Improving the Ergonomics of the Modern Gastrointestinal Endoscope

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On my honor as a student, I have neither given nor received unauthorized aid on this assignment as defined by Honor Guidelines of the Thesis-Related Assignments.

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Improving the Ergonomics of the Modern GI Endoscope

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Abstract

In the US, a minimum of 19 million colonoscopies are conducted annually as the primary diagnostic tool to identify otherwise undetectable gastrointestinal pathologies. However, with a high case load of up to 22 procedures per week, 89% of practicing gastroenterologists report related musculoskeletal overuse injuries, with 28% of the population citing left thumb pain as a result of their work. Therefore, advancements to the ergonomics of the modern colonoscope are required to ameliorate the risk of developing musculoskeletal overuse injuries, such as De Quervain's Tenosynovitis. Therefore, the aim of this study is to develop a mechanical solution that mitigates the three primary risk factors associated with daily colonoscope usage: exertion frequency, magnitude, and duration. After performing a Pugh Analysis, we chose and pursued a medical device solution that centered around a dial-locking mechanism. Our design incorporates an overarching handle-based housing that interfaces a pair of dial masks with a bidirectional ratcheting mechanism. Static stress analysis identified failure points within the interface of the ratchet with the dial masks at the pawls of the ratchet and at the interface between the mask and the dials. Lastly, electromyography and tactile force tests measured a 79.5% ± 1.5% ($p = 0.0021$) decrease in muscle activation and a 50.4% ± 9.2% ($p = 0.0048$) decrease in forces imparted on the left thumb during 90° of dial rotation. Our results validate the efficacy of our device and motivate further pursuit in improving ergonomics in endoscopy.

Keywords: Medical Device, Ergonomics, Endoscopy, De Quervain's Tenosynovitis

Introduction

Colorectal cancer is the 3rd leading cause of cancer-related deaths in the US, and in the current standard of care, colonoscopies remain as the only procedure to screen for colorectal polyps and cancers.[1] Every year, a minimum of 19 million colonoscopies, in the US alone, are conducted as the primary diagnostic tool used by gastroenterologists to identify these otherwise undetectable gastrointestinal pathologies.[2] On average, gastroenterologists perform 22.3 colonoscopies per week,[3] and higher volumes of cases have been associated with increased risk of injury.[4] As the demand grows with the aging population, a projected shortage of gastroenterologists will place an even heavier burden in terms of workload for the current endoscopists, with an even greater associated risk of overuse injury.[5]

A high frequency of colonoscopies has been associated with MSK overuse injuries due to the mechanical challenges posed by operating the scope. Under the status quo, the modern colonoscope consists of a cylindrical handle attached to a 1.68 meter long scope. The distal end of the scope is deflected by using the left thumb and fingers to apply torque to a system of dials and locks built onto the handle. Deflection of the scope allows the endoscopist to navigate the tortuous bends in the gastrointestinal tract.

Many studies have attempted to identify the root cause of these musculoskeletal injuries, and research has suggested that they are due to the poor ergonomic design of the modern endoscope. Current literature suggests that three primary risk factors, the magnitude of the applied forces required to operate the dials, the duration that the forces are maintained, and the repetitive abduction and extension of the left thumb while operating the endoscope's dials may lead to MSK injuries.[4,6–9] De Quervain's tenosynovitis is a common endoscopy-related injury which accounts for 19% of common MSK overuse pathologies affecting up to 89% of the colonoscopists.[6,7] This injury is typically characterized by a painful inflammation of two tendons that run between the thumb and the wrist: the abductor pollicis longus (APL) and the extensor pollicis brevis (EPB). Shergill, Harris-Adamson, Lee, McQuaid, & Rempel, (2016) found over a cohort of 12 endoscopists that while performing colon insertion, their hands exerted an average peak left thumb force of 15 Newtons (N) and spent 17% of their procedure time exerting high pinch forces above 10 N.[10] A separate study also found that those with occupations that require them to spend more than 11% of their work exerting high pinch forces increased their risk of overuse injury.[11]

Currently, many mechanical and technique-oriented solutions have already been proposed, but no solution has been either FDA-approved or widely implemented to address the shortcomings in the ergonomics of the modern endoscope. Ergonomic designs being developed today tend to reinvent the way endoscopy is performed instead of addressing the root problem of common endoscopes. Some major concepts include self-propelling scopes, joy-stick controlled scopes, and capsule robots, but their key downfall is that highly-skilled gastroenterologists are reluctant to exchange their years of experience and training operating the dials on the traditional endoscope for the sake of learning an entirely different system.[9] Evidently, there needs to be a design solution capable of reducing the ergonomic hazards of the colonoscope. Therefore, the aim of this study was to design, iterate and test a mechanical device solution that could be implemented seamlessly onto the traditional colonoscope to improve the ergonomics and mitigate the risk of the musculoskeletal overuse injuries, such as De Quervain's Tenosynovitis.

