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Design and validation of a test set-up to measure the optical quality of rigid endoscopes

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Abstract

The quality of rigid endoscopes deteriorates during clinical use due to the sterilization process, mechanical forces and wear and tear during regular use. Regulations and standards on ensuring the quality of these instruments are currently non-existent or contain only qualitative measures, resulting in subjective examinations . Defective rigid endoscopes still reach the operating room, resulting in direct and indirect patient risks. An experimental test set-up has been developed to quantify the sharpness, contrast, distortion, light transmission, vignetting and colour correctness of the optical system of rigid endoscopes. Results are given for 85 measurements performed on 33 endoscopes, including 7 high quality endoscopes and 26 low quality endoscopes. 37 measurements have been performed on a reference rigid endoscope. The results for sharpness, contrast and distortion provide valuable insights but the current design of the test set-up proved not stable enough to draw significant conclusions. The results for light transmission, vignetting and colour correctness produce stable results and display the expected values for damaged lens systems such as loose or broken lenses. Although the current design requires significant optimization, 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.

Competing interest: During the execution of this study the author has been employed part-time at Zign Medical, a product development company committed to supporting technical and sterilization departments in hospitals with testing and materials management solutions.

Keywords
biomedical engineering, minimally invasive surgery, rigid endoscopes, laparoscopy, quality, test method, reprocessing

Introduction

Minimally Invasive Surgery (MIS) is a rapidly growing surgical technique that has replaced many open surgical procedures with an equal or better result, shorter patient recovery times due to smaller incisions, lower patient morbidity and shorter hospital stay. The majority of surgical endoscopic applications are nowadays performed with the aid of rigid endoscopes, used to visualize hollow cavities inside the body, the surface of organs or the interior of joints. Any MIS procedure is guided by the images produced through an endoscope, acting as an extension of the eyes of the surgeon. As such, surgeons heavily depend on high quality endoscopes for MIS procedures, but as the global medical device industry keeps innovating, medical devices such as rigid endoscopes are becoming more complex and delicate, and problems related to these instruments are inevitable. (7) The World Health Organisation (WHO) even stated that problems related to medical devices are globally underreported and its actual scale unknown. (4) In current practices defective endoscopes are reaching the operating room, resulting in direct and indirect patient risks. (8) (2) (10) (1) (5)

The typical set up for endoscopic system in the operating room consists of a cold light source, light guide cable, the rigid endoscope, a camera, a video processor and a monitor. The rigid endoscope is the most fragile and most critical component of this set up, with every reprocessing cycle it risks potential damage during the actual use in the OR, during transportation, cleaning, packing and sterilization.

A rigid endoscope is shown in figure 1. Rigid endoscopes can be compared to a small telescope, entering the human body through a natural orifice or a small incision in the skin. Flexible glass fibers transmit light from the light post through the tubing towards the distal end of the endoscope and is projected, often in an angle, onto the target area. The light reflecting on the target area travels back through the rod-lens-system towards the ocular system. A camera is attached to the coupler window of the endoscope to transmit the image to the video monitor. (6)

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

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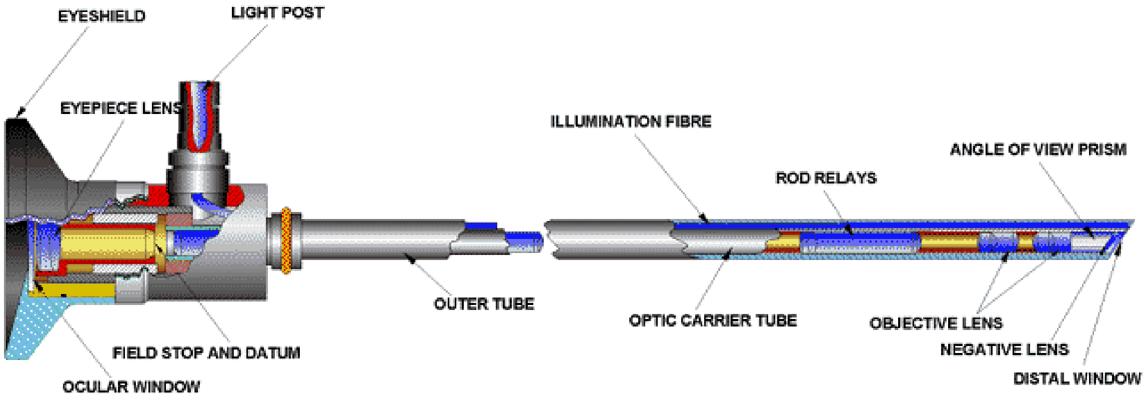


Figure 1. Rigid Endoscope: A Schematic Overview

procedures and sometimes even the specific requirements of a surgeon.

While medical technology keeps evolving with a continuous focus on increasing patient safety, rigid endoscopes are only subject to a brief manual quality check during the reprocessing cycle. High workloads, time-constraints and often limited training results in irregular and subjective quality checks of these essential medical devices just before they are sterilized and transported to the operating room (OR) for clinical use. (10)

Current Situation

On a global scale, there are hardly any minimum requirements or standards available on ensuring the quality of these instruments. Moreover, the test-methods for certain aspects of the quality of rigid endoscopes that are described in an ISO standard are time-consuming, require expert knowledge on optics and/or are not always objective measurements. (3)

Dutch regulations involve a quality check of a rigid endoscope before every reuse. These checks are performed at the Central Sterilization Services Department (CSSD) after the instruments are cleaned but before they are sterilized in the autoclave. Although regulations require a quality check, often the inspection of a rigid endoscope is limited to a brief visual check of the exterior and optics of the endoscope. When an endoscope fails this inspection they are send out to the original manufacturer or a repair company to get replaced or repaired. 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. (10)

There are a few devices and methods available to measure the quality of endoscopes. Karl Storz sells a test bench with a single target and fibre transmission measurement. This instrument is intended to be used by highly trained personnel rather then the CSSD employee under time pressure. The EndoBench from Lighthouse Imaging can measure a great number of quality indicators, but is again not designed for the routine use at the CSSD. ScopeControl from Dovideq is an automated test device for rigid endoscopes intended for the CSSD. This device measures 6 quality indicators but with a measure time of approximately 4 minutes per endoscope and a test that is not as complete as the test by the EndoBench from Lighthouse Imaging, this device is still not widely adopted in the routine at the CSSD.

Devices to test the quality of the light fibers transporting light towards the target area of the endoscope do exist and have successfully been implemented at the CSSD, such as the MedZense LG20-e and the Endolume from Lighthouse Imaging. The focus of this study is therefor on a testmethod for the optical lens quality indicators.

Goal

The aim of this study is to develop a new optical quality testing method for rigid endoscopes at the CSSD during the reprocessing cycle to prevent defective rigid endoscopes reaching the OR. Developing a new method that can be integrated in the current workflow of the CSSD requires the method to be objective, fast and automated as much as possible. To reach these goals, mechanical movable parts must be kept to a minimum while software can be developed to perform and analyze multiple measurements within a short time frame.
First, all aspects that can be measured to indicate a deterioration of the overall quality of a rigid endoscope have been identified and categorized. Then, to develop a method to measure all the optical quality indicators for rigid endoscopes, an experimental test set-up was created adapting existing optical measurement methods to the optical system of rigid endoscopes and combining them in one set-up. Finally, an experiment was designed to validate the stability of the system as well as the test results for both high quality and low quality rigid endoscopes.

