Beating-heart implantation of adjustable length mitral valve chordae: acute and chronic experience in an animal model[☆],[☆☆]

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Abstract

Objective: This study aimed to determine the acute and chronic performance of a new system designed to conduct beating-heart implantation and off-pump adjustment of neochordal length. **Methods:** In 14 adult sheep (group A) selected to undergo beating-heart cardiopulmonary bypass, the left atrium was opened through a left thoracotomy. Two or more primary chordae in the A2 region were severed to produce a model of a flail leaflet. A chordal adjustment mechanism (V-Chordal, Valtech Cardio Ltd., Or-Yehuda, Israel) was affixed to the head of the papillary muscle. The system includes two adjustable neochordae. The distal end of the neochordae was sutured to the flail segment without estimating the appropriate length. The neochordal length was adjusted off-pump under real-time echo-guidance. The adjustment tool was removed and the atriotomy was closed with a purse-string suture. Control animals (group B, n = 4) were implanted with the conventional neochordae. Animals in both groups were sacrificed 3 months after the procedure. **Results:** In both groups, prior to repair, mitral regurgitation (MR) was severe in all animals. In group A, following adjustment of neochordae, MR was absent in all animals, with the exception of two animals that had residual 2+ MR irresponsive to neochordae adjustments. In group B, MR was 2+ in two of the four animals following repair. At 3 months, mitral competence was stable in all animals. At necropsy, normal healing of the papillary head and leaflet was observed in both the groups. **Conclusions:** The V-Chordal system simplifies the process of neochordal implantation and precise off-pump adjustment of the neochordal length to correct MR occurring due to a flail leaflet. This technology may improve the technical feasibility for adoption of chordal repair during open or minimally invasive surgical procedures.

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Keywords: Mitral valve repair; Neochordae; Dynamic repair; Adjustable

1. Introduction

The implantation of neochordae is a proven surgical technique for the correction of mitral regurgitation (MR) occurring due to prolapse and flail leaflet [1—4]. Although neochordae implantation has been mainly adopted to treat anterior leaflet prolapse, in recent times, it has been used as an alternative to quadrangular resection of the posterior leaflet [3], with comparable results [2]. Compared with resection, the implantation of neochordae restores mitral anatomy while preserving leaflet tissue. The main advantage of this technique is attributed to its ability for creation of a larger surface for coaptation, which favors better and more durable hemodynamics [5].

Although its intrinsic superiority, compared with other techniques, has been recognized for several years, neochordae implantation has only been adopted slowly, primarily due to the challenge of determining the optimal neochordal length during cardioplegic arrest. In this study, a device designed to allow beating-heart adjustment of neochordal length after implantation was investigated. By using this feature, the surgeon could correct neochordal length under physiologic conditions to improve prolapse correction.

This article reports acute and chronic results from a comparative study designed to evaluate the safety and performance of a device-based, adjustable neochordal

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implantation, using the V-Chordal device (Valtech Cardio Ltd., Or-Yehuda, Israel), versus conventional neochordae implantation in an animal model of MR secondary to flail leaflet.

2. Methods

2.1. The flail model

Eighteen adult sheep underwent general anesthesia with a standardized protocol. Anesthesia was induced and maintained by the administration of isoflurane (2%). A minimally invasive left thoracotomy (muscle-sparing approach) was performed on all animals.

Baseline echocardiography was performed using epicardial probes. The probe was positioned at the atrioventricular groove, in the region of the anterolateral commissure. Short-axis views of the annulus were taken and measurements recorded. Intercommissural (CC) and septolateral (SS) dimensions were recorded in each animal during both systole and diastole. In addition, the annular area in diastole and the degree of baseline MR was determined by Color Doppler. The degree of MR was assessed by a multiparametric method, using the jet area in the left atrium, the width of the vena contracta, and the duration of MR in the cardiac cycle with Color-Doppler M-mode [6]. The baseline data for both groups are reported in Table 1.

Following full heparinization, the descending aorta (arterial line) and pulmonary artery (venous line) were cannulated and cardiopulmonary bypass was initiated. Vacuum-assisted venous return was used in most of the cases. With the heart decompressed, the left atrium was opened longitudinally 2 cm above the atrioventricular groove without aortic cross-clamping. A 4/0 polypropylene suture was then positioned in the middle of the anterior leaflet, at the junction of the chordae originating from the posterior and anterior leaflets to improve exposure of the papillary muscle and to support the leaflet during implantation of the neochordae. To create a consistent model of flail anterior leaflet, a variable number (between two and four) of chordae originating from the anterior (two animals, both in the experimental group) or posterior (16 animals) papillary muscle and attached to the A2 were cut in order to create an unsupported segment of leaflet extending for approximately 1 cm along the free edge. The 4/0 polypropylene suture was left in place to support the flail segment until reconstruction with either the experimental device or the conventional polytetrafluoroethylene (PTFE) suture was completed, and was removed thereafter.

