MEDICAL PRODUCT DESIGN: EVOLUTION OR REVOLUTION?

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Abstract. *When designing for medical products many aspects have to be taken into consideration – safety and usability being the two that would probably be foremost in most people's minds when confronted with the task of designing a new piece of medical equipment. At some point the designer would then start to think about size, material, whether single use/sterilizable and any number of other factors depending upon the exact nature of the task. There are many software tools available to the designer to assist with these choices and help with the design, but what is available to the designer to assist with the choice between following tradition and taking a revolutionary approach? As part of the undergraduate and postgraduate programmes at the University of Dundee there is a strong emphasis on design and the choices available to the designer using the research experience of the lecturers. This paper will highlight some aspects of the teaching and give practical examples of two research projects, one evolutionary the other revolutionary.*

Keywords*: Design, evolution, revolution, medical equipment, software tools*

1. Introduction

It is accepted that any piece of medical equipment is safe and fit-for-purpose, but how is this arrived at? Yes, there are standards to be met and exceeded - that is one measure. Ignoring the actual drawing up of theses standards by the various regulatory bodies around the world, what is required is an understanding of the actual purpose of the individual piece of equipment and how it interacts with the patient and the clinitian.

Design, per se, cannot be taught, either a person has a flair for making things happen or not. What can be taught though is the interaction between the various elements in a 'design' and how these can be measured and controlled. The packaging is also something that can be taught and it is this element that is normally refered to as 'design', often with no concept of how the parts inside the package work, or even if they will fit into the package.

In the Division of Mechanical Enginering and Mechatronics at the University of Dundee we have started a degree course called Innovative Product Design in collaboration with Duncan of Jordanstone College of Art and Design, now part of the University of Dundee. The rationalé behind this course is to expose engineers to design and artists to engineering so that both sectors have an understanding of the underlying principles of the two very different disciplines, and through integrated project work, produce working prototype models. These projects often also include the use of micro-controllers to control an electro-mechanical sub-system, and optical output and the design and manufacture of a suitable packaging for the finished project. In other words a complete mechatronics process. The projects often incorporate the research interests of the individual members of staff.

2. Teaching examples

Because of the interdisciplinary nature of the Innovative Product Design course there are certain modules that are taken by both the MEM and IPD student cohort, these are EG21002 Engineering Design and Communication, EG21003 Engineering Software, ME30001 Engineering Design and Communication and ME40001 Computer Aided Engineering (Dundee, 2004). These modules inroduce the students to the concepts of design and through worked examples expose the students to to the various elements that they will have to cope with in their working lives. These modules are described briefly in the following sections.

2.1. EG21002 Engineering Design and Communication

In the third semester the students are exposed to report writing, artefact analysis - where artifacts are dismantled, critically analyzed for manufacturing processes and materials and recomendations made for improvements - and also to the basic concepts of drawing and sketching using a conventional drawing board. This may seem a little unusual in this day and age, but the author takes the view that engineeering drawing is a language and as such needs formal teaching so that students are able to converse fluently in it. This cannot be undertaken purely by the use of a computer. Exercises that the students undertake include;

a) a simple visualisation exercises where they given an isometric drawing of an object asked to list the various features in the different views (front, plan end)
b) copying basic 2-D drawings and adding dimensions
c) sketching sectional views of simple objects
d) completing 2-D drawings by adding a suitable design for a missing part and explaining how it would work.

These are all individual pieces of work.

There is also a group project where students are placed in multi-disciplinary groups for a major design project. Currently this is the design of a central heating system for a six room apartment.

2.2. EG21003 Engineering Software

This module is also undertaken in the third semester and as part of the module the students have a six week course on programming micro-controllers using C, and are expected to undertake a variety of assignments such as;
a) simple I/O control using a LED as an example
b) read a thermistor and display the temperature on an LCD display
c) control of a dc motor
d) use a simple radio link between two micro-controller modules.

