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Original Article

An Accessible Laparoscope for Surgery in Low- and Middle- Income Countries

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Associate Editor Jane Grande-Allen oversaw the review of this article.

Abstract—Laparoscopic surgery is the standard of care in high-income countries for many procedures in the chest and abdomen. It avoids large incisions by using a tiny camera and fine instruments manipulated through keyhole incisions, but it is generally unavailable in low- and middle-income countries (LMICs) due to the high cost of installment, lack of qualified maintenance personnel, unreliable electricity, and shortage of consumable items. Patients in LMICs would benefit from laparoscopic surgery, as advantages include decreased pain, improved recovery time, fewer wound infections, and shorter hospital stays. To address this need, we developed an accessible laparoscopic system, called the ReadyView laparoscope for use in LMICs. The device includes an integrated camera and LED light source that can be displayed on any monitor. The ReadyView laparoscope was evaluated with standard optical imaging targets to determine its performance against a state-of-the-art commercial laparoscope. The ReadyView laparoscope has a comparable resolving power, lens distortion, field of view, depth of field, and color reproduction accuracy to a commercially available endoscope, particularly at shorter, commonly-used working distances (3-5 cm). Additionally, the ReadyView has a cooler temperature profile, decreasing the risk for tissue injury and operating room fires. The ReadyView features a waterproof design, enabling sterilization by submersion, as commonly performed in LMICs. A custom desktop software was developed to view the video on a laptop computer with a frame rate greater than 30 frames per second and to white balance the image, which is critical for clinical use. The ReadyView laparoscope is capable of providing the image quality and overall performance needed for laparoscopic surgery. This portable low-cost system is well suited to increase access to laparoscopic surgery in LMICs.

Keywords—Biomedical devices, Laparoscopic surgery, Global surgery.

INTRODUCTION

Laparoscopic surgery is the standard of care in high-income countries for many procedures in the abdomen and chest, such as cancer excision,[11] organ resection, and treatment of other surgical diseases.[4,10] It avoids large incisions associated with open surgery by using a small camera and fine instruments manipulated through keyhole incisions.[33] Advantages of laparoscopic surgery include smaller incisions, decreased pain, improved recovery time, minimized post-surgical infections, and shorter hospital stays.[2] Patients in low- and middle- income countries (LMICs) would further benefit from laparoscopic surgery since the reduced recovery time would enable patients to return to home and work more quickly, thus mitigating impoverishing health costs.[10,27] Laparoscopic surgery would reduce postoperative complications in overcrowded wards [3,10] and minimize the stigma associated with certain surgical conditions.[16,30]

Despite these advantages, laparoscopic surgery is rare in LMICs and patients often receive open surgery instead, representing a great health care dispar-

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ity.[21,35,37] There is an initial equipment purchase cost of $133,000-136,000 for each operating room that includes the components of the laparoscope, viewing monitors and related equipment—a cost that is prohibitive for most health systems in LMICs.[17,29,33,34] Current laparoscopic technology uses fragile fiber optic cables, cameras, and lenses that require repair, necessitating annual service contracts.[36] Moreover, the current standard of care laparoscope requires a continuous power source, which is not always attainable in countries with frequent power outages.[12] Laparoscopes are also composed of several components, which must be sterilized and reassembled after each use.[9,31] If one of these parts is lost or broken, it is often difficult to replace in LMICs.[32]

Previous work has explored developing new imaging systems for surgical use. For example, investigators in LMICs have recently described attaching a 10 mm scope to the camera of a smartphone.[15] This system continues to use fiber optic cables for the light source, which are fragile, and thus not ideal for LMICs. It also uses elastic bands to hold the camera in place, while covering the apparatus with plastic sheets to obtain sterility. The design is cumbersome, and not easily sterilizable. In high-income countries, others have investigated the utility of using a color complementary metal–oxide–semiconductor (CMOS) camera to include fluorescent images in laparoscopic surgery,[1] and those interested in single incision laparoscopic surgery have devised a laparoscopic port that contains a CMOS camera and light-emitting diodes (LEDs). The latter two technologies were designed to augment laparoscopic surgery in high-income countries and therefore do not address the needs of LMICs. These designs still rely on expensive components that must be separately sterilized and reassembled after each use. If one component is lost, it is difficult to obtain replacement parts in LMICs, and the device becomes unusable. The port designed for single-incision laparoscopy contains a camera that rotates out of the port after insertion, and it is not difficult to envision that this design will break easily with multiples uses. Therefore, there is a need to design a laparoscope that is affordable and attends to the technological barriers encountered in LMICs.

To address this unmet clinical need, we designed an accessible device called the ReadyView laparoscope that addresses the technological barriers described above. The design of our device replaces expensive and fragile fiber optics with small LEDs and a CMOS detector that sits at the tip of the scope. This design enables a significant decrease in cost and complexity and does not require disassembly prior to sterilization by immersion. Moreover, images can be displayed on any laptop computer or device screen *via* a universal serial bus (USB) cord, obviating the need for expensive monitors and preventing loss of function during power outages.

METHODS

ReadyView System Design

The ReadyView laparoscope (Fig. 1a) contains a 4.5 mm diameter CMOS detector (Aliexpress, 4.5 mm 720P USB Endoscope Module, 8 bit) for video and image capture surrounded by a custom ring of LEDs (Mouser, High Power LEDs, Cool White, 6500 K, 500 mA, 2.8 V) to illuminate the abdomen with white light (Fig. 1b). The camera was selected because of its small diameter, which is less than 5 mm, allowing it to fit within a standard trocar port. The working distance of the camera is 3–7 cm, which are common distances used by surgeons during laparoscopy. The CMOS camera is joined to a USB cord that can be connected to a laptop computer for imaging. A custom printed circuit board was designed to mount the LEDs, with an outer diameter less than 5 mm and the inner diameter to accommodate the aperture of the CMOS detector. The LED ring is connected to a Bayonet Neill–Concelman (BNC) cable and can be plugged into a small battery-powered source to provide power to the LEDs.