Results

Identification of Design Criteria

In order to design a device that can be widely adapted, we began by interviewing 5 physicians at the UVA Medical Center Department of Gastroenterology and 1 physician at the Charlottesville Gastroenterology Associates. Key attributes that were mentioned by the physicians, as well as major risk factors that the team identified from literature review. From these criteria, we weighted the importance of each attribute and subsequently ranked them according to its priority (Fig. S1). These design criteria ultimately guided our device design.

Pugh Analysis of Initial Solutions

To begin identifying a viable solution to the ergonomic problem at hand, the team brainstormed a list of 32 ideas as an initial starting point. Using the list of weighted design criteria, we then conducted a Pugh Analysis to rank the solutions in order of desirability and applicability. After we found the top 5 solutions (Table S1), we then had a discussion with the relevant stakeholders, and we decided to combine these top solutions together.

1st Prototype Iteration

Our initial solution consisted of a dial mask and an internal locking mechanism inside the outer casing of the assembly. The dial mask would be fitted onto the existing dials of the Olympus Colonoscope (Fig. 1A-B). The dial mask would have a bigger radius than the existing dials. Therefore, a bigger moment arm would result in a larger amount of torque from the same amount of exerted thumb force. By directly addressing one of the major risk factors that were identified in our literature review, this feature can potentially mitigate the risk of developing repetitive strain injury. To fit the dial onto an irregularly shaped dial, we developed a two-piece snap-fit mechanism for an easy and snug installation onto the current endoscope dials (Fig. 1B). The exterior of the dial mask has two antiparallel layers of

Fig. 1. Initial CAD Prototype of Solution. (A) A CAD rendering of the classic Olympus CF-140S colonoscope model limited to the proximal handle portion. (B) The original dial mask used in the first iteration of the prototype that features two snap-together clamps to secure the mask onto the dial of interest. (C) A CAD rendering of the first medical device solution featuring a ratcheting mechanism housed in a casing on top of the endoscope dials.

60 protrusions along its circumference, which is designed to seamlessly interact with an internal ratcheting pawl inside the assembly housing. The locking mechanism, although not clearly spelled out at this point of our design process, would have a bidirectional ratcheting mechanism that interacts with the two layers of opposite protrusions, allowing rotation in one direction while preventing the opposite motion. As a result, physicians would no longer need to hold strenuous positions for long periods of time during procedures, which leads to an improved comfort during operation. The outer casing would cover both the dial masks and the locking mechanism (Fig. 1C), while leaving almost half of the dial exposed to allow room for the user interface. Together, the major features of this initial solution would address two of the 3 major risk factors, while taking ease of installation and physician learning curve into consideration, which sounded like a promising solution on paper.

After designing the CAD rendering of this initial solution, we decided to ask for some clinical feedback on the desirability and feasibility of this solution. Although the physicians at the UVA Medical Center liked that the solution is mechanical, and that it addresses two major risk factors, they were concerned about the added bulk impeding their ability to operate the dials. Another issue is that physicians with smaller hands may no longer be able to operate the scope if the dials are effectively larger. Furthermore, the two layers of protrusions that run in opposite directions might prove to be uncomfortable for physicians to use. Taking these limitations into consideration, we made several key adjustments to the design in the next iterations. The iterative design process was repeated several times before we arrived at our final assembly design.

Design of the Final Assembly

The final design consists of 3 major features (Fig. 2A), the dial mask, the ratchet assembly and housing, and the ergonomic handle attachment. The dial mask, instead of using the older two-piece fitting mechanism, is adapted into one single part that can snap onto the existing endoscope dials from above (Fig. 2B). The dial masks for both the bigger U/D dial and the smaller L/R dial have 3 locking sites that securely fit onto 3 corners of the dial, so that the dial mask will rotate in unison with the endoscope dials. The circumferential protrusions that serve as both the user interface and the ratchet teeth are changed into a one layer design with rounded edges, so that the grooves feel more smooth on the user's thumb. Since the radius of the dial mask is greater than the dial, the bigger moment arm still holds the potential to reduce the amount of force the physicians need to exert with their left thumb, thereby reducing the risk of injury.

Both the ratchet assembly housing and the handle attachment are designed to fit snugly onto the curvature of the Olympus endoscope handle (Fig. 2C-D). The fitted portions both consist of a hook on one side and a loop on the other, so that a hook and loop strap (Trilancer Reusable Cable Straps) can be installed to tighten and secure the device around the endoscope handle. The handle is designed to offer room for the physician's fingers to wrap around the handle and manipulate the toggles of the ratchet with the

