Development of a Novel Endoscopic Platform for the Treatment of Gastrointestinal Conditions

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Declaration of Authenticity and Author's Rights

This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.

Signed: Baldwin Po Man Yeung

Date: 5th January 2015

Declaration of Contribution to Previously Published Work

Chapter 2: The entire content of this chapter has been written solely by the Author, Baldwin Po Man Yeung. It has been incorporated into the Royal College of Surgeons (Edinburgh) position statement in robotic surgery 2013.

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Signed: ____________________ Baldwin Po Man Yeung

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Acknowledgement

"Commit your work to the Lord, and your plans will be established."

Proverbs 16:3

I would like to thank my family and especially my wife, who is always lovingly patient and supportive.

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Abstract

The main deficiency in the modern medical flexible endoscope is that it confers limited independent instrument movement. Endoscopic multitasking platforms have been designed to overcome this deficiency. These platforms deliver independent instrument movement through the use of traction cables. However, traction cable confers limited instrument movement precision in a flexible endoscope. Improved instrument control could enable more clinicians to perform advanced endoscopic techniques. The aim of this PhD is to design, build and test a novel robotic endoscopic platform which uses micro motors. The use of inbuilt micro motor for instrument actuation in a flexible endoscope has never been described before in the literature. With an improved platform, more patients could benefit from effective and safe minimally invasive therapy.

The proposed platform uses in-built motors located at the endoscope tip, endoscope handle and an external unit which together exert forces on any suitable flexible instruments in order to produce up to five degree of independent instrument movement. The design and construction of the twin channel endoscopic platform is performed using computer aided design and rapid prototyping metal printing technology. The key to the successful development of the platform is the development of a novel four-piece linkage mechanism located at the tip of the endoscope, which is capable of guiding instrument movement with two degrees of freedom.

Bench top analysis consisted of three parts. Firstly, kinematic performance of the prototype is compared with the predicted performance based on computer simulation. Secondly, force analysis is performed using a traction force gauge. Thirdly, an upper gastrointestinal phantom is used to test the ability of the novel platform in accessing the human upper gastrointestinal tract.

A basic functional prototype of the novel platform is constructed. The motors can be controlled with a standard game controller. Kinematic analysis demonstrated that the prototype range of movement is similar to that of the computer simulation model. Force analysis revealed that the prototype is capable of generating a force of 0.45 – 5.94N dependent on the direction of instrument movement. This compares favourably with the conventional endoscope, which is capable of generating 0.4N force. Currently, the prototype is designed to be manufactured using metal printing technology. Therefore, the prototype has been designed with especially thick parts in order to overcome the limitations of this manufacturing technology. The dimensions of the manufactured prototype are 25mm (horizontal), 16.4 mm (vertical) and 61 mm (length). Although this dimension is similar to other published endoscopic multitasking platform and existing endoscopic ultrasound probes, the prototype could not negotiate beyond the oropharynx of the phantom.

Based on these findings, a modified computer design of the platform is produced. Through further refinement of the four piece mechanism and other aspects of the design, the modified design front unit's dimension is 13.9 mm (horizontal), 12.2 mm (vertical) and 34.5mm (length). This is a 44.8% reduction in horizontal dimension, 25.6% reduction in vertical dimension and 43.4% reduction in length compared to the original design.

In conclusion, this thesis presented a novel concept in endoscopic multitasking platform design, namely the application of in-built micromotors in the flexible endoscope for instrument actuation. This concept is akin to the "fly-by-wire" technology utilized by the aerospace industry. The development of the compact four piece mechanism has made it possible to place two 2 degree of freedom instrument channels at the tip of the flexible endoscope. In the future, more conventional manufacturing technology such as computer numerical control multi axis milling should be used to develop more refined parts. With further development, the micro motor controlled endoscope may prove to be a useful tool in performing advanced endoscopic therapeutic procedures such as endoscopic submucosal dissection.

Chapter 1: From Darkness into Light

Part of the research gathered in this chapter has been used to successfully apply for funding from Tenovus Scotland.

1.1 Introduction

Over the last century, medical endoscopy has been developed with the focus of visualizing the internal structures of the human body. Only since the 1980’s has therapeutics been developed to treat various conditions in various organ systems such as the gastrointestinal, respiratory, urological systems. The modern endoscope is a culmination of more than 200 years of design refinement and development. This chapter will briefly review the origin of medical endoscopy in order to better emphasize and illustrate the future directions of medical endoscopy in the chapters that follow.

Medical endoscopy requires an effective light source of suitable size, brightness, temperature and an effective light conduction system for light exposure and image transmission. In the 1950s, advances in fibre optics and material science allowed the creation of the modern endoscope.

Figure 1: A modern twin channel therapeutic endoscope. (Olympus EVIS EXERA II GIF 2TH180 Gastroscope UK)

1.2 Era Prior to Modern Endoscopy

People have used natural ambient light or candle light to inspect human natural orifices since ancient times. Hippocrates (460 – 377 BC) of Greece described the use of rectal speculums. Marasaumel in the Babylonian Talmud (257 AD) described the siphopherot vaginal speculum. Albucasis of Cordoba (936 – 1013 AD) described the used of glass mirror to view the uterine cervix.[1], [2] Giulio Cesare Aranzi (1529 – 1589 AD), an eminent professor of anatomy and surgery at the University of Bologna attempted to illuminate deeper body cavities by use of a camera obscura.[3] However, these early attempts at endoscopy were limited.

Figure 2: The Bozzini Lichleiter. (www.facs.org/archives/bozzinihighlight.html)

With improved manufacturing techniques, attempts at endoscopy became more sophisticated but remain far from what we recognize as modern endoscopy. Philipp Bozzini (1773 – 1809 AD), a military physician while in service in the army of the Archduke Karl Ludwig of Austria, developed the candlelight conductor “lichtleiter”. (Figure 2) It consisted of a leather covered vase-like device with an eyepiece, a reflecting mirror and an assortment of tubes for insertion for inspection of the vagina, urethra, female bladder, rectum and upper air passages. It used external candle light and measured more than a foot high and several inches wide. Unfortunately, the lichtleiter was rejected by the Viennese medical community as a mere toy, and Bozzini never gained proper recognition for his work in his life time.[4,5,6] In 1826, following Bozzini's footsteps, Pierre-Salomon Segalas (1792 – 1875 AD), a French surgeon, constructed the speculum urethra-cystique.[5] He made various improvements including the use of a double lens system and a large conical mirror to concentrate and magnify light from two candles (rather than one as in the Lichtleiter), as well as black tubing to prevent light scattering.[7] He also used gum elastic catheter to provide atraumatic introduction of the instrument. In 1827, a physician from Boston, John D. Fisher (1798-1850 AD) published designs of the oesophagus mirror. Using the principle of the periscope and reflecting mirrors, he designed an instrument with two right angles. Fisher demonstrated that he clearly recognized that in order for proper human endoscopy, instruments must allow inspection around corners. He also designed a wire mechanical system for manoeuvring an external candle light source.[7]

1.3 The Era of Improved Light Source

In order for effective endoscopy, an alternative light source must be developed. In 1865, a French urologist Antonin J Desormeaux (1815-1894 AD), presented his cystoscope in the Academy of Medicine in Paris. He used an incandescent lamp burning alcohol and turpentine. In addition, he used a lens to focus the light. It allowed inspection of the urinary bladder as it was accessible using rigid straight instruments. However, it was too dim for visualizing the upper gastrointestinal tract.[2,3,7] During the few decades thereafter, endoscopes were mainly made for cystoscopic examination.

With the increased utilization of electricity, people began to experiment with incandescent electric wire or “galvanized wire” as a light source. In 1828, CH Pfaff (1773 – 1852) discovered that platinum wire could be made incandescent with electric current. A major hurdle with electric incandescent lighting was tissue injury secondary to heat generation, and thus inventors focused on designing effective small cooling systems. In 1867, Julius Bruck, a dentist from Breslau, using his understanding of electrocauterisation in dentistry, designed a self-cooling light source consisted of an eight by two centimetre double compartmented glass bottle which housed circulating cool water externally and an electric incandescent platinum wires internally. (Figure 3) But his design was bulky and could not completely eliminate heat transmission, thus resulted in rectal thermal injury. It did not gain widespread acceptance.[3,5]

Figure 3: Bruck's water cooled platinum incandescent light source

With the discovery of a light source of sufficient intensity and the recognition that rigid straight instruments can effectively access the lower urinary tract, endoscopy development was ready for a great leap forward. Maximilian Carl Friedrich Nitze (1848 – 1906) a Dresden urologist, inspired by Bruck's work, designed the first functional cystoscope that was to be used well into the twentieth century with minimal modification. Over time, with the help of most notably instrument maker Joseph Leiter, the Nitze endoscope had a series of lens with air intervals to transmit magnified image to the eye. In 1878, Joseph Wilson Swan (1828 – 1914), a British scientist described the incandescent filament lamp in a vacuum bulb. Around the same time, Thomas Alva Edison (1847 – 1931), an American scientist, developed the incandescent carbon filament vacuum light bulb. These bulbs do not burn out as easily. Nitze, with the aid of Paul Hartwig (1846 – 1928), and Leiter, incorporated a distally placed vacuum light bulb in the endoscope.[8] (Figure 4) Nitze was the first to take in vivo cystoscopic photographs.[9] (Figure 5) He also used movable loops for bladder operations. His cystoscopic observations were published in his textbook of cystoscopy in 1889. [10]

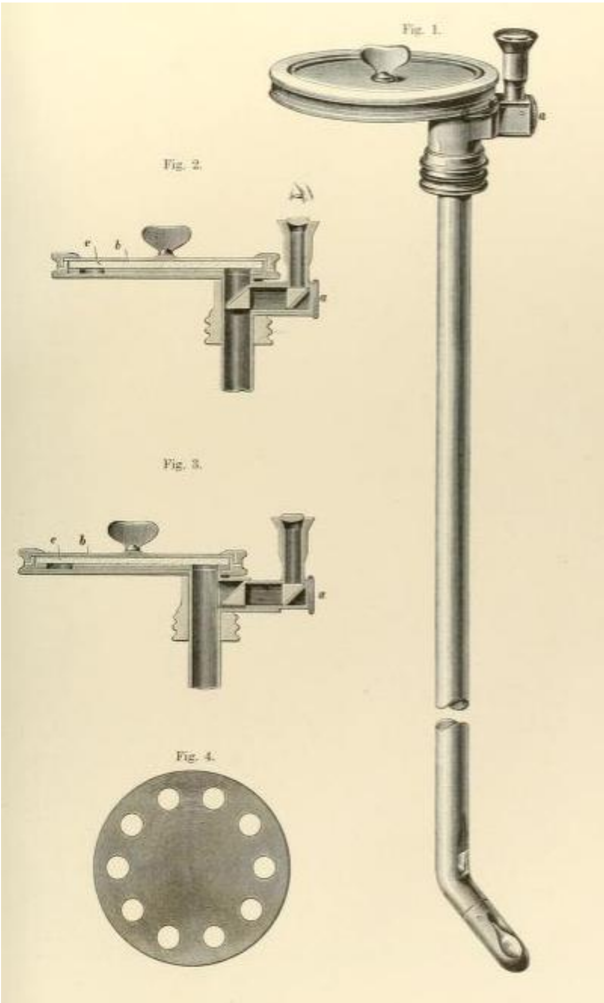


Figure 4: The Nitze cystoscope using glass lens series and incandescent light bulb. (Nitze 1894)

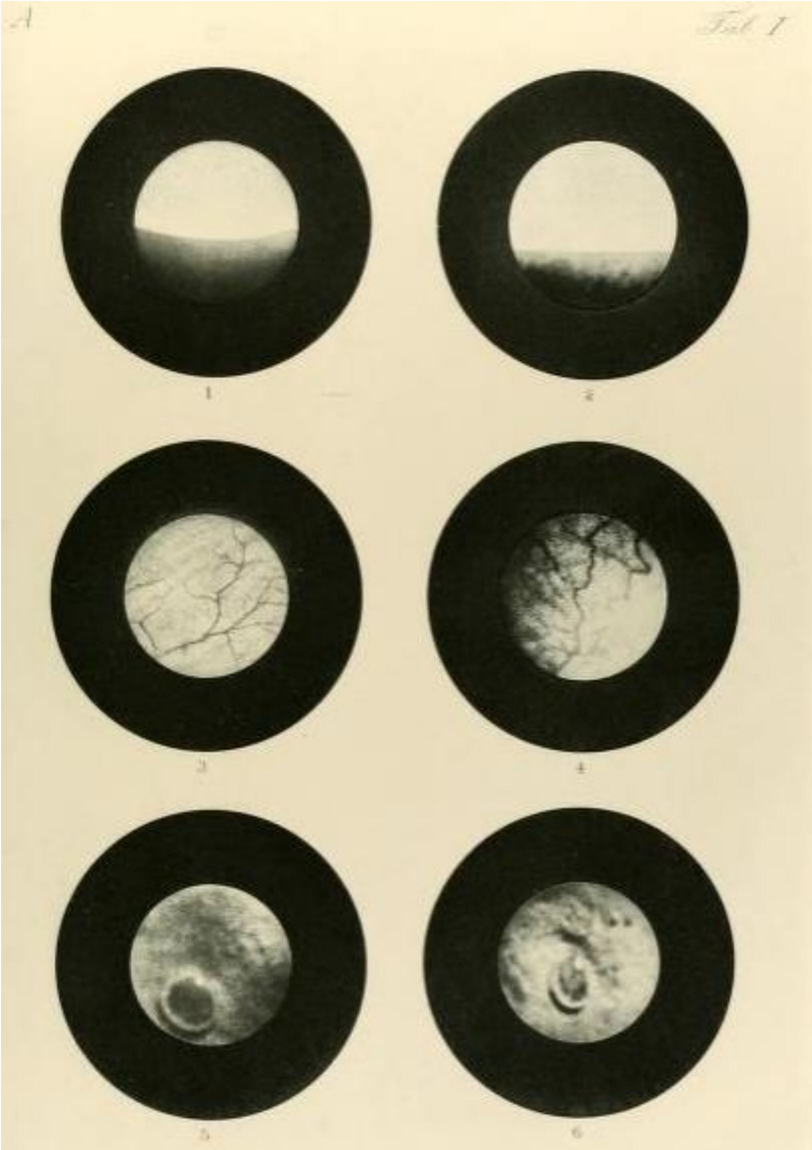


Figure 5: First endoscopic photographs of the normal urinary bladder using Nitze's cystoscope. (Nitze 1894)

As for upper gastrointestinal endoscopy, the challenge of negotiating the natural curvatures in the UGI anatomy remains to be overcome. Johann von Mikulicz Radecki (1850 – 1905), a Polish surgeon created a gastroscope with the aid of Joseph Leiter. The gastroscope was 650 mm long and 13mm in diameter. It was straight and had an angulated distal tip at 30degrees. It also had an air insufflation channel and used a distal electric light bulb as a light source. He successfully performed gastroscopy in patients under morphine sedation and removed oesophageal foreign bodies. Complete visualization of the UGI tract, especially areas such as the gastric antrum, gastric fundus and the duodenum, were impossible with the rigid instrument.[2,3,4,5,11] In 1896, Theodore Rosenheim designed a triple lumen gastroscope. It consisted of an inner tube containing small focusing lenses, a middle tube containing a water cooled incandescent platinum tube and an outer tube with markings serving as a scale for measurement. Instruments were passed external to the endoscope. However, for reason unknown, Rosenheim completely stopped using his instrument. It was not until 1911, when Henry Leopold Elsner repopularized Rosenheim's gastroscope.

Efforts were made to create a flexible endoscope for visualization of the UGI tract. In 1887, Stoerk used a right angled open tube with a bendable mechanism to examine the oesophagus. In 1898, Kelling with the help of Albright designed a distally flexible gastroscope using a series of prism and lenses. The tip was controlled by a guide wire system controlling the tip to bend on one plane on both sides to 135 degrees. In the same year, Lange and Meltzing used a flexible gastrocamera to take photographs of patients' stomach. Their camera consisted of a rubber tube channelling electric wires and a distal rigid 66mm segment composed of an air insufflation device, a distal electric globe, a camera head for film exposure and a pulling mechanism for film exchange. It used a 5mm wide filmstrip that was

400-500mm long to obtain multiple images by serially exposing segments of the film. This is an inspired design as it sought to eliminate the problem of poor light transmission with endo-photography. In fact, Lange and Meltzing's design is very similar to the modern day endoscopy which has a digital camera at the distal tip.[5] In 1907, Chevalier Jackson promoted the use of a rigid gastroscope with a side aspirating channel for foreign body removal. Later, Edwin Boros modified Jackson's endoscope with a flexible distal metal coil which eases instrument insertion and was then straightened out with a rigid internal instrument. However, these essentially rigid instruments did not gain popularity.

In 1936, Schindler and Wolf, building on Lange and Meltzing's work, introduced a semi flexible instrument consisting of a distal flexible segment containing 26 serial lenses capable of bending up to 30 degrees in several planes without image distortion. The distal segment tip was made of rubber and was designed for blind insertion of the endoscope. Air insufflation was by pumping air between 2 layers of rubber coating. He recognized that his new instrument could not visualize the fundus or the pylorus.[12]

1.4 The Era of Fibre Optics

The transmission of light through fibre optics and later digital photography made modern endoscopy possible. It is of interest that in 1870, John Tyndall, demonstrated that by illuminating the interior of a tank of water, light would travel within a stream of flowing water from the side hole of a water tank.[13] Unfortunately, this finding was largely ignored. Logie Baird of Glasgow made a patent application of the conduction of light through a curved glass rod in 1927. In 1928, Heinrich Lamm, a medical student approached the aforementioned Schindler and suggested to Schindler that glass rod bundles might conduct light better than the standard serial lens system with multiple lens-air interfaces. Schindler financed Lamm to produce a prototype gastroscope which consisted of uncoated glass rods. Due to the scattering of light through an uncoated glass rod, the gastroscope produced very poor image. As a result, this early attempt in using glass fibres for image conduction was abandoned. It was not until 1954, when Harold H Hopkins and NS Kapany, successfully used bundled coated borosilicate crown glass filament for image conduction. They utilized glass fibres of 0.025mm diameter and 750 mm length bundled in a coherent fashion and successfully demonstrated the principle of static scanning where each fibre conveys light from one element of the image formed on it to the other end of the bundle.[14] Van Heel concurrently published his findings on using glass fibres coated with low refractive index coating for light transmission in the same issue of Nature as Hopkins.[15] In 1957, Hopkins patented the rod lens system where the traditional glass positive lens series with large air interval were replaced with air lenses and glass intervals. In 1960, Basil I Hirshowitz, C Wilbur Peters and Lawrence Curtis from the University of Michigan used fibre glass bundles bought from Hopkins and made the first flexible fibreglass gastroscope. Interestingly, he tested the instrument on himself prior to using it on patients. In 1960, the first commercial flexible gastroscope was made. The instrument measured 92 cm long and 11 mm in diameter. It had a proximal magnifying lens eyepiece, glass fibre shaft protected by a bronze spiral and smooth plastic sheath, a distal prism which provides side viewing capability and used a distally placed light bulb as a light source. It had a ratchet for focusing the distal lens and connections for air and electricity transmission. This first flexible gastroscope still had difficulty visualizing the gastric fundus. Further refinement led to the development of the end viewing endoscope.[16] In 1960, Karl Storz having seen Hirschowitz' endoscope in a congress in Holland realized that fibre optics can be used to transmit external light into the hollow organ. He patented this idea. In 1965, Storz and Hopkins began to work together to create laparoscopes and endoscopes using the rod lens system and incoherent glass fibre bundles for illumination. Their instrument was presented in Munich in 1967.[10]

1.5 Photoendoscopy

The next development was to replace visualization through fibre optics with direct photoendoscopy using a distally placed digital camera. Instead of visualization through an eyepiece, cameras were developed to project the endoscopic image onto a monitor. In 1956, Soulas developed the first televised endoscopy visualizing the bronchial tree. In 1960, Berci, an Australian surgeon, developed the first attachable camera system that could be attached onto a fibre endoscope eyepiece. This invention allowed endoscopic image to be televised.[5] In the years that followed, charge couple devices and later, complementary metal-oxide-semiconductor (CMOS) camera chip were placed at the tip of the endoscope. These new technology not only allowed the transmission of high definition images but also made advanced imaging techniques such as real time autofluorescence imaging, confocal endomicroscopy, and spectroscopy possible. These techniques allow further appreciation of tissue abnormality otherwise impossible with conventional white light endoscopy.[8] Wireless capsule endoscopy was developed in 2000. To this date, capsule endoscopy remains a passive diagnostic technology. [17] Precise affordable manoeuvring technology remains to be developed for it to be used as a therapeutic instrument.

It can be seen that the diagnostic endoscope is now a mature technology. Moreover, therapeutic endoscopy has been an "add-on" development. The requirement of simultaneous and precise control of multiple instruments with multiple degrees of freedom is ideally suited for robotics. In the next chapter, a review of the current status of robotic surgery will be undertaken.

1.6 Chapter Summary

1. Early attempts at endoscopy failed because of a lack of appropriate technology to provide flexible light transmission.

2. In the 1950's, the development of modern flexible endoscopy was made possible by the development of coherent fibre optic technology by Hopkins and Kapany, and its application by clinical pioneers such as Hirshowitz.

3. Later breakthrough in digital camera chip technology and display technologies allowed improved image quality, further increasing the diagnostic capability of the endoscope.

4. With improved visualization capability, endoscopic therapy, such as peptic ulcer haemostasis, became possible. Endoscopic therapy is delivered by insertion of flexible instruments through passive channels incorporated into the flexible diagnostic endoscope. The current endoscope design does not allow significant independent instrument movement, rendering complex endoscopic therapy very difficult to perform.

5. The requirement of simultaneous and effective control of multiple instruments with multiple degrees of freedom is ideally suited for robotics.

Chapter 2: Current Status of Robotic Surgery

This chapter has been published as part of the Royal College of Surgeons (Edinburgh) position statement in robotic surgery 2013

2.1 Definition of Robotic Surgery

The term "robot" was derived from the Old Church Slavonic word orbota meaning "slave labour". It was originally used to describe manmade human-like machines from the fictional work "Rossum's Universal Robots" by Karel Čapek in 1920.[18] Being a term originated from fiction, it does not have a precise scientific definition. With advances in computer processing, sensor and motion control technologies, the field of robotics has been developed. The Robotic Institute of America defines a robot as "a reprogrammable, multifunctional manipulator designed to move materials, parts, tools, or specialized devices through various programmed motions for the performance of a variety of tasks". [19] Other definitions include "an intelligent connection between perception & action"[20], "a machine capable of carrying out a complex series of actions automatically, especially one programmable by a computer"[21]. In summary, a robot is a machine which can manipulate the physical world according to an in-built computer program. It is of note that the engineering community has placed an emphasis on the element of programmable automation in the definition of a robot.

Robotic surgery is the use of robots in performing surgery. Currently, the devices used in the various fields of surgery differ in its ability to deliver programmable automated movement. Recognizing the limitation of currently available "surgical robots", The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has loosely defined robotic surgery as a "surgical procedure or technology that adds a computer technology enhanced device to the interaction between a surgeon and a patient during a surgical operation and assumes some degree of control heretofore completely reserved for the surgeon".[22]

It can be seen that the concept of robotics differ significantly between the engineering and medical profession. In this thesis, robotic surgery is defined as *the performance of surgery using a machine capable of planning and executing surgical manoeuvres based on its ability to integrate various sources of external information*. The current state of robotic surgery may fall short of this definition. However, it is believed that this definition will be fitting for the eventual goal of robotic surgery.

2.2 Current Clinical Applications of Robotic Surgery

Robotic surgery was first adopted in the field of neurosurgery. The requirement of performing very precise stereotactic surgery in a relatively static operative field made robotic surgery suitable. Various types of robot have been used. Neuromate (Integrated Surgical Systems, US) was the first FDA approved frameless tool guidance system for stereotactic neurosurgery.[23] Cyberknife (Accuray Inc., CA, USA), a system capable of automatically calculating radiation beam vectors based on pre-planned target node path has been used to apply stereotactic radiotherapy. It can compensate for limited body movement, such as during respiration, by monitoring motion with orthogonal fluoroscopy. It was first used for intracranial and spinal radiosurgery, but has since been used for cancer treatment in the prostate, lung, liver, and pancreas.[24] Neuroarm (Calgary, Canada), a tele-manipulator with haptic feedback has been recently introduced for open neurosurgery.[25] Renaissance SpineAssist (Mazor Robotics, Israel) aids spinal fusion surgery by allowing direct correlation of preoperative and intraoperative imaging. By fixing the device to the patient's spine, it provides a reference platform from which it directs pin insertion.[26]

The orthopaedic surgeons became the next adopters of robotic surgery. Performance of surgery on bone, which can be stably fixated, allows robots to be designed with a relatively simple three dimensional registration and planning software. The first clinical system used for Computer Assisted Orthopaedic Surgery (CAOS) was the ROBODOC ((ISS, Sacramento, CA, USA). With the use of preoperative imaging, it allows virtual planning of a suitable hip prosthesis and automatic milling using a 5 degree of freedom milling arm.[27] As they are capable of automated movements, they are termed active systems. However, human errors and unexpected target tissue movement can lead to system failure.[28], [29] Caspar (URS, Rastatt, Germany) is another system similar to the ROBODOC.[30] In order to gain acceptance by the medical community, newer robotic systems abandoned automatic milling and favoured robotic guided manoeuvres where the mill is manipulated by the surgeon but motion is limited within a pre-planned milling boundary. The Stanmore Sculptor Robotic Guidance Arm (Stanmore Implants Worldwide Limited, London, UK)[31] and the RIO (Mako Surgical Corp., Fort Lauderdale, FL, USA)[32] are examples of these boundary-constrained milling systems. The NavioPFS (Precision Freehand Sculpting) surgical system (Blue Belt Technologies, Plymouth, MN, USA) is also a boundary-constrained milling system but instead of using a traditional robotic arm, it utilizes a hand held milling device which the computer can track its position in a virtual environment according to preoperative and intraoperative imaging. (Figure 6) The computer will automatically stop milling if milling goes off intended trajectory.

Figure 6: NavioPFS hand held boundary constrained milling system. (http://www.bluebelttech.com/products/)

The advent of minimally invasive surgery provided a paradigm for the development of a soft tissue robot. Various robotic laparoscope holders have been developed.[33], [34] Historical systems such as the Zeus/AESOP system (Computer Motion, CA, USA) was used to perform procedures including cholecystectomy [35], bariatric surgery [36], gastrectomy [37], adrenalectomy [38], colonic resection [39], antireflux surgery [40] and aortic aneurysm surgery[41]. Currently, the only Food and Drugs Administration (FDA) approved system for soft tissue robotic surgery is the Da Vinci System (Intuitive Systems, USA). (Figure 7) The Da Vinci System is simply a remote presence telemanipulator mimicking the movement of the surgeon’s hands. It does provide the advantage of 7 degree of freedom of movement termed “endowrist action”, as well as scale motioning and three-dimensional visualization. It was originally developed for closed chest cardiac surgery such as mitral valve surgery[42] and totally endoscopic coronary artery bypass grafting (TECAB)[43]. It has since been adopted by various surgical specialties.

Figure 7: Da Vinci system (Intuitive Systems, USA).

Urology has been an early adopter of the Da Vinci system in performing prostatectomy[44] [45]where the added degrees of instrument movement helped with pelvic dissection and formation of the urethra-cystic anastomosis. It has also been used in other urological procedures such as nephrectomy[46], pyeloplasty[47],[48], ureteric reimplantation[49], cystectomy[50],[51] and Mitrofanoff procedure.[52]

In gynaecology, it has been used for hysterectomy[53],[54], ovarian surgery[55], colpopexy[56], and tubal re-anastomosis.[57]

In head and neck surgery, the Da Vinci system has been used to perform transoral robotic surgery (TORS). The extra instrument movement allows cancer and reconstructive surgery to be performed in the posterior oral cavity, pharynx and larynx transorally thus obviating access surgery which can be deforming.[58] It has also been used to perform transaxillary thyroidectomy[59] and parathyroidectomy[60].

The large instrument size offered by the Da Vinci system has rendered it less suitable for the performance of paediatric surgery. Smaller calibre instruments are available but they offer less instrument manoeuvrability. It has been used to perform a variety of procedures such as anti-reflux surgery, renal pelvis surgery, atrial septal defect and patent ductus arteriosus closure, choledochal cystectomy, diaphragmatic hernia repair, Kasai portoenterostomy, nephrectomy, Mitrofanoff procedure, and bladder augmentation.[61]

One of the main difficulties encountered in adapting the Da Vinci system for general surgical procedures is the requirement of multi-quadrant abdominal surgery. Camera exchange and movement between ports can be cumbersome. It has been used to perform oesophagectomy [62], gastrectomy[63], bariatric surgery[64], Heller's myotomy[65], antireflux surgery[66], cholecystectomy[67], liver resection[68], pancreaticoduodenectomy[69], hernia repair [70] [71], adrenalectomy [72], thymectomy [73], colonic resection [74], [75], [76], rectopexy[77], and even emergency colonic surgery[78].

It is likely that in the near future, alternate robotic systems will be applied in soft tissue surgery.[79] A significant number of robotic platforms has been developed, these include: Raven II – open source robot (US), Titan Amadeus (Canada), Alf-X (Italy), Surgenius (Italy), Artemis (Germany), MIRO microsurge (Germany), and Microhand A (China).

Current robotic surgery technologies have some limitations. These include the requirement of large external actuators, the lack of haptic feedback and the lack of ability to assimilate and apply clinical information to aid the performance of surgery. However, it does hold enormous potential in improving minimally invasive surgical therapy and enforcing safe effective healthcare delivery. In particular, it will be very useful for performing complex surgical tasks in the endo luminal environment through a flexible endoscope. However, flexible endoscopic robotic surgery is only beginning to be developed. The next chapter will discuss the evolution of endoscopic platforms designed to overcome the challenge presented by evermore advanced and difficult to perform endoscopic techniques.

2.3 Chapter Summary

1. Robotic surgery can be defined as the performance of surgery using a machine capable of planning and executing surgical manoeuvres based on its ability to integrate various sources of external information.

2. The medical community is increasingly accepting the role of robotics in the delivery of surgical care. Currently, robotic surgery in the gastrointestinal tract is largely limited to the Da Vinci System, which is a rigid externally actuated master slave robotic system based on the laparoscopic paradigm.

3. Robotic technology is ideal in aiding the performance of surgical procedures in the confined spaces of human internal anatomy. This novel field of endoscopic robotics is only in the early stages of development.

Chapter 3: A Technical Review of Endoscopic Multitasking Platforms

This chapter has been published in the International Journal of Surgery (2012) 10:345 – 354. (Top 25 articles IJS 2012)

Part of the research gathered in this chapter has been used to successfully apply for funding from Tenovus Scotland.

3.1 Introduction

In 2004, Kalloo et al introduced the concept of Natural Orifice Translumenal Endoscopic Surgery (NOTES). The first case reported involved the performance of transgastric peritoneoscopy in a porcine model using a flexible endoscope. Since then, the benefits of NOTES have been disputed.[80] The purported benefit of NOTES is that it reduces parietal injury thus minimizes pain, scar and acute injury response associated with surgery. Various routes have been experimented; transgastric and transvaginal routes are the two most popular access routes for intra-abdominal surgery.[81] Currently there is a lack of evidence that performing intraperitoneal surgery via NOTES technique is superior to conventional open or laparoscopic techniques. A review of 432 human NOTES cases demonstrated that the majority of procedures involved combination of conventional laparoscopy and translumenal endoscopic therapy.[82] This may be associated with increased number of operators required per procedure. Operative times presented in an international prospective case series which assessed a total of 362 transvaginal and transgastric NOTES procedures, appeared to be longer than what would be expected when compared to conventional laparoscopic procedures. Additional complications that would not be encountered in standard laparoscopic or open techniques were noted, these include vaginal laceration, oesophageal injury and mediastinitis.[83] In a German case series consisted of 551 patients who underwent transvaginal NOTES procedure, of which 85.3% were cholecystectomy; it reported four cases of bladder injuries, two cases of rectal injury, two cases of vaginal bleed, and three cases of vaginal infection.[84]

Although the benefit of NOTES in performing intraperitoneal surgery remains unproven, the benefit of advanced endolumenal therapy is tantalizing. These techniques target conditions treatable within the lumen without iatrogenic breech of viscus wall. Endoscopic submucosal dissection (ESD) for early gastrointestinal cancer and peroral endoscopic myotomy (POEM) for oesophageal achalasia are examples of these techniques. Endoscopic submucosal dissection is a technique developed with the aim of removing lesions en bloc that would otherwise be impossible with endoscopic mucosal resection (EMR).[85] The Japanese Gastric Cancer Association recommends that moderately or well differentiated gastric cancer that is not associated with an ulcer; limited to the mucosal layer; and of less than 2 cm in diameter in elevated type lesion and less than 1cm in diameter in depressed type lesion, is suitable for endoscopic excision.[86],[87] EMR is proven to be an effective treatment for early gastric cancer.[88] With histological evidence that even larger mucosal tumours[89] , as well as undifferentiated tumours involving only the upper third of the submucosal layer (Sm1) can be without lymph node involvement[90], some have suggested that tumour lesser than 3 cm with minimal submucosal involvement can be treated endoscopically. EMR for these expanded criteria lesions may be associated with risk of incomplete excision. ESD is associated with improved en bloc resection rate and thus allow better assessment of resection margin.[91] Case studies suggest that

ESD is associated with superior complete resection rates for larger lesions and has a lower risk of local recurrence.[92],[93] There remains a need for prospective randomized controlled trials comparing endoscopic treatment of gastric cancer versus conventional surgery. More recently, ESD has also been applied to oesophageal cancer. Early reports are promising.[94] With the success of endoscopic treatment of early gastric cancer, EMR and ESD have been used to treat large sessile colonic polyps and early colonic cancers. The indication is much less defined than for gastric cancer. Early colonic cancers involving only the mucosa or with minimal submucosal involvement (<500 – 1000 microns) is associated with very low risk of lymph node involvement. Other factors such as lymphovascular invasion, tumour grade are also predictors of lymph node involvement.[95],[96],[97] Lesions demonstrating favourable histopathologic criteria are potentially suitable for endoscopic resection. Some have suggested that lateral spreading mucosal tumours, tumours associated with fibrosis, ulcerative colitis and lesions incompletely resected by EMR are suitable for ESD.[98] The prevalence of these suitable lesions is low.[99] However, with the introduction of colorectal cancer screening programmes, the incidence of detection of early colonic cancer is likely to increase. A meta-analysis of 25 case series reported curative en bloc resection rate of 58.7% with EMR technique. This is superior to conventional polypectomy snare technique.[100] ESD is especially useful in large lesions. A meta-analysis of ESD in resection of colonic lesions reported a margin free en bloc resection rate of 88%.[101] However, special consideration has to be paid to colonic endoscopic resection. Unlike the stomach, the colon is long, tortuous, thin walled and has multiple haustrations.[102] Paradoxical movement of the endoscope due to looping can make resection in the right colon difficult to perform. ESD for colonic lesions can potentially be more technically demanding than ESD for gastric lesions. Another recently introduced advanced endolumenal technique is peroral endoscopic myotomy (POEM) for the treatment of achalasia. The concept of endoscopic oesophageal transmucosal myotomy is first proposed in 1980.[103] POEM differs in that it aims to divide only the circular muscular layer within a submucosal tunnel. It is hoped that this modification can minimize the risk of mediastinal contamination in the event of oesophageal perforation.[104], [105] Several case series with a total of 81 patients have demonstrated that it is effective in reducing dysphagia symptom score and resting lower oesophageal pressure among patients with achalasia. [106],[107],[108],[109],[110] However, these series, performed by enthusiasts, at most report a follow up period of three months. Long term follow up studies are needed. An animal study suggested that POEM may reduce lower oesophageal sphincter pressure by a lesser degree when compared to open Heller's myotomy. However, there was no difference in distensibility as measured by the EndoFLIP device.[111] Clinical trials are needed to compare POEM efficacy with that of the standard Heller's myotomy.

The aforementioned innovative endolumenal techniques remain difficult to perform. Currently, published case series of these techniques uses either single or dual channel conventional flexible endoscope. An endoscopic multitasking platform with improved instrument manoeuvrability can potentially make these techniques easier to perform.[112] Increased uptake of these techniques can also make validation studies easier to perform. For this to be possible and to be accepted, the development of an effective flexible multitasking platform is paramount. There are obvious challenges to NOTES including instrument access, surgical instrumentation, spatial orientation and luminal closure which are yet to be effectively overcome.[113] The ASGE/SAGES Working Group on Natural Orifice Translumenal recommended that a suitable multitasking platform will be a stable but flexible platform where upon adequate anchorage is provided for traction and tissue dissection, as well as allowing the therapist to control multiple devices.[114] To date, the majority of systems are designed with the aim of performing NOTES intraperitoneal surgery. In this review we aim to review the ever changing landscape of the field of flexible endoscopic multitasking platforms, with specific focus on its visualization method, method of actuation, its limitations and its extent of clinical application.

3.2 Method

Medline search was performed to identify literature relating to flexible endoscopic multitasking platform from year 2004 to 2011 using keywords: Flexible endoscopic multitasking platforms", "NOTES", "Endoscopic robotic surgery", and specific names of various endoscopic multitasking platforms. Key articles from articles references were reviewed.

3.3 Summary of Various Platforms

Flexible multitasking platforms can be classified as either mechanical or robotic. (Table 1) Purely mechanical systems include the dual channel endoscope (DCE) (Olympus), R-Scope (Olympus), the EndoSamurai (Olympus), the ANUBIScope (Karl-Storz), Incisionless Operating Platform (IOP) (USGI), and DDES system (Boston Scientific). Robotic systems include the MASTER system (Nanyang University, Singapore) and the Viacath (Hansen Medical). The DCE, the R-Scope, the EndoSamurai and the ANUBIScope have integrated visual function and instrument manipulation function. The other systems rely on the conventional flexible endoscope for visualization, and instrument manipulation is integrated through the use of a flexible, often lockable, multichannel overtube called an access device. The advantage of the access device concept is that it allows optics and instrument dissociation. However, it is a less compact method of instrument organization. Due to the anatomical constrains of the pharynx, systems have to be less than 20mm in diameter. Current systems are controlled by traction cable system actuated either by hand or by digital control. In a flexible system, this method of actuation inevitably leads to significant hysteresis. To date, the DCE, the R-Scope, the IOP, and the Viacath system have data published relating to their application in human. Other than the DCE, all systems are currently either in prototype or early human trials stage, as such, there is limited data regarding comparative performance of various systems. Practicalities such as day to day sterilisation protocols and cost-effectiveness remain unclear.

Name	Outer diameter (mm)	Number of instrument channels	Channel size (mm)	Length (cm)	Degree of freedom of movements	
Mechanical systems						
Integrated Mechanical Platforms						
Dual channel UGI Endoscope (Olympus, Japan)	12.6	2	3.7, 2.8	103	Endoscope Up/Down Left/Right Rotation Translation	Instrument Translation Open/Close
R-Scope (Olympus, Japan)	14.3	2	2.8 (deflectable)	133	Endoscope Up/down Left/right Rotation Translation	Instrument Translation Open/Close Up/Down Left/Right
EndoSamurai (Olympus, Japan)	15 (endoscope) 18 (over-tube)	3	2.8	103	Endoscope Up/down Left/right Rotation Translation	Instrument Up/Down Left/Right Translation Open/close Rotation
Anubis (KarlStorz, Germany)	16	3	4.2 * 2 (deflectable) 3.2 (central)	110	Endoscope Up/down Left/right Rotation Translation	Instrument Up/down Left/Right Open/close Translation Rotation
Platforms based on an access device						
Incisionless Operating Platform (USGI, USA)	18	4	7,6,4,4	110	Oversheath Up/down Left/right Rotation Translation	Instrument Up/down Left/right Open/close Translation Rotation
DDES (Boston Scientific, USA)	16 * 22	3	7, 4.2, 4.2	55	Oversheath Up/down Left/right Rotation Translation	Instrument Up/down Left/right Open/close Translation Rotation
Robotic systems						
MASTER (NanYang Tech Uni, Singapore)	22	Externally attached to endoscope 2 manipulator arms	–	150 cm (sheath) 41.7 mm (manipulator)	Endoscope Up/down Left/right Rotation Translation	Robotic arm Translation Elbow Flex/Ext Elbow Sup/Pron Wrist Flex/Ext Gripper Open/Close
ViaCath (Hansen medical, USA)	16	–	–	90	Instrument Up/Down/ Left/Right (in each of two distal segments) Translation Rotation Open/Close	

Table 1: Summary table of mechanical and robotic flexible endoscopic platforms

3.4 Mechanical Endoscopic Multitasking Platforms

3.4.1 Dual Channel Endoscope

The conventional dual channel endoscope was developed to allow the insertion of two therapeutic instruments simultaneously. It only provides two degree of instrument motion that is independent of the endoscope movement. Bimanual instrument coordination is nearly impossible. Numerous techniques have been developed to endeavour to overcome this. For example, various ingenious EMR grasp and snare techniques have been described.[115], [116], [117] Endoscopic adjuncts have also been developed to give a degree of tissue traction and counter traction, for example: the EndoLifter (Olympus) and magnetic anchored micro forceps were developed to provide tissue lifting to ease ESD.[118] Early examples of combined laparoscopic/NOTES procedures in human were performed using the DCE.[119],[120],[121] More recently, Ethicon has developed a set of prototype endoscopic instruments called the NOTES toolbox. These consist of articulated grasper and rotatable instruments (such as hook knife, scissors, clipper and haemostatic bipolar forceps).[122],[123] (Figure 8) These new instruments have been used in the DCE platform to perform totally transvaginal cholecystectomy in a porcine model with a 80% completion rate.[124] Although the DCE is the gold standard platform for performing advanced endoscopic technique, it offers very minimal bimanual instrument coordination. In order for advanced endoscopic procedure to be widely practiced, a novel platform is needed.

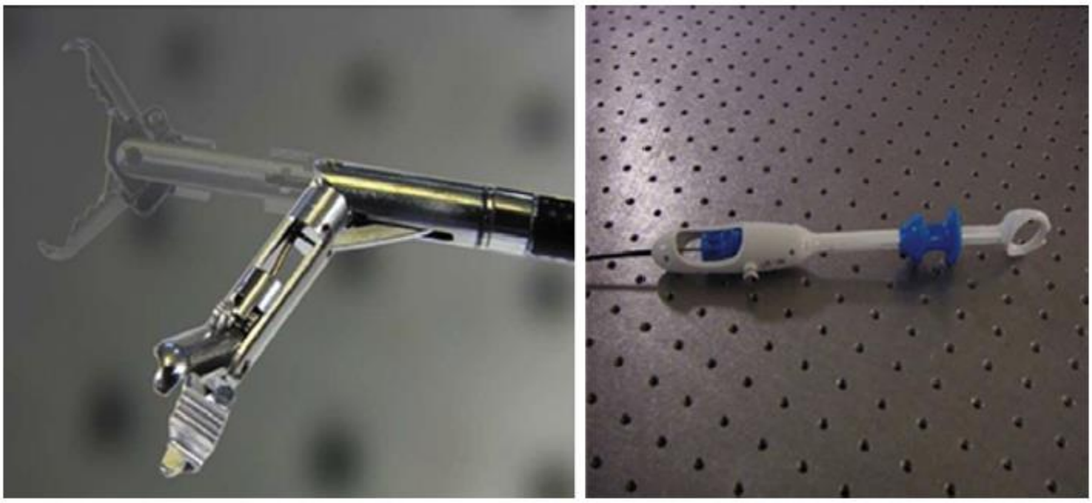


Figure 8: Articulated grasper featured in the NOTES toolbox (Ethicon). (Whang et al, 2010)

3.5 Integrated Mechanical Platforms

3.5.1 R-Scope (XGIF-2TQ160R Olympus, Japan)

The R-Scope is designed with the hope of having improved performance when operating in the lesser curvature of the antrum, the posterior wall and lesser curvature of the gastric body, and the gastric cardia; as well as offering improved independent instrument movement that is not possible with the DCE. [125], [126] It is a prototype multi-bending endoscope with two 2.8 mm deflectable operative channels. Its shaft consists of a proximal bending section which allows up and down movement and a distal bending section which allows up/down and left/right movement (as in a traditional endoscope). This two segment multi-bending shaft design was adapted from an earlier Olympus endoscope called the M-Scope. Initially, the multi-bending function was anticipated to be useful in a capacious environment where there is an absence of a viscus wall for endoscope anchorage. However, in later versions, the two multi-bending segments are reduced to one as it was felt to contribute little to function.[127], [128] It has two channels with deflectors which allow instrument movement in perpendicular planes. (Figure 9) The left working channel can be manipulated in a vertical direction relative to the visual axis by a deflector control next to the endoscopic steering wheel in a similar fashion to a side-viewing endoscope used for bile duct exploration. The right working channel can be manipulated in the horizontal direction below the visual plane by a wheel in the shaft of the endoscope. It also requires one to two assistants to control the advancement, and opening and closing of the end effectors. Early versions of the R-scope had a distal swan neck to accommodate the additional mechanisms, and it was noted that its function is significantly impaired in retroflexion. Early human clinical study therefore was limited to distal gastric lesions.[129] When used to perform ESD for excision of gastric lesions by expert hands, it has been shown to reduce operating time from a mean of 92.8 minutes with the DCE to 57.9 minutes with the RScope.[130] Later bench top studies of an improved R-scope demonstrated its superiority in performing ESD in the lesser curvature when compared to the DCE.[131] Experimentally, it has been used to perform transgastric cholecystectomy and distal pancreatectomy in survival porcine models.[132], [133], [134] It has also been used to perform transgastric peritoneoscopy. A study compared the diagnostic ability of laparoscopy against transgastric peritoneoscopy using the R-scope in porcine model with simulated pathology, identified that the latter was inferior in its rate of detection of pathology.[135] Although the R-Scope gives therapeutic instrument up to four degrees of freedom, its controls does not allow intuitive bimanual instrument coordination. An American study which compared the DCE, R-Scope and DDES systems (see below) demonstrated that the R-scope, with its multiple controls, makes instrument coordination difficult. In contrast to previous studies, it was not superior to the DCE in the performance of bench top endoscopic tasks.[136] This suggests that the complex instrument control of the R-Scope renders the instrument difficult to master. It will therefore limit its widespread adoption.

