Role of Automated Suturing Technology in Minimally Invasive Aortic and Mitral Valve Surgery

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ABSTRACT
Minimally invasive cardiac surgery continues to evolve and expand as technology and surgeon experience develops. Among the barriers to the adoption of non-sternotomy minimally invasive valve surgery are the challenges associated with suture placement. Automated technology enables ergonomic remote suture placement that allows for reproducible results while shortening the learning curve. The objective of this review is to describe the latest advancements in automated suturing technology for minimally invasive valve surgery.

INTRODUCTION
Valvular heart disease is a significant source of illness across the world and one of the most frequent causes of heart failure. Conservative management is associated with a poor prognosis. Minimally invasive structural heart disease procedures have been rapidly expanding, especially in cases of aortic and mitral valve disease. With the advent of new technologies, the range of procedures amenable to less invasive approaches continues to grow. Patients are increasingly interested in minimally invasive cardiac surgery.

In this review, we describe our approach for minimally invasive aortic valve replacement (MIAVR) through right anterior mini-thoracotomy, including recently introduced automated suturing technology. In addition, we describe the role of automated suturing technology in mitral valve replacement and mitral valve repair using right lateral mini-thoracotomy access.

MINIMALLY INVASIVE AORTIC VALVE REPLACEMENT
MIAVR is defined as an aortic valve replacement (AVR) procedure performed through a smaller chest wall access, as opposed to a full median sternotomy. Upper ‘J’ mini-sternotomy, inverted ‘T’ incision, right parasternal incision, transverse sternotomy and right anterior mini-thoracotomy have all been reported as MIAVR. The first MIAVR procedures were performed by Rao and Kumar via a right thoracotomy in 1992 and by Cosgrove and Sabik via a right parasternal approach in 1996. Today, right anterior thoracotomy and upper hemi-sternotomy are the predominant approaches for less invasive surgical AVR.

While current MIAVR surgery is associated with mortality and stroke rates that are comparable to those with conventional surgical AVR, MIAVR is also associated
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with a lower risk of bleeding and use of perioperative blood products, shorter duration of ICU and hospital stay, reduced duration of assisted ventilation and a greater improvement in the quality of life postoperatively.5-10

Despite these potential advantages, MIAVR has not been widely adopted by most surgeons due to several factors, including surgeons’ acceptance of the results and risks of conventional AVR along with the perceived increased complexity and steep learning curve associated with MIAVR.

The use of automated suturing technology can facilitate less invasive cardiac valve surgery by reducing the technical difficulty of these operations, thus improving the learning curve and allowing more surgeons to offer this potentially beneficial approach.

Surgical technique
In our approach to MIAVR via right anterior mini-thoracotomy, as previously reported, we employ a camera and automated suturing technology for supra-annular valve implantation.11 A 4-5 cm incision in the right second intercostal space is made with a camera port placed lateral to the incision. Cardiopulmonary bypass is established via central aortic and percutaneous peripheral venous cannulation, and patients are cooled to 30°C. An aortic cross-clamp is placed through a 5 mm incision in the third interspace anterior to the mid axillary line. Antegrade Histidine Tryptophan Ketoglutarate (HTK) cardioplegia is administered. The aorta is opened at the site of the cardioplegia cannula. After aortic leaflet removal and annular decalcification, annular and prosthetic sutures are placed with automated suturing technology. The valve is then seated, and the sutures are secured using the COR-KNOT® device and titanium fasteners (LSI SOLUTIONS®, Victor, NY). Cardiopulmonary bypass is discontinued. The wound is then closed in layers with excellent cosmesis.

The two automated suturing devices used to place annular and prosthetic sutures are the RAM® automated suturing device (LSI SOLUTIONS®, Victor, NY) and the SEW-EASY® device (LSI SOLUTIONS®, Victor, NY), respectively (Figs. 1 and 2). The RAM® automated suturing device is a manually controlled and operator adjustable shafted device. The distal

Figure 1. RAM® 5mm automated suturing device. (All images reprinted with permission of LSI SOLUTIONS)

Figure 2. SEW-EASY® 5mm prosthetic suturing device.

Figure 3. Minimally invasive AVR using the RAM® automated suturing device.
end of the RAM® device provides two curved needles that are simultaneously driven by squeezing of the lever to place a sub-annular pledgeted 2-0 polyester horizontal mattress stitch at the targeted site in the aortic annulus. The proximal end of the RAM® device has 2 rotating knobs that manipulate the device tip and shaft for improved ergonomics and suturing accuracy. One knob rotates the shaft 360 degrees, and the other provides flexion/extension of the tip. After the operator orients the desired portion of the annulus within the tissue gap of the device, squeezing the device lever extends the two curved needles simultaneously in a fixed arc following the curve of the needles through the annular tissue to engage the suture located within the tip of the device (Figs. 3 and 4). Releasing the lever retracts the needles through the tissue with the ends of the suture back into the device, and automatically seats a pledgeted horizontal mattress suture in the sub-annular position. Pulling forward on the device lever automatically releases the suture ends, allowing the device to be reloaded with the next suture. The surgical assistant methodically secures the sutures in the RAM® Ring device (LSI SOLUTIONS®, Victor, NY) for suture management or installs the suture ends directly into a SEW-EASY® cassette (see below). This process is repeated until all sutures are placed in the annulus and stored.

