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Active fixation mechanism complicates coronary sinus lead extraction and limits subsequent reimplantation targets

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Abstract
Introduction Implantation of cardiac resynchronization therapy (CRT) devices is technically challenging and can be limited by lead dislodgement. The Attain Starfix active fixation coronary sinus (CS) lead (model 4195, Medtronic, Minneapolis, MN, USA) was introduced to reduce the rate of lead dislodgement, but the active fixation mechanism presents additional difficulties should these leads require extraction.
Methods CS lead extraction procedures at our institution from 2003 to 2011 were reviewed. Procedural variables were compared between extraction of the Starfix lead and passive fixation CS leads. Attempts at reimplantation post Starfix lead extraction were examined.
Results Four Starfix CS leads were extracted in four patients during this time period. The mean implant duration was 784 days (range, 392–1,029 days). The indication for extraction was infection in all four cases. Mean total procedure time was 141.5 min (range, 92–205 min). None of the fixation lobes could be retracted in one lead and only the most proximal lobes could be retracted in the remaining three leads. All four leads were removed in their entirety. The excimer laser sheath (Spectranetics Laser Sheath II, Spectranetics Corp., Colorado Springs, CO,USA) was required to remove the lead in all 4 cases (100 %) compared to 25 of 131 (19.1 %) of passive fixation CS lead extractions (mean implant duration, 659±697 days) performed at our institution over the same time period ($P<0.001$). In three cases, the laser sheath had to be advanced past the CS ostium to remove the Starfix lead. After extraction, fibrous material which had grown between the lobes of the fixation mechanism was noted in all four cases. No complications occurred. Transvenous CS lead reimplantation was attempted at a median of 7.5 days post extraction in all four patients. The original target branch was occluded in three patients and the main CS in one patient. Reimplantation was successful in another branch of the CS in three of four patients; one underwent minimally invasive epicardial lead placement.
Conclusions The Starfix active fixation CS lead presents additional procedural complexity and uniform use of excimer laser sheath compared to other CS leads. Reimplantation was not possible in the same venous branch in our experience.

Keywords Cardiac resynchronization therapy (CRT) · Coronary sinus · Lead extraction · Active fixation lead

1 Introduction

Cardiac resynchronization therapy (CRT) improves symptoms, quality of life, and survival in patients with heart failure, left ventricular systolic dysfunction, and left bundle branch block [1, 2]. Implantation of CRT devices is technically challenging and can be limited by coronary sinus (CS) anatomy, including inability to achieve stable CS lead position and subsequent lead dislodgement. In contemporary clinical trials of CRT, the rate of successful transvenous CS lead implantation was between 92.5 and 97 %, but the rate of subsequent lead dislodgement was up to 6.9 % [3–5]. While gross lead dislodgement leads to loss of biventricular pacing, more subtle "microdislodgement" can lead to diaphragmatic stimulation or elevated capture threshold and would require reoperation. A meta-analysis of the Multicenter InSync

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Randomized Clinical Evaluation program (incorporating the MIRACLE, MIRACLE-ICD, and InSync III studies) found that 7.7 % of patients required lead repositioning or replacement for these complications during 6 months of follow-up [6].

The Attain Starfix model 4195 lead (Medtronic, Minneapolis, MN, USA) was introduced to ameliorate the problem of lead dislodgement. It is a 5-Fr, unipolar, steroid-eluting CS lead with an extendable lobe active fixation mechanism which, when deployed, is designed to fixate the lead in place in the chosen CS branch location (Fig. 1). Early nonrandomized single-center reports suggested a lower rate of dislodgement and stable thresholds over time [7, 8]. This was supported by the results of an open-label, prospective, multicenter clinical trial, which found a 0.7 % dislodgement rate over a mean follow-up period of 23 months [9]. The lead was approved by the Food and Drug Administration in 2008, and to date, an estimated 12,633 leads have been implanted in the USA [10].

However, we have reported fibrotic tissue ingrowth complicating extraction, which required a locking stylet, prolonged firm traction, and use of a laser sheath to succeed [11]. In addition, little data exist on the implications of the active fixation mechanism, and its extraction, on coronary venous patency and subsequent CS lead implantation success [8]. Therefore, we examined our experience with the extraction of the Starfix lead and subsequent reimplantation attempts to better understand the implications of this novel design.