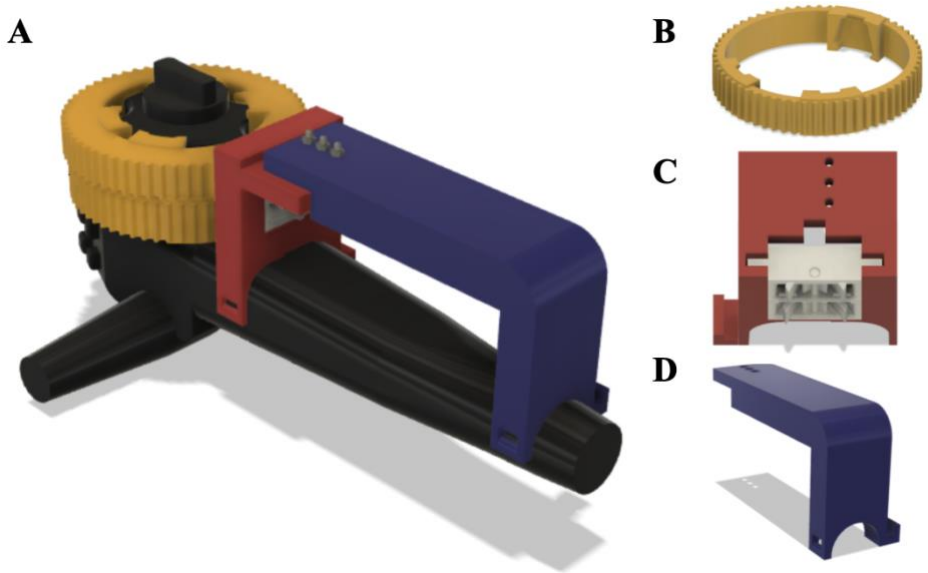

Fig. 2. A 3D CAD Rendering of the final medical device solution assembled on a model endoscope. (A) The fully assembled medical device solution, which contains 3 key features. (B) A CAD rendering representing one of the dial masks featuring a one-piece snap-onto-dial design with 3 locking sites and exterior ratcheting grooves to interact with the ratchet pawls. The individual dials are designed to be compatible with either dials of the traditional endoscope (Up/Down or Left/Right). (C) This CAD model represents the upper part of the medical device handle that houses the bidirectional ratcheting mechanism. The white shows the ratchet assembly, and the red portion shows the ratchet holder. (D) This CAD rendering represents the distal portion of the handle. The overhang of this device allows for assembly with the ratchet housing, while the bottom portion of the handle possesses a hook-and-loop mating feature to secure the device onto the endoscope.

user's thumb. By locking the distal end of the handle onto the ratchet housing, the device assembly is fastened onto the endoscope at two separate sites on the endoscope to enhance its ability to remain stationary.

The full assembly is designed to build off of the base operating mechanisms of the traditional endoscope thereby reducing the learning curve physicians may experience while transitioning. The full assembly is designed with the intention to provide minimal changes to the current operating mechanism of the endoscope so that physicians may still rely on their previously learned skills in endoscopy, thus lowering the learning curve of this novel device. Accordingly, compared to the initial solution, the two endoscope dials are no longer covered by an outer casing. Instead, most of the dial remains exposed to give physicians maximum access to allow for variability in operating techniques and personal preferences.

Mechanism of the Ratcheting Assembly

The locking mechanism is achieved through the interaction between the circumferential protrusions on the dial mask and the pawls in the ratchet assembly. The angled tip of the pawls, when activated, align flush with one side of the dial mask protrusions (Fig. 3). This achieves locking in one direction while permitting rotation in the opposite direction).

Inspired by the design of the socket wrench, we developed a two-layer ratchet assembly, one for each of the endoscope dials, with a bi-directional toggle that can be easily toggled with one hand to switch the locking direction. The internal mechanism is as follows: four pawls in total are housed within the ratchet assembly, two for each dial. Four compression conical springs, one for each pawl, are installed between the pawl and the angled exterior wall of the ratchet assembly to generate a constant push force that creates a tendency for the dial to engage with the dial mask protrusions. In the present design, three total toggle states can be achieved: Clockwise, Neutral, and Counterclockwise. In the neutral state of the ratchet toggle, both pawls are pushed away from the ratchet teeth on the dial mask symmetrically about the midline. It serves as a fail-safe

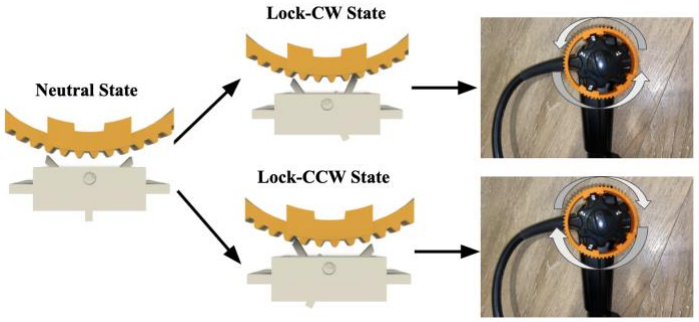

Fig. 3. Flowchart of the ratcheting mechanism. This provides an overview of the ratcheting mechanism that allows the locks device into a unidirectional rotation. During normal usage, the toggle can remain in the neutral position, perpendicular to the axis of rotation, which allows for bidirectional operation of the endoscope. When needed, the physician can flip the toggle in the desired direction of rotation to lock the dial into a unidirectional mode of operation, which prevents the natural tendency for the dial to restore to its neutral position, thereby easing the burden of the left thumb.

