

# Use of an Expanded Polytetrafluoroethylene Patch as an Artificial Leaflet in Mitral Valve Plasty: An Early Experience

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**Purpose.** The purpose of this study was to examine the usefulness of polytetrafluoroethylene (PTFE) patches as artificial mitral leaflets in complex mitral valve plasty.

**Description.** Nineteen patients (mean age,  $66 \pm 9$  years) who were in need of mitral valve replacement successfully underwent mitral valve plasty with enlargement of the basal anterior leaflet using a PTFE patch.

**Evaluation.** Operative and in-hospital mortality was 0%. Patients were followed-up by maintaining their history, physical examinations, and echocardiography. The mean follow-up period was  $30 \pm 15$  months (2 to 52 months) with one late mortality and one reoperation. A thin neointimal layer was observed on the explanted PTFE patch. The PTFE patch maintained its pliability with no signs of calcification, excessive thickening, or perforation for 4 years. Mean motion angle of the patch on echocardiography decreased from  $41.1 \pm 10.6$  to  $35.2 \pm 12.5$  degrees ( $p < 0.05$ ) during  $26.7 \pm 15.5$  months of study (range, 6–46 months). The mean mitral valve area was  $2.9 \pm 0.7$  cm<sup>2</sup> at last follow-up.

**Conclusions.** The PTFE patches may be a promising material for artificial mitral leaflets.

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In mitral valve plasty there are several supplemental materials (eg, artificial chordae) that have been used in addition to the resection and suture of the native tissue. Gore-Tex sutures (W.L. Gore & Assoc, Flagstaff, AZ) have been successfully used as artificial chordae for more than 20 years [1]. The Gore-Tex suture (W.L. Gore & Assoc) is a microporous, nonabsorbable monofilament made of expanded polytetrafluoroethylene (PTFE) [2]. The long-term durability and biocompatibility of PTFE sutures have been confirmed by numerous investigators. As a result, Gore-Tex sutures have supplanted previously used biomaterials [3], and this is now the standard material for artificial chordae [4, 5].

Patch supplementation of mitral valve leaflets is sometimes useful for complex mitral valve plasty. Fresh or glutaraldehyde-treated pericardium or xenopericardium has been used for this purpose [6–8]. However, these biomaterials are at risk of showing calcification, shrinkage, or even disruption [9], as bioprosthetic valves also have limited longevity. Their long-term durability as patch materials for the mitral valve is not necessarily assured.

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## Technology

The Gore-Tex cardiovascular patch has a very similar microporous structure to the Gore-Tex suture. Its microporous structure is designed to allow the ingrowth of native tissue and improve biocompatibility. The PTFE is also both chemically and physically a very stable material in vivo, and PTFE does not degrade with time [10]. Therefore we hypothesized that PTFE cardiovascular patches would be useful for supplementation of mitral leaflets in complex mitral valve plasty.

## Technique

### Operative Technique

Patch enlargement of the anterior leaflet was performed in all cases. First, the annular attachment of the anterior leaflet was incised from one commissure to the other, leaving a 3-mm remnant tissue. An elliptical Gore-Tex patch (0.4 mm thick) was used in 15 cases. In four cases, a longitudinally opened Advanta SST, thin-walled PTFE, vascular graft (8 mm in diameter) (Atrium, Hudson, NH) was used as the patching material instead of a Gore-Tex patch. The Advanta SST graft (Atrium) is composed of three layers of PTFE (ie, two outer microporous layers, similar to the Gore-Tex patch, and one dense middle layer). The Advanta SST graft is thinner and more pliable

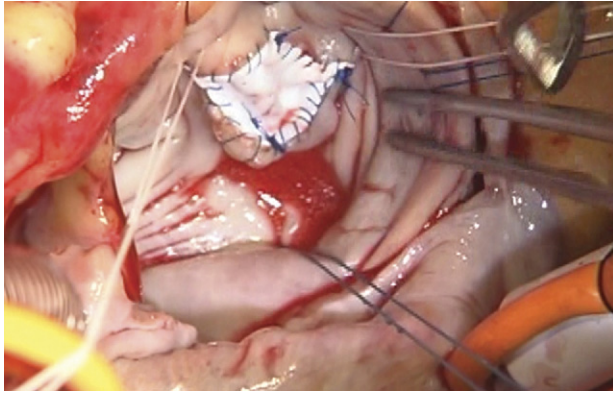


Fig 1. A 0.4-mm Gore-Tex patch (W.L. Gore & Assoc, Flagstaff, AZ) sutured at the base of the anterior mitral leaflet in ischemic mitral regurgitation.

