

Design, development and testing of miniature instruments for flexible endoscopy

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ABSTRACT

This thesis describes the design and development of single-stitch and chain-stitch endoscopic sewing machines for flexible endoscopy as well as devices and methods for tying knots and cutting thread at flexible endoscopy. The work also includes a comparative study of clipping methods for endoscopic haemostasis and a feasibility study of a wireless endoscope that might allow images to be transmitted from sites in the gastrointestinal tract without wires, cables or fibre optic bundles. The development and testing of simple prototypes of such an endoscope are reported.

Chapter 1 reviews the surgical instruments and methods used for tissue approximation in general surgery, laparoscopic surgery and flexible endoscopic surgery. The design of existing, conventional sewing machines and the ways in which they form stitches are also considered. In Chapter 2, a comparative study of clipping methods for endoscopic haemostasis is reported. In Chapter 3, the design and development of new single-stitch endoscopic sewing machines are described, together with data on the clinical use of one of these machines. In Chapter 4, studies of ways of improving endoscopic vision during endoscopic sewing and the effects of needle size and the size and shape of the suction cavity are reported. In Chapter 5, the design and development of novel chain-stitch endoscopic sewing machines are reported. These make use of two new catch mechanisms. In Chapter 6, knot tying at flexible endoscopy is considered, and a number of new devices and methods are described and clinical results reported. In Chapter 7, cutting thread at flexible endoscopy is described. Several new endoscopic thread cutting devices and methods together with results are presented.

In Chapter 8, a feasibility study of wireless endoscopy is reported. The study includes tests of the concept of wireless endoscopes made using prototypes constructed

from miniature CCD cameras and microwave transmitters.

Finally, some concluding remarks relating to the work described in this thesis are given.

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LIST OF SYMBOLS

SYMBOLS		Unit
A_{eff}	the effective area of the receiving antenna	m^2
d	the depth of penetration	cm
dBi	gain in dB relative to an isotropic radiator	
f	radio frequency	Hz
G_t	the gain of transmitting antenna	
G_r	the gain of the receiving antenna	
P_d	the power density	Wm^{-2}
P_r	the received power	W
P_t	the transmitted power	W
r	the radius of the sphere	m
R	the distance	km
t	time	s
x	the thickness of tissue	cm
α	attenuation constant	mm^{-1}
δ	the loss angle	rad
ϵ	the permittivity	Fm^{-1}
ω	angular frequency	rads^{-1}
μ	the permeability of the tissue	Hm^{-1}
λ	wavelength	m

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Chapter 1 Introduction

1.1. Introduction

For many hundreds of years, clinicians have been trying hard to explore possible means of curing disorders and diseases of the human body. Apart from medication, they need specially designed instruments and devices to enable them to "see" inside the body and to "extend" their hands to manipulate and treat internal organs. With the development of modern technologies, many instruments and devices have been designed and perfected for diagnostic, therapeutic and surgical purposes. Using these instruments and devices, diseases can be diagnosed precisely and treated immediately, and surgical operations can be performed with ease and accuracy.

Surgery is an art of working with the hands, but no surgeon can fulfil himself in his profession without surgical instruments. In this chapter, the usages of some basic surgical instruments and devices designed for tissue approximation in general surgery, laparoscopic surgery and flexible endoscopic surgery are reviewed. The surgical instruments of particular relevance to the subject of this thesis are described in some detail together with an analysis of the inventive steps taken in their development. The invention of sewing machines and the ways in which they form stitches are reviewed. Within the last hundred years, much original thought has been given to the design and development of industrial sewing machines and it is likely that several of these ideas can be applied to joining and sewing tissues in man.

1.2. Tissue approximation in general surgery

Tissue approximation is an important and basic part of surgery. The use of thread either passed through the eye of a needle or attached to a needle is one of the most commonly used methods of tissue approximation in surgery.

1.2.1. Needle with suture thread

The needles used in surgery are generally made of stainless steel, due to its hardness and resistance to corrosion. There are different shaped needles: straight or curved, the cross section may take various forms, they may have a cutting edge. Many types of needle can be held between the fingers by surgeons to perform tissue approximations; most needles are more commonly held by forceps-type needle holders. In the commonest surgical situation, a curved needle attached to the suture thread is used to perform the stitching.

1.2.2. Needle holders for general surgery

The needle holder is a modified forceps. It is one of the simplest surgical devices used by a surgeon to hold the needle, especially tiny, or curved needles. This enables a surgeon to manipulate the needle with ease during the procedure. The opposing surfaces of the jaws of the forceps are cross-hatched, in order to hold the needle safely and prevent it from slipping [1]. The use of Tungsten-carbide jaws can prolong the life of the device considerably.

1.2.3. Clips for general surgery

There are a number of metal clips for closing the tissue wound. They include the Michel clip and the Kifa clip. Michel clips, made of alloys of titanium or silver due to their high ductility and resistance to corrosion, are only used for skin closure. The design incorporates one or two barbs at each end of the clip for holding the skin tissue well (Figure 1.1). While holding the skin edges together using forceps, the clip can be compressed onto the skin edges with a clip applicator [2]. When closed, the closing force of the clip is not significant because of its softness. This implies that the clip may not hold the skin tissue for a long time or more than one clip is needed to close the

wound.

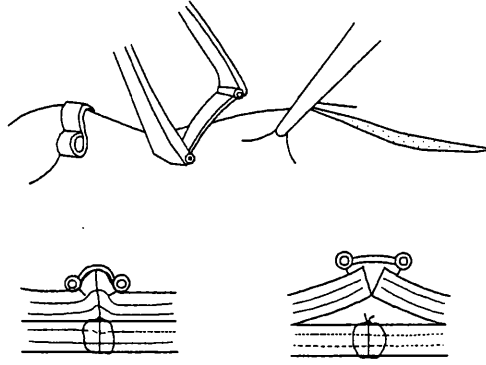


Figure 1.1 Michel clips for closing skin wound.

1.2.4. Stapling devices for general surgery

Mechanical wound-closure using a staple-like method was perhaps first described by the Indian physician Susruta [3] in 350 B.C. He used the jaws of large ants for skin approximation. In the late 19th century, surgeons began to have confidence in closing wounds in the bowel wall and performing anastomoses using staples. Mechanical devices were then designed to aid the closure procedure. The first stapling device was developed by Hultl [4] for stomach and intestinal surgery in 1908. The staples closed into a B shape, which is still used to this day. Reloadable stapling devices were developed by Androsov [5], a Russian, in 1956, and disposable staplers for clinical use were made practical mainly by Ravitch and Steichen [6] of USA in 1972. Over the past 30 years, stapling devices have become standard surgical instruments.

A common design of stapling device consists of jaws to grip the tissues. A number of U shaped staples are pressed through the gripped tissues and against an anvil to be bent into a B shape. The B-shape is important for maintenance of the capillary blood supply

within the approximated tissue edges [7].

Mechanical stapling devices do not replace the need for surgical skill and meticulous technique. However, they may allow a procedure to be performed more rapidly. The results from stapling can be more consistent than those from hand suturing [8].

1.3. Tissue approximation in rigid endoscopic surgery

Tissue approximation at laparoscopic surgery can be achieved in three ways by using instruments and devices that are similar to those used at open surgery.

1.3.1. Hand suturing

To achieve hand suturing, the surgeon uses a needle holder to manipulate the needle and another forceps to grab the needle or thread. The needle holder and the forceps are operated through cannulae penetrating through the abdominal wall. The needle is forced to pierce the tissue and grasped by another forceps as the needle emerges from the other side [9]. Knotting may be performed either intracorporeally by tying the thread with one or two forceps inside the abdominal cavity or may be tied extracorporeally by tying a slip knot, for example, a Roeder loop [10] and then running this down to tighten on the tissue through one of the laparoscopy ports.

1.3.2. The cannulae (ports) and rigid endoscopes (laparoscopes)

Cannulae (ports) and rigid telescopes are needed to allow access and visual control of instruments while hand suturing during laparoscopic surgery. The cannulae are in principle hollow tubes made of stainless steel or plastic. They are inserted into the peritoneum over a sharp introducer called a trocar. One end of the cannula must be

equipped with a good seal so that the pressure required to distend the abdominal cavity is not lost when a needle holder is inserted into it. The rigid optical laparoscope or more commonly now a video laparoscope is used for providing the surgeon with a good view of the operative field.

1.3.3. Needle holders

The common design of the first generation needle holders consisted of a transverse closure mechanism for keeping the jaws open and closed. They were designed for holding straight needles [11]. The second generation needle holders had improved handle design. The axial handles enable the surgeon to rotate the device through 360 degrees.

1.3.4. Clips for securing suture thread at laparoscopy

Absorbable or metal clips can be used for securing continuous suture at its end. These clips are V - shaped before application. Standard metal clips have quite sharp edges which may cut the suture itself when connected to the thread at a wrong angle of inclination. Standard absorbable clips are unsafe because their grip on the thread is unable to prevent the clip from slipping off under traction [12]. Silver clips have been specially designed for securing a continuous polydioxane suture (PDS) [1] in endoluminal rectal surgery using a rigid operating sigmoidoscope following the technique developed by Buess [13] in 1983. This technique allows continuous suturing in endoscopic surgery and requires the use of a special clip applicator. Silver clips can normally be used inside the body cavities because of their good corrosion resistance. Later, hand-made titanium clips were used for securing PDS suture thread with a special clip applicator. More recently, newly designed absorbable polydioxane clips (Ethicon Endo-Surgery) have become available.

1.3.5. A rigid suturoscope for endoscopic suturing

Silva's "suturoscope" [14] reported in 1990 was designed and constructed to be compatible with the sheath of a 9 mm diameter resectoscope. It consisted of two parallel metal conduct tubes (26 cm long, 1.8 mm in diameter), placed side by side 5 mm apart. Each tube had a full length 0.2 mm slit that allowed passage of suture threads up to 2/0 suture size. The distal end of each tube was curved so that both lumens were lined in front of each other and were seen in the visual field of a zero-degree endoscopic lens. The "needle" was a 1 mm in diameter, 60 cm long plastic fibre with one sharp end. A 60 cm long suture thread of size 2/0 or less was attached to the other end of the fibre. It was introduced via the proximal end of the conduct tube and pushed until the sharp end was seen. The sharp end was then forced to pass through the wound edges to be sewn, this led to the suture thread being pulled through the tissue. The tails of the suture thread were left outside where the knot was made. To push the knot, a rigid knot pusher was required. The pusher could push the knot all the way through the sheath (Figure 1.2).

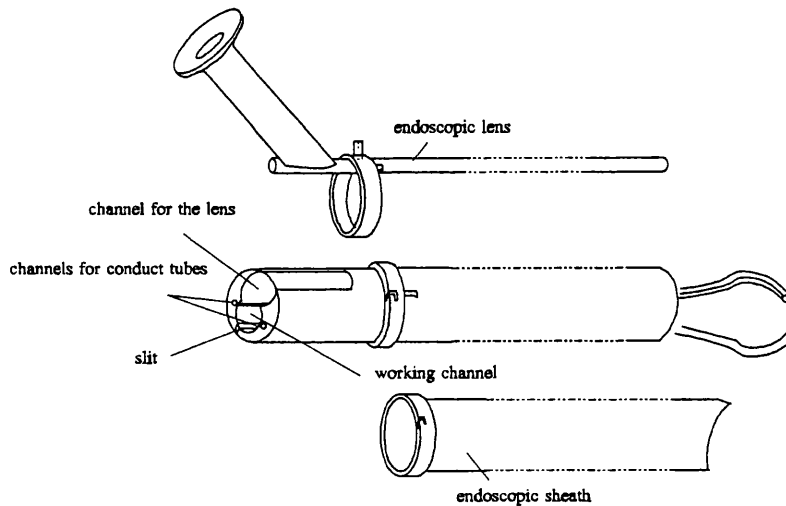


Figure 1.2 Silva's suturoscope.

Although it was claimed that this device was easy and quick to use, the procedure could be complicated and time-consuming. For example, in order to keep the "needle" penetrating two edges of tissue in one go, by just pushing the fibre from outside to inside through the conducting tube, it certainly required positioning the two curved distal ends of the device over the wound precisely. Furthermore, it required repeating the procedure if more than one stitch was needed.

1.3.6. A pneumatically controlled sewing device for laparoscopic surgery

Melzer's device [15] allows the transfer of a needle between two jaws, similar to the shuttle employed in weave looms. The "T" needle has a central cross-bore for the thread and two trocar point tips. It can be transferred sequentially between the jaws of the device and is intermittently docked to miniaturised grip elements integrated in the jaws. This is achieved by an active pneumatic gripper which is controlled by a foot-switch. The other gripper is a passive spring-loaded attachment. If the needle is held with the pneumatic gripper, the force of the spring-loaded grip is overcome and the needle is held by the pneumatic grip. If this grip is released the needle is fixed in the spring-loaded grip. The elaborate handling of the needle with two holders is eliminated and the transfer can also be used to tie a knot.

1.3.7. A suturing instrument

Andersson's suturing instrument [16] was designed for joining two edges of tissue together. This rigid device comprised a suture thread attached to a curved needle moved back and forth by two rollers held in contact with a wheel rotated by a pneumatically-driven, reciprocating piston. When an external pressure made the piston move to drive the fly wheel, the rotary motion of the fly wheel was transmitted to the two smaller

friction rollers which abutted the needle. This resulted that the needle and suture thread could be driven through the two tissue edges to be joined (Figure 1.3).

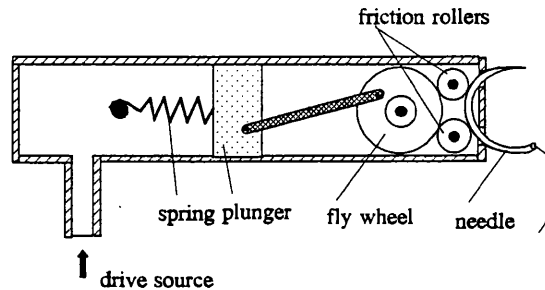


Figure 1.3 Andersson's suturing device.

If used, as claimed, for sewing vessels, nerves or stomach incisions, the device would need very precise positioning over the tissue. As the needle is driven by the fly wheel via the two friction rollers, accurate synchronisation is crucial. Otherwise, adequate rotation of the needle would not be achieved. The diameter of the cylinder that contained these components was not mentioned, leading to suspicions that the device existed only as a large-scale prototype.

1.3.8. A suturing instrument for performing stitches surgically

Eguchi's device [17] was designed to form a chain of stitches made by causing a shuttle carrying a thread to move back and forth over the cut edges of the tissue. The device comprised a curved needle with an eye and oblong groove for guiding the thread. The needle was fixed onto the end of the needle operating handle. When the threaded needle was forced to pierce the tissue, the thread loop could be picked up by a shuttle thread via another operating handle. Then, the needle withdrew and moved to the next point for stitching. Thus, a chain of lock stitches were formed. This device might be used at

laparoscopic surgery if its size was small enough. The mechanism of the device seemed simple, but in practice, the formation of the stitches had to rely on an extra means e.g. a forceps was needed for holding the thread to form the chain-stitch. This might make the procedure even more complicated (Figure 1.4).

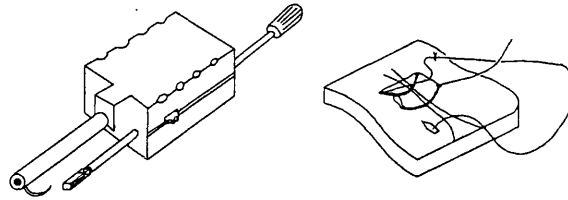


Figure 1.4 Eguchi's device.

1.4. Tissue approximation in flexible endoscopic surgery

At laparotomy or laparoscopy, tissue approximation, or end-to-end anastomosis in the gastrointestinal tract can be performed by using hand suturing, mechanical stapling and some sewing instruments. Without laparotomy or laparoscopy, tissue approximation in the gastrointestinal tract is far more difficult to achieve and needs different solutions.

1.4.1. An apparatus for suturing "coeliac" tissues

A patent for an apparatus for placing stitches at flexible endoscopy was granted to Ogiu and Shimonaka [18] of Japan in 1979. This device comprised of a Bowden cable to which a sharp stainless steel needle was securely fitted. One end of the needle was hollow, coaxial with the Bowden cable and had the same outside diameter as the Bowden cable. In order to avoid damaging the surface of the channel of an endoscope by the needle or the Bowden cable, a flexible protecting tube was also used for

protecting the "direct contact" between the device and the channel of the endoscope. The method of sewing was to load the tag attached with a thread into the hollow needle, then push the device through the biopsy channel of the endoscope. When in position, the needle was advanced to pierce two sites of tissue, then the tag was pushed by a push-rod running through the Bowden cable. As one end of the thread was retained by the tag, a clip or other means was needed to secure the thread at the other end (Figure 1.5).

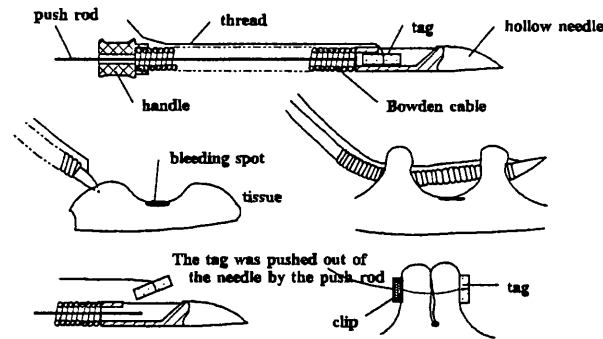


Figure 1.5 Ogiu's device for suturing tissues.

This device involved a complex design of needle, tag delivering system and the way of securing the thread. It is an interesting early attempt at solving some of the problems inherent in sewing at flexible endoscopy. The device, however, has a serious drawback since it is very difficult to force a needle through tissue in such a way that it will return into the lumen of the gut. There are also problems associated with the size of the needle and the force required to penetrate the tissue. The needle had to pierce two target tissues precisely, returning to the lumen each time before the tag was released, and an extra means was required to secure the two stitches together. To deliver a chain of stitches, the thread handling would be even more difficult to achieve. It was not clear that this device was ever used in experimental or clinical studies or that it was even usable for sewing tissue around a bleeding point as envisioned.

1.4.2. An endoscopic sewing machine

This machine was reported by Swain and Mills [19] in 1986. The invention aimed to allow clinicians to perform a range of internal surgical procedures without having to make an external incision in the patient. The proposed clinical applications included: 1. Attachment of a pH sensor to the wall of the gastrointestinal tract. 2. Closure of perforations. 3. Attachment of a naso-feeding tube to the stomach wall. 4. Treatment of gastro-oesophageal reflux disease.

The mechanism of this machine was based to some extent on the mechanism of a conventional sewing machine. All previous sewing machines required access to both sides of the tissue to be sewn. This machine differed from other sewing machines by using suction to form the tissue into a double layer which did not require access to both sides of the material. The body of the sewing machine was formed from a solid rod of transparent PMMA, 14 mm in diameter and 38 mm long. Two cavities were machined into the side of the body. The dimensions of one cavity were chosen so that a small fold of tissue could be sucked into it and pierced by a threaded needle running in a hole drilled through the length of the body. The other cavity housed a mechanism comprising a hook and sprung shoe designed to catch the loop of thread once the needle had pierced the tissue. Both the needle and the catch mechanism were actuated by wires running through the biopsy channels of a standard two-channel endoscope (Figure 1.6).

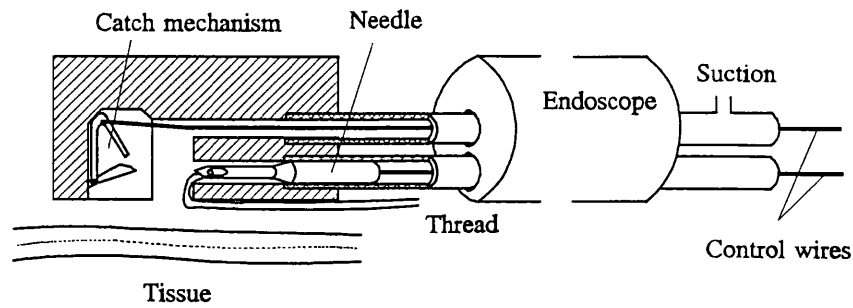


Figure 1.6 The Swain and Mills first endoscopic sewing machine.

This invention explored the possibility of "sewing" gastrointestinal tissue by applying and simplifying the principles of conventional sewing machines. However, there were problems in the design: (i) The size of the machine - the device was 14 mm in diameter, 38 mm long, which was rather too large for easy use in patients. (ii) The cavity size - the cavity designed to hold the tissue should ideally be enlarged in order to ensure that the needle would penetrate the full thickness of the tissue. (iii) The chain-stitch mechanism - a hooked catch mechanism catches the first loop of thread and retains it until the second loop is formed and passed through the first loop. In practise the chain-stitch mechanism was somewhat unreliable, particularly when used on wet gastrointestinal tissue. (iv) The vision - if the machine was mounted onto the end of a flexible endoscope, the endoscopic vision was impaired. Even though the machine was made of transparent PMMA, mucus or blood tended to adhere to the machine blurring the view. If the machine was inserted into the stomach without mounting it onto the endoscope, the machine was operated "blind", thereby lessening its clinical value.

1.4.3. An endoscopic stapling machine

Swain, Brown and Mills [20] reported the development of an endoscopic stapling machine in 1989. It was the first flexible endoscopically controlled device designed to place multiple transmural staples remotely through gastrointestinal tissue without requiring laparotomy. The proposed clinical applications included the stapling of bleeding varices, closure of internal wounds or fistulae, assistance in the removal of normal or abnormal tissue, safe full-thickness biopsy of gastrointestinal tissue, and stapling across bleeding or perforating ulcers.

The device was mounted in front of a conventional endoscope with a control cable passing through the biopsy channel of the endoscope. It was machined in clear PMMA to allow the action of the stapling device to be visualised. Metal parts were made of stainless steel to minimise corrosion in a wet acid environment. This device was able to deliver up to five staples in a staggered double row. The dimensions of the device were 16 mm in outer diameter and 8 cm in length.

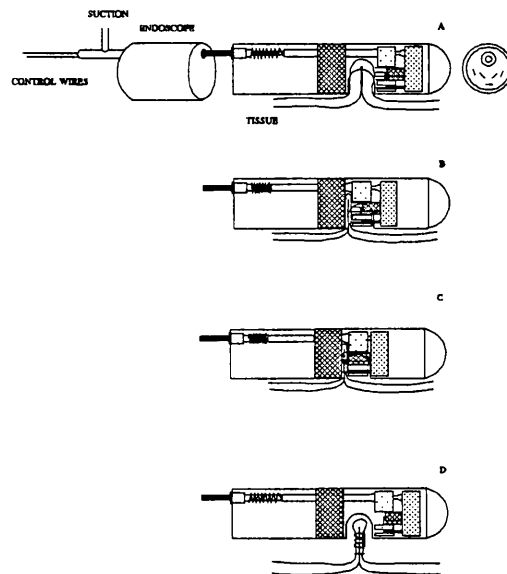


Figure 1.7 An endoscopic stapling machine.

Gastrointestinal tissue to be stapled was first sucked into a cavity within the body of the machine to form a double layer (A). The cavity dimensions controlled the depth of staple penetration. The cavity was designed to deliver staples that penetrated the full thickness of the tissue. The action of the machine involved three individual steps. The tissue must be compressed after suction into an optimal thickness for staple closure (B). The second movement (C) pushed the staples through their location slots by means of staple rammers so that the staples penetrated the double layer of tissue to engage in shaped anvils that caused the staples to bend inwards and backwards on themselves to exert compressive force on the tissue. The considerable force of 5.5 - 6.8 kg required to close the staples over the tissue was exerted by means of strong steel wires inside a wire-wound flexible cable. The third action (D) was to release the force transmitted to the staples through these wires to allow a release spring within the body of the stapling device to open the cavity and allow the stapled tissue to slide out of the device.

There were still some problems remaining in the design: (i) The size - the machine was 16 mm in diameter and 80 mm long, which was rather too large to be easily swallowed by the patient. (ii) The cavity size imposed limitations on the number of staples that could be delivered. (iii) The vision - the endoscopist had rather a poor and distant view of the target tissue when the machine was in action. The design required improvement.

1.5. Hand sewing and sewing machines for sewing material with thread

1.5.1. Needles for hand sewing

For thousands of years, the only means of stitching two pieces of fabric together had been with a needle and a length of thread [22]. The commonest form of a needle was a pointed slender piece of metal or other material with a hole in it through which thread

is passed [23]. The needle with a thread-carrying hole had been an ingenious improvement over the sharp bone, stick, or other object used to pierce a hole through which a lace or thread then had to be passed.

1.5.2. Hand sewing

The way of hand sewing is to pass the needle carrying the thread completely through the fabric and to re-enter from the other side. The drawback is that only a limited length of thread can be used and the whole length must be drawn right through the fabric or other material at each stitch, and the length of the thread continuously diminishes as the sewing proceeds [24]. This may cause a problem of friction because the frictional force to push the needle through many layers of material increases as does the friction that the material exerts on the thread as it is pulled through.

1.5.3. Sewing machines

A sewing machine is a complicated precision machine designed for sewing materials together [23]. A sewing machine usually involves a rotation of an axle which is powered by a driving wheel or a small electric motor. This axle is linked to a crank or cam which is used to convert the rotational movement of the axle into the up-and-down movement of the needle.

A modern sewing machine uses two threads to make a stitch. The thread is passed through the eye of the needle. When the needle moves down through the material, a rotating hook catches the loop of thread running through the eye of the needle and pushes it around a small reel that contains the bobbin thread. When the needle lifts up, the thread is pulled tight with the bobbin thread which is now running through the loop.

It prevents the needle thread from being pulled from the material. The stitch is now complete.

1.5.3.1. Review of the mechanisms for moving the needle in conventional sewing machines

A simple, reliable mechanism is required for controlling the movement of the needle in conventional sewing machines. For more than 100 years, there have been over a hundred types of mechanism designed or proposed for this purpose, but most of the mechanisms have been discarded. There are three commonly used mechanisms for controlling the movement of the needle in modern day, conventional sewing machines [25]. By analysing these mechanisms, we may lay a foundation for a better design of a new endoscopic sewing machine.

A crank - connecting rod mechanism

Figure 1.8 shows that a crank-connecting rod mechanism consists of an axle 1, a driving wheel 2, a crank 3, a connecting rod 4, and a rod 5 for holding the needle. When the wheel 2 is driven, the rotation of the axle 1 leads to the rotation of the crank 3. Since the connecting rod 4 is linked to the rod 5 by the connecting head 7 and screw, when crank 3 rotates, the rod 5 is driven up and down. As the needle is fixed at the end of rod 5, reciprocating movement of the needle is achieved by the rotation of crank 3. It is clear that the distance moved by the needle is determined by, and is equal to, twice the length of the crank.

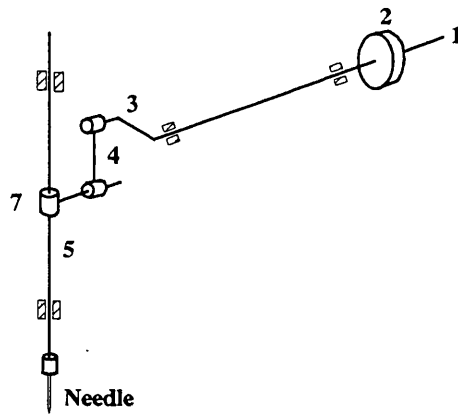


Figure 1.8 A crank-connecting rod mechanism.

A crank - slide piece - connecting rod mechanism

This mechanism involves an axle 1, a crank 2, a connecting rod 3, a rod 4 for holding the needle, and a sliding cylinder 5. When axle 1 rotates, crank 3 rotates and drives rod 4 up and down. Pin 6 which runs between the guides 5 prevents rod 4 rotating (Figure 1.9).

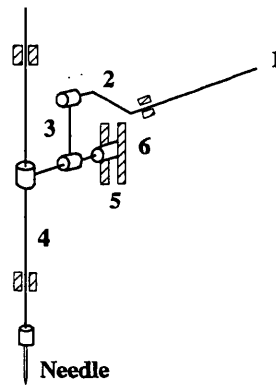


Figure 1.9 A crank-sliding rod mechanism.

A cam-driven mechanism

This mechanism consists of an axle 1, an off-centred cam 2, a sliding fork 3, and a rod 4 for holding the needle. When axle 1 is rotated, it leads to the rotation of off-centred

cam 2. The rotation of cam 2 leads to moving the sliding fork 3, and thus leads to the up and down movement of the rod 4 and the needle (Figure 1.10).

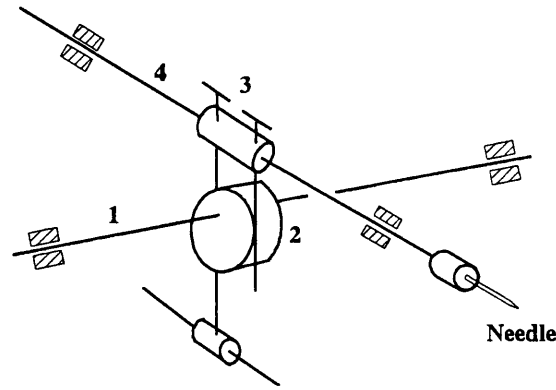


Figure 1.10 A cam driven mechanism.

1.5.3.2. The sewing machine needle

Compared to an ordinary needle, the eye of the sewing machine needle is close to the sharp tip of the needle rather than at the end opposite to the tip. The eye close to the needle point conveys the thread through the cloth, without having the whole needle to pass right through. The sewing machine needle also features a longitudinal deep groove on one side, in which the thread can lie, and a short transverse groove on the other near the eye to allow the catch mechanism, a shuttle, for example, to pass between the thread and needle to facilitate capture of the thread.

1.5.3.3. Types of stitch formed by sewing machines

According to Knight's American Mechanical Dictionary [26], there were 68 sewing machine stitch types in use by 1882. Gradually, most of these types of stitch were abandoned. At present, there are three types of stitch in common use.

Lock-stitch

The under-thread, of which there is a supply on a spool, is passed through the loop, which is then tightened in many machines by a take-up lever. The resulting stitch should look the same from either side and the threads should cross over in the centre of the fabrics being joined. The machine can thus make a succession of stitches until the supply of thread runs out, with both ends of each thread remaining on their own side of the fabric [24].

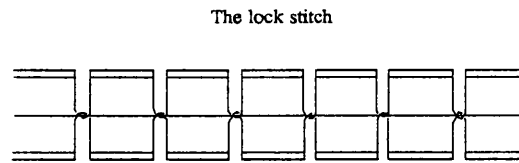


Figure 1.11 The lock-stitch.

Single thread chain-stitch

The needle descends through the cloth and rises, throwing out a loop of thread, which is then caught by a looper which usually twists the thread underneath the material being sewn. The cloth moves on and the needle in its next descent passes through the previous loop of thread, which is then released from the looper but held in position by the needle and the tension on the thread. In this way each stitch is held in place by its predecessor; and while the seam above the cloth resembles the lock-stitch, below the cloth there is a succession of loops. This stitch formation has the disadvantage that it may very easily be undone, if pulled from the end [24].

The single thread chain stitch

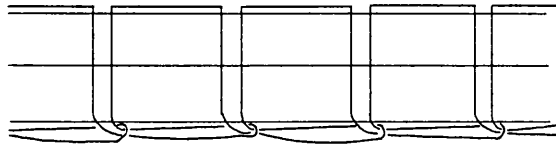


Figure 1.12 Single thread chain-stitch.

Double thread chain-stitch

The machine, with a double thread chain-stitch mechanism, makes a secure stitch by interlooping the needle and thread below the cloth with another thread, which is carried by an oscillating looper and is supplied from a second reel [24].

The double thread chain stitch

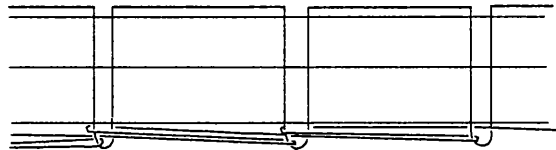


Figure 1.13 Double thread chain-stitch.

1.5.3.4. The early invention of the sewing machines

Saint sewing machine

Thomas Saint [27], a London cabinet maker, was granted a patent for the first sewing machine in 1790 but this invention remained unnoticed in the patent office library until 1874. It is a chain-stitch machine and has such features of later machines as the

horizontal table, overhanging arm, reciprocating needle-bar, a feed mechanism, and a continuous supply of thread from a reel on the arm.

The needle-bar carries an awl and a needle, which instead of an eye has a notch at the lower end, the thread being carried by the notch through the hole already made by the awl. The loop formed below the fabric was caught by a looper and held for the next stitch to pass through. At each rotation of the driving shaft a tappet advanced the cog wheel by one tooth, so causing the lead-screw to traverse the table by the length of a stitch.

Howe sewing machine

In Howe's lock-stitch machine [24], the needle is curved and near its point has an eye, through which the thread passes from the reel above. The needle is attached to a swinging lever, and when its point has passed some distance through the cloth and is returning, a loop is thrown, through which a shuttle is passed, driven by a picker as in a loom. The needle then withdraws completely, leaving the needle thread and shuttle thread interlocked in the cloth. The needle is curved to conform to the arc traced out by its point, so that it should not displace the cloth when passing through. The motions needed for moving the needle, shuttle, and baster plate are driven by cams on a shaft rotated by a hand wheel.

Singer sewing machine

In Singer's lock-stitch machine [24], the shuttle is propelled by a driver moved by a crank pin on the lower shaft below the work table. The needle motion, obtained from a crank pin on the upper shaft, is straight and vertical. The cloth feed is provided by a

finely grooved and serrated wheel, which is moved intermittently by a band worked by a rocking lever from a cam on the underneath shaft, a wooden brake-block preventing by its friction the backward motion of the feed wheel during the return of the band. The feed worked in conjunction with the vertical yielding presser-foot.

