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A PHYSICAL SIMULATION TO INVESTIGATE THE EFFECT OF ANORECTAL ANGLE ON CONTINENCE

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ABSTRACT
This paper investigates the effect of the anorectal angle on continence using a physical model of the anatomical system. A method to fabricate, measure and control a physical model for the simulation of human faecal continence is presented. A model rectum and associated soft tissues, based on geometry from an anonymised CT dataset, was fabricated from silicone and showed behavioural realism to ex vivo tissue. Simulated stool matter with similar rheological properties to human faeces was developed. Instrumentation and control hardware are used to regulate injection of simulated stool into the system, define the anorectal angle and monitor stool flow rate, intra-rectal pressure and puborectalis force. A study was then conducted in which simulated stool was introduced to the system for anorectal angles between 80° and 100°. Results obtained from the study give insight into the effect of the anorectal angle on continence. Stool leakage was reduced as the angle became more acute. Conversely, intra-rectal pressure increased. These data demonstrate that the anorectal angle is fundamental in maintaining continence. This work is valuable in helping improve our understanding of the physical behaviour of the faecal system. It has particular relevance facilitating improved technologies to treat or manage severe faecal incontinence.

KEY WORDS
Faecal incontinence, anorectal angle, rectum model

1. Introduction

Faecal Incontinence (FI) is the inability to carry out controlled defecation and leads to the involuntary passing of bowel content, including flatus, mucus and liquid and solid faeces. The overall prevalence of FI in adults is estimated between 11 and 15% and increases with age, with approximately 33% of people living in retirement homes (or similar institutions) affected [1]. Stigma and social taboo are associated with FI, leading to its underreporting [2].

1.1 Anatomy and Physiology of Continence

The rectum is a hollow muscular tube, typically 13cm in length when non-distended [3], composed of a continuous layer of longitudinal muscle that interlaces with the underlying circular muscle. The anus is a muscular tube 2.5-4cm in length [4]. At rest, it forms an angle of approximately 104.5° [5] with the axis of the rectum. During voluntary squeeze the angle becomes more acute, whereas during defecation, the angle becomes more obtuse, Figure 1.

Continence relies on the coordinated function of the nervous systems, gastrointestinal (GI) tract, and anal sphincter and pelvic floor musculature [6-10]. The sphincter complex (internal and external sphincters) applies pressure over the length of the anal canal creating occlusion, while the puborectalis (PR) and levator muscles produce occlusion in the upper anal canal. The PR also creates angulation between the anal canal and the rectum, termed the anorectal angle (ARA). The presence of an acute ARA has been considered important in maintaining continence [11, 12]. Dysfunction of only one of these components can result in severe FI, with common

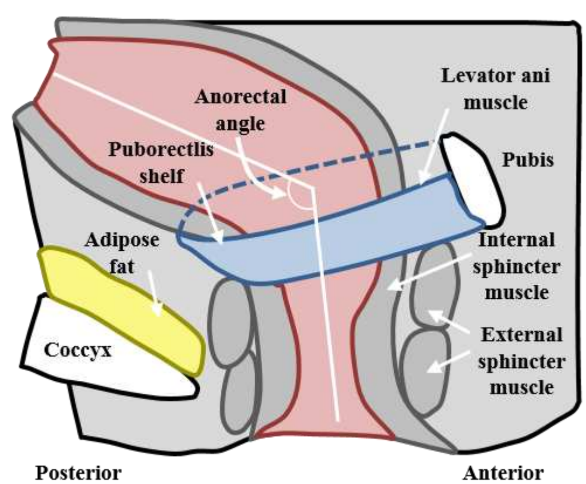

Figure 1 *Anatomy of the anorectum, components which are modelled include the rectum (red), puborectalis muscle (blue) and Adipose fat (yellow)*

causes including diarrhoea, obstetric trauma, spinal cord injury and rectal prolapse [13]. Faecal incontinence (FI) is a condition with profound consequences for individuals, their family/friends, and the wider healthcare system [14].

Efforts to improve the technology to treat FI have taken inspiration from those applied for urinary incontinence. These techniques involve using an inflatable cuff to occlude the urethra [15, 16]. Efforts to use a similar approach to treat FI by occluding the sphincter [17, 18] have been plagued with complications including local ischaemia due to the occlusive pressures necessary to maintain continence [9, 19-21].