mechanism for cases where a physician wants to discard the locking capability of the device to achieve finer degrees of movement. When the toggle is switched to either direction, the rotation of the toggle pushes one pawl away while creating more room for the compression spring to push the other pawl towards the midline, which activates the pawl to engage with the ratchet teeth on the dial mask. The engaged pawl will then permit a one-directional rotation and prevent the dial from spinning back to its neutral state. By eliminating the need for physicians to hold strenuous dial positions during procedures, which is another major risk factor for De Quervain's tenosynovitis, the locking mechanism can also help mitigate the risk of injury.

Identifying Failure Points

The results of the study indicate sufficient strength throughout the bulk of the housing model under normal loading conditions, as simulated with the conditions laid out in the *Materials and Methods* section. As indicated by Fig. 4B, application of a 10 N•m torque predicted a failure point at the engaged pawls that are responsible for resisting the applied torque. Another failure point was identified at the clamps of the dial mask closest to the ratchet interface. Where the pawl interfaces with the dial, the relative safety factors were 0.262 (considered insufficiently strong) and

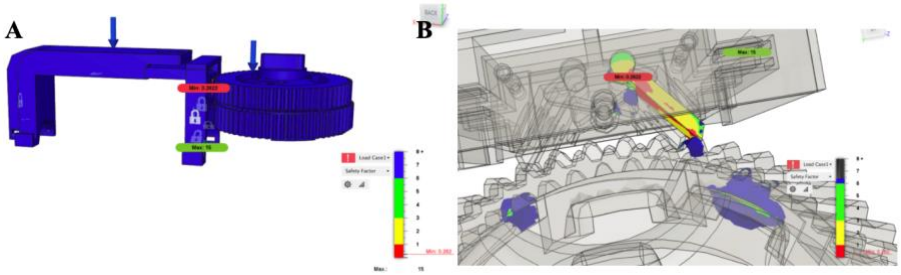

Fig. 4. Static stress Finite Element analysis of prototype. A heat map is used to depict regions of low (Red) and high structural stability (Blue). (A) The device assembly's response to application of loads. (B) A cross-sectional perspective of the interface between the ratcheting assembly and the corresponding dial masks. The colored regions show regions of possible failure.

0.142 (insufficiently strong), for Polyether ether ketone (PEEK) plastics and Acrylonitrile butadiene styrene (ABS) plastics, respectively. At the interface between the dial and the mask, the relative safety factors were 4.17 (sufficiently strong) and 3.86 (marginally strong), for PEEK and ABS plastics, respectively. After a comparison of the two materials of interest at the main failure points; PEEK proved to have a higher relative safety score than ABS at both the pawls and the dial mask interface.

Preliminary Data from Electromyograph and Force Testing

In order to quantify the efficacy of our current prototype, we measured muscle exertion of the abductor pollicis longus (APL) and forces imparted on the left thumb using an electromyograph (EMG) and a SingleTact force sensor, respectively (Materials and Methods). Comparisons were made before (control) and after the implementation with the device (test group). We found that the forces imparted on the left thumb during the operation of the endoscope to be 7.58 N ± 0.7 N (n = 5) for the control and 3.75 N ± 0.31 N (n = 5) for the test group, demonstrating that the implementation of the device decreased musculoskeletal impact by 50.4% ± 9.2% (Fig. 5A). A paired t-test of the results found that the results were statistically significant with a p-value of 0.0048 ($p \leq 0.005$). The conclusions suggested by these results are expected because the increased diameter of the dial mask should offer the same amount of torque for a smaller amount of force when compared to the dial alone. If the point of contact on the endoscope dials is at approximately 23.5 mm (located within the grooves of the endoscope dial) and the force imparted on the left thumb is measured to be 7.58 N ± 0.7 N, then the torque required to turn the dials must equal 178.13 N•mm ± 16.45 N•mm. If the torque arm is increased to 40 mm by the dial mask, then the amount of force required to turn the dials equals 4.45 N ± 0.41 N. This puts the estimated amount of force required to turn the dial mask within the standard error of the mean of the actual measured force. The results reported in this section validate that our device is capable of reducing forces imparted on the left thumb.

