Modelling of Anal Sphincter Tone based on Pneumatic and Cable-driven Mechanisms

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***Abstract*— Motivated by the need for improving a haptics-based simulation tool for learning and training digital rectal examinations, a sphincter tone model and its actuation is conceived and developed. Two approaches are presented: one based on pneumatics actuation and the other using cable-driven mechanical actuation using servo motors. Clinical scenarios are modelled as profiles based on studies of anorectal manometry and adapted with clinical input. Both designed mechanisms and scenarios were experimentally evaluated by six experts, Nurse Practitioners in Continence and Colorectal Surgeons. Results show that both mechanisms produce enough pressure on examining finger and profiles are able to generate a wide range of healthy and abnormal cases. Either approach could be used to provide a more realistic experience during training of sphincter tone assessment.**

I. Introduction

Digital rectal examination (DRE) is routinely performed by varied specialties in the primary and secondary care settings as part of the diagnosis of anorectal and prostate abnormalities, including prostate and rectum cancer diagnosis, and it provides useful prognostic information. During DRE, a clinician inserts the index finger through the anus in order to palpate the anal canal, assess anal sphincter function, examine the rectal lumen, i.e. the lower region of the rectal walls and, in men, to examine the posterior regions of the prostate, among other anatomical structures. Despite its importance, DRE is challenging to learn and teach since visual cues are minimal, plastic benchtop models are not realistic and opportunities to practise on a wide range of cases are insufficient. As a result, trainees undergo training that lacks adequate feedback and assessment, acquiring their skills whilst practising on patients, subject to adequate clinical exposure and confirmation of findings supported by peers and other diagnostic tools (imaging, manometry, etc.).

Current learning tools include plastic models and computer-based tools, or a combination of them. Plastic benchtop models are widely used in under-graduate clinical skills training sessions and current models include: the AR321 Rectal Examination Model (Adam, Rouilly Ltd, Sittingbourne, UK), the M92 Digital Rectal Examination Simulator (Kyoto Kagaku Co., Ltd, Kyoto, Japan) and the Rectal Examination Trainer Mk 2 (Limbs & Things Ltd, Bristol, UK). Simulation-based training tools based on sensors embedded into prostate models [1, 2], particle-jamming [3], and haptics [4, 5] have been proposed to overcome some of the limitations and challenges in learning and to better understand performance. However, available benchtop models and simulators are mostly prostate models, and only a few include basic representations of anorectal abnormalities. Therefore, anorectal abnormalities and the dynamic behaviour of anal sphincters, i.e. internal anal sphincter, external anal sphincter, and puborectalis muscle structures are commonly under-represented.

The assessment of sphincter tone is commonly performed for a wide range of clinical problems including faecal incontinence, constipation and disordered defecation [6]. The voluntary ability to squeeze and the resting tone are assessed qualitatively using DRE and quantitatively using anorectal manometry (ARM). During a physical examination, a clinician would typically look for signs of scars, gaping, resistance to finger insertion, perineal descent and cough reflex during resting tone; assess strength and endurance of maximum squeeze, and coordination during squeeze; and evaluate paradoxical contraction, propulsive effort and relaxation of the anal canal during evacuation when asking the patient to 'bear down' [6]. Quantitatively, the anorectal physiology can be assessed through ARM, which consists of a catheter and a balloon inserted through the anus and then inflated to study the pressures of the anal sphincter muscles (in millimetres of mercury - mmHg) during rest (40-80 mmHg; contributed 85% by IAS and 15% by EAS), squeeze (80-160 mmHg; 100% due to EAS), cough and while 'bearing down', sensations in the rectum and neural reflexes which are needed for bowel movements [7].

The primary goal of our research is to explore different mechanisms to model the dynamic function of the anal sphincters in order to provide a learning tool with a wide range of cases that will allow trainees to practise more efficiently. Previously, we started modelling this behaviour using a representative sphincter model coiled with two cables that are pulled and released by motors and controlled with

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encoders [5], consequently extending our haptics-based simulator for learning and training DRE [4]. In this paper, two different mechanisms actuated with servo motors are introduced: a) a pneumatic approach consisting of chambers that are operated by air pressure and b) a cable-based approach consisting of two cables coiled around a sphincter model that are pulled and released. Then, we study the dynamic function of the sphincters by characterising the pressure inside the anal canal and creating profiles that can describe clinical cases presented in the literature. Feedback from a group of nurse practitioners in continence care and colorectal surgeons is also reported. Last, we discuss and conclude our findings and indicate areas of future work.