Also in this module the students are introduced to Computer Aided Drafting using AutoCAD for 2-D drawings and Computer Aided Design using Pro/Wildfire for 3-D solid modelling. For the first part of this section of the module the students use AutoCAD to undertake simple exercises to gain familiarity with the software package, and then they are expected to correct a series of partially complete given drawings and also to provide suggestions for, and the design of, the missing parts. This involves them in searching for information on standard components and then incorporating them into their AutoCAD drawings. The second part of this section follows a similar pattern to the first but this time using Pro/Wildfire. After a series of introductory examples the students are then asked to use the AutoCAD drawings they produced previously to model the parts in Pro/Wildfire and then to make an assembly of the Pro/Wildfire parts. It is at this stage in the process where any deficiencies in the 2-D part drawings become readily apparent.

This part of the module is linked to the micro-controller part of the module where the students are asked to produce a packaging solution using Pro/Wildfire for the project that they undertook at the beginning of the module. This requires that the students have a basic knowledge of materials and manufacturing for assembly processes.

2.3. ME30001 Engineering Design and Communication

This module, undertaken in semesters five and six, follows on from the second year module and the students are exposed to a greater depth of knowledge regarding material properties such as stress, strain and vibration, hydrodynamics, bearings, gears, limits and fits, etc.. There is a large practical element to this module and students work individually and in groups on various design projects such as a simple car jack and an epicyclic gearbox. Also as part of this module there is further 3-D CAD work where the students have to undertake a partial re-design of their model from EG21003 using Pro/Wildfire and then use Pro/Manufacturing (part of the integrated software suite) to simulate the machining process and when the machining process is correct they then post-process the simulation to produce CNC files for manufacturing their models. These post-processed files are then sent to the Divisional workshop where they are manufactured using CNC machines. Again giving the students exposure to the total manufacturing process.

2.4. ME40001 Computer Aided Engineering

This module, taken in Semesters seven & eight, provides an introduction to the use of the computer as a tool for solving general engineering problems, particularly in the areas of aerodynamic simulation, structural analysis and the design of dynamic systems. The module is divided into three parts namely finite element methods, computational fluid dynamics (CFD) and 3-D solid model mechanism design and analysis using ANSYS, Matlab and Pro/Wildfire. Students learn to apply the basic computational/numerical methods that are necessary to solve real engineering problems industry standard software packages, so they will be well prepared for computer aided engineering in modern engineering industries.

This is a highly practical module where the students are expected solve the many different aspects of real world design problems. They are expected to apply finite elements to structural design and optimization problems, solve fluid mechanics problems and use Pro/MECHANICA and MECHANICA/Motion to design, model, mechanise and analyse such artifacts as support systems, seats, lifting hooks, derive cam profiles and pendulum and crank-slider mechanisms.

3. Design for Medical Research

When designing for medical products many aspects have to be taken into consideration – safety and usability being the two that would probably be foremost in most people's minds when confronted with the task of designing a new piece of medical equipment. At some point the designer would then start to think about size, material, whether single use/sterilizable and any number of other factors depending upon the exact nature of the task. There are many software tools available to the designer to assist with these choices and help with the design, but what is available to the designer to assist with the choice between following tradition and taking a revolutionary approach? It is accepted that any piece of medical equipment is safe and fit-for-purpose, but how is this arrived at? Yes, there are standards to be met and exceeded - that is one measure. Ignoring the actual drawing up of theses standards by the various regulatory bodies around the world, what is required is an understanding of the actual purpose of the individual piece of equipment and how it interacts with the patient and the clinitian.

The following parts of this paper will show how these design considerations have been used to produce two differing pieces of medical equipment for cancer resection, one evolutionary and one revolutionary.

4. Transanal endoscopic microsurgery

Transanal endoscopic microsurgery (TEM) is used to treat lesions within the rectum (Buess, 1992). Existing TEM equipment comprises a long rigid tube which is inserted through the anus and then long slender instruments, including an endoscope, are deployed through this tube to perform operations within the rectal cavity. The rectal cavity is insufflated with CO_2 gas at a pressure of 15 mm Hg requiring the tube to be equipped with seals to prevent loss of insufflation pressure. This in turn requires the use of glands through which the instruments are passed. The seals and glands, together with the length and narrowness of the tube make it very awkward for the surgeon to use the instruments. Furthermore, the seals and glands prevent the surgeon from obtaining much useful force and tactile feedback. This lack of feel can lead to surgical errors being made. Apart from its poor functionality, existing TEM equipment is very expensive. These problems have militated against TEM becoming a popular procedure. Recognising that these problems derive from the use of gas for insufflation, various attempts have been made to design glassless systems.