2.2. The control group

In four animals, following chordal cutting, a 5/0 PTFE suture was used to perform a conventional neochordal implant. The neochordal technique used has been consistent, and is described in the following. A double-ended PTFE suture was positioned at the tip of the posterior papillary muscle in a figure-of-eight manner and tied. The two ends of the suture were then attached to the free edge of the flail segment, in a locking manner to reduce the slippery tendency of the PTFE. Neochordal length was assessed on the beating heart by comparison of coaptation height of the posterior leaflet. Following determination of neochordal length, the PTFE suture was tied on the ventricular surface of the leaflets, the 4/0 polypropylene stay suture was removed, and the left atrium was closed with 4/0 polypropylene. A left vent was left in place for de-airing. Weaning from cardiopulmonary bypass was performed easily. Echo measurements of mitral valve competence were repeated (Fig. 1A). Protamine was administered. Cardiopulmonary bypass cannulae were removed, and the chest was closed in the usual manner.

2.3. The experimental group

Fourteen animals underwent implantation of the adjustable neochordae device following severing of native chordae.

The Valtech V-Chordal Adjustable System consists of two primary elements (Fig. 2): the neochordal implant and the delivery system. The neochordal implant has a metallic helical fixation element, for sutureless implantation of the device in the papillary muscle. The implant core is a Dacron-covered, micro-locking, adjustment spool preloaded with a double-ended 3/0 polyester-braided suture coated with PTFE and connected to tapered needles. The delivery system comprises a flexible shaft that engages the spool mechanism during fixation and adjustment of neochordal length, and an adjusting handle. The handle has two knobs, one to activate the sutureless fixation on the papillary muscle and another to perform high-resolution regulation of neochordae length in the beating heart under physiologic loading conditions prior to surgical closure (Fig. 2). Following implantation, neochordal length can be increased or decreased (within a range of 3 cm), and any adjustment is fully reversible. The flexible shaft is detached from the neochordal implant at the end of the adjustment.

Following chordal cutting, the V-Chordal Delivery System was inserted across the mitral valve. The head of the posterior papillary muscle was stabilized. The V-Chordal device was then implanted in the fibrous tissue at the tip of

Table 1. Baseline anatomical variables. Baseline dimensions of the mitral valve in the experimental and the control groups are reported as means ± standard deviation (range in brackets).

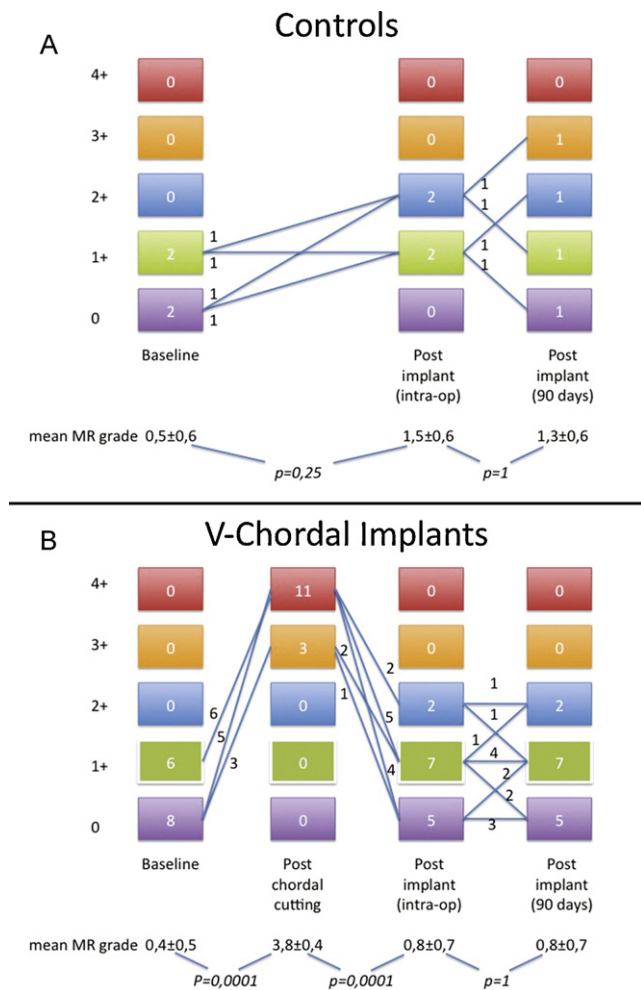|	Overall	V-Chordal group	Control group
n		14	4
AP diastolic diameter (mm)	2.4 ± 0.2 (2.0—2.7)	2.4 ± 0.2 (2.0—2.7)	2.4 ± 0.2 (2.1—2.6)
AP systolic diameter (mm)	1.9 ± 0.2 (1.7—2.2)	1.9 ± 0.1 (1.7—2.2)	2.0 ± 0.2 (1.7—2.2)
CC diastolic diameter (mm)	3.5 ± 0.3 (3.0—4.1)	3.5 ± 0.3 (3.1—4.1)	3.5 ± 0.3 (3.0—3.8)
CC systolic diameter (mm)	2.8 ± 0.2 (2.4—3.2)	2.8 ± 0.2 (2.4—3.2)	2.9 ± 0.3 (2.4—3.2)
Area (cm^2)	6.5 ± 0.4 (5.9—7.2)	6.5 ± 0.3 (5.9—7.1)	6.7 ± 0.5 (6.1—7.2)
MR baseline (0—4)	0.4 ± 0.5 (0—1)	0.4 ± 0.5 (0—1)	0.5 ± 0.6 (0—1)