Quality Indicators

Based on literature studies, field research in three hospitals in the Netherlands and with the help of an endoscope repair company and optical experts, a number of quality indicators have been determined to objectively determine the quality of a rigid endoscope. More detail on each quality indicator can be found in Chapter 3 of this master thesis ”The development of a new method to test the optical quality of rigid endoscopes at the CSSD”. The following quality indicators have been determined for rigid endoscopes:

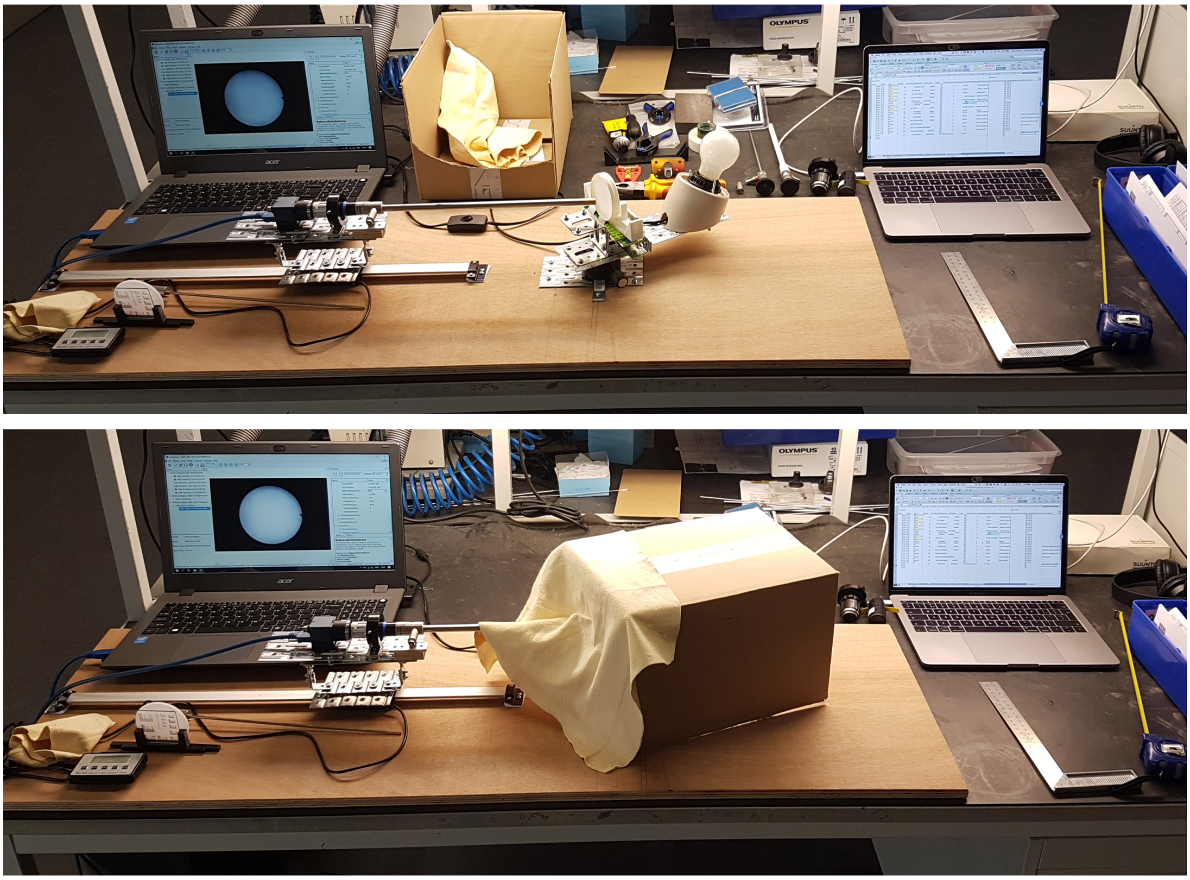


Figure 2. Test Set-Up

- Optical Failure
    1. Fractures in the lenses
    2. Direction of View
    3. Field of View
    4. Sharpness
    5. Contrast
    6. Vignetting
    7. Distortion
    8. Colour Correctness: Lens system
    9. Light Transmission: Lens system
- Illumination Failure
    1. Colour Correctness: Light fibers
    2. Light Transmission: Light fibers
    3. Shadowing
- Mechanical Failure
    1. Broken seals resulting in leakage
    2. Damaged distal end or tip
    3. Bent shaft

A test set-up was created to measure the optical quality indicators for rigid endoscopes.

Considerations for current test set-up

Figure 2 illustrates the experimental test set-up to measure optical quality indicators for rigid endoscopes. This test set-up has adapted and combined existing test methods for optical quality of lenses in general to the optical quality of rigid endoscopes. The following optical quality indicators have been combined in this test set-up:

- Direction of View
- Field of View
- Lens Characteristics:
    - Sharpness
    - Contrast
    - Distortion
- Lens Light Transmittance:
    - Light Transmittance center of the lens
    - Vignetting: Light transmittance edges compared to center
    - Colour correctness of the lenses

Due to accuracy limitations of the panoramic platform in the measuring station, measurements for Direction of View and Field of View cannot be accurately determined. Methods to accurately determine these two lens system qualities are described in ISO 8600-3 and the test results for Direction of View and Field of View in this experiment are therefore not discussed in this study.

One of the previously defined optical quality indicators cannot be measured in this test set-up; Fractures in the lenses.
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. This makes it possible to project the image of each lens in the lens system

and inspect it for fractures, dirt/debris on the surfaces and adhesive degradation.

Another technique involves bundles of light directed from different angles into the objective lens assembly at the distal end of the endoscope. 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 it will influence the final projected image.

Due to the relative short time span of this study it was not possible to implement either of these techniques in this experimental test set-up. Further research will be necessary to implement this.

Methods

Technical Approach

A test set-up was developed to measure the abovementioned optical quality indicators for rigid endoscopes in a experiment. The test set-up consists of two main components; the mounting station and the measuring station. See figure 2.

The mounting station is where the endoscope is mounted on the test set-up. The endoscope is attached to a 25mm endoscope coupler which is attached to a MER-2000-19U3C camera sensor, with a 1 inch optical sensor and 20MP resolution. The camera sensor is attached through USB to a computer to record the images. The camera sensor is mounted on a digital ruler. Depending on the type of endoscope and its length, the camera sensor on the digital ruler was positioned in the correct position to center the distal tip of the endoscope above the rotation point of the measuring station.

The measuring station is where the targets for the endoscope are placed. The base of the measuring station is a 360° panoramic platform with a horizontal slider to move targets closer and further from the rotation point of the platform. Mounted on this slider is a frame to hold different targets, and a lamp serving as an external light source. The frame for the targets is placed on a slight angle for the sharpness measurements. When the endoscope is mounted and placed with its tip above the rotation point of the panoramic platform, the platform is set to match the viewing angle of the endoscope mounted. A box is placed over the measuring station before the image of the target through the endoscope is taken to prevent influences from external light.

Software Used

Imatest software is used to analyze the images taken from the targets through the endoscope. This software contains image quality testing functionalities that are able to analyze a variety of image qualities including image sharpness, lens distortion, colour response, noise, vignetting, etc. The function Reschart allows analyzing the checkerboard target for image sharpness, contrast and distortion, and the function Uniformity provides analyzing tools for vignetting and light transmittance.

Adobe Photoshop is used to analyze colour correctness in the center of the lens, by analyzing the RGB value in the center of the lens.

Daheng Imaging Software is used to capture the image from the camera sensor.

Targets Used

The optical quality indicators are measured by saving an image taken of a specific target through the lenses of the rigid endoscope. Three different targets are used in this experiment. Two of these are displayed on a digital display of a smartphone (Samsung Galaxy S7), the third target is a physical target.

The first (digital) target used has a white background and black circles with an increasing diameter around a centerpoint. This target is used to position the measurement station in the desired position by using the specified Angle of View and Field of View per endoscope type and rotating the panoramic platform until the target is centered in the projected image.

Lens Characteristics The second (digital) target used to measure the lens characteristics consists of a dark and white checkerboard (see figure 3) displayed digitally. This checkerboard target has 45x30 squares. Tests were also performed with a checkerboard target with 30x20 squares and with 60x40 squares, but turned out too large and too small squares to be able to get sufficient results to compare all types of endoscopes tested. The checkerboard target is used to measure the three lens characteristics: sharpness, contrast and distortion.

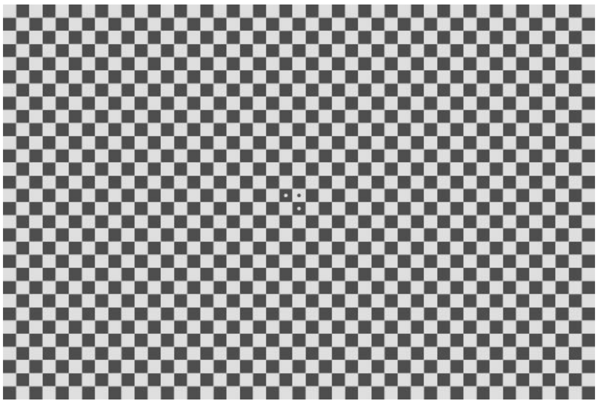


Figure 3. Checkerboard Target

Sharpness and Contrast are measured on the horizontal and vertical edges in five regions of interest (ROI): Center, Top Left, Top Right, Bottom Left and Bottom Right of the lens. Imatest software automatically detects these ROI on the image of the checkerboard target, where the center of the image is recognized by the three squares with a dot in the middle (see figure 4) and the four corners are recognized as the squares still clearly distinguishable but furthest away from the center.

