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Future Trends in Endoscopic Suturing

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This paper deals with future aspects and developments in endoscopic sutures, needles, needle drivers, and sewing devices. Shape memory alloys such as superelastic nickel-titanium can be used for surgical needles and hingeless needle drivers. A sewing device consists of a T-Needle which can be shuttled between the jaws of specially designed instruments. The jaws possess small elements that grip the needle tips. The "Needle Rotor" facilitates intracorporeal swivelling and positioning of the needle because one jaw can be moved longitudinally over the other. A new "cutting knot pusher" permits immediate cutting of a slip knot subsequent to tightening.

Keywords: Endoscopic Suturing, Shape Memory Alloy, Superelastic Nitinol, Instruments

Introduction

Endoscopic surgical manipulations are physically limited (see *M. M. Lirici* in this issue). The relatively invariant point of insertion (IPI) of the cannula in the abdominal or thoracic wall leads to a geometrically defined endoscopic operating field. This space can virtually be seen as two hollow inverted cones. The central axis is created by the rigid cannula and the shaft of the instrument (Figure 1).

Thus defined, the area in which the instrument can be manoeuvred leads both to restriction of degrees of freedom and the necessity of conversion of all movements. For example, if the instrument tip is supposed to be directed upwards, the instrument grip needs to be moved correspondingly downwards due to the joint-like invariant point of insertion IPI. This mental conversion of movements requires some training. However, due to stiffness of the shaft, it permits adequate control of tip movements and facilitates positioning. Although a fully flexible instrument widens the operative field, manoeuvring is hampered due to lack of guidance of the invariant point of insertion IPI, so that converse positioning is nearly impossible.

Nevertheless, additional degrees of movements are required for needle positioning and tissue bites. Figure 2 illustrates the optimal degrees of movement. This is of considerable benefit, especially in case of instrument positions with an angle of less than 90°. As *Szabo* et al. have well described, an angle of approximately 90° is one of the important prerequisites for intracorporeal suturing and knotting (see *Z. Szabo* in this issue). Thus optimal choreography of forceps, needle, and needle driver is regulated both by the invariant point of insertion IPI and orientation of the tissue defect. The tissue defect, which has to be closed, however, is rarely in an optimal position, since the optimal angle of the edges relative to the instruments is only one of several possibilities. By grasping the tissue with the corresponding forceps the tissue can be correctly positioned depending on its elasticity. In open surgery, however, adequate guidance of the needle is achieved by motion of the hand, arm and finger joints. Additional features are tactile and force feedback, which protect tissue from unintended overstress. The correct eye-hand-coordination-axis and 3-D visualisation facilitate the manoeuvres.

Adequate needle repositioning is achieved by withdrawal of the needle driver and re-adjustment of the needle. In summary, four important physical problems occur during endoscopic suturing:

1. Unnatural hand-eye-co-ordination axis
2. Converted movements restricted by the relatively invariant point of insertion IPI
3. Limited degrees of freedom of instrument tip movements within the operative field
4. 2-D visualisation (3-D video is optionally available)

To overcome these physical limitations several technological solutions have been realised experimentally. The development has concentrated on knotting, needle design, needle holder function, tactile feedback, and dexterity. Our main projects are described in the following section.

Knot Pushers

Numerous knot pushers have been designed for endoscopy since the push rod was popularised by *Semm* in 1970. Most of the re-usable knot pushers have grooves, small terminal slits, or forks. All of them have a tendency to lose the thread when the knot is pushed down. All disposable pushers consist of simple plastic tubes. Although the loss of the thread is impossible, the insertion of a new thread through the rod is difficult.

A suitable reusable knot pusher should entail a concavity at its distal end to accommodate the knot in position. This permits an easy insertion of the thread and eliminates slipping. To provide a fast reproducible, safe cutting of the thread, an outer sleeve can be employed to cut the thread immediately after the tightening (Figure 3).

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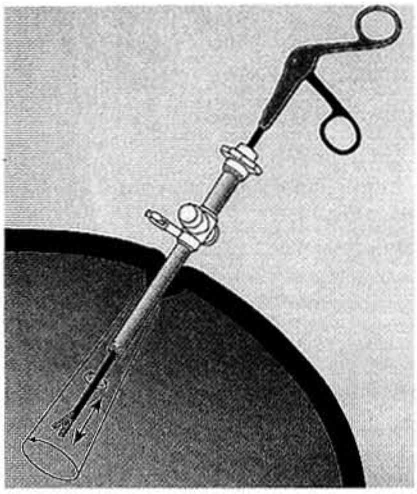


Figure 1: Schematic drawing of the defined endoscopic operative field. The invariant point of insertion IPI leads to conversion of movements from external to internal.

