

Preclinical Animal Study of a Dual-Set Artificial Chordae Mitral Valve Repair System in a Porcine Model

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Preclinical Animal Study of a Dual-Set Artificial Chordae Mitral Valve Repair System in a Porcine Model

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Abstract

Background: Implantation of expanded polytetrafluoroethylene (ePTFE) artificial chordae is an established approach for mitral valve repair, but current transapical systems are typically limited to single-thread implantation per delivery and remain procedurally complex. This study evaluated the feasibility, safety, and mid-term efficacy of the HaloChord® system, which delivers up to two sets (four threads) of ePTFE chordae per sequence, in a porcine model of acute mitral regurgitation (MR).

Methods: Five adult Large White pigs (60–80 kg) underwent transapical induction of acute moderate to moderately severe MR via surgical blunt disconnection of the primary chordae tendineae attached to the P2 segment. Under beating-heart transesophageal echocardiographic (TEE) guidance, one or two suturing devices per animal were deployed with the HaloChord® system and anchored at the left ventricular apex. Animals followed a staged terminal-endpoint design (n = 1 at 30 days, n = 1 at 90 days, n = 3 at 180 days). Evaluations included serial echocardiography, clinical pathology, gross examination, and histopathological scoring per GB/T 16886.6-2022 Annex E.

Results: Implantation succeeded in all 5 animals; two received one suturing device (4 equivalent chordae) and three received two suturing devices (8 equivalent chordae). Suturing-device operation time was 10.5 ± 5.10 min per device; fixation-device operation time was 5.2 ± 6.14 min per cycle, with the wide fixation-time variability reflecting iterative echocardiographic length titration. MR grade was reduced from 2+ to 3+ post-modeling to $\leq 1+$ immediately post-procedure and remained stable through each terminal endpoint. Vena contracta width decreased substantially and remained stable at follow-up. Gross examination confirmed stable anchoring with no

detachment, rupture, or thrombus. Histopathological scoring showed a more pronounced tissue response at 30 days that moderated to predominantly moderate scores at 90 and 180 days, driven primarily by fibrosis and neovascularization rather than active inflammation.

Conclusions: In this porcine acute MR model, the HaloChord® system demonstrated procedural feasibility on the beating heart, effective acute MR reduction, and acceptable mid-term device stability and biocompatibility. The dual-set delivery design simplifies transapical chordal implantation, providing a foundation for clinical evaluation.

Keywords: mitral regurgitation; transapical chordal repair; ePTFE artificial chordae; porcine model; animal experiment

1. Background

Mitral regurgitation (MR) is the third most common valvular heart disease worldwide, and its prevalence continues to rise with population aging, posing a substantial burden on patient prognosis [1, 2]. Although conventional open-chest mitral valve repair remains the standard of care, it is highly invasive, requires prolonged postoperative recovery, and carries considerable perioperative risk. Its suitability is therefore limited, particularly for elderly patients and those with multiple comorbidities [3].

Recent advances in minimally invasive interventional therapies have expanded treatment options for patients with MR. Transcatheter artificial chordal implantation platforms—including NeoChord, Harpoon, and MitralStitch—have become a major direction in minimally invasive mitral repair [4-6]. These platforms enable artificial chordal implantation on the beating heart under real-time echocardiographic guidance, markedly reducing surgical trauma and shortening recovery time [3, 7]. Nevertheless, current systems continue to face important clinical challenges, including suboptimal implantation efficiency, the need for multiple apical punctures, the complexity of chordal length adjustment, and limited positioning accuracy, all of which warrant further improvement [4, 8].

Expanded polytetrafluoroethylene (ePTFE) has become the preferred material for artificial chordae owing to its mechanical strength and biocompatibility [9]. Building on these clinical needs, Halocinch Medical Technology (Shenzhen) Co., Ltd. has developed the HaloChord® mitral valve repair system, which enables precise implantation of two sets of ePTFE artificial chordae within a single delivery sequence. The system is designed to enhance implantation efficiency, reduce the number of cardiac punctures, and improve the accuracy of chordal positioning. To assess its safety and performance, an in vivo study was conducted in a porcine acute MR model. This study systematically evaluated intraoperative operability, postoperative valve function, and

tissue compatibility, providing preclinical evidence to support future clinical translation.

2. Materials and Methods

2.1 Study Design and Animal Model

This in vivo study used 5 adult Large White pigs (60–80 kg) to evaluate the safety, feasibility, and mid-term performance of the HaloChord® mitral chordal repair system. All procedures complied with institutional animal welfare guidelines and were approved by the Animal Ethics Committee of Shanghai Xinova Medical Research Co., Ltd. (Approval No. XNM-YX-20241212-01). All five animals underwent transapical induction of acute moderate to moderately severe MR via surgical blunt disconnection of the primary chordae tendineae of the posterior mitral leaflet (P2 segment), followed by HaloChord® implantation in the same operative session. Animals were assigned to a prespecified staged terminal-endpoint design: n = 1 at 30 days, n = 1 at 90 days, and n = 3 at 180 days, enabling histopathological evaluation across the mid-term healing window.

