

Proof of Concept

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Title of Study:	Modelling the Physiology of Faecal Incontinence for the Development of a Smart Device
Aims and Objectives: (max 400 words)	<p>The background for this project is the design of a smart device for fighting faecal incontinence. In two parallel projects, a sensing modality using TACTIP technology was contributed by the Bristol Robotics Laboratory, an anatomical test rig and material testing was contributed by the University of Leeds, and computational modelling was contributed by Imperial College London - with the latter providing the focus of this report.</p> <p>It is the on-going ambition of this work to understand the physiological causes of faecal incontinence and tie them to the design of a device that is able to prevent the symptoms and also offer diagnostic capabilities. An anal plug is one method for alleviating the symptoms of faecal incontinence and it was anticipated that a device of this type, with high resolution pressure sensing, would be able to indicate where physiological damage or weakness was contributing to the condition.</p> <p>At the University of Leeds, three critical components in the problem of faecal incontinence have been identified, among others, for further study. These are the anorectal angle and the performance of the internal and external anal sphincters. A phantom consisting of a rectum, anal canal (with sphincters) and puborectalis muscle were used as a basis for their investigation.</p> <p>The principal aim of the work presented here is to develop a numerical platform that captures the anatomical features of the test rig, enables investigation of physiological behaviour and can contribute to the most effective design of a smart device addressing faecal incontinence. A secondary aim is to provide a modelling environment that can be used for future analysis, including development to include the flow of faecal matter.</p> <p>The objectives of the work carried out were as follows:</p> <ol style="list-style-type: none"> 1) Create a finite element model of the anatomical, physical test rig. This will include the material characteristics of soft tissue taken from previous studies and the following anatomical features: pelvis; rectum; sphincters; pubo rectalis muscle; and pelvic floor. 2) Investigate loading scenarios with clear medical analogies. Types of loading to be simulated will include individual instances of sphincter pressures, rectal pressures, and forces and strains in the puborectalis muscle. 3) Investigate conditions that may lead to reduction in faecal incontinence.

Description of research work:
(max 400 words)

The finite element modelling carried out here was based on the anatomical test rig developed at the University of Leeds as part of the PhD research of Will Stokes. Figure 1 shows the main elements including pelvis, sphincter, rectum and anal canal.

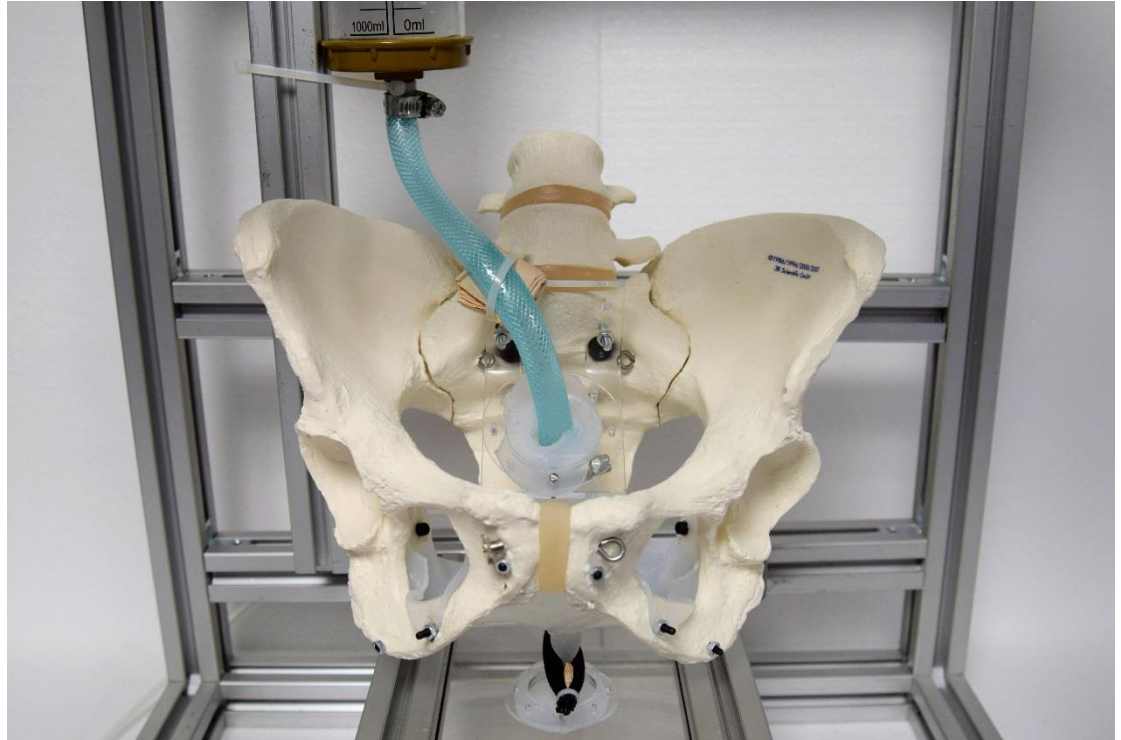


Figure 1. The anatomical test rig developed by Will Stokes at the University of Leeds.

