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PERFORMANCE IMPROVEMENT OF SURGICAL INSTRUMENTATION THROUGH THE USE OF NITINOL MATERIALS

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ABSTRACT

Design considerations and material selection play important roles in the development of surgical instruments. The substitution of shape memory or superelastic Nitinol for conventional materials used in instrumentation for endoscopic and interventional procedures can lead to a significant improvement in overall performance of the instruments. Simplicity of design, reduced number of parts and ease of assembly and disassembly result in cost reductions. The paper describes examples of Nitinol instruments and accessories already on the market or in clinical evaluation

INTRODUCTION

Diagnosis and therapy in medicine have advanced considerably during recent years. Therapeutic procedures, in particular, show impressive results mainly in the area of minimally invasive, or key-hole surgery. The application of endoscopic procedures, catheterization and percutaneous interventions minimizes the trauma of access and pain with the same or, in many cases even better, therapeutic success rates.

Design of and material selection for devices and instruments for interventional procedures is dictated by considerations like reliability, safety, hygiene, functionality, biocompatibility, dimensions and, last not least, cost. The operating physician is asking for instruments which combine multi-functionality with ease of use and minimum size. The healthcare provider adds lowest cost to the list of requirements. Conventional instruments are either reusable, made from stainless steel precision crafted for highest performance and best feel, or disposable, made from plastics or combinations of plastic and stainless steel. The use of Nitinol, in particular superelastic Nitinol, allows the improvement of many instruments and devices by reducing the number of parts, simplifying assembly and improving the overall performance through the characteristic properties of the material.

INSTRUMENTS FOR ENDOSCOPIC PROCEDURES

Minimally invasive endoscopic surgery is intended to minimize the trauma of access and pain without compromising exposure of the operating field. In addition to avoiding large painful access wounds, the instruments used for dissection are small and fine, and thus the tissue trauma inherent to surgical dissection is reduced further. Other benefits include diminished cost of therapy due to a reduced hospital stay and accelerated recovery with early return to full activity. Over the past several years the number of endoscopic surgery procedures has grown explosively [1].

Endoscopic surgery involves several procedure types:

- Laparoscopic
- Thoracoscopic
- Endoluminal
- Perivisceral endoscopic
- Intra-articular

Among these approaches, the laparoscopic approach has been the most significant advance in general surgery in recent years [2].

Endoscopic surgery is characterized by the small size of a number of access ports, and requires specialized instruments capable of performing various tasks inside the body while making a gas-tight seal to the entry port into the body. Instruments available today are miniaturized versions of instruments used in conventional open surgery or are modified gynaecological instruments. Thus, compromises in performance have to be accepted. Forceps and scissors have hinged jaws, which limits miniaturisation. The opening gap of the jaws as well as their length is limited, making precise dissection difficult.

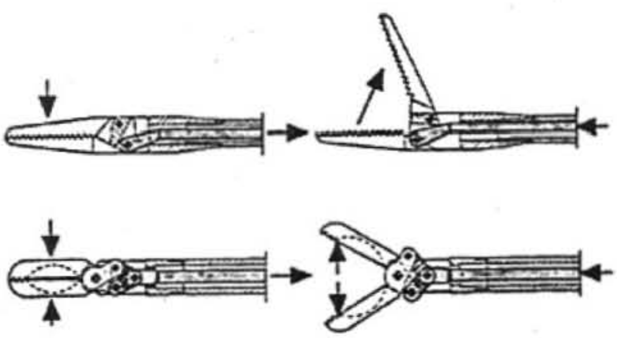


Figure 1 (left): Conventional design of hinged instrument tips [3]
Figure 2 (right): Dimensions of freedom of a conventional instrument [4]

Another problem with endoscopic surgery vs. open surgery is the reduced number of degrees of freedom for manipulation. Most laparoscopic instruments have two to three degrees of freedom [4]: translation (the movement of the instruments in the direction of their longitudinal axis), axial rotation (rotation of the instrument around its longitudinal axis) and relative rotation around the entry point. To overcome this problem, the instruments should be steerable or articulating.