2.2 Device Description and Terminology

The HaloChord® system consists of two complementary but independent components: a transapical leaflet-suturing device and an apical fixation device (Figure 1). Each suturing device is pre-loaded with two ePTFE monofilaments and two independent puncture needles. When both needles are deployed through the target leaflet, each pre-loaded monofilament passes across the leaflet and, upon retrieval, is folded back through the leaflet to exit at the ventricular side as two limbs, thereby yielding two equivalent artificial chordae per monofilament and four equivalent artificial chordae per fully deployed device (Figure 1). Depending on the anatomical requirements of the target leaflet segment, either one or two suturing devices may be deployed per animal, delivering four or eight equivalent artificial chordae, respectively. All deployed ePTFE limbs from either one or two suturing devices are consolidated at a single apical fixation device, which permits real-time intraoperative adjustment of chordal length under echocardiographic guidance prior to definitive fixation at the left ventricular apex. An animated overview of the device design and implantation sequence is provided in Additional file 2.

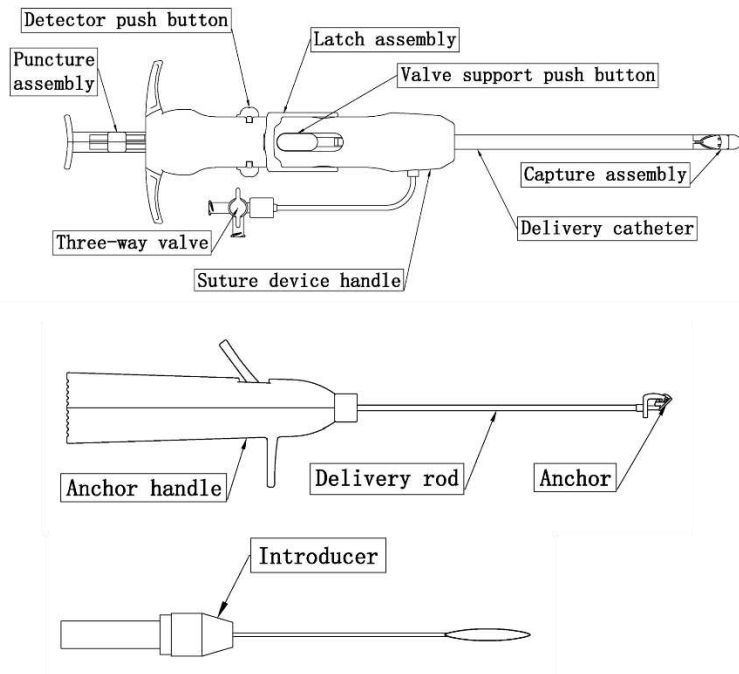


Figure 1. The HaloChord® system: delivery catheter, apical anchor, and introducer. The ePTFE artificial chordae are pre-loaded into the delivery catheter.

2.3 Surgical Procedure

2.3.1 Anesthesia and Preparation

Animals were fasted for 12 hours preoperatively. Anesthesia was induced by intramuscular injection of tiletamine–zolazepam (Telazol) and maintained with inhalational isoflurane. Transesophageal echocardiography (TEE) was used to identify the left ventricular apex; access was obtained through a small thoracotomy and transapical purse-string.

2.3.2 Establishment of the MR Model

Through the apical purse-string access, a custom-designed chordae-cutting device was introduced into the left ventricle. Under echocardiographic guidance, the device was positioned beneath the P2 segment of the posterior leaflet and used to bluntly disconnect the primary chordae tendineae, inducing posterior leaflet prolapse. Moderate to moderately severe MR was confirmed by TEE in the apical two-chamber view prior to device implantation.

2.3.3 HaloChord® Implantation

With the heart beating, the HaloChord® suturing device was advanced transapically into the left ventricle and across the mitral valve. In the left atrium, the distal capture unit was opened. The leaflet support frame was positioned beneath the target leaflet and the leaflet was secured between the support and capture arms. A leaflet-engagement detector confirmed adequate leaflet capture

(Figure 2). After confirmation, the two puncture needles were deployed through the leaflet and the two pre-loaded ePTFE monofilaments were passed transleaflet. The suturing device was then withdrawn from the heart and the ePTFE limbs were exteriorized and passed through the apical fixation device. Where anatomically indicated, a second suturing device was deployed by the same workflow to place an additional 2 sets of chordae; otherwise a single device was used. Under real-time TEE guidance, chordal length was iteratively adjusted using the fixation device until residual MR was minimized. The apical fixation implant was then secured at the ventricular apex.

