Prosthetic Aortic Valve Fixation Study

48 Replacement Valves Analyzed Using Digital Pressure Mapping

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Objective: Prostheses attachment is critical in aortic valve replacement surgery, yet reliable prosthetic security remains a challenge. Accurate techniques to analyze prosthetic fixation pressures may enable the use of fewer sutures while reducing the risk of paravalvular leaks (PVL).
Methods: Customized digital thin film pressure transducers were sutured between aortic annulus models and 21-mm bioprosthetic valves with 15 × 4-mm, 12 × 4-mm, or 9 × 6-mm-wide pledgeted mattress sutures. Simulating open and minimally invasive access, 4 surgeons, blinded to data acquisition, each secured 12 valves using manual knot-tying (hand-tied [HT] or knot-pusher [KP]) or automated titanium fasteners (TFs). Real-time pressure measurements and times were recorded. Two-dimensional (2D) and 3D pressure maps were generated for all valves. Pressures less than 80 mm Hg were considered at risk for PVL.
Results: Pressures under each knot (*intrasuture*) fell less than 80 mm Hg for 12 of 144 manual knots (5/144 HT, 7/144 KP) versus 0 of 288 TF ($P < 0.001$). Pressures outside adjacent sutures (*extrasuture*) were less than 80 mm Hg in 10 of 60 HT, zero of 60 KP, and zero of 120 TF sites for 15 × 4-mm valves; 17 of 48 HT, 25 of 48 KP, and 12 of 96 TF for 12 × 4-mm valves; and 15 of 36 HT, 17 of 36 KP, and 9 and 72 TF for 9 × 6-mm valves; $P < 0.001$ all manual versus TF. Annular areas with pressures less than 80 mm Hg ranged from 0% of the sewing-ring area (all open TF) to 31% (12 × 4 mm, KP). The average time per manual knot, 46 seconds (HT, 31 seconds; KP, 61 seconds), was greater than TF, 14 seconds ($P < 0.005$).
Conclusions: Reduced operative times and PVL risk would fortify the advantages of surgical aortic valve replacement. This research encourages continued exploration of technical factors in optimizing prosthetic valve security.

Key Words: Aortic valve replacement, Automated titanium fasteners, Minimally invasive surgery, Digital pressure mapping, Pressure transducer.

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Secure prostheses attachment is a critical component of cardiac valve surgery, particularly in preventing valve dehiscence and the development of paravalvular leaks (PVLs). Paravalvular leaks occur when there is inadequate apposition of the prosthesis to the underlying annulus, which leads to retrograde flow between the sewing cuff and native valve annulus.[1,2] The incidence of PVLs varies widely in the literature; clinically significant PVLs requiring reoperation develop in 1% to 3% of cases,[3,4] whereas asymptomatic paravalvular jets detected by echocardiography occur in approximately 15% to 79% of patients.[1,5] The main factors associated with increased risk of developing PVL include infective endocarditis, suturing technique, tissue characteristics, and technical factors related to valve fixation.[1,2,6] Large paravalvular jets detected intraoperatively can result in prolonged operative times with reinstitution of cardiopulmonary bypass, cross-clamping, and repair. When detected postoperatively on echocardiography, small asymptomatic PVLs reportedly follow a benign course.[1,6,7] However, larger PVLs can result in significant morbidity with resultant hemolysis, endocarditis, and heart failure. This ultimately necessitates a reoperation, which is associated with an 8% to 25% perioperative mortality,[8] poor long-term durability, and survival.[2,8]

Increasing the efficiency of prostheses attachment while preserving valve security can improve procedure times and overall patient outcomes. In our efforts to evaluate the technical factors influencing prosthetic valve attachment and the formation of PVLs, we developed a bench top aortic valve replacement (AVR) simulation model that uses digital thin film pressure transducer technology to obtain real-time measurements of the

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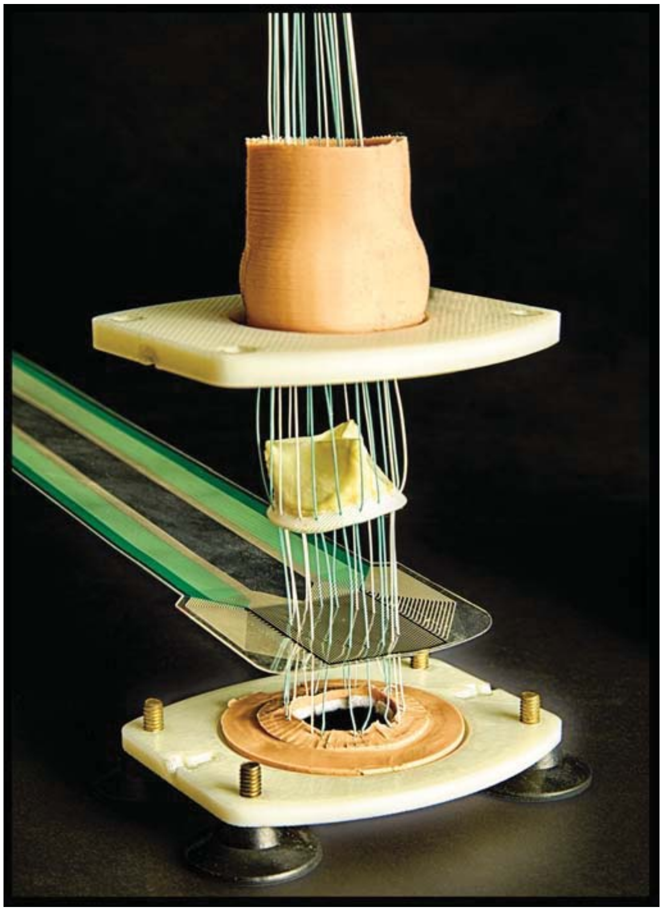

FIGURE 1. An exploded view of the aortic root model assembly demonstrating supra-annular valve placement with pledgeted 2-0 mattress sutures. From top to bottom: sinuses of Valsalva, bioprosthetic valve, thin-film pressure transducer, contoured aortic annular plane.

attachment pressures generated between the prosthesis and the underlying aortic annulus. We describe, in this study our innovative AVR simulation model and discuss its potential application in advancing our understanding of surgical valve replacement procedures. Using this model, we examined several technical factors—number of sutures, suture spacing, and method of securing suture—that may influence optimal aortic valve fixation under simulated open and minimally invasive cardiac surgery (MICS) conditions.