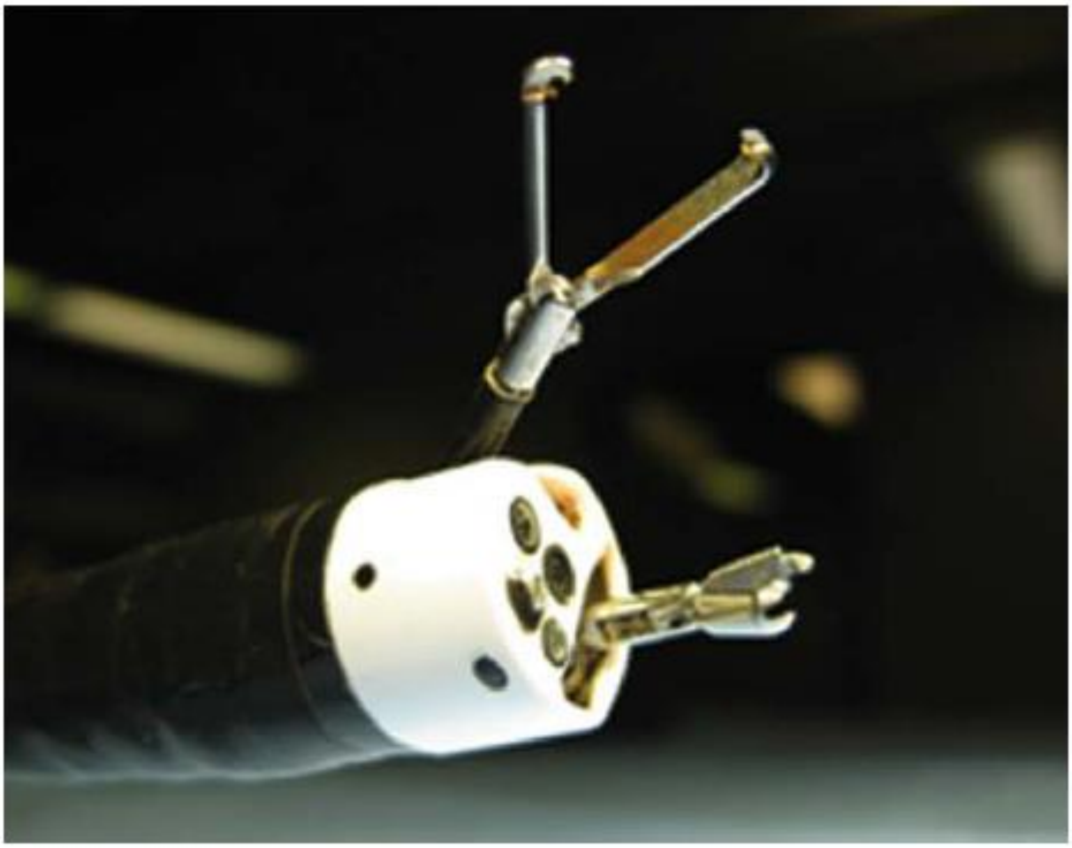


Figure 9: Distal tip of the R-Scope with its two deflectable channels in perpendicular planes. (Moyer et al, 2010)

3.5.2 EndoSamurai (Olympus, Japan)

EndoSamurai is a prototype platform which consists of a 15mm flexible endoscope integrated with lens irrigation function, air insufflation function, two hollow steerable instrument guide arms and one conventional operating channel. (Figure 10) The instrument is introduced into the gastrointestinal tract via an 18mm flexible steerable lockable over-tube. The steerable arms are mechanically cable actuated. It has five degrees of independent instrument motion. It has a mechanical control console very similar to conventional laparoscopic instruments. The advantage of this system is that endoscopic instrument of various natures such as insulated tip electrosurgical knife, grasper, and forceps can be interchanged without the withdrawal of the endoscope. The system is capable of performing suturing and bimanual manipulation of targets. It requires at least two operators: one for guiding the over-tube and instrumentation of the third instrument channel and one for controlling the instrument guidance arms.[137] It is noted that its arms are too long thus rendering operation in the retroflexed position difficult. It also suffers from the problem of relative parallel orientation of the instruments with the optical axis. It has been used for endoscopic full thickness resection for gastric lesion in ex vivo porcine model, and was found to improve procedural accuracy and reduce procedure time from a mean of 23 minutes observed with the DCE to 13 minutes.[138] The position of the instruments intended to allow instrument triangulation may reduce its manoeuvrability in a narrow lumen such as in the oesophagus and small bowel. Its instrument control console which simulates laparoscopic surgery may make it a more intuitive to learn to control the platform. The hollow guide arm concept allows the use of generic endoscopic instrument, unlike the ANUBIScope, Incisionless Operating Platform (IOP) and Direct Drive Endoscope System (DDES) which advocates the use of articulated instruments (see below). The use of generic instruments could potentially bring down the cost of utilization. Overall, EndoSamurai is a promising platform with intuitive instrument control interface. Further clinical studies are awaited.

Figure 10: Endosamurai with its control console similar to a laparoscopic system (left) and two hollow cable controlled instrument guide arms (right). (Ikeda et al 2011, Spaun et al 2009)

3.5.3 ANUBIScope (Karl-Storz/IRCAD, Europe)

The ANUBIScope is a flexible endoscope prototype with a special tulip shaped tip that allows two deflectable instrument channels to be positioned for instrument triangulation, as well as providing a third central channel for suction. The special tip is composed of two flexible flaps that can be opened by a cable system which can dilate incisions to the necessary diameter to provide translumenal access. (Figure 11) Another purported function of the flaps is that it can provide retraction thus clearing the operative field. Flexible instruments with four degrees of independent motion can be introduced to perform dissection and suturing. These instruments are controlled through a trigger handle similar to that seen in laparoscopic surgery.[139] The use of these specialized instruments could increase cost per procedure. It has been used to perform NOTES cholecystectomy and mucosal closure in animal models and cadaveric models.[140] There is no published literature comparing its performance to any of the above systems. It also integrates visualization and instruments, an advantage seen in the EndoSamurai. Unlike the EndoSamurai, it also has the added advantage that its instrument channels are deployable. Therefore, unlike the EndoSamurai, instrument insertion does not require an overtube. The instrument flaps, however, can potentially limit platform manoeuvrability in a narrow endolumenal environment. Of the available integrated platforms, the ANUBIScope is likely to be the most successful. Further clinical studies are awaited.

Figure 11: The ANUBISCOPE with its tulip shaped deployable instrument channels. (Karl Storz 2011)

3.6 Platforms Based on an Access Device

3.6.1 Incisionless Operating Platform (USGI, USA)

The Incisionless Operating Platform (IOP) is a commercially available system based on the TransPort multi-lumen access device. It also includes other adjuncts such as grasping tissue approximation device, tissue anchors and various graspers. The TransPort device is a steerable flexible over-sheath with ShapeLock function. Shapelock was originally developed for facilitation of multiple colon polypectomies in a single session. [141], [142] Shapelock function is achieved by a series of titanium rings connected by wires, and the rings lock into a set position when the connecting wires are tightened.[143] The stiffened over-sheath also offers better anchorage, thus allowing better force transmission when compared to fully flexible platforms.[144] Torsional and lifting strength are found to be superior to the standard endoscope.[145] The system can be table mounted. Visualization is provided by a 4-6mm conventional flexible endoscope through a 6 mm channel. In addition, the over-sheath has one 7mm, and two 4mm channels allowing the insertion of larger calibre suction irrigation device adapted from standard laparoscopic surgery, as well as articulated instruments.[146] Intralumenal procedures such as cardial mucosal resections, gastroplication for gastroesophageal reflux and closure of full-thickness incisions have been studied in survival porcine studies.[147] Various extra-lumenal procedures including those requiring significant retroflexion, such as cholecystectomy, fundoplication, gastric restriction and diaphragmatic repair have been attempted in animal and human cadaver study.[148],[149],[150] Combined Laparoscopic/NOTES hybrid procedures on human have been performed safely and effectively. These include cholecystectomy through transgastric, transvaginal or transumbilical routes, transgastric appendectomy, endolumenal gastric pouch formation and stoma reduction in patients with Roux-en-Y gastrojejunal anastomosis.[151],[152] The IOP is a platform designed mainly for performing intraperitoneal NOTES procedure. Although the concept of an oversheath is a simple method of integrating visualization and allows passage of large diameter instruments; its large diameter and short length may limit its ability to perform advanced endolumenal procedures. The Cobra system is another prototype system developed by the same company based on the Transport platform. (Figure 12) It has three independent cable controlled arms with fixed end effectors. The end effectors are fixed to the instrument arms and therefore instrument exchange require removal of the entire endoscope.[153] There are no published studies regarding its performance.

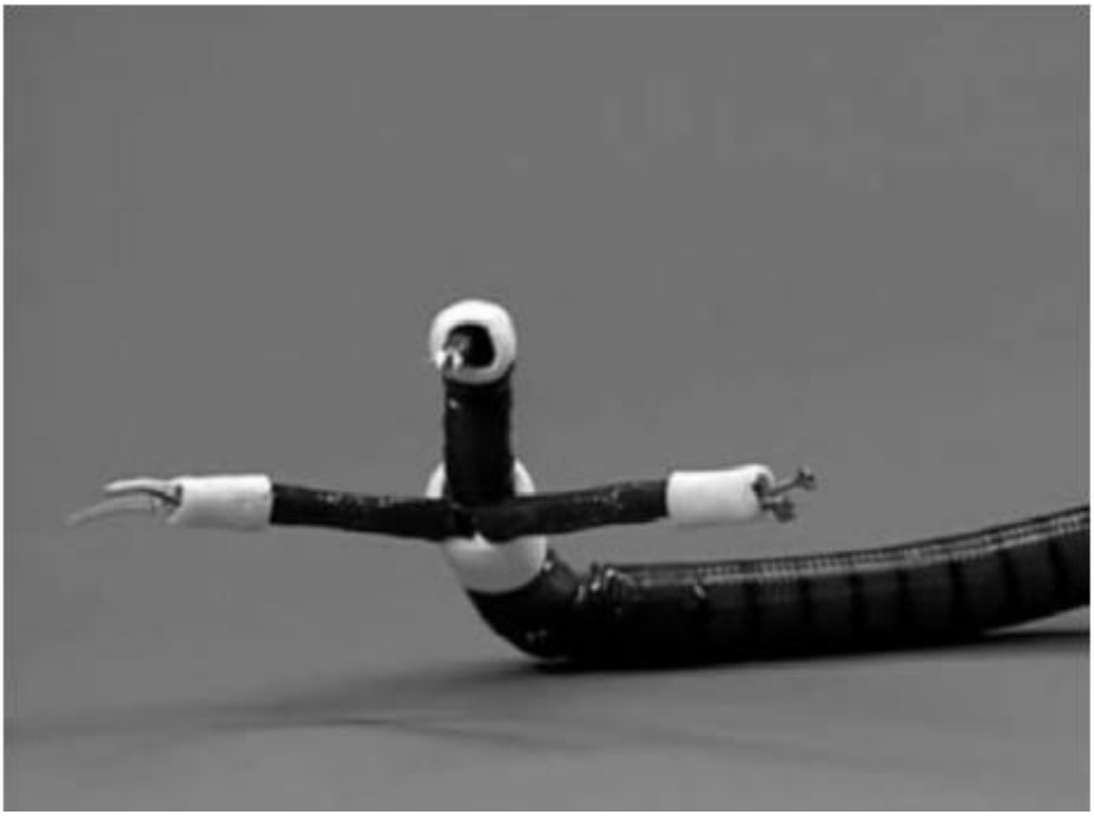


Figure 12: Cobra system with its three wire controlled arms. (Bardaro et al 2006)

3.6.2 Direct Drive Endoscopic system DDES (Boston Scientific, USA)

The Direct Drive Endoscopic System (DDES) is a prototype access device platform consisting of four elements: a steerable flexible articulating guide sheath with a 6mm visualization channel and two 4mm instrument channels; articulated flexible mechanically controlled 4mm instruments; a conventional neonatal endoscope; and a mobile rail platform which integrates the aforementioned elements.[154] (Figure 13) The guide sheath is manipulated in a similar fashion to the traditional endoscope. Similar to the IOP system, it uses an endoscope for visualization, therefore providing a degree of optics and instrument decoupling. In contrast to the IOP system, it offers a special mechanical handle which provides ergonomic control of proprietary flexible instruments. The instruments are capable of movements of up to five degrees of freedom. These instruments have a working length of 12cm beyond the over-sheath. The flexible instruments are traction cable controlled, and therefore have the problem of hysteresis. Other reported limitations include limited torque transmission and relatively parallel orientation of forceps with the optical axis. Ex-vivo EMR and full thickness suturing in non-surviving animal models have been demonstrated. DDES has been found to provide more efficient bimanual coordination and reduce time needed to perform bench top tasks when compared to DCE and R-Scope.[155] Of note, it has a working length of only 55 cm, and therefore instrumentation is only possible up to the level of the stomach when assuming scope entry through the mouth. To date, application is limited to animal models. The DDES will have shortcomings that are associated with an access device system. However, its special traction cable controlled instruments and novel mechanical instrument control interface make this a promising platform.

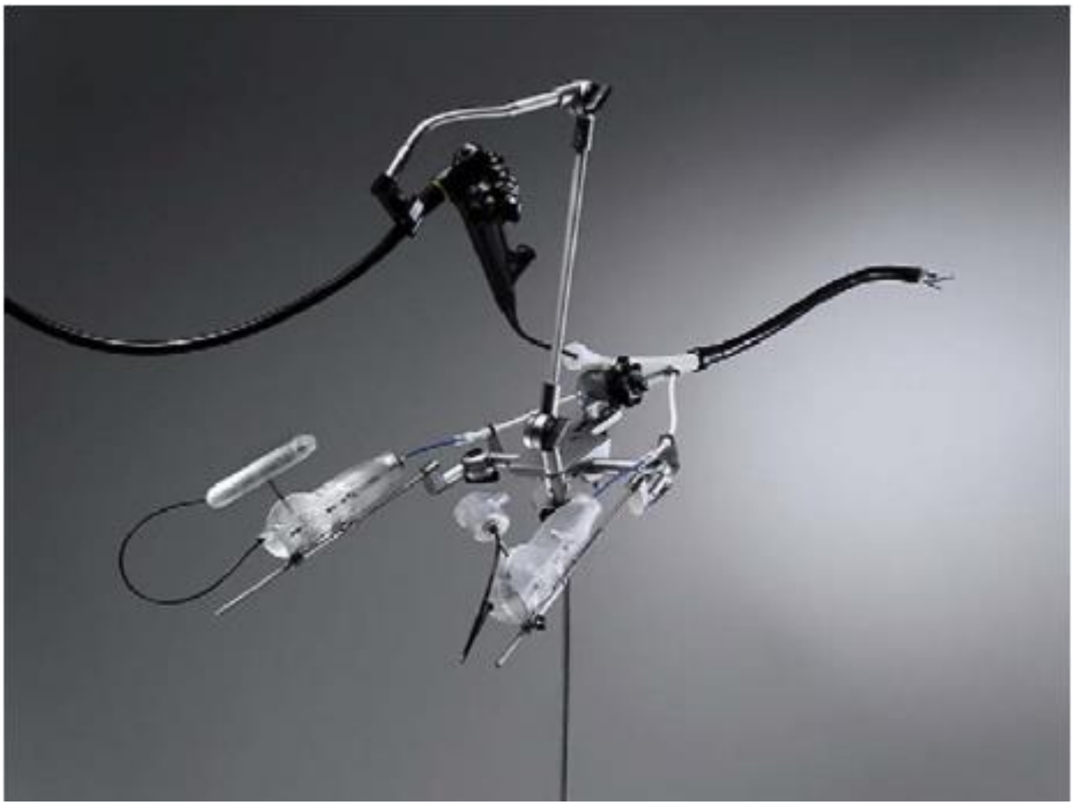


Figure 13: DDES system (Boston Scientific). (Thompson et al 2009)

3.7 Robotic Endoscopic Multitasking Platforms

3.7.1 MASTER (Nan Yang Technological University, Singapore)

Master and Slave Translumenal Endoscopic Robot (MASTER) is a cable driven flexible robotic manipulator developed by Nanyang Technological University, Singapore. It is attachable to the conventional endoscope. (Figure 14) It requires an endoscopist as well as a robotic operator. It employs electromechanically controlled cable actuation system. Externally located actuators manipulate cables to achieve actuation of manipulator joints. The tendon sheath bundle can be fitted through instrument channels of an Olympus 2T160 endoscope, thus obviating the need of over-tubes.[156], [157] Initial robotic arm prototype had an anthropomorphic design with four joints:

shoulder (in/out, up/down), elbow (flexion/extension, supination/pronation), wrist (flexion/extension) and end effector gripper motion, giving the manipulator a total of six degrees of motion. The original master console was a wearable console. The motions of the operator's shoulder, elbow, wrist and hand are encoded by cable actuated position sensors and optical rotary encoders. However, it was realized that positioning of the endoscopic manipulator did not simply correlate with the operator's arm at rest and therefore, a non-wearable console design providing joint to joint control was used. Also, motion at the shoulder was excluded, resulting in a shortened instrument as well as improve ergonomics for the operator. In its current form, it has fixed end instrument effectors. The tendon sheath system is capable of generating high retraction force upward of 5.2N. [158] It was noted that a tendon sheath system has the drawback of friction resulting in delays and movement hysteresis.[159] A pre-tension device and software adjustment were used to mitigate this problem. However, difficulty in predicting tendon elongation renders the system only capable of being an open-looped control system where the main feedback reference is through operator vision. This makes any automation of movements difficult. Acute bending of the tendon system such as during endoscope retroflexion will also compromise precision of the robotic arms.[160], [161] Haptic feedback through the use of external load cells on the tendon cables is being developed. Interventional navigational system using data from preoperative images such as that from CT/MRI and intraoperative visual images and magnetic tracking system is in development.[162] The MASTER system has been used to perform ESD in ex vivo and in vivo porcine models and was found to be comparable to standard endoscopic therapy in terms of operation time. It is of note that the time required to setup the system will likely prolong the operation time with the MASTER system.[163] It has also been used to perform limited hepatic resection and endoscopic submucosal dissection in non-survival porcine model.[164] The MASTER system has fixed end effectors and a cumbersome external mechanical actuator. It also compromises by being a retrofitted device against a conventional endoscope. It is therefore likely to be an interval technology. Further development of additional capabilities, such as automation of camera control, improvement in ease of instrument change and reduction in the number of assistants, is required before the added cost of robotic surgery can be justified. Further studies are required to assess its capability against other platforms. The system has been used to perform endoscopic submucosal dissection for early gastric neoplasia in humans.[165]

Figure 14: The MASTER system with its two cable actuated robotic arms with fixed end effectors (left) attached to a conventional endoscope (right). (Phee et al 2008)

3.7.2 Viacath System (Hansen Medical Systems, USA)

The main feature of the Viacath system is the electronically controlled, long shafted, flexible, narrow bore instruments which have fixed end effectors. Instrument shafts are built with close wound stainless steel spring lined with Teflon to provide a low friction, incompressible, flexible conduit for its cable control system. (Figure 15) It is a flexible instrument with a diameter of 4.5mm. It has seven degree of freedom controlled by 14 tension cables orientated in a special manner to allow instrument axial torque, axial loading and bending. The instrument has two distal multi-bending segments. It is capable of generating a tip force of up to 3N. It shares the control platform and external actuation mechanisms with the Laprotek surgical robotic system (a robotic system developed by the same company for laparoscopic surgery).[166] A steerable over-tube orientates a standard endoscope and two instrument channels in a triangular fashion through a rigid nose cone in a similar fashion to the IOP and DDES system. This over-tube has two flexible joints in series distally providing two and one degree of freedom respectively, similar to the R-Scope. Interestingly, in contrast to the other systems, the rigid nose cone consists of cable actuated rotary gripper devices which provides additional front end induced rotary motion.[167] The flexible instrument has been used for endovascular and urological indications.[168] It has also been used to perform endoscopic mucosal resection in live porcine model. Information such as operative time, en bloc resection rate and comparative performance against alternative platforms are not available.[169] The easy instrument interchange offered by the Viacath system makes it a very flexible platform. Much of current usage of the system is in endovascular intervention. It would be interesting to see its application in endoscopic gastrointestinal surgery. Being a cable actuating flexible system, significant hysteresis may be observed especially when used to perform procedures over a long distance, such as that seen in right colonic ESD.

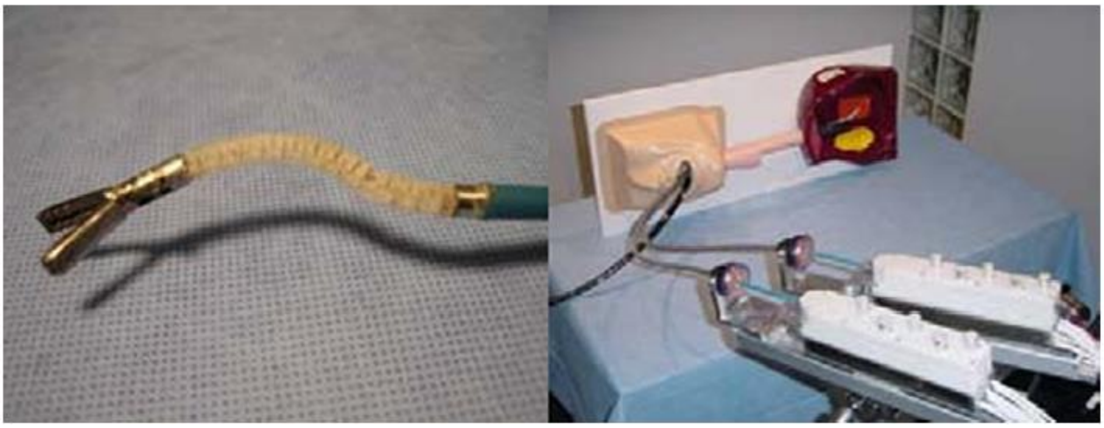


Figure 15: Viacath system. The flexible instrument with fixed end effectors (left). External actuators (right). (Abott et al 2007)

3.8 Optimal Design for Advanced Endolumenal Therapy

Instrument field of action in various systems when flexible endoscope movement is excluded is summarised in Figure 16. In the narrow endolumenal environment, gross flexible endoscope movement is often limited. Due to the use of traction cable, the current systems' instrument arms are bulky and require a minimum working length. An ideal system should allow instrumentation to any aspect of the visualized area at any one endoscope position. This ideal is yet to be achieved.

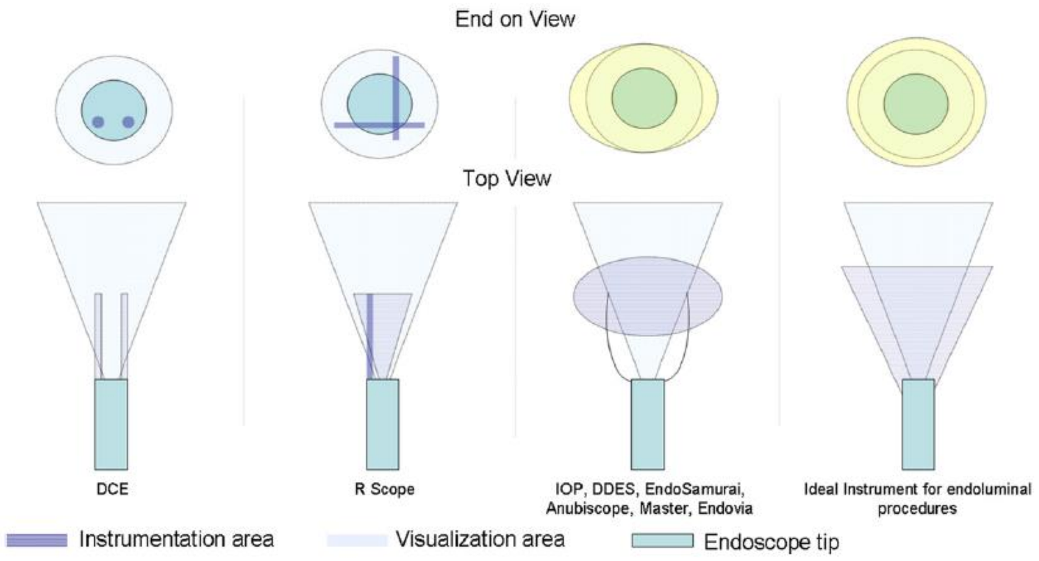


Figure 16: Instrument field of action in various systems when endoscope movement is excluded.

3.9 Overcoming the Conventional Endoscopic Paradigm

To date, designs of multitasking platforms have been limited by the requirement of a flexible control shaft capable of passage down the upper gastrointestinal tract. The basic design of the conventional endoscope is retained to a various degree. The concept of employing cable controlled instrument arms is universal. This type of system is inherently prone to distortion in a flexible system. Friction generated during wire actuation means that there is significant amount of hysteresis and ineffective force transmission, thus resulting in lack of instrument responsiveness and accuracy. This problem is further accentuated during endoscope retroflexion and long instrument length. Cable elongation can impair the design of effective haptic feedback and motion automation. Some systems use instrument arms with fixed end effectors, which can render instrument change difficult. An alternative would be in vivo multitasking platforms which does not require mechanical control shaft. The Nebraska miniature robot is one such design. It is a three piece magnetically articulated tubular shaped robot. It has a cross sectional area of 14*17mm. The central piece is an 80mm body with stereovision and ultra-bright LED lighting. On each end, 53mm robotic arms with fixed end effectors articulate with the body. This articulation is detachable therefore allowing the robot to assume a linear orientation for insertion down the upper gastrointestinal tract through an over-tube. It is actuated through short range motors. It has three degree of freedom (rotation, shoulder abduction/adduction and instrument extension/retraction). It has magnetic anchors coupled to extracorporeal magnets. It has been used to perform cholecystectomy in non-survival porcine model. However, it was found to have insufficient anchorage and the shoulder joint suffered premature mechanical failure.[170] (Figure 17) An in vivo robot capable of exploring the peritoneal cavity by use of spiral grooved wheels has also been described.[171], [172] Alternative methods capable of providing short range actuation should be explored. Short range actuation minimizes. Pneumatic or hydraulic actuation should be explored.[173] Currently, commercially available brushless micro motors can be as small as 2mm in diameter.[174] Solid state actuators, which generate motion through stress variations from a change of material states by application of heat or electricity, such as thermal bimorph, shape memory alloy (SMA) or piezoelectric actuators, should be explored. With mechanical motion amplification, these solid state actuators can be applied in endoscopic instrumentation.[175] For example, SMA has been used to produce a micro manipulator in the shape of a 2mm hollow tube.[176] (Figure 18) Alternative power transmission systems should also be explored.[177] Wireless technology and new micro-camera technologies should be employed. [178]

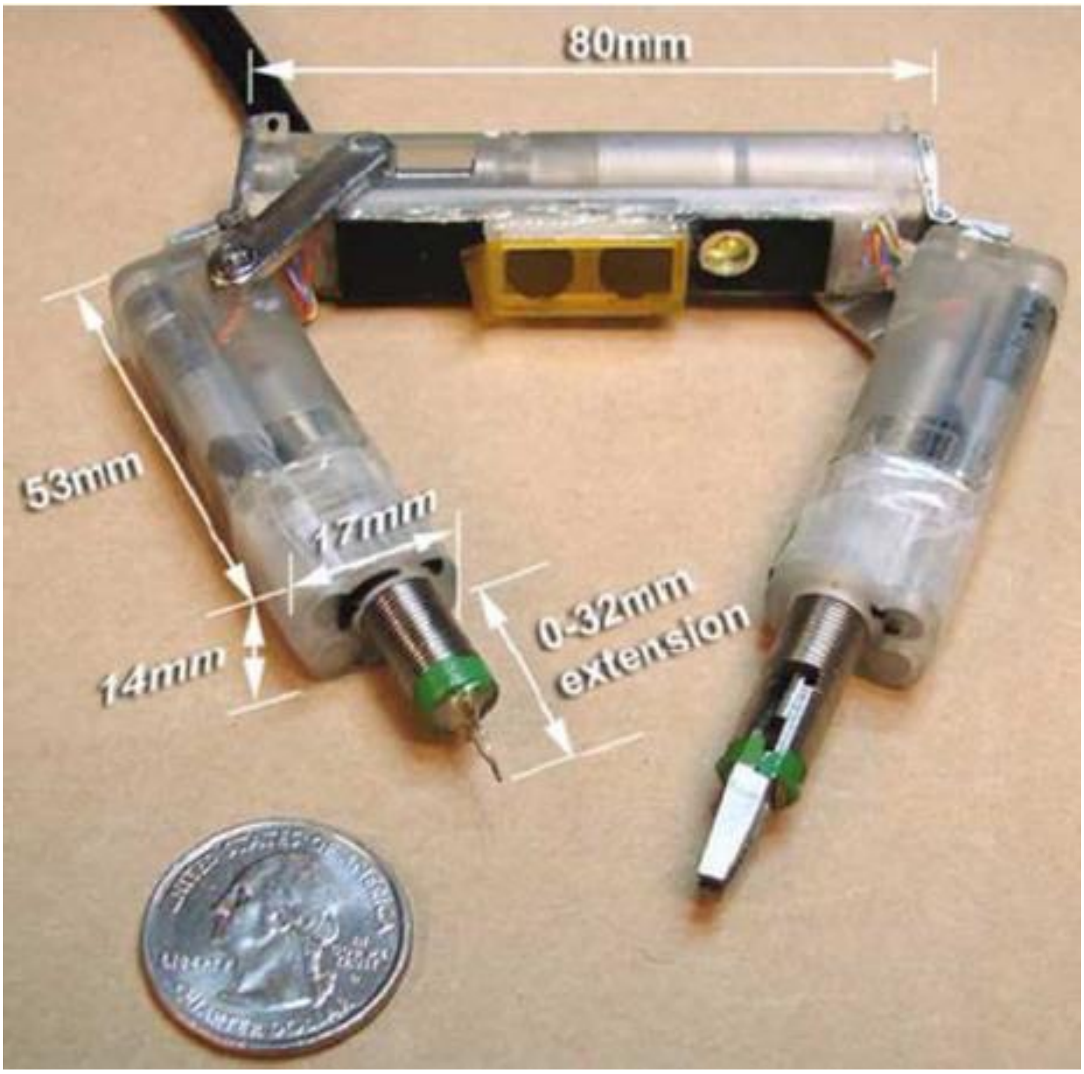


Figure 17: Intra-peritoneal miniature robot developed by University of Nebraska. (Lehman et al 2009)

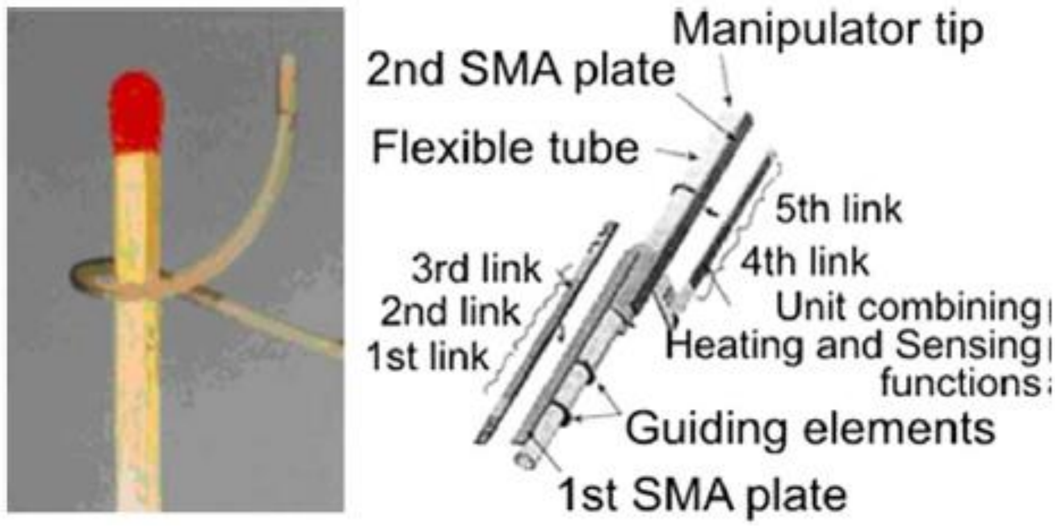


Figure 18: SMA actuated micro tube manipulator. (Kaneko et al 1996)

3.10 Chapter Summary

1. Whether NOTES translumenal intraperitoneal surgery provides any additional benefit to conventional laparoscopic surgery remains to be answered. However, advanced endolumenal procedures, such as ESD, are likely to provide significant benefit to patients.

2. Current endoscope design has limited instrument freedom rendering the performance of advanced endolumenal procedures difficult.

3. Endoscopic multitasking platforms are attempts in overcoming the limitation of current endoscope. They can be classified as either mechanical or robotic. Purely mechanical systems include the dual channel endoscope (DCE) (Olympus), R-Scope (Olympus), the EndoSamurai (Olympus), the ANUBIScope (Karl-Storz), Incisionless Operating Platform (IOP) (USGI), and DDES system (Boston Scientific). Robotic systems include the MASTER

system (Nanyang University, Singapore) and the Viacath (Hansen Medical). To date, the DCE, the R-Scope, the IOP, the Viacath system and the MASTER system have data published relating to their application in human.

4. To date, all systems are controlled by traction cable systems actuated either by hand or by robotic machinery. In a flexible system, this method of actuation inevitably leads to significant hysteresis. This problem will be accentuated by a long endoscope, such as that used in performing colonic procedures. They are complex and have poor endoscope manoeuvrability. They require multiple operators.

5. In the narrow endolumenal environment, gross flexible endoscope movement is often limited. An ideal system should allow instrumentation to any aspect of the visualized area at any one endoscope position. This ideal is yet to be achieved.

6. Alternative forms of instrument actuation, camera control and master console ergonomics should be explored to improve instrument precision, instrument sphere of action and minimize the number of assistants required.

7. Robotics will be ideally suited to improve therapeutic endoscopy as it will allow clinicians to control multiple instruments simultaneously and efficiently.

Chapter 4: Thesis Aims and Objectives

4. Thesis Aims and Objectives

Widespread application of novel endoscopic therapeutic techniques such as endoscopic submucosal dissection will require an endoscope with enhanced dissection capabilities. As detailed in chapter 1, novel camera technologies has increased the diagnostic capability of the endoscope. Moreover, the optic component of an endoscope has significantly been miniaturized when compared to the early version of the flexible endoscope in the 1960's. Flexible endoscopic multitasking platforms have been developed to increase the therapeutic capability. These novel platforms are far from ideal as evident by their lack of clinical uptake. Firstly, they all rely on traction cables to actuate instrument movements, which is inaccurate in a flexible system. Secondly, a significant number of platforms work as an adjunct, to a conventional endoscope, thus significantly impairing its manoeuvrability. Robotics has been applied in this field, such as that seen in the MASTER system and the Hansen Viacath system. However, these systems rely on the conventional traction cable system actuated through large external actuators akin to that of the Da Vinci system. However, this method of actuation is not suitable in a flexible system. In addition, current flexible robotic systems have fixed instruments attached to the actuators therefore offering limited flexibility during tissue dissection.

There is no doubt that clinicians have become very skilled in the use of the conventional endoscope. A small group of specialist are capable of performing highly complex endoscopic therapies. There is a need to design an endoscope which acts as an enabling technology to encourage the uptake of these useful techniques. Since the current endoscope is so widely accepted in the medical community, a novel device should retain the basic design of the conventional endoscope.

The aim of this thesis is therefore **to develop a novel robotic endoscopic multitasking platform for the performance of advanced endoscopic therapy.** This will be achieved through the following objectives:

1. To explore the anatomy and the biomechanical properties of the upper gastrointestinal tract.

The first stage of the project will involve gaining detailed understanding of the anatomy and biomechanical properties of the upper gastrointestinal tract. Data from the visible human project will be used to generate highly accurate three dimensional model of the upper gastrointestinal tract. This information will be used to select a suitable upper gastrointestinal model.

2. To develop a suitable upper gastrointestinal model for the testing of the novel robotic endoscopic multitasking platform.

The second stage of the project will involve gaining understanding in the existing gastrointestinal simulators available commercially. Based on the information gained from stage one and two of the project, an appropriate upper gastrointestinal model will be developed. This will serve as a bench top model for the testing of the novel platform.

3. To design a novel robotic endoscopic platform using computer aided design.

The third stage of the project will involve the design of the robotic platform using computer aided design and virtual simulation. The design criteria are:

1.	The novel endoscope should have a similar outlay and manoeuvrability as the current endoscope (ie four degrees of movement)
2.	The novel endoscope should have two instrument channels.
3.	It should allow rapid instrument exchange.
4.	It should apply micro motor technology to manipulate instruments in a fashion akin to the fly-by-wire concept as seen in the aerospace industry.
5.	The design should allow up to five degrees of freedom of independent instrument movement.
6.	Instrument control will be delivered through digital controls.
7.	Ideally, it should utilize off the shelf technologies to minimize the cost of development.

4. To produce a basic functional prototype of the novel platform.

The fourth stage of the project will involve the use of polymer and metal rapid prototyping technologies to manufacture a 1:1 scale functional prototype. Basic controlling software will also be designed.

5. Bench top testing of the functional prototype.

The fifth stage of the project will entail the testing of the prototype to assess

- kinematic performance as compared to computer simulation
- force analysis
- its ability to access the upper gastrointestinal simulator

6. A computer design of the second generation prototype should be designed based on the information gained.

Chapter 5: Upper Gastrointestinal Tract Modelling

5.1 Relevant Upper Gastrointestinal Anatomy for an Endoscopist

5.1.1 Oral cavity/Pharynx

The oral cavity is a complex cavity bordered by: the upper and lower jaw with teeth (4 incisor 2 canine 4 premolars and 6 molars in both upper and lower jaw), the facial muscles laterally, tongue inferiorly and the hard and soft palate superiorly. Posteriorly, it is defined by the palatoglossal and palatopharyngeal arch and uvula superolaterally and the base of the tongue inferiorly. The pharynx is a tubular structure which connects the oral cavity to the oesophagus. Its widest point is approximately 5 cm at the level of hyoid, and its narrowest point is approximately 1.5 cm which is located at its most inferior end. (Figure 19) The lower end of the pharynx is also known as the hypopharynx, which is of endoscopic importance as this is the first point of anatomy which commonly makes the passage of the endoscope difficult. Structures of the hypopharynx that could be visualized during endoscopy are: The base of the tongue, the vallecula, the epiglottis, the larynx (visible structures include the vocal cord, arytenoid folds), the piriform recess and the upper oesophageal sphincter formed by the cricopharyngeus muscle. (Figure 20) The upper oesophageal sphincter is located18-20cm from the incisor, and it is normally closed and opens during swallowing and upon application of gentle pressure. In the majority of time, the endoscope could be negotiated beyond the upper oesophageal sphincter into the oesophagus guided by tactile sensation. However, the endoscope could also navigate through this part of the UGI tract under direct vision, thus making recognition of hypopharyngeal anatomy important. [179], [180]

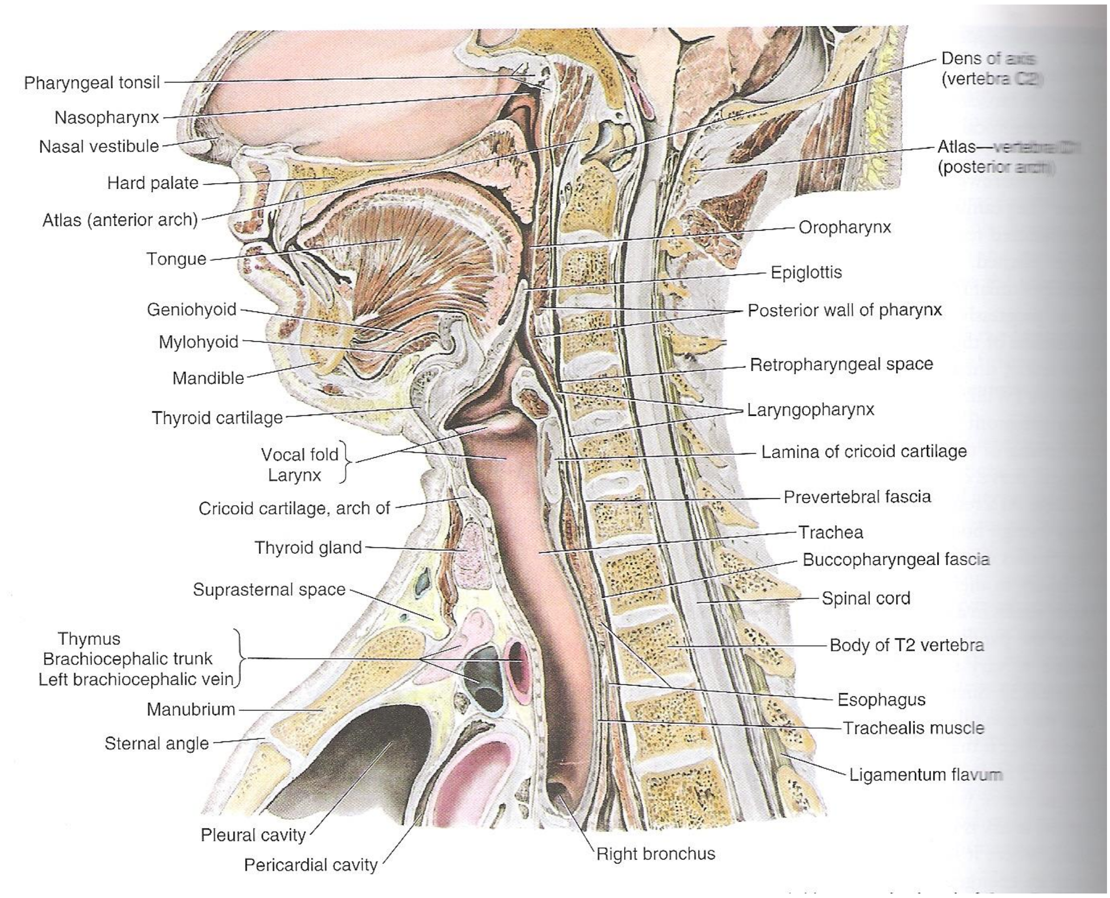


Figure 19: Sagittal view of the oral cavity, pharynx, and upper oesophagus. (Moore & Dalley 2006)

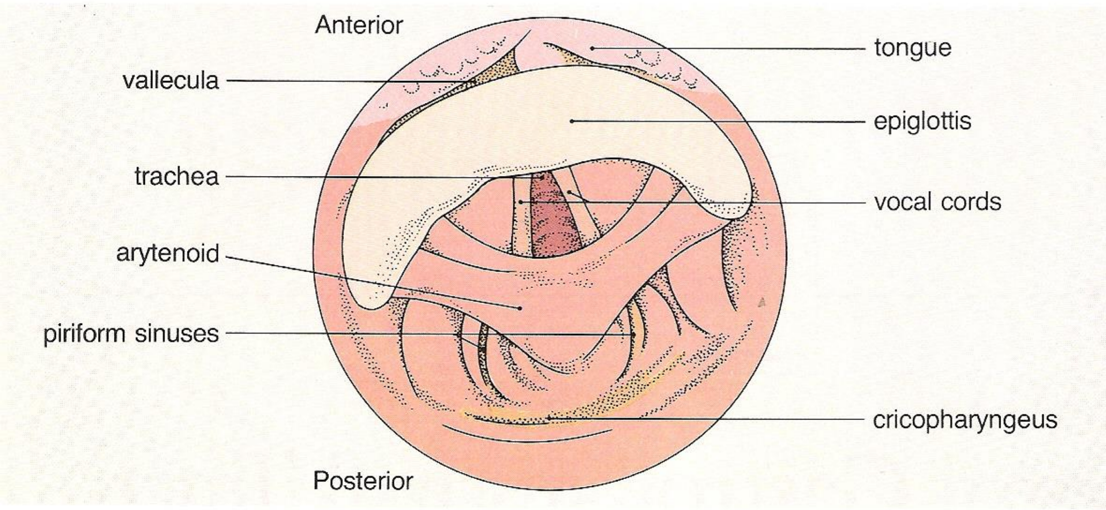


Figure 20: Hypopharynx (Silverstein & Tytgat 1987)

5.1.2 Oesophagus and Gastro-oesophageal junction

The oesophagus is a tubular structure extending from upper oesophageal sphincter (18-20cm from incisor) to gastro-oesophageal junction (GOJ) (40cm from incisor in health). The oesophageal diameter is 1.5-2.0 cm. Oesophageal peristalsis is occasionally seen during endoscopy. Subtle depression on the oesophagus from external compression from the aorta (22.5 cm from incisor) on the posterior left of the oesophagus and the left main bronchus (27.5 cm from incisor) on the anterior left of the oesophagus below the aortic depression. The gastro-oesophageal junction (GOJ) is the point where the oesophagus becomes the stomach. Endoscopically, this junction is defined as the junction where the appearance of gastric longitudinal folds begin, the termination of oesophageal longitudinal vascular marking and the point of flaring of the stomach from the collapsed tubular oesophagus. At this point, the oesophageal lining consisted of squamous epithelium becomes that of the stomach lining consisted of columnar epithelium. (Figure 21) The squamo-columnar junction should lie within 0.5 cm below or 1 cm above the GOJ. The GOJ is normally 40 cm from the incisor and is normally compressed by the diaphragmatic crura. Note that about 2 cm of distal oesophagus is intraabdominal below the crura. The basal pressure as measured by intraluminal manometry in the lower gastroesophageal junction is between 10 - 40mmHg, with a peak pressure of up to 80 mmHg.[181]

The gastro-oesophageal junction is an area of great interest as defective function of this region leads to gastro-oesophageal reflux disease. Common abnormality in this region includes Barrett's oesophagus (more recently renamed to a more specific term columnar lined oesophagus), hiatus hernia, reflux oesophagitis, oesophageal varices (bead tortuous like chains of dilated submucosal veins). (BSG Guidelines: Barrett's oesophagus 2005) Other common oesophageal pathology of importance includes malignancy and stricture.

Figure 21: Endoscopic appearance of the oesophago-gastric junction.

5.1.3 Stomach

The stomach is a J shaped organ divided into: the fundus, the cardia, the body, the antrum. There is the lesser and greater curvature. The angularis (or incisura) on the lesser curvature marks the anatomical junction between the body and the antrum of the stomach, albeit histopathologically, antral mucosa actually extends proximal to the angularis. (Figure 22) Endoscopically, the gastric mucosa when not distended gives the appearance of longitudinal folds. Upon insufflation, the gastric mucosa smoothens out to give a salmon pink, glistening appearance. The stomach is a very distensible organ. Its dimension when it is empty is around 20cm in length and 8-10 cm in diameter. Newton et al used an intragastric barostat to measure the compliance of the stomach and found that to be about 60 ml/mmHg in healthy individuals. The study only filled the stomach up to about 800 ml. However, it is known that the stomach can accommodate up to 3L. The stomach accommodates mainly by increasing its diameter as well as increasing the length of the greater curvature. It is of note that the lesser curvature length and the incisura remain very much constant during insufflations. The process of the stomach accommodating to an increase in intragastric volume by increasing its diameter and greater curvature length is easily seen during endoscopy. This is especially important during ERCP where the side viewing endoscope is guided toward the pylorus by the greater curvature. This is also the mechanism of formation of a long gastric loop which can make entrance into the duodenum difficult. The stomach is a dynamic organ involved in storing, mechanically and chemically digesting food. The mechanical digestion of food is executed by frequent gastric peristalsis which begins from mid stomach body and head towards the pylorus at a frequency of 3 per minute. (Figure 23) The pylorus is normally opened at 1 to 2 cm in diameter but closes upon the arrival of the antral peristaltic waves. It is of note that the stomach overlies the spine, the aorta and the inferior vena cava. This gives it an inverted v shape when a patient is supine.

