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History and Current Situation of Shape Memory Alloys Devices for Minimally Invasive Surgery

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Abstract: Because of their unique mechanical properties and biocompatibility, shape memory alloys (SMAs) have found many applications in minimally invasive surgery (MIS). Many novel surgical devices have been developed based on SMAs, which have become essential tools for MIS. In this paper, the historical development of SMAs for MIS is reviewed, including devices for cardiovascular surgery, laparoscopic and endoscopic surgery, orthopaedic surgery and other minimally invasive procedures. Current trends of the SMAs technologies are identified and future directions are discussed with research opportunities of SMAs for the emerging minimally invasive or noninvasive surgical technologies.

Keywords: Shape memory alloys, minimally invasive surgery, cardiovascular surgery, laparoscopic surgery, orthopaedic surgery.

1. INTRODUCTION

Minimally invasive surgery (MIS) has been developed since the late 1980s, it has been regarded as one of the most important achievements in modern medicine. Laparoscopic cholecystectomy was the first minimally invasive procedure to be developed and widely accepted [1-3]. Since then, many minimally invasive techniques have been developed and gained widespread applications, they are now well established in surgery and routinely practiced, including cholecystectomy, Nissen fundoplication for gastro-oesophageal reflux disease, appendicectomy, adrenalectomy, splenectomy and many other advanced procedures.

Minimally invasive surgery offers great benefits to patients over conventional open surgery, the major benefits include reduced surgical trauma, reduced wound complications, shorter hospital stay, and accelerated recovery [4]. However, MIS is technically more demanding as compared with conventional surgery, because the surgical intervention is executed remotely via two-dimensional imaging of the operative field, with loss of tactile feedback, restricted maneuverability, and less efficient control of major bleeding [5].

The success of MIS was enabled by many technological breakthroughs, such as cold light source, flexible optical fibers and miniature video camera, particularly the Hopkins rod-lens endoscope [6, 7]. MIS is advanced in term of technology but is also technology-dependent. The requirements of minimal invasiveness have presented great technical challenges to surgeons and medical devices engineers as well.

MIS is performed within a close space through small access entries (5 or 10 mm), surgeon's hands are outside the operative field, and surgical manipulations are performed remotely under visual control of monitor screen. In contrast to the larger movement of human hand-arm coordination in open surgery, only 4 degrees of freedom are available to surgeons because of the long and slender instruments used in MIS [8]. All standard MIS instruments were straight devices with extended length, however, their functions have not been optimized for minimally invasive procedures. The ergonomics of instruments design is poor and the force-feedback is lost. Purposely designed surgical instruments that can overcome these limitations are urgently needed for MIS to perform better.

Many engineering technologies have been brought to solve the problems associated with MIS, the use of shape memory alloys (SMAs) in surgery is a wonderful example of all those successful stories. The unique materials properties of SMAs, i.e. shape memory effect and superelasticity, have provided perfect answers to the strict design requirements in MIS, novel surgical devices have been developed based on SMAs, and they have become essential tools for many minimally invasive procedures.

In this paper, the historical development of SMAs for MIS is reviewed, including surgical devices for cardiovascular surgery, laparoscopic and endoscopic surgery, orthopaedic surgery and other minimal invasive interventions. Current trends of SMAs technologies and their potential applications in the emerging surgical techniques are discussed.

2. HISTORICAL DEVELOPMENT

During the past century, many types of shape memory materials have been discovered including alloys, ceramics and polymers [9-13]. Among them the nickel-titanium SMA (trade name known as Nitinol) is the only one that has been used in medicine for implants and medical devices [14-18]. Nitinol was first discovered by Buehler and colleagues in 1963 [19], it has inspired a long-standing interest both in material research and industrial development.