than the Gore-Tex 0.4-mm patch. The patch was approximately 1.5 to 2.0 cm wide, and the length was adjusted according to the inter-commissure distance of each patient. The patch was sewn with a running 5-0 polypropylene suture (Fig 1). Leaflet resection and suture technique was added in 2 patients, and posterior leaflet plication was performed in 1 patient who had systolic anterior movement of the anterior leaflet and obstructive cardiomyopathy. Leaflet slicing was used in another patient. A flexible posterior annuloplasty band was installed in all cases except the one who had obstructive cardiomyopathy. A standard-size band was selected based on the inter-trigone distance of each patient. A Cosgrove-Edwards annuloplasty band (Edwards Lifesciences, Irvine, CA) was used in 14 patients, and a Tailor annuloplasty band (St. Jude Medical, St. Paul, MN) in 4. The average size of the flexible bands was  $30 \pm 2$  (range, 27-34).

## Clinical Experience

### Patient Selection

This prospective study was started in February 2005. Patients destined to undergo mitral valve surgery were assessed using preoperative transthoracic or transesophageal echocardiography, or both. Selected potential candidates for leaflet augmentation with PTFE patches were those patients in whom valve plasty was difficult either because of severe leaflet tethering due to cardiomyopathy or because of shrunken leaflet tissue due to rheumatic or previous bacterial inflammation or other causes. Written informed consent was obtained preoperatively from all patients. The study was carried out under the approval of our institutional review board.

Until the end of April 2009, the anterior leaflet augmentation technique with PTFE patch was first tried in 23 patients and was completed in 19 patients. In 4 patients in whom patch augmentation was intraoperatively aborted, sclerosis in the coaptation zone was the main reason. Nineteen patients were eventually enrolled in this study. They represented 9% of all patients (19 of

212) undergoing mitral valve surgery (150 plasty and 62 replacement surgeries) at our institution during this study period. The demographic characteristics of patients are presented in Table 1. Two patients had prior mitral valve plasty and recurrence of regurgitation. Of these, 1 patient had undergone ring annuloplasty for cardiomyopathy and annular dilatation, and the other had undergone quadrangular resection of posterior leaflet and ring annuloplasty for degenerative disease.

Patients were followed-up every 6 to 12 months by maintaining their history, physical examinations, and echocardiography.

As an objective index of pliability of the PTFE patch, its angle against the annular plane at the maximal opening position during diastole and closing position during mid-systole were measured on the long-axis B-mode echocardiographic images. When the patch flexed beyond the annular plane toward the left atrium during systole, the angle was designated as negative. The Digital Imaging and Communications in Medicine (DICOM) files or digitized video movies were downloaded onto a Macintosh com-

Table 1. Patient Demographics And Operative Data (n = 19)

Variables	Data
Age (y)	66.1 ± 9.0
Sex (male/female)	10/9
Pathology	
Primary DCM	10
Ischemic DCM	5
Infective endocarditis	1
Rheumatic	1
Myxomatous degeneration	1
HOCM	1
Preoperative NYHA functional class	
II	5
III	12
IV	2
Preoperative MR	
Severe	14
Moderate	5
Preoperative LV ejection fraction	0.49 ± 0.15 (range, 0.28-0.74)
LVDd (mm)	61.3 ± 7.8 (range, 48-73)
LVDs (mm)	45.8 ± 10.2 (range, 30-63)
Reoperative surgery	2
Concomitant operation	
CABG	5
AVR	2
TAP	4
Maze	2
Septal myectomy	1

AVR = aortic valve replacement; CABG = coronary artery bypass grafting; DCM = dilated cardiomyopathy; HOCM = hypertrophic obstructive cardiomyopathy; LV = left ventricle; LVDd = diastolic left ventricular diameter; LVDs = systolic left ventricular diameter; MR = mitral regurgitation; NYHA = New York Heart Association; TAP = tricuspid annuloplasty.