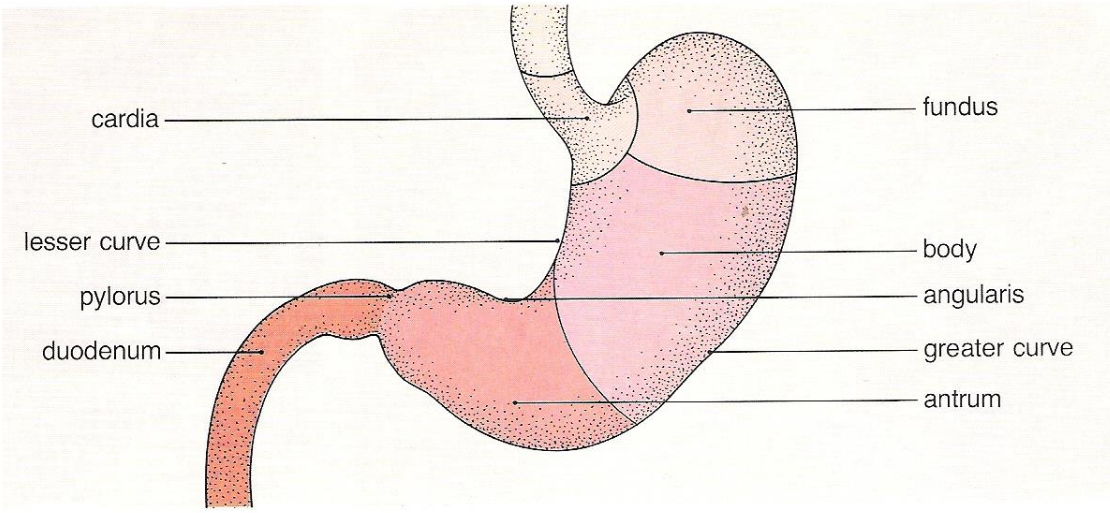


Figure 22: The shape of the stomach. (Moore & Dalley 2006)

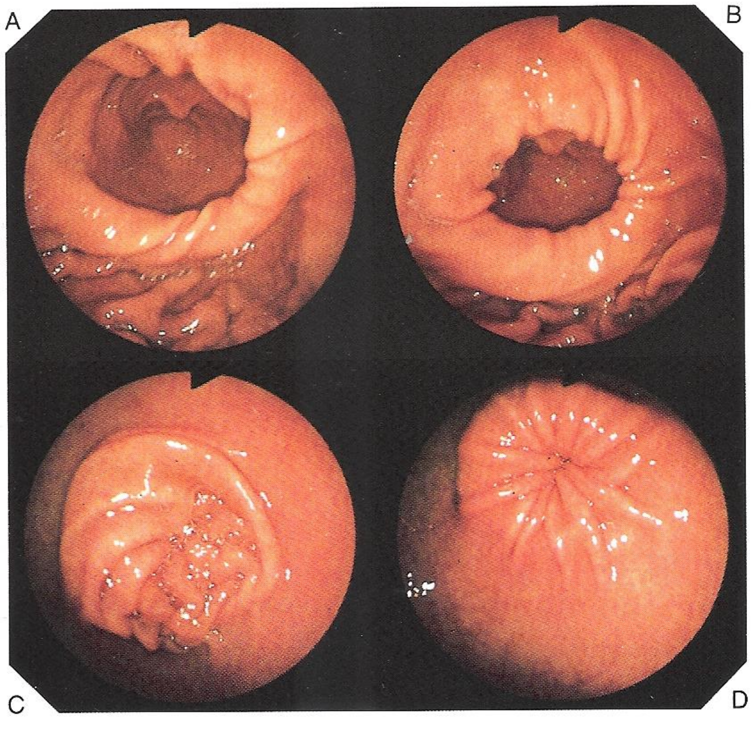


Figure 23: Antral peristalsis and closure of the pylorus. (Silverstein & Tytgat 1987)

5.1.4 Duodenum

The duodenum is the first part of the small bowel of 25-30 cm in length with a c shaped layout. It is about 3 cm in diameter. It is divided into 4 sections: The bulb (1st part), the descending (2nd) part, the transverse (3rd) part and the ascending (4th) part. The first part begins from the pylorus and is 4 to 5 cm long. Due to the curvature of the spine, the bulb and the 1st part of the duodenum is directed posterolaterally. The 2nd part is 7-8 cm long and runs caudally; the major and minor duodenal papilla could be located here. The major duodenal papilla is the landmark for locating the ampulla of Vater, the common bile duct and the main pancreatic duct. The minor duodenal papilla is the landmark for locating the minor pancreatic duct. The minor duodenal papilla is located about 2-4cm proximal to the major papilla. ERCP and biliary procedures take place in the second part of the duodenum. Endoscopes are rarely passed beyond the 2nd part of the duodenum. The 3rd part is 10 cm long and runs anteriorly and transversely towards the midline over the spine, inferior vena cava and the aorta. The 4th part is 5 cm long and runs cranially toward the duodenojejunal junction to the left of midline at the level of 1st lumbar vertebral transverse process in the pyloric plane. There are circular folds of Kerckring throughout the duodenum. The bulb of the duodenum may be difficult to visualize and operate on, especially in the presence of a J shaped stomach, where upon a long gastric endoscope loop is created in order to advance the endoscope through the pylorus. Upon entrance of the pylorus, elastic pressure stored in the endoscope gastric loop will advance the endoscope rapidly beyond the bulb. Upon withdrawal and straightening of the endoscope, it can often slip out of the bulb rapidly. This creates difficulty when one is trying to perform therapeutic procedures such as clipping of a bleeding ulcer in the first part of the duodenum.

5.2 Biomechanical properties of the human gastrointestinal tract

Studies of gastrointestinal mechanical property often neglect the organ's anatomical relation to the body; however, they provide insight into the mechanical properties of different UGI tissues. A Russian group studied the mechanical properties of the human oesophagus, stomach and small intestine using surgically resected specimens and cadaveric specimens.[182] It reported that the maximum stress and destructive strain for the oesophagus was 1.2 MPa and 140% respectively; for the stomach (axial) was 0.7 MPa and 190%; for the stomach (transverse) 0.5 MPa and 190%; and for the small intestine was 0.9 MPa and 140%. A graphic representation of the mechanical property of the stomach is presented in Figure 24.

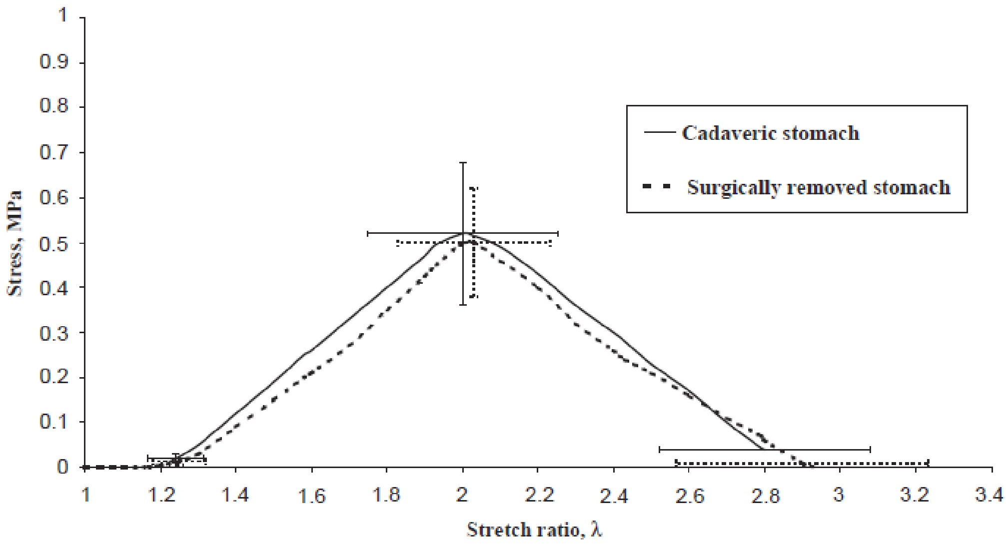


Figure 24: Mechanical testing of preserved cadaveric and fresh human stomach at 2λ strain rate. (Egorov et al 2002)

In vivo human biomechanical data has been a focus of investigation in the study of functional abdominal pain. Gastric accommodation is commonly investigated using intragastric barostat to investigate functional abdominal pain. The pressure volume relationship in healthy subjects is shown in Figure 25. [183] This demonstrates that the pressure-volume relationship of the human stomach is linear as suggested by the aforementioned human ex vivo data.

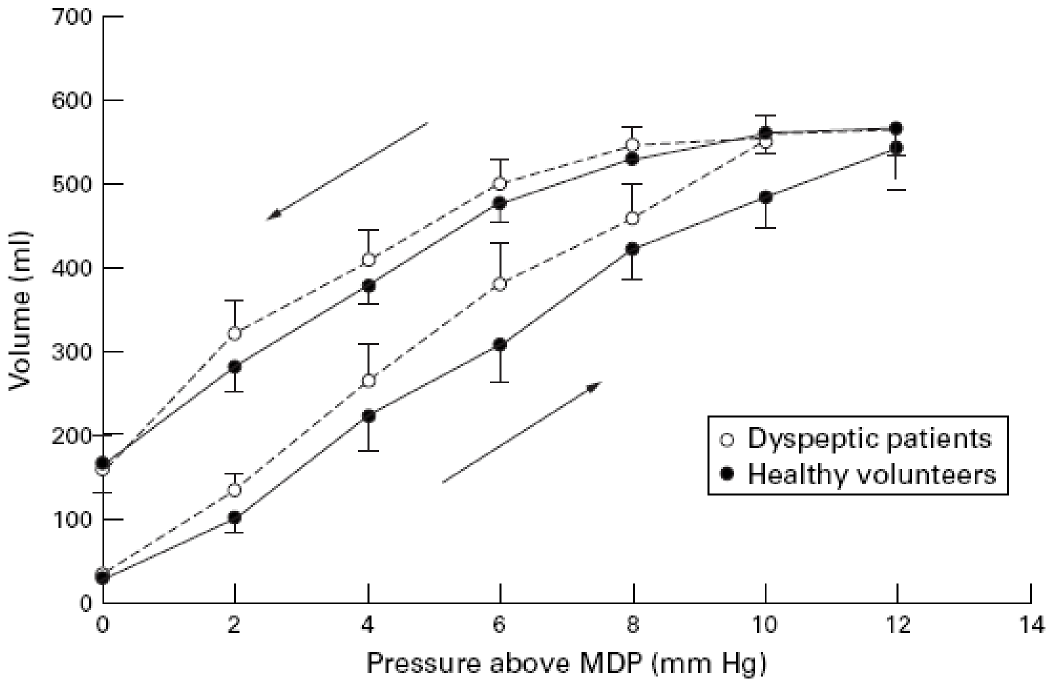


Figure 25: Mean volume-pressure curve in dyspeptic and healthy volunteers. (Salet et al 1998)

Different stomach regions have been shown to distend differentially in animal studies. In the rat stomach, it has been shown that the radii of curvature of the glandular portion of the stomach were greater than that of the non-glandular portion when insufflations pressure is less than 100Pa. When pressure exceeded 200pa, the vice versa is true.[184] Anisotropic mechanical behaviour of the stomach has also been shown in the porcine stomach, where the gastric fundus was found to be more stretchable longitudinally and circumferentially followed by the antrum then the body. (Figure 26) Although this has not been clearly demonstrated in human cadaveric study, in vivo study using ultrasound has demonstrated that during gastric distension, the stomach displays positive strain in the circumferential direction and negative strain in the radial direction and no strain in the longitudinal direction. [185], [186] The stomach is also a dynamic organ. Antral peristalsis can generate pressure of >100mmHg. [187] During distension, peristalsis has been demonstrated to increase in frequency. (Figure 27)

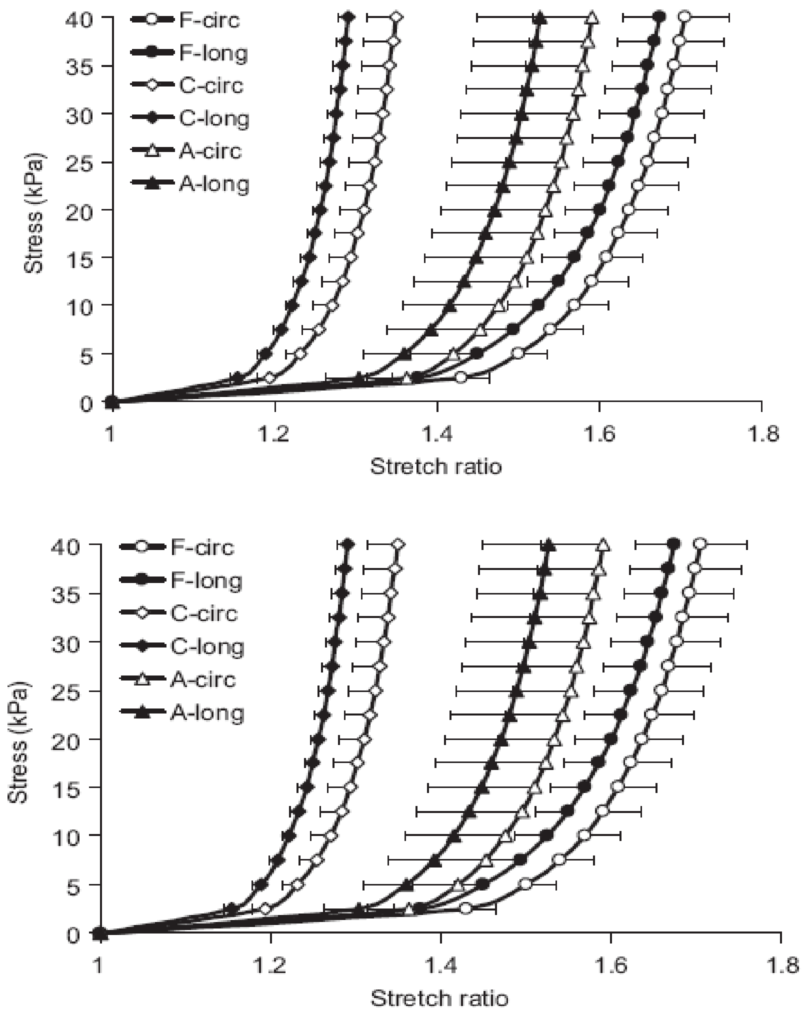


Figure 26: Regional stress strain relationship difference between gastric fundus (F), corpus (C) and antrum (A). This highlights the anisotropic mechanical property of the stomach. (Zhao et al 2008)

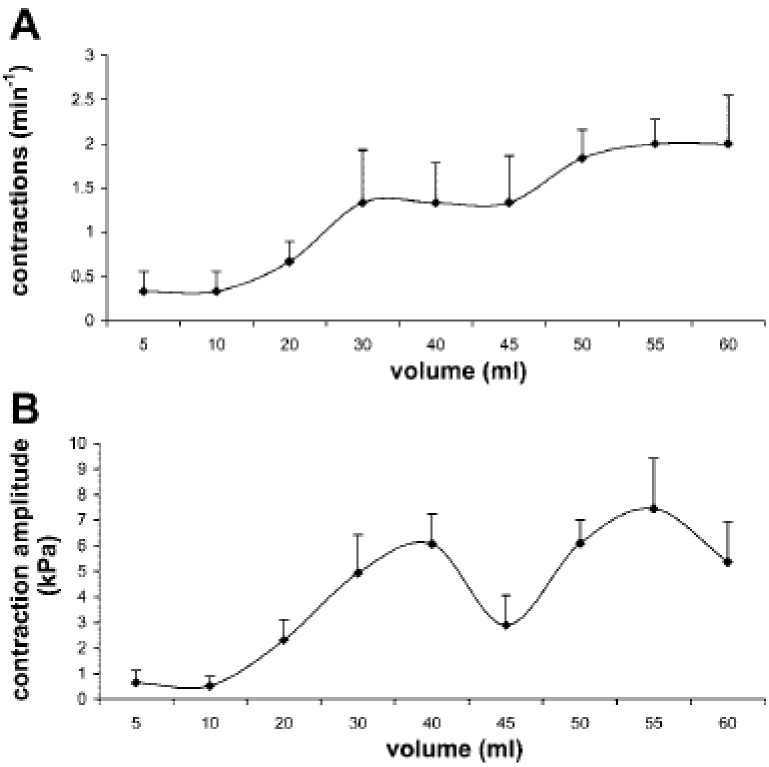


Figure 27: Antral contraction frequency (A) and amplitude (B) as a function of gastric distension. (Gregerson et al 2002)

5.3 Three dimensional reconstruction of the human upper gastrointestinal tract

5.3.1 The Visible Human Project

The Visible Human Project was originally conceived to create a data set of cross sectional images of the human body for the purpose of creating anatomy visualization applications. It is run by the United States National Library of Medicine. It consists of digital data based on frozen sections in the axial plane at 1 mm intervals of a male cadaver and a female cadaver.[188] MRI and CT data of the cadavers are also available. Datasets could be obtained through the NLM VHP ftp site. The data is in .BMP format. (Figure 28)

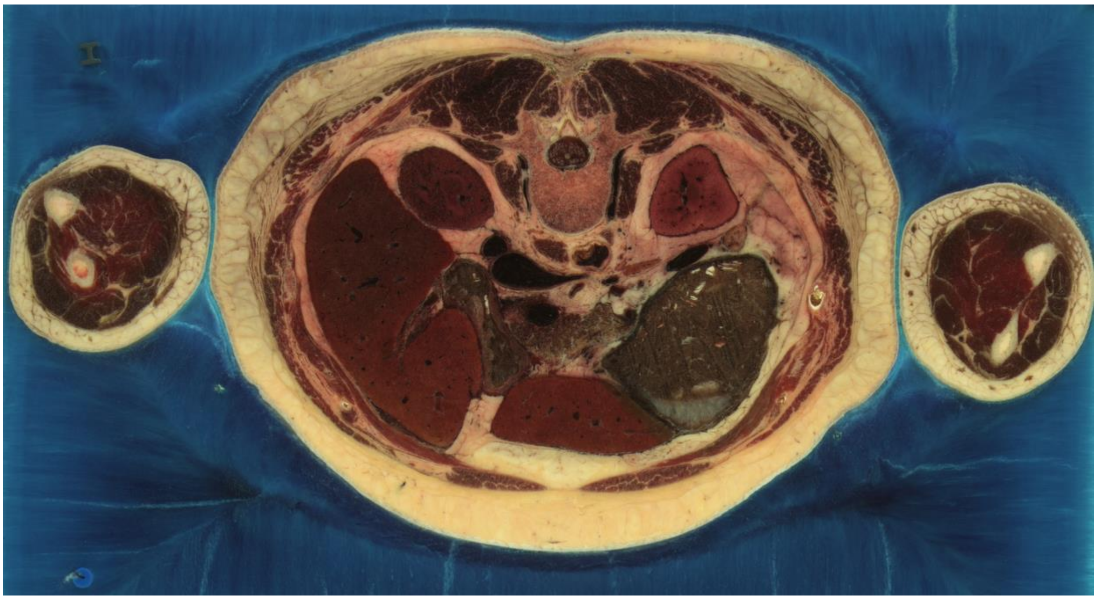


Figure 28: Cross sectional image of the human body at the level of L1 from the Visible Human Project database. (Visible Human Project, NLM)

5.3.2 Development of three dimensional computer model of the human upper gastrointestinal tract

Although numerous softwares have been created for the visualization of the VHP data, the quality of soft tissue organ rendering remains poor.[189] In order to gain a clear understanding of the upper gastrointestinal tract, the VHP cross sectional images were analysed using 3 dimensional reconstruction softer Materialise Mimics software. Three dimensional model can be reconstructed though automatic thresholding function offered by the mimics software. However, unlike bone, soft tissue has a large range of densities, thereby rendering the technique of automatic thresholding an unsuitable technique to generate an accurate three dimensional model of the upper gastrointestinal tract and biliary tract. In order to optimize the accuracy and quality of the model, a significant amount of manual thresholding was required to create a high resolution upper gastrointestinal model. (Figure 29) Based on this work a detailed three dimensional computer model was created. The result is superior to previously published models. (Figure 30) It can be seen that the human stomach and duodenum curves in the coronal, sagittal and the transverse planes as dictated by its neighbouring relations with the human spine, major vessels of the abdomen and the pancreas. This is not easily appreciated in the classical anatomical presentations of the stomach. Based on the one to one scaled model, an inflated stomach at 200% is also modelled. (Figure 31) This serves as a representation of what the stomach might look like during distension.

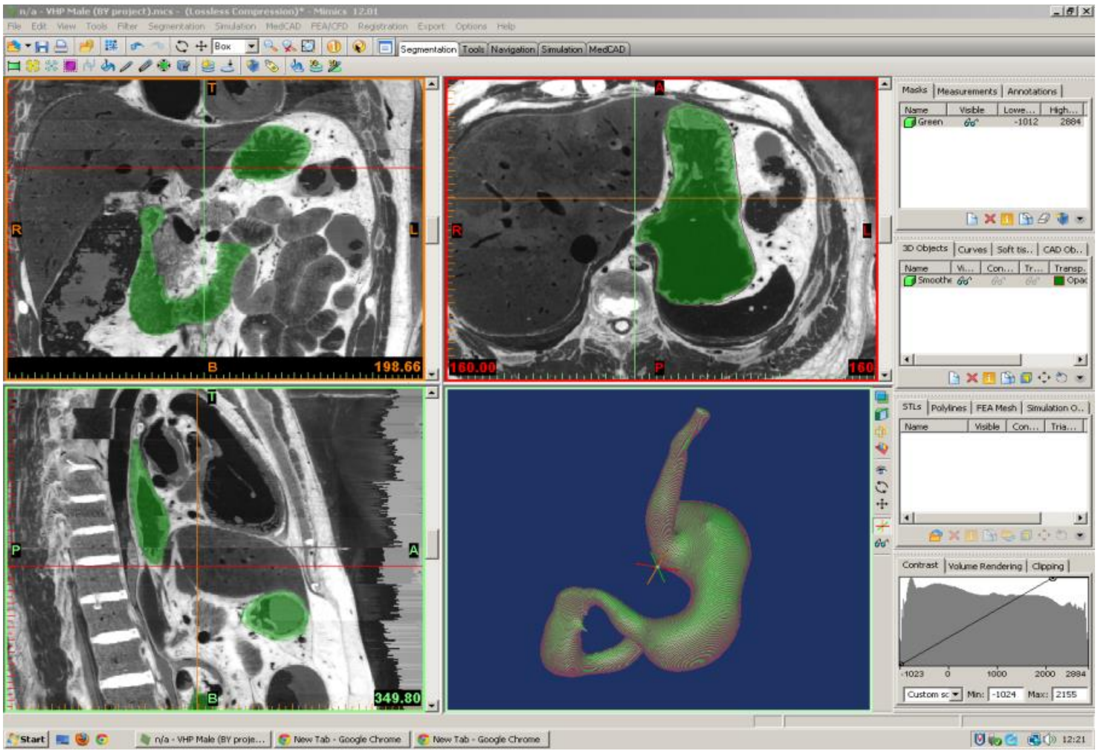


Figure 29: Process of manual thresholding using Mimics software.

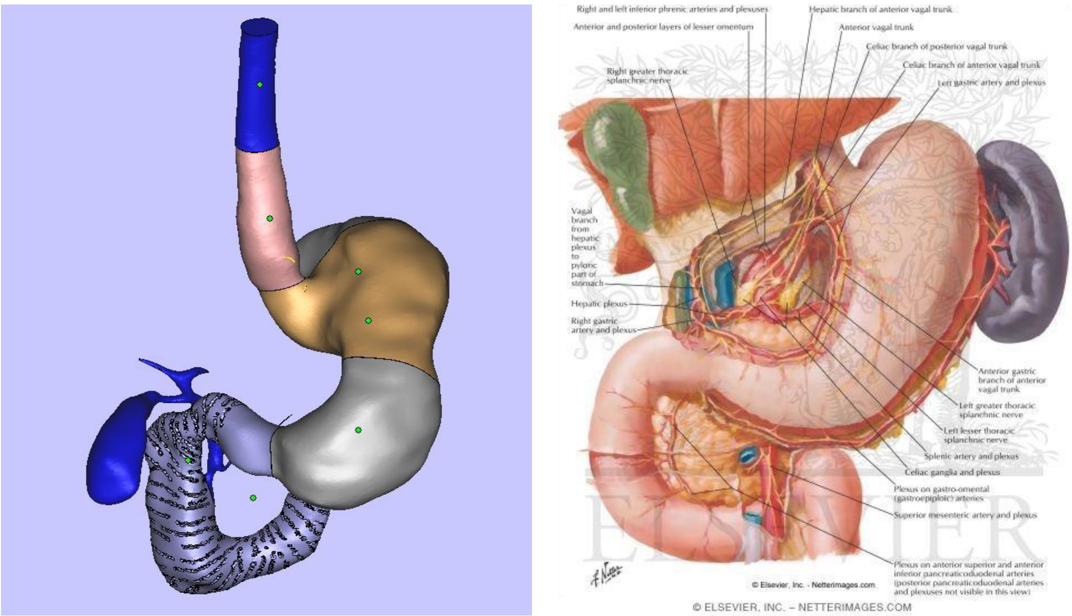


Figure 30: UGI tract including the oesophagus, stomach, duodenum and biliary tree is developed. In contrast to conventional human anatomy images on the right, the three dimensional model of the left allows one to appreciate the three dimensional nature of the upper gastrointestinal tract.

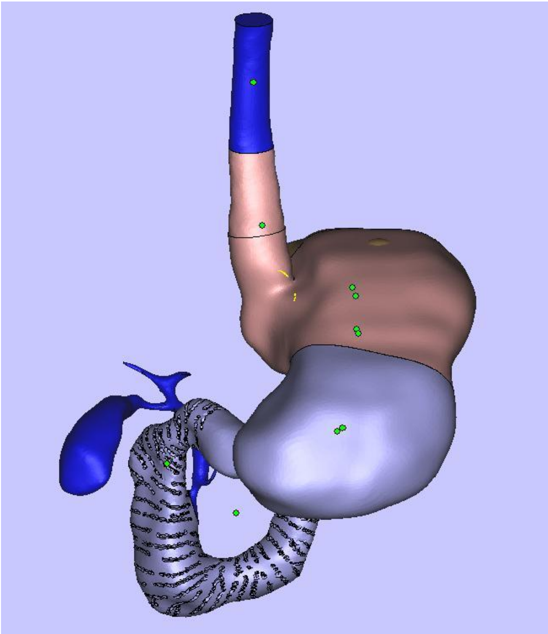


Figure 31: UGI tract model with stomach enlarged to 200% of original size to simulate gastric distension after insufflation.

5.3.3 Rapid prototype of upper gastrointestinal model

In order to further appreciate the upper gastrointestinal tract, the aforementioned computer models were manufactured using selective laser sintering of polyamide. (Figure 32) This service was purchased from http://www.11th-hour-prototypes.co.uk. In order to minimize the cost of prototyping, the 3 dimensional models are shelled out to create a hollow 3 D model of the UGI tract. Due to the dimension limitation of the prototyping technology utilized, the oesophagus and stomach are divided into 3 pieces respectively. The duodenum is printed in one piece.

Figure 32: Prototyped UGI models in nylon. Parts to the left include oesophagus and duodenum. Parts in the middle consist of the fundus, body and antrum of the stomach at 100% size. The parts to the right consist of fundus, body and antrum of the stomach at 200%.

5.4 Existing Upper Gastrointestinal Models

Mechanical simulators were developed soon after the development of modern flexible endoscopy, and ever since have been further refined. Reduction in clinical exposure and increasing medico legal consequences of health care related complications have led to an increase interest in creating effective endoscopic simulators. Upper gastrointestinal (UGI) endoscopic models can be classified into 3 groups: mechanical models with or without ex-vivo organ components, computer simulators and live animal models.

5.4.1 Mechanical Models with or without Ex Vivo Organs

In 1971, Heinkel from Germany designed a rubber UGI model.[190] In 1974, Classen and Ruppin from Erlangen developed an anatomically shaped mannequin for UGI endoscopy training.[191] However, these models do not simulate real life endoscopic experience effectively enough to gain wide spread usage. Indeed, a survey of upper gastrointestinal experts from South Africa, Japan, Australia, and Belgium all suggested that either plastic models are of limited use or not available within their training programme.[192]

In 1997, Hochberger and colleagues from Erlangen, Germany, published their design of an endoscopic simulator which became one of the most popular endoscopic simulators. Based on the Neumann biosimulation model, which was a surgical model using ex-vivo porcine UGI tract in a mechanical frame, Hochberger modified it by adding endoscopic pathology simulation such as bleeding peptic ulcer. He incorporated ideas such as the use of a pulsatile vessel to simulate bleeding vessels. This model was called the EASIE (Erlangen Active Simulator for Interventional Endoscopy/Erlanger Ausbildungssimulator für die Interventionelle Endoskopie) simulator (Figure 33). In 2001, it became commercially available as the Erlangen Endo Trainer. [193] The endo trainer provides a mechanical framework to attach an ex-vivo specimen of porcine UGI tract procured and frozen according to food & hygiene regulation. The mechanical framework consists of an anatomically formed torso and head which could be rotated on along the cranio-caudal axis. The typical ex-vivo specimen consists of an oesophagus 25cm proximal to the

GOJ, the stomach and duodenum extending 15 cm distally from the pylorus. Studies from Swain's group in London, suggested that porcine stomach from 20-30 kg animals provides the closest match to the human stomach in terms of tissue thickness and stiffness.[194] Additional anatomical detail such as neo-papilla has been devised.[195] Simulated bleeding ulcers are created by securing short segments of blood vessels through the stomach wall. The vessel is then attached to a perfusion pump which simulates pulsatile projection similar to a bleeding artery (Figure 34). A narrow gauge catheter was tried as a blood vessel substitute, but this was found to be unsatisfactory. Other pathologies were simulated including: polyps (by bunching up mucosa and securing it with a ligature at the base thus creating a pedunculated polyp), varices (by injecting gelatine or implanting beef tongue submucosally). Other procedures such as endoscopic retrograde cholangiopancreatography (ERCP), endoscopic mucosal resection (EMR), and chromoendoscopy could also be simulated. The advantage of using ex vivo tissue is that tissue compliance, handling and response to therapeutic procedures closely mimic real life situation and have been shown to be well received by endoscopic trainees.[196] The Erlangen Endo trainer weighs 30kg. The CompactEASIE was designed to be a portable endoscopic trainer (Figure 35). It consists of a plastic basin which allowed the attachment of the oesophagus, and a perfusion pump. The Compact EASIE system can be purchased for around 5000 Euros, which includes 2 simulators with pumps and a training the trainer session with Hochberger's team at Hildesheim, Germany.[197] The cost of additional training specimens, technician for specimen preparation, and disposal of used specimens is about $150-200 USD per training session.[198] The Erlangen Endo trainer has been used to test endoscopic instruments, such as the Eagleclaw II endoscopic suturing device.[199]

Figure 33: Erlangen Endo Trainer (Hu et al 2005)

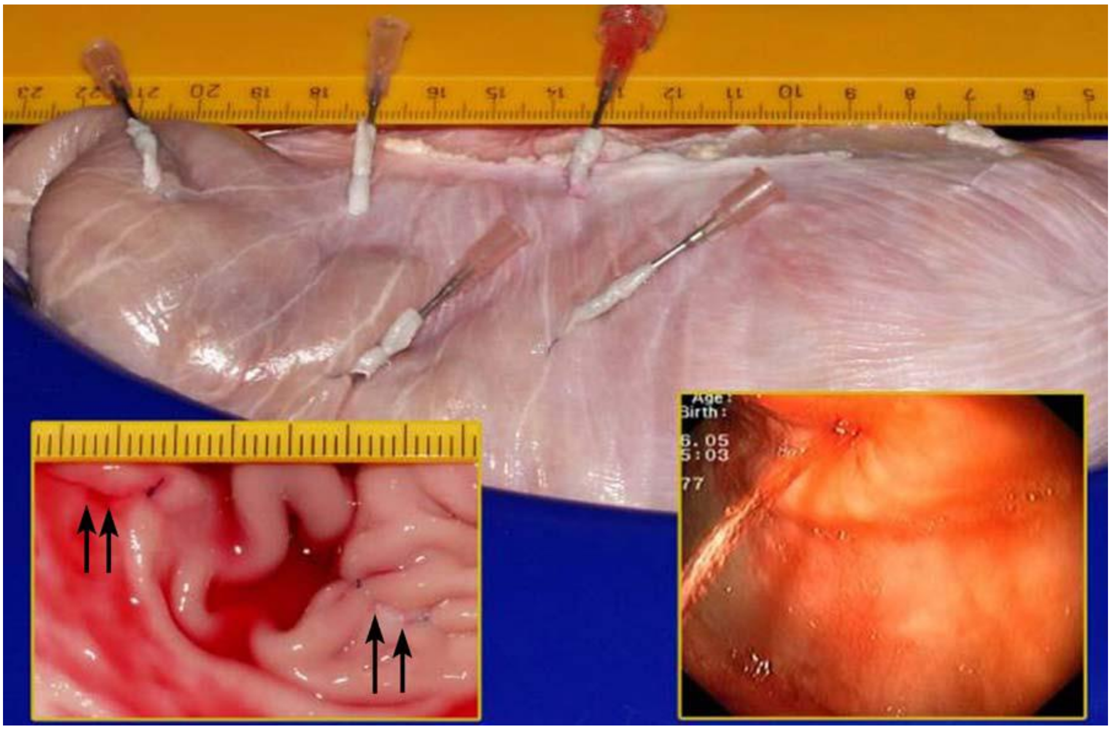


Figure 34: Vessels implanted transmurally to simulate a bleeding ulcer (Matthes et al 2006)

Figure 35: CompactEASIE system (Hochberger et al 2006)

Around the same period, in 1998, Grund's group from Tübingen University described a UGI simulator that was wholly mechanical. The Interphant simulator has not been commercialized. This group designed a simulator which allowed simulated use of electrocautery by using materials such as Artitex, (a waxy electroconductive waxy material) to mimic polyps.[200]

The Endoscopic-Laparoscopic Interdisciplinary Training Entity (ELITE) model is designed to simulate NOTES surgery. (Figure 36) It is a synthetic model that allows simulation of endoscopy and laparoscopic surgery. [201], [202] It is developed by the research group MITI (Klinikum Rechts der Isar), Germany and manufactured by Coburger Lehrmittelanstalt (CLA, Coburg, Germany). It is a one to one scaled reproduction of a female human torso. The abdominal wall is air tight and allows insertion of trocars for laparoscopic surgery simulation. It contains a synthetic gastrointestinal tract with gas tight valves at the oesophagus and the rectum, thus allow insufflation and endoscope insertion. It is not dynamic. It also has simulated latex organs including liver, gallbladder and spleen. Tissue planes are simulated by a special cotton sponge layer soaked with saline solution. This electrically conductive layer allows the application of diathermy dissection. Respiratory movement is simulated by intermittent insufflation of two elastic balloons integrated into the diaphragm domes below the artificial organs. Validation study for transanal endoscopic access, identification of intra-abdominal targets showed that the model distinguished between novices and experts in terms of speed in completing the identification of targets.[203]

Figure 36: ELITE simulator designed for natural orifice transendoscopic surgery (NOTES) experimentation.

Other wholly mechanical simulators of the UGI tract are available and they are mainly focused for simulating ERCP. Koken Company, Japan commercialized the ERCP training model type E which is made of silicone rubber. It has optical sensors throughout the model that ensures the endoscopist had visualized important areas during endoscopy examination. (Figure 37) Leung et al from Sacramento USA described an UGI simulator for use in endoscopic retrograde cholangiopancreatography (ERCP) training.[204] The model was not anatomically accurate. It consisted of 2 tubular parts: the "upper gut" made of flexible corrugated tube and the second part of duodenum made of molded soft rubber tube contained in an acrylic cage. The second part of duodenum had a window which allowed the placement of a foam model of the major duodenal papilla with two 8F tubing representing the biliary and pancreatic duct lying in correct anatomical orientation with electrical contacts. The bile duct tubing was replaceable with different designs to mimic various pathologies and was made of transparent Tygon (United States Plastic Corp, Lima, Ohio) which allowed visualization of the biliary tree procedure by an optical camera. (Figure 38) ERCP performance scoring scales and training outcomes have been assessed base on this model. This model however does not simulate the main challenge of ERCP such as driving and navigating a side viewing endoscope, managing the consequences of gastric loop formation, and performing precise therapeutic procedures use the long or short endoscopic positions.

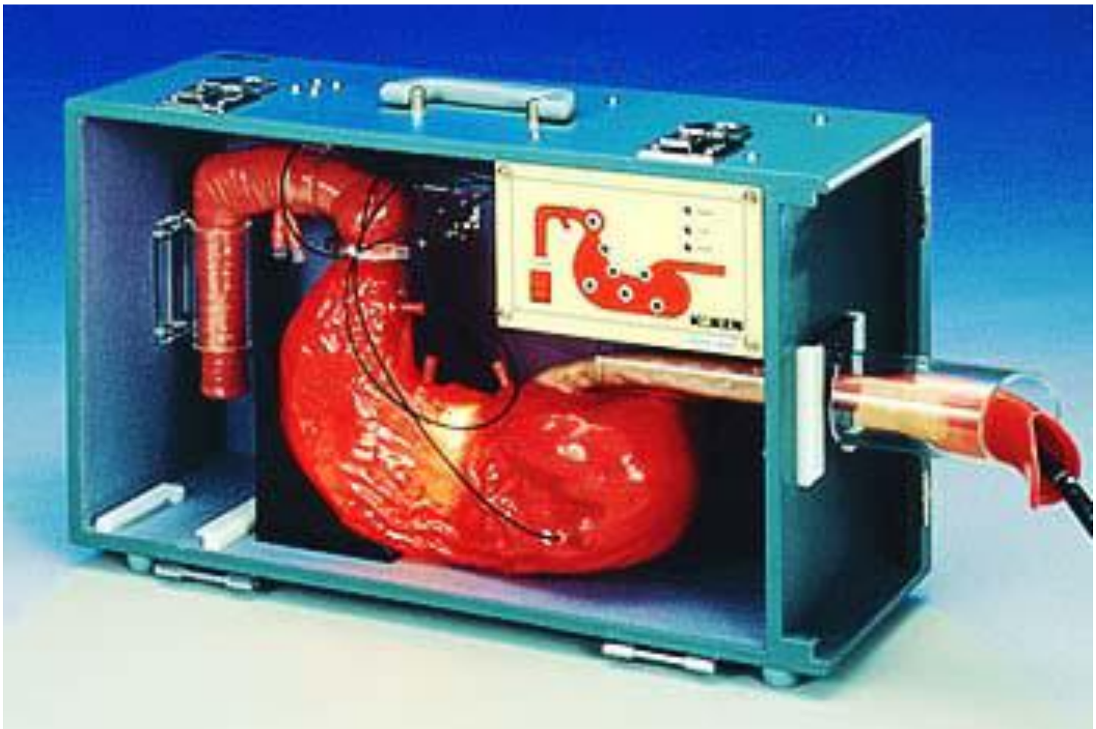


Figure 37: Koken ERCP training model type E with indication function

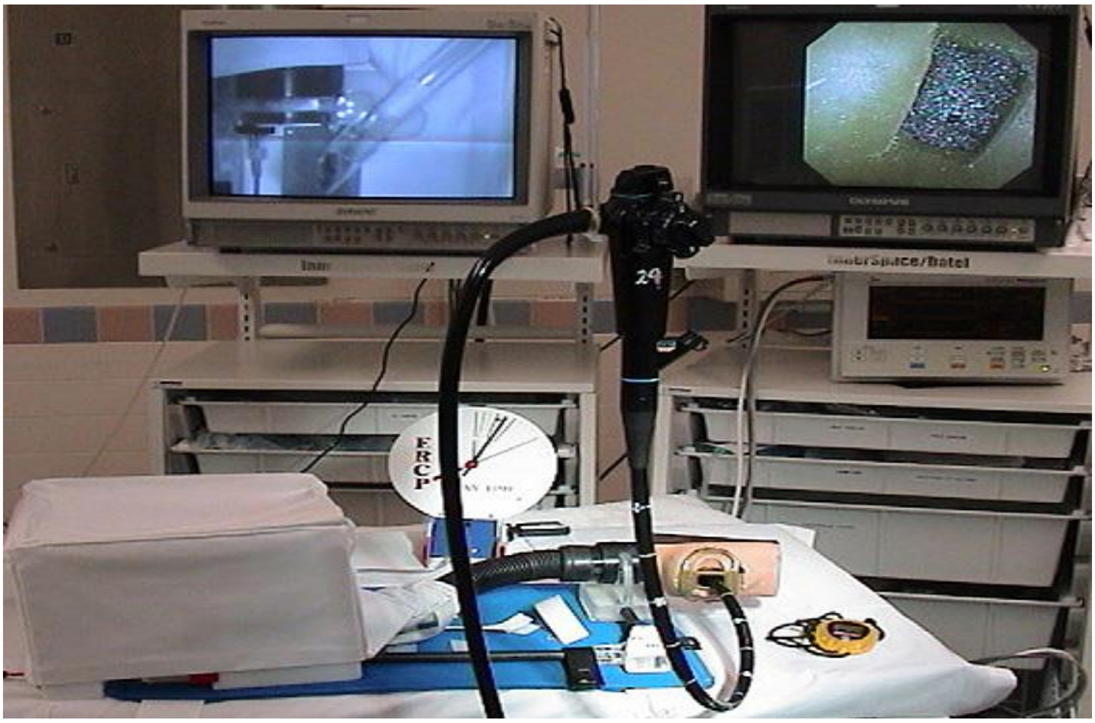


Figure 38: Leung's ERCP simulator

5.4.2 Computer Simulators

The complexity of UGI diagnostic and therapeutic endoscopy has made computer simulations unpopular as they are expensive and provide limited realism. However, they do provide ergonomic data feedback which theoretically should improve performance, and do not require the purchase and setup of ex vivo tissue or animal tissue. They do not provide very good tactile feedback. One of the more available simulators is the Simbionix GI mentor. (Figure 39) The system consists of a mannequin and a modified Pentax endoscope. Tissue response is mimicked by using data from endoscopies. It contains UGI, colonoscopy, sigmoidoscopy, ERCP, EUS modules. In the haemostasis module, it has 10 virtual patients with upper GI bleeding and allows the practice of using epinephrine injection and electrocoagulation. The price range is $50,000 to $100,000 USD depending on the number of modules required.[205], [206]

Figure 39: Simbionix GI mentor

The Accutouch simulator is another popular model of endoscopic computer simulator. It is designed by Immersion Medical (Maryland USA, founded in 1993). It provides auditory, visual and tactile feedback during endoscopy simulation. It consists of a mechanical interface with an orifice for introduction of a simulated endoscope. The computer simulations were developed from real CT images used in the Visible Human Project. It has OGD, ERCP and colonoscopy with polypectomy modules. It attempts to simulate loop formation, contractions and resistance through force feedback onto the simulated endoscope. A computer voice gives feedback to performance, for example, a voice mimicking pain will be sounded upon excessive air insufflation and induction of pain. The computer also simulates complication such as oversedation, and provides ergonomic and economy of movement data. Early experience suggests that its ergonomic data correlates with the level of experience of the endoscopist. [207] A small study by Gerson & Van Dam 2003 suggested that it is inferior to real life training when trainees who used the system unlimited times were compare to those who did 10 sigmodoscopies. Other studies have shown that it compliments real life training at least in the early stage of endoscopic training. [208] Currently, computer simulators are deficient in accurate simulation of organ insufflation and endoscope resistance.[209]

5.4.3 Live animal models

Live animal models are the gold standard for testing endoscopic therapies such as endoscopic haemostasis. They require ethics approval, and animal caring facilities and expertise before, during and after testing. Pigs will take up to 2 days to clear its gastric contents after fasting and they have different biliary anatomy when compared to humans. [210] They also require an anaesthetist. Therefore, although live animals offer a very realistic dynamic simulation, they are expensive; and its use have been limited to research purposes rather than for training endoscopists.

Numerous designs have been created to simulate upper gastrointestinal pathologies, such as peptic ulcers. In 1981, Dennis et al created a reproducible ulcer model which became the standard for testing endoscopic haemostatic therapies.[211] Pinkas et al in 1995 created an ulcer model in dogs. They anaesthetized the dogs and performed a laparotomy. The stomach is then opened and the penetrating left gastric artery branches were identified. The mucosa covering the vicinity of the artery is removed thereby creating a non-bleeding ulcer.[212] Sugawa et al 1999 used a similar technique, but used the gastroepiploic vessels to simulate torrential UGI bleeding.[213] Hepworth et al used the mesenteric vessel as a model for bleeding.[214]

5.4.4 Limitations of current simulators

Currently, no endoscopic simulator can fully simulate the environment where therapeutic endoscopy is undertaken.

1) Simple mechanical models do not simulate the dynamism of the UGI tract, and the biomechanical properties of human tissue.

2) The Erlangen Endotrainer, although uses ex vivo organs and therefore offer realistic tissue response and simulation, does not offer a dynamic environment (such as the effect of antral persistalsis). It also does not simulate the anatomy of the UGI tract fully (such as the effect of the spine in creating a curvature of the stomach and the duodenum three dimensional orientations). It will be difficult to replicate the challenging bleeding ulcer (such as those in the first part of the duodenum and the posterior wall of the

antrum along the lesser curvature) if UGI tract three dimensional spatial orientation within the abdomen is not simulated.

3) Computer simulation is expensive and does not offer a realistic environment. It does not allow the testing of a novel platform for endoscopic therapy.

4) Animal models are expensive and pose many logistical challenges to testing early proof of concept models.

5) Other factors such as the physical characteristic of an ulcer, such as the rigid base which makes endoscopic suturing difficult, are not effectively simulated in ex vivo models.

5.5 An Ideal Upper Gastrointestinal Simulator

Based on the accurate anatomical model achieved, a mechanical UGI model is proposed. Possible materials required include rubber or silicone, Lycra, a plastic basin, electric motor and peristalsis mechanism. Potentially, the stomach and duodenum could be made in 2 layers: an external layer of Lycra and an internal layer of coloured silicone laid down in a plicated fashion. (Figure 41) The lesser curvature would be fixed to prevent distortion as in real life situation. The antrum will be encircled by a peristalsis generator. UGI pathologies can be simulated in a similar fashion to that of the Erlangen Endotrainer using ex vivo animal tissue and in built pulsatile perfusion pump. Small squares of ex vivo animal stomach with a simulated pathology such as a bleeding gastric ulcer is prefabricated and contained in an electrically conductive frame. These simulated pathology frames can then be inserted in windows premade within the UGI model. The metal frames can be linked with electric wires to allow the use of electrocoagulation. This can be safely conducted if the entire UGI simulator is enclosed within an insulated box. The use of prefabricated simulated pathologies obviates the need of using whole ex vivo organs, which are troublesome to set up. These simulated pathologies can be mass produced, easily stored and accessed when required. (Figure 42)

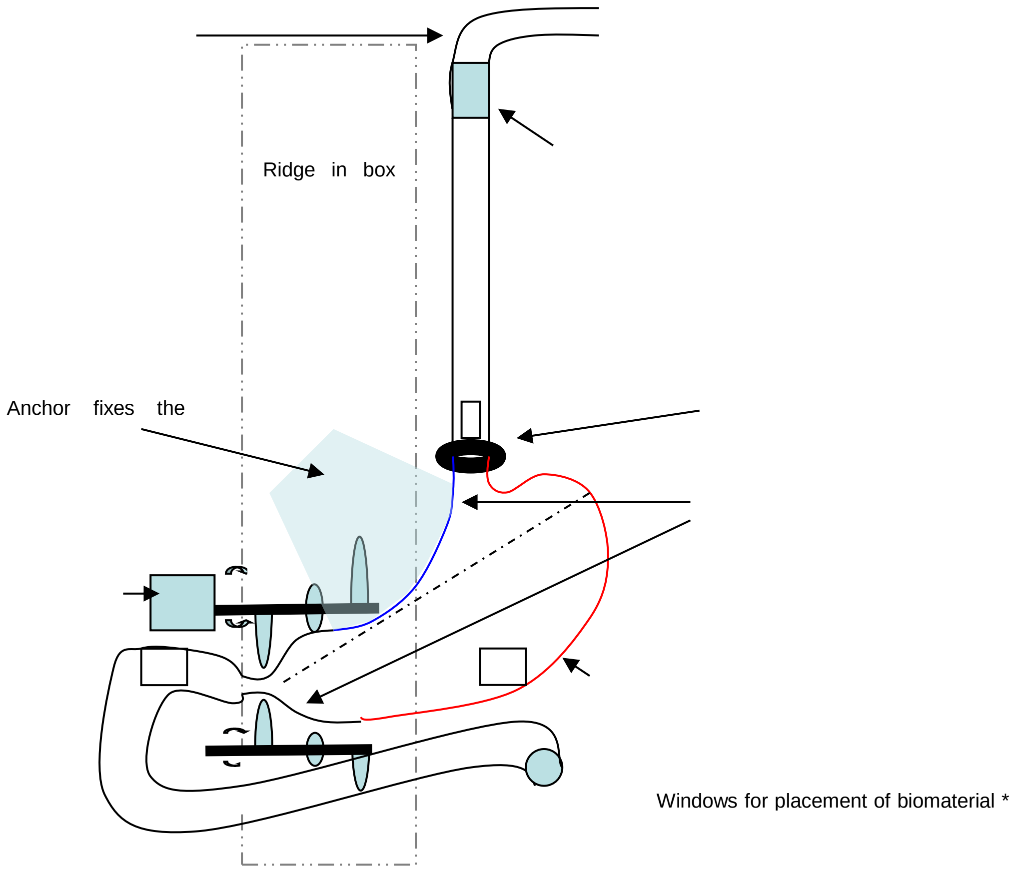


Figure 40: Initial proposed simulator design.

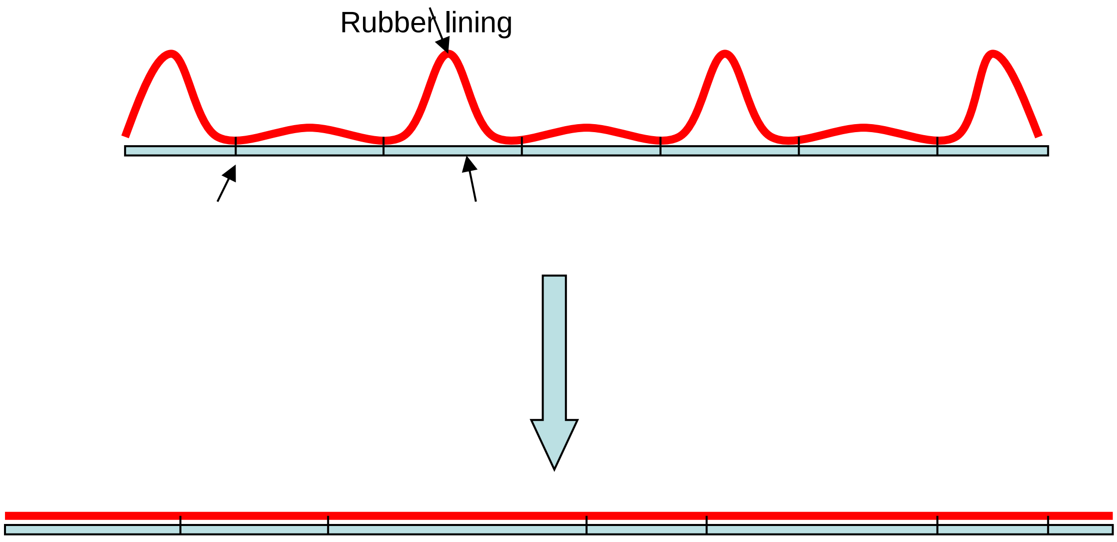


Figure 41: Double layer configuration for the stomach and the duodenum.

