs to be connected to the light post of a rigid endoscope during use. The light post is the entrance for light entering the light fibers towards the tip of the endoscope.
- **Shaft** - This stainless steel tube houses the lens train and the light fibers. Usually there is an inner tube and an outer tube. The length of the shaft is the working length of the rigid endoscope.
- **Lens Train** - The lens train includes a series of rod lenses and spacers between the rod lenses. This system transfers the image through the endoscope's shaft towards the ocular system.
- **Objective Lens Assembly** - The objective lens assembly is an assembly of lenses, windows and/or prisms located at the distal end of a rigid endoscope. This assembly captures the image and transfers it to the rod lenses.
- **Distal Window** - The distal window is located at the tip of the endoscope and protects the objective lens system.
- **Light Fibers** - Glass light fibers transfer light from the light post to the distal end of the scope towards the target area.

A rigid endoscope does not contain any moving elements. Damage to a rigid endoscope is therefor often a result of human interaction with the instrument during the usage cycle in the hospital. [23]

## 1.3 Rigid endoscope: Instrument Reprocessing Cycle

Decontamination and sterilization of medical instruments is the process that destroys all forms of microorganisms present on the surface of these instruments. Surgical instruments inserted

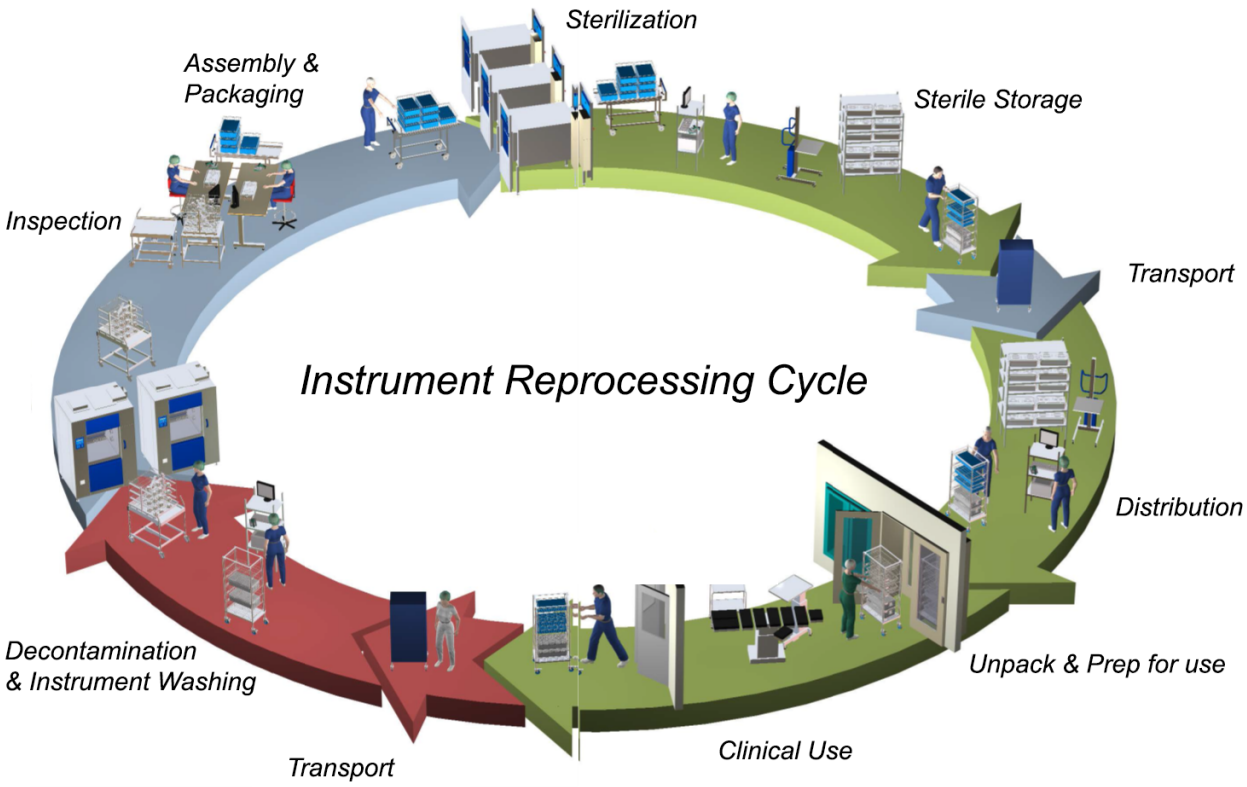


Figure 1.4: Instrument Reprocessing Cycle

into the human body are required to be sterile to prevent the spread of pathogens due to cross-contamination. Generally speaking, this includes all instruments and devices used in the operating room (OR) that come in direct contact with the patient. These instruments are either sterile disposable instruments which are discarded after a single use, or reusable instruments that are sterilized after every single use. Rigid endoscopes are reusable instruments and are therefor subject to the instrument reprocessing cycle shown in figure 1.4.

### 1.3.1 Steps of Instrument Reprocessing

When not in use or being decontaminated, a rigid endoscope is stored in either a single tray as shown in figure 1.5 or in a combined instrument tray.

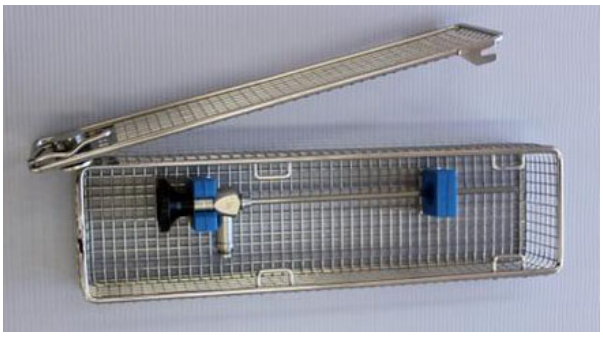

Figure 1.5: Rigid Endoscope in Sterilization Tray

After being used in the OR, the contaminated rigid endoscope is placed back in its tray and placed on a transport trolley. This trolley is then covered and/or sealed to prevent cross-contamination during transport to the instruments reprocessing area.

**Decontamination**

The Decontamination Area of the CSSD is the first stop for any contaminated instrument after use. The endoscope is taken out of the tray by a CSSD employee wearing fully protective clothing and a facemask. All removable parts are separated from each other and all parts are manually rinsed and soaked before placing the endoscope in a washer. The endoscope is then placed in the washer where it undergoes several cycles of washes and rinses on temperatures of 90 degrees Celsius. The washers in the CSSD form a physical barrier between the Decontamination Area and the Inspection Packaging Area, with a door on one side where the instruments enter the washer, and a door on the other side where the instruments exit the washer into the Inspection & Packaging Area.

**Inspection and Packaging**

A cleaned endoscope exits the washer and is manually inspected. Standardized inspection protocols for rigid endoscopes do not exist. Hospitals base their inspection protocols on recommended practices (such as ”Recommended Practices for Cleaning and Caring for Surgical instruments and Powered Equipment” [4]). These documents on recommended practices often do not specify the guidelines for inspection of rigid endoscopes specifically but recommend to handle equipment according to manufacturers’ instructions. Different hospitals may work with different manufacturers of rigid endoscopes, which results in varying inspection protocols from hospital to hospital. A proper inspection generally includes:

- Visual inspection:
  - Light post: Check if all adapters were removed. Check for dead fibers in fiber bundle.

  - Shaft connection to eyepiece: Check welding for cracks.
  - Shaft: Check for dents, damage, bent shaft,
  - Distal tip: extra cleaning with alcohol if necessary. Check for shaver damage, sharp edges, protruding elements, damaged light fibers.
  - Accessory Items: Check for smooth fit.
- Optical inspection. Look through endoscope and:
  - Check for sharpness and brightness of the image.
  - Check for shadows, fractures, dirt visible in the image.

After the rigid endoscope has been inspected, they are placed back in their tray and prepared for sterilization. The trays are packaged separately in material that allows steam to penetrate during sterilization but protect the instrument from contamination during storage and transport before it is used.

#### Sterilization

Rigid endoscopes are steam-sterilized in an autoclave. Steam in itself is not sufficient for proper sterilization. High pressure in combination with steam is necessary to destroy microbial life. [1] A steam sterilization cycle consists of three phases:

- Pre-Conditioning: Air is removed and the instruments are humidified through alternating vacuum pulses and pressure pulses.
- Exposure: Temperature is raised to at least 132 degrees Celsius and pressure is raised to 2.3 bar for at least 4 minutes.
- Post-Conditioning: The instruments are cooled and dried and the pressure is brought back to atmospheric. [13]

#### Storage and Distribution

The packaged tray with the rigid endoscope exits the autoclave and is then sorted and stored in the clean room of the CSSD. Transport trolleys are used to transport the trays to their designated location for clinical use upon request from the Surgical Services department.

#### Clinical Use

Before use, the still sterile packaged instruments are unpacked in the unpacking area next to the designated OR and placed on an instrument trolley covered in sterile sheets. This trolley is then placed in the OR at the position the surgeon requests. All sterile instruments necessary for that procedure should be present on the instrument trolley, and are taken from and placed back on this trolley only to ensure sterility during the procedure. After the procedure is finished, the trolley is taken back to the unpacking area outside of the OR and the contaminated instruments are placed in their trays and onto a transport trolley, starting another Instrument Reprocessing Cycle.

### 1.3.2 Defective Instruments in the OR

After sterilization, packages cannot be opened until they arrive at the OR in order to ensure they remain sterile. The CSSD is therefore responsible for removing damaged instruments from the reprocessing cycle. Under perfect circumstances, not a single defective instrument should reach the OR.
In the occurrence of a defective instrument during a procedure in the OR, the surgical team will discuss if it is possible to replace the defective instrument. If this is not possible, the team will determine if the instrument is still adequate to perform the procedure, or decide to delay the procedure if no replacing instruments are available immediately.

The defective instrument is then labeled defective with a short description and then sent back to the CSSD. The contaminated instrument has to be cleaned first and is then taken out of the reprocessing cycle, either to be repaired or to be discarded. A replacing instrument will be added to the hospital's instrument inventory as soon as possible.

# Chapter 2

# Problem Definition

## 2.1 Defective Rigid Endoscopes reaching the OR

As has been stated in the introduction, rigid endoscopes enable the surgeon to visualize the surgical field which is essential to the success of MIS procedures. In conventional (open) surgery, the quality of a surgical procedure is directly related to the skills of the surgeon. MIS procedures depend heavily on dedicated medical devices to perform the procedures. The success of MIS procedures is therefore not just dependent on the surgeons' skills, but also highly dependent on properly functioning equipment. [8] [11] [34]

During the Instrument Reprocessing Cycle, the rigid endoscope is subject to a regular inspection by a CSSD employee. After this inspection the endoscope is packed for the sterilization process, only to be unpacked in the unpacking area next to the designated OR in preparation for clinical use.

Since a sterile instrument cannot be inspected after it has been sterilized in an autoclave until it is unpacked for clinical use, a defective rigid endoscope reaching the OR can have a number of causes:

- Failure of recognizing a defective endoscope during the inspection at the CSSD.
- Damage during transport to the OR
- Damage during unpacking for OR
- Damage through inappropriate use by surgeons and staff during the surgical procedures themselves

Once a defective rigid endoscope has reached the operating room, it may lead to one or multiple of the following consequences for patient safety:

- Direct harm to patient safety
  - Physical damage to the endoscope, such as sharp edges, may lead to internal cuts during surgery.
  - Unclear vision through the endoscope may lead to improper assessment of the surgical site and incorrect surgical actions.
  - Cross-contamination if the defective endoscope could not be sterilized properly.
- Indirect harm to patient safety
  - Frustration and stress for the OR team, possibly causing more errors.
  - Patient longer under anaesthesia.
  - Rescheduling of the procedure if no replacement endoscope is available.
  - In rare occasions an endoscopic procedure might be converted to open surgery if the surgeon sees no other option.