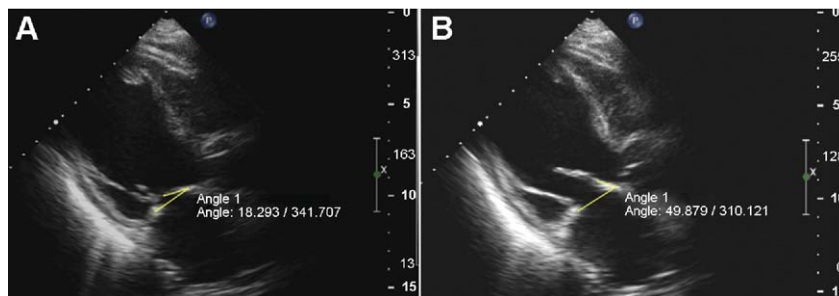


Fig 2. (A) Systolic and (B) diastolic echocardiographic images at 46 months postoperatively in a 72-year-old man who underwent anterior mitral valve augmentation with a Gore-Tex patch (W.L. Gore & Assoc, Flagstaff, AZ) for ischemic mitral regurgitation. The motion of the Gore-Tex patch at the basal portion of the anterior leaflet is preserved. The high echocardiographic image of the patch is due to the properties of Gore-Tex and does not imply calcification. The motion angle of the patch was directly measured on digital images.

puter (Apple, Cupertino, CA), and the angles were measured offline using OsiriX DICOM viewer software (OsiriX Foundation, Geneva, Switzerland) (Fig 2).

Other routine measurement data were collected using the functions available with each echocardiographic machine.

#### Statistical Analysis

Results are expressed as mean  $\pm$  standard deviation unless otherwise indicated. Early and late postoperative echocardiographic data are compared using the paired *t* test. A *p* value of below 0.05 was considered significant. Statistical analyses were performed using StatView version 5.0 (SAS Institute, Cary, NC).

#### Mortality and Morbidity

There were no operative or in-hospital deaths.

Eighteen patients were followed-up to the end of this study. Mean follow-up period was 30 months (2-51 months). One patient was lost to follow-up at 5 months. No infective endocarditis, thromboembolic events, or hemolysis were observed. One patient, a 55-year-old man, underwent a reoperation due to recurrent mitral regurgitation at 6 months postoperatively. Initial operation was commissurotomy, leaflet slicing, splitting of fused chordae, chordal reattachment, and leaflet augmentation for advanced rheumatic mitral stenosis and regurgitation. An Advanta SST graft was used as the patch material. During the reoperation, suture line dehiscence was observed that had been caused by disruption of the native leaflet tissue side. The PTFE patch was intact and showed no thickening, calcification, or laceration by suture materials. In this patient, postoperative echocardiography showed undue flexion of the leaflet tissue at the suture line due to the excessive size of the patch. He successfully underwent mitral valve replacement. Pathologic examination of the excised mitral tissue revealed a smooth neointimal layer (approximately 30  $\mu$ m thick) on the atrial surface of the patch (Fig 3). An endothelial layer was observed on the surface of the neointimal layer. One patient with ischemic cardiomyopathy died 27 months postoperatively of congestive heart failure. No mitral regurgitation was observed in this patient. Excluding one late death, one reoperation, and

one lost to follow-up, 12 patients were in the New York Heart Association functional class I, 3 were in class II, and 1 was in class III at last follow-up examination.

#### Echocardiographic Results

Early (before discharge) and late (6 months or later) echocardiographic studies were performed in 17 patients. Mean period between pre-discharge and last follow-up study was 26.7  $\pm$  15.5 months (range, 6 to 46 months). Data are presented in Table 2. Late recurrence of moderate mitral regurgitation was observed in 1 patient due to sclerosis of the native leaflet tissue in the coaptation zone, which was not directly related to the site of patch enlargement. Severe regurgitation developed in 1 patient because of suture line dehiscence, and he underwent a reoperation as previously mentioned. In this patient, postoperative maximal opening angle, minimal closing angle, and motion angles of the patch were 52, -15, and 67 degrees. The excessive size of the patch may have caused undue bending motion of the suture line between the patch and the leaflet, leading to the subsequent disruption.