II. Materials and Methods

A. Pneumatic mechanism

We designed a ring actuator made of polymer material that surrounds the silicone model of the sphincters proposed in [5] (Fig. 1). It is endowed with two separated chambers in which air pressure can be applied. The choice of the material, Dragon Skin Fx (SmoothOn, Macungie, Pen, USA), the geometry and the dimension of the actuator have been defined after finite element modelling simulations with the extensive suite of SOLIDWORKS Simulation packages by applying pressure inside the chambers and analysing the simulated output pressure exerted on the sphincter model (Fig. 2). As the Dragon Skin FX properties were not available, we referred to [8] for the mechanical properties of the polymer materials and used the parameters of the constitutive model for the Ecoflex 0050 as an input to the FEA simulation package since it has similar properties.

We designed and fabricated three different structures to investigate various ways of applying forces on the finger and test the clinicians' perception of the sphincter tone simulation when the soft actuator is used alone without any sphincter model (*A*), integrated within the sphincter model (*B*) and surrounding the sphincter model (*C*) (Fig. 3). *Actuator A* has two chambers forming a ring structure with inner diameter of 22 mm and outer diameter of 52 mm and does not require the sphincter model. *Actuator B* consists of two ring-shaped chambers embedded into the sphincter model. *Actuator C* has two ring-shaped chambers with inner diameter of 28 mm and outer diameter 58 mm that encircles the sphincter model. The pressure is applied and release into each cavity by actuating a syringe with a S3101 servo motor (Futaba Corp., Chiba, Japan) and controlled by an Arduino Uno microcontroller.

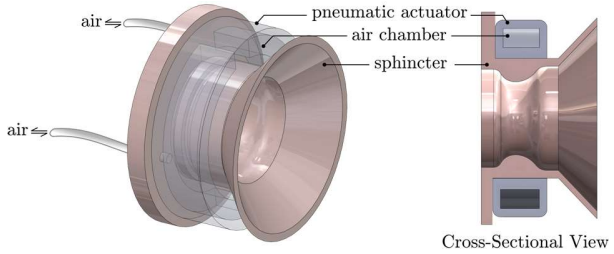


Figure 1. Principle of the pneumatic actuation of the sphincter. Air pressure is independently applied to the chambers via a pneumatic tube. When inflated, the chambers expand and push the inner wall of the actuator against the anal canal of the sphincter model.

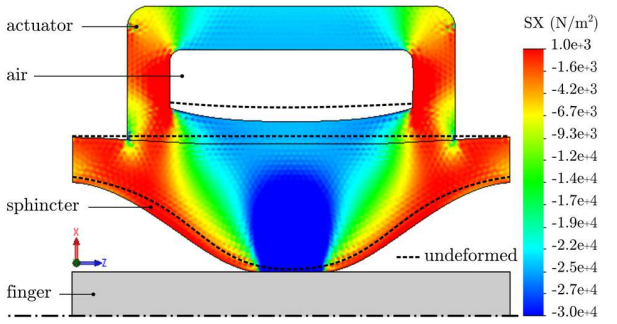


Figure 2. Example of finite element simulation of the pneumatic *Actuator C* in place around the shpincter model (axisymmetric cross sectional view). Air at 25 kPa is applied as input in the chamber. The output of the simulation exhibits the stress at the contact of the finger.

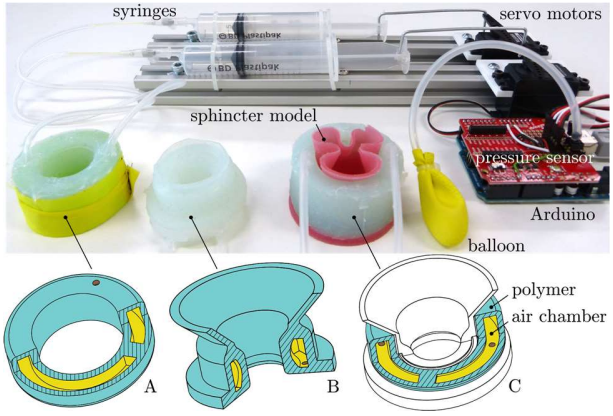


Figure 3. Pneumatic mechanisms: Actuator A, Actuator B, and Actuator C from left to right. A thin layer of non extensible spi fabric (in yellow on A) encapsulates the actuators in order to prevent balloonning burst effect and keep the boundary conditions.