Alternative strategies to sphincter augmentation have also been explored. Notably, in vitro studies have shown that increasing ARA reduces the occlusion pressure required to hold back solids and semi-solids [22, 23]. Similarly, another study reported increased retention of semisolid material when increasing ARA in an ex vivo porcine rectum, but no effect for water [23]. The question of whether the ARA or sphincter occlusion pressure is a greater contributor to continence remains unanswered, despite previous studies comparing the two [24, 25]. It is evident that modulating ARA is a key feature in maintaining continence and provides a complementary strategy to sphincter augmentation. There are currently no clinically available devices that exploit these features.

Currently only a small number of surgical treatments are available for patients with severe FI and these focus on augmentation of the anal sphincter. Two treatments currently on the market include the passive FENIX [26] system and the active Acticon Neosphincter^{TM} [27], for which studies have shown success rates (for people with a functioning device) of 65%, at a mean follow up of 26.5 months [28]. An alternative strategy is the post-anal repair operation for idiopathic FI, designed to correct an overly obtuse ARA [7] by reducing the angulation [29, 30].

The paucity of commercially available, clinically viable, systems to treat FI reflect the difficulty of designing to meet the multi-faceted challenges surrounding this complex condition. A key failure mode in existing systems occurs when device-tissue interaction causes tissue erosion, resulting in device migration or rejection [31, 32].

There is a clear clinical need to develop improved devices to treat FI, and recent research reveals promising opportunities to exploit ARA modulation. To further advance this work requires an in-depth biomechanical understanding of continence mechanisms and models to capture their complex behaviour. This would allow detailed investigation into the complex device-tissue interactions which occur in the biological system and provide test environments to speed development prior to pre-clinical and human trials.

Little work exists in this area; previous work has focussed on computational models. Finite element models of the pelvic floor have been developed in attempts to understand its function in the urinary and faecal continence mechanisms. One model has been developed to investigate the effect of stool consistency on continence [33]. While another looks at the effect of damaged ligaments on stress urinary continence [34]. Computational models have also been developed to characterise the global behaviour of the pelvic floor muscles [35-39]. However, there are large quantitative differences between the models and parameters used.

Whilst computational studies have been developed, a physical model provides opportunities to further understand the biomechanics of FI to help develop and optimise new systems for treatment. In particular, physical models can readily simulate the complex physical properties of faecal matter and the physical interactions between this and different tissues. Furthermore, they provide a convenient means to evaluate new treatment concepts. Accordingly, our research concerns the development of a physical model to investigate the effect of ARA on continence for the future development and evaluation of novel FI technologies.

This paper presents a compliant soft model of the human rectum, integrated with an in-vitro simulation, consisting of physical models and computational measurement and control, which provides a stable platform for repeatable testing. We demonstrate the capabilities of this model in a study which investigates the effect of changing ARA on continence. Results from the study are then discussed to evaluate the performance of the model and its implications for future treatments of FI.

2. Materials and Methods

This section details the development of our faecal system model and the testing regime used to investigate the effect of varying ARA on continence.

2.1 Model Overview

Our approach in developing a physical model of the faecal system is to combine soft silicone representations of key parts of the anatomy, computerised control and instrumentation to objectively monitor and regulate physiologically relevant parameters and a stool simulant to obtain a realistic flow regime in the system.

The full biological continence mechanism is complex and consists of the coordinated function of the nervous systems, GI tract, and anal sphincter and pelvic floor musculature. Our current model is focussed on investigating the effect of varying ARA and accordingly we have simplified the system to facilitate fabrication and detailed analysis of this function.

The rectum, adipose fat and PR muscle components are simulated by cast, 1:1 scale, silicone models, anatomically positioned within a housing linking these elements to control and instrumentation, as shown in Figure 2. The system is driven through a stool injection mechanism (detailed in section 2.4) while the ARA is regulated through an active PR muscle as part of the continence mechanism. By varying the pressure exerted by the PR muscle on the rectum, the ARA can be controlled and its effects on faecal leakage are observed during influx of simulated stool. The anal canal is represented within the rectum geometry with no occlusion from the anal sphincter.

