NextStitch: Double-Stranded Suture Chain, a Tool to Optimize Approximation of Sutures in Valve Surgery with Echocardiographic Correlation

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Robert J. Wiechmann, MD, Richard D. Hanna, MD, Joseph A. Stange, RDCS, Gilbert H. Johnson, PA-C, Regis I. Fernandes, MD, John D. Rozich, MD, PhD, MBA

Luther Midelfort, Mayo Health System, Eau Claire, Wisconsin, USA

ABSTRACT

Suture technique for valve replacement surgery has often focused on decreasing the soft tissue injury that leads to pseudoaneurysm formation and associated latent infection. There is universal recognition that precise suture placement is essential for avoiding adverse sequelae while allowing flexibility during the implantation of the prosthesis. The use of a continuous chain of linked horizontal mattress sutures (NextStitch) has allowed maximal precision in the approximation of sutures within the valve annulus. The product was used in a series of consecutive mitral and aortic valve replacements, and typical echocardiographic images from each type of implantation are presented. Postoperative echocardiography images revealed that no perivalvular leaks occurred and that NextStitch did not obscure detailed interrogation or assessment of the valve prosthesis.

INTRODUCTION

The search for optimal suture technique for valve replacement surgery has long been debated, and concern has focused upon techniques to eliminate perivalvular leak, valvular disruption, and myocardial rupture [Katz 1981, Dhasmana 1983, Stiles 1986]. Much of the literature has been devoted to understanding the best suture technique for mitral valve replacement, but overlapping concerns exist for aortic valve replacement [Kirsh 1980, Newton 1984, Heath 1991]. These concerns have focused in large part on decreasing perivalvular leakage and associated latent infection or soft tissue injury. These efforts have resulted in reports demonstrating that placement of horizontal mattress sutures with pledgets in the subannular position are superior to placement in a supra-annular location [Bedderman 1978]. However, debate continues because flexibility in implantation technique is balanced against the universal recognition that precision in suture placement is essential to avoid perivalvular leaks and their associated sequelae [Heath 1991]. This consideration underscores the logic behind the development of a continuous chain of linked horizontal mattress sutures (NextStitch; Genzyme Biosurgery, Cambridge, MA, USA), which has allowed maximal precision in the approximation of sutures within the valve annulus. This development has resulted in potentially shorter bypass and operative times and has eliminated the risk of damaging a suture with adjacent needle passes. In effect, NextStitch has the potential to decrease perivalvular leaks. The purpose of the present report is to describe a study of the use of the NextStitch product, to present its safety and practical advantages in valve replacement surgery, and to provide images of intraoperative and postoperative correlative echocardiography of valves implanted using the linked double-stranded suture.

METHODOLOGY

After approval was obtained from the Institutional Review Board for Human Investigations Committee, 30 patients underwent surgery for valve replacement. Three of these patients had mitral valve replacement, 21 had aortic valve replacement, and 6 patients had both aortic and mitral valves replaced. The patients were not randomized but were selected sequentially to receive a valve without screening or preselection, and the continuous chain of linked horizontal mattress sutures was used in each patient.

Operative Technique

In brief, aortic valve replacement is performed with standard cannulation with aortic and single 2-stage venous cannula and an aortic vent through the right superior pulmonary vein. A combination of antegrade and retrograde blood cardioplegia is used to arrest the heart, and a transverse incision is made in the aorta and extended obliquely into the center of the noncoronary sinus. The valve leaflets are resected, the annulus is appropriately debrided, and the field is irrigated to remove all particulate matter. The size of the aortic annulus is determined, and the appropriate prosthesis is selected. Before using the continuous suture chain, NextStitch, we use a combination of pledgeted horizontal mattress suture or interrupted suture of 2-0 Ti-cron (US Surgical, Norwalk, CT, USA). When using pledgeted horizontal mattress suture, we place the pledgets on the ventric-

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Address correspondence and reprint requests to: John D. Rozich, Luther Midelfort, Mayo Health System, Eau Claire, WI 54703, USA; 1-715-838-3311 (e-mail: rozich.john@mayo.edu).