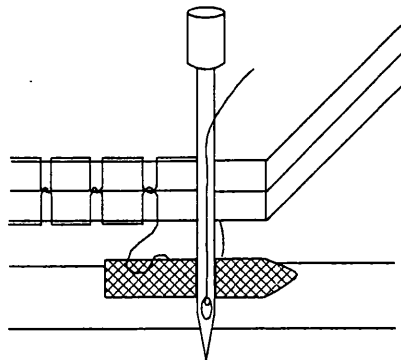


Figure 1.14 Singer sewing machine.

Willcox and Gibbs sewing machine (1857)

In this chain-stitch machine using a single thread, the hook catches the loop of needle thread and holds it while the cloth moves forwards. At the next descent of the needle the hook catches the second loop, which in being expanded tightens the previous loop, drawing it off the hook into the cloth. The chain-stitch made in this way has a twist in each loop, which makes it more secure than an untwisted chain-stitch [22].

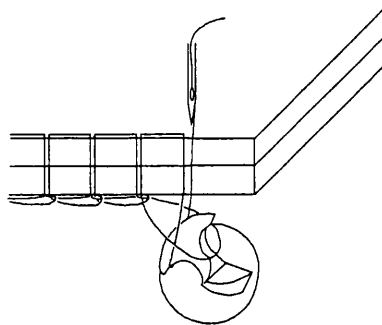


Figure 1.15 Willcox and Gibbs sewing machine.

Weir sewing machine (1872)

In this chain-stitch machine, when the needle begins to rise from its lowest position, the needle throws out a loop of thread, which the point of the looper enters and retains. When the needle descends for the next stitch, it passes through the previous loop, which is then cast off. In this way, a chain-stitch is formed below the cloth [24]. The chain-stitch made by this method differs from that made by the rotating hook type of machine in that the loops are not twisted and consequently are less secure.

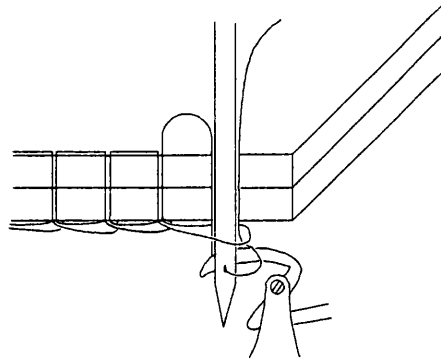


Figure 1.16 Weir sewing machine.

1.6. The aims of the project

The aims of the research described in this thesis were to (i) compare various clipping methods for endoscopic haemostasis, (ii) design, develop, and test improved, single and multiple stitch endoscopic sewing machines for use at flexible endoscopy, (iii) design and develop devices and methods for tying knots and cutting thread at flexible endoscopy, (iv) conduct a feasibility study of a wireless endoscope which could be swallowed by a patient and transmit images of his entire gastrointestinal tract.

**Chapter 2 A Comparison of
Clipping Methods for
Endoscopic Haemostasis**

2.1. Introduction

Injection methods are ineffective in stopping bleeding from vessels over 0.5 mm and thermal methods are ineffective for vessels over 2 mm in diameter [53]. Arterial diameter in bleeding gastric and duodenal ulcer may be as great as 3.5 mm [28]. Improvements in endoscopic haemostasis require the development and application of surgically sound mechanical methods. The bulk of the work described in this thesis is devoted to investigations into, and the development of, endoscopic sewing machines. In this chapter, however, the work on designing and testing new clips that might offer a simpler but somewhat limited method of mechanical haemostasis at flexible endoscopy is reported. The newly designed clips are compared with existing Olympus clips in models of arterial ulcer haemostasis.

Clips (Hayashi type) that could be passed through the biopsy channel of a flexible endoscope and applied to tissue were originally developed by Hayashi in 1971 [29-34]; he developed two types of clips, one being detachable and another connected to a long polyethylene tube for peroral indwelling use. Modified detachable clips (Kuramata Type) were subsequently developed by Kuramata in 1972 [35]. Then a further modified Kuramata clip (Sakura J-Type) was developed by Hachisu in 1982 [36]. Later, clips (Hayashi type) were further modified by Hayashi in 1983 and have been commercially available from Olympus Optical Co. Ltd. for over 27 years. Their design was ingenious, utilizing a figure of 8 configuration which allowed an expansion during deployment from 2 mm to 10 mm before closure of the two jaws and an elegant release mechanism in which a small partly severed metal plate is deformed until the clip is released from the delivery system. These clips were used in early descriptions both for haemostasis and for marking tissue [42-47] and more recently for closing small perforations

associated with submucosal resection. Further modification of the clips was reported by Hachisu in 1985 [36, 37]. Clinical results reported by Hachisu suggest that the clips (Sakura J-type) modified by Hachisu were easy to handle and offered effective haemostasis [38]. His clip measured 1.3 mm x 6 mm with a “straddle” which expanded from 7.2 mm to 10 mm when maximally opened. Accommodated in a 2.2 mm diameter teflon tube, it could be introduced through a conventional 2.8 mm biopsy channel of flexible endoscopes. More recently, the delivery system has been modified to allow rotation of the clips. Four geometric configurations of the original clip are available commercially. The differences are minor: one has a tip angle of 90 degrees, another has a tip angle of 135 degrees which is the angle recommended for haemostasis. Two others (both with 90 degree tip angles) have longer and shorter lengths.

Clips were relatively rarely used for haemostasis until 1993 when they were taken up by Binmoeller, Thonke and Soehendra [39] who reported excellent results in clinical studies in 88 patients with bleeding ulcer (a total of 255 clips were placed). A recent randomised study by Villanueva [51,52] initially suggested an advantage with a reduction of rebleeding using clips when compared with injection of epinephrine in an abstract but the final study did not confirm this advantage. There is a small literature describing their use in the treatment of bleeding varices. Hepworth et al. [53] studied the efficacy of clips and other mechanical methods in models of experimental bleeding and observed that these clips were unable to stop bleeding because the force exerted by the clip on the vessel wall was weak and that the gap in the clip due to its tip configuration prevented the necessary flattening required to occlude an artery.

2.2. Methods

2.2.1. Design and testing of new clips for endoscopic haemostasis.

New clip design

A variety of new clips, as illustrated in Figure 2.1, were designed and constructed. The most promising clip design, described below, was selected for further testing.

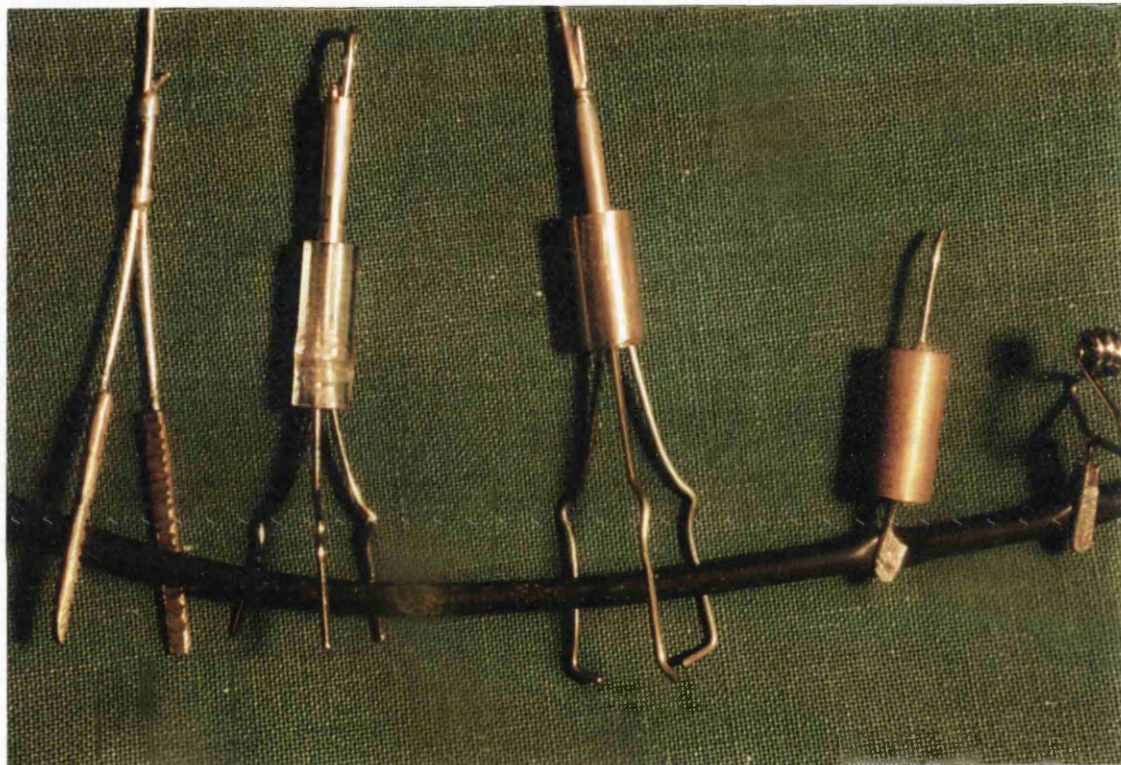


Figure 2.1 A variety of newly designed clips.

A three-pronged clip

This clip comprises three resilient arms which were attached at their proximal ends to a common mounting and which, in the illustrated rest position (Figure 2.2), diverge towards the proximal ends. Each arm has a tip portion extending at an angle, for example at about 90 degrees, to the adjoining portion of the arm. Each arm was made of a hard stainless steel wire of about 0.8 mm diameter and each tip portion was an

integral end portion of the respective wire. Preferably, the tip portions were so oriented that when the diverging arm portions were brought together (see below) the tip portions extend approximately parallel to one another, so that any two adjacent tip portions could form a parallel sided, tissue engaging clamp. Part way along its length, each diverging arm portion has a V-shaped section. A sleeve was slidably received on the arms. The bore of the sleeve has a widened section half way along its length.

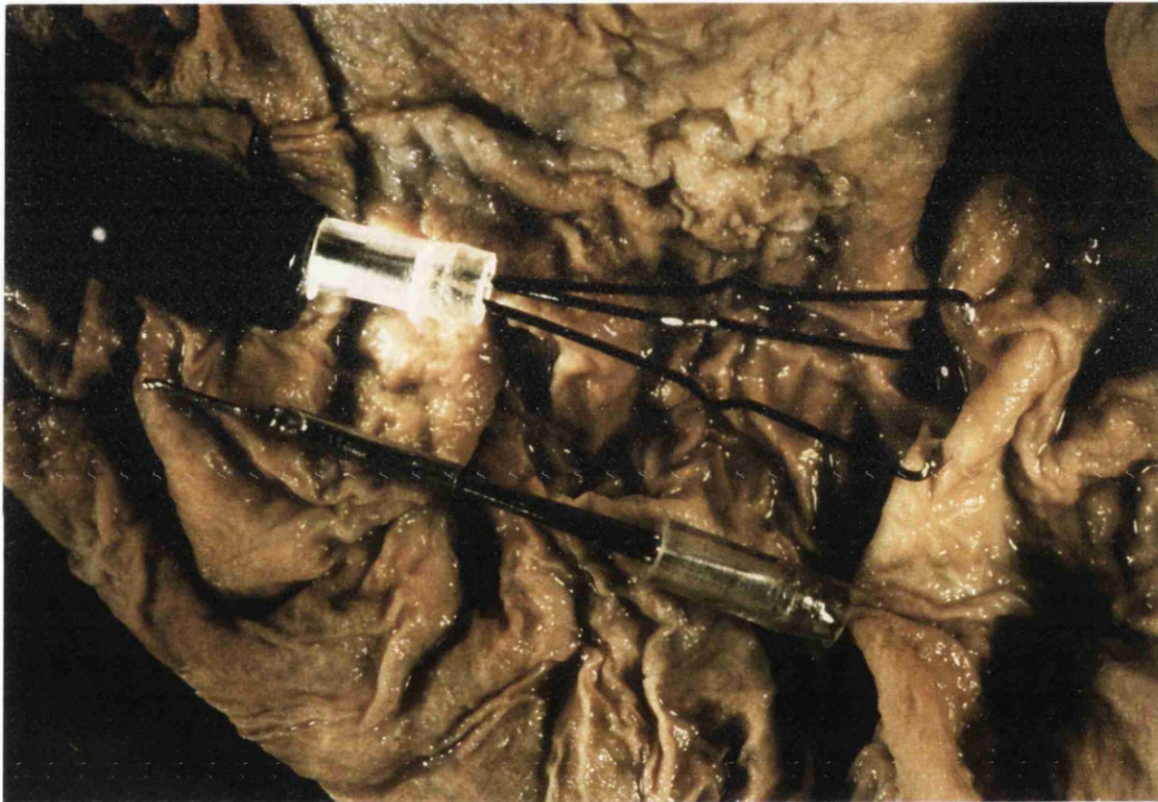


Figure 2.2 A three-pronged clip.

Figure 2.3 shows the use of the clip in clamping a bleeding blood vessel. The clip is introduced into the patient's body through a biopsy channel of a flexible endoscope. The clip is held in place with respect to the endoscope by a wire running in a sheath, both of which extend along the biopsy channel. The clip is releasably attached to the wire.

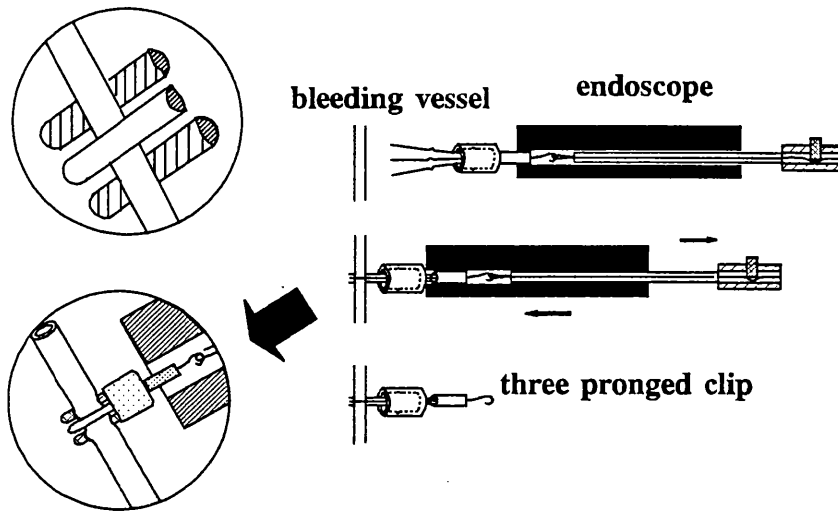


Figure 2.3 The use of a three pronged clip for clamping a vessel.

To clamp the blood vessel, the clip is moved towards the blood vessel until two of the arms pass one side of the vessel and the third arm passes the other side. It will be appreciated that it is not necessary to rotate the clip to grasp the vessel on both sides. This will be achieved whatever the rotational orientation of the clip (Figure 2.4).

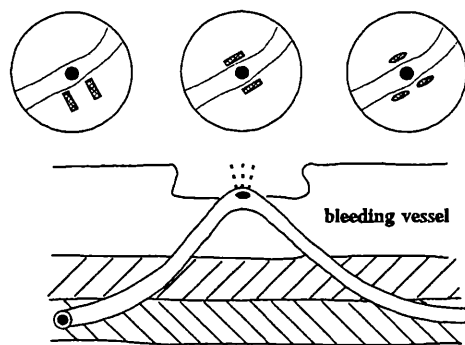


Figure 2.4 A comparison of two and three pronged clips indicating that a three pronged clip can close an artery without knowledge of the orientation of the vessel.

To position the clip, the endoscope is moved forwards onto the site where the clip is to be attached to the blood vessel, whilst a restraining force is exerted on the wire clamp. Since the outer diameter of the sleeve is greater than the internal diameter of the biopsy channel, the sleeve forces the arms until the V-shaped section of the arm engages in the widened section of the sleeve bore. Finally, the wire clamp is released and the endoscope withdrawn, leaving the clip in place on the blood vessel.

Olympus endoscopic clip

For comparison, two types of endoscopic clip (Olympus Optical Co. Ltd) were used: marker (MD 59) and haemostatic (MD 850). The marker (MD 59) had a 90 degree angulation at the tip of its 2 arms (Figure 2.5) while the MD 850 was at 135 degrees. These two types were 10 mm long. All were administered by means of the endoscopic clip fixing device (Olympus HX 3L) which can be passed through a 2.8 mm diameter biopsy channel of the gastroscope. The thickness of the limbs of the clips was the same (0.2 mm).

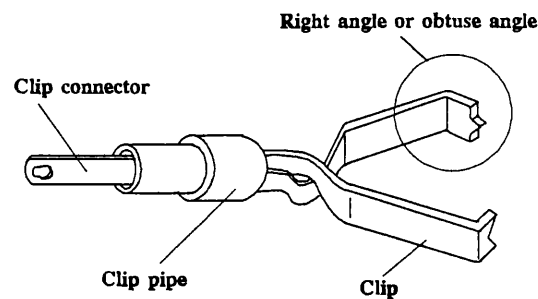


Figure 2.5 Olympus MD clip.

2.2.2. Models

Model to measure the pressure required to overcome clip compression

Silastic tubing (SILASTIC, Medical-Grade Tubing, Dow Corning Co., Midland, Michigan, USA), 3 mm outer diameter, 1.6 mm internal diameter, and of an elasticity subjectively similar to the wall of an artery, was used to measure the bursting pressure when occluded by the clips. One end of the tubing was connected to a sphygmomanometer (Accoson, Hospital Model BS 2744, UK) which allowed the pressure inside the tubing to be increased and monitored. The other end of the tubing was immersed in water to test for leakage once the clip had been applied (Figure 2.6). Air bubbled out of the tubing immersed in water if the clip failed to occlude the tubing model of an artery. If no air bubbled out and the clip appeared to be occluding the "artery", the pressure could be raised by hand pumping air into the sphygmomanometer. The pressure was then raised to 300 mmHg which is well above conventional levels of human arterial blood pressure (120 mmHg).

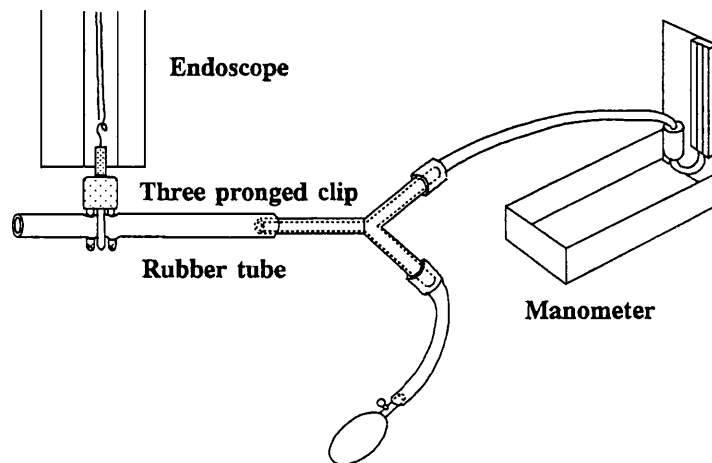


Figure 2.6 The set-up of the tubing model for checking the efficacy of new clips.

Measurement of force required to pull clips off postmortem gastric tissue

The force required to pull a clip from post mortem tissue was measured using a spring force gauge (Salter 15) attached to the clip by a loop of thread (Figure 2.7).

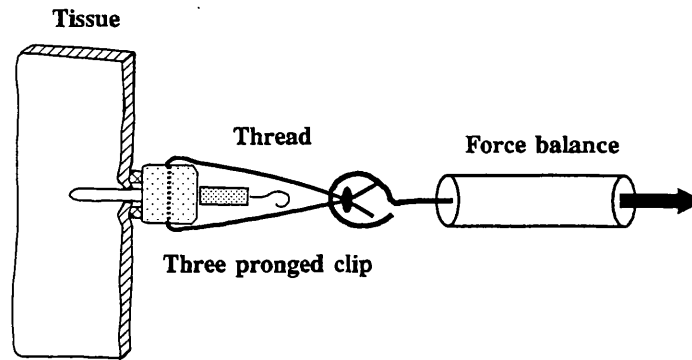


Figure 2.7 The set-up of the model for measuring the forces required to pull the clips off the tissue.

2.2.3. Experimental studies on bleeding vessels

Under anaesthetic induced with halothane, 4 female white pigs weighing between 70-85 kg underwent laparotomy. Gastric serosal vessels were identified and lesser curve artery/vein complexes measuring 2-4 mm on the lesser curve were selected for study. Two clips were applied to the vessel which was then severed at a point between them to check for haemostatic integrity.

2.3. Results

New clips occluded the bench model artery to pressures exceeding 300 mmHg in 40/40 applications vs 0/10 applications with Olympus MD clips ($p<0.001$). In other words the new clips were highly effective in occluding the tubing while the Olympus clips always failed to occlude the tubing in this model.

When tested on porcine gastric serosal vessels 0/10 Olympus MD clips vs 10/10 New clips stopped bleeding ($p<0.001$). Again the new clips were invariably successful in stopping the bleeding while the Olympus clips never stopped the bleeding in this model.

Force measurements showed that the mean force required to pull the clips off the tissue for the Olympus MD clip was 40.6 g ($n=10$, range 37.6 - 42.8, $SD=2.46$). The corresponding mean force using the new clips was 405.1 g ($n=10$, range 380.4 - 420.5, $SD=13.52$). The new clips required significantly 10 times more force to pull the clips off tissue when compared with the Olympus MD clips ($p<0.05$).

2.4. Discussion

These results show that alteration in clip strength and design markedly improve efficacy when tested in models of bleeding vessels. If clips are not strong enough to occlude the arteries, they are unlikely to work. It is also important that the artery is totally occluded by the closure of the clip.

The three pronged clip design of the new clips increased the chances of compressing an artery when its direction could not be identified. This is important if the clips are to be used in the treatment of bleeding peptic ulcer since the orientation of the vessel in the

ulcer is almost never apparent. The visible vessel has the appearance of a rounded central pigmented protrusion in the floor of the ulcer. Although the Olympus clip design has been improved to allow the clip to be rotated before delivery this is of little practical help because the orientation of the underlying vessel cannot be recognized at endoscopy. Some endoscopists place one clip in one orientation and then another at 90 degrees to the first in order to increase the chance of straddling the vessel with this two pronged clip. A three (or four) pronged clip markedly increases the chances of the clip straddling the artery whatever the orientation of the vessel in the floor of the ulcer.

Clips applied to stop bleeding at endoscopy might allow large vessels to be occluded. Other methods of endoscopic haemostasis including lasers, thermal probes and injection methods are not effective at stopping bleeding when the arterial size is greater than 1.5 mm.

The application of clips at flexible endoscopy does have some limitations. The Olympus clips are fiddly to load and require practise and the assistance of a skilled assistant. Because torrential bleeding from ulcers is not that common clips may have to be used in an emergency when skilled assistance may not be available. It would be helpful if the clips were easier to load.

The Olympus clips have a good safety record. No perforations have been described with their use. There is a trade off between efficacy and safety. The Olympus clips are very superficially applied and tend only to attach to the mucosal surface. The artery that is bleeding is always in a deeper layer. Clips probably have to occlude arteries in these deeper layers if they are to be effective in stopping bleeding and it is conceivable that

deeper penetration with clips might incur some risk of perforation. Tip design needs to be optimized to maximize efficacy and minimize perforation risk.

Mechanical trauma to eroded vessel in a bleeding ulcer could start bleeding and all clip methods will occasionally make bleeding worse.

Since the clips usually fall off the bleeding vessel with time they are likely to be released into the gut lumen with some potential for damage of the lumen. Alternatively they may occasionally migrate into the peritoneum like staples which are placed surgically. The small size of the Olympus MD clips and their shape when closed means that when they fall off the tissue they usually pass through the gut without problems and there are no reports of adverse events after clip detachment. Larger clips and clips with sharp edges might become impacted in the gut and fail to pass.

Some anatomical abnormalities for example the presence of scarring may make application of clips difficult. They may be difficult to use on cancerous tissue.

Clips that need to apply greater force to the arterial wall and have more limbs need to be bigger and may in consequence be too large to pass through conventional endoscopes with a 2.8 mm biopsy channel. Some commercially available endoscopes have larger biopsy channels and so called therapeutic endoscopes are available with channels of 3.6 mm or even 5 mm. These would allow the delivery of larger clip designs. An alternative method of delivering large clips would be to back-load the clips i.e. load the clip in front of the tip of the endoscope onto its delivery system which passes through the biopsy channel and then introduce the clip through an overtube which has been placed

through the mouth of the patient into the oesophagus.

If endoscopic surgery is to develop it is essential that more effective methods of mechanical haemostasis are available to deal with vessels of all sizes that are encountered in the gastrointestinal tract.

**Chapter 3 Design & development of
single-stitch endoscopic
sewing machines**

3.1. Introduction

Based on the original design and development of the endoscopic chain-stitch sewing machine developed by Swain and Mills and described in Chapter 1, it was realised that many of the operations that might be carried out using an endoscopic sewing machine at flexible endoscopy could be performed using a single stitch machine. Such a machine would be very much simpler than a chain-stitch machine with consequent benefits in respect of reliability and ease of operation. In this chapter, two newly designed single-stitch sewing machines are presented. The first machine which will be called "machine one" has also been designated as a "tissue-transfixing device", uses a hollow needle to pass a deformable nylon tag through the tissue. The second machine called "machine two" is something of a hybrid of the single-stitch tagging machine and the chain-stitch machines. The experimental results using the both single-stitch endoscopic sewing machines are reported and discussed. Solutions to some of the problems that occurred during the development of the second single-stitch sewing machine (machine two) are discussed.

A number of different single stitch mechanisms were designed, constructed and tested using large-scale bench models. The mechanisms eventually chosen for incorporation in two single-stitch endoscopic sewing machines were simple and easy to manufacture using available workshop facilities.

3.2. Design and development of single-stitch endoscopic sewing machines

3.2.1. An endoscopically deliverable tissue-transfixing device for securing biosensors in the gastrointestinal tract (machine one)

This device was designed for securing biosensors in the gastrointestinal tract without

laparotomy, but with adaptation might be used to approximate tissues at flexible endoscopy. The device utilized a novel mechanism designed to deliver strong transmural nylon tags remotely to gastrointestinal tissue. Machined from stainless steel and operated by means of flexible cables, the device was torpedo-shaped measuring 145 x 11 mm. The device was able to be front-loaded with its control cables passing through the biopsy channels of a conventional endoscope or be guided using an endoscope positioned alongside the control cables [21].

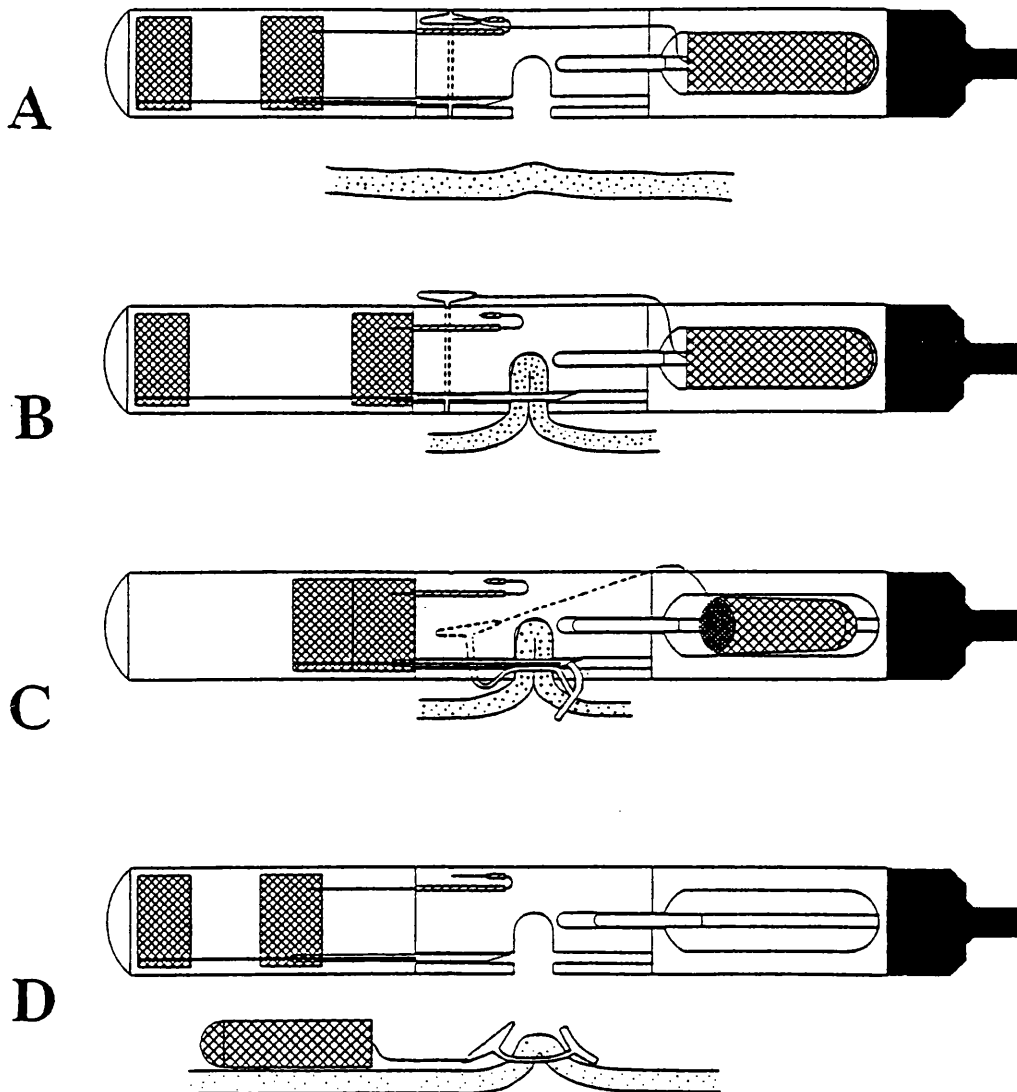


Figure 3.1 The mechanism of action of the endoscopic tissue transfixing device

Cylindrical in shape, the device had two cavities which were cut in its side. Into one cavity, a folded double layer of gastrointestinal tissue could be sucked. In the other, a payload such as a biosensor could be stored and ejected when desired by moving a cam. The needle was hollow to allow it to be loaded with the tilt arm of the tag. A coaxial push-rod could then force the tilt arm out of the hollow needle. The needle ran in a passage which was drilled along the length of the machine and through the suction cavity. Two wire-wound, hollow cables allowed passage of the machine's control wires and an airtight connection between the suction cavity and a vacuum pump [21].

The design problems were: (i) The rigid length - although the machine's diameter was only 11 mm, its length was 145 mm to allow space for the cam mechanism used to eject the biosensor. It was easy to use it in the relatively straight oesophagus and also in the proximal stomach but, despite some design modifications to allow endoscopic manipulation, it was very difficult to advance the device into the antrum of the stomach or duodenum; (ii) The vision - if the machine was mounted on to the distal end of the endoscope, the endoscopic vision was partially blocked by the end of the machine. If the machine was operated with a separate supervising small diameter endoscope, precise positioning of the machine to the target tissue was difficult. In practice, the machine's position in the stomach was determined by marking the outside of the operating cables with numbers indicating distance from the teeth which was adequate for use in the oesophagus or proximal stomach.

3.2.2. A single-stitch endoscopic sewing machine using a tag and thread (machine two)

This single-stitch endoscopic sewing machine is shown in Figure 3.2. It worked as follows:

1. A tilt-tag attached to a suture thread was front-loaded into a 17 gauge hollow needle. The needle was 36 mm long and had a 0.3 mm slot cut along its length to accept the 0.2 mm suture thread.
2. A double layer (full thickness) of tissue was sucked into a cavity cut in the side of the machine.
3. The needle was then pressed through the tissue using a Bowden cable positioned within the biopsy channel of the endoscope.
4. A push wire in the Bowden cable pushed the tilt-tag out of the needle to leave it trapped in the distal chamber of the machine with the suture thread passing to the other side of the fold of tissue.
5. The suction was released to allow the threaded tissue to fall from the machine.
6. The machine and endoscope, along with the two tails of the thread, were removed from the gut.
7. The tilt-tag was able to be removed from the machine or re-loaded to form another stitch.

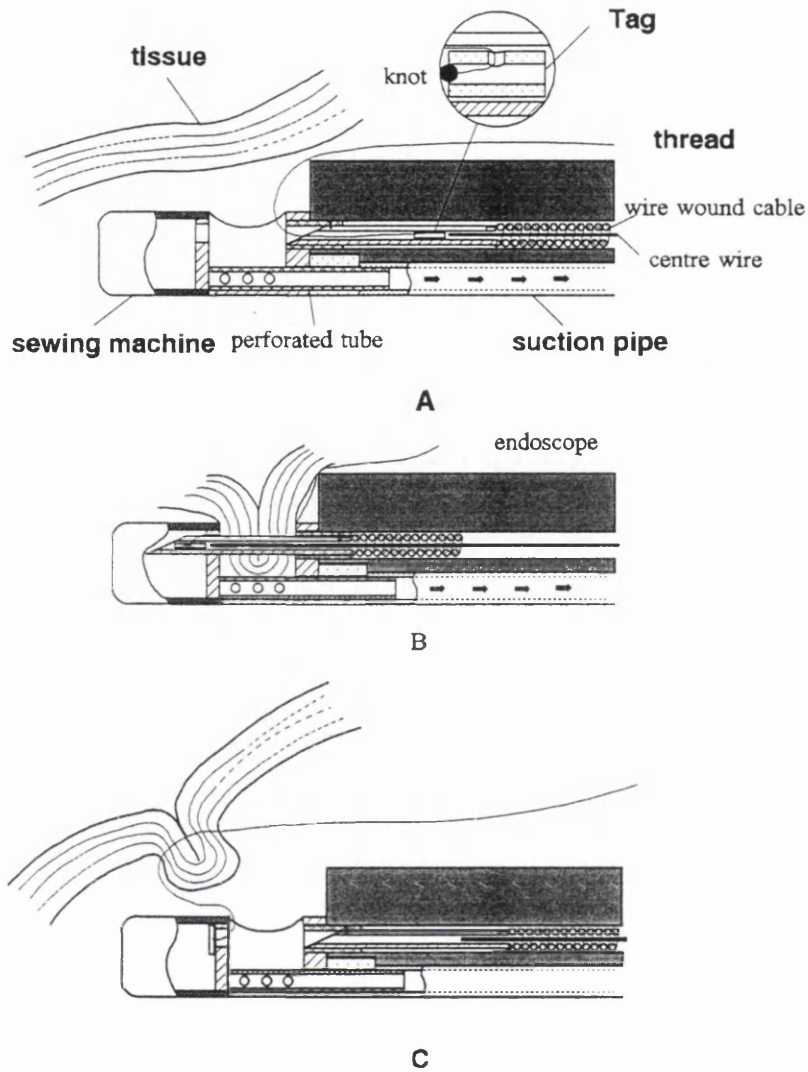


Figure 3.2 single-stitch endoscopic sewing machine.