Rather than using multiple components that must be pieced together after each sterilization, our device has been constructed as an integrated instrument. The camera and light source have been moved to the tip, which is protected by a hydrophobic window to prevent fogging that could obscure the image during surgery. The scope was made from stainless steel while the handle was 3D printed using Acrylonitrile Butadiene Styrene. These materials are easily sterilizable and biocompatible. The laparoscope and handle contain only the wires from the light source and camera, contributing to a light-weight design of 0.23 kg. The resulting cord from the light source and camera can be attached to a laptop computer for image viewing and powering the device. A gray strain relief is included on the back of the handle to prevent the user from damaging the solder joints inside the device. To prevent any bodily fluids from entering the device and damaging the inner electronics, waterproof seals (two rounds of clear epoxy with a 24-h cure) were created between the hydrophobic window and probe, between the probe and the handle, and along the handle. As an additional protective measure, a catheter glue plug (also waterproof) was formed in the backend of the probe to mitigate any fluid leakage through the handle.
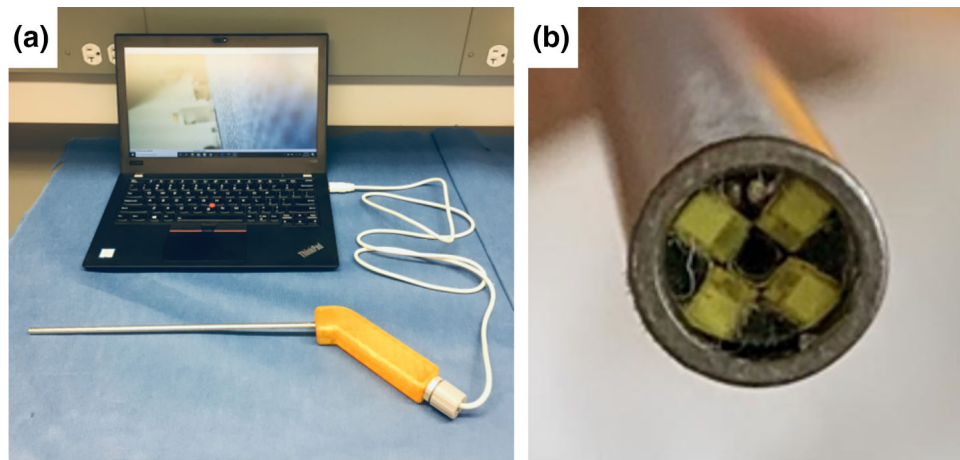
FIGURE 1. ReadyView laparoscope. (a) The ReadyView can be plugged directly into a laptop to view the image and power the device. (b) The ReadyView contains a CMOS camera and ring of LEDs placed at the tip of the probe.
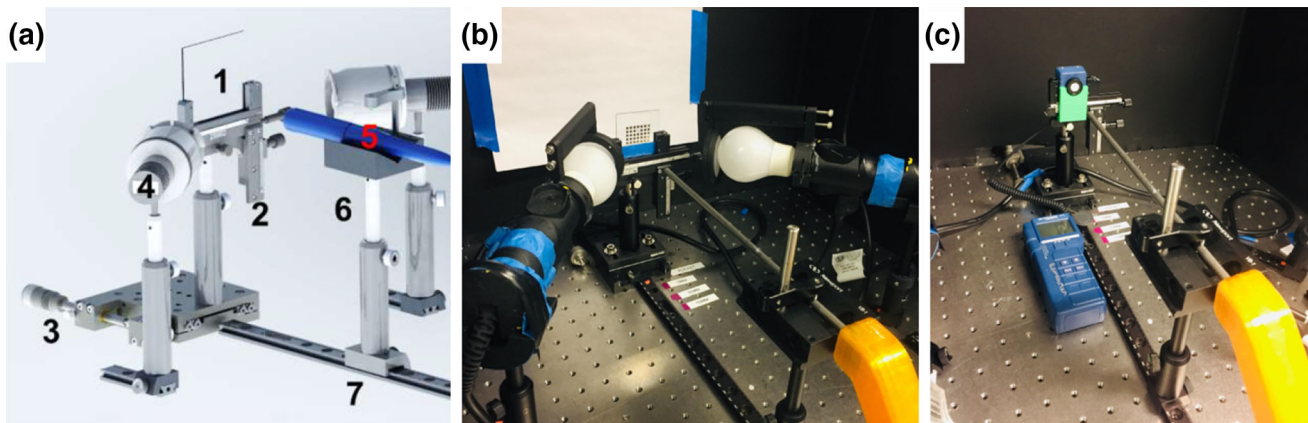

FIGURE 2. (a) Diagram of custom optical hardware setup for testing the laparoscope prototype, which included: (1) An imaging target, (2) *XY*-axes translation stage, (3) *Z*-axis translation stage, (4) collimated white LED sources, (5) tested device, (6) v-mount clamp and (7) dovetail sliding rail for coarse *z*-axis adjustment. The collimated white LED sources with diffuser were set between 20° and 40° (relative to the dovetail sliding rail) to provide uniform lighting and minimize specular reflection from the imaging target (per ISO 12233:2017 guidelines). Photographs of testing setup to assess (b) image quality and (c) light intensity of the laparoscope prototype. In (c), the white LED sources have been removed and the imaging target has been replaced with a lux meter to measure light intensity.