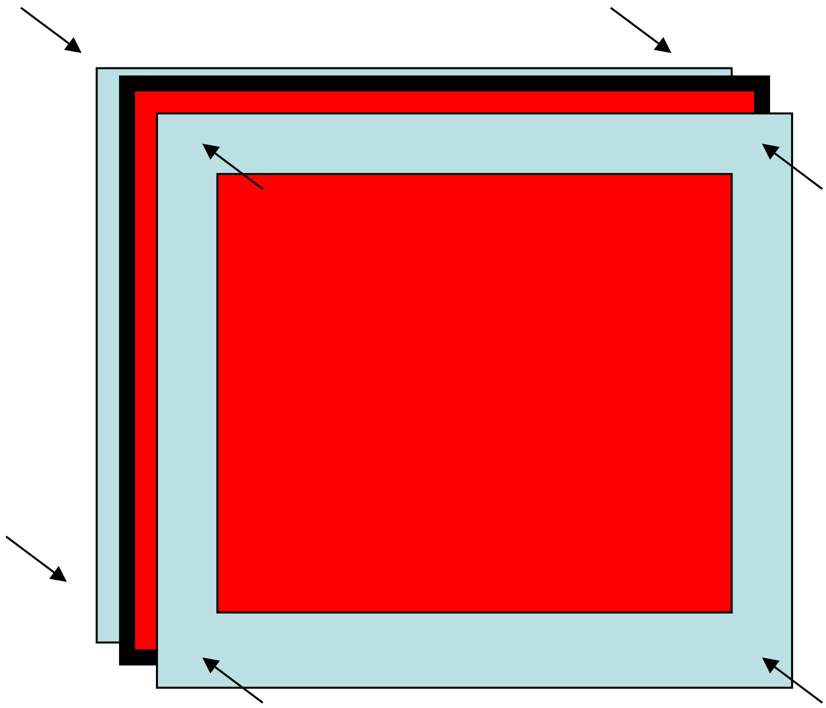


Figure 42: Prefabricated simulated pathology created from ex vivo porcine tissue sandwiched between 2 metal (electrically conductive) frames which slots into prefabricated electrically linked metal grooves in the UGI model.

5.5.1 Change in Research Direction

During the period of development, it became apparent that high quality anatomical phantoms are commercially available at reasonable cost. Therefore, it was determined that the proposed complex upper gastrointestinal simulator offered no real advantage over existing highly improved phantoms. For the purpose of the present work, which is to test the ability of the platform to access the upper gastrointestinal tract, we decided to use an existing phantom to characterise our novel platform's functionality.

The AC4 OGI phantom (Figure 43) is purchased from www.adam-rouilly.co.uk. It is specifically designed for the purpose of training endoscopists in the performance of oesophagoscopy and endoscopic retrograde cholangiopancreatography. It is anatomical and made of durable plastic.

Figure 43: Stomach, duodenum, bile duct model – AC4 OGI Phantom. (http://www.adam-rouilly.co.uk)

A Trucorp Airsim Model (Multi) was purchased for testing of the novel platform’s ability to negotiate through the oral cavity and pharynx. (Figure 44) The model is constructed based on anatomical data of the nasal cavity, oral cavity, pharynx, upper airway and upper oesophagus. In addition, its neck construction allows the head to be moved and secured in life-like fashion.

Figure 44: Trucorp Airsim Model (Multi). Endoscopic view of the vocal cords can be seen on the right. (www.trucorp.com)

5.6 Chapter Summary

1. The human upper gastrointestinal tract is complex and a novel device has to have significant manoeuvrability in order to negotiate through it.

2. Three dimensional reconstruction of the upper gastrointestinal tract has clearly demonstrated the three dimensional nature of the upper gastrointestinal tract.

3. Endoscopic simulators are used by endoscopists to practice endoscope techniques. They can be categorized into mechanical models, animal models or computer models. Each type of simulator has its benefits and deficiencies.

4. During the period of development, it became apparent that high quality anatomical phantoms are commercially available at reasonable cost. Therefore, it was determined that the proposed complex upper gastrointestinal simulator offered no real advantage over existing highly improved phantoms. For the purpose of the present work, which is to tests the ability of the platform to access the upper gastrointestinal tract, we decided to use an existing phantom to characterise our novel platform's functionality.

Chapter 6: Design Overview of a Novel Endoscopic Multitasking Platform

Details of the design and control software algorithm can be found in appendix A, B, C & D.

6.1 Design Objectives

The design of the modern endoscope has been refined significantly since its inception in the 1950's. Its ergonomics has been well adapted to negotiate the complex upper gastrointestinal tract as demonstrated in chapter 5. The proposed device therefore will continue to adopt the outlay of the modern endoscope. However, it should confer a level of independent instrument freedom akin to that seen in conventional laparoscopic surgery. In conventional laparoscopic surgery, instruments typically have up to 5 degrees of freedom. The aim of the device is to allow intuitive bimanual performance of endoscopic therapy without compromising its manoeuvrability. The design objectives are:

1.	The novel endoscope should have a similar outlay and manoeuvrability as the current endoscope (ie four degrees of movement)
2.	The novel endoscope should have two instrument channels.
3.	It should allow rapid instrument exchange.
4.	It should apply micro motor technology to manipulate instruments in a fashion akin to the fly-by-wire concept as seen in the aerospace industry.
5.	The design should allow up to five degrees of freedom of independent instrument movement.
6.	Instrument control will be delivered through digital controls.
7.	Ideally, it should utilize off the shelf technologies to minimize the cost of development.

Table 2: Robotic endoscopic platform design objectives.

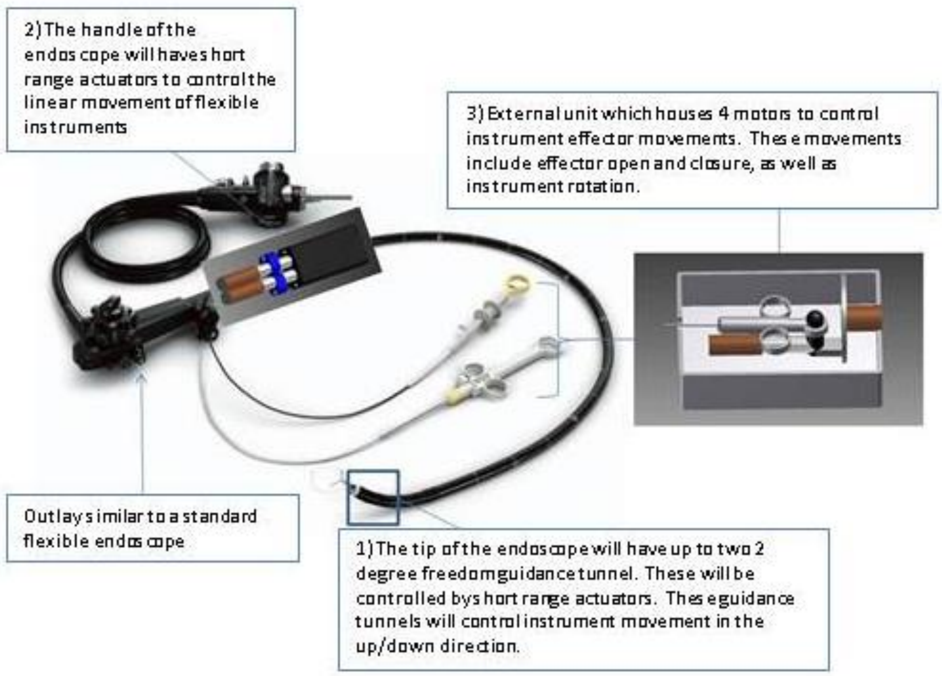


Figure 45: Overview of the setup of the design.

The novel endoscope has three components: the front unit, the handle and the external unit which houses any compatible endoscopic instruments. An overview representation can be seen in Figure 45.

6.2 The Front Unit

The front unit is the most important part of the device. It houses four micromotors which in turn manipulates two guidance channels with two degrees of movement. When an endoscopic instrument is passed through the guidance channel, it will be able to deform the instrument in up/down/left/right direction. Currently, servo micromotors (ie motor with inbuilt position sensing) of sufficiently small size are not available. Therefore, position sensing through alternate method is necessary. With this information, the guidance channel position can be calculated. This is important as the information obtained by comparing expected position change and actual position change of the micro motors will allow the inference of tissue resistance, thereby calculation of haptic feedback. The front unit also houses a micro camera, air/water insufflation channel, and light source. In its entirety, the front unit can be no wider than 22mm as indicated by previously described endoscopic multitasking platform in chapter 3. (Table 1) In order to replicate the manoeuvrability seen in a conventional endoscope, the front unit will attach to a standard endoscope bending section and insertion tube. (Figure 46) A generic bending section consists of a chain of interlocking metal rings which bends in 2 planes up to 270 degrees. A generic insertion tube forms the bulk of the endoscope acting as the conduit between the endoscope handle and the front unit. An insertion tube is usually a composite structure consisting of flexible spring steel coil, stainless steel mesh, and fluid resistant plastic such as neoprene.

Figure 46: The front unit which houses the motor mechanism to control two guidance tunnels are connected proximally to a generic bending section and insertion tube.

In designing the front unit, we focused on five key objectives:

1. To actuate a two degree of freedom guidance channel from two actuators held in a fixed position.

2. To create a compact design which allows two set of mechanism (two guidance channels) to be housed in a small front unit as dictated by the necessity of it being able to negotiate through the human gastrointestinal tract.

3. To design a mechanism that will allow free passage and exchange of endoscopic instruments.

4. To design a mechanism that is sufficiently small yet robust enough to be manufactured using metal rapid prototyping technology which has a minimum wall thickness of 0.5 mm.

5. To design a mechanism that is able to transmit sufficient force that is able to manipulate soft tissue in a meaningful way.

6.2.1 Front Unit Frame

The front unit frame serves as the skeleton of the front unit. It will encase 4 micro motors and provide anchorage of two guidance channels each capable of two degrees of freedom of movement. It will also provide sufficient space to allow the passage of endoscopic instruments, electrical wiring and air/water insufflation channel.

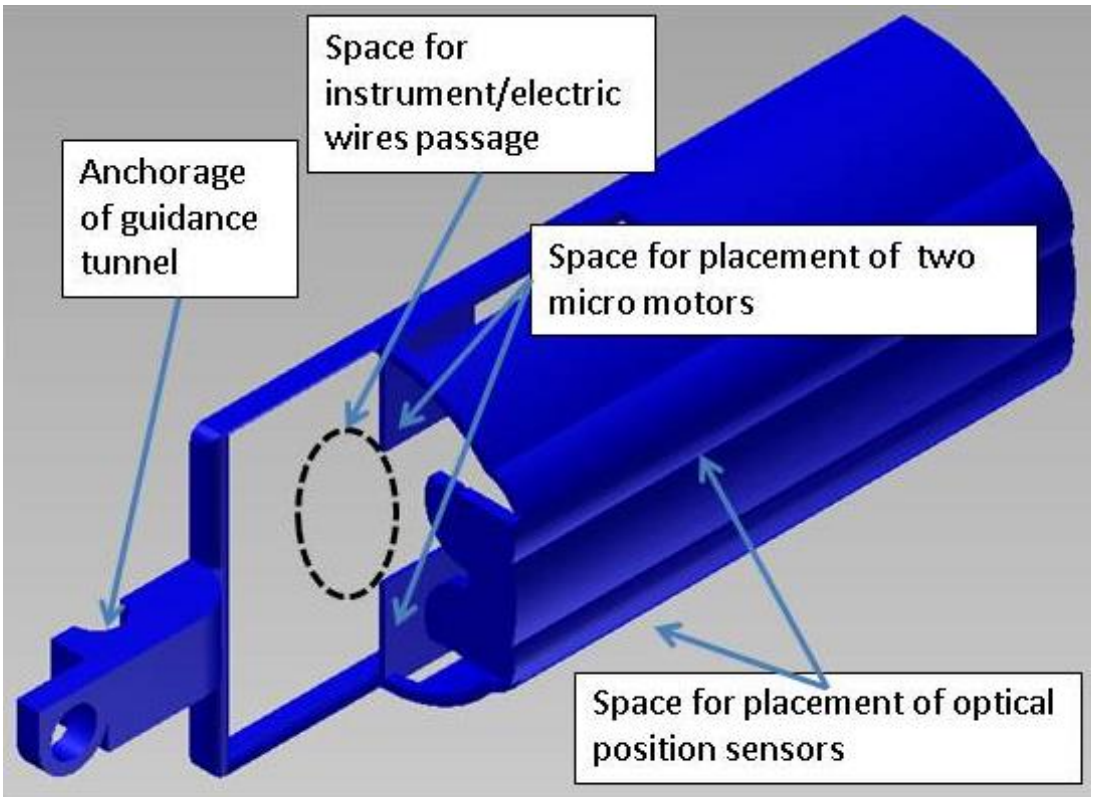


Figure 47: Front unit frame (hemisection) from design iteration 10.

In the early designs, the micromotors were designated to be placed on the outer perimeter of the frame while the central space was designated for the passage of endoscopic instruments and electricity wires. For example, the front unit frame from design iteration 10 (Figure 47) has such an arrangement. Also of note, the frame has space provision for the placement of optical sensor chips for micro motor position feedback. During computer simulation, it was felt that this design configuration is difficult to construct and limits efficient endoscopic instrument passage.

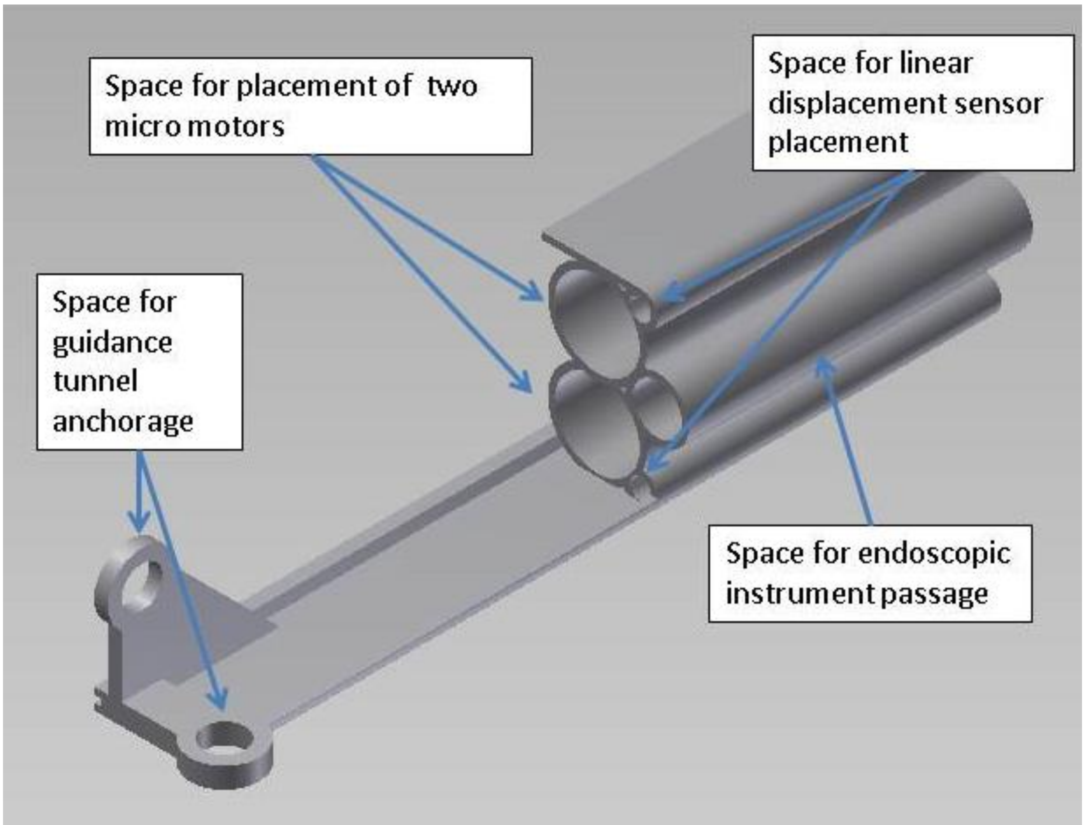


Figure 48: Front unit frame (hemisection) from Mk1.

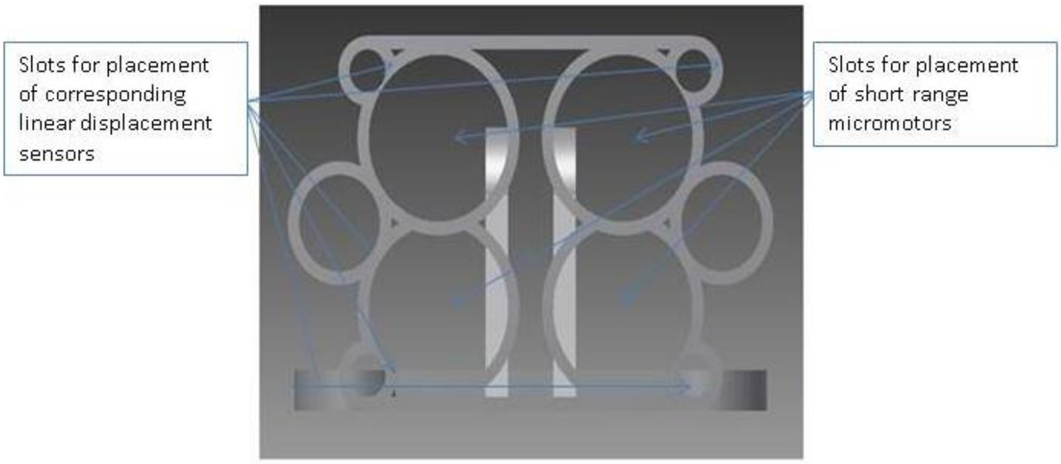


Figure 49: Cross section configuration of the front unit frame from Mk1.

The front unit frame from Mk1 adopted a different configuration when compared to early design iterations. (Figure 48 and Figure 49) In this design, the micro motors are housed in the centre of the unit while the peripheral space was utilized for the transmission of endoscopic instrument. Two point fixations are adopted for the guidance channel anchorage. (See below) Optical position sensors are no longer to be incorporated into the design. Instead, micro linear displacement sensors are adopted because of its simplicity, accuracy and small diameter. Microcamera, lighting and air/water irrigation channel is designed to be placed in the inferior aspects of the front unit frame.

6.2.2 Front Unit Guidance Channel

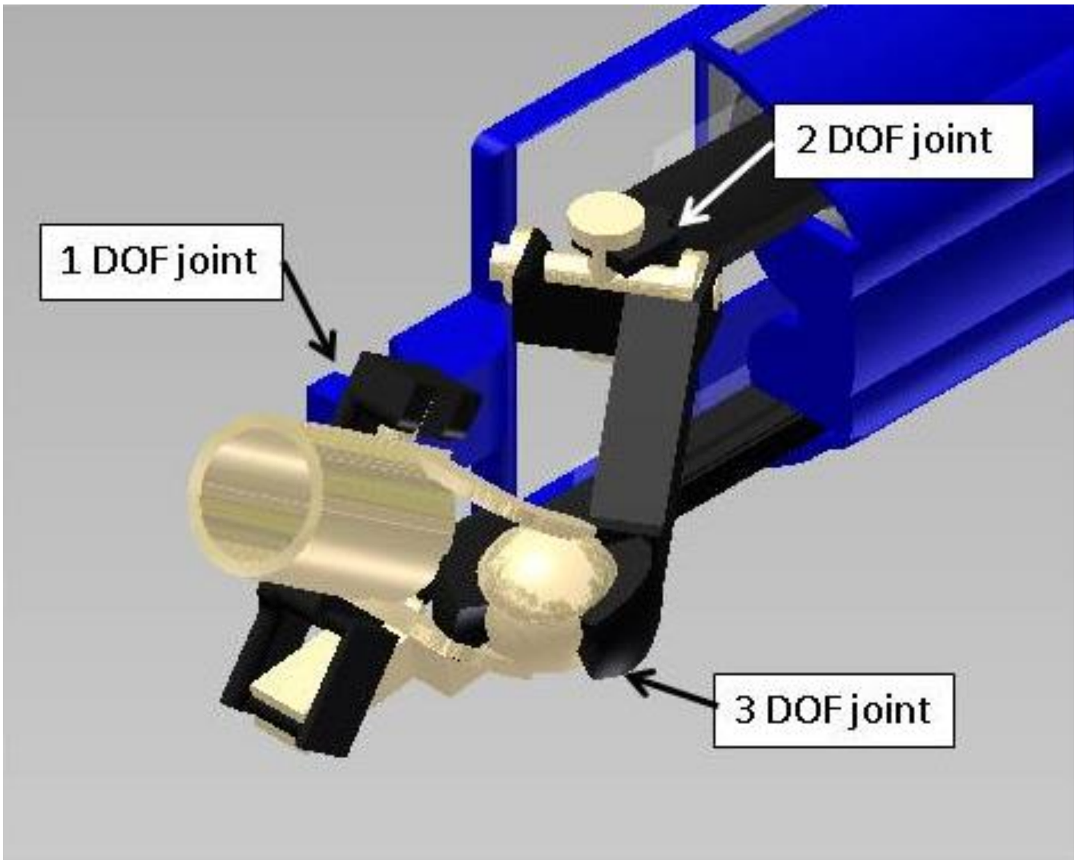


Figure 50: Guidance channel linkage mechanism from design iteration 10.

The design of a two degree freedom guidance channel actuated from two fixed micro motor while allowing sufficient space for free passage of endoscopic instrument proved to be challenging. The design of the four part linkage mechanism culminated from multiple computer design iterations. Early attempts resulted in a bulky mechanism with multiple joints with various degrees of freedom. An example of an early design is demonstrated in Figure 50. In this design, the guidance channel is anchored to the front unit frame only at one point. The left and right movement of the guidance tunnel was controlled by a micro motor located in the superior position through a 3 bar linkage connected by one 2 degree of freedom and one 3 degree of freedom joint. The up and down movement of the guidance tunnel was designated to be controlled by the inferior motor through a simple two bar linkage with one degree of freedom. During computer simulation, this design proved dissatisfactory as there was significant instability. Furthermore, the design was perceived to be difficult to manufacture due to its complexity.

6.2.3 The Four Part Linkage Mechanism

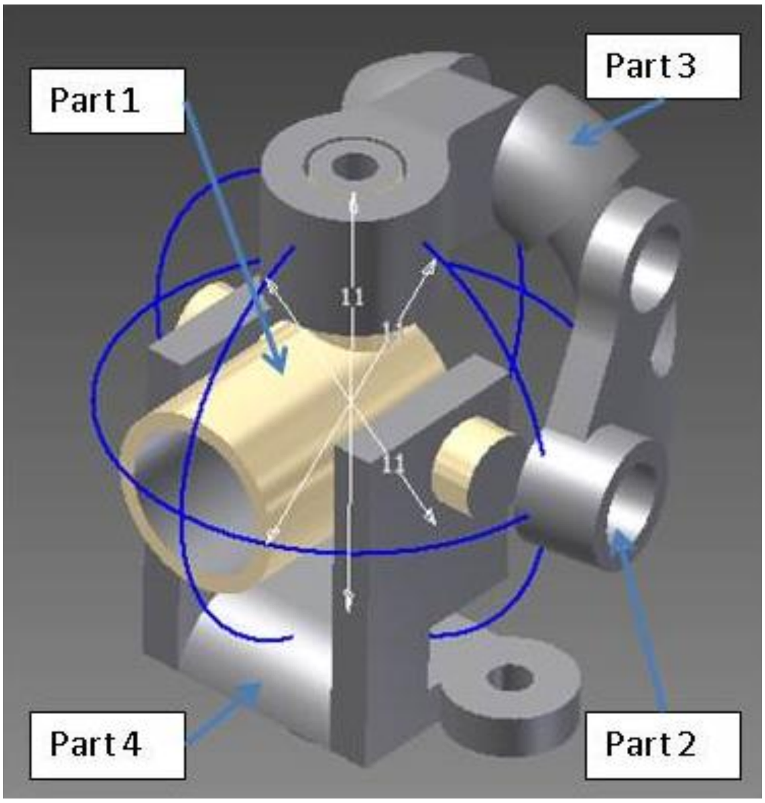


Figure 51: Part 1, 2, 3 and 4 assembled to work in a sphere of action of 11mm diameter.

The four part linkage mechanism proved to be the compact solution for controlling the guidance channel from two fixed actuator. Figure 51 shows the four part linkage mechanism from Mk1. The two degrees of freedom guidance channels located at the front of the endoscope. They are anchored at two points in perpendicular planes. The rigid linkages are designed to fit in a confined space. In essence, the linkage mechanism works by transmitting force within a sphere with a diameter of 11mm. Currently, a sphere with a diameter of 11mm is chosen because the parts are designed with extra thickness (1mm) due to the limitation of current rapid prototyping material. The following will discuss in detail the functioning of the four part linkage mechanism.

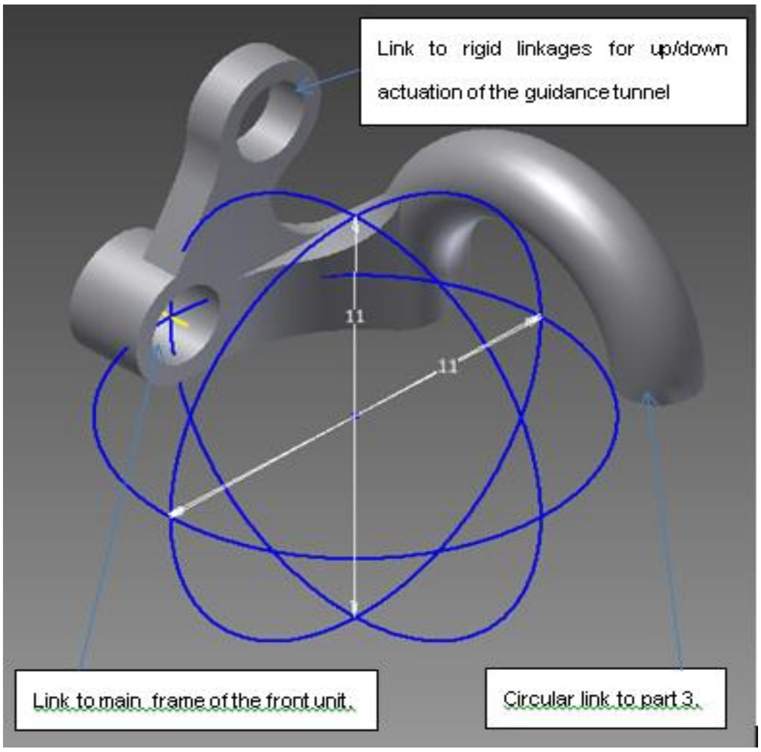


Figure 52: Part 2.

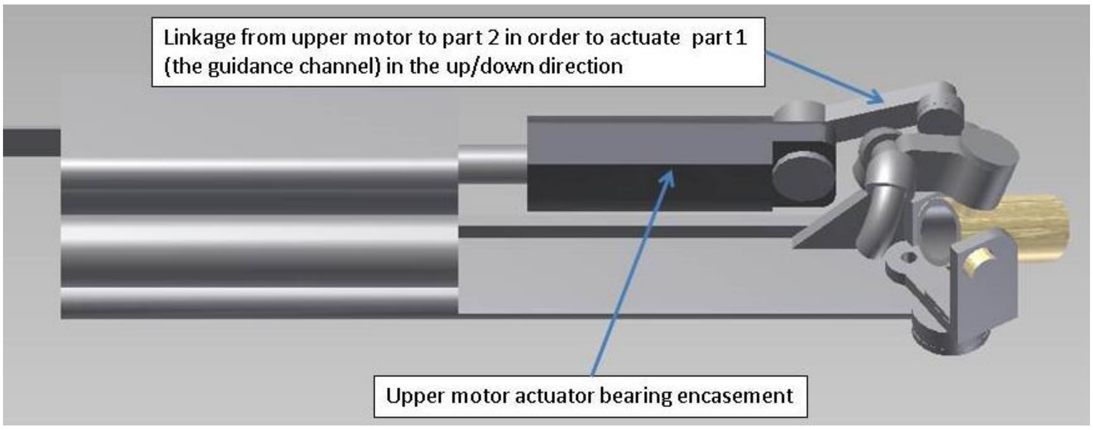


Figure 53: Linkage linking upper motor to part 2 for the control of the guidance tunnel (part 1) movement in the up and down direction.

Part 2 (Figure 52) serves to link the guidance channel to the main frame of the front unit. It is responsible for transmitting force from the upper motor to direct part 1 (guidance channel) in an up and down movement. (Figure 53) Part 2 is L-shaped with two curved sections perpendicular to each other. The semi-circular arch allows the attachment of part 3 (Figure 53) onto itself.

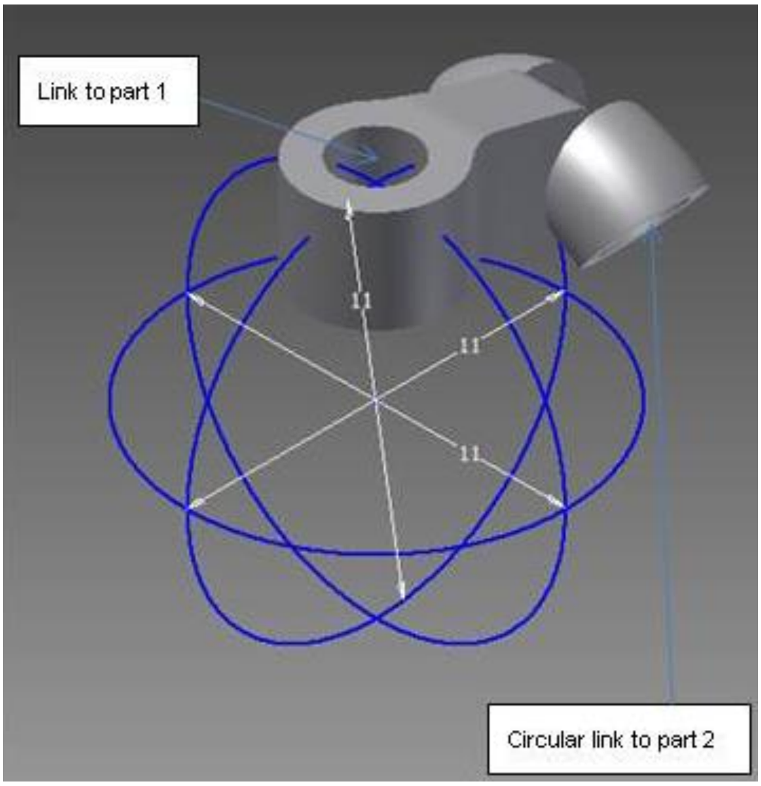


Figure 54: Part 3.

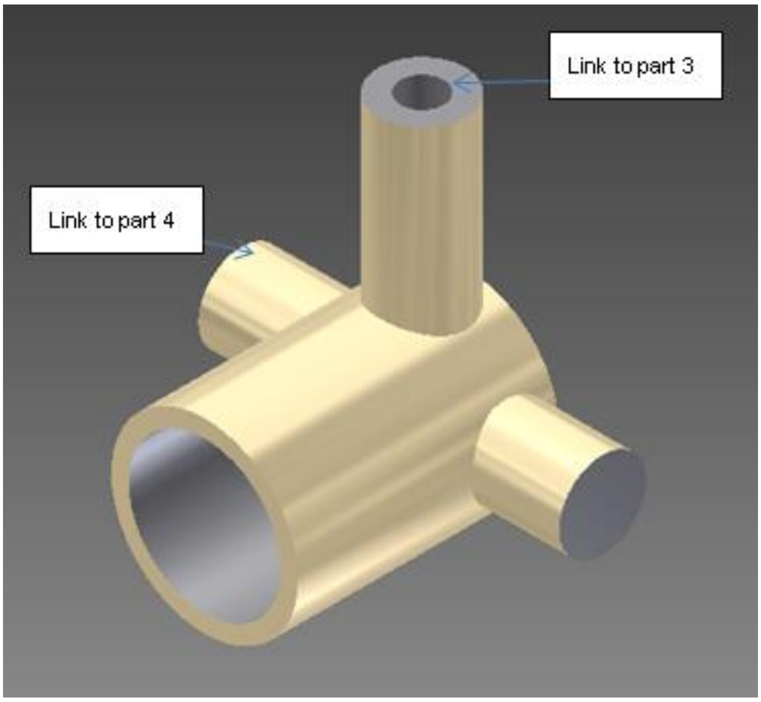


Figure 55: Part 1.

Part 3 acts as a linkage to part 1 (the guidance tunnel) (Figure 55). By allowing part 3 to slide on part 2 on an arc, the design allowed the reconciliation of two conflicting forces (up/down movement and left/right movement) from the two parallel placed micro motors.

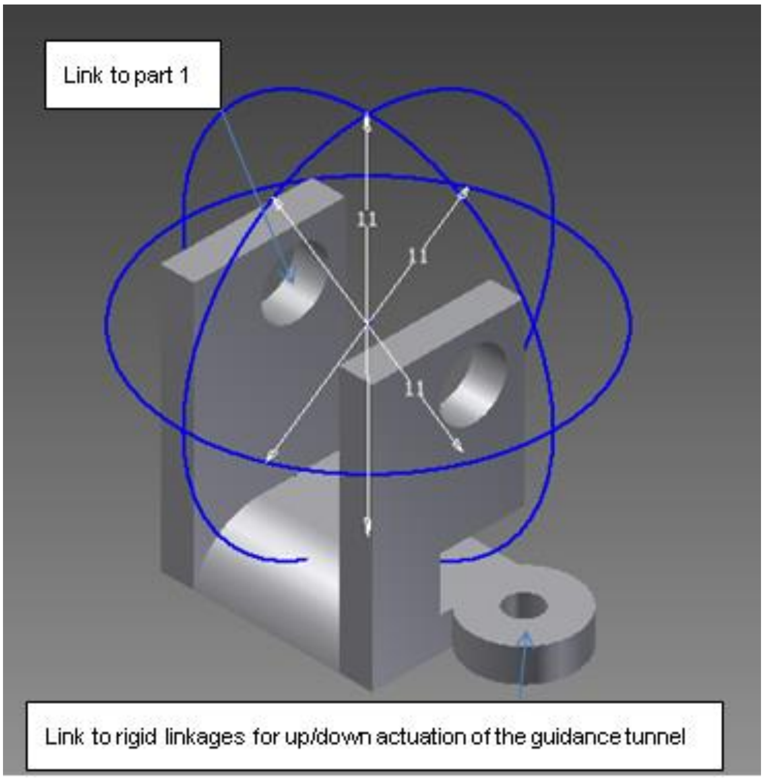


Figure 56: Part 4.

Part 4 serves to link part 1 (the guidance channel) to the main frame of the front unit. Part 4 is actuated by linkages between itself and the lower motor, which rotate it in the horizontal plane. (Figure 57)

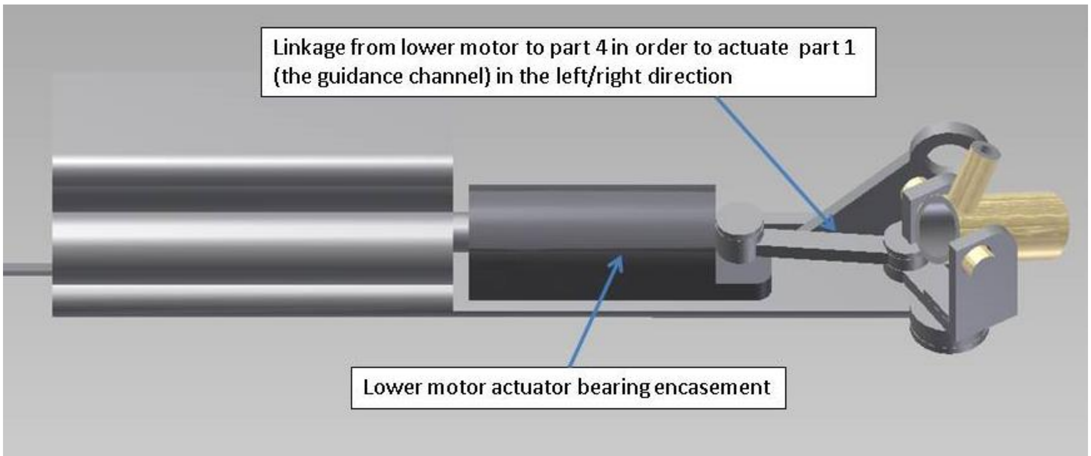


Figure 57: Linkage linking lower motor to part 4 for the control of the guidance tunnel (part 1) movement in the left and right direction.

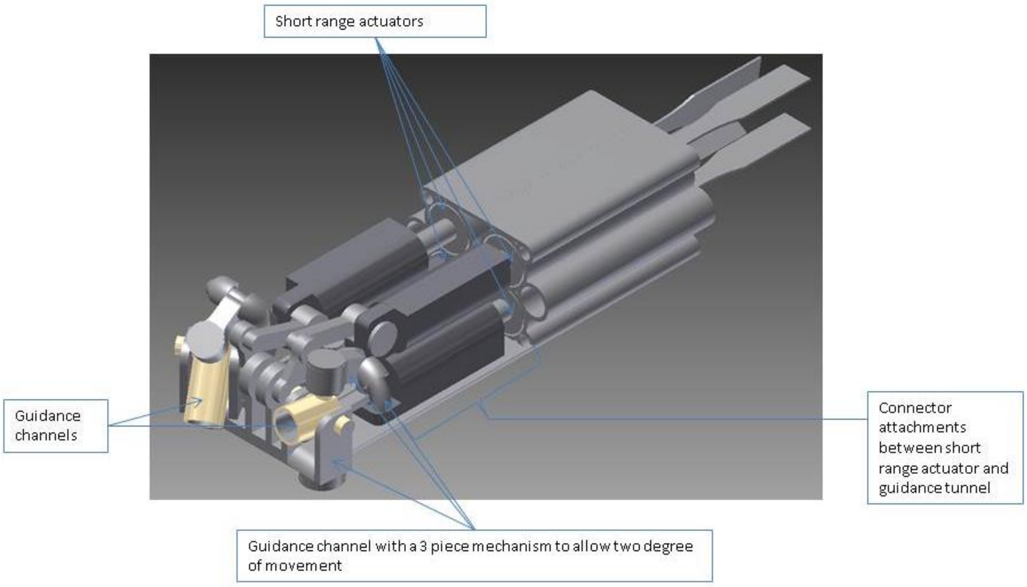


Figure 58: Oblique view of the front unit including 2 degree freedom guidance tunnels and attachments to short range actuators.

In Figure 58, we can see how the aforementioned parts come together to form the front unit in its entirety. The front unit frame hemi-sections are combined to form a unit, housing two pairs of micro motors controlling the two guidance tunnel in up/down/left/right directions. The final front unit ready for prototyping has a maximum width of 25mm, maximum height of 16.4mm and length of 61mm. Basic rivets such as that seen in Figure 59 are used to integrate the various parts of the design. With this design, it was felt possible to manufacture a functional prototype, which is detailed in Chapter 7. Detail drawings of the front unit can be seen in Appendix A.

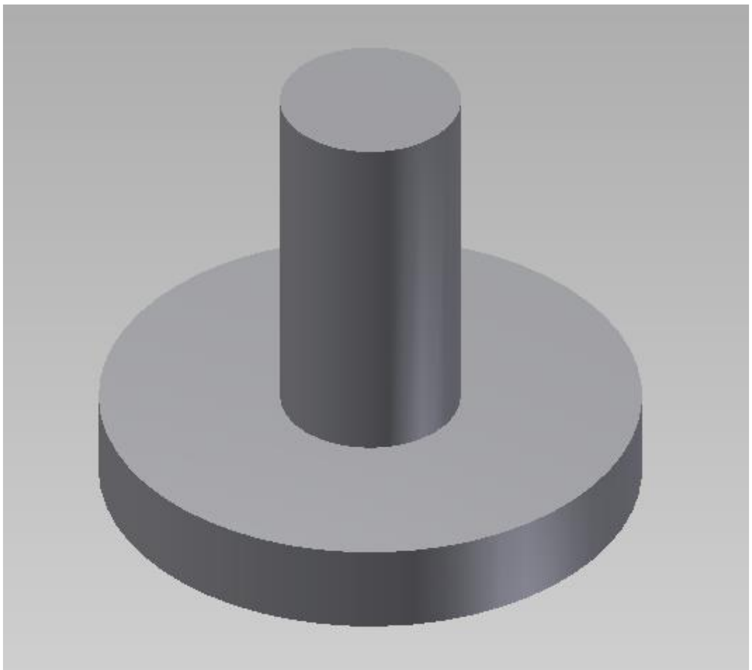


Figure 59: Basic rivet with 1 mm pin and 3mm diameter flange.

6.3 The Handle

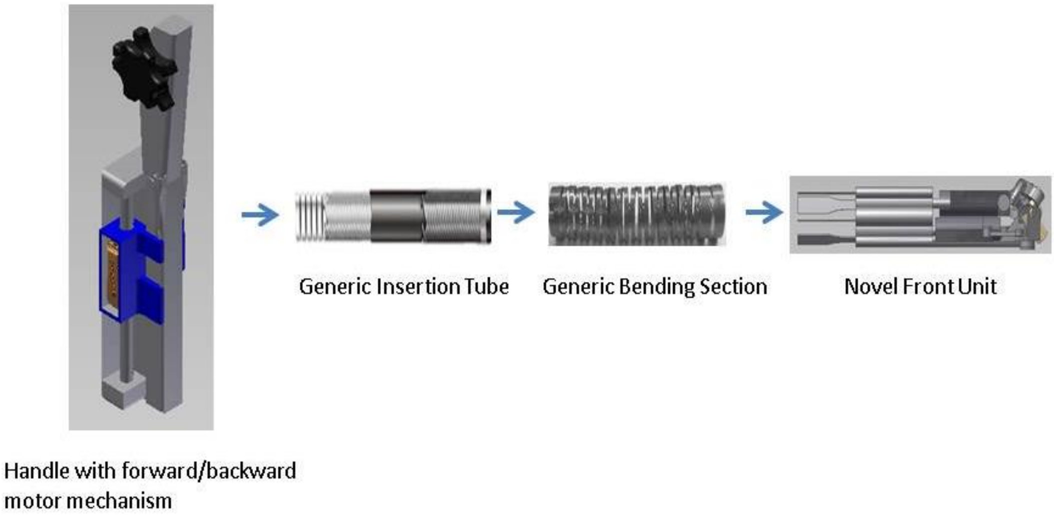


Figure 60: A schematic diagram of the automatic instrument engager for recognition of compatible instruments and linear actuator arrangement for control of linear movement of instrument.

At the handle of the endoscope, two linear actuators with automatic engagement mechanism are installed to allow engagement and execute forward/backward movement of any suitable flexible endoscopic instrument. (Figure 60) This part of the endoscope does not have to be inserted into the human body and therefore larger integrated servo linear actuators are used. Upon insertion of an endoscopic instrument, the servo motor and its housing moves distally from its starting position and engage any generic flexible endoscopic instrument of suitable calibre. Figure 61 demonstrates a schematic representation of this part of the endoscope.

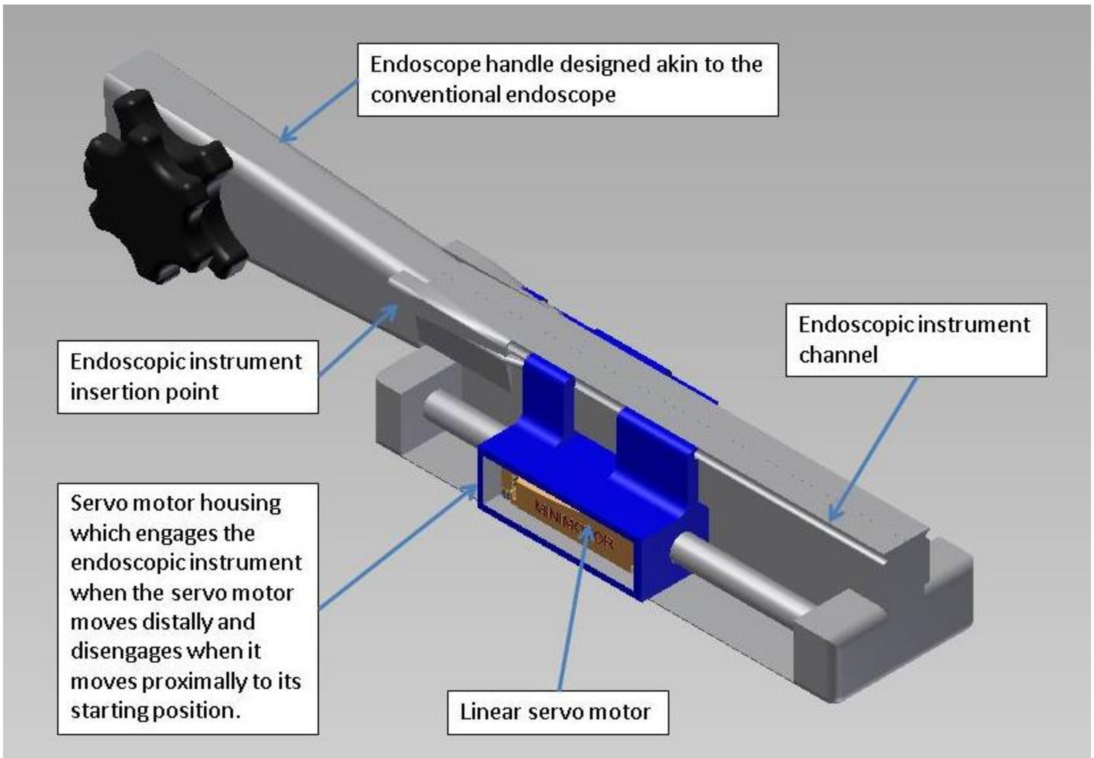


Figure 61: Device handle with two linear servo motors which engage an endoscopic instrument upon its insertion.

6.4 External unit

In order to control the open/close and rotation movements (in certain rotatable instruments only) of the flexible instrument, a separate external container will house the handles of any flexible endoscopic instrument. In essence, this external unit performs the task of an endoscopic nurse who controls the endoscopic instrument upon request by the endoscopist. The container contains actuators which will control open/closure/rotation movement of the instrument. Preferably, control of this unit is by wireless communication. A schematic diagram of the external control unit can be seen in Figure 62.

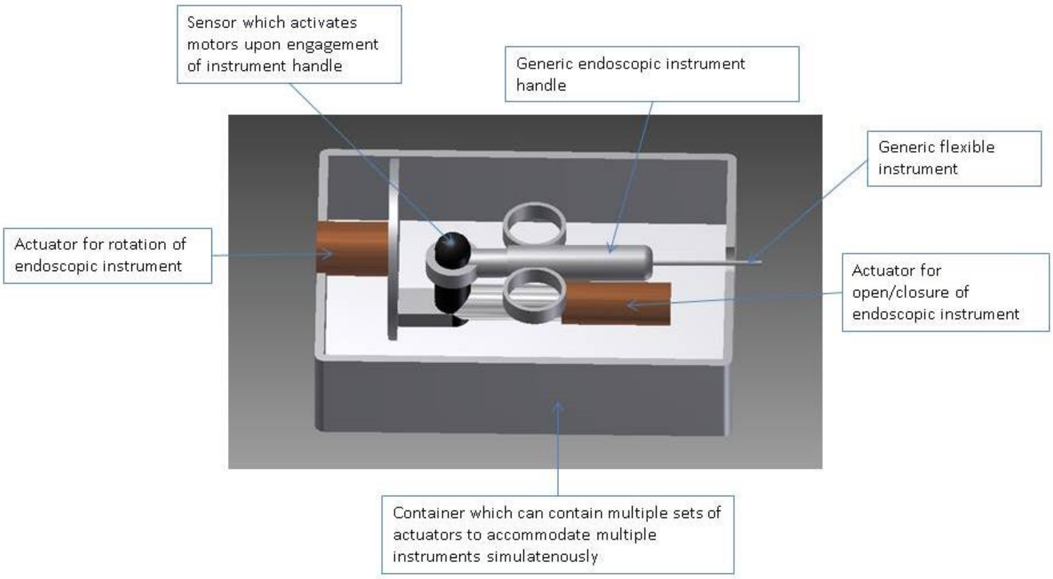


Figure 62: A schematic diagram of the external unit for control of open/closure/rotation of a flexible instrument.