In addition to force sensor data, our team measured the level of muscle activation in the APL between the control and test groups using an EMG (BioRadio) (Materials and Methods). We report that the APL activates 41.73% ± 4.55% and 8.54% ± 0.18% of its maximal measured voluntary contraction for the control and test groups, respectively (Fig. 5B). A paired t-test of the results found that the results were statistically significant with a p-value of 0.0021 ($p \leq 0.005$). The results show a 79.5% ± 1.5% decrease in percent maximal contraction after the implementation of the device**.** We hypothesize that the decrease in APL muscle activation relates to the nature of our device's locking mechanism. In order to achieve 90° of dial rotation in the control group, the left thumb APL must be engaged for the entirety of the rotation, and must abduct farther from the joint as the rotation proceeds. In contrast, the locking mechanism of our device does not require continuous APL engagement and the thumb is allowed to release contact to reposition itself into a neutral position before further rotation. The process of being able to return to a neutral position must substantially decrease the level of APL activation, as indicated by the results.

Discussion

With a broad and growing gastroenterology market, there are several growth opportunities for the implementation of an ergonomic device solution in the colonoscopy suite. As the demand continues to grow with the aging population, a projected shortage of gastroenterologists will place an even heavier burden in terms of workload for the current endoscopists, with an even greater associated risk of overuse injury.[11] By focusing on reducing this oft-neglected

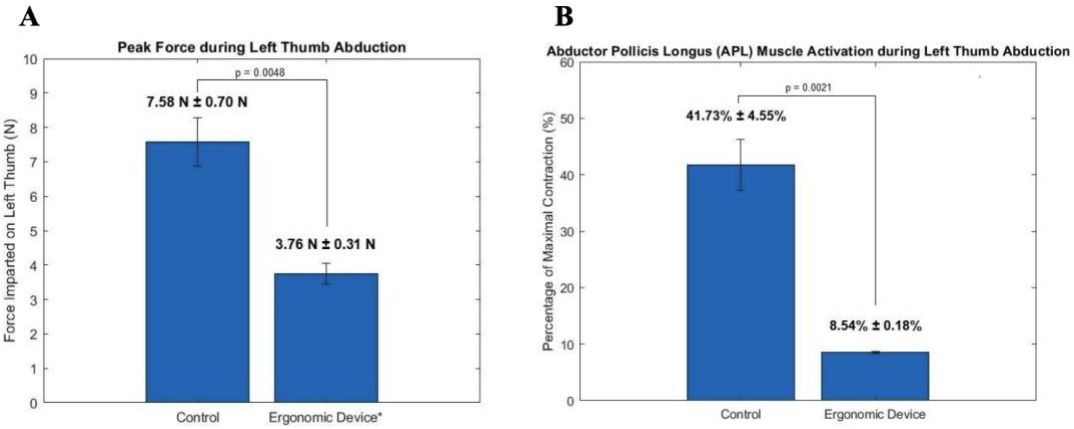

Fig. 5. Primary testing results of the device solution. (A) A comparison of applied peak force during left thumb abduction as measured by the testing apparatus depicted in Fig. 7A without (Control) and with the device solution installed. A statistical significance was identified between the two test groups (P<0.005; N=5). (B) A comparison of the measured muscle activation of the left APL without and with the device solution installed on the endoscope. A statistical significance was identified between the two test groups (P<0.005; N=5);

risk, our device provides a solution that would not only protect physician health, but also prevent the added costs associated with treating injured endoscopists. Currently, about 55% of injured physicians seeks out practice modifications or therapeutic interventions.[8] Considering both the direct costs of medical expenses and indirect costs of wages lost, we calculated the total preventable costs of De Quervain's tenosynovitis from performing endoscopy to be roughly $10 million, and its related forearm endoscopy-related injury preventable costs sum to approximately $14 million (Table S2). With the integration of our auxiliary device, physicians and hospitals can increase efficiency while saving money to invest into more useful avenues. Furthermore, our long-term goal is to design a device that integrates the locking mechanism directly into an endoscopy, which will serve as a more attractive, user-friendly, and ergonomic alternative to current scopes. This innovation will position our company inside the global colonoscopes market that is currently valued at approximately $1.70 billion, with a compounded annual growth rate (CAGR) of 5.1%.[12] The target market has traditionally been a B2B-driven market by the traditional medical devices companies selling to a multitude of clinical settings: hospitals and ambulatory surgery centers, diagnostic centers, clinics, etc.. Specifically, the endoscope market is considered to be split based on innovation type (colonoscope, visualization systems, accessories) and user interactions. The market segment that we are most interested in is the advanced endoscopes and their associated add-on instruments. In the near future, our team is ready to expand into the global endoscopes market, which is projected to reach $17 billion by 2025, with an annual CAGR of 8.8%,[13] given the similarities between colonoscopes and other types of endoscopes.