B. Cable-driven mechanism

Two loops of nylon cables are symmetrically positioned around the exterior anal canal of the silicone model of the sphincters (Fig. 4). Each of these is actuated by a servomotor, mounted on each side of the sphincter and controlled by the Arduino Uno.

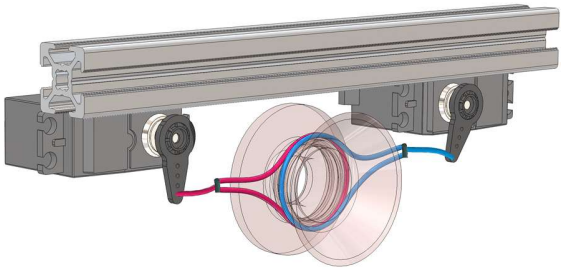


Figure 4. Principle of the mechanical actuation of the sphincter. Each nylon cable forms a loop around the sphincter model and are attached to the horn of the servo motor. They are independently actuated and squeeze the sphincter canal when pulled.

C. Sphincter tone analysis

The analysis of the sphincter tone in clinical practice and for various pathologies is a prerequisite to the system specifications in order to define the range of pressure, motions and constraints of the simulation model.

Quantification of the anal sphincter tone is obtained by means of anorectal manometry.

Although there is a large variability between patients when performing rectal function tests, we used reference pressure profiles of the anal canal available in the literature [9, 10] (Fig. 5) for:

- the rest and the squeeze of a healthy patient *(HS)*,
- the rest and the squeeze of a patient with faecal incontinence *(WS)*,
- the cough reflex test of a healthy patient *(CR)*.

These measurements reveal that the response of the sphincter catheter has a specific pattern with regards to the pathology or "exercise" and the representative pressure profile can be used as a basis for designing simulation scenarios.

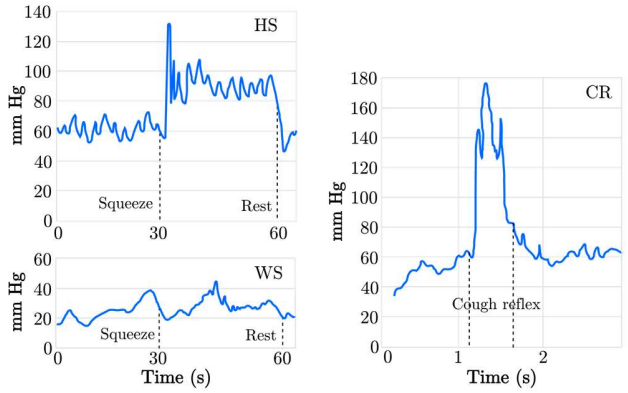


Figure 5. ARM of the anal sphincter tone for different scenarios: *HS)* a healthy normal subject in whom resting and squeeze pressures are normal; *WS)* a patient with fecal incontinence in whom resting and squeeze pressures are weak; and *CR)* normal cough reflex test response (Adapted from [9, 10]).

C. Modelling

We developed a system in Unity3D that included the mathematical representation of these pressure profiles within a native plugin in C++ using multi-threading.

First, we define the relax $relaxThreshold_i$ and squeeze $squeezeThreshold_i$ thresholds for each motor i independently, as well as the total duration T (in seconds) in Unity3D. Relax and squeeze thresholds correspond to servo motor positions and were set for healthy cases to 130 and 70; and for weak cases 130 and 95, respectively (the lower the value of the squeeze threshold, the higher the pressure). A clinical case (gentle pressure, healthy squeeze, asymmetrical squeeze, weak squeeze, or cough reflex) is selected using the keyboard.