The University of Leeds provided each item in the model as part of a SolidWorks assembly. The part of the rectum included in the anatomical rig was moulded on the OpenHELP medical imaging data and was provided as an .stl file. It was assumed that the anal canal was cylindrical.

While providing crucial structural support in the anatomical rig, the pelvis was predominantly used to provide a geometric reference frame for locating the rectum and anal canal in the finite element models.

Some pre-processing was performed to transfer the SolidWorks model into a form that could be analysed in Abaqus finite element software. This included the following tasks:

- 1) Resampling, at lower resolution, of the surfaces where the rectum and anal canal joined each other.
- 2) Manual repositioning of a small number of nodes in the rectum to create elements with sufficient shape quality.
- 3) Creating an analytical cylinder to replace the SolidWorks surface approximation of the anal canal.

Key features of the finite element model shown in Figure 2 were:

- A rigid body assumption applied to the pelvis/spinal component.
- Linear shell elements used for the rectum and anal canal.
- An elastic modulus of 0.06MPa in all deformable tissue. This was based on tensile tests performed by Will Stokes.,

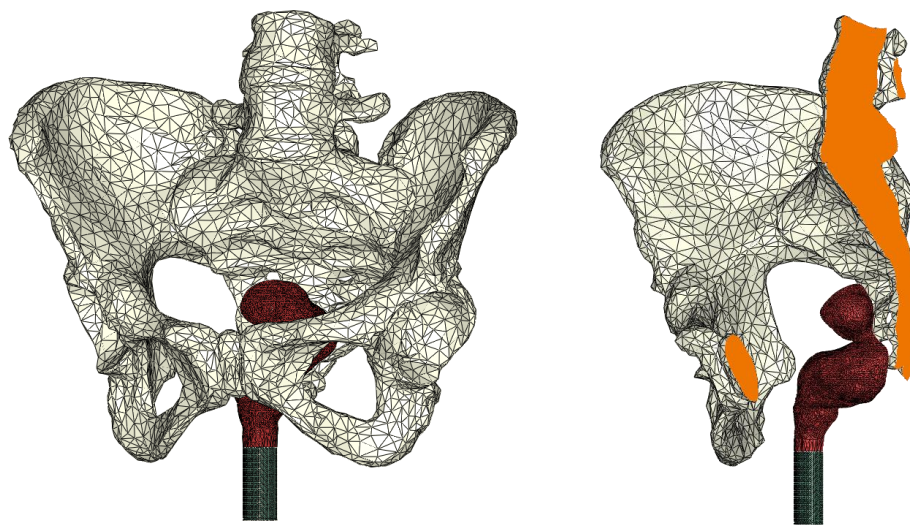


Figure 2. Finite element model of critical anatomical components featuring the pelvis, rectum and anal canal. Typical element lengths on the anal canal are 1mm and on the rectum between 1mm and 3mm.

A series of simulations were performed to replicate critical physiological behaviour in maintaining continence. A summary of the conditions and necessary boundary constraints is as follows:

- 1) Internal and external pressures applied to the rectum. Uniform pressures were applied to the rectum surfaces.
- 2) Contribution of the puborectalis muscle to the anorectal angle. Both nodal displacements and element pressures were used to approximate this condition. The direction of the displacements was calibrated by the alignment of the rectum with the pelvis structure.
- 3) Descent of the pelvic floor. The anal canal was displaced vertically.
- 4) Contraction of sphincter muscles. Displacement boundary conditions were applied to nodes on the anal canal.

Key findings:

The first finite element test considers the response of the rectum to both internal and external pressures (Figure 3). This is beneficial in testing the response of the model to distributed loads. Physiologically, the output captures the expansion of the rectum when an internal pressure is applied.