2 Methods

Extraction procedures performed at the Cleveland Clinic from 2003 to 2011 were reviewed. Our approach to extraction has recently been reviewed [12]. Procedures were included if they involved removal of leads more than 1 year old or the use of specialized tools such as locking stylets or extraction sheaths. Procedural details were extracted from the electronic medical record and electrophysiology laboratory database. Procedural variables including use of laser extraction sheath were compared between extraction of the Starfix lead and passive fixation CS leads. Attempts at reimplantation post Starfix lead extraction, including comparison of venograms with pre-extraction imaging, were examined.

3 Results

Of 135 CS leads extracted during the study period, 4 were Starfix active fixation leads. Of these four leads, the indication for extraction was infection in each case. The mean implant duration was 784 days (range, 392–1,029 days). Mean total procedure time was 141.5 min (range, 92–205 min), and time required to extract the CS lead was 8 min (range, 5–12 min). Despite firm traction on the fixation mechanism, none of the fixation lobes could be retracted in one lead and only the most proximal lobes in the remaining three leads. Locking stylets and the excimer laser sheath (Spectranetics Laser Sheath II,

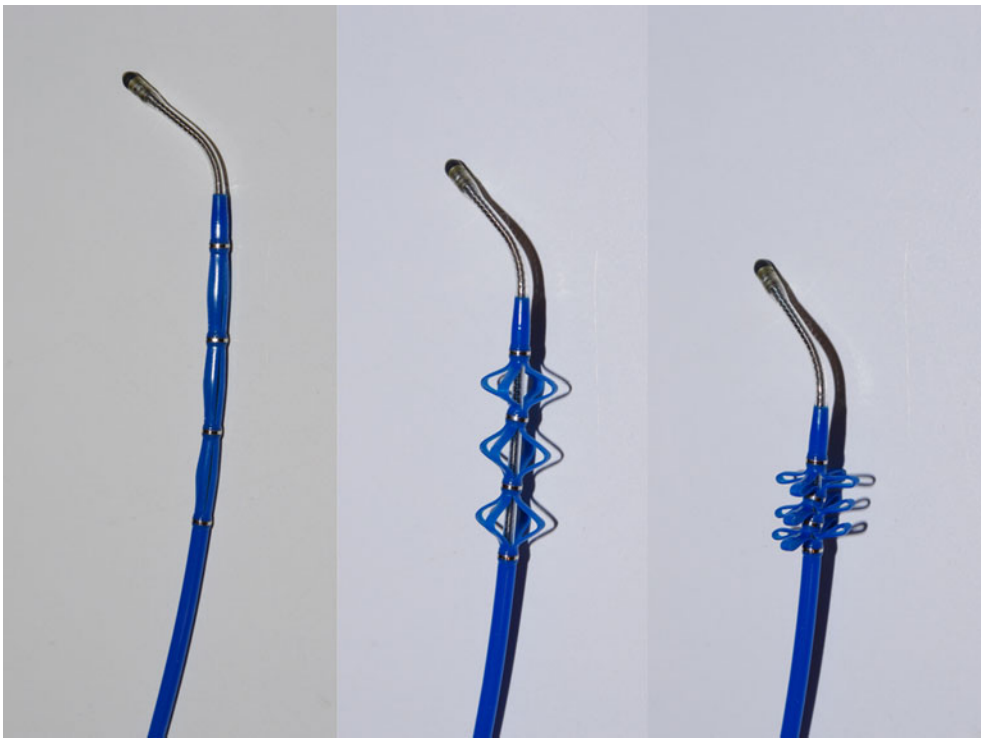

Fig. 1 Attain Starfix model 4195 CS lead. The lead is introduced to the body with the active fixation lobes retracted (*left*) and these are extended once the lead is in the desired location in the coronary venous system (*center* and *right*)

Spectranetics, Colorado Springs, CO, USA) were required to remove the lead in all four cases. In three cases, the laser sheath had to be advanced past the CS ostium to remove the Starfix lead. After extraction, fibrous material which had grown between the lobes of the fixation mechanism was noted in all four cases (Fig. 2). Histology of the material in patient 1 confirmed fibrous connective tissue. All four leads were removed in their entirety, along with other hardware, without complication.