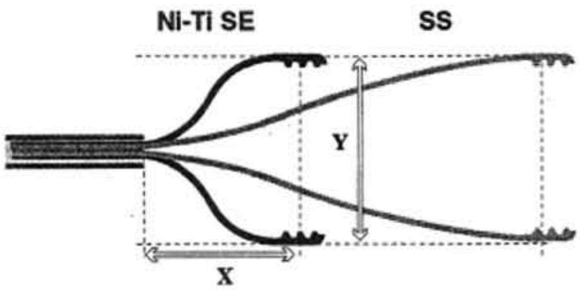
The requirement of perfect hygiene made disposable instruments very popular. However, single use instruments using plastic components for many functional parts, do not provide the exactness and repeatability of precision crafted steel instruments. Moreover, cost per procedure recently became a major issue. Although less expensive than a reusable instrument, cost per procedure can be much higher in the case of single use instruments. Reusable instruments, on the other hand, have to be cleaned and sterilized after each use. The more complex they are, the more difficult is the disassembly and reassembly for cleaning purposes.

New approaches have to be chosen in designing and producing instruments which overcome the problems associated with cost-effective, safe and reliable endoscopic procedures. By substituting steel parts in instruments with parts made from Nitinol, significant performance improvements can be achieved. Nitinol alloys provide a unique combination of properties, not found in any other material, which makes these alloys particularly interesting for medical applications:

- shape recovery (thermal or mechanical)
- extrem elasticity
- low deformation force/stress
- constant force over wide strain range
- high strength
- good ductility
- corrosion resistance
- biocompatibility
- excellent MRI visibility
- sufficient radioopacity

Hingeless Instruments

Conventional instrument development efforts have taken the form of miniaturization of mechanical linkages in hinged-type designs, resulting in highly complicated systems with many individual parts, which are difficult to assemble. Worldwide cost containement efforts favor the use of reusable or hybrid instruments, which have to be cleaned and sterilized after each use. As mentioned above, ease of assembly and disassembly, therefore, becomes an issue.



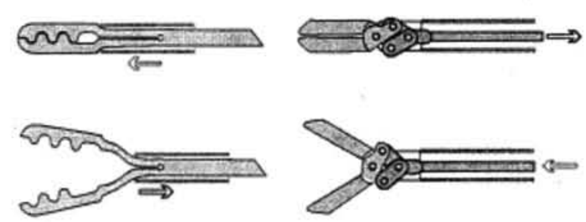


Figure 3 (left): Schematic performance comparison Nitinol vs. steel
Figure 4 (right): Hingeless vs. conventional instrument design

Hingeless instruments use the elasticity of spring materials instead of pivoting joints to open and close the jaws of grasping forceps or the blades of scissors. Because of their simple design without moving parts and hidden crevices, they are easier to clean and sterilize. The function of a hingeless instrument is illustrated in Figure 3. A new generation of hingeless instruments uses superelastic Nitinol for the actuating component of these instruments, which provides elasticity higher than stainless steel by at least a factor of 10. This results in an increased opening span and/or reduced displacement of the constraining tube for ergonomic handling (Figure 4). In many cases the functional tip can be a monolithic superelastic component, vs. multiple intricate, precision machined components and linkages of conventional instruments. This allows the design of instruments with very small profiles.

The non-linear stress/strain characteristics of Nitinol provides constant force gripping of large and small objects and built -in overload protection. This reduces the risk of tissue damage (Figure 5).

The unsophisticated design of the hingeless instruments allows a modular construction, consisting of merely three parts and a standard grip (Figure 6). Equipped with a quick-lock feature, disassembly and reassembly is simple and fast. All parts can be cleaned and sterilized. Moreover, they are exchangeable, if necessary. The technology can be used for disposable, reusable and hybrid instruments.