Table 1. Demographics of Patients Undergoing Valve Replacement*

Age, y	
Range	43-85
Mean	66.6
Sex, n	
Male	21
Female	9
Length of stay, d	
Range	2-25
Mean ± SD	8.16 ± 4.85
No. of valve replacements, M/T (TV)	
AVR	4/16 (20)
MVR	2/2 (4)
AVR + MVR (6 patients)	6/6 (12)
Operations	
Total, n	30
Mortality, n (%)	1 (3.33%)

*M indicates mechanical valve; T, tissue valve; TV, total number of valves replaced; AVR, aortic valve replacement; MVR, mitral valve replacement.

ular side of the annulus for tissue valves and supra-annular mechanical valves and on the aortic side of the annulus for standard mechanical valves. Both supra-annular and subannular placements of the pledgeted sutures are possible with the continuous chain NextStitch suture. We begin suturing with a needle from one end of the suture chain and proceed suturing around the circumference of the annulus. A second chain of NextStitch suture is used when necessary. The sutures are then passed through the sewing ring of the valve, and the valve is secured into place by tying the color-coded individual horizontal mattress sutures (white to white, green to green, cobraid to cobraid).

After insertion of the valve, the aortotomy is closed as the heart is filled with blood to remove air. After the aortotomy is closed, deairing maneuvers are performed, and the aortic cross-clamp is removed. After a stable rhythm is established, the left ventricular vent is removed, and the patient is weaned from cardiopulmonary bypass. Intraoperative transesophageal echocardiograms are obtained by experienced cardiologists for all patients.

Mitral valve replacement is performed with aortic cannulation and bicaval (inferior vena cava, superior vena cava) venous cannulation. The intra-atrial groove is developed, and the aorta is cross-clamped. A combination of antegrade and retrograde blood cardioplegia is used, and the left atrium is opened widely to expose the mitral valve. If a mitral valve repair cannot be performed, we proceed with mitral valve replacement using a valve-sparing approach. The anterior leaflet is resected when we perform a mechanical valve replacement, and both leaflets are left intact when a tissue mitral valve replacement is performed. Once the valve is excised, the left atrium and ventricle are irrigated with cold solution, and all debris is removed. The valve annulus is sized, and the NextStitch pledgeted continuous suture chain is placed with the pledgets on the ventricular side of the annulus for tissue valve replacement and on the atrial side for mechanical valve replacement. The atrium is then closed, warm blood is infused through the retrograde cannula, deairing maneuvers are performed, and the aortic cross-clamp is removed. The patient is weaned from cardiopulmonary bypass, and an intraoperative transesophageal echocardiogram is performed. There is no change in overall operative technique with the exception of the sequence using the NextStitch product.

Echocardiography

Each patient had a preoperative transthoracic echocardiogram and an intraoperative transesophageal echocardiogram performed with the standard views recommended by the American Society of Echocardiography guidelines to check the location and function of the prosthesis and to evaluate for perivalvular leakage or flow [Cerqueira 2002]. A transthoracic echocardiography was performed within 1 week and then again at 2 months postoperative. The final echocardiogram was ordered and paid for as part of the study design, because it was judged to be outside of the standard practice patterns.

RESULTS

Thirty patents received valvular replacement over a period of 7 months. Three of these valve replacements were mitral valve replacements, 21 were aortic valve replacements, and 6 were combined aortic and mitral valve replacements. Table 1 shows the range of ages, 43 to 85 years with a mean age of 66.6 years. There were 21 male and 9 female patients, and the operative mortality was 3.3% (1 patient). The incidence of significant operative morbidity as defined by the Society of Thoracic Surgery database is presented in Table 2.

Echocardiography

The 30 patients undergoing surgery each had a preoperative transthoracic echocardiogram and intraoperative transesophageal echocardiogram performed and interpreted by a staff cardiologist. Representative images from 2 patients, 1 with an aortic prosthesis and 1 with a mitral prosthesis, were obtained from transthoracic echocardiograms and are shown in Figures 1 and 2. The figures show the typical postoperative appearance of both aortic and mitral prosthetic valves paired with the preoperative images. Parasternal long views demonstrate that the prosthetic valves are well seated, and Doppler studies reveal no evidence of perivalvular leaks. Importantly, NextStitch does not alter the normal appearance of the postoperative prosthesis-annulus interface. There is no evidence of "ring-down" artifact or acoustic shadowing related to the close approximation of interlocking sutures. At 2 months following surgery, a transthoracic echocardiogram was performed with 25 of the 29 patients who survived. Specific attention was directed to the prosthetic valve function and the presence or absence of perivalvular leakage. In this small initial group of patients, valve function was normal, and no perivalvular leakage was detected.