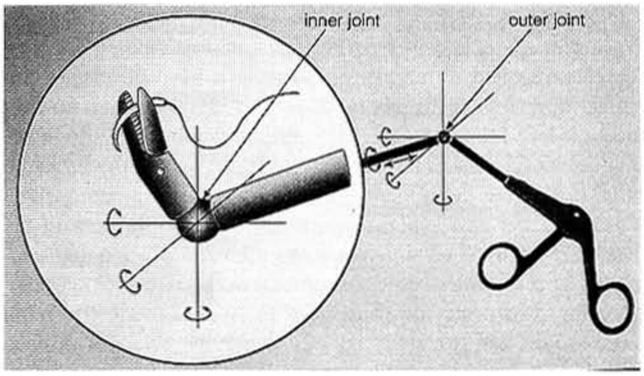


Figure 2: Illustration of optimal degrees of freedom for suturing purposes. All external movements should be transmitted to the distal end of the instrument.

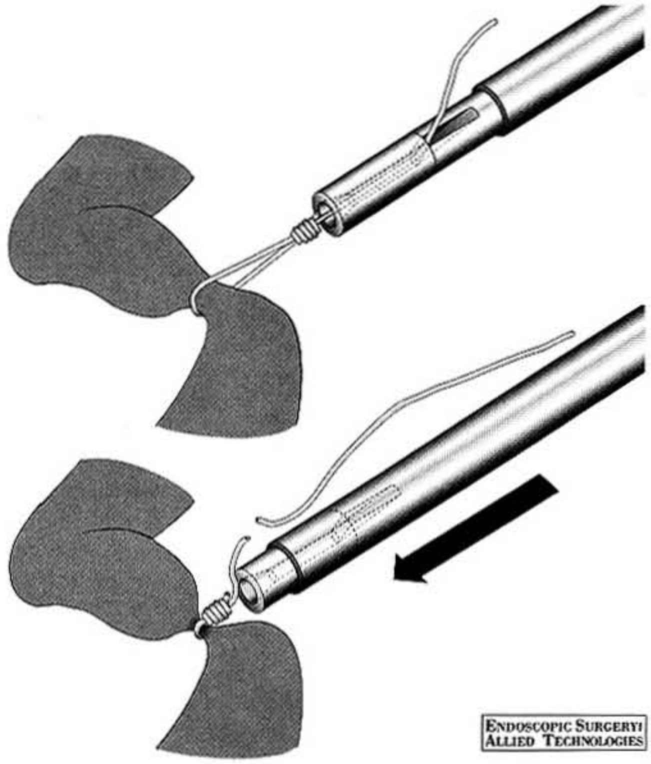


Figure 3: The "cutting knot pusher" entails an outer sleeve which permits exact cutting of the thread subsequent to pushing down and tightening of an external slip knot.

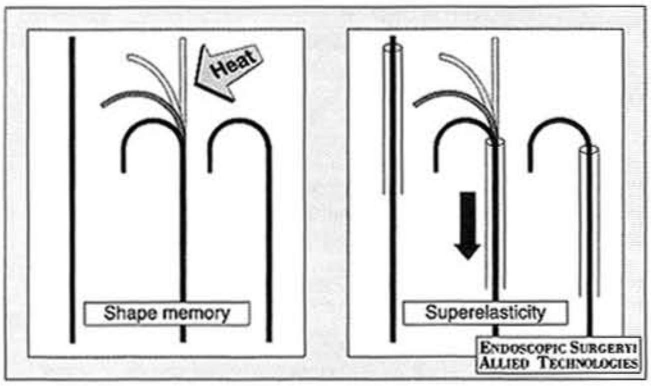


Figure 4: Thermoelastic phase transformation of shape memory alloy. Stress induced transformation leads to superelasticity and heating above a certain temperature to recovery of a previous shape.

Recently introduced knot pushing forceps permit pushing down of single throws of the classic surgical knot. However, this is delicate, and tension on the first knot is not easy to maintain.

Improvement of Conventional Needles and Drivers

In collaboration with Nitinol Devices and Components, Inc., Fremont, CA, we are currently evaluating the application of shape memory alloys such as Nickel-Titanium for endoscopic surgical needles and needle drivers.

The first prototypes make use of the superelasticity of Nickel-Titanium alloys. These alloys were originally developed by the Naval Ordinance Laboratory (Nitinol) and subsequently by Raychem Corp., Menlo Park, CA, for the use as hydraulic couplings in fighter aircraft. Shape memory alloys feature two closely related effects: thermal shape memory and superelasticity (Figure 4).

