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Multi-Center Evaluation of Optical Degradation Patterns in Rigid Endoscopes: A Data-Driven Approach

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Introduction: The ScopeControl (Dovideq Medical, Hengelo, The Netherlands) measures the optical quality of rigid endoscopes in the sterilization department's cleanroom. Endoscopes with low quality are rejected for use and must be repaired or replaced.

Methods: An analysis of 500,000 measurements from 95 ScopeControls worldwide was conducted to evaluate hospital strategies, such as endoscope replacement timing, repair versus replace decisions, brand selection, and the impact of operating room to central sterile department processes. For the UMC Utrecht, repair data and usage data from surgery were included in the analysis. Custom software was used to filter out inexplicable, deviating measurements and calculate trend parameters such as initial and average quality, average quality decrease, and time to failure.

Results: The ScopeControl measurements are generally of good quality. Data exploration revealed significant variations between endoscopes. Lifespan ranged from 15 to 400 usages, with endoscopes often failing suddenly due to a broken lens, likely caused by mechanical or thermal shock. For specific endoscope types, comparisons between new and repaired endoscopes showed that repaired endoscopes have a median lifespan of 30% fewer usages and median light transmission that is 11% lower than new endoscopes. Entry measurements are highly recommended due to the large variation in the optical quality of both new and repaired endoscopes. Additionally, users appear to accept lower quality for vulnerable, long, thin pediatric endoscopes, possibly due to the high replacement cost, compared to endoscopes used for adult applications.

Conclusion: ScopeControl enables objective assessment of endoscope quality and supports data-driven decisions on repair and replacement. Our analysis suggests that repaired endoscopes generally do not match the optical quality of new ones, and we provide initial estimates of this difference. These findings highlight the need for further data collection and may encourage improvements in repair processes. Sudden failures underline the importance of regular checks, and linking ScopeControl data with repair and usage information remains essential for optimizing maintenance strategies and improving endoscope longevity.

Keywords: rigid endoscopes, optical quality assessment, medical device quality control, predictive maintenance, repair versus replacement, data-driven healthcare

Introduction

As endoscopes used for minimally invasive surgeries are complex optical devices and thus expensive, they are used hundreds of times before being discarded.[1] To guarantee their optical and mechanical quality, they need to be checked after each surgery.[2–4] Often, this consists of manually checking the optical and mechanical properties of an endoscope and sending it for repair or replacement when its quality drops below a certain threshold. However, manual inspections can be subjective and less precise. To automate this task and provide a more robust and quantitative measurement, the company Dovideq Medical (Hengelo, The Netherlands) has developed the ScopeControl (Figure 1). This device measures the optical quality of endoscopes in the cleanroom of the sterilization department to determine whether the

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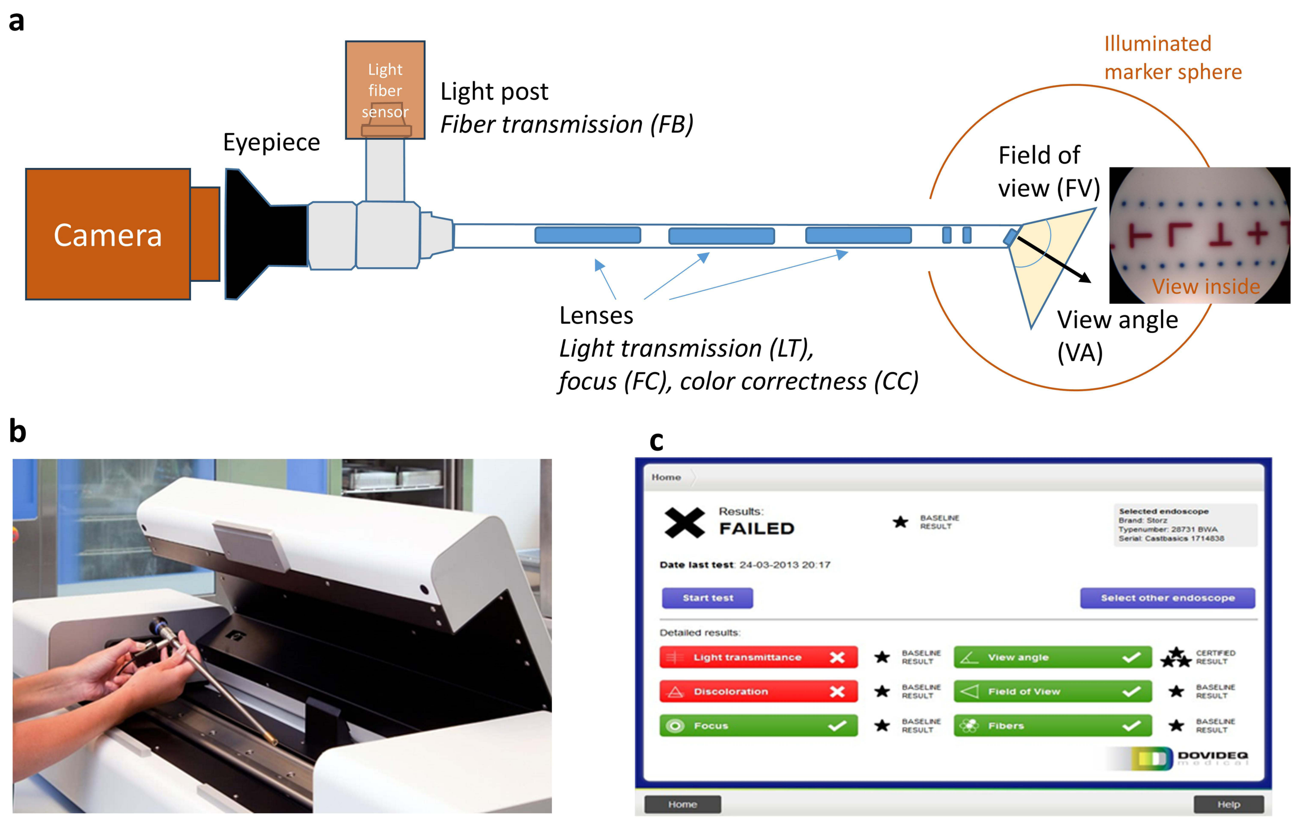