Then, the plugin instantiates a function model SPHINCTERTONETIMEFUNCTIONMODEL class which establishes connection with the Arduino microcontroller, starts a thread for reading the pressure from a balloon and starts a *loop* with another thread for running the time function at 10Hz (Algorithm 1).

```
LOOP
Initialise current timestamp ts to zero
do
   Compute f(ts,i) for each motor i
   Compute servo motor position m_i:
      m_i = relaxT_i − f(ts,i) * (relaxT_i − squeeze_i)
   Send m_i to controller
      controller → setServo(m_1, m_2)
   Compute elapsed time and update ts
while(ts < T)
```

Algorithm 1. Time function model thread

Force profiles for modelling the behaviour of the sphincter tone have been implemented in $f(ts,i)$ based on the pressure characterisation of different scenarios shown in Fig. 5. These include: healthy squeeze (HS), weak squeeze (WS) and cough reflex (CR). Using the profile of a healthy squeeze, we also model asymmetrical abnormalities by assigning weak thresholds only to one of the servomotors. In addition to these profiles, we characterise the behaviour of the sphincters when a clinician applies gentle pressure (GP) before inserting the examining finger into the anal canal. The modelling function $f(ts,i)$ outputs a value between 0 and 1 for each motor i indicating how weak or tight the sphincters should be at time ts for a total duration T of 10 seconds as it is commonly performed in clinical practice. We used this approach to compare both pneumatic and cable-driven mechanisms.

D. Experimental study and evaluation

In a preliminary systematic qualitative evaluation, we asked three experienced Nurse Practitioners in Continence to evaluate the pressure profiles pertaining to the different clinical cases. Their comments suggested that pressure profiles should be smoother to make them more realistic, since there were noticeable differences in tone. Therefore, we adapted the reference profiles by tuning the squeeze pressure thresholds in order to match the feeling by the experts. Based on their input, we also introduced a common abnormality named decaying (non-enduring) squeeze (DS), which typifies patients that are unable to hold a squeeze, resulting in the tone to decay gradually.

The pressure profiles generated by the pneumatic and the cable-driven mechanism were compared before the study by inserting a custom-made inflated balloon inside the sphincter silicone model of the anal canal and measuring the pressure in it with an ADP5131 pressure sensor [5].

We then conducted a pilot study and a semi-structured interview with a total of six experts including Nurse Practitioners in Continence and Colorectal Surgeons with clinical experience ranging from 8 to 35 years. They were asked to answer a questionnaire that included demographics, questions about current learning and training of sphincter tone assessment and questions related to both mechanisms (Likert scale: 1 – Definitely Disagree; 5 – Definitely Agree), namely pneumatic and cable-driven control, as well as aspects to capture clinical input related to the modelling of different cases.

The participants were then asked to evaluate the modelling of the sphincter tone for: a) relaxation on gentle pressure, b) healthy squeeze, c) decaying (non-enduring) squeeze, d)

asymmetrical squeeze, e) weak abnormal squeeze, and f) cough reflex.

The generation and control of the pressure profiles was computationally performed to generate the different clinical cases. The focus was first on the perceived sensation of the maximum pressure applied on the finger. Then, we investigated how realistic the pressure applied by the model feels on the finger and whether the presented mechanism is able to reproduce enough pressure and generate a wide range of healthy and abnormal cases.

III. Results

A. Questionnaires

The most common abnormalities of the anal sphincters indicated by clinicians include: weakness or absence of anal sphincter tone, anismus, haemorrhoids, anorectal angle and anal tags. The experts acknowledged that there is an expectation of graduating medical students to be able to identify these abnormalities. When asked about how trainees practise, they included clinical practice or by using models, and that assessment is either not done, is self-assessed or done by observation. However, participants recognised that current models are not realistic and they are unable to assess the difference in anal tone or anorectal angle. Participants strongly agreed that more efficient tools are necessary for learning and teaching sphincter tone assessment, that being able to reproduce varying cases has an educational value and that our mechanisms can enhance current training by providing more realistic models, giving more opportunities to practice and being able to discuss and compare findings.

B. Pneumatic mechanism

Overall, the pneumatic approaches presented to clinicians were perceived to be sufficient to reproduce enough pressure for varying healthy and abnormal cases (Likert scale μ =4.0), were able to realistically reproduce the feeling when palpating the anal canal (μ=3.8) and whilst assessing sphincter tone (μ = 4.2), as well as reproducing asymmetrical cases. When asked to rank the approaches from most to least realistic, participants selected *approach C* as the most realistic in terms of pressure and tone.

C. Cable-driven mechanism

When asked about the cable-driven mechanism, clinicians perceived it as sufficient to reproduce enough pressure for a wide range of cases (μ=4.3) and to realistically reproduce the feeling when assessing sphincter tone (μ=3.8). When asked about the mechanism to reproduce the feeling when palpating the anal canal, participants agreed on its realism (μ=4.2).

