Using Shape Memory Alloys

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Design considerations and material selection play important roles in the development of surgical instruments for minimally-invasive procedures. Substituting shape-memory or superelastic metals or alloys for conventional materials can lead to a significant improvement in the overall performance of those instruments. In addition, simplicity of design, a reduced number of parts, and ease of assembly and disassembly result in cost reductions.

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Diagnosis and therapy in medicine have advanced considerably during recent years. In particular, therapeutic procedures 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, and produces therapeutic success rates that are similar to, or better than, conventional open-surgery methods.

The design of devices for interventional procedures, and the selection of materials for those devices, is dictated by considerations such as reliability, safety, hygiene, functionality, biocompatibility, physical dimensions, and cost. The operating physician requires instruments that combine multifunctionality with ease of use and minimum size. The health care provider adds lowest cost to the list of requirements. Conventional instruments are either reusable and made from stainless steel that is precision-crafted for optimum performance and handling, or disposable and made from plastics or combinations of plastic and stainless steel. The use of shape-memory alloys, in particular superelastic versions, allows many instruments and devices to be improved by reducing the number of parts, simplifying assembly, and improving overall performance through the characteristic properties of the materials.

Instruments for endoscopic procedures

Minimally-invasive endoscopic surgery is intended to reduce the trauma of access and pain without compromising exposure of the region of the body that is being operated on. In addition to avoiding large, painful access wounds, the instruments used for dissection are small and fine, and thus the tissue trauma inherent in surgical dissection is further reduced. Other benefits include reduced cost of therapy as a result of a shorter hospital stay and accelerated recovery and early return to full activity. The number of endoscopic surgical procedures has grown dramatically.[1] Endoscopic surgery involves several types of procedure: laparoscopic (via the abdominal wall), thoracoscopic (via the chest wall), endoluminal (through a tube), perivisceral endoscopic (via the intestine), and arthroscopic (via joints) procedures. Of

these, 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 (three to five in the case of laparoscropic cholecystectomy), and requires specialized instruments that are capable of performing tasks inside the body while maintaining a gas-tight seal with the entry port into the body. The instruments that are available today are miniaturized versions of instruments used in conventional open surgery, or are modified gynaecological instruments. Thus, compromises in performance are inevitable. Forceps and scissors have hinged jaws, which restricts miniaturization. The opening gap and length of the jaws is limited, making precise dissection difficult.

Another problem associated with endoscopic surgery is the reduced number of degrees of freedom for manipulation compared to open surgery. Most instruments have two or three degrees of freedom:[3] translation (the movement of the instrument in the direction of its longitudinal axis), axial rotation (rotation of the instrument round its longitudinal axis), and relative rotation around the entry point. To overcome this problem, the instruments should be steerable or articulated.

The requirement for perfect hygiene has made disposable instruments very popular. However, single-use instruments that use plastic components for many functional parts do not provide the exactness and repeatability of precision-crafted steel instruments. Moreover, cost per procedure has become a major issue. Although a single-use instrument is less expensive than a reusable one, the cost per procedure can be much higher in the case of single-use instruments. However, reusable instruments need to be cleaned and sterilized after each use. The more complex they are, the more difficult it is to disassemble and reassemble them for cleaning.

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

- shape recovery (thermal or mechanical)
- highly elastic (considerable expansion without permanent deformation)
- low elastic modulus (large strains with low stress)
- constant force over a wide strain range
- considerable strength
- good ductility
- corrosion resistance
- biocompatibility
- magnetic resonance imaging compatibility
- sufficient radiopacity.

Hingeless instruments

Development efforts for conventional instruments have taken the form of miniaturizing the mechanical linkages in hinged-type designs, and resulted in highly complicated systems, with many individual parts, that are difficult to assemble. Worldwide cost containment efforts favour the use of reusable or semi-reusable, or reposable, instruments that require cleaning and sterilization after each use. As mentioned above, ease of assembly and disassembly thus becomes an issue.