If both the camera sensor and the digital target display are placed horizontally, there is a chance the edges of the squares alight perfectly with a ray of pixels on the camera sensor, which can influence the measurements. To avoid this, the target is placed on a slight angle.

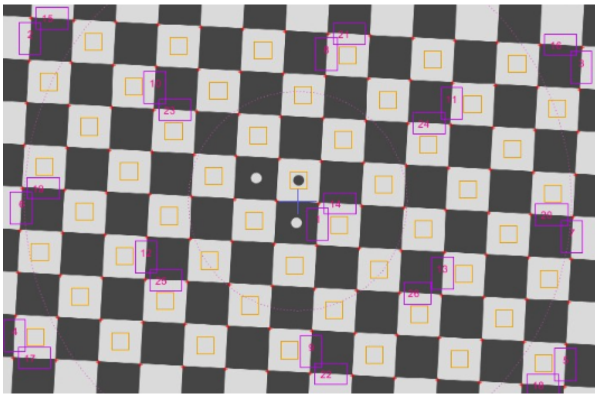


Figure 4. ROI, determined by Imatest

Distortion is calculated using the following 3rd order equation for radial distortion:

$$r_u = r_d + kr_d^3 \tag{1}$$

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.

Lens Light Transmittance Characteristics The third (physical) target used to measure the lens light transmittance characteristics is a physical target. This target consists of a white light diffuse screen with a lamp placed behind this screen and is used to measure three lens light transmittance properties: vignetting, light transmittance of the lenses and colour correctness of the lenses.

Maximum light transmittance of the lenses and the difference in light transmission between the center and the edges of the lenses (vignetting) are determined with Imatest software functionality Uniformity. Luminance (y) is defined as

$$Y = 0.30 * r + 0.59 * g + 0.11 * b \tag{2}$$

where a maximum value of y = 1 corresponds to pixel level = 255 for red, green and blue 8bits per pixel. The maximum measured luminance is determined for the maximum light transmission. The percentage decrease between the sides (5% from the edge of the projected image) and the center is determined to describe the vignetting for each endoscope.

The RGB values are found using the software Adobe Photoshop to determine the colour correctness of the endoscope and are measured in the center of the projected image.

Reference Endoscope

A reference endoscope is tested in between every endoscope tested during this experiment to assess the stability of the test set-up. The reference endoscope used for this experiment is a used WA53005A Olympus Laparoscope with a 10mm shaft diameter and a 30° viewing angle.

Since the reference endoscope needs to stay the same during the complete duration of the experiment and its results are used to assess the stability of the system, a used (slightly damaged) endoscope was chosen to ensure its availability during the experiment.

Experiment Scope

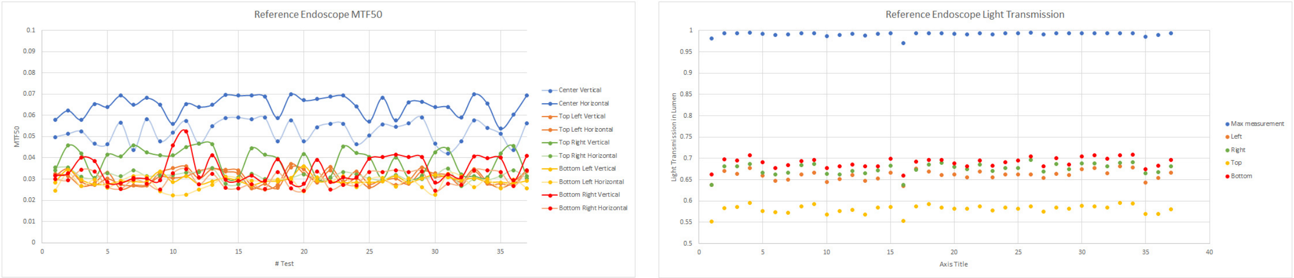
Test data was gathered at ERPA Instruments, a maintenance and repair company and manufacturer of rigid and flexible endoscopes. Damaged rigid endoscopes are sent here for repair, these endoscopes are considered low quality endoscopes during this study. After the rigid endoscopes have been repaired to a fully functioning new state, they are considered high quality endoscopes during this study. Test data was gathered during five days at ERPA Instruments. All repaired high quality endoscopes during these five days were either Cystoscopes, Laparoscopes or Arthroscopes. To equally compare this data to data from low quality endoscopes, only low quality Cystoscopes, Laparoscopes and Arthroscopes have been included in the results of this experiment.

In this experiment the optical quality of rigid endoscopes is measured. Damaged, low quality endoscopes with zero vision (a black image when looking through the lenses) have been taken out of the scope of this experiment.

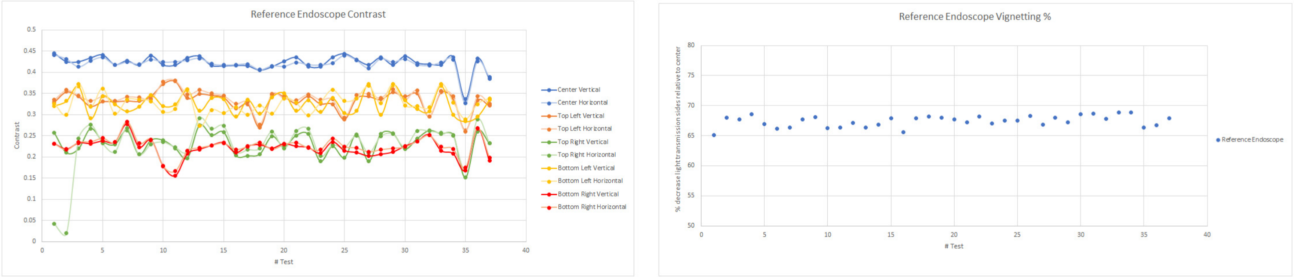
Testing Procedure

For every tested endoscope the testing procedure is as follows:

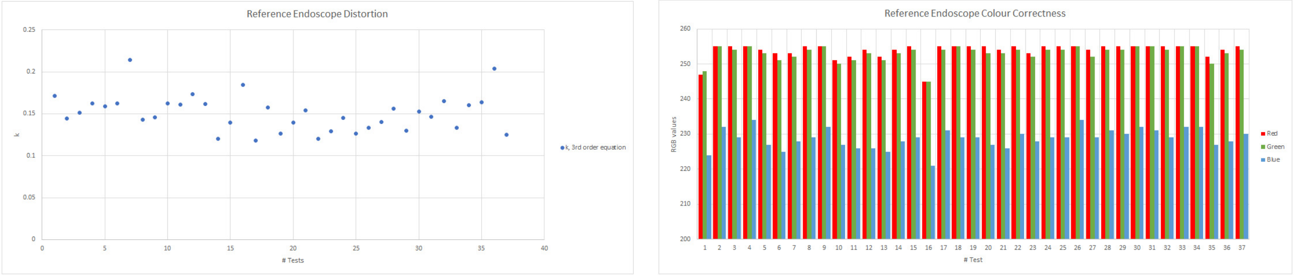
1. The following endoscope details are registered if known: Brand, Type, Modelnumber, Serialnumber, Angle of View, Field of View, Total Length, Diameter Shaft, Position of center of Light Post relative to the eyepiece (in mm), and its status (high quality or low quality).
2. The endoscope is mounted on the mounting station and is moved with the digital ruler to the correct distance (within 0.1mm) relative to the measuring station.
3. The rotating panoramic platform is set to match the Angle of View of the rigid endoscope. The digital target with circles is mounted in the frame on the panoramic platform to check if the rigid endoscope is in the correct position. If not, adjust the position of the target until the target is centered in the image seen through the endoscope.
4. When the endoscope and the panoramic platform are both in the correct position, the target is switched to the checkerboard target. The box to prevent influences from external light is placed over the measuring station and the first image is recorded.
5. The box is removed to change the digital target to the physical white target. The light bulb is switched on and the box is placed back over the measuring station. A second image is recorded.
6. The box is removed from the measuring station, the light bulb switched off and the rigid endoscope is unmounted.



a) Sharpness d) Light Transmission



b) Contrast e) Vignetting



c) Distortion f) Colour Correctness

Figure 5. Reference Endoscope - Results

7. The first recorded image (checkerboard) is then analyzed in Imatest with the Reschart function to determine the MTF50 values in the center and in four corners of the image, values for light and dark in the same areas to determine contrast, and the value for the distortion of the image.
8. The second recorded image (white target) is then analyzed in Imatest with the Uniformity function to determine vignetting and light transmission, and is analyzed in Adobe Photoshop to determine the RGB values of the center of the image taken.

