


Initial experiences of transapical beating-heart mitral valve repair with a novel artificial chordal implantation device

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Abstract

Background: Severe mitral regurgitation (MR) is associated with progressive heart failure and impairment of survival. Degenerative MR accounts for most MV repair surgeries. Conventional mitral valve repair surgery requires cardiopulmonary bypass and is associated with significant morbidity and risks. Transapical beating-heart mitral valve repair by artificial chordae implantation with transesophageal echocardiography (TEE) guidance has the potential to significantly reduce surgical morbidity. We report the first-in-human experience of degenerative MR repair using a novel artificial chordae implantation device (Mitralstitch™ system).

Methods: Ten patients with severe MR underwent transapical artificial chordae implantation using Mitralstitch™ system. The procedure was performed through a small left thoracotomy under general anesthesia and TEE guidance. Patients underwent transthoracic echocardiography and other assessments during the follow-up.

Results: All 10 patients with an average age of 63.7 ± 9.6 years successfully received transapical artificial chordae implantation. Their MR reduced from severe to none or trace in five patients, mild in five patients before discharge. Five patients received one artificial chordal implantation, four patients received two, and one patient received three and edge-to-edge repair by locking two of them. The safety and efficacy endpoint were achieved in all patients at 1-month follow-up. At 1-year follow-up, six patients had mild MR, three patients had moderate MR, one patient had recurrence of severe MR and underwent surgical repair.

Conclusions: The results of this first-in-human study show safety and feasibility of transapical mitral valve repair using MitralStitch system. Patient selection and technical refinement are crucial to improve the outcomes.

KEYWORDS

artificial chordae, mitral regurgitation, transapical

1 | INTRODUCTION

Mitral valve disease is the most prevalent heart valve disorder. Severe mitral regurgitation (MR) is associated with adverse prognosis of heightened risk of heart failure and impaired long-term survival if left untreated.¹ Degenerative MR is the most common etiology in Western countries and has become more prevalent in China.² Mitral valve repair with expanded polytetrafluoroethylene (ePTFE) artificial chordae implantation has been demonstrated to have clinical outcomes comparable with those of leaflet resection and is increasing used in the conventional mitral valve surgery repair operation.^{3,4} However, conventional surgery requires cardiopulmonary bypass and cardioplegia, and is associated with significant trauma and various risks. Therefore, less invasive therapies for the treatment of MR have received increased attention. Recently, transapical mitral valve repair by implantation of artificial chordae emerged from various technologies. This technology with devices like Neochord (Neochord, Inc.) and Harpoon (Harpoon Medical, Inc.) has been reported with results suggesting safe and effective treatment for MR. In this study, we report the initial experience of a first-in-human study of a novel device to implant a combination of ePTFE suture and a pledget as the artificial chordae to repair degenerative MR through the transapical approach with echocardiographic guidance.

2 | METHODS

2.1 | Study design

We conducted this prospective, observational, early-feasibility trial to test the safety and performance of a novel artificial chordal implantation system for mitral valve repair. This trial was conducted at two clinical centers (Yunnan Fuwai Cardiovascular Hospital, China, and Beijing Anzhen Hospital, China). The protocol was approved by

the ethics committee of the participating hospitals. All patients were informed about the specific risks of transapical off-pump mitral valve repair and alternative surgical procedures. All patients provided written informed consent before enrollment. This trial was registered in Chinese Clinical Trial Registry (ChiCTR1900021888, <http://www.chictr.org.cn>).

2.2 | Study patients

Patients more than 18 years old with severe degenerative MR due to prolapse of the posterior, anterior, or both leaflets were enrolled. The inclusion criteria included the necessity of MV-repair in patients with a Society of Thoracic Surgeons Predicted Risk of Mortality (for repair) >4%. Transesophageal echocardiography (TEE) assessment played a critical role in patient selection to ensure adequate coaptation surface of the mitral valve after artificial chordae implantation. Patients were excluded if they had other cardiac diseases requiring concomitant cardiac surgery, functional MR, unfavorable mitral valve anatomy (heavy calcification, leaflet perforation, significant leaflet tethering), severe pulmonary hypertension, excessive mitral annular dilation (anterior-posterior diameter >45 mm) and left ventricular dilatation (end-systolic diameter >55 mm), severe left ventricular dysfunction with ejection fraction less than 20%, or history of infective endocarditis.