Figure 1 (**a**) Measurement values as determined by the ScopeControl device. An illumination sphere provides a test image containing characters like "L", "T", and a plus sign that can be seen by the camera to determine the light transmission, focus, color correctness, field of view, and angle of view. A light fiber sensor measures the amount of light passing through the illumination fibers. (**b**) The ScopeControl in action in the sterilization department. (**c**) The results of the measurement are shown on the cover screen. Green buttons indicate values corresponding to good quality, while a red button means that a measurement value has dropped below the rejection threshold.

endoscopes still have sufficient optical quality to be used for the next minimally invasive operation.[5] The ScopeControl uses a central database (called endoscopemanager.com) to store all measurements and obtain reference values of new endoscopes. When the lens quality drops below 70% of that of a new one or when the fiber transmission drops below 30% of that of a new one, the endoscope should be set aside and checked by a technician. The ScopeControl makes the following measurements to characterize the optical quality of an endoscope:

- Illumination Fibers:
  - **Fiber transmission (FT):** The amount of light passing through the illumination fibers by measuring the amount of light transmitted from the tip of the endoscope to a sensor at the light post.
- Lenses:
  - **Light Transmission (LT):** The amount of light coming from the tip to the camera.
  - **Focus/Sharpness (FC):** Determined by blur edge detection at a fixed focus point.[6]
  - **Colour Correctness (CC):** Deviation from "white" transmission due to color shift resulting from thermal or chemical alteration of lens coatings or adhesives.
  - **View Angle (VA):** The angle of view of the tip of the endoscope, measured by calculating the angle to targets visible on the inside of the illuminated marker sphere.
  - **Field of View (FV):** The aperture angle of the tip of the endoscope, measured by the size of visible targets on the inside of the marker sphere.

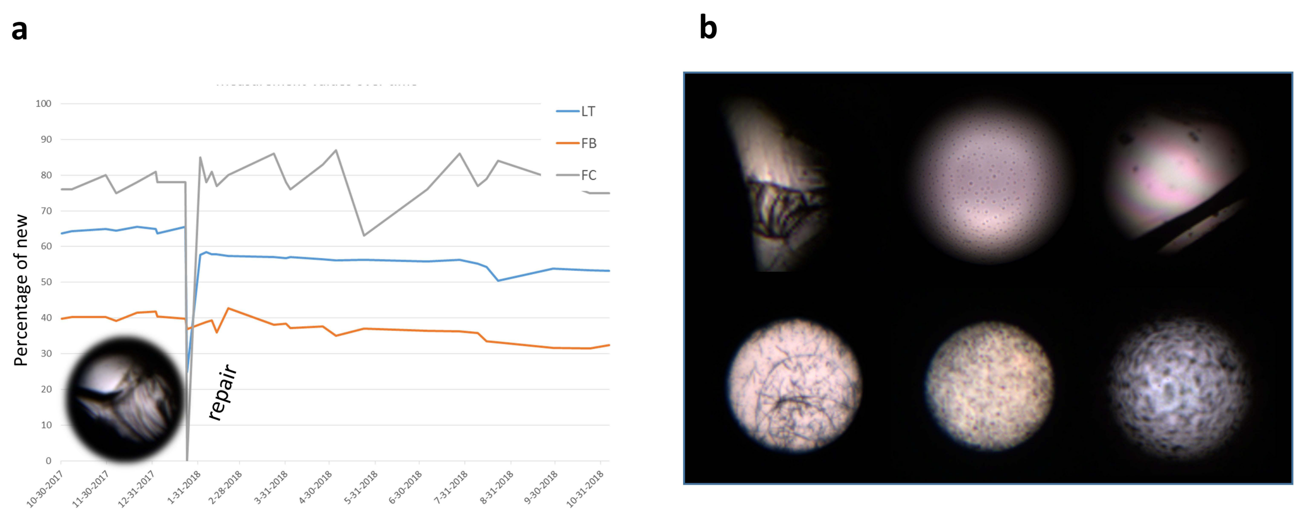

Figure 2 (**a**) The endoscope degradation is often observed as sudden lens breakage. After repair or replacement, the quality is restored. (**b**) Examples of lens damage or contamination can be seen on the inner lens surfaces. The ScopeControl can be configured to capture contrast seen on internal lens surfaces.

Apart from these measurements, the ScopeControl captures images of the rod lenses within the endoscope when relevant structures like lens cracks, dirt, or moisture are visible on them. These images are also stored in the cloud at endoscopemanager.com and can be assessed to understand the damage to the endoscope (Figure 2).

The VA and FV values often do not change during normal use. These parameters are relevant when checking new or repaired endoscopes. Among the other parameters, the LT and FT values best represent the optical quality of an endoscope, meaning that these values drop earlier than the other parameters when the endoscope deteriorates. Therefore, in the rest of this paper, we will concentrate on the LT and FT values.