Results

A total number of 34 endoscopes have been successfully tested during this experiment. Depending on the availability of the endoscopes at ERPA instruments, multiple measurements were performed wherever possible. 86 measurements were performed in total. 37 of these measurements were performed on the reference endoscope. See table 1 for an overview.

33 of these endoscopes have been included in the scope of this experiment, one of these 33 endoscopes is the reference endoscope. One low quality technical scope (non-medical endoscope used to examine building structures) was tested once during the experiment but as it cannot be compared to a high quality technical scope its measurement results have not been included in the results of this study.

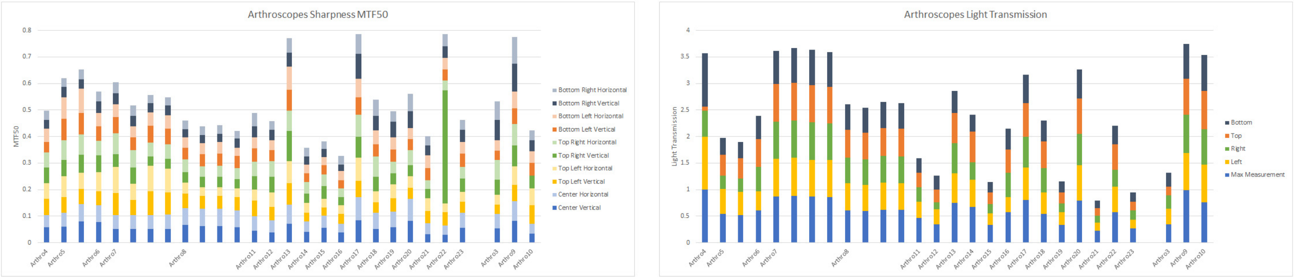
	# endoscopes	# tests performed
Reference Endoscope	1	37
Arthroscopes	21	28
Cystoscopes	8	9
Laparoscopes	3	11
Technical Scopes	1	1
Total	34	86

Table 1. Number of endoscopes and measurements performed. The Technical Scope has been excluded from the results of this study.

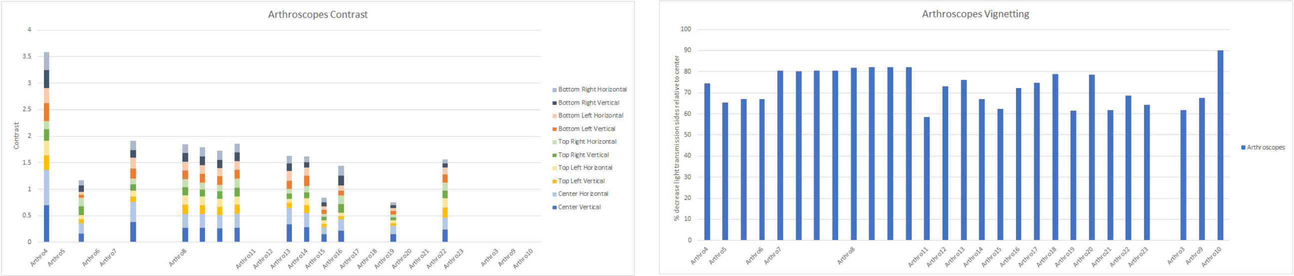
Included in the results of this study:
21 arthroscopes were tested, of which 3 high quality arthroscopes and 18 low quality arthroscopes.
8 cystoscopes were tested, of which 3 high quality cystoscopes and 5 low quality cystoscopes.
4 laparoscopes were tested, of which 1 high quality laparoscope and 3 low quality laparoscopes (of which one was the reference endoscope).

Stability of the test set-up

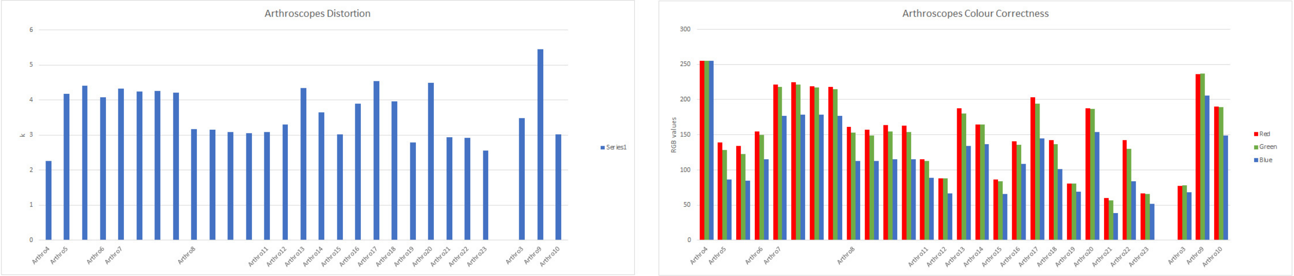
The Reference Endoscope has been tested 37 times, in between every other measured rigid endoscope during the experiment. The test results for the three lens characteristics and three lens light transmittance characteristics of the reference endoscope are shown in figure 5. The mean and standard deviations are calculated and can be found in table 2.



a) Sharpness d) Light Transmission



b) Contrast e) Vignetting



c) Distortion f) Colour Correctness

Figure 6. Arthroscopes - Results

QI		MEAN	STDEV	CV
Sharpness (MTF50)	Center	0.059	0.008	13%
	Top Left	0.031	0.003	9%
	Top Right	0.035	0.006	17%
	Bottom Left	0.029	0.003	10%
	Bottom Right	0.032	0.006	19%
Contrast (%)	Center	42.1%	1.9%	4%
	Top Left	33.6%	2.3%	7%
	Top Right	23.0%	4.3%	19%
	Bottom Left	32.6%	2.4%	7%
	Bottom Right	22.3%	2.3%	10%
Distortion	(k)	0.15	0.02	13%
Light Transmission (y)	Max luminance	0.99	0.01	1%
	Left	0.66	0.01	1.5%
	Right	0.68	0.01	1.5%
	Top	0.58	0.01	1.7%
	Bottom	0.69	0.01	1.4 %
Vignetting	(%) degradation	67.4 %	0.9 %	1.3%
Colour Correctness	Red	254	2	0.8%
	Green	253	2	0.8%
	Blue	229	3	1.3%

Table 2. Mean, Standard Deviation and Coefficient of Variation - Reference Endoscope

The Sharpness results show a 10% or more deviation from the mean in 57% of the results, and 20% or more deviation from the mean in 95% of the results.
Contrast results show a with 10% or more deviation from the mean in 76% of the results, and a 20% or more deviation from the mean in 94% of the results.

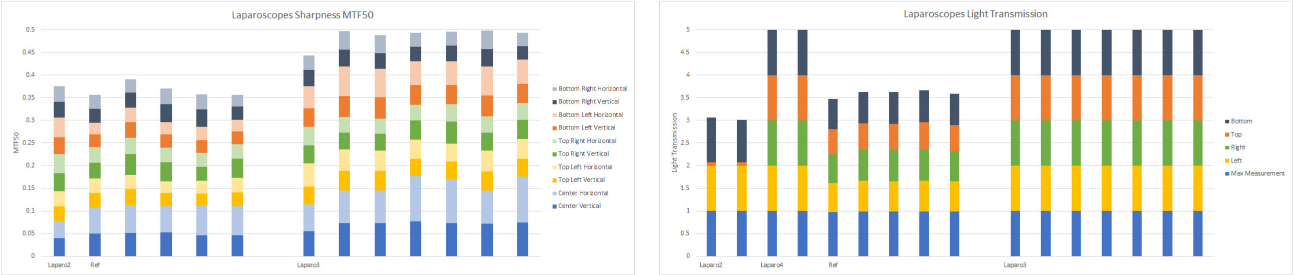
Distortion results show a with 10% or more deviation from the mean in 62% of the results, and a 20% or more deviation from the mean in 86% of the results.