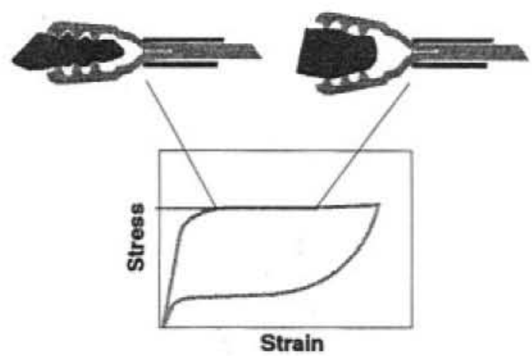


Figure 5: Constant force grasping and overload protection

Figure 6: Modular design of hingeless instruments

Articulating and Steerable Instruments

The concept of minimally invasive surgery is to enter the body with a minimum profile through small incisions with or without a portal, and then changing shape inside the body cavity. This can be accomplished with Nitinol alloys either thermally or elastically. A hook, for example, can be preformed using an alloy with Af between room temperature and body temperature. The hook is then deformed at room temperature into a straight configuration and introduced into the body. Through body heat the device will recover its original hooked shape. The same function can be achieved using a superelastic hook, and constraining it inside a straight cannula during insertion into the body. Once inside the body, the superelastic component is deployed from the constraining cannula and returns into its curved shape.

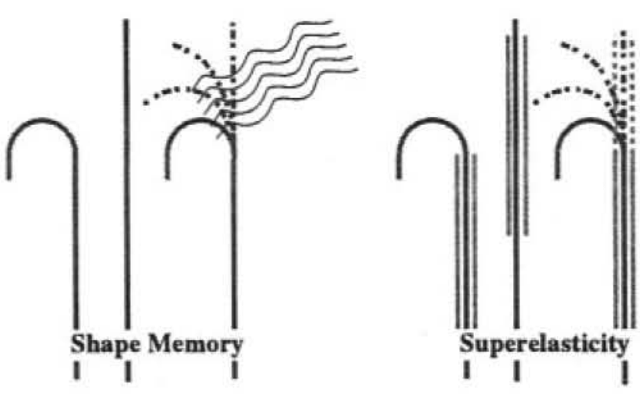


Figure 7: Shape memory vs. superelasticity

The concept of constraining a curved superelastic component inside a cannula during insertion into the body is used in a variety of instruments for minimally invasive surgery. Figure 8 shows a dissecting spatula, the curvature of which is increased by progressive extrusion of the superelastic blade. Different blade configurations are used for variable curvature suture and sling passers [5].

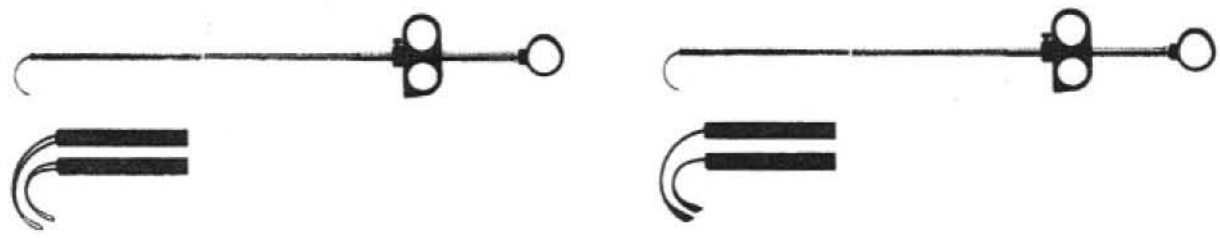
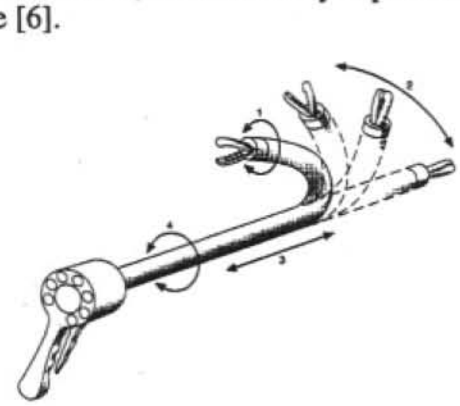


Figure 8: Variable curvature suture passer and dissector [5]

As mentioned earlier, a problem with endoscopic surgery vs. open surgery is the reduced number of degrees of freedom for manipulation. Steerable or at least deflectable instruments provide additional degrees of freedom. A system developed by the Center for Nuclear Research in Karlsruhe together with the University Hospital in Tübingen (Germany) adapts remote handling concepts used in robotics. The movements of the distal tip, which can be equipped with different functional heads, is achieved by superelastic Nitinol wires/rods controlled by a multifunctional handle [6].