METHODS

Aortic Root Model and Pressure Mapping System

Plastic aortic root models were constructed to mimic supra-annular valve fixation. This simulator model incorporated a contoured, compliant thermoplastic elastomer (Dynaflex G6713-0001, PolyOne GLS Corporation, McHenry, IL USA), which was designed to reflect the shape of an aortic annulus and have similar properties (durometer hardness: 14 Shore A) to noncalcific annular tissue.

High-resolution digital pressure transducers captured real-time pressure measurements across a 27.9 × 27.9 × 0.2-mm sensing film (248 sensels/cm^2), which enabled acquisition of precise pressure measurements generated between the prosthetic valve and underlying annulus. Sensing films were perforated to fit either 15 sutures with 4-mm bite spacing (15 × 4 mm), 12 sutures with 4-mm bite spacing (12 × 4 mm), or 9 sutures with 6-mm bite spacing (9 × 6 mm). Standard suture configuration was considered to be 15 × 4 mm, whereas the alternate suture configurations (12 × 4 mm and 9 × 6 mm) were selected to evaluate the effect of using fewer sutures and wider bite spacing on the pressures generated between the prosthesis and underlying annulus.

Number 21 St. Jude Trifecta valves (St. Jude Medical, St. Paul, MN USA) were sewn into appropriately sized aortic root models using alternating white and green 2-0 polyester mattress sutures with Teflon pledgets (Fig. 1). The valves were seated and sutures organized into suture guides before the start of the timed procedures.

Participants and Procedures

Four operators of varying experience levels (2 attending cardiac surgeons, 1 cardiothoracic surgery fellow, and 1 general surgery resident) participated in this study. Each operator performed 12 procedures (6 open and 6 MICS via right anterior thoracotomy access) for a total of 48 valves placed (Table 1). Operators were introduced to the model and provided the opportunity to familiarize themselves with the technology before starting the procedures. The operators remained blinded to data acquisition until all 12 procedures had been completed.

Open AVR simulations were performed on a bench top model comparing manually hand-tied (HT) knots to titanium fasteners (TFs) placed using the COR-KNOT MINI device (LSI SOLUTIONS, Victor, NY USA). For MICS simulations, the aortic roots were placed within a thoracic skeleton model (Fig. 2), and manual knot tying was completed using a knot pusher (KP) (Edwards Lifesciences Corp, Irvine, CA USA), whereas TFs were placed using the COR-KNOT MIS device (LSI SOLUTIONS, Victor, NY USA) (Fig. 3). Six knots were thrown per suture for manually tied procedures, and one titanium fastener was used per suture for automated procedures (Figs. 4A–D, 5A–D).

Data Collection and Statistical Analysis

Data collection and statistical analysis were performed using I-SCAN System and Microsoft Office Excel (Microsoft, Redmond,

TABLE 1. Experimental Plan for Aortic Valve Placement Simulation Testing

Configuration (mm)		15 × 4	12 × 4	9 × 6	
Sutures/Knots		15	12	9	
Bite Width (mm)		4	4	6	Total
Access	Method	Number of Valves (Total Sutures)			
OPEN	Manual HT	4 (60)	4 (48)	4 (36)	12 (144)
	Automated TF	4 (60)	4 (48)	4 (36)	12 (144)
MIICS	Manual KP	4 (60)	4 (48)	4 (36)	12 (144)
	Automated TF	4 (60)	4 (48)	4 (36)	12 (144)
Total		16 (240)	16 (192)	16 (144)	48 (576)

A breakdown of 48 simulated aortic valve replacements by surgical access and knot placement method. Abbreviations: HT, hand-tied knots; KP, knot pusher; MICS, minimally invasive cardiac surgery; TF, titanium fastener.

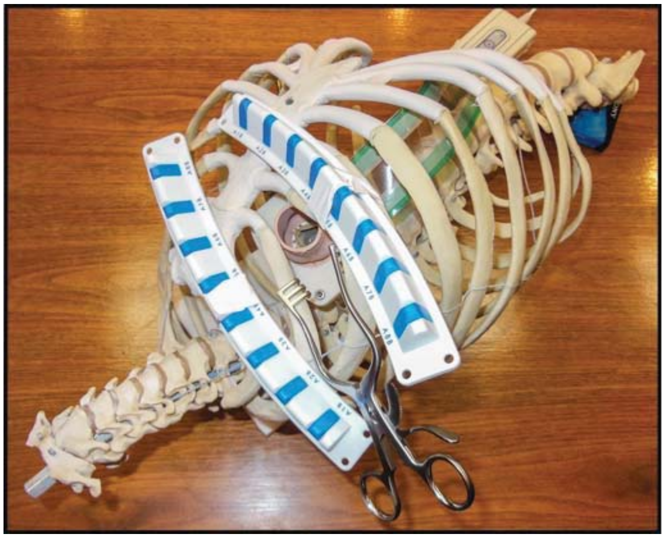

FIGURE 2. Minimally invasive setup with aortic root model in its anatomical position.