The following reports of defective rigid endoscopes reaching the operating room have been analyzed:

Verdaasdonk et al. report 58 cases of problems with technical equipment of which 1 defect endoscope in 30 laparoscopic cholecystectomies during a period of 6 months time. [31]

Courdier et al. report 58 cases of defective equipment of which 4 missing/damaged rigid endoscopes in 116 endoscopic interventions during a period of 3 months. They also state that despite current systems of control, equipment failure in endoscopic surgery in general is frequent and affects more then 1 in 3 interventions on average. [11]

Yasuhara et al. report 2656 endoscopic procedures during a period of 2 years. 14 cases of defective endoscopic instruments (including rigid scopes, fiberoptic endoscopes, endoscopic forceps, etc.) were found in the OR. 117 defective endoscopic instruments were found at in-house inspection. 346 defective endoscopic instruments were found at monthly manufacturer inspections. It is not specified how many defective rigid endoscopes were found. They also state that the in-house inspection for instruments for endoscopic surgery remains to be improved, and that a regular manufacturer inspection might be a minimal requirement for safe endoscopic surgery in current practices. [35]

Blikkendaal et al. report 202 surgical flow disturbances due to endoscopic devices and instruments in 40 endoscopic procedures during a period of 2 years. 5 were related to rigid endoscopes. Causes for surgical flow disturbance related to medical equipment can include malfunctioning, among other causes. [8]

Jung et al. report 28 Visual Device related interruptions, of which 8 Device Failures, in 210 endoscopic surgeries during a period of 2 years. Visual Devices in this study included laparoscopes (rigid endoscopes) and monitors. [22]

In order to guarantee the sterility of rigid endoscopes, it is impossible to inspect the instruments after they have been sterilized. To reduce the number of defect rigid endoscopes reaching the operating room, it is necessary to develop an objective testing method which does not significantly compromises or delay the current workflow at the CSSD.

## 2.2 Current Regulations and reports on Quality Control for Rigid Endoscopes

Even though the health care and medical device industries are highly regulated, there are currently no globally accepted reprocessing guidelines and procedures that include clear instructions for instrument inspection available for rigid endoscopes. The guidelines available are the general ISO standard for reprocessing Medical Devices (ISO 17664, [20]), general guidelines on Quality Control in Endoscopy Units [28], and guidelines provided by manufacturers, which can vary from

one manufacturer to another. These manufacturer guidelines on the inspection of rigid endoscopes have been described in chapter 1.3. Inspections of rigid endoscopes at most hospitals are regular but minimal and subjective, and research has shown that current in-house inspection does not guarantee safe endoscopic procedures. [35]

The lack of global standards and regulations is a major concern for the World Health Organisation (WHO), which started a global alliance for patient safety and quality improvement in healthcare in 2005. [5] In their "Summary of the evidence on patient safety" published in 2008 [21] it is stated that even though adverse medical device events are common, there is little information available on the actual severity of this problem. The WHO suggests in this report that without global interventions on measuring and reporting adverse medical device events, it will be impossible to improve patient safety around medical instruments and devices. The WHO Technology for Patient Safety program, a result from the global alliance on patient safety, includes a working group on making existing technologies safer. Control systems for medical technologies to ensure their safety is a global point of concern. [7] [26]

The lack of regulations on instruments and devices used in MIS procedures in the Netherlands have been described in two reports from projectgroup MICADO (Minimaal Invasieve Chirurgie Adequaat Door Ondersteuning) from 2008 and 2012, as a response to the Dutch Health Inspection raising questions about the underestimated risks involved in MIS in 2007. [9] [10] The MICADO report from 2012 states the following:

- Maintenance guidelines and procedures with regard to endoscopes and light cables from manufacturers are often insufficient or missing.
- Not all manufacturers are able to provide objective criteria and methods to inspect their instruments.
- In-house inspection must include basic inspection on image quality and light transmission as described in their protocol. Every other method available at the moment of writing this report involves too much time and interrupts the workflow of the CSSD. Objective tests are only possible when taking the rigid endoscope out of the Reprocessing Cycle.
- Future developments of objective test devices for rigid endoscopes seem necessary and promising.
- Quantitative data on factors reducing the lifespan of rigid endoscopes is necessary to implement standards and protocols.

## 2.3 Instrument level: Failure risks for rigid endoscopes

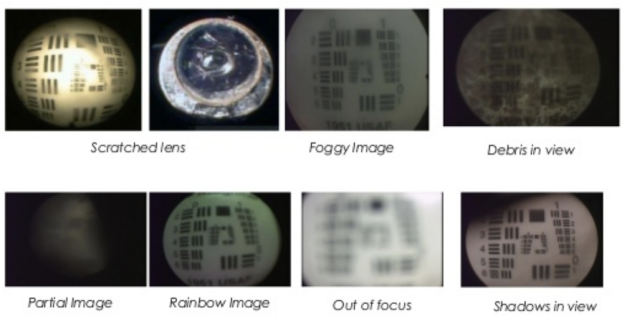


Figure 2.1: Poor image quality in rigid endoscopes

Failures reported with defective rigid endoscopes either involve poor image quality, illumination failure and/or mechanical failure. Figure 2.1 shows some examples of poor image quality in rigid endoscopes, directly affecting the primary purpose of the rigid endoscope which is providing a visual of the surgical field.

Illumination failure results in limited or no light reaching the surgical field, which also directly effects the primary purpose of a rigid endoscope. During current in-house inspections, signs of illumination failures might be detected as dark spots in the fiber bundle, burnt light cone or damage to the tip of the endoscope. Figure 2.2 shows some examples of detected illumination failure.


Figure 2.2: Signs of illumination failure

Mechanical failure refers to any physical damage to the device such as dents, broken welds, shaver damage and bent shafts. The consequences of mechanical failure can range from poor image quality and illumination failure, but also pose infection risks and physical harm to the patient.

### 2.3.1 General causes

Since there are no moving parts in a rigid endoscope, most failures are a result of someone or something doing something to the rigid endoscope.

#### Impact, shock or stress

During the instrument reprocessing cycle, a rigid endoscope is being handled by many different people, transported from one place to another, placed in and out of containers, washers, trolleys, etc. Some of the risks in this cycle can be minimized, but as it involves human work in every step of the cycle, human errors cannot be fully prevented.

For example, the rod lenses are easily damaged or misaligned either due to impact damage (dropping the endoscope) or by applying high torques on the shaft of the endoscope. These torques can be applied to the endoscopes shaft in all steps of the reprocessing cycle, such as:

- A surgeon using the endoscope to move tissue (inappropriate use) or see the surgical field from another angle which is not reachable without bending the endoscope
- A surgeon removing the endoscope from a working sheath at an angle instead of straight out.
- Placing something heavy on top of the endoscope while it is unprotected and ready for use on an instrument trolley in the OR
- Transporting, cleaning or processing the endoscope outside of a protective case and something heavy impacts it

Another commonly reported defect is shaver damage. Shaver damage can occur when an (orthopedic) surgeon damages the tip of the endoscope with a Shaver during the procedure. Mild shaver damage might result in scratches on the glass and the light fibers, diminishing the visual for the surgeon. Severe shaver damage might result in sharp edges, complete loss of vision and possibly breaking the epoxy seal between the glass tip and metal shaft. If the seal is broken, fluids can enter the endoscope. The sterility of the endoscope then cannot be guaranteed resulting in contamination risks for the patient. See figure 2.3 for an example of shaver damage and a broken rod lens.

Figure 2.3: Shaver Damage and a Broken Rod Lens

### Reprocessing

Most rigid endoscopes are autoclavable endoscopes. All manufacturers of autoclavable endoscopes will strictly state that their rigid endoscope can be sterilized, not flash sterilized (or ”immediate use sterilization”). Flash sterilization for rigid endoscopes results in a break in the epoxy seal between the glass and metal at the distal tip, allowing fluids to enter the endoscope and therefore breaking its sterility.

The regular steam sterilization process has the effect of accelerating aging and staining of the lenses due to the chemicals used and the heat and pressure applied to the rigid endoscope on a regular basis.

### Wear and tear

Wear and tear due to regular use of a rigid endoscope can include:

- Lens delamination: The rod lenses are aligned and fixated with an adhesive. This adhesive can lose its structure over time and after repeated steam sterilization, resulting in the lenses slowly separating.
- Light Fibre bundles deteriorate over time, often due to repeated steam sterilization and regular use.
- Joints/seals failure can cause leaking in different parts of the endoscope.
- The brass spacers between the rod lenses might flake off, casting off debris that is visible when looking through the endoscope. An example of this is shown in figure 2.4.

### 2.3.2 Specific risks at the CSSD

From field research in three hospitals in the Netherlands, the following risks at the CSSD have been noted:

- Time between procedure and pre-cleaning should be as short as possible, a longer time increases the risk of hardened soil and debris that becomes harder to clean, and increases difficulty to properly disassemble removable accessories such as light post adapters and working sheaths.

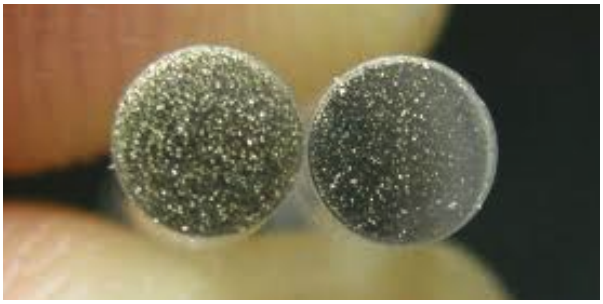

Figure 2.4: Brass flakes on rod lenses

- A rigid endoscope is not allowed to be pre-cleaned by ultrasonic waves as this can break the seals and allow fluids to enter.
- The manual inspection performed by a CSSD employee should be performed while properly handling the endoscope only by the eyepiece, never at the shaft.
- Forgetting to disassemble the light post adapter may result in corrosion and bio burden building up. This poses contamination risks but may also cause the loss of light intensity when this creates a debris film over the light post itself.

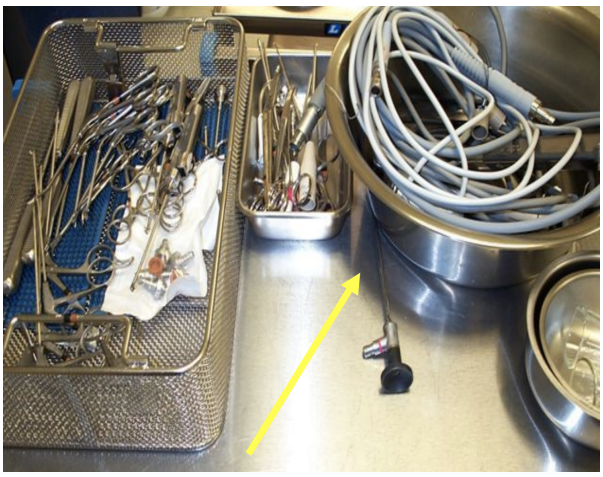

Figure 2.5: Basin placed on top of rigid endoscope

### 2.3.3 Specific risks at the OR

From field research in three hospitals in the Netherlands, the following risks at the OR have been noted:

- Stacking heavy items on top of endoscope while it is outside of its protective tray. See figure 2.5.
- During general use in the OR, the surgeon can damage the endoscope with other surgical instruments resulting in shaver damage or laser damage to the endoscope.
- Forgetting to disassemble the endoscope from the camera may result in another member of the OR team accidentally pulling on the camera cable and with that the endoscope might be damaged due to impact with other items or with the floor.

## 2.4 Thesis Statement

High quality rigid endoscopes are crucial for the success of any MIS procedure. These delicate instruments go through the reprocessing cycle after each clinical use, which imposes failure

risks along every step of this cycle. Current in-house inspection practices at the CSSD to detect defective rigid endoscopes reaching the operating room are subjective and are stated to be insufficient to guarantee safe endoscopic procedures, while the need for objective measurements and global regulations is raised on a global level by the WHO and on a national level by MICADO.

In order to address this problem, the failure risks for rigid endoscopes during the reprocessing cycle have been described in the previous section. The next step is to identify all measurable indicators of these failure risks, and define and analyze current objective testing methods for each quality indicator. The final step is to combine these testing methods for each quality indicator in one set-up to obtain objective results for each quality indicator.

Therefor, the challenge of this thesis is to: ”Develop an objective method to test the overall quality of rigid endoscopes at the CSSD.”

And answers the question: ”How to measure and ensure the quality of a rigid endoscope during the sterilization cycle in a hospital?”

## 2.5 Approach

To be able to answer the question stated above, relevant literature has been consulted and all parameters found that can be measured to indicate a deterioration of the overall quality of a rigid endoscope have been identified and categorized. In order to fill in the gaps of the literature research, the findings have been discussed during field research visiting the CSSD and OR of three hospitals in the Netherlands, with an optical expert in telescopes and working together with an endoscope repair and manufacturing company. Research to the current state of the art in testing methods developed for rigid endoscopes has been done and described in chapter 4. The included quality indicators for each testing device have been summarized in table 4.1.

Finally, a test set-up combining nine quality indicators of optical quality in rigid endoscopes has been developed and an experiment testing high quality and low quality rigid endoscopes has been performed at ERPA Instruments. The quantitative results for six of these quality indicators have been analyzed and discussed in the research paper accompanying this master thesis.