Fig. 1. Echo-Doppler assessment of MR. Top: Control group, four animals. Assessments were performed at baseline, after neochordal implant, following discontinuation of cardiopulmonary bypass and at 90 days, prior to sacrifice. The numbers in the boxes indicate how many animals presented with a certain degree of MR at the selected time. Connecting lines show variations of MR degree at each time point. Below are reported average MR degrees at the three time points, with *P*-value of the statistical differences. Bottom: V-Chordal group, 14 animals. Assessment was performed, with the addition of assessment just following chordal cutting and V-Chordal reimplantation before adjustment. The interpretation of data as above.

the papillary muscle using the helical fixation element (Fig. 3A). Fixation was accomplished by slowly rotating (four clockwise turns) the fixation knob on the adjustment handle (Fig. 2). Appropriate engagement of the papillary muscle was verified by application of gentle traction. Then, surgical sutures, connected to the implanted device, were detached from the shaft of the delivery system and sutured to the edge of the mitral leaflet using the attached needles (Fig. 3B). No assessment of neochordal length was conducted at this time, and neochordae were tied longer than required to demonstrate prolapse and to test the efficacy of the adjustment system (Fig. 3C). The atrium was then closed with a running stitch, with the shaft of the adjustment handle across the atriotomy line (Fig. 3D); the animals were then weaned from cardiopulmonary bypass. Thereafter, epicardial Doppler echocardiography was performed to determine the degree of MR due to prolapse. The implanted neochordal length was
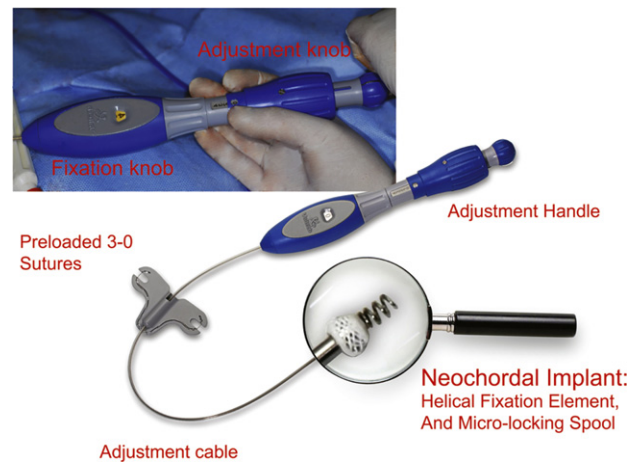

Fig. 2. V-Chordal concept the V-Chordal system is composed of a neochordae implant device (with a self-fixating helical element and a micro-locking spool) and of a delivery system (adjusting handle and cable). A surgical view of the adjusting handle shows the location of the fixation and of the adjustment knob.

adjusted by rotating the control knob on the adjustment handle under real-time echocardiographic guidance until the desired reduction of MR was achieved (Fig. 4). After releasing the neochordae implant, the flexible delivery-system shaft was withdrawn from the atrium. A final Doppler echocardiography was performed to determine the degree of MR at the end of the adjustment and following the removal of the delivery system. The chest was then closed in the standard manner.

Animals were prepared for long-term survival, antibiotics were administered, and animals recovered while under observation. Animals in the chronic group were housed and fed for 90 days prior to sacrifice. In the week prior to sacrifice, all animals underwent transthoracic echocardiography. Gross anatomical and histopathological examinations of the tip of the papillary muscle were performed in all animals. For histopathological examination, tissue samples were stained with standard hematoxylin and eosin stains.

2.4. Statistical methods

All data were collected in an electronic case report form and assimilated prior to analysis. Statistical analysis was conducted using the JMP version 5.1.1 software (SAS institute Inc, Cary, NC, USA). Continuous variables are presented as mean ± SD. Univariate comparisons have been performed using the Wilcoxon's signed rank test for paired data. The level of significance was set at $P < 0.05$. No comparisons between experimental and control groups were undertaken due to the disparity in group sizes.

3. Results

Baseline echocardiographic findings were equal in both groups (Table 1).