2.3 | Device description and implantation procedure

The MitralStitch™ System (Hangzhou DeJin Medtech Co., Ltd.) consists of two devices (Figure 1). One is Valve Stitcher, which has a retractable arm made by a Nitinol frame as the positioner, which could be clearly identified in TEE imaging to effectively facilitate

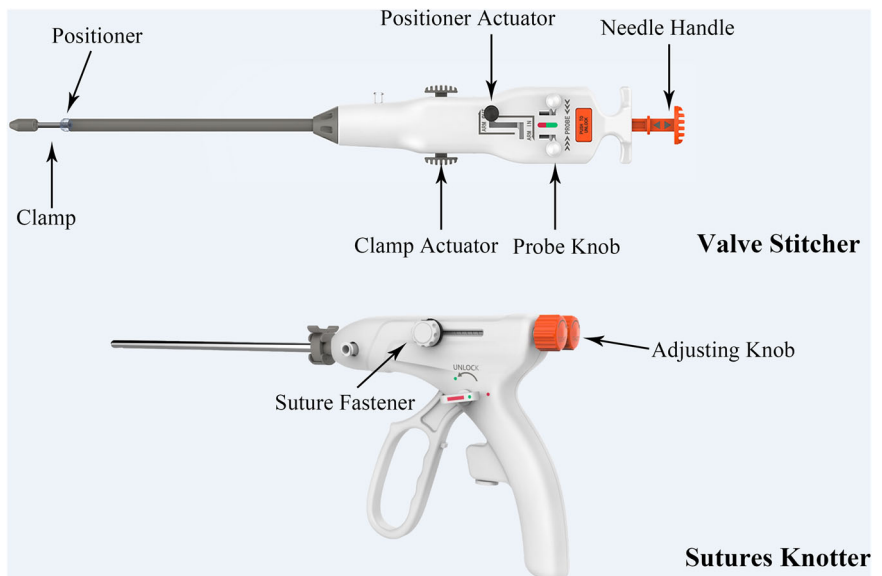


FIGURE 1 The MitralStitch™ system device, Valve Stitcher and Sutures Knotter. The suture and pledget are preloaded in the head of the Valve Stitcher

grasping of the target prolapsing leaflet. The positioner has two different sizes for anterior and posterior leaflet grasping. After the Valve Stitcher catches the leaflet, the probe could be used to detect whether the clamp has grasped enough length of the leaflet or not; the mechanism of detection by the probe is showed in Figure S1. The detection starts by pushing the two probe knobs on the device inwardly. If the probe meets the leaflet, the knob will point to the green marker. Otherwise, the knob will slide to the red marker. Only when the two knobs point to the green marker, the clamp has grasped enough leaflet. The Mitralstitch™ system uses ePTFE suture as the artificial chordae with PET pledget anchored on the leaflet. The suture sewed on the pledget with two connectors on both ends of the suture is preloaded in the tip of the device. After the clamp grasps leaflet and closes, the needle handle is pressed to make the two needles puncture across the leaflet and connect with the connectors. Then open the clamp and withdraw the needle holder, the suture will be pulled out from the tip of the device and the pledget will be left on the atrium side of leaflet (Figure 2). The other device is the Suture Knotter, to deliver a Titanium knot, which is used for fixing the implanted chordae on the epicardium or locking implanted chordae together for edge-to-edge repair. Suture Knotter allows precise adjustment of implanted chords length by rotating the adjusting knob.

