

Clinical trial Synopsis

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Scientific Research shows: Even a surgeon can't see if an endoscope is bad

Keywords

Endoscope, ScopeControl, Surgeon, Parameter, Control, Surgery, Threshold, Lyon, Optical, Quality control, Control of functionality - Sterilization - Optical quality

Background

In central sterile services departments (CSSD), the functionality of rigid endoscopes, which are complex and fragile reusable devices, is usually controlled visually and is considered a complex and subjective task. The objective of this study was to assess the ability of ScopeControl to pre-emptively identify optical defects before the surgeon considers the endoscope as defective.

ScopeControl was developed to provide an automated quality control of rigid endoscopes by measuring the value of six parameters: viewing angle (VA), field of view (FV), color correctness (CC), light transmission (LT), fibers transmission (FT), and focus (FC). The aim of the study was to assess the ability of ScopeControl to pre-emptively identify endoscope defects before the surgeon considers them as defective.

Methods

The study was done between July 2017 and January 2018 to test the optical quality of endoscopes used in the urological surgery department of the Lyon Sud hospital (Hospices Civils de Lyon, Lyon, France). The same endoscopes were evaluated by surgeons during surgery as well as the CSSD staff using Dovidge's ScopeControl during reprocessing.

After use of the endoscope in the operating room, the surgeon completed a score scale comprising of five items: image quality, brightness quality, settings on the video column, necessity of changing of the light cable, or the endoscope during surgery. The ScopeControl categorized the endoscope into 3 groups: passed, in danger and failed. The Surgeon categorized into 5 groups: very satisfactory, satisfactory, quite satisfactory, unsatisfactory, not at all satisfactory.

For each endoscope, a folder was generated and considered complete only if the surgeon's form was correctly filled out and the endoscope had been checked using ScopeControl. Correlations between the surgeon's evaluation and results of the ScopeControl were calculated.

Findings

According to the Focus parameter, endoscopes were classified as "Failed" in only 4.8% of cases compared to 38.0% for Fibre transission and 37.4% for light transmission. It was therefore considered that Fibre Transission and Light Throughput were the most discriminant parameters to characterize endoscope quality and focused only on these 2 parameters when comparing ScopeControl's results and the surgeons' evaluations.



Results

166 controls were carried out concerning 51 different endoscopes. According to the surgeon's evaluation, 78.9% and 80.7% of controls were considered as acceptable for image and brightness quality.

ScopeControl found that 13.3% of the same endoscopes were considered as "passed," 31.3% "in danger," and 55.4% "failed". LT and FT parameters represented 95.2% of the reasons for failures.

The ability of ScopeControl to detect endoscope defects earlier than surgeons was validated by tracking the results of endoscopes used and controlled several times.

The same endoscope could be used and tested several times, and a new folder was created each time the endoscope was checked by both the surgeons and the ScopeControl.

Surgeon's evaluation

	Image Quality	Brightness Quality
Very Satisfactory	53 (31,9%)	55 (33,1%)
Satisfactory	78 (47,0%)	79 (47,6%)
Quite Satisfactory	14 (8,5%)	10 (6,0%)
Unsatisfactory	13 (7,8%)	13 (7,8%)
Not Satisfactory	8 (4,8%)	9 (5,5%)

ScopeControl Results

	VA	FV	FC	FB	LT	CC	Final evaluation
Passed	166 (100%)	166 (100%)	155 (93,4%)	44 (26,5%)	61 (36,7%)	166 (100%)	22 (13,3%)
In danger	-	-	3 (1,8%)	59 (35,5%)	43 (25,9%)	-	53 (31,3%)
Failed	-	-	8 (4,8%)	63 (38,0%)	62 (37,4%)	-	92 (55,4%)

'80% of defects were not seen by the Surgeon'

Conclusion

ScopeControl achieved an objective and consistent quality control of endoscopes. 80% of defects were not seen by the Surgeon. In practice, the ScopeControl could avoid the use of defective endoscopes in the surgery unit, improving the quality of the surgical procedure.