4.1. Gasless TEM – existing methods

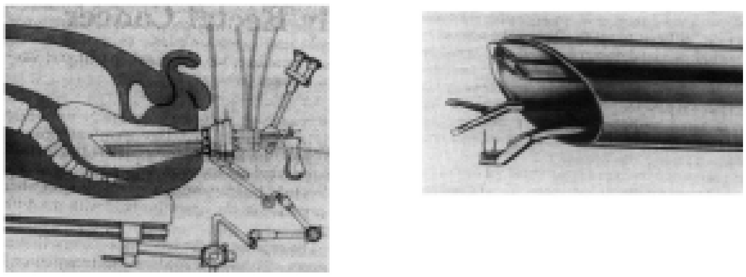

Figure 1: Conventional TEM equipment.

A number of gasless TEM approaches have been reported - Yamashita (1998) described a front lifting hood rectoscope for TEM, which comprised a stainless steel tube 40mm in diameter and 150mm in length. The forward half of the tube could be opened longitudinally by hand to expand the mouth up to 70 mm in diameter. This approach provided only limited expansion, insufficient exposure of surgical site and a very small access angle for the tools. Kakizoe (1998) developed a rectal expander, made from a plastic beverage bottle, with two legs. The diameter of the rectal expander was 30mm in the legs-folded position and 58mm after unfolding. Although it could provide a limited expansion, it was not reliable or stable. Kanehira (2001) reported early clinical results of endorectal surgery using a rectal tube with a side window. The tube, made of transparent plastic, was 40mm in diameter and 150mm in length. It was tapered and closed at the forward tip and had a round window on its side, intended to entrap the target lesion, so that the surgical procedure could be performed inside the tube. This device posed a risk of damaging tissue on the rim of the side window, especially during rotating or sliding of the tube. In summary, all existing gasless TEM approaches were found to be either because of poor visualisation or insufficient access.

4.2. Objectives of the research

The objectives of the research were to;

- research the design issues relevant to the main difficulties of using existing transanal endoscopic surgical systems for colorectal cancer surgery, so that transanal surgery is made much easier and safer to perform
- gain a thorough understanding of the features required of a good ergonomic design of TEM systems
- produce generic design concepts and hardware applicable to other surgery, such as vaginal and oesophageal
- develop an integrated endostructure for support, access and service provision (lighting, video, input and output fluids, etc.) that incorporates the best use of mechatronics, control and modern materials
- investigate methods for providing feedback to the surgeon of the tissue-tool interface forces during TEM

- investigate the feasibility of internal (endoluminal) lighting and video camera solutions for reducing the bulk and complexity of transanal optical interfacing.

4.3. The experimental designs

Several mechanisms and actuation methods were investigated for expanding or dilating the rectal cavity, and are briefly described below together with the experimental prototypes. The outcome of tests using these prototypes in the Surgical Skills Unit at Ninewells Hospital, Dundee led to the design of an easy-to-operate mechanical system integrated with a novel rectal tubular structure to achieve gasless dilation of the rectal cavity. By this means, the operating site is exposed without the constraints imposed by the gas seals and glands. The surgeon is better able to access the site and perform the procedures.

4.3.1. Designs 1 to 3 - the use of elastic strips

In this set of experimental designs, two elastic strips are attached to the sides of the proximal and distal tubes. Linear displacement of the proximal ends of the strips causes them to expand outwards in the region of the surgical site. This provides a wide and deep exposure (hatched area in Fig. 2), which can be up to 120mm long by 75mm wide. The exposed width W depends upon the displacement X of the strip at the proximal end, so that the exposed field can be easily controlled by an external actuation mechanism. Most tumours with sizes of 40mm or smaller can be easily accessed and resected with a margin of 10mm, even without rotating or adjusting the rectal tube. Tumours larger than 40mm can be fully resected by accessing and resecting part of the tumour first, then rotating the rectal tube (temporarily collapsing the strips to facilitating rotation) and then resecting the rest of the tumour.