WA USA). Pressures were measured in kilopascal and converted into millimeters of mercury (mm Hg) for greater clinical relevance. Pressures below 80 mm Hg were considered at risk for PVL.

Pressures were measured and recorded over the entire prosthetic compression zone around the aortic annulus. Sample pressure measurements were obtained across the narrowest detectable radially oriented zone to minimize overestimation and were centered within each suture (*intrasuture*) and between adjacent sutures (*extrasuture*). The length of the measured samples extended the width of the sewing cuff from its inner diameter to the outer diameter. Data was recorded in real time during and at the completion of each procedure. Intrasuture and extrasuture pressure sample sites were pooled for data analysis and comparison of suture configurations and method of suture securement. The average area greater than 80 mm Hg was measured for each surgical approach, suture configuration, and knotting method. For purposes of comparison, these averages were then calculated as a percentage relative to the test sample with the largest measured area greater than 80 mm Hg in this study. This largest area was observed during a MICS 15 × 4-mm TF prosthetic placement test and measured 386.1 mm^2 (Table 2).

Procedure time was defined as the time it took the surgeon to start tying the first suture to the time that the last suture tail was cut. Two-dimensional and 3D representations of pressures around the annular area were generated for visual analysis and illustration (Figs. 4E–F, 5E–F, and 6).

Continuous data were summarized as mean ± standard deviation (SD) and ranges and compared using Student *t* tests and analysis of variance. Categorical variables were described as proportions and compared using χ^2 tests. Denominators for each procedure type were calculated by the number of sutures per procedure multiplied by the number of surgeons. Statistical significance was determined using 2-sided tests and accepted at the $P < 0.05$ level.

RESULTS

A total of 48 simulated AVR procedures were performed by the 4 surgeons, with each operator completing 12 AVRs; 3 prosthetic valves were secured using HT knots, 3 were secured with KP, and 6 were secured using TF, for a total of 144 HT, 144 KP, and 288 TF surgical knots placed. A total of 8 sutures were broken during the 48 procedures: 1 suture in the 9 × 6-mm HT group, 1 suture in the 15 × 4-mm KP group, 2 sutures in the 12 × 4-mm

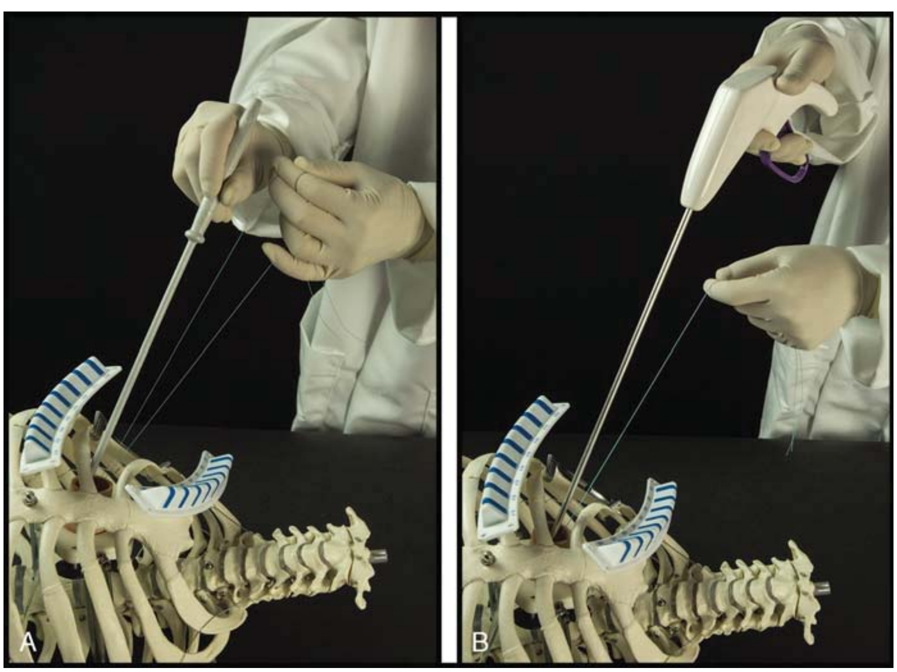

FIGURE 3. Simulated minimally invasive procedure using a knot pusher to secure surgical knots (A) and automated TFs (B).