Image Quality Characterization

To assess the image quality and performance of the device, a series of targets were imaged with ReadyView camera and compared to a commercial laparoscope (Karl Storz, Tuttlingen, Germany). A custom optical set-up (shown in Fig. 2) was used to acquire images of various imaging targets as previously described.[24] Each target was imaged at working distances commonly used by surgeons during laparoscopic surgery. Three images were acquired at each working distance, so that an average and standard deviation of various image parameters could be calculated from the images of the targets. To maintain consistent illumination, two lightbulbs angled at 20° to 40° were placed on either side of the target and a white backdrop was placed behind the target. The entire system was then enclosed

in a black box to minimize reflections and outside light interference.

First, a USAF 1951 resolution target (Thorlabs, R3L3S1P) was used to discern the minimal line width that could be resolved by the camera. The resolving power (in microns) was assessed using open-source software, ImageJ (University of Wisconsin – Madison). Specifically, a line was drawn through all of the elements within a group, and the pixel values were plotted using the 'plot profile' function in ImageJ. The point at which the ratio of peak (white pixels) to trough (black pixels) fell below 2 was considered the limit of resolution. This testing was completed with the ReadyView laparoscope and compared to the standard of care (SOC) laparoscope.

The radial lens distortion was assessed by imaging a checkerboard geometric distortion target (Applied Image Incl, QI-SFR15-P-CG) at multiple working distances. The images were analyzed using Imatest (Imatest, Boulder CO), which determined if distortion was present.[38] Specifically, the percentage of distortion was calculated by using standard mobile imaging architecture (SMIA) TV Distortion:

$$\%Distortion = \frac{100 \times (A - B)}{B} \qquad (1)$$

$$A = \frac{A_2 - A_1}{2} \qquad (2)$$

where A_1 and A_2 are the outer side lengths of a square while B is the distance between the midpoints of the sides of the square.[24] The distortion target was also used to calculate the diagonal of view (DFOV) of the camera in Imatest software.[38] The DFOV was calculated to determine the projected field and compared with the SOC laparoscope.

To determine the furthest discernable distance from the camera's tip, the depth of field of the camera was assessed by imaging a depth of field gauge (Edmund Optics, 54-440) at various working distances with a similar optical setup as described previously. The images were analyzed using ImageJ and compared to the SOC endoscope. A line was drawn through the column of lines at the righthand side of the target, which has 5 line pairs per millimeter. The pixel values were plotted using the 'plot profile' function in ImageJ, and the difference between the first full peak (white pixels) to trough (black pixels) was determined. The point at which the difference between the peak and trough fell below half of the initial value was considered the depth of field.

The color accuracy and tone of the camera was assessed by imaging the NIST-calibrated X-Rite Rez Checker Target (Edmund Optics, 87-422).[25] The target was imaged using a similar optical setup. The working distance was adjusted so that the entire color target could be captured in a single image. The images of the color target were assessed using open-source image processing software, Imatest.[23] The software calculated the difference between the known reference and measured color space values using the Euclidean distance equation accounting for luminance differences between the reference and measured data:

$$\Delta E*_{ab} = \left[\sqrt{\left((\Delta L*)^2 + (\Delta a*)^2 + (\Delta b*)^2 \right)} \right] \qquad (3)$$

where $\Delta L*$ is the difference in luminance between the reference and measured data, and $\Delta a*$ and $\Delta b*$ are the color-opponent dimensions. The perceptible color dif-

ference that does not account for luminance difference can be calculated using the following:

$$\Delta C*_{ab} = \left[\sqrt{(\Delta a*)^2 + (\Delta b*)^2} \right] \qquad (4)$$

Characterization of Illumination

Light intensity quantification of the device was completed by mounting the device into the custom optical setup, as seen in Fig. 2b. The illumination was measured with a B&K Precision 615 Light Meter (Digikey, BK615-ND) at common working distances used by surgeons. The device was aimed towards the center of the detector on the lux meter and enclosed in a black box to remove any outside light or interference. These measurements were then compared to the SOC laparoscope, which could be varied from 0 to 100% illumination. Specifically, for each working distance we took measurements at 30% intensity (which is the minimum light intensity currently used during surgery) up to where the lux meter was saturated. Three repeated measurements were taken at each working distance from which the average and standard deviation were calculated.

Thermal Testing

To ensure patient safety, thermal testing of the device was conducted. The device was placed in the optical setup described in previous sections, turned on, and measurements were taken at 10-min intervals over a 90-min period using a non-contact IR thermometer (Fluke, 62 Max +). Each measurement was taken at the probe tip, near the inner electronics of the device, at the mid-way point along the probe and at the probe-handle interface.

Waterproofing of Device

Autoclave machines are commonly used in HICs and use pressurized steam at 121 °C for 15–20 min to achieve sterilization of medical instruments.[18] In many LMIC hospitals, autoclave machines are unavailable due to issues with power supply, water pressure, or steam capacity.[31] Thus it is common practice to sterilize medical instruments by immersion using agents such as bleach, chlorine, or Cidex OPA solutions.[13] In our device, both the stainless steel probe and APA handle are Cidex OPA compatible materials. Waterproof testing was performed to ensure the isolation of the inner electronics of the device at two junctions: at the window-scope tip junction and the scope tip-handle junction. These two junctions were selected specifically

because all electronics in the ReadyView laparoscope are contained within the tip of the probe. The remainder of the laparoscope only carries insulated cord, which is waterproof. Thus, if the probe tip is waterproofed from both the front and back of the probe, then the entire laparoscope can be submerged. To assess whether each junction was waterproofed, a strip of Hydrion water finding test paper (Micro Essential Laboratory Inc, Brooklyn NY) was inserted into the probe and the junction was fully submerged in water for 1 h. The paper was removed from the probe and inspected for color change, which would indicate the junction was not effectively waterproofed. For completeness, the entire ReadyView laparoscope was submerged in water for 1 h, with the exception of the USB connector at the end of the cord, and then tested for functionality.

