

Transapical off-pump mitral valve repair. First experience with the NeoChord system in Poland (report of two cases)

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Abstract

Background: Artificial chord implantation to repair a flail or prolapsing mitral valve leaflet requires open heart surgery and cardiopulmonary bypass.

Aim: Transapical off-pump artificial chordae implantation is a new surgical technique proposed to treat degenerative mitral valve regurgitation. The procedure is performed using the NeoChord DS1000 system (NeoChord, Inc., St. Louis Park, MN, USA), which facilitates both implantation and length adjustment of the artificial chordae under two (2D)- and three (3D)-dimensional transoesophageal echocardiographic (TEE) guidance on a beating heart.

Methods: Two male patients aged 60 and 55 years with severe mitral regurgitation due to posterior leaflet prolapse underwent transapical off-pump artificial chordae implantation on September 3, 2015. The procedure was performed by left minithoracotomy under general anaesthesia in a cardiac surgical theatre, using 2D and 3D TEE guidance.

Results: Early procedural success as confirmed by 3D TEE was achieved in both patients, with implantation of 6 artificial chordae in the first patient and 3 artificial chordae in the second patient. Both procedures were uneventful, and no postoperative complications were noted. The patients were discharged home on the 8th and 6th postoperative day, respectively.

Conclusions: The NeoChord DS1000 system allows both implantation and length adjustment of artificial chordae under 2D and 3D TEE guidance on a beating heart. Our initial experience in 2 patients with posterior mitral leaflet prolapse indicates that the procedure is feasible and safe.

Key words: mitral valve repair, severe mitral regurgitation, artificial chordae, NeoChord

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INTRODUCTION

Techniques of subvalvular apparatus reconstruction, including tendinous chords, are successfully used in the treatment of type II mitral regurgitation (MR) which is due to tendinous chord rupture or elongation [1]. A number of surgical techniques are available to correct a prolapsing mitral valve leaflet. One of these is implantation of artificial chords (neochords) to the prolapsing leaflet without its resection, combined with mitral annuloplasty [2]. All these techniques

require the use of cardiopulmonary bypass, cardioplegia, and open heart surgery.

The technique of transapical artificial chord implantation using the NeoChord DS1000 (NeoChord, Inc., St. Louis Park, MN, USA) system allows restoration of normal leaflet motion under real-time two (2D)- and three (3D)-dimensional transoesophageal echocardiography (TEE) guidance. With this technique, chord implantation and adjustment of their length is possible without the use of cardiopulmonary bypass.

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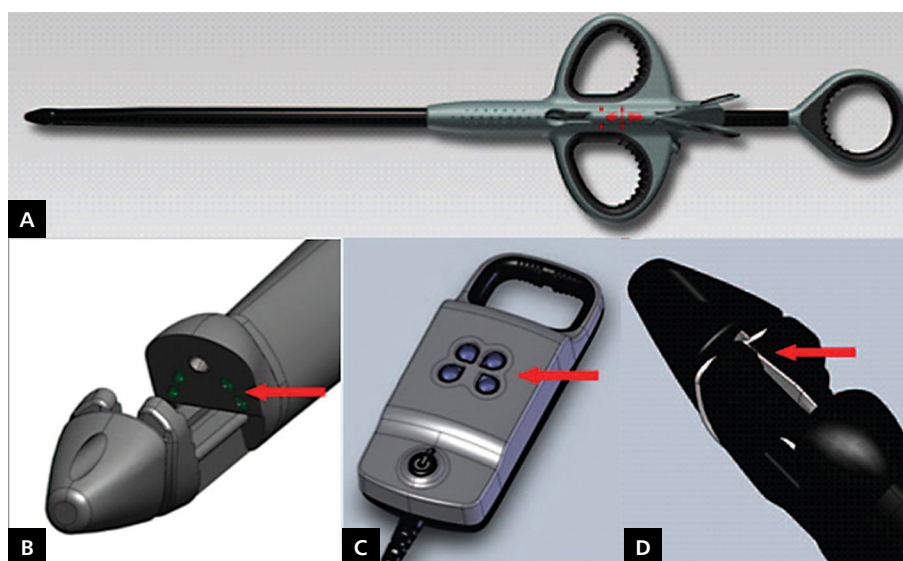