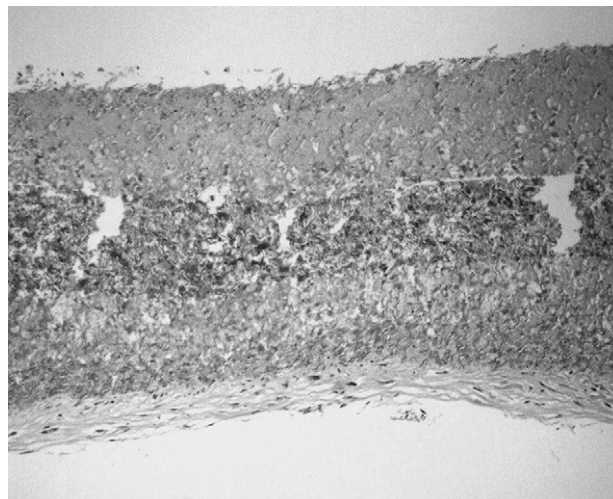


Fig 3. Pathologic findings of the polytetrafluoroethylene (PTFE) patch (Advanta SST PTFE graft) explanted 6 months postoperatively. (Hematoxylin and eosin;  $\times 40$ .)

Table 2. Echocardiographic Data (n = 17)

Variables	Early	Late	p
LVDd (mm)	58.1 ± 8.5	53.9 ± 6.0	0.064
LVDs (mm)	43.5 ± 11.1	38.5 ± 8.6	0.068
EF	0.49 ± 0.16	0.54 ± 0.16	0.17
MR			
None to trivial	11	9	
Mild	6	6	
Moderate	0	1	
Severe	0	1	
Max OA (degree)	49.6 ± 7.5	43.3 ± 9.1	0.13
Min CA (degree)	8.5 ± 8.5	8.1 ± 9.1	0.8
Motion angle (degree)	41.1 ± 10.6	35.2 ± 12.5	0.005
MVA (cm <sup>2</sup> )	2.8 ± 0.5	2.9 ± 0.7	0.25

CA = closing angle; EF = ejection fraction; LVDd = diastolic left ventricular diameter; LVDs = systolic left ventricular diameter; Max = maximum; Min = minimum; MR = mitral regurgitation; MVA = mitral valve area; OA = opening angle.

Mean maximal opening angle of the PTFE patch showed a tendency to decrease, but minimal closing angle remained constant. Motion angle (difference of angle between maximal opening and closing) significantly decreased during follow-up, but an average motion angle of 35° was observed in the late period, which indicated sufficient pliability of the patch. Average mitral valve area was 2.9 cm<sup>2</sup> at late follow-up with no signs of mitral stenosis observed in any of the cases. Echocardiographic findings of patch motion and thickness were similar between the Gore-Tex patch and Advanta SST graft. Average motion angle of the patch at last follow-up examination was 42 ± 20 degrees for Advanta SST and 33 ± 10 for Gore-Tex (p = 0.24).

## Comment

### Safety of the PTFE Patch for Mitral Valve Plasty

The suture line dehiscence that necessitated reoperation occurred in 1 patient, but the disruption was due to the cutting of native valve tissue by the suture material, not disruption of the PTFE patch. This type of failure could occur, irrespective of patch materials. Excessive motion of the patch due to redundant patch size was observed in this patient.

No recurrence of mitral regurgitation directly related to the PTFE patch failure was observed in other patients.

### Comparison Between the PTFE and Other Materials as Artificial Mitral Leaflet

Since the advent of open heart surgery, several surgeons have performed patch enlargement of mitral leaflet tissue for complex mitral valve plasty. In 1960, Sauvage and associates [6] performed mitral leaflet advancement using fresh pericardium. Glutaraldehyde-treated autologous pericardium [7] or xenopericardium [8] have also been used for this purpose. However, Grabenwöger and associates [9] reported that brief immersion of autolo-

gous pericardium in glutaraldehyde resulted in incomplete link formation of collagen fibers and led to late disruption of the tissue when using the Autogenics valve (Autogenics, Santa Barbara, CA). They also reported that xenopericardium valves tend to become calcified.