Custom Software Platform

A custom software platform was developed for use with the ReadyView laparoscope using JavaScript, CSS, and HTML. White balancing of the camera ensures proper image quality before beginning a laparoscopic surgery. It is commonly performed by focusing the laparoscope on a white gauze. White balancing corrects the video color tone to minimize erroneous color perceptions in the middle of a procedure.[5] To test the white balance capabilities of the software code, a series of testing protocols were designed. First, the software captures an image of a white target for reference. The average red, green and blue (RGB) values are extracted for the white target. Next, the software runs the white balance script to optimize the image. Another photo of the white target was taken post-optimization and average RGB values were extracted. These images were analyzed quantitatively, by calculating the difference between the average true white RGB values and the average optimized RGB values:

$$\Delta RGB = A_{truewhite} - A_{optimized} \qquad (5)$$

Video Delay Time of the Camera

To ensure that the white balance feature did not affect the lag time of the video, a series of qualitative tests were designed. A function *TimeElapsed* was used to assess the time it takes to refresh the screen pre- and post-white balance. The reciprocal of the *TimeElapsed* output was used to estimate the frames per second and determine whether the white balance feature adds a delay time.

RESULTS

Image Quality

A resolution target was imaged with both the ReadyView laparoscope and the SOC laparoscope (Fig. 3). Lower values indicate a superior resolution since smaller objects are more easily discernable. Thus, these results portray that the ReadyView has a comparable resolution to the SOC laparoscope at a working distance of 3 and 4 cm, while at 5, 6, and 7 cm, the SOC resolution is slightly better (Fig. 3c). Considering that laparoscopes are used at working distances around 5 cm during operations, this is an acceptable range of resolutions.

During surgery, it is important to have an accurate representation of the size and shape of structures and limit the projected image's distortion percentage. To assess distortion, a distortion target was imaged with both the ReadyView and SOC laparoscopes (Fig. 4). At 3 cm and 5 cm, the ReadyView laparoscope has a lower percentage of distortion in comparison to the SOC laparoscope. At 4 cm, the ReadyView has a larger percentage of distortion in comparison to the SOC laparoscope, as seen in Fig. 4c. This analysis shows that the ReadyView laparoscope does not have significant optical aberrations, indicating that this camera can accurately image targets with minimal distortion.

The diagonal field of view (DFOV) is directly proportional to the area that can be viewed, thus a larger field of view during surgery would allow a surgeon to observe a larger imaging field. It is beneficial during surgery to have an increased field of view to obtain a complete visual of the body. The experimental results show that the ReadyView had a larger DFOV at all three working distances in comparison to the SOC (Fig. 4d). This indicates that the ReadyView can capture a larger area at each working distance in comparison to the SOC.

While the DFOV provides information about the area that can be viewed in a single image/frame, the camera's depth of field capabilities determines the distance between the nearest and furthest objects in an image that is in focus with the camera. During surgery, it may be beneficial to achieve a large depth of field in order to obtain all information without needing to refocus or relocate the device. The depth of field assessment can be seen in Fig. 5, in which the ReadyView had a superior depth of field at a working distance of 3 cm. At 4 cm and 5 cm, the ReadyView had an inferior depth of field in comparison to the standard of care. This can be attributed to the fact that the SOC laparoscope can be re-focused at various distances whereas the ReadyView has an optimal focal length around 3 cm.
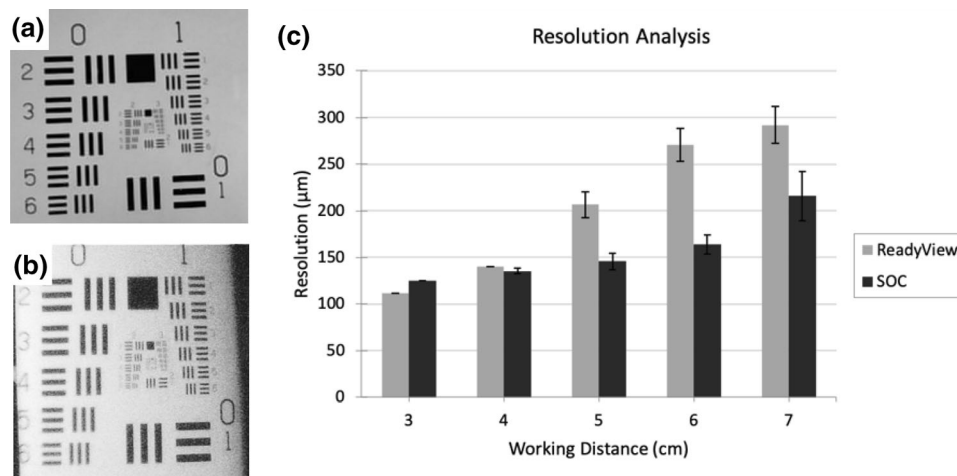
FIGURE 3. Resolution target testing. Image of 1951 resolution target captured with (a) ReadyView and (b) standard-of-care (SOC) laparoscope. (c) Comparison of the resolution achieved by the ReadyView and SOC laparoscopes at various working distances indicated that the ReadyView has comparable resolution at 3 and 4 cm. Error bars indicated standard deviation, and all groups had a sample size of *n* = 3.
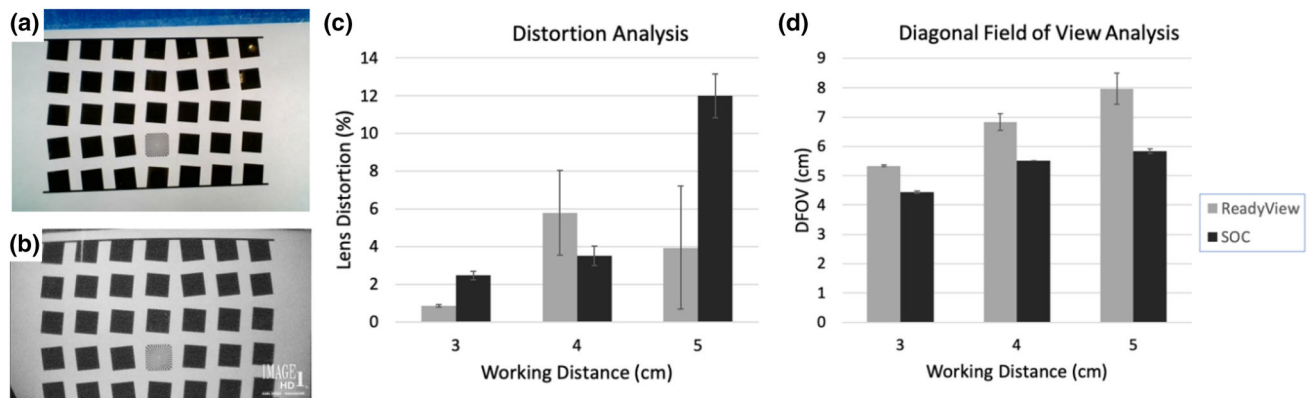