The term "superelasticity" is used to describe the property of certain Nitinol alloys to return to their original shape upon unloading after a substantial deformation. Nitinol alloys can be strained ten times more than ordinary spring materials without being plastically deformed. This unusual large elasticity is also called pseudoelasticity, because the mechanism is non conventional in nature, or transformational superelasticity because it is caused by a stress induced phase transformation. Alloys that show superelasticity undergo a thermoelastic martensitic transformation which is also the prerequisite for the shape memory effect. While superelastic components recover elastically into their prestressed shape after being released from a constraining means, shape memory components recover a previous shape upon heating above a certain temperature (1,2).

The stress/strain characteristics of superelastic materials is distinctly different from conventional materials like spring steel. A plateau is reached at low stresses and large elastic strains can be

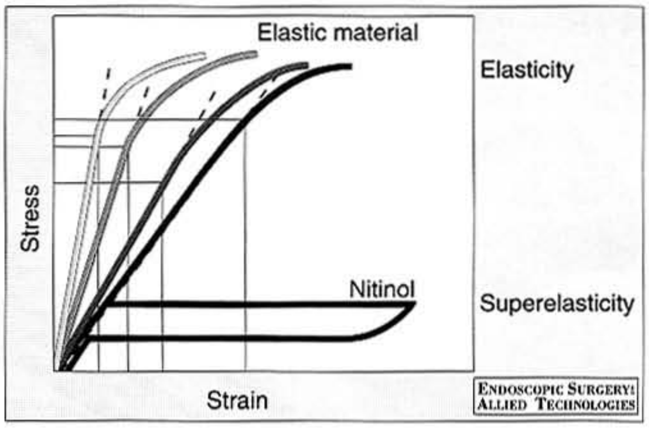


Figure 5: Schematic comparison of stress/strain of elastic and superelastic materials. While conventional materials allow approx. 2 % elastic strain, superelastic material permits 10 % deformation without significant permanent set.

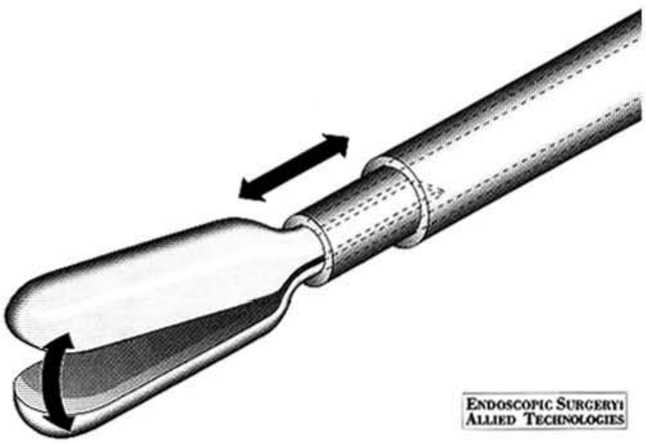


Figure 6: Schematic drawing of a new generation of hingeless needle drivers. The instrument consists of an intermediate tube which closes the two jaws by advancing the tube over the flexible parts of the jaws.

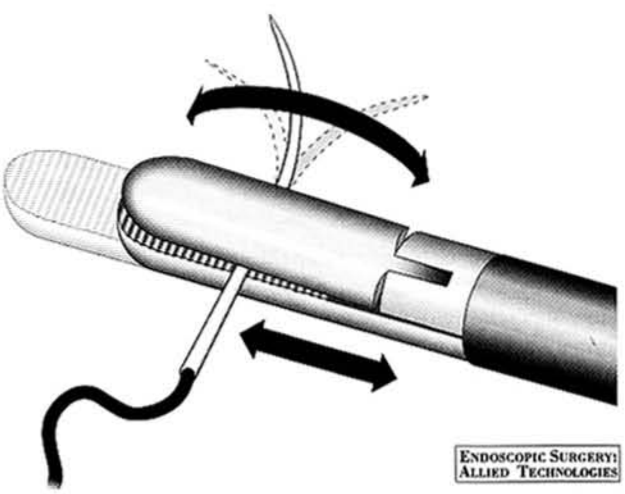


Figure 7: A new needle holder (Needle Rotor) allows movement of one jaw over the other for rotation of the needle.

accumulated with little stress increase (Figure **5**). This behavior allows promising new designs and functions of endoscopic suturing devices.