Through the combined actuators of the front unit, the handle unit and the external unit, each endoscopic instrument will have up to five degree of instrument movement. The coordination of these three units will be performed by a microcontroller and a control device.

6.5 Chapter Summary

1. The design of the novel endoscopic platform has adopted the outlay of a conventional endoscope. This allows the platform to retain the manoeuvrability and functionality of the conventional endoscope which is familiar to currently practicing endoscopist.

2. The design aforementioned will enhance existing endoscopes with tissue dissection capability previously not achievable. It specifically avoids the use of traction cable where its disadvantages are detailed in chapter 3. The design will not significantly enlarge endoscope diameter. Its modular design allows easy setup, thus minimizing any disruption incurred during its setup within an endoscope unit. Added capability will enhance the accuracy of day to day procedures such as polypectomy, as well as act as an enabler technology to increase the ease of uptake of advanced techniques such as endoscopic submucosal dissection.

3. The design has three parts: the front unit which confers instrument movement in the up/down/left/right direction; the handle unit which confers instrument movement in the forward/backward direction; and the external unit which confers instrument open/close/rotation movement. Together, these three units allow each endoscopic instrument to move with five degrees of freedom.

4. The design of the front unit is critical. This unit has significant size restriction due to the requirement of it being inserted into the human gastrointestinal tract. The novel compact four part linkage mechanism allowed the control of the two degrees of freedom guidance tunnel with two fixed micro motor.

Chapter 7: Construction of a Basic Functional Prototype of the Novel Endoscopic Multitasking Platform

7.1 Material & Methods

The focus of the basic functional prototype is to validate the functionality of the front unit and its four part linkage mechanism.

Rapid prototyping service providers:

1. imaterialise.com (based in EU) – polyamide rapid prototyping
2. finelineprototyping.com (based in the US) – stainless steel rapid prototyping.

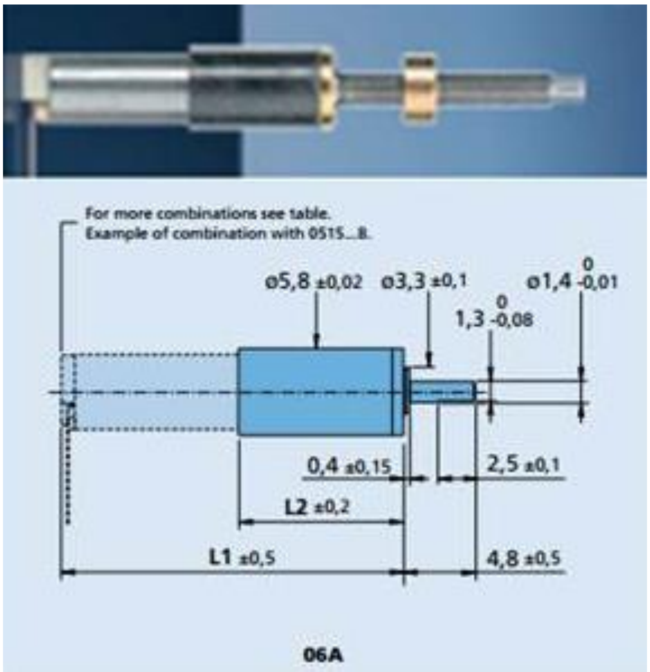


Figure 63: Faulhaber 06A S2 linear micromotor. Measurements in mm.

Materials:

1. Faulhaber 06A S2 micromotors. (Figure 63) The motor has 3 gear stages with a reduction ration of 125:1. It is capable of generating a continuous push force of 15.7 N and an intermittent push force of 23.6N. The maximum

speed of linear displacement is 30mm/min. Its length is 22.8mm and has a maximum diameter of 5.8mm.

2. Medigus microcamera. (Figure 64) This charge couple device (CCD) microcamera has a diameter of 3mm and length of 15mm. Its resolution is 500H * 582V, with effective pixel resolution of 291,000 pixels. Its optics allows 140 degree viewing angle. It has a 3m cable. Its video outputs are S-Video (PAL) or Composite (PAL).

Figure 64: Medigus 3mm microcamera.

3. For the purposes of this functional prototype, 3mm diameter PVC tubing and 15mm composite rubber tubing will serve as insertion channels and insertion tube respectively.

4. For the handle unit, linear actuators Firgelli L12 linear actuators will provide the forward and backward actuation. (Figure 65) These motors are

integrated controller with interface for direct control using pulse wave modulation (PWM) signal. The Firgelli linear actuator has a stroke length of 100mm and a gear reduction ratio of 100. Its peak power point is 23N at 6mm/s. Its positional accuracy is within 0.3mm. Its maximum speed is 12 mm/s.

Figure 65: Firgelli L12 linear servo motors.

5. The Arduino Mega 2560 microcontroller will be used as the microcontroller for the system. It has 16 analog input pins and 54 digital I/O pins with 256kb flash memory. In addition, a USB host shield will be used to enable the Arduino Mega 2560 microcontroller to be USB compatible. (Figure 66)

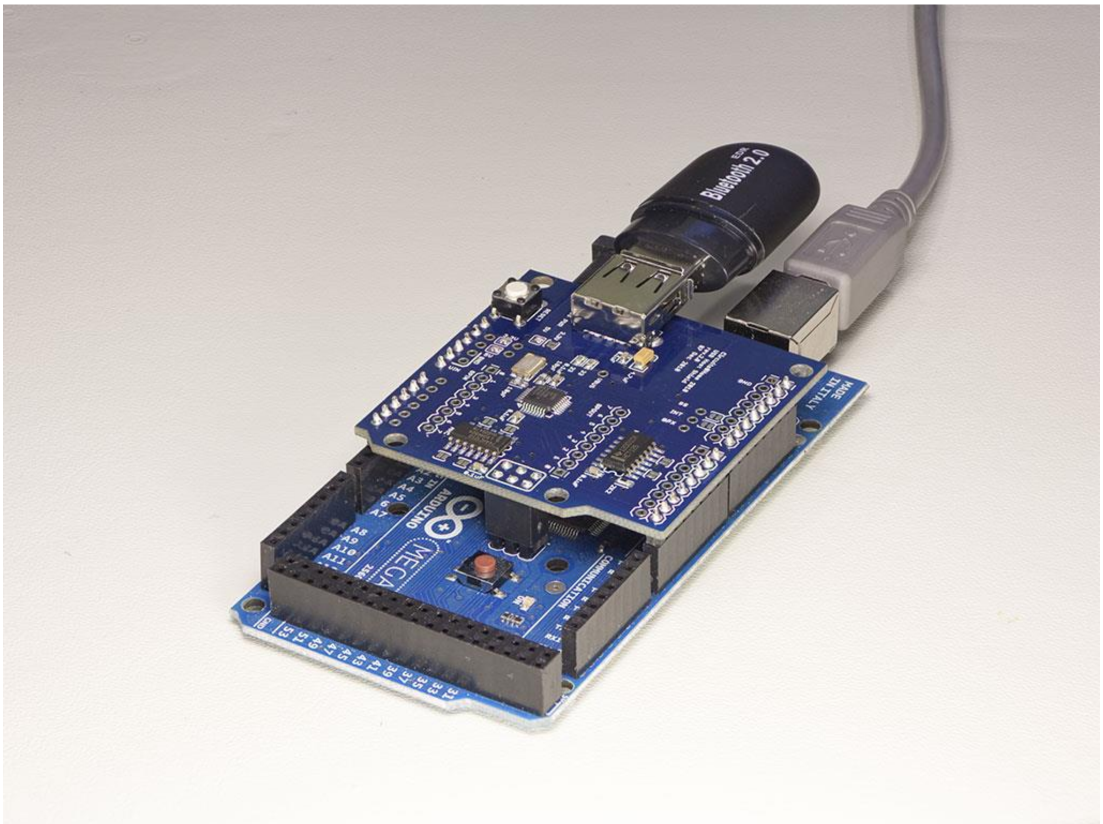


Figure 66: Arduino Mega 2560 microcontroller with USB host shield.

6. For the purposes of this basic functional prototype, a PS3 dual shock controller will be used as the controller. (Figure 67) The PS3 controller is unique amongst standard game controllers in that its buttons have a digital output from 0 to 255. This feature renders the controller very easy to

integrate into various applications. It also has basic haptic feedback function.

Figure 67: PS3 Dualshock controller.

7.2 Construction of the Prototype

For the purpose of this project, prototyping is limited to the front tip unit and handle unit as these are the most critical and novel parts of the design.

7.2.1 Construction of a Polyamide Prototype (3:1 Scale)

In order to test the functionality of front unit four part linkage mechanism based on the Mk1 design (see Chapter 6), the design was first prototyped in 3:1 scale using polyamide. Prototype service was purchased from imaterialise.com. The prototype can be seen from Figure 68 to Figure 72. This prototype has adequately demonstrated the functionality of the design. The results of the testing of the polyamide prototype are detailed in chapter 8.

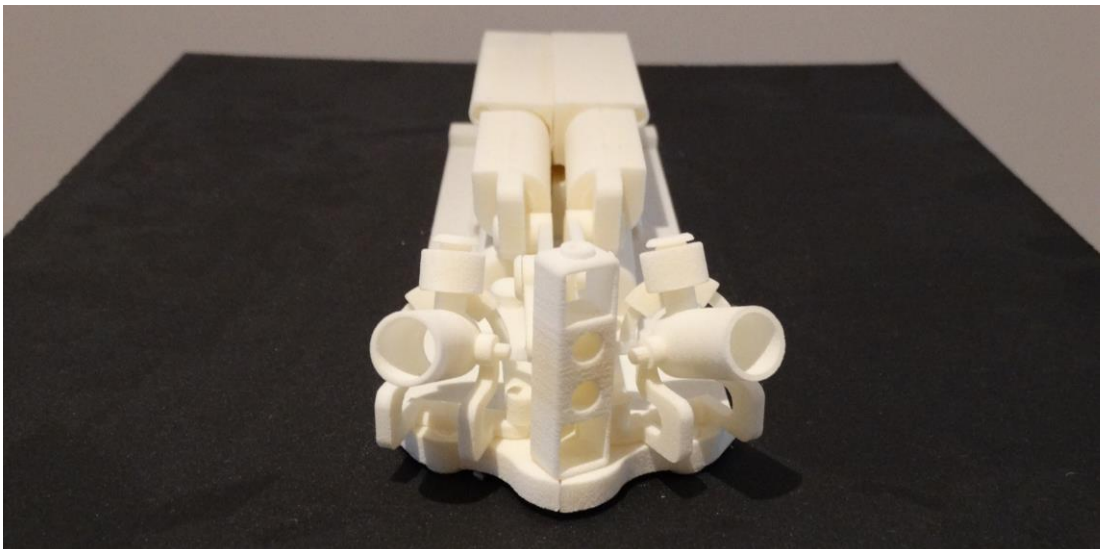


Figure 68: Front bird's eye view of the Mk1 prototype (3:1 scale)

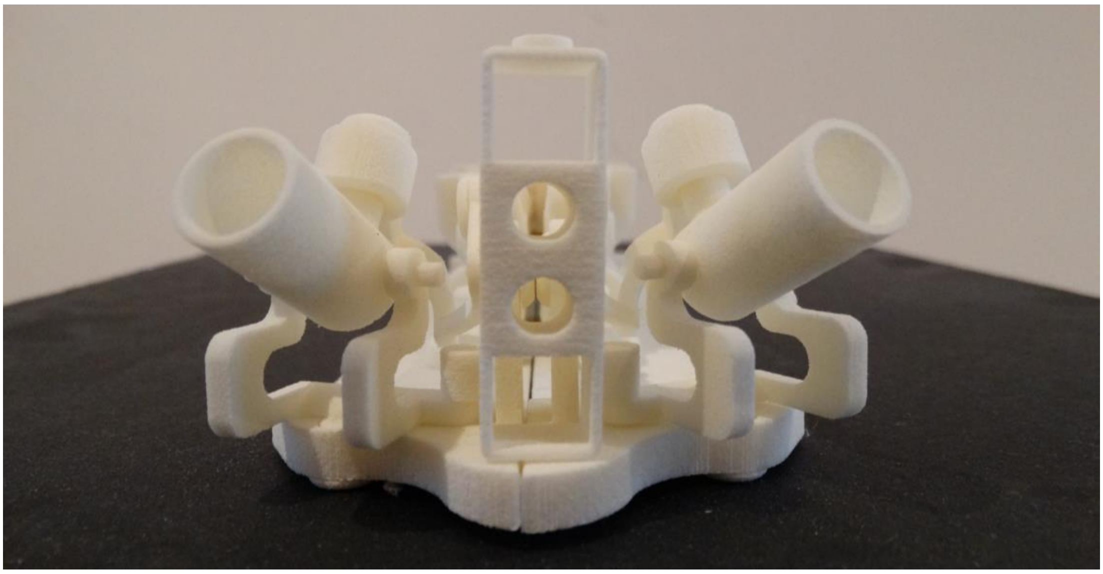


Figure 69: Front view of the Mk1 prototype (3:1 scale).

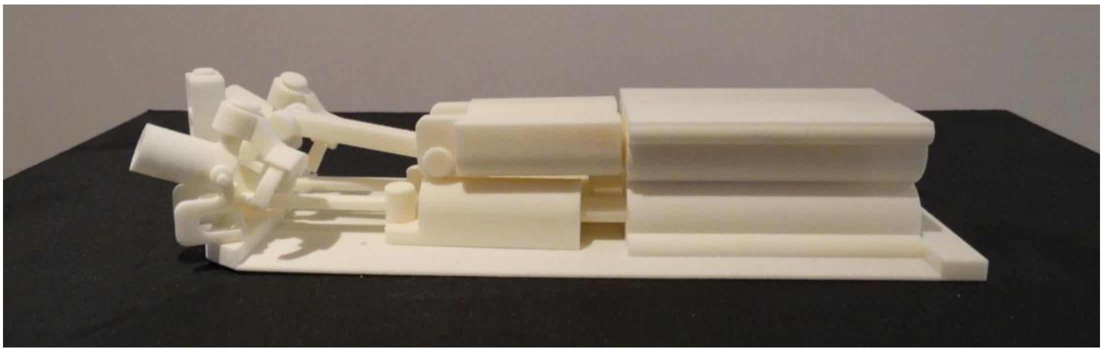


Figure 70: Lateral view of the Mk1 prototype (3:1 scale).

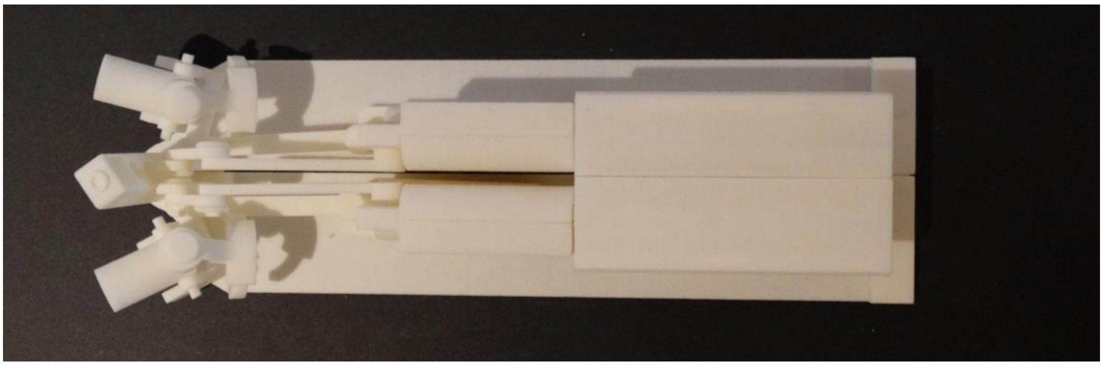


Figure 71: Top view of the Mk1 prototype (3:1 scale)

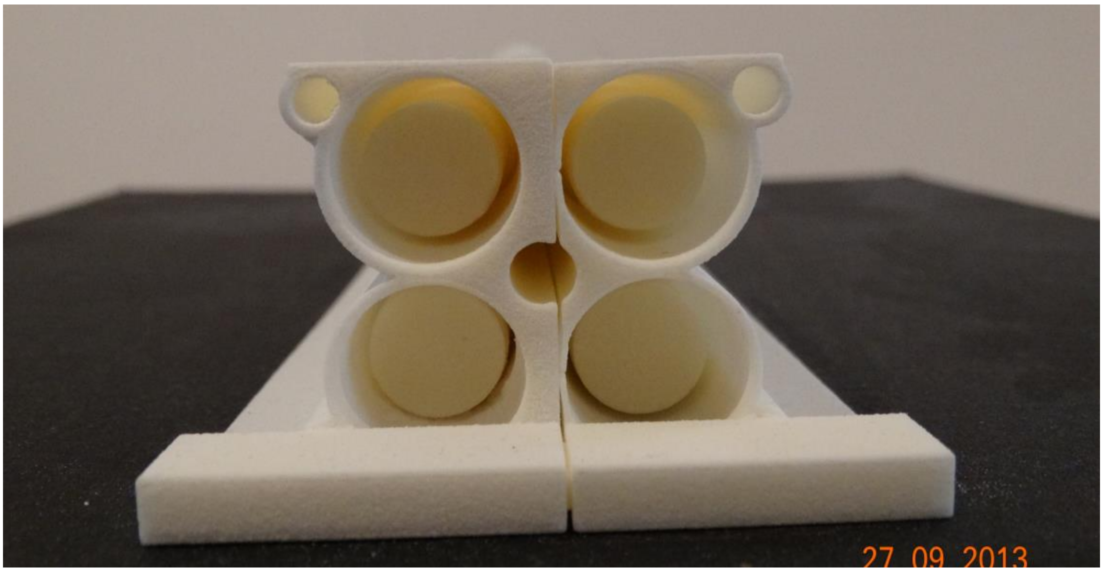


Figure 72: Posterior view of the Mk1 prototype (3:1 scale).

7.2.2 Construction of a Stainless Steel Prototype (1:1 Scale)

With the satisfactory validation of the design based on the polyamide prototype, the design was then prototyped in 1:1 scale using stainless steel. Prototype service was purchased from finelineprototyping.com.

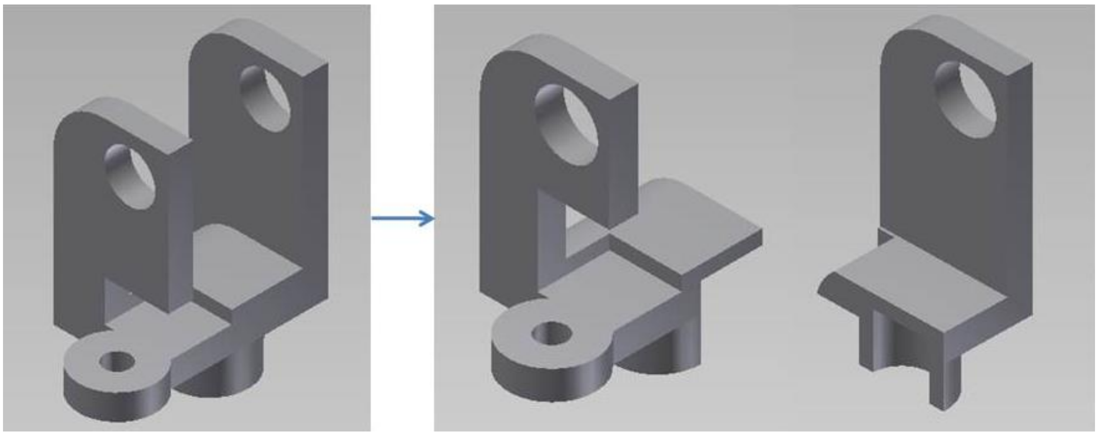


Figure 73: In order to overcome the limitations of the rapid prototyping stainless steel, part 4 (left) was divide into two pieces (right). This allowed success integration of the part to part 1 (guidance channel).

Due to current limitation of metal prototyping technology, there were minor size discrepancies between the parts. During integration of the parts, a significant amount of manual filing was required. In addition, the stainless steel material was very brittle due to the presence of micro bubbles. This is an inherent flaw of the current metal prototyping technology. As a result, during assembly, part 4 was not compliant enough to fit around part 1 (guidance channel). Early attempts resulted in breakage of part 4. In order to overcome this, part 4 was re-designed and prototyped in two pieces. (Figure 73) After careful filing of the parts, the prototype was assembled. Four aforementioned Faulhaber Series 06A S2 micromotors were placed and connected to the actuator housing and integrated into the front unit. The front unit was in turn integrated to a composite rubber tube. The rubber tube's diameter was 15mm and its length was 1 meter. Two 4mm diameter internal PVC tubing were placed inside the 15mm rubber tubing to act as channels for insertion of flexible instruments. (Figure 77) At the hilt of the endoscope, two L12 Firgelli linear actuators are attached. For the purpose of the preliminary prototype, flexible instruments are attached to the Firgelli motors using cable ties. Testing of the stainless steel prototype is detailed in chapter 8. The prototype can be seen from Figure 74 to Figure 77.

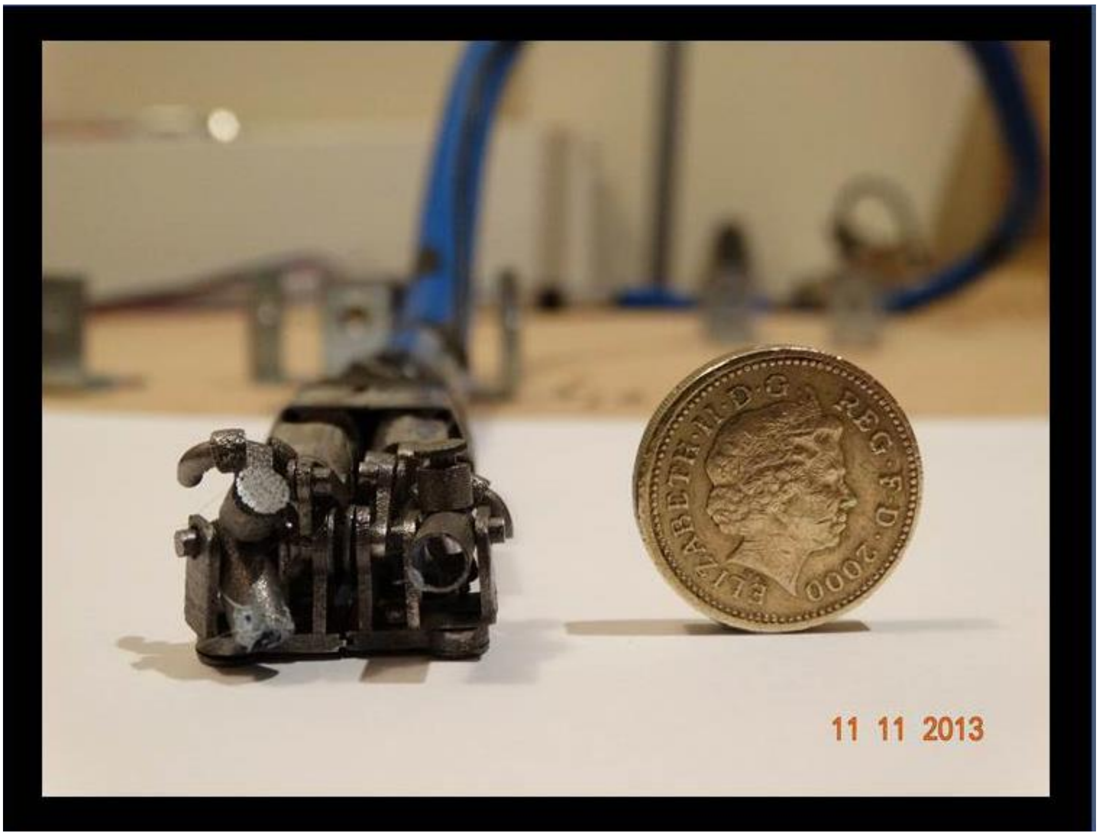


Figure 74: 1:1 stainless steel prototype front view. A £1 coin was used for size comparison.

Figure 75: 1:1 stainless steel prototype top view. A £1 coin was used for size comparison.

Figure 76: 1:1 stainless steel prototype side view. A £1 coin was used for size comparison.

Figure 77: Endoscope prototype. A £1 coin was used for size comparison.

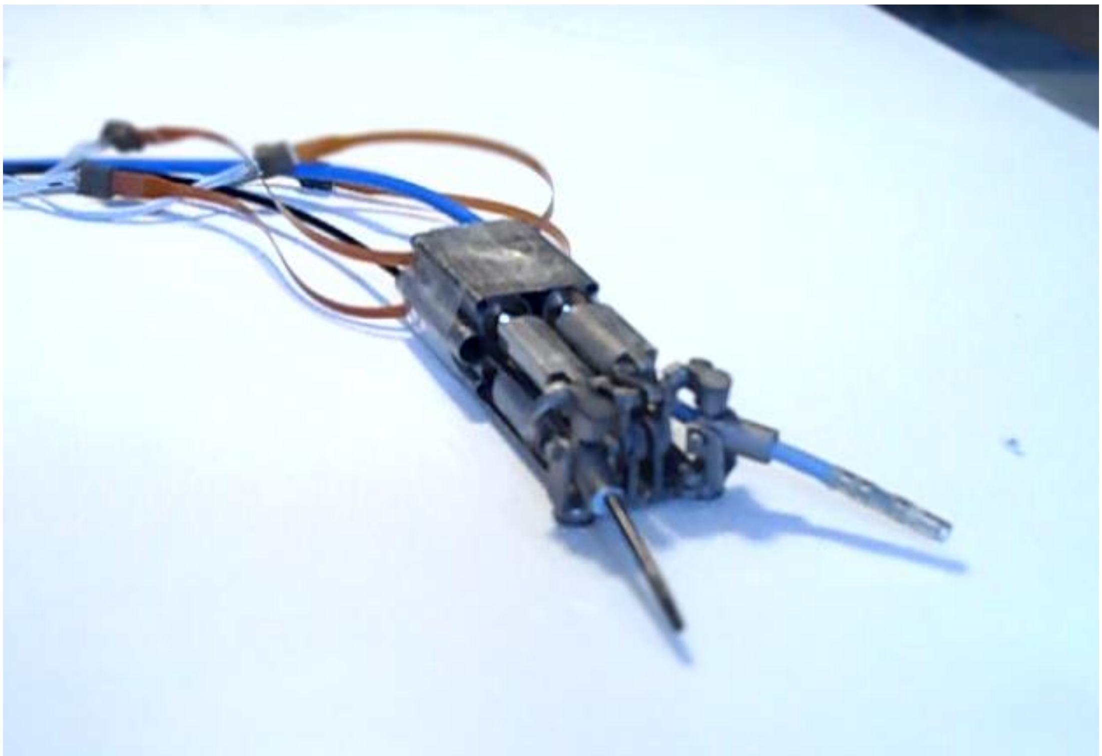


Figure 78: 1:1 stainless steel prototype with endoscopic instruments. For video demonstration please refer to accompanying video file in Appendix D.

7.3 Integration with Microcontroller and PS3 Controller

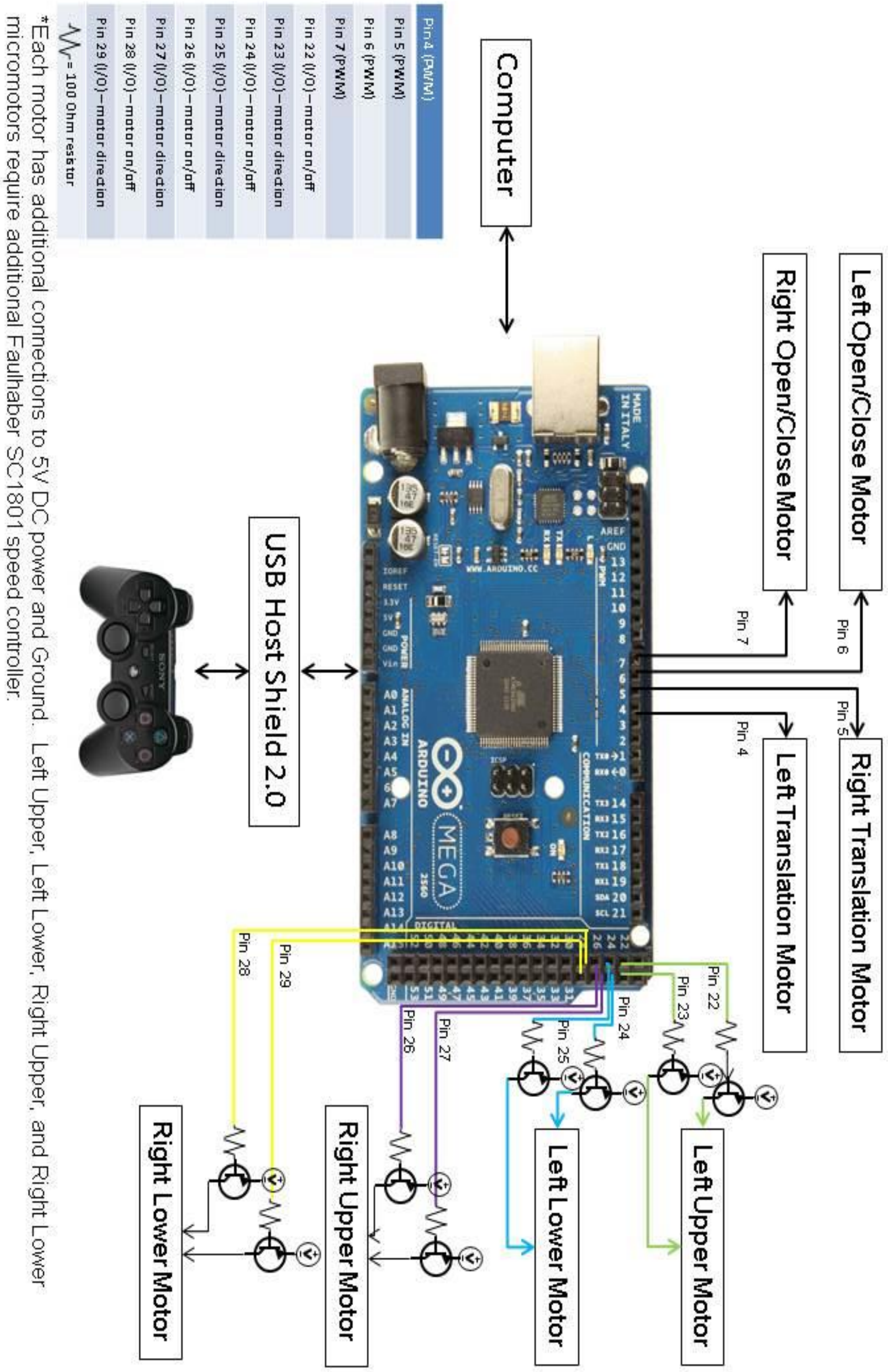


Figure 79: Schematic diagram of the device circuitry.

Figure 79 demonstrates a schematic diagram detailing the circuitry for the integration of the device with the Arduino microcontroller and the PS3 controller. The Firgelli L12 motors were directly connected to the Arduino Mega 2560 pulse wave modulation (PWM) output pins (pin 4 to pin 7). The micro motors located in the front unit (left upper, left lower, right upper and right lower motors) are controlled through the digital I/O pins on the microcontroller. For each motor, one digital pins controls the on/off status of the motor (e.g. pins 22, 24, 26, and 28) and one digital pin controls the direction of the motor revolution (e.g. pins 23, 25, 27, and 29). The PS3 controller is directly connected to the microcontroller through the USB host shield. Overall setup of the device can be seen in Figure 80.

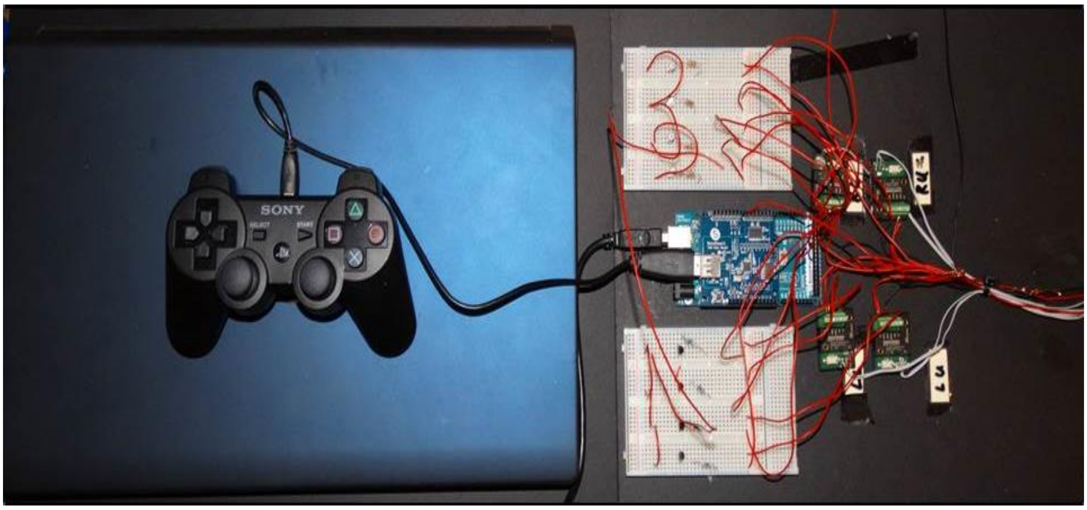


Figure 80: Circuitry, computer and game controller for coordination of micromotor movement in an open loop fashion.

7.4 Control Software

The control software is written in Arduino programming language based on Wiring and Processing. The PS3USB library was used. In essence, the program has a loop structure. At the beginning of the loop, the program will interrogate the positions of the various buttons and joysticks in the PS3 controller. The PS3 will return a digital output from 0 – 255 for each button and joystick position. This information is used to adjust the variables within the program. At the end of the loop, the program will generate pin output signals accordingly to control the motors. This loop repeats continuously thereby allowing precise control of the various motors. The control software is detailed in appendix C.

7.5 Chapter Summary

1. The real challenge of the design is in the migration of the functional element from the extracorporeal part of the device (as seen in all existing rival robotic endoscopic multitasking platform) to the intracorporeal part of the device. When the actuating motors are located externally and actuation is conducted through actuation cable, there is no size limitation to the external unit. The proposed design has tried to overcome the genuine limitation in deploying the functional element within the intracorporeal part of the device.

2. A basic functional prototype was developed using state of the art rapid prototyping technology.

3. Currently, the resolution of metal prototyping remains poor. This is evident when significant amount of manual filing was required to integrate the parts.

4. Arduino microcontroller and PS3 controller has been used for the development of this basic functional model because of their low cost and wide availability.

5. A basic control software has been written in Arduino language.

Chapter 8: Bench Top Testing of the Novel Endoscopic Multitasking Platform

8.1 Kinematic Analysis

8.1.1 Method

The actual physical range of linear displacement of the upper actuator (controlling vertical guidance tunnel position) and lower actuator (controlling horizontal guidance tunnel position) were measured against the theoretical actuator linear displacement range predicted using computer aided design software. The measurements were obtained from the posterior surface of the motor bearing housing to the front surface of motor using an electronic digital caliper (Maplin) (range: 0-150mm resolution 0.01mm accuracy +/- 0.02mm repeatability 0.01mm). (Figure 81) Measurement obtainment was repeated 5 times. Measurements were taken from the polyamide prototype (3:1 scale) and stainless steel prototype (1:1 scale). Angular displacement of the guidance channel was measured digitally on digital images taken of the guidance tunnel at various actuator positions using GNU Image Manipulation Program (GIMP 2.8.6). Corresponding measurements were obtained from CAD drawings using AutoCAD Inventor software.

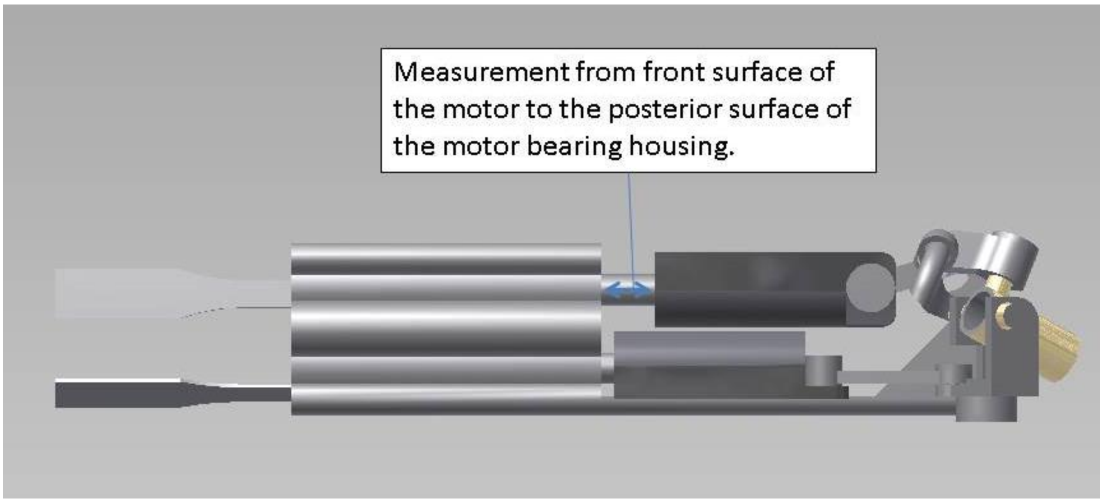


Figure 81: Method of measurement for the comparison of actual physical range of motor movement to simulated range of motor movement.

8.1.2 Results

8.1.2.1 Polyamide Prototype (3:1 Scale)

Table 3 and Figure 82 detail the comparison of the actual and simulated positions of the upper and lower actuators. It demonstrates that there is good correspondence between actual and simulated position when lower actuator position is between 0 – 10 mm. Thereafter, the range of upper actuator motion significantly deteriorated in the polyamide prototype when compared to the predicted range of actuator movement. This is due to the flexibility of the polyamide material, lending itself to be a poor material for force transmission through the four part linkage mechanism.

Lower actuator position (mm)			Upper actuator position (mm)		
Simulated	Actual	S.E (mm)	Simulated	Actual	S.E (mm)
0.00	1.33	0.12	18.00	21.08	0.19
1.00	0.36	0.02	18.00	20.57	0.27
2.00	3.37	0.22	18.40	19.06	0.05
3.00	0.25	0.02	18.00	20.18	0.10
4.00	0.39	0.01	21.50	21.11	0.04
5.00	0.37	0.02	18.00	20.78	0.03
6.00	0.38	0.06	18.10	20.94	0.06
7.00	0.40	0.03	18.10	19.30	0.06
8.00	0.63	0.07	18.10	19.69	0.07
9.00	1.44	0.07	18.10	19.32	0.06
10.00	2.13	0.11	18.10	19.19	0.06
11.00	3.93	0.02	18.10	19.88	0.07
12.00	4.98	0.13	18.10	19.34	0.11
13.00	7.95	0.04	18.10	19.93	0.04
14.00	8.11	0.05	18.10	20.02	0.08
16.00	8.40	0.04	17.10	18.51	0.04
17.00	8.91	0.07	17.10	19.64	0.12
18.00	10.40	0.19	18.00	16.51	0.06
19.00	9.47	0.24	17.80	14.02	0.14

Table 3: Comparison of simulated actuator position vs actual measured actuator position in 3:1 scale polyamide model.

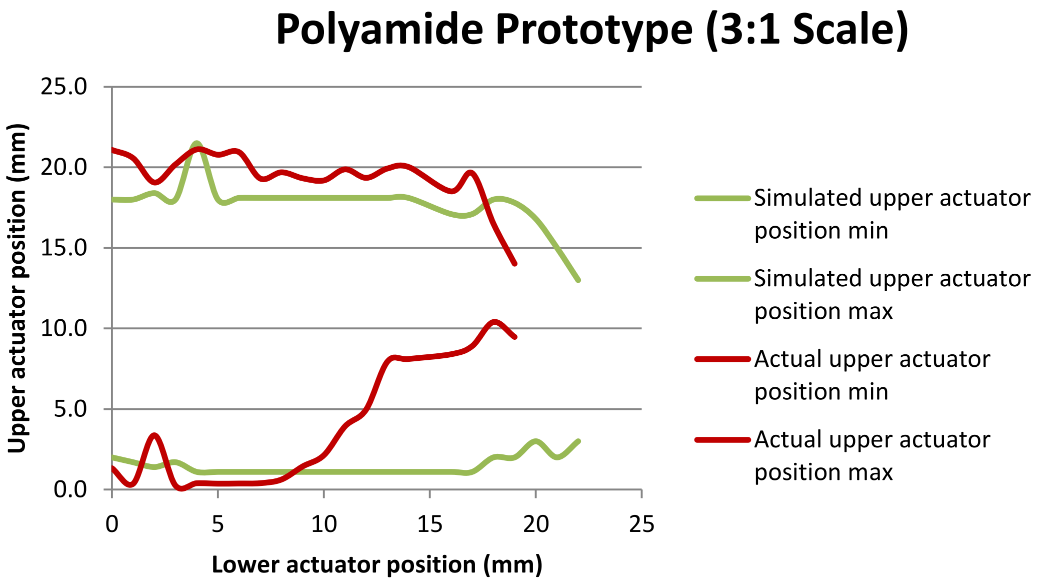


Figure 82: Graphical representation of the comparison of simulated actuator position vs actual measured actuator position in 3:1 scale polyamide model.

8.1.2.2 Stainless Steel Prototype (1:1 Scale)

Table 4 and Figure 83 demonstrate the actual and simulated range of actuator positions in the stainless steel prototype (1:1 scale). It is of note that the actual measurements closely matched with the simulated values. The rigid nature of the stainless steel has allowed good force transmission through the four part linkage mechanism, unlike the polyamide model mentioned above. Of note, although the micro motor has a range of 0 – 10mm movement, the design can only utilize a range of movement from 0.21 – 6.15mm. Upper actuator has maximum range of movement when lower actuator position is between 1 – 6mm.

Horizontal actuator position (mm)	Upper actuator position min (mm)			Upper actuator position max (mm)		
	Simulated	Mean	S.E (mm)	Simulated	Mean	S.E (mm)
0.50	0.60	-	-	4.60	-	-
1.00	1.12	0.63	0.03	6.12	6.04	0.03
1.50	1.10	0.86	0.03	6.31	5.90	0.06
2.00	0.22	0.74	0.05	6.42	5.78	0.04
2.50	0.22	0.38	0.01	6.48	5.98	0.02
3.00	0.22	0.23	0.01	6.50	6.05	0.02
3.50	0.22	0.31	0.02	6.49	5.82	0.04
4.00	0.22	0.21	0.02	6.45	6.06	0.02
4.50	0.22	0.22	0.01	6.37	6.15	0.06
5.00	0.22	0.22	0.02	6.26	5.87	0.04
5.50	0.22	0.32	0.02	6.09	6.13	0.03
6.00	1.10	0.29	0.04	5.85	5.48	0.04
6.50	1.10	1.30	0.03	5.51	5.72	0.04
7.00	-	1.20	0.03	-	5.13	0.06
7.50	-	2.99	0.04	-	5.50	0.04

Table 4: Comparison of simulated actuator position vs actual measured actuator position in 1:1 scale stainless steel prototype.

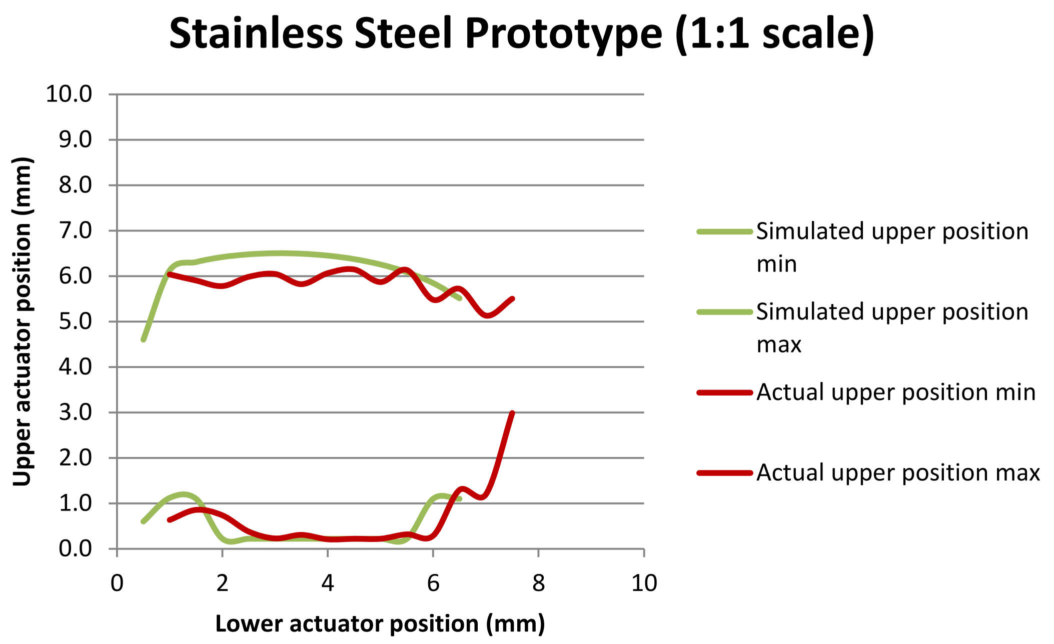


Figure 83: Comparison of simulated actuator position vs actual measured actuator position in 1:1 scale stainless steel model.

The guidance tunnel position angle relative to the horizontal plane in various positions in the horizontal actuator position is demonstrated in Table 5 and Figure 84. Again, it can be seen that the actual range of guidance tunnel motion closely corresponds to that of the simulated model. Video of the endoscopic multitasking platform can be seen in Appendix D.

Horizontal actuator position (mm)	Tunnel angle relative to horizontal plane (upper actuator position minimum) (°)		Tunnel angle relative to horizontal plane (upper actuator position maximum) (°)	
	Simulated	Actual	Simulated	Actual
1.00	38.54	35.83	-45.48	-52.42
1.50	33.48	28.72	-45.48	-50.85
2.00	37.52	25.38	-45.48	-48.52
2.50	36.81	31.84	-45.48	-46.37
3.00	36.46	34.59	-45.48	-45.62
3.50	36.39	34.35	-45.48	-44.91
4.00	36.46	36.40	-45.48	-47.07
4.50	36.18	37.77	-45.48	-46.12
5.00	39.22	41.46	-45.48	-47.38
5.50	41.31	39.71	-45.48	-49.67
6.00	16.91	41.24	-45.48	-49.02
6.50	12.89	19.15	-45.48	-52.21
7.00	-	30.68	-	-53.65
7.50	-	1.03	-	-52.37

Table 5: Comparison of simulated guidance tunnel position vs actual measured guidance tunnel position relative to the horizontal plane in 1:1 scale stainless steel model.