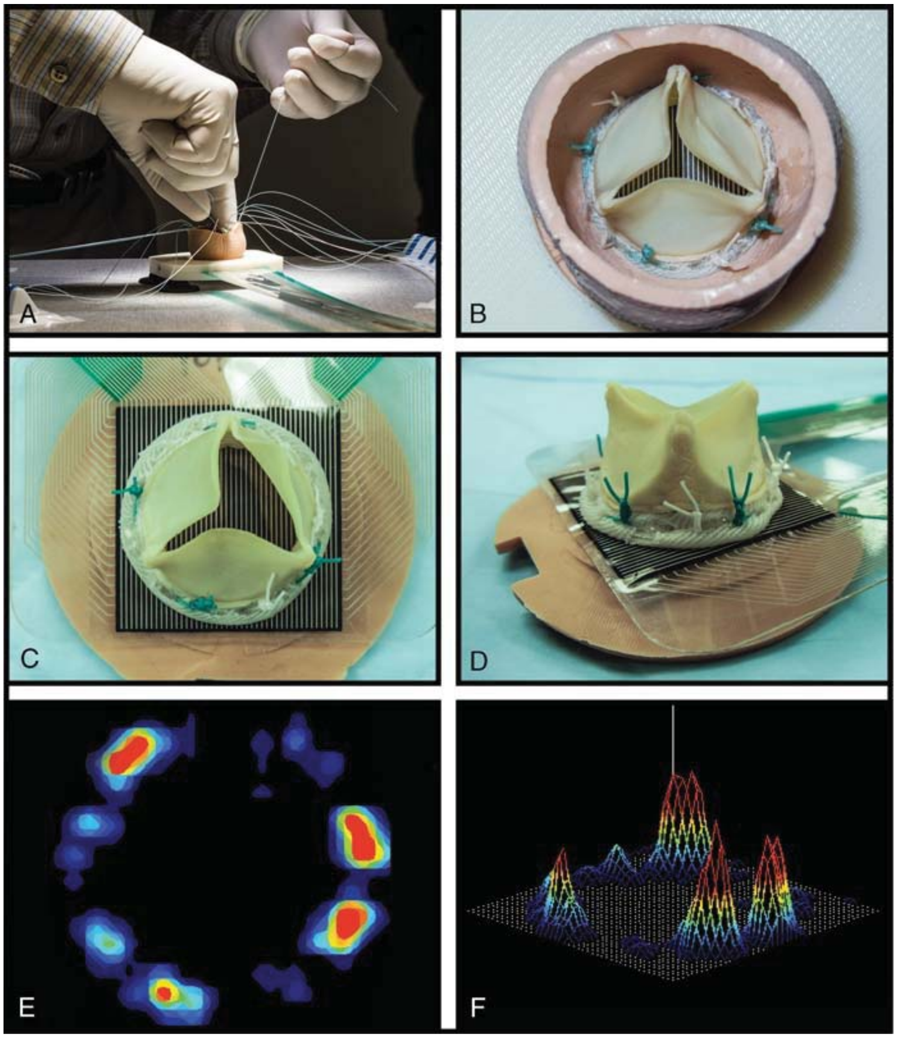

FIGURE 4. Simulated open procedure using hand-tied knots (A), top view of aortic root model (B), top view with aorta removed (C), side view with aorta removed (D), 2D pressure map (E), 3D pressure map (F).

KP group, and 4 sutures in the 9 × 6-mm KP group. No sutures were broken during AVR procedures using TF.

The mean ± SD intrasuture pressures generated for all HT, KP, and TF placed were 1067.1 ± 626.9 mm Hg, 1195.0 ± 640.3 mm Hg, and 2436.8 ± 791.8 mm Hg, respectively. Statistically significant differences existed between intrasuture pressures with the use of TF versus either HT ($P < 0.0001$) or KP ($P < 0.0001$); however, intrasuture pressures generated with KP and HT did not differ significantly ($P = 0.08$).

For simulated AVRs performed using the 15 × 4-mm configuration, the mean extrasuture pressure was 366.4 ± 248.1 mm Hg for manually tied knots (HT and KP) versus 697.6 ± 363.1 mm Hg for TF ($P < 0.05$). The mean extrasuture pressures were lower for simulated procedures using the 12 × 4-mm configuration [139.4 ± 147.9 mm Hg for manually tied knots vs 341.0 ± 252.5 mm Hg for TF ($P < 0.05$)] and the 9 × 6-mm configuration [138.1 ± 130.0 mm Hg for manually tied knots vs 292.8 ± 211.5 mm Hg for TF ($P < 0.05$)] (Table 2).

Annular areas with sample site pressures below 80 mm Hg ranged from 0% of the sewing-ring area (all open TF) to 31% (12 × 4 mm, KP). When pressures were compared by the method of securing suture, intrasuture pressures fell below 80 mm Hg more often when using manual knots [12/288 (4.2%): 5/144 HT, 7/144 KP] compared to TF [0/288 (0.0%)] ($P < 0.001$) (Table 2). This also held true when comparing extrasuture pressures; with more extrasuture pressure falling below 80 mm Hg for manual knots [84/288 (29.2%): 42/144 HT, 42/144 KP] versus TF [21/244 (8.6%)] ($P < 0.0001$) (Table 2). In a subanalysis of manual knots alone, there was no difference in intrasuture pressure sites less than 80 mm Hg between HT [5/144 (3.5%)] and KP [7/144 (4.9%)] methods ($P = 0.77$).

As the number of sutures decreased and bite spacing increased, there were more intrasuture and extrasuture pressures that fell below 80 mm Hg (Fig. 7). Intrasuture pressures fell below 80 mm Hg in 1 (0.8%) of 120 manual versus 0 (0.0%) of 120 TF sites in the 15 × 4-mm valves ($P = 0.318$); 6 (6.3%) of 96 manual versus 0 (0.0%) of 96 TF sites in the 12 × 4-mm valves ($P = 0.015$); and 5 (6.9%) of 72 manual versus 0 (0.0%) of 72 TF in the 9 × 6-mm valves ($P = 0.026$;