Light Transmission in the Center of the image shows less then 1% deviation of the mean in 97% of the results. Light Transmission in the other 4 Regions of Interest show less then 3% deviation of the mean in 95% of the results.
Vignetting results show less then 3% deviation of the mean in 100% of the results, and less then 1% deviation of the mean in 30% of the results.
Colour Correctness results show less then 3% deviation of the mean in 100% of the results, and less then 1% deviation of the mean in 92% of the results.

The Coefficients of Variation (see table 2) display that the results for the three lens characteristics show a larger variation compared to the results for the three light transmittance characteristics.

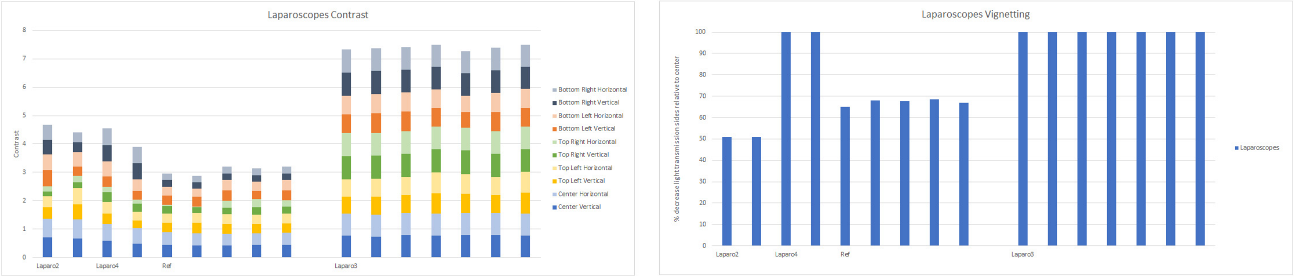
Performance Arthroscopes

The test results for the lens characteristics and lens light transmittance of the arthroscopes are shown in figure 6. For a number of measurements the Imatest software was unable to calculate the contrast values. The graph shows an empty bar for the arthroscopes where the contrast values were not calculated. The values for sharpness, contrast and light transmission measured in the five ROI's of the image



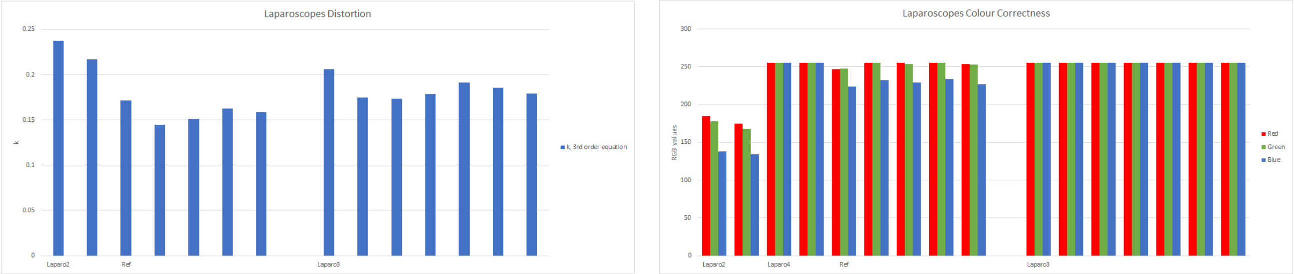
a) Sharpness

d) Light Transmission



b) Contrast

e) Vignetting



c) Distortion

f) Colour Correctness

Figure 7. Laparoscopes - Results

are added up. A higher total score indicates overall higher values compared to other measurements.

Performance Laparoscopes

The test results for the lens characteristics and lens light tranmittance of the laparoscopes are shown in figure 7. The first 5 measurements of the reference endoscope have been included in the test result graphs in figure 7.
Three outlier measurements have been taken out of the sharpness results graph in figure 7. All sharpness results of the Laparoscopes including the three outliers can be seen in figure 8. The outliers include a second measurement of Laparo2, and both measurements of Laparo4.
Two outlier measurements have been taken out of the distortion results graph in figure 7. All distortion results of the laparoscopes including the two outliers can be seen in figure 9. The outliers are both measurements of Laparo4.

Performance Cystoscopes

Cysto8, Cysto9 and Cysto11 are good quality endoscopes. For a number of measurements the Imatest software was unable to calculate the contrast values. The graph shows an empty bar for the cystoscopes where the contrast values were not calculated.

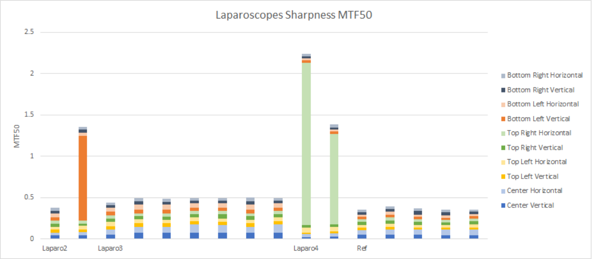


Figure 8. Laparoscopes Sharpness MTF50 results - including outliers

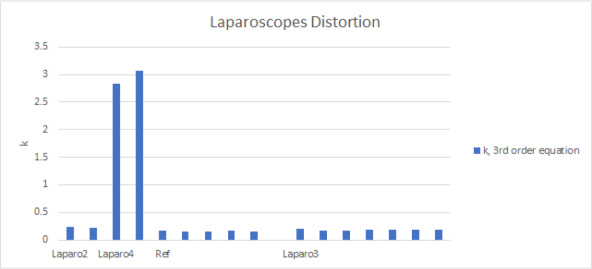
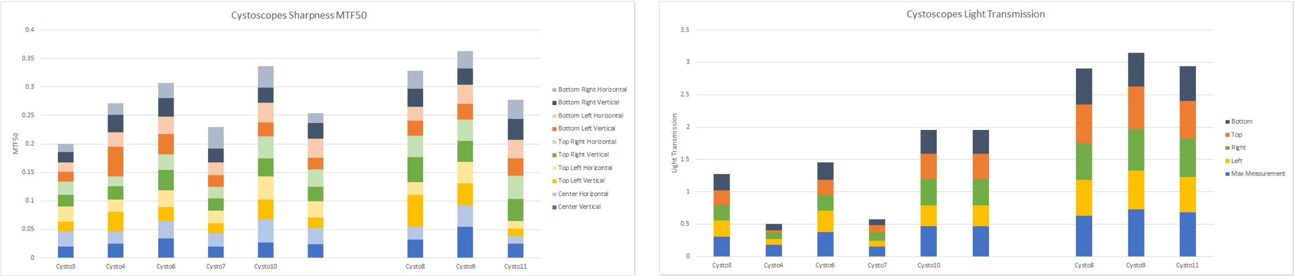


Figure 9. Laparoscopes Distortion results - including outliers

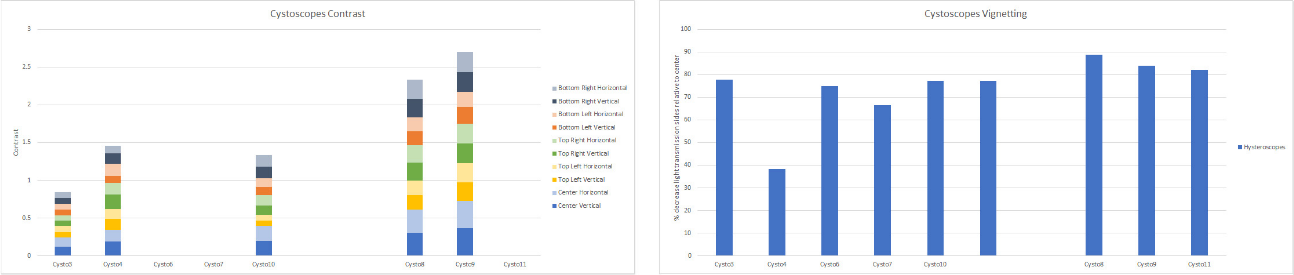
Discussion

The aim of this study was to develop a new optical quality testing method for rigid endoscopes. By combining existing optical measuring methods, integrating these in one test



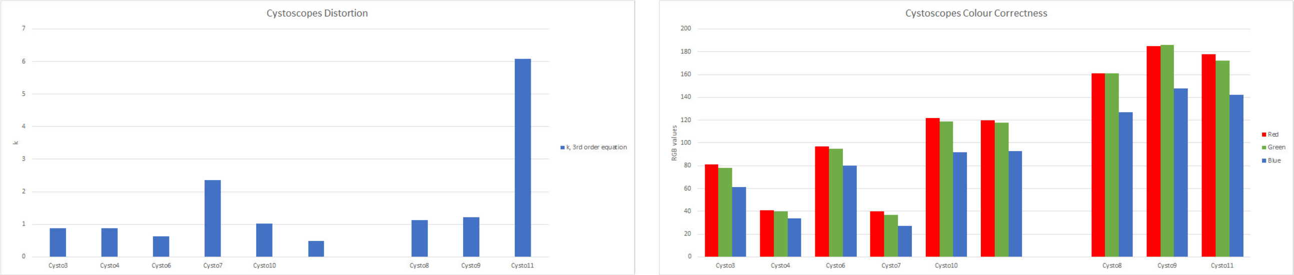
a) Sharpness

d) Light Transmission



b) Contrast

e) Vignetting



c) Distortion

f) Colour Correctness

Figure 10. Cystoscopes - Results

set-up and adapting them to the variable optical system found within rigid endoscopes, a test set-up has been developed and tested. It was an exploratory study including the measurement methods for six optical quality indicators for rigid endoscopes. With this test set-up the feasibility is investigated of developing a new testing device for quality management of clinically used endoscopes at the central sterilization department of hospitals.