A second instrument, the SEW-EASY® device, is an automated suturing device with two straight needles that transfer the two ends of the horizontal mattress suture from the aortic annulus through the prosthetic valve sewing cuff (Fig. 5). After the suture ends are loaded into the SEW-EASY® device via disposable cassettes, the valve cuff is placed within a recess in the cassette tip and viewed through a transparent window. Squeezing the lever drives the two straight needles simultaneously through the sewing cuff to engage the suture ends. Releasing the lever pulls the needles and suture ends back through the sewing cuff. The suture and cassette are then removed from the SEW-EASY® device. Once all the sutures are placed in the sewing cuff, the prosthetic valve is parachuted into place. Sutures can be hand-tied and trimmed, or, preferably, secured and trimmed automatically using titanium fasteners and the COR-KNOT® device.

In addition to minimally invasive AVR, this new automatic suturing technology is used to facilitate our approach for minimally invasive mitral valve replacement (MIMVR) through a right mini-thoracotomy (Fig. 6).
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Upcoming automated suturing technology for mitral valve chordal replacement

Mitral valve repair, as opposed to replacement, can be the treatment of choice for many patients with structural mitral insufficiency. The role of automated suturing technology in minimally invasive aortic and mitral valve surgery is rapidly changing in both the interventional and surgical fields. Transcatheter aortic valve implantation (TAVI) has emerged as a minimally invasive alternative for patients with aortic valve disease who are at high risk for surgery. However, the increasing use of TAVI has highlighted the need for improved techniques for mitral valve repair, especially in patients with concomitant aortic and mitral valve disease.

The Mi-STITCH™ device (LSI SOLUTIONS®, Victor, NY) is a newly developed product (not yet available commercially) designed to precisely place surgical ePTFE suture using mechanically controlled needles (Fig. 7). This device is preloaded with ePTFE suture, and two curved needles are contained within the distal end of the device shaft. When the device is appropriately positioned at the targeted mitral valve leaflet, squeezing the lever simultaneously advances both curved needles through the valve leaflet, with each needle picking up one end of the single strand of ePTFE suture. Squeezing the lever again enables re-arming of the suture ends for subsequent pick-up. By next positioning the Mi-STITCH™ device at the corresponding papillary muscle and taking another bite, both suture ends are drawn through the papillary muscle to exit near its base oriented towards the apex of the left ventricle. After the ePTFE suture is placed through the valve leaflet and corresponding papillary muscle, the suture ends are loaded into the distal shaft of a preloaded Mi-KNOT™ device (LSI SOLUTIONS®, Victor, NY). The replacement ePTFE suture chord is then adjusted to a desired length. Squeezing the Mi-KNOT™ device lever crimps a titanium fastener onto the ePTFE suture to secure the length of the suture chord and trim away excess suture tails (Figs. 8 and 9). This new suture functions as a replacement chord, securing the mitral leaflets so that appropriate coaptation is maintained and leaflet prolapse is prevented.

This automated suturing technology can enable accurate remote placement of ePTFE artificial chordae while the Mi-KNOT™ titanium fastener can provide real-time adjustment of chordae length during mitral valve repair, potentially reducing the technical challenges associated with this procedure.

Conclusions

The face of AVR is rapidly changing in both the interventional and surgical fields. Transcatheter aortic valve implantation (TAVI) has emerged as a minimally invasive alternative for patients with aortic valve disease who are at high risk for surgery. However, the increasing use of TAVI has highlighted the need for improved techniques for mitral valve repair, especially in patients with concomitant aortic and mitral valve disease.
invasive option for patients who are deemed to be too high risk for surgical AVR, and studies have shown that TAVI is superior to medical therapy in those patients. However, concerns persist regarding the durability of these new transcatheter valves, which do not allow for removal of the diseased native valve during the intervention. Also, TAVI is associated with greater rates of vascular complications and paravalvular (PVL) leaks, as well as a 10% or greater risk of compared to conventional AVR.14-16

In the surgical field, the introduction of “sutureless” or “rapid deployment” valve technology is reported to reduce the complexity associated with minimally invasive approaches. This technology has been demonstrated to reduce cardiopulmonary bypass, cross-clamp and overall operative times.17 Most related studies report lower rates of PVL with the use of sutureless valves compared to TAVI,18 but higher rates than with standard surgical valves. The rate of PPM implantation has been significantly higher with the use of sutureless valve technology; most studies report PPM rates of 6 to 9%, and even as high as 23%.19 Today, there is still a lack of data on long-term durability for sutureless and rapid deployment valves. Conventional stented bioprosthesis and mechanical valves remain the gold standard for aortic valve replacement in surgery. Improvements in innovative technology, such as ergonomic automated suturing, may eliminate some of the technical challenges of minimally invasive valve surgery. These automated devices will facilitate fast and more consistent surgical suturing in both open and, more importantly, minimally invasive surgery where accurate and effective suturing can be challenging or even unachievable at some remote targeted tissue sites.

The potential benefits of the application of this technology could result in standardization and simplification of what was previously a complex procedure, resulting in improved operative times even for less experienced surgeons. Such technology and techniques could influence the adoption of a minimally invasive approach by many surgeons for cardiac valve replacement and repair, and potentially lead to significant improvements in patient outcomes.

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REFERENCES