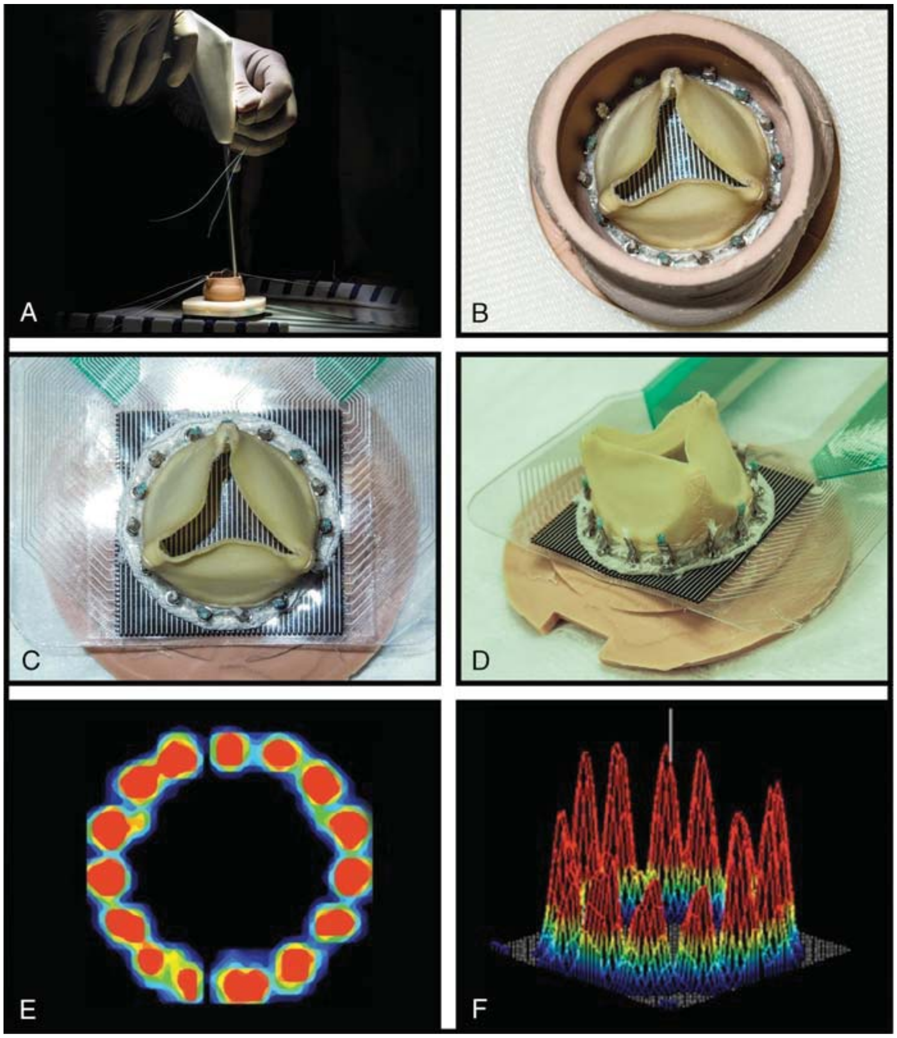

FIGURE 5. Simulated open procedure using TFs (A), top view of aortic root model (B), top view with aorta removed (C), side view with aorta removed (D), 2D pressure map (E), 3D pressure map (F).

Table 2). Extrasuture pressures fell below 80 mm Hg in 10 (8.3%) of 120 manual versus 0 (0%) of 120 TF sites in the 15 × 4-mm valves ($P = 0.002$); 42 (43.8%) of 96 manual versus 12 (12.5%) of 96 TFs in the 12 × 4-mm valves ($P < 0.0001$); and 32/72 (44.4%) manual versus 9/72 (12.5%) TFs in the 9 × 6-mm valves ($P < 0.0001$; Table 2).

The current standard technique for securing a size 21-mm bioprosthetic aortic valve typically uses 15 pledgeted hand-tied sutures with annular bites of approximately 3 to 4 mm in width, which in this simulation study is best represented by the open HT 15 × 4 mm procedure. The average surface area greater than 80 mm Hg was 74% for open HT 15 × 4 mm. The only other manually tied suture configuration with an average surface area that exceeded this was the MICS KP 15 × 4-mm procedure, with 84% surface area greater than 80 mm Hg. All TF suture configurations exceeded 74% with a range of 78% for MICS TF 9 × 6 mm to 95% for open TF 15 × 4 mm (Table 2).

When comparing the average time to secure suture by method, TF required the least amount of time (mean, 14 seconds per fastener), and the mean time difference required to secure suture between all manually placed knots and TF was 32 seconds (manual, 46 seconds per knot vs TF, 14 seconds per fastener) ($P < 0.005$). There was also a significant difference in the mean time required to secure suture between HT (31 seconds per knot) and KP (61 seconds per knot) techniques ($P < 0.001$).

DISCUSSION

A critical step of AVR surgery is obtaining an adequate seal during valve placement, thereby preventing the development of prosthetic valve dehiscence or PVL. Reported rates of PVL vary widely in the literature depending on the timing and method of echocardiography, the type of valve implanted, surgical technique, and valve location.[1,6–9] Although several studies report the benign nature of small PVLs detected early in postoperative course,[1,6,7] progression of PVL can result in clinically significant morbidity and mortality.[6,8] The first step toward reducing the incidence of this complication is to understand the forces acting within the prosthetic-annular complex and to identify the technical factors that influence these forces.