The procedure was performed with patients under general anesthesia in a cardiac surgery operation room. Access to the left ventricle was achieved through a left lateral thoracotomy in the fifth intercostal space. The left ventricular puncture site was at the apex and gradually dilated after two purse-string sutures with polyester felts were placed. The Valve Stitcher was advanced towards the mitral valve under the guidance of both two- and three-dimensional TEE images. After the tip of the device was introduced into the left atrium, the clamp was opened and the positioner was released. The device was retrieved back gently to place the positioner below the target mitral leaflet in the left ventricle with TEE guidance. The clamp was then closed and the probe knob was steered to test the grasping effect. If the two knobs kept pointing to the

green marker, it indicated enough leaflet capturing. Otherwise, repeated orientation and grasp were required until a good result was obtained. Then the target leaflet segment was punctured by pressing the needle handle and the ePTFE suture was implanted on the prolapsing segment with a PET pledget left on the atrial side of the prolapsing leaflet. The implanted artificial chordae tensioning was performed during TEE evaluation of MR under normal left ventricular filling conditions (Figure 3). If edge-to-edge repair was necessary, the implanted artificial chordae on anterior and posterior leaflets could be locked together using the Titanium knot released by the Sutures Knotter. After enough coaptation area of the mitral valve and satisfactory MR reduction was confirmed by TEE, the ePTFE sutures were fixed on the epicardium with polyester felts by the Sutures Knotter. The thoracotomy was then closed in a standard fashion.

2.4 | Study endpoints

The safety endpoint was freedom from major adverse events during the procedure and within 30 days after the procedure. The efficacy endpoint was procedural success, defined as successful implantation of one or more artificial chords on the mitral valve and reduction of MR from severe to moderate or less at the conclusion of the procedure and at 30 days after the procedure.

2.5 | Statistical analysis

Patients characteristics and clinical outcomes were described by counts and percentages for categorical variables and mean \pm SD, sometimes supported by ranges, for continuous measures. Statistical testing of preprocedural and postprocedural echocardiography measurements was performed with matched-pair *t* tests. Statistical significance was based on a significance level of $p = .05$. Analyses were performed with IBM SPSS Statistics 25.0 software (IBM Corporation).

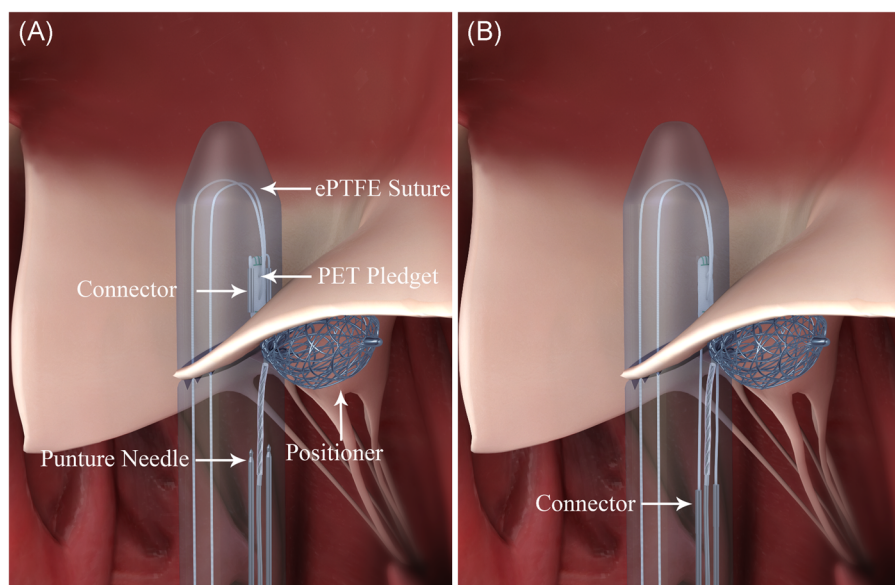


FIGURE 2 Mechanism of artificial chordae implantation by Valve Stitcher. (A) It shows the clamp had grasped the leaflet. The suture with two connectors on both ends sewed on the pledget is preloaded in the tip of the device. (B) It shows the needles had been pulled back after they punctured across the leaflet and connected with the connectors