For use with small diameter, flexible fibre optic endoscopes, it was 9 mm in diameter and 35 mm long, machined entirely from stainless steel (Figure 3.3). Coupling of the machine to the distal end of the endoscope followed the scheme will be illustrated in chapter 4, resulting in a total diameter of the endoscope plus machine of 12 mm and leaving 3/4 of the field of view of the endoscope unobstructed.

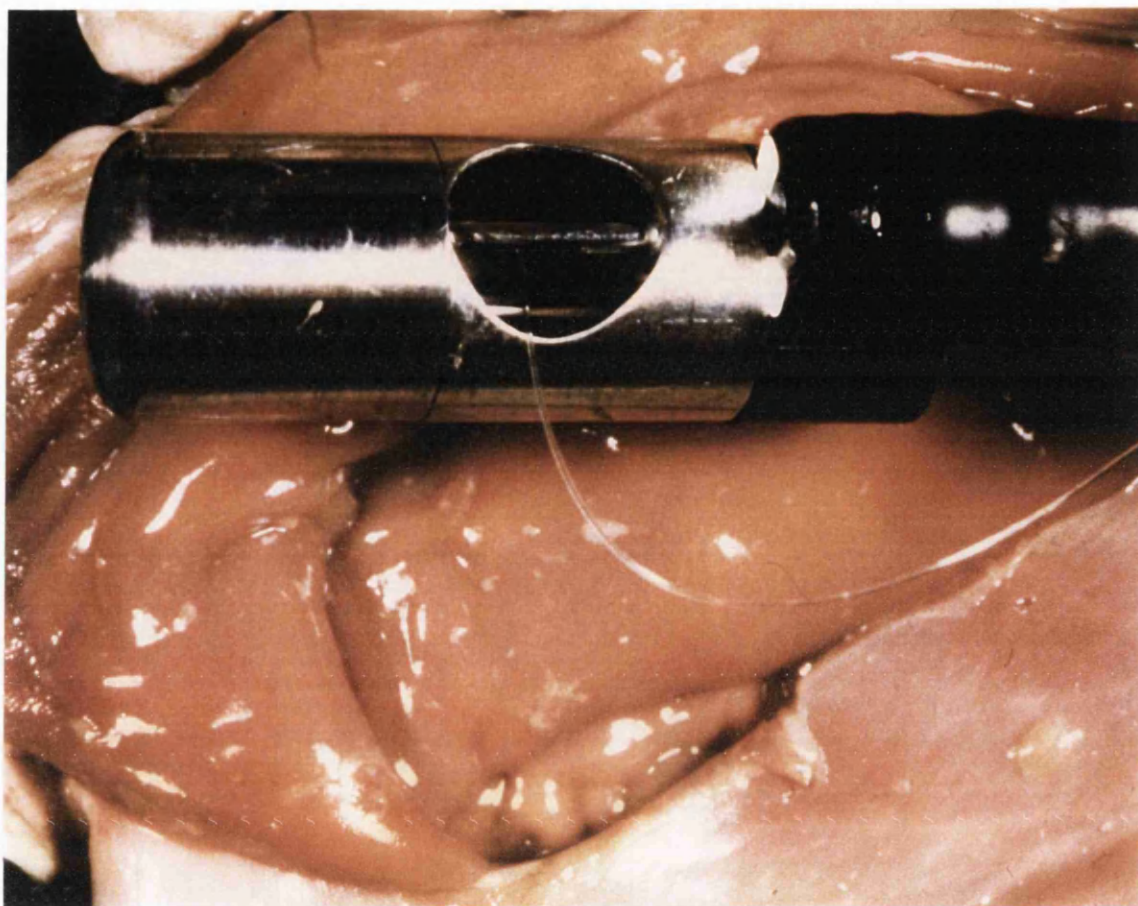


Figure 3.3 Photograph of the single-stitch endoscopic sewing machine which was mounted on the end of the Olympus PQ20 endoscope.

With the same mechanism, another machine was constructed for use with large diameter, flexible fibre optic endoscopes, particularly for use with colonoscopes. It was 12.7 mm in diameter and 30 mm long, machined entirely from stainless steel. The only difference was that the 12.7 mm single-stitch endoscopic sewing machine had a greater cavity size.

3.3. Experimental results

3.3.1. Results for the tissue-transfixing device (machine one)

Tagging experiments in cadaveric oesophagus, stomach, small bowel, colon

1000 tags were delivered successfully in 25 post-mortem human stomachs, 50 in 5 post-mortem human oesophagi, 100 in 5 post-mortem canine stomachs, 20 in 2 post-mortem human small bowel, and 20 in 2 post-mortem human colon.

Depth of tag

The machine was used to deliver tags to the post-mortem human and canine stomachs and the post-mortem human oesophagus. The tags were delivered to 25 human stomachs, reaching the serosal surface in every instance. Using one early prototype the tags were found to be submucosal in 45% of experiments on canine stomach and human oesophagus. The thickness and rigidity of the muscle layer of the human oesophagus and the canine stomach were found to be greater than those of the human stomach which could explain this result. A later prototype of the machine with increased cavity size and superior suction performance was able to deliver tags to the serosal surface of canine stomach and human oesophagus in all cases.

Force required to pull out tag

The force required to pull the tag out of the post-mortem human stomach was measured using a spring force gauge attached to the tag, the tissue held by hand. In 10 experiments on tags penetrating the full thickness of the stomach, the mean force was 2 kg (range 1.2 kg to 4 kg). In 10 experiments on tags confined to the mucosa without penetrating the deep muscle, the mean force was 0.95 kg (range 0.5 kg to 1.6 kg). Addition of a 10 mm diameter, 1 mm thick washer of silicone rubber to spread the load

of the tag over a larger surface area of tissue increased the required force to a mean of 2.9 kg in 10 measurements (range 2 kg to 3.3 kg).

Preliminary use in animal and human studies.

This device has been used in experimental studies in dogs for long term measurements of gastric pH [54] and the effect of drugs on gastric pH [63]. It has been used to make physiological and pharmacological measurements of oesophageal pH and colonic pressure [59]. It was used in a human volunteer to attach a radiotelemetry capsule to the gastric wall for continuous measurement of gastric pH for 159 days [55]. This method has allowed far longer continuous periods of ambulatory monitoring of gastrointestinal pH and pressure than has been achieved by other means.

3.3.2. Results for the single-stitch endoscopic sewing machine (machine two)

3.3.2.1. Bench experiments

An Olympus PQ20 endoscope, postmortem tissue, suture thread, a suction pump and an overtube were used for undertaking the experiments. Once the 9 mm machine was mounted onto the distal end of the endoscope, the tilt tag attached by a 0.2 mm diameter nylon line could then be loaded in the slot of the needle. The machine was then placed over the tissue, and suction applied using a suction pump to suck the tissue into the cavity, and then the needle was advanced to pierce the tissue. The suction was then released and the machine withdrawn with the endoscope. The tag was retrieved and reloaded for performing the next stitch.

The results showed that this machine worked reliably on the bench. It could deliver 10 or more continuous stitches if needed. Care had to be taken not to cross the thread of

the previous stitches which would tend to lock the stitches. A large number of stitches made it difficult to pull the tails of the thread together because of the large number of thread-tissue and thread-thread contacts and the greater contact pressures. If increased tip deflection was applied to the endoscope, increased force on the hand-piece was required to drive the needle through tissue. This was because of increasing frictional forces between the needle and the push-rod, and the Bowden cable and the inner surface of the biopsy channel. Bending the endoscope sometimes badly deformed the push-rod until improvements in choice of materials helped to eliminate this problem.

3.3.2.2. Animal studies

Radiotelemetry

The 9 mm single-stitch endoscopic sewing machine was used to attach pH-sensitive radiotelemetry capsules on 14 occasions for up to 87 days to the stomach wall of 8 unrestrained beagle dogs. Continuous records were made in 48-hour periods using a belt aerial and solid-state recorder worn in a jacket. Studies were carried out during normal feeding and with 20 and 40 mg (2-4 mg/kg) omeprazole (a proton pump inhibitor of acid secretion) once daily. There were no complications (haemorrhage or perforation) during the period of implantation, and follow-up endoscopies disclosed no evidence of ulceration or focal gastritis. The median intragastric control pH was 3.4 (range 2.8-7.2). The median pH during acid inhibition after five days' administration of 20 mg of omeprazole was 4.2 (range 1.2-7.6), and 5.2 (2.0-7.6) after a similar period on 40 mg of omeprazole ($P=0.1$ control vs. 20 mg and 40 mg of omeprazole). After the drug was stopped, the median pH returned to 2.8 (1.0-6.8) on days 1-3, but fell to 1.2 (1.0-3.2) by days 5-7 ($P<0.01$). This technique has for the first time allowed monitoring of gastric pH for long periods without the use of wires or tubes [55, 56].

Anti-reflux operations

The 9 mm single stitch endoscopic sewing machine was used in 6 beagle dogs to perform 3 anti-reflux operations (gastroplasty, fundoplication, and anterior gastropexy) without laparoscopy or laparotomy. Endoscopic gastroplasty (n=10) was accomplished by suturing the anterior and posterior wall of the stomach to create a gastric tube (neoesophagus) along the lesser curve. An anatomic arrangement similar to fundoplication (n=6) was achieved by invaginating the oesophagus and fixing it to the stomach 2 cm distal to the cardioesophageal junction. Anterior gastropexy (n=6) was performed using a technique similar to that used in creating percutaneous gastrostomies. There was no mortality. Ninety percent of sutures were seen at repeat endoscopy at 4 to 8 week intervals. These operations were evaluated by assessing (1) survival, (2) morbidity, (3) duration of the operation, (4) stitch survival, and (5) lower oesophageal sphincter function. Gastroplasty was selected for more extensive manometric evaluation [56].

Comparative studies of haemostatic efficacy of sewing and other mechanical methods of haemostasis with injection and thermal methods.

20 experiments were performed on 6 adult beagle dogs (14-17 kg, median 15 kg) to compare the haemostatic efficacy of mechanical, injection, and thermal methods of haemostasis. The studies were to test the hypothesis that mechanical methods of haemostasis are more effective in controlling haemorrhage than injection or thermal methods. The diameter of arteries in human bleeding ulcers measures up to 3.5 mm; mesenteric vessels up to 5 mm were studied.

The results showed that injection sclerotherapy and clips failed to stop bleeding from

vessels of 1 mm (n=20) and 2 mm (n=20). Bipolar diathermy was effective on 8/10 vessels of 2 mm but failed on 3 mm vessels (n=5). Unstretched elastic bands succeeded on 13/15 vessels of 2 mm but on only 3/10 vessels of 3 mm. The 9 mm single-stitch endoscopic sewing machine achieved haemostasis on vessels of 1 mm (n=5), 2 mm (n=5), 3 mm (n=5) and 8/10 vessels of 4 mm but failed on 5 mm vessels (n=5) because the vessel was too large to be sucked into the cavity so that the needle and thread could not be passed completely round the vessel complex. Endoloops were effective on all 5 mm vessels (n=5) [57].

It was concluded from the above three studies that (1) The 9 mm endoscopic sewing machine could be used successfully to endoscopically deliver a radiotelemetry capsule to the stomach of a dog to measure continuously the gastric pH over long periods. (2) By using the endoscopic sewing machine, conventional anti-reflux operations could be performed effectively and safely without laparoscopy or laparotomy. (3) Both unstretched elastic bands and the endoscopic sewing machine were significantly more effective in stopping bleeding from vessels up to 2 mm than injection therapy. Only sewing and tying stopped bleeding from vessels 2 mm to 4 mm in diameter.

3.3.2.3. Human studies

Radiotelemetry

The single-stitch endoscopic sewing machine was used in 2 patients for long term pH monitoring. The procedure was achieved in the 2 subjects by sewing radiotelemetry capsules (RTC) to the gastric wall in 2 patients who had a vagal stimulator inserted into the neck by neurosurgeons to treat refractory epilepsy. Vagal stimulation might be expected to increase gastric acid secretion (The vagus nerve is a crucial nerve that

passes through the neck and chest to supply sensory, motor and secretory fibres to the stomach). Unexpectedly the results suggested a diminution of acid secretion suggesting that inhibitory rather than excitatory fibres were being preferentially stimulated by the surgically implanted stimulator. The gastric RTC's transmitted for 90 and 14 days allowing continuous monitoring of pH [58]. They were removed by cutting the stitch at endoscopy and showed no calibration drift.

Securing feeding tubes

Naso-gastric feeding tubes sewn to the gastric wall of 6 patients who had all failed to retain conventionally placed nasogastric tubes for more than 12 hours on at least 3 occasions and were not candidates for percutaneous gastrostomy. Feeding tubes were retained for a median of 30 days (range 8 - 69). In one patient with poor gastric emptying a feeding tube was positioned in the jejunum over a guide-wire and the tube was prevented from falling out by placing a stitch in the stomach and securing the tube to the stomach wall by tying it with 4 half hitches. The stitches were seen to be secure at the time of removal. The feeding tubes were subsequently removed by cutting the thread at the knot using endoscopic stitch cutters (Olympus FS-1K).

Closure of oesophageal and gastric perforations, stent attachment.

A 76 year old patient with terminal squamous oesophageal cancer who had a dilatation induced perforation of the oesophagus followed by urgent thoracotomy at which the perforation could not be closed had the hole closed with stitches placed at with the sewing machine. A 71 year old man who had a gastric resection for cancer developed a perforation with a fistula allowing gastric secretions to enter the right side of his thoracic cavity. This failed to heal when a drain was inserted. The gastric perforation

was closed with six stitches placed using the endoscopic sewing machine tying three pairs of stitches with 4 half hitches each. A post procedure x-ray contrast study showed that the perforation had been effectively sealed. A 56 year old patient with an intrathoracic lymphoma had chemotherapy and developed a perforation with a chronic oesophagobronchial fistula. Attempts were made to seal this with expanding covered metal stents but these slipped down into the stomach because there was no stricture in the oesophagus to hold the stents. Stents were placed on two occasions but both fell into the stomach and the patient remained in intensive care for a period of 4 months. A covered expanding metal stent (Wilson Cook, covered Gianturco type) was placed across the perforation and sewn into the oesophagus using the endoscopic sewing machine. A single stitch was placed at the upper or proximal margin of the site in the oesophagus where the stent was to be optimally positioned and the thread was passed through the proximal margin of this stent which is formed of z shaped stainless steel wire with a plastic coating. The stent was tied into place with four half hitches. This stent remained in position without slipping and the patient became well enough to leave the intensive care unit.

Anti-reflux operations

Endoscopic gastroplasty was performed using endoscopic sewing, thread handling technique in 70 patients (median age: 59 years old (35-81)) with gastroesophageal reflux disease (GORD) unresponsive to omeprazole who declined or were unfit for conventional and laparoscopic surgery. The sewing machine was used to place a single suture below the gastroesophageal junction. The sewing machine was reloaded to place the second stitch. Two or more rows of sutures were placed to create a neosphincter. These patients had decreased reflux symptoms, reduced measured acid reflux and

increased lower oesophageal sphincter (LES) length and pressure with few complications [60].

These results indicated that stitching at flexible endoscopy in the human oesophagus and stomach is feasible for a variety of purposes and may facilitate the development of a new type of less invasive surgery.

3.4. Discussion

3.4.1. Summary of the requirements of the design

The technical requirements of a single-stitch endoscopic sewing machine can be summarized as follows:

1. A cavity with a suitable size and shape is needed to suck the full thickness of tissue.
2. A needle is required to pierce the tissue and carry a thread to the other side. The needle must be driven using a mechanism which can be manipulated within or run coaxial to a flexible endoscope.
3. A mechanism is needed to catch the thread once it has passed through the tissue.
4. The needle and catch mechanism must be remotely operated by the endoscopist ie. from outside the mouth or anus.
5. If an eyed needle is used to form the stitch, two tails of the threads are pulled through the tissue and the loop is caught to form the stitch. If a metal or plastic tag attached to the end of the thread can be passed through the tissue using a hollow needle and it can be retained in a cavity on the other side of the machine. On removing the machine and endoscope, the tag can be retrieved by removing the cap of the distal chamber and reloaded for further stitching. This mechanism

passes a single end of the thread through the tissue.

6. For such a mechanism, a push wire is needed to push the tag out of the hollow needle. The push wire may run through the Bowden cable used to push the needle through the tissue.

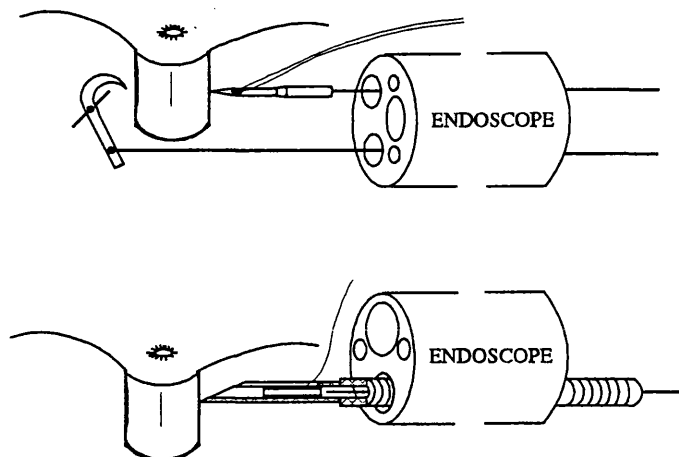


Figure 3.4 Two mechanisms for single-stitch endoscopic sewing machines.

3.4.2. The drive and control of the needle

The needle used in the Swain and Mills original endoscopic sewing machine was a conventional sewing machine needle which incorporated a hole close to the needle tip a solid shaft and a slot cut into the mid-body of the needle to allow the catch-mechanism to pass more easily between the needle and thread. The clearance between the large diameter end of the needle and the stainless steel tube inserted into the body of the sewing machine was 0.1 mm (Figure 3.5). The tube extended out of the proximal end of the body of the sewing machine and was used to couple the machine onto the distal end of the endoscope. Because the 0.5 mm diameter hard stainless steel control wire used as the push wire was soldered directly onto the end of the needle, its stiffness

tended to make the needle rock or rotate in the tube and lose its proper alignment. This misalignment had an important adverse influence on the thread handling of the endoscopic sewing machine.

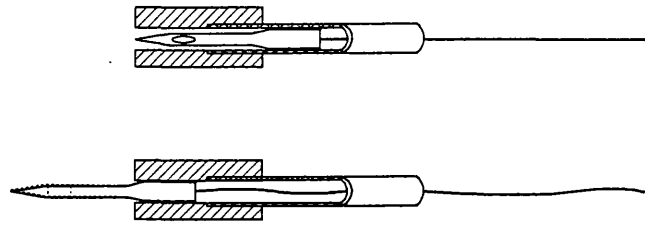


Figure 3.5 The stiffness of 0.5 mm control wire caused the needle rock or rotate.

If the eyed needle rotated, then the endoscopic sewing machine would fail because the hook-catch mechanism might fail to pass between the needle and the thread and thus failing to catch the loop. It was also found that the rotation caused the single-stitch endoscopic sewing machines to fail because the thread rotated around the needle and thus increased the frictional force and in consequence the force required to push the needle through the tissue.

One solution to resolve this problem was to fix a small locating pin (or peg) close to the end of the needle. This pin, which ran in a longitudinal slot cut in the coupling tube, restricted the rotation of the needle (Figure 3.6).

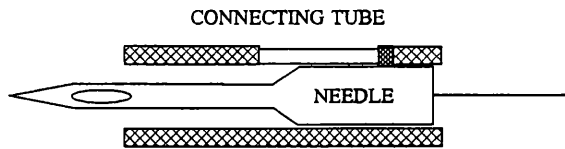


Figure 3.6 A small locating pin was fixed onto the end of the needle.

When a 1.5 mm, 17 French gauge hollow needle was used in the design, it was found that this type of needle also rotated, as did the conventional solid sewing machine needle. To overcome this problem, a locating pin was fixed in the wall of the coupling tube and a 0.3 mm wide locating slot was cut in the needle. Tests showed that the pin restricted the rotational movement of the needle (Figure 3.7). This proved a highly successful solution to needle rotation and has been used in employed in the machines used in most human cases performed to date.

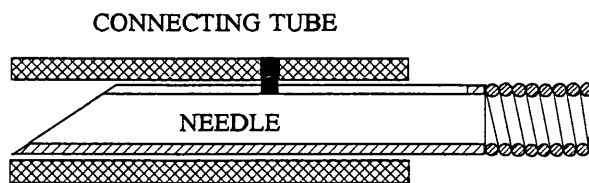


Figure 3.7 A small locating pin was fixed in the wall of the coupling tube.

There were problems with placing the pin to the exact depth for large scale production. Another method was therefore devised to address this problem. A "D" shaped rod was

inserted into the needle sleeve. A punch then deforms the end of the sleeve to adopt an open "D" shape. The needle is shaped by grinding to adopt a "D" shape. The needle is constrained in the sleeve by the double "D" shape and can not rotate but can move smoothly backwards and forwards. This method has been used successfully in the more recent clinical cases.

3.4.3. Control wires

The control wires were some of the most important components in the endoscopic sewing machines. They were used to drive the conventional solid sewing machine needle through the tissue in the original Swain and Mills endoscopic sewing machine and used to push the tag out of the hollow needle used in the later single-stitch endoscopic sewing machine. Stainless steel was considered the most suitable choice of material for the control wires due to its corrosion resistance and ready availability, but to determine the optimal size and hardness, a range of different diameters of both hard and soft stainless steels were tested.

Choice of drive wire for the conventional sewing machine needle

Five different diameter (0.3, 0.4, 0.5, 0.6, 0.7 mm) hard stainless steel wires were tested for using as the wire to drive the needle. The tests showed that if the wire was less than 0.4 mm in diameter, and the wire was fixed at both ends (one end connected with the needle, the other end was connected with the handle), the wire buckled in the biopsy channel (2.8 mm in diameter). If the wire was over 0.6 mm in diameter, the clearance between the wire and the PTFE tube was insufficient for smooth movement.

Choice of push wire for pushing the tag out of the needle

This push wire was used to push the tag out of the hollow needle used in the single stitch sewing machine. It ran coaxially within the 0.8 mm internal diameter Bowden cable used to drive the hollow needle through the tissue. Five different diameter (0.3, 0.4, 0.5, 0.6, 0.7 mm) hard and soft stainless steel wires were tested. It was found that the push wires made of hard stainless steel (Grade 316, K. C. Smith & Co., UK) required greater forces to push the tag out of the needle because of the greater frictional forces caused by the high contact pressures occurring between the rigid hard wires and the Bowden cable.

The tests showed that if the push wire made of soft stainless steel wire was less than 0.4 mm in diameter, it buckled. If the push wire was greater than 0.7 mm in diameter, it required greater force to push the tag out of the needle because there was insufficient clearance for smooth movement. The optimum choice for the push wire was found to be 0.6 mm diameter soft stainless steel wire.

3.4.4. The influence of endoscope tip deflection on the performance of the endoscopic sewing machines

Bending the endoscope can influence the performance of the endoscopic sewing machine or without proper attention to design can even cause the failure of the operation of the machine. Factors influencing the performance of the sewing machine when the endoscope tip is bent include a. diminution of the force transmitted to the needle tip b. increasing frictional resistance as the bent biopsy channel presses against the needle c. the moving distance required to penetrate the tissue and push the tag out increases. To ensure adequate support of the needle and reduce frictional losses within the biopsy

channel, the rigid stainless steel tube in which the needle ran extended 10 mm from the back of the machine. When the endoscopic sewing machine was coupled to an endoscope, this tube was positioned within the endoscope's biopsy channel. The presence of the rigid tube within the biopsy channel in practise barely restricted the maximum possible angulation of the endoscope tip (Figure 3.8).

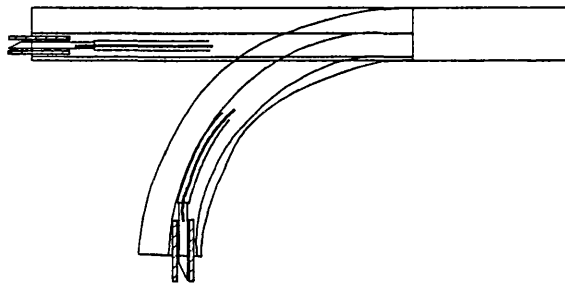


Figure 3.8 Bending the endoscope tip can impede the performance of the endoscopic sewing machines.

When withdrawn, the needle extended out of the tube and into the biopsy channel, thereby restricting angulation still further. Frictional forces that resisted the movement of the Bowden cable used to drive the needle were also increased as the endoscope was angled and the needle and Bowden cable were forced harder against the inside of the biopsy channel. With careful attention to design, it was eventually possible to stitch effectively even with extreme endoscope tip deflection. The use of low friction FEP (fluorinated ethyl propylene) polymer coating over the wire wound Bowden cable reduced the frictional forces during the needle movement. In tests using coated and uncoated Bowden cables attached to the identical needles, the coated version placed stitches on 20 out of 20 occasions using the sewing machine with the tip of the endoscope extreme angulation. This compared with only 5 out of 20 successful stitches

with uncoated Bowden cable ($p < 0.05$). These experiments were carried out on gastric postmortem tissue. The tip of the pushing rod varied from 3 to 5 mm in the distance it would protrude beyond the tip of the needle when the endoscope tip was held straight or in extreme angulation in a series of 20 measurements. Bending the tip lengthens the distance that the push rod had to travel, because the length of the midline of the outer coiled wire cable increases, and the central wire is not completely constrained and therefore tends to follow the outer edge of the curve. It was surprising how much difference this effect made to the function of the sewing machine until measurements were made of the distance travelled in experiments on the bench.

3.4.5. Repeated use of the push wire

As discussed in Section 3.4.3, a 0.6 mm soft stainless steel wire was used to push the tag out of the needle. The frictional forces encountered when using a hard stainless steel wire were found to be excessive. A problem with the use of the soft stainless steel wire, however, was that repeated bending of the endoscope resulted in permanent plastic deformation and shortening of the wire. It was therefore necessary to replace the wire after every fourth stitch. A soft wire push wire has been used in most human cases. More recently small bore hypodermic tubing has been successfully used as the push wire. An external FEP (fluorinated ethylene propylene) coating further reduced the frictional force required to push the tag out of the needle. Buckling of the push wire during the clinical use of the endoscopic sewing machines has not been a problem.

**Chapter 4 Studies on the individual
elements of the
endoscopic sewing
machines**

4.1. Introduction

In this chapter, the preliminary studies related to the development of endoscopic sewing machines are described. The work which tried to determine the optimum shape and size of the suction cavity to be used in the proposed machines is presented and the results are analyzed. The experiments designed to improve the endoscopic sewing machines' optical systems and consequently the endoscopist's view of the target tissue and action of the endoscopic sewing machines are reported. A comparison between the performances and the suitability of different needle shapes for use in the endoscopic sewing machines is also presented.

4.2. Cavity shape and size

Based on the experience of designing and developing the endoscopic sewing machines, it was found empirically that the cavity shape and size and the correct arrangement of suction channel(s) has an impact on the performance of these machines. In Figure 4.1(a), if the cavity size is too small, the tissue is not sucked adequately and the needle does not penetrate the tissue at all. (b) if the cavity size is still not large enough to suck all the layers of the tissue, the needle only penetrates the superficial layer ie. the mucosa. A stitch of this depth is likely to cut out. For most surgical purposes, it is essential to place stitches through the full thickness of the tissue ie. through the deep muscle layer to the serosa. (c) the cavity size is adequate to allow adequate penetration by the needle so that an effective surgical result can be achieved with a secure stitch. (d) the cavity size is too large and allows other organs to enter the cavity and be pierced by the needle, for example the colon, spleen or cardiac atrium.

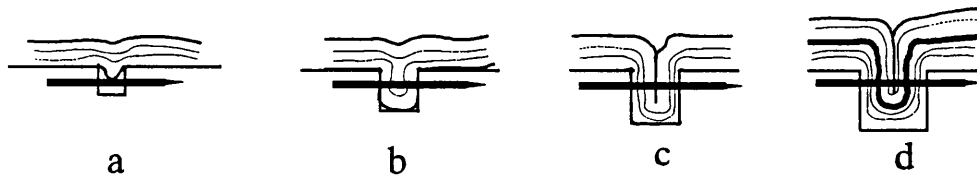


Figure 4.1 The relationship between cavity dimensions and length and depth of needle penetration of the tissue.

4.2.1. Experimental models

Model 1 was a piece of rectangular transparent polymethylmethacrylate (PMMA) with eight circular holes (3.1 - 7.8 mm in diameter) drilled to a depth of 7.8 mm. The other test facilities included a double-stage high vacuum pump (Javac PTY., LTD.), a filter bottle, a 1.3 mm diameter sewing machine needle. The set-up of the experiment is shown in Figure 4.2.

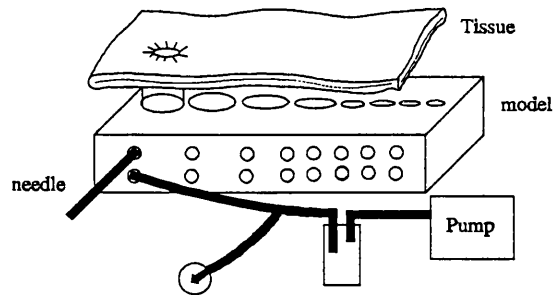


Figure 4.2 The set-up of the experiment.

To begin the experiment, post mortem human stomach was placed over an individual cavity of the test model. The suction pump was connected and the tissue sucked into the

cavity under the pressure of 750 mmHg. The suction depth (from the top surface of PMMA slab to the bottom of the sucked tissue) was firstly measured using a steel ruler held against the test model. The needle was pressed through the needle hole to penetrate the tissue. The length of the stitch (the distance between two holes made by the needle on the serosal surface of the tissue) was then measured using the ruler. The measurements are shown in Tables 4.2.

Table 4.1 The cavity shape and size

cavity no.	shape	diameter (mm)	depth (mm)
H1	cylinder	7.7	7.8
H2		7.8	7.8
H3		6.4	7.8
H4		6.4	7.8
H5		3.1	7.6
H6		4.7	7.7
H7		3.1	7.7
H8		4.8	7.8

Table 4.2 The experimental results

cavity no.	the suction depth (mm)	the stitch length (mm)	tissue thickness (mm)
H1	7.5	5.0	2.5
H2	7.5	4.5	3.0
H3	6.5	3.0	3.0
H4	7.0	3.5	3.0
H5	7.0	No full penetration	2.5
H6	7.5	No full penetration	2.5
H7	7.5	No full penetration	2.5
H8	7.5	No full penetration	4.0

The results showed that the cavity holes, between 3.1 - 4.8 mm in diameter were too

small to allow the needle to penetrate the full thickness of the tissue. Cavities with diameters greater than 6.4 mm allowed the full-thickness of the tissue to be penetrated by the needle. The conclusion was that only the latter range of holes were suitable for use in the endoscopic sewing machine, but in this particular instance, only one cavity shape (cylindrical) was tested.

Model 2 comprised 16 machined PMMA cylinders (12.7 mm in diameter) with two different cavity shapes: circular or oval (Figure 4.3). The diameters of the circular cavities were chosen in the range, 5 mm to 11 mm, and their depths in the range, 3 mm and 8 mm. The dimensions of the oval cavities were presented in Table 4.3.

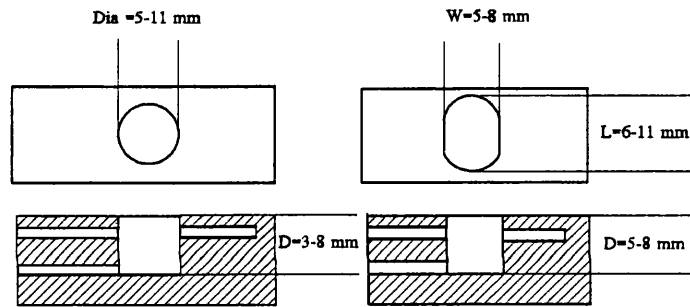


Figure 4.3 Cavity sizes and shapes.

Table 4.3 The dimensions of oval cavities

Cavity no	Depth (mm)	Length (mm)	Width (mm)
C1	5.0	6.0	5.0
C2	5.0	7.0	5.0
C3	6.0	8.0	6.0
C4	6.0	9.0	6.0
C5	7.0	10.0	7.0
C6	7.0	11.0	7.0
C7	8.0	11.0	8.0
C8	8.0	11.0	8.0

The tests showed that with a 5 mm diameter, 4 mm deep circular cavity, the needle did not pierce the full-thickness of the tissue but only the submucosal layer ie to a depth of about 1.5 mm. The tissue was about 3.5 mm thick. With an oval cavity (L = 11 mm, W = 8 mm, D = 8 mm), the needle pierced the full thickness of the tissue, and produced the greatest length of stitch (15 mm) for the space available in the machine. Stitch length was defined by distance from 2 needle holes on the serosal surface of the tissue in a flat relaxed state (NB. the tissue is relatively elastic which makes precise measurements difficult). Thus, this cavity size and shape was chosen for use in the endoscopic sewing machines.

Model 3 comprised a 12.7 mm diameter, 50 mm long PMMA rod into which was cut a L shaped cavity, as shown in Figure 2.4. The suction end of the cavity was formed by a movable piston so that the dimensions of the cavity could be easily adjusted. Two such test models were formed, one with a circular cavity, the other with an oval cavity.