2.2 Soft Tissue Modelling

For accurate biomechanical representation of the soft tissues in the model, their geometry and mechanical properties were recreated using a silicone casting process and informed by data in the literature.

The rectum represents the most complex component in the system. The open source 3D-IRCADb model [40], Figure 3a, provides full 3D geometry of the rectum with appropriate levels of detail to enable fabrication. The dataset consists of segmented CT data from a 44 year old male patient with focal nodular hyperplasia of the liver, but no condition relating to FI. This model showed close agreement with other published works on the size and shape of the human rectum. However, it should be noted that this component could be interchanged with alternate geometries if required (e.g. to represent different anatomy).

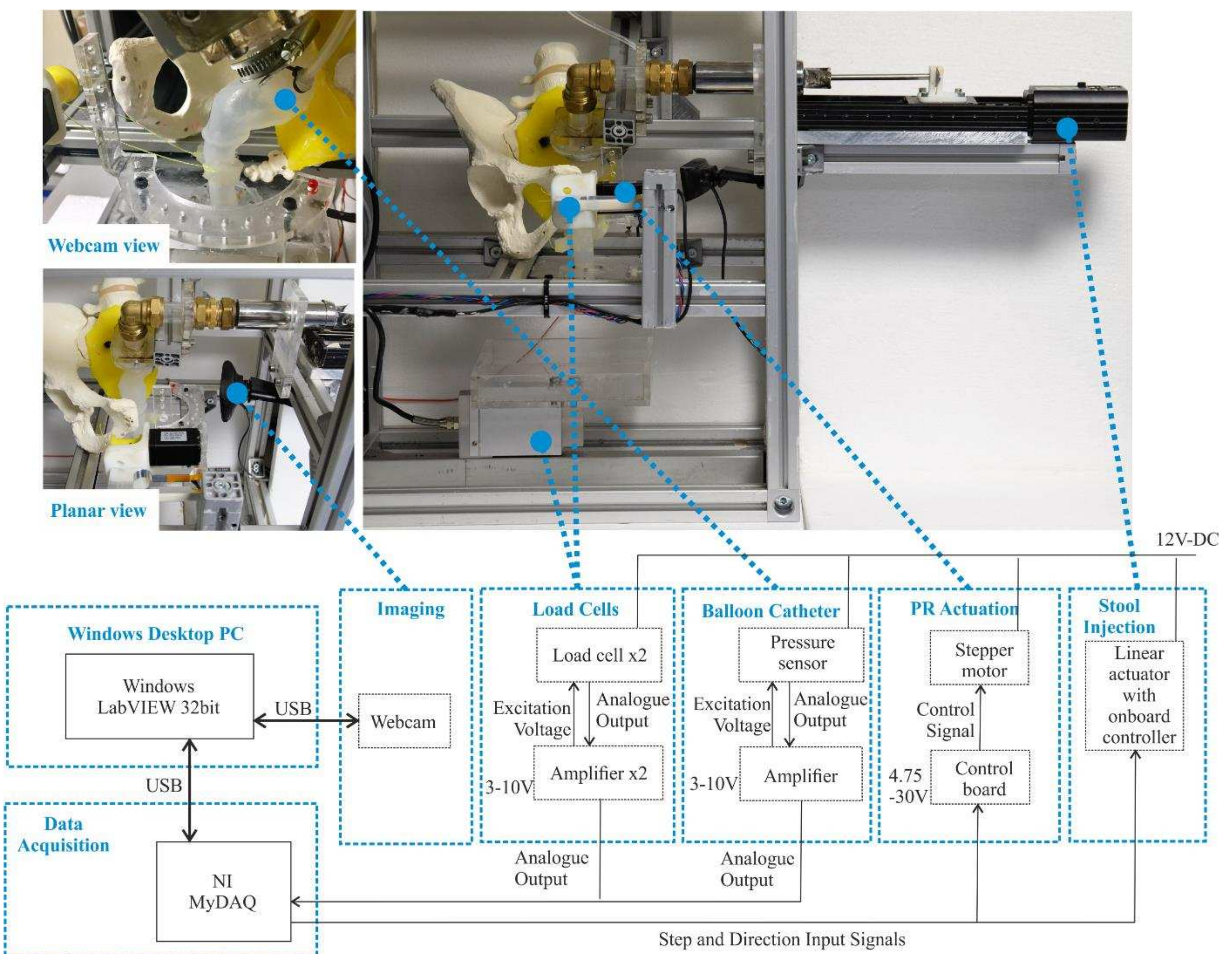

Figure 2 *A schematic overview of the faecal system simulation*

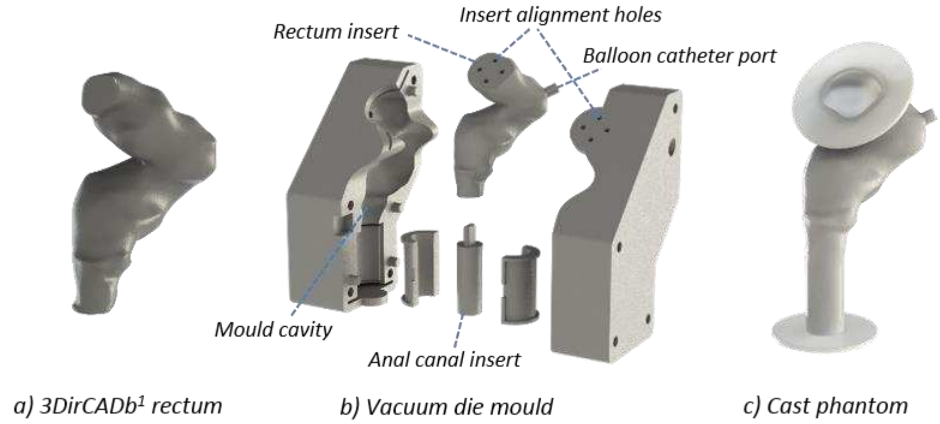

Figure 3 *Fabrication process for the rectum phantom model detailing a) the segmented 3D-IRCADb dataset geometry b) the 3D printed vacuum injection mould and c) cast phantom rectum phantom*

The 3D-IRCADb rectum model was imported into a 3D CAD package (SolidWorks™, Dassault Systèmes). The addition of flanges enabled the mechanical fixation of the soft model into the faecal simulation. A 3D CAD model of the mould, Figure 3b, was then constructed using the modified rectum geometry. The mould consisted of two halves with an insert. Fixation points allowed the rectum insert to be correctly aligned within the mould cavity such that a uniform