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Table 1. Historical Development of SMAs for MIS

Year	Device	Reference
1963	Discovery of Nitinol	[19]
1971	Orthodontic braces	[11]
1976	Harrington rod for scoliosis	[11]
1977	Simon vena cava filter	[22]
1981	Orthopaedic Staple	[23]
1983	Prosthetic joint	[24]
1983	Nitinol stent	[25]
1990	Thin film SMA	[26, 27]
1990	Thin film microdevices	[28]
1991	Variable curvature spatula	[29]
1993	Laparoscopic hernia repair mesh	[30]
1995	Laparoscopic clamp	[31]
1995	Laparoscopic retractor	[32]
1995	Thin film microgripper	[33]
1996	RF ablation device	[34, 35]
1996	Hernia repair retractor	[36]
1998	Atrial septal occluder	[37, 38]
1999	Thin film SMA microvalve	[39]
1999	Laparoscopic suturing clip	[40]
2000	Abdominal wall lift	[41]
2000	Vascular ligation clip	[42]
2000	Multipoint injector	[43]
2000	Gastric loop snare	[44]
2001	Drug-eluting stent	[45]
2001	Thin film microwrapper	[46]
2001	Thin film microstents	[47]
2004	Laparoscopic anastomosis ring	[48-50]
2005	Thin film heart valve	[51]
2007	Endoscopic bleeding control device	[52, 53]
2008	Thin film microtube and stent	[54, 55]

Although many applications of Nitinol have been developed for different industries, their real success only came after the introduction of MIS. Nitinol provides a perfect solution for problems presented by MIS because of its unique mechanical properties – 'shape memory effect', 'superelasticity' and their excellent biocompatibility. The shape memory effect (SME) is characterized by a reversible phase transition between martensite (low temperature phase, soft) and austenite (high temperature phase, hard). At low temperature Nitinol can be plastically deformed, the deformation can be recovered by heating through a phase transition. If the Nitinol is deformed at a higher temperature above the phase transition temperature, the stress induced martensite phase transition can be recovered spontaneously once the stress is removed. This is known as superelasticity (SE). Both SME and SE can achieve up to 7% recoverable strain within a relatively constant stress plateau.

These remarkable shape memory properties are not present in any other conventional materials. Both superelastic and thermal recovery SMAs can provide large deformation and force for robust surgical devices for MIS. The shape recovery devices are particularly useful for temperature driven actuation where mechanical manipulation is difficult and applying heating is convenient, such as in the MIS environment. More importantly, the Nitinol is biocompatible with low toxicity and high corrosion resistance [20], thus, it can be used for implants, e.g., stent, staple and sutures without any adverse long-term effects on patients. The Nitinol is also non-ferromagnetic and can thus be used as medical devices for MRI-guided surgery and minimal invasive interventions [21]. The devices made of Nitinol can be sterilized by autoclave (i.e. steaming at 134°C for 3 minutes), as this is the most common type of sterilization used in practice [14].

A brief history of SMAs (bulk materials and SMA thin films) for medicine is summarized in Table **1**, with an em-

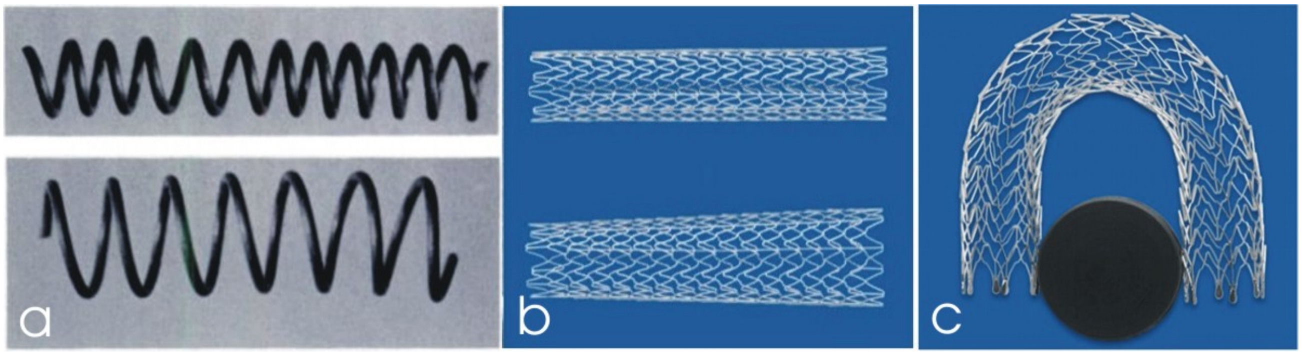

Fig. (1). Nitinol stents. a) First Nitinol coil wire stent, the compacted shape is for catheter placement and the expanded shape after saline heating at 60°C. (From [25], reproduced with permission from the Radiological Society of North America). b) The latest Abbott Acculink stent with complex patterns and optimized tapered design to fit individual patient anatomies. c) Demonstration of kink resistance of a Nitinol biliary stent (images courtesy from Abbott Laboratories).