Now that the ScopeControl has been in use in multiple hospitals for around 10 years, it has yielded a substantial amount of data on the optical quality of endoscopes used in the clinic. In this paper, we want to explore to what extent this data can be used to answer questions such as:

1. What is the average lifetime of an endoscope or reduction over time or per use in quality parameters such as light transmission through lenses and fibers?
2. Are the rejection thresholds of 70% for lens transmission (LT) and 30% for fiber transmission (FT) still valid?
3. What can be said about different strategies used by hospitals for replacement, such as repairing endoscopes versus buying new ones?

This approach complements that of Courault et al,[7] who aimed to determine meaningful rejection thresholds for LT and FT in a laboratory setting by asking a select group of surgeons to indicate when image quality became unacceptable In contrast, our analysis is based on large-scale, real-world data, providing an objective, quantitative view of optical degradation under routine clinical conditions.

Materials and Methods

More than 500,000 measurements from 2014 to 2023 (representing almost 2 years of continuous measurement time) from 95 ScopeControls used globally were gathered into one Excel file. We enriched the dataset with additional data from our hospital (University Medical Center (UMC) Utrecht), including: 1) an overview and costs of endoscope replacement and repair, and 2) data from surgeries from the electronic healthcare system related to a ScopeControl measurement, such as instrument usage, operating time, and type of surgery. This linkage was possible because the endoscope tray number was also recorded during a ScopeControl measurement.

From those measurements, many were useful, but we had to consider the following factors in the analysis:

Periods with no data or deviating measurements, mostly due to cable breakage of the light fiber sensor, but also because the ScopeControl camera had to be adapted to new types of endoscopes.

- Sometimes deviating measurements occurred because the camera or light fiber sensor was defective.
- Incorrect serial numbers were selected when performing a measurement. Since machine identification of endoscopes was not feasible (barcodes and QR codes wore down quickly due to the harsh cleaning and sterilization process), personnel from the sterilization department had to manually select the right type and serial number of the endoscope when performing a measurement. Often, the serial number is visible on the outside, on the shaft or the housing, but for some brands, it is hidden, eg, under the light post. In that case, the LOT number of the shaft was often selected as a serial number. As this number can be present on multiple endoscopes of that type, it introduced measurements stored under invalid serial numbers.
- Missing tray numbers with a ScopeControl measurement because tray number scanning was not enforced.

A special analysis tool was written in the C++ language to enable the comparison of endoscope degradation over time between endoscope types, brands, and hospitals. After starting the software, a single Excel file must be loaded with different sheets containing:

- A sheet containing all ScopeControl measurements from all hospitals.
- A sheet with additional information when data was missing in the ScopeControl data about the endoscope types, such as length, diameter, viewing angle, and clinical type (eg, laparoscope, cystoscope, bronchoscope, etc).

Further, three additional sheets may be present with specific data from the UMC Utrecht (as this information was not available for the other hospitals):

- A sheet with repair data. This file contains the serial number, type, start date, and end date of each repair.
- A sheet with scan moments of each tray number of endoscopes, extracted from the electronic health record system (HiX, ChipSoft, Amsterdam, The Netherlands), to supplement the ScopeControl measurements with actual usage data. The rationale for this is that users are not obliged to perform a ScopeControl measurement when processing the endoscope in the sterilization department. To identify a usage moment, a distinction is made between tray scans in the dirty room, the clean room in the sterilization department, and the OR locations. Because an endoscope may go through the washing machine a second time but not enter the OR, only round trips from dirty, clean, to OR are considered as one usage.
- A sheet with surgeries where trays of the same endoscope type are used twice (data also extracted from the HiX system), suggesting that one endoscope may have been rejected during the procedure.

After loading this data, the LT, FT, and FC data can be viewed in a graph. The data can be filtered by hospital, brand, and type. Further analysis involves: 1) splitting a graph into two if repair data was available and a repair had taken place within the selected time frame; 2) discarding graphs with fewer than ten measurements to allow robust trend estimation; and 3) determining different parameters for each graph (Figure 3) (MV stands for measurement value, such as LT, FT, or FC):

- *ttf*: Number of measurements or usages (when tray information was available) for a specific endoscope, representing time to failure.
- *Ys, Ym, Ye*: representing start, mean, and end value, respectively.
- *a*: slope coefficient determined for each graph by fitting a straight line to it.

Together with the length and diameter of an endoscope, this results in a parameter set of six values. In the software, these values can be plotted against each other to search for distinguishable point clouds. Also, to calculate specific relations, box-whisker plots have been generated using this software or in Excel.