All animals underwent weaning from cardiopulmonary bypass uneventfully and survived surgery. Anterior leaflet flail lesions were effectively created in all animals by cutting between two and four primary chordae in the A2 region.
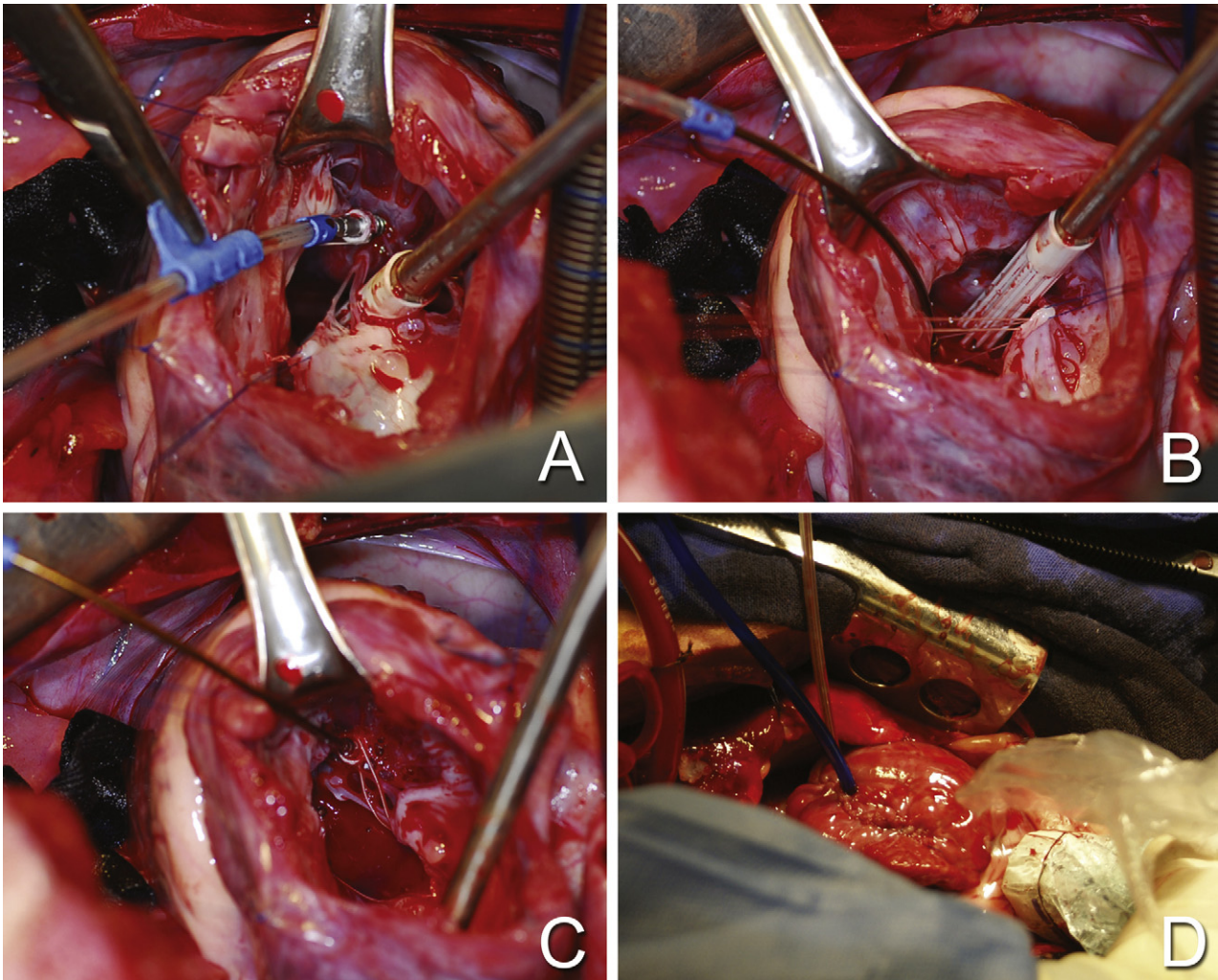
Fig. 3. Intraoperative view of the implant of the V-Chordal system. A: The V-Chordal device is implanted with a sutureless procedure in the tip of the papillary muscle using the self-fixating helical element, activated by the handle. Note the 4-0 polypropylene stay suture in the middle of the anterior leaflet. B: The 3-0 braided sutures are positioned in the free edge of the anterior leaflet. At this time, the connecting cable is left aside, lying on the posterior commissure while the sutures are implanted on the leaflet. C: Neochordae suture view prior to atrial closure. The connecting cable is still attached to the neochordae implant and is left across the mitral coaptation line and across the atriotomy until beating-heart adjustment is done. D: The left atrium has been closed. The sutures are kept tight with a tourniquet (blue tube) around the connecting cable (transparent tube). Epicardial echo probe is now positioned in the atrioventricular groove to guide adjustment. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.)

Following discontinuation of cardiopulmonary bypass, the flail leaflet was apparent in animals that underwent V-Chordal system implant, and was evident as a severe grade of eccentric MR (Fig. 4A). Guided by echocardiographic monitoring, flail lesions were corrected in all cases by using either anatomical landmarks or the degree of MR for real-time guidance. In certain cases, residual MR was nonresponsive to adjustments. In such cases, the MR jet was centrally directed, and there was evidence of the normal height of coaptation of the treated leaflet. In such circumstances, the neochordal length was determined solely on the basis of the anatomical effect, and disregarding the Doppler findings. In cases, the delivery system was easily disconnected from the implant, with no bleeding from the atriotomy line and no damage to the surrounding tissue. During final echocardiographic measurements, all animals, with the exception of two, showed no, or a trivial amount of, MR without any evidence of residual flail lesions (Fig. 1B); in two animals

(14%), there was persistent MR grade 2+/4+ with a non-eccentric jet. The neochordae were visible on echo, as was the implant position at the tip of the posteromedial papillary muscle. It is notable that, in most cases, the connecting cable induced a minimal degree of MR due to the interference with leaflets, but this did not impede assessment of neochordal length.

In the control group, two animals showed residual MR of grade 2+/4+, with non-eccentric jets (Fig. 1A).