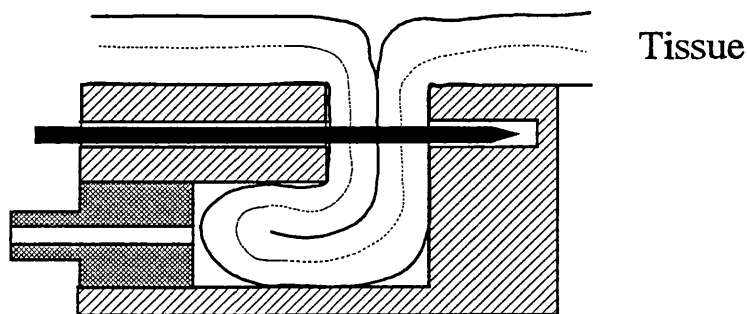


Figure 4.4 The L shaped cavity.

The results showed that both cavities at these dimensions had an effective suction capacity for tissue. All tissues tested were sucked fully into the cavities so that the needle could pierce the full-thickness layered tissue. However, two different inlet shapes,

circular and oval made no differences to length or depth of penetration of the needle in the tissue. A disadvantage of this cavity size and shape was that it made the machine longer.

The above studies showed that the cavity size and shape could affect the depth and length of tissue penetration by a needle. These empirical experiments with simple models were helpful in understanding and improving the performance of the suction capacity of the endoscopic sewing machines.

4.2.2. Experiments to determine the optimum position of the suction channel

The position of the suction channel was found to influence the suction capacity of the sewing machines and their consequent performances. Three suction channel positions were considered in these experiments: A. bottom; B. below the needle channel; C. opposite and below the needle channel (Figure 4.5).

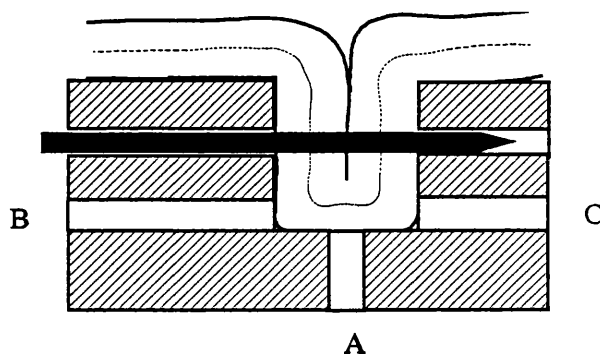


Figure 4.5 Three different suction channel positions.

Position A

If a single small diameter suction channel was sited in the bottom of the cavity, the tissue was sucked into the cavity until the suction channel was plugged with the tissue. This stopped suction being applied to the tissue at other sites in the cavity which made the tissue adopt a conical or tapered shape held by suction exerted over a small area (Figure 4.6). When the needle was advanced, the tissue was pushed forwards since it was not held firmly by suction. This led to a shortening of the length and perhaps the depth of the stitch. Since the tissue was free to move forwards with the needle and became compressed in the exit hole this increased the drag or resistance exerted on the needle and in consequence increased the force required to pierce the tissue.

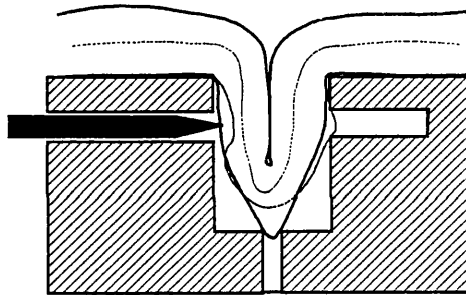


Figure 4.6 Suction and piercing in position A.

Position B

If the suction channel was in position B, the tissue was sucked into the cavity in the shape shown in Figure 4.7. When pierced, the needle required more force since a greater volume of tissue had to be pierced and the distance over which the needle could be accelerated before entering the tissue was least. With the suction channel in this position, the greatest length of stitch was obtained.

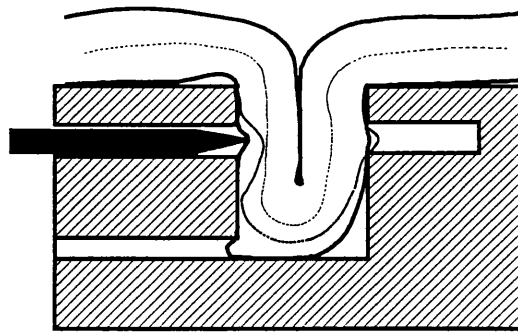


Figure 4.7 Suction and piercing in position B.

Position C

If the suction position was placed opposite and below the needle channel, tissue could be sucked into the cavity in the shape shown in Figure 4.8. When the needle was advanced, tissue was pushed forwards by the needle. Forwards and upwards displacement of tissue tended to allow air to enter the cavity on the needle side. The force required to pierce the tissue was the least among the three cases.

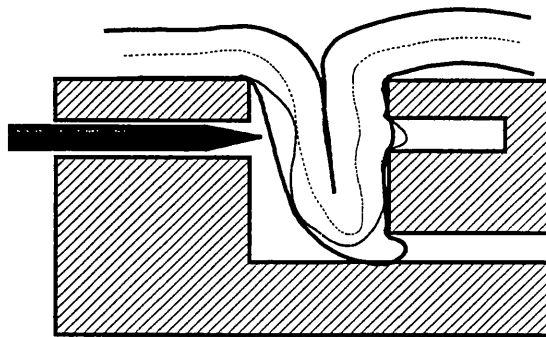


Figure 4.8 Suction and piercing in position C.

In all three cases, the diameter of the suction channel was 3 mm, which was as large as was possible given the close proximity of the channel to the needle hole.

4.2.3. The best Option

Based on the results of the experiments described above, a new cavity size and shape with a better suction channel arrangement was proposed, built and tested. This cavity had a larger interior space than earlier designs made in PMMA because the machine's body was now made of a thinner walled hollow stainless steel cylinder sealed at both ends. A suction tube with two arrays of holes (four holes each array) was soldered to the bottom of the cavity (Figure 4.9). The test results showed that this cavity was able to suck a greater volume of the double layer of full thickness tissue than the other designs that were tested.

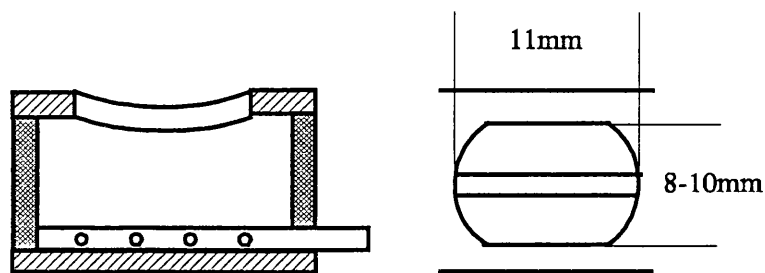


Figure 4.9 A new cavity design.

4.2.4. Conclusion

The cavity size and shape was determined (1) by the maximum outer diameter that could pass through an overtube that can easily be placed in the oesophagus of a patient; (2) by the requirement for a deep stitch penetrating all layers of tissue; (3) by the elasticity of gastrointestinal tissue; (4) by the influence of the diameter and the spatial arrangement of the optics, biopsy channel at the tip of the endoscope. Since effective suction is such an important component of the sewing machine's function, the displacement of the vacuum pump as well as the cross-sectional area of suction entry

point(s) in the cavity should be kept as large as possible in order to achieve the best performances. A high volume displacement may be important to overcome leaks which are inherent in the design of such a machine with moving components and the requirement to displace a variable amount of air or fluid from the stomach before the tissue is held within the cavity. For optimal performance, the cavity dimensions should be a few millimetres larger than the minimum cavity size found to suck a double layer of tissue into it to allow for variations in tissue thickness and elasticity. An oval shaped inlet and/or an L-shaped cavity offers some advantages if it is desirable to increase the sucked volume of tissue without increasing the outer diameter of the instrument. There may be better options than oval shaped inlets, but it may be difficult and expensive to machine these more complex shapes in practice.

4.3. Vision

Based on the experiments of using the Swain and Mills first endoscopic sewing machine, it was found that if the control wires were passed through the two operating channels of the endoscope, the machine had to be attached to the end of the endoscope. This obstructed the endoscopic view of the operation of the machine. If the control wires were attached along side the endoscope, the overall diameter of the machine plus endoscope would be too great [19]. Having realised the importance of the endoscopic view of the operation of the machine, an attempt was made to find some possible solutions to improve or overcome the problem of poor endoscopic vision.

By analysing the optical system design of the Olympus Gastrointestinal Fibrescopes, it was found that it provides a field of view of 100° - 120° as shown in Figure 4.10a. This makes it difficult to mount the endoscopic sewing machine on the tip of this endoscope

since some or all of visual field of the endoscope will be lost (Figure 4.10b).

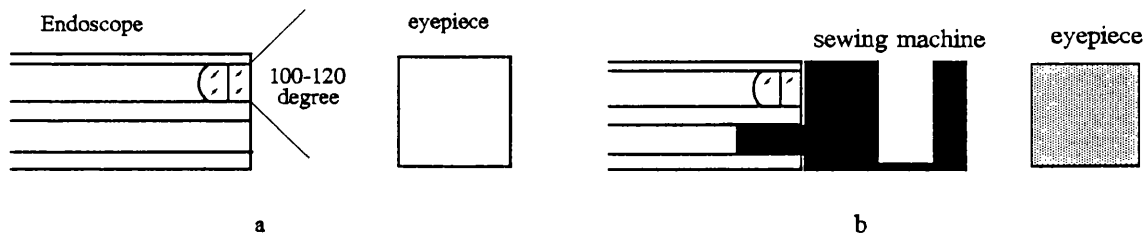


Figure 4.10 a. endoscopic vision without the machine. b. endoscopic vision with the machine.

If the field of view is badly obstructed by the sewing machine, the endoscopist will be unable to position the machine accurately on the tissue. Some procedures could be carried out almost blindly but a clear view is necessary for precise placement of stitches. The endoscope can not be easily altered, and so a compromise had to be reached between some loss of vision and some loss of usability (Figure 4.10c).

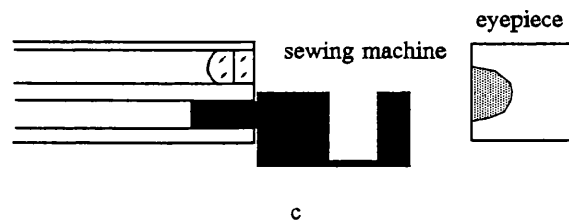


Figure 4.10 c. Endoscopic vision with the machine which was offset with respect to the end of the endoscope.

4.3.1. Coupling to the Olympus 2T10 endoscope

The 2T10 endoscope is an optical fibre colonoscope (outer diameter 12.6 mm) designed primarily for therapeutic procedures. Its optical system is designed for forward viewing with a field of view of 100 degrees. It has two biopsy channels (3.7 mm and 2.8 mm

diameter). The field of view seen through the endoscope is shown in Figure 4.11. It was found that if a sewing machine was mounted on the endoscope, the whole view from the endoscope would be blocked, so that the clinician could not see to operate the endoscopic sewing machine.

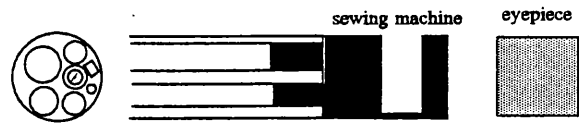


Figure 4.11 Endoscopic vision with a cylindrical machine.

From Figure 4.11, it is clear that the visual loss is largely determined by the shape of the sewing machine. If the machine is cylindrical, and it is positioned close to the endoscope, the endoscopic view is almost entirely blocked. This observation led to the production of a sewing machine with a hemi-cylindrical shape as shown in Figure 4.12. Compared with the cylindrically shaped machine, this offered only a small improvement to vision, $2/3$ of the field of view remaining obstructed. Furthermore, there were another two disadvantages arising from this hemi-cylindrical shape:

1. The suction cavity which had been reduced in size was too small to suck enough tissue, so the tissue was not always penetrated to its full thickness by the needle.
2. Difficulties were encountered in the fabrication of this irregular shaped machine.
3. The cavity was at some distance (3 mm) from the tip of the endoscope.

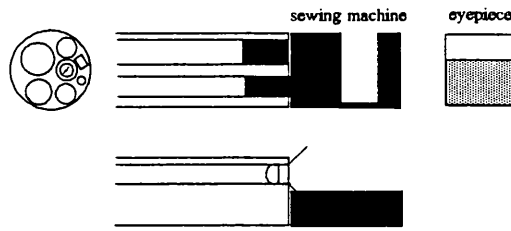


Figure 4.12 Endoscopic vision with a hemi-cylindrical machine.

4.3.2. Possible machine designs to improve the vision of the endoscope

Without adequate vision, the clinician could not see the tissue over the cavity of the machine. This led to two new machines, each designed to offer improved vision of the target tissue during their operation.

One design made use of a small sheet of PMMA that was glued to the body of the sewing machine to form a window (Figure 4.13) through which the clinician could view the tissue as it was sucked into the cavity. Tests showed that with this design the clinician would still be unable to see the target tissue before it was sucked into the cavity but would be able to see when the cavity had been filled with the tissue.

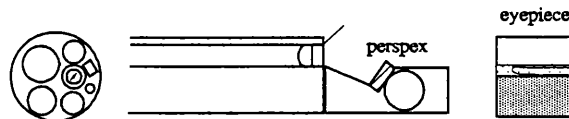


Figure 4.13 An improved endoscopic vision with a PMMA window which was fixed in the cavity of the machine.

The observations showed that the window offered a slight improvement to vision. However, it was found that strong reflections of the endoscope light from the window tended to confuse the view of the tissue and the cavity.

The other design incorporated a mirror that was introduced and glued to the bottom of the cavity at an angle of 45° . It was hoped that the illumination light passing through the plastic window would be reflected by the mirror and the image of the tissue over the cavity could be reflected by the mirror and observed through the endoscope eye piece (Figure 4.14).

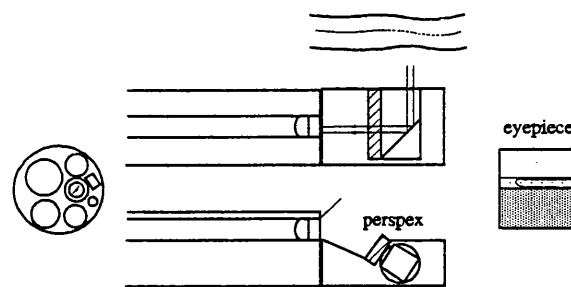


Figure 4.14 An improved endoscopic vision with a mirror which was glued to the bottom of the cavity of the machine.

Experimental observations showed that this proposal was feasible. However, the quality of the image of the target tissue was not good enough due to inadequate illumination of the tissue, and the size of the mirror, being limited by the size of the cavity, was not large enough. Furthermore, the presence of the mirror within the cavity reduced the volume of tissue that could be sucked into it. This configuration was therefore considered unsuitable.

Based on the above two experiments, the conclusion is that it is feasible to couple the

sewing machine to the end of a two-channel endoscope and use the two channels for the purpose of operating the sewing machine, but the loss of endoscopic vision is great, almost two thirds of the field of view being obstructed. It would be impossible for the endoscopist to locate the sewing machine accurately on the target tissue. In conclusion, attempts were made to improve the optics of the coupling of the sewing machine to the endoscope, but none proved successful. Inclusion of optical fibre bundles in the body of the sewing machine for illumination and imaging of the target tissue was considered but would have necessitated irreversible alteration of the endoscope.

4.3.3. Coupling to the Olympus PQ20 endoscope

The Olympus PQ20 endoscope is a gastrointestinal fibrescope (outer diameter 9 mm) designed for multiple purposes. Its optical system is designed for forward viewing with a field of view of 100 degrees. It has only one channel for endoscopic instrumentation (2.8 mm in diameter).

The coupling between the endoscope and sewing machine is shown in Figure 4.15. Because of the small diameter of the endoscope, it was possible to mount the sewing machine away from the longitudinal axis of the endoscope. Although this increased the total diameter of the system over the diameter of the endoscope, the improvement in unobstructed vision was considerable. Because the endoscope had only one operating channel, it was necessary to supply suction to the machine externally using a 2.2 mm o/d nylon tube which was run alongside the endoscope. Offsetting the machine on the endoscope was not found to impair the angulation or manipulation characteristics. The offset position was designed not to interfere with the coherent optical bundle and lens, light carrying non-coherent bundles, water or air channels.

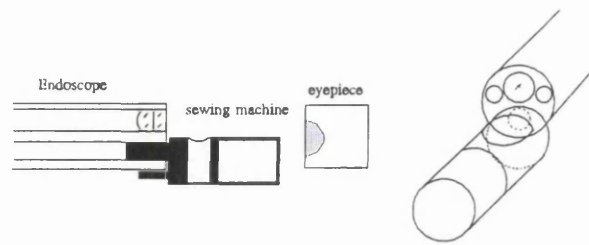


Figure 4.15 Illustration of the improved endoscopic vision achieved when the sewing machine was offset to one side of the tip of the endoscope.



Figure 4.16 This endoscopic view shows that although the endoscopic sewing machine was mounted on the end of the endoscope, the endoscopist's view of the tissue was still good.

The advantages of this coupling method are as follows:

1. The endoscopic vision is greatly improved. More than 3/4 of the visual field of the endoscope can now be seen. The machine allows clear views and precise localization of the point of the tissue to be sewn.
2. There is almost no impairment of movement, angulation, inflation or lens washing functions.
3. No additional optical system is required.
4. It allows a unique and strong attachment to the tip of the endoscope.
5. It allows visual confirmation that the thread and tag are held with the hollow needle prior to firing the stitch. Once the tissue is released from the cavity, it is possible to view both the entry and exit points of the thread and also to confirm that the tag and thread have been caught within the distal chamber of the sewing machine.

On the other hand, some minor problems still remain:

1. It was found that once tissue is sucked into the cavity (L=10 mm, W=8 mm, D=8 mm), the objective lens of the endoscope was covered by tissue (red-out) and other gastric materials, so the needle could not be seen passing through the tissue.
2. It requires some practise and experience to position the sewing machine on the target tissue accurately.

4.4. Comparison of the suitability of different needle shapes for use in the endoscopic sewing machines

To sew tissues together, the needle is one of the most important components in the

endoscopic sewing machine. For the different catch mechanisms that could be chosen for use in the endoscopic sewing machines, two basic types of needle were considered: 1. conventional sewing machine needles, 2. solid and hollow surgical needles.

4.4.1. The use of a domestic sewing machine needle for the endoscopic sewing machine

A conventional sewing machine needle has a sharp, centred point for penetrating cloth. Unlike most needles used for sewing by hand, the eye of the sewing machine needle is located close to the point of the needle. The eye is threaded to carry the thread through the cloth. A groove cut in the side of the needle makes space for the thread as the needle passes through the cloth. On the other side from the groove is a flat which makes space for the hook of the catch mechanism to pass easily between the needle and the thread [22]. As the needle is pulled back, the frictional force tends to throw the thread outwards to form a loop and the catch mechanism, a shuttle, for example, passes between the groove of the needle and the loop of the thread. In the original Swain and Mills endoscopic sewing machine, a sewing machine needle was used.

4.4.2. A mechanical analysis of the use of a conventional sewing machine needle in an endoscopic sewing machine

When the tissue is sucked into the cavity, a folded layer is formed and ready to be penetrated by the sewing machine needle. Since the sharp point of the needle is in the centre, when the needle just reaches the hole on the other side of the cavity opposite to the needle (the size of the hole is slightly larger than the overall diameter of the working portion of the needle) the pierced tissue around the tapered tip of the needle is forced into the hole where it resists further movement of the needle. The thread running

through the eye of the needle increases the effective diameter of the needle making passage of the needle into the hole yet more difficult. Increasing the force is required for this type of the needle to pass through tissue to form a stitch.

4.4.3. The use of a surgical needle in the endoscopic sewing machine

There are many different types of surgical needle that might be appropriate for use in the endoscopic sewing machine. These were tested and compared.

Shapes of surgical needles

Surgical needles may be straight or curved. Although curved needles are commonly used at surgery to sew internal tissue, the rotational force required and the control needed to pull the needle through the tissue once the needle point has emerged are difficult to deploy at flexible endoscopy. Consequently only straight needles were considered in these studies.

There are two types of straight needle: solid needles with one end fixed to a suture usually by crimping, and hollow needles used for injection purposes. The problem with a solid needle is that the a force has to be exerted to push the needle through the tissue and eventually the needle together with the thread must be pulled on the other side of the tissue. Hollow needles might offer some advantages for a mechanism of an endoscopic sewing machine because the thread might be passed through the needle.

Needle points

The tips of the needle may be pointed or wedge shaped. The wedge shape can readily form a cutting edge. A needle with a sharp cutting edge facilitates pushing the needle

through firm tissue but might make undesirably large holes, thus might lacerate vessels, causing troublesome bleeding. With a hollow needle, the needle point is not in the centre of the needle. It is always wedge shaped.

4.4.4. A mechanical analysis of the needle point when used to penetrate the tissue

The needle point is usually located in the centre of the tip if the needle is made out of a solid rod while the needle point is always eccentrically placed if the needle is made from hollow metal tubing.

When driven through the tissue, the centrally placed needle point was pushed forwards until it pierced through the tissue. Because the tip of the needle was tapered, as the tissue was penetrated it tended to be pushed laterally and compressed against to the wall of the hole through which the needle can pass. For a hollow needle passing through tissue, the mechanics are somewhat different. As the tissue was pierced through by the eccentrically placed needle, the tip passes close to the wall of the hole in the receiving place and is less likely to compress tissue between the needle and the receiving place. This means that the alignment of this type of needle has to be more precise to prevent the needle from striking the metal edge of the receiving hole. This type of needle may have the advantage that less force is required for successful penetration of tissue because there is less drag on the tissue. Compared with a needle with the sharp point in the centre, a hollow needle may require a higher accuracy of the alignment between the needle and the needle hole in the endoscopic sewing machine. In practise it was found that if the needle was held within the biopsy channel of the endoscope and the tip of the endoscope was placed into an extreme of angulation by using the left/right or up/down angulation that the tip of the needle sometimes became bent and would not run

smoothly. This problem was overcome by choosing a stronger needle, and by holding the needle in the forward position so that it was held straight within the rigid part of the sewing machine body so that it could not be distorted during endoscopic manipulation (Figure 4.17).

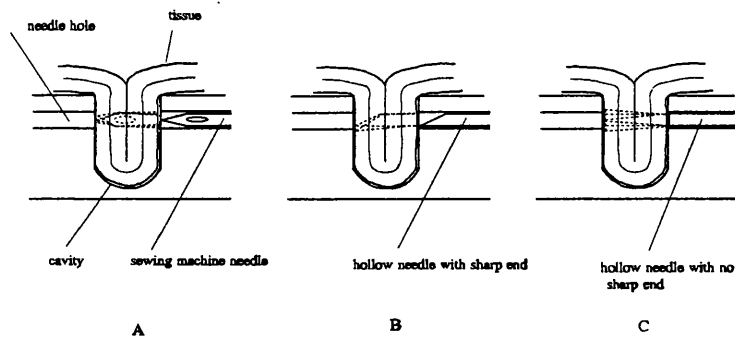


Figure 4.17 A comparison of three different needles.

4.4.5. Forces required to drive small diameter needles into tissue at flexible endoscopy

Endoscopists sometimes use needles, particularly small diameter needles (< 2 mm) to perform procedures. For example, a small needle can be used to inject drugs, e.g. sclerotherapy, into oesophageal varices at flexible endoscopy. The information on the forces required to drive small diameter needles into tissue is limited. In this study, force requirements for small diameter needles to penetrate gastric tissue at flexible endoscopy were investigated. A model was set-up for measuring the forces exerted on the needles. Six different diameter needles were used to pierce tissue and the results are presented below. A commercial Oesophageal Varices Needle Injector (Model TW1V/6F, 0.25 mm diameter) was also tested for the purpose of comparison.

Needles

Six small diameter hypodermic needles (range 0.5 to 1.8 mm) were cut to lengths of 20 mm. The cut end of each needle was inserted to a depth of 5 mm into one end of a 2.2 mm outer diameter Bowden cable and soldered. This was then passed through the biopsy channel of a flexible fiberoptic endoscope (Olympus GIF Q10) supported by 3 metal posts and clamps. The distal steerable end of the endoscope was left unsupported.

A 0.12 mm thick rubber sheet cut from a latex medical glove (Johnson & Johnson) or specimens of post mortem porcine gastric tissue were placed on a 25 mm diameter PMMA hollow cylinder, and held tightly using a suture thread tied circumferentially. To prevent damage to the endoscope's biopsy channel, each needle and Bowden cable was back-loaded into the endoscope using a guide wire (Figure 4.18).

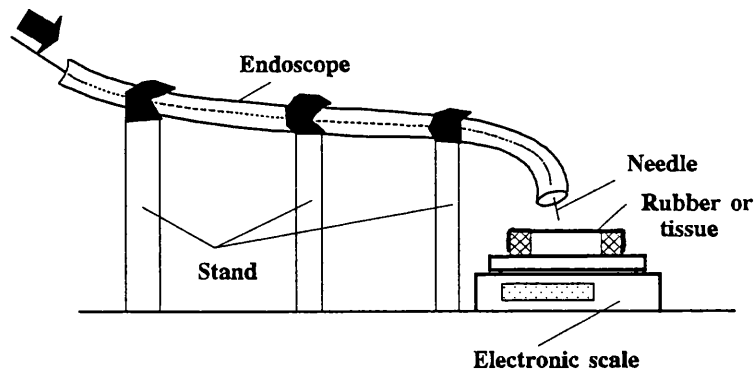


Figure 4.18 The set-up of the force measurements of the small diameter needles.

The tissue holder covered with either rubber or post mortem gastric tissue was placed on the surface of an electronics scale (Portable balance, range 30 - 30,000 g, Sartorius Ltd, UK) and just under the needle. The needle was then pushed (or jerked) into the tissue or rubber by pushing the Bowden cable from the far end. 10 measurements of forces exerted for one needle were taken. The Oesophageal Varices Needle Injector (Model TW1V/6F, the needle tip was 0.25 mm in diameter, 5 mm long) was also used in the investigation.

Results

For the rubber material, the 0.25 mm diameter Oesophageal Varices Needle Injector could penetrate it (range 10 - 30 g, mean 21.5), a 0.5 mm diameter needle could penetrate it (range 10 - 40 g, mean 27.6 g), a 0.65 mm diameter needle could penetrate the material as well (range 27 - 68 g, mean 44.6 g), a 0.8 mm diameter needle penetrated the material 4 times (range 56 - 72 g, mean 64.8 g) and then failed to penetrate the material on a further 6 attempts, because the needle tip was blunt. The needles (>1 mm diameter) failed to penetrate the rubber.

When tested on gastric tissue, none of the six needles nor the 0.25 mm diameter Oesophageal Varices Needle Injector were able to penetrate right through the tissue. It was observed that these needles could pierce the tissue to a certain depth, but did not achieve full penetration.

The results also showed that the method of pushing on a needle influenced its performance. When a needle was pushed slowly, the force required to drive the needle through the rubber model was greater (mean 65 g). When a needle was accelerated by

jerking on the controls of the endoscope or pushing hard on the cable passing through the biopsy channel of the endoscope, the force required to drive the needle through the rubber was less (mean 40 g).

The force requirements to penetrate the gastric tissue and rubber were investigated. A simple model for the investigation was set up. None of these needles plus the Oesophageal Varices Needle Injector could penetrate the tissue fully when the bending portion of the endoscope was held free. For a deep tissue penetration, either the tissue or the scope must be supported and greater force is required. For the needles to penetrate the tissue in an endoscopic sewing machine, the tissue needs to be supported and the force transmitted through the endoscope should be maximised.

4.4.6. Force required to puncture postmortem gastric tissue in a supported jig

The force required to puncture tissue was measured using a jig (Figure 4.19) that held the needle vertically attached to a tray upon which weights could be placed. The tissue was positioned horizontally in a single or double layer with the needle resting on its surface. It was found that a mean force of 169 g was required to press a 1.5 mm diameter hollow needle identical to that used in the endoscopic sewing machine through a double layer of the post mortem gastric tissue; a mean force of 167 g was required to press the same needle through a single layer of the tissue. It was found that moving the needle more quickly could lead to improve the needle's penetration to the tissue.

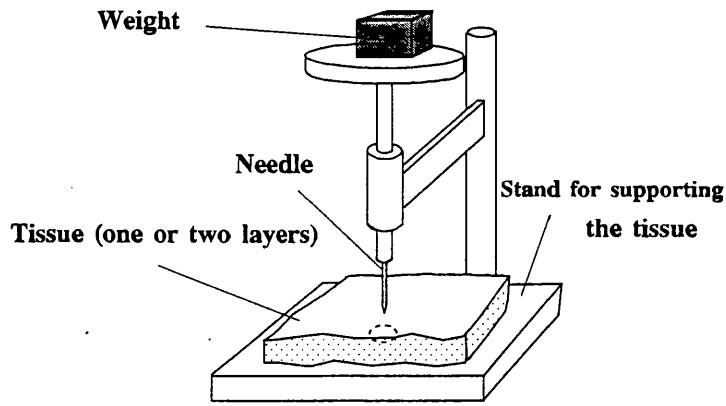


Figure 4.19 The set-up of the jig for force measurements.

In conclusion, the forces required to penetrate a single layer or double layer of the tissue were almost identical. This was because that the resistance of an extra layer of the tissue to the needle was minimum. Therefore, there was no need requiring extra force to push the needle right through a double layer tissue. However, in practice, when the tip of the endoscope was bent, the needle should be pushed with more force as the Bowden cable (or wire) that was used to drive the needle has contacts with the biopsy channel of the endoscope and the push-wire which passes through the Bowden cable.

4.4.7. The effect of speed and momentum on needle penetration

This study was to investigate the sewing machine needle's ability to penetrate tissue when it was moved at speed and with added mass, hence momentum. A specially constructed pendulum, shown in Fig 4.20, was used to perform these experiments. Different masses in the form of lead weights were attached to the bottom of the pendulum, and for each mass, the minimum speed, and hence momentum, with which

the needle was able to penetrate post mortem porcine gastric tissue was determined by dropping the needle from different heights.

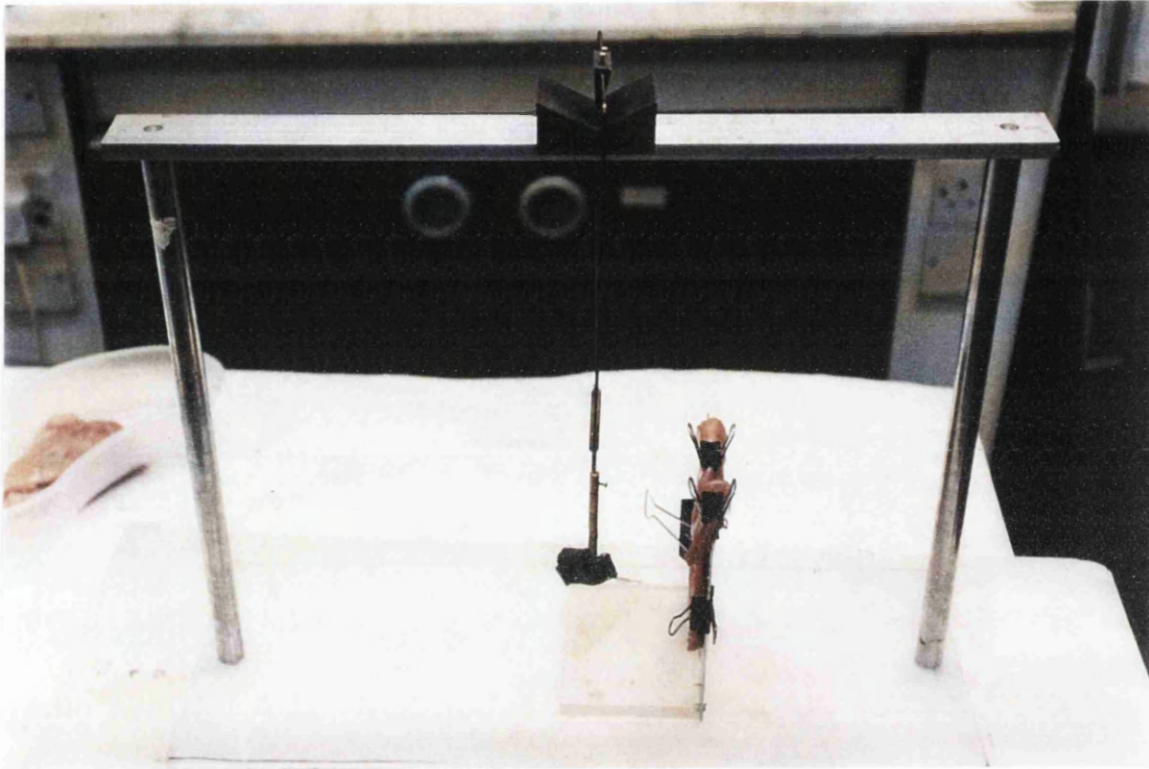


Figure 4.20 Photograph of the pendulum jig that was used to investigate the effect of speed on the needle's penetration of tissue.

Needles

The needle used in these experiments was the wedge-tipped, 1.5 mm diameter, hollow needle employed in the single-stitch endoscopic sewing machines.

Tissue

The tissue was post mortem porcine stomach supported between two aluminium plates positioned vertically beneath the point of rotation of the pendulum.

Experiments

The mass m of the needle was adjusted by adding pieces of lead sheet to the bottom of the pendulum. The speed v of the needle was calculated by equating the potential and kinetic energies:

$$m g h = \frac{m v^2}{2} \quad (1)$$

where h was the initial height of the needle.

So,

$$v = (2 g h)^{1/2} \quad (2)$$

and h can be derived from,

$$h = L - L \cos\theta = L (1 - \cos\theta) \quad (3)$$

where θ is the angle between the pendulum at its starting point and the vertical. So

$$v = (2 g L (1 - \cos\theta))^{1/2} \quad (4)$$

Results

The measurements and calculated results from these experiments are presented below in Table 4.4.

