Off-pump transapical implantation of artificial chordae to correct mitral regurgitation: Early results of a single-center experience

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Objectives: This study evaluated the safety and efficiency of the NeoChord DS1000 system (NeoChord, Inc, Minneapolis, Minn), a device designed to deliver artificial chordae tendineae (*neochords*) in a beating heart with minimally invasive techniques through left anterolateral minithoracotomy.

Methods: Thirteen patients with severe mitral regurgitation and isolated posterior mitral valve leaflet prolapsed underwent operation with the NeoChord DS1000 system. Mitral valve dimensions were anteroposterior 34 mm (29-45 mm) and mediolateral 40 mm (29-58 mm). All patients had an ejection fraction greater than 55%. With a beating heart, through a left anterolateral thoracotomy, under transesophageal echocardiographic guidance, the NeoChord DS1000 was introduced into the left ventricle 2 to 4 cm posterolateral from the apex. The prolapsed leaflet was grasped with the device, and expanded polytetrafluoroethylene suture deployed and attached to the posterior leaflet. Six patients received 2 sutures, 4 received 3 sutures, and 2 received 4 sutures. All patients reached 6 months' follow-up and underwent transthoracic echocardiography to evaluate mitral regurgitation.

Results: Median operative duration was 113 minutes (80-150 minutes). Less than second-degree mitral regurgitation in 6 months was achieved in 11 patients (85%). One patient (8%) had recurrent mitral regurgitation in 1 month, and another had conversion to conventional mitral valve repair because of leaflet damage with the device. There were no further serious procedure-related complications.

Conclusions: Beating-heart transapical neochord implantation was feasible, could be performed safely, and resulted in a relatively short procedure time. Larger studies and longer follow-up are needed to validate these promising results. (J Thorac Cardiovasc Surg 2014;147:95-9)

ACD

Techniques for mitral valve repair have undergone continual evolution during the past 50 years.[1] Simple posterior leaflet prolapse is associated with very high mitral repair rates in many centers.[2,3] The overall repair rate of 69% observed in the Society of Thoracic Surgeons database[4] represents a progressive increase through an 8-year period but remains significantly lower than is achievable. Acute mitral repair rates are now approximating 98% for all common mitral disease etiologies in referral centers,[1] even when applied to all comers.[5] The lower overall Society of Thoracic Surgeons rate is at least partially explained by more complex scenarios (including anterior or bileaflet involvement, lesion complexity, and patient comorbidities) and less experience on the part of many surgeons relative to those at reference centers.[5]

Cumulative evidence obtained worldwide shows that early surgery should be the preferred management approach.[6] Specifically, mitral repair should be performed

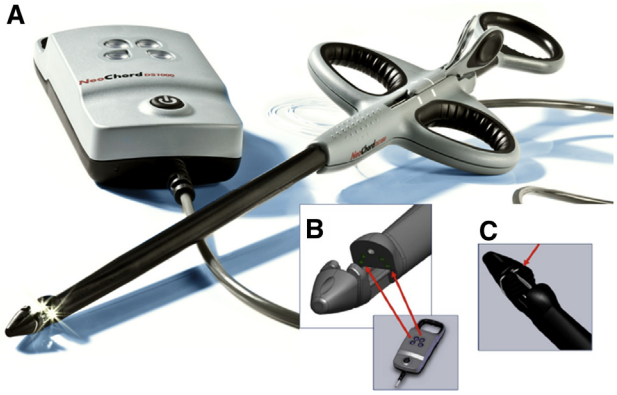

FIGURE 1. NeoChord device. A, The NeoChord DS1000 consists of the hand-held delivery instrument and a tethered Leaflet Verification Display. B, As the device apex grasps the leaflet, the Leaflet Verification Display gives information on leaflet grasping quality. C, The device deploys a suture 4 mm from the leading edge of the target leaflet.

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Abbreviations and Acronyms
LV = left ventricle
MR = mitral regurgitation
TACT = Transapical Artificial Chordae Tendineae [trial]
TEE = transesophageal echocardiography

before New York Heart Association functional class III to IV symptoms develop.[7,8] NeoChord (NeoChord, Inc, Minneapolis, Minn) has developed a new surgical tool for less invasive off-pump, beating-heart mitral valve repair. The NeoChord DS1000 system (Figure 1) is designed to deliver artificial chordae tendineae, or *neochords*, under beating-heart conditions with transesophageal echocardiography used (TEE) to guide the device to the target leaflet for deployment of the neochords. The multicenter, nonrandomized, prospective Transapical Artificial Chordae Tendineae (TACT) trial (clinicaltrials.gov ID: NCT01777815) for evaluation of the NeoChord DS1000 system safety and feasibility is ongoing. In this article, we report our first experience with this device.