System Stability

The measurements of the reference endoscope for Light Transmission, Vignetting and Colour Correctness are stable and show minimal deviation of the mean. For future experiments we consider changes of 5% or more between the current measurement and the previous measurement of that instrument to be significant.

The measurements of the reference endoscope for Sharpness, Contrast and Distortion show promising results within a clear range. However, the measurements for these three quality indicators performed with this test set-up show a higher variability then desired.

Currently, a checkerboard target with 45x30 squares was displayed on a Samsung Galaxy S7. To achieve a higher system stability in a future evaluation, it needs to be examined if different checkerboard sizes are needed for different rigid endoscope types. The currently used digital display for the checkerboard target must be further optimized by examining the results of using a display with a significantly higher resolution and the results of using a physical target with a significantly higher resolution print in a future evaluation.

Both vertical and horizontal edges have been used to calculate Sharpness and Contrast. It is recommended to further evaluate if there is a significant difference between the vertical and horizontal edges to possibly reduce the calculating power and therefor time necessary to perform all measurements.

Finally, optimizing the test set-up to be able to position the endoscope relative to the targets in a more precise manner is expected to produce more stable results and is highly recommended to pursue in a future evaluation. A slightly different position of the checkerboard target may influence the measurement results significantly.

Identifying high and low quality endoscopes

The test set-up was able to distinguish between high quality endoscopes and low quality endoscopes per type of endoscope. Absolute values for high and low quality endoscopes per endoscope type to determine rejection criteria have not been have not been determined based on this study due to the small sample size, specially for high quality endoscopes tested during this study. As the absolute values for the quality indicators vary between endoscope types and models, measurements of both high and low quality endoscopes of a larger sample size should be analyzed to determine the relevant acceptance and rejection criteria for each type and/or model.

The results of the measured laparoscopes and cystoscopes show a clear distinction between the high quality and low quality endoscopes. The results of the measured arthroscopes show variable results between the high quality and low quality endoscopes.

Laparoscopes The results for the high quality Laparo3 (see figure 7) show consistently equal or higher measured values compared to the low quality laparoscopes that have been measured. The results display higher MTF50 results in all five ROI's, significantly higher contrast, and 100% scores on Light Transmission, Vignetting and Colour Correctness. Furthermore, when comparing the high quality Laparo3 with the low quality Laparo2, we see that the Top and Right values for Light Transmission are very low, indicating the top-right part of the image being very dark. As the values for Sharpness, Contrast and Distortion are calculated from the visible image of the checkerboard target, these results are heavily influenced by the image being partly dark and show significant deviation from the good quality Laparo3.

Since only four laparoscopes have been tested, this sample size does not provide enough results to determine a threshold for these optical quality indicators, but the results look promising to continue with further research to optimize the measurement methods for laparoscopes.

The outliers seen in figure 8 (Sharpness) and 9 (Distortion) are from Laparo2 and Lapar4. The recorded images of the checkerboard target for these endoscopes have been included in the appendix in figure 11 (Laparo2) and 12 (Laparo4). Imatest software calculates the values for Sharpness, Contrast and Distortion based on the largest rectangle of black and white squares the software is able to detect in the image.

The recorded image of Laparo2 shows only part of the recorded image was visible and the Imatest software had to perform the measurements for the lens characteristics on a significantly smaller rectangle compared to the other tested laparoscopes, which could have led to the outlier measurement for Sharpness.

The recorded image of Laparo4 shows that the image is very unsharp in a large area (center, left, bottom). As the Imatest software detects the squares based on clear edges and corners between dark and light squares, the software has performed the measurements for the lens characteristics on a narrow rectangle on the right side of the center. This may have been the reason for the extremely high values for sharpness and distortion.

Cystoscopes The results for the three high quality cystoscopes included in this study show consistently equal or higher measured values compared to the low quality cystoscopes that have been measured. (See figure 10) The high quality cystoscopes show almost double the values for contrast and significantly higher values for Light Transmission and Colour Correctness.

Since only eight cystoscopes have been included in this experiment, this sample size does not provide us with enough results to determine thresholds for these optical quality indicators, but the results for the cystoscopes do look promising to continue with further research to the threshold values for rigid endoscopes.

After performing all measurements for this experiment I learned that the prism to accommodate the different viewing angles in cystoscopes can influence the comparison between the different cystoscopes. All measured cystoscopes in this dataset have a viewing angle of 30°, except for Cysto10 and Cysto11, they have a viewing angle of 12°. The prism used for 12°cystoscopes results in a distorted projected image which might be an explanation for the high k value for Cysto11 for Distortion.

Arthroscopes The results for the measured arthroscopes (see figure 6) are less conclusive in showing a clear distinction between high and low quality arthroscopes. The three high quality arthroscopes show variable results, with especially Arthro3 and Arthro10 often performing equal or worse than the low quality endoscopes.

Even though this sample size was larger than the sample size for the laparoscopes and cystoscopes, more measurement results are necessary to determine thresholds for these optical quality indicators.

Arthroscopes often have to endure more physical damage compared to other types of endoscopes, as the target area during an arthroscopy is often narrow and complicated to reach. This results in impact with shavers and other surgical instruments, damaging the distal tip. The arthroscope is also often wrongly used to provide leverage to move structures and tissues away from the target area. The deflection resulting from these actions can easily 'snap' the lenses within the shaft of the endoscope. Low quality arthroscopes are therefor often sent out for repair after major damage has occured, compared to other types of endoscopes with low quality due to many reprocessing cycles and general wear.

To be able to further discuss the measurement results of the arthroscopes the observed damages by ERPA Instruments have been summarized in the appendix in table 3. Furthermore, the recorded images of the three high quality arthroscopes have been provided in the appendix in figure 13, 14 and 15.

High quality arthroscopes: The three tested high quality arthroscopes each have a different DOV, and Arthro9 was 10cm shorter compared to all other tested arthroscopes during this experiment. As the sample size was small, the results for Arthro9 (figure 14) have been included in this study but must be critically looked at when comparing the results.

The diameter of all tested arthroscopes was 4mm, while Arthro9 had a diameter of 2.7mm. The smaller diameter explains the higher distortion and higher values for sharpness as the Imatest software has calculated sharpness on edges closer to the center of the image compared to the other arthroscopes.

Arthro3 (figure 13) has a significantly darker image compared to other arthroscopes, which leads to lower contrast and explains the low sharpness results, low light

transmission results and low colour correctness results.
A larger set of high quality endoscopes to compare with low quality endoscopes must be included in a future evaluation to examine the effect of the different specifications of each modeltype within one group of rigid endoscopes such as arthroscopes.