TABLE 2. Aortic Valve Fixation Study Pressure and Time Data

Access	Knot Method Sample Site	Mean SD (mm Hg)	Range (mm Hg)	No. of Sample Sites <80 mm Hg	% Average Area >80 mm Hg*	Average Time/Valve Average Time/Knot
OPEN	15 × 4 mm					
	60 HT Intra-	1167 ± 669	58–2535	1	74%	7 m 55 s
	60 HT Extra-	328 ± 255	0–972	10		31.7 s
	60 TF Intra-	2438 ± 593	1270–3830	0	95%	3 m 14 s
	60 TF Extra-	724 ± 365	84–2052	0		12.9 s
	12 × 4 mm					
	48 HT Intra-	1062 ± 677	0–2688	3	62%	6 m 7 s
	48 HT Extra-	170 ± 165	0–712	17		30.6 s
	48 TF Intra-	2453 ± 741	764–4289	0	83%	2 m 36 s
	48 TF Extra-	332 ± 290	7–1343	9		13.0 s
	9 × 6 mm					
	36 HT Intra-	907 ± 439	0–1698	1	66%	4 m 38 s
	36 HT Extra-	139 ± 120	6–487	15		30.9 s
	36 TF Intra-	2074 ± 983	751–4806	0	82%	2 m 16 s
	36 TF Extra-	309 ± 240	28–1079	5		15.1 s
MICS	15 × 4 mm					
	60 KP Intra-	1423 ± 537	140–2432	0	83%	15 m 40 s
	60 KP Extra-	405 ± 237	86–1166	0		62.7 s
	60 TF Intra-	2852 ± 804	1262–4466	0	93%	3 m 25 s
	60 TF Extra-	671 ± 362	96–1870	0		13.7 s
	12 × 4 mm					
	48 KP Intra-	1135 ± 697	0–2592	3	56%	11 m 38 s
	48 KP Extra-	109 ± 122	0–606	25		58.2 s
	48 TF Intra-	2499 ± 729	1196–4124	0	81%	2 m 32 s
	48 TF Extra-	350 ± 212	43–836	3		12.7 s
	9 × 6 mm					
	36 KP Intra-	896 ± 593	0–2103	4	65%	9 m 5 s
	36 KP Extra-	137 ± 141	0–581	17		60.6 s
	36 TF Intra-	2002 ± 642	862–3777	0	78%	2 m 3 s
	36 TF Extra-	276 ± 181	15–813	4		13.7 s

Pressure and time data for all events. *Calculated by dividing the average annular surface area > 80 mm Hg over the maximum surface area captured by the technology (386.1 mm^2).

We have previously published a study that quantified pressures exerted within the mitral prosthesis-annular complex in ex vivo porcine hearts, comparing TF to manually tied knots using a knot pusher.[10] After fixation of mitral annuloplasty rings, microtransducer probes were introduced within and between suture loops to measure the resulting compressional forces around the annulus. To the best of our knowledge, this was the first study to evaluate prosthesis security using pressures obtained from within the prosthesis-annular complex. However, the previous study was limited by the destructive nature of the testing, with introduction of a probe into a potential space created between the prosthesis and annulus. In the current study, thin film digital pressure transducers were sewn into the prosthesis-annular complex, which enabled procurement of precise pressure data in real time during seating and fixation of the prosthetic valves and with less distortion of the annular complex. Results using this method are consistent with those obtained from our previous study, indicating that the use of TF resulted in more complete and quicker prosthesis apposition to the annulus compared to the use of HT or KP.[10] The strong attachment pressures noted with the use of TF technology is likely due to the ability of the surgeon to compress the sewing ring cuff onto the annulus—by simultaneously pulling up on both suture tails and pushing down on the sewing cuff with the tip of the device—while instantly securing suture, which is much harder to do with manually tied knots, particularly in a minimally invasive setting.

Another advantage of this study was the ability to test the effect of suture spacing on prosthesis security. The finding that 9% of aorto-annular-prosthesis attachment pressures (intrasuture and extrasuture) were less than 80 mm Hg for HT knots in the commonly used 15 × 4-mm valve configuration was an interesting finding, which could potentially explain the relatively high rate of PVL jets detected on postoperative transesophageal echocardiography with conventional methods of knot tying.[1,5,7] Although most of these small PVL jets have minor clinical significance, some do progressively worsen, which can lead to secondary complications such as hemolytic anemia, infective endocarditis and congestive heart failure, ultimately resulting in reoperation with associated increased morbidity and mortality.[8] In contrast, none of the attachment pressures for 15 × 4-mm valve configuration secured using TF decreased to less than 80 mm Hg.

In conclusion, the use of this aortic root model enabled quantitative evaluation of the effect of suture technique on the strength of prosthetic valve fixation. This study demonstrates