MATERIALS AND METHODS

Patient Selection

The local bioethics committee has approved this prospective study, and every patient provided individual consented to undergo the procedure. From December 2011 to August 2012, 13 patients (5 male and 8 female) underwent mitral valve repair with the DS1000 system at Vilnius University Hospital Santariskiu Klinikos, Vilnius, Lithuania. Median patient age was 60 years, with a range from 33 to 73 years. Median body mass index was 27 kg/m^2, with a range from 20 to 34 kg/m^2. All patients had good function of the left ventricle (LV), with an ejection fraction greater than 55%. Per the protocol, all patients had severe mitral regurgitation (MR, grade 3 or 4) with isolated posterior leaflet prolapse. All patients were candidates for conventional mitral valve surgery. Most patients had symptoms of severe MR contributing to early-stage progression of heart failure, and all patients were under medical treatment. Patients with functional or ischemic MR, severe LV dysfunction, anterior or bileaflet prolapse, or permanent atrial fibrillation were excluded from this study. Baseline patient characteristics are presented in Table 1. These patients were at low surgical risk with an average euroSCORE II of 1.06% (0.56%-1.59%). With our preoperative TEE assessment, we targeted patients exhibiting wide prolapsing segments and patients in which clinically significant coaptation depth (6-12 mm) could be restored.

Patient Screening

All patients underwent preoperative transthoracic echocardioscopy, and most of the patients had 3-dimensional TEE to determine suitability for transapical neochord implantation. Preoperative baseline echocardiograms were used to determine the optimal planned number of neochords to be deployed and their target location on the posterior leaflet. In general, deployment of more than 2 neochords is desired for each patient to balance the load per neochord. Preoperative examination of the width of the prolapsing segment or location of clefts in the leaflet tissue guided the target sites for the planned neochords.

DS1000 Device

As shown in Figure 1, The NeoChord DS1000 consists of the handheld delivery instrument and a tethered Leaflet Verification Display with 4 fiber-optic lumens enabling confirmation of leaflet capture. Through a limited left lateral thoracotomy in a beating heart, the device transapically accesses the mitral valve, grasps the flailing leaflet, and deploys a suture as an artificial chord (4 mm from the leading edge of the target leaflet). Fiber optics gives information of leaflet-grasping quality. If a leaflet is grasped with the full depth of the device jaws, the Leaflet Verification Display will show 4

TABLE 1. Baseline characteristics, intraoperative data, and postoperative results

	Baseline										
							MV annulus distance (mm)		MV leaflet (mm)		
Patient	Age (y)	Sex	Height (cm)	Weight (kg)	NYHA	LVEF (%)	AP	ML	Anterior	Posterior	MR grade
1	65	F	162	75	II	55	26	33	15	13	3
2	61	M	176	92	II	55	32	44	21	17	3
3	69	F	156	60	III	55	32	33	21	18	3
4	73	F	155	65	II	55	30	37	20	11	3
5	63	M	178	93	II	55	30	29	17	14	3
6	49	M	186	97	II	55	35	28	20	11	3
7	38	M	185	87	II	55	45	57	27	22	3
8	62	F	170	98	II	55					3
9	72	F	167	75	III	55	29	35	17	20	3
10	62	F	167	80	III	55	35	53	24	21	3
11	69	F	170	65	III	55	34	39	17	28	4
12	68	M	183	90	III	55	33	41	21	23	4
13	33	F	172	58	II	55	30	40	22	17	4
Mean ± SD	60 ± 13		171 ± 10	80 ± 14			33 ± 5	39 ± 8.9	20 ± 3	18 ± 5	
Range	33-73		155-186	58-98			26-45	28-57	15-27	11-28	

MV, Mitral valve; *NYHA*, New York Heart Association functional class; *LVEF*, Left ventricular ejection fraction; *AP*, anteroposterior; *ML*, mediolateral; *MR*, mitral regurgitation; *LVESD*, left ventricular end-systolic diameter; *LVEDD*, left ventricular end-diastolic diameter; *LA*, left atrial; *F*, female; *M*, male.