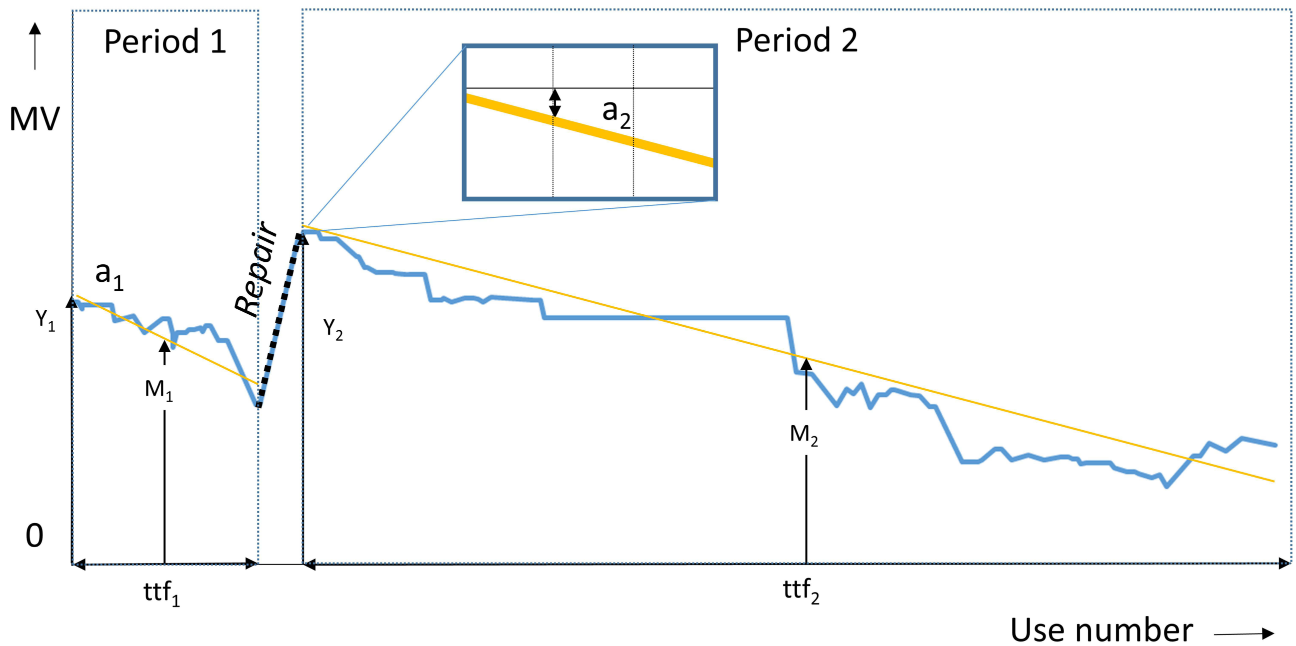

Figure 3 Trend parameters *Y* (start), *M* (mean), *ttf* (time to failure) and slope *a* are determined for each MV (measurement value) graph and usage period.

Results and Discussion

ScopeControl

During the measurement period, the ScopeControl appears to provide stable measurements. As long as the endoscope was sufficiently dried after the washing process, a measurement of good quality could be obtained. However, occasionally the cable of the light fiber sensor broke, resulting in FT values of zero. In addition, the ScopeControl camera had to be adjusted to measure the Olympus optics properly. A difficulty is that the light post connector has no standard shape and may differ from one manufacturer to another, making it challenging to design a clamp mechanism that fits every connector. At the moment, the Storz light post is used as the standard. For other brands, light posts might need to be changed for measurements with the ScopeControl. If this is omitted, the FT measurement can suddenly be much higher or lower.

Time to Failure

From the measurement data, we can calculate the time to failure of the different types of endoscopes from the seven major brands with sufficient data. Since we only have repair and replacement data available from the UMC Utrecht, we will initially limit ourselves to measurements performed at the UMC Utrecht.

In these measurements, we accounted for the fact that the endoscope was not always measured using the ScopeControl. By also registering the tray number during a measurement and tracking how often the endoscope was used in surgeries by checking the electronic healthcare system, we could determine a ratio between the number of measurements in the ScopeControl and the actual usage. At UMC Utrecht, this ratio was 2.2 ± 0.6, meaning that, on average, 1 measurement was performed in the ScopeControl for every 2.2 uses. Possible reasons for this discrepancy may include that a measurement is not always possible because the ScopeControl is not functioning, or that the employee does not have the time or inclination to perform the measurement.

Including actual usage data, we were able to create a graph showing the variation in time to failure as a function of thickness, viewing angle, and length (Figure 4).

We observe clear differences in the number of times an endoscope is used. Some types are used up to 400 times before they are replaced or repaired, while other endoscopes last only a few dozen uses. This lower value aligns with the number 36, as reported by Skogas and Marvik,[8] but in general, the time to failure of rigid endoscopes at UMC