phasis on applications in MIS during the last twenty years. The application of shape memory technology in medicine has shown an increasing momentum during the last twenty years. A literature analysis has been carried out by the authors using the Web of Science (2009) with searching terms of 'shape memory alloys' and 'medical' and between 1991 to 2009, the total number of publications is 212, and reached 29 in 2008 alone, while USA, Japan and China are the top three countries that produced the most papers which account for more than 60% of the total publications.

Following the historical review, detailed applications of SMAs for MIS will be discussed in: 1) Cardiovascular surgery, 2) Laparoscopic and Endoscopic surgery, 3) Orthopaedic surgery, 4) Other minimally invasive procedures.

3. SMAS FOR MIS

The early examples of Nitinol applications for medicine include orthodontic braces, Harrington rod for scoliosis treatment [16], and the Simon filter in 1977 [22]. However, it was not until the 1990s that Nitinol has started to make serious impact on medicine with technology breakthroughs in the design, modeling and manufacturing. Since then, many medical devices were developed and achieved great success, such as stent for cardiovascular interventions, surgical devices for endoscopic and laparoscopic surgery, and orthopaedic implants.

3.1. Cardiovascular Surgery

Stent probably is the best example of SMAs in medicine, and also the most successful product in term of commercial and life-saving achievements. The first Nitinol stent was made by Dotter's group in 1983 [25], it was a simple coiled Nitinol wire and was delivered into a dog's femoral artery by guide catheter (Fig. **1a**).

The stainless steel stent was introduced into clinical use by Palmaz and Schatz in 1987, which was approved by the US Food and Drug Administration (FDA) in 1994 [56]. The concept of Nitinol stent covered with fabric graft was first introduced in 1993 [57], and the *in-vivo* study in human of drug-eluting stent was published in 2001 [45], which marked the stent has evolved into an enabling technology as drug delivery device rather than a pure mechanical scaffold.

It is a remarkable achievement for the Nitinol stent to develop from a simple form of coiled wire to the latest stents of complex structures by laser cutting (Fig. **1b** and **c**). Since May 2000, the US FDA has approved 24 stents, nearly half of them are SMA stents (FDA website 2009). It is expected that the self-expanding Nitinol stents are going to play a bigger role in the growing global market of drug-eluting stent, which is forecast to reach US$6.3 billion by 2010 [58].

Although stent is the most widely known SMA device in minimally invasive cardiovascular therapy to revascularize arteries, Nitinol stent have also been used in other parts of human body including stents for esophagus [59], gastrointestinal tract [60], ureter [61], tracheal airway [62], and vascular anastomosis device [63, 64], radiofrequency ablation catheter [30] and prosthetic heart valves [37].

3.2. Laparoscopic and Endoscopic Surgery

Endoscopic surgery uses rigid or flexible endoscope to gain access to operative fields to diagnose and treat diseases. Surgical operations are conducted by remote surgical manipulation within the closed body cavities under visual control via endoscope. In addition to avoiding large painful access wounds, the endoscopic instruments used for dissection are small and fine, usually less than 10 mm in diameter, thus the tissue trauma inherent to surgical dissection is reduced further. Laparoscopic surgery has been the most significant advance in endoscopic surgery, laparoscopic cholecystectomy has become the standard method of treatment of gallstone disease applicable to over 90% patients.

A range of Nitinol based surgical instruments have been developed for endoscopic surgery. They are purposely designed instruments to overcome the limited degrees of freedom caused by the approach of minimal invasiveness. The devices made of Nitinol enable surgeons to achieve complex surgical tasks, such as tissue holding (tissue graspers and retractors), suturing (needle holder and suturing clip), anastomosis (anastomosis ring), homeostasis (bleeding control clip), dissection (scissors), ablation (multiple radiofrequency electrodes), surgical materials delivery, and hernia repair.

Curved Surgical Instruments – The first use of SMA in MIS was a variable curvature spatula for laparoscopic sur-

Fig. (2). Variable-curvature devices for laparoscopic surgery. **a**) Dissecting spatula, **b**) suture passer, **c**) flexible drive for an articulating needle holder. (From [29], reproduced with permission from Springer).