The necessary characteristics of supplemental materials for mitral leaflet tissue are stability of size without eventual stretching or shrinkage, mechanical strength sufficient to withstand the repeated stress caused by heartbeat and long-lasting pliability without calcification or excessive thickening. In this respect, autologous or xenopericardium is not necessarily an ideal substitute for mitral leaflet, making it important to search for better materials. The Gore-Tex suture and Gore-Tex patch have a similar microporous structures designed to maximize biocompatibility [10].

The PTFE patch is basically the same material as the PTFE suture that has been successfully used for 20 years [4, 5]. Accelerated fatigue tests have shown it to have mechanical strength sufficient to withstand the repeated stress caused by blood pressure for 100 years, and to be chemically inert and stable in the human body, showing no degradation [10]. This makes the PTFE patch a potentially more reliable material than pericardium, at least with respect to stability of size and freedom from disruption. If the thin and smooth tissue covering on the PTFE patch, as seen in Figure 3, does not show excessive tissue proliferation over the long term, a microporous PTFE patch could act as a scaffold for neo-mitral leaflet tissue and maintain its pliability. Echocardiographic findings have supported this hypothesis so far. However, care should be taken because the opening angle of the patch showed a tendency to decrease during follow-up.

### Study Limitations

This study is limited in case number and follow-up period, and thus it is merely descriptive, lacking randomization or control groups. Therefore, we have no firm evidence that PTFE is superior to pericardium as an artificial leaflet material. We have demonstrated the feasibility of PTFE patch as an artificial mitral leaflet.

We used a PTFE patch at the base of the anterior leaflet, not at the coaptation zone, so there is no evidence as yet that PTFE can be used in every part of the mitral valve as an artificial leaflet.

In conclusion, PTFE patches can be safely used to supplement leaflet tissue in complex mitral valve plasty, and showed sufficient performance as an artificial leaflet for up to 4 years.

### Disclosures and Freedom of Investigation

No funds were used to perform this study. Gore-Tex patches were covered by public health insurance and Advanta-SST grafts were supplied at full cost to the authors' department. The authors had full control in the patient selection, operative technique, study design, data analysis, and preparation of the article.

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## Disclaimer

The Society of Thoracic Surgeons, the Southern Thoracic Surgical Association, and *The Annals of Thoracic Surgery* neither endorse nor discourage use of the new technology described in this article.

## INVITED COMMENTARY

Ischemic mitral regurgitation (MR) is a serious clinical problem in coronary artery disease and it is associated with poor long-term outcomes. Mitral valve repair has been reported to be better than mitral valve replacement regarding early mortality and late outcomes. Lateral replacement of the papillary muscle with the enlarged left ventricle caused tethering of the chordae, and resulted in restricted systolic motion of the mitral leaflet. Undersized ring annuloplasty has been the first choice for reduction of the dilated mitral annulus. However, because the incidence of recurrent MR was greater than 30%, a more sophisticated approach to ischemic MR is necessary. Mitral leaflet augmentation is one of the options to repair tethered mitral leaflet, besides papillary muscle approximation, secondary chordal cutting, and surgical relocation of the papillary muscle. The authors [1] reported anterior mitral leaflet augmentation with the polytetrafluoroethylene (PTFE) patch to increase coaptation zone against posterior leaflet. This procedure was similar to a previously used technique, which was leaflet augmentation with autologous or xenopericardium for functional MR or rheumatic MR. The fate of the pericardium has been shrinkage or calcification with time. Redo surgery is sometimes the situation after coronary artery bypass grafting for the treatment of ischemic MR. As autologous pericardium is difficult or impossible to harvest during a redo situation, the commercially available PTFE patch must be useful.

We have used expanded PTFE sutures for chordal replacement in degenerative mitral regurgitation for 20

years [2]. The sutures became completely endothelialized with anti-thrombotic characteristics. Although the Gore-Tex sutures (Ethicon, Somerville, NJ) were thicker than the original material with absorption of protein from the serum with time, the CV-4 sutures have been flexibly working even 15 years after the operation in all cases. As the authors [1] reported the motion angle of the patch decreased from 41 degrees to 35 degrees in 2 years, meticulous follow-up of the PTFE with echocardiography should be mandatory. In addition, there must be a limitation of this procedure for functional MR. The indication of this procedure with regard to the tethering height or other index should be delineated in the future.

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