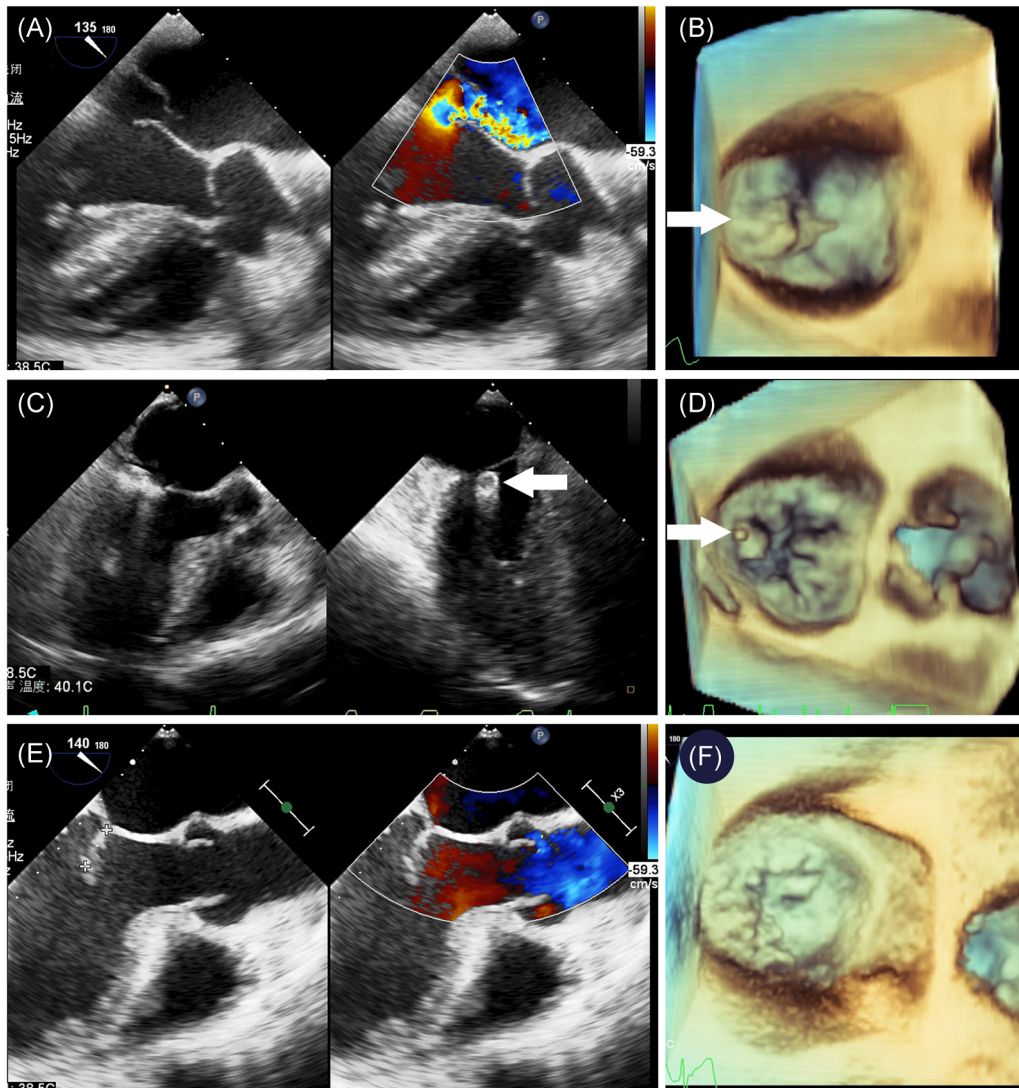


FIGURE 3 Intraoperative echocardiography images of leaflet capture. (A) Two-dimensional and color TEE image showing severe MR due to P2 region leaflet prolapse. (B) Three-dimensional TEE image of P2 region leaflet prolapse (arrow). (C) The course of leaflet capture. The arrow indicates the positioner under the leaflet. (D) Three-dimensional TEE image of leaflet capture. The arrow indicates the tip of the device. (E) Two-dimensional and color TEE image showing sufficient leaflets coaptation and no obvious MR. (F) Three-dimensional TEE image of mitral valve shutting. MR, mitral regurgitation; TEE, transesophageal echocardiography

3 | RESULTS

3.1 | Baseline characteristics

From February 2018 to June 2018, 26 consecutive patients were screened and 10 patients were enrolled in this study. The mean age of the patients was 63.7 ± 9.6 years (range 45–71 years), and the mean weight was 67.1 ± 11.1 kg (range 49–82 kg). The baseline characteristics of the patients are shown in Table 1. Class I indications for mitral valve surgery were present in all these ten patients.⁵ Among these 10 patients, 6 patients had coronary artery disease, with 2 patients requiring percutaneous intervention before this transapical mitral valve repair procedure. Three patients had a previous history of cardiac interventions, including aortic valve

replacement, thoracoscopic mitral valve repair and radiofrequency ablation. One patient had Sick Sinus Syndrome. One patient had severe chronic obstructive pulmonary disease. The risk for conventional mitral valve repair was $5.87 \pm 2.44\%$ (Society of Thoracic Surgeons Predicted Risk of Mortality).