4.3.1.1. Actuation by manual screw-turning mechanism

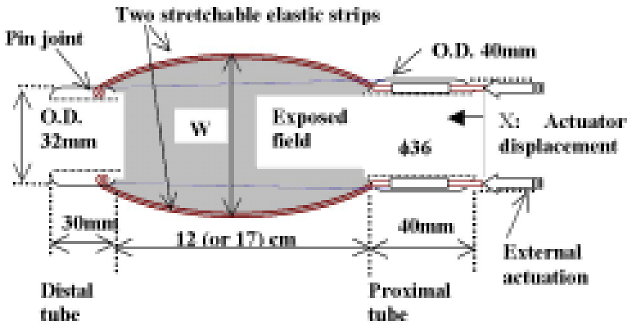

Figure 2. The principle of operation of the elastic strips method.

One possible method of external displacement is provided by a manual screw-turning mechanism, and the prototype device is shown in Fig. 3. A handle structure is mounted to the rectal tube at its proximal end. The elastic strips are pin-jointed at the distal tube end and its proximal end is mounted to an external slider mechanism which is attached to a screw mechanism. When the screw is rotated the slider moves forwards and flexes the expendable strips. To facilitate easier operation of the screw and to provide better access for the surgeon a detachable handle was fitted. The benefit of the screw system of expansion is that little effort is required to operate it and precise inflation is achieved. The surgeon can easily feel the amount of pressure being applied to the walls of the rectum.

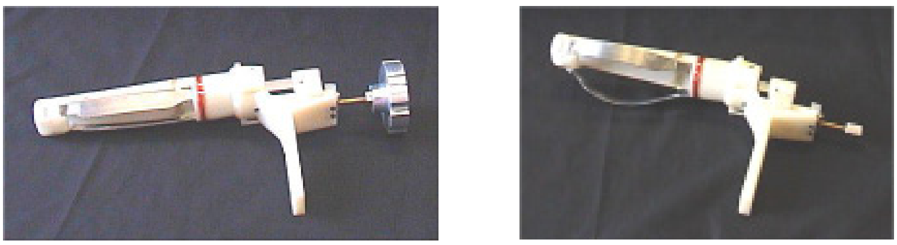

Figure 3. The manual screw design.

4.3.1.2. Actuation by manual ratchet mechanism

A modification to the previous design uses a manual sliding ratchet-locking mechanism as shown in Fig. 4. The figure shows a 3-D image of the device in collapsed state, pushing on the handle expands the strips and a locking mechanism holds the configuration in place. The handle can be removed to allow for improved viewing. A rubber membrane cover was attached to the device to form a tent-like dilator of the rectal cavity.

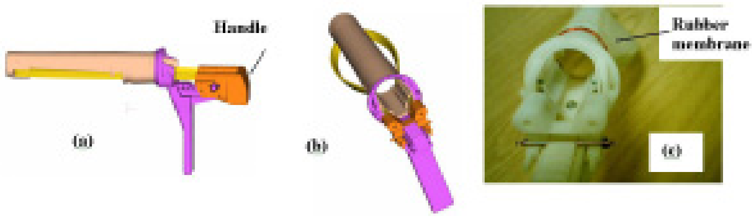

Figure 4. The manual ratchet design.

4.4. Actuation by SMA

A shape memory alloy (SMA) spring actuator was integrated with the device at its distal end, Fig.5. The SMA compression spring is made of 2mm diameter SMA wire with a 25mm outer spring diameter and 5 active coils. In its ‘cold’ condition, the coil spring can be easily compressed or collapsed, and in its ‘hot’ condition, it extends to its pre-set length of 50mm. This will displace the strips attached to a sliding disc. The advantage of mounting the actuator at the distal tube is to have more open space at its proximal end.