Table 2. Clinical Characteristics of the Patients Undergoing Valve Replacement*

Procedure	Age, y	Prothesis Type	Length of Stay, d	Complications
Redo AVR/MVR	43	M	5	None
AVR/MVR, CABG ×1	62	M	4	None
AVR, CABG ×4	57	M	5	None
AVR/MVR	68	T	19	Stroke, pacemaker
AVR	63	T	5	RIND
AVR/MVR, CABG ×3	75	T	20	AF, RF, pacemaker
AVR, CABG ×2	72	T	25	Stroke, ARDS, AF, RF/dialysis
Ascending aortic aneurysm repair w/AVR, CABG ×4	65	T	7	None
AVR, patent formen ovale repair	63	M	6	AF
AVR, CABG ×4	83	T	6	Confusion, AF, RF
MVR, CABG ×3	74	T	12	Reoperate aortic valve dysfunction, AF
AVR	74	T	5	None
AVR, CABG ×4	76	T	15	AF
AVR, CABG ×2	70	T	6	None
AVR/MVR, CABG ×1	72	T	6	None
Redo MVR	72	T	6	Stroke
AVR	68	T	6	None
MVR/total valve repair	52	M	5	None
AVR/MVR	65	M	6	None
AVR, CABG ×4	78	T	11	Confusion, AF, RF/dialysis
AVR	74	T	8	Pacemaker
Redo AVR, CABG ×2	78	T	11	RF, AF, persistent VT/VF, death
AVR	84	T	6	None
AVR, Redo CABG ×3	85	T	11	AF, RF/dialysis
AVR	59	M	6	None
AVR	58	T	5	None
Redo AVR, Aortic annulus reconstruction, TV resection	58	T	8	None
Redo AVR, CABG ×1	81	T	14	Prolonged ventilator use, RF
AVR	66	M	2	None
MVR	44	M	5	Reoperate bleeding

*AVR indicates aortic valve replacement; MVR, mitral valve replacement; M, mechanical; CABG, coronary artery bypass graft; T, tissue; RIND, reversible ischemic neurologic deficit; AF, artrial fibrillation; RF, renal failure; ARDS, acute respiratory distress syndrome; PFO, patent foramen ovale; VT, ventricular tachycardia; VF, ventricular fibrillation; TV, total valve.

DISCUSSION

Optimal suture technique for prosthetic valve replacement surgery has progressed with a reduction in valve dehiscence and perivalvular leak secondary to suture line disruption [Kirsh 1980, Katz 1981, Dhasmana 1983, Newton 1984, Stiles 1986]. Efforts over time have compared interrupted figure-of-8 sutures, interrupted sutures, and horizontal mattress sutures [Bedderman 1978, Heath 1991]. These studies determined that using pledgets, increased suture depth, and closer pacing increased suture line strength. These studies also compared subannular and supra-annular placement of pledgeted sutures [Bedderman 1978]. Most authorities have favored horizontal mattress sutures with subannular or supra-annular pledgets over simple interrupted sutures or horizontal mattress sutures without pledgets [Bedderman 1978, Chambers 1991, Laks 1993]. A primary goal has been to eliminate factors that destabilize the suture line and lead to perivalvular leaks and their associated complications [Kirsh 1980, Newton 1984, Stiles 1986, Heath 1991]. Our report shows that a continuous chain of linked horizontal mattress sutures, NextStitch, can be safely used with pledgets to successfully implant both mitral and aortic prostheses. Given that our series represents 30 consecutive cases, statistical comparisons could not be addressed. However, perivalvular leakage was not encountered, and operative times were comparable, if not reduced, during the period of actual valve implantation.