Table 4.4 The needle's speed and momentum when at the tissue penetration threshold

m (kg)	Angle θ of the pendulum to the vertical (degrees)	v (ms^{-1})	P (kgms^{-1})
0.028	64	1.8	0.050
0.040	45	1.3	0.052
0.052	25	0.7	0.036
0.064	17	0.5	0.032

Discussion

Without added mass, the needle was unable to penetrate the tissue at the highest speed (1.8 ms^{-1}) attainable using this pendulum. When a lead weight of 12 g was added to the bottom of the pendulum, the needle was able to penetrate the tissue when it was accelerated to 1.8 ms^{-1} .

It was expected that the momentum of the needle at the tissue penetration threshold would be largely the same for the different needle weights and speeds. However, over the range tested, the momentums varied by a factor of 1.6.

These experiments demonstrate that the sewing machine needle can penetrate the tissue more easily if it is moved at speed and has increased mass. The tissue penetration successfully achieved with a total needle mass of 28 g and a speed of 1.8 ms^{-1} could if necessary be attained at the distal end of a flexible endoscope by using a spring and adding a weight to the needle. However the addition of such a mechanism would complicate the design of the sewing machine. In practise, the machine was found to work adequately by simply pushing the needle through the tissue using the Bowden cable passed through the biopsy channel of the endoscope.

**Chapter 5 Design & development
of chain-stitch
endoscopic sewing
machines**

5.1. Introduction

In this chapter, the design of the Swain and Mills original endoscopic chain-stitch sewing machine and its performance are reviewed and technically assessed. The purpose of analysing the problems related to the original machine's performance was to work out a better design. Based on this assessment, the design and development of new chain-stitch endoscopic sewing machines were carried out and reported. Two new catch-mechanisms for the chain-stitch endoscopic sewing machines are described and the problems with the designs are discussed as well. The experimental results of using these new chain-stitch endoscopic sewing machines are reported. The designs of the endoscopic sewing machines and related problems are discussed further.

5.2. The Swain and Mills original endoscopic sewing machine and its performance - A technical assessment

The body of the Swain and Mills original endoscopic sewing machine was formed from a solid rod of transparent PMMA (Perspex), 14 mm in diameter and 38 mm long. Two cavities were machined into the side of the body. The dimensions of one cavity were chosen so that a small fold of tissue could be sucked into it and pierced by a threaded needle running in a hole drilled through the length of the body. The other cavity housed a mechanism comprising a hook and sprung shoe designed to catch the loop of thread once the needle had pierced the tissue. Both the needle and the catch mechanism were actuated by wires running through the biopsy channels of a standard two-channel endoscope [19].

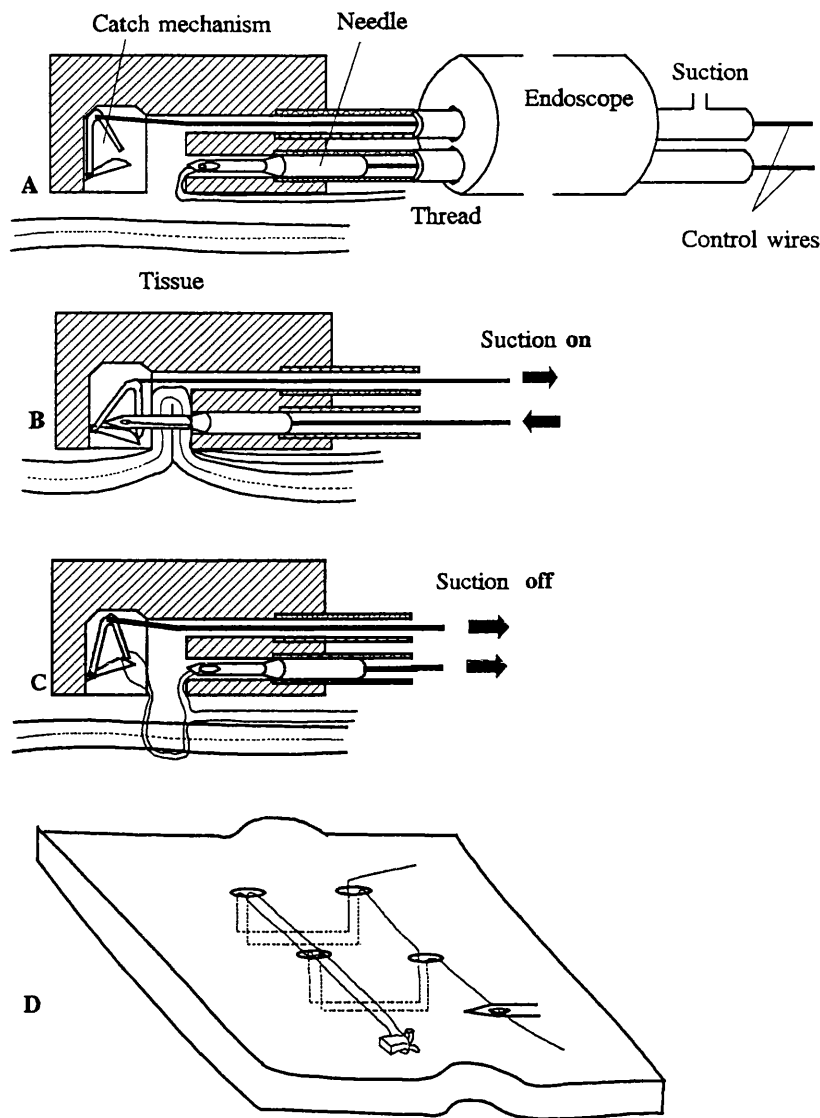


Figure 5.1A-D The Swain and Mills original chain-stitch endoscopic sewing machine.

The machine operated as follows. The machine was positioned as shown in Figure 5.1A above a layer of tissue in which stitches were to be formed. As shown in Figure 5.1B suction was then applied through the machine to suck into the slot a double layer of tissue. The shape and depth of the slot controlled the volume and depth of tissue which was sucked in. The needle was then forced forward carrying a loop of thread held in the

eye of the needle through the double layer of tissue. The tip of the needle pressed against the sprung shoe which was caused to pivot down against the biasing force of the spring of the shoe. A control wire was then pulled to cause the hook to pivot so as to catch the loop of thread carried by the eye of the needle. The head portion of the needle had a groove formed in it to allow the hook to pass between the needle and the thread.

The needle was then withdrawn, leaving the loop of thread held between the hook and the shoe. Suction was then released to allow the double layer of tissue to leave the slot. As shown in Figure 5.1C, the effect of these steps was to pass a loop of thread from one side of the tissue through the tissue at a first position and back out of the tissue on the same side at second position, a controlled distance from the first position. This was achieved without requiring access to the opposite or serosal side of the tissue which would be endoscopically inaccessible under normal circumstance [19].

The machine was then moved to the site of the next stitch, suction was then reapplied, and the needle passed through a double layer of tissue at a different point. The forward end of the needle passed through the loop of thread caught between the hook and shoe, carrying a new loop of thread with it. To assist this process a small groove was formed in the upper surface of the shoe in which the tip of the needle might slide. This enabled the needle to pass under the loop of thread already caught between the hook and shoe, without the risk that the needle might simply push the existing loop further up the surface of the shoe. Once the needle had placed the second loop through the first loop, the hook was then pivoted by pushing on the control wire to allow the first loop to be cast off by pulling on the thread. The hook was then pivoted downward by pushing on the control wire, the hook passing between needle and thread, so that the second loop

of thread was caught before the needle was withdrawn. In this way a chain of stitches was formed as indicated in Figure 5.1D in which each of the loops formed by the hook and the shoe passed through the preceding loop [19].

This machine was an attempt at "sewing " gastrointestinal tissue by applying and simplifying the principles of conventional sewing machines. However, some problems were unresolved in the design. (i) The design of the chain-stitch mechanism - a hook-catch mechanism was designed to catch the first loop of thread and maintain the loop until the second loop was formed and passed through the first loop to form the chain stitches. As there was no mechanism for the thread handling, the tension of thread was only controlled by operator's hands. This made the formation of the chain stitches unreliable in practice. (ii) The vision - if the machine was mounted onto the distal end of a two-channel endoscope, the endoscopic vision was poor. (iii) The cavity - one cavity in the machine was designed to suck a double layer of tissue and keep the tissue in it until the needle pierced the tissue. The size of this cavity was inadequate and needed to be enlarged. Furthermore, because the orientation of the suction cavity was perpendicular to the length of the machine and at some distance from the endoscope, this made it difficult for the endoscopist to locate the target tissue.

5.3. Design and development of new chain-stitch endoscopic sewing machines.

5.3.1. A new hook-catch mechanism

A new hook-catch mechanism was designed. This hook-catch mechanism used a hook to catch the first loop of thread and maintain the loop until the second loop was formed and passed through the first loop. This design allowed a push and pull mechanism to move it which could be precisely controlled by a linear movement of the control wire

inside the machine.

The design of the hook and its control wire

As shown in Figure 5.2a-c, the hook was made of a thin piece of stainless steel plate (0.5 mm thick). There was a 1.5 mm hole drilled in the middle of the hook. On each side of the hole, a 3 mm collar was soldered. This enabled a 1.5 mm screw positioned in the distal end of the body of the machine to act as an axle about which the hook could rotate. The long arm of the hook was positioned within a 0.5 mm longitudinal slot cut in a small diameter stainless-steel tube soldered to the end of the control wire. Movement of the control wire could therefore move the tip of the hook up and down (Figure 5.2c).

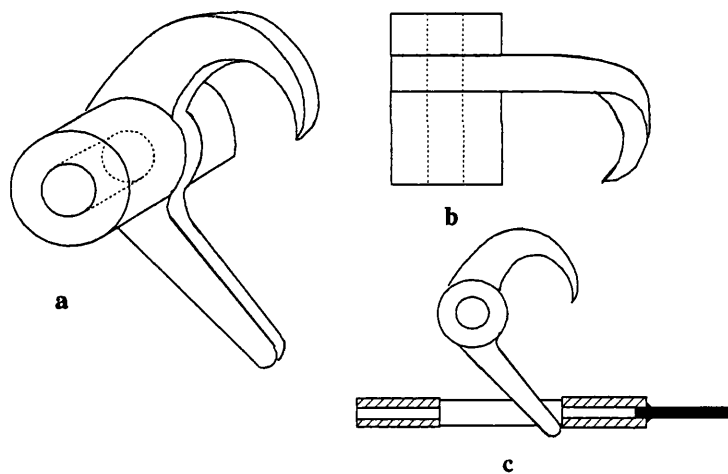


Figure 5.2a-c The hook and control wire.

When the hook was rotated by moving the control wire, the tapered tip of the hook passed between the thread and the needle, and was thereby able to catch a loop of thread before the needle was withdrawn back into the machine. Because the arm of the hook

was twisted (Figure 5.2b), the loop of thread caught by the hook was spread open, allowing it to be pierced by the subsequent pass of the needle carrying the second loop of thread. By pulling back the control wire, the hook was then rotated to drop the first loop and pick-up the second loop. The first loop was pulled tight by tugging on the free tail of thread.

5.3.2. Two chain-stitch sewing machines employing the new hook-catch mechanism

Two prototype sewing machines employing the new hook catch-mechanism were designed and constructed.

A chain-stitch sewing machine with a cylindrical shape

The machine was formed from a rod of stainless steel, 12.8 mm in diameter and 60 mm long as shown in Figure 5.3a. The oval suction cavity (L=7 mm, W=10 mm, D=7 mm) was machined into the side of the body. In the distal end of the machine, a 3.5 mm wide, 16 mm long slot was made in order to house the hook and the tube used to terminate the control wire. Making use of the conclusions drawn from the preliminary study in chapter 4 and to ensure the tissue was stitched to its full thickness, the cavity size was larger than that used in the original Swain and Mills endoscopic sewing machine (Figure 5.3a-d).

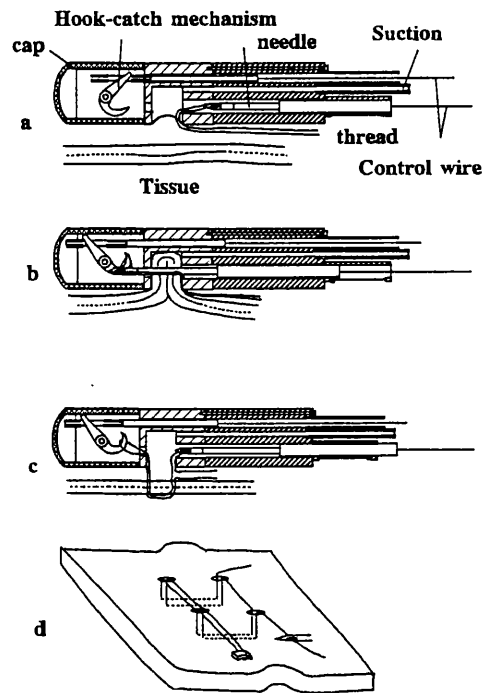


Figure 5.3a-d New chain-stitch endoscopic sewing machine with a cylindrical shape.

The machine worked as follows. The machine was positioned as shown in Figure 5.3a above a layer of tissue in which stitches were to be formed. As shown in Figure 5.3b, suction was then applied through the machine to suck into the cavity a double layer of tissue. By then pushing on the needle control wire, the needle was forced forward through the double layer of tissue carrying a loop of thread held in its eye. The catch mechanism control wire was then pulled to lift the hook up. The control wire was then pushed to catch the loop of thread carried by the eye of the needle. The head portion of the needle had a groove formed in it to allow the hook to pass between the needle and the thread.

The needle was then withdrawn, leaving the loop of thread held by keeping the hook down. Suction was then released to allow the double layer of tissue to leave the suction

cavity. As shown in Figure 5.3c, the effect of these steps was to pass a loop of thread from one side of the tissue through the tissue at a first position and back out of the tissue on the same side at a second position. This was achieved without requiring access to the opposite site or serosal side of the tissue which would be endoscopically inaccessible under normal circumstance.

The machine was then moved to the site of the next stitch, suction was then reapplied, and the needle passed through a double layer of tissue at a different point. When the forward end of the needle passed through the loop of thread held by the hook, it carried a new loop of thread with it. The hook was lifted to drop the first loop which was pulled by hand and to catch the second loop of thread and hold it before the needle was withdrawn. In this way a chain of stitches was formed as indicated in Figure 5.3d in which each of the loops passed through the preceding loop.

One advantage of this design of machine was that although its overall size was smaller than the Swain and Mills machine, the size of the suction cavity was greater, thereby ensuring that the tissue was stitched to its full thickness.

A limitation of this design was that when the first loop of thread was dropped by the hook, it still required the thread to be tugged to reduce the size of the first loop so that the second loop of thread was able to be caught and held by the hook without recatching the first loop. A second problem was that when connected with a two-channel endoscope, the end of the machine obstructed the endoscopic vision making it difficult for the endoscopist to locate the target tissue and form the stitches.

A chain-stitch sewing machine with a hemi-cylindrical shape

Having recognized the problem of thread handling, it was thought that this problem could be resolved if the endoscopic vision of the machine could be improved. In order to overcome the problem of poor vision, it was decided that the body of the machine should be designed and machined as a hemi-cylindrical shape (Figure 5.4).

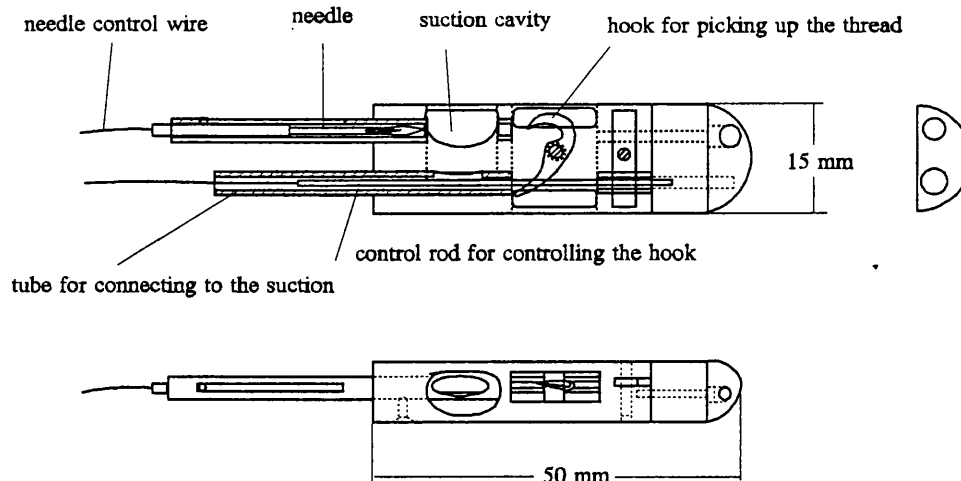


Figure 5.4 New chain-stitch endoscopic sewing machine with a hemi-cylindrical shape.

Although this design allowed approximately 50 % of the field of view to be unobstructed, it was still difficult to see the entrance to the suction cavity, so that the thread handling could not be visually monitored. The operating principle of the machine was the same as the one of the machine with a cylindrical shaped body, but the cavity size (5 mm in diameter, 5 mm deep) was decreased due to the half-sized shape of the body of the machine. Another problem was that the rigid length of the machine was 50 mm which made it difficult to pass through the mouth into the patient's oesophagus.

5.3.3. Summary

The problems occurred in the design of the machines employing the hook-catch

mechanism were as follows:

1. Endoscopic vision was improved but not sufficiently to allow visualisation of the operation of the machine and the stitches as they are being formed.
2. The cavity size in the machine with a hemi-cylindrical shape was not big enough to suck adequate tissue.
3. The length of the machines was still too great to ensure the easy and safe intubation of the patient.

One positive achievement in this design exercise was that the performance of the suction in the machine with a cylindrical shape was improved.

5.3.4. A shuttle-catch mechanism

Based on the design of the single-stitch endoscopic sewing machine, a shuttle-catch mechanism for forming a chain-stitch was designed and developed. This mechanism comprised a shuttle carrying a suture thread, a barbed operating rod, and a sprung peg located within a hole in the body of the distal end of the sewing machine. The shuttle was held in place by the barbed operating rod positioned coaxially within the needle, and attached to a control wire running through the middle of the Bowden cable.

A chain-stitch sewing machine with the shuttle catch mechanism

This machine was designed to use the shuttle-catch mechanism to achieve the chain stitches. The size of the machine was 9 mm in diameter and 40 mm long. The machine was designed to be connected to a 9 mm diameter, one-channel, flexible endoscope (Olympus PQ20). The machine was designed to be positioned off the central axis of the endoscope and so improve vision as discussed in Chapter 4 (Figure 5.5).

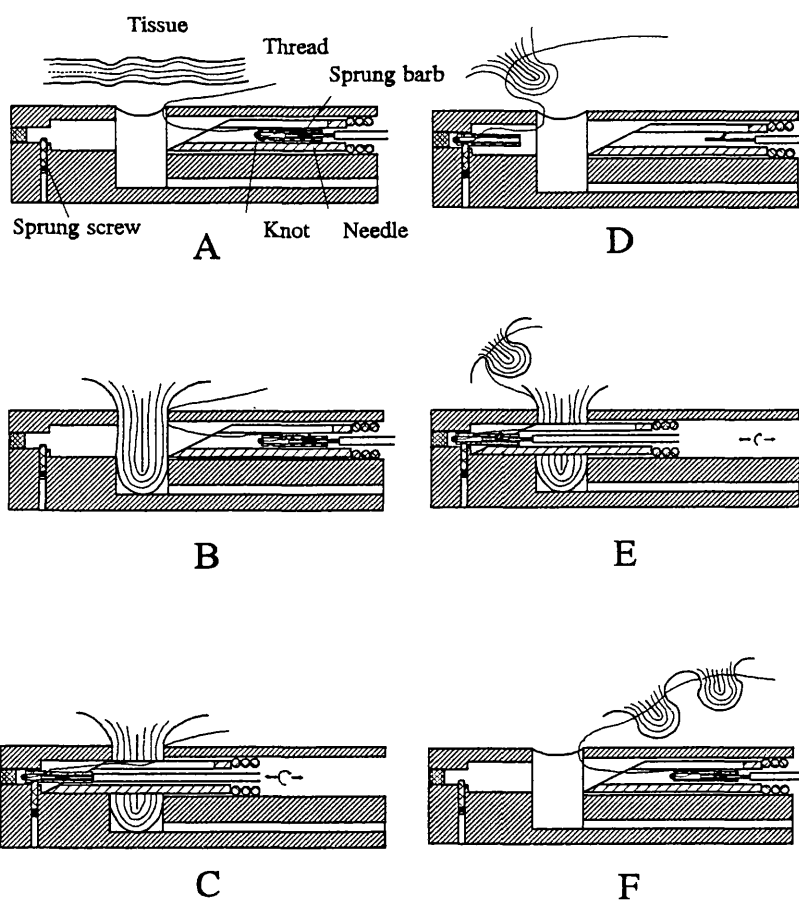


Figure 5.5 New chain-stitch endoscopic sewing machine with a shuttle tag mechanism.

As shown in Figure 5.5A-F, this machine worked as follows:

1. A shuttle carrying a suture thread is front-loaded into a hollow needle attached to a Bowden cable running through the operating channel of a standard, flexible, fibre optic endoscope. The shuttle is held in place by a barbed push-rod positioned coaxially within the needle, and attached to a control wire running through the middle of the Bowden cable.
2. A double, full-thickness layer of tissue is sucked into a cavity cut in the side of the machine, and the needle is pressed through the tissue by pushing on the Bowden cable.

3. The push-rod is then used to advance the shuttle out of the needle and into a hole drilled in the opposite wall of the cavity where it is held secure by a sprung peg. By rotating the control wire, the barbed push-rod is disengaged from the shuttle and withdrawn back into the needle.
4. The needle is withdrawn back into the machine and the suction released to let the tissue fall from the cavity. The thread is left running through the tissue and to the shuttle held on the opposite side of the suction cavity.
5. The machine is moved to the location chosen for the second stitch. Tissue is sucked into the cavity and pierced by the needle. The push-rod is advanced and twisted so that the barb locates with the recess in the shuttle. The push-rod and shuttle are then drawn back into the needle by pulling on the control wire.
6. The needle is pulled back through the tissue and the suction released to allow the tissue to fall from the cavity with the thread now forming a total of two continuous stitches in the tissue.
7. Any number of further stitches can be formed by repeating these actions.

Two machines were designed and constructed for the purpose of testing in bench experiments. One was fabricated from PMMA, the other from stainless-steel. PMMA was chosen in the hope that it would improve visualisation of the mechanism of the machine in action. This in fact was not the case - the PMMA distorted the image to the extent that no additional visual information was obtained compared to the machine made of stainless steel.

5.4. Experimental results

The machine with a cylindrical shape

The tests showed that the machine could form up to 3 stitches in post mortem tissue provided that the control cable was held straight and the thread was kept tight so as to ensure that the hook dropped the first loop and caught the second loop. If the control cable was bent, the tip of the hook could miss catching the thread because the movement of the needle was reduced.

The machine with a hemi-cylindrical shape

The tests showed that the machine did not suck tissue into the cavity in a fashion that reliably allowed the needle to penetrate the tissue. This was in part due to the needle running close to the edge of the cavity. Although the vision was improved, it was still not good enough to see the operation of the machine.

The machine with the shuttle-catch mechanism

The machine with the shuttle-catch mechanism was tested on the post-mortem human and canine stomach and *in vivo* on two beagle dogs to deliver chains of between 3 and 5 stitches. To test the machine on the bench, a 0.2 mm nylon line was used, and the machine was connected to the end of an Olympus PQ20 endoscope. When tested in the beagle dogs, an overtube (KeyMed, Southend-on-sea, UK) was used to ease intubation of the animals and provide better thread handling.

These experiments showed that the machine with the shuttle-catch mechanism worked well and reliably, but only when the endoscope was held straight. When bent, as would be frequently the case when used in the human gastrointestinal tract, the machines

frequently failed to operate correctly. This was because the needle and operating wire were moved by the bending of the endoscope interfering with the precise positioning required for successful stitching.

5.5. Discussion

The accuracy of catching the loops of thread or retrieving the shuttle tag

For all chain-stitch sewing machines, precision of movement and timing are essential for successful sewing of multiple stitches. Achieving such precision in a miniature machine at the end of a flexible endoscope imposes severe design constraints some of which have been indicated above. For the new hook-catch mechanism, the control wires were operated only by pushing or pulling. No rotation of the control wires was involved since precision control of rotating components of the tip of a flexible endoscope is difficult to achieve. This simplification increased the reliability of catching thread when compared with the method of retrieving the shuttle tag by rotating the central control wire. As the endoscope bent, despite the variation in length of travel of the control wires, the hook-catch mechanism would still work.

For the shuttle-catch mechanism, the risk of the misalignment for the shuttle tag was high when the rotation of the operating rod was needed, because the transmission of the rotation of the operating rod over a long distance was variable. Furthermore, the barbed central push-rod was small in diameter and fragile. When the endoscope was bent, this had greatest impact on the variation of the length of the central push-rod. This caused a disengagement between the shuttle tag and the barbed central push-rod. The principle of this method seems sound but more work is needed to make it work reliably. Most successful chain stitch sewing machines take thread for the next stitch from the free

side, i.e. from thread that has not passed through the cloth that is being sewn so that the frictional force on the thread is always the same. Very few running stitch sewing machines have been patented because the frictional force increases for each stitch that is passed. For clinical purposes, a running stitch that can sew two or perhaps three stitches would be very useful if it were simple to make and worked reliably. There is room for further development of multiple stitch methods for endoscopic sewing machines.

Vision

Changing the shape of the machine from cylindrical to hemi-cylindrical did improve the overall vision of the gut but did not much improve the vision of the target tissue or the machine and its operation because the endoscope tip was a few centimetres from the machine's action and the choice of PMMA did not give as much transparency as was hoped. As the endoscope used for the machines with a hook catch-mechanism was a two-channel endoscope there would probably be room for the development of methods for connecting the machines with a hook catch-mechanism to the end of a one-channel endoscope with better vision.

The machine with the shuttle-catch mechanism only needed one operating channel as the central operating-rod could be passed through the middle of the Bowden cable. The method of connecting this machine to the end of the endoscope which is similar to the single-stitch sewing machine (see Chapter 3) was definitely superior to the way of connecting the machine with a hook catch-mechanism. This greatly improved endoscopic vision.

The thread handling

The problem of thread handling in the machine with the hook-catch mechanism was still unresolved. Problems were encountered which are not seen with conventional sewing machines. The wetness of the tissue to be sewn caused the thread to adhere to the needle which made it more difficult for the catch mechanism to slide between the needle and thread. Most sewing machines rely on a loop of thread being thrown out laterally to the needle to allow the catch to be made reliably. This requirement was also impaired by the wetness and the mucus of the tissue to be sewn. The mechanical movements of a sewing machine have to be very precise to be reproducible. There are difficulties inherent in the use of flexible wires and cables passing through an endoscope which make such precision difficult though not impossible to achieve. Improvement in vision might allow for easier thread handling. On the other hand it would be better to design a multiple stitch machine which did not depend on operator skill in adjusting variations in thread movement. It still remains possible that a useful hook-catch mechanism could be developed for this purpose. The thread handling in the machine with the shuttle-catch mechanism was easier to manage than in the machine with a hook-catch mechanism.

**Chapter 6 Knot Tying at
flexible endoscopy**

6.1. Introduction

This study describes methods for tying knots or locking thread at sites in the gastrointestinal tract using flexible endoscopes. Tying secure knots in the gastrointestinal tract at flexible endoscopy requires solutions to certain specific difficulties. Access is through a small diameter orifice (mouth or anus) so the instruments for knot tying must either pass through the biopsy channel of the endoscope or be mounted on the end of the endoscope without interfering with intubation or endoscope function. Remoteness from the site of action may require long lengths of thread to run through a curved course. Thread may have to be pulled a considerable distance through tissue sometimes using that tissue as a fulcrum. One specific problem to be solved for knot tying with flexible endoscopes is the difficulty in applying lateral traction to tighten knots. The development of methods for tying knots at flexible endoscopy might extend the range of less-invasive surgical procedures that could be performed without laparotomy and was a necessary development if methods of stitching at flexible endoscopy were to be applied to achieve specific surgical goals. These methods were developed in order to assist in the application of flexible endoscopic methods for sewing in the gastrointestinal tract but they might also find applications in rigid laparoscopic surgery.

6.2. Methods and materials

Knots

1. Half-hitches tied with a knot-pusher

A knot-pusher designed to tie knots at flexible endoscopy is illustrated in Figure 6.1. A hollow cylinder was machined to be press-fitted onto the tip of a flexible endoscope. Two holes were drilled at three and nine o'clock through the cylinder. This device allows a half-hitch to be run ahead of the endoscope maintaining a view of the knot and

threads as light traction to the threads is applied by hand outside the mouth. Once the knot has reached the tissue or the object to be tied, forward pressure on the endoscope combined with cephalad traction on the threads then exerts lateral traction which is necessary to tighten the knot (Figure 6.1).

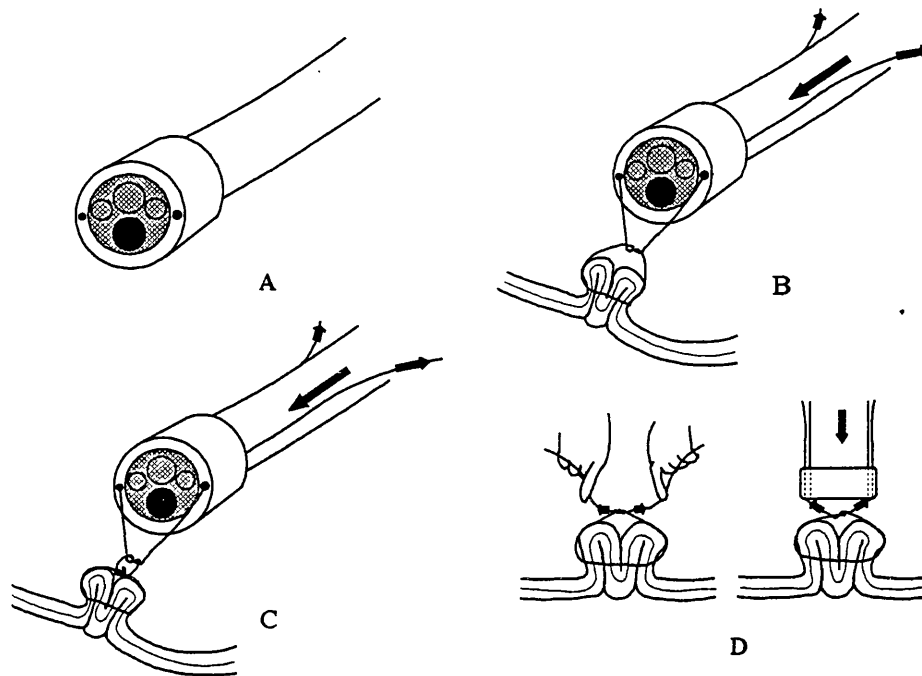


Figure 6.1 A newly designed knot pusher.

This procedure needs to be repeated at least three times to tie a secure knot. This method is made easier if the endoscope and threads are passed through an oro-oesophageal overtube but knots can be tied in this way without using an overtube. Problems were sometimes encountered with one thread coiling round the endotracheal tube in anaesthetised animals but this did not occur with an overtube in place. "Square knots" and some other knots can also be run and tightened using this device. It is easy to alternate the orientation of the half-hitch by removing one thread alternately from one side and then the other of the device to tie the next half-hitch.

A new flexible knot-pusher was also designed and constructed which could be pushed and pulled by means of a Bowden cable within the biopsy channel of the endoscope. The aim of this knot-pusher was to overcome the problem of vision of tying knots using the cylinder knotting device. This knot-pusher was designed to be front-loaded and passed through the biopsy channel of the endoscope. This is achieved by passing a guide-wire through the biopsy channel of the endoscope and then running the hollow cable of the knot-pusher back up from the tip of the endoscope until it emerges from the entrance of the biopsy channel. There are two holes in the oval-shaped head part of the knot-pusher. These 0.5 mm diameter holes were designed for allowing the threads passing through smoothly. Between two holes, there is a "window" designed for providing a view of the front to the clinician who will advance the knot-pusher to deliver knots down to the tissue. The advantages of this flexible knot-pusher are that it may be easier to push every knot against the tissue tightly and to see better while tying knots (Figure 6.2 and Figure 6.3).

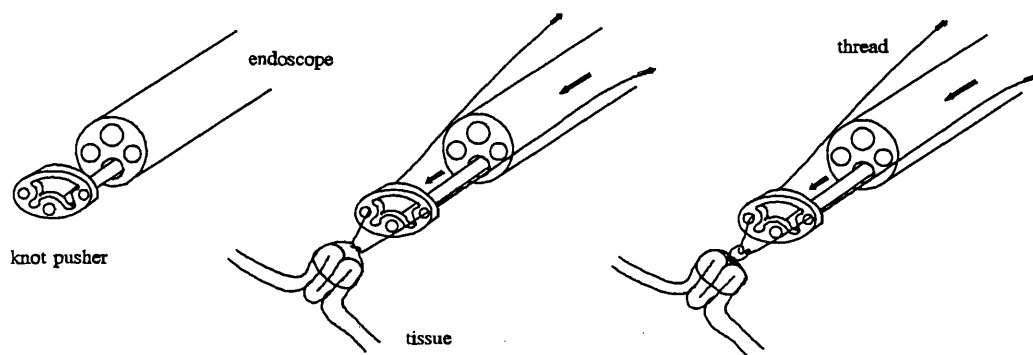


Figure 6.2 A newly designed flexible knot-pusher.