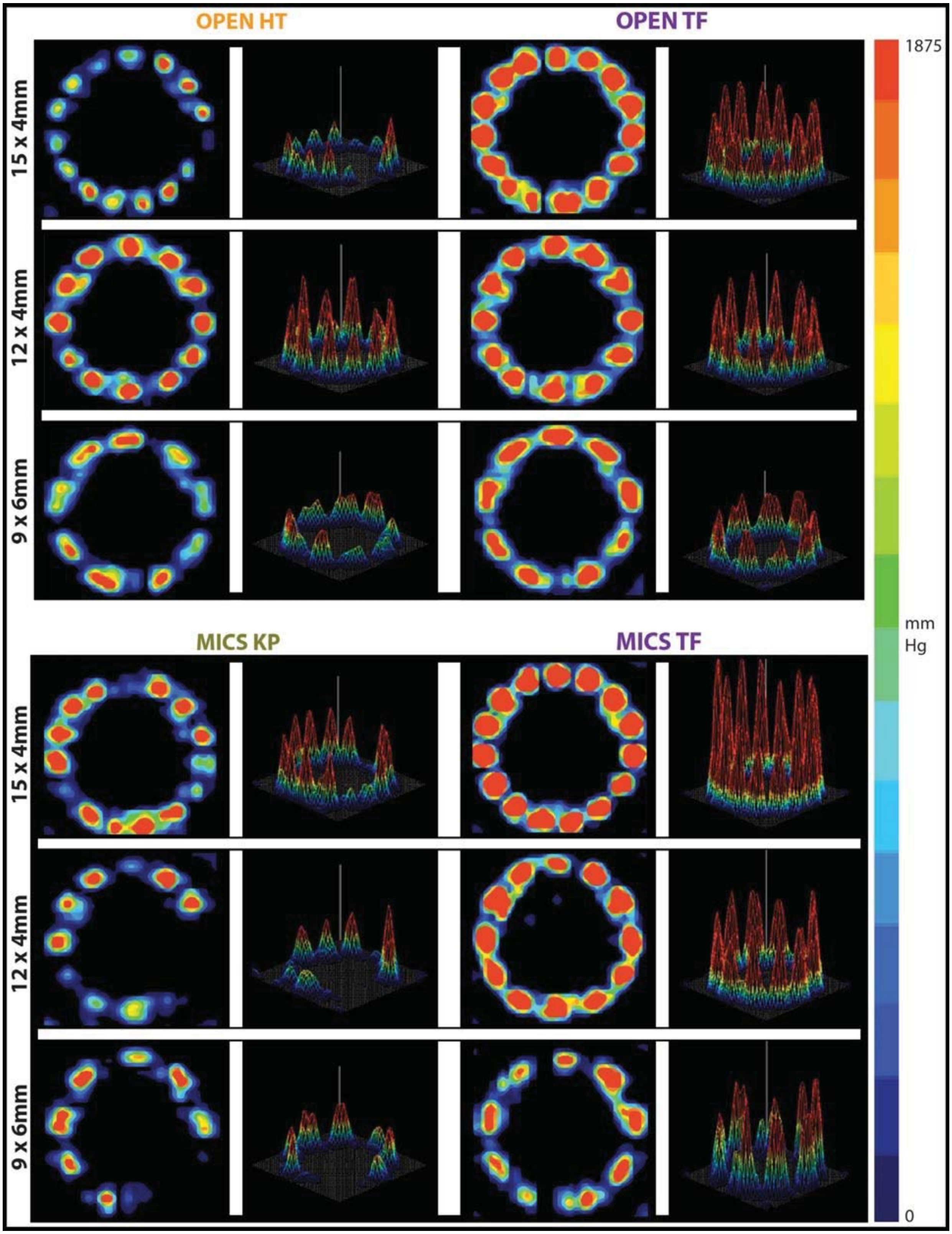

FIGURE 6. Sample 2D and 3D pressure maps generated by a single operator using open HT (top left), open TF (top right), MICS KP (bottom left), and MICS TF (bottom right) techniques. Three configurations per technique are shown (top, 15 × 4 mm; middle, 12 × 4 mm; bottom, 9 × 6 mm) with 2D pressure maps displayed on the left and 3D maps displayed on the right. HT, hand-tied knots; KP, knot pusher; TF, titanium fasteners; MICS, minimally invasive cardiac surgery.