3.2 | Perioperative results

All the 10 patients were treated with the MitralStitch system. The procedure was successfully performed with a significant reduction in MR, to no more than mild MR on intraoperative TEE, in all the 10 patients immediately after the artificial chordae implantation. Five patients received one chord; Four patients received two chords

TABLE 1 Baseline characteristics

Characteristic	
Age, year	63.7 ± 9.6
Male sex, n (%)	7 (70)
Weight, kg	67.1 ± 11.1
NYHA class, n (%)	
I	0
II	3 (30)
III	7 (70)
IV	0
Leaflet prolapse	
Anterior	2
Posterior	6
Bileaflet	2
Complications	
AF, n (%)	3 (30)
Paroxysmal	0
Persistent	3
Hypertension, n (%)	4 (40)
Diabetes mellitus, n (%)	1 (10)
Coronary artery disease, n (%)	6 (60)
Chronic obstructive pulmonary disease, n (%)	1 (10)
Sick sinus syndrome	1 (10)
Previous cardiac operations	
Aortic valve replacement, n (%)	1 (10)
Thoracoscopic mitral valve repair, n (%)	1 (10)
Radiofrequency ablation, n (%)	1 (10)
Cardiac structure/function	
LV ejection fraction, %	68.8 ± 8.3
LA diameter, mm	47.7 ± 8.9
LV end-diastolic dimension, mm	58.6 ± 6.5
LV end-systolic dimension, mm	39.7 ± 5.5
STS risk of mortality for MV repair	5.87 ± 2.44%

Note: Values are mean ± SD when appropriate.

Abbreviations: AF, atrial fibrillation; LA, left atrial; LV, left ventricular; MV, mitral valve; NYHA, New York Heart Association.

and one patient received three. The patient received three chords had bileaflet prolapse (A2, P2, P3 prolapse) with dilated annulus. P2 and P3 leaflet prolapse width and height was 21 and 18 mm, respectively. She had two chords implantations on the posterior leaflet (P2 and P3, respectively) and one chord on the anterior leaflet (A2). Then edge-to-edge repair was performed by locking the chords on A2 and P2 segments together (Figure 4). The total

procedure time, defined from device (Valve Stitcher) insertion into the left ventricle to artificial chordae fixation on the epicardium, ranged from 20 to 121 min, with a mean of 50 ± 30 min (Table 2). Cell saved auto-transfusion was 239 ± 119 ml on average. The postoperative course was uneventful in all 10 patients, with no adverse events like pericardial effusion, blood transfusion, pacemaker implantation, stroke, prolonged ventilation, new onset of renal failure, or reoperation. Before discharge, MR was none/trace in five patients, mild in five patients. All patients were discharged from the hospital uneventfully in a good clinical condition, with postoperative length of stay of 4.6 ± 0.8 days.

3.3 | Follow-up results

3.3.1 | Endpoints

All the 10 patients completed 1-year follow-up including physical examination and transthoracic echocardiography (TTE). The efficacy end point at 1 month was achieved in all of them. The freedom from major adverse event at 1 month after the procedure was 100%.

3.3.2 | MR results

At 1-month follow-up, MR was none or trace in three patients, mild in six patients, and moderate in one patient. At 6-month follow-up, MR was none or trace in two patients, mild in six patients, moderate in two patients. TTE at follow-up revealed the possible mechanism of the moderate MR recurrence in these two patients. Case 7 with P1 prolapse had a re prolapse of the treated leaflet as a result of reverse remodeling of the left ventricle causing relative elongation of implanted chordae. Case 2 with A2, A3 prolapse had moderate MR recurrence caused by prolapse of untreated posterior leaflet. At 1-year follow-up, case 7 who complained of chest tightness and breath shortness had severe MR due to implanted artificial chorda rupture detected by TTE and underwent surgical repair. Case 2 did not have significant increase of MR compared with examination at 6-month follow-up. Cases 5 and 9 had moderate MR due to re prolapse of treated leaflet. The rest patients had mild MR.