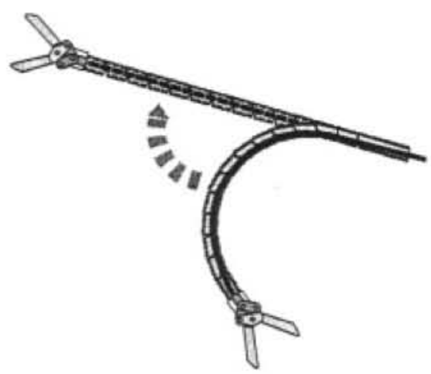


Figure 9 (left): Steerable instrument with superelastic Nitinol actuation rods [6]
Figure 10 (right): Articulating instrument with superelastic Nitinol actuation rods [7]

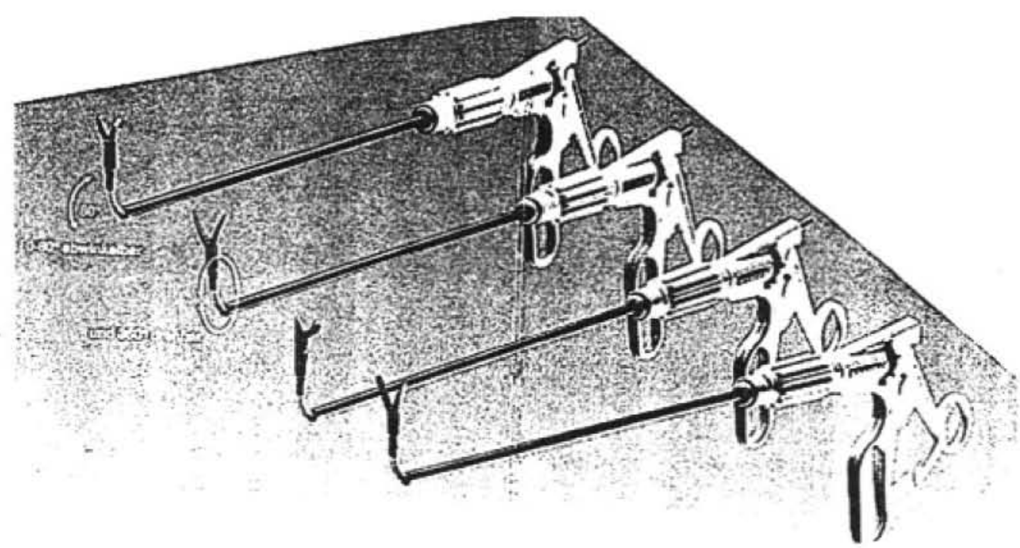
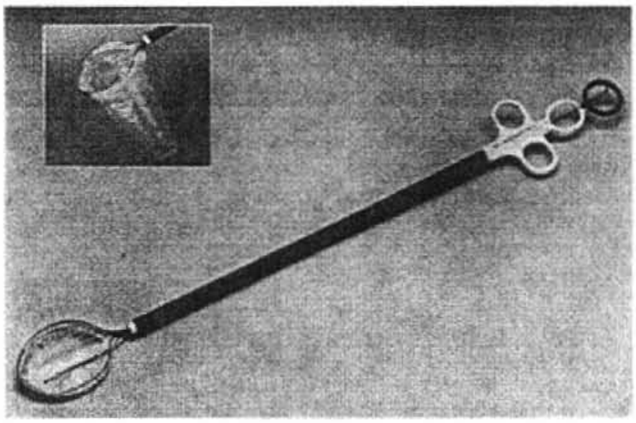


Figure 11: Articulating laparoscopic instruments with superelastic Nitinol deflecting tips [8]

A similar concept is used in the "Endoflex" devices. For steering and/or actuation, Nitinol rods are used instead of bowden cables or twisted cables, providing an inherent structural strength and stiffness when unstressed. They go around tight bends transmitting motion and/or force without being permanently deformed (Figure 10) [7].