D. Modelling of sphincter tone

The profiles obtained from modelling the anal sphincter behaviour with the servo motor actuation are plotted in Fig. 6. When simulation starts, the sphincter tone is squeezed to the maximum, i.e. $f(0,i) = 1$, to characterise the scenario of a patient before being examined. When a clinician applies gentle pressure on the anus, the anal sphincter gradually relaxes giving way for the finger insertion. During healthy squeeze, the pressure on the finger is increased suddenly and hold for few seconds (Fig. 6 HS). However, during a decaying (non-enduring) squeeze the tone gradually decreases as soon as the pressure reaches its maximum (Fig. 6 DS), whereas an abnormal/weak squeeze is manifested in lower pressure and with a couple of intentional attempts (Fig. 6 WS). Then, cough reflex is characterised as a high pressure on finger for about a second (Fig. 6 CR).

Table I. summarizes the generic functions created to generate the actuation of the different clinical scenarios. They are constructed using piecewise-defined simple mathematical functions on their subdomains (delineated by different line styles in Fig.6).

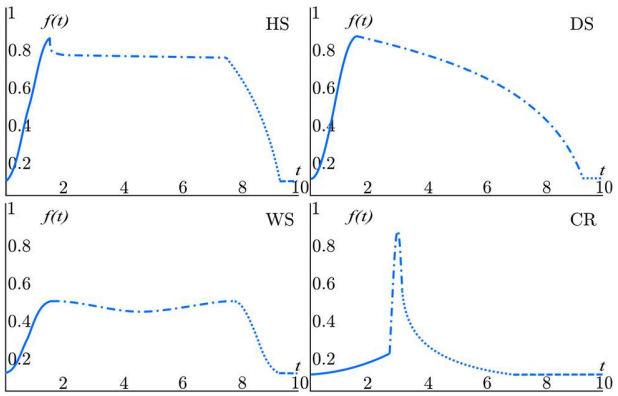


Figure 6. Adapted modelling based on clinical input (Table I) of sphincter tone behaviour for healthy sphincter tone (*HS*), decaying squeeze (*DS*), abnormal (weak) sphincter tone (*WS*) and cough reflex (*CR*). With the exception of relaxation, the characterisation of these profiles was modelled as a simplification of the ARM taken for these scenarios (Fig. 5). The x-axis refers to time in seconds whereas the y-axis refers to the degree of relax/squeeze and is a unit long [0,1].

TABLE I. Modelling of Sphincter Tone

GP	$f(t,i) =$	$0.5\sin\frac{\frac{10t}{T}+5}{3}+0.5$	$0 \le t < 0.72T$
		0.1	$0.72T \le t \le T$
HS	$f(t,i) =$	$0.4\sin\left(\frac{20t}{T}-1.5\right)+0.5$	$0 \le t < 0.150T$
		$0.5\log\left((\frac{10t}{T}-1.5)^{-1}+3\right)+0.5$	$0.150T \le t < 0.756T$
		$0.5\ln(-\frac{20t}{T}+20)$	$0.756T \le t < 0.939T$
		0.1	$0.939T \le t \le T$
DS	$f(t,i) =$	$0.4\sin\left(\frac{20t}{T}-1.5\right)+0.5$	$0 \le t < 0.150T$
		$0.317\ln(-\frac{20t}{T}+20)$	$0.150001T \le t < 0.931T$
		0.1	$0.931T \le t \le T$
WS	$f(t,i) =$	$0.2\sin(\frac{20t}{T}-1.5)+0.3$	$0 \le t < 0.156T$ $0.784T \le t \le 0.939T$
		$0.3\sin\frac{10t}{T}+0.47$	$0.156T \le t < 0.784T$
		0.1	$0.939T \le t \le T$
CR	$f(t,i) =$	$0.2\sin(\frac{10t}{2.5T}-1.5)+0.3$	$0 \le t < 0.2706T$
		$0.4\sin\frac{90t}{T}+0.5$	$0.2706T \le t < 0.3125T$
		$0.9\log((\frac{10t}{T}-3)^{-.5}+0.5)+0.1$	$0.3125T \le t < 0.7T$
		0.1	$0.7T \le t \le T$

E. *Validation and Assessment*

Figure 7 shows the pressure profile measured by the pressure sensor connected to the inflated balloon positioned inside the anal canal for both the pneumatic *Actuator C*, and the cable-driven system, while controlling the servo motors for various simulated cases. The two mechanisms were able to adequately render the pressure profiles. However, the pneumatic approach suffers from a lack of dynamics in order to satisfactorily reproduce the cough reflex.