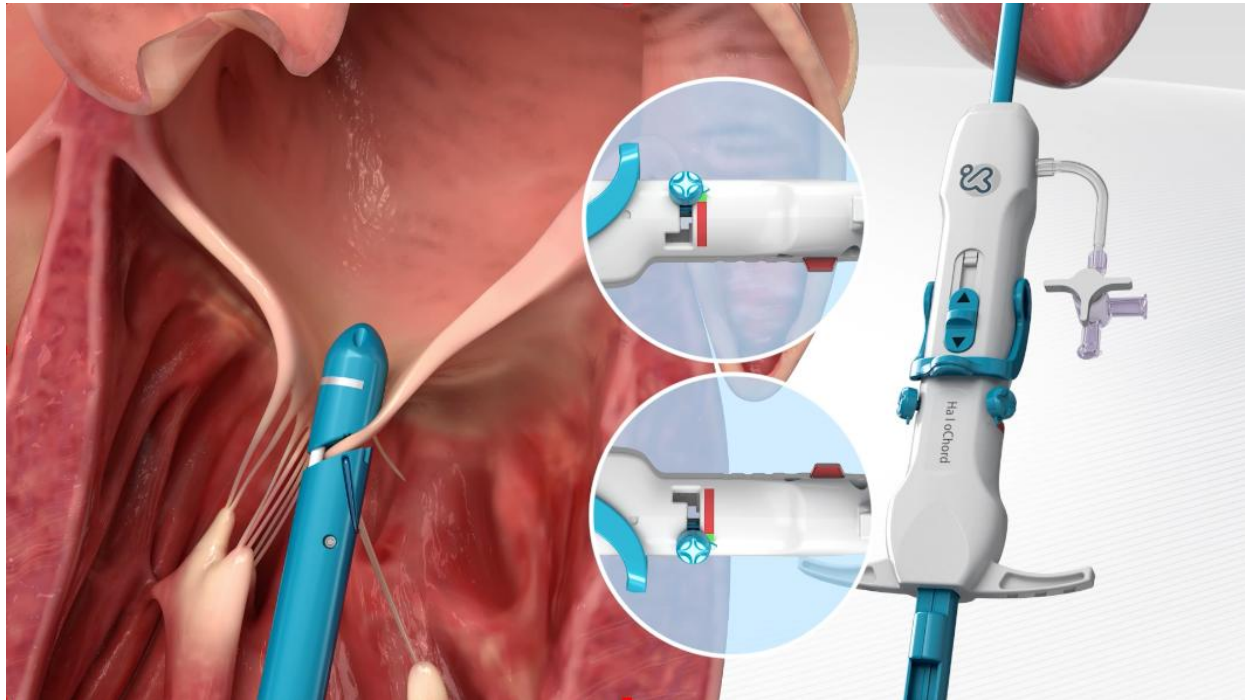


Figure 2. Leaflet engagement detector. The pointer moves from the red zone to the green zone to confirm that the valve leaflet has been correctly clamped between the support and capture arms.

2.3.4 Procedural Time Measurements

Two per-device procedural time metrics were prospectively recorded for each deployed suturing device and each fixation cycle. Suturing-device operation time was defined as the interval from insertion of the suturing device into the apical purse-string access to complete withdrawal of the device from the heart following successful transleaflet deployment of both ePTFE monofilaments. Fixation-device operation time was defined as the interval from initiation of chordal length titration at the apical fixation device to final closure of the apical fixation implant, encompassing the iterative echocardiographic assessment cycles required to eliminate residual MR. Total procedure duration, defined as the interval from anesthetic induction (surgical table entry) to surgical closure completion, was also recorded but was not used as a primary efficiency indicator because it includes model-establishment steps not attributable to the HaloChord®

workflow.

2.4 Assessment and Follow-Up

TEE was performed preoperatively (baseline), after MR induction (post-modeling), immediately after implantation, and at each scheduled follow-up to quantify MR severity and assess left ventricular function. Hematologic and serum biochemical analyses were conducted to monitor systemic status, organ function, and inflammation. At each animal's terminal endpoint, the heart and major organs (lungs, liver, kidneys, brain) were harvested for gross and histopathological evaluation of leaflet integrity, chordal stability, tissue response, thrombus, and embolic events. Hematoxylin–eosin (HE)–stained sections were used to assess inflammatory cell infiltration, fibrosis, neovascularization, fat infiltration, and necrosis at the chordae and anchor sites. Local tissue response was graded per GB/T 16886.6-2022 Annex E (irritation scoring).

2.5 Statistical Analysis

Given the exploratory nature of this preclinical feasibility study and the limited sample size with staged terminal endpoints, analyses were primarily descriptive. Continuous variables are presented as mean $\pm$ standard deviation or individual values where appropriate. No formal hypothesis testing was performed.

3. Results

3.1 Procedural Success and Operability

All 5 of 5 animals successfully underwent acute MR modeling and transapical HaloChord® implantation, yielding an immediate technical success rate of 100%. Equivalent artificial chordae were deployed to the P2 segment of the posterior mitral leaflet in all animals. Two animals received a single suturing device—delivering 2 sets of 4 equivalent chordae each. Three animals received two suturing devices, delivering 4 sets of 8 equivalent chordae each. The number of devices used per animal was determined intraoperatively based on residual regurgitation on TEE after initial deployment and did not correspond to any predefined animal grouping.

Per-device procedural time metrics across all deployed devices were as follows: suturing-device operation time was 10.5 ± 5.10 minutes per device (range 7–19 min across 8 deployed devices), and fixation-device operation time was 5.2 ± 6.14 minutes per fixation cycle. The wide fixation-time variability reflects iterative TEE-guided titration of chordal length required to eliminate residual MR before definitive apical fixation—an intended feature of the adjustable-fixation workflow rather than a marker of procedural inefficiency. Detailed per-animal procedural timing is provided in Supplementary Table S1.

The apical anchor achieved stable fixation in each animal, with firm tissue engagement and no evidence of displacement. Device advancement was unimpeded, and all procedural steps—leaflet capture, transleaflet monofilament deployment, and system retrieval—were completed without technical difficulty. Hemodynamics remained stable throughout all procedures, and no major intra-procedural adverse events occurred, including massive hemorrhage, cardiac perforation, leaflet laceration, left ventricular outflow tract (LVOT) obstruction, or procedure-related mortality.

3.2 Acute MR Reduction After Implantation

Serial echocardiographic assessments at preoperative baseline, after acute MR modeling, and immediately after HaloChord® implantation demonstrated a consistent and reproducible pattern of MR reduction. At baseline, all animals exhibited trivial or no MR. Following chordal disconnection, MR was induced to grade 2+ (moderate) in three animals and grade 3+ (moderately severe) in two animals (Table 2). Immediately after P2 chordal implantation and tension titration, MR was reduced to mild (grade 1+) or less in all animals, achieving an acute technical success rate of 100%. Vena contracta width (VCW) decreased from 3.67 ± 0.25 mm post-modeling to 1.36 ± 0.23 mm immediately post-implantation (Table 1). Transmitral mean pressure gradients remained within physiological ranges, with no evidence of iatrogenic mitral stenosis or LVOT obstruction (Table 1).