Instruments with deflectable distal ends use curved superelastic components which are constrained in a cannula during insertion into the body and deployed once inside the body. Graspers, needle holders and scissors can be inserted through straight trocar cannulae. Once inside the peritoneal cavity, they can change into their curved configuration, thus increasing the degrees of freedom for manipulation (Figure 11) [8]. For the retrieval of diseased and dissected tissue, organs etc. bags are used, which are entered into the body through a port folded inside a cannula. Inside the body the bag is unfolded using a circular superelastic spring. Figure 12 shows a version of this device [8].



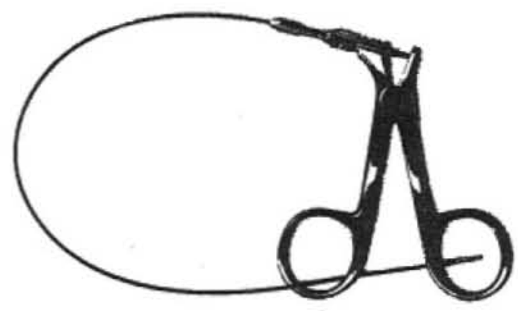


Figure 12 (left): Retrieval bag [8]
Figure 13 (right): Kink resistant biopsy forceps with superelastic tubular shaft

Kink Resitant Instruments

Instruments used in flexible endoscopy, like intraoperative choledochoscopy, gastroenterology or urology are usually rather long and thin. Made from thin-wall stainless steel tubing, they tend to kink easily. For certain procedures, they are expected to be flexible enough to withstand bending and allow torquing when maneuvered during the surgical procedure. Instruments for these purposes use stainless steel coils for the instrument shafts. However, coils do not provide a smooth surface for sealing in the endoscope. Moreover, they are very difficult to clean. Superelastic Nitinol tubes provide a smooth and sealable surface and are resistant to kinking.

INSTRUMENTS AND COMPONENTS FOR INTERVENTIONAL PROCEDURES

Superelastic Nitinol guidewires are increasingly used because of their extreme flexibility and kink resistance. They also show enhanced torquability (the ability to translate a twist at one end of the guidewire into a turn of nearly identical degree at the other end) [9], thus significantly improving steerability. The low force required for bending the wire is considered to cause less trauma than stainless steel guidewires. Short superelastic rods are also used as guide pins for guiding cannulated screws in orthopaedic surgical procedures.

Another application which utilizes the extreme elasticity of Nitinol materials very effectively is self-expanding stents for the treatment of stenosis of hollow organs or duct systems. The small profile of the compressed stent facilitates safe, atraumatic placement of the stent. After being released from the delivery system, the stent self-expands to over twice its compressed diameter and exerts a constant, gentle radial force on the vessel wall. In one specific configuration, the compressed stent is encased in gelatin, which begins to dissolve immediately after release from the delivery system [10]. Other systems use the shape memory effect of Nitinol to self-expand the stent after placement in the vessel. The material is treated to a transformation temperature Af of approx. 32°C, slightly below body temperature. For insertion, the stent is cooled in ice water, compressed and placed into the delivery catheter. It recovers through body heat after being released in the vessel [11].

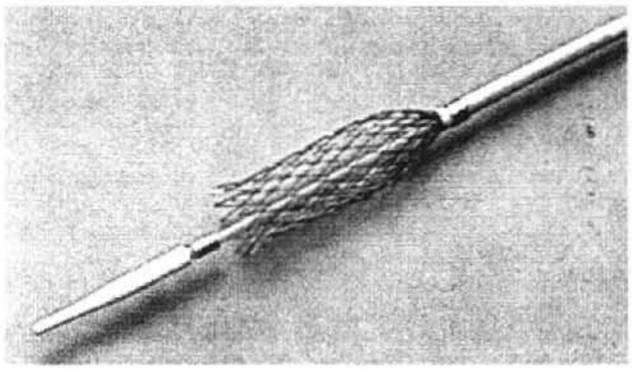


Figure 14 (left): Self-expanding Nitinol stent [11]
Figure 15 (right): Nitinol vena cava filter [12]

For the prevention of recurrent pulmonary embolism, a Nitinol filter is introduced into the vena cava. The umbrella shaped Simon Nitinol Filter traps emboli efficiently without adding significantly to blood flow turbulences. The filter is introduced percutaneously into the inferior vena cava through a catheter while cooled with an ice cooled saline infusion. Once released from the delivery system, it is warmed to body temperature, assuming its clot-trapping shape (Fig. 15) [12].