Surgical Needles

Surgical needles made from Nitinol resist irreversible kinking and give a "built-in indication" of the stress applied to tissue, since the needle continuously bends once a certain stress level is reached. The stress remains nearly constant for further bending of the needle, thus tissue damage can be avoided. This seems crucial in endoscopic sewing because the tactile feedback is very much reduced, so that optical perception is the only precise means of control. However, the needles require further experimental test and the delicate processing needs further development.

Needle Drivers

To improve needle driver performance and enhance the design for cleaning and durability purposes, we have developed so-called hingeless instruments (Jakoubek/PCI, Liptingen, Germany; NDC, Fremont, Ca). All hinges and bolts at the tip of the instrument have been replaced by a single part for the jaws and inner rod. The instrument uses an intermediate tube which closes the two jaws when slipped over the flexible parts of the jaws (Figure **6**). The superelasticity allows a precise and controlled grip of both needle and thread. In the first locking position, the thread can be grasped without destroying the inner structure, as this is usually the case when the suture is gripped with a conventional needle driver. The grasping of any suture with tungsten-reinforced holders may lead to severe damage to the suture, with subsequent breakage.

In the second locking position, a firm grip is achieved to maintain the needle position. The instrument can easily be disassembled and cleaned and the jaws element can be replaced if wear and tear occurs. Further tests and clinical trials are required to confirm the initial findings on hingeless needle drivers.

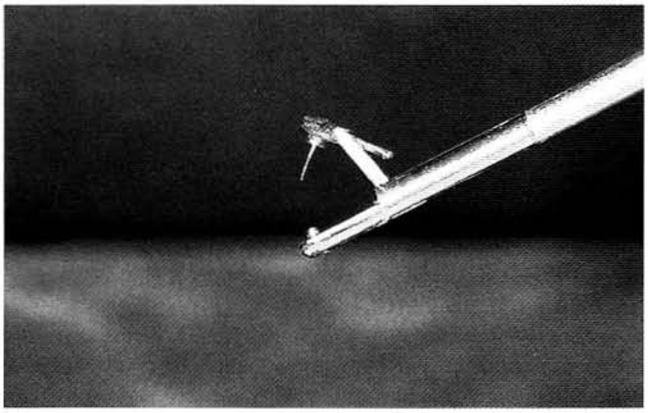
Needle Rotor

A new needle holder allows movement of one jaw over the other (Figure **7**).

This principle reveals some advantages in handling of the needle. The appropriate position of the needle can be achieved by moving the jaw in longitudinal direction. In combination with a specially-designed helical curved needle, the jaw movement results in rotation of the needle tip in the exact radius of its curvature.

Sewing Devices

The shuttle needle and applicator are practically a sewing machine. This device, developed in co-operation with the KFK, allows the transfer of a needle between two jaws, similar to a sewing shuttle employed in weave looms (Figure **8**).



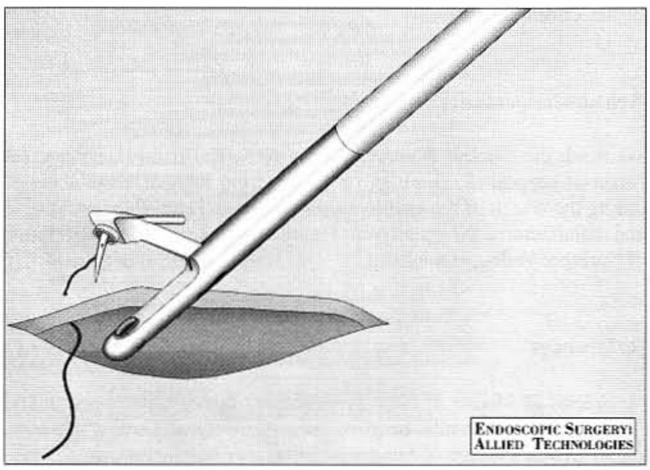


Figure 8 a, b: Illustration of suturing with the experimental "shuttle needle" device, developed in co-operation with the Nuclear Research Centre, Karlsruhe, Germany. The T-Needle can sequentially be transferred between the two jaws; thus the thread is transported through the tissue, and needle re-positioning is eliminated.

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 instrument 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 footswitch. 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. Different shapes and cross-sections of the needle and two transfer directions "vertical" and "axial" have been designed and tested in animals and as a result the shuttle needle facilitates laparoscopic and endoscopic suturing but its use requires training. The device is now undergoing further prototype tests and final product design.