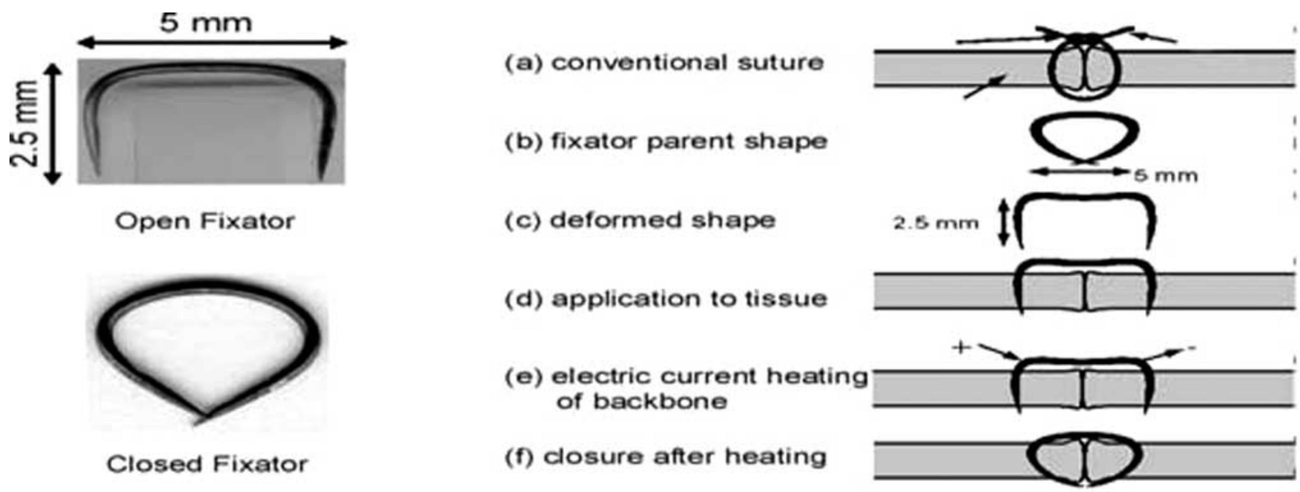

Fig. (3). Prototype and working principle of a self-closing clip for MIS (From [41]).

gery (Fig. **2a**), which was designed by a pioneer surgeon Alfred Cuschieri in 1991 [29]. Due to the superelastic deformability, Nitinol enable the functional part retracted inside a straight tube, following insertion through a standard access port. The dissecting blade or the suture passer wire (Fig. **2b**) can be extruded to the right length appropriate for the surgical tasks which may have different needs in term of the curvature of the instrument. A recent development of a curved instrument is an articulating needle holder that is able to transmit pulling and rotational forces in angulated positions to facilitate suturing in difficult situations. One key component of the needle holder is the flexible drive coupling which is a complex-shaped helix after design optimisation, and the superelastic Nitinol is the only material that could meet all the design challenges (Fig. **2c**).

Suturing Devices – Tissue suturing in MIS is an essential and difficult skill that would require surgeons to have special training to master, and the quality of sutures varies depending on surgeons' experience [65], an alternative approach is to use self-closing clips (Fig. **3**). The thermal shape recovery property of Nitinol offers the best potential to design a very simple device with strong gripping force that is analogous to that of thread sutures. The shape of the suturing clip can be optimized through finite element analysis to ensure the maximum strain remained within safe range. In addition, thermography had been used to optimise the clip deployment to minimize thermal collateral damage to surrounding tissues [40]. These self-closing clips enable efficient and easy tissue approximation during endoscopic surgery.

Anastomotic Devices – Gastrointestinal (GI) anastomosis is a major operation in GI surgery. For over two centuries, surgeons have attempted to explore many different techniques in order to produce an ideal gastrointestinal anastomosis, which is able to maintain a good blood supply, watertight seal, and accurate serosal apposition with no tension on the anastomosis line [66]. The most widely used techniques today are suturing and mechanical stapling, both methods involve foreign materials penetrating and staying in tissue to realize anastomosis.