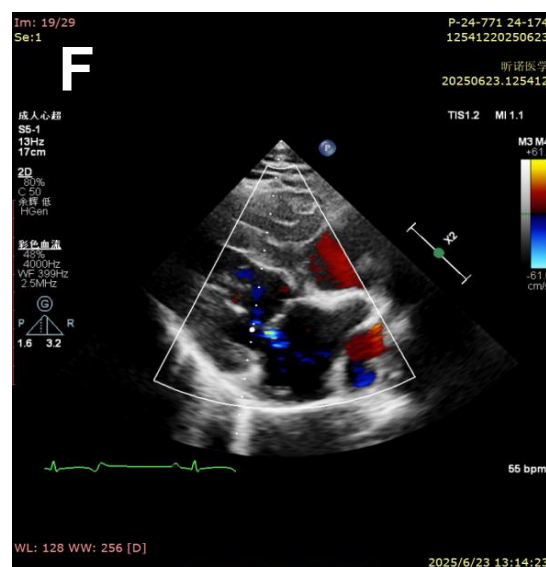
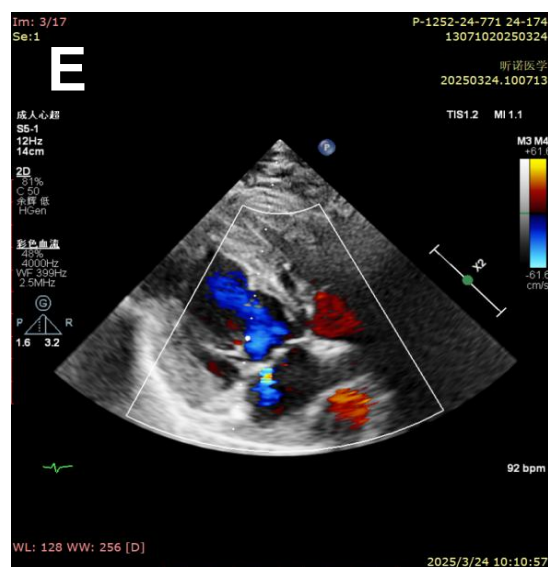
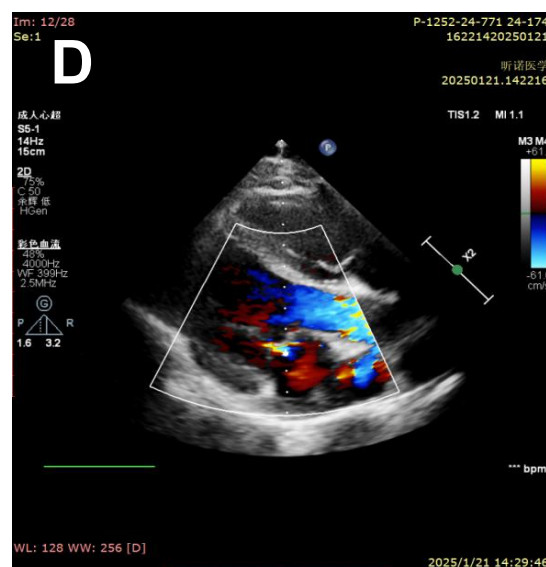
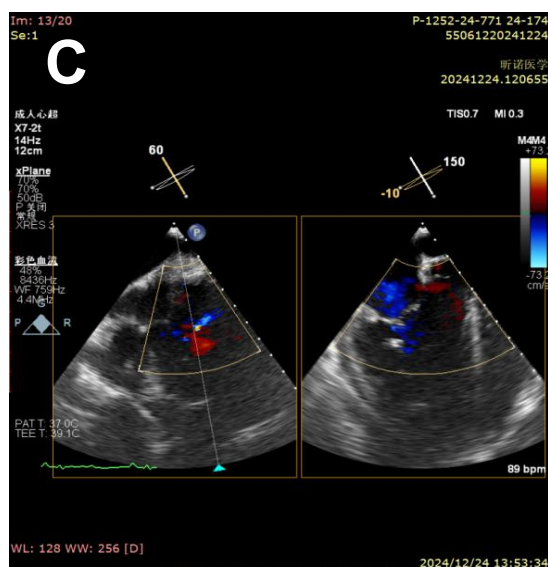
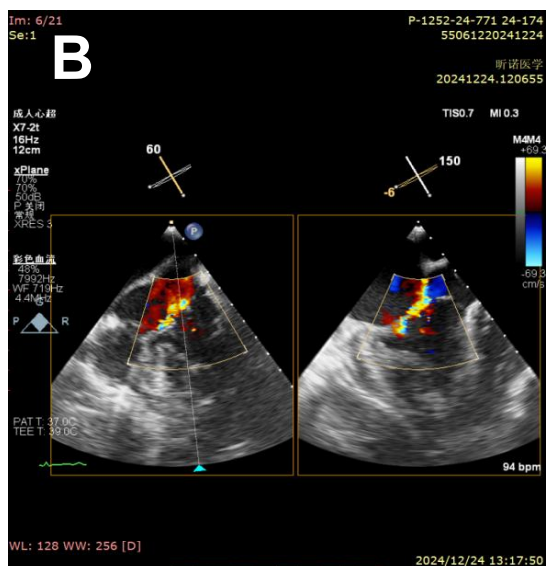
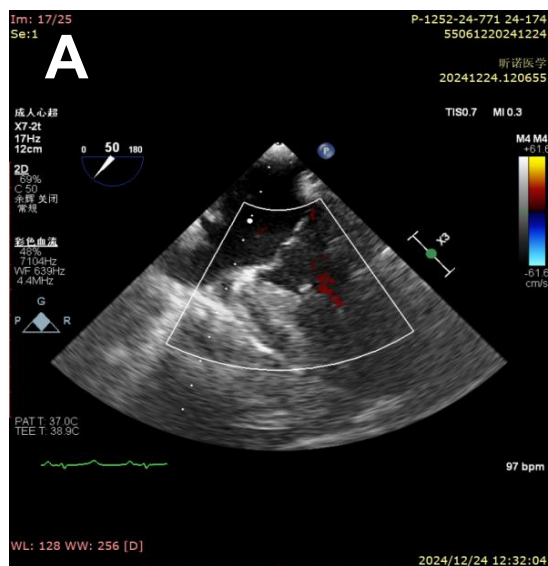