All animals survived following the acute experiment and up to the predefined time of sacrifice at 90 days. Prior to sacrifice, at transthoracic Doppler echocardiography, mitral competence was stable, and there were no significant differences in degrees of MR in both groups (Fig. 1A and B). At the post-mortem gross examination, the implant and the neochordae were completely healed and there was evidence of tissue ingrowth, with no gaps (Figs. 5 and 6). No tissue tears were found adjacent to the neochordal implant
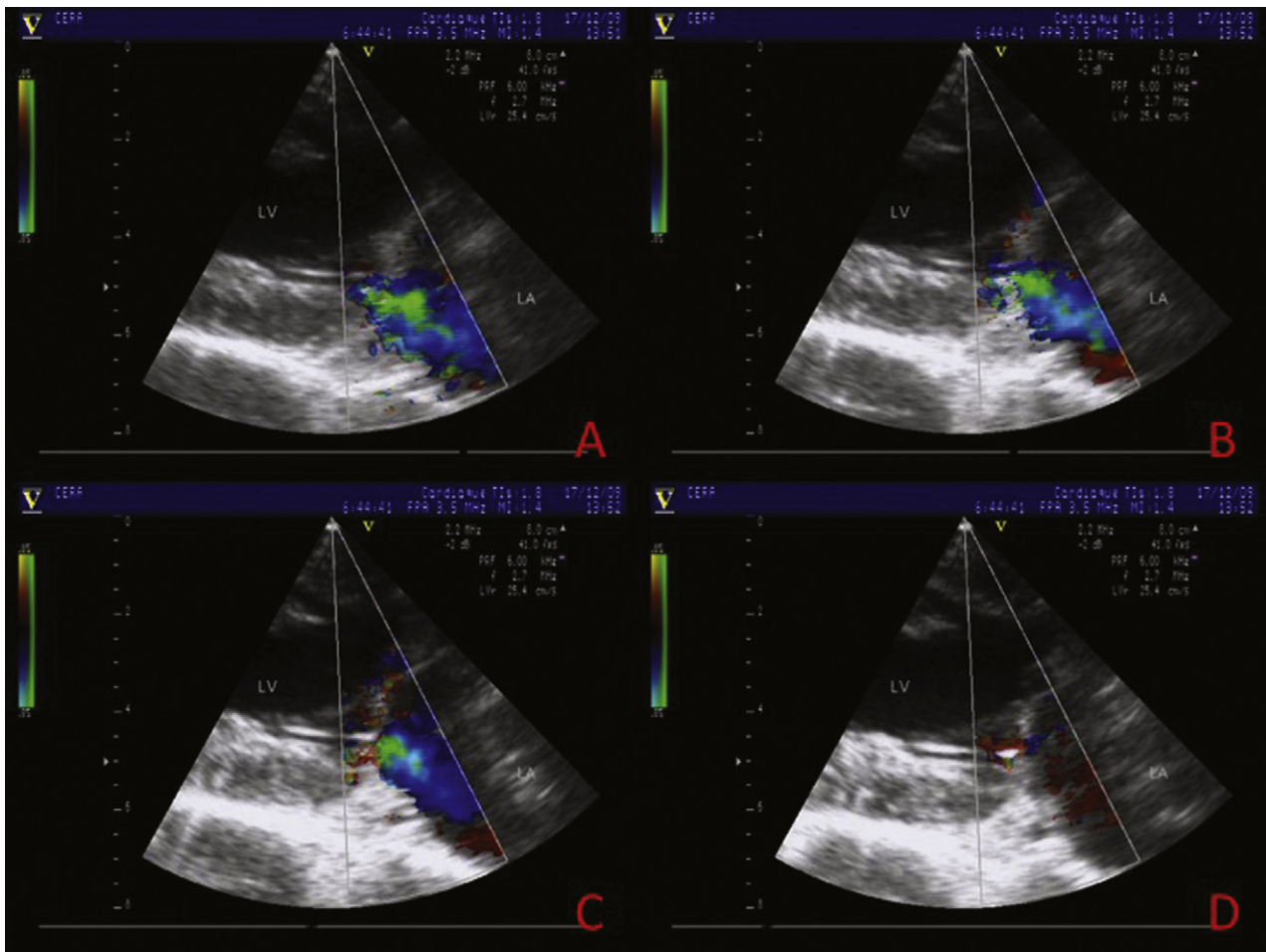
Fig. 4. Echo-guided adjustment. Figures A—D show progressive reduction of systolic jet as the neochordae length is optimized under beating-heart conditions.

on the free edge of leaflets. Papillary muscles exhibited fibrous healing that was confined to the area of the implant and there was no evidence of damage to the surrounding tissue (Fig. 6). Histopathological examination revealed good tissue ingrowths within the helical fixation element, and no
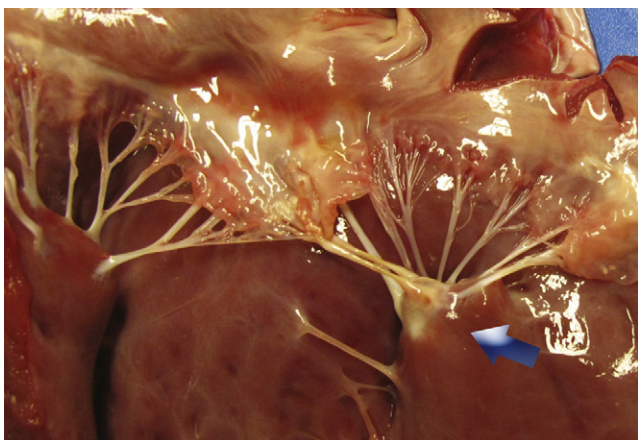

Fig. 5. Gross anatomy at post-mortem examination in a chronic animal demonstrates normal healing of both the neochordae implant (arrow) and of the neochordae sutures.

sign of adverse cellular reaction to the implant. In addition, gross pathology and histopathology findings in the control group were normal.