FIGURE 4. Distortion target testing. Image of a geometrical distortion target captured with (a) ReadyView and (b) standard-of-care (SOC) laparoscope. (c) Comparison of the image distortion achieved by the ReadyView and SOC laparoscopes at various working distances indicating the ReadyView has less distortion at 3 and 5 cm and slightly higher distortion at 4 cm. (d) Comparison of the diagonal field of view achieved by the ReadyView and SOC laparoscopes at commonly used working distances. The ReadyView has a superior diagonal field of view at all three working distances. Error bars indicate standard deviation and all groups had a sample size of n = 3.

The color accuracy of the projected image is important during surgery because certain procedures require accurate classification of tissue which is dependent on the color.[26] The mean color error comparing the ReadyView and the SOC can be seen in Fig. 6. For both color accuracy tests, the ReadyView had a superior color accuracy in comparison to the SOC laparoscope, which would benefit surgeons during laparoscopy.

Illumination Testing

During laparoscopic surgery, the area under investigation must be illuminated in order to produce a clear image. To assess the illumination quality, a series of experimental tests were conducted at various working distances and compared to the SOC laparoscope at 30% intensity (minimum light intensity currently used during surgery). As seen in Fig. 7, the ReadyView had an inferior light intensity value (lux) in comparison to the SOC because it uses an LED light source. *In vivo* testing will be used to confirm that the light intensity of the ReadyView is sufficient for surgery.

Thermal Testing

To determine whether the ReadyView operates at a safe temperature for insertion in the human body, thermal testing was completed. First-degree skin burns occur at 48 °C for direct contact with human skin
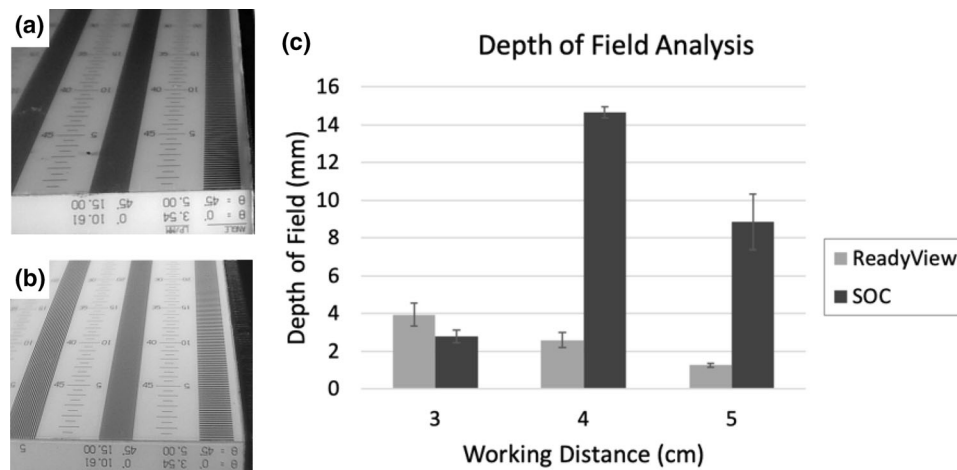
FIGURE 5. Depth of field testing. Image of Edmund Optic's 1–40 depth of field gauge target captured with (a) ReadyView and (b) standard-of-care (SOC) laparoscope. (c) Comparison of the depth of field achieved with the ReadyView and SOC laparoscopes at various working distances indicated that ReadyView has a comparable depth of field at 3 cm and a smaller depth of field at 4 and 5 cm. Error bars indicate standard deviation and all groups had a sample size of *n* = 3.
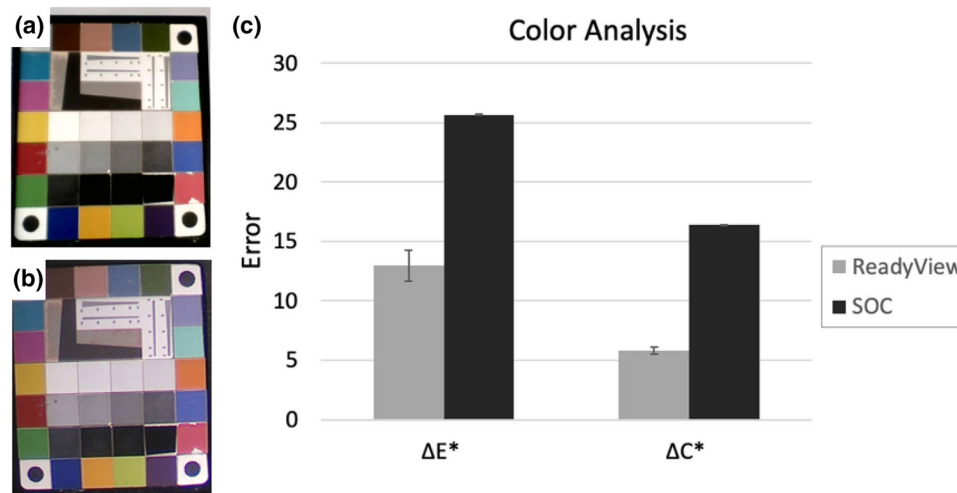