Figure 3. Serial echocardiographic assessment of mitral valve competence and repair stability. (A) Baseline: normal valve function. (B) Acute MR model: successful induction of MR. (C) Immediately post-implantation: MR reduced to mild. (D–F) Follow-up at 30, 90, and 180 days: repair remained stable with no recurrence of moderate or greater MR.

Table 1. Echocardiographic parameters at the indicated time points (mean $\pm$ SD).

Parameter	Baseline	Post-Modeling	Immediate	30 Days	90 Days	180 Days
VCW (mm)	0	3.67 $\pm$ 0.25	1.36 $\pm$ 0.23	1.09 $\pm$ 0.75	1.64 $\pm$ 0.73	1.25 $\pm$ 1.02
RVol (mL) ^a	0	48.61 $\pm$ 33.94	—	—	—	—
EROA (cm ²) ^a	0	0.46 $\pm$ 0.20	—	—	—	—
Mean Gradient (mmHg)	0.8 $\pm$ 0.45	3.2 $\pm$ 4.49	1.0 $\pm$ 1.0	1.4 $\pm$ 0.89	1.0 $\pm$ 0.82	1.0 $\pm$ 0
LVEF (%)	64.9 $\pm$ 5.5	64.9 $\pm$ 1.3	61.8 $\pm$ 2.9	62.5 $\pm$ 3.9	65.0 $\pm$ 3.5	66.7 $\pm$ 1.8
LVEDD (mm)	45.0 $\pm$ 6.6	48.4 $\pm$ 8.1	45.4 $\pm$ 7.2	45.1 $\pm$ 2.6	44.9 $\pm$ 4.5	50.6 $\pm$ 5.9
LA Area (cm ²)	11.0 $\pm$ 3.6	10.6 $\pm$ 3.0	8.8 $\pm$ 2.5	11.0 $\pm$ 2.2	11.1 $\pm$ 2.3	14.6 $\pm$ 7.5

^a RVol (regurgitant volume) and EROA (effective regurgitant orifice area) were quantified at baseline and post-modeling only. Following chordal repair, MR was reduced to grade 1+ or less and these quantitative regurgitation indices were not re-measured at subsequent timepoints; VCW was used as the primary tracking parameter. VCW, vena contracta width; LVEF, left ventricular ejection fraction; LVEDD, left ventricular end-diastolic diameter; LA, left atrium.

Table 2. Mitral regurgitation grade in each animal at each time point.

Animal ID	Baseline	Post-Modeling	Immediate	30 Days	90 Days	180 Days
P-1251-24-770	0	2+	1+	1+	—	—
P-1257-24-768	0	2+	1+	0+	1+	—
P-1252-24-771	0	3+	1+	1+	1+	1+
P-1250-24-778	0	3+	1+	0+	1+	1+
P-25-236	0	2+	1+	1+	1+	1+

MR grade: 0 = none/trivial; 1+ = mild; 2+ = moderate; 3+ = moderately severe; 4+ = severe. 0+ denotes minimal/borderline residual MR not meeting the 1+ threshold. "—" indicates timepoint not applicable because the animal had already reached its terminal endpoint.

3.3 Mid-Term Echocardiographic Follow-Up

Across the staged follow-up timepoints (30, 90, and 180 days), MR remained at mild (grade 1+) or less in all animals up to their scheduled terminal endpoint, with no recurrence of moderate (2+) or greater MR (Table 2, Figure 3). The ePTFE artificial chordae maintained stable positioning and appropriate tension, with firm attachment to the P2 scallop and no evidence of detachment, migration, or leaflet deformity at any follow-up timepoint. Left ventricular systolic and diastolic function parameters remained overall stable through 180 days (Table 1). No intracardiac thrombus formation or device-associated thromboembolic event was identified.

3.4 Hematology and Clinical Biochemistry

Hematologic, coagulation, biochemical, and inflammatory parameters remained within physiological reference ranges at all postoperative and follow-up time points across all animals. No progressive anemia or sustained leukocytosis was observed, and coagulation profiles were uniformly within normal limits without evidence of coagulopathy. No biochemical signs of device-related mechanical hemolysis were identified across the follow-up series. Inflammatory markers showed mild transient elevations in the early postoperative period and returned to reference values thereafter, with no evidence of sustained systemic inflammatory response. Hepatic, renal, and metabolic parameters remained stable at all predefined time points, with no biochemical evidence of device- or procedure-related organ dysfunction through the 180-day evaluation. Summary values are provided in Additional file 1.