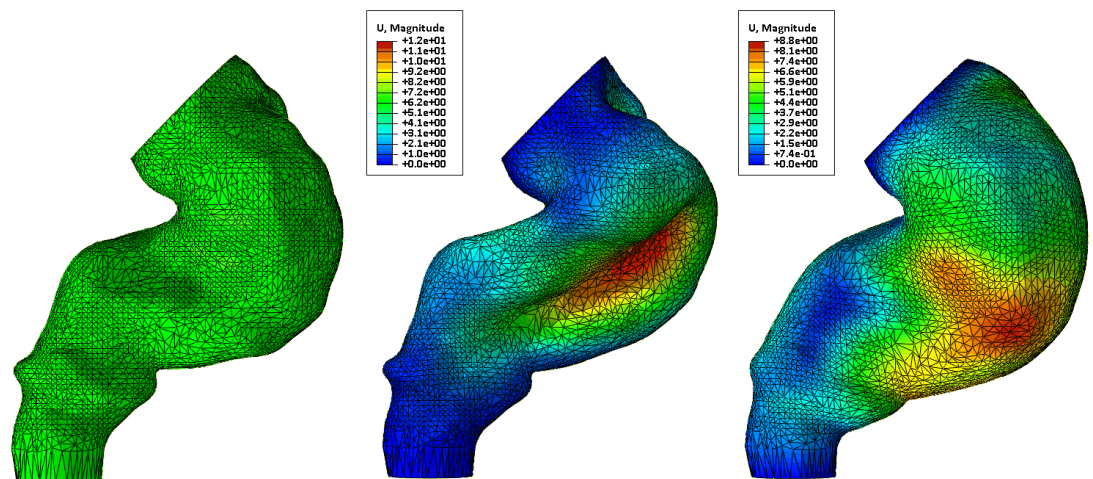


Figure 3. The undeformed rectum (left) in comparison and when a uniform pressure is applied to the external surfaces (centre) and internal surfaces (right). Contour plots show the displacement magnitudes in millimetres.

Of even greater significance is the response to an external pressure. As the medical imaging could neither confirm nor deny the presence of matter in the rectum, the contraction due to external pressures could be used to approximate the geometry of the rectum when empty. Critical to this process would be the inclusion of surrounding support structures and gravitational loading. These, however, cannot be inferred from the initial medical images. A future challenge for this type of loading is also to include boundary conditions at the top and bottom of the rectum that capture the realistic support of the anatomy.

In the second finite element test, the impact of the puborectalis muscle acting as a 'sling' is investigated. Two conditions are considered. In the first, it is assumed that nodal displacements are recreating the effect of the 'sling', whereas in the second, a pressure load is assumed. The selection of nodes and elements for loading are shown in Figure 4. Also highlighted are assumed points of fixation of the puborectalis muscles on the pubic bone structure. This provides a projection for the nodal displacements. Again, boundary conditions provided by supporting anatomy are inferred.

The output from the study of the effect of the puborectalis shows how significant the boundary conditions are. However, it is clear that whether in the form of concentrated nodal loads/displacements or distributed elemental pressures, the contraction of the puborectalis 'sling' decreases the anorectal angle and therefore contributes to continence (Figure 5). Regardless of whether the boundary conditions and the implied anatomical support are applied at the upper or lower ends of the anal canal, the 'sling' effect contributes to decreasing the anorectal angle but with very different impact on the strains and stresses developed in the tissue. The 'sling' effect also causes a crimping of the lower end of the rectum that would contribute to faecal continence.

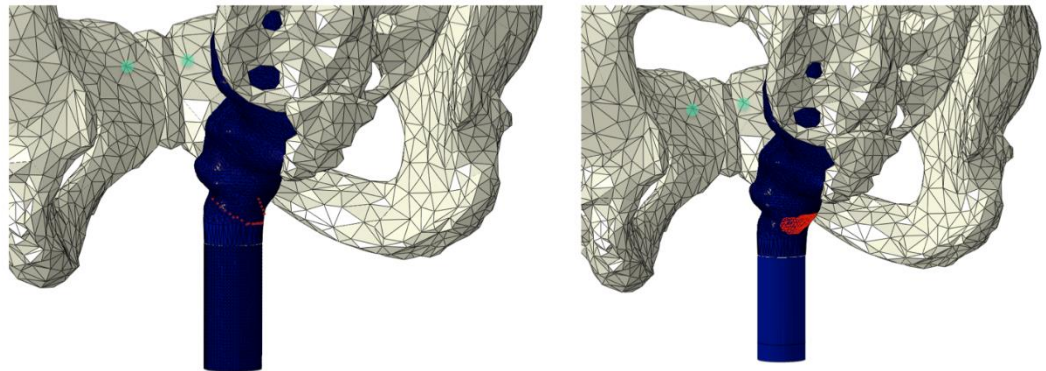


Figure 4. Nodes (left) and elements (right) used to load the rectum to recreate the effect of the 'sling' provided by the puborectalis muscle. Assumed points of contact of the 'sling' are highlighted indicated in green.