FIGURE 6. Color target testing. Image of a color target captured with (a) ReadyView and (b) standard-of-care (SOC) laparoscope. (c) Comparison of the color reproduction error achieved with both the ReadyView and SOC laparoscopes. ΔE_{ab} accounts for luminance difference while ΔC_{ab} does not account for luminance. The ReadyView has lower errors, indicating it has superior color accuracy. Error bars indicate standard deviation and all groups had a sample size of *n* = 3.

lasting less than 10 min in duration, and this is the IEC 60,601 approved temperature limit.[19] Figure 8 illustrates that the ReadyView performed at temperatures of 25–43 °C. This is well below 48 °C, indicating a safe operating temperature for surgical use.

Waterproof Testing

To protect the inner electronics while the laparoscope is in use and during sterilization by immersion, a waterproof seal at the hydrophobic window juncture of the handle is required. As described in the methods section, the window-probe seal and probe-handle seal were waterproof tested as shown in Fig. 9a. These interfaces were submerged first for 30 s and then for 1 h. This was repeated for 2 different prototypes. In all testing scenarios, the water detection paper remained dry, as summarized in Fig. 9b. The ReadyView laparoscope was also submerged in its entirety for 1 h with the exception of the USB connector, then tested and demonstrated to be fully functional.

Software Testing

The effects of the white-balancing algorithm are shown in Fig. 10. The white balance algorithm was intended to normalize the color channels to 128 in the video stream. Normalizing the color channel averages
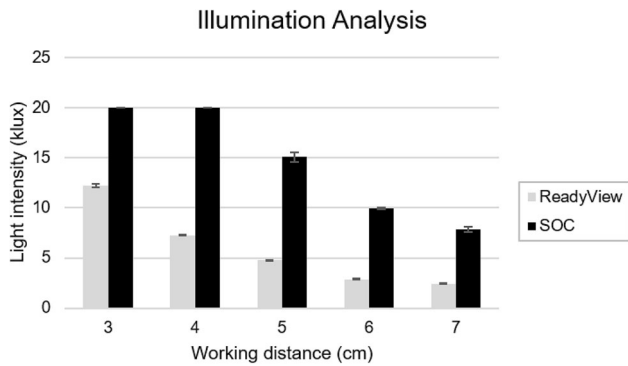
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FIGURE 7. Illumination testing. Lux testing comparing the prototype laparoscope at max intensity and the standard-of-care (SOC) set at 30% of the maximum light intensity. The ReadyView has lower light intensity than the SOC. Error bars indicate standard deviation and all groups had a sample size of $n = 3$.

removes undesirable tints in the video stream, allowing for the best image during surgery. Prior to applying the white balance, the average pixel values for the red, green, and blue channels each was approximately 115 with large standard deviations. After applying the algorithm to the image, the pixel values for all three channels changed to approximately 128 with much smaller standard deviations. The algorithm centered the color channels to 128 and tightened the distribution of pixels, therefore making a more consistent image and removing irregular shades. Likewise, the frame rate of the video was observed with the white balance algorithm applied and not applied. When the white balance is off, the stream provides approximately 57.9 frames per second; when the white balance is on, the stream provides approximately 30.3 frames per
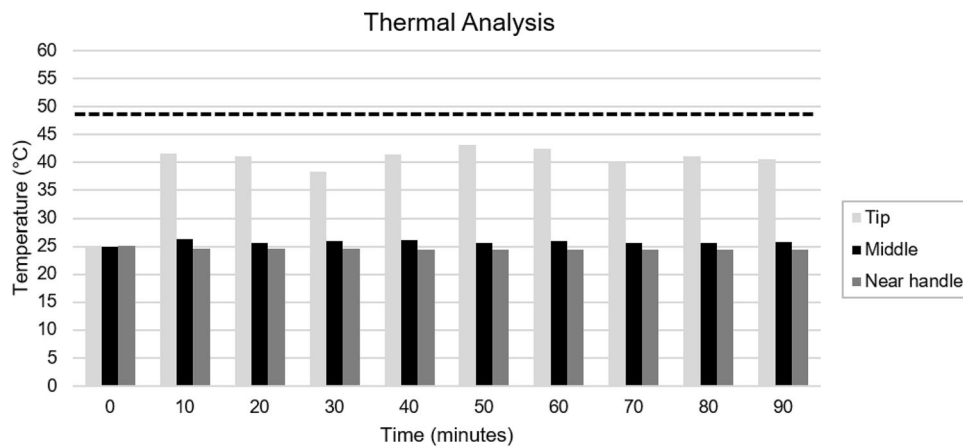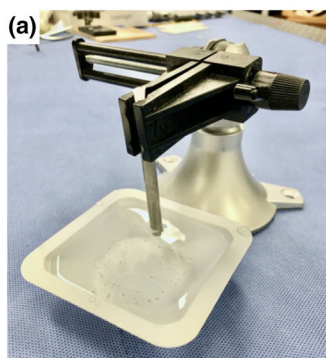

FIGURE 8. Thermal testing. Time vs. temperature graph at the ReadyView scope tip, middle of the scope, and end of the scope near the handle. The ReadyView does not exceed 48 °C (indicated by the dashed line), which is the IEC 60601 approved temperature limit for direction contact with human skin (< 10 min duration).

