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TOWARDS MANUFACTURING SCALE-UP OF AIR RETENTION DEVICE FOR COLONOSCOPY

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ABSTRACT

Colonoscopy is a very common diagnostic procedure and is considered relatively safe. Air insufflation is often used to increase the effectiveness of the procedure and decrease its duration. However, it is not uncommon for poor sphincter tone to cause loss of insufflation gas, thus complicating the workflow and lengthening the procedure. Air retention devices may address this shortcoming. In this paper we present an improved air retention device for colonoscopy and demonstrate its effectiveness through testing.

Keywords: colonoscopy, air retention device.

1 BACKGROUND AND INTRODUCTION

Colonoscopy is a standard procedure in which a long colonoscope is inserted via the anus to diagnose or treat problems in the large intestine. During this procedure, air is pumped into the large intestine to improve visualization, reduce friction, and reduce the risk of the colonoscope becoming "looped" or snagged within the large intestine. However, due to insufficient sphincter tone at the anus, some patients experience gas leaking; as a result, the air must be replenished during the procedure, which increases risk due to time under anesthesia.

The colonoscopy device described in this paper is called an air retention device. As the name suggests, it helps to prevent air leaking from the anus, thus shortening the overall procedure time (which reduces overall risk), and reducing residual pain for the patient. The primary aim of this study is to improve the design of an air retention device (ARD) to improve its manufacturability, as well as validate its functionality.

This ARD aims to help:

(1) reduce the overall time spent during the colonoscopy process,

(2) reduce post-procedural pain experienced by the patient,

(3) improve clinical capabilities by improving visualization, allowing smooth colonoscope motion, and

(4) improve air retention compared to without ARD.

The previous design [2] based on [1] consists of (1) a main tube made of soft latex rubber, (2) a trileaflet patterned seal manufactured using a multi-step process, and (3) inner and outer retention balloons that hold the device in position.

2 METHODS

Similar to the previous design, the iterations of ARD presented in this paper comprise a main tube through which the colonoscope can be inserted, a seal to prevent air leaking between the colonoscope and the main tube, and rings which hold the device in position by mounting on either side of the anal sphincter. The differences between the old and new designs include the materials used, the use of flexible anchoring rings instead of anchoring balloons, and the manufacturing methods involved.

2.1 Material selection

As this device will be in direct contact with the patient's anus (which is classified as a mucosal membrane for purposes of material biocompatibility testing), a safe product must be chosen. According to FDA guidelines, the evaluation tests for considerations are the same between intact skin and mucosal membrane under limited contact duration with surface device (less than or equal to 24 hours). Latex is to be avoided due to concerns of latex sensitivity.

The Ecoflex™ series of silicone products (Smooth-On) was selected as it was certified skin-safe (OECD TG 439 standard). Comparing the products in the series, 00-35 stands out as it has a pot life of 2.5 minutes, which ensures sufficient time for mixing and pouring during the molding process (see Table 1). Furthermore, 5 minutes cure time is relatively short when compared to other materials in the series (0.5 ~ 4 hours). A shrinkage of <0.1% ensures that there are no significant shape changes.

Following the reasoning above, the material for the prototype was chosen to be commercially available Ecoflex™ 00-35 (Smooth-On).

TABLE 1: POT LIFE AND CURE TIME FOR ECOFLEX™ SERIES PRODUCTS [4].

Product (Ecoflex™)	Pot Life (mins)	Cure Time (hrs)
00-10	30	4
00-20	30	4
00-30	45	4
00-33AF Anti Fungal	45	4
00-35	2.5	5
00-50	18	3
5	1	5
GEL	15	2

2.2 Manufacturing process

After selecting silicone as the primary material of the ARD, injection molding was chosen as the fabrication method, as molds can be designed and fabricated rapidly thanks to advancements in additive manufacturing.

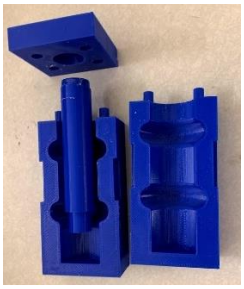

FIGURE 1: THE MOLD USED FOR INJECTION MOLDING.

2.3 Validation tests

According to [3], the maximum pressure during colonoscopy was measured to be 57 mmHg (approximately 1.1 psi or 0.77 mH_2O). This was set as the baseline for the prototype; in other words, in order to be deemed satisfactory, the ARD must hold a pressure of at least 0.77 mH_2O. Three tests were conceived to assess device functionality across a series of prototypes developed iteratively. The first test addressed the need for smooth relative motion between the ARD and the colonoscope, the second test addressed the need to retain air pressure, and the third test quantified retained pressure under both static and moving conditions of a mock colonoscope through the ARD.