Figure 1. The NeoChord system; **A.** The whole instrument with a needle inside; **B.** Device jaw with a fibre optic sensor; **C.** Display used to confirm an appropriate depth of leaflet grasp; **D.** Needle with a hook inside the instrument

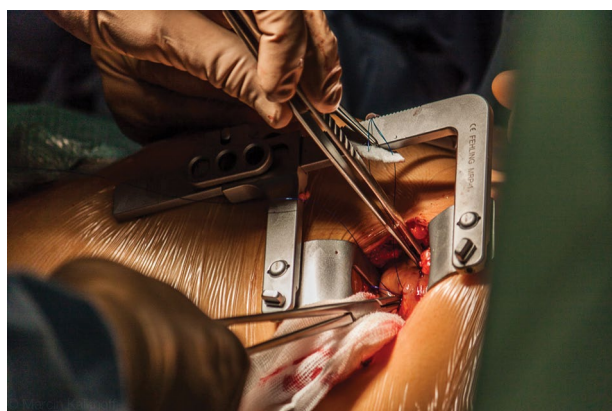


Figure 2. Minithoracotomy in the fifth left intercostal space superiorly to the apex, following identification of the access site by transthoracic echocardiography

METHODS

The NeoChord DS 1000 system consists of a single-use instrument which allows grasping the valve leaflet (Fig. 1A). Pressing one of the thumb ring of the system handle opens jaws at the tip of the device, which returns to the baseline position once the thumb ring is released. Jaws of the device are equipped with four fibre optic sensors which allows for confirmation of an adequate tissue within the jaws using an external display (Fig. 1B, C). The system includes a needle with a hooked end (Fig. 1D) which allows for puncturing the leaflet held between the jaws. During needle retraction, expanded polytetrafluoroethylene suture are passed through the hole in the leaflet and retracted from the heart creating the artificial chordae. The leaflet is punctured approximately 4 mm away from the free edge. Following jaw opening, the leaflet is released, and the system is pulled out from the ventricle.

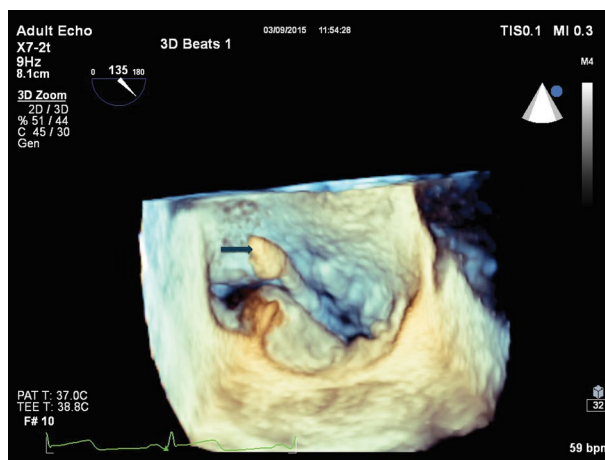


Figure 3. The posterior leaflet is grasped under three-dimensional echocardiographic guidance. Arrow indicates the tip of the instrument

Description of the procedure

Procedures were performed under general anaesthesia with full haemodynamic monitoring, in a cardiac surgical theatre with cardiopulmonary bypass capability. Two- and three-dimensional transoesophageal images were obtained using the Epic7C system (Phillips, Eindhoven, NL). Echocardiographic images were displayed on an serial monitor which was well visible for the surgical team. The patient was placed in slight right lateral position to facilitate access to the apical area. Following apex identification by transthoracic echocardiography (TTE), a minithoracotomy was performed in the left, fifth intercostal space (Fig. 2).

After pericardial sac opening, ultrasound was used to identify the site of access to the left ventricle 2–3 cm pos-

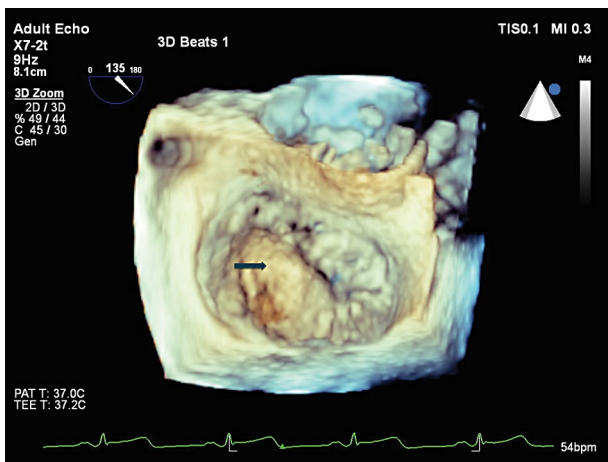


Figure 4. Preoperative three-dimensional transoesophageal echocardiography. Extensive posterior leaflet prolapse involving the P2 and P1 segments is seen (arrow)