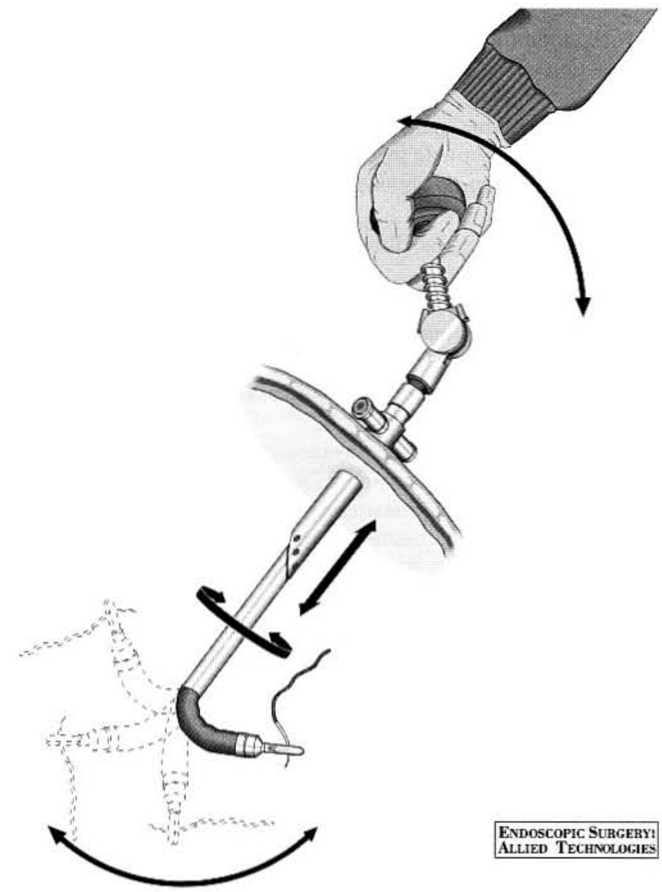


Figure 9 a, b: Endoscopic suturing by means of experimental dextrous instruments and needle drivers (developed in co-operation with the Nuclear Research Centre, Karlsruhe, Germany) permits the whole range of required needle positions relative to the tissue defect. However, adequate needle friction is difficult to achieve and the process requires considerable training.

Dextrous Needle Drivers

Aside from the improvement of endoscopic suturing instruments and the effector functions, the increase of the internal degrees of freedom has been a project of our research in cooperation with the KFK.

Our experimental work with steerable endoscopic instruments (3,4) has demonstrated the considerable advantages of additional internal instrument motions. The first prototypes are operated mechanically and enable the surgeon to manoeuvre the instrument tip in six degrees of freedom.

- Translation of the shaft along the longitudinal axis
- Rotation of the shaft in the longitudinal axis
- Two axes of movements within the invariant point of insertion
- Inclination of the tip approximately ± 180°
- Rotation of the tip 360°

In addition to experimental applications in phantom and animal operations, the steerable instruments were tested with regard to their suturing purposes in endoscopic surgery (4).

Advantages as well as disadvantages were found during the execution of sutures.

In contrast to rigid instruments, the needle can adequately be orientated relatively to the tissue defect (Figure **9**). However, handling is more delicate and requires some training.

Operating with two steerable instruments enables additional bite directions because positioning of the needle and tissue defect relative to each other is nearly optimal. However, passing the curved needle through tissue requires compensating movements because the rotation axis of the jaws is not congruent to the needle's rotation axis. Although these compensating movements are required for all rigid needle drivers, steerable instruments make suturing more difficult. Since the dexterity leads to various geometric configurations of the instruments, the handling requires more training than simply curved instruments. Once the surgeon is familiar with a specific curvature or angle of the shaft, he can perform correctly converted movements (5). If various curvatures occur during a manoeuvre, orientation problems increase.

Recent improvement of mechanically controlled dextrous devices includes integration of servo motors. This will enhance controllability of manoeuvres within the human body, since the surgeon has only to cope with buttons or switches to set the desired positions of the effector (tip of the instrument).

In advanced master-slave manipulators, the problem of continuous movements of all joints and links is solved by means of algorithmic transformation. All drives are activated with variable speeds to achieve a continuous and optimal movement of the effector.

Conclusion

Suturing plays an important role in endoscopic tissue approximation. Although stapling devices today have limited applicability, their performance is excellent, fast, and the result of clip sutures has been proven to be safe. There is no doubt that stapling devices enhance the scope of thoracoscopic and laparoscopic surgery (6). However, staplers are expensive and foreign non-absorbable material is left within the body. In advanced endoscopic procedures, interrupted as well as running sutures are often required. Thus, the surgeon must be familiar with endoscopic suturing and knotting. Hence, further development, experimental and clinical evaluation of needles, suture materials, drivers, holders, and sewing devices is an important task for the future to find the optimal procedure for endoscopic tissue connection.

Acknowledgements

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