The idea of compression-based sutureless anastomosis has a long history since the early 19th century, for example, Denan's rings in 1826, Murphy's button in 1892, the biofragmentable anastomosis ring (BAR) device in 1985. Each time the idea of compression anastomosis made it more and more appealing to surgeons by improved design and function [67]. The most recent and a very promising development is the Nitinol compression anastomosis clip from the NiTi Medical Technologies in Israel [47].

The Nitinol compression anastomosis clip is designed to be in closed shape (Fig. **4**) at body temperature. The clip is cooled in ice water of 0°C for 1 minute, an applicator is then used to hold the clip open up to 8 mm. After inserting into bowel lumen, the clip tends to close to recover its original

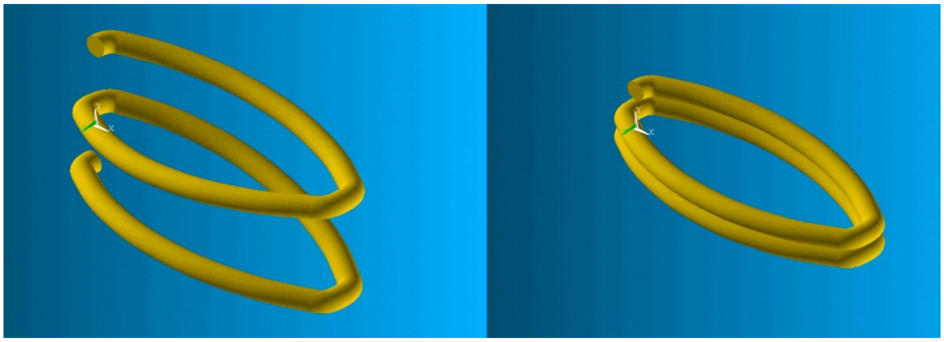

Fig. (4). Colon anastomosis clip in open (left) and closed shapes (right) (From [50], reproduced with permission from ASME).

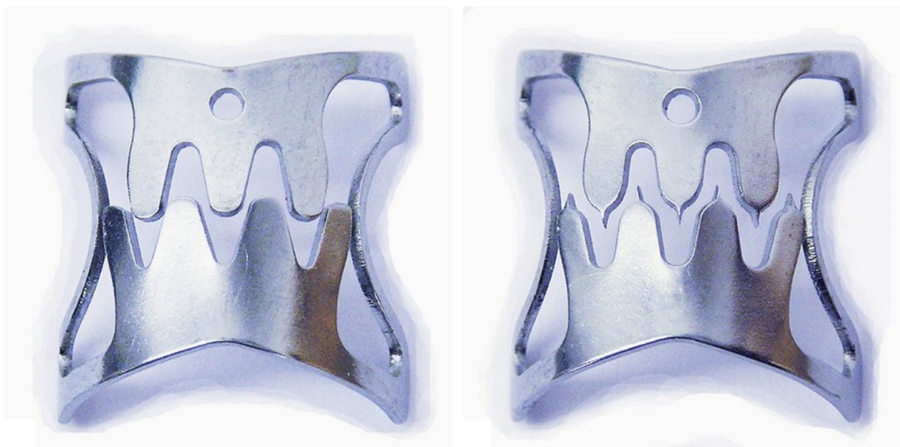

Fig. (5). Over-the-scope clip system for gastrointestinal bleeding control. Left, atraumatic and right, traumatic versions (From [53], reproduced with permission from Elsevier).

shape at body temperature of 37°C. The constant pressure is exerted on the bowel walls that lead to necrosis within 7 days. Following complete necrosis, the clip detaches itself and is expelled outside the body. Both animal and human trials have suggested that the Nitinol clip is a simple and effective method to achieve a smooth gastrointestinal anastomosis without foreign materials left in the body.

Bleeding Control Devices – Gastrointestinal lesion, perforation and bleeding can be treated by applying mechanical clips through flexible endoscope, but the currently available clips are difficult to use. They have limited compression force for tissues, especially in scarred or hardened tissues, which often need a number of clips applied in order to have acceptable treatment. Larger, strong and easy-to-use clips or devices for gastrointestinal intervention are needed for better treatment of GI diseases [68].