Estimates of the time saved with the use of NextStitch must be conservative because the individual surgical techniques used were highly variable. Instead of listing the actual time saved in minutes when using NextStitch compared with the conventional technique, we felt that it was appropriate to list the percentages of time saved. Accordingly, we estimate that the percentage of time to be saved during the interval of valve implantation will be between 30% and 50%. The need for precise placement of each needle is well understood and critical, because 2 sutures are positioned at one time. However, there is the potential for a slight delay in spacing the pledget because of the continuous nature of the connected sutures and the potential for inadvertent tangling of the suture if care is not

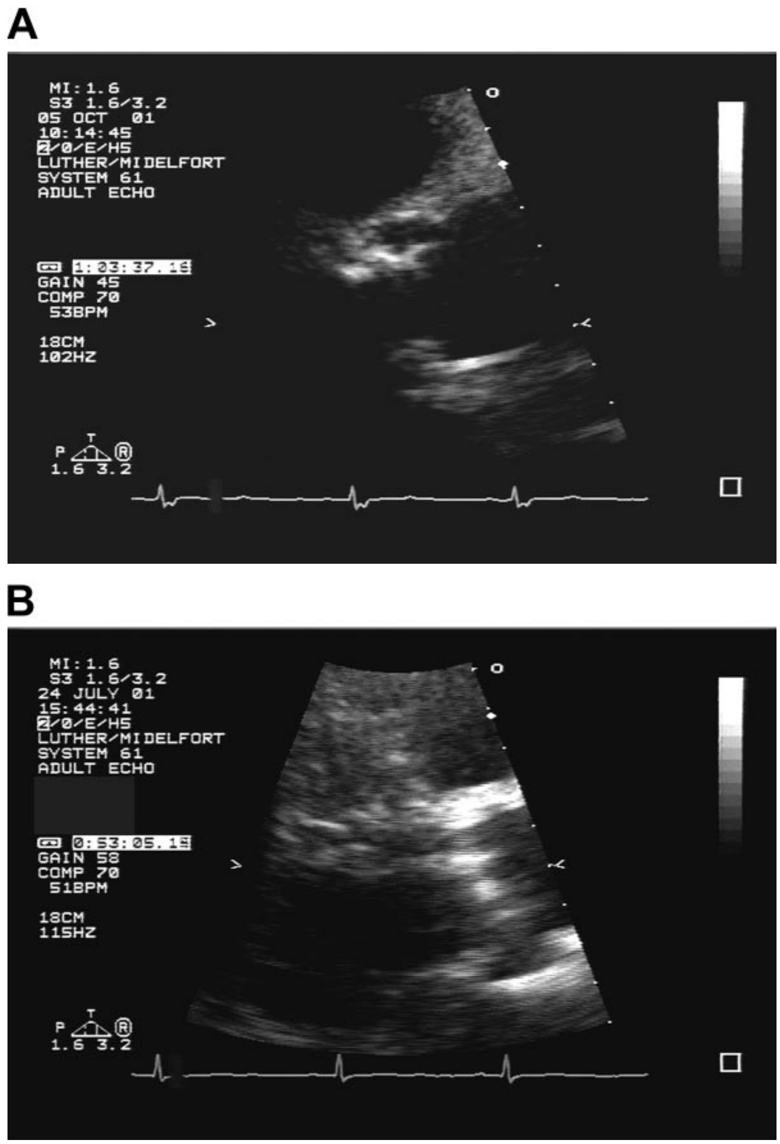

Figure 1. Preoperative transthoracic echocardiogram showing heavily calcified aortic valve (A) paired with same patient with postoperative transthoracic echocardiogram showing properly functioning prosthesis (23-mm Medtronic Hall prosthesis; Medtronic, Minneapolis, MN) with NextStitch used as the suture material (B). Note that there is no evidence of ring-down or acoustic shadowing specifically related to the NextStitch material.

taken to align the involved strands correctly. However, placing sutures into the prosthetic valve ring is virtually twice as fast, because each needle used implants 2 sutures with 1 "bite."