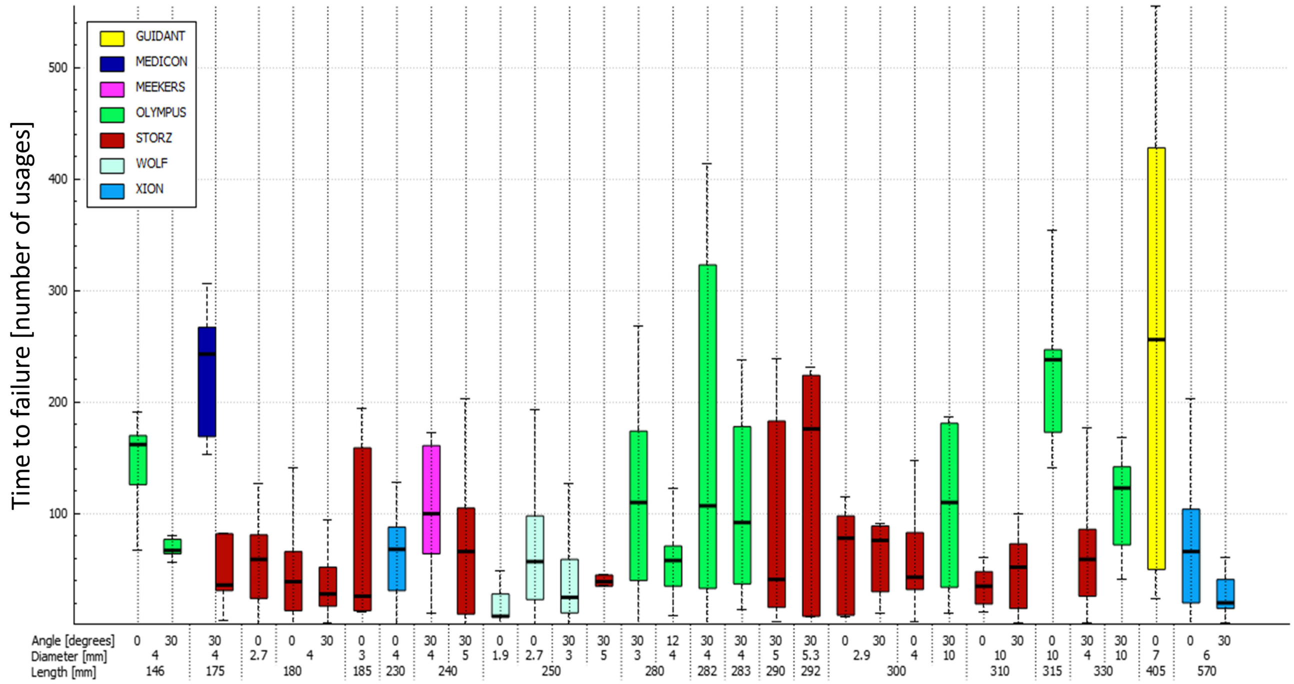

Figure 4 Time to failure of the seven major brands of rigid endoscopes in the UMC Utrecht, split for repairs or replacements. The higher the time of failure, the longer the endoscope is used without repair or replacement. Some types of endoscopes last for more than 400 usages, while others last only for tens of usages.

Utrecht is higher where steam is used for sterilization. Perhaps the quality of the endoscopes and sterilization has improved over the last 20 years, or it could be that users are handling endoscopes with more care. The hypothesis that thinner endoscopes break faster than thicker ones is not directly evident from this data; even thicker types sometimes break quickly.

Repaired Versus New Endoscopes

When an endoscope has become too worn out for use in subsequent surgeries, it can be replaced with a new one. However, hospitals often choose to have it repaired because it is usually cheaper. To understand the difference in quality between a new endoscope and a repaired one, we analyzed the data in various ways.

Initially, we examined the progression of the quality of new endoscopes compared to the values of endoscopes in use and those that have been repaired. For example, in Figure 5, we observe the light transmission values of 24 pediatric cystoscopes from 2014 to 2016 at UMC Utrecht. Dotted lines indicate the times when an endoscope was repaired. Often, the rod lens of these thin endoscopes suddenly breaks, after which they are sometimes still used for a while before undergoing repair. The LT value often returns to its previous level after repair. Two new endoscopes are shown for comparison. After about six months, their quality drops to a level similar to that of the other endoscopes.

In another comparison, all data were taken at UMC Utrecht from endoscope types with at least 10 new and 10 repaired units (28 types, 5 brands). From these data, the trend parameters *ttf*, LT (*ys* and *a*), and FT (*ys* and *a*) were compared between repaired and new (Figure 6). To standardize the *ys* values across all endoscopes, the *ys* values were normalized (new and repaired value sum to 1) before being compared. Overall, repaired endoscopes had a shorter time-to-failure (median 50 vs 82 uses; p=0.06), slightly lower initial LT (ratio 0.89; p<0.001), and clearly lower initial FT (ratio 0.74; p<0.000001). These findings confirm that new endoscopes start with better quality, although they tend to degrade faster (a). Note that these results reflect one repair company at UMC Utrecht; other providers may yield different results.

The graph also shows that the variation in practice is large, including in initial optical quality. An entrance inspection is therefore strongly recommended when procuring a new or repaired endoscope.