3.1 Reimplantation

Transvenous reimplantation was attempted at a median of 7.5 days (range, 5–11 days) post extraction in all four patients, once blood cultures were negative for ≥48 h. Occlusive CS venography demonstrated that the branch in which the Starfix lead had been extracted was occluded in three patients and that the CS was occluded in one patient (Fig. 3). Reimplantation was successful in another branch of the CS in the three patients with a patent CS; one patient with an occluded CS later underwent minimally invasive surgical epicardial lead placement. Clinical characteristics, extraction procedure variables, and fate of the original implant branch at reimplantation attempt are presented in Table 1.

3.2 Comparison with passive fixation CS lead extraction

Of 131 passive fixation CS lead extractions (mean implant duration, 659±697 days) performed at our institution over the same time period, the excimer laser sheath was required in 25 (19.1 %) compared to 4 of 4 (100 %) of Starfix leads ($P<0.001$). Furthermore, the excimer laser sheath was advanced within the CS in three of four cases, compared to <4 % of passive fixation CS lead extractions.

4 Discussion

Little published data exist regarding the extraction of active fixation CS leads and its effect on CS anatomy [9]. Case reports suggest that extraction of active fixation CS leads is far more complex and challenging then passive fixation CS leads [7, 8, 11, 13–15]. We present our initial experience extracting four consecutive active fixation CS leads. Extraction was feasible in all four cases; however, the procedures are far more complex than we typically encounter with passive fixation CS leads, involving uniform use of the excimer laser sheath and frequent use of the laser sheath past the CS ostium.

Our findings are in keeping with previous reports of active fixation CS lead extraction (Table 2). Williams et al. recently published their 10-year experience of CS lead extraction [13]. Overall, 59 of 60 CS leads were extracted successfully, and most with simple manual traction—the only extraction failure being a Starfix lead that was approximately 26 months old [13]. This was the only active fixation lead in the cohort. Similar to our experience, the fixation lobes of the lead could not be retracted and manual traction alone failed to remove the lead. A 12-Fr laser was used to enter the proximal CS;

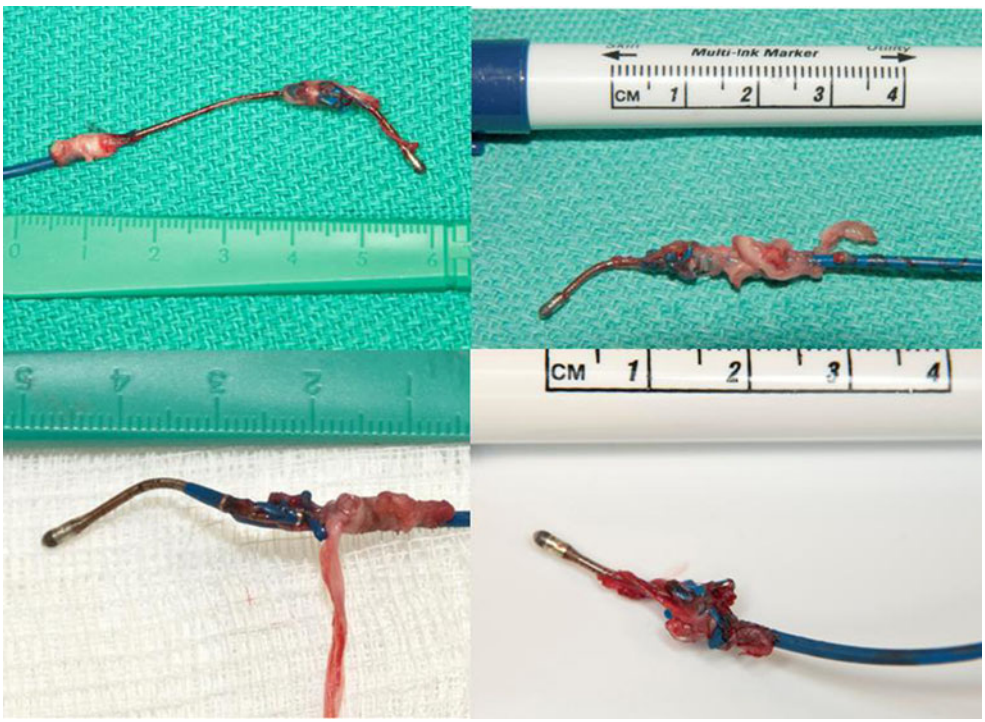

Fig. 2 Four Starfix active fixation CS leads post extraction. Fibrous ingrowth can be seen in the fixation lobes of all four leads