Recently a novel SMA clip (OTSC, Ovesco Endoscopy GmbH, Tubingen, Germany) has been developed to address the long-lasting clinical problems of gastrointestinal intervention. The OTSC clip (Fig. **5**) is made of Nitinol, and can be mounted on the tip of an endoscope and released by a wire. The arms of the clip can protrude 4.5 mm deep into the wall of the GI tract. The superelastic SMA clip is strong enough to apply a force of 8-9 N to achieve sufficient compression to stop bleeding. During the first clinical trials, the OTSC clip was successfully applied to 11 patients with severe bleeding, deep wall lesion or perforation in the GI tract [52].

3.3. Orthopaedic Surgery

The early applications of Nitinol in orthopaedic surgery were staples and clamps to treat adolescent scoliosis [11] and bone fractures [23]. The fusionless scoliosis correction using minimally invasive SMA staple was examined in animal models and the early results were promising in correcting moderate to severe scoliosis and halting the malignant progression without fusion [69-71]. The Nitinol implants found no negative effect on new bone formation, and even the bone modeling could be controlled by a constant bending force applied to the bone through a functional SMA implant [72, 73]. Recent development of porous Nitinol has shown good biocompatibility and excellent bone ingrowths, which could be used as ideal bone substitute [74, 75].

3.4. Others

There are many SMA based devices developed for other minimally invasive procedures. For example, a SMA prosthetic patch for hernia repair surgery can be tightly rolled into a cylindrical configuration for delivery through a laparoscopic instrument [76]. An endoscopic loop snare is an effective tool for precise localization of gastric cancer in photodynamic therapy [44]. A multiple hypodermic needle can achieve a bigger injection volume with one access point [77].

In urological field, a SMA ureter stent was used in 15 patients to treat ureter stricture with encouraging results [61]. On the other hand, an artificial urethral valve using SMA was developed to treat urinary incontinence [78, 79]. A SMA-based cochlear implant can achieve greater implantation depth for the electrode array to restore partial hearing to those who are deaf or severely hearing-impaired [80].

After more than 20 years of extensive development, minimally invasive procedures based on catheters and endoscopes are now well established. Natural orifice surgery, single port access surgery and robotic surgery are new surgical technologies that have emerged during the past few years. While the trend of surgical technologies continues toward even less invasiveness or no-scar diagnostics and treatment, shape memory technology continues to find exciting applications. A superelastic structure has been designed as legs for wireless capsule endoscope to move within gastrointestinal tract [81]. A microactuator in capsule endoscope was developed for biopsy with a SMA heating wire to trigger the device [82]. A novel Nitinol clip has been developed for chordae fixation during robotic surgery and the clinical outcomes in 30 patients were excellent [83].

4. CONCLUSION

It has been more than two decades since the first SMA based device was developed for laparoscopic surgery. Combining the breakthroughs in medicine and technology, MIS has made a great impact on the society and achieved a great success. SMA technology is a perfect example for this combination, looking through the historical development, two trends are clearly notable, i.e. strong healthcare requirements and rapid technology advances.

- There are continuous demands from patients for less traumatic, less or non-invasive surgical treatments. If scars could be avoided, pains and traumas could be minimized through novel treatments that will bring great benefits to patients. But the skills required for surgeons and clinicians could be even greater, and economic pressures for the healthcare system could be even higher.
- As the modern medicine is getting more complex and more technology-dependent, the solutions must also come from technology innovation. For example, continuous technological advances are moving surgery forward to cross its traditional borders to offer better services and reduce costs. Significant breakthroughs in biomaterials, computer aided design and manufacturing, and information technologies make it possible to develop smaller, more complex and robust, and multifunctional surgical devices. The cardiovascular stent serves as an excellent example of integrated approach using sophisticated software with refined algorithms, modeling, manufacturing and testing technologies.

This paper has reviewed the historical development SMAs for MIS, including devices in cardiovascular surgery, laparoscopic and endoscopic surgery, orthopaedic surgery and other minimally invasive procedures. The shape memory technology has played a significant role in the advances of modern surgery, numerous instruments and devices have been invented for MIS.

By no means has this review covered every aspect of SMAs or every surgical specialty, but it is the aim to illustrate the trend of the technology development and serve as guidance for many more medical innovations envisaged looking towards the future. As we gain more understanding of the shape memory technologies through collaboration between scientists and clinicians, we are more capable to develop more advanced and more robust devices for the next generation of surgery in the 21st century.

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