3.3.3 | Other parameters of echocardiography

Accompanied by MR reduction, left ventricle dimension reduction had been observed at 1-month follow-up, TTE examination showed a decrease in the left ventricular end-diastolic dimension from 58.6 ± 6.5 mm to 54.9 ± 6.9 mm ($p = .044$) and a decrease in end-diastolic volumes from 165.7 ± 45.7 ml to 148.5 ± 44.5 ml ($p = .038$) (Table 3). There was no obvious difference in left ventricular ejection fraction. There was no evidence of mitral valve stenosis.

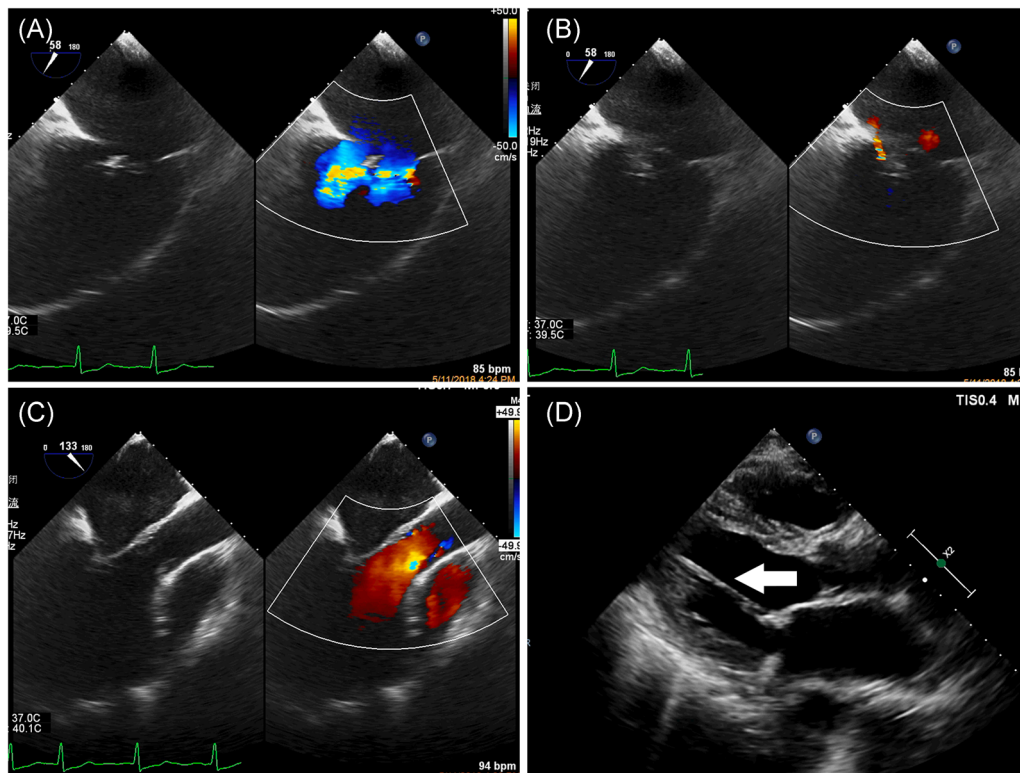


FIGURE 4 Postprocedural echocardiography images of edge-to-edge repair. (A) Color image showing a double orifice of the mitral valve during diastole. (B, C) Different views showing only trivial regurgitation detected after the chordae were tightened properly. (D) TTE view showing the implanted artificial chordae (arrow). TTE, transthoracic echocardiography

TABLE 2 Individual perioperative and 1-year follow-up results

Case	Leaflet prolapse	No. of implanted cords	Procedure time (min)	MR degrade				
				Preprocedure	Before discharge	30 days	6 months	1 year
1	P2	1	28	4+	1+	0	0	1+
2	A2 A3	2	70	4+	0	0	2+	2+
3	P1, P2	1	61	4+	1+	1+	1+	1+
4	P2	1	30	4+	0	1+	0	1+
5	A2, A3	2	29	4+	0	1+	1+	2+
6	A2, A3	2	121	4+	1+	1+	1+	1+
7	P1	1	33	4+	1+	2+	2+	4+
8	P2, P3	2	57	4+	0	1+	1+	1+
9	P2, P3	1	23	4+	0	0	1+	2+
10	A2, P2, P3	3 (edge-to-edge)	60	4+	1+	1+	1+	1+

Note: MR grade, none or trace (0), mild (1+), moderate (2+), moderate to severe (3+), severe (4+).