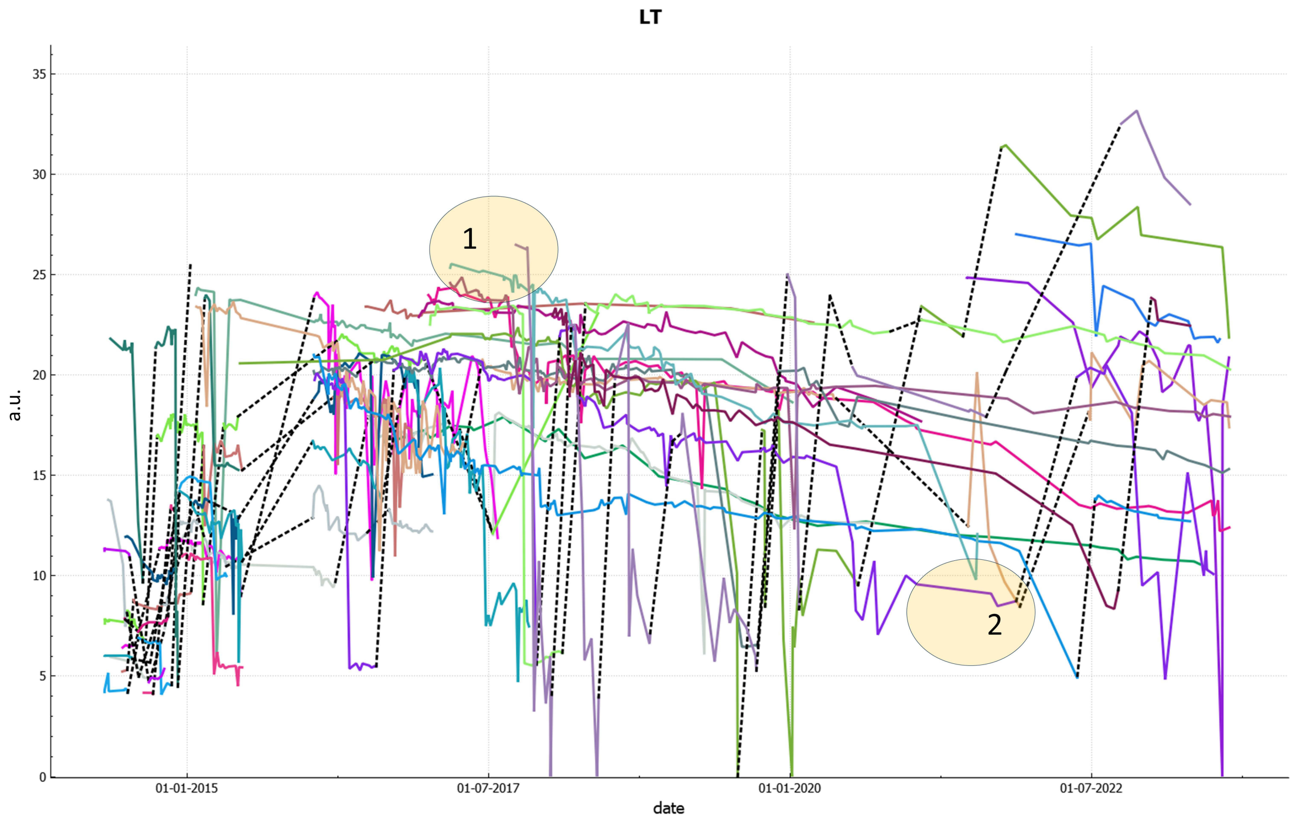

Figure 5 An example of plots showing the light transmission (LT) over time for 24 pediatric cystoscopes (27 cm long, 2.7 mm thick). Often, endoscopes show better LT values after repair. Two new endoscopes have better quality than repaired endoscopes, but after half a year, they fall into the same value range as the others. Note that the y-axis is cut off at 4.

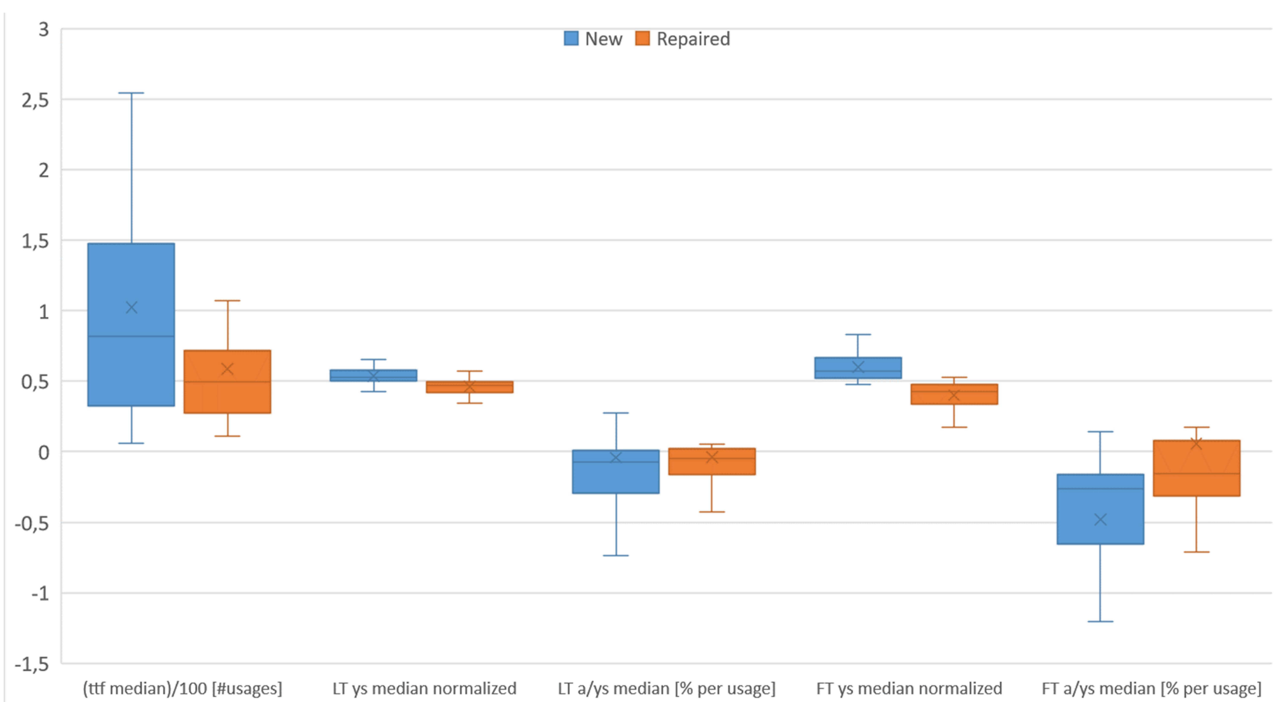

Figure 6 Parameter differences between new versus repaired endoscopes. New endoscopes last longer before they fail and have higher starting values for light and fiber transmission, but the fibers seem to degrade faster.