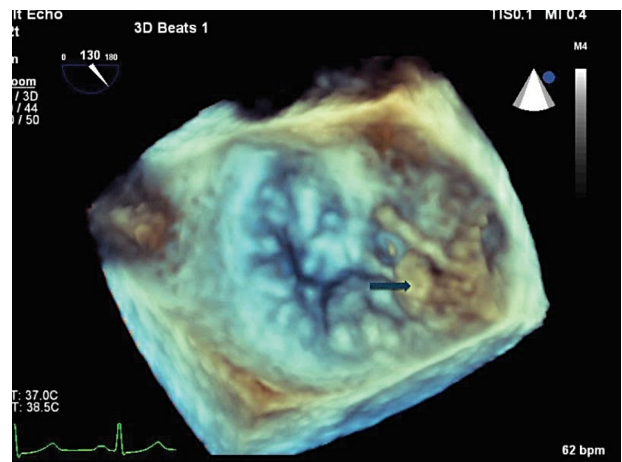


Figure 5. Preoperative three-dimensional transoesophageal echocardiography. Posterior leaflet prolapse involving the P3 segment is seen (arrow).

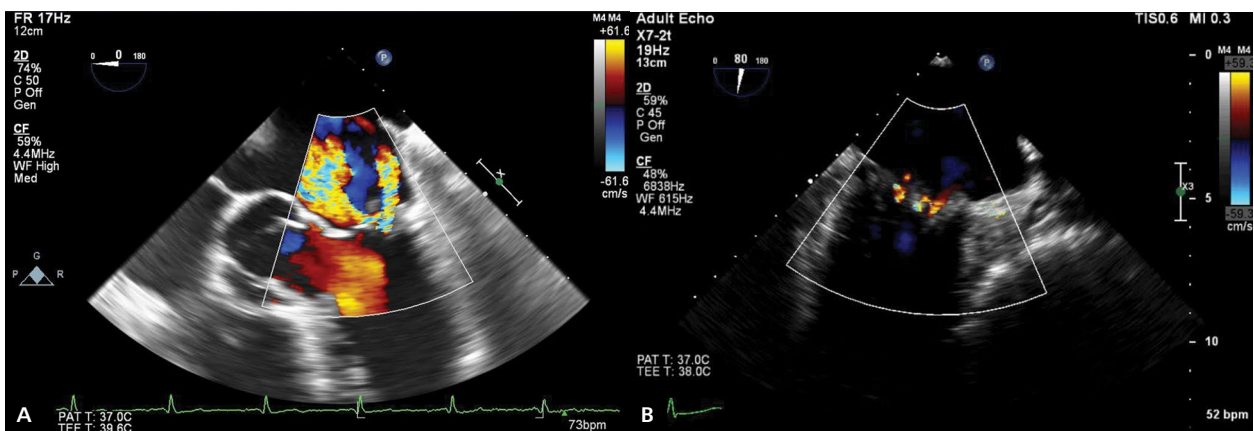


Figure 6. Transoesophageal echocardiography in Patient 1 with posterior leaflet prolapse involving the P2 and P1 segments — a colour Doppler study; **A.** Before the procedure; **B.** After the procedure