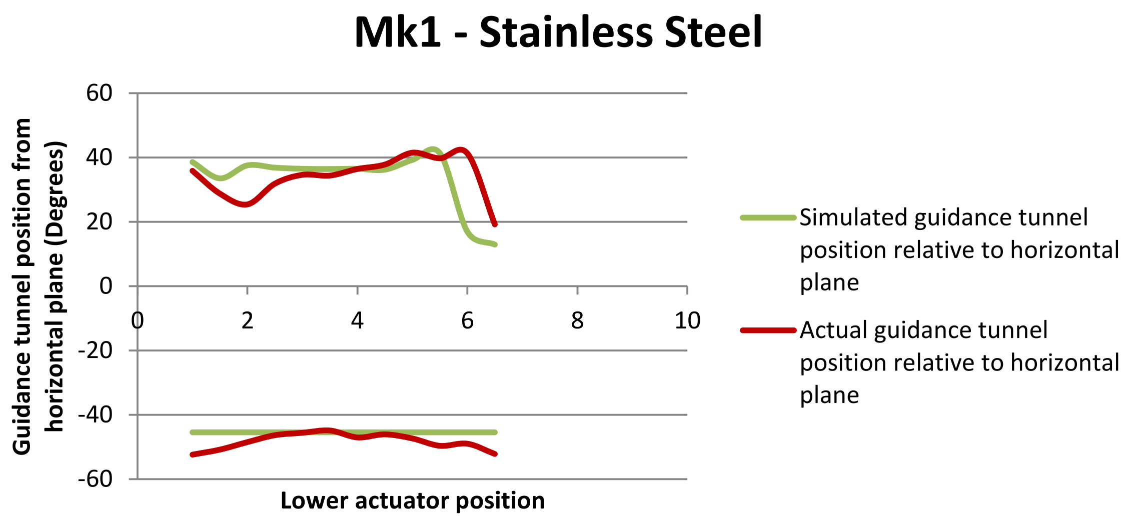


Figure 84: Comparison of simulated guidance tunnel position vs actual measured guidance tunnel position from horizontal plane in 1:1 scale stainless steel model (Mk1)

8.2 Force Analysis

8.2.1 Method

Traction force generated by the endoscopic platform in medial, lateral, upward, downward, forward and backward direction is measured using a Sauter FK25 Digital Force Gauge (measure range 25N, readout 0.01N, precision 0.5% of 25N). For measurement of medial and lateral traction forces, the guidance tunnel is placed perpendicular to the horizontal plane. For measurement of upward and downward forces, the guidance tunnel is placed parallel to the horizontal plane. The positions at which the forces are measured are seen in Figure 85.

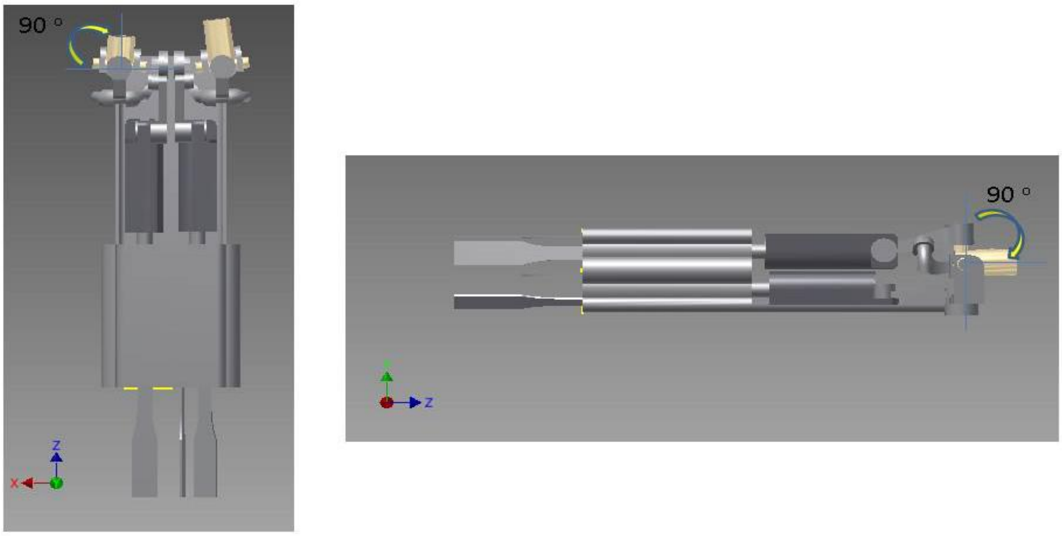


Figure 85: Guidance tunnel positions at which the forces were measured

In order for the accurate measurement of the traction forces, the stainless steel prototype and the digital force gauge is anchored on a wooden board with metal mounts. The general setup for measuring different force direction can be seen from Figure 86 to Figure 89. For anchorage of the tension wire on the side of the prototype, a Boston Scientific Radial Jaw 3 flexible forcep (a commonly used forcep in daily clinical practice) is used. For measurement of lateral, medial, upward and downward traction, the forcep is protruded from the guidance tunnel by 1cm. In general, the primary position of the guidance tunnel is at the maximum of the opposite direction of the force being measured. For example, when measuring lateral traction force, the guidance tunnel is placed as far medially as possible in the horizontal plane. For measurement of backward traction, the forcep is protruded from the guidance tunnel at 3cm. For measurement of forward traction, the forcep is protruded from the guidance tunnel at 1cm. Each test is run until either a maximum position has been reached or the motor ceases to function due to the load. Ten runs of measurement is obtained for each traction direction.

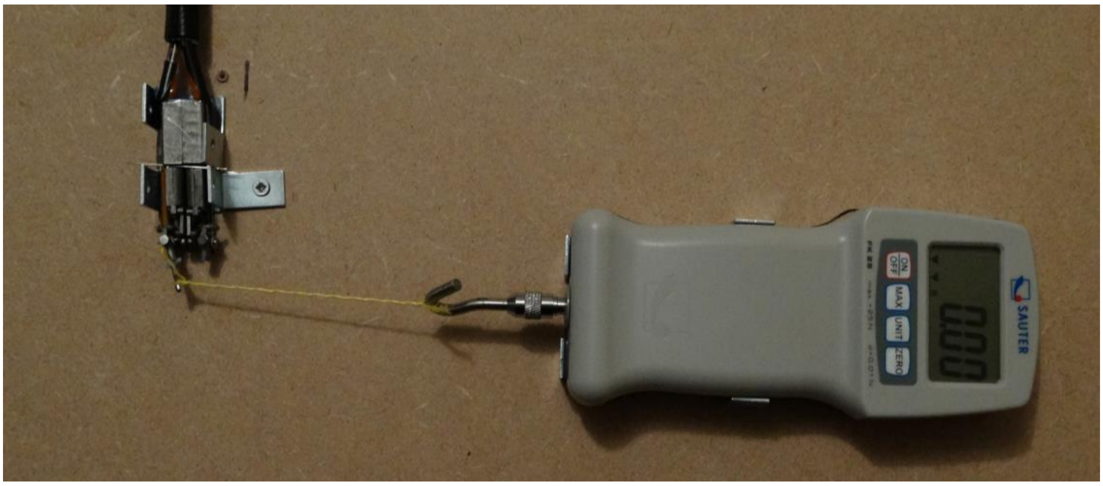


Figure 86: General setup for measurement of lateral, medial, upward and downward traction.

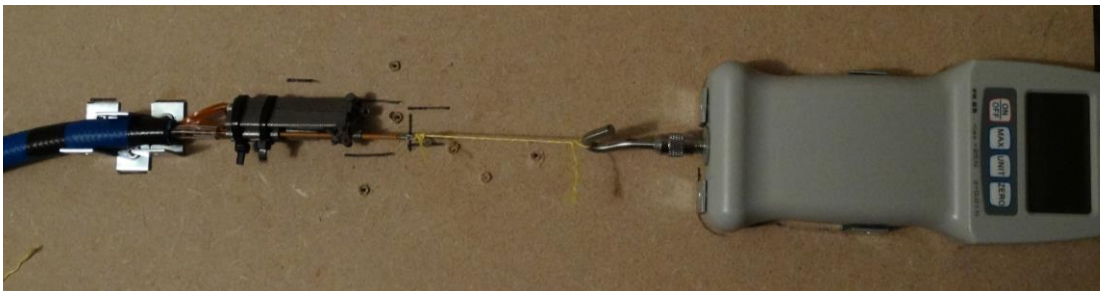


Figure 87: Setup for measurement of backward instrument traction.

Figure 88: Pulley setup for measuring forward instrument traction.

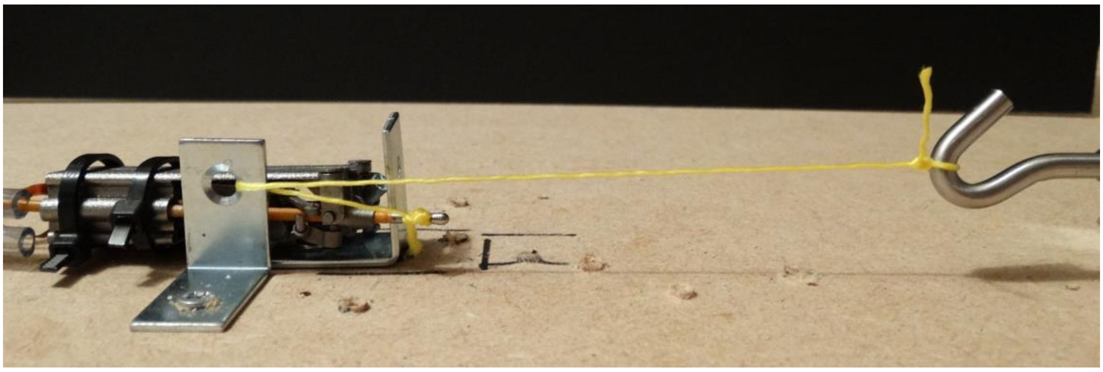


Figure 89: Side view of setup for measuring forward instrument traction.

8.2.2 Results

A summary of the mean force generated in different directions of traction can be seen in Table 6. For medial traction, a mean force of 0.69 N is obtained. Lateral traction generated a mean of 0.45 N. The mean upward traction force generated was 1.22 N and the mean downward traction generated 3.36N. It can be seen that the four part linkage mechanism is better at transmitting force from the micro motor in the up and down direction. The mean forward traction force generated was 1.42N. The mean backward traction generated was 5.94 N.

Instrument traction direction and initial positions	Average Force (Standard Error) Newton
Medial Traction (90 degrees vertical plane)	0.69 (0.03) N
Lateral Traction (90 degrees vertical plane)	0.45 (0.02) N
Upward Traction (0 degree horizontal plane)	1.22 (0.04) N
Downward Traction (0 degree horizontal plane)	3.36 (0.31) N
Forward Traction (from 1cm instrument protrusion)	1.42 (0.02) N
Backward Traction (from 3cm instrument protrusion)	5.94 (0.43) N

Table 6: Mean traction forces of endoscopic platform in medial, lateral, upward, downward, forward and backward directions.

It can be seen that the standard error for downward traction and backward traction is significantly higher than other directions. Due to the inadequate motor anchorage in the front unit frame design, micro motor migration anteriorly and posteriorly during upward traction and lower traction respectively proved to be a significant issue. (Figure 90) This problem was particularly significant during downward. In order to mitigate this problem, temporary external anchorage were mounted to the prototype. During backward traction, since the traction was generated from the handle of the endoscope, there was occasional deformation of the entire endoscope prototype. As a result, the force measurements were variable. However, it is likely that forces generated during normal tissue dissection will not be sufficient to deform the entire endoscope. This is further evidence that traction cables actuation in a flexible system has the shortcoming of hysteresis. The flexible instruments used also deformed during maximal traction force. Flexible forceps deformation under strain can be seen in Figure 91 and Figure 92. This deformation can limit the amount of traction force generated. However, with the device capable of generating 3.36N in the downward direction and 1.42N in the forward direction, it is likely this level of force is sufficient for soft tissue manipulation.

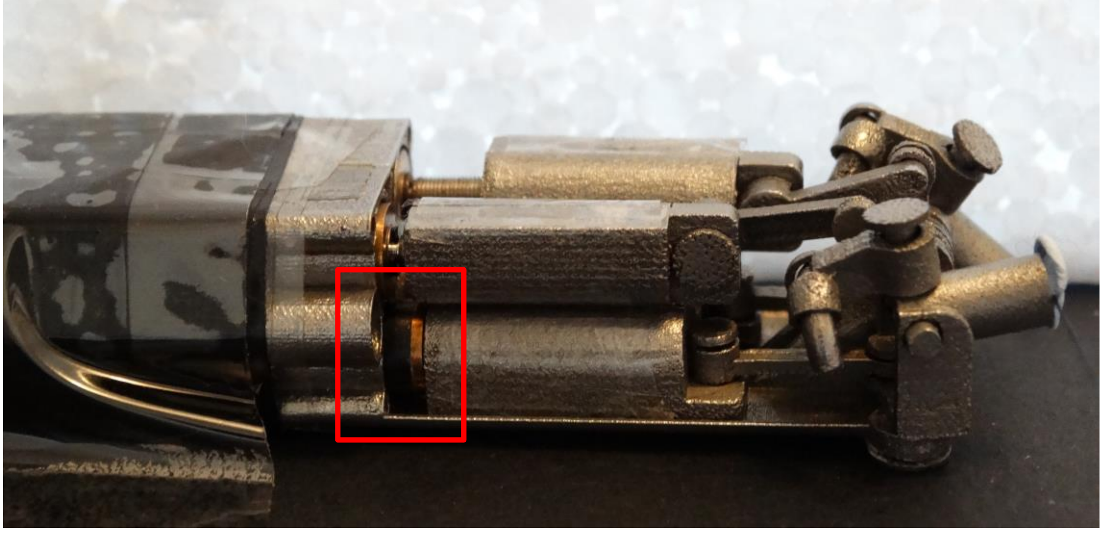


Figure 90: Micro motor migration (red box) due to inadequate anchorage in the design of the prototype.

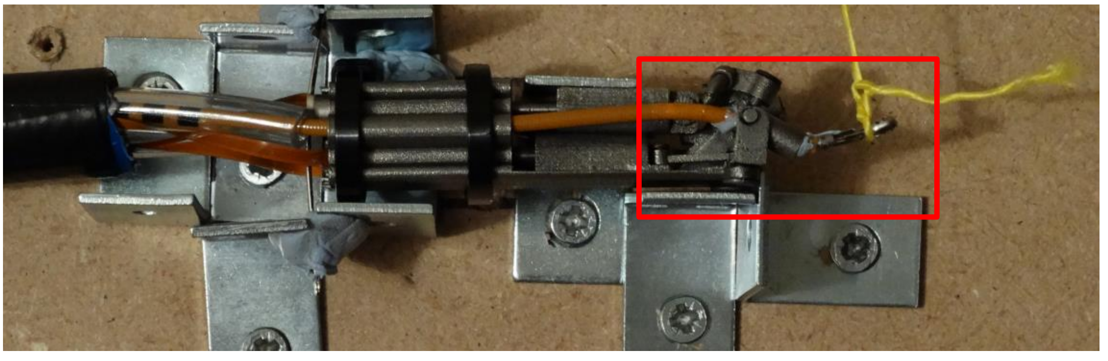


Figure 91: Deformation of flexible instrument (red box) during downward traction of up to 4.58 N.

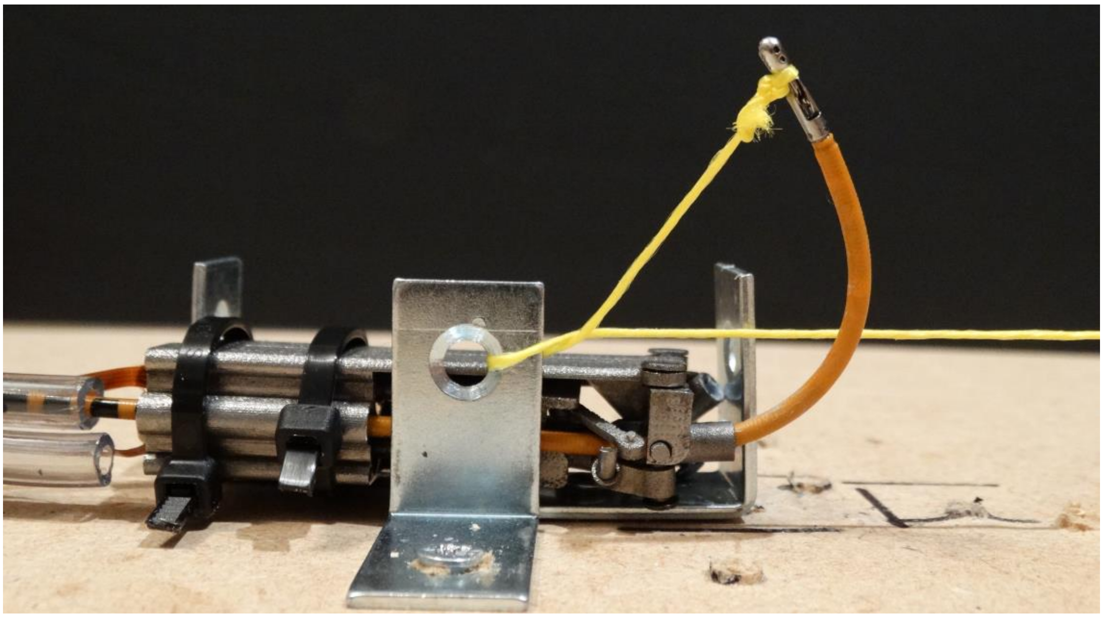


Figure 92: Deformation of flexible instrument during maximum forward traction of up to 1.53N.

8.3 Access to UGI Tract Model

8.3.1 Method

The purpose of this test is to see whether the prototype in its current dimension can negotiate through simulated human anatomy.

8.3.2 Results

Although the dimension of the prototype (16.4 mm (V) * 25mm (H) * 61mm (L)) is similar to that reported in the literature (Table 1 in chapter 3), it has proved to be difficult in accessing our simulated UGI tract. (Figure 94 and Figure 94) The relatively long front unit makes negotiation of the endoscope into the pharynx difficult. However, the endoscope at its current dimension is able to pass through the stomach into the duodenum. (Figure 95)

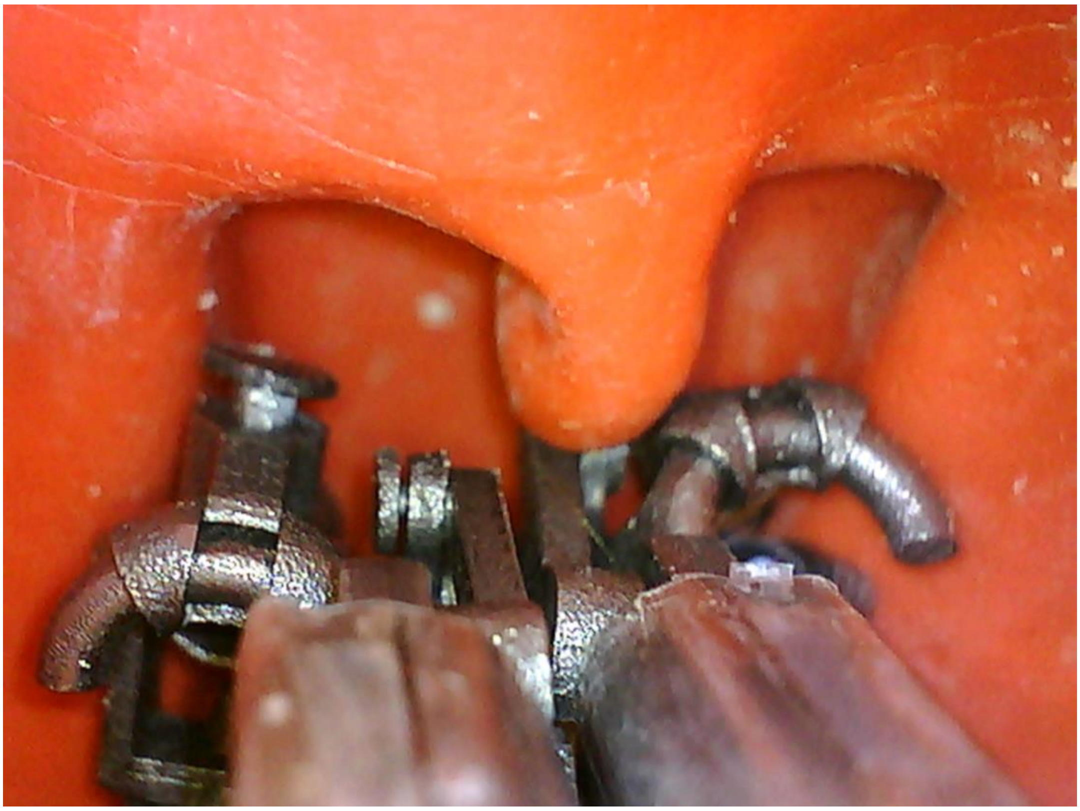


Figure 93: Endoscope in the oral cavity. The length of the front unit rendered intubation through the pharynx impossible.

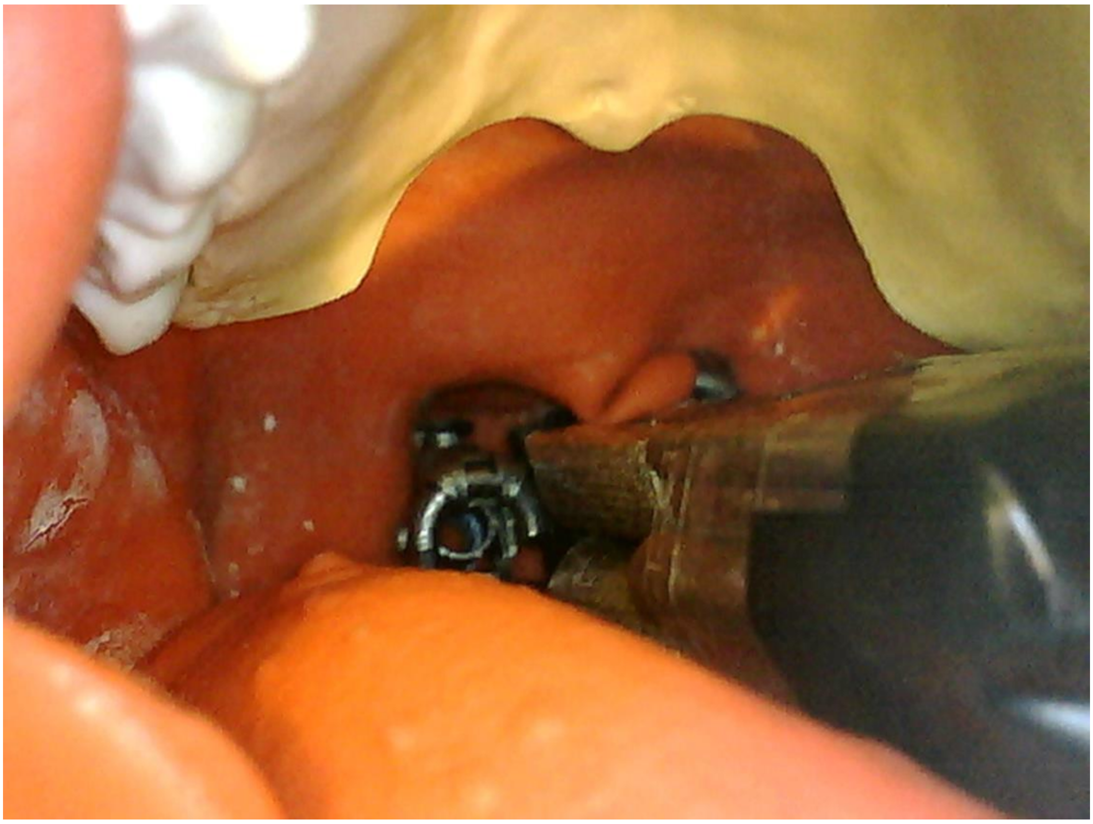


Figure 94: Endoscope in the oral cavity. The length of the front unit rendered intubation through the pharynx impossible.

Figure 95: The device can be seen in the third part of the duodenum.

8.4 Chapter Summary

1. This chapter demonstrates that the prototype has similar kinematic characteristics to that of the simulated computer model. The flexibility of polyamide renders it a poor material for force transmission through the four part mechanism. The kinematic characteristics of the metal prototype are very similar to that of the simulated computer model.

2. Force analysis of the metal prototype showed that the range of traction force generated ranges from 0.45N to 5.94N depending of the direction of traction. This level of force is likely to be sufficient for endoscopic tissue manipulation as indicated in the literature.

3. The current prototype however is unable to access the UGI tract. This demonstrates the significant challenge posed by the migration of the functional element from the extracorporeal part of the device (as seen in all existing rival robotic endoscopic multitasking platform) to the intracorporeal part of the device. Further improvement is required to minimize the size of the device and to streamline the contour of the device.

Chapter 9: Mk2 design

Through the above tests, it is clear that the dimension of the prototype should be reduced to allow better access into the UGI tract. Further compaction of the four part linkage mechanism will be the key to further reducing the size of the front unit. Currently, metal printing technology did not offer sufficient manufacture resolution for the purpose of producing this device. The new design will utilize more conventional prototyping technology such as computer numerical control (CNC) multi axis milling. The use of CNC milling dictates that the parts must be simpler in order for it to be suitable for 5 axis milling. Simple reduction in the part sizes is unlikely to offer a sufficiently strong mechanism for force transmission. Therefore, the four part mechanism was redesigned to increase its inherent strength. Secondly, it will utilize the Faulhaber 03A S3 linear actuator which has a shorter length and smaller diameter. With a reduction ratio of 125:1, the 03A S3 linear actuator can generate 2.8 N of continuous push force and 4.2 N of intermittent push force at a maximum speed of 24mm/min. (Figure 96) Due to financial limitation, the manufacturing of the Mk2 design is beyond the scope of the current project.

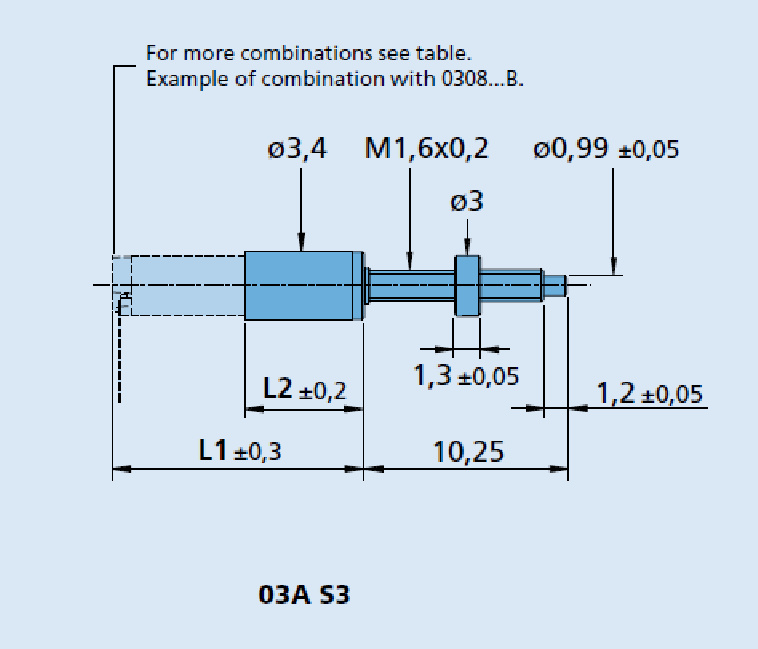


Figure 96: Schematic representation of the Faulhaber 03A S3 linear actuator which is shorter and of smaller diameter.

Mk2 design objectives:

1. The dimensions of the front unit must be further reduced and streamlined in order for the device to access the upper gastrointestinal tract. The design should be tailored to using CNC milling technology and small micro motors. The aim is to reduce the size of the front unit by 33%.

2. The design of the four piece mechanism must be more compact and robust.

3. Micro motor anchorage and encasement needs to be improved in order to avoid motor migration. This will improve force transmission to the guidance channel. This will also be vital in waterproofing the design.

4. The method of assembly must be improved in order for a more robust assembly.

5. The choice of micromotor must be optimized for power and size.

6. The front unit must have a robust connector mechanism with the bending section.

9.1 Improvement in the Four Part Linkage Mechanism

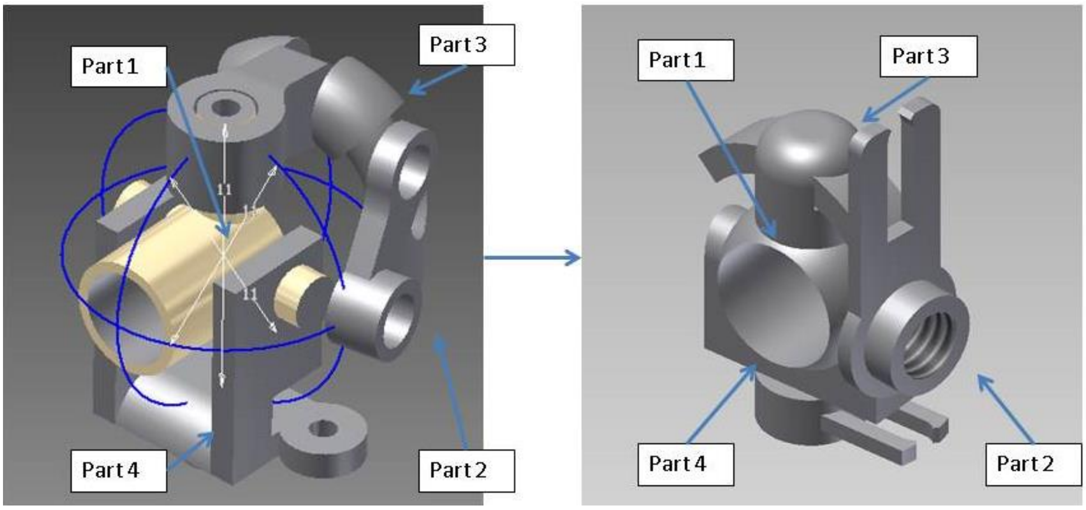


Figure 97: Four part mechanism from the aforementioned Mk1 (left). The four part mechanism is redesigned to be more compact in the Mk 2 design (right).

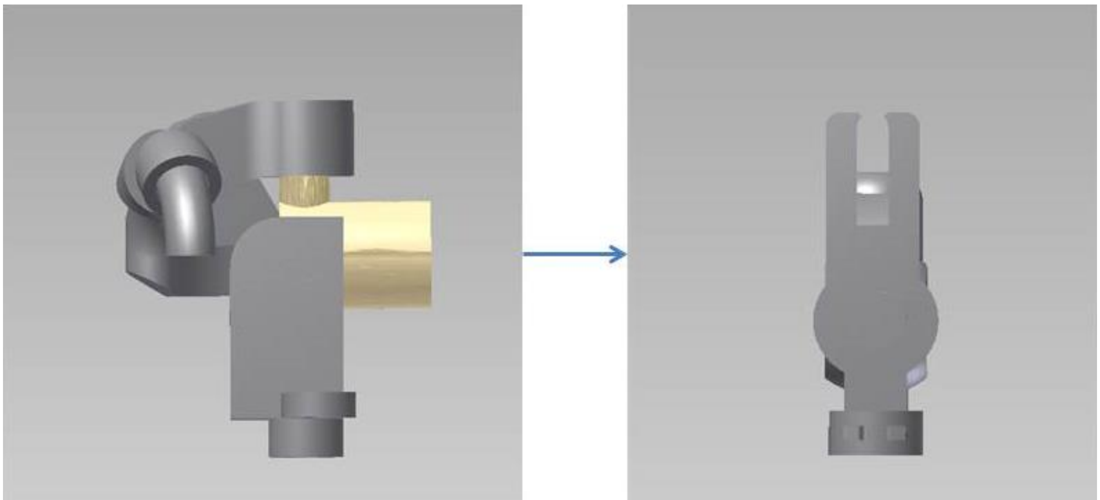


Figure 98: Side profile of the four part mechanism from the aforementioned Mk1 (left). The four part mechanism is redesigned to be more compact in the Mk 2 design (right).

Figure 97 and Figure 98 demonstrate the evolution of the four part mechanism from that of Mk1, which was manufactured and the Mk2 design. As an overview, the parts are much more compact.

Firstly, the compactness of the Mk2 four part mechanism has been achieved through designing the parts with 0.5mm -1 mm wall thickness.

Secondly, Part 1 is transformed into a spherical structure braced by the curvature of part 4. (Figure 99, Figure 100) As a result, although the individual parts have thinner wall thickness, the combined thicknesses at force exertion points are greater than that of Mk1.

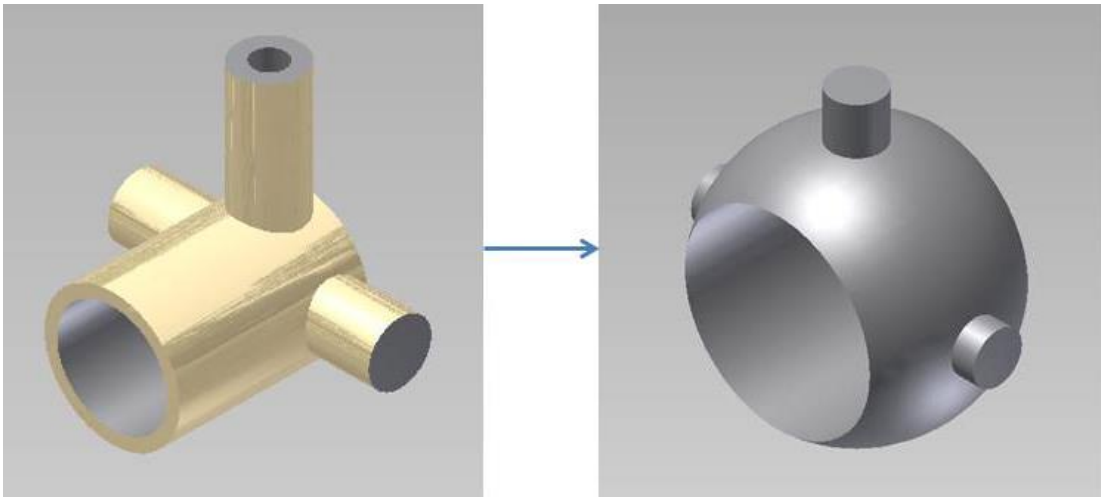


Figure 99: Part 1 from Mk1 (left). On the right, part 1 in Mk2 has a spherical structure designed to fit into the curvature of part 4.

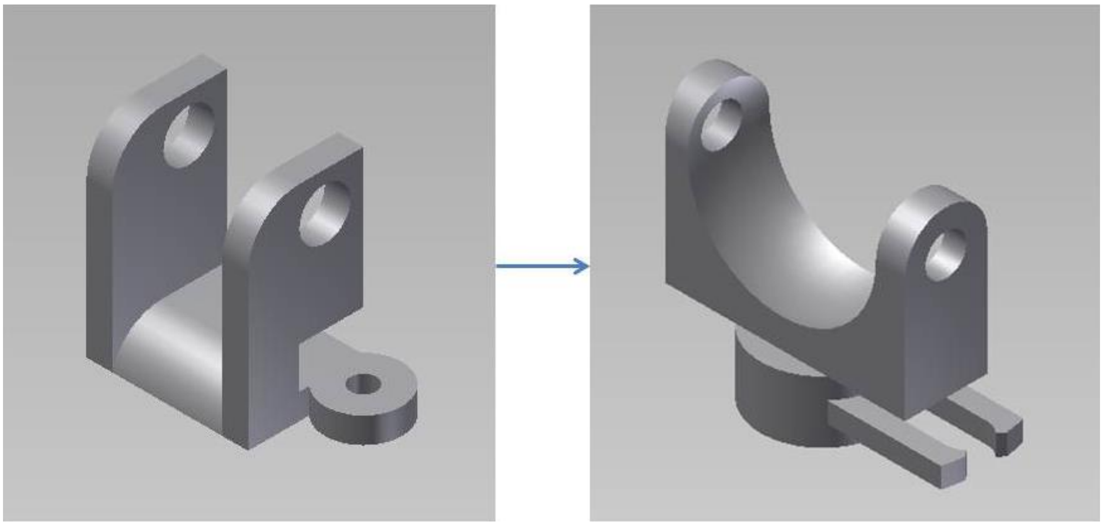


Figure 100: Part 4 from Mk1 (left). On the right, part 4 in Mk2 has a spherical inner surface designed to accommodate the spherical surface of part 1.

Thirdly, with further computer simulation, it became clear that the key interaction between part 2 and 3 is that they must move along a spherical plane concordant with that of part 1. All parts must have its centre point aligned with that of part 1 in order for the mechanism to work properly. With this insight, part 2 no longer needed an L-shaped configuration. In the Mk2 design, the arch of part 2 is placed in the same vertical plane as that of its main body structure. (Figure 101) As a result, part 3 has a much simpler structure. (Figure 102) In the Mk2 design, a 7.9mm diameter spherical plane has been chosen. In contrast, an 11mm spherical plane was chosen for Mk1. The intimately overlapping parts confer additional strength. By simplifying the parts, it will likely lead to improve manufacturability. The Mk2 design has a 3.7mm channel and 2.7mm channel in the fashion akin to any standard dual channel endoscope available commercially.

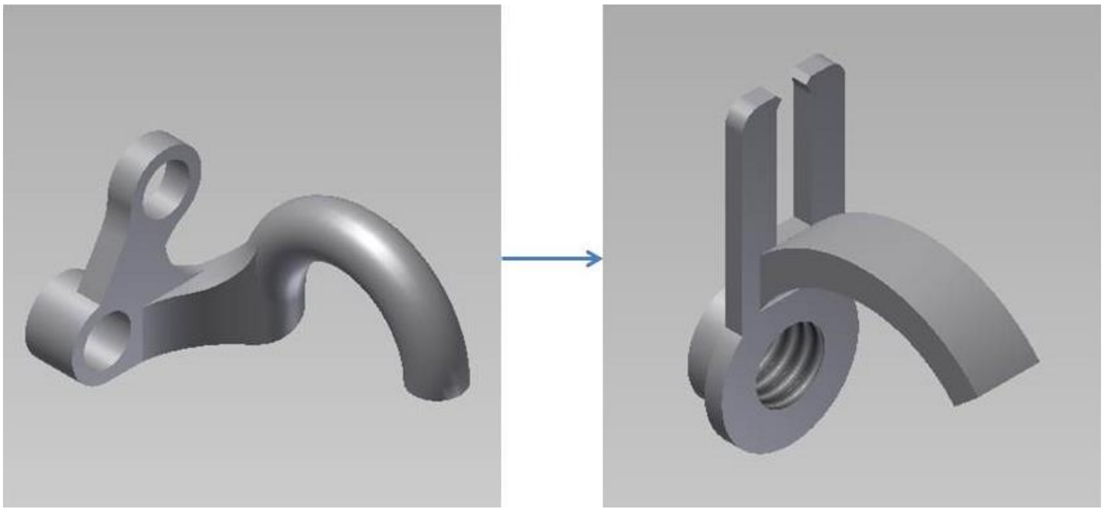


Figure 101: Part 2 from Mk1 (left). On the right, part 2 in Mk2 no longer has the L shaped configuration. The simplification of the design has improved its strength.

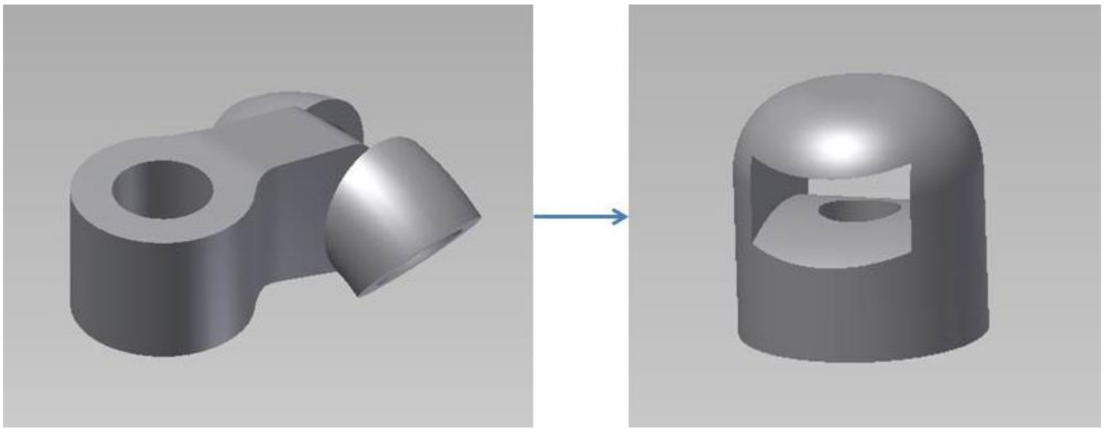


Figure 102: Part 3 from Mk1 (left). On the right, part 3 in Mk2 has a simpler design further improving it manufacturability.

9.2 Front unit frame

During force analysis, it became clear that when the motors are working against a load, there is a tendency for the motors to migrate in the opposite direction. This could be prevented by adding apertures at the anterior aspect of the micro motor mount which will allow the passage of the motor shaft to interact with the actuator but keeping the motor body anchored within the mount. (Figure 103) During assembly of the device, the micro motor can be slotted into the encasement and enclosed in the rear by a connector piece. The connector piece will in turn connect to a 12.9mm diameter generic bending section. (Figure 104) In this configuration, additional space can be gained by directly opposing the 4 micro motors against each other. During the testing of the Mk1 prototype, it is noted that when the motors are working at maximum range (ie>10mm linear displacement), the motor bearing can become detached from the motor shaft. Proper anchorage of the motors should prevent this problem from occurring. During testing, it was also evident that when the motor is working beyond its minimum range, the body of the motor will rotate. This could lead to potential disruption of its electronic connections. This problem can be prevented through the use of adhesives during assembly process to ensure the motors are fixed in relation to the front unit frame.

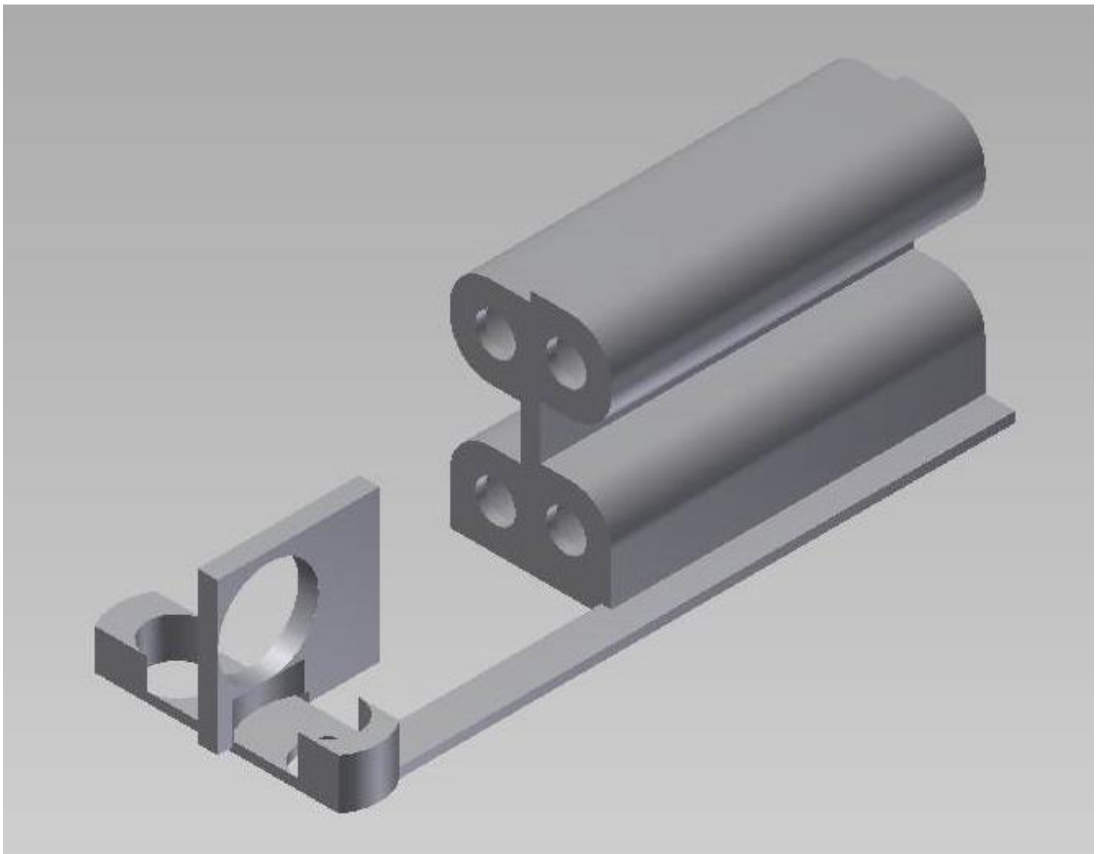


Figure 103: Mk2 front unit frame. The motor cover has apertures in the anterior aspect to allow the passage of the micro motor shaft while anchoring the motor body within the encasement.

Figure 104: Front unit frame end cover which connects to a 12.9mm diameter generic bending section.

9.3 Improvement in Assembly Method

During the assembly of the prototype detailed in chapter 7, it became clear that the rivet system is not sufficient for secure assembly. Therefore, miniature screws will be used for assembly of the Mk2. The new design will accommodate screws with ANSI Metric M2 * 0.4 specification. (Figure 105)

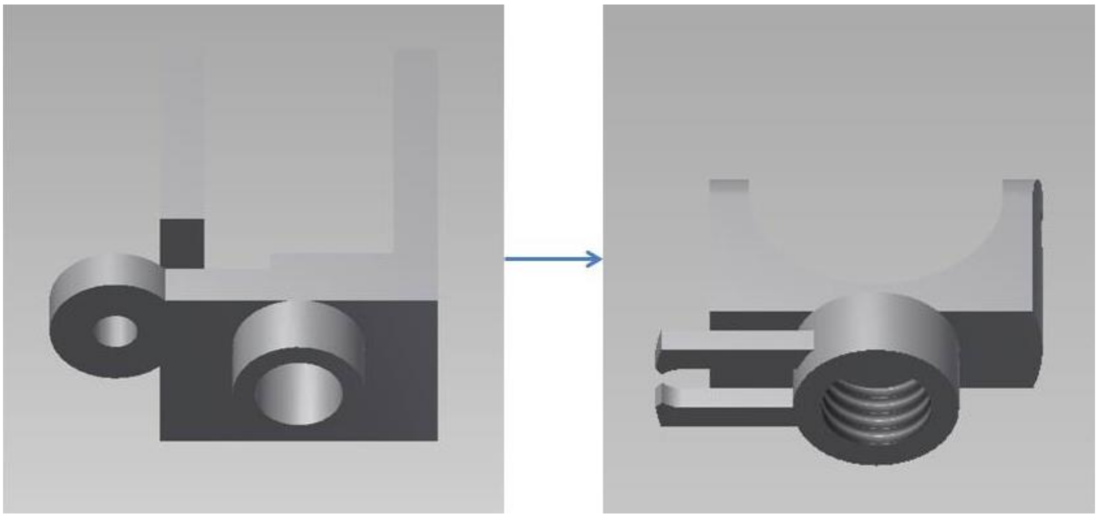


Figure 105: The screw system is adopted in the Mk2 design. The above images demonstrate that part 4 will be secured to the front unit frame using screws in the Mk2 design (right), in contrast to simple rivets in Mk1 (left).

Furthermore, the corresponding left and right sides of part 2 are held together against the front unit frame with a single M2 * 0.4 screw. (Figure 106)

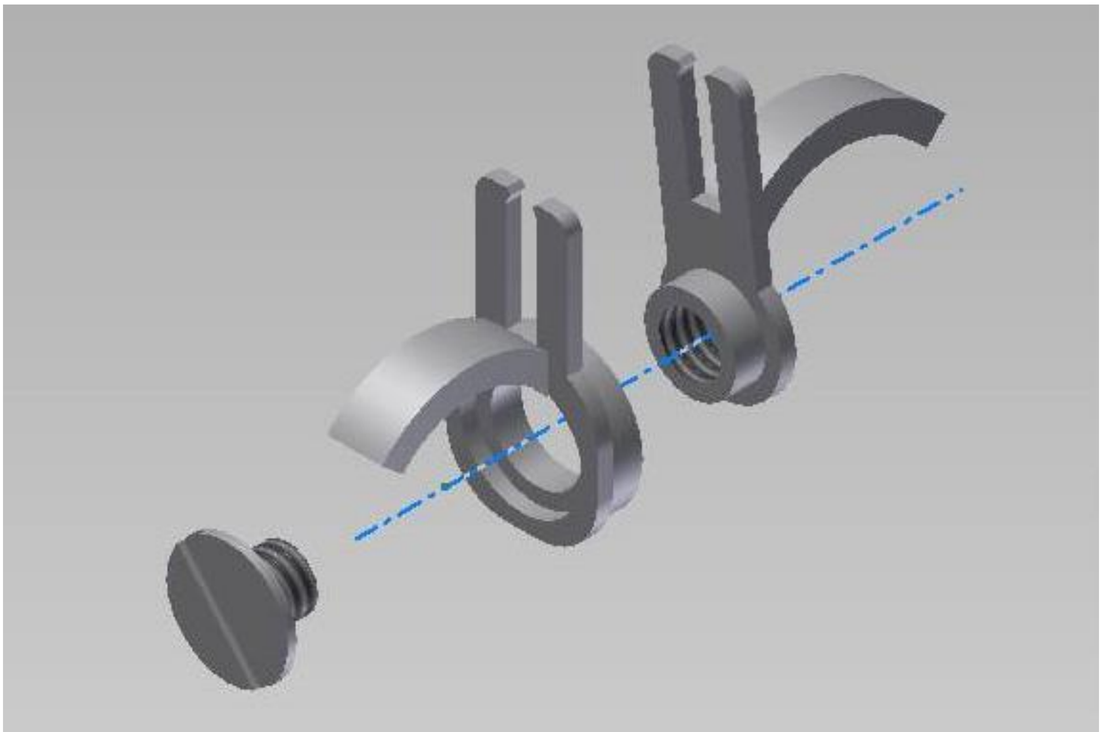


Figure 106: The left and right sides of part 2 are held together by a single screw.