The product consists of multiple double-stranded needles with a single-stranded needle at each end of the chain. This configuration of the double-stranded needle allows the surgeon to introduce 2 sutures through the same hole in a single needle pass. This approach has several practical benefits. First, the ability to place 2 sutures through the same hole increases stability and reinforces the annulus-prosthesis interface but does so without the potential risk of damage to adjacent sutures. Because material damage to the adjacent structure can be hidden from the surgeon's direct inspection, use of NextStitch may therefore decrease the potential for interruption or compromise of the suture line and the resultant perivalvular flow or pseudoaneurysm formation [Bedderman 1978, Stiles 1986, Chambers 1991, Laks 1993]. In addition, the ability to deliver 2 sutures with a single needle bite aligns these 2 adjacent mattress sutures and eliminates the potential for gap formation between them. This ability to increase the precision of locating adjacent sutures decreases the potential for clinically important gaps that may contribute to perivalvular leak and the resultant consequences of increased turbulence, ie, infection complications. Perivalvular leaks occur in approximately 3% to 15% of all cases and are believed to be clinically important in 1% to 4% of cases with the attendant risks of infection and prosthesis instability [Bedderman 1978, Newton 1984]. Any ability to use a product that can reduce

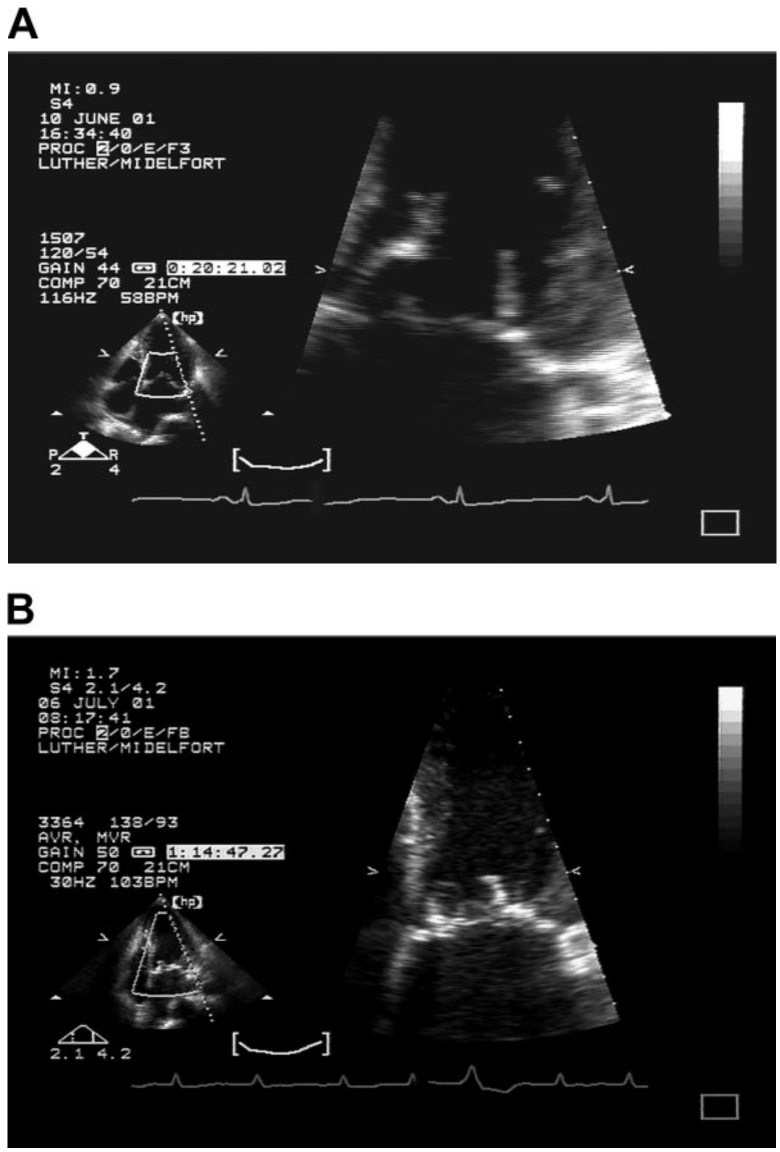

Figure 2. Preoperative transthoracic echocardiogram showing diseased mitral valve (A) paired with a postoperative echocardiogram from same patient showing a properly functioning prosthesis (30-mm Hancock prosthesis; Medtronic) with NextStitch used as the suture material (B). Note that there is no evidence of ring-down or acoustic shadowing related to the NextStitch material.

this incidence while preserving prosthetic stability brings benefits that are readily apparent.