Low quality arthroscopes: Arthro13, Arthro17 and Arthro22 show significantly higher values for Sharpness. The observed damage for Arthro13 included spots/stains in the image suspecting moisture damage. Apart from the spots in the image, the sharpness of the arthroscope remained high. Observed damage for Arthro17 included shaver damage and scratches visible on the image. The sharpness results remained high. Observed damage for Arthro22 included a yellow image and spots due to shaver damage. The extremely high value for sharpness for Top Right Vertical is assumed to be a miscalculation by Imatest, possibly due to the lower contrast resulting from the yellow image.
Comparing the results for light transmission shows large deviations between the arthroscopes. Very low results were recorded for Arthro12, Arthro15, Arthro19, Arthro21 and Arthro23. The observed damage by ERPA for these arthroscopes all include the notice of either a dark image, a dirty image, debris on lenses or hazy images. High results for light transmission were recorded for Arthro4, Arthro7, Arthro13, Artho17 and Arthro20. The observed damage by ERPA for these five arthroscopes all include shaver damage and/or a specific issue with the lenses. Arthro4 is observed to have loose lenses in the lens train, explaining the low light transmission in the Top and Right of the image but otherwise scoring high results. Scratches and spots due to shaver damage influence specific area's of the recorded image but might not be identified as a low quality endoscope based on these six quality indicators tested in this study. It is therefor highly encouraged to integrate more of the discussed quality indicators in chapter 3 of the accompanying master thesis. A method to record images of the exterior of the distal tip of the rigid endoscope to identify shaver damage is further discussed in the discussion of the accompanying marter thesis.

Measured differences between types of endoscopes

The test set-up was able to distinguish between good quality and bad quality laparoscopes and cystoscopes. The measured results also show differences between different types of rigid endoscopes.

Sharpness, Contrast and Distortion As can be concluded from the Distortion results of arthroscopes (figure 6.c), the small diameter, relatively short shaft length and large Field of View result in more distortion in the projected image compared to other types of endoscopes such as laparoscopes and cystoscopes. Both Sharpness and Contrast measurements are performed with the same size checkerboard target as has been used for the laparoscopes, but as the arthroscopes have a smaller diameter lenses in combination with a relatively large Field of View, the four ROI's on the edges of the image are less far away from the center and the edges of the squares in these projected images are relatively longer compared to laparoscopes. This might explain why the sharpness results for arthroscopes are relatively higher compared to laparoscopes. The higher distortion compared to the cystoscopes might explain why the sharpness results for arthroscopes are relatively higher compared to cystoscopes.

Laparoscopes have achieved higher results for the light transmission lens characteristics compared to other types of endoscopes. This influences the Contrast measurements, showing significanly higher contrast values for laparoscopes compared to cystoscopes and arthroscopes. The large diameter lenses and relatively smaller Field of View also provide the laparoscopes with a seemingly undistorted projected image.

Light Tranmission, Vignetting and Colour Due to the large diameter lenses found in laparoscopes it is expected to achieve higher results for the light transmission lens characteristics compared to other types of endoscopes with a smaller diameter lenses. Good quality cystoscopes have an equal or even lower Light Transmission compared to the bad quality laparoscopes tested.

Vignetting occurs in almost all lenses, and is more and more apparent towards the edge of the lens. Laparoscopes have a large diameter lenssystem and relatively small Field of View, resulting in minimal vignetting as the light travels mostly trough the center of the lens. Arthroscopes have a smaller diameter lenssystem and a relatively large Field of View, resulting in more vignetting as the light also travels through the edges of the lenses. Cystoscopes have a smaller diameter lenssystem but also a smaller Field of View compared to Arthroscopes, and the vignetting results for cystoscopes are on average higher then the arthroscopes.

Colour Correctness for laparoscopes often achieves a 100% score as the large diameter lenses allow all wavelengths of light to travel through. Due to the abovementioned mechanical differences between the laparoscopes and the arthroscopes and cystoscopes, we see that arthroscopes results vary and cystoscopes results are relatively low compared to laparoscopes. In general, blue colour comes through less than the red and green colour due to the shorter wavelength of blue. Longer wavelengths such as the red and green colour can travel through the lenses even if minor damages in the lenses occur. Shorter wavelengths such as blue might be more blocked by minor damages in the lenses.

Test Set-Up Limitations

Mechanical Limitations The developed test set-up contained two main components; the mounting station and the measuring station. The mounting station has been manually aligned during the development of the test set-up. As the endoscopes each have a different length, the mounting station can be repositioned to position the distal tip over the rotation point of the measuring station. The manual alignment of the mounting station may influence test results for different lengths of endoscopes.
The length of each endoscope was measuring to determine the position of the digital ruler. The digital ruler was set manually within 0.1mm of the determined position. The manual handling of the mounting station may have influenced the alignment of the shaft of the mounted rigid

endoscopes, as the slider on the digital ruler showed some room for movement.

The light post was aligned against a block of wood to position the distal window perpendicular to the target of the measuring station. This block of wood was manually crafted and may have influenced the alignment of endoscopes with differently positioned light posts. In general, this block of wood may have been slightly too high or too low, resulting in the distal window not aligning exactly perpendicular to the target.

The measuring station includes a rotating platform with a printed scale of the rotational angle. The platform was manually locked in the correct position, leaving room for slight deviations between measurements. The multiple targets were exchanged to perform all measurements. Even though the targets were placed in a target holder, there was some slack between the targets and the targetholder.

Using different manufacturing techniques and materials may greatly benefit these parameters. The repeatability and stability of this test set-up can and should be improved in a future evaluation to obtain higher accuracy in the performed measurements.

Target limitations and considerations Recommendations for the target designs have already been mentioned during the discussion of the stability of the test set-up.

Software limitations Imatest software and Adobe Photoshop have been used to analyse the recorded images during this study. Imatest software is highly specialized software to determine image quality of lenses and camera systems. It is developed for the main application of analyzing images of (photo) camera's, introducing certain assumptions for the calculating algorithms. For example, the software often assumes it is analyzing a rectangular image recorded by a camera sensor. The recorded images of the rigid endoscopes in this study show the circular image through the endoscope and black where no light fell on the camera sensor.

To produce more accurate results and take into account the differences between different types of endoscopes it is recommended to develop specific software to analyze the image quality of rigid endoscopes.

Unadressed Quality Indicators

This study included measurement methods for nine quality indicators, of which six have been quantified and analyzed. The remaining six quality indicators that have been unadressed in this study are:

1. Shadowing
2. Light Transmittance of the Light Fibers
3. Colour Correctness of the Light Fibers
4. Fractures in the lenses
5. Leakage or Moisture Damage
6. Damaged Distal Tip

The scope of this study has been focused on the optical quality of rigid endoscopes. Shadowing, light transmittance of the light fibers and colour correctness of the light fibers have not been considered in this study as they provide a measure for the quality of the light fibers and not the optical system.

The remaining three quality indicators do provide a measure for the quality of the optical system of rigid endoscopes. Only qualitative measurement methods currently exist for these measures, while the aim of this study was to develop an objective measurement method for the optical quality of rigid endoscopes. Quantitative measurement methods to detect fractures, moisture damage and external damage to the distal tip remain to be explored and developed. An alternative suggestion for a method to analyze the overall quality of rigid endoscopes would be to introduce qualitative measurement methods for these quality indicators, and save the recorded images where the results are based upon as a reference.

Previous Research on Objective Examination of Optical Quality of Rigid Endoscopes

Wientjes et al. (9) have described an experimental test bench to assess contrast of the lenses and the light transmission of the light fiber of a rigid endoscope prior to the development of the ScopeControl system by DOVIDEQ Medical. This experimental test bench has performed 1599 measurements on 288 rigid endoscopes of 46 different types during an eight month period.

The test set-up discussed in this study currently provides less stable results for contrast compared to the results of Wientjes et al. However, deteriorated quality of rigid endoscopes can be manifested in more quality indicators then only contrast. A clear example of this are the high contrast results of Arthro4 even though part of the image was dark due to loose lenses in the lens train.

Wientjes et al. have measured contrast in the center of the recorded image only, assuming the entire image of the rigid endoscope is affected when the quality is deteriorated. The measurements performed in this study include the results of the center of the image and four regions of interest in the top, bottom, left and right of the recorded image.

Wientjes et al. also describe the results of measuring the light transmission of the light fibers of rigid endoscopes. Even though this has not been included in this study, the results of light transmission of the lenses itself have proven to provide valuable insight on the optical quality of the tested rigid endoscopes. The results for light transmission of the lenses in combination with the sharpness and contrast results together seem to be the most informative on the optical quality of rigid endoscopes, although this suspicion should be validated with a larger sample size measured over a longer period of time.

Future Development and Recommendations

Recommendations to improve the current design of the test set-up have already been mentioned in previous sections. The following overview also includes recommendations aimed at future research towards developing an objective measurement method to determine the overall quality of rigid endoscopes that will improve patient safety in the OR:

- Optimize Checkerboard target design to increase the stability of the lens characteristic measurements. This includes investigating different displays either digital or physical.