# Chapter 3

# Quality Indicators for Rigid Endoscopes

## 3.1 Introduction

Based on extensive analysis of, and discussions about the results of literature studies, field research in three hospitals in the Netherlands and with the help of an endoscope repair company and optical experts, this chapter provides an overview of the aspects of a rigid endoscope that provide insights on the deterioration of the overall quality of a rigid endoscope. For this thesis these aspects have been named: Quality Indicators for Rigid Endoscopes.

As has been described in chapter 2, failures reported with defective rigid endoscopes generally involve either mechanical failure, poor image quality and/or illumination failure. The quality indicators have been divided over these three types of failures.

## 3.2 Mechanical failure - Quality Indicators

### 3.2.1 Fluid/Moisture due to Leakage

**Definition:**
To prevent cross-contamination between surgical instruments, a rigid endoscope needs to be completely closed to any fluids to enter the instrument. Seals are welded with special procedures or closed with epoxy to ensure the fluids do not enter the endoscope. [16] A broken seal results in the possibility of contaminated fluids entering the rigid endoscope at any step of the reprocessing cycle. Once this has happened, the CSSD cannot guarantee the sterility of the instrument and the rigid endoscope must be send out for repair before it can continue in the reprocessing cycle.

Seals can be broken due to a number of reasons:

- Flash sterilization, or ”immediate use sterilization”, is a process of quickly heating up and cooling down which places excessive stress on seals between dissimilar materials in a rigid endoscope such as metals and glass. These seals are then easily broken down in the process, allowing fluids to enter through the cracks.
- Bending an endoscope shaft can result in the separation of the shaft from the body, the eyepiece, of the endoscope and with that allowing fluids to enter the instrument.
- Dropping an endoscope can cause cracks in the eyepiece or in the epoxy separation between glass and shaft at the distal end of the endoscope, creating a pathway for fluids to enter the instrument.

Fluids inside the rigid endoscope can be detected as it forms condensation on one of the lenses inside the total lens system.

**Relevance:**
The number one responsibility of the CSSD is to provide sterile instruments ready for surgery. Detecting potentially contaminated instruments before they reach the OR is therefore crucial.

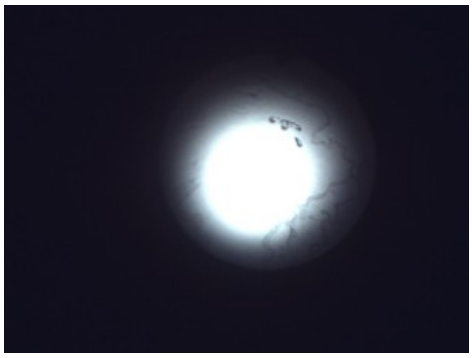

Figure 3.1: Endoscopic image with stains due to fluid damage

**Measurement method:**
A manual inspection of the weld between the shaft and the eyepiece, the distal end and the proximal lens at the eyepiece should already be a part of the testing procedure of every rigid endoscope at a CSSD. Fluid invasion without mechanical damage is considered a manufacturers defect.

Fluids that have entered the optical system of the rigid endoscope can be detected in condensed form or fluid form. When fluids have condensed onto one or multiple lenses, the projected image through the endoscope will (partially) be blurry and have a lower contrast. Measurements of sharpness and contrast will be discussed later in this chapter. Still in fluid form, fluids can form spots or stains on the lenses. An example of the projected image from an endoscope with fluid damage can be seen in figure 3.1. Very rarely, a rainbow effect or a pinkish glow can be detected, specifically when looking at the individual rod lenses with an extra optical system such as EndoScan by Lighthouse Imaging (see figure 4.7).

Unfortunately, fluids in other parts of the rigid endoscope currently cannot be measured or detected. A rigid endoscope with visible damage to its exterior should therefore always be taken out for repair to be able to guarantee the sterility of a rigid endoscope after sterilization, even if no fluid invasion can be detected. An optimal method to detect moisture inside rigid endoscopes has not yet been described.

### 3.2.2 Damaged Distal Tip

**Definition:**
The current regular testing procedure at the CSSD involves a visual inspection of the outer appearance of an endoscope. Damaged distal tips are often the result of surgical instruments shaving the tip of the endoscope during surgery, flash sterilization, impact due to bumping into objects or drops on the floor.

The distal window can also contain dried up debris from previous clinical use that was not properly removed in the initial cleaning process before inspection at the CSSD.

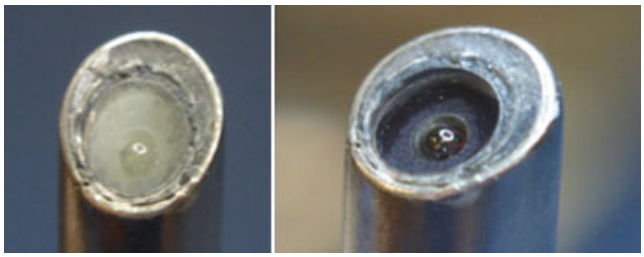

Figure 3.2: Damaged and dirty distal windows

**Relevance:**
Damage to the distal end of the endoscope can result in internal injury, poor visualization and/or contamination risks for patients. [16]

Failing to notice a foggy distal window due to dried up debris might result in poor visualization and contamination risks during the next clinical use.

**Measurement method:**
An objective and quantitative measurement method for this has not yet been developed. A proposal for this is described in the discussion of this report.

### 3.2.3 Bent shaft

**Definition:**
A rigid endoscope has a relatively long and thin shaft which has a durably appearance due to the rigid steel tubes used in its construction. This shaft seems durable but the rod lenses and illumination fibers inside are sensitive to impact and bending and/or torsion forces. In all steps of the reprocessing cycle measures have to be taken to protect the rigid endoscope from bending its shaft.

Figure 3.3: A rigid endoscope is not supposed to bend!

**Relevance:**
During clinical use, a rigid endoscope often needs to fit through trocars, housings and other tubes used in surgery. For practical reasons alone, a rigid endoscope with a bent shaft that cannot be fitted through the aforementioned instruments will need to be sent away for repair. An endoscope with a bent shaft as such may also have compromised seals along the welds between the shaft and the oculair, as has been described in section 3.2.1.

However, smaller deviations can also be troublesome, since the light fibers and rod lenses inside the steel shaft will have been affected by the cause of the bent shaft. Illumination fibers are bundled together, when the shaft is bent these fibers can be damaged, resulting in either a loss of light all together or a discoloration of the light send towards the target area. Rod lenses can easily snap and break when the shaft is bent.

**Measurement method:**
A clearly bent shaft is easily spotted during a visual inspection of the rigid endoscope. Smaller deviations can be detected by carefully rolling the endoscope over a flat surface such as the working desk of the CSSD employees. When mounting a rigid endoscope onto a measuring set-up, the alignment of the endoscope must be checked before other measurements take place. This can be done either manually or automatically with the aid of, for example, force sensors that detect the applied force of the bent shaft while trying to move the endoscope through a target hole. A straight shaft should not apply any force when moving through the target hole.

## 3.3 Optical failure - Quality Indicators

### 3.3.1 Fractures in the lenses

**Definition:**
As is described in the section 1.2, the total lens system consists of two lens assemblies at the proximal and distal ends of the rigid endoscope, enclosing the lens train which includes a series of rod lenses. The complete lens system inside a rigid endoscope is complex, meaning a minor shift of one lens can disturb the overall image quality, and fragile, meaning the lenses can fracture easily. Fractures occur mostly through impact when the endoscope is dropped or through bending/torsion of the shaft of the endoscope.

Fractures are seen in both lens assemblies at the proximal and distal end of the endoscope, and in the rod lenses in the shaft of the rigid endoscope. [17] A collection of complete and broken rod lenses can be seen in figure 3.4.

Figure 3.4: Rod lenses of different sizes, including two broken pieces.

**Relevance:**
The direct impact of a broken lens anywhere in the lens system of a rigid endoscope can be a hairline crack visible in the image, a partially obstructed image or a completely dark image. Indirectly, a broken lens in the objective lens assembly, such as the distal window, might also result in contamination risks if fluids are able to enter the shaft of the endoscope. A broken lens in the rod lenses might also be a result of impact or bending/torsion of the endoscope, which on its own can also cause a break in the welded seals, causing a fluid leakage. Even if a broken lens

only partially obstructs the image seen through the instrument, an underlying problem might not be recognized. An endoscope with broken lenses needs to be repaired before it can be used in clinical practice again.

**Measurement method:**
In theory, most fractures in a system of lenses should be visible at least as a hairline when inspecting the image projected through that system with proper light. However, since the lenses are placed in a tube and the lens properties near the center of the lenses is more uniform compared to closer to the edges, usually the image projected through the lens system of a rigid endoscope comes only through the center of the lenses. In other words, this is a permanent aperture stop to unify the lens properties as much as possible. A fracture near the edges of a lens can therefore easily be missed.

There are different techniques to inspect a lens system on fractures:

One technique includes an extra set of lenses such as in the EndoScan by Lighthouse Imaging (see figure 4.7), enables you to project the image of each lens in the lens system and inspect it on fractures, dirt/debris on the surfaces and adhesive degradation.


Figure 3.5: EndoScan by Lighthouse Imaging

Another technique involves bundles of light directed from different angles into the objective lens assembly at the distal end of the endoscope. Usually, light enters from the surgical field into the complete field of view, and the optical system inside the endoscope is designed in such a way that it will project the total field of view into an image. See figure 3.6 for a schematic overview of the optical layout, simplified with just two rod lenses in the lens train.

If all light entering the optical system travels through a broken lens, this is clearly visible on the final projected image. If only a small amount of light entering the optical system travels through a broken (part of) a lens, this might not be clearly visible on the final projected image. In this case, the majority of the light entering the optical system travelled through lenses in good condition, and will be able to project the final image without clear disturbances.
When light is entered from one specific angle on an edge of the field of view, it will travel over a specific path through the lens system. If this specific path runs through a broken lens, the final image will be influenced by this. With this technique it is possible to detect smaller fractures away from the center of the lenses that otherwise can be missed.

### 3.3.2 Direction of View

**Definition:**
The Direction Of View (also called: Angle of View) is the angle between the optical axis (the center of the visual field) and the longitudinal axis of the shaft of the endoscope. This angle can vary from 0°(looking straight forward), 30°(forward-oblique),

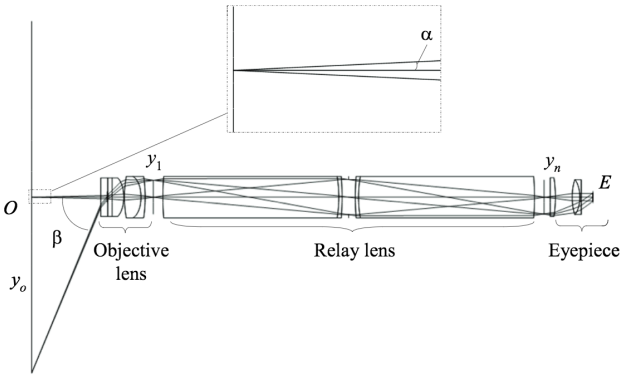


Figure 3.6: Schematic overview of a typical optical layout of a rigid endoscope with a Hopkins Rod Lens system. It consists of the three types of lens systems: the objective lens assembly, the lens train or relay lenses, and the ocular lens assembly located in the eyepiece. $y_0$ is the height of the target area, defines the field of view, $y_1$ and $y_n$ is the image height at specific points in the optical layout, and E is the location of the observer's pupil or the camera sensor.

45°(oblique), 90°(side view), 120°(retrograde). See figure 3.8. Other directions of view are also available on the market.

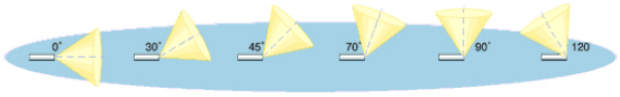


Figure 3.7: Different Direction of View angles available for rigid endoscopes

The Direction of View is important for the user (the surgeon). In many procedures there are limited options for the entry point of the endoscope as the target area for the procedure must be visible through the endoscope. An endoscope with the required Direction of View is ordered before each clinical use. This can depend both on the type of procedure and on the user's preferences.

The Direction of View of an endoscope is set by the manufacturer and is not supposed to change over time. Most endoscopes have the Direction of View engraved on the eyepiece and/or indicated by a colored ring around the eyepiece.

**Relevance:**
It is generally known that the Direction of View of a brand new rigid endoscope might be off by approximately 5°either positively or negatively. This is commonly not seen as a defect, and surgeons have accepted these deviations and often are able to work without any problem with these instruments.