4.5. Actuation using inflatable rubber tubes

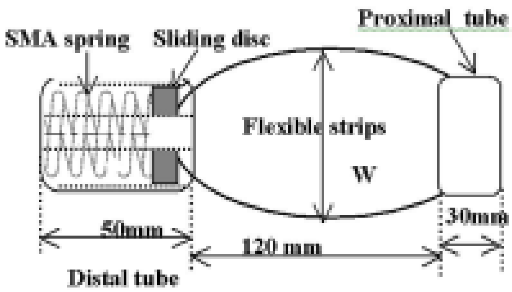

Figure 5. Principle of the SMA design.

Inflatable structures were also investigated (Fig. 6). In one design two inflatable rubber tubes are mounted on the distal and proximal tubes (Fig. 6a-b) so that the exposed surgical site is between the two tubes. Controllable lighting by LED’s is integrated within the structure, together with a 7mm diameter CCD camera (Fig. 6a). A variation in this design is to mount only one inflatable tube at the distal end of the rectal tube (Fig. 6c) so that the operative site is beyond the distal tube end in a similar manner to gas insufflation TEM. In a second design two rubber tubes are mounted against the rectal tubular support structure (Fig. 6d). At its design pressure, the width of the inflated rubber tube is about 120 mm. Figure 6e shows an expanded rectum of a pig during tests using this design.

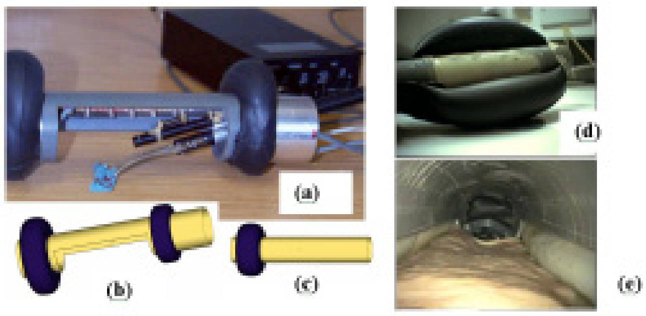

Figure 6. The designs using rubber inflators.

4.6 Design 5 - dilation of the rectal cavity using SMA

A two-way SMA mechanism has been investigated as a means of obtaining dilation of the rectal cavity. Figure 7 illustrates the SMA wires in cold shape and hot shape in the design of a dilating “cage”.

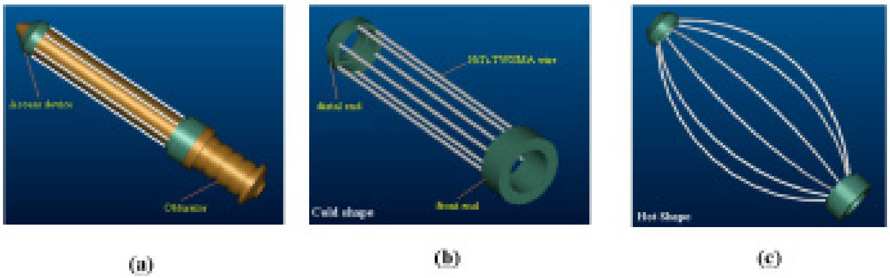

Figure 7. Computer models of the SMA designs.

4.7 Assessment

The performance of each of the different design prototypes was assessed and compared using standard benchmarking techniques. The outcome was that the design using a manual screw actuation of an elastic strip performed best overall according to the relevant criteria. However, all designs may have advantages in different situations.

This design of TEM instrumentation provides a means for faster, less constrained and safer operations. It is also far less complicated and much cheaper than existing systems that use gas. The designs also allows for lighting, cleaning and viewing services to be easily fitted within the access tube and integrated with the operating instruments. The freedom of this type of design from the constraints imposed by conventional instrumentation using gas seals and glands gives the surgeon a far more natural ‘sense of feel’ while performing the operation. In addition, we have developed the basic concepts for a revolutionary new tactile sensing array.

Using this design of gasless mechanically expanding TEM device, rectal lesions of up to 60mm diameter and up to 160mm away from the anus can be treated. Larger diameter lesions can be treated by manually rotating the device, with control of the expanding mechanism. Lesions further from the anus can be treated by a slight modification of the structural configuration.