Before entering the market, the finalized device solution will need to proceed and complete the United States Food and Drug Administration (FDA) regulatory pathways prior to broad clinical implementations. The regulatory pathway will start with the acquisition of an Investigational Device Exemption (IDE) designation, which is necessary for us to move forward with clinical study to verify the efficacy of our device. This exemption is necessary given the potential for patient and physician harm and the novelty of the device solution. An IDE is also necessary for the legal approval of Institutional Review Board (IRB) studies that assess the safety and efficacy of our device. Although risk may be low to physicians, products that fail pose a high risk to patients. As originally designed, this study will need to incorporate elements of traditional feasibility studies to answer basic research questions of safety and effectiveness. Given the novelty of the existing solution, we anticipate that the solution is not substantially equivalent to other patented devices. If true, our device will require a concurrent de novo request from the FDA based on the closest prior art (traditional colonoscope apparatus: US7387606B2). Once, the preliminary data to support an application is collected, a 510(k) pre-market notification will be submitted to the FDA with the logistics for the eventual product launch. Ultimately, it is anticipated that the solution will be classified as Class II and placed into a department category overseen by the Center for the Devices and Radiological Health.[14,15] At the conclusion of this pathway, this project may undergo post-market surveillance, but will have the room for an extensive product launch.

Our team was limited in our ability to address specific design flaws due to an expected decrease in available mentors and resources during the second half of the semester. We were able to receive feedback for our initial design solutions by only a small selection of 6 local gastroenterologists, the majority of which were composed of the University of Virginia gastroenterology team. As such, recommendations of the device modifications were biased towards the University's clinical network. Furthermore, our team was unable to pursue our clinical study that was initially submitted to the IRB. The purpose of the preliminary clinical study was to test the application of the device solution through a colonoscopy simulator with a cohort of current UVA residents and physicians. However the circumstances of the ongoing epidemic required a replacement of the clinical study with a modified cardboard simulator and a restricted testing population to only one team member, Kevin Chang. As such, the clinical insight utilized to inform the design creation processes, like the Pugh Analysis, was not available for the final developments.

The design of the current prototype also has several remaining flaws that need to be addressed. Both dial masks loosely fit onto the existing endoscope dials which causes a slight wobble when the dial masks are rotated. Although the ratcheting mechanism worked for the L/R dial mask, it did not function properly for the U/D dial due to imperfect dimensions in the CAD design and the more imprecise tolerance of the TAZ 6 3D printer. Another problem with the ratchet assembly is that once the pawl engages with the ratchet teeth of the dial mask, the toggle is unable to release the pawl from its locked position; thus, it must be manually released by pushing on the pawl itself. This is due to an under sizing of the toggle, which does not sufficiently push the pawl out of the way of the ratchet teeth. Additionally, the SLA resin that was used to print

the ratchet holder is mechanically weak, which caused a slight crack during the installation onto the endoscope handle. Finally, the current hook-and-loop locking method does not sufficiently prevent the device prototype from slipping down the handle away from the endoscope dials. The slippage occasionally displaces the locking mechanism from the dial masks, making the ratchet system ineffective until further readjustment.

Materials and Methods

Fabrication of Device Prototypes

The current prototypes were designed using the CAD software: Autodesk Fusion 360. The current device prototype is modeled to be fitted onto the Olympus Sigmoidoscope (Olympus, CF-140S). Prototype iterations were printed using a combination of the FormLabs's Form 5 Stereolithography 3D printers and the TAZ Lulzbot 6 3D printer. To assemble the present device onto the endoscope, the two dial masks are first snapped onto the endoscope dials from above, U/D first, then L/R (Fig. 6). Then, the ratchet holder is clamped onto the handle first distally close to the instrumentation port, followed by sliding up the handle toward the endoscope dials, until the width of the handle widens enough to no longer permit any further movement. At this point, a Trilancer hook-and-loop strap is secured onto the device and threaded underneath the endoscope and back through the device, allowing us to tighten our device around the endoscope handle. The lower handle is assembled in a similar fashion by sliding the fitted portion in a distal to proximal motion until the widening radius of the handle no longer permits further movement, then secured with a hook and loop strap. When installed correctly, the handle should overlap portions of the ratchet holder, and the through holes on the overlapped portions should align. An M2 bolt and nut (Hilitchi) is then used to lock the two pieces in place. Finally, the individual components of the ratchet assembly are stacked and locked vertically in position. The entire ratchet assembly is then inserted into the ratchet holder and locked with a lid, completing the entire assembly of the prototype.

Obtaining and Documenting Feedback Processes

Clinical feedback was acquired informally from 6 clinical gastroenterologists who often perform several colonoscopies per week. The main source of initial clinical feedback was gathered after direct one-on-one meetings with Dushant Uppal, M.D.. Once we moved beyond the initial prototyping stage, we were able to receive feedback from female gastroenterologists Rachel Ann Hays, M.D., Anne G. Tuskey, M.D., and Cynthia M. Yoshida, M.D., who were willing to offer feedback on the device. David H. Balaban, M.D. of the Charlottesville Gastroenterology Associates offered specific clinical feedback in a formal one-on-one interview. Lastly, we were able to enrich our understanding of the problem by shadowing some of these physicians in the clinic, thus gaining insight to bring back to the drawing board.