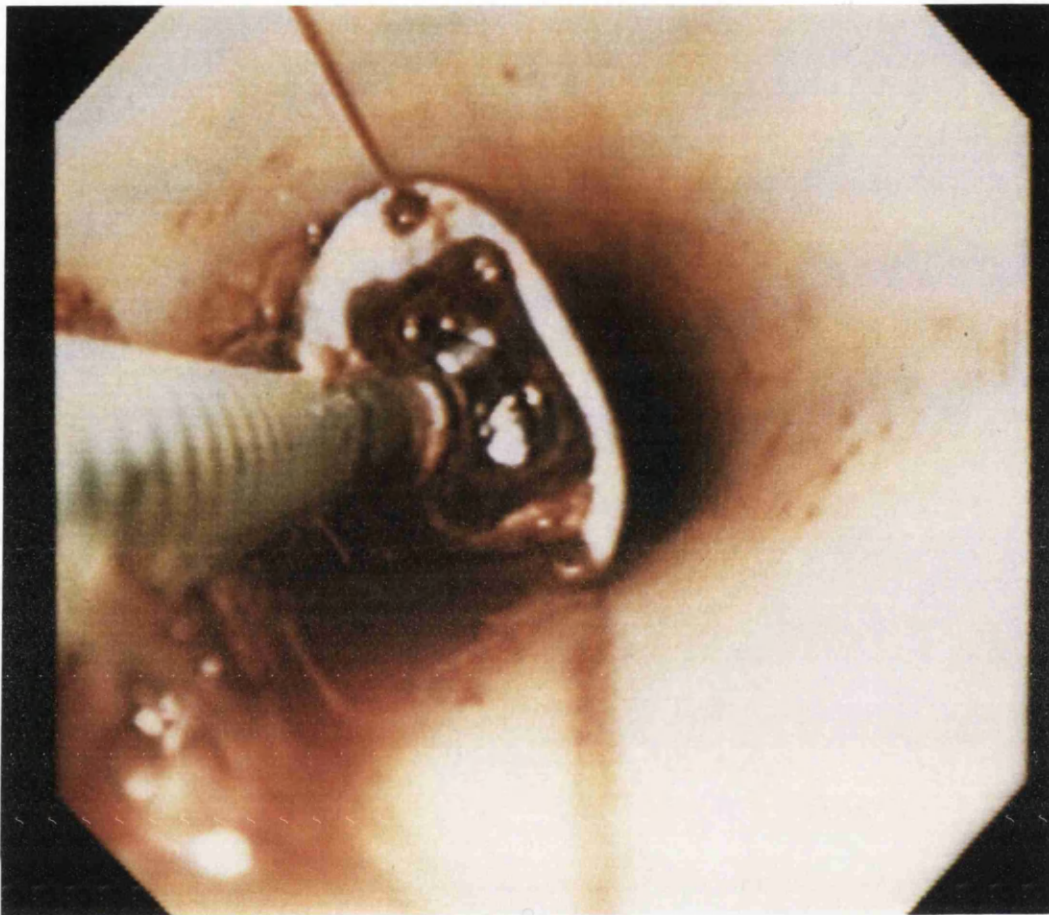


Figure 6.3 This endoscopic view shows that the flexible knot-pusher was used to tie half hitches at flexible endoscopy.

2. Thread-locking device

A device was designed to lock thread and exert pressure on tissue without having to tie a knot externally or internally. It was small enough to pass through the biopsy channel of a flexible endoscope (Figure 6.4). This device featured a thread-lock which was formed from a cylindrical sleeve with a distal central entry hole (Figure 6.4A) into which the one or two threads to be locked could be passed, a proximal side hole through

which the thread(s) could be passed to run freely prior to locking (Figure 6.4B). A central locking pin could be forced forwards by a push rod into the proximal central hole in the cylinder of the device which would exert frictional force on the thread, holding the thread tight against the tissue. The delivery system was formed from a flexible tube which could be passed through the biopsy channel of an endoscope to allow the pin to be passed through the endoscope into the thread lock by pushing on the flexible rod. A moveable control wire was run through two channels externally to this flexible channel. The control wire was used in the closed position to hold the thread-lock steady as the pin was forced into it to exert frictional force on the thread (Figure 6.4B). Once the thread was locked in the sleeve against the tissue the wires were pushed forwards (Figure 6.4C) to allow the thread-lock to fall free of the delivery system (Figure 6.4D).

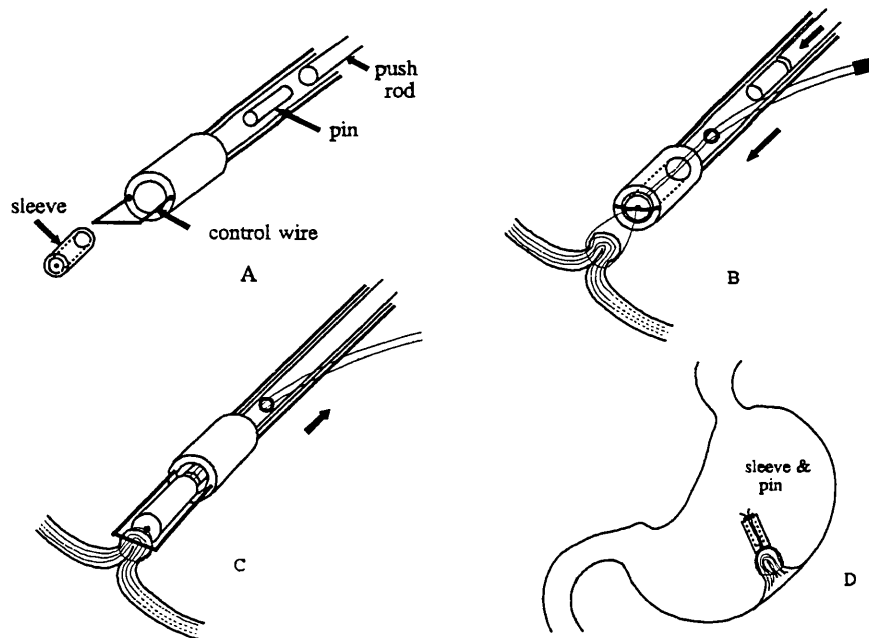


Figure 6.4 A thread locking device A-D.

3. Self-tightening slip-knots

Slip knots that can be tied extracorporeally were examined, i.e. knots which are tied externally to the patient and then run down to be tightened against the tissue by pulling on one or two threads. A self-tightening knot that has not been previously used for surgical purposes is illustrated in Figure 6.5. It was called Tim's knot. The continuous end of a double length of thread which has been passed through or around tissue is doubled back on itself to form a loop (A). Both of the discontinuous ends are passed through that loop (B), and both ends are passed through the loop again (C), traction on both discontinuous ends of the thread allows the knot to slip down freely until it tightens on the tissue. This was compared with another slip-knot, sometimes known as a Roeder loop or endoloop is illustrated in Figure 6.5 which has been fairly widely used in laparoscopic procedures.

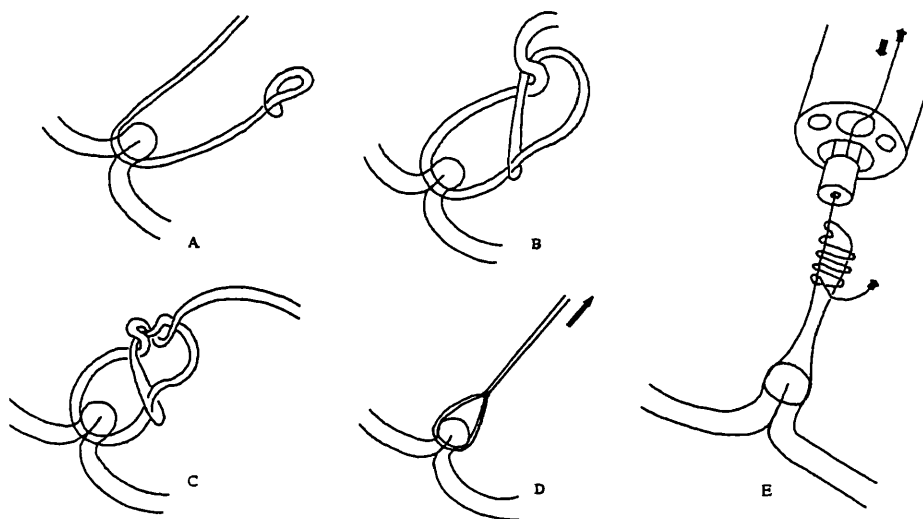


Figure 6.5 Self-tightening slip-knots - A B C D show the formation of Tim's knot, E shows a Roeder loop knot.

4. Externally releasable knot

A method was developed which would allow feeding tubes or other objects to be secured releasably to the stomach or other parts of the gastrointestinal tract without having to re-endoscope the patient in order to cut the thread. This method which was used clinically is outlined below (Figure 6.6).

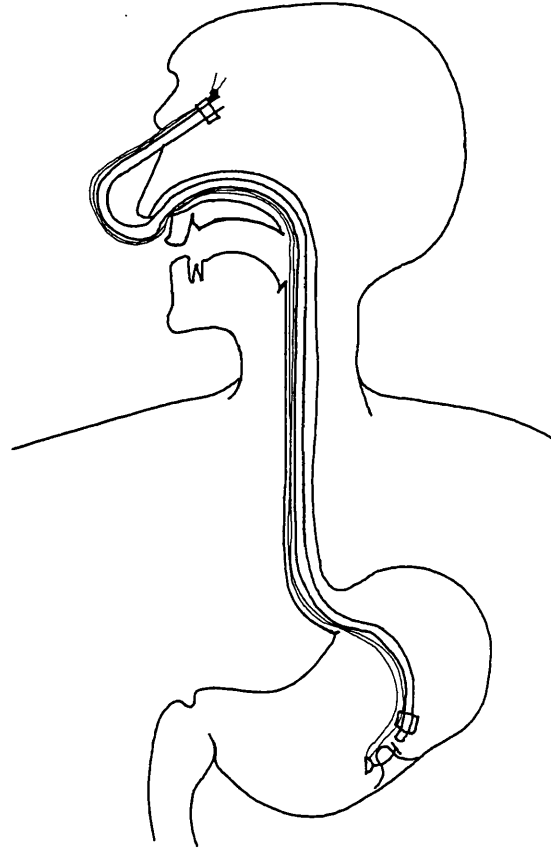


Figure 6.6 Externally releasable knot.

Using an endoscopically deliverable tissue transfixing device, a single nylon tag, with a small hole in it through which a length of thread had been passed, was sewn in a full thickness bite into the body of the stomach. The device was removed leaving a length of nylon thread running freely through the hole in the tag in the stomach with both ends outside the mouth of the patient. A guide wire was then placed into the third part of the

duodenum through the biopsy channel of an endoscope, and the feeding tube was passed over the guide-wire. The feeding tube was secured to the thread outside the mouth by means of an elastic O ring which was tight enough to hold the thread without compressing the feeding tube. The feeding tube pushed over the guide wire and traction was then exerted on the thread until the feeding tube was tight against the plastic suture with the distal end of the feeding tube in the third part of the duodenum. Both the feeding tube and the thread were then routed through the nose and secured just outside the nose. The naso-jejunal or naso-gastric feeding tube was thus secured by means of thread that runs down through the nose to the nylon tag and came back up adjacent to the feeding tube, both ends being secured outside the nose. When the feeding tube was to be withdrawn the thread was cut externally to the patient which allowed the feeding tube to be withdrawn without traction being exerted on the transgastric stitch before it is pulled in order to avoid pulling the stomach back up into the oesophagus if it is securely attached. A method for securing feeding tubes internally should allow the tube to separate from the stomach without causing internal damage if the tube is inadvertently or advertently pulled. A breaking strain of 0.9 kg was chosen to allow the restraining thread to break without tearing the stitch out of the tissue. For 3 patients the thread was passed directly through the gastric wall rather than through a tag.

Sewing machines

1. An endoscopic sewing machine was used to place single, double or treble full-thickness stitches of nylon thread through the wall of the stomach prior to studying knot tying [19].

2. A different endoscopic sewing machine (endoscopically deliverable tissue transfixing device) designed to place a plastic tag by means of a tilt stitch was used for the externally releasable knot [21].

Thread

For most studies nylon 0.2 mm diameter thread with a breaking strain of 2.3 kg was used (Maxima Manufacturing Company, Germany). Because longer lengths of thread were required than are conventionally used in surgery, nylon fishing line was used. A wide variety of alternatives from the textile industry and surgical thread manufacturers including silk, polyester, Vicryl (3/0), catgut were used, but none worked as well in these experiments as nylon.

Glues

Cyanoacrylate (Loctite UK, Herts, UK) or Epoxy resin (Plastic Padding Ltd, High Wycombe, UK), silastic medical adhesive (Dow Corning Corporation, Michigan, USA) were used to see if the application of glue could increase the security of knotting methods.

Feeding tubes, connectors and bands.

The PVC feeding tubing which is a preferred material for endoscopically placed feeding naso-gastric tubes is 1.5 mm inner diameter 2.5 mm outer diameter (Portex Ltd, Hythe, Kent). A Cook plastic Luer lock adaptor (PFLLA-UCC-L) (Letchworth, Herts, UK) was fitted to the external end. Short lengths of silicone rubber sleeving of 2 mm (RS399-423) (RS Components, Corby, Northants, UK) was stretched over the PVC feeding tubing to secure the thread to the tubing at the stomach and outside the mouth.

Measurements of knot strength

Measurements of the force required to undo the knots (or break the knotted thread) were carried out in bench experiments as follows. By means of a needle, thread was passed from the mucosal surface of the stomach, through to the serosal surface and then back through to the mucosal surface at a point 1.5 cm from the entry point. The two ends of the thread were tied to include a ring of tape or steel. The stomach was held firmly and increasing traction could then be exerted on the knot via the loop using a spring force gauge until the force required to undo the knot or break the thread was determined. Because the force required to test the knot strength sometimes caused the thread to cut out of the tissue, for some experiments the thread was passed round the outside of the whole oesophagus, stomach or duodenum and then tied.

Tissue studies

Postmortem human oesophagus, stomach and duodenum (n=15).

Animal studies

Beagles (n=10)

Knots tied by all four methods were studied in the course of experimental studies developing less invasive surgical procedures using flexible endoscopic sewing methods for experimental anti-reflux procedures [62] and for securing radiotelemetry capsules to the stomach [63] oesophagus and colon.

Surgical hand-tied knots

Thread sewn through or looped around post-mortem human oesophagus, stomach or duodenum was hand-tied tightly with 2-6 half-hitches by an experienced surgeon.

Thread cutting methods

Cutting thread with endoscopic 'suture cutting forceps' (Olympus FS-1K; Keymed, Southend-on-Sea, Essex, UK). Backloading the thread outside the mouth through the open stitch cutting forceps and closing the cutting forceps once they were close to the knot on the tissue was found to speed thread cutting for most applications.

Statistical methods

Statistical significance of differences between groups were assessed using a non parametric method - the Mann Whitney U test.

6.3. Results

Measurements were made of the force required to undo or break knots and thread suitable for flexible endoscopic use using a force gauge. The breaking strain of the nylon thread was first measured experimentally: in 10 experiments the median breaking strain of the thread was 5 kg, range 4.0-5.5. These experiments indicated a higher breaking strain than the manufacturers had suggested (2.3 kg).

6.3.1. Measurements of force required to undo or break knots suitable for endoscopic use.

The force required to undo (or break) the knot tied with the knot pusher tying three half-hitches was measured in 10 experiments and the median knot strength was 2.5 kg, range 2-3. In experiments using three or more half hitches, the knot never slipped, rather the knotted thread was broken.

The force required to undo or break the "knot" formed with the thread locking device

was measured in 10 experiments giving a median knot strength of 3 kg, range 2-3.5. Increasing force on the locked thread always broke the thread and the thread lock did not slip.

Measurements of the security of the two slip knots studied showed that these knots were not as strong as three half hitches or the thread locking device. Tim's knot (a "new" slip knot) in 10 experiments was found to have a median knot strength of 1 kg, range 0.4-1.2. Increasing traction on the knot invariably caused it to slip open. Roeder loop (endolooop slip knot) in 10 experiments had a similar median knot strength of 1 kg, range 0.3-2. Increasing traction on the knot also invariably caused it to slip open.

There were no statistical differences comparing the strength of three half-hitches tied with a knot pusher with the knot locking device. Both slip knots (Roeder loop and Tim's knot) were significantly ($p < 0.001$) weaker than 3 half hitches or knot locking. The strength of the two slip-knots were not significantly different (Figure 6.7).

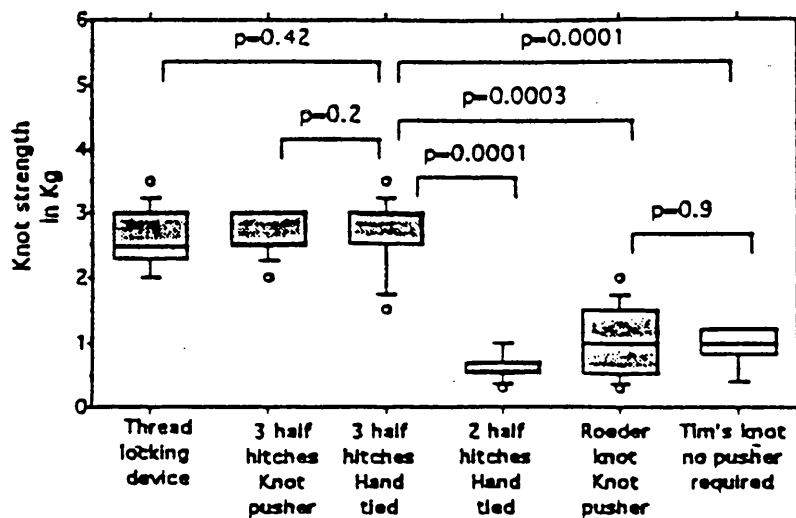


Figure 6.7 Types of knot

6.3.2. Comparisons of endoscopically and surgically tied knots (3 half-hitches)

Ten knots formed from 3 half hitches were tied using the knot pusher mounted on a flexible endoscope and another 10 were tied by an experienced surgeon. The median for 3 half-hitches hand tied was 3 kg, range 1.5-3.5 while the median for 3 half hitches tied with endoscopic knot pusher was 2.5 kg, range 2.0-3.0. There were no statistically significant differences ($p=0.2$) between the force required to undo or break endoscopically formed knots when compared with similar hand tied knots formed by a surgeon.

6.3.3. The effect of the addition of glue to knot strength.

To test whether the addition of glue might increase knot security, a series of two half-hitches were tied having passed thread through gastric tissue as well as tightened Roeder loops. Glue was added to the knots and allowed to set. Control unglued knots were compared with glued knots. The median knot strength of 10 Roeder loops unglued was 1 kg (range 0.3-2), glued with silastic medical adhesive was 1 kg (range 0.75-2), glued with epoxy resin was 0.55 kg (range 0.4-0.7). The median strength of 2 half hitches unglued was 0.55 kg (range 0.3-0.7), glued with silastic medical adhesive was 0.55 kg (range 0.4-0.7), glued with epoxy resin median was 1.25 kg (0.5-2.5), glued with cyanoacrylate was 0.55 kg (range 0.4-0.7). The addition of epoxy resin ($p<0.02$) but not of silastic medical adhesive or cyanoacrylate, increased the security of 2 half-hitches but the addition of glues did not significantly alter the strength of the Roeder loop knot.

6.3.4. Comparison of the addition of extra half-hitches to the strength of the knot

The strengths of 2 through 6 half hitches were compared using 10 knots each. The median knot strength of 2 half-hitches was 0.5 kg (range 0.3-1), of 3 half-hitches was

1.5 kg (range 1-2.25), of 4 half-hitches was 2.5 kg (range 2-3), of 5 half-hitches was 2.5 kg (range 2-3), of 6 half-hitches was 2.9 kg (range 1.75-3.5).

3-6 half hitches were highly significantly more secure than 2 half-hitches ($p < 0.0001$). 4 half hitches were stronger ($p = 0.001$) than 3, but 5 and 6 half hitches were not significantly superior to 4 ($p = 0.15$).

6.3.5. Time required to tie knots

Both the slip knots and the knot of the thread locking device were formed in a significantly ($p < 0.05$) shorter time (median: 3 minutes) than were 3 half hitches (median: 5 minutes). It was quicker to tie a slip knot or use the thread locking device. Practice markedly shortened the time required to tie knots.

6.3.6. Use of knot tying techniques at flexible endoscopy in patients

A 46 year old asian lady requiring chronic peritoneal dialysis for chronic renal failure due to systemic lupus erythematosus (SLE) and treatment for miliary tuberculosis experienced severe nausea and vomiting. She lost 2 kg in weight and nasogastric feeding was attempted. 5 nasogastric tubes and 2 endoscopically placed jejunal feeding tubes were vomited out all within 24 hours. The risk of infecting the peritoneal cavity by placing a percutaneous gastrostomy was considered too great in view of her requirement for peritoneal dialysis. A nasojejunal tube was stitched into the stomach using an endoscopic sewing machine in order to allow long term enteral feeding despite her persistent vomiting. The feeding tube remained in situ for 63 days and was removed electively after cutting the retaining thread at the nose. Nasogastric feeds were administered through out this period and she gained weight. Her vomiting improved as

her tuberculosis and SLE responded to medical treatment.

This method of securing feeding tubes has been used in 4 other patients who had failed to retain nasogastric tubes for more than 12 hours on more than three occasions and allowed feeding tubes to stay in place for 10, 14, 18 and 47 days before they were removed electively. Repeat endoscopy was performed in 4 of these cases and showed that the stitch holding the nasogastric tube was still in place at the time of elective removal. The knot pushers have been used to tie knots (four half-hitches) in more than 70 patients.

6.4. Discussion

Knots are formed by twisting or looping a line into a formation which will exert sufficient frictional force in order to prevent the line from slipping. The practical art of knot tying is best expounded in nautical texts [64-69]. A theoretical analysis and descriptive numerical categorization or topology of knots of increasing complexity has been systematized in a mathematical literature dating from the 19th century [70-80].

Knot tying is an essential aspect of surgical technology [78-85]. Significant progress has recently been made towards solving the problems of knot tying during rigid laparoscopic surgical procedures for gynaecological procedures [86,87], appendicectomy [88], hernia repair [89] and fundoplication [90]. The pioneering gynaecologist Semm popularized for laparoscopic use the slip-knot called the Roeder loop (after H Roeder [1866-1918] who recommended a special loop for tonsillectomy in children) [86,87]: other slip-knots have been described [91,92]. More recently there has been a trend in laparoscopic surgery towards forming conventional surgical knots in the form of half-hitches inside the

peritoneal cavity rather than forming or using preformed knots outside the abdomen [93].

Surgeons most commonly tie three simple half-hitches per knot. Three half-hitches are thought to be sufficient, but extra throws are sometimes used for greater security [94,95]. The second most commonly tied knot, the "surgeon's" or friction knot, is a square knot in which the first half-hitch is made with two twists to reduce slipping [96]. Three squarely tied double throws were "found adequate" to hold these materials safely [97]. There have been some recent innovations in surgical knot tying especially with methods for tying one handed knots [95-101].

Knot tying at flexible endoscopy is in some ways more difficult than at rigid laparoscopy since access is not straight, the channel through the endoscope is smaller and the use of multiple trocars to give access to different instruments at different angles is not an option. This study shows that, despite the limitations of access and apparent mechanical disadvantage, knots can be tied almost as tightly at flexible endoscopy as hand-tied surgical knots.

One disadvantage of having to tie knots externally to the patient and push a series of throws down to the tissue when using endoscopes or laparoscopes is that it is time consuming and requires at least three passes if a series of half-hitches are to be turned into a secure knot. An alternative might be to use a device that can be passed through the biopsy channel of a flexible endoscope to deliver a thread locking device which can exert sufficient frictional force to hold two threads tight against the tissue or to hold one thread with the thread locking device exerting pressure on the tissue. The advantage of

such a device is that repeated intubations are unnecessary. The thread locking device used in this study could "tie" two thread together as tightly as any surgical hand-tied knots, and did not slip.

Tying a complex knot which can run smoothly until it reaches the object around which it is to tighten has been used for nautical and other purposes [64-69] and more recently has been used for laparoscopic purposes especially for appendectomy [88]. Initially it was found difficult to make the Roeder loop work well at flexible endoscopy since the force required to pull the thread through the tissue tended to tighten this knot prematurely. The use of a flexible knot pusher that could be passed through an endoscope biopsy channel (Figure 6.5 E) solved this difficulty. The slip knot (Tim's Knot) shown in Figure 6.5 A-D ran down to tissue without requiring a knot pusher and was as secure as the Roeder loop in the measurements of knot strength. Both slip knots may suffer from the possible disadvantage of a tendency to cut through friable tissue as they are tightened because the long length of thread pulled through tissue can act as a saw.

These simple methods of measurements of knot strength using a purpose built force gauge have allowed a comparative analysis of knotting techniques which has not been applied previously in the surgical literature. These measurements outlined in Figure 6.6 allow the following conclusions. Three endoscopically tied half-hitches can be tied as tightly using an endoscopic knot pusher as the same knots hand tied by a surgeon. The thread locking device was as secure as any hand-tied method. Both slip knots were significantly less secure than three half-hitches and tended to slip back open if sufficient force was exerted on them. Both slip-knots were similar in security. The Roeder loop

required a flexible knot pusher, Tim's knot could be run to the tissue without a knot pusher. Three half-hitches did not slip and if sufficient force was exerted, it broke the thread rather than undoing the knot. Three half-hitches were twice as secure as two; the addition of a fourth added a little to the security of the knot while further throws did not add to the knot strength. The addition of glue added little or no additional strength to slip knots and is probably not worth the trouble.

The strength of knot required varies with the surgical aim. Although slip-knots were less secure than three or more half-hitches the security of slip-knots may well be sufficient for many purposes. For some potential applications of flexible endoscopic surgery for example oversewing of a large bleeding artery or anti-reflux surgery strong thread and secure knots may be important. The tension of a knotted thread can be adjusted to suit various clinical needs.

An endoscopic method for securing feeding tubes in the stomach tract might reduce uncomfortable repeated intubations and the requirement for endoscopic gastrostomy placement which is a more dangerous procedure. Nasogastric feeding tube displacement is a depressingly common occurrence in hospital [102] and occurs for three reasons. Patients may make unintentional movements which exert cephalad traction on the feeding tube. Retching or other retrograde intraluminal forces may tend to push the tube out. Confused patients and patients who find the discomfort of a nasogastric tube intolerable sometimes pull the tube out forcefully. This method worked well in these patients who failed to keep nasogastric tubes in place and probably saved the life of the patient described in the case report. This study indicates that knot tying can be effectively performed at flexible endoscopy by a variety of methods.

Chapter 7 Cutting thread at flexible endoscopy

7.1. Introduction

Suture cutting forceps for use at flexible endoscopy were introduced in the late 1960s and were formed by a modification of endoscopic biopsy forceps in which a wire wound flexible Bowden cable exerts mechanical force on two hinged parts by means of a wire which passes through the cable. In order to exert greater force while cutting the thread, the suture cutter is closed by pulling rather than pushing on a single activating wire. Because the distance from the lever to the fulcrum or pivot is necessarily small since the device has to pass through a 2.8 mm biopsy channel, the mechanical advantage is small and the force exerted on the thread is not great. These devices have been used occasionally usually to cut thread found in the postoperative gastrointestinal tract. The literature on cutting thread at endoscopy is quite small [103,104,105,106]. A change to the use of absorbable suture material and the marked reduction in gastric surgery for peptic ulcer has probably further reduced the need for thread cutting at endoscopy.

The development and application of endoscopic sewing methods [19,21,106] necessitated an examination of cutting methods at flexible endoscopy and the development of new techniques for rapid reliable thread cutting at flexible endoscopy. Thread is loaded into the endoscopic sewing machine [19,21,106] and passed by means of a needle deeply through the muscle layer of gastrointestinal tissue and then pulled through the tissue so that both ends of the thread are held at the mouth or anus. Knots are tied extracorporeally i.e. outside the mouth or anus and pushed by means of a knot pusher until they are snug against the tissue [107]. Both end of the thread have to be cut after the knot is tied, preferably leaving ends 3 or 4 mm long. Although existing standard endoscopic suture cutters can be used freehand to cut the thread, there are limitations especially in precision cutting of threads running from knots tied to secure thread to

tissue with the ends held outside the mouth. The cutters tend to open parallel to rather than at 90 degrees to the thread; the axis in which the cutters open cannot be varied by twisting the wire-wound cable at the biopsy channel port; it can be difficult to spot which is the cutting and non cutting side of the suture cutters because both look the same through the endoscope. The suture cutters deteriorated with frequent use and required replacement usually after about 10 threads are cut. Worse is the problem that occasionally it can be difficult to see the thread or the knot clearly because it has become buried in a fold of tissue or is obscured below the cardio-oesophageal junction, or by mucus or blood. Poor vision or an awkward angle of approach at endoscopy can make it very difficult to cut the thread at all using suture cutters freehand and occasionally the knot itself can be inadvertently cut using suture cutters in a conventional manner.

Since the threads to be cut were held outside the mouth, if the thread could be passed in some way through the cutters external to the patient, run down over the thread to the position where it was desired to cut the thread, usually near the knot, it would avoid the difficulty of finding or getting a good angle for cutting the thread, since the thread itself could act as a guide.

7.2. Devices, materials and methods

7.2.1. Devices

New thread cutting guillotine

A 2.4 mm diameter thread cutting guillotine was designed and made of stainless steel featuring two angled holes with sharp edges through which threads to be cut are passed. The guillotine end measuring 5 mm in length was soldered to one end of a 2.3 mm

diameter coated sheath (Bard Interventional Products, Mentor, Ohio, USA) with a central wire and the other to a handle. This flexible guillotine can be easily passed through a 2.8 mm or greater diameter biopsy channel of a flexible endoscope (Figure 7.1).

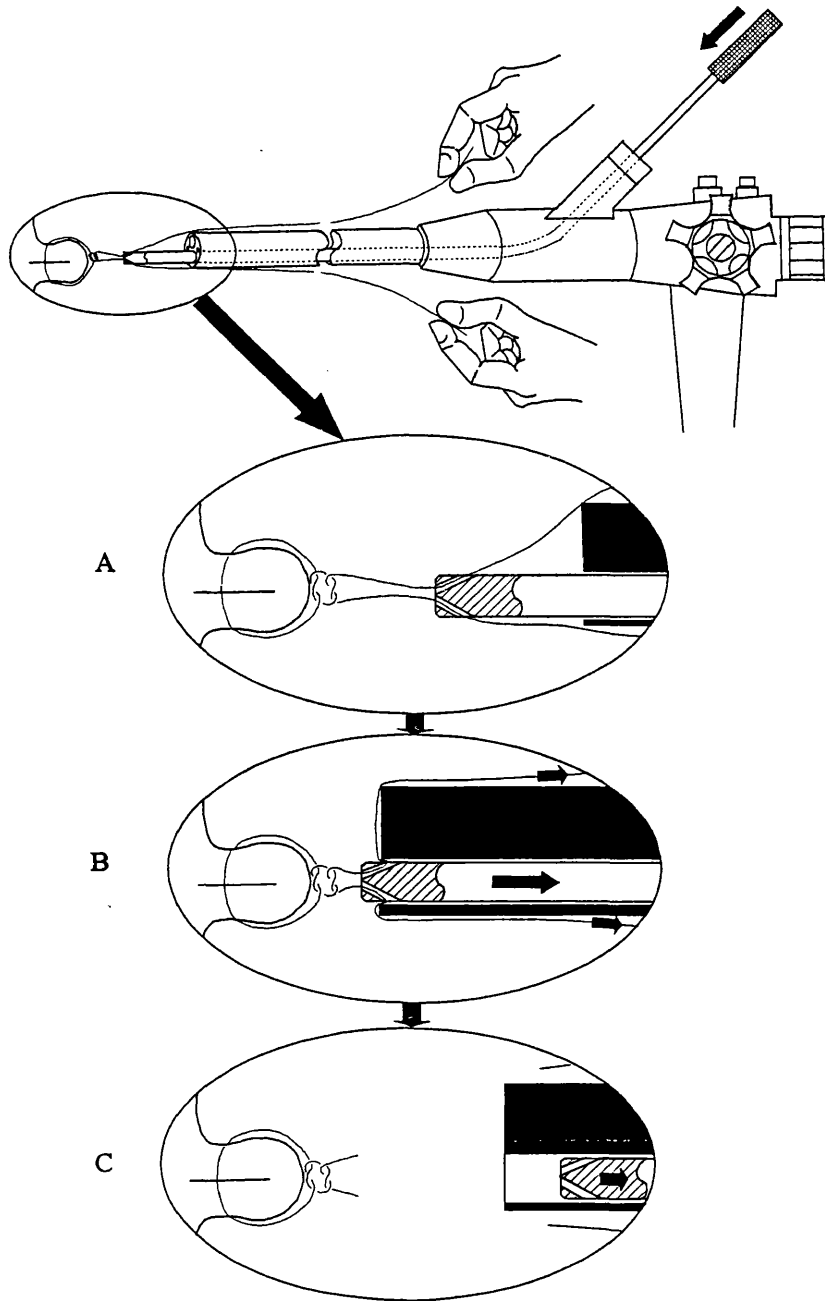


Figure 7.1 An endoscopic thread cutting guillotine.