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, which contains no moving parts and hidden crevices, they are easier to clean and sterilize. A new generation of hingeless instruments uses superelastic alloys for the actuating component of these instruments to provide elasticity of at least one factor of 10 higher than stainless steel. This results in an increased opening span and/or reduced displacement of the constraining tube for ergonomic handling (see Figure 1). In many cases the functional tip can be a single superelastic component, as opposed to the multiple intricate, precision-machined components and linkages of conventional instruments. This allows the design of instruments with very small profiles.

The nonlinear stress/strain characteristics of shape-memory alloys provide constant-force gripping of large and small objects and built-in overload protection. This reduces the risk of tissue damage.

The unsophisticated design of hingeless instruments allows a modular construction that consists of merely three parts: a centre rod with integrated superelastic jaws/blades, a movable constraining tube, and an outer insulating sleeve; and a standard grip. Equipped with simple, quick-lock couplings, disassembly and reassembly is easy and fast and all parts can be cleaned and sterilized. Moreover, the parts are exchangeable, if necessary and the technology can be used for disposable, reusable, or reposable instruments.

Articulated and steerable instruments

The concept of minimally-invasive surgery requires instruments with a minimum profile to enter the body through small incisions with or without a portal, such as a trocar or cannula, and then change shape inside the body cavity. This can be accomplished thermally or elastically with shape-memory alloys. A hook, for example, can be preformed using an alloy with transformation temperature, Af, between room and body temperature. The hook is then deformed at room temperature into a straight configuration and introduced into the body. Body heat causes the device to 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 to its curved shape.

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. For example, the curvature of a dissecting spatula can be increased by progressive extrusion of the superelastic blade. Different blade configurations are used for variable curvature suture and sling passers (see Figure 2).[4]

As mentioned above, a problem with endoscopic surgery is the reduced number of degrees of freedom for manipulation, compared to open surgery. Deflectable instruments provide additional degrees of freedom. A system developed by the Karlsruhe Research Centre (Karlsruhe, Germany) and Tübingen University Hospital (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 alloy wires/rods controlled by a multifunctional handle (see Figure 3).[5]

A similar concept is used in commercially-available devices.[6] For steering and/or actuation, shape-memory alloy rods are used instead of Bowden or twisted cables, to provide an inherent structural strength and rigidity when unstressed. They navigate tight bends, transmitting motion and/or force without being permanently deformed.

Instruments with deflectable distal ends use curved superelastic components that are constrained in cannulae during insertion into the body and deployed once inside the body.[7] 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. Bags are used for the capture of diseased or dissected tissue or organs. They are folded inside a cannula and enter the body through a port; when in position, they are unfolded using a circular superelastic spring.

Kink-resistant instruments

Flexible endoscopy procedures such as intraoperative choledochoscopy (surgery via the gall bladder), gastroenterology, or urology frequently use long, thin instruments. Made from thin-wall stainless-steel tubing, these instruments tend to kink easily. For certain procedures, they are expected to be flexible enough to withstand bending and allow torquing (the ability to translate a twist at one end of the guidewire into a turn at the other end through almost the same number of degrees)[8] when manoeu-