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Rejection Thresholds

To see if the set rejection criteria (70% LT, 30% FT) are met in practice, we compared the median of the last values of a measurement series *ye* with the median of the values at the beginning *ys*. These ratios for LT and FT have been plotted for the 5 largest brands at UMC Utrecht (Figure 7). The first thing that stands out is that some endoscopes are still being used at a low quality (Wolf, Xion) compared to others. We observe that more rejections occur based on LT than FT, which is explained by the fact that image quality is considered more important than illumination quality. Olympus optics are comparatively more likely to be rejected, which may be because there is an exchange contract for them, meaning it does not cost extra money to exchange an endoscope for a new one. The endoscopes of Guidant, Storz, and Xion are rejected at LT around 70%, which corresponds to the set value. For Wolf endoscopes, the LT value is apparently allowed to drop to 55%. This is probably due to the fact that these thin pediatric endoscopes are very fragile, and the pediatric department cannot afford to have them repaired or replaced quickly. It is also notable that the spread in FT reaches 30% only for Wolf endoscopes; apparently, most endoscopes are already rejected based on their lenses rather than their fibers.

Based on these results, we cannot conclude that the LT and FT thresholds should be adjusted as suggested by Courault,[7] who proposed thresholds of 55% for LT and 25% for FT based on surgeon perception. This is not directly supported by our data. However, our findings do show that the range of accepted values in practice can be large and may depend on the clinical application and the cost of replacement or repair. For example, Figure 7 shows that Wolf endoscopes are routinely used at LT values around 55%, well below the default 70% threshold. This likely reflects cost tolerance in pediatric settings, where replacement is expensive and less feasible, and serves as a clear example of a cost–quality trade-off in clinical decision-making. While these deviations do not justify changing the default thresholds, they highlight that threshold application may involve cost–quality trade-offs. If the cost of replacement is low, the LT threshold could be set even higher, eg, at 80%, whereas if these costs are high, the threshold could drop to 60%. Since most endoscopes are rejected on the basis of LT, our results do not suggest adjusting the FT threshold.

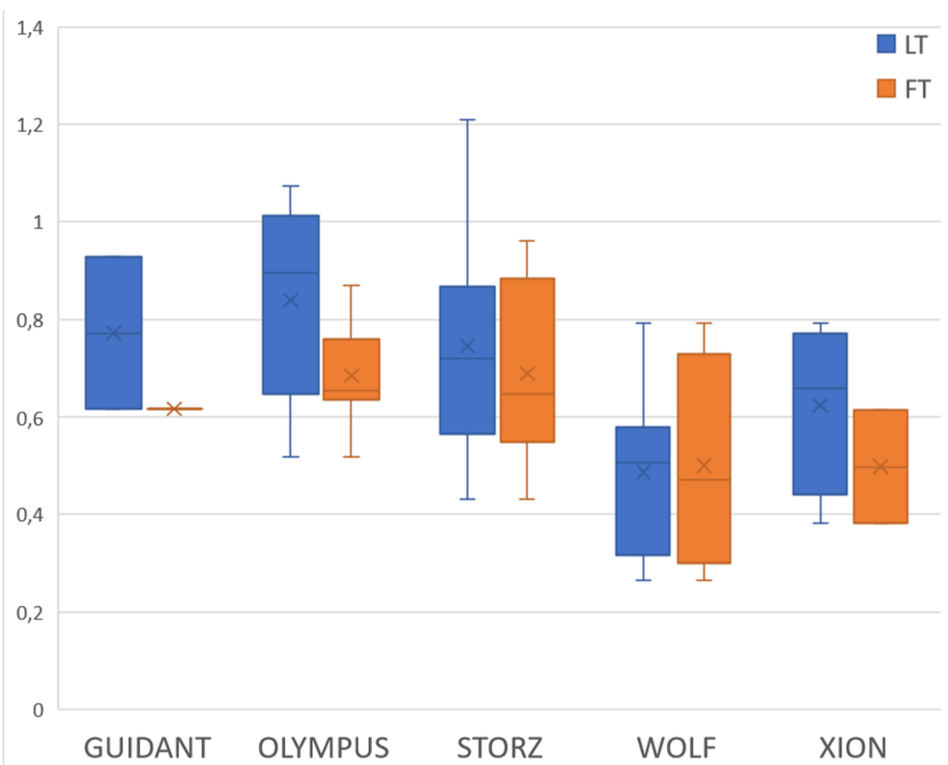

Figure 7 Ratios of the last to new measurement values for light and fiber transmissions.

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Figure 8 Start LT and FT values for the seven major brands in all hospitals are arranged by length, diameter, and view angle. Clearly, thicker endoscopes have higher LT and FT values. There are almost no endoscopes (with sufficient data) from different brands with the same specifications, which makes comparison difficult. A comparison can be made for endoscopes that are 175 mm long, 4 mm wide, and have a 30-degree angle. In this case, Storz endoscopes seem to have a larger start LT value than the Medicon alternative, but this might be explained by an (unknown) larger field of view.

Start Quality for Different Brands Depending on Length, Diameter and Viewing Angle

The previous analyses are unfortunately not possible due to the lack of repair and OR usage data from hospitals other than UMC Utrecht. However, we can examine the optical quality at the beginning of a measurement series. By including only those measurement series with more than 10 measurement points and more than 10 endoscopes, we created a box-and-whisker plot (excluding outliers) for the *ys* values of LT and FT, depending on brand, length, diameter, and viewing angle (Figure 8). As expected, thicker endoscopes transmit more light than thinner ones, but sometimes one type of endoscope with similar thickness transmits more light than another. For example, in the Storz 175/4/45°, both the start LT and FT are relatively high. In the Storz 180/2.4/0°, especially the start LT is relatively high. This may be due to a different design or a larger opening angle, but we could not verify this as these specifications are not public and would need to be obtained from the manufacturer.