The linkage between the micro motor and the four part mechanism is further simplified. (Figure 107)

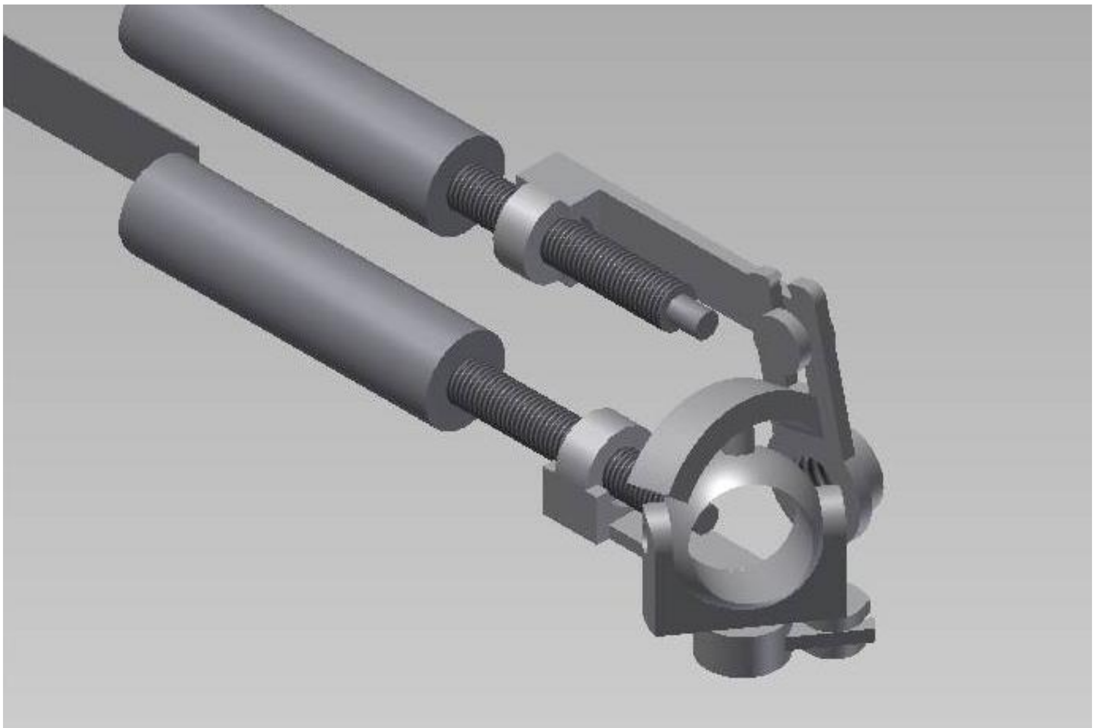


Figure 107: In Mk2, the motor linkage to the four part mechanism does not use rivets or screws.

Based on the above modification, the front unit dimension is 13.9 mm (horizontal), 12.2 mm (vertical) and 34.5mm (length). In contrast, the dimension of the manufactured prototype in chapter 7 is 25mm (horizontal), 16.4 mm (vertical) and 61 mm (length). This is a 44.8% reduction in horizontal dimension, 25.6% reduction in vertical dimension and 43.4% reduction in length. Figure 108 to Figure 112 demonstrate the comparison between the Mk1 design and the Mk2 design. The design drawings of Mk2 can be seen in appendix B.

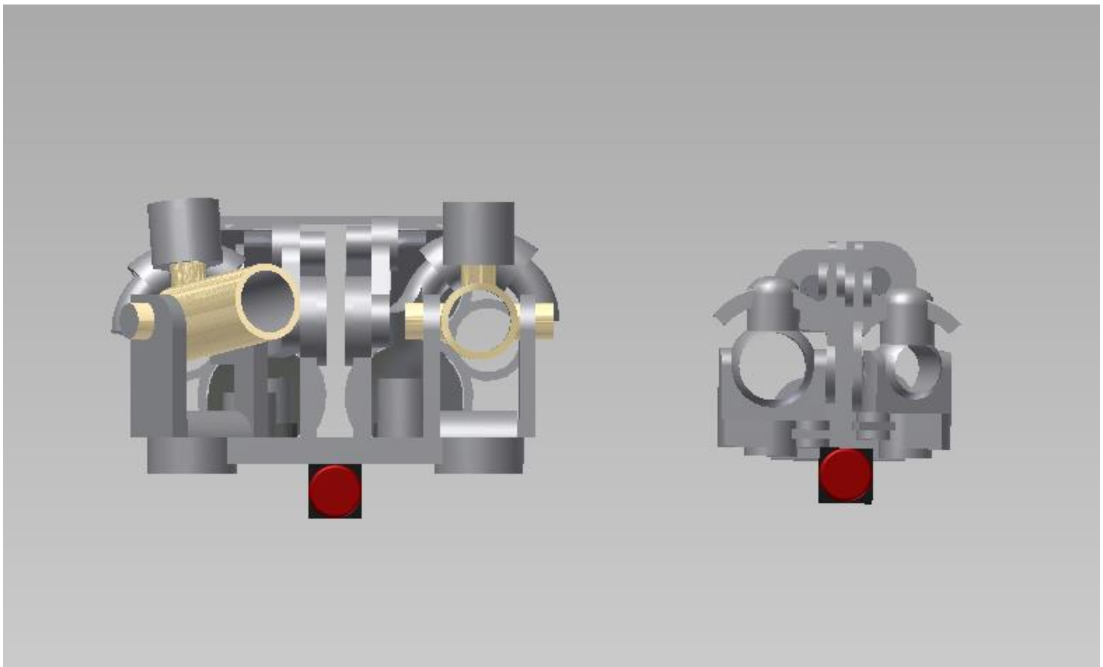


Figure 108: Mk1 (left) vs Mk2 (right): front view.

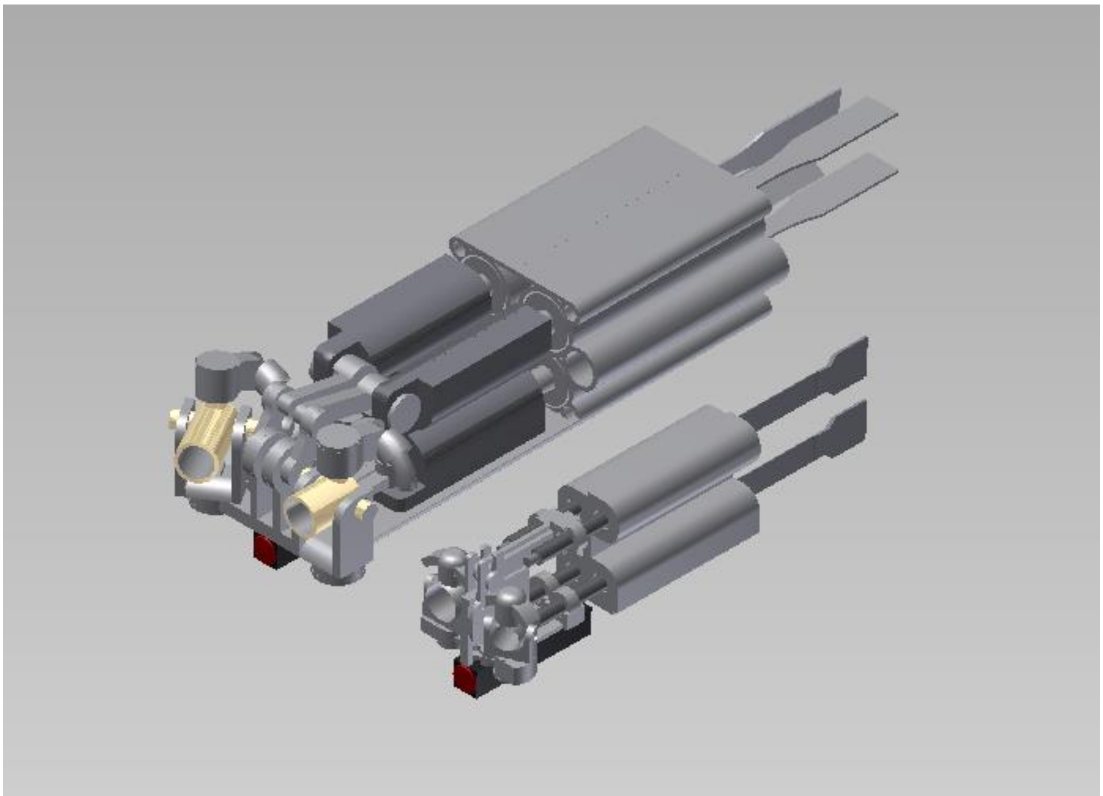


Figure 109: Mk1 (top) vs Mk2 (bottom): oblique front view

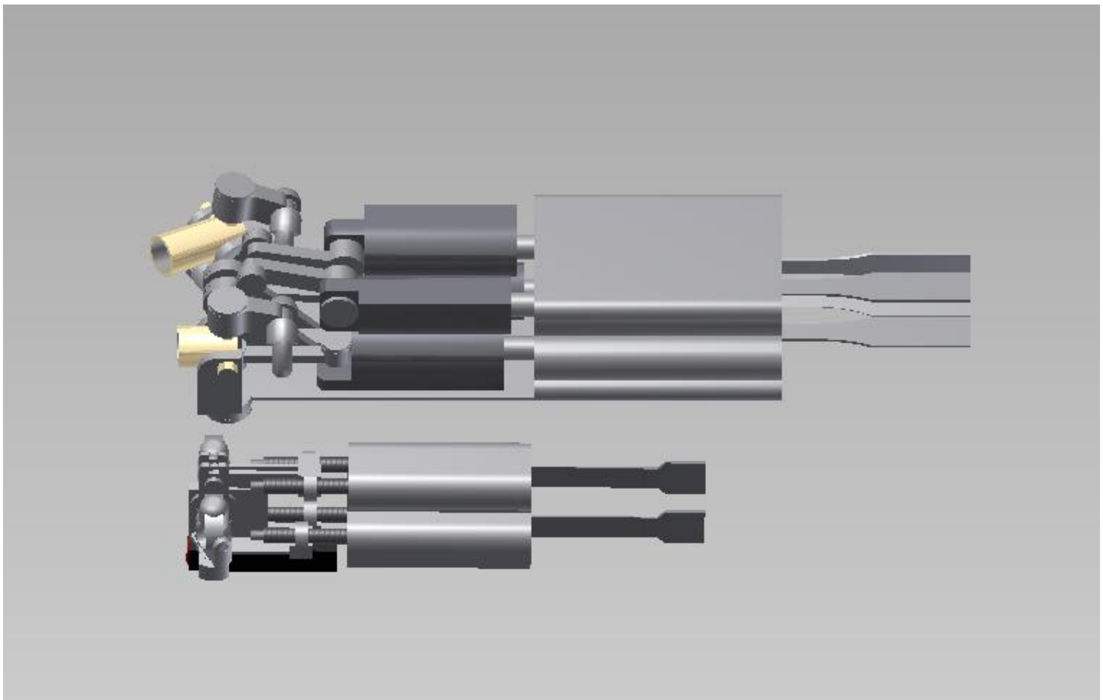


Figure 110: Mk1 (top) vs Mk2 (bottom): oblique side view

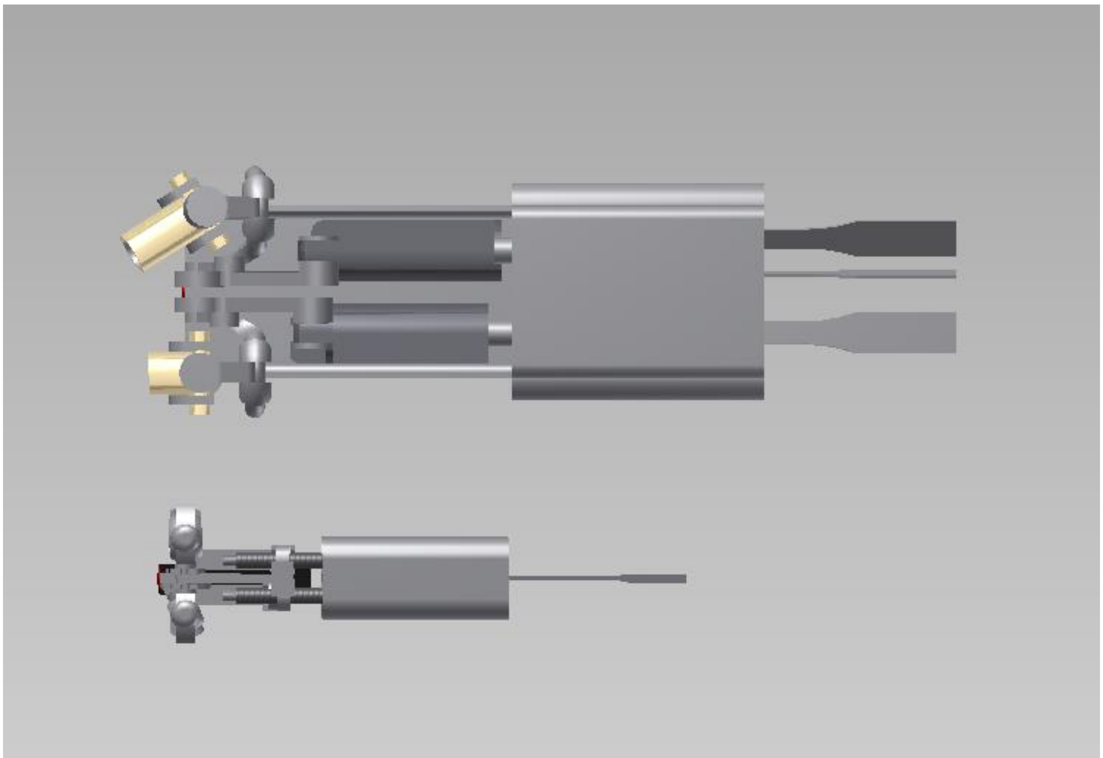


Figure 111: Mk1 (top) vs Mk2 (bottom): top view

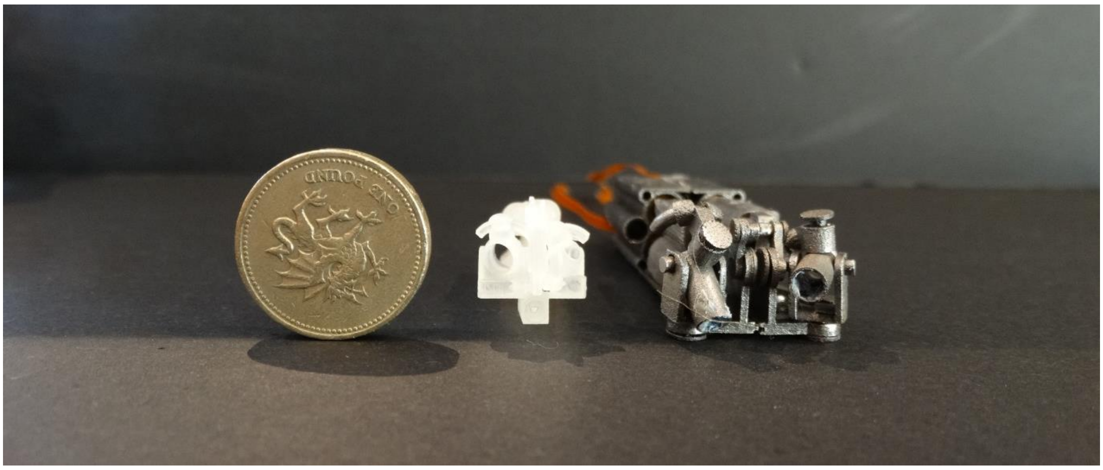


Figure 112: Comparison of Mk2 polymer prototype (middle) and Mk1 metal prototype (right). A pound coin is placed for size reference.

9.4 Chapter Summary

1. The front unit dimension must be reduced in order to achieve access into the upper gastrointestinal tract. The challenge of moving the functional element from the extracorporeal part of the device (as seen in all existing rival robotic endoscopic multitasking platform) to the intracorporeal part of the device proved to be a significant task. With the above modifications, we have successfully reduced the size of the front unit by more than 33%. The Mk2 design has achieved a 44.8% reduction in horizontal dimension, 25.6% reduction in vertical dimension and 43.4% reduction in length when compared to the Mk1 design.

2. A smaller micro motor and thinner part wall thickness is used. In order to achieve thinner part wall thickness, it is anticipated that more conventional

manufacturing technology such as computer numerical control milling will be used. In order to achieve this, the parts must be significantly simpler.

3. The four part mechanism is modified to have a much more compact architecture. The simpler parts will be easier to manufacture.

4. Screws will be adopted for the assembly of the parts in the Mk2 design.

5. The manufacturing of the Mk2 design is beyond the scope of the current project. Further funding will be required to develop a clinically applicable prototype which should be tested using a live animal model (the gold standard simulator).

Chapter 10: Discussion

10.1 Discussion

With the development of fibre optic technology, true flexible endoscopy became a reality in the 1950's. Since then, development of charge couple device (CCD) and complementary metal oxide semiconductor (CMOS) image technology, high definition endoscopes with superior diagnostic capability has been achieved. With improved vision, endoscopic therapy has also matured with advanced techniques such as endoscopic submucosal dissection (ESD) developed. Due to the limited independent instrument freedom that the current endoscope offers, only a small group of endoscopist are able to perform these techniques competently. An improved endoscope with improved independent instrument freedom will act as an enabler technology to popularize these techniques. As a direct result, more patients will be able to benefit from these useful and truly minimally invasive therapies.

The endoscope industry recognizes the need for improved endoscopic instrument freedom. Initially, the focus of research was to enable natural orifice translumenal endoscopic surgery (NOTES). Since the identification of numerous new surgical complications related to NOTES surgery, NOTES' popularity has been reduced significantly. A new found focus for the industry is to develop a platform for the performance of advanced endoscopic therapy. A class of endoscopic multitasking platform is therefore developed. These platforms combine visualization with two instrument channels, therefore allowing endoscopic bimanual task performance. These platforms are either mechanical or robotically controlled. Some of the designs retrofit a conventional endoscope with flexible cable controlled instruments (eg DDES system). The MASTER system also uses the retrofit concept; however, it incorporates robotically controlled fixed instrument arms to the retrofitted device. Others designs incorporate large therapeutic channels into the endoscope through which cable controlled multi-directional flexible instruments are inserted (eg. EndoSamurai or Anubis system). The Viacath system offers a robotically controlled multi-directional flexible instrument. Yet another concept is to have a mechanical bridge at each of the therapeutic channel outlet, thereby increasing instrument freedom by one degree (eg. R scope). All these concepts rely on the use of actuation cables for actuation; in a flexible system, this is inherently unstable.

It is not possible for two endoscopists to simultaneously control an endoscope and two instruments with independent movement of more than five degrees of freedom efficiently. Therefore, robotically controlled platforms are ideally suited for this application. The rigid robotic laparoscopic system Da Vinci, has gained significant acceptance by the global medical community. Widespread acceptance of robotic endolumenal surgery is without doubt rapidly emerging.

This thesis proposes a novel design for an endoscope for the performance of advanced endolumenal therapy. Using three-dimensional reconstruction software and the visible human project data, a high resolution 3-D anatomical upper gastro intestinal computer model and physical model was constructed to help further understand the demanding anatomy which an endoscope must negotiate through. Based on this knowledge, appropriate mechanical phantoms have been chosen for the purposes of testing the proposed endoscopic device. This has satisfied the objectives: To explore the anatomy and the biomechanical properties of the upper gastrointestinal tract and to develop a suitable upper gastrointestinal model for the testing of the novel robotic endoscopic multitasking platform.

Using computer aided design, a novel endoscopic platform basic functional prototype was constructed. The design followed the outlay of the conventional endoscope. It utilized off the shelf technologies to minimize development cost. It is hoped that by adopting the conventional endoscope outlay; the novel design will inherit its manoeuvrability and reduce the barrier to acceptance by the medical community. It has two instrument channels and allows rapid instrument exchange. Most importantly, the novel electromechanical design of the two degree freedom instrument channel that is controlled by two fixed micro motor is central to the platform. The novel four part mechanism has never been described in both academic literature search or in patent searches through patent databases. By utilizing short range micro motor, accurate and precise instrument movement could be achieved. This is akin to the fly by wire technology used in the aerospace industry. Through the combination of actions from the front unit, handle unit and the external unit, independent instrument movements of up to five degrees of freedom can be achieved. It has been demonstrated that the motors can be control to actuate instrument movement through a digital controller (PS3 controller) and a digital microcontroller (Arduino Mega 2560 microcontroller). The objectives: to design a novel robotic endoscopic platform using computer aided design; to produce a basic functional prototype of the novel platform have therefore been achieved.

The basic functional prototype was tested to assess its kinematic performance, its force generation capability and its ability to access the upper gastrointestinal phantom. The metal prototype instrument movements correlated well with that of the computer simulated model. Moreover, it is capable of delivering significantly larger traction forces than a conventional endoscope which is only capable of producing instrument force in the region of 0.4N.[215] However, the basic functional prototype performed poorly in gaining access into the upper gastrointestinal tract phantom. This is largely due to the length of the prototype, which prevented it from negotiating beyond the oropharynx. In part, the prototype has an excessive length because a larger and high power micro motor was chosen. Furthermore, it has been designed with excessive part wall thickness. This excessive part wall thickness has been intentionally designed to overcome the limitation of current metal printing technology. Although metal printing technology offered the advantage of build very complex parts, the current metal and bonding technology dictates that a significant wall thickness (>0.5mm) must be designed in order to have a robust part. Furthermore, the precision of metal printing remains to be desired. The material is also brittle and prone to fracture. For further development, an alternative metal prototyping technology such as computer numerical controlled multi axis milling may be suitable. In this thesis, the objectives: to produce a basic functional prototype of the novel platform; and to perform bench top testing of the functional prototype has been achieved.

Based on the insights gained from manufacturing and bench top testing of the first generation prototype, a second generation prototype was designed using computer aided design. The second generation prototype has been designed to further reduce the size of the front unit. The Mk2 design has also made improvements on the micro motor housing, the instrument channel four-part mechanism and its connection with the endoscope bending section. The Mk2 design is designed to utilize a smaller micro motor which is slower and has lower force generation capability. Alternative method of actuation can be explored. For example, hydraulic actuation of distally located actuators can be used in place of micro motors. However, maintenance of this hydraulic system is likely to be more cumbersome. In the future, more powerful micro motors can be incorporated into the design.

10.2 Future work

The development of a novel robotic endoscopic multitasking platform is complex and involves many components. This thesis produced a framework for a novel endoscopic multitasking platform design. The basic functional prototype has demonstrated the utility of the concept of micro motor instrument actuation. This is novel and has not been applied in the field of endoscopy. However, there remains are large volume of work to be performed in order to produce a functional endoscope suitable for clinical application. Significant amount of funding will be required to achieve this.

1. In the first instance, the Mk2 design should be prototyped to assess its function. Conventional elements such as conventional endoscope control, insertion tube, bending section, visualization components, gas insufflation and water irrigation channel should be incorporated to build a functional prototype for the performance of soft tissue dissection on a bench top model. Waterproofing of the design is also necessary. Haptic feedback development and refinement of control interface and software is also necessary. Further refinement of the design should be made according to test findings. The functional platform should be tested in a preclinical animal setting.

2. The next stage of development would involve adapting the design to become suitable for clinical usage. For example, the novel platform must be compatible with deep cleaning using commercial endoscope cleaning machines. Development of a range of compatible endoscopic instrument will be necessary.

3. In the near future, 3D metal printing, with its ability to rapidly manufacture precise and small metal parts, may be suitable for manufacturing this novel endoscope. Regulatory review is necessary to further assess the suitability

of the use of 3D metal printing technology for the manufacture of medical devices for human usage.

Thereafter, novel features could be incorporated into the design. These may include:

4. Development of camera technology such as the use of three dimensional rotatable cameras.

5. Development of a 360 degree camera for better diagnostic capability and flexibility. Imaging software can be designed to correct the distortion so that the endoscope can be operated in a conventional manner but has the added ability of “looking around corners”.

6. Haptic feedback development.

7. Wireless control unit can be designed to minimize the physical complexity of setting up the platform in an already crowded endoscope unit.

10.3 Conclusions

1. Improvement in endoscope therapeutic capability is needed to widen patient access to minimally invasive endolumenal therapy. Improvements in camera technology, micromotor technology and manufacturing technology mean that a paradigm shift in endoscope design is imminent.

2. Robotic control of the novel endoscope platform will be essential as it is impossible for a human operator to simultaneously control multiple instruments with multiple degrees of freedom of movement effectively. This thesis proposes the use of short range micromotor embedded within the front unit of the endoscope for instrument actuation. This is different from all existing mechanical or robotic endoscopic multitasking platforms which employ actuation cables and external actuation mechanisms.

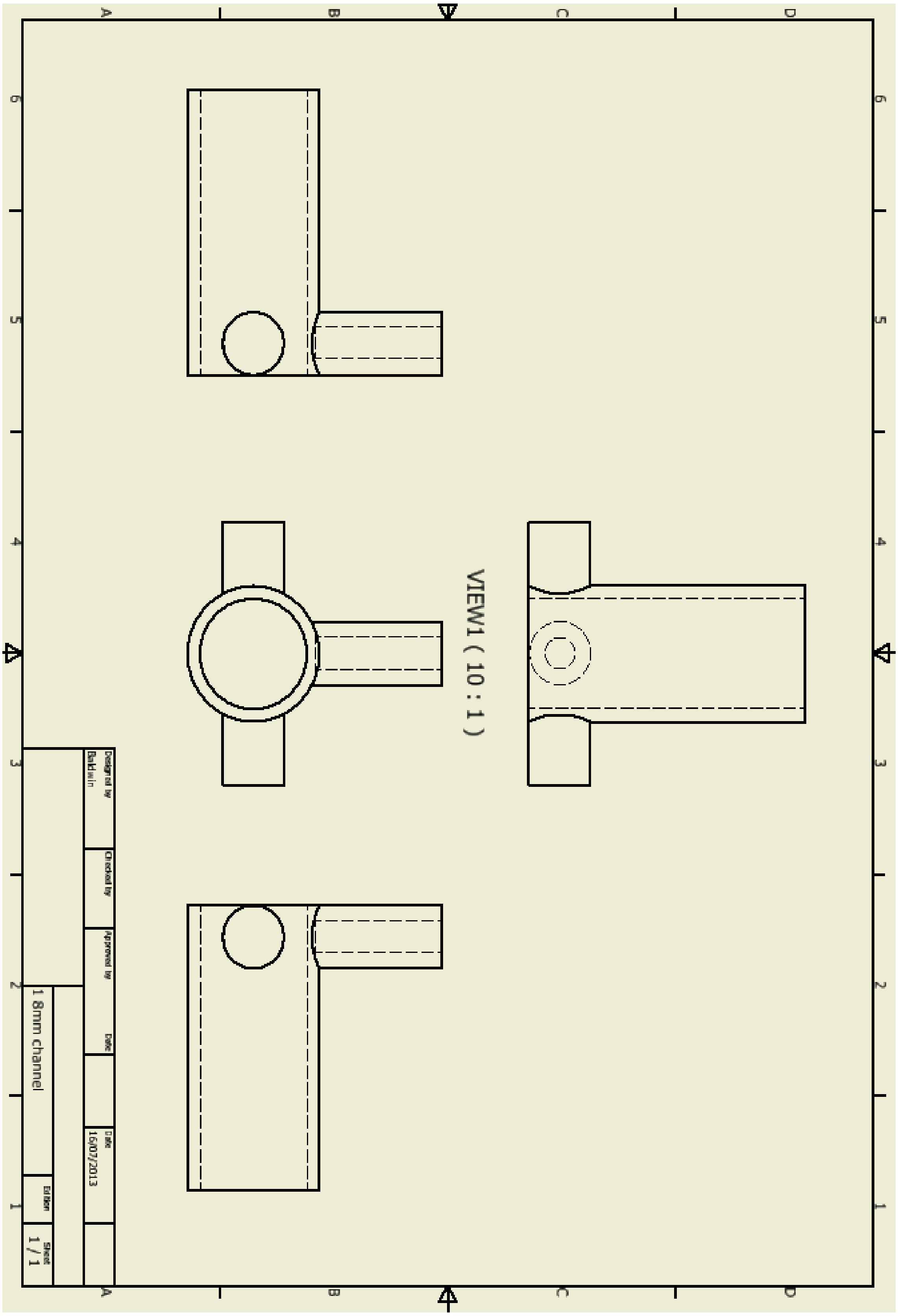
3. The challenge of the migration of the actuation element from extracorporeal part of the device (as seen in all existing rival robotic endoscopic multitasking platform) to the intracorporeal part of the device proved to be a significant task. This thesis focused on developing an aspect of the design which is truly novel, namely the use of short range actuators located within the front unit to manipulate flexible endoscopic instruments. A novel compact four part mechanism has been demonstrated. This mechanism alone allowed the manipulation of flexible instruments with two degree of freedom. Bench top testing confirmed the functionality of the concept. The force generated is superior to the conventional endoscope. However, the Mk1 could not negotiate through the oropharynx.

4. The proposed Mk 2 design has exceeded the design objective of reducing the overall size by 33%. The Mk2 design has achieve a 44.8% reduction in

horizontal dimension, 25.6% reduction in vertical dimension and 43.4% reduction in length when compared to the Mk1 design.

5. The novel concept of applying short range micromotor in the flexible endoscope for instrument actuation has significant potential. With further funding and development, a truly functional clinically applicable endoscope can be manufactured.