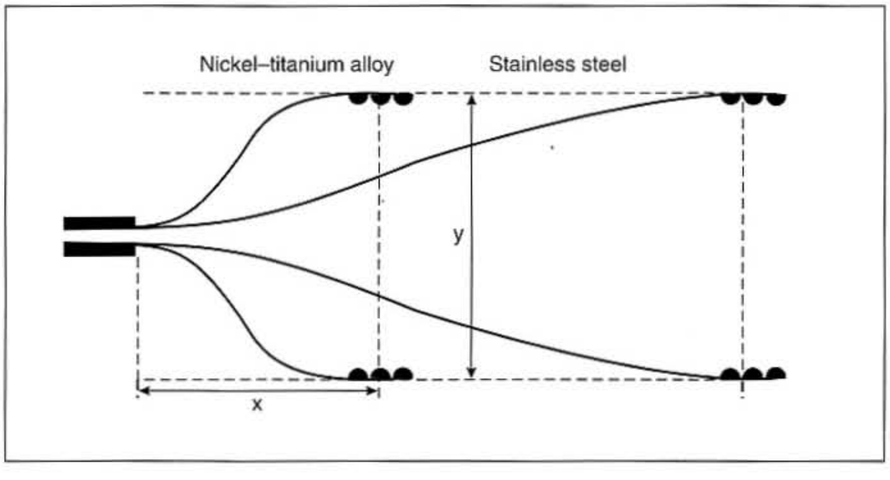

Figure 1: Performance comparison between a nickel–titanium superelastic alloy and stainless steel.

vred 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 and are difficult to clean. Superelastic alloy tubes provide a smooth and sealable surface and are resistant to kinking.

Devices for interventional procedures

Superelastic alloy guidewires are increasingly used because of their extreme flexibility and kink resistance. They also show enhanced torquability, thus significantly improving steerability. The low force required to bend 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.

Self-expanding stents for the treatment of stenosis of hollow organs or duct systems is another application that effectively utilizes the elasticity of shape-memory alloy materials. The small profile of the compressed stent facilitates safe, atraumatic placement. After being released from the delivery system, the stent self-expands to more than 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.[9] Other systems use the shape-memory effect of nickel–titanium alloys to self-expand the stent after placement in the vessel. The material is treated to a transformation temperature of approximately 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 the action of body heat after being released in the vessel.[10]

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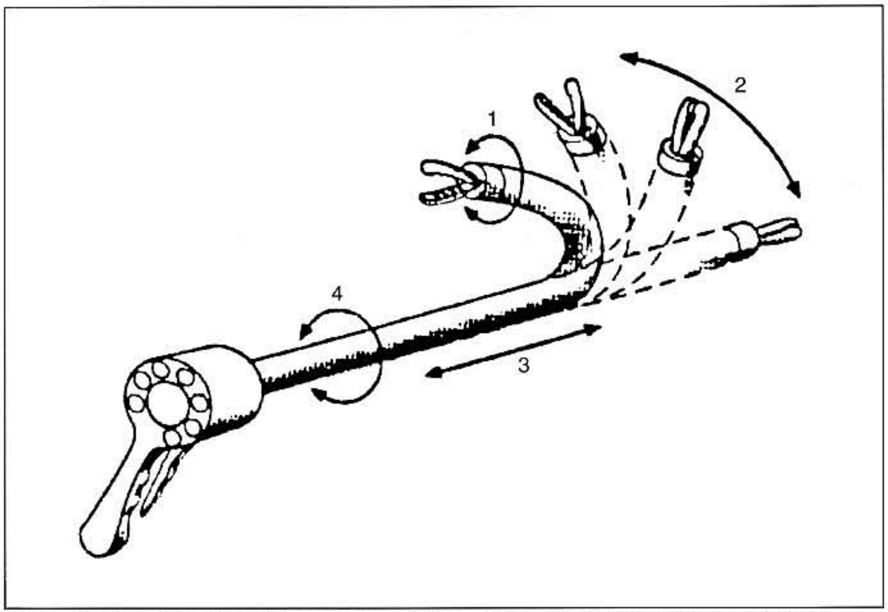

Figure 3: Steerable, shape-memory alloy instrument, showing its four degrees of freedom.