An early concern among surgeons using the dual suture technique was that that adjacent sutures entering the annulus of a valve might have the vector of force applied to each suture in opposite directions. Thus, the advantages of a single entry site of the needle would be offset if the 2 sutures were pulled sufficiently in opposite directions to injure or devitalize the native tissue [Bedderman 1978, Chambers 1991]. The actual vector of force for both sutures is directed in parallel until they pass through the prosthesis sewing ring. Once through the sewing ring, the 2 sutures are pulled in opposite directions, but the force of these competing vectors is buffered by the prosthetic sewing ring and not by native tissue (see Figure 3). This process reinforces the advantage of the single entry site of the needle and obviates concern of adjacent tissue damage. Our intraoperative and postoperative echocardiographic assessment of our 36 valve replacements in 30 patients failed to show any needle jets or perivalvular leaks associated with this potential problem.

Another related concern of surgeons stabilizing these prostheses is the potential to unknowingly transect sutures already implanted with the needle during the placement of a new suture. This has been called the "William Tell" phenomenon and represents the unlikely but significant problem of piercing or cutting an exiting suture with the needle from the new suture. Because surgical fields are compact and visualization of suture depth may be restricted, the ability to dis-

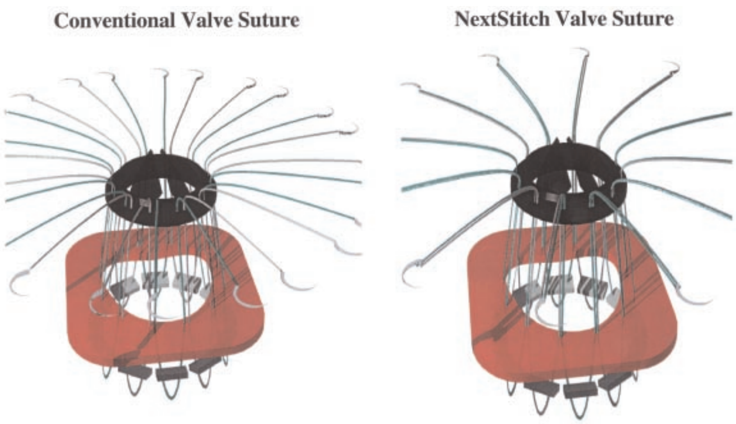

Figure 3. NextStitch valve suture versus conventional valve suture.

cern the exact location of placement of each suture is limited. NextStitch offers a straightforward solution to this concern, because the design of a multiple double-stranded needle setup in effect provides each single bite with needle precision in the placement of 2 sutures. Their placement relative to each other is ensured, and occult damage to adjacent structures is avoided. This latter point may be particularly important in avoiding injury to contiguous soft tissue associated with the cardiac conduction system.

A final interest in the use of this product was to review echocardiograms of both mitral and aortic prosthetic replacement. We wanted the suture line created by NextStitch not to have any unique ultrasound appearance characteristics or imaging properties that warranted special comment. As the figures illustrate, the images obtained are similar to other prosthesis images, and comments regarding important attributes are more likely to be centered on the prosthesis. As has been mentioned, no perivalvular leaks were identified.

In summary, we report on our first 30 cases that used NextStitch, a series of multiple double-stranded needles with a single-stranded needle at each end of a chain. A variety of aortic and mitral prosthetic valves were successfully implanted without complications. Operative times were qualitatively reduced or not affected, and no perivalvular leaks were identified. Our small number of patients in this early report precludes statements that more generally address the potential of this procedure to significantly reduce the occurrence of perivalvular leaks. Similarly, we cannot comment definitively on the potential for changes in postoperative infection rates. However, given the potential impact of precise placement of sutures leading to a reduction in perivalvular leaks, it is reasonable to theorize that this device can reduce the potential for infections by decreasing the incidence of pseudoaneurysm formation. An additional advantage may be the avoidance of injury to the contiguous soft tissue constituting the cardiac conduction system. Our study shows that NextStitch can be placed in the aortic and mitral positions without causing any apparent unique ultrasound characteristics. Further investigation is required to determine if perivalvular leakage, infection incidence, or valve stability is improved with the placement of parallel sutures by a single needle.

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