wall thickness was achieved. The addition of a material reservoir and inlet ducts enabled fabrication of the rectum by vacuum casting. The mould was positioned in a vacuum chamber with pre-mixed, de-gassed silicone in the silicone reservoir. Air in the mould cavity is displaced by silicone as it escapes through holes between silicone trough and mould cavity. Once cured, the model could be de-cast.

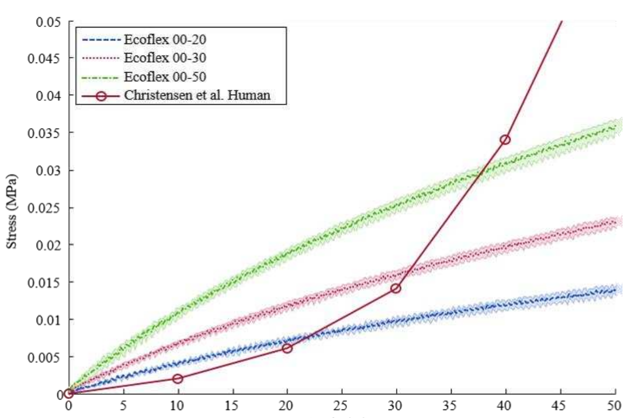

Figure 4 *Stress strain curves comparing different grades of silicone (with ±1STD shaded errors) to human rectum tissue [41]*

For mechanically realistic silicone models, linear force-displacement tests were carried out on 3 different grades of silicone for comparison to the loading curves for the biological tissues. Due to the non-linear mechanical behaviour exhibited by soft tissues like the rectum, an approximation was made, treating them as isotropic and matching their stress-strain profile across a normal physiological strain regime shown in Figure 4. The same methodology was applied to model the PR muscle and adipose fat components. Properties of the PR component were matched to tensile data of longitudinal external anal sphincter muscle tissue and the adipose fat component to properties of human adipose tissue [42]. The grades of silicone chosen to model each component are detailed in Table 1. Moulds for adipose tissue and PR were made using laser cut sections of laminar acrylic sheet glued together to form the 3D moulds. The posterior of the PR muscle was lined with an inextensible mesh to prevent longitudinal extension while maintaining a soft interface with the rectum.