4. Discussion

The V-Chordal system enabled neochordal implantation and precise off-pump adjustment of the neochordal length to correct MR due to flail leaflet. Compared with conventional neochordal implantation, the new system investigated in the present study proved to be of similar safety and efficacy, while minimizing the risk of inaccurate length determination, and simplifying the implantation technique.

The device is implantable on the tip of the papillary muscle with a sutureless semi-automated method. The simplified method of fixation was effective and durable in a beating, open, heart model, and it is expected to be equally valuable under cardioplegic heart conditions. Neochordal length is precisely regulated with high-resolution adjustment on the beating heart, under echocardiographic guidance, to safely and effectively optimize functional performance of the mitral valve.

The implantation of neochordae is a well-established method to treat leaflet prolapse and flail [1,7]. The
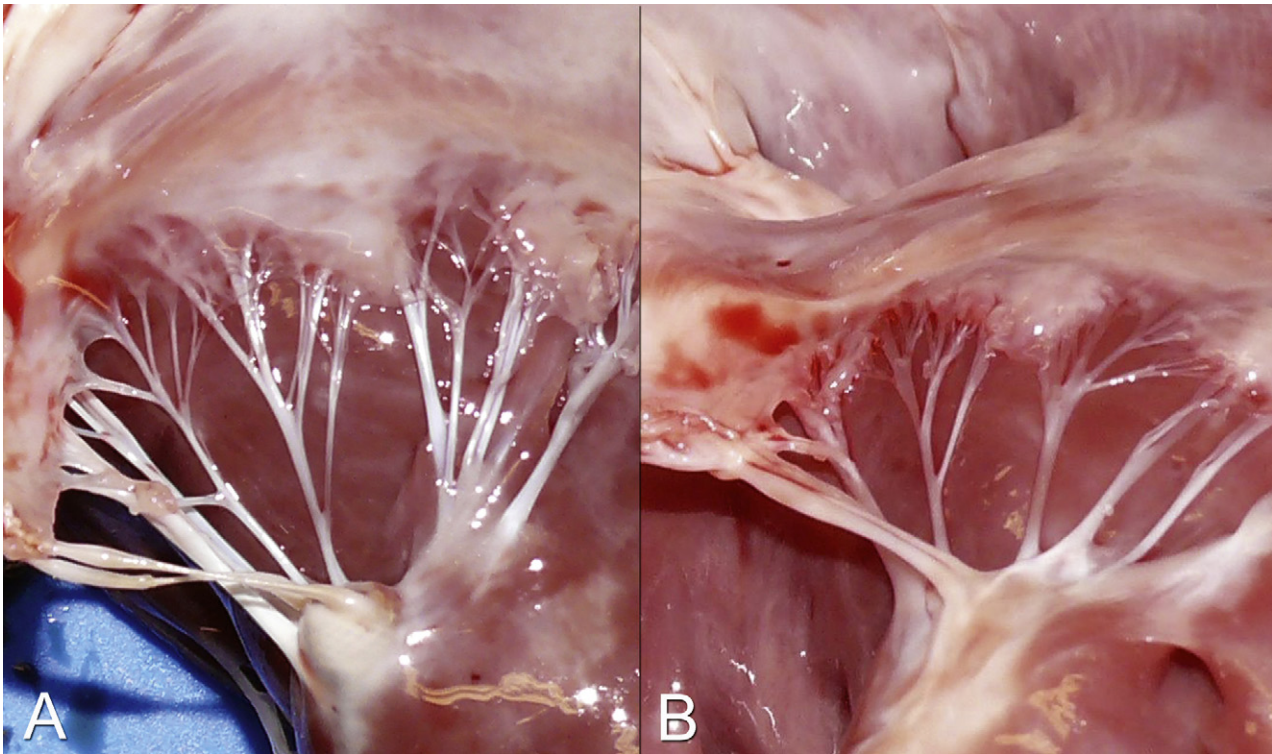
Fig. 6. Gross anatomy at post-mortem examination in a chronic animal demonstrates the tip of papillary muscle in a V-Chordal (A) and a control (B) animal. Note the absence of fibrosis in the surrounding tissue in picture A demonstrating minimal invasiveness of the device.

implantation of artificial chordae is intrinsically more physiologic than the method of leaflet resection [5], and it has been associated with a larger orifice area following repair, as compared with leaflet resection [2]. Further, the preservation of leaflets is possibly associated with a wider surface of coaptation [3], implying a potential for longer durability of the repair and implant [8]. Although the potential benefits of neochordae implantation are recognized, the application of the procedure is limited by the difficulty involved in determining appropriate length of artificial PTFE sutures during cardioplegia. Several techniques have been reported to accurately estimate the length of the neochordae that are created during surgery, with sutures anchored in the head of the papillary muscle [9]. The most frequently used technique involves the adjustment of chordal length during hydraulic testing of the static heart (on cardiopulmonary bypass). This method is usually effective; however, it can be unreliable, particularly in cases of difficult exposure. In addition, the need for repeated injections in the left ventricular cavity could increase the risk of air embolization into the coronary circulation.