There are cases in which the lenses in the objective lens assembly are damaged in such a way that the Direction of View has changed. If the actual Direction of View does not correspond with the Direction of View determined by the manufacturer, the user might not be able to see the target area properly through the endoscope and will have difficulty performing the procedure. Also, since the Direction of View is not supposed to change after manufacturing, a change in the Direction of View often implies more damage to the endoscope, even if this cannot be detected by a manual inspection.

Lastly, to be able to properly measure other optic Quality Indicators such as sharpness and distortion, it is crucial to place the targets used for these measurements parallel to the distal window.

**Measurement method:**
The Direction of View of a rigid endoscope can be determined by looking through the endoscope towards a target with a pattern that enables you to center the endoscope's image on the center of the target. For example, this can be a target with multiple circles around a center point, each with a bigger diameter then the last. The target should be positioned in such a way that the outer visible circle coincides with the edge of the image visible through the endoscope. Moving the target closer and further to the distal end of the endoscope will provide feedback about the Direction of View of the endoscope. If the the target is not parallel to the distal window of the endoscope, the center point of the target will move out of the center of the image seen through the endoscope when moving the target closer and further away. Re-adjust until the center point of the target stays in the center of the endoscope's image.

Once the target is in the correct position seen through the endoscope, the position of the target can be determined and gives the Direction of View of that endoscope.

### 3.3.3 Field of View

**Definition:**
The (angular) Field of View (FOV) is defined as the angle in object space over which objects are viewed, or recorded on for example a video sensor. At a given distance from the lens, the larger the Field of View, the greater the diameter of the image that can be observed through the lens.

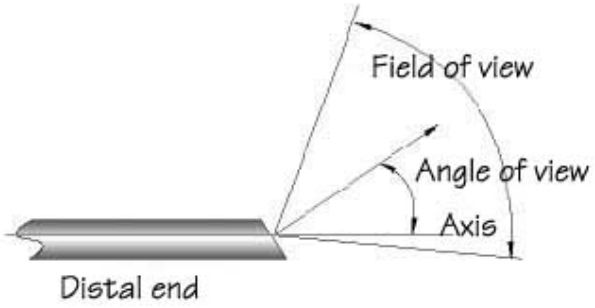


Figure 3.8: Field of View & Angle of View relative to the axis of the distal end of an endoscope

Rigid endoscopes often have a relatively wide FOV to compensate for the restricted space and the range of motion required during a procedure in the operating room. Endoscopes with a smaller FOV require moving and refocusing the endoscope frequently, which results in complicated hand-eye coordination and increases the procedure time.
The FOV of rigid endoscopes ranges usually from 70°to 110°. The FOV of an endoscope is dependent on the focal length of the lens system inside the endoscope and is limited by the aperture stop. When projecting the image onto an image sensor, the physical size of the image sensor can also be a limiting factor. See figure 3.9. For a given focal length and image sensor size, the FOV is always constant.

The working distance for most rigid endoscopes is 20mm distance from the distal end. Only for laparoscopes (with a FOV of approximately 70°) the working distance for the target area is usually 40mm.

**Relevance:**
Similarly to the Direction of View, the Field of View of a rigid endoscope is set by the manufacturers' design and is not supposed to change over time. The measured FOV can

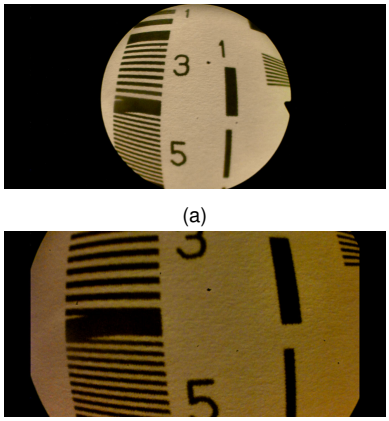


Figure 3.9: (a) Field of view diameter fits exactly on image sensor. (b) Field of view does not fit on image sensor.

deviate slightly from the FOV listed by the manufacturer. This is commonly not seen as a defect.

A change in the measured FOV is often an indication for other defects, such as damage to the objective lenses at the distal end or displaced or broken rod lenses. If the current Field of View does not correspond with the Field of View determined by the manufacturer, the user might not be able to see the target area properly through the endoscope and might have difficulty performing the procedure.

**Measurement method:**
ISO 8600-3 describes the current standard for determining the Field of View of an endoscope. ISO 8600-3 defines FOV as "view of an endoscope with optics as stated by the manufacturer or distributor, expressed as the vertex angle (in degrees) of the cone whose vertex is at the distal window surface (WS) of the endoscope". [18]

Wang et al. have described a more accurate measurement method for measuring FOV of endoscopes, since in practice the cone vertex of the FOV of an endoscope is rarely located at the distal WS. The FOV calculated from the WS overestimates the FOV in general, see figure 3.10. [32]

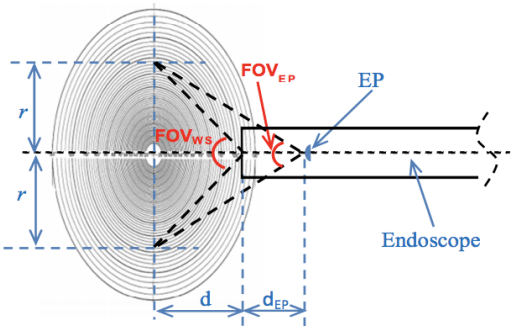


Figure 3.10: FOV angle determined from WS and FOV angle determined from Entrance Pupil [32]

The method described in ISO 8600-3 is in general acceptable for endoscopes whose entrance pupil is located at the distal WS, or endoscopes with a working distance much longer then the distance between the distal WS and the entrance pupil. The method described by Wang et al. is especially accurate for endoscopes with a short working distance and a relatively long distance between the distal WS andd the entrance pupil.

### 3.3.4 Sharpness

**Definition:**
Sharpness quantifies the amount of detail a complete imaging system can reproduce. This makes it arguably one of the most important quality indicators for (medical) imaging systems. The complete imaging system for rigid endoscopes consists of the lenses inside the endoscope, the lenses in the coupler and the camera sensor. Sharpness is further defined by the boundaries between contrasting colors. A sharp image has clear, crisp boundaries between two different tones or colors, with high edge contrast. Unsharp images, images with a low resolution, lack detail and show blurring.
When reproducing an image with a complete image system as described above, all lenses will degrade that image to some degree, some more then others. This is illustrated in figure 3.11. [15]

Figure 3.11: Top: Bar pattern; Bottom: bar pattern with lens degradation [15]

Sharpness of a reproduced image is also dependent on the amount of pixels on a camera sensor. The image travels through the rigid endoscope and coupler onto the camera sensor. A minimum of two pixels per line pair is needed: one pixel is used for the dark line and the other pixel for the blank space between the lines. The image resolution (Line pairs per distance (mm, pixels, image height)) in this case is equal to twice its pixel size. See figure 3.12 for an example.

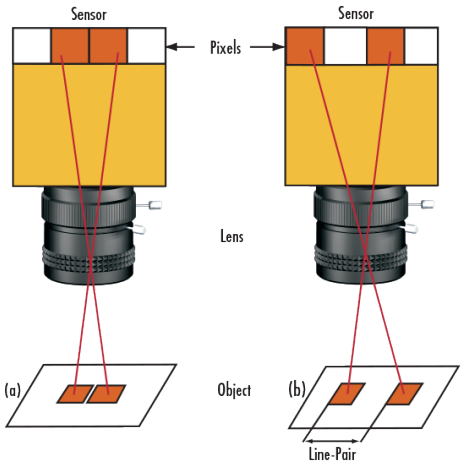


Figure 3.12: (a) Line pair is not visible on image sensor.
(b) Line pair is visible on image sensor [14]

**Relevance:**
The sharpness of the image is (one of) the most important quality indicator for rigid endoscopes. Surgeons are heavily dependent on the amount of detail in the image of their working area to successfully perform MIS procedures. Lack of sharpness can result in unintentionally damaging healthy tissue, misdiagnoses, failing to notice area's of interest and many more. On top of the direct patient harm, an unsharp image often results in frustration among the OR team with all its consequences.

**Measurement method:**
Sharpness can be quantified using the Modular Transfer Functions (MTF). Sharpness is calculated in the frequency domain. The spatial frequency is then described in line pairs (where one line-pair is one black line and one white line next to each other) per distance (mm, pixels or image height).

Low (or zero) spatial frequency (i.e. broad stripes) allows for a contrast of (nearly) 100%. The higher the spatial frequency, the lower the contrast. The spatial frequency at which the contrast has dropped to 50% is called MTF50. MTF50 correlates closely with perceived sharpness and is commonly determined to compare image sharpness. MTF10, the spatial frequency at which contrast has dropped to 10%, is the spatial frequency at which the human eye cannot distinquish lines anymore, resulting in a blur. Multiple methods for measuring the spatial frequency exists, one of which is the slanted edge method. A more thorough explanation on the slanted edge method to determine MTF has been described in Appendix A.

To measure the Sharpness of the lenssystem of a rigid endoscope, the spatial frequency at which contrast has dropped to 50% (MTF50) will be calculated for a minimum of five Region's Of Interest (ROI): one ROI is located at the center of the image, the other four ROI's are located at an equal distance from the center at the top, bottom, left and right of the image. The calculated values are either above or below an acceptable threshold. Calculating the standard deviation between the ROI's also determines if one ROI has a lower sharpness compared to other area's of the image.

A checkerboard target with black and white squares tilted slightly (4 to 6 degrees) will be used to determine the MTF50 value for at least 5 ROI's for a horizontal and a vertical edge on the checkerboard. See figure 3.13. A detailed explanation of this technique can be found in Appendix A.

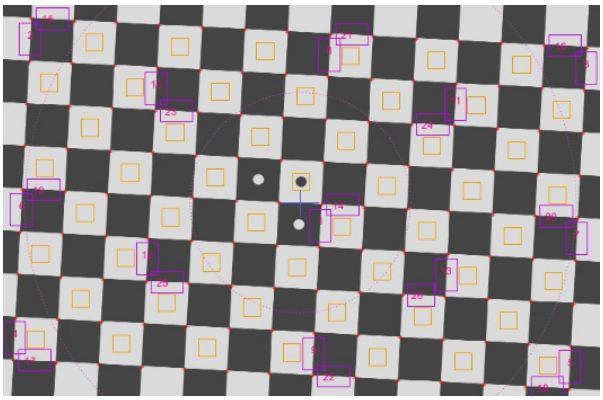

Figure 3.13: Checkerboard with Regions of Interest. Image Source: Imatest Software

### 3.3.5 Contrast

**Definition:**
Contrast defines the relative difference between dark and light areas. White gives the maximum value for the amount of light, black gives the minimum value for the amount of light. An example of this is shown in figure 3.14.

An image of an object traveling through a lens or lens system onto an image sensor is subject to the lens degradation already discussed in section 3.3.4 (Sharpness). Keeping this in mind, contrast, or modulation, can then be described as how correct the maximum and minimum amounts of light are transferred from the object to the image sensor.

**Relevance:**
The relevance to have high contrast and sharpness in a medical imaging system are highly correlating. High contrast is

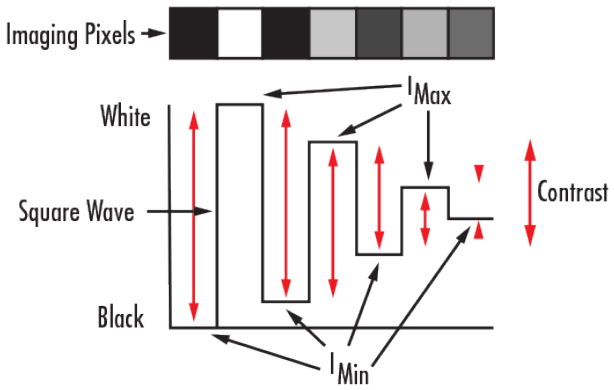


Figure 3.14: Contrast for several grey tones

necessary to produce the highest amount of detail, and therefore just as important as sharpness is. The risks and consequences are similar as well.

**Measurement method:**
Mathematically, contrast can be calculated using the following equation:

$$\% \text{ Contrast} = \left[\frac{(lmax - lmin)}{(lmax + lmin)}\right] \text{ x } 100 \qquad (3.1)$$

with lmax being the maximum amount of light measured and lmin being the minimum amount of light measured.

Figure 3.15 shows an object (left) with a certain spatial frequency. When this object travels through the lens assembly, it is projected as an image (right) with a decreased contrast.