Abbreviation: MR, mitral regurgitation.

3.3.4 | Heart function

At 6-month follow-up, all the 10 patients had at least one New York Heart Association class improvement from baseline. The improvement was observed continuously at 1-year follow-up inpatients except for case 2.

4 | DISCUSSION

In the present study, we describe the initial experience with using the transapical artificial chordal implantation system in a first-in-human series of 10 patients with severe degenerative MR. All the 10 patients completed 6-month follow-up and MR

TABLE 3 Echocardiographic results

Index of morphological changes of LV	Preoperation	Prior to discharge	30 Days after operation
LVEDV, ml	165.7 ± 45.7	159.4 ± 57.7	148.5 ± 44.5
LVESV, ml	63.2 ± 25.5	50.8 ± 32.12	58.0 ± 26.4
LVEDD, mm	58.6 ± 6.5	53.3 ± 5.7	54.9 ± 6.9
LVESD, mm	39.7 ± 5.5	38.7 ± 7.9	36.1 ± 6.5

Abbreviations: LVEDD, left ventricle end-diastolic dimension; LVEDV, left ventricle end-diastolic volume; LVESD, left ventricle end-systolic dimension; LVESV, left ventricle end-systolic volume.

was improved significantly, which revealed a favorable repair effect.

Great efforts have been taken to reduce the invasiveness of mitral valve repair, moving from full sternotomy to minithoracotomy to robotic approach. However, these approaches do not have essential changes, still requiring cardiopulmonary bypass and cardioplegic arrest. Percutaneous mitral valve repair using MitraClip (Abbott Vascular Inc.), the first and only Food and Drug Administration approved transcatheter mitral valve repair device performing edge-to-edge repair, offers repair results with a high success, good safety, and functional improvement in patients with primary and secondary MR.^{6,7} However, it changes the natural mitral valve anatomy and may close the door on some future interventions like transcatheter valve replacement. Transapical artificial chordae implantation is a novel therapy allowing mitral valve repair through a minimally invasive approach and on the beating heart, without requiring cardiopulmonary bypass. ePTFE sutures as artificial chordae were first used in surgical mitral valve repair clinically in 1985.⁸ Recent studies have suggested that replacement with ePTFE sutures leads to a greater coaptation surface and durable repair effect, leading to better left ventricular performance.^{3,4,9} It is reasonable that artificial chordae implantation through a less invasive approach on a beating heart would have reliable mitral valve repair results, because this therapy overcomes the challenge of conventional mitral valve repair with ePTFE sutures, in which it is difficult to determine the length of ePTFE sutures. The advantage of this therapy is that the length of the ePTFE sutures can be adjusted on the beating heart to maximize leaflet coaptation and to minimize MR, to ensure optimal repair quality finally, according to the real-time TEE assessment. Up to now, two other transapical artificial chordal implantation devices, Neochord (Neochord, Inc.) and Harpoon (Harpoon, Inc.), have been reported with good safety and effectiveness and stable MR reduction during early-term and midterm follow-up.¹⁰⁻¹⁶

