Significant reduction in annuloplasty operative time with the use of nitinol clips in robotically assisted mitral valve repair

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Objective: A substantial barrier to widespread adoption of robotically assisted mitral valve repair surgery is increased operative time compared with that of median sternotomy. Nitinol U-clips (Medtronic, Minneapolis, Minn) made of a shape-memory alloy eliminate intrathoracic suturing and may reduce operative times.

Methods: A retrospective review of robotically assisted mitral valve repair surgery was done at East Carolina University, where preoperative, intraoperative, and postoperative data were collected prospectively. The total time for U-clip or suture placement, as well as those for cardiopulmonary bypass, crossclamp, and annuloplasty band placement, were studied. Patients in whom only U-clips were used ("U-clips" cohort) were compared with those in whom only sutures were used ("sutures" cohort). Comparisons between groups were by two-tailed Student *t* test.

Results: Between May 2000 and June 2004, U-clips were used exclusively in 50 patients (mean age 58.4 ± 13.2 years), and sutures were used exclusively in 72 patients (mean age 56.2 ± 12.9 years). The mean total time for placement and deployment of U-clips was shorter than for placement and tying of sutures (101 ± 45 seconds vs 186 ± 79 seconds, respectively, $P < .001$). Cardiopulmonary bypass, crossclamp, and annuloplasty band placement times were shorter in the U-clips cohort (144 ± 50 minutes vs 169 ± 35 minutes, 105 ± 30 minutes vs 132 ± 29 minutes, and 26 ± 5 minutes vs 40 ± 10 minutes, U-clips vs sutures, respectively, all $P < .01$).

Conclusions: Significantly shorter times were observed for placement and deployment of U-clips versus placement and tying of sutures, resulting in a reduction in mean band placement time of 14 minutes and significantly shorter cardiopulmonary bypass and crossclamp times in the U-clips cohort. Therefore, use of Nitinol U-clips instead of sutures may allow for significantly faster robotically assisted mitral valve repair surgery.

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The enhanced dexterity and 3-dimensional visualization provided by the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, Calif) has allowed for relatively rapid adoption of robotically assisted mitral valve repair (RAMVP).¹ Despite these advances, operative times for RAMVP (mean 4.4 ± 0.1 hours) are longer than those for mitral valve repair performed through a median sternotomy.² Selection of younger patients with relatively normal left ventricular

Abbreviations and Acronyms

ABP	= annuloplasty band placement
CPB	= cardiopulmonary bypass
ECU	= East Carolina University
RAMVP	= robotically assisted mitral valve repair

function has allowed for excellent results for RAMVP so far;² however, longer crossclamp and cardiopulmonary bypass (CPB) times may not be tolerated as well by older patients or patients with subnormal left ventricular function. Therefore, ongoing refinements in techniques and application of new technologies are required to allow for more widespread applicability of RAMVP.

One recently developed adjunctive technology is the Nitinol U-clip (Medtronic, Minneapolis, Minn). The clip is made of nitinol, an alloy with super-elastic properties that allow the material to return to a preformed pattern. Recently, a double-arm U-clip designed at East Carolina University (ECU) was introduced, which allows placement of a mattress stitch for annuloplasty band placement (ABP) (Figure 1).³ Clip deployment times were significantly faster than knot tying, and total clip placement was significantly faster than total suture placement. Although U-clips have been available for use in performing coronary anastomoses since the year 2000, with more than 35,000 anastomoses performed to date, only minimal experience with a double-arm U-clip in mitral valve repair has been reported.⁴

Figure 1. Nitinol U-clip (Medtronic, Minneapolis, Minn).

In March 2003, we started using U-clips instead of sutures to secure the annuloplasty band in most patients undergoing RAMVP at ECU. The objective of this study was to examine our experience with the use of U-clips to determine whether their use was associated with a reduction in operative times for RAMVP.

Materials and Methods**Patients**

RAMVP was first performed at ECU in May 2000. Between May 2000 and June 2004, patients in whom only U-clips were used ("U-clips" cohort) were compared with those in whom only sutures were used ("sutures" cohort). Patients in whom both U-clips and sutures were used were not included in this analysis (n = 29).

Robotically Assisted Mitral Valve Repair Technique

RAMVP was performed using the da Vinci robotic system (Intuitive Surgical, Sunnyvale, Calif) through a 4-cm right minithoracotomy using techniques previously described.² U-clips or Ticon sutures (US Surgical Corp, Norwalk, Conn) were used to secure a Cosgrove Edwards annuloplasty band (Edwards Lifesciences, Irvine, Calif), a flexible annuloplasty device, to the posterior mitral valve annulus from trigone to trigone. First, the annuloplasty band was removed from the support stent and then passed into the left atrium. This allowed for easier manipulation of the band while placing the U-clips or sutures, which were then placed in clockwise fashion, starting at the posteromedial trigone. In either case, each individual U-clip or suture was secured to the annuloplasty band immediately after placement through the annulus.