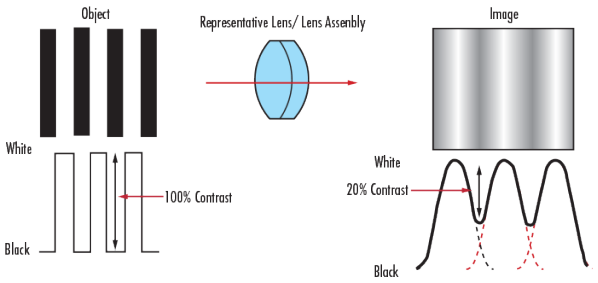


Figure 3.15: Contrast comparison for the original object (left) and the image (right) through the lens

Using the same checkerboard target as will be used to calculate the spatial frequency MTF50 can be used to calculate contrast. RGB values of dark and light area's will be determined after the image has been reproduced on the camera sensor, and with the abovementioned formula the contrast will be determined.

### 3.3.6 Vignetting withing a lens

**Definition:**
Vignetting is the reduction of an image's illumination towards the periphery (edge of the image) compared to the image center. This phenomenon can have multiple causes. Relevant for rigid endoscopes is vignetting due to light rays from an object entering the lens system but failing to exit the lens system onto the sensor. These light rays might be blocked by the edge of one of the lenses inside the lens system or by mechanical/physical stops inside this system. See figure 3.16. Blocking of light rays results in less light on the camera sensor, creating a darker periphery on the image taken.

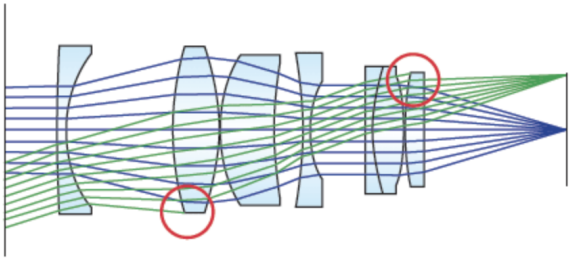

Figure 3.16: Light rays cut off by lens edges resulting in vignetting on the sensor

**Relevance:**
The surgeons available sight of the target area is already limited by the field of view of the rigid endoscope. If the lenssystem starts showing any signs of vignetting, regardless of its cause, this limits the field of view even further.
However, increased vignetting usually is a sign for damage in the lenssystem, such as a broken lens, shifted lenses, etc.

**Measurement method:**
To measure the amount of vignetting of a lens system a calibrated white target with a calibrated and even illumination should be used. The light fibers inside the rigid endoscopes should not have an active light source attached. By taking an image through the lens system of a white target, the luminance per pixel will be calculated and used to create a luminance contour plot. An example of such a plot is shown in figure 3.17.

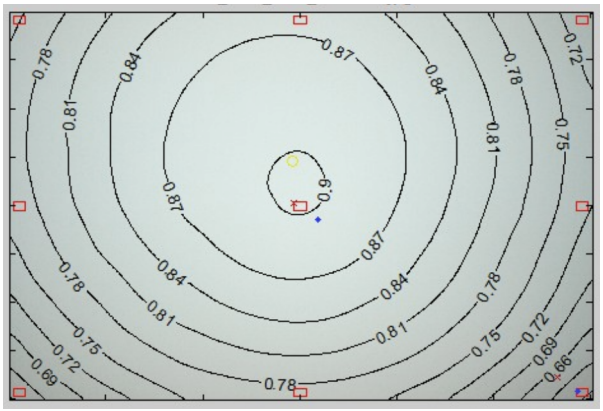


Figure 3.17: Example of a luminance contour plot to determine the amount of vignetting. Source: Imatest Software

### 3.3.7 Distortion

**Definition:**
In geometric optics, distortion is a deviation from rectilinear projection (a projection in which straight lines in a scene remain straight in an image). In contrast to most quality indicators discussed in this chapter, distortion does not actually reduce information in the image, the information is simply displaced geometrically. Only in extremely high distortion area's information and detail can be lost due to too much information compressed onto a single pixel.

**Relevance:**
All lenssystems in rigid endoscopes show some sign of distortion, some more then others. For example, a laparoscope generally has little distortion, where arthroscopes generally

have quite some distortion as a standard. A change in the distortion is often a sign of damaged or displaced lenses in the system.

**Measurement method:**
Distortion is often described as a percentage of the chosen fields' height. In simple lenses, two main typed of distortion can be measured: negative distortion (barrel distortion), where points in the chosen field appear closer to the center then they actually are, and positive distortion (pincushion distortion), where the points in the chosen field appear further away then they actually are. See figure 3.18 for an example of this.

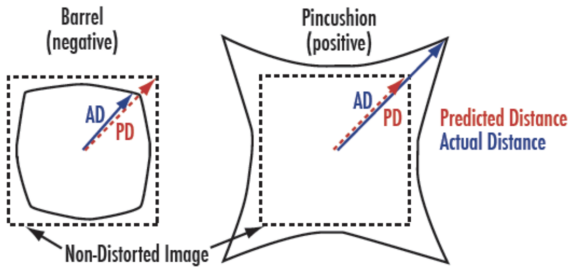


Figure 3.18: Illustration of negative and positive distortion

As can be seen in figure 3.18, distortion can be calculated the relation between the Actual Distance (AD) and the Predicted Distance (PD). See equation 3.2.

$$\text{Distortion (\%)} = \frac{AD - PD}{PD} \text{ x } 100 \tag{3.2}$$

More often in photographic systems, radial distortion is calculated using the following 3rd order equation seen in equation 3.3.

$$r_u = r_d + kr_d^3 \tag{3.3}$$

where $r_d$ is the distorted radius of the image taken through the rigid endoscope, which can be determined by the amount of squares visible, and $r_u$ is the undistorted radius of the checkerboard target. If the value k equals 0, there is no distortion in the image.

Even though distortion generally is either positive or negative in a lens (system), it is not necessarily linear in the entire image. Wavelength changes, changes in working distance and multi-element lens assemblies can all change the level of distortion in an image.

### 3.3.8 Colour Correctness: Lens system

**Definition:**
After many sterilization cycles where a rigid endoscope endures major temperature differences, the glue between the rod lenses inside the lens train of the endoscope can change color. This results in a yellow/brown image with a reduced contrast. This discoloration can be seen as regular use degradation.

**Relevance:**
The quality of rigid endoscopes is often deteriorated by impact far before the discoloration of the glue becomes apparent due to general use. It is however important to quantify the colour correctness to ensure high quality instruments are used during MIS procedures, and low quality instruments are repaired when necessary, even though the instruments might not be externally damaged.

**Measurement method:**
Using the same setup when measuring the amount of vignetting and shadowing (See 3.3.6 and 3.3.7), it is possible to measure the colors in the image recorded on the image sensor. A software algorithm can calculate the deviation from the calibrated white target and compare with earlier measurements to find the relative degradation.

### 3.3.9 Light Transmittance: Lens system

**Definition:**
A rigid endoscope has two pathways for light: one pathway from the external light source through the light fibers towards the target area, and another pathway from the target area through the lens system onto the camera sensor. The less light is transmitted from the target area to the camera sensor, the darker the image.

**Relevance:**
A clear and sharp image of the target area is necessary to successfully perform MIS surgery. The darker the image, the lower the contrast which results in similar risks as has been described for Sharpness and Contrast.

**Measurement method:**
Using the same setup when measuring the amount of vignetting and shadowing (See 3.3.6 and 3.3.7), the light transmittance of the lens system can be calculated by measuring the luminance per pixel. To check for irregularities, this will be calculated for a minimum of five Region's Of Interest (ROI): one ROI is located at the center of the image, the other four ROI's are located at an equal distance from the center at the top, bottom, left and right of the image. The calculated values are either above or below an acceptable threshold for light transmittance. Calculating the standard deviation between the ROI's also determines if one ROI has a lower light transmittance compared to other area's of the image.

## 3.4 Illumination failure - Quality Indicators

### 3.4.1 Light Transmittance: Light fibers

**Definition:**
If a light fiber is not only damaged but completely broken, this fiber cannot transmit any light of any wavelength towards the target area. If this happens for a small number of fibers, the impact on the performance during surgery is nihil. The more fibers are broken, the less light is transmitted onto the target area, eventually resulting in a darker image for the surgeon to work with.

Current guidelines for light fibers in rigid endoscopes state that the rigid endoscope should be sent out for repair when 30% of the light fibers are damaged or broken. This is often visually inspected, by checking for dark spots on the light post.

**Relevance:**
A clear and sharp image of the target area is necessary to successfully perform MIS surgery. The darker the image, the lower the contrast which results in similar risks as has been described for Sharpness and Contrast.

**Measurement method:**
A calibrated cold light source producing white light serves as the light input. A (PIN) photodiode is then used to measure the light output. Photodiodes are semiconductors that convert light into an electrical current, which is proportional to the amount of light it detects and therefor the light output can be quantified.

### 3.4.2 Colour Correctness: Light fibers

**Definition:**
Light travelling from the external light source trough the light fibers onto the target area should be bright white light. White light is build up of many different wavelengths that all together project as white. When certain wavelengths cannot travel through the light fibers, the output light onto the target area will not be white.

Simplifying the colour spectrum, the three main colours in this spectrum are red, green and blue. Red light has the longest wavelengths, green light has shorter wavelengths compared to red light, and blue light has the shortest wavelengths of these three main colours. See figure 3.19.

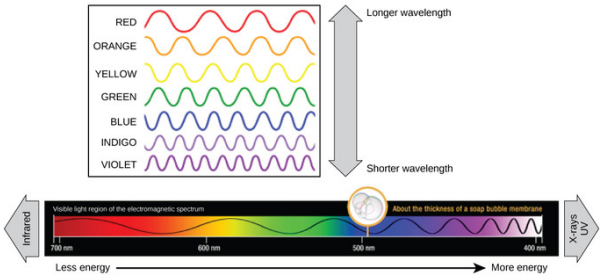


Figure 3.19: Wavelengths of different colours in the colour spectrum

It is possible for a damaged light fiber to still allow longer wavelengths of light to pass but shorter wavelengths of light to be blocked, resulting in a predominantly red image with lower contrast over time.

**Relevance:**
A clear and sharp image of the target area is necessary to successfully perform MIS surgery. The lower the contrast is, the higher the risks are. Low contrast due to light fiber damage results in similar risks as have been described for Sharpness and Contrast.

**Measurement method:**
To analyze the color spectrum of the light transmitted through the light fibers, the same method to quantify the light transmission of the light fibers is used but not with white light but with calibrated red light, green light and blue light. For all these colours the transmission is measured, which indicates the ability of different wavelengths of light travelling through the fibers.
This technique is widely accepted to measure light intensity and is therefor recommended to pursue during further research.

### 3.4.3 Shadowing

**Definition:**
Where vignetting is the term for darker edges in an image due to the lens system, shadowing is a phenomenon that is related to the light from the light fibers in the rigid endoscope. The light fiber bundle should shine in the same direction as the direction of view, and should be just wider then the field of view, in order to have concentrated light on the target area seen through the lenses.

If the light bundle shines in a different angle then the direction of view, there will be a shadow on one side of the image. If the light bundle is smaller then the field of view, shadows similar to a vignetting pattern will be seen on the image. If the light bundle is much bigger then the field of view, the light rays are more spread out and the overall image is darker then expected.

**Relevance:**
The surgeons available sight of the target area is already limited by the field of view of the rigid endoscope. Similar to the relevance of vignetting: If the lenssystem starts showing any signs of shadowing, regardless of its cause, this limits the field of view even further.
However, increased vignetting usually is a sign for damage in the light fibers. This can be a result of shaver damage during surgery, damage to the tip during transport or reprocessing or bending/impact on the shaft of the endoscope.

**Measurement method:**
The measurement method of shadowing is similar to the measurement method of vignetting. To measure shadowing it is necessary to illuminate the target by the light rays from the light fibers from the rigid endoscope.

# Chapter 4

# State of the Art: Quality Assurance Methods & Devices for Rigid Endoscopes

Testing a rigid endoscopes happens regularly in the clean room of the CSSD at a hospital. Repair companies of (rigid) endoscopes also test and check their incoming and outgoing endoscopes. This chapter describes the common practices and currently available devices for testing a rigid endoscope on certain Quality Indicators.

## 4.1 Current practice: Manual Post Cleaning Inspection

Recommended practices and guidelines for post cleaning inspection and function testing often state: "Telescopes and light cables should be function checked as per manufacturers' instructions." [2]

### 4.1.1 Manufacturer's instructions

Rigid Endoscope manufacturers often provide brief and subjective instructions for the inspection of their products.

Karl Storz provides the following instructions for the inspection of their rigid endoscopes:

- The cleaned and disinfected medical device must be visually inspected for cleanliness, completeness, damage and dryness:
  - If residues or contamination are still present, the medical device must be manually re-cleaned and subjected to another full cleaning and disinfection procedure.
  - Damaged or corroded medical devices must be withdrawn from use.
  - Dismantled medical devices must be assembled.
  - Afterwards, a functional check must be carried out.