Appendix A: Design Drawings of Prototyped Endoscopic Multitasking Platform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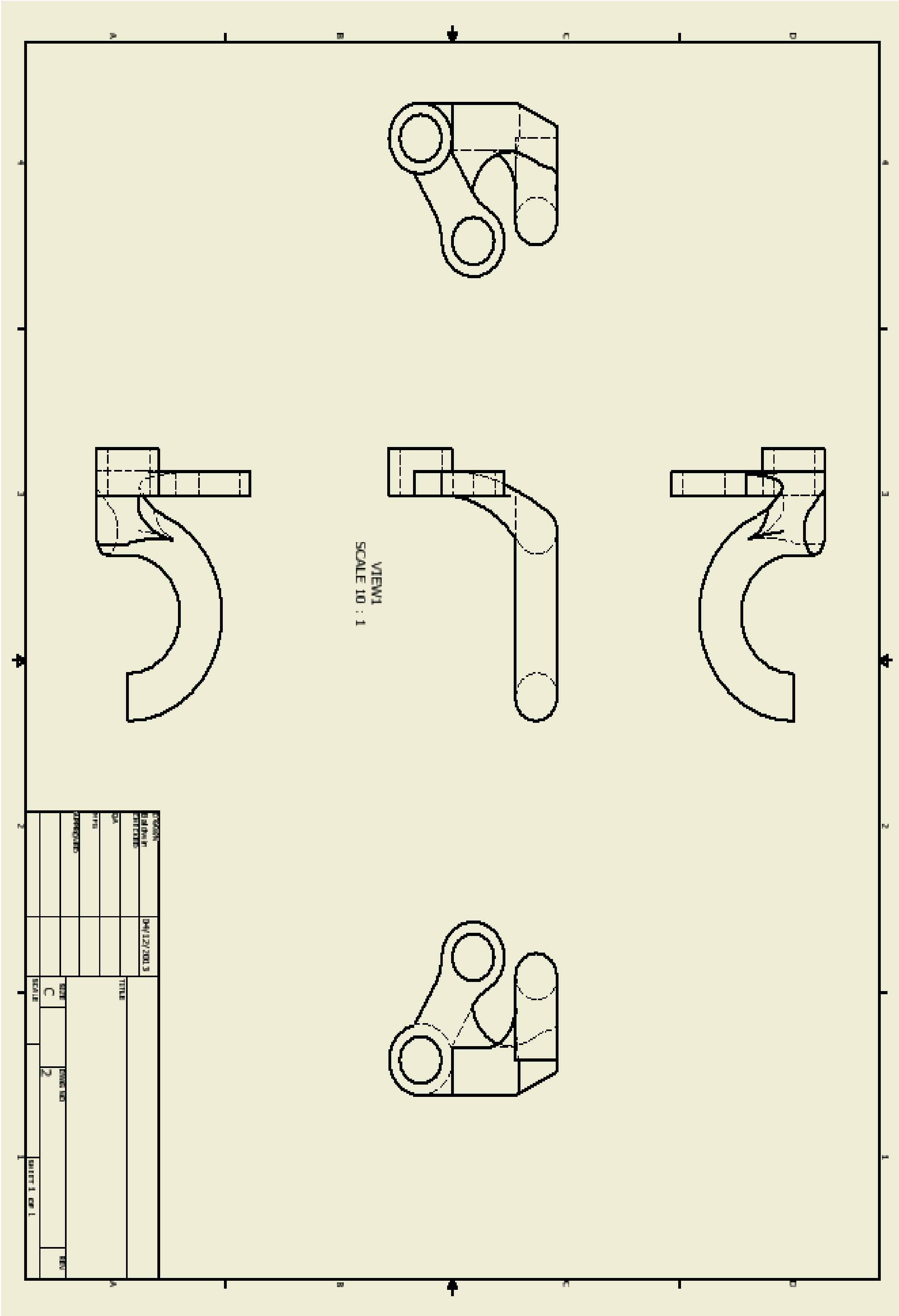
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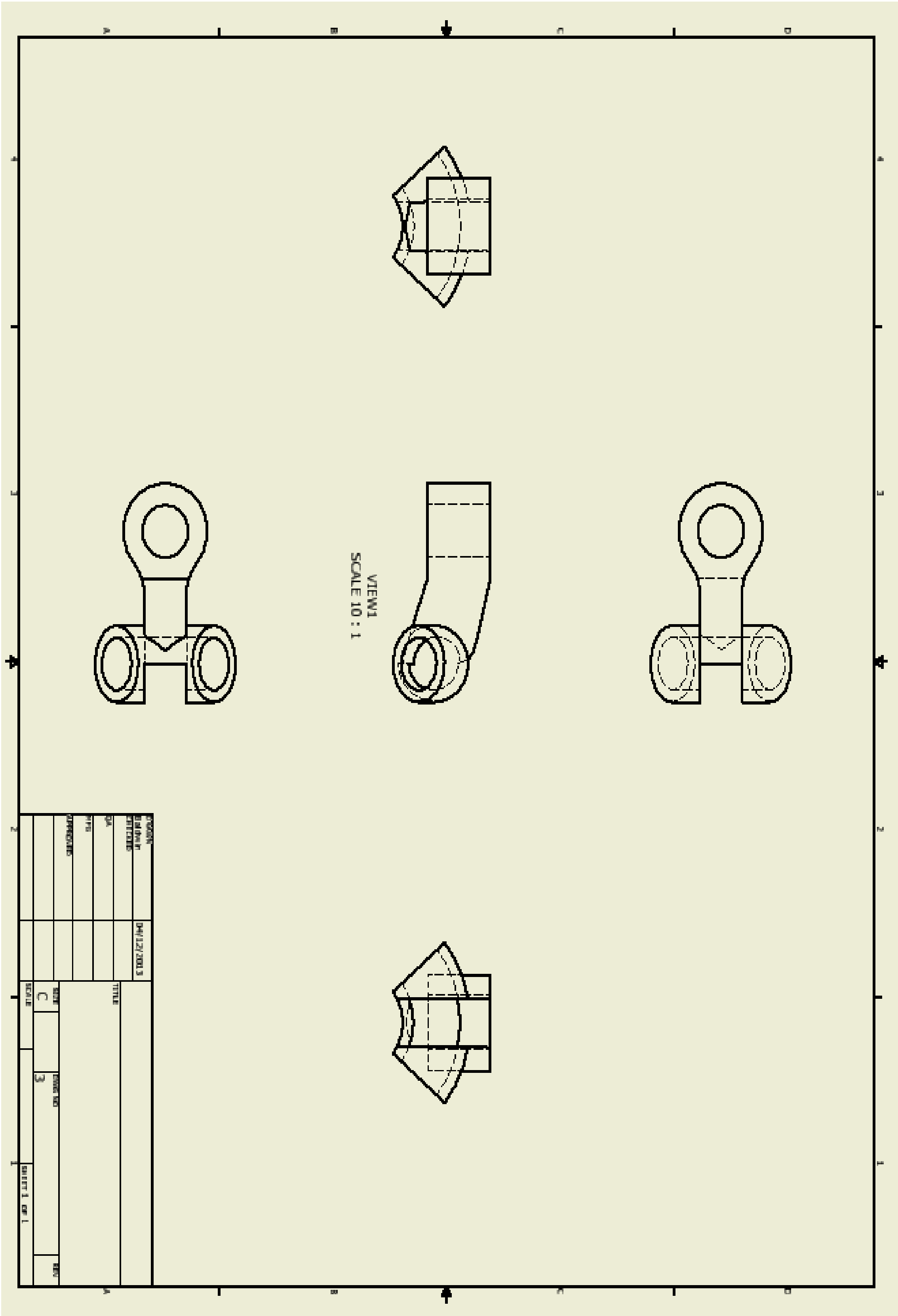
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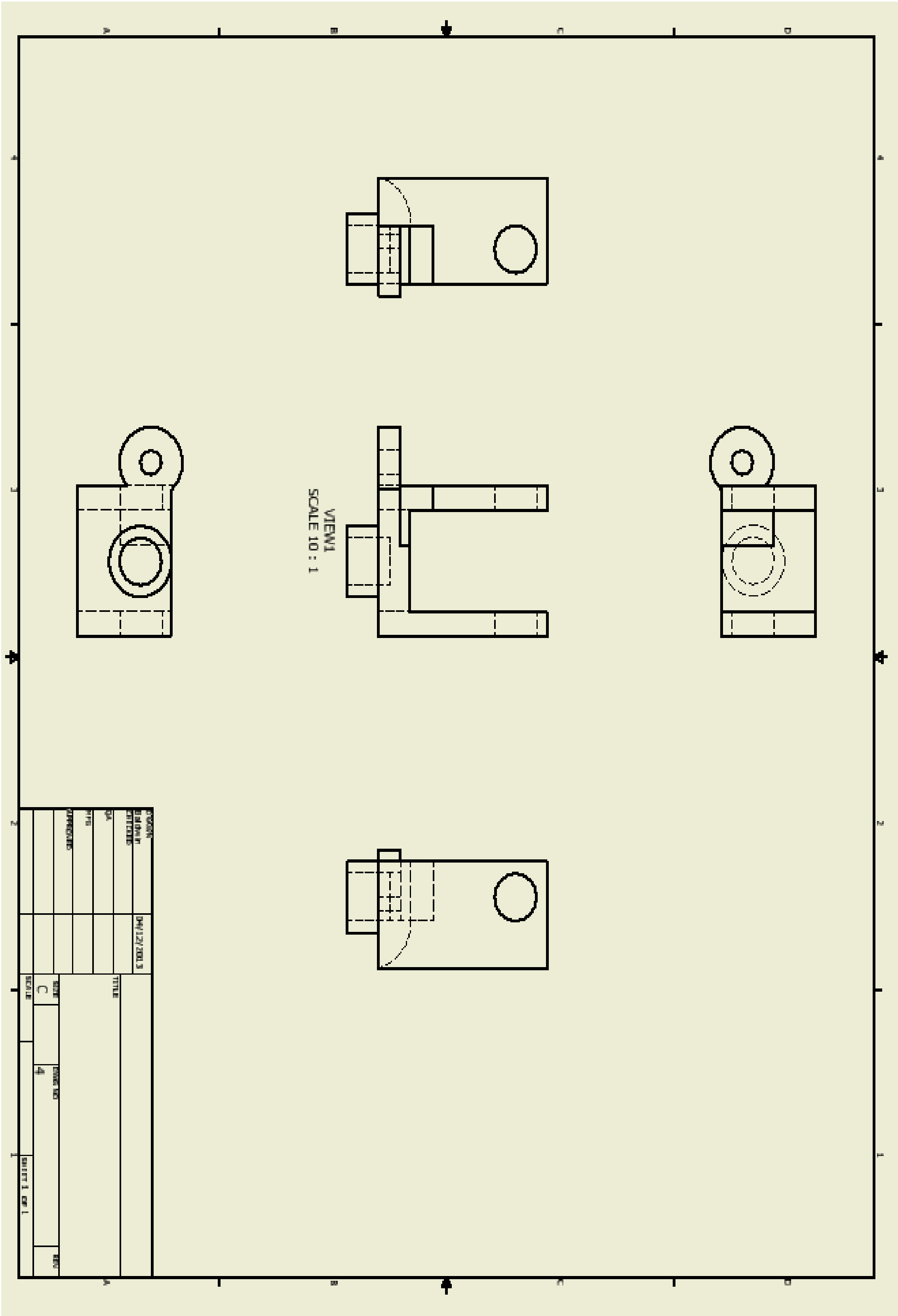
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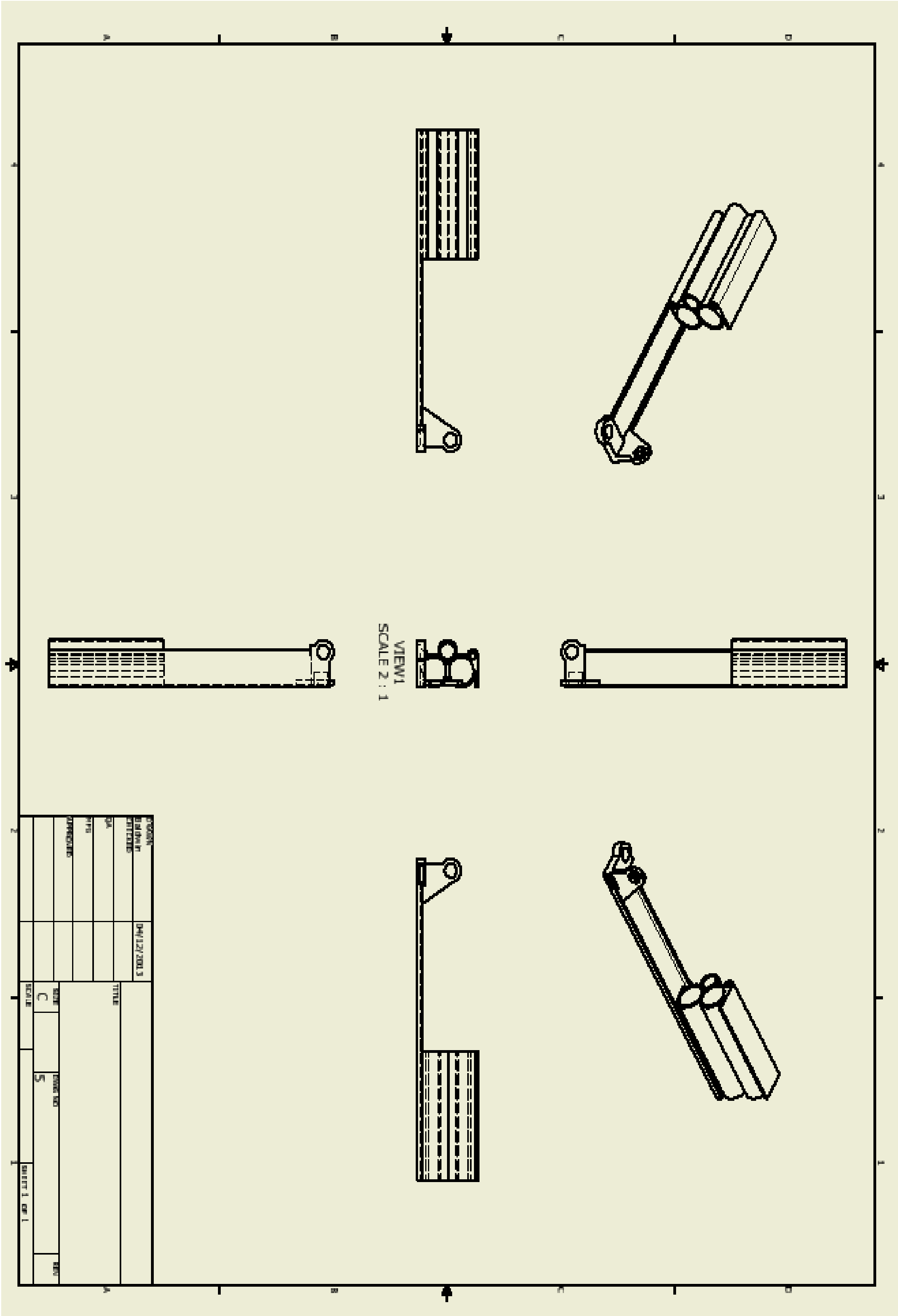
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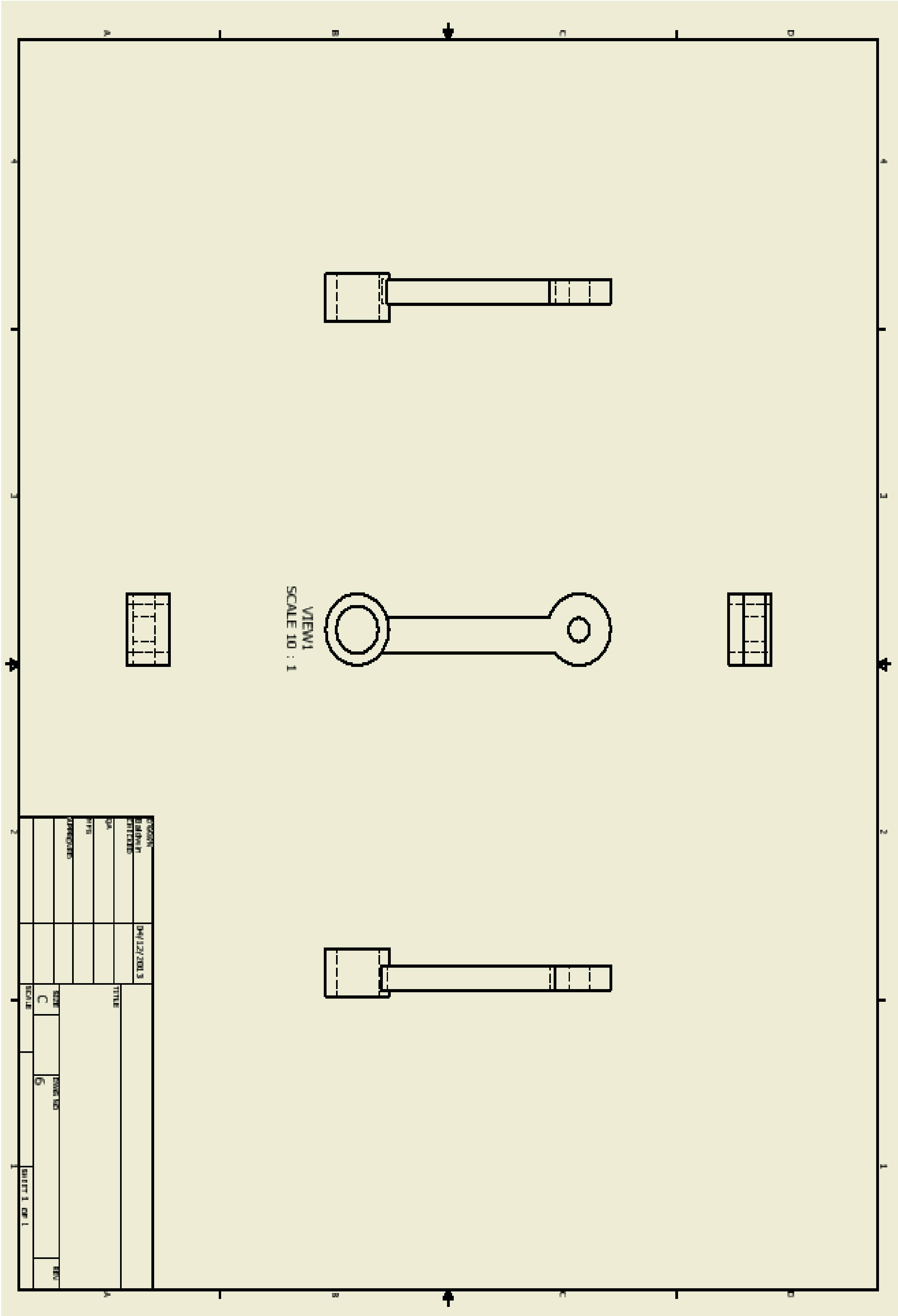
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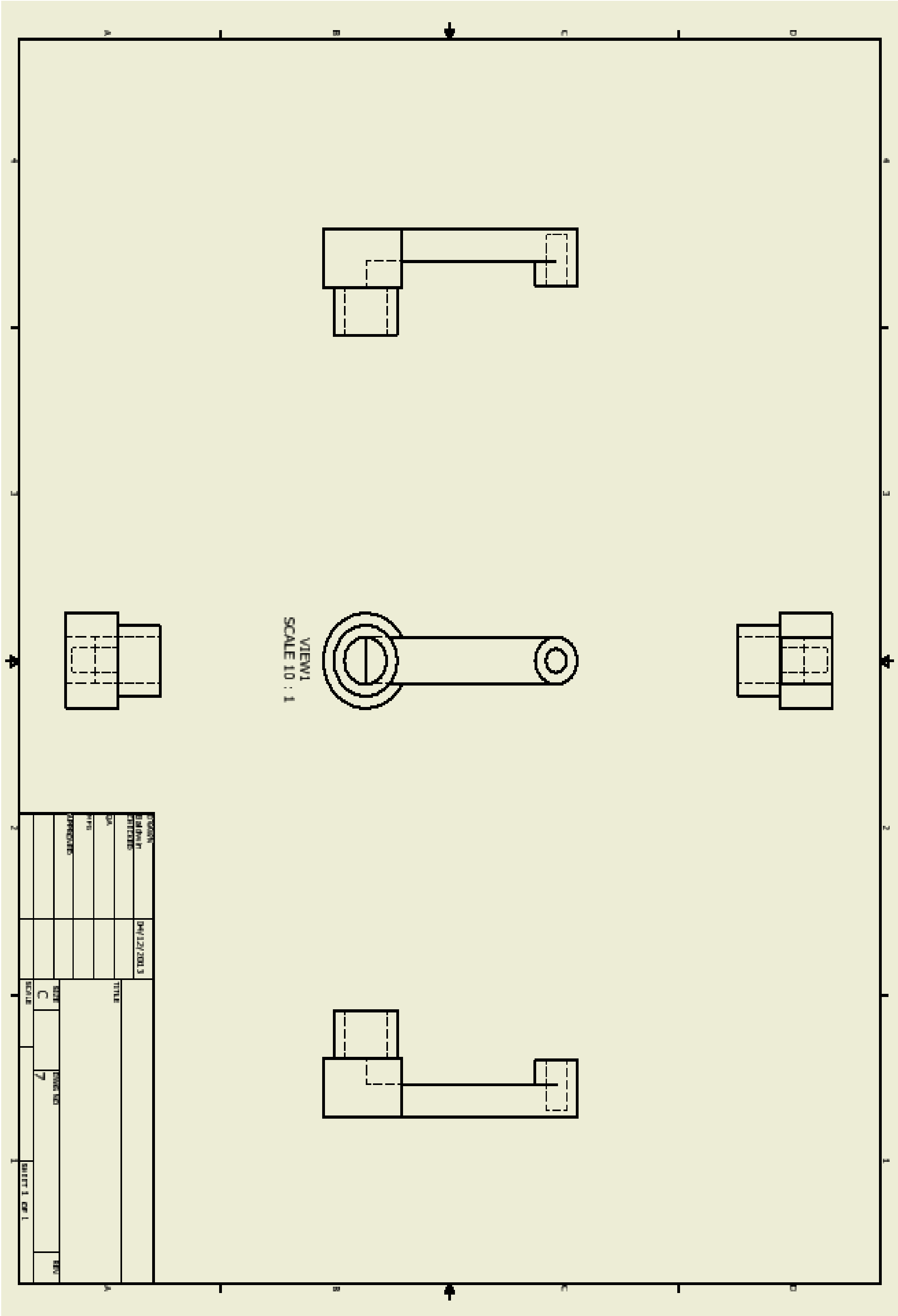
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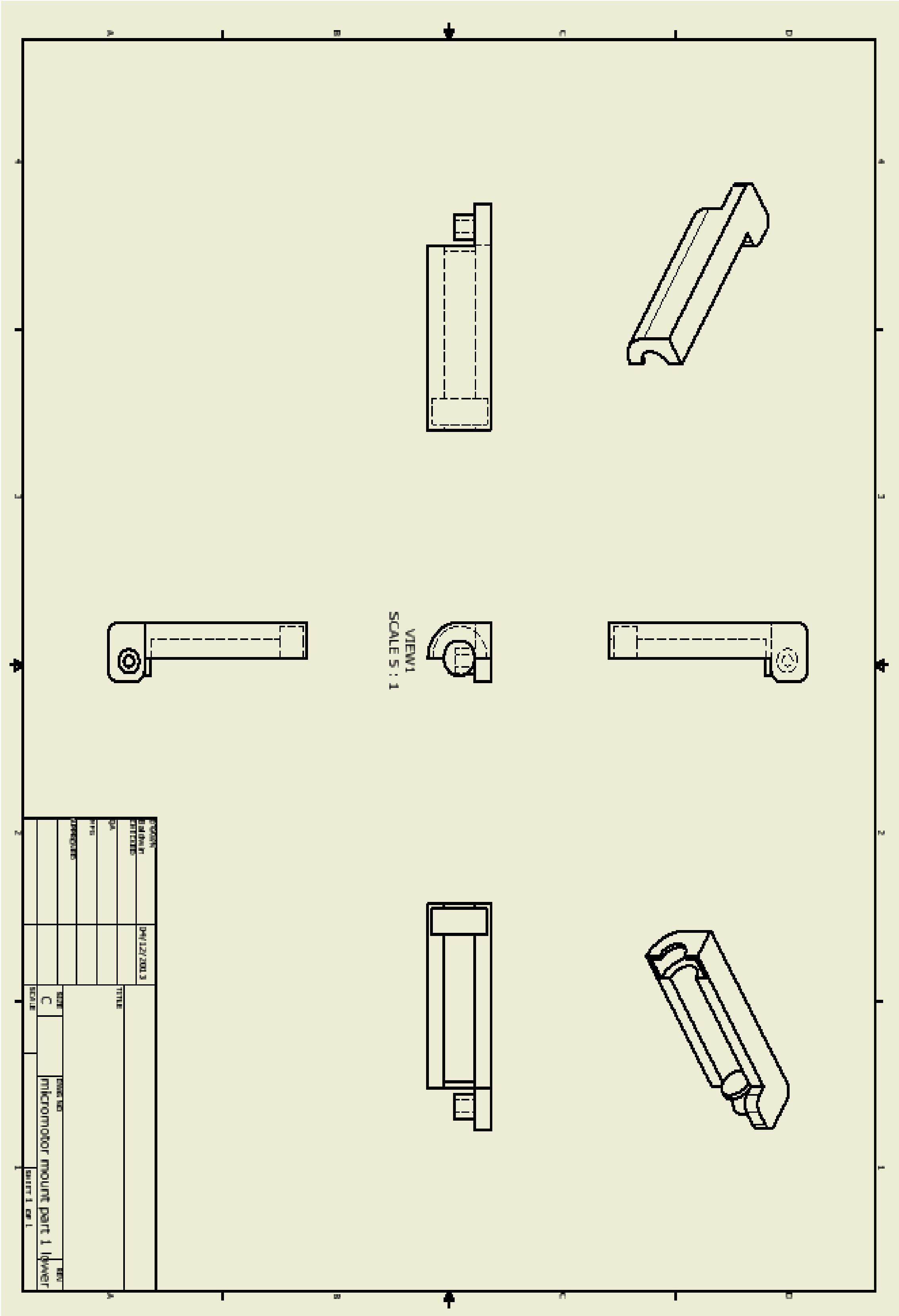
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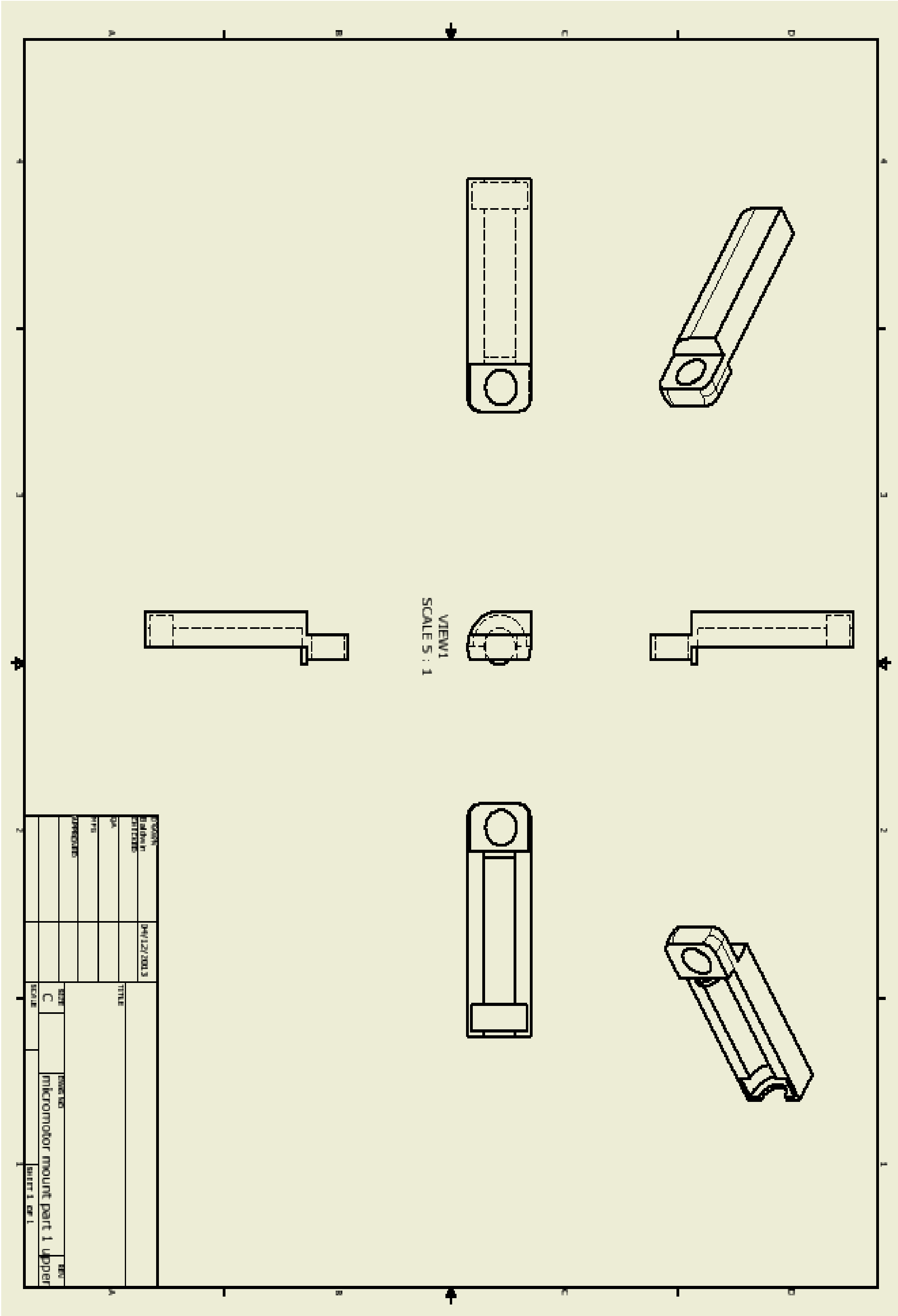
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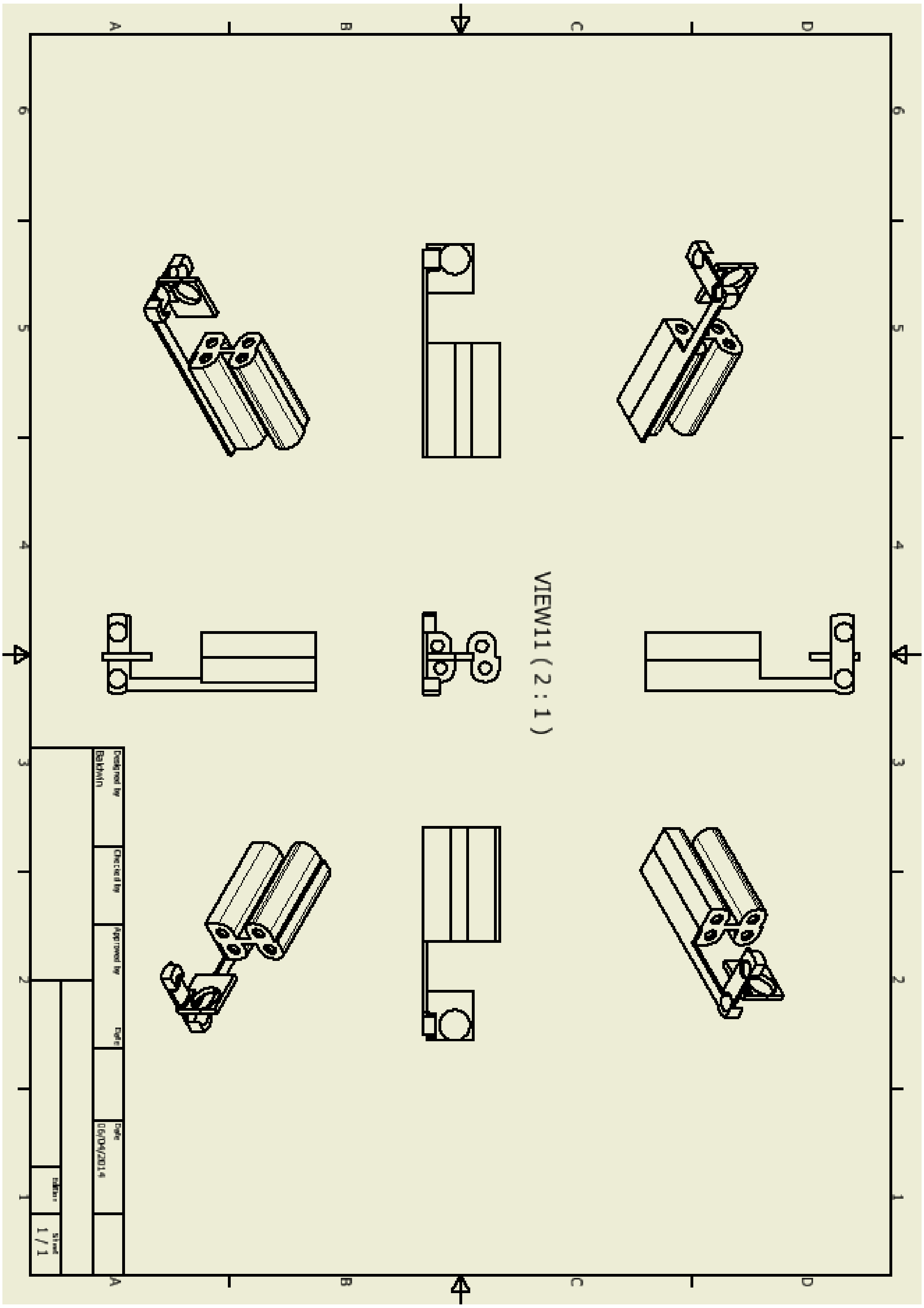
Appendix B: Drawings of the Current Mk2 Design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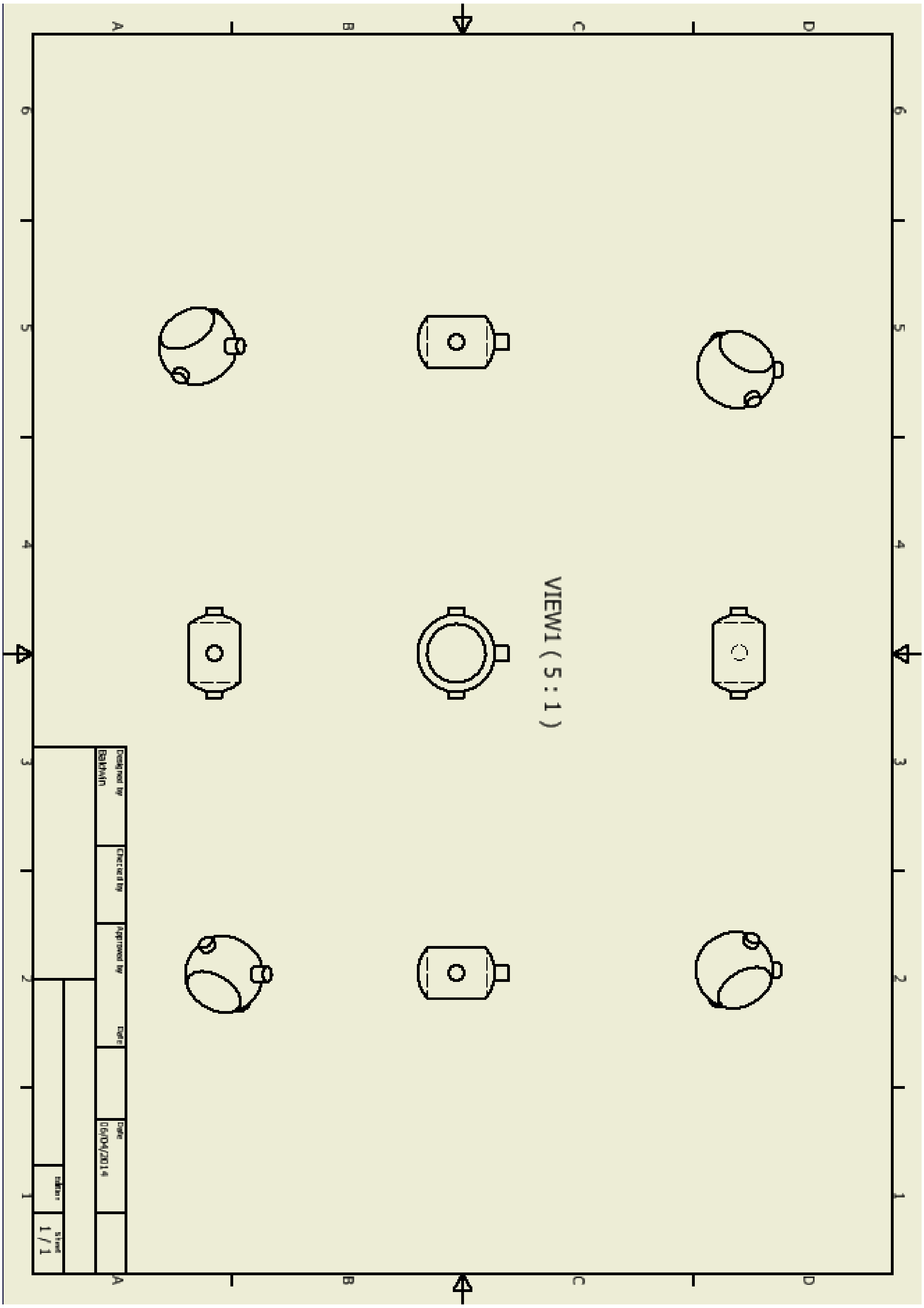
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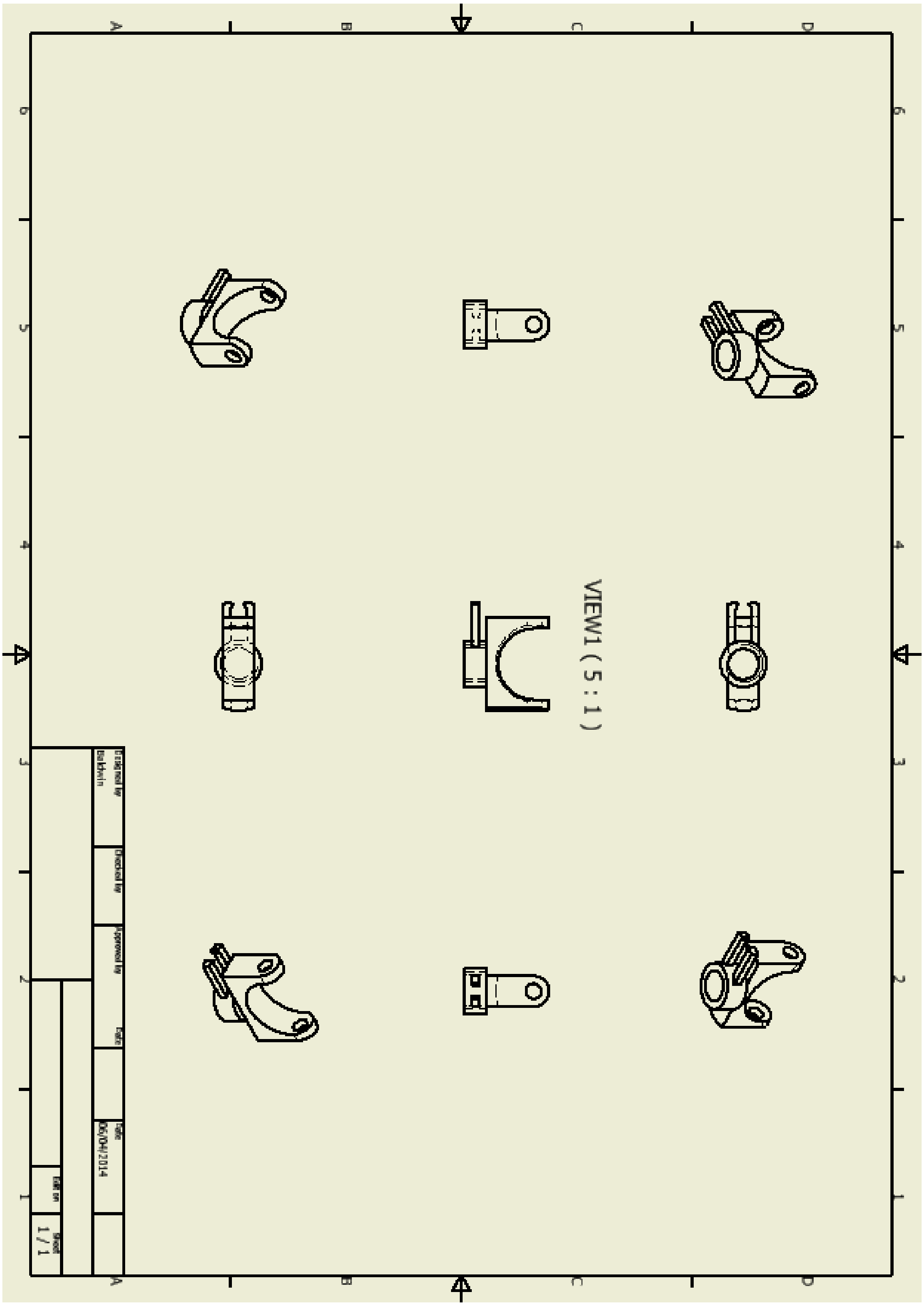
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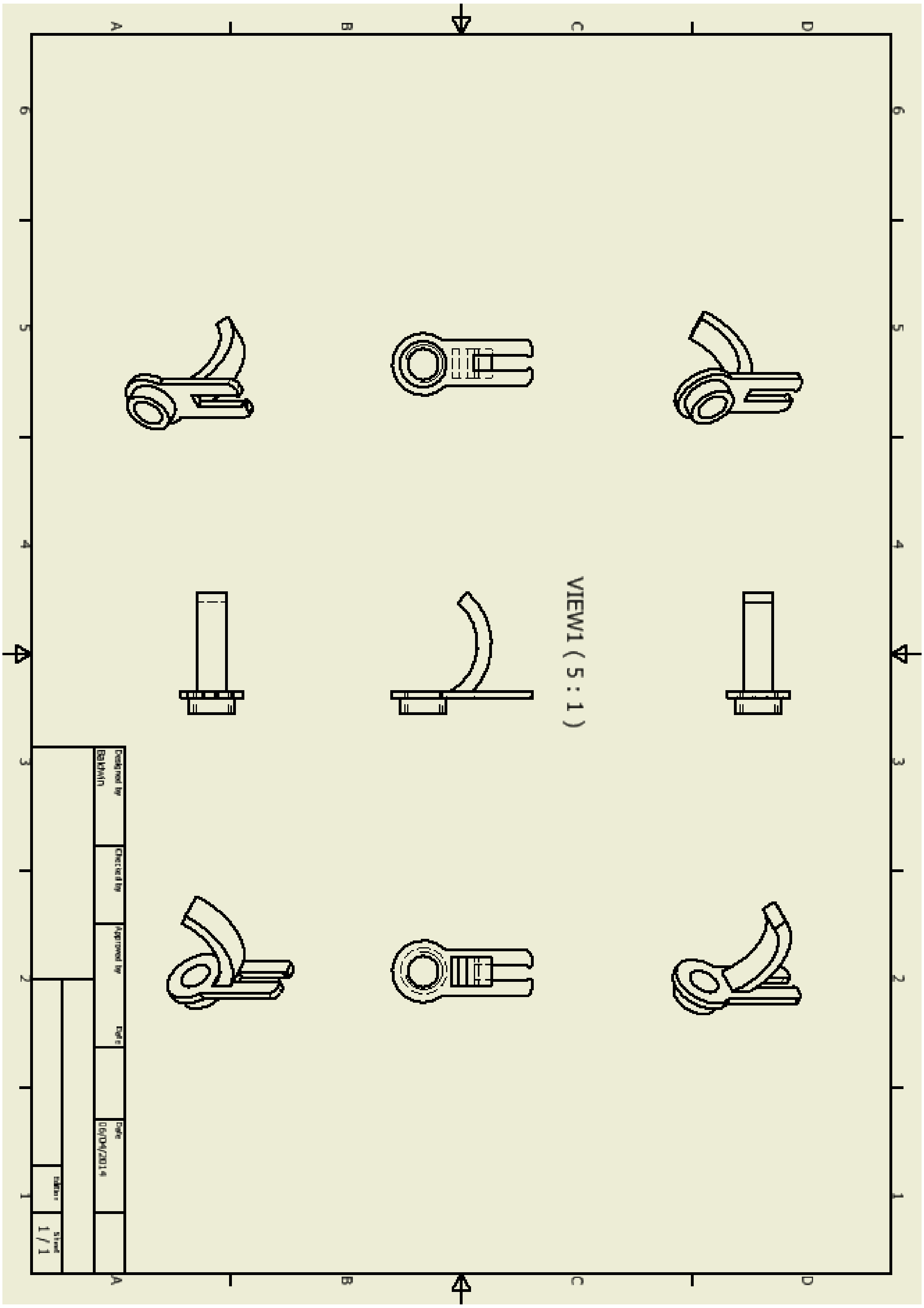
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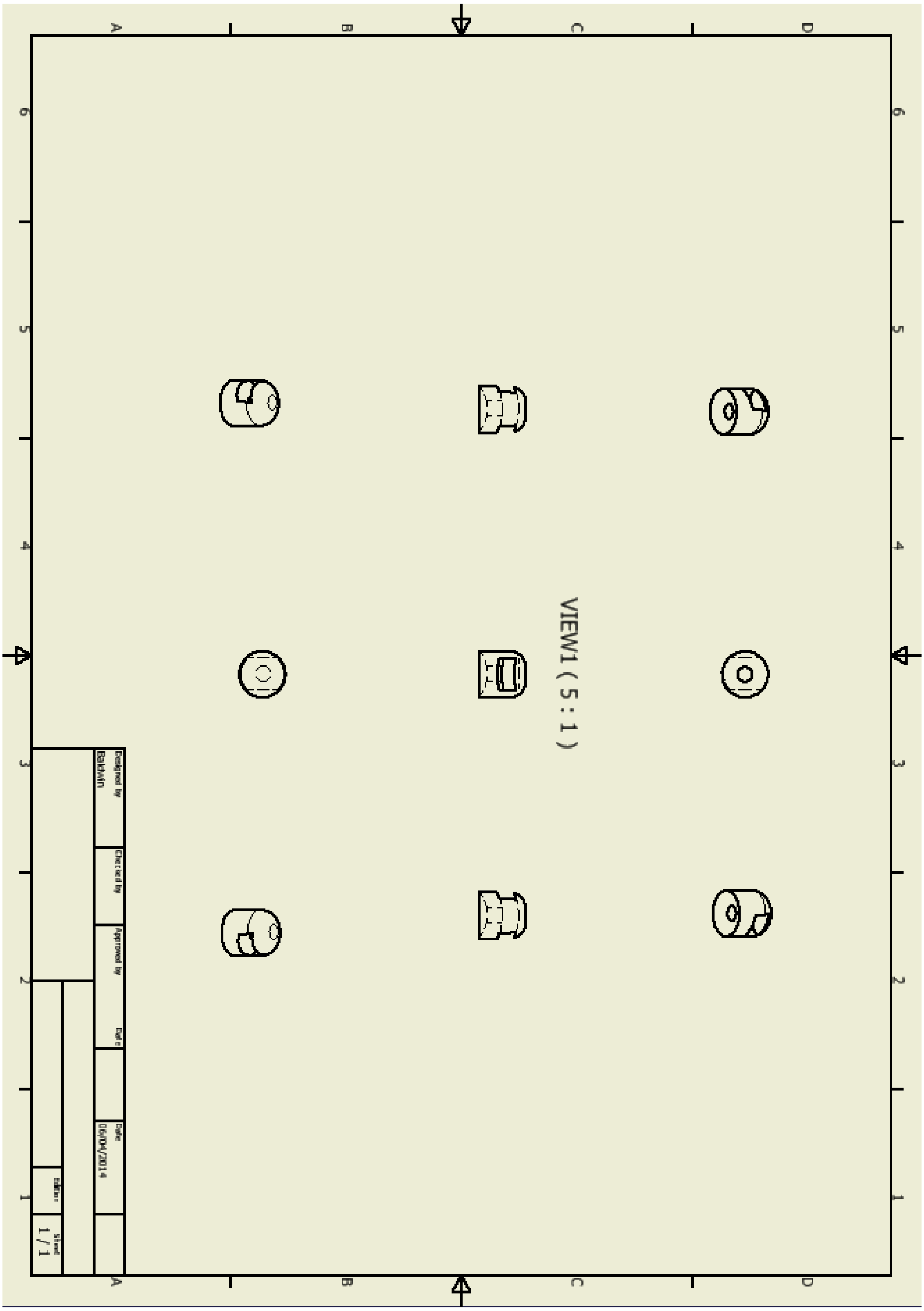
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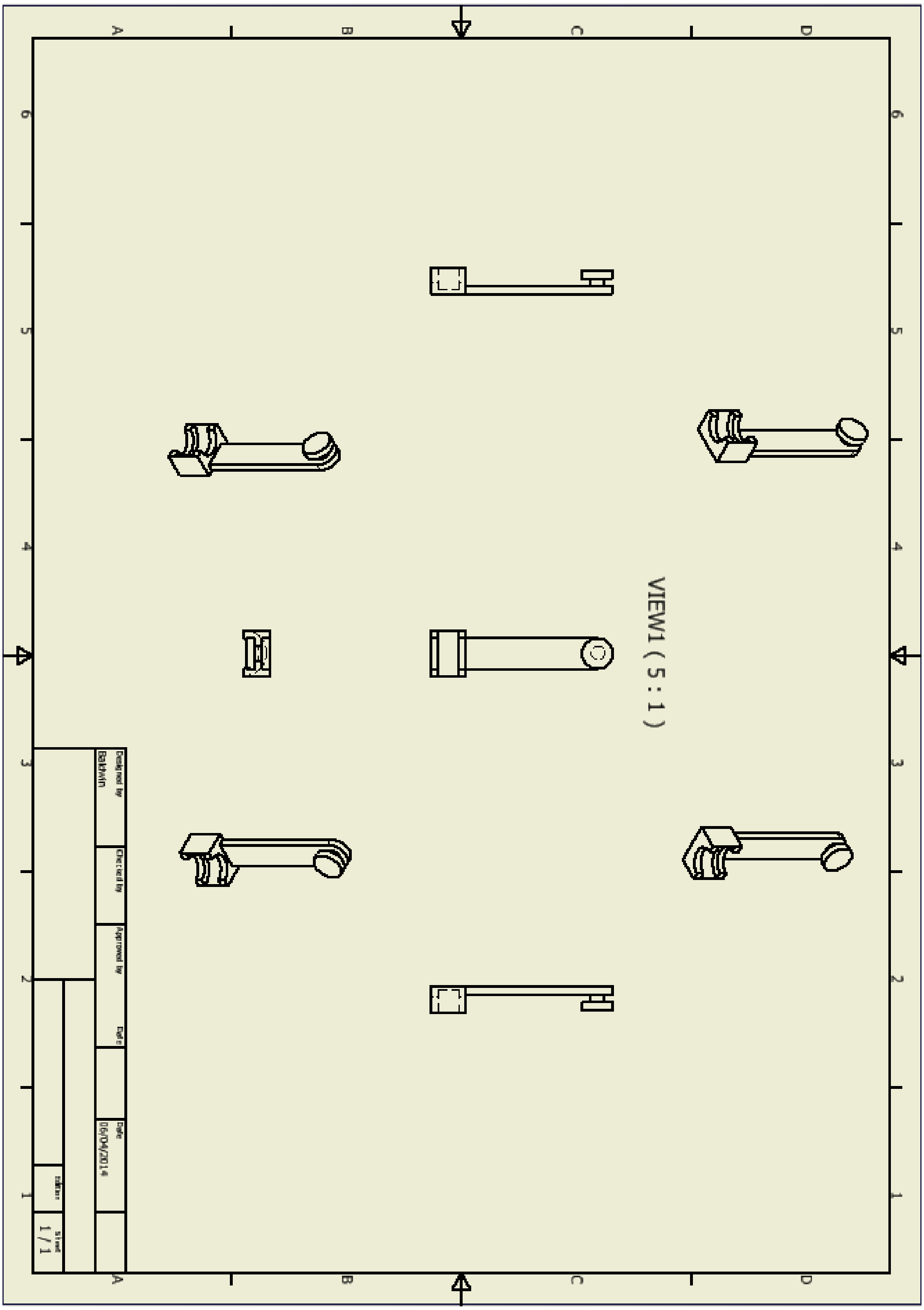
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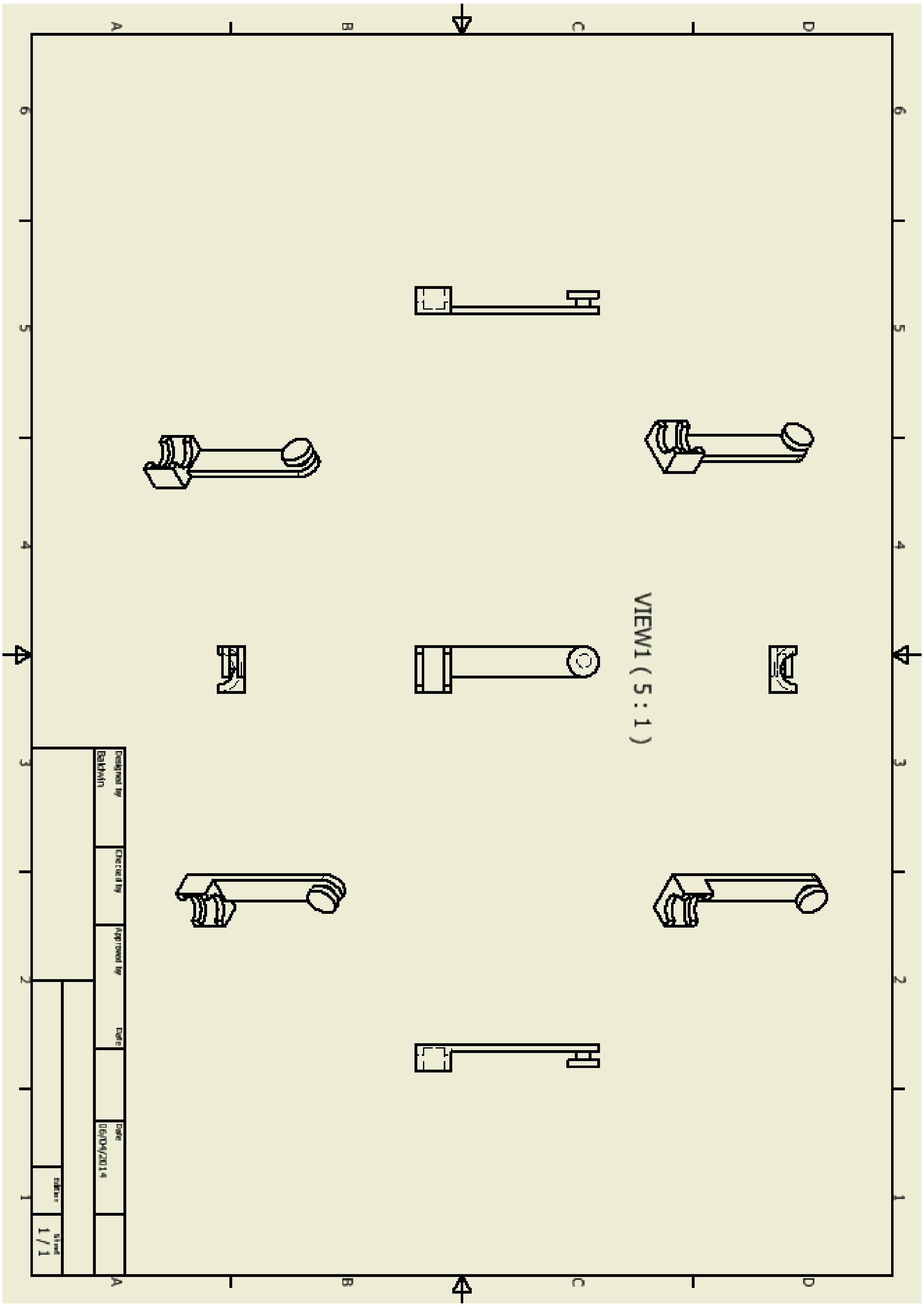
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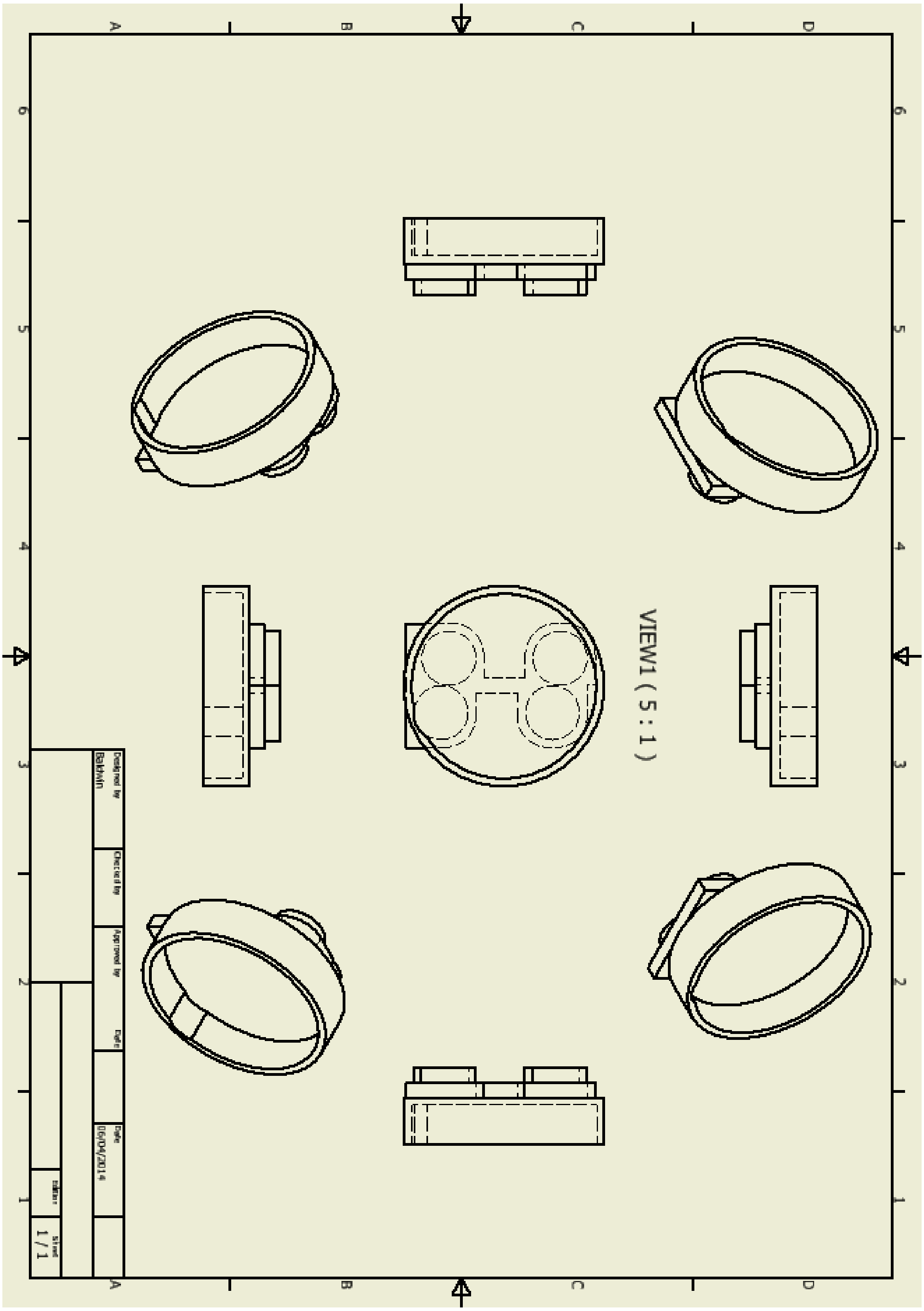
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Appendix C: Arduino Control Software for PS3 Controller to Control Endoscopic Multitasking Platform

```
#include <PS3USB.h>

USB Usb;
PS3USB PS3(&Usb);

boolean LeftYMotor;
boolean LeftYDir;
boolean LeftXMotor;
boolean LeftXDir;
boolean RightYMotor;
boolean RightYDir;
boolean RightXMotor;
boolean RightXDir;
int LeftFB;
int LeftFB1;
int LeftOC;
int LeftOC1;
int LeftRotate;
int LeftRotate1;
int RightFB;
int RightFB1;
int RightOC;
int RightOC1;
int RightRotate;
int RightRotate1;


void setup()
{
  pinMode(22, OUTPUT);
  pinMode(23, OUTPUT);
  pinMode(24, OUTPUT);
  pinMode(25, OUTPUT);
  pinMode(26, OUTPUT);
  pinMode(27, OUTPUT);
  pinMode(28, OUTPUT);
```

```
  pinMode(29, OUTPUT);
  pinMode(7, OUTPUT);
  pinMode(6, OUTPUT);
  pinMode(5, OUTPUT);
  pinMode(4, OUTPUT);

  Serial.begin(115200);
  if (Usb.Init() == -1)
  {
    Serial.print(F("\r\nOSC did not start"));
    while(1); //halt
  }
  Serial.print(F("\r\nPS3 USB Library Started"));
}

void loop()
{
  Usb.Task();

  if(PS3.PS3Connected || PS3.PS3NavigationConnected)
  {
    if(PS3.getButtonPress(L2))
    {
      if (LeftFB < 25500)
        LeftFB += 1;
      else
        LeftFB = 25500;
    }
    if (PS3.getButtonPress(L1))
    {
      if (LeftFB > 0)
        LeftFB -= 1;
      else
        LeftFB = 0;
    }
    if(PS3.getButtonPress(R2))
```

```
{
  if (RightFB < 25500)
    RightFB += 1;
  else
    RightFB = 25500;
}
if (PS3.getButtonPress(R1))
{
  if (RightFB > 0)
    RightFB -= 1;
  else
    RightFB = 0;
}
if(PS3.getButtonPress(UP))
{
  if (LeftOC < 25500)
    LeftOC += 1;
  else
    LeftOC = 25500;
}
if (PS3.getButtonPress(DOWN))
{
  if (LeftOC > 0)
    LeftOC -= 1;
  else
    LeftOC = 0;
}
if(PS3.getButtonPress(TRIANGLE))
{
  if (RightOC < 25500)
    RightOC += 1;
  else
    RightOC = 25500;
}
if (PS3.getButtonPress(CROSS))
{
```

```
    if (RightOC > 0)
      RightOC -= 1;

    else
      RightOC = 0;
  }
  if(PS3.getButtonPress(LEFT))
  {
    if (LeftRotate < 25500)
      LeftRotate += 1;
    else
      LeftRotate = 25500;
  }
  if (PS3.getButtonPress(RIGHT))
  {
    if (LeftRotate > 0)
      LeftRotate -= 1;
    else
      LeftRotate = 0;
  }
  if(PS3.getButtonPress(SQUARE))
  {
    if (RightRotate < 25500)
        RightRotate += 1;
    else
        RightRotate = 25500;
  }
  if (PS3.getButtonPress(CIRCLE))
  {
    if (RightRotate > 0)
      RightRotate -= 1;
    else
      RightRotate = 0;
  }
```

```
    if(PS3.getAnalogHat(LeftHatX) > 175 || PS3.getAnalogHat(LeftHatX) < 75 || PS3.getAnalogHat(LeftHatY) > 175
|| PS3.getAnalogHat(LeftHatY) < 75 || PS3.getAnalogHat(RightHatX) > 175 || PS3.getAnalogHat(RightHatX) < 75 ||
PS3.getAnalogHat(RightHatY) > 175 || PS3.getAnalogHat(RightHatY) < 75)
    {
      if(PS3.getAnalogHat(LeftHatX) > 175 || PS3.getAnalogHat(LeftHatX) < 75)
      {
        LeftXMotor = true;
        if (PS3.getAnalogHat(LeftHatX) < 75)
        {
          LeftXDir = true;
        }
        if (PS3.getAnalogHat(LeftHatX) > 175)
        {
          LeftXDir = false;
        }
      }
      else
      {
        LeftXMotor = false;
        LeftXDir = false;
      }
      if(PS3.getAnalogHat(LeftHatY) > 175 || PS3.getAnalogHat(LeftHatY) < 75)
      {
        LeftYMotor = true;
        if (PS3.getAnalogHat(LeftHatY) < 75)
        {
          LeftYDir = true;
        }
        if (PS3.getAnalogHat(LeftHatY) > 175)
        {
          LeftYDir = false;
        }
      }
      else
      {
        LeftYMotor = false;
```

```
    LeftYDir = false;
  }
  if(PS3.getAnalogHat(RightHatX) > 175 || PS3.getAnalogHat(RightHatX) < 75)
  {
    RightXMotor = true;
    if (PS3.getAnalogHat(RightHatX) > 75)
    {
      RightXDir = true;
    }
    if (PS3.getAnalogHat(RightHatX) < 175)
    {
      RightXDir = false;
    }
  }
  else
  {
    RightXMotor = false;
    RightXDir = false;
  }
  if(PS3.getAnalogHat(RightHatY) > 175 || PS3.getAnalogHat(RightHatY) < 75)
  {
    RightYMotor = true;
    if (PS3.getAnalogHat(RightHatY) < 75)
    {
      RightYDir = true;
    }
    else if (PS3.getAnalogHat(RightHatY) > 175)
    {
      RightYDir = false;
    }
  }
  else
  {
    RightYMotor = false;
    RightYDir = false;
  }
```

```
    }
    else
    {
      LeftXMotor = false;
      LeftXDir = false;
      LeftYMotor = false;
      LeftYDir = false;
      RightXMotor = false;
      RightXDir = false;
      RightYMotor = false;
      RightYDir = false;
    }

    LeftFB1 = abs(LeftFB/100);
    RightFB1 = abs(RightFB/100);
    LeftOC1 = abs(LeftOC/100);
    RightOC1 = abs(RightOC/100);
    LeftRotate1 = abs(LeftRotate/100);
    RightRotate1 = abs(RightRotate/100);

    digitalWrite(22, LeftYMotor);
    digitalWrite(23, LeftYDir);
    digitalWrite(24, LeftXMotor);
    digitalWrite(25, LeftXDir);
    digitalWrite(26, RightYMotor);
    digitalWrite(27, RightYDir);
    digitalWrite(28, RightXMotor);
    digitalWrite(29, RightXDir);
    analogWrite (4, LeftFB1);
    analogWrite (5, RightFB1);
    analogWrite (6, LeftOC1);
    analogWrite (7, RightOC1);
  }
}
```

Appendix D: Video of the Endoscopic Multitasking Platform

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