TABLE 2: VALIDATION TESTS RAN FOR ALL THREE VERSIONS.

	Test 1	Test 2	Test 3
Version 1	✓	✓	
Version 2	✓	✓	✓
Version 3	✓	✓	✓

2.3.1 Test 1 – Simulated colonoscope movement

A simple, initial test was carried out to test the basic functionality of the ARD. A rod with outer diameter similar to that of a colonoscope was inserted into the ARD.

As water-based lubricant is used during typical colonoscopy procedures, hand soap was used in the validation tests to facilitate colonoscope motion, by reducing the friction between the colonoscope device and ARD.

2.3.2 Test 2 - Air retention

In this test, the ARD was connected to one end of a PVC tube, and a balloon attached at another end of the tube; then the air was pumped through a small hole drilled in the PVC tube. Air leakage can be seen by observing the size change (and rate of change) of the balloon.

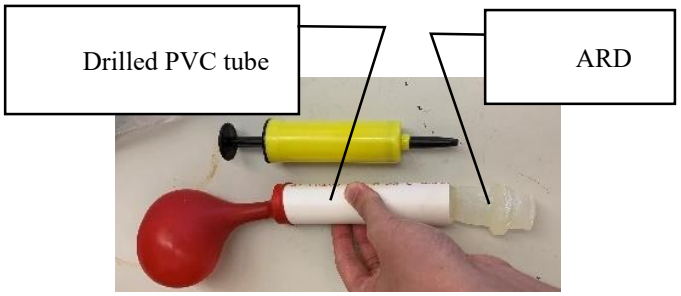

FIGURE 2: VALIDATION TEST SETUP FOR TEST 2.

2.3.3 Test 3 - Air retention with movement

A hydrostatic test was then carried out to quantify the amount of pressure the ARD can withstand without leaking. Furthermore, the mock colonoscope was moved while the ARD was under pressure, and any leakage was observed visually.

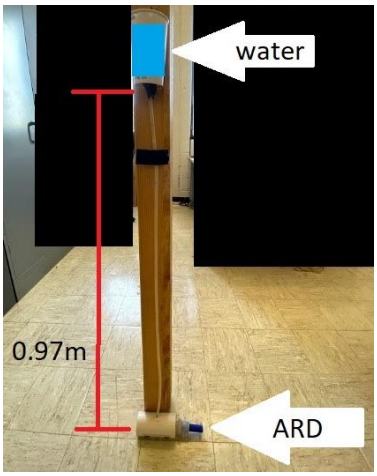

FIGURE 3: VALIDATION TEST SETUP FOR ARD V3.

3 DESIGN ITERATIONS

Three versions of a new ARD have been developed to resolve the shortcomings of previous ARDs. All three versions use solid deformable rings for anchoring the device as opposed to inflatable balloons; this is intended to improve usability and simplify workflow.

Version 1 mimicked most geometric aspects of the previous design [2] but used different material and manufacturing methods; version 2 changed the sealing method to improve manufacturability and usability; version 3 used a different

sealing method that streamlined the injection molding process and simplified the use of the product. Further details about each iteration are given below.

Across all three versions, the main tube had an OD of 1.00 in, ID of 0.75 in, and overall length of 3.50 in. The two rings each had a radius of 0.25 in, and are spaced 1.50 in from each other.

3.1 Version 1

In this first version, the main aim was to produce a prototype based largely on the previous design [2] using the newly chosen Ecoflex™ 00-35. As such, a silicone model with flaps was created based on Figure 3 left. Flaps were designed to have a base width of 0.38 in, length of 0.50 in, and a thickness of 0.06 in. A 3D-printed ring cap of OD 1.20 in, ID 0.5 in, and thickness 0.50 in was then fabricated to fold and hold the flaps in place to create a leaflet pattern as described in [2], functioning as an air seal.

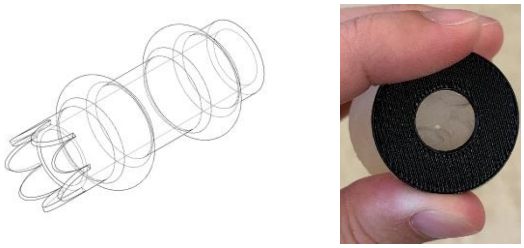

FIGURE 4: ARD VERSION 1 (LEAFLET FLAPS WITH RING CAP).