Richard Wolf provides the following instructions for the inspection of their rigid endoscopes:

- Inspect Physical Integrity:
  - Scope Shaft: dents, bends, laser burns
  - Eyepiece: Cracks, scratches, loose epoxy, fogging or water under the lens. Check clarity by viewing through eyepiece on image 5-6" away.
  - Distal Lens: cracks, scratches, loose epoxy fogging or water under the lens.
  - Fiber optics light carrier: hold scope straight up to ceiling light, look into light post. If more than 30% black spots, send for repair.
- Inspect for cleanliness:
  - Scope surface, channels
  - Eyepiece and distal lens: wide with 70% alcohol swab or pad.
  - Light post and light post adapter

These instructions are interpreted by each individual medical institution and incorporated in the post cleaning inspection protocols for the CSSD employees of that institution.

### 4.1.2 General practices

A proper post cleaning inspection of a rigid endoscope generally includes:

Physical Damage:

- Check for scratched and dents on distal- and proximal glass surfaces. The glass surfaces must be clean and free from deposit layers. If at the time of visual inspection of the glass covers you notice stubborn encrusting, these can be removed using appropriate cleaning liquids.
- All surfaces should appear flat, shiny and without distortion. Surfaces should not have any sharp edges, scratches and/or dents. Bent or loose components should be repaired immediately prior to use.

Optics:

- Look through the rigid endoscope (proximal end) into the light while rotating the rigid endoscope. The image should remain clear and sharp. Aim the rigid endoscope at a target at the corresponding working distance. Again, the image should be clear and sharp.
- Moisture inside the rigid endoscope as well as damaged rod lenses cause a cloudy/hazy image or complete loss of the image.

Light Transmission:

- Hold one side of the fiber optic (e.g. the distal endoscope end) in the direction of a bright ceiling lamp. View the other side (light connection) holding it relatively close to the eye. The individual fibers must now appear to be bright. Move the side held against the lamp a little. The brightness of the fibers might change a little. If more than 30% of the fibers remain dark, it is difficult to work with the rigid endoscope and it must be sent out for repair.
- The surfaces of the light inlets and outlets should be smooth and clean. If the surfaces show certain deposit layers, or rough fibers can be felt or are withdrawn, this can lead to inadequate illumination.

## 4.2 Test Devices - Lens & Fiber Quality

There are a few test devices developed for testing rigid endoscopes on both Optical Quality Indicators as well as Illumination Quality Indicators.

### 4.2.1 Lighthouse Imaging - EndoBench

The EndoBench by Lighthouse Imaging is an endoscope image quality test system intended for endoscope manufacturing and repair quality control testing. The EndoBench is available in both a portable system and a bench-mounted system. Figure 4.1 shows the bench-mounted system.

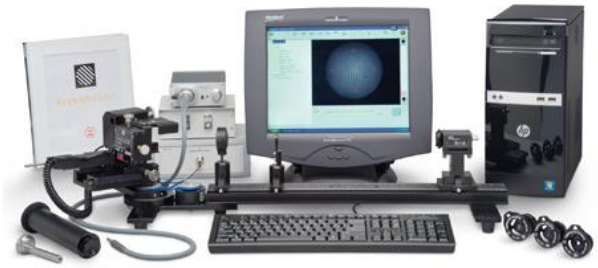

Figure 4.1: Lighthouse Imaging - EndobenchXTB, bench-mounted system

The EndoBench provides an extensive set of available measurements for rigid endoscopes. The test device is manually controlled and requires in-depth specialized training and knowledge to be able to work with the device. Performing all actions for the complete inspection of one instrument take up a considerable amount of time and is very dependent on the competences of the operator.

**EndoBench Specifications**

Diameters: 2-16mm
Lengths: 90-550mm
Endoscope types that can be tested: Rigid endoscopes, flexible endoscopes, video endoscopes.

Available measurements:

- Field of View
- Direction of View
- Apparent Field of View
- MTF (image sharpness)
- Distortion
- Transmission
- Vignetting
- Coloration
- Eyepiece diopter
- Fiber optic illumination brightness and distribution

### 4.2.2 Dovideq - ScopeControl

ScopeControl by Dovideq Medical is a test and measurement device to verify the quality of rigid endoscopes and sequring quality assurance. ScopeControl is intended for use at the CSSD of a hospital, after washing and before the sterilization process. The device tests rigid endoscopes for six key causes of defects. Figure 4.2 shows the ScopeControl.

Figure 4.2: Dovideq - ScopeControl

**ScopeControl Specifications**

Lengths: 140-650 mm
Endoscope types that can be tested: Rigid endoscopes

Available measurements:

- Direction of View
- Field of View
- Focus (sharpness)
- Fibers (percentage of damaged fibers)
- Light Transmission
- Colour Correctness

### 4.2.3 The EndoTester

The EndoTester, an optical bench designed for quantitative testing of the light fibers and the lens system in rigid and flexible endoscopes, is discussed in a casestudy in the Clinical Engineering Handbook in 2004. [33] Figure 4.3 shows the EndoTester.

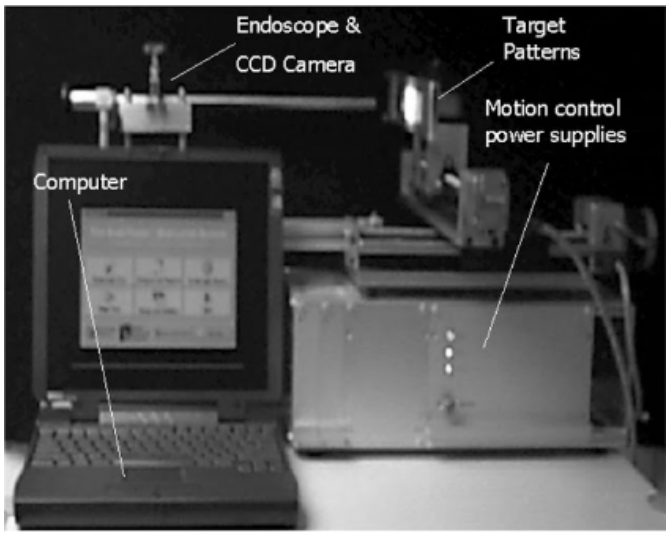


Figure 4.3: The EndoTester - Basic Test Fixture

Even though the authors of the article discussing the EndoTester express their sincere hope that this technology will help to provide accurate, easy-to-acquire and objective data on endoscope performance characteristics, there is no evidence of the EndoTester being further developed into a commercially available product unfortunately.

**EndoTester Specifications**

Available measurements:

- Relative Light Loss
- Reflective Symmetry (quantifying the effective distribution of light in the endoscope's field of view)
- Percentage of Lighted Fibers
- Geometric Distortion
- Modular Transfer Function (MTF)

## 4.3 Test Devices - Fiber Quality

Testing the fiber quality of light guide cables is relatively mainstream and therefore there are quite a few light guide cable test devices available on the market. However, there are just two test devices that can also determine the quality of the light fibers in rigid endoscopes commercially available.

### 4.3.1 ZiGN Medical - MedZense LG20-e

The MedZense LG20-e by Zign Medical assesses the light transmitting quality of light guide cables and endoscopes objectively and efficiently. The MedZense LG20 is a universal light guide cable testing device that supports all major cable fittings. The LG20 can be expanded (LG20-e) with a separate testing probe for endoscopes. With this probe connected to the LG20 you can test the complete system of both cable and endoscope. The MedZense LG20-e can be seen in figure 4.4.

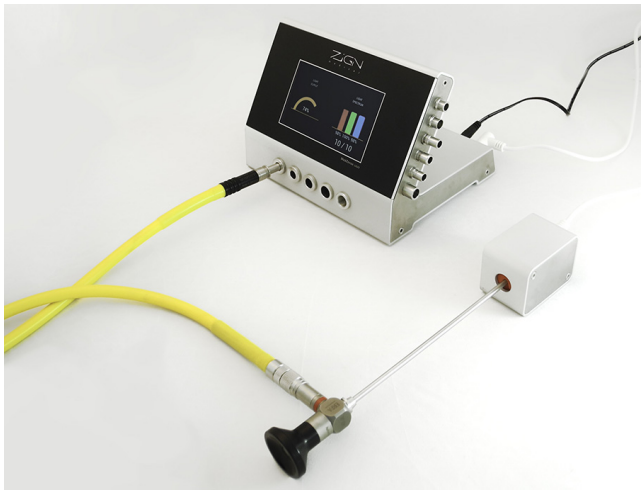


Figure 4.4: ZiGN Medical - MedZense LG20-e

**MedZense LG20-e Specifications**

Diameters: 2.7-10 mm
Lengths: All lengths
Endoscope types that can be tested: Rigid endoscopes, video endoscopes

Available measurements:

- Light Transmission
- Colour Spectrum

### 4.3.2 Lighthouse Imaging - EndoLume

The EndoLume by Lighthouse Imaging is an endoscopic system light meter that can quantitatively measure the light output of endoscopic light sources, light transmission through fiberoptic light cables and the light transmission through the optical fibers in both flexible and rigid endoscopes. It is a handheld device with a connected sphere and includes adapters to connect with all endoscopic equipments common in medical institutions.

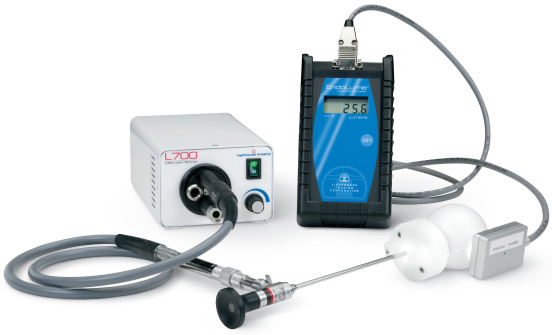

Figure 4.5: Lighthouse Imaging - EndoLume

**EndoLume Specifications**

Diameters: 2-15 mm
Lengths: All lengths
Endoscope types that can be tested: Rigid endoscopes, flexible endoscopes, video endoscopes

Available measurements:

- Light Transmission

## 4.4 Test Devices - Lens Quality

Measuring one or more lens characteristics of rigid endoscopes can be performed with one of the following commercially available devices:

### 4.4.1 Capital Medical Resources - Rigid Scope QC Testing Device

The Rigid Scope QC (Quality Control) Testing Device by Capital Medical Resources provides a set-up to manually measure lens characteristics of rigid endoscopes. This test bench is intended for OEM (original equipment manufacturer) and third-party repair organizations. FIgure 4.6 shows the Rigid Scope QC Testing Device.

Figure 4.6: Capital Medical Resources - Rigid Scope QC Testing Device

**Rigid Scope QC Specifications**

Available measurements:

- Direction of View
- Field of View
- Resolution
- Centering (Run-out)

### 4.4.2 Lighthouse Imaging - EndoScan

The EndoScan by Lighthouse Imaging is a lens tester designed to assess the inner surfaces of all diameters and lengths of rigid endoscopes. The EndoScan is shown in figure 4.7.


Figure 4.7: Lighthouse Imaging - EndoScan

**EndoScan Specifications**

Diameters: All diameters
Length: All lengths
Endoscope types that can be tested: Rigid endoscopes

Available measurements:

- Cracked relay lenses
- Moisture in optical system
- Dirt on surfaces
- Adhesive degradation

### 4.4.3 Fluke Biomedical - DALE301

The DALE301 by Fluke Biomedical is a simple tool to perform a quick evaluation of some lens characteristics of rigid endoscopes. The device is similar to the EndoScan (4.4.2) and can be seen in figure 4.8.