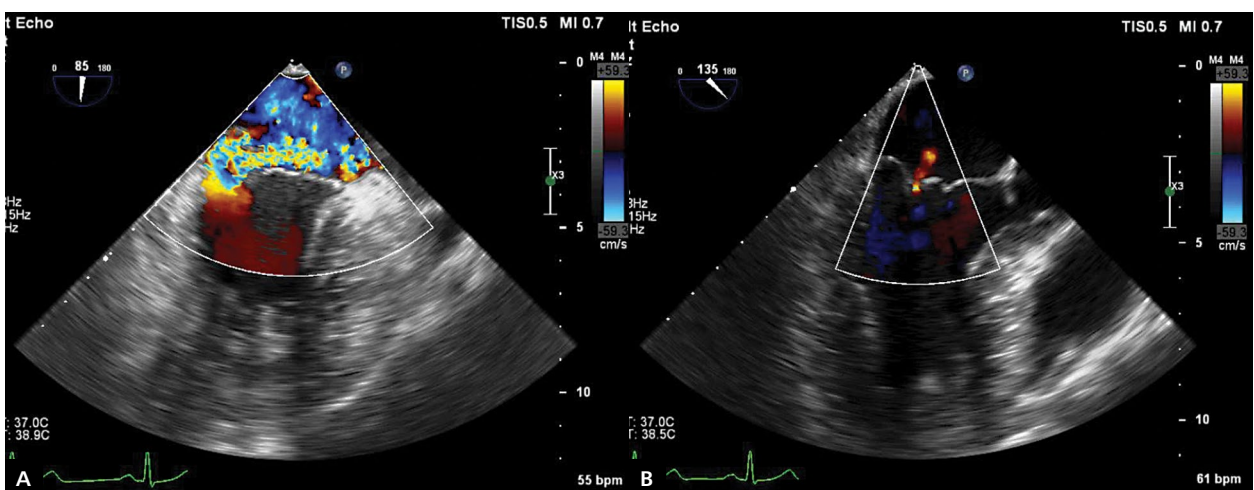


Figure 7. Transoesophageal echocardiography in Patient 2 with posterior leaflet prolapse involving the P3 segment — a colour Doppler study; **A.** Before the procedure; **B.** After the procedure

teriorly and laterally from the apex. Following placement of two perpendicular purse strings with felt pledgets, heparin was administered at 1 mg/kg to increase the activated clotting time (ACT) above 300 seconds. The NeoChord system was introduced into the left ventricle by a small incision. Under 2D/3D echocardiographic guidance, the tip of the instrument was manoeuvred through the mitral valve at the site of leaflet prolapse. Then, a segment of the posterior leaflet with the native ruptured or elongated tendinous chords was grasped under 2D/3D echocardiographic guidance (Fig. 3). After fibre optic confirmation of leaflet capture, the leaflet was punctured with the instrument needle. The hooked needle was pulled back through the opening in the leaflet, and a loop and two ends of an artificial chord were pulled out from the heart. The leaflet was released and the instrument was withdrawn from the left ventricle. Then, after passing the two ends of the chord through the loop, a hitch knot secured the artificial chordae on the leaflet. Following insertion of 3 chordae in the first patient and 6 chordae in the second patient, apical purse strings were tied and protamine was administered. The free ends of all the artificial chordae were passed through a single felt pledget. Artificial chordae length was adjusted under 2D/3D echocardiographic guidance to obtain adequate mitral valve competence, and finally they were secured on the pledget surface. The pericardial sac was sutured, with one drain placed into the pleural space. Thoracotomy was closed.

Case reports

Patient 1. A 55-year-old man after two kidney transplantations (2008 and 2010) due to end-stage renal failure, graftectomy in 2009 due to graft vessel thrombosis, and infective endocarditis in 2007. Echocardiography (TTE, 2D/3D TEE) showed flaccid tendinous chords of the mitral subvalvular apparatus and evidence of myxomatous degeneration of mitral leaflets with large posterior leaflet prolapse involving the P2 and partially the P1 segment (Fig. 4). Leaflet prolapse was accompanied by a significant MR with an eccentric jet impinging on the interatrial septum and flowing around an enlarged left atrial chamber, with systolic pulmonary vein flow reversal (Fig. 6A). Mitral regurgitant orifice area was about 0.7 cm², and the width of the mitral annulus was 39–42 mm.

Patient 2. A 60-year-old man without significant past medical history. Echocardiography (TTE, 2D/3D TEE) revealed slightly thickened mitral leaflets and severe prolapse of the segment P3 of the posterior leaflet due to ruptured tendinous chords with a significant coaptation defect (Fig. 5). Severe multiple-jet, eccentric MR was noted, reaching the posterior atrial wall, recorded in the left and right pulmonary veins and the atrial appendage, with vena contracta of the major jet of about 7 mm and a large convergence zone (Fig. 7A). The width of the mitral annulus was about 43 mm.