Other maneuvers include the estimation of the length of healthy chordate adjacent to the affected chordae, and the use of the annular-to-papillary-muscle distance [10]. In addition, there are devices to guide chordal implantation by adjusting the length using the annuloplasty level as a reference [11].

In addition to the above-mentioned methods, the loop technique has been developed to standardize and facilitate minimally invasive implantation of neochordae: this method comprises the implant of a pre-sized group of looped sutures.

In this method, the length is determined on either anatomical or echocardiographic measurements [12]. The loops are connected to the tip of papillary muscles and to free edges of leaflets with polypropylene sutures, thus minimizing the risk of overreduction of length during knot tying. This feature, associated with the avoidance of intraoperative sizing, is particularly desirable in the setting of minimally invasive repair.

All the above-mentioned techniques for sizing of chordal length are limited by the static determination of chordal length during cardioplegic arrest. The post-implant control of appropriate sizing is based on ventricular saline injection and direct view of valve competence. Although this method is often valuable, it is not always reliable, because it assesses coaptation during non-physiologic conditions [13]. In an effort for a more physiologic control of chordal length, transapical off-pump implantation of neochordae has been proposed as an alternative to conventional techniques [14,15]. This technology is promising; nonetheless, its clinical role has yet to be determined in clinical trials to elucidate the durability of implants. In addition, its applicability could be influenced by leaflet anatomy, presence of leaflet segments requiring resections, or the need for an annuloplasty.

To date, the V-Chordal system is the only device designed for sutureless implantation of neochordae under cardioplegic arrest that allows subsequent adjustment on the beating heart. The device has a flexible shaft that allows remote activation of a fixation element in the head of the papillary muscle. The use of this mode of fixation simplifies the process by reducing suture handling, and it is possibly safer because

the papillary muscle implant constitutes less interference with the native chordae than a conventional figure-of-eight suture. Papillary muscle fixation has been performed with no complications in the experimental series, although this step has been performed under beating-heart conditions. Gross anatomical examination following sacrifice at 3 months showed complete healing of the neochordal implant, which was covered by endothelium, and the absence of lesions in the surrounding tissue (no chordal abrasions and no ischemic lesions in papillary muscle). Sutureless implantation enables minimally invasive utilization of the device, which has been designed with a long shaft to enable use through a port access [16]. Maximal pull force of the device on the papillary muscle head has been tested extensively in isolated hearts and has demonstrated similar pulling force to that of sutures (average of 1.5 kg).

In the model used for this animal trial, the neochordal implant released double-ended 3/0 polyester-braided sutures with tapered needles. This allowed the implantation of a couple of neochordae for each device. Although this experiment was carried out with single implants, there is potential for multiple devices to be used to address more complex anatomies with multiple prolapsing segments. New-generation devices are being developed with loops (single or double) at the end of the neochordae to allow multiple neochordal implants for each device.

The neochordal material used in the V-Chordal system has demonstrated reliability similar to that of the conventional PTFE in terms of durability and tissue healing (all neochords were covered by endothelium on examination following sacrifice). Braided sutures have been chosen because of better durability on device fatigue-testing compared with PTFE.

The device enabled fine tuning of the neochordal length, following implantation, under physiologic loading conditions. In all cases, by intention, the neochordae length was initially kept longer than required. This was associated with a clear demonstration of leaflet prolapse in all animals following left atriotomy closure and weaning from cardiopulmonary bypass. Subsequently, the neochordal length was adjusted with sub-millimetric precision, under echocardiographic guidance. Echocardiographic guidance has been reliable overall; however, in a few animals, the region of the implant showed certain Color Doppler artifacts generated by the adjustment cable hitting the free edge. In such cases, the neochordal length was tuned based on the correction of coaptation height rather than on the reduction of regurgitation. This limitation is expected to be addressed by second-generation technology, which will allow disconnection of the adjustment cable, leaving only a soft 0.014″ wire across the valve. This wire will allow eventual re-connection of the adjustment cable in case of need for an additional adjustment. In addition, due to the model employed in the present study, certain regurgitant jets unresponsive to neochordal adjustment were observed. These jets were usually oriented perpendicular to the coaptation area. These jets were attributed to a consequence of the acute flail model: in the healthy animal, the coaptation surface is limited and leaflets are extremely thin. Following native chordal cutting, the free edge of the leaflet tends to roll. This tendency has been addressed by the 4/0 polypropylene stay

suture; however, neochordal implantation on the free edge of the leaflet and subsequent knot tying resulted in lack of tissue with the reduction of the coaptation surface area responsible for the above-mentioned jets. Such an effect is not expected in human valves with naturally occurring prolapse and flail because diseased segments are usually affected by tissue. In addition, differing from such experimental conditions, the clinical use of the V-Chordal device would be expected to occur in combination with an annuloplasty device to increase the surface area for coaptation.

In terms of efficacy, the new device was demonstrated to be at least as efficacious as the conventional neochordae implant, with appropriate acute correction of MR, and stable chronic results. Chronic implants showed normal healing of the neochordae and the Dacron-covered spool implanted on the papillary muscle, implying the need for the same anticoagulant regimen as that followed for conventional mitral repair, in clinical use.