Then, as part of the assessment test, the participants were asked to rate how realistic the models were perceived in a 5-point Likert scale (1 – Very Unrealistic; 5 – Very Realistic) (Fig. 8). The relaxation as a result of applying gentle pressure was perceived to be realistic (μ=3.8) with only one comment related to the silicone sphincter model not fully closing on inspection, which later was mentioned also as a possible abnormality since in some incontinence patients the anus gapes open as a result of low resting tone.

Related to a healthy squeeze, participants found the tone realistic although two main observations were made: a) the squeeze pressure was felt a bit lower than on the majority of patients and b) the tone was perceived as a thin ring on knuckles rather than a wide band. Related to the decaying tone, participants commented that the drop in pressure could be faster.

The rating for asymmetrical squeeze varied amongst participants and depended on whether they perceived the asymmetry or not. The functional section of the sphincter was better detected with the cable-driven system.

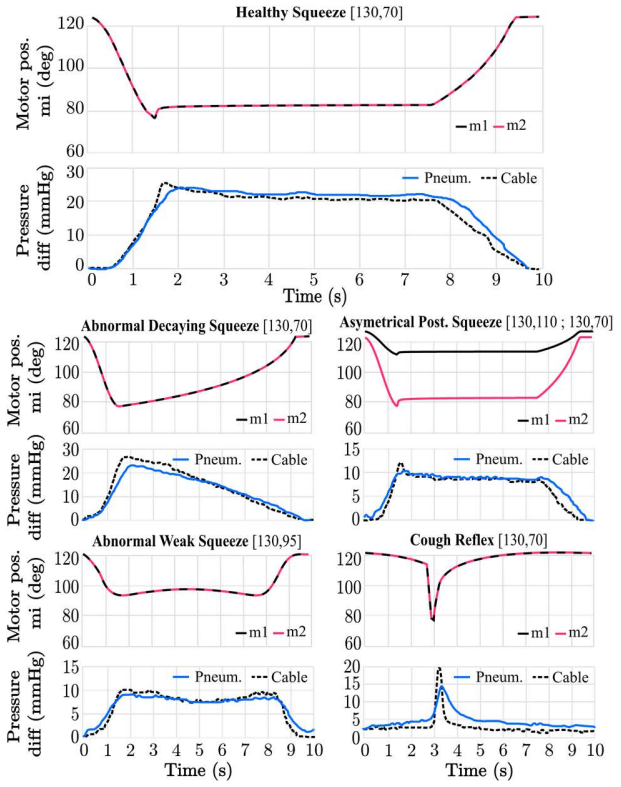


Figure 7. Measured pressure during different scenarios. Resulting servo motor position m_i based on profiles (with Thresholds: [*restingThreshold*, *squeezeThreshold*]) and difference in pressure taking the initial pressure as baseline.

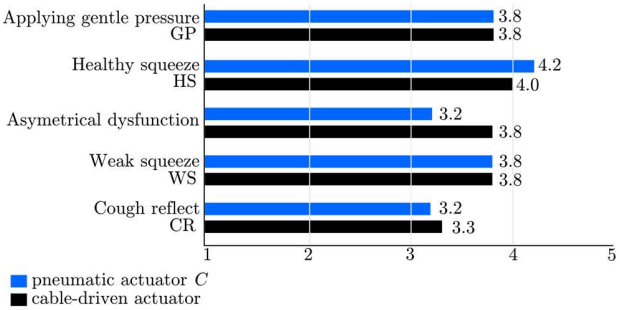


Figure 8. Evaluation of modelling of sphincter tone behaviour by six expert practicioners (1 – Very unrealistic; 3 – Neutral, 5 – Very realistic) for the two actuation systems and multiple clinical cases.

Participants mostly agreed that the weak abnormal tone may even be slightly weaker compared to the other scenarios. Cough reflex, was rated mostly as unrealistic amongst clinicians (unrealistic and realistic: μ=3.2 for pneumatic and μ=3.3 for cable-driven approach) and their clinical input was related to the lack of a "bear down" effect, pushing the finger out in addition to squeezing the finger, during cough reflex.