Pelvic constituent	**Model material**
Rectum	Ecoflex 00-30 [6]
Adipose fat	1:1 wt% Ecoflex 00-20:SlackerTM [6]
PR	Inextensible mesh & Ecoflex 00-50 [6]

Table 1 *Test rig components and material details*

2.3 Modelling faeces

Tests to determine the physical properties of faeces have shown that they vary considerably in viscosity, hardness and consistency. Magnesium Aluminum Silicate NF Type IA (Vanderbilt Company) was used, as a pharmaceutical grade smectite clay it is also used as simulated stool for nuclear medicine proctographic studies. It forms a homogenous substance with physical properties of density and viscosity comparable to those reported for soft faeces [43].

The shear rheological properties of fresh human faeces have been analysed. The method here adapts that presented by Woolley et al. [43] for analysing the effect of shear rate on dynamic viscosity of VEEGUM solutions.

Simulated homogeneous stool solutions were made by adding a predetermined wt% of VEEGUM R magnesium silicate powder to distilled water. The samples were dispersed using a chemical homogeniser for 2 minutes before being transferred immediately to the rheometer. Following homogenisation, samples were transferred to the rheometer vessel in preparation for testing. Experiments were performed repetitively (5 cycles) at 25°C on the same sample to determine the repeatability of flow curves and to establish if any breakdown or reconstruction had occurred during tests. Shear rate-apparent viscosity flow curves were produced for stool simulated samples of various moisture contents. Interpolated viscosity was plotted against moisture content (at a shear rate of $1s^{-1}$) and a power-law relationship enabled determination of the viscosity of stool simulant tested in the faecal simulation.

The measured moisture contents of human faeces range from 58.5% to 88.7% by mass [43], with apparent viscosities at $1s^{-1}$ ranging between 52.8 and 3306.3 Pa.s based on a power law relationship. In this study a stool simulant was selected at 90.5% water content, producing an apparent viscosity of 47.065 (Pa.s), within the bounds of high moisture content semisolid faecal samples.

2.4 Control and Data Acquisition

The faecal simulation was instrumented with a range of hardware detailed in Table 2. Sensing hardware was used to sample the PR muscle force, IR pressures and mass leakage. These data were recorded at a sample rate of 100HZ to monitor these variables over time as stool simulant was injected into the system.

Augmentation of the ARA was driven using a stepper motor and spool assembly, controlled by a host PC. The PR muscle is connected to the spool through an inextensible nylon cord and tightened against the anorectum through rotation of the spool, causing augmentation of the ARA. The stepper motor was mounted to a load cell allowing the forces acting on the anorectum by the PR to be measured. Stool simulant was introduced to the system by controlled injection using a lead-screw linear actuator which drove a syringe containing the stool simulant. Stool leakage from the anal canal is collected in a tray mounted to a second load cell such that mass, and mass flow rate, can be measured.

Testing variable	Hardware	Manufacturer and model
Anorectal angle	Stepper motor	RS Pro, 535-0366
Intra-rectal pressure	Balloon catheter	Medi Plus, 2309
	Pressure transducer	Utah Medical, Deltran® 6199
PR muscle force	Load cell	RS, 1004
Mass leakage	Load cell	RDP, RLS005kg

Table 2 Control and sensing hardware

LabVIEW™ (National Instruments) was used as a programming platform for the data acquisition, control and data logging described above.

2.5 Experimental Protocol: Effect of ARA on Continence

A test protocol was defined to investigate the effect of ARA on continence using the model system. In each test the system was configured and a fixed volume of stool simulant was injected into the rectum model at a constant flow rate. PR muscles forces were configured to produce a range of ARA values. Intra-rectal (IR) pressure, PR force and stool mass leakage values were recorded throughout.

The following protocol was followed for each test with the faecal system simulator.