The present experiment presents certain limitations. The lack of a naturally occurring animal model of prolapse necessitated the generation of an acute flail model by chordal cutting. This resulted in a prolapse geometry solely related to lack of primary chordae attachment, whereas in naturally occurring prolapse, the unsupported segment is also affected by tissue redundancy. This experiment was conducted with single implants in each animal. In most cases, multiple implants would be required to address valve pathology, and studies are being conducted, at present, to prove the feasibility of multiple implants. Further, to eliminate any influence of adjunctive maneuvers, the experiment also tested the isolated neochordal implant without annuloplasty, which is not the intended use in clinical practice. A final limitation of this study is that it utilized epicardial echocardiography as a guiding method, because transesophageal echocardiography is unreliable in the animal model.

In conclusion, these authors investigated the functionality of a device enabling a simple and reproducible technique for the implantation and precise adjustment of neochordae. The procedure can be safely and effectively performed; further, it can be used in a minimally invasive environment because of the long, flexible shaft design of the delivery system.

This study implies that intra-procedural, real-time adjustment techniques are technically feasible and may result in a wider application of neochordal repair, thus enhancing chances of a successful repair and improving potential adoption of minimally invasive approaches for the correction of MR.

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Appendix A. Conference discussion

Dr J. Grunenfelder (*Zurich, Switzerland*): Well, I have to say that this is just an ingenious invention. I think it is something which is probably going to change our practice, and I hope so, because everybody has been struggling with adjusting the length of the chordae and having to go back on pump to replace the chordae. I have no doubt looking at the list of authors of this study that this idea will take off. But I have just a few questions.

First, has the maximum pull force of this device been measured, and is it possible to actually go onto the free wall of the left ventricle if there is no papillary muscle? Sometimes there is just underdeveloped papillary muscle, and I was just wondering whether you can go to the free wall and is this strong enough to get enough force to pull the leaflet back?

And the other thing you just explained to me during the presentation. I mean, the beating-heart left atrial approach might be difficult or dangerous for air embolism, but you explained that in the presentation.

Dr Maisano: I think the most important issue that we faced from phase 1 was the decision about whether to go for a suture-implanted device or a sutureless-implanted device using this pigtail design. Our preclinical animal and bench tests showed that the force of pulling the device is much higher than is needed to keep the chords in place. The possibility of implanting this device in a location different from the tip of the papillary muscle has not yet been addressed, although the next generation device which we are planning to design is one which will be implantable through a transvenous and trans-septal approach, and we will plan to implant the device initially in the tip of the apex. So this issue will be discussed in the future.

There is one other limitation for the application of this device in a location different from the papillary muscle tip. In this case, if LV remodeling happens following the procedure, there might be an inappropriate length if you implant in a location different from the papillary muscle. In addition, the maximal length of the device that we can design represents a constraint for implants in a location different from the papillary muscle. At this time implant location is not an issue, because, as you see, two sutures with needles are released. But we are developing a new-generation device where neochordae loops will be delivered instead of the sutures, to replicate the procedure that Professor Mohr designed in the past.

Dr A. El-Essawi (*Braunschweig, Germany*): I have a technical question. If you were doing this on a human, would you do it on the beating heart on cardiopulmonary bypass, or after weaning from cardiopulmonary bypass, which would be functionally more reasonable?

Dr Maisano: These questions are very important to clarify the details of the technique. In the animal testing we decided to proceed with beating-heart implantation because of the safety of the CPB setup in the animal. In a human we would advise, obviously, implantation on cross-clamp under cardioplegia. Initial adjustment can be done under cardioplegia, which is easy to do with this automatic device. In addition, the device offers the option of leaving the connecting cable in place, and in the event of any residual leak due to either too long or too short chordae, the length can be adjusted afterwards.

Dr A. Calafiore (*Riyadh, Saudi Arabia*): Francesco, I would just like to ask you a question. How many chords do you think you can implant with this technique? You are limited by the tips of the papillary muscle.

Dr Maisano: This is one limitation that we already addressed. I think in most patients probably two implants will be enough to treat the underlying pathology. To overcome this limitation, we are designing the loop technique. So instead of two chords coming off from the device system, we will have multiple chords. We have already designed and implanted multiple-chord devices, so that the next generation will be with chordal loops to implant neochords on both leaflets from each papillary muscle.

Dr Calafiore: Just one more question. I would like to know what you think about the problem that sometimes occurs when you unclamp the aorta and you are off pump, the heart often is not exactly the same as the heart you will find the day after. So adjusting the chords with a heart that often is smaller, is more hyperactive, and the papillary muscle is closer to the other, what will happen 24 hours later? This is the question.

Dr Maisano: That is a good question. Actually we designed this device to improve our ability to adjust the chords after implantation. Now, you are asking me to design a device to adjust it the day after. Maybe next year we will present the data.

Dr Calafiore: But the problem is then that you use chords that 24 hours later will be a little bit more rested. This is my concern.

Dr Maisano: I understand your point. We occasionally see some patients where the ventricle shrinks and it looks like the chordal length probably is too long because of this very prominent LV remodeling, and it would be nice to have something to go back again and readjust the length. But this is probably very difficult to do at this time.

Dr Calafiore: Often you leave the OR with sometimes mild MR and the day after it disappears with the neochords. Anyway, we will see.