3.5 Gross Anatomy and Histopathology

At each terminal endpoint, gross examination confirmed positional stability of the device in all animals. The apical anchor remained firmly attached, all ePTFE artificial chordae were intact without rupture or displacement, and no thrombus was observed on the valve leaflets or device surfaces (Figure 4).

Histopathological evaluation demonstrated progressive tissue integration. Endothelial coverage of the artificial chordae was evident by day 30 and progressed to a confluent fibroendothelial covering by day 180 (Figure 5). The local tissue response peaked at 30 days, with both chordae and anchor sites showing severe irritation scores driven by inflammatory infiltration, early fibrosis, and neovascularization typical of acute healing. By 90 and 180 days, the response moderated to predominantly moderate at both sites (Table 3). Systematic histopathological examination of major organs—including lungs, liver, kidneys, and brain—revealed no embolic lesions, infarcts, or device-related parenchymal injury, with all examined organs showing unremarkable findings.

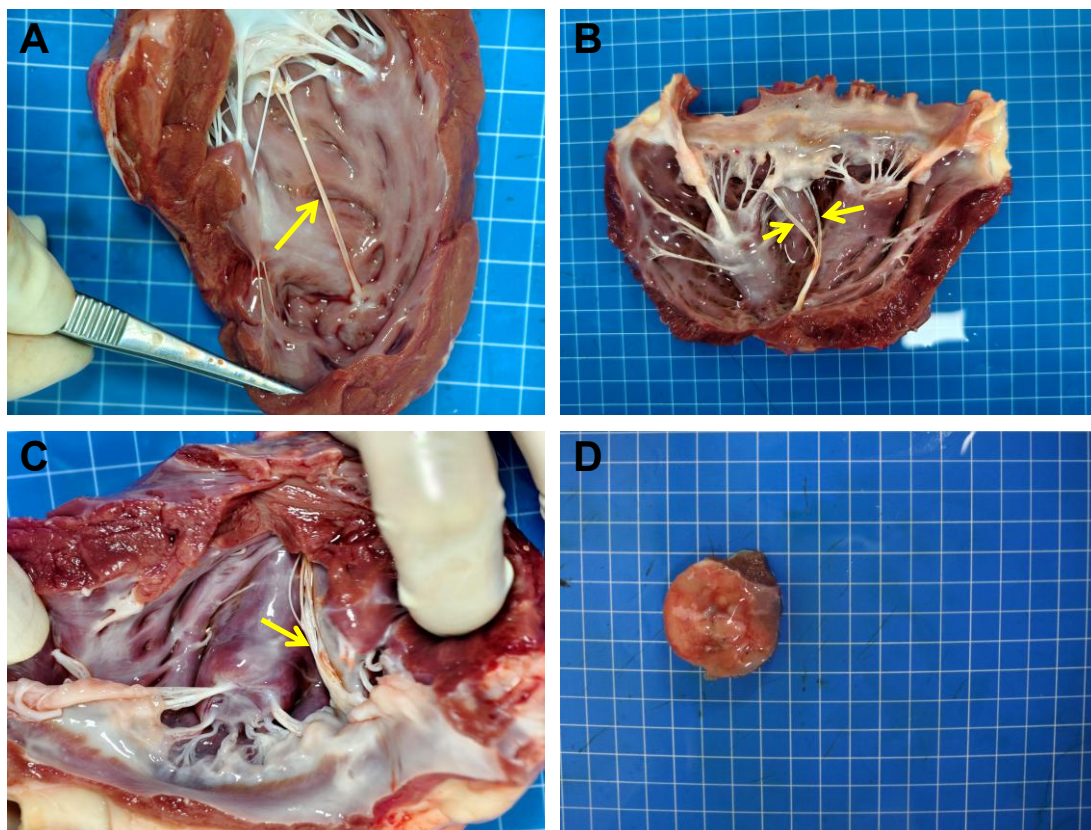


Figure 4. Mid-term assessment of artificial chordal stability and apical anchor integration in the porcine model. (A–C) Gross pathology of the mitral valve at 30, 90, and 180 days post-implantation, respectively. Artificial chordae (yellow arrows) show stable attachment to the P2 leaflet and secure anchoring at the cardiac apex. No device detachment, leaflet tear, or thrombotic deposit was observed at any timepoint. (D) Magnified view of the apical fixation site at 180 days, showing complete coverage of the anchoring mechanism by a smooth fibrous tissue layer.

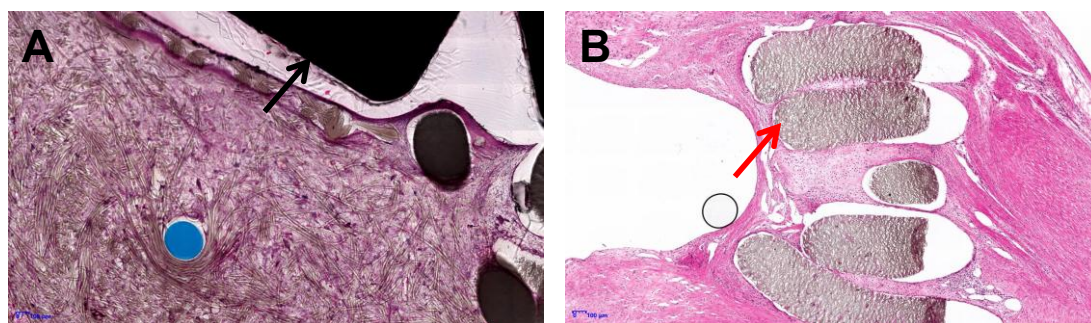


Figure 5. Representative HE-stained section at 180 days post-operation. Black arrow indicates the apical anchor; red arrow indicates the artificial chordae tendineae.