Figure 4.8: Fluke Biomedical - DALE301

**DALE301 Specifications**

Diameters: Maximum diameter of 10mm
Lengths: All lengths
Endoscope types that can be tested: Rigid endoscopes

Available measurements:

- Broken lenses
- Crooked rod shaft
- Internal moisture
- Presence of contamination
- Lens debris

## 4.5 Overview tested Quality Indicators per testing device

Table 4.1 provides an overview of the Quality Indicators previously defined in chapter 3 and indicates which quality indicators can be measured with the State of the Art test devices discussed in this chapter. It also indicates the quality indicators incorporated in the experimental test set-up which is further discussed in my research paper ”Design and validation of a test set-up to measure the optical quality of rigid endoscopes”.

| | Quality Indicators | EndoBench | ScopeControl | EndoTester | MedZense LG20-e | EndoLume | Rigid Scope QC | EndoScan | DALE301 | Test Set-up |
|---|---|---|---|---|---|---|---|---|---|---|
| Mechanical Failure | Broken seals resulting in leakage | | | | | | | x | x | |
| | Damaged distal end or tip | | | | | | | | | |
| | Bent Shaft | | x | | | | | | x | x |
| Optical Failure | Fractures in the lenses | | | | | | | x | x | |
| | Direction of View | x | x | | | | x | | | x |
| | Field of View | x | x | | | | x | | | x |
| | Sharpness | x | x | x | | | x | | | x |
| | Contrast | | | | | | | | | x |
| | Vignetting | x | | x | | | | | | x |
| | Distortion | x | | x | | | | | | x |
| | Colour Correctness | x | x | | | | | x | x | x |
| | Light Transmittance | x | x | x | | | | | | x |
| Illumination Failure | Colour Correctness | | | | x | | | | | |
| | Light Transmittance | x | x | x | x | x | | | | |
| | Shadowing | x | | | | | | | | |

Table 4.1: Overview Quality Indicators available in Test Devices

# Chapter 5

# Discussion & Recommendations for Further Research

This chapter contains the discussion and recommendations for further research following the study performed to complete this master thesis. An elaborate discussion of the performed experiment can be found in the research paper "Design and validation of a test set-up to measure the optical quality of rigid endoscopes.".

## 5.1 Field Research

Three Dutch hospitals (Reinier de Graaf Ziekenhuis/Combi-Ster in Delft, Jeroen Bosch Ziekenhuis in Den Bosch, Leiden Universitair Medisch Centrum (LUMC)) have been visited to research the quality requirements for the users of rigid endoscopes and to understand the workflow and processes of the environment in which the new method will be actively applied. Even though all three hospitals are considered large hospitals, they have shown a number of differences in their approach and processes regarding the reprocessing cycle of rigid endoscopes. Smaller facilities have not been visited within the scope of this project, but may provide further valuable insights.

Overall, it was observed that recommended practices provided by the original manufacturers of rigid endoscopes are sometimes valued higher in comparison with decontamination processes learned during the education for CSSD Employees (Medewerker Steriele Medische Hulpmiddelen (MSMH)). For example, where it is common practice to separate all detachable components of a surgical instrument to ensure the sterilization process is able to sterilize all surfaces, some manufacturers have recommended to leave the Storz adapter on the light post of rigid endoscopes screwed on during this process to protect the glass window where the light fibers pick up light from the external light source. While it is important to ensure high quality light transmission during surgery, this should not be at the expense of fully sterilized surgical instrumentation. Creating more insight in the deterioration of the light fibers during the sterilization process might give objective arguments to standardize the overall process of reprocessing rigid endoscopes. Furthermore, the design of a new method must promote and encourage proper care for delicate surgical instruments and avoid unnecessary risks for cross-contamination.

## 5.2 Further Development of the Method

### 5.2.1 Unaddressed Quality Indicators

The research paper described a test set-up containing measurement methods for nine quality indicators, of which six have been quantified and analyzed. Chapter 3 of this report describes a total of 15 quality indicators for rigid endoscopes. The remaining six quality indicators not incorporated in the test set-up are discussed here, including recommendations for further development of the measurement methods and suggestions for integrating these with the measurement methods for the nine quality indicators combined in the test set-up of this study.

**Shadowing**

The test set-up developed during this study did not incorporate any measurements for the quality of the light fibers transporting light from the external light source onto the target area inside the patient. However, as shadowing is the phenomenon where the direction of view or field of view of the light bundle from the light fibers does not match the direction of view and/or field of view of the lens system of the rigid endoscope, the measurement method for shadowing is identical to the measurement method for vignetting, with the exception of the light source used. An external light source must be attached to the light post of the rigid endoscope to illuminate the white target instead of illuminating the target with a separate light source not attached to the light fibers.

**Colour Correctness and Light Transmittance of the Light Fibers**

The State of the Art in test devices that can evaluate the fiber quality of the light fibers in rigid endoscopes (EndoLume by Lighthouse Imaging and MedZense LG20-e by Zign Medical) both use a calibrated cold light source as light input, and measure the light output with (PIN) photodiodes. Photodiodes are semiconductors that convert light into an electrical current, which is proportional to the amount of light it detects and thus the light output can be quantified.
To analyze the color spectrum of the light transmitted through the light fibers, the same method to quantify the light transmission of the light fibers is used but not with white light but with calibrated red light, green light and blue light. For all these colours the transmission is measured, which indicates the ability of different wavelengths of light travelling through the fibers.
This technique is widely accepted to measure light intensity and is therefore recommended to pursue during further research.

**Fractures in the lenses**

Two possible measurement methods for the detection of fractures in one or multiple lenses of the complex lens system of a rigid endoscope have been described previously in chapter 3.3.1.
One consists of the technique used by the EndoScan by Lighthouse Imaging (see figure 4.7) and DALE301 by Fluke Biomedical (see figure 4.8) where an extra set of lenses enables you to project the image of each lens in the lens system to inspect it for fractures, dirt and debris on the surfaces and adhesive degradation.
The second technique described in 3.3.1 is an experimental method involving multiple bundles of light directed from different angles into the objective lens assembly at the distal end of the endoscope. As this technique requires no moving elements and can be optimized through software algoritms to shorten the duration of the measurements, it is expected that if this method is

proven to produce the desirable results, it will be preferred over the previously described technique.

#### Leakage or Moisture Damage

Fluids that have entered the optical system of the rigid endoscope can be detected in condensed form or fluid form. In the condensed form, moisture results in unsharp images which will be picked up during a sharpness measurement. In fluid form, moisture can take on different shapes and forms producing spots or stains on the lenses. An objective measurement method to detect this has yet to be developed. This quality indicator remains an interesting topic for further research, as an endoscope containing moisture inside its system must immediately be taken out of use to be repaired since this inherently means the endoscope cannot be fully sterilized which results in the risk of cross-contamination for patients.

#### Damaged Distal End or Tip

The distal end of a rigid endoscope is manually inspected for damages such as shaver damage, dried up debris and the epoxy between the glass and the tube during current practices. Recommendations for objective and quantitative measurement methods for this have yet to be developed. I would like to propose the following method to document and analyze a possible deterioration of the materials at the distal end of a rigid endoscope:
Images of at least three different angles of the distal end of a rigid endoscope are to be taken during a base measurement and during every following measurement. During every following measurement, the images taken are enlarged and displayed next to the images taken during the initial base measurement. These can then be either accepted by a CSSD employee if they show no or very little deterioration compared to the base measurement, or rejected if any damage/deterioration becomes apparent.

### 5.2.2 Test set-up vs State of the Art

The test set-up that has been created during this study is currently far from clinical implementation, but the method to produce objective measures for six optical quality indicators already shows promising results compared to the current State of the Art. Commercially available test systems and devices that can measure the optical quality of rigid endoscopes are still limited, and their designs can often not be implemented in the workflow of the CSSD.

The EndoBench by Lighthouse Imaging is currently the most flexible rigid endoscope test system and, according to their product documentation, is able to perform measurements for nine out of the 15 quality indicators described in this report. Comparing this system to the test set-up described in the research paper, the EndoBench contains measurement methods for the Direction of View, Field of View, Sharpness, Vignetting, Distortion, Colour Correctness and Light Transmission. They do not describe a measurement method for Contrast, although their measurement method for Sharpness can be easily adapted to also produce objective results for Contrast.
However, the EndoBench has been commercially available for years but cannot be implemented at the CSSD due to the extensive knowledge necessary to be able to manually perform the measurements and interpret the results. The test set-up described in the research paper also has to be manually operated, but the considerations for its design are aimed towards developing an automated product that performs the measurements and produces objective results within a short time-frame.

ScopeControl by Dovideq Medical is the only commercially available test system that has been designed for use at the CSSD. Their advertisement states that ScopeControl contains six automated test and measurement functions. On top of that they advise a manual check for rigid endoscopes with a bend shaft and have incorporated a manual check for this in their product. Comparing this product to the test set-up described in the research paper, ScopeControl contains measurement functions for the Direction of View, Field of View, Sharpness, Colour Correctness and Light Transmission. They do not describe measurement functions for Contrast, Vignetting and Distortion.
Even though this product has been designed for use at the CSSD, during the field research and interviews with expert endoscope technicians it has become clear that this product has not yet been fully optimized for the workflow at the CSSD. Because of the design choice to obligate users to use a Storz adapter on the light post to attach the light source, this encourages the above-mentioned risk for not detaching this adapter after the device has finished testing the endoscope. Leaving the Storz adapter attached to the light post during sterilization can result in cross-contamination. Furthermore, the measurement of one rigid endoscope can take up to four minutes. In general, but especially when working under high pressure to deliver necessary sterile instrumentation on time to the OR, these four minutes then prove too long and interrupt the workflow, delaying the entire process in the cleanroom of the CSSD. This may lead to employees skipping the quality control and immediately packing the instruments for the autoclave. It is highly recommended for future evaluations of the newly developed test set-up to keep the total amount of time for the measurements to be performed in mind as this is a crucial requirement for the implementation at the CSSD.

The analog test devices for optical quality such as the EndoScan by Lighthouse Imaging and the DALE301 by Fluke Biomedical are currently the only devices that are able to detect fractures in the lenssystem and moisture inside the rigid endoscope and should therefor be carefully looked at for inspiration during future studies. Currently these quality indicators were not integrated in the developed test set-up for this study.

### 5.2.3 Acceptance and Rejection Criteria

One of the next steps during and after the development of quantitative measurement methods for the indicated quality indicators is to determine the acceptance and rejection criteria for rigid endoscopes. Currently there are hardly any quantitative criteria for these quality indicators. On top of that are manufacturers of rigid endoscopes unwilling to provide exact specifications of their products. This has contributed to the lack of quantitative criteria for rigid endoscopes. Determining the specifications of newly produced rigid endoscopes will provide a baseline to further determine acceptance and rejection criteria.
Thresholds need to be determined for each of the measured quality indicators. Relationships between any number of quality indicators must then be further evaluated, as a relatively small deterioration seen in multiple measured quality indicators might be a similar indication of significant deterioration of the quality of a rigid endoscope as a large deterioration of just one of the measured quality indicators can be.
Collaborations between the end-users (the surgeons and OR personnel) and the CSSD will be vital in exploring the acceptance and rejection criteria. Similar types of endoscopes used for different applications might require different thresholds. For example, a hysteroscope can be used during a hysteroscopic diagnosis to closely inspect the target area. The image through the hysteroscope for this procedure is required to have a clear

and sharp image in the center of the image. Edges of the image showing signs of deteriorated optical quality is less relevant for these procedures, and surgeons accept lower quality hysteroscopes to work with compared to other procedures such as a TURP (transurethral resection of the prostate). The same type of hysteroscope can be used during a TURP where a clear and sharp image both in the center and near the edges of the image is required as unexpected bleeding's can occur and must be recognized and treated as quickly as possible.

Another aspect about the acceptance and rejection criteria is that for most of the described quality indicators it is impossible to determine values indicating a 'perfect' quality or a score of 100%. For example, measuring the quality indicator of light transmission through light fibers results in a percentage between the input light source and the light output. There is always a loss of light between the input and output, resulting in absolute scores that will never reach 100%. Results between new instruments of the same type also vary, although they stay in the same region.
Because of this, I highly recommend performing a base measurement to record the initial values for the quality indicators, and compare future test results of that specific instrument with the results obtained during the base measurement.

### 5.2.4 Perceptual Impact of Objective Measures of Display Characteristics

Interesting research has been published in 2010 discussing the perceptual impact of objective physical measurements of display characteristics such as sharpness, contrast, brightness, etc. for surgeons performing MIS procedures. [29] F. Jacob Seagull et al. have created a rating scale for seven dimensions of display characteristics (contrast, detail, brighntess, lighting uniformity, focus uniformity, color, sharpness) and have concluded this scale is sensitive to endoscope quality differences and produces reliable results.
Exploring the relationship between the perceptual image quality of a rigid endoscope and the quantitative measurement results for the same characteristics is highly encouraged and is expected to help determining and provide more insights in the acceptance and rejection criteria.

### 5.2.5 Test Method for Flexible Endoscopes

This master thesis has focused on developing an objective test method for the quality of rigid endoscopes. Another next step after the successful development of this method could be to develop an objective test method for flexible endoscopes. One of the main reasons this was not part of the scope of this study is the different reprocessing cycle for the flexible endoscope compared to the rigid endoscope. A rigid endoscope can be sterilized in an autoclave, whereas a flexible endoscope cannot be sterilized but is washed and decontaminated after each use.
As both rigid and flexible endoscopes seem to share similar issues regarding the lack of objective test methods and general quantitative regulations on instrument quality, it is highly recommended to explore the possibilities of developing an objective test method for flexible endoscopes.