Seal Type	Seal Location	30 second submersion	1 hour submersion
Two rounds of epoxy	Between hydrophobic window and front of probe	Passed	Passed
Catheter glue	At back of probe inside handle	Passed	Passed

FIGURE 9. Waterproof testing. (a) Waterproof experimental set-up for testing various plugs for the scope tip and window junction. (b) Summary of waterproof testing for two different seal types and locations indicates our waterproofing strategy is effective.
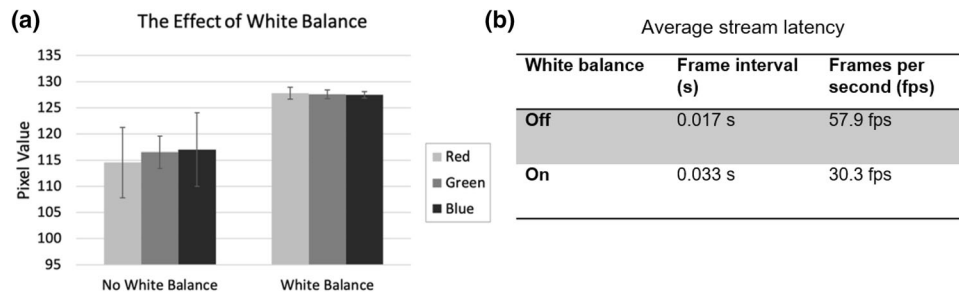
FIGURE 10. Custom software for visualizing laparoscopic video. The software application is able to take pictures, record video, and white balance the video. (a) White balancing removes color tints and normalizes the color to a desired white. The bar graph depicts the effect of the white balancing function on the pixel values of an image stream. Seven pictures before and after white balancing were captured. The values (average ± standard deviation) depicted are the ΔRGB values with respect to pure white. White balancing function yields average pixel values of approximately 128, indicating it is performing correctly. (b) The average latency of the software application with white balancing on and off. The frame interval is the time to refresh the stream. The frames per second (inverse of the frame interval) is the count of frames presented every second. Video stream performance measured using frames per second (fps) achieves > 30 fps with white balancing, which results in no video lag.
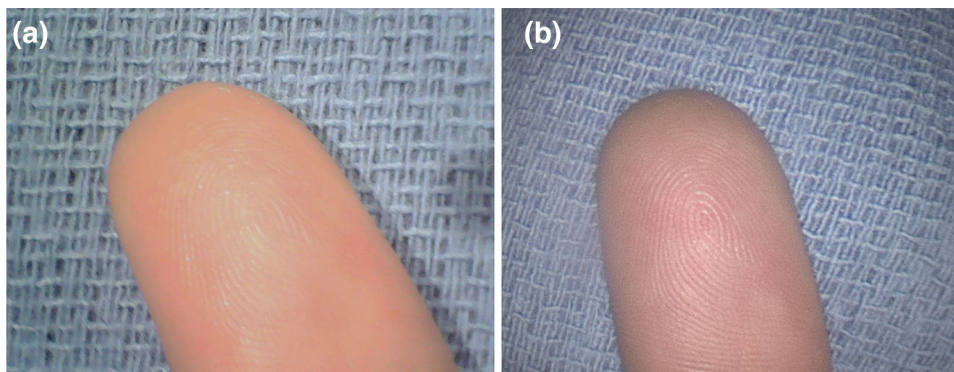

FIGURE 11. Picture of human skin acquired with the (a) ReadyView and (b) standard-of-care (SOC) laparoscope.

second. While the human eye can process individual images at 10–12 frames per second, the National Television System Committee recommends a minimum of 30 frames per second for smooth-appearing video.[8,28] Both methods were observed to meet this minimum, as depicted in Fig. 10b.

Biological Tissue Imaging

Representative images of human skin acquired with the ReadyView and SOC laparoscopes are shown in Fig. 11. Both images were taken at a 5 cm working distance. As seen, similar features such as fingerprints and the grains of the blue towel can be detected in each image.

DISCUSSION

The ReadyView laparoscope was uniquely designed to address the specific needs of LMICs (Table 1). This simple design uses affordable and robust electrical components that are securely enclosed in a lightweight case. The waterproofed enclosure allows for sterilization by immersion, a common technique used in LMICs. Due to elimination of fragile fiber optics and replacement with inexpensive electronics, the need for annual service contracts and expensive replacements are eliminated. Furthermore, the live video image can be displayed *via* USB to any viewing monitor such as a laptop, smartphone, or television.

It has been shown through various analyses that the ReadyView camera has comparable functionality to that of a SOC laparoscope and can be safely used during surgery. The ReadyView camera resolved the smallest feature size of 111 μm at a working distance of 3 cm, exceeding the SOC's resolution capability of 125 μm at this working distance. While the ReadyView demonstrated a small amount of lens distortion, this value was a fraction of the SOC's image distortion at 3 and 5 cm. The ReadyView achieved < 5% of distortion at both distances indicating that while there are minor distortions, it will not significantly hinder a surgeon's capability to operate. Further, the Ready-View can capture a larger area at all relevant working distances in comparison to the SOC, with a significant

TABLE 1. Overview of specifications and features of laparoscopic systems.