Performing a Static Stress Study

The static stress finite element analysis was simulated using the AutoDesk Fusion 360 Simulator (Student Version). A static stress study was conducted using the CAD renderings of both the device solution and colonoscope model using the

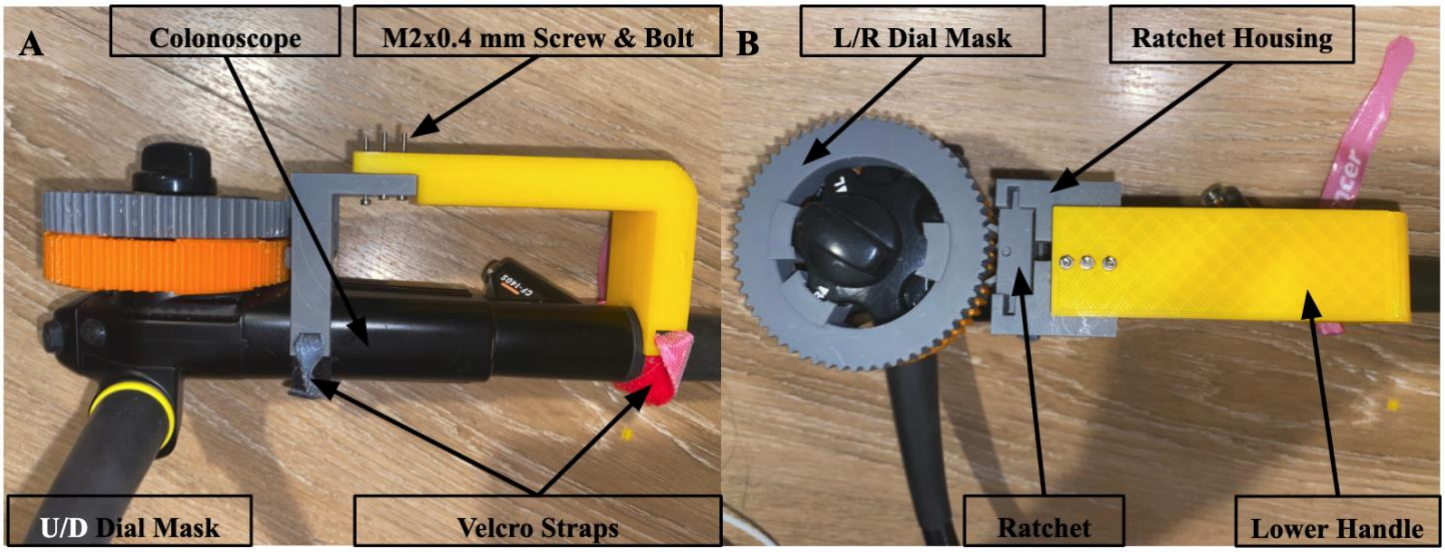

Fig. 6. Overview of the final 3D printed device solution with key components labeled. (A) A side perspective of the medical device (B) A top-down perspective of the device prototype.

AutoDesk Fusion Simulation Suite. The goal of the study was to identify the primary failure points amidst common applications of loads and stresses while comparing two common manufacturing materials: Polyether ether ketone (PEEK) plastics and Acrylonitrile butadiene styrene (ABS) plastics. The device was constrained to the colonoscope model with an application of a 50 newton (N) load perpendicular to the plantar surface of the device, as shown by the blue arrows in Fig. 4A. The same study also applied a torque of 10 Newton-meter (N•m) onto the masks about the dials rotational axis with the bidirectional ratchet locked in the clockwise direction (Fig. 4B).

Electromyograph (EMG) and Force Sensor Measurement Setup

In order to hold the distal end of the endoscope in a static, constant position, as well as to simulate a colon, the end of the endoscope was fit through a hole drilled into an expanded polyethylene (EPE) plastic foam. The foam was housed in a cardboard box and the end of the scope was protruded out the other end, allowing scope flexion (Fig. 7A,E).

In order to collect force sensor data, we designed a fingerless glove apparatus to house an Arduino Uno, a SingleTact force sensor and its I2C board, as well as the respective wiring. The Arduino Uno and I2C board were both secured to the glove using Strenco 1" wide black adhesive hook and loop fastener tape. The Arduino Uno was programmed according to manufacturer's instructions. The flexible force sensor was wrapped around the left thumb and kept in place by rolling a TechMed Medium 4404M Nitrile Finger Cot over the thumb and sensor. The end of the sensor was positioned in the center tactile part of the thumb (Fig. 7B). This apparatus allowed freedom of thumb movement was well as the ability to collect data on the forces imparted on the thumb (Fig. 7C). Data was collected using the SingleTactDemo software (Fig. 7D).

Muscle activation data was collected using Great Lakes NeuroTechnologies BioRadio EMG capabilities as well as their BioCapture software. Electrodes were on the alcohol-prepped skin above the abductor pollicis longus (APL) of the left arm, approximately 1 inch apart, and a grounded electrode was placed right above the elbow of the same arm (Fig. 7F). BioCapture software was used to record and visualize muscle activation during endoscope operation (Fig. 7G-H).