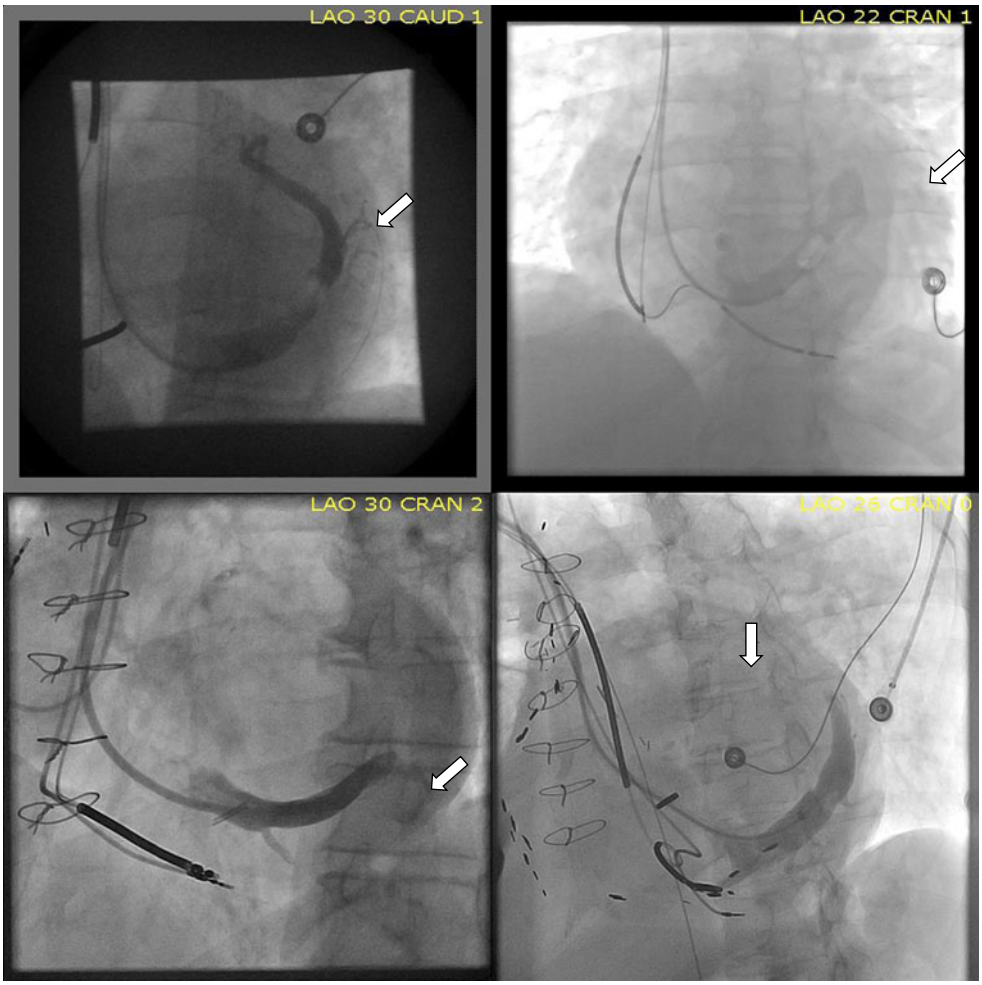

Fig. 3 CS venograms obtained in the left anterior oblique projection at the time of attempted lead reimplantation. *Clockwise from top left* patients 1 through 4. The site of the branch where the 4195 lead was originally implanted is indicated by *arrows*. In patient 4, the CS was occluded in its midportion, just proximal to the site of the target branch

however, applying traction–countertraction on the lead, the distal tip (including the implantable lobes) fractured, leaving a small portion of the lead *in situ*.

Similar complexity was also encountered in a case presented by Bongiorni et al. [14]. During an attempt to extract a 12-month-old Starfix lead, retraction of the fixation lobes of the lead was unsuccessful and manual traction alone was ineffective. Mechanical dilation up to the proximal part of the CS side branch was required for its removal. An attempt to reimplant a CS lead several days later failed as the branch from which the lead was extracted was occluded and no additional targets were seen.