5. Colon Inspection System

Robotic systems are finding increasing application as assistants to surgeons during operations. Early applications were in orthopaedic and minimal access surgery (Bouazza-Marouf, 1999; Cuschieri *et al*, 1997, Cuschieri *et al*, 1998) which required very little intervention by the robots. Now, more invasive applications are opening up. Many patients require some form of diagnosis within the gastrointestinal tract. A large and increasing amount of this diagnosis is performed today by colonoscopy. Colonoscopy has assumed ever-increasing importance since colorectal cancer has become the second most common form of malignant tumour in the developed world (Cancer Research Campaign, 1993). The vast majority of cases of colon cancer develop from initially benign internal polyps. If these can be detected at an early stage the chances of successful treatment are good.

To enable diagnosis further and further up the colon, use can be made of a flexible endoscope such as the fiberoptic type in which an image of the inspection site is transmitted to the surgeon via a coherent bundle of optical fibres. Unfortunately, flexible endoscopes are controllable only at the tip and are positionally uncontrollable over most of their length and this makes it extremely difficult to manipulate a flexible colonoscope from its transanal insertion point up the colon to the inspection site. This difficulty is exacerbated by the labyrinthine nature of the colon, by the complexity of folding of its walls and by its relative fragility. In addition, some parts of the colon are affected by the breathing of the patient and by other movements of the intestine such as peristaltic actions, which attempt to expel the intruding instrument.

Successful operation and manipulation of a flexible endoscope requires great skill and the inspection process may take a considerable time. At present even the most skilled colonoscopist can only achieve inspection of the first metre of colon. This leaves over half of the colon unable to be inspected.

5.1 Colonoscopy assist devices

Because of the importance of colonoscopy and the difficulties and dangers of manually deploying flexible endoscopes, research has been undertaken on methods to assist the insertion and manipulation of these instruments. A comprehensive study has been reported (Mosse, 1999). Here four different ways of assisting a colonoscope to traverse the bowel are described. These are: (1) a water-jet propulsion system for driving the colonoscope tip, (2) a suction crawling system, similar to an inchworm robot but with suckers to help adhesion to the bowel wall, (3) a concept for stimulating the gut muscle to propel a cigar-shaped module along by peristaltic action, (4) a specially lubricated sleeve to house the colonoscope tip and ease its passage through the bowel.

If nothing else, this study highlights the extreme difficulties involved in designing semi-autonomous machines for colonoscopy. The author admits, of the four methods, that “...*no one approach* (is) *particularly promising*.”.

Other researchers have proposed climbing robotic devices to carry miniature cameras through the bowel to the colon. One particular embodiment of this concept is the microrobot of Pisa University (Carrozza, 1996) and the related MUSYC system (BIOMED 2). Here, an extensible body is mounted between two cylindrical pistons. These pistons have variable a diameter, which may be changed by internal actuation. The robot moves along inside the bowel using an inching movement. This kind of robot, like any that uses the bowel wall for traction, is intrinsically difficult to make safe. There is a conflict between gaining enough purchase on the wall and protecting the wall from high forces. It may also be rather slow, find corner-turning a problem and be difficult to extricate in the event of power failure.

This kind of design problem is often found where robots are proposed for use in a surgical-assist role but where there is an *ab-initic* assumption of what a robot is. A commonly held view of a robot is that of the well-known industrial version found doing tasks such as welding or automatic assembly. However, the industrial robot is not a good template for the surgical robot where the task constraints are entirely different. The previously mentioned bowel-climbing robot has taken as its template the pipe-traversing "pig" familiar in the oil and gas industries.

5.2 The CIRWISS design for a climbing robot

The basic aim of designing a system for colonoscopy is to allow the transport of an inspection module from the point of insertion (the anus) to, ideally, the ceasum, but in practice as far as possible along the bowel. In the manually operated flexible endoscope described above, the module is the optical head that captures the images. The means of transport is the semi-rigid tube that also carries the optical fibres. In the bowel-climbing robot device, the module is a miniature camera and the means of transport is the inchworm vehicle. In each of these two cases, the major constraint of patient safety is violated. The flexible endoscope applies high forces to the bowel wall to push its way around corners; the robot applies high forces to obtain traction. What is needed is a means of deployment and transport that does not threaten damage to the bowel wall.