Table 3. Local tissue response scoring at the artificial chordae and apical anchor sites.

Animal ID	Time	Tissue	PMN	Lymph	Plasma	Macro	Giant	Necr.	Fibr.	Neovasc.	Fat	Total	Grade
P-1251-24-770	30 d	Chordae	1	3	0	2	0	1	2	2	0	18	Severe
		Anchor	3	4	0	3	0	1	4	3	0	29	Severe
P-1257-24-768	90 d	Chordae	1	3	0	2	0	0	2	1	0	15	Moderate
		Anchor	0	3	0	2	0	0	3	2	0	15	Moderate
P-1252-24-771	180 d	Chordae	1	2	0	0	1	0	2	1	0	11	Moderate
		Anchor	1	2	0	1	0	0	2	1	0	11	Moderate
P-1250-24-778	180 d	Chordae	0	3	0	0	1	0	2	1	0	11	Moderate
		Anchor	0	2	0	2	0	0	2	1	0	11	Moderate
P-25-236	180 d	Chordae	0	1	0	0	1	0	2	1	0	7	Slight
		Anchor	0	3	0	1	0	0	3	1	0	12	Moderate

Each cellular and tissue response parameter is graded 0–4 per GB/T 16886.6-2022 Annex E. Sub-totals are weighted (cellular response components $\times 2$; tissue response components $\times 1$) to yield the total irritation score; irritation grade is assigned as: minimal (0.0–2.9), slight (3.0–8.9), moderate (9.0–15.0), or severe (≥ 15.1). PMN, polymorphonuclear leukocytes; Lymph, lymphocytes; Macro, macrophages; Giant, multinucleated giant cells; Necr., necrosis; Fibr., fibrosis; Neovasc., neovascularization; Fat, fat infiltration.

4. Discussion

In this porcine acute MR model, HaloChord® demonstrated that a multi-neochord transapical repair strategy can be performed on the beating heart with immediate MR reduction and mid-term device stability sustained to each animal's terminal endpoint. These findings should be interpreted as a feasibility and safety signal rather than evidence of mechanical superiority. Early transapical animal work established that off-pump chordal implantation can eliminate or reduce acute MR under echocardiographic guidance, with implanted chordal tensions remaining within the physiologic range [10]. Our observations are consistent with a recent porcine study using another ePTFE-based transapical system, which reported favorable device stability and tissue compatibility through 180 days [12].

The main contribution of HaloChord® is procedural simplification while preserving intraoperative adjustability. Existing transapical platforms—NeoChord, Harpoon, and MitralStitch—have established the feasibility of beating-heart chordal repair, but the workflow remains technically demanding, requiring precise leaflet capture, secure deployment, and iterative length adjustment [11, 13-15]. Acute workflow analysis of the NeoChord procedure in a porcine model quantified this technical burden directly: expert surgeons required significantly less time and fewer attempts to grasp the leaflet and successfully deploy the neochord than beginner

surgeons [11, 16]. HaloChord® integrates leaflet capture, dual-group chord release, and apical fixation into a single sequence, delivering multiple neochordae through one transapical access. The value of the platform is not a new biological concept but a more reproducible way to perform an established repair principle—which matters because reproducibility beyond expert centers, remains the recurrent translational bottleneck in this field [14, 15, 18].

A central advantage of transapical chordal repair is the ability to titrate chordal length on the beating heart under real-time echocardiography, allowing coaptation to be assessed under physiologic loading rather than static intraoperative judgment. Length titration has consistently been identified as one of the key procedural challenges of this approach, described in early workflow analysis as an iterative echocardiography-guided process [10, 11, 13]. The HaloChord® workflow preserves this real-time adjustability while consolidating length titration to a single apical fixation cycle per animal. The observed per-cycle fixation-device time variability in our cohort (5.2 ± 6.14 min per cycle) reflects this iterative titration and represents an intended feature of the adjustable-fixation design rather than a procedural inefficiency—though also a clear target for future workflow standardization.

The biomechanical implications of the dual-group strategy warrant cautious interpretation. This study did not measure chordal tension distribution, leaflet stress, fatigue life, or wear, and no claim of superior mechanical performance or long-term durability can be supported. Existing translational evidence indicates that repair configuration substantially influences chordal loading: in a standardized ovine mitral valve prolapse model, implantation of 4 neochordae compared with 2 significantly reduced peak forces on both native primary chordae and the implanted neochordae themselves, with no statistically significant difference between 6 and 4 neochordae [19]. Complementary ex vivo biomechanical work supports the same principle, showing that even modest geometric changes—whether at the papillary end via an artificial papillary muscle device that dampens peak artificial chordal force and rate of force rise [20], or at the annular level under different annuloplasty configurations [21]—meaningfully alter the mechanical environment of the repair. Accordingly, the most defensible interpretation of the HaloChord® dual-group strategy is that it may offer a more controlled deployment geometry that warrants dedicated biomechanical validation, not that superior durability has been established.