The types of repairs performed are summarized in Table 1 and listed in order of increasing complexity.

Data Analysis

Preoperative, intraoperative, and postoperative data were collected prospectively for all patients undergoing RAMVP. A retrospective review of the data was performed to compare total times for U-clip or suture placement, CPB, crossclamp, and ABP times between the two groups.

After verification that all variables were normally distributed, the Student *t* test was used to evaluate differences between the 2 groups. All tests were 2-sided. All analyses were conducted using the Statistical Package for the Social Sciences for Windows version 11.5 (SPSS Inc, Chicago, Ill).

Results

Between May 2000 and June 2004, U-clips were used exclusively in 50 patients (14 women, mean age 58.4 ± 13.2 years), and sutures were used exclusively in 72 patients (22 women, mean age 56.2 ± 12.9 years). Sutures were used exclusively between May 3, 2000, and March 10, 2003. After March 10, 2003, sutures and/or U-clips were used.

The operative times and number of U-clips or sutures per band are summarized in Table 2. There was no difference in the mean number of U-clips or sutures per annuloplasty band (Table 1). When the U-clips cohort was compared with

TABLE 1. Types and distribution of repairs

Type of repair (in order of increasing complexity)	U-clips		Sutures	
	n/50	%	n/72	%
Annuloplasty band only	12	24	12	17
Alfieri stitch	0	0	5	7
Chordal procedure	5	10	4	6
Posterior leaflet resection	11	22	32	44
Resection + chordal procedure	13	26	14	19
Resection + chordal procedure + sliding plasty	9	18	5	7

"Chordal procedure" refers to transfer of primary posterior leaflet chordae to the anterior leaflet or to an unsupported portion of the posterior leaflet, transfer of secondary anterior leaflet chordae to the free edge of the anterior leaflet, or placement of a neochoord of polytetrafluoroethylene (Gore-Tex; W. L. Gore & Associates, Flagstaff, Ariz) from a papillary muscle to an unsupported portion of the anterior leaflet. "Posterior leaflet resection" refers to triangular or quadrangular resection of a portion of the posterior leaflet. "Resection + chordal procedure" refers to a repair involving both of the above types of procedures. "Sliding plasty" refers to detachment of part of the posterior leaflet from the annulus, with or without resection of part of the posterior leaflet, followed by reattachment of the posterior leaflet to the annulus using a running suture.

the entire suture cohort ("suture cohort A," $n = 72$), the mean time for placement and deployment of individual U-clips was significantly shorter than for placement and tying of individual sutures. The majority of the differences in times was attributable to the increased time required for tying of sutures compared with deploying the U-clips. This translated into a significantly shorter ABP time in the U-clips cohort. The mean time for placement of the annuloplasty band was 13.9 minutes shorter in the U-clips cohort. The U-clips cohort also had significantly shorter mean cross-clamp and CPB times than the patients in suture cohort A.

Because all of the bands in the first 67 patients were placed using sutures only, a second analysis was performed to control for the effect of the learning curve on operative times. Separate analysis of the learning curves for RAMVP performed at ECU demonstrated that 90% efficiency for placement and tying of the sutures was achieved after the first 40 cases (Nifong LW, personal communication). Therefore a second analysis of the data was performed after removing the first 40 cases ("suture cohort B," $n = 34$). The total mean U-clip time was still significantly shorter than the total mean suture time; however, the difference between these times was primarily the result of the difference in the time required to deploy the U-clips compared with the time

required for tying sutures: There was no longer a significant difference in the time required to place a U-clip compared with a suture. After removal of the first 40 patients from the sutures cohort, the mean time for placement of the annuloplasty band was still 12.2 minutes shorter in the U-clips cohort. Although the U-clips cohort still had a significantly shorter mean crossclamp time, the mean CPB time was no longer significantly shorter than that of the sutures cohort; however, the absolute difference in mean crossclamp and CPB times between groups was 18 minutes for both parameters (shorter in the U-clips cohort).

Discussion

Robotically assisted cardiac surgery offers patients a less-invasive alternative to sternotomy-based procedures. Apart from cosmetic benefits, patients may have shorter hospital stays and faster recovery times to normal activity.² However, the benefits of RAMVP have been achieved at the cost of increased operative times.