Preliminary Testing

Data was collected while operating the endoscope by simply rotating the left-right dials (top dial) by approximately 90° counterclockwise with the left thumb; however, 90° of rotation was achieved differently between the control and with the test group. For the control, the left thumb was required to continuously maintain pressure on the dials during rotation in order to achieve 90° of rotation. If the thumb is released during this process, the resistance of the flexing scope will relax and revert the dials back toward its normal position. As for the test group, the locking mechanism allows every rotation to be locked in place; thus, the thumb may be released intermittently to reassume a neutral position before further rotation. This procedure was used to simulate one consistent action during the operation of the endoscope and was repeated five times for both the

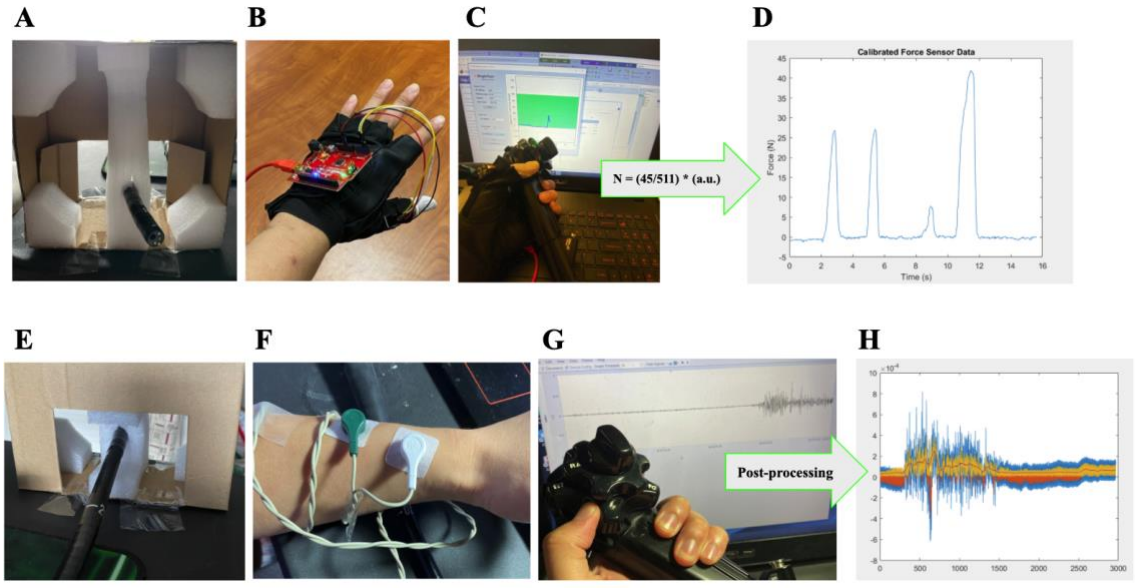

Fig. 7. Force and EMG data collection methodology. (A-D) Experimental setup for collecting peak force data. (A,E) Mock colon used to simulate an *in vivo* testing environment. (B) A force measurement glove depicting the Arduino circuitry. (C) Raw force data collection process showing force responses during abduction of the left thumb. (D) Example calibrated force graph. (E-H) Experimental setup for collecting EMG data. (F) Placement of electrodes on the left APL muscle. (G) Example raw EMG data collection process showing muscle activation during abduction of the left thumb. (H) Example post-processed EMG data used in the analysis

control and test group for the force sensor and EMG experiments.

Force sensor data was analyzed in MATLAB by identifying peak force for each trial, averaging them and finding the standard error of the mean. Raw EMG data was often measured offset from the origin; thus, in order to correct for this error, a baseline was visually determined and 50 points of data in that origin were averaged. All data points were then shifted by that average. Next, the EMG data was imported into MATLAB to undergo further processing. The dataset was filtered using the filter() function with a window size of 5 data points. Next, the dataset was rectified to convert any negative values to a positive value and then smoothed using a Savitzky-Golay polynomial filter. The resulting maximum signal was determined out of this dataset and compared to the maximum voluntary contraction (MVC). MVC was measured by EMG by pressing the left thumb onto a table and abducting as hard as voluntarily possible.

Statistical Analysis

Paired Student's t-test were performed between the control and test group (n = 5 trials for each group) for both the force sensor and the electromyography data and p-values were reported. Data were considered statistically significant for $p \leq 0.005$.

End Matter

Author Contributions and Notes

K.C., V. Sciortino, and V. Seshadri. wrote the paper, prototyped, and designed research protocol, V. Sciortino created CAD model of main assembly of device solution, V. Seshadri created CAD model of L/R dial mask and lower handle and conducted Finite Element analysis, K.C. performed data collection and analysis, W.G. and D.U. provided feedback, and W.G. aided in 3D printing.

The authors declare no conflict of interest.

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