The histopathological findings support progressive mid-term tissue integration rather than a minimal-response profile. Per GB/T 16886.6-2022 Annex E scoring, the local tissue response was most pronounced at 30 days, with the apical anchor reaching the severe grade—consistent with expected early healing at a transmural fixation interface (inflammatory cell infiltration combined with early fibrosis and neovascularization). By 90 and 180 days the response had moderated to

predominantly moderate grade, driven mainly by fibrosis and neovascularization rather than active acute inflammation; one 180-day animal exhibited a mild grade at the chordae site. Importantly, no device fracture, detachment, thrombosis, or embolic event was identified at any timepoint. This temporal pattern is consistent with the broader literature on ePTFE-based chordal repair, where the material is stably incorporated over time [12, 22]—in the E-Chord porcine study, chordae and anchors were fully endothelialized by 90 days without thrombosis or infection [12]. Nevertheless, biocompatibility should not be conflated with long-term durability: reviews of interventional chordal devices emphasize that late chordal rupture and recurrent MR can still occur when repair geometry is suboptimal or when ventricular remodeling alters loading conditions [16, 22].

Translation of transapical chordal repair depends heavily on anatomy and patient selection. The first-in-human MitralStitch experience concluded that patient selection and technical refinement are crucial to improving outcomes; at 1-year follow-up, recurrent MR in this cohort arose from three distinct mechanisms—untreated leaflet prolapse in a bileaflet case, relative elongation of implanted chordae attributable to reverse ventricular remodeling, and chordal rupture [13]. Similar messages recur in NeoChord and transseptal chordal replacement reports: favorable results are most consistent in isolated posterior leaflet prolapse (particularly P2) with sufficient leaflet tissue and limited annular dilation, while thin or fragile leaflets, complex anatomy, and significant remodeling remain durable-repair barriers [11, 15-18]. HaloChord® should therefore be viewed as a platform that may make technically demanding anatomy more manageable, not one that removes the need for careful selection. Several limitations apply. First, the sample size, while appropriate for feasibility, limits generalizability. Second, the acute chordal-cutting model reproduces sudden loss of leaflet support in the setting of degenerative-type mechanisms but cannot fully recapitulate chronic human degenerative MR, including myxomatous degeneration, annular dilatation, and long-standing ventricular remodeling that alter loading conditions over time [10]. Third, no head-to-head comparison against established transapical platforms was performed. Procedural failure is not merely theoretical: a double transapical access strategy has been reported as rescue during neochord implantation, emphasizing the need for contingency planning [23]. Finally, this study cannot address reverse remodeling, late recurrence, or the durability of multi-chord synchronization. Taken together, HaloChord® supports the case for a preclinical platform that simplifies transapical chordal implantation while preserving intraoperative adjustability—a meaningful step in a field where reproducibility, patient selection, and long-term durability remain the principal challenges [14, 15, 24]. The clinical trial of the HaloChord® system began in 2023 and is currently in follow-up. Future work should focus on chronic large-animal studies, dedicated biomechanical testing, and comparative evaluation against established platforms to determine whether the observed procedural simplification translates into sustained functional benefit at scale.

5. Conclusions

In a porcine acute MR model, the HaloChord® system demonstrated procedural feasibility on a beating heart, achieved acute MR reduction sustained to each animal's mid-term terminal endpoint, and exhibited acceptable biocompatibility consistent with progressive chronic tissue integration. The integrated dual-set chordal delivery workflow provides a simplified and standardized procedural pathway for transapical mitral valve repair, providing a foundation for ongoing clinical evaluation.

List of abbreviations

ePTFE: Expanded polytetrafluoroethylene
EROA: Effective regurgitant orifice area
HE: Hematoxylin and eosin
LA: Left atrium
LVEDD: Left ventricular end-diastolic diameter
LVEF: Left ventricular ejection fraction
LVOT: Left ventricular outflow tract
MR: Mitral regurgitation
PMN: Polymorphonuclear leukocytes
RVol: Regurgitant volume
SD: Standard deviation
TEE: Transesophageal echocardiography
VCW: Vena contracta width

Declarations

Ethics approval and consent to participate

All animal experiments were conducted in accordance with GB/T 16886.2-2011 and were approved by the Animal Ethics Committee of Shanghai Xinova Medical Research Co., Ltd. (Approval No. XNM-YX-20241212-01, approved on 12 December 2024). All procedures were performed in accordance with the relevant guidelines and regulations.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

All authors are employees of Halocinch Medical Technology (Shenzhen) Co., Ltd., the manufacturer of the HaloChord® system evaluated in this study. The authors declare that this employment relationship did not influence the design, conduct, analysis, or reporting of the study.

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Authors' contributions

Qizong Xie conceived the study, supervised the overall project, reviewed the manuscript for important intellectual content, and provided final approval of the version to be submitted. Jia Li coordinated the experimental workflow, analysed the data, and drafted the manuscript. Haiming Wu and Xusheng Zhang contributed to study design and interpretation of results. Hui Huang and Nu'an Xing participated in data acquisition and technical execution of device deployment. All authors read and approved the final manuscript.

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Additional files

Additional file 1: Supplementary Tables S1 and S2. Table S1: Per-animal procedural timing. Table S2: Summary of hematology, coagulation, and biochemistry parameters.

Additional file 2: Supplementary Video. Animated overview of the HaloChord® device design, illustrating leaflet engagement, dual-set ePTFE monofilament deployment, and apical fixation sequence.

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