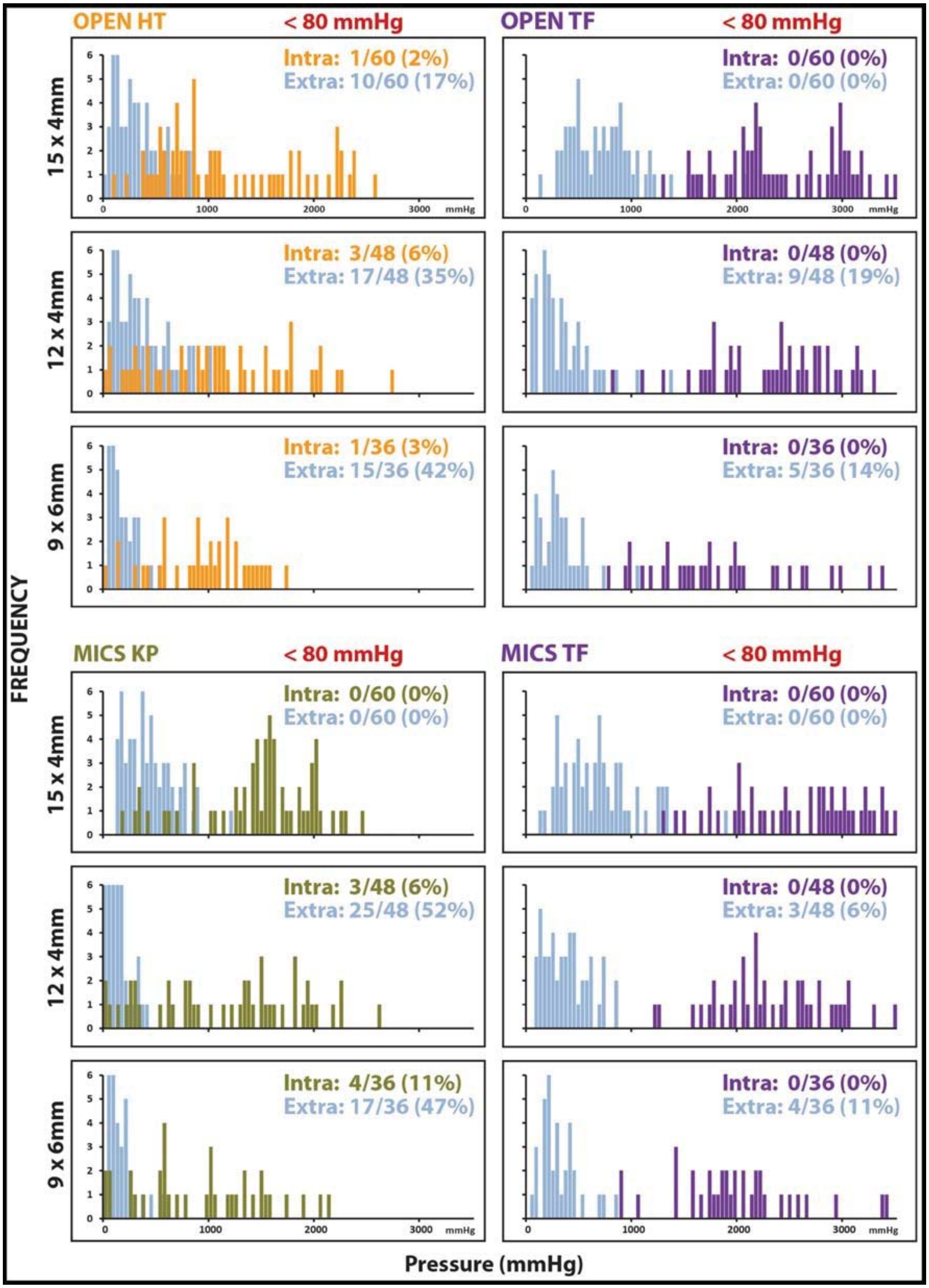

FIGURE 7. Histogram depicting pooled data from all 4 operators for open HT (top left), open TF (top right), MICS KP (bottom left), and MICS TF (bottom right) techniques. Increasing *y*-axis values represent increasing frequency of occurrence, whereas increasing *x*-axis values represent increasing prostheses attachment pressures (mm Hg). Three configurations per technique are shown (top, 15 × 4 mm; middle, 12 × 4 mm; bottom, 9 × 6 mm). Intrasuture and extrasuture pressures are color coded according to the text in the figure. HT, hand-tied knots; KP, knot pusher; MICS, minimally invasive cardiac surgery; TF, titanium fasteners.

that the use of TF and the 15 × 4-mm suture configuration resulted in the lowest potential for developing areas less than 80 mm Hg in the aorto-annular-prosthesis complex owing to the strong prostheses attachment forces that TFs generate when used; this may ultimately translate to a lower risk of developing PVLs. All average surface areas for configurations using TF were higher than the average surface areas for open, manually tied prosthetic placements. Furthermore, these data suggest that the placement of 12 sutures or less during a simulated AVR can increase the likelihood of generating aorto-annular-prosthesis attachment pressures less than 80 mm Hg. This study provides further insight into the forces generated during suture-mediated attachment of valve prostheses to the annulus. Digital pressure mapping technology provides an innovative platform on which to objectively evaluate current and novel valve replacement strategies and surgical techniques. Future exploration using this digital pressure mapping system to evaluate prosthetic attachment pressures can enhance our knowledge of cardiac prosthetic valve securement with goals to ultimately reduce operative times, invasiveness, and consequently improve patient outcomes.

Limitations

A major assumption made during this study was that aorto-annular-prosthesis attachment pressures less than 80 mm Hg represented areas at risk of developing PVL, which was the value used, as there has not been any study to date that measured such an association. The authors are of the opinion that until further data can be obtained in vivo to measure attachment pressures in AVRs with PVL, a threshold of less than 80 mm Hg, representing the minimum pressure exerted by blood on the aortic valve and the prosthesis during the cardiac cycle, is a reasonable estimate in determining areas at risk of developing PVL.

Another limitation is the generalizability of our pressure data, which inherently arises from using an aortic root model to simulate AVR procedures as opposed to studying this in human patients. Recognizing the differences in using simulated materials, we made efforts to replicate the compliance of noncalcific human tissue and mimic human anatomy with scalloping of the aortic annulus and sinuses of Valsalva. We acknowledge that the pressures obtained in this study are not directly translatable to pressures generated in a human patient. Furthermore, the use of a simulated normal annulus in this study prevents the generalization of our results to procedures involving a severely diseased annulus, where tissue distortion due to calcification and decalcification techniques can make uniform suture spacing, placement, and fixation difficult. In such circumstances, techniques that provide good tactile feedback while delivering strong and consistent pressures should be considered.

Lastly, the results in this study are not generalizable to the newer sutureless valves that are available for clinical use, as the pressure-sensing transducers that we used in this study measure tangential pressure to the film (located between the prosthesis and model annulus). Sutureless prosthetic valves are maintained in place primarily by the radial force exerted by the stent and as such, our model will not be able to sense such pressures.

Despite these limitations, our data provide valid trends that help to elucidate forces working within the annular complex. Moreover, this model of testing provides data that would otherwise be unobtainable. Translating the fixation force data to the clinical arena will require further study.

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CLINICAL PERSPECTIVE

This is an interesting report by Dr. Lee and colleagues from the University of Rochester examining the use of automated titanium fastener compared to manual knot tying or the use of knot pushers for the implantation of prosthetic aortic valves. The authors used an in vitro model and examined results using 4 operators of varying experience levels. Real-time pressure measurements and the time required for tying were recorded. Low recorded pressures were considered to be at risk for creating a paravalvular leak.

Titanium fasteners were found to be more effective than both manual hand tying and knot pushers with regard to avoiding low knot pressures. Knot tying was significantly quicker with the titanium fasteners. This study is an important contribution to the literature and adds more evidence to support of the use of titanium fasteners in valve surgery.

This study has several limitations. First of all, the assumption that attachment pressures below 80 mm Hg represent areas at risk for the development of paravalvular leaks is not widely accepted as a surrogate end point and is not supported by strong evidence. Moreover, the applicability of this model to the clinical situation remains to be proven. Despite these limitations, the authors are to be congratulated for this nice experimental work and for providing a scientific foundation for the evaluation of the efficacy of knot tying. This is a topic that is clearly of great importance to cardiac surgeons, as secure knot tying plays an important role in avoiding complications.