5.2.1. Balloon eversion

If a long cylindrical balloon is lightly inflated, it may be turned inside out by pushing the closed end back down inside the balloon body. If, at any stage during this process the pushing on the closed end is released, the balloon will roll itself back out, under the inflationary pressure, to its original configuration. This can be used as a simple and effective method for the delivering a track or 'ladder' for an inspection module to 'climb' the colon.

The balloon is deployed as follows. First the closed end carrying the module is pushed along the inside of the balloon to turn it inside out. The body of the balloon is offered up to the anus of the patient. The balloon is gradually turned the right way out by the application of low pressure compressed air. In the process the balloon passes through the anus and unrolls along the bowel wall taking the track with it. It should be noted that damage to the bowel wall is avoided by four mechanisms. First the balloon itself always lies between the module and the bowel wall and so protects the wall. Second, there is no relative movement between the balloon wall and the bowel wall as the unrolling takes place. Thirdly, pressure on the wall due to the inflation process is smoothly distributed and there are no points of high loading. Last, the module itself is designed to have a smooth cigar-shaped body with no sharp edges to protect the wall during retraction.

5.2.2. Inspection system

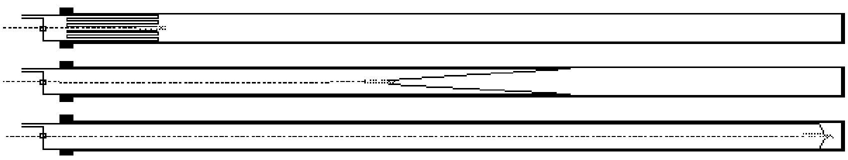

Figure 8. Balloon deployment system.

In this design the track, or ladder, that is deployed by the balloon is in the form of a 'string of beads' that are attached to the inner distal end of the balloon. The beads are semi-rigid when deployed and are then rigidised after deployment. At this point after the rigidisation the balloon is detached from the beads and pulled back out of the colon. An inspection/ intervention system can now be attached to the proximal end of the ladder protruding from the anus and climb up the ladder along the whole length of the colon with very little risk to the integretity of the colon walls. Figure 9 shows a CAD model of a 'robot' on the ladder. The inspection/intervention system is not shown as this is still subject to patenting. Depending on the driving mechanism, pneumatic or electrical, would define the requirements for any umbilical to take power to the module. Biopsies can be taken and stored in the module for analysis.

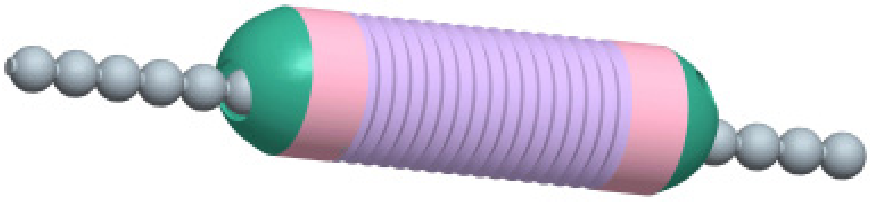

Figure 9. The CIRWISS design of colon climbing robot.

5.3. Assessment

A novel concept for the design of a colonoscopy instrument has been described. It may be regarded as a mobile robot, but its mobility is by unconventional means. Unlike other extant systems it does not make use of the bowel wall to achieve its mobility. Instead, the eversion of a balloon under air pressure is used to drive an inspection module along the bowel. The system is inherently safe because the balloon skin protects the bowel wall during the insertion process and because there is no relative motion between the balloon and the bowel wall.

A number of experiments have been undertaken to test the feasibility of the system. All have been successful. A considerable amount of engineering design remains to be done before clinical trials can begin.

6. Conclusion

A brief overview of how students are exposed to design at the University of Dundee has been given, along with two designs for medical systems. One of these is considered to be evolutionary in that the design has reflected the wishes of the clinitian in providing a single step change to a better working environment while the other is considered to be revolutionary in that the design is totally different to anything else that has been proposed or researched in this field. But both are clear examples of how understanding the underlying principles of mechanical systems and structures can lead to new designs in medical systems.

7. Acknowledgements

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