A further anatomical effect under consideration is the descent of the pelvic floor muscles. It is anticipated that this will reduce the anorectal angle and therefore contribute to the passing of stools. Figure 6 shows the anorectal angle becoming less acute as the anal canal displaces downwards. The critical boundary condition in this instance is the vertical displacement of the top of the anal canal.

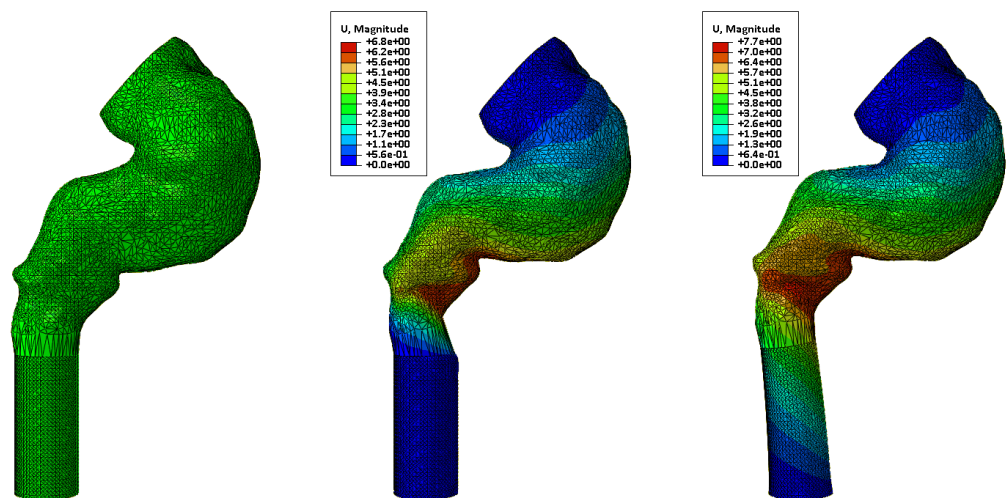


Figure 5. The impact of different boundary conditions when the 'sling' provided by the puborectalis muscle is tightened. In both loaded cases, the anorectal angle increases in comparison to the undeformed anatomy (left). Assumed boundary conditions near the top of the anal canal (centre) result in far greater local strains than when this boundary is assumed to be free (right). Plots show displacement magnitudes in millimetres.

The final test presented here is one that is crucial to maintaining continence and to assessing the performance of an anal plug style of device. Effective sphincter muscles are vital to maintaining continence and are one of the most important elements considered in ultrasonic or barometric clinical investigations. In all of the simulations presented to this point, the anal canal is assumed to be open and therefore relaxed. The structures of the internal and external sphincter are complex. Here, contraction of the anal canal is performed as part of an initial feasibility study. Figure 7 shows the result when four points are deformed inwards to the centre of the anal canal.

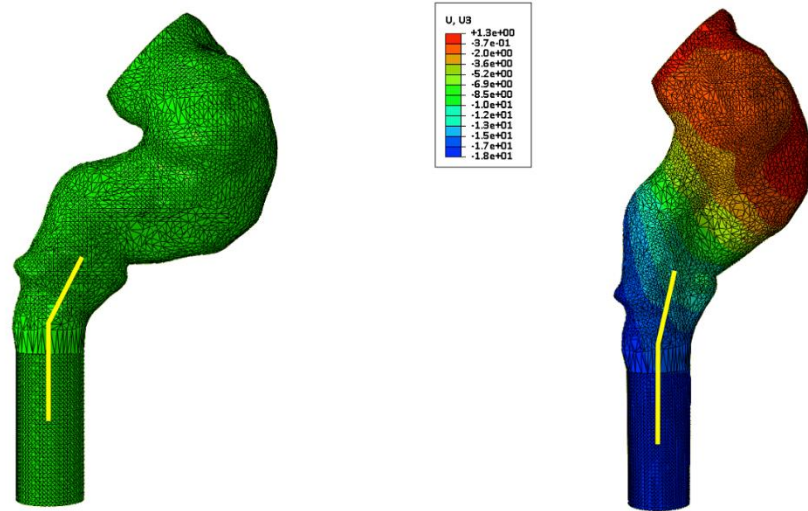


Figure 6. The anorectal angle increases as the anorectal junction is displaced vertically downwards. The undeformed model (left) is assumed to be in the toned position and the deformed model (right) has a relaxed puborectalis and descended pelvic floor. Vertical displacement in millimetres is shown.