	Karl Storz laparoscope (standard of care)	CMOS image sensorAoki *et al.*	Affordable laparoscopic camera systemGheza *et al.*	Port cameraTerry *et al.*	ReadyViewLaparoscope
Price (USD)	>$100,000	–	$1296	$300	–
Cost of goods (USD)	–	–	–	–	$125
Assembled laparoscope weight (kg)	6.5	0.17 camera + scope + light cord	0.28 camera + phone	–	0.23
Light source	Xenon	Xenon	Xenon	LEDs	LEDs
Tip temperature	45 °C	–	–	–	42 °C
Detector type	High Definition Analog Camera (CCD)	CMOS	Smart phone	CMOS	CMOS
Resolution (MP)	2.07 MP (1920 × 1080)	1.47 MP	8 MP	0.3 MP (640 × 480)	0.23 MP (640 × 360)
Frames/second	50	–	30	30	30
Image display	Monitor	Monitor	Smartphone	LCD screen	Laptop computer
Power source	Outlet	Outlet	Outlet	Battery	Laptop computer
Sterilization	Autoclave, Gas	Autoclave, Gas	Covered in sterile drapes	Single Use	Immersion
Components	Fiber optic light cable, light cable adapter, scope, camera head, camera control unit, equipment cart	Fiber optic light cable, light cable adapter, scope, camera head, camera control unit, equipment cart	Fiber optic light cable, smart phone, coupling system, elastic bands, HDMI cable, sterile drape, tripod	Integrated system, but with a rotating camera that may easily break.	Single unit

Features conducive to LMICs are in italics.
– indicates that a value is not reported.

increase in diagonal field of view at the 3 and 5 cm working distances. This allows surgeons to image a larger area and gain more information about the area of interest in the patient. The ReadyView possesses a minor color error of 6%, which is a significant improvement in comparison to the SOC's color error of 16%. Imaging accurate colors allows surgeons to differentiate between diseased and healthy tissue and is a necessity during surgery. The aforementioned camera characterization indicates that the ReadyView has comparable imaging capabilities to current commercial laparoscopes and can produce an accurate image during surgery.

The ReadyView offers many safety advantages in comparison to current commercial laparoscopic systems. The ReadyView scope tip remained well below 48 °C, a temperature significantly lower than the SOC's operating temperature of 100 °C.[39] The LEDs allow for cooler operating temperatures and can decrease the number of operating room fires.[14] These cooler temperatures will also minimize inadvertent intestinal burns, which can cause delayed bowel perforation and subsequent abdominal sepsis.[7] Additionally, the current weight of the ReadyView (0.23 kg) is significantly lighter than the SOC laparoscope (6.5 kg).[22] The lightweight handle and elimination of heavy fiber optics contributes to the ergonomic design and will alleviate surgeon fatigue.[20]

Moreover, in the event of a power outage, the ReadyView will have continued functionality due to the device's outlet-free design. Because the ReadyView can be plugged into any electronic display system *via* USB, the laparoscope cord length can be adjusted by simply adding a retractable USB extender. This distinct feature would minimize operating room injuries due to tripping over exposed medical equipment cords.[6]

The ReadyView lacks a comparable depth of field and image resolution to the SOC at larger working distances since the integrated camera has an optimal focal length of 3 cm. However, the current ReadyView prototype can be moved closer to the target to achieve a finer resolution and produce an image of similar quality to the commercial laparoscope. Additionally, other cameras that have optimal focal lengths of 5-10 cm are currently being identified and tested to address this limitation in future prototypes. Due to the compact and affordable design, the ReadyView laparoscope does not have a comparable light intensity to the output of the SOC. Although the lux values are inferior to the SOC, the results indicate that the ReadyView achieves approximately a third to half that of the SOC. *In vivo* testing will be conducted to assess if the ReadyView light intensity is sufficient to perform surgery. If needed, a voltage booster will be incorporated into the ReadyView design which will increase the voltage delivered to the LEDs to increase the illumination. The design of the ReadyView will continue to be optimized for manufacturing through work with an industry partner, which will facilitate the construction of more units. Parts that are currently 3D printed will be transitioned to injection molding, and other parts will be available for bulk purchase. These modifications will likely decrease the cost of goods per unit, but labor costs may be higher for units made by an industry partner.

Laparoscopic procedures will be performed in a porcine model by surgeons with proficiency in laparoscopic surgery to compare the safety and performance of the device to the SOC laparoscope. Additionally, surgeons will provide feedback on the usability of the design, and the lifetime and durability of the protype will be evaluated. After conducting laparoscopic procedures in a porcine model, the ReadyView design will be improved in response to surgeon feedback. These studies will also provide preclinical safety and efficacy data in preparation for regulatory submission and clinical trials. Specifically, the ReadyView could be cleared through the Food and Drug Administration's (FDA) 510(k) pathway by demonstrating substantial equivalence (in terms of image quality and safety) to a predicate device, such as the SOC laparoscope tested here. FDA clearance is accepted in many LMICs.

In conclusion, laboratory testing of the ReadyView prototype indicates comparable performance (resolution, field of view, distortion, depth of field, color accuracy) to the SOC laparoscope while also addressing some of the barriers to implementation in LMICs. Specifically, the ReadyView is built with low-cost consumer grade electronics, does not rely on consistent electricity, does not require regular maintenance or qualified maintenance personnel, can be easily sterilized with chemical immersion, and can be used with a standard laptop computer. This portable system is well suited to increase access to laparoscopic surgery in LMICs.

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AUTHOR CONTRIBUTIONS

DISCLOSURES

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