MitralStitch™ system is a novel transapical artificial chordae implantation system with three distinguished characteristics. First, this system has a unique designed retractable arm made by a Nitinol frame as the positioner, which could be clearly identified in TEE imaging and effectively facilitate grasping of the target prolapsing leaflet. Moreover, the system implants the preloaded ePTFE suture and PET pledget, which mimics the surgical pledgeted suture rather than making direct suture loop or knot on the leaflet, and significantly decreases the tension on the

mitral leaflet while preserving the coaptation surface by avoiding leaflet folding. In our series, most patients underwent no more than two artificial chord implantations, resulting in no more than mild MR immediately after the procedure. The implanted chords number was less in the present study, compared with using other transapical artificial chordae implantation devices.^{10,12,14,15} This may be explained by the pledgeted suture joint of artificial chordae and the leaflet. Besides, this system can perform two therapies including artificial chordal implantation and edge-to-edge repair, even in one operation if single therapy does not work well in patients with a complex mitral valve anatomy. Performing edge-to-edge repair in challenging patients using other transapical artificial chordae implantation systems was also reported.¹⁷ The advantage of MitralStitch system is providing a device to achieve handy and reliable lock of the anterior and posterior chordae. In this series, the patient who had A2, P2, P3 prolapse with dilated annulus received both artificial chordal implantation and edge-to-edge repair and got satisfactory MR reduction during 1-year follow-up. Therefore, combining edge-to-edge repair and artificial chordal implantation by this novel system may be an attractive solution, especially for patients with prolapse of both leaflets and a dilated annulus, or other challenging pathologies, and perhaps even for patients with functional MR. However, larger studies and longer follow-up are needed to validate the results.

Considering this trial was an initial clinical study and the obvious different joint between the artificial chordae and leaflet, MR patients with various MV morphologies including isolated and multisegment posterior leaflet prolapse, multisegment anterior leaflet prolapse and bileaflet prolapse were enrolled. Gammie et al.¹⁴ reported outcomes in 30 patients with isolated posterior leaflet prolapse using Harpoon system. Colli et al invented a new mitral valve anatomical classification and concluded that patients with isolated central posterior leaflet and posterior multisegment prolapse benefited more from transapical mitral valve repair by Neochord system.^{15,16} Different mitral valve morphologies were included in this initial study to identify optimal mitral valve morphology for further studies. Although the number of patients enrolled in this study was limited, 1-year follow-up results showed a trend that patients with isolated central posterior leaflet prolapse and multisegment prolapse but dominated by central segment had more stable MR improvement, which was consistent with other reports.^{15,16}

Four patients had recurrence of moderate or more MR during 1-year follow-up. The possible reasons included untreated leaflet prolapse (one patient), implanted artificial chordae relative elongation (two patients), implanted artificial chordae rupture (one patient). These mechanism have been analyzed and reported previously.¹⁸ It was worth noting that the patient with P1 prolapse receiving only one chord implantation had recurrence of moderate MR due to implanted chorda relative elongation and artificial chordae rupture resulting in severe MR sequentially. The possible reason was re prolapse of the leaflet and nonphysiological stress angle of artificial chordae. Therefore, the patient with P2, P3 prolapse receiving only one chorda implantation and having recurrence of moderate MR have been given closer observation. This suggested that more chordae may ensure better long-term results even though implantation of only one chorda achieved immediately satisfactory MR correction, especially in patients with marginal leaflet prolapse.

Other studies also concluded that one chorda was possibly related to higher risk of relative elongation after ventricle reverse remodeling and rupture due to more stress on it. Therefore, they recommended that the ideal number of implanted chordae is 1 or 2 chords more than the number required to reduce regurgitation.^{16,18} Whether the different joint of artificial chordae on the leaflet will improve MR correction in the patients with marginal posterior leaflet prolapse or anterior leaflet prolapse need to be validated by long-term outcomes.

5 | CONCLUSIONS

The results of this first-in-human study show safety and feasibility of transapical mitral valve repair using MitralStitch system, with reliable reduction of MR and heart function improvement in most patients. Identification of suitable morphology and technical refinement were learned from this pilot study at a price, which are crucial to improve the outcomes in the necessary trial to access long-term durability.

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CONFLICT OF INTERESTS

Xiangbin Pan is one of the inventors of Mitralstitch™ system. Other Authors have no conflict of interests.

AUTHOR CONTRIBUTIONS

Shouzheng Wang: drafting article, critical revision of article, data collection, funding secured by. **Xu Meng, Shengshou Hu, Horst Sievert:** study design, critical revision of article. **Yongquan Xie, Xiaopeng Hu, Yi Sun, Zhiling Luo, Hongyan Zhou, Guimin Zhang:** data collection and analysis. **Xiangbin Pan:** study design, critical revision of article, funding secured by, approval of article.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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