IV. Discussion

The participants agreed that both mechanisms were able to reproduce enough pressure on examining finger and a wide range of healthy and abnormal cases.

Pneumatic mechanism. Clinical input and experiments with clinicians suggest that a pneumatic mechanism with two chambers around a silicone model of the sphincter (*alternative C*) was preferred, since it produces pressure on a wider section of the finger and feels realistic enough. However, they pointed out that, for the cough reflex, the squeeze was too smooth and not rapid enough to realistically simulate this case. Compared to other alternatives, without the silicone model of the sphincter, the chambers were reported to feel like a balloon inflating, something hollow, without body. The results also indicate that a healthy squeeze requires only about 15 ml of air pumped through the syringe, leaving ample scope to generate different clinical scenarios. The participants favoured this mechanism in terms of pressure distribution on the finger.

Cable-driven mechanism. Building on our previous approach based on motors and encoders [5], we enhanced the mechanism by using servomotors that are smaller, simpler to control, and less noisy. Clinical input indicates that a wide range of cases can be generated with this mechanism. However, we found that the silicone model of the sphincter needs to be modified in two ways: the prominence in the internal walls needs to be closer to the anal verge and should be wider, so that the squeeze resembles a band surrounding the finger rather than a ring.

Modelling. The methodology used in this paper is versatile and simple to adjust. This can be easily adjusted since the presented piece-wise mathematical functions are normalised. Or approach takes into account ARM to generate mathematical models, actuate servo motors

throughout time, assess their realism by experts qualitatively, modify the profiles based on clinical input and close the loop by quantitatively reporting pressure on an inflating balloon. After clinical input, the initial profiles were reported to be varying considerable during squeeze and therefore were adjusted to reflect a smoother pressure profile (Fig. 6). We also added a model of an abnormal decaying tone (DS), which occurs when a patient is unable to hold a squeeze for a number of seconds and manifested by a gradual descent. In addition, we noticed that the maximum difference in pressure measured during cough reflex was smaller than that reported in the literature. We speculate that this difference observed between our measurements and the literature is due to the force that pushes the finger out during cough reflex, a force that is not modelled with our mechanisms yet.

V. Conclusion and Future Work

Current training methods for learning how to assess anal sphincter tone are not sufficient and better approaches are necessary. To achieve this, we explored two different approaches, a pneumatic and a cable-driven mechanism, that simulate the behaviour of the anal sphincter on palpation. We further propose a methodology to generate different clinical scenarios taking into account ARM to derive mathematical models that are adjusted after clinical input, and validated based on measurements of pressure. Six Nurse Practitioners in Continence Care and Colorectal Surgeons were recruited to evaluate our methods and to provide clinical input to improve our models.

We conclude that both mechanisms, pneumatic and cable-based actuation, produce enough pressure on the examining finger and are suitable for generating a wide range of clinical cases. The final choice will depend on other factors such as portability, robustness, flexibility of changing the mounting location of actuators, the amount of noise caused by actuating the mechanism, and that its components do not obstruct other equipment once it is integrated into a plastic benchtop model or a haptic-based simulator.

Based on the comments from clinicians, we will change the geometry of the inner shape of the sphincter model so that the internal walls are closer to the anal verge in order to distribute less locally the force applied on the finger.

We also plan to carry out tensile tests on Dragon Skin FX dumbbell samples and fit the mechanical properties of the material with a hyperplastic model, in order to obtain the parameters for this material.

The mathematical profiles of the behaviour of sphincter tone were simple to implement and customise, and is able to reproduce a wide range of cases.

We acknowledge the small number of participants in our study, but the focus of this initial pilot study was to get crucial input from experts in primary care to evaluate and improve our approaches. Once we delineate the most important clinical cases for teaching and learning sphincter tone assessment, we will run a thorough study with more participants in primary and secondary care. Another current limitation of our work is that there is no mechanism that can push the finger out during cough reflex. Although one participant mentioned that that effect may not be necessary for learning, we expect to investigate this in future work. The experiment related to the relaxation of the anal sphincter whilst applying gentle pressure was coordinated manually. A pressure sensor around the anal verge could improve this effect. The sound produced during sudden changes of actuation by the servo motors was noticed by participants. Although this sound is much less than the sound caused by our previous approach using motors and encoders, it is still conspicuous and may affect assessment during training. We will further investigate how these sounds could be minimised. Lastly, we intend to improve the dynamics of our pneumatic approach.

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