- Improve the materials used and the manufacturing techniques during the development of this test set-up. This is expected to increase the accuracy and stability of the system.
- Develop software specifically for measuring the optical quality of rigid endoscopes.
- Research including separate proof of concepts for measurement methods for fractures, moisture damage and damaged distal tips is necessary to investigate the possibility of integrating all fifteen quality indicators in one method to determine the overall quality of rigid endoscopes.
- It is recommended to include larger sample sizes to be able to distinguish between different modeltypes of rigid endoscopes is expected to provide more insight on the relationship between the results of the measured parameters.
- To be able to develop failure thresholds for each quality indicator, it is recommended to investigate the acceptance and rejection criteria for clinically used rigid endoscopes. These may be dependent on endoscope type, surgical application, and personal preferences of the surgeons. The results of this study also suggest that the combined result of multiple quality indicators may sometimes be just as relevant on the quality of that instrument compared to a single measured value of one quality indicator.
- This study included rigid endoscopes stored at ERPA Instruments, a repair facility and manufacturer of rigid and flexible endoscopes. It is recommended to investigate the results of a similar test set-up in a clinical environment over a longer period of time.

Conclusion

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 provide valuable insights, the current design of the test set-up including the target proved not stable enough to draw significant conclusions. 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 loose or broken lenses.

Further research in this field is greatly encouraged as the scope of this study has been limited. 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 include validating the technical solution and further investigating the acceptance and rejection criteria in a clinical study.

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 and will need significant optimization, 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.

Disclosure

The author has been part time employed at Zign Medical per September 2018, and has received financial support for the materials used in the development of the test set-up discussed in this study.

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Appendix

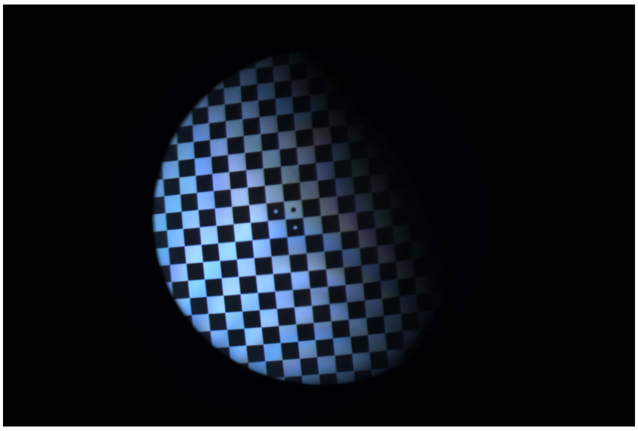

Figure 11. Recorded image of checkerboard target through Laparo2

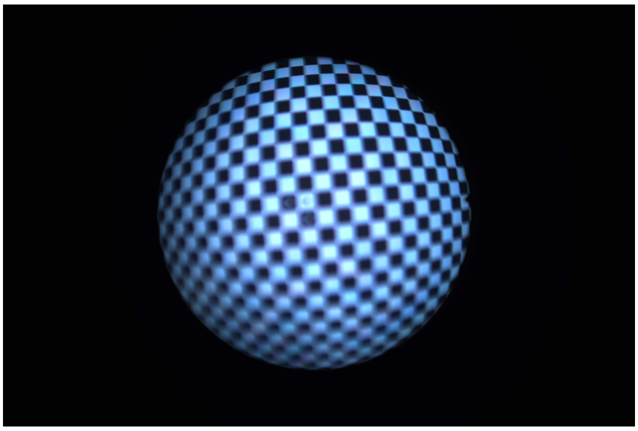

Figure 12. Recorded image of checkerboard target through Laparo4

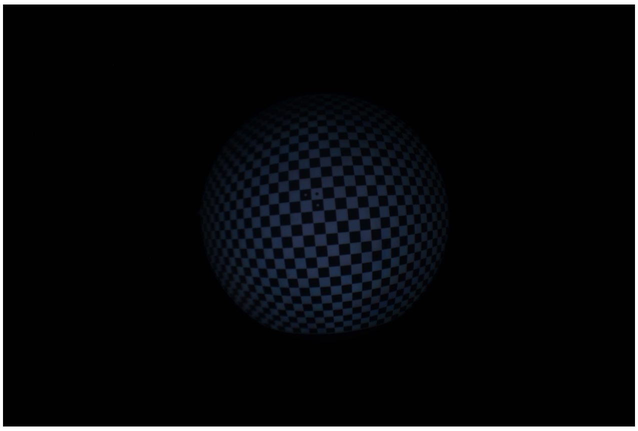

Figure 13. Recorded image of checkerboard target through Arthro3

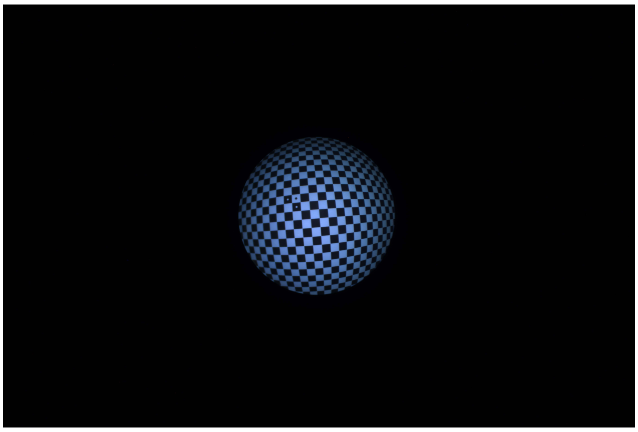

Figure 14. Recorded image of checkerboard target through Arthro9

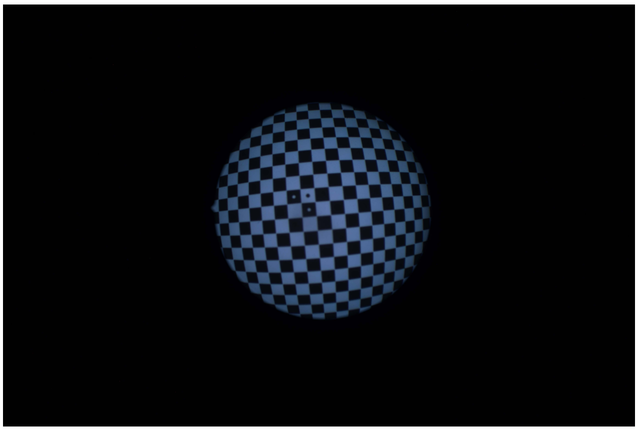

Figure 15. Recorded image of checkerboard target through Arthro10

	Manufacturer	DOV	FOV	Observed Damage
Arthro4	Arthrex	30	?	Loose lenses in lens train
Arthro5	Stryker	30	?	Misty, yellow image, shaver damage
Arthro6	Storz	30	?	Shaver damage, broken lens in distal tip
Arthro7	Storz	45	105	Slightly out of focus, dirty/dusty
Arthro8	Smiths & Nephew	45	80	Hazy image
Arthro11	ERPA	30	105	Darker image, dirt on lenses
Arthro12	LUT	30	?	Hazy image
Arthro13	Arthrex	30	?	Spots/stains in image, suspected moisture damage
Arthro 14	Olympus	30	?	Shaver damage, Lens distal tip damages including 2 big scratches
Arthro15	Atlantec	30	100	Spots/stains, dark, DOV incorrect
Arthro16	Storz	30	100	Shaver damage, out of focus, hazy image with spots
Arthro17	Dionics	30	105	Shaver damage, spots and scratches visible in image
Arthro18	Arthrex	30	90	Hazy & dirty image
Arthro19	ERPA	30	95	Moisture debris on distal window, shaver damage
Arthro20	Olympus	70	110	Shaver damage, bent shaft
Arthro21	ERPA	30	100	Hazy image, slight shaver damage
Arthro22	Strycker	30	80	Yellow image, spots/stains, shaver damage
Arthro23	ERPA	30	90	Unsharp, dirty image, shaver damage
High Quality				
Arthro3	Storz	30	?	Just repaired
Arthro9	Xion	0	?	Just repaired, 10cm shorter then all other arthroscopes tested, smaller diameter (2.7mm)
Arthro10	Storz	45	?	Just repaird

Table 3. Observed damages for each arthroscope by ERPA Instruments