The complexity of extraction of the Starfix lead may be time dependent. All of the cases discussed thus far involve

Table 1 Clinical characteristics, extraction procedure variables, and fate of the original implant branch at reimplantation attempt

Age	Sex	Duration of implant (days)	Indication for extraction	Retract ion of fixation lobes	Extraction tools	Use of laser	Time to extract (min)	Branch at reimplant attempt	Successful endocardial reimplant
58	M	392	Lead infection	Proximal only	LLD-E, 14 Fr excimer laser	Brachiocephalic vein, CS os	5	Subtotally occluded	Yes. In another branch
55	M	811	MRSA lead infection	Proximal only	LLD-EZ, 14 Fr excimer laser	Subclavian, brachiocephalic, SVC, RA, CS os	5	Occluded	Yes. In another branch
71	M	1,029	MRSA lead infection	None	LLD-EZ, 12 Fr excimer laser	Subclavian, brachiocephalic, SVC, RA	10	Occluded	Yes. In another branch
65	M	885	CNS lead infection	Proximal only	LLD-EZ, 12 Fr excimer laser	RA, proximal CS	12	CS occluded	No. Epicardial lead placed

MRSA methicillin-resistant *Staphylococcus aureus*, *LLD* lead locking device (Spectranetics, Colorado Springs, CO, USA), *CS* coronary sinus, *SVC* superior vena cava, *RA* right atrium, *CNS* coagulase negative staphylococcus

Table 2 Existing reports of Attain Starfix model 4195 lead extraction or repositioning attempts

	Extraction/ repositioning attempts	Implant duration (months)	Mechanical dilation/laser sheath used	Mechanical or laser sheath in CS	Retraction of fixation lobes (partial or complete)	Successful extraction or repositioning	Branch occluded on venography
Williams et al. [13]	1	26.5	1	1	1 partial	0	Not reported
Bongiorni et al. [14]	1	12	1	1	No	1	1/1
Crossley et al. [9]	24	0–31	2	Not reported	19 some partial	19	Not reported
Naegele et al. [7]	2	1	0	N/A	1 partial	1	N/A
Breuls and Res [15]	1	1	1	1	Not reported	0	1/1
Luedorff et al. [8]	3	6–15	0	N/A	Not reported	3	1/3
Cleveland Clinic	4	13–34	4	3	3 partial	4	4/4

leads at least 12 months old and extraction proved to be very difficult. The Medtronic 4195 Study, which reported the clinical performance of the lead, also includes the largest series of extraction and repositioning attempts involving Starfix leads [9]. Nineteen of 24 leads in this series were either repositioned or extracted successfully, with a large majority (88 %) requiring only simple manual traction to do so. Furthermore, the lead lobes could be either partially or fully retracted in 79 % of the cases. The relative ease of lead manipulation in this series compared to our findings may be related to implant duration. Seventeen of 24 leads were <12 months old, and more than half were <2 months old. All leads under 2 months old were successfully repositioned or extracted without the need for extraction tools.

Although implant duration may be a factor that contributes to the complexity of lead extraction, two published reports describe extraction failure in Starfix leads implanted <2 months previously [7, 15]. In a case presented by Nagele et al., the extendable lobes could not be retracted and the lead could not be removed [7]. In the case presented by Breuls and Res, the extendable lobe active fixation mechanism was never deployed at the initial implant [15]. Despite this, with "progressive forceful manual pulling," the lead could not be retracted and was eventually abandoned. A venogram of the CS at the time of extraction revealed complete occlusion of the posterolateral branch of the CS in which the lead was positioned.

The finding of branch occlusion reported by both Bongiorni et al. [14] and Breuls and Res [15] was similar to our observations during CS lead reimplantation. All four of our patients underwent an attempt at transvenous reimplantation a median of 7.5 days post extraction. All four patients (100 %) demonstrated some form of venous occlusion. The original target branch was occluded in three patients and the main CS in one patient. Despite this, reimplantation was successful in another branch of the CS in three of four patients. This high rate of venous occlusion may be related to accelerated fibrosis formation at the site of the extendable lobes with avulsion at extraction. This fibrotic material, typically found encasing chronically implanted pacing leads of all types, may be more exuberant around Starfix leads due to trauma to the vessel wall from deployment of the active fixation mechanism and may have increased surface area due to the extended lobes of the mechanism. It has also been proposed that the lobes create an area of turbulent flow which may act as a trigger for thrombosis and fibrosis [15]. In all four extracted leads, extensive fibrosis was noted to be invading the extendable lobes of the lead (Fig. 2). While we cannot make direct comparisons with passive fixation CS leads, difficulty of extraction is in part related to the amount of fibrosis and our experience strongly suggests that the amount of fibrotic material is greater with Starfix leads.

Whether the rate of target vessel occlusion differs significantly between