Although the deformation profiles of the anal canal are highly artificial, the reduction in cross sectional area could be utilised in future simulations. The contraction of the anal canal would still be useful in assessing the flow of faecal matter when compared to the open condition seen throughout the rest of the report. It is a surprising outcome of this study that modelling the axisymmetric behaviour of sphincter muscles proved so challenging. It will, therefore, form a key part of future work.

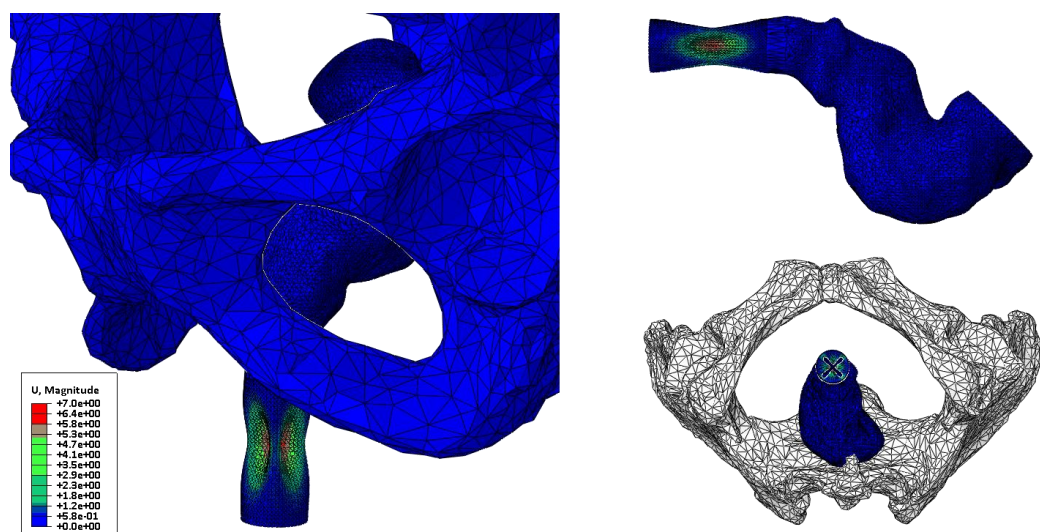


Figure 7. The walls of the anal canal contracting as nodal displacements are used to simulate the effect of sphincter muscles. Displacements magnitudes are in millimetres. The artificially regular deformation does not show axis-symmetry as would be expected physically. This kind of contraction could, however, be used to assess the relative simulated flow rate of faecal matter.

<p>Outputs: e.g. publications, new links etc.</p>	<p>The finite element models of the anatomical structures and physiology presented here, are linked intrinsically both to the sensing work done at the Bristol Robotics Laboratory and the wider investigation into device development for faecal incontinence at the University of Leeds. One of the main outcomes of this project has been to forge collaborative links between the three research groups (the third being Imperial College London). It is anticipated that a research publication will follow that addresses the combined contribution of simulation work, anatomical testing and development of a smart device for faecal incontinence</p> <p>There is also scope to use finite element modelling to assist in the development of the sensing technology itself. This has particular potential in predicting the impact of material selections on the response of the TACTIP device, which is part of a parallel IMPRESS POC project.</p> <p>Following the IMPRESS meeting in February 2016, the possibility has been raised of accessing comprehensive medical imaging to aid in this work. Currently, the anatomical datasets require further detail, particularly when incorporating support structures around the rectum, pelvis and anal canal presented here. This will be explored through a different research group at Imperial College London.</p>
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PROPOSED NEXT STEPS

<p>Follow on funding Strategy:</p>	<p>It is hoped that the investigation presented here will provide context, early data and a structure for work in the preparation of a proposal to the EPSRC. This proposal will include the aim of developing a community of researchers in the area of numerical simulations for addressing issues surrounding incontinence. Currently, even at an international level, numerical finite element modelling has been presented, in limited form, by only a handful of groups.</p>
<p>Future research work plan:</p>	<p>The preliminary work in this proof-of-concept project raises the prospect of extensive development in the future. As well as incorporating greater anatomical detail, there is scope for research into material characterisation of all of the soft tissue structures involved in the area of faecal incontinence.</p> <p>More specifically, further improvements to the finite element modelling will include:</p> <ul style="list-style-type: none"> More realistic sphincter muscles. Representation of both the internal and external anal sphincters. Techniques to characterise the naturally toned states of muscle structures. More anatomical detail, in particular the full pelvic floor structure. <p>Highly novel and previously untested modelling of the flow of faecal matter through the anatomical structures. This could possibly be achieved by using solid particle hydrodynamic techniques.</p>

We encourage you to use diagrams and figures to illustrate your work and you may also submit additional material such as videos.