It was observed that having a separate 3D-printed ring is undesirable, as it requires additional support geometry (or adhesive, or other fastening method) to hold it against the leaflets to form the seal. Moreover, the stiffer 3D-printed material may interfere with deformation of the device during insertion, and was shown to cause stress concentrations on the leaflets during testing (evidenced by cracks at the leaflet roots as shown in Figure 5). Having a separate part also means creating more manufacturing steps, violating principles of design for manufacturing.

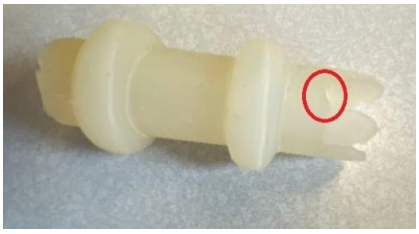

FIGURE 5: CRACKS OBSERVED IN ARD V1.

3.2 Version 2

In this iteration of ARD, it was constructed as a single piece, instead of separate parts. The valve-like feature was changed to a cross-cut pattern as opposed to overlapping leaflets, as shown in Figure 4. The cross-cut face had a thickness of 0.10 in.

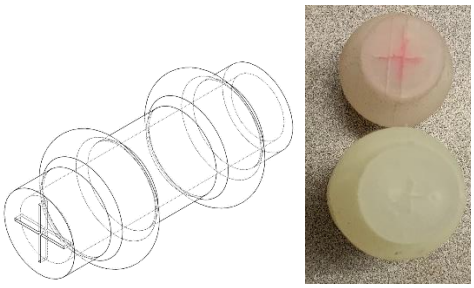

FIGURE 6: ARD VERSION 2 (CROSS-CUT VALVE).

Test 2 was performed for this version of ARD to validate air retention. In this test, it was observed in this version of ARD that the crosscut seal was unable to hold pressure during translation of the mock colonoscope; the air leaked readily during movement.

3.3 Version 3

The next generation of ARD was designed to have an inner diameter at the entrance slightly smaller than the colonoscope, creating a tight fit. Motion is allowed via standard lubricant.

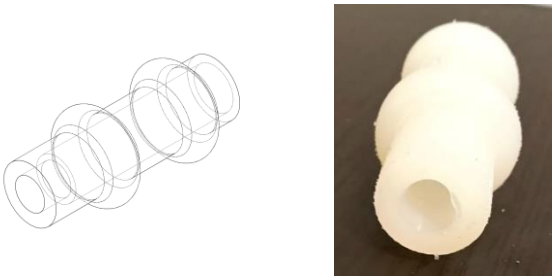

FIGURE 7: ARD VERSION 3 (TIGHT-FITTING ENTRY DIAMETER).

Tests 1 and 2 were performed, and it was observed that the ARD successfully retained air. To verify the amount of pressure that can be maintained, at least three measurements were taken for test 3, and the results are promising. The ARD could hold pressure exceeding the specification of 57 mmHg (1.1 psi or 0.77 mH_2O), even when the simulated colonoscope was moving.

4 RESULTS AND DISCUSSION

In the final iteration of this device, the main tube, rings, and seal were fabricated as a single piece using a plastic mold. This shortens the overall manufacturing time, as there are no additional assembly or post-processing steps.

TABLE 3: EVALUATION RESULTS OF ALL THREE VERSIONS.

	Test 1	Test 2	Test 3
Version 1	Pass	Fail	
Version 2	Pass	Pass	Fail
Version 3	Pass	Pass	Pass

For the final prototype, proper sealing between the colonoscope and ARD up to a satisfactory pressure was

observed, and this was validated by the hydrostatic test. At approximately 0.77 mH_2O, no significant escape of fluid was observed (in other words, the water column always maintained its height), even when there was movement at the insertion interface.

5 CONCLUSIONS AND FUTURE WORK

A simple, inexpensive (<$10) prototype ARD for facilitating colonoscopy procedures was fabricated and tested to improve on a previous design [2]. A molding-based method for quick and accurate production was developed, which helps keep the device production cost low, improving the potential for market acceptance.

The device was demonstrated to fulfill the primary functional requirements of allowing smooth colonoscope motion and retaining fluid pressure. This expected outcome is improved air retention compared to a colonoscopy procedure without using the ARD. The authors believe this can significantly improve diagnostic visibility and increase efficiency in colonoscopy procedures.

Future work includes carrying out further validation experiments to quantify system functionality. This experimental work will be carried out using a synthetic-tissue colon simulator, also allowing observation of possible migration of the ARD with respect to the anal sphincter.

ACKNOWLEDGMENTS

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