1. Initialise System
Prime rectum with stool simulant using a rigid rectum housing until leakage from the anal canal occurs (to fill rectum without inducing strain)
2. Configure ARA position
Adjust PR until the desired ARA is achieved
3. Run Test
Initiate webcam recording and inject metered volume of stool simulate into the rectum at desired rate

4. End test
Wait until steady state (stool mass) is achieved, stop recording and save acquired data

During the tests, 59ml of stool simulate was delivered to the system at a constant flow of 9.26ml/s, a typical flow rate for stool being passed during defecation [44]. The tests were performed at room temperature (25°C). Stool simulant was prepared using the same technique as during rheology tests. Images of the rectum were analysed using ImageJ™ (National Institutes of Health) to measure the augmented ARA, varying PR force iteratively until it was correct within 0.5°. Measured outputs in each test were stool mass passed, PR muscle force and IR pressure. Tests for ARA effects were carried out at angles of 80°, 90°, and 100° with the previously described stool simulant. 5 repeats were carried out for each test. Each test was recorded using a high definition universal serial bus webcam (C920 HD Pro, Logitech).

3. Results

The full test protocol was successfully completed. Figure 5 shows images of each experimental configuration (obtained from the webcam) and the variation in ARA obtained by tensioning the model PR muscle.

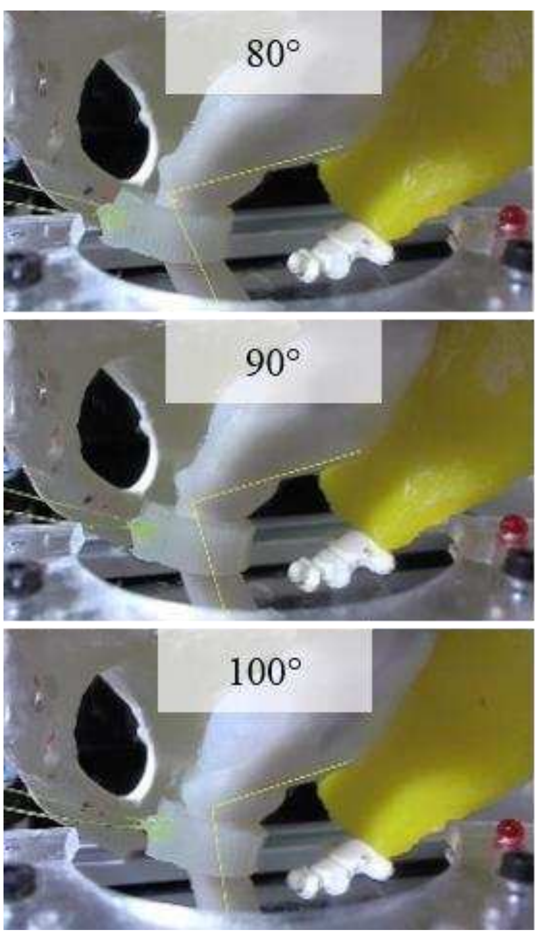

Figure 5 *View of the model rectum for the range of ARA values used in the experimental study*

The faecal mass, PR force- and IR pressure data recorded are displayed in Figure 6. These data demonstrate an effect of ARA on the resultant faecal leakage, evident in the reduction of total faecal mass passed increasing from 0.0139 kg at 80° to 0.0301 kg at 100°. The associated IR pressures show a similar increase during the initial phase of stool injection but diverge as the process approaches steady state, with higher pressures observed for lower values of ARA.

4. Discussion

Although rectal filling starts at t=0s, leakage of mass from the system doesn't occur until a period of around two seconds have passed. This delay is due to rectal filling whilst holdback pressures are great enough to overcome pressures produced by elastic energy stored in rectal walls. Fluctuation of the mass flow curve is apparent for all ARA values tested, with the phase of the fluctuation appearing larger at more acute ARA values and lower flow rates. These are formed as the semisolid exits the system in fluid globules, characteristic of viscous fluids