Degradation Process

Our observations suggest that optical degradation is a continuum rather than a binary process. All endoscopes exhibit gradual wear over time, typically caused by glass dust, spacer debris, or discoloration of coatings and adhesives. Lens fractures also occur frequently, but their impact varies: minor edge cracks may only slightly reduce image quality, whereas major fractures can render the endoscope unusable. Large, sudden drops in LT values are likely associated with significant lens fractures, while slow declines are more consistent with contamination or coating degradation. Although repair records were linked in this study, they do not provide a reliable basis for classifying failure modes, as these are often mixed and depend on what the technician reports. For example, a repair note may state “lens replaced”, while the shaft was also cleaned or straightened without being documented. In practice, distinguishing between gradual and sudden failure is challenging and may not be clinically relevant for hospitals, which are more concerned with preventing damage than with identifying the exact mechanism. Although the image may still be viewable, such obstructions can disturb the view of the human tissue and compromise the accuracy of the diagnosis. Therefore, it is advisable to repair the endoscope promptly and to clean or replace it to maintain optimal imaging quality. Future work could explore whether combining ScopeControl data with detailed, standardized repair logs adds value, but this may be difficult to implement in routine practice.

Future

In our analysis, we often encountered cases where a measurement was recorded under the wrong endoscope. This issue occurred because personnel mistook the LOT number for the serial number and they were allowed to add such numbers to the ScopeControl database. As a result, many measurements were recorded under the same LOT number. To prevent this problem, we experimented extensively with barcodes and QR codes on stickers and laser engravings. Unfortunately, many of these codes faded quickly due to the harsh washing and sterilization processes. Recently, the KeyDot™ has become available, which seems to last longer through these processes. In combination with the DoviSCAN (Dovideq Medical, Hengelo, The Netherlands), we hope to achieve more unique registration and a faster measurement process, as users will no longer need to look up the serial number.

In our analysis, we found that the ScopeControl can reliably measure the quality of an endoscope and indicate when it becomes unsuitable for subsequent surgery. At UMC Utrecht, however, we encountered an issue where OR staff did not trust the measurement of a rejected endoscope and still wanted to keep the endoscope because they could “see through it” themselves. Consequently, the sterilization department staff struggled to take responsibility for enforcing the rejection. To ensure that responsibility remains with the end user, the surgeon, we plan to print the result of the ScopeControl measurement on a label and attach it to the outside of the sterile package. This will allow the surgeon to decide whether to use the endoscope of that quality for the next surgery. Conceivably, the surgeon may choose a less reliable endoscope for tasks like placing a catheter and opt for a better endoscope for diagnostic procedures.

The ScopeControl measurements could be even more valuable if we could determine where in the process—whether in the sterilization department, during transport, or in the operating room—the damage occurs. Is it due to heat/cold shocks in the sterilization department, or does the damage mainly occur during unpacking, use, and cleanup in the operating room? Additionally, one should not underestimate the role of transport, where long distances can be covered at high speeds, causing high G-forces—especially during return transport when the double sterile paper packaging is missing.

Our results show that, for proper trend analysis, ScopeControl data must be enriched with process data such as repair and tray scan data. Only then can we make substantiated statements about lifetime and practical rejection criteria. By enriching the data in the future with information on the type of sterilization (eg, plasma versus steam[8,9]) and the method of transport, we could gain a better understanding of where improvements are possible. Enhancing the data with exact specifications from manufacturers would also allow us to determine which endoscopes have better optical quality—not only at the beginning but also during use.

Repair-versus-replacement decisions are often driven by perceived cost advantages of repair. While our results indicate that repaired endoscopes generally do not match the quality of new ones, a full cost-benefit analysis was beyond the scope of this study. Nevertheless, these data provide a first evidence base for such analyses and suggest that the economic advantage of repair should be critically evaluated in future work, ideally across multiple repair providers.

Conclusions

When analyzing the ScopeControl measurements stored in the cloud by DOVIDEQ Medical, a few conclusions can be drawn. The time to failure, expressed in the number of uses, varies widely between 40 and 400. Repaired endoscopes do not always return to the quality of a new endoscope. This may be up to 15% lower for lens transmission and 20% lower for transmission through the illumination fibers. The data does not indicate that the default rejection thresholds of 70% (LT) and 30% (FT) should be changed. Depending on the cost of repair or replacement, the LT threshold may be increased for cheaper repair/replacement and lowered for more expensive repair/replacement. As expected, thicker endoscopes typically have better initial LT and FT values than thinner endoscopes, although this is not always the case, perhaps due to a higher (unknown) field of view. Additionally, endoscopes often degrade suddenly, making regular checks necessary.

For further analysis, a connection to repair and tray scan data is essential. This would enable extending the presented conclusions beyond the data from UMC Utrecht. Enriching ScopeControl measurements with sterilization, transport, and usage data can also greatly help in understanding what causes endoscopes to deteriorate.

Ethical Approval

This study did not involve human participants or animals. The data analyzed were obtained from existing, anonymized measurements of medical equipment (rigid endoscopes) and did not require ethical approval according to institutional and national guidelines.

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Disclosure

Menno de Braak is Sales Director of DOVIDEQ Medical. Menno Braak also reports affiliation with UMCU, outside the submitted work; In addition, Mr Menno Braak has a patent US9354160B2 issued to DOVIDEQ Medical. The authors report no other conflicts of interest in this work.

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