RESULTS

Patient 1. Six artificial chordae were implanted to the wide P2 segment, and a coaptation length of 7.5 mm was achieved. Follow-up 2D TEE with colour Doppler showed a mild, dual-jet MR (Fig. 6B). The duration of the procedure was 2 h 25 min. The patient did not require transfusion of blood products. Postoperative drainage was 170 mL. The duration of hospital stay from the procedure to the discharge was 8 days, including 2 days in an intensive care unit. Duration of hospitalisation was extended due to elevated inflammatory markers without evidence of an overt infection (the patient was receiving immunosuppressive treatment following kidney transplantation).

Patient 2. Three artificial chordae were implanted to the P3 segment, and a coaptation length of 6.5 mm was achieved. After the artificial chordae were anchored to the epicardium, follow-up 2D TEE with colour Doppler showed only a trace MR (Fig. 7B). The duration of the procedure was 1 h 48 min. The patient did not require transfusion of blood products. Postoperative drainage was 150 mL. The patient was discharged home on the sixth postoperative day, and the duration of stay in an intensive care unit was 2 days.

Further follow-up imaging at 1, 3, 6 and 12 months did not show any change or progression in MR when compared to the previous studies.

DISCUSSION

Techniques of subvalvular apparatus reconstruction, including tendinous chords, are successfully used in the treatment of type II MR which is due to tendinous chord rupture or elongation [1]. Mitral valve repair is a routinely performed procedure, particularly in case of posterior leaflet pathology. Several surgical techniques are available. One commonly used approach to mitral valve repair with established early and long-term effectiveness is artificial chordae implantation combined with mitral annuloplasty [2].

Patients with severe MR are referred for surgical treatment but the decision to undergo surgery is often postponed by the patient if the valve disease is asymptomatic or produces few symptoms. This delay in surgical treatment results in gradual development of valve disease consequences and occurrence of significant symptoms. At the same time, long-term survival of patients with severe MR is 6.3% per year lower than expected [3]. With time, volume overload leads to cardiac chamber enlargement, atrial fibrillation, pulmonary hypertension, and gradual worsening of left ventricular systolic function. Over 10 years, atrial fibrillation develops in 30% of patients, and symptoms of heart failure in 63% of patients [3]. Disease symptoms are usually developing late in the course of the disease. For this reason, the above consequences of valve disease are usually already present in patients with severe MR presenting for cardiac surgical treatment. At 10 years after the diagnosis

of severe MR, 90% patients die or require surgical treatment and thus surgical correction should be considered as early as possible [3].

Referring asymptomatic patients with severe MR for surgical treatment is somewhat controversial (a class IIa indication) due to a risk associated with the surgery [1]. Earlier consideration of surgery is justified if treatment outcomes are excellent (zero mortality and good quality of valve repair). Another potential advantage of early consideration of surgery is the fact that the mitral annulus may be only be slightly dilated which would allow good leaflet coaptation by re-suspending the leaflet with artificial chordae and without requiring mitral annuloplasty [4].

The NeoChord system allows for artificial chordae implantation to a mitral leaflet using a small surgical access without the use of cardiopulmonary bypass [5]. This procedure is even less invasive than the current approach by right-sided minithoracotomy which requires the use of cardiopulmonary bypass, cardioplegia, and open heart surgery. In addition, this technique allows valve repair on the beating heart guided by real-time 3D echocardiography, which is not possible in case of the conventional surgical technique. The effectiveness of this method was confirmed in animals [5, 6] and clinical studies [4, 7–9]. To date, the largest published series includes 62 patients from Padova, Italy, and Vilnius, Lithuania [4]. Effective implantation of artificial chordae was possible in all patients, including 88.9% with posterior leaflet prolapse. On average, 3 or 4 artificial chordae were implanted in the majority of patients (76%). The authors observed that treatment outcomes depended heavily on the valve prolapse morphology. The highest early treatment effectiveness (95%) was achieved in patients with posterior leaflet prolapse involving the P2 segment. Somewhat lower treatment effectiveness (92%) was observed in patients with posterior leaflet prolapse involving the P2 segment and adjacent portions of the P1 or P3 segment, or with prolapse of several separate segments. In patients with complex prolapse including the anterior leaflet and or bileaflet involvement, treatment effectiveness was reduced to 71%. Both procedures reported in this experience were performed in patients with prolapse involving the posterior leaflet segments of P2 and P3. Both procedures were effective and uncomplicated. In addition to leaflet morphology, the site of left ventricular puncture is another significant factor affecting treatment outcomes. The technique used during these first procedures in Poland was modified based on the previous experience [10], with left ventricular puncture performed more posteriorly.