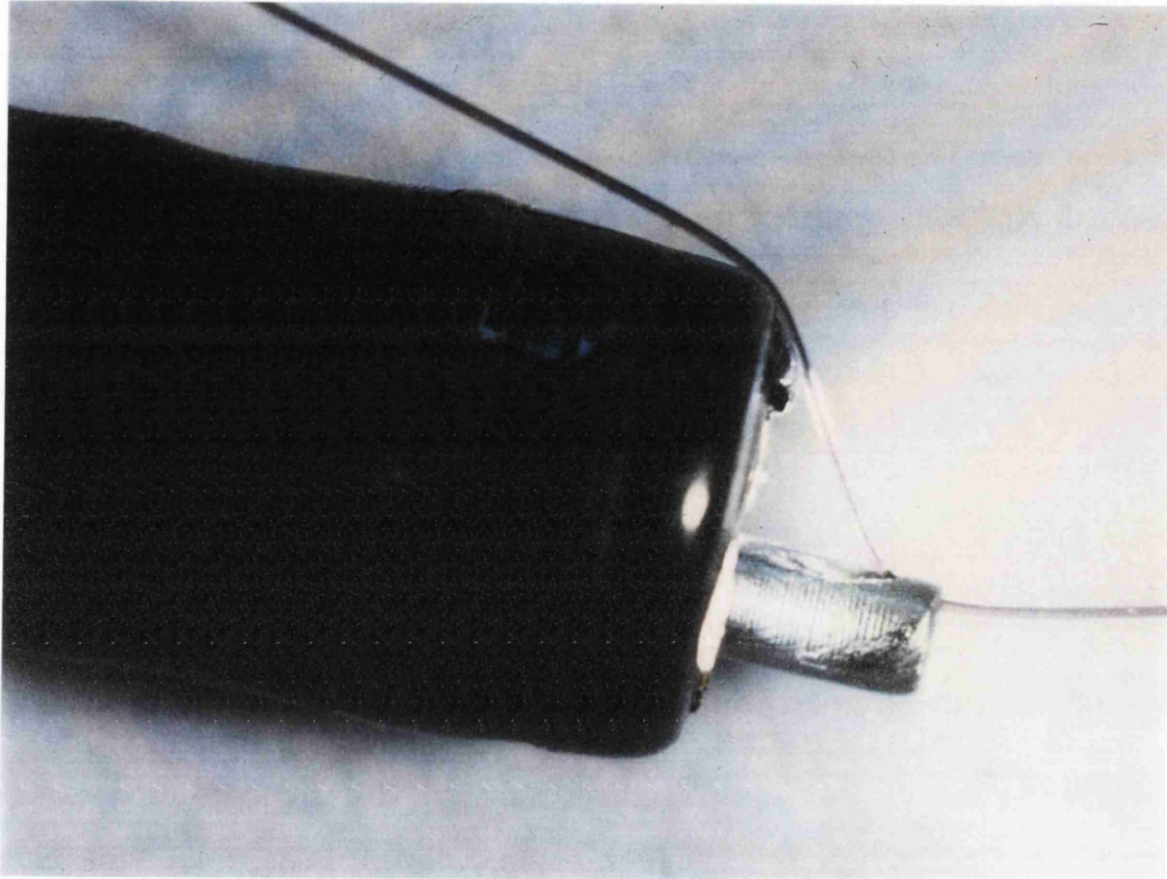


Figure 7.2 The endoscopic thread cutting guillotine was positioned and ready for cutting the thread.

In order to cut the thread, this device was first passed through the biopsy channel of the endoscope. Once the tip of the guillotine had emerged from the tip of the endoscope, one or both ends of the thread to be cut, held outside the patient's mouth, was or were passed through one or each of the angled holes on the cutting part of the guillotine by the endoscopist or an assistant. The endoscopist then passes the endoscope and cutter using the thread as a guide down until the cutter touches or almost touches the tissue

at the site of the knot. The assistant exerts cephalad traction on the thread at the mouth to keep the thread under tension splinted against the outside edge of the endoscope, and the endoscopist pulls on the guillotine. A guillotine comprises a blade moving across a static block. In this case the block is formed by the distal tip of the endoscope and the biopsy channel and the blade moving into the biopsy channel severs the thread. This method of cutting can be used with or without an oro-oesophageal overtube.

Pushing forwards on the endoscope while the thread is gently held taut causes the device and the endoscope to follow the thread to the tissue. The thread cannot be cut by pulling back inadvertently on the endoscope or the cutter unless the assistant simultaneously tenses the thread running coaxial to the endoscope. It is the action of simultaneously tensing the thread against the endoscope tip and pulling on the wire wound cable where it emerges from the endoscope biopsy channel which causes the guillotine edge to cut the thread at the endoscope tip.

Because the cutting part was made and shaped from a cylinder of stainless steel, the cutting edges, which were formed by drilling the two angled holes from the one end of the cutting part, were curved on a cylindrical surface. This gives an advantage during thread cutting - the thread tends to remain approximately central with respect to the length of the cutting edges. If the cutting edges were straight or rectangular, there would be a tendency for the thread tails to slip to one or other end of the cutting edge and become jammed in a "dead corner" which might impede an effective thread cutting at flexible endoscopy.

The maximum diameter of thread that could be passed through the endoscopic guillotine is 0.4 mm diameter (2/0 suture size).

Alternative guillotine for cutting strong thread.

A cutting device was constructed using 2.4 mm cylindrical stainless steel tubing. Two holes of 1.8 mm diameter were drilled on both sides of the cylinder through which the thread to cut could be easily passed. A blade of stainless steel of 0.4 mm thickness was inserted into a groove cut into the cylinder. The cylinder was soldered to a wire-wound sheath. This device was designed to cut threads made out of new very strong materials such as Spectra and Abulon.

Snare cutting device

A polished stainless steel tube of 2.4 mm diameter with a sharp ground circular cutting edge was soldered on to the end of a flexible wire-wound sheath-covered cable. A snare wire of 0.3 mm diameter was preformed to expand into a loop was passed through the cable and attached to a handle which could advance and withdraw the snare loop. This device was designed to retrieve objects that had been sewn to the gastrointestinal tract by looping the snare over the object to be retrieved and then closed thus forcing the thread to be pressed against the cutting edge on the tip of the snare.

Suture cutting forceps

Olympus FS-1K suture cutting forceps. This device is illustrated in Figure 7.3.

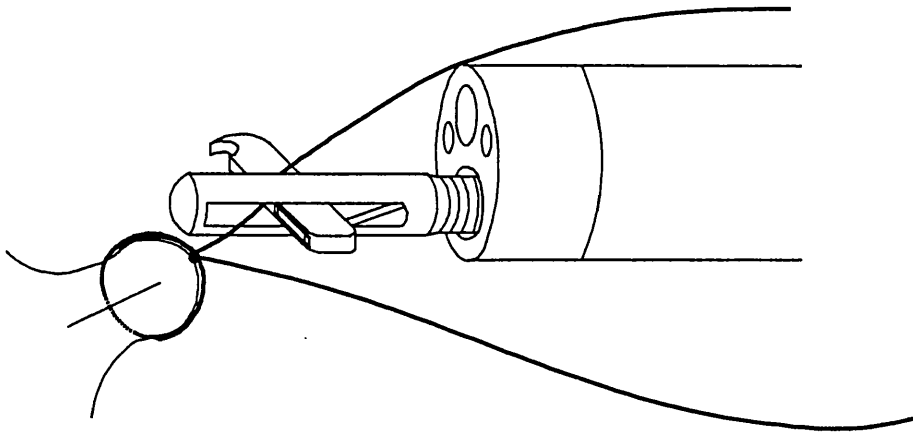


Figure 7.3 Cutting thread using the Olympus FS-1K suture cutting forceps.

Laser

Nd:YAG Laser (MBB MEDILAS 4060N, Munich, Germany) - the power setting chosen was 30 Watts following bench experiments to find effective power levels. Thread was cut with the waveguide (600 micron diameter) held 1 cm from the thread. The spot size was 2 mm at this distance. A low flow of CO₂ was used to cool the tip and to prevent ignited material landing on the waveguide.

7.2.2. Materials

Thread

Eight types of surgical thread were studied. Blue coloured nylon suture (Dermalon®, Davis-Geck, Gosport, UK), black coloured nylon (Ethicon Ltd, Edinburgh, UK), purple polyglactin 910 (Vicryl, Ethicon Ltd, UK), white transparent polydioxone (PDS, Ethicon Ltd, UK), white polytetrafluoroethylene (PTFE, W.L Gore & Associates, Inc., Medical Products, Flagstaff, Arizona, USA), braided black silk (Mersilk, Ethicon Ltd, UK), light

brown catgut (Chromic, Ethicon, UK), white or blue braided polyester (Ticon, Davis-Geck, UK), green or white braided polyester (Ethibond, Ethicon, UK) and black polyamide 66 (Nurolon, Ethicon, UK). For some experiments in which long lengths of line were required brown coloured nylon fishing line was used (Maxima, Geretsreid, Germany). Two recently introduced strong fishing lines were also studied and included light blue Abulon (Garcia, Tokyo, Japan) which is a variant of Kevlar - a polyaramid fibre which was first introduced by DuPont in 1965 and white Spectra (Ontario, California, USA) - a new class of fibre, an ultra high molecular weight polyethylene which was introduced by Allied Signal Inc. in 1985.

Post mortem tissue

For bench experiments testing cutting of threads, isolated postmortem human gastric tissue was used. This material was frozen when removed at postmortem and defrosted prior to use. Thread was passed through the full thickness of the stomach wall and then passed back through the tissue one centimetre from the first passage and tied securely with 4 half hitches prior to cutting.

7.2.3 Methods and models

Method of measuring suture diameter

The diameter of each suture material was measured using Digimatic callipers (Mitutoyo, RS Components Ltd, Corby, UK). Each thread type was measured 10 times.

Method of measuring strength of suture materials

The tensile breaking strength or the load to failure of the 8 suture materials were measured using a mechanical testing machine (Instron, model 6025, High Wycombe,

UK). Each material was tested 10 times.

Methods for cutting thread with standard Olympus FS-1K suture cutting forceps.

1. Conventional cutting method

The suture cutting forceps was passed through the biopsy channel of the endoscope and the cutter was opened and manipulated until the thread was held between the jaws of the cutter which were then closed. Sometimes it was found helpful to apply tension to the thread while cutting by pulling the cutters closed inside the endoscope biopsy channel.

2. Backloaded method

Once the suture cutters had been passed through the biopsy channel of the endoscope, thread was back loaded with the cutters open through a slot in the cutters which is formed by opening the cutting blade. The suture cutters, held open, were then run down to the tissue (through an oro-pharyngeal overtube) using the thread as a guide and closed when the cutter was about 3 mm from the knot. The maximum diameter of thread that can be cut when passed through the Olympus FS-1K suture cutting forceps using the backloaded method is 0.3 mm diameter.

Model for testing efficacy of mechanical cutting devices.

Thread was sewn through post-mortem human stomach to form a centimetre long full-thickness stitch and a knot tied with four half hitches. The mechanical cutters were passed through the biopsy channel of an endoscope (Olympus PQ20) and the free ends of the thread were cut without tension being exerted on the thread. Each thread was cut 10 times.

Model for testing speed of mechanical cutting devices.

A model set up was constructed to test the speed with which the cutters could be used. This comprised a post mortem human stomach in which thread had been tied with a knot tied with four half hitches and the two free ends had been passed through the oesophagus and through an overtube. The overtube had been tied to the upper oesophagus. One operator had to pass the suture cutter through the endoscope, load each thread through the suture cutter, then pass the endoscope with the protruding suture cutter down the length of the thread until the suture cutter was within 5 mm of the tissue and then to cut the thread. For the freehand experiments the cutter had to be passed down the endoscope biopsy channel and the endoscope passed through the overtube, then the oesophagus into the stomach and the thread cut by manipulating the endoscope until the stitch cutters could be closed around the thread. Nylon was used for all these experiments. Each procedure was timed with a stopwatch.

Model for testing efficacy of laser cutting methods.

Thread was passed through post-mortem human stomach to form a centimetre long full-thickness stitch and a knot tied with four half hitches. The laser fibre was held by hand at approximately 1 cm from the knot and was fired until the thread had been cut and the knot was undone. Coaxial CO₂ gas was used in order to reduce the chance of hot material damaging the laser fibre. The laser spot size was 2 mm diameter. The length of duration of the laser impulse was measured with a stopwatch. In order to compare laser cutting with mechanical cutting separate experiments were undertaken using the laser to cut an easy material (black silk) and a more difficult material (violet coloured PDS) using the same model used for testing the speed of mechanical cutting devices. These experiments were then repeated to compare speed of cutting using the model

described in the previous paragraph.

Performance of thread cutting devices in live experimental and clinical studies

The performance of thread cutting methods was recorded in the course of experimental studies in which radiotelemetry capsules were sewn to sites in the gastrointestinal tract, and experimental methods for treating gastro oesophageal reflux disease were developed. The performance of cutting methods used during clinical studies was also recorded.

7.3. Results

7.3.1. Bench experiments

a. Measurement of sizes of suture materials

The median diameters of the sutures were as follows: nylon - 0.24 mm, polydioxone (PDS) - 0.29 mm, polytetrafluoroethylene (PTFE) - 0.31 mm, polyglactin 910 (Vicryl) - 0.215 mm, braided polyester fibre (Ticron)- 0.21 mm, braided polyester suture (Ethibond) - 0.23 mm, polyamide 66 (Nuralon) - 0.21 mm, braided silk 0.23 mm, polyaramid (Kevlar) (Abulon) - 0.2 mm, and ultra high molecular weight polyethylene (Spectra) - 0.15 mm.

b. Measurements of strength of suture materials

In order of increasing strength measured in Newtons, the median breaking strain of the different unknotted threads were: Nurolon - 30 (28.6 - 31.2), PTFE - 42.8 (42.4 - 43.6), silk - 44 (44 - 44.8), Ticron - 56 (56 - 56.4), Nylon - 60 (54.2 - 61.2), PDS - 69.6 (64.4 - 74), Ethibond - 71.2 (71 - 71.6), Vicryl - 83.6 (72.6 - 86.8), Spectra - 94.6 (87.2 - 102) and Abulon - 144.8 (137.6 - 152). Nurolon and PTFE were the weakest materials tested and Abulon and Spectra were the strongest.

c. Efficacy of cutting devices

The endoscopic guillotine and the Olympus FS-1K suture cutting forceps were tested cutting a variety of suture threads including Nylon, Dexon, Vicryl, PDS, Silk, PTFE, Spectra, Ethibond, Ticron, Nurolon, Catgut and Abulon. Each suture material was cut 10 times in bench experiments.

Cutting with Olympus FS-1K suture cutting forceps freehand (without back loading the thread): Dexon Plus, Dexon DG, PDS*II, Chromic catgut, Nylon, PTFE (Goretex) were easily cut 100% of the time. Some difficulty was experienced with Mersilk (Braided silk suture), after 3 cuts the cutter became jammed with fibres which accumulated between the blades and in the slot. It was easier to cut this material if it was held under tension. In a series of experiments the attempt was made to cut thread with about 100 g of tension applied to the thread and then with no tension applied to the thread allowing the thread to lie loose across the cutting edge. In 10 experiments without tension the thread was cut 0/10 times and when tension was applied the thread was cut 10/10 times ($p < 0.05$). Using Spectra wire which is a braided thread 10 times stronger than steel the cutters failed to cut the thread but broke a few of the fibres.

Cutting with Olympus FS-1K suture cutting forceps using the backloaded technique in which tension of about 100 g was exerted on the thread: Dexon Plus, Dexon DG, PDS*II, Chromic catgut, Nylon, PTFE (Goretex) were easily cut 100% of the time. Difficulty was experienced usually after 3 cuts using Mersilk with fibres jamming the cutter and it was not possible to cut Spectra thread with these cutters used in this way. Some threads deformed more easily during this method of cutting than others: in particular monofilament threads, nylon, PDS and Catgut deformed more than PTFE, silk

and spectra. An exception was monofilament PTFE which tended not to deform with manipulation or cutting. The cutters tended to deteriorate and require attention after cutting 10 or less threads.

When cutting with the endoscopic guillotine, all the sutures with the exception of Spectra wire thread were cut 100% of the time. It was able to cut all other threads including Mersilk more than 25 times before the cutting edge needed to be reset. A modification of this guillotine constructed using commercial blades was effective in cutting the Spectra wire thread but tended to damage the cutting edge requiring frequent repolishing.

Backloading thread through the FS-1K suture cutters and endoscopic guillotine, it was possible up to a diameter of 0.4 mm equivalent to 2/0 suture size. The FS-1K was not strong enough to cut any thread of diameter of 0.5 mm or greater equivalent to "1" suture size material that was tested.

d. Comparison of speed of cutting with backloaded Olympus FS-1K suture cutting forceps and the new cutting device

The median time taken to cut the thread using the FS-1K suture cutting forceps freehand was 90 seconds with a range of 30-270 seconds. The median time taken to cut the thread backloaded using the FS-1K suture cutting forceps was 45 seconds with a range of 20-70 seconds. The time taken to cut the thread using the endoscopic guillotine was 25 seconds with a range of 20-40 seconds (Figure 7.3). The endoscopic guillotine was significantly quicker than either method using the FS-1K suture cutting forceps ($p < 0.05$). Although it was occasionally easy to cut the thread freehand with the FS-1K suture

cutting forceps, sometimes it was quite difficult and took up to four and a half minutes before the thread could be cut.

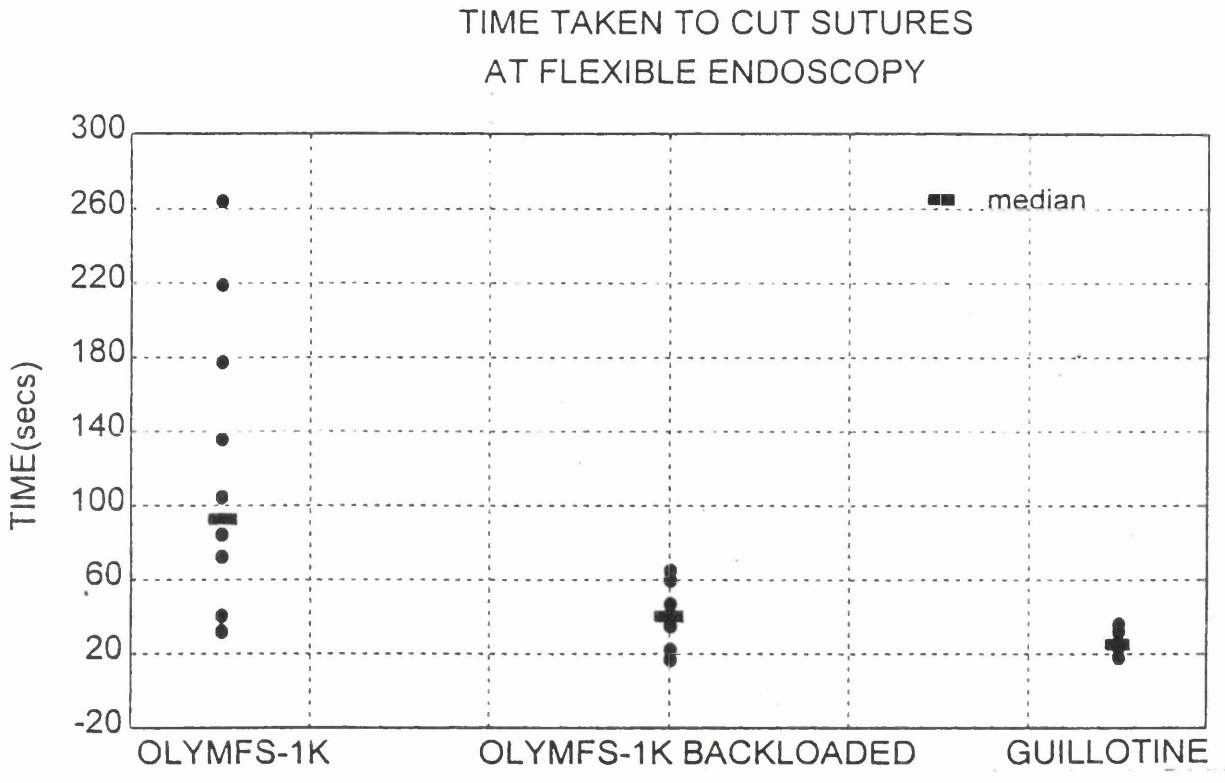


Figure 7.4 Different methods of thread cutting

e. Laser used to cut suture threads

The effectiveness of the Nd:YAG laser was also tested in cutting different threads (Nylon, Dexon, Vicryl, Polydioxone, Silk, Catgut and Spectra). The test results showed that Nd:YAG laser can cut some coloured threads effectively and power requirement to cut coloured threads especially silk was small (median=20 Watts, range 5-50), but the laser did not cut non-coloured threads such as light green Nylon or white Dexon and cut

some coloured plastics poorly. The time taken for the laser to cut sutures was 1-11 seconds. The area of tissue damage caused by laser was minor (median area of tissue damage = 2x2 mm, range 1-5). The laser did not cause full thickness damage in any instances when it cut coloured thread but of course did if the power was continued on thread that could not be cut. There was little laser induced knot damage.

The time taken to pass the laser probe through the biopsy channel of the endoscope and aim it at the thread was measured for silk, 2/0,3/0,4/0, Nylon 3/0, Vicryl 3/0, PDS 1 and spectra 3/0. On average it took 55 seconds to pass the laser fibre through the endoscope, down through the overtube into the oesophagus and stomach and to aim the laser and cut the thread. The total endoscopic time taken to cut black silk was 65-70 seconds immaterial of the size of the silk and we were unable to cut the violet coloured PDS. It was difficult to cut the Spectra thread with the laser but was managed after 10-20 second of laser ablation. The time taken to cut thread with the laser was significantly longer than with any of the mechanical methods ($p<0.05$).

7.3.2. Animal experiments

In the course of experimental studies of sewing either to attach radiotelemetry capsules (n=17) to the gastrointestinal tract or to perform anti-reflux operations in pigs or dogs a total of 162 nylon threads were cut successfully. Both threads were cut simultaneously on 12 occasions. Spectra thread was cut on 8 occasions using the modification of the new guillotine cutter with a commercial blade. PTFE thread was cut on 2 occasions. Abulon thread was cut twice. Nylon T tags were cut 10 times. The snare cutter was used twice.

7.3.3. Human studies

In the course of clinical studies [107,109] in 81 patients of sewing either to attach radiotelemetry capsules (n = 3 patients, number of threads cut was 9) or to perform anti-reflux operations (n = 70 patients, number of threads cut was 280) or to oversee perforations (n = 2 patients, number of threads cut was 10) or to secure feeding tubes (n = 6 patients, number of threads cut was 12). The total number of thread cut was 311. It is preferred to cut one thread at a time rather than two since this allows a check to be made on the knot security. If the knot were to be cut or avulsed from the tissue by the first cutting of thread, traction on the other thread at the mouth would pull it out.

The cutting devices used in human studies were: a. the Olympus FS-1K suture cutting forceps for cutting all threads, n = 3, b. for some of the first clinical studies nylon thread was cut using the backloaded method with the FS-1K forceps, n = 16, c. the endoscopic guillotine was used for all subsequent thread cutting procedures, n = 58.

7.4. Discussion

Cutting thread can be achieved effectively by a variety of methods at flexible endoscopy. This study shows that thread cutting can be achieved using a variety of endoscopic tools. The scissor like action of standard suture cutting forceps is needed to cut short lengths of thread. For many years this has been virtually the only available endoscopic method for removing thread found in the gastrointestinal tract following surgery apart from pulling on the thread with biopsy forceps [110]. Classen described the design and use of a diathermy hook [105] to remove thread in 10 patients in 1971 - diathermy cannot melt or cut thread but may cause a sufficient rise in tissue temperature to allow a thread or knot to be removed. Since thread only rarely needed

to be cut in normal clinical practice, the suture cutting forceps rarely emerged from its drawer. It is suggested that a proportion of patients with ulcers in which thread is seen to emerge can improve symptomatically if the thread is removed. A surgical literature suggests that some patients require excision of the ulcer and thread [110,111,112,113] but only one of the patients had a further operation and in four patients the thread was probably an incidental finding not causing symptoms. The requirement to cut thread during the development and application of new less invasive procedures using suture material and endoscopic sewing methods led to the development of alternative methods.

Backloading the thread through the standard suture cutters or the new thread cutters offered the advantage of always being able to reach the thread close to the knot when threads were held outside the mouth. This method had the practical advantage of speeding up the thread cutting part of the sewing procedure and making it more reliable. Using the suture cutter backloaded over the thread has the disadvantage that the cutters have to be run open through the upper oesophagus which requires the use of a protective oro-oesophageal overtube. It can only cut with the thread running in one direction over the cutting edge and if the thread is wrongly loaded or the cutters rotate during the endoscopy it will not cut. The frictional force exerted on the thread can damage the thread preventing free running. The cutters tend to deteriorate and cut less effectively if they are used frequently. Suture cutters can be used to cut thread without exerting tension on the knot or tissue. The cutters also become less effective if used with much tip angulation of the endoscope. This method has been extensively used in animal experiments and was the first method we used in clinical studies in patients.

The new thread cutting method using an endoscopic guillotine was developed and has become a preferred method when cutting lengths of thread held outside the mouth or anus. This method is quicker than either method using suture cutting forceps, causes less frictional damage to the thread, can be used safely without an overtube and has now been extensively used in animal and human studies. The thread and knot can be seen better through the endoscope with this than with the other methods. The thread can be cut reliably even when the view is poor by running the endoscope over the thread until the cutter can be felt to be in contact with the tissue then tightening the thread and pulling on the cutter. One reservation about this method is that it tends to exert some force on the knot and the tissue that has been tied but it has been never observed it to pull the thread or knot out of the tissue. It is simple to construct, cheap to make and can cut more threads before the edge requires sharpening than the suture cutter. A modification of this method incorporating a sharp commercial razor blade has successfully cut Spectra thread which is very strong and is too tough to be cut by the suture forceps or the new cutter without this blade. A guillotine for cutting thread at laparoscopy has been reported [15]. This works by forcing a circular cutting blade forwards inside a rigid tube which would probably be hard to make and apply at flexible endoscopy.

Because it is sometimes tricky to cut thread which has been cut and knotted tightly into tissue using suture cutters at endoscopy, a new snare cutting method for releasing objects such as radiotelemetry capsules once they have been sewn to the oesophageal, gastric, duodenal or colonic wall, was developed. This method has been used in bench and experimental studies but not yet in clinical trials.

Analysis of the mechanical forces exerted during cutting at endoscopy shows the following features. Mechanical advantage of the Olympus FS-1K suture cutters is limited because the force closing the cutter is applied so close to the fulcrum. This force diminishes as the cutter closes. Any misalignment between the cutting and static blades tends to diminish performance further because the thread tends to jam between the two blades. Tension on the thread makes cutting easier to achieve by minimizing the forces tending to part the blades.

Accelerating the cutter onto the thread tends to decrease the force required for effective cutting by making optimum use of the momentum of the blade and the inertia of the thread. The cutting tools work using one or other of two different principles, namely, those of the knife and the guillotine. The knife works by producing very high pressures at the contact between a sharp blade and the object to be cut. These pressures indent, fracture and part the surface of the object, exposing deeper layers which are similarly indented, fractured and parted. This process continues until the entire object has been cut into two. The guillotine works by shearing the entire cross-section of the object in one action.

Nd:YAG lasers can cut thread but lasers are expensive and their ability to cut is limited by optical absorption (colour) and material of the thread. This study shows that black silk threads can be cut very easily at low power. Aiming of the laser has to be precise and some thermal tissue damage occurs which does not occur with mechanical methods. Some threads cannot be cut especially transparent, white or lightly coloured threads. Some of the plastic threads tended to melt and thin out without parting and the knot can be damaged during cutting. Lasers can cut some threads but are not as quick, safe and

reliable as the mechanical methods. The Nd:YAG laser has not been used to cut thread in human studies. Cutting thread at flexible endoscopy can be quickly and reliably accomplished by a variety of techniques.

Chapter 8 Wireless endoscopy

8.1. Introduction

Miniaturisation of CCD cameras, transmitters, antennae, batteries, and light sources might make the creation of a new type of endoscopy possible. This study assesses the feasibility of making prototype endoscopes which can transmit images from the gut without wires or cables by studying the size and power requirements of available small electronic devices needed to form the parts of this endoscope. This wireless endoscope would need to be small enough to be swallowed easily and pass through the human gastrointestinal tract [114]. This device might be passed into the gastrointestinal tract like a radio-telemetry pH capsule being haphazardly propelled by peristalsis but more usefully might also be sewn to the wall of the gastrointestinal tract or attached to propulsion mechanisms allowing controlled movement and transmission of images from inside the body without wires, fibre optic bundles or cables.

There may be a niche for a wireless video-endoscope which could traverse and transmit colour television images of the gastrointestinal tract. This type of endoscope might offer a new way to examine the small bowel or the colon. It is conceivable that if such a device were small enough to be swallowed like a capsule, pain free endoscopy, enteroscopy and colonoscopy might become reality. The aim of this study was to explore the discrepancy between the fantasy of a tiny robotic endoscope crawling down and perhaps up the bowel transmitting high quality endoscopic images and allowing therapeutic maneuvers to be performed and the reality of commercially available miniature electronic components.

In this chapter, the development of the micro-robotic technology is reviewed. In order to assess the feasibility of miniature wireless transmission of moving colour images from

the stomach, an analysis was undertaken of the data relating the size, power dissipation and biocompatibility of the smallest, commercially available CCD cameras, microwave transmitters, and light sources. A study comparing the energy capacity to size ratios of small batteries was also undertaken. Possible methods of propulsion and signal transmission, the choice of light source and battery type, were proposed and studied. Some consideration of the sensitivity of the CCD camera, the brightness and colour temperature of the light source, and the time over which each video frame must be collected, considering the continuous movement of the gut, are also given. Using the smallest commercially available components, prototype wireless endoscopes were constructed and used to test the hypothesis that transmission of a high quality colour television moving image from a wireless endoscope is possible in the gastrointestinal tract.

8.2. Background

Development of micro-robotic technology and miniaturisation of CCD video cameras have important implications for the creation of the robotic endoscopy. The hypothesis is that a combination of techniques from micro robotics and video endoscopy is possible and could be used to develop a range of "wireless endoscope". This "wireless endoscope" could navigate the human gastrointestinal tract to make diagnoses and perhaps also to perform operations. This might make robotic endoscopy possible in the near future.

8.2.1. The development of micro-robotic technology

Fukuda, et al [115] of Japan reported the development of two cable-less micro mobile robots. It was claimed that the two micro mobile robots required no power supply

cables, as a giant magnetostrictive alloy (GMA) was used as micro actuators in the robots. These robots can be controlled by magnetic fields applied externally. The mechanism of the motions are based on inch-worm type mechanisms. Two mechanisms of the motions (one-way and reversible) were presented. The sizes of the robots were 21 mm in diameter for the reversible motion and 6 mm in diameter for the one-way motion. The motion was controlled by the regulated motion of the outer electro-magnetic coil, so that the in-pipe micro robot can move by following the outer coil. The authors claimed that these micro mobile robots have many possible applications for small pipe inspections and the miniature device might find application in the small space of the human body.

A micro robot which could twist itself around to move forward in narrow pipes was developed by Toshiba Corp. [116] in 1991. This robot shaped by connecting two pieces of rubber tubes, could "snake" through pipes at the speed of 10 mm/min by the force of air pressure. The rubber tubes functioning as the robot body structure were divided into three compartments with partitions (Figure 8.1).

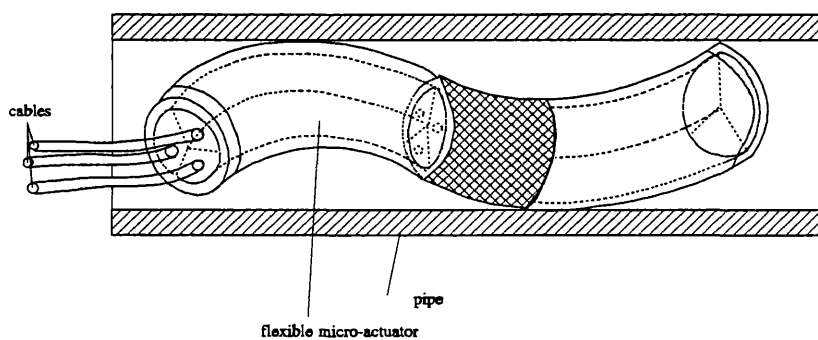


Figure 8.1 The Toshiba micro-robot.

The body was bent by changing the level of air pressure in the compartments and snaky forward moving action was created through slightly staggering the motion of each of two rubber tubes. By reversing this motion, the robot could go backward. There were two prototype robots, one was 12 mm in diameter and the other was 2 mm in diameter. The larger one was designed could be used in 25 mm tubes in nuclear power stations. The smaller robot was designed for use in 3 mm pipes which is the size of some catheters in medical use. The fact that no electricity is used for motion control is a major advantage for medical applications.

Suzumori, Kondo (Toshiba Corp) and Tanaka [117] designed and constructed two types of walking robots in 1993. This might feasibly lead to the development of devices which could move inside human bodies in the future, although walking might not be an optimal method of propulsion for such a clinical application. The "mammalian-type" had six legs (15 mm long) which directly projected downward from the body. The "reptiliform-type" had six legs (15 mm long) which projected outward from both sides of the body. The authors used the hydraulic pressure actuators FMA (flexible micro actuator, 12 mm long, 2 mm in diameter) as the legs. The FMA is a fluid actuator and is developed for small flexible robots. It is made of a composite material of fibre and rubber (fibre-reinforced rubber), has three chambers. The FMA is operated by controlling the internal pressure of each chamber. The walking robots moved at 20 cm/min. The authors claimed that the robots can be easily miniaturized and can move as animals (Figure 8.2).

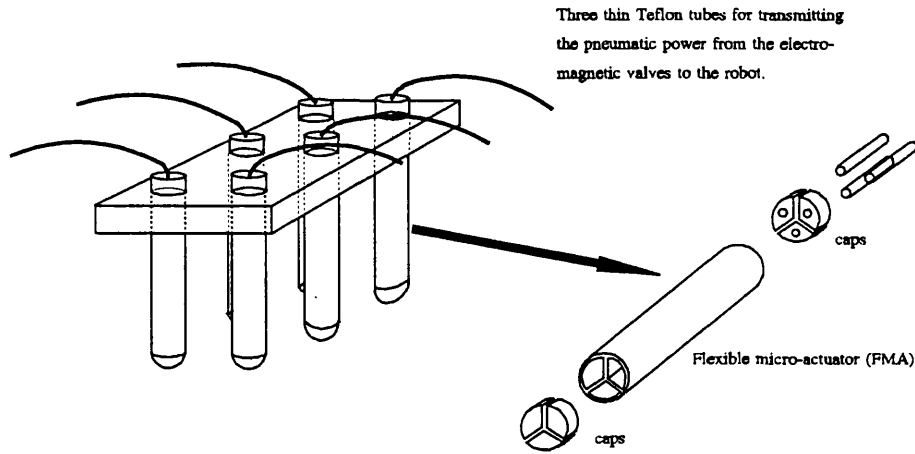


Figure 8.2 One six-leg flexible walking robot.