## 5.3 Possible Effects for the Rigid Endoscope Manufacturing Market

Manufacturers of rigid endoscopes have gained a lot of control on the current market, providing little information about the specifications of their products and implying that third-party repair-companies are unable to meet similar standards as the original manufacturers. As it is currently hardly possible to objectively measure the quality of rigid endoscopes, these manufacturers remain their status. Introducing a new system to quantify the quality of rigid endoscopes is expected to seem like a threat to these companies. Eventually, being able to compare the quality of endoscopes of different manufacturers might motivate these companies to provide higher quality instruments and provide more information about their products, which is beneficial to the overall patient safety and quality of medical care.

# Chapter 6

# Conclusion

The goal of this master thesis was to develop an objective testing method to evaluate the quality of rigid endoscopes at the CSSD. Based on literature and field research in both hospitals and a manufacturer and expert technician of rigid and flexible endoscopes, 15 quality indicators have been identified and described, providing an overview of all the aspects that can indicate deteriorating quality in rigid endoscopes. To further develop an objective test method to evaluate the quality of clinically used rigid endoscopes, both the technical requirements for the measurements and the workflow requirements of the CSSD must be addressed. To prevent defective rigid endoscopes reaching the OR while remaining the sterility of the instruments, a quality check must be performed in the cleanroom of a CSSD after the rigid endoscopes have been thoroughly washed and before they are sterilized in an autoclave. The current workflow in the cleanroom requires this quality check to be quick, automated as much as possible and produce objective results that are easy to interpret.

In the exploratory study described in the research paper "Design and validation of a test set-up to measure the optical quality of rigid endoscopes" accompanying this report, six optical quality indicators have been integrated in an experimental test set-up. With this test set-up the feasibility of developing a new testing device for quality management of clinically used endoscopes at the central sterilization department of hospitals was investigated.

The developed test set-up has proven to be both promising and successful in providing an integrated test method for six optical quality indicators in rigid endoscopes.
Although the measurements for Sharpness, Contrast and Distortion show promising results, the current design of the target and the limitations of the test set-up will need further research and evaluation to optimize the method and increase the stability of the system.
The measurements performed for Light Transmission, Vignetting and Colour Correctness produce stable results and display the expected values for specific types of damaged lens systems such as shifted and broken lenses.

Further research in this field is greatly encouraged as the scope of this study has been limited and many unanswered questions have been raised. Integrating measurement methods for most, if not all of the described quality indicators to produce an objective and quick evaluation of the quality of a rigid endoscope will lead to a technical solution. With the technical ability to objectively measure the indicated parameters, a next step will be to determine failure thresholds and acceptance criteria for all measured parameters. These thresholds or criteria are expected to vary between different types of rigid endoscopes and different surgical applications. Another next step will be to investigate if the quality of flexible endoscopes can be evaluated using a similar method, and possible alter the developed method for this purpose.

Although the discussed test set-up is not yet the full answer to provide an objective test method to evaluate the overall quality of rigid endoscopes, this study has both given an account of the need for an objective method to evaluate the quality of rigid endoscopes as well as provided a promising step towards this new method and greatly encourages further research. An objective test method for rigid endoscopes will lead to short term benefits such as directly and indirectly increasing patient safety, and long term benefits such as creating valuable insights in the quality of rigid endoscopes for different manufacturers, ultimately leading to improved instrument quality of newly manufactured rigid endoscopes to begin with.

# Bibliography


[1] Basics on Processing & Sterilization -Sterile Materials Processing Department - University of Rochester Medical Center.

[2] HSE Standards and Recommended Practices for Central Decontamination Units. QPSD-D-003-2.1 V2.1 Health Service Executive Standards and Recommended Practices for Central Decontamination Units. Technical report.

[3] The Slanted Edge Method — Strolls with my Dog.

[4] Recommended Practices for Cleaning and Caring for Surgical Instruments and Powered Equipment. *AORN Journal*, 75(3):627–641, 3 2002.

[5] WORLD ALLIANCE FOR PATIENT SAFETY FORWARD PROGRAMME 2005. Technical report, 2004.

[6] The New Regulations on Medical Devices - European Commission. Technical report, 2017.

[7] R. Aggarwal, O. T. Mytton, F. Greaves, and C. Vincent. Technology as applied to patient safety: an overview. *BMJ*, 2010.

[8] M. D. Blikkendaal, S. R. C. Driessen, S. P. Rodrigues, J. P. T. Rhemrev, M. J. G. H. Smeets, J. Dankelman, J. J. van den Dobbelsteen, and F. W. Jansen. Surgical flow disturbances in dedicated minimally invasive surgery suites: an observational study to assess its supposed superiority over conventional suites. *Surgical Endoscopy*, 31(1):288–298, 1 2017.

[9] I. D. Boer, H. Noordman, H. V. D. Brink, R. Gips, M. Janssen, R. Sloos, and L. Zwarekant. Kwaliteitsborging van Instrumenten en Apparatuur gebruikt bij Minimaal Invasieve Chirurgie. *Wibaz*, (November), 2008.

[10] I. D. Boer, H. Noordman, H. V. D. Brink, R. Gips, M. Janssen, R. Sloos, and L. Zwarekant. Kwaliteitsborging van Instrumenten en Apparatuur gebruikt bij Minimaal Invasieve Chirurgie, versie 2.1. *Wibaz*, (November), 2012.

[11] S. Courdier, O. Garbin, M. Hummel, V. Thoma, E. Ball, R. Favre, and A. Wattiez. Equipment Failure: Causes and Consequences in Endoscopic Gynecologic Surgery. *Journal of Minimally Invasive Gynecology*, 16(1):28–33, 1 2009.

[12] P. C. De Groen. History of the Endoscope. *Proceedings of the IEEE*, 105(10):1987–1995, 2017.

[13] M. Dion and W. Parker. Steam Sterilization Principles. Technical report, 2013.

[14] Edmund Optics. Introduction to Modulation Transfer Function.

[15] Imatest. Sharpness: What is it and how is it measured?

[16] Infection Control Today. Anatomy of an Endoscope - Endoscope Repair Issues, 2000.

[17] Integrated Medical Systems International. Rigid Endoscope Damage Diagram. Technical report, 2011.

[18] ISO. Endoscopes – Medical endoscopes and endotherapy devices – Part 3: Determination of field of view and direction of view of endoscopes with optics. *ISO/DIS 8600-3*, 2003.

[19] ISO. *ISO 8600 - Endoscopes - Medical endoscopes and endotherapy devices*. 2015.

[20] ISO. *ISO 17664:2017(en), Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*. 2017.

[21] A. Jha. *WHO Summary of the evidence on Patient Safety: Implications for research*. 2008.

[22] J. J. Jung, A. Kashfi, S. Sharma, and T. Grantcharov. Characterization of device-related interruptions in minimally invasive surgery: need for intraoperative data and effective mitigation strategies. 33:717–723, 2019.

[23] B. Kern. Anatomy of an Endoscope — Infection Control Today, 2000.

[24] R. Khandpur. *Handbook of Biomedical Instrumentation*. 1987.

[25] I. o. Medicine. *Sources of Medical Technology: Universities and Industry*. Washington, DC, 1995.

[26] R. C. Newton, O. T. Mytton, R. Aggarwal, W. B. Runciman, M. Free, B. Fahlgren, M. Akiyama, B. Farlow, S. Yaron, G. Locke, and S. Whittaker. Making existing technology safer in healthcare. *BMJ*, 2010.

[27] G. Powell-Cope, A. L. Nelson, and E. S. Patterson. *Patient Care Technology and Safety*. Agency for Healthcare Research and Quality (US), 2008.

[28] J.-F. Rey. Quality Control in Endoscopy Unit: Safety Considerations for the Patient. *Applications and Experiences of Quality Control*, (April 2011), 2012.

[29] F. J. Seagull, E. Sutton, T. Lee, C. Godinez, G. Lee, and A. Park. A validated subjective rating of display quality: the Maryland Visual Comfort Scale. *Surgical Endoscopy*, 25(2):567–571, 2 2011.

[30] H. Thimbleby. Technology and the future of healthcare. Technical report, 2013.

[31] E. G. G. Verdaasdonk, L. P. S. Stassen, M. Van Der Elst, T. M. Karsten, and J. Dankelman. Problems with technical equipment during laparoscopic surgery An observational study. *Surgical Endoscopy*, 21:275–279, 2007.

[32] Q. Wang, A. Khanicheh, D. Leiner, D. Shafer, J. Zobel, J. J. Van Gompel, M. H. Tabor, A. S. Youssef, T. Lau, A. P. Carlson, H. R. van Loveren, and S. Agazzi. Endoscope field of view measurement. 2017.

[33] J. O. Wear. 92 - Machine Vision. In *Clinical Engineering Handbook*. 2004.

[34] J. Wong, K. J. Khu, Z. Kaderali, and M. Bernstein. Delays in the operating room: signs of an imperfect system.

*Canadian journal of surgery. Journal canadien de chirurgie*, 53(3):189–95, 6 2010.

[35] H. Yasuhara, K. Fukatsu, T. Komatsu, T. Obayashi, Y. Saito, and Y. Uetera. Prevention of medical accidents caused by defective surgical instruments. 2012.

# Appendix A

# Slanted Edge Method for MTF

The slanted edge method is a method to measure the spatial resolution performance of lenssystems. It provides a good approximation of the Modulation Transfer Function (MTF) of the two-dimensional Point Spread Function (PSF) perpendicular to the edge recorded through a lenssystem. [3]

The Modulation Transfer Function is the Spatial Frequency Response of a linear, space-invariant system, obtained by taking the modulus of the Fourier transform of a (lens) system's PSF. Through this method, sharpness' performance at all spatial frequencies can be determined at once.

It is difficult to derive the PSF of a lens system by capturing an image of a single point, for example a single star against a black sky, because of the intensity and size of the target. The intensity could be build up and noise could be reduced by capturing an array of closely spaced stars or multiple points closely aligned forming a straight line to determine the MTF in the direction perpendicular to this line. Noise could be further reduced by capturing an image of a white edge against a black background. See figure A.1.

Figure A.1: A white edge against a black background: a slanted edge. [3]

The Fourier transform of the 2-dimensional PSF is equal to the Fourier transform of the 1-dimensional Line Spread Function (LSF). By applying ths slanted-edge method it is possible to obtain a measurement of the 2-dimensional MTF of the lenssystem in just one direction. See figure A.2.

The edge captured by the lenssystem is ideally perfectly straight and has a very high contrast, and tilted slightly between 4 and 6 degrees off the vertical or horizontal to avoid the edge to coincide with an array of pixels in the image sensor.

The edge itself has its own MTF which is multiplied with the MTF of the other components of the imaging system producing the system's MTF. The relative quality of the edge will act as the as the upper limit of the measured system's MTF. Lower quality edges such as a printed edge on paper may produce less sensitive results but still provide comparative value to images taken of the same target.

Effectively, the slanted-edge method samples the edge by the number of pixels along it. The resulting Edge Spread Function

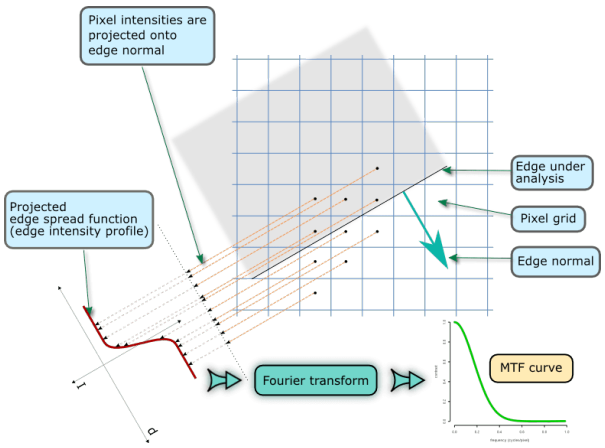


Figure A.2: 2D capture of a slanted edge converts to a 1D Edge Spread Function. [3]

(ESF) (figure A.2) is a 1-dimensional representation of the light intensity profile around the edge after it has been recorded by the lenssystem. If the recorded edge was perfect with high contrast, no distortion in the system and low noise, this ESF is a step function. Any degradation in the ESF from this step function can be interpreted as a loss of sharpness due to the lenssystem.

The derivative of the ESF results in the LSF, which can be though of as the projection of the impulse response of the imaging system in the direction perpendicular to the edge. By taking the modulus of the Fourier transform of the this LSF it is possible to determine fairly accurately the MTF curve of the complete system of the captured edge, camera and lenssystem at the location of the edge, calculated in the direction perpendicular to this edge. MTF50, the spatial frequency at which contrast has dropped to 50%, can then be determined from this MTF curve. [3]