Kink resistance and steerability are the main reasons for using Nitinol in stone retrieval and fragmentation baskets [13]. The shaft as well as the basketwires can be made from superelastic Nitinol. Baskets are available with three to eight wires. The smaller the stone is, the more wires are needed to trap and hold it. Conversely, large stones will not be able to work their way between closely spaced wires [14].

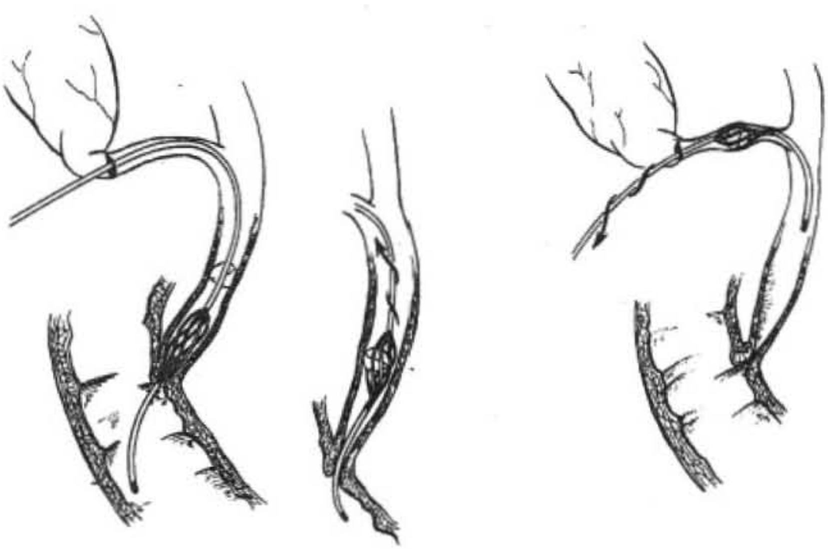


Figure 16: Stone retrieval with a basket [14]

In a new electrosurgical device for transurethral ablation of prostatic tissue, radiofrequency energy is delivered directly into the prostate via two side-deploying needles to reduce prostate hyperplasia. These needles, made from superelastic Nitinol, are deflected from the axis of the catheter around a sharp bend to be deployed radially through the urethral wall into the prostate tissue. After passing the guiding channel, they protrude straight out of the catheter tip [15].

Figure 17: TUNA catheter with Nitinol electrode needles [15]

One of the first instruments to use superelastic Nitinol was the Mammalok® needle wire localizer (Figure 18), used to locate and mark breast tumors so that subsequent surgery can be more exact and less invasive [16]. A hook shaped Ni-Ti wire straightens when it is pulled into a hollow needle. The needle is then inserted into the breast using a mammogram as a guide to the location of the lesion. At the right location the wire is pushed out of the needle, thereby deploying itself around the lesion. If the mammogram after placement shows that the needle was improperly positioned, the superelastic hook can be pulled back into the needle and repositioned. This done in radiology. The patient is then taken to the operating room for surgery.

Figure 18: Mammalok® needle wire localizer [16]

CONCLUSIONS

Nitinol alloys provide a unique combination of properties, not found in any other material, which makes these alloys particularly interesting for medical applications: shape recovery (thermal or mechanical), extrem elasticity, low deformation force/stress, constant force over wide strain range, high strength, good ductility, corrosion resistance, biocompatibility, good MRI visibility, and sufficient radioopacity. The use of superelastic or shape memory Nitinol alloys allows the design of instruments with fewer parts, simple construction and enhanced performance.

Hingeless instruments are easy to disassemble and reassemble for cleaning and sterilization. They provide a "physiologic feel" and built-in overload protection. The kink resistance of superelastic Nitinol is used in guidewires, baskets and long and thin instruments. Articulation, steerability and "deployability" is made possible with unsophisticated designs, thus increasing the number of degrees of freedom for manipulation during endoscopic procedures. The shape memory of Nitinol is effectively used in self-expanding stents and filters.

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