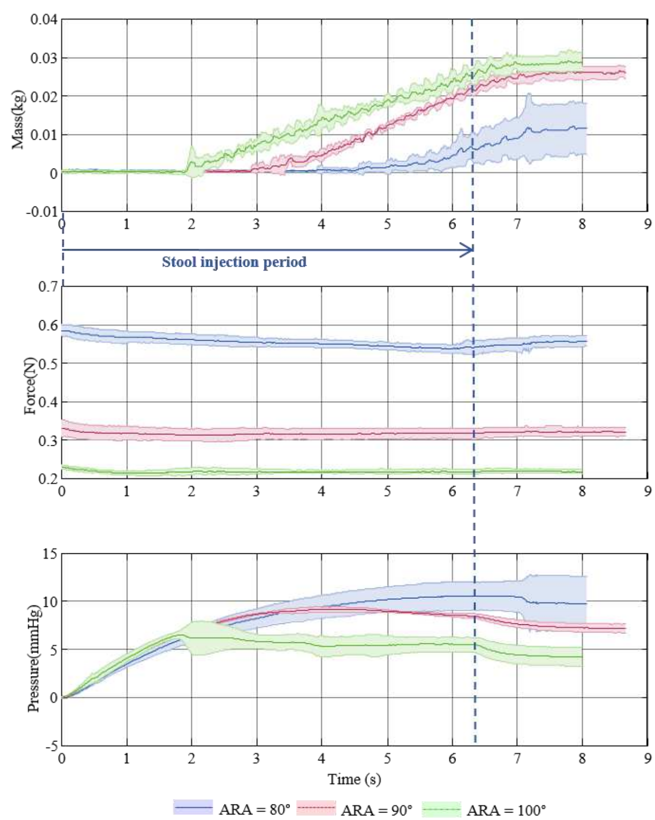

Figure 6 *Faecal mass passed, PR force and IR pressure versus time for different ARA values. Each plot shows mean (N=5) in solid with 1 STD as shaded region.*

with low surface tension under shear.

If the hold back pressure produced by PR muscle forces is sufficient, in relation to the simulated IR pressures, faecal leakage is reduced. Upon varying the ARA, a notable difference in leakage was observed between an ARA of 80° and 90°, increasing from 0.0139 to 0.0273kg. This demonstrates that as the ARA becomes more acute, a greater amount of stool is contained within the rectum during a controlled influx of stool. It would also appear that if a threshold ARA is exceeded, the amount of leakage is drastically improved. Whereas at more obtuse ARA values, small changes in angle have little effect on leakage.

This study demonstrates that to improve retention of semisolid material in the model rectum, it is not necessary to completely close the sphincter. Angulation of the rectum alone provides sufficient resistance to reduce stool leakage. Mean biological ARA values for healthy, nulliparous patients are measured at 104.5±10.3° at rest and 84.5±14.2° during squeeze [5]. These values are in agreement with the ARA's observed for the reduction in leakage in this study.

Due to the high variability and complexity of biological systems, the faecal system model has some limitations. The non-linear, anisotropic behaviour typically found in human soft tissue have been approximated with an isotropic silicone model. Furthermore, complex surface interactions which occur between the between the rectum, pelvic floor, bladder and other surrounding tissues have been neglected. Lastly, the current model uses a passive model, the active musculature in the rectum and sphincter have been neglected, most significantly the intrinsic contraction of the rectum and anal sphincter complex have not been included. Despite these simplifications it is evident that the behaviour of the model is informative and in agreement with that found in human subjects. Further refinements to this model will help increase its fidelity. In particular, continence relies upon the effects of ARA being augmented with anal sphincter contraction and these aspects will form the basis of future enhancements to the model, with active sphincter contraction and anisotropic material properties for the soft tissues.

4. Conclusion

The physical model has given an insight into the biomechanics of the human faecal system and the effect of the ARA on continence. As stool simulant is fed into the rectum, the volume expands as elastic potential energy is stored in the rectal walls. When the contraction of the rectum leads to IR pressures which are sufficient to overcome holdback pressures incurred by PR muscle forces, leakage from the anal canal occurs. As pressures reach an equilibrium, stool flows steadily from the anal canal. When the influx of stool into the rectum ceases, leakage continues at a reduced rate until the holdback pressure is sufficient to contain any remaining faeces in the rectum.

This work has shown that increasing the ARA increases continence. The study provides rational that augmenting the ARA could help relieve symptoms of chronic leakage associated with more severe cases of FI. Future work will consider the inclusion of an active anal sphincter system to explore their combined effects on continence.

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