Miwa developed a tiny six-leg robot using shape memory alloy (SMA). It could walk under the control of a microcomputer. A single TiNi wire, as part of the mechanism, drove the robot when it changed electrical energy (electric current from the wires at the rear) into mechanical energy. Among these creature robots, the smallest one was only 2 mm long. Miwa suggested that such miniaturised robots could be used to enter tiny holes for inspection and repair purposes or for medical experiments. The wire connection might be replaced by laser beams [118].

Menz [119] presented his futuristic endoscopic operation system. This "Intelligent endoscope" consists of a catheter that is divided into two parts. The front and the rear part are connected by a hydraulic section. To be supported in the body cavities, mini-balloons are applied. They are controlled by a central microvalve system. On the basis of the inch-worm principle, the entire system can move independently through the body

cavities. The tip of the catheter is equipped with high-performance optics. Using micro actuators, operations can be performed in the smallest cavities. It was emphasized that, however, this "Intelligent endoscope" can not be moved through the body from outside in an remote-controlled manner similar to a mini-submarine, as the permanent connection with the outer world would be required. An array of ultrasonic sensors are proposed to use to supply the sensory data (Figure 8.3).

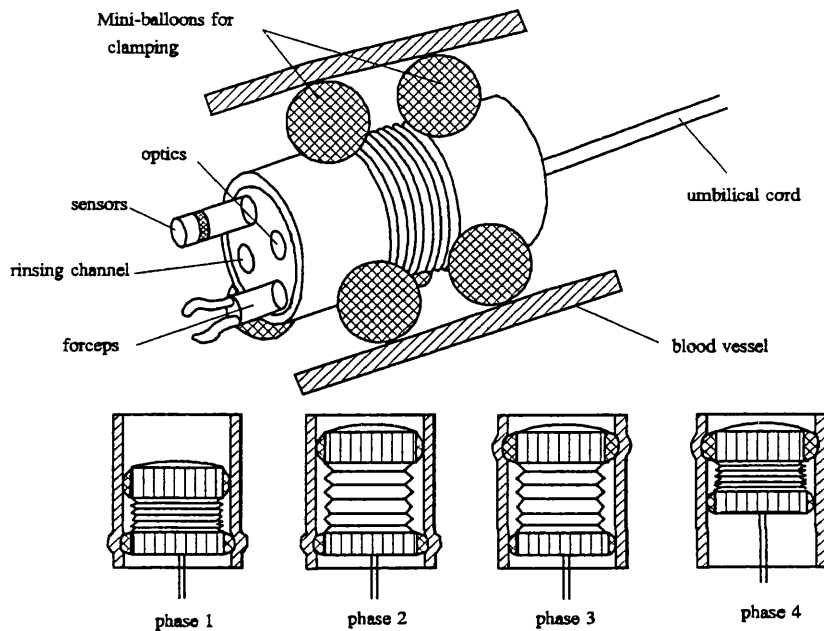


Figure 8.3 An "Intelligent endoscope".

Slatkin, Burdick and Grundfest [120] designed and developed a prototype robotic endoscope for gastrointestinal diagnosis and therapy. The aim of designing the robotic endoscope was to access and inspect the portion of the gastrointestinal tract which can not be accessed by the conventional endoscopes. This prototype robotic endoscope consisted of: electrical wiring for control signals; tubing to connect the pneumatic actuators to high/low pressure sources; a fibre-optical bundle for illumination and imaging of the area in front of the robot. This mechanism of the propulsion along its

length consisted of "grippers" and "extensors". These devices were used for achieving the gripping and stretching actions. The experimental results showed only that contracted/expanded traction could be observed when the prototype robotic endoscope was inserted into the small intestine of a pig (Figure 8.4).

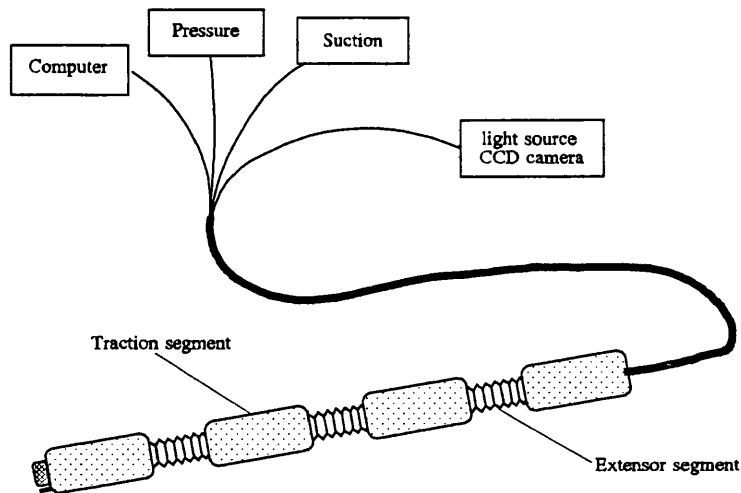


Figure 8.4 A robotic endoscope for accessing the intestines of human.

8.3. Study of the possibility of transmitting a video signal through tissue

This aims to provide a fundamental, theoretical basis for the design of the "wireless endoscope" which can navigate through the whole human gastrointestinal tract and transmit video images from inside the stomach. This would also make it possible to optimise the choice of radio frequency and electronic components such as the CCD camera and transmitter, etc. In the study, the different frequency bands have been considered and compared with regard to the dielectric properties of the tissues. A theoretical calculation has also been undertaken for calculating the free space propagation loss and propagation loss in tissues.

8.3.1. The propagation of radio waves

A starting point for considering the propagation of radio waves is the isotropic radiator, a point source radiating equally in all directions in free space. Such a radiator placed at the centre of a sphere illuminates equally the complete surface of the sphere. As the surface area of a sphere is given by $4\pi r^2$ where r is the radius of the sphere, the brilliance of illumination at any point on the surface varies inversely with the square of the distance from the radiator. In radio terms, the power density P_d (W/m^2) at distance r from the source is given by [121]:

$$P_d = \frac{P_t}{4 \pi r^2} \quad (5)$$

when r is sufficiently large to be in the far-field of the antenna, where P_t = transmitted power (W).

The received power (W) is:

$$P_r = P_d A_{eff} = \frac{P_t}{4 \pi r^2} \times \frac{\lambda^2}{4\pi} = \frac{P_t \lambda^2}{16 \pi^2 r^2} \quad (6)$$

where A_{eff} is the effective area of the receiving antenna.

$$A_{eff} = \frac{\lambda^2 G_r}{4 \pi} \quad (7)$$

Where G_r is the antenna gain.

8.3.2. Free space propagation loss

For a direct ray the power transfer between transmitting and receiving isotropic radiator is inversely proportional to the distance between them in wavelengths. The free space power loss is given by [121]:

$$\text{Free space loss (dB)} = 10 \log_{10} \frac{(4 \pi R)^2}{\lambda^2} \quad (8)$$

where R and λ are in metres, or:

$$\text{Free space loss (dB)} = 32.4 + 20 \times \log_{10} R + 20 \times \log_{10} f \quad (9)$$

where R = distance in km and f = frequency in MHz.

The free space power loss, therefore, increases as the square of the distance and the frequency. With practical antennas, the power gains of transmitting and receiving antennas, in dBi, must be subtracted from the free space loss calculated as above. Alternatively, the loss may be calculated by:

$$\text{Free space loss (dB)} = 10 \log_{10} \left[\frac{(4 \pi R)^2}{\lambda^2} \times \frac{1}{G_t \times G_r} \right] \quad (10)$$

where G_t and G_r are the respective actual gains, not in dB, of the transmitting and receiving antennas.

8.3.3. Propagation loss in tissue

When an RF signal is transmitted from inside the stomach, it propagates through several tissue layers including gastric mucosa, gastric muscle, abdominal wall muscle, fat and

skin. To simplify the analysis of the problem, an assumption is made to assume that this complex multi-layer tissue could be considered as a single-layer tissue behaving similarly to muscle, and therefore, the reflections of the waves between two adjacent layers are ignored.

The absorption of radio wave power will result in a progressive reduction of wave power density as the waves penetrate into the tissues. A calculation was made by defining a depth of penetration (the skin depth) $d = 1/\alpha$ or a distance that the propagating wave will travel before the power density decreases by a factor of e^{-2} . So, the transmitted power is given by:

$$P(x) = P_0 e^{-2\alpha x} = P_0 e^{-\frac{2x}{d}} \quad (11)$$

where α is the attenuation constant of the RF signal through the tissue, x is the thickness of the tissue.

The propagation loss in tissue (dB) can be derived according to the equation (5):

$$\text{Tissue loss (dB)} = 10 \log_{10} e^{-2\alpha x} \quad (12)$$

So, the total propagation losses (dB) of an RF signal propagated from inside the stomach should be the free space propagation loss (dB) + the tissue propagation loss (dB). The equation can be given by:

$$\text{Total propagation loss (dB)} = 10 \log_{10} \frac{(4\pi R_f^2)}{\lambda^2} + 10 \log_{10} e^{-2\alpha x} \quad (13)$$

Since the attenuation coefficient α in tissue is in general given by [122]:

$$\alpha = \omega \left[\frac{\mu \epsilon'}{2} (1 + \tan^2 \delta)^{1/2} - 1 \right]^{1/2} \quad (14)$$

where ω is angular frequency in rad/s, μ is the permeability of the tissue, ϵ' is the permittivity, δ is the loss angle. If α can be calculated, then the depth of penetration $d = 1/\alpha$ can be calculated, this leads to possibility of calculating the propagation loss in tissue (dB).

The results showed that when radio frequency increases from 100 MHz to 10 GHz, the penetration depth decreases from 51 cm to 3 cm. The propagation loss in tissue (dB) changes from 0.6 dB to 12 dB. The total losses (free space loss + tissue loss) change from 25 dB to 18 dB. It can be concluded that one should choose as lower frequency as possible for the carrier frequency. However, the wavelength of a lower frequency is longer than the one of a higher frequency. For example, if 100 MHz is chosen, the wavelength of this frequency is 3 metre. Considering the design of an antenna, the length of a dipole should be half the wavelength 1.5 m. If the frequency is chosen to be lower than 100 MHz, the wavelength is even longer. A compromise is therefore required in order to design a best transmitter for the wireless endoscope.

Given that the bandwidth of a colour video signal is about 8 MHz, it should be adequate to choose 100 MHz as the carrier frequency. However, It was found that most compact commercial video transmitters are using microwave frequencies. For example, the carrier frequency is 10.6 GHz, the depth of penetration is only 3 cm and the loss in tissue is about 12 dB.

In Equation (13), if tissue thickness (x) varies little, changing the distance between the transmitter and receiver (R) would determine the quality of transmission. When the distance between the transmitter and the receiver is about 1 metre, the total losses is about 40 dB.

8.4. The design of the wireless endoscope

In its simplest form, a "wireless endoscope" would comprise a miniature CCD camera, a transmitter, a light source, the batteries (Figure 8.5). The shape of the wireless endoscope should be small enough to be inserted into the gastrointestinal tract.

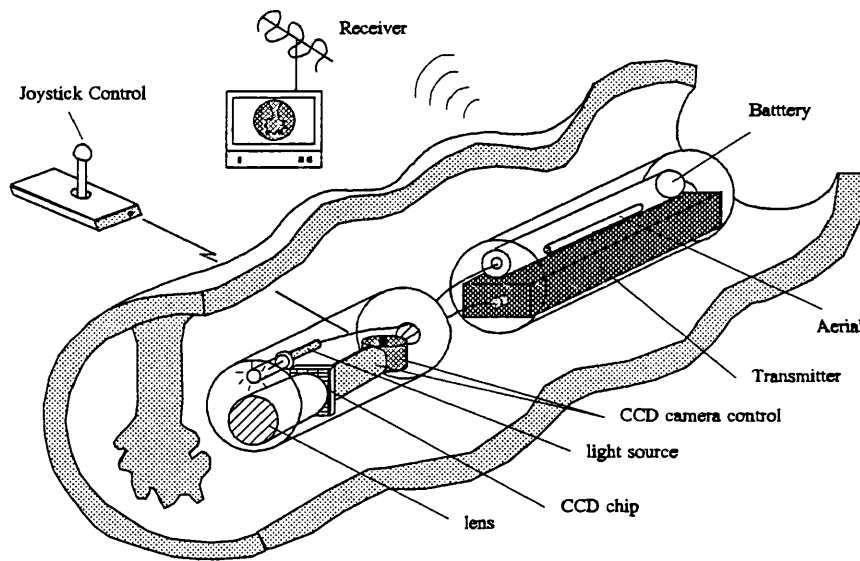


Figure 8.5 Schematic design of a wireless endoscope.

8.5. Results

8.5.1. Data acquisition of existing commercially electronics devices

Miniature CCD Cameras

Following the original description of the charge-coupled device (CCD) in 1970 [123] there have been steady improvements in pixel number density with consequent

reductions in size [124]. Careful design of the associated video-processor has also contributed to the commercial production of a number of very small cameras incorporating both CCD and video-processor [125]. The eight smallest commercially available miniature colour CCD cameras and three monochrome CCD cameras incorporating both charge-coupled device and processor that could be identified had the power requirements shown in Table 8.1.

Table 8.1 Dimensions and power requirements of miniature CCD Cameras

Type	Current (mA)	Voltage (V)	Power (W)	· Dim. (mm)
Sony XC-999P	292	12	3.5	22 x 22 x 50
Panasonic WVKS202	460	12	5.5	12 x 25.4
Panasonic WVKS152	500	12	6	17 x 37.8
Model CS6100	583	12	7	12 x 27.4
ELMO MP481	483	12	5.8	16 x 34
Peach (mono)	30	5	0.15	14 x 11.5 x 2.5
ELMO EM102	350	12	4.2	12 x 30
Wat-205A	270	6	1.6	22x23x75
Hitachi VKC27ES	276	12	3.3	20x30
Pulnix TM-4 (mono)	150	9	1.35	32x32x30
Wat-704R (mono)	100	9	0.9	18 x 50

Two colour CCD cameras with video-processors (Hitachi VKC27ES, Hitachi Corp. Tokyo, Japan; WAT-205A, Watec Co. Ltd, Yamagata-Ken, Japan) were chosen for their small size and low power consumption. Both were considered suitable for testing in the proposed application. Two monochrome CCD cameras with video-processors (Pulnix TM-4, Pulnix Co. Ltd, Japan; WAT-704R, Watec Co. Ltd, Yamagata-Ken, Japan) were

chosen for further consideration because of their very low power consumption. The power consumption of a colour CCD camera is about 4 times greater than a black and white camera assuming that they both have the same number of pixels.

Miniature transmitters

In the early stage, two small size colour video microwave transmitters (Miniature Microwave Link, OpTex, London, UK) with the lowest power consumption were chosen for testing, one with an umbrella shaped aerial and one without. Both operate at 10.6 GHz. The third microwave transmitter (AV Surveillance Co. Ltd, London, UK) for colour video transmission was identified and purchased later and used for prototype testing. It has a smaller size and operates at 1.57 GHz.

Table 8.2 Power output and dissipation of miniature microwave transmitters

Type	MIC/MVT/ 10/31	MIC/MVT/ 10/35	AV Sur. Tx
RF Output	10 mW	10 mW	10 mW
Vol.	12 V	12 V	9 V
Fre.	10.6 GHz	10.6 GHz	1.57 GHz
Power Con.	2.6 W	2.6 W	0.16 W

Light source

Halogen and small torch bulbs were examined and a miniature low power torch bulb (0.3 W, 3 mm diameter, 7 mm long) (MAG Instrument, Ontario, California, USA) which produced little heat was chosen for use in the prototype endoscopes. When supplied by 1.5 volts, it provided sufficient optical output to illuminate the wall of the gastrointestinal tract at close range.

Battery

A zinc-air cell has the greatest energy to volume ratio but requires an oxygen rich atmosphere which may not be present in the gut (Table 8.3). A lithium battery or silver oxide cell can also supply adequate energy but can operate *in vacuo* and can be hermetically sealed. In practice, two different lithium batteries (Energizer 2CR5, 6V; Sanyo CR2, 3V) were used for powering the prototype wireless endoscopes. An alkaline (AAA size, 1.5 V) battery was used for powering the miniature bulbs.

Table 8.3 Comparison of Energy/Size Ratios of Small Batteries

Type	Voltage (V)	E/S (J/mm ³)
Duracell alkaline MN1300-2400	1.5	1.57-1.67
Duracell alkaline MN9100, LR43-54	1.5	0.65-1.3
Varta alkaline MN1300-2400	1.5	0.86-1.35
Duracell silver oxide D357-391	1.5	1.19-1.51
Panasonic silver oxide SR43W-SR1120W	1.55	0.95-1.79
Duracell zinc-air DA13-675	1.4	2.02-3.53
Zinc-air DA13-675	1.4	2.57-4.49
UCAR zinc-chloride 1212-1250	1.5	0.59-0.76
Lithium-mang. dioxide 596	3	1.51-1.84
Duracell lithium mang. DL2016-2430	3	1.51-2.05
Lithium coin CR1220-2450	3	1.51-2.38
Nickel cadmium AAA, AA, C, D, N	1.25	0.22-0.36
Nickel cadmium button 591-168, 593-518	1.2	0.21-0.28

8.5.2. Power requirements

Power is needed at the very least for 3 functions: 1. to operate the camera, 2. to run the transmitter and 3. to illuminate the tissue. Using a Peach monochrome CCD camera

(0.15 W), continuous illumination with a halogen bulb light source (0.3 W), and a miniature microwave transmitter (0.16 W), a miniature lithium battery (7 mm in diameter, 30 mm long, 1870 Joules) will provide a wireless endoscope working time

$$t = \frac{\text{Battery capacity [Joules]}}{\text{Total power consumption [Watts]}}$$

$$= \frac{1870}{0.15 \text{ (CCD)} + 0.16 \text{ (Transmitter)} + 0.3 \text{ (Lamp)}}$$

$$= 3066 \text{ seconds} = 52 \text{ minutes}$$

Using a colour CCD camera (i.e. Wat-205A, 1.62 W), the endoscope working time would be 17 minutes. It was calculated that the same battery could provide only 100 CCD video frames using illumination by 20 mJ flashes from a miniature xenon flash lamp.

8.5.3. Construction of prototypes

Four prototype wireless endoscopes comprising a video camera, light sources and transmitter were constructed and tested. The first and second were constructed using a black and white CCD camera (Pulnix TM4) and a colour CCD camera (Hitachi VKC27ES). These were used to test feasibility and principles of image transmission through tissue. A third prototype was constructed using a colour CCD camera (Watec 205A). The fourth prototype was constructed using a black and white CCD camera (Watec 704E). The third and fourth prototypes were used in all the tests for transmission through post-mortem stomach and through the human body.

8.5.4. Testing these prototype wireless endoscopes

Transmission through postmortem gastric tissue

The microwave transmitters and prototype wireless endoscopes were wrapped in post mortem gastric tissue to check on transmission characteristics. A receiver without special aerial augmentation was used to receive the signal and pass it to a monitor. This was positioned 50 cm from the transmitter. High quality moving colour television signals were received. This test demonstrated that transgastric transmission was feasible. It also demonstrated that methods had to be devised to distance the tissue from the camera. If the tissue came in contact with the camera lens or pinhole, or overlay the light source, no image would be received or transmitted. A simple interim solution was achieved by using a hemi-spherical cage placed over the front of the camera for most experiments. In another experiment, the camera, transmitter and light source were placed in a transparent plastic casing so that the tissue was held at least 1.5 cm distance from the tissue.

8.5.5. Live transmission of colour television images from pig stomach at surgery.

Surgical implantation of a wireless endoscope

A prototype wireless endoscope comprising camera, light source, microwave transmitter and battery in a transparent container was inserted at surgery into the stomachs of anaesthetized white pigs of 145 and 150 kg on two occasions via an anterior abdominal wall incision and gastrotomy. The gastrotomy and anterior abdominal wall were then closed. Using receiving aerial augmentation with a parabolic horn aerial good quality colour television images were received showing detail of the stomach wall and contractions of the pylorus. The camera was removed surgically after the experiment.

8.6 Methods of propulsion for the wireless endoscope

8.6.1 A pneumatic method of propulsion

Some consideration was given to developing a method of propelling a wireless endoscope. One possible system was devised and constructed in a prototype form. This method is to link two rigid parts of the wireless endoscope with a double layered rubber tube. The inner layer is softer than the out layer. This confines the radial increase/decrease of the soft part when inflated, and the change in the total length of the wireless endoscope will be significant. On each of the tubular parts, a cavity is needed. A three-channel suction pipe is needed to provide pneumatic capacity in order to drive the wireless endoscope forwards/backwards and even rotation.

This mechanism works as follows:

The soft part C is inflated through the three-channel tubing to increase the length of the wireless endoscope. Switching on the suction channel linked to the suction cavity in part A, the tissue will be sucked into the cavity and this will hold part A without moving back. Releasing the pressure in part C, the soft part will be contracted, this will drag part B forward. Switching on the suction channel linked to the suction cavity in part B, the tissue will be sucked into the cavity and this will hold part B without allowing it to move back. Releasing the suction in part A and inflating part C, the tissue will be dropped from the cavity in part A, and part A will be pushed forward. Repeating the above procedures, the wireless endoscope can be driven either forwards or backwards. If more than three-channel suction pipe tubing can be introduced, and there are 3 or 4 cavities in each part A and B, rotation of the endoscope can be achieved. One limitation to this design is that a multi-channel suction pipe is needed for the propulsion (Figure 8.6).

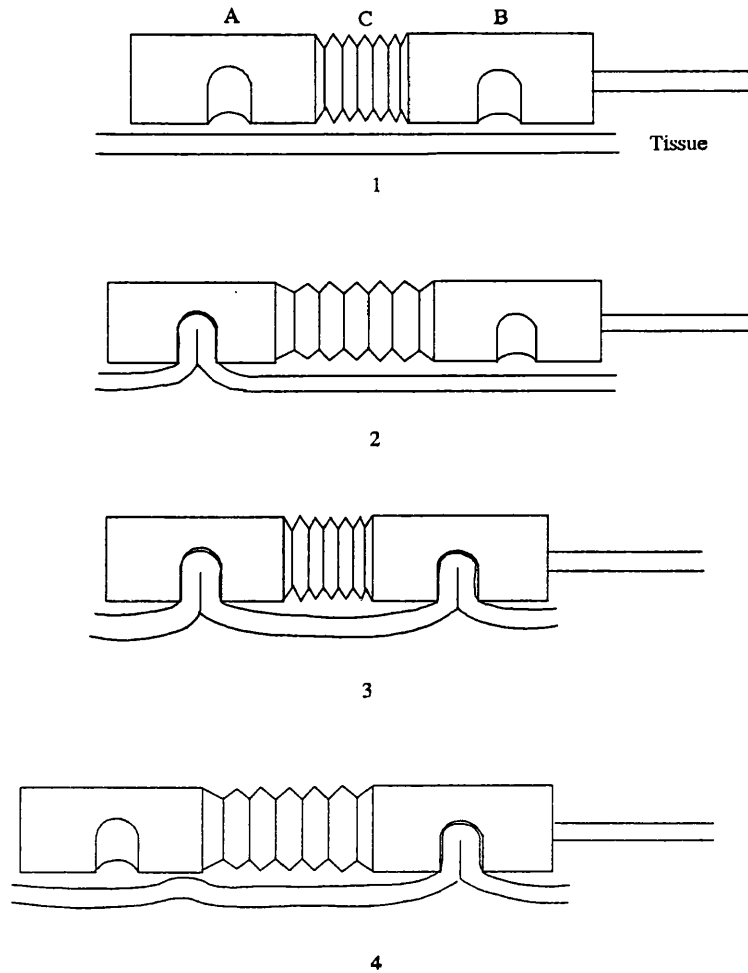


Figure 8.6 The propulsion mechanism.

8.6.2. Other options

1. The wireless endoscope might be controlled by a rotating external magnetic field without requiring an internal power source for movement.
2. The FMA can be added as the legs for the wireless endoscope walking in the GI tract.
3. So called " Intelligent gels" [126,127] which expand or contract by varying the electrical field might be used for altering the direction of the wireless endoscope

or moving it.

8.7. Discussion

The calculations of energy-to-size ratios using best available small battery performance suggest that a combination of existing technologies in miniature transmission and video endoscopy could make it possible to build a swallowable, simple wireless endoscope featuring a battery-powered CCD camera, light-source, and transmitter giving a continuous 52 minutes monochrome moving image of the gut or a continuous 17 minutes colour moving image of the gut. The power requirements of more complex endoscopes with robotic movements are likely to demand thin flexible cables for power and control until new technical advances allow them to walk free. These machines are likely to be first tested in GI organs, the largest endoscopable part of the human body.

CONCLUDING REMARKS

The purpose of the work described in this thesis was to research and develop new surgical methods and instrumentation deliverable using flexible endoscopes. Firstly, endoscopic mechanical methods for treating gastrointestinal bleeding were explored. This involved the design and development of new, improved endoscopic surgical clips and novel single-stitch and multiple-stitch endoscopic sewing machines.

The performance of the new methods was assessed using bench models and animal experiments. In the case of the single-stitch endoscopic sewing machine, tests were made on more than 70 patients; it was also used to treat gastro-oesophageal reflux disease (GORD). The new surgical clips, when compared with the Olympus MD clips that were the only endoscopic clips commercially available, performed very much better in respect of the size of vessel that could be successfully occluded and the ease with which they could be delivered to the bleeding site. The newly developed endoscopic single-stitch sewing machine was not used to treat gastrointestinal bleeding, but of the 70 patients treated for GORD, all showed symptomatic relief one year following the treatment. It remained to be seen whether the improvement was permanent.

Development of the endoscopic sewing machines necessitated the parallel development of new methods of handling thread at flexible endoscopy. Devices and methods were developed for tying knots and cutting thread at the distal end of flexible endoscopes. These methods were used successfully in more than 80 patients, not just in conjunction with the endoscopic sewing machine but also for securing feeding tubes to the stomach walls of neurologically compromised patients. They were also used to secure pH sensing

radiotelemetry capsules to the stomach walls of 2 patients suffering refractory epilepsy and 1 volunteer. In the volunteer, the capsule remained in place for 159 days after which time it was removed endoscopically using the Olympus suture-cutting forceps. The new thread handling methods were also used successfully to secure stents in the oesophagi of patients with oesophageal strictures and fistulae.

Two multiple-stitch endoscopic sewing machines were developed in the course of this work. One machine made use of a hook catch mechanism, the other a hollow needle and threaded shuttle. Preliminary bench tests and animal experiments showed the hook catch mechanism to be unsatisfactory, whilst the hollow needle and shuttle mechanism, though successful some of the time, required further refinements and improvements to reliability. Unfortunately, there was insufficient time available to pursue this further.

In a preliminary study, a series of experiments was conducted to determine the best choice of needle to use in the endoscopic sewing machines and the optimal shape and size of their suction cavities. A hollow needle was found to penetrate gastrointestinal tissue as readily as a conventional sewing machine needle of the same diameter, and, given the eventual choice of catch mechanisms, was chosen for use in the machines. To explore the benefits of adding mass to the needle and moving the needle at speed, an experimental jig based on a pendulum was constructed. An important result of this work was that successful tissue penetration was largely determined by the momentum of the needle. Whilst it would have been possible to use a spring-loaded mechanism to accelerate the needle at the distal end of the endoscope, the simpler and inherently more reliable method of using a Bowden cable to simply press the needle through the tissue was employed in the endoscopic sewing machines. The preliminary study also showed

that an L-shaped suction cavity evacuated via judiciously positioned suction pipes produced the maximum length of stitch. Furthermore, it was shown that the endoscopist's view of the target tissue and the placement of stitches were disturbed least by mounting the sewing machines away from the longitudinal axis of the endoscope.

As a final part of the project, a study was conducted into the feasibility of constructing a miniature robotic endoscope that would transmit images from inside the gastrointestinal tract without any physical connection to the outside world i.e. without passing electrical or optical cables through the mouth or anus. To this end, a detailed study was made of commercially available, miniature CCD video cameras, radio transmitters, possible propulsion mechanisms and batteries. A number of experimental, radio-transmitting, video endoscopes were constructed and tested using post mortem gastric tissues and the stomachs of two anaesthetised pigs from which high quality, colour video images could be received. It was concluded that such a system was feasible, though further improvements in component miniaturisation and power consumption would be required before this radically new, potentially very useful form of endoscopy could be realised clinically.

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STATEMENT OF ORIGINALITY

Because this project has been a group effort, I thought it would be helpful to indicate the areas in which the work included in this thesis is original and is the sole result of my endeavour.

I was involved in the design, development and testing of the single-stitch sewing machine which is the device that has been most extensively tested in patients. I carried out all the experimental studies on cavity size and vision improvement. I was involved in many of the studies that lead to improvements in performance of these machines including material choice and analysis of machine design faults and their subsequent improvement. Handle design, optimizing wire wound cables and pushing rods as well as empirical studies on needle length and movement were studied by me. I have assisted and tied knots at almost all the experimental and clinical studies using the endoscopic sewing machine.

I was involved in the design and construction of new multiple-stitch sewing machines. I carried out the experimental studies of knot tying, have originated new improved methods for knot tying. I have assisted in almost all the experimental and clinical studies of knot tying at flexible endoscopy. I originated a new method for cutting thread at endoscopy which has now been adopted as the commonest method for cutting thread at flexible endoscopy. The new clips were designed and constructed and tested by me. I constructed the first wireless endoscope and was involved in its testing. The pneumatic/suction method of propelling an endoscope was an original idea of mine.

APPENDIX

LIST OF PUBLICATIONS ARISING FROM THIS WORK

PAPERS:

1. Hepworth CC, Kadiramanathan SS, Gong F, Swain CP.

A randomised controlled comparison of injection, thermal and mechanical endoscopic methods of haemostasis on mesenteric vessels.

Gut 1998;42:462-469.

2. Gong F, Swain CP, Kadiramanathan SS, Hepworth C, Laufer J, Shelton J, Mills TN.

Cutting thread at flexible endoscopy.

Gastrointestinal Endoscopy. 1996;44:667-674.

3. Kadiramanathan SS, Evans DF, Gong F, Yazaki E, Scott M, Swain CP.

Antireflux operations at flexible endoscopy using endoluminal stitching techniques: an experimental study.

Gastrointestinal Endoscopy. 1996;44(2):133-43.

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Knot Tying At Flexible endoscopy.

Gastrointestinal Endoscopy. 1994;40:722-9.

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An Endoscopically Deliverable Tissue Transfixing Device For Securing Biosensors in The Gastrointestinal Tract.

Gastrointestinal Endoscopy. 1994;40:730-4.

ABSTRACTS:

1. Gong F, Mills TN, Hepworth C, Swain P.

A Comparison Of Clipping Methods For Endoscopic Haemostasis.

Endoscopy. 1997;29:E61.

2. Swain CP, Kadirkamanathan SS, Gong F, Evans DF.

Endoscopic Gastroplasty For Gastro-oesophageal Reflux Disease.

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An Endorobot For Gastrointestinal Endoscopy.

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An "Endorobot" - An Endoscope Which Might Navigate And Inspect The Full Length Of The Gastrointestinal Tract.

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Knot tying at Flexible Endoscopy.

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6. Kadirkamanathan SS, Evans DF, Brown G, Gong F, Scott M, Yazaki E, Swain CP.

Endoscopic Gastroplasty and Anterior Gastropexy for Gastro-Oesophageal Reflux Disease.

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Knot Tying at Flexible Endoscopy.

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Knot Tying At Flexible Endoscopy.

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Development Of Less Invasive Operations For Gastro-Oesophageal Reflux.

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11. Kadiramanathan SS, Swain CP, Gong F, Evans DF, Yazaki E, Scott M

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Minimally Invasive Therapy 1993;2(1):32

12. Swain CP, Kadiramanathan SS, Evans DF, Brown G, Gong F, Scott M, Yazaki E,

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Comparison Of Endoscopic Mechanical And Injection Methods Of Haemostasis On Mesenteric Vessels.

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14. Swain CP, Kadiramanathan SS, Brown G, Gong F, Evans DF, Mills TN.

Sewing At Flexible Endoscopy In Human Gastrointestinal Tract.

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Gut. 1994;35:S79-F315

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Comparison of Endoscopic, Mechanical and Injection Methods of Haemostasis on Mesenteric Vessels.

Gastroenterology 1994;106:A237

18. Kadiramanathan SS, Hepworth CC, Laufer JG, Gong F, Swain CP.

Cutting Threads At Flexible endoscopy.

Gut. 1994;35:S80-F317

19. Swain CP, Kadiramanathan SS, Brown G, Gong F, Evans DF, Mills TN.

Sewing At Flexible Endoscopy In Human Gastrointestinal Tract.

Gastrointestinal Endoscopy. 1994;40(2/2):P35

LIST OF PATENTS RELATING TO THIS WORK

1. Sewing Device

PCT/GB95/00652 (WO 95/25468)

EP 95912339.9 (pending)

US Patent Number 5792153 (11/08/98)

JP (number not assigned) (designated)

2. Knot Pushing Devices - Device For Use In Tying Knots

PCT/GB93/01859 (WO 94/05220)

EP 93919495.7 (pending)

US 08/397,152 (designated)

JP 506989/94 (designated)

3. Device For Use In Cutting Threads

PCT/GB95/00653 (WO 95/25470)

EP 95912340.7 (pending)

US Patent No. 5755730 (26/05/98)

JP (number not assigned) (designated)

4. Thread Securing Devices - Device For Securing Threads

PCT/GB93/1860 (WO 94/05218)

EP 93919496.5 (pending)

US 08/397,156 (designated)

JP 506990/94 (designated)

5. Control Handle For Endoscopic Sewing Device

US Patent Application (pending and filed April 14, 1997)

6. Imaging Apparatus

International Patent Application No. PCT/GB97/02523 (pending)

7. Surgical clip

UK Patent Application No. 9722203.8 (pending)

International Patent Application (pending)