One major factor contributing to longer operative times is the time required to tie sutures within the chest or heart using the robotic instruments. With sutures, knots are tied as "instrument ties" using grasping forceps and needle holders. Given that mitral valve repairs involve 60 to 90 knots for

TABLE 2. Operative times and number of U-clips or sutures per band

	U-clips (Medtronic, Minneapolis, Minn) cohort (n = 50)	Suture cohort "A" (n = 72)	P value*	Suture cohort "B" (n = 34)	P value†
U-clip vs suture placement time (sec)	81 ± 42	94 ± 64	<.0001	83 ± 51	.51
U-clip deployment vs suture tie time (sec)	21 ± 13	92 ± 33	<.0001	87 ± 32	<.0001
Total U-clip vs suture time (sec)	101 ± 45	186 ± 79	<.0001	169 ± 68	<.0001
Annuloplasty band placement time (min)	26.3 ± 5.4	40.2 ± 10.1	<.0001	38.5 ± 10.5	<.0001
U-clips vs sutures per annuloplasty band	10.5 ± 1.6	10.0 ± 2.0	.18	11.0 ± 1.9	.47
Crossclamp time (min)	105.2 ± 29.6	132.4 ± 28.6	<.001	124 ± 27	.005
Cardiopulmonary bypass time (min)	144 ± 50	169 ± 35	.002	162 ± 38	.08

*P value = suture cohort "A" vs U-clips cohort. †P value = suture cohort "B" vs U-clips cohort.

placement of an annuloplasty band alone (10–15 sutures at 6 knots/suture), elimination of this technically demanding step should reduce operative times.

The key finding of this study was that there is a highly significant reduction in mean operative times (of ABP, crossclamp, and CPB) observed in patients in whom only U-clips were used to secure the annuloplasty band. After adjustment for the learning curve of performing a RAMVP by removing the first 40 patients from the sutures cohort, there was no difference observed in the time required to place a U-clip or a suture in the mitral valve annulus; however, the mean time to tie a suture was 1 minute and 27 seconds (suture cohort B) compared with only 21 seconds to deploy a U-clip.

Nitinol U-clips have been available for use in performing coronary anastomoses since the year 2000. More than 35,000 anastomoses have been performed to date. The clips are made of nitinol, an alloy with super-elastic properties that allow the material to return to a preformed pattern. Recently, a double-armed U-clip was designed and tested at ECU, which allows placement of a mattress stitch for ABP (Figure 1). These clips have been extensively tested in acute and chronic animal models at ECU, with results previously reported.⁴ In these studies, clip deployment times were significantly faster than knot tying and total clip placement was significantly faster than total suture placement. No clip fractures or dislodgments were demonstrated. Six-month postoperative echocardiography showed preservation of mitral competence and no clip fracture, migration, or dehiscence. Nitinol double-arm U-clips are now Food and Drug Administration approved for tissue approximation in humans.

No difference in durability has been found between sutures and clips.⁴ Prior animal studies with explanted histology at 6 months showed that annuloplasties performed with U-clips show complete fibrous in-growth with preservation of U-clips.⁴ In fact, the low profile shape may potentially speed fibrotic in-growth of the ring by reducing impedance.

Limitations

There was 1 failed repair (2%) in this group, attributable to the use of U-clips. This patient underwent a quadrangular resection of P2, with a sliding plasty, chordal transfer, and placement of a Number 32 Cosgrove Edwards band. The

patient presented with shortness of breath and hemolysis to a hospital in a different city 175 days postoperatively. An echocardiogram demonstrated severe mitral regurgitation and a dehiscence band. At reoperation, there was separation of a U-clip from the mitral annular tissue. The U-clips were all intact and attached to the annuloplasty band.

An ongoing evaluation of the entire experience with RAMVP at ECU is currently being performed. Preliminary results indicate that there was no difference in the rate of failed repairs between patients in whom annuloplasty bands were placed with U-clips compared with sutures.

Apart from the potential advantages of the U-clips, there are 2 notable disadvantages of the U-clips that were not addressed by this study. First, nitinol U-clips are currently recommended for use with flexible annuloplasty devices only. Second, in contrast with sutures, it should be noted that removal of U-clips after deployment can be difficult and time-consuming, and could cause tissue damage if not done carefully and properly.

Conclusions

Because the first 151 patients who underwent RAMVP at ECU were selected patients with a low risk for mortality or morbidity (younger and with normal ejection fraction), long crossclamp and CPB times were well tolerated. More widespread application of RAMVP will be accepted as operative times approach those of sternotomy-based procedures. The use of U-clips has advanced RAMVP 1 small step closer to that objective by allowing for more rapid placement of annuloplasty bands. Long-term follow-up is ongoing to ensure the durability of both U-clips and the mitral valve repairs in which U-clips were used to secure the annuloplasty bands.

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