The absence of concomitant mitral annuloplasty in the transapical, off-pump artificial chordae implantation procedure has been identified as a variable that may affect the long-term durability of the beating hear repair procedure using the NeoChord system. Currently, the largest series of patients with the longest reported follow-up was reported

by for 23 patients at 2 years. While this series of subjects is considered too short for assessing long-term durability, the results are promising. In site-reported echo assessment, 86% (20/24) of patients were observed to have complete freedom from recurrent MR $\leq 1+$, while 96% (23/24) of patients were observed to have complete freedom from recurrent MR $\leq 2+$ at the 2-year follow-up period. Patient selection has been reported as a key differentiator when assessing recurrent MR. For this reason, the best candidates for this approach are patients without significant annular dilatation, with postoperative coaptation height above 7 mm. Coaptation height below 5 mm a risk factor for recurrent valve regurgitation. To date, over 500 procedures of this type were performed including the reported procedures performed in Poland.

Limitations of the study

The case reports are a single centre experience reporting on the results from 2 patients.

CONCLUSIONS

Transapical, off-pump artificial chordae implantation with the NeoChord system has been reported as a safe and effective procedure. Use of the NeoChord system in patients with severe renal compromise has demonstrated it to be a viable alternative therapy to mitral repair procedures using cardiopulmonary bypass. Off-pump, 2D and 3D echocardiography-guided implantation of artificial chordae to the posterior mitral leaflet via an apical ventriculotomy and left-sided mini-thoracotomy helps achieve mitral valve competence in select patients with posterior leaflet prolapse.

Conflict of interest: Krzysztof Wróbel — Surgical Consultant of NeoChord.

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Plastyka zastawki mitralnej bez zastosowania krążenia pozaustrojowego z dostępu przez koniuszek i lewostronną mitorakotomię. Pierwsze doświadczenia w Polsce z zastosowaniem systemu NeoChord (opis dwóch przypadków)

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Streszczenie

Wstęp: Wszczepienie sztucznych nici ścięgniętych w celu naprawy niedomykalnej zastawki mitralnej z powodu wypadania płatków wymaga zastosowania krążenia pozaustrojowego (CPB).

Cel: Celem niniejszej pracy było przedstawienie nowej techniki przekoniuszkowego wszczepienia nici ścięgniętych za pomocą systemu NeoChord DS1000 (NeoChord, Inc., St. Louis Park, MN, USA) z dostępu przez mitorakotomię. Zastosowany system umożliwia wszczepienie nici ścięgniętych i dostosowanie ich długości na bijącym sercu, pod kontrolą przezprzetykowej echokardiografii dwu- i trójwymiarowej (TEE 2D/3D), bez użycia CPB.

Metody: U 2 mężczyzn w wieku 55 lat i 60 lat z ciężką niedomykalnością zastawki mitralnej z powodu wypadania tylnego płatków przeprowadzono zabieg wszczepienia nici ścięgniętych do tylnego płatków zastawki mitralnej na bijącym sercu. Zabiegi wykonano bez CPB, z dostępu przez koniuszek serca i lewostronną mitorakotomię. Pacjentów przygotowano jak do rutynowego zabiegu kardiochirurgicznego. Zastosowano TEE 2D/3D.

Wyniki: Zarówno bezpośrednio po zabiegu, jak i przy wypisywaniu ze szpitala potwierdzono prawidłową funkcję zastawki mitralnej u obu chorych. U pierwszego pacjenta implantowano 6, a u drugiego 3 nici ścięgnięte do prolapsujących segmentów tylnego płatków zastawki. Następnie nici zawiązano na powierzchni serca, po dostosowaniu ich długości pod kontrolą echokardiografii.

Wnioski: System NeoChord umożliwia wszczepienie nici ścięgniętych do tylnego płatków zastawki mitralnej na bijącym sercu z dostępu przez koniuszek i lewostronną mitorakotomię pod kontrolą TEE 2D/3D. Pomaga uzyskać szczelność zastawki mitralnej u pacjentów z wypadaniem tylnego płatków, bez istotnego poszerzenia pierścienia mitralnego na bijącym sercu i bez użycia CPB.

Słowa kluczowe: plastyka zastawki mitralnej, ciężka niedomykalność mitralna, NeoChord

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