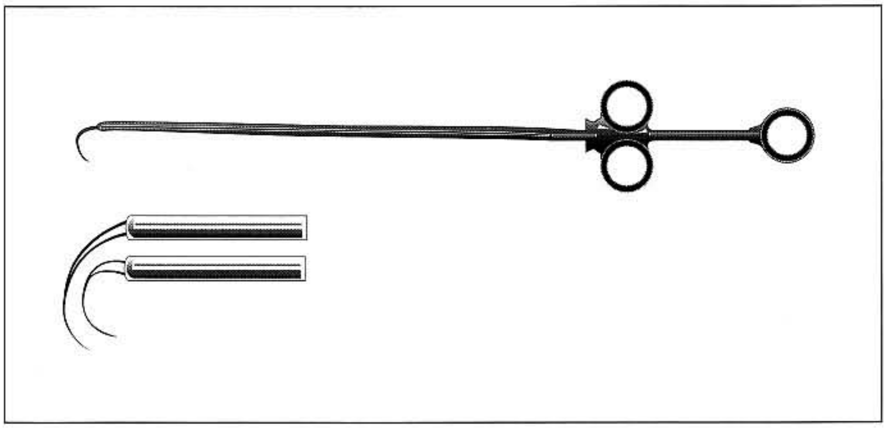

Figure 2: Variable curvature suture passer.

For the prevention of recurrent pulmonary embolism, a shape-memory alloy filter is introduced into the vena cava. The umbrella-shaped filter[11] traps emboli efficiently without adding significantly to blood flow turbulence. The filter is introduced percutaneously into the inferior vena cava through a catheter, while being cooled with an ice-cooled saline infusion. Once released from the delivery system, it is warmed to body temperature and assumes its clot-trapping shape (see Figure 4).

Kink resistance and steerability are the main reasons for using shape-memory alloys in stone retrieval and fragmentation baskets.[9] The shaft

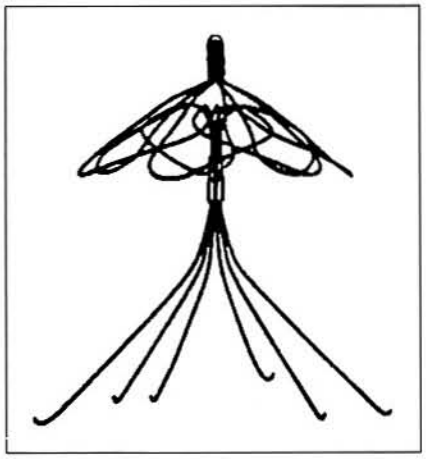

Figure 4: Shape-memory filter for treatment of pulmonary embolism.

and the basket wires can be made from superelastic alloys. Baskets are available with three to eight wires; the smaller the stone, the more wires are needed to trap and hold it.[12]

In an electrosurgical device for transurethral removal of prostatic tissue, radiofrequency energy is delivered directly into the prostate via two side-deploying needles, to reduce excessive cell formation in the prostate gland.[13] These needles, made from superelastic nickel-titanium alloys, are deflected from the axis of the catheter round a sharp bend, to be deployed radially through the urethral wall into the prostate tissue. After passing through the guiding channel, they protrude straight out of the catheter tip.

One of the first instruments to use superelastic alloys was the Mammalok needle-wire localizer (Mitek Surgical, Westwood, Massachussets, USA), which was used to locate and mark breast tumours so that subsequent surgery can be more exact and less invasive.[14] A hook-shaped nickel–titanium wire is straightened by being 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 correct location, the wire is pushed out of the needle, deploying it around the lesion. If, after placement, the mammogram shows that the needle was improperly positioned, the superelastic hook can be pulled back into the needle and repositioned. This is done in a radiology department. The patient is then taken to an operating room for surgery.

Conclusions

Shape-memory alloys provide a unique combination of properties, not found in any other material that makes them particularly interesting for medical applications. The use of superelastic or shape-memory alloys allows the design of instruments with fewer parts, simpler construction, and enhanced performance. Hingeless instruments are easy to disassemble and reassemble for cleaning and sterilization. They provide built-in overload protection. Articulation and deflection is made possible in unsophisticated designs, thus increasing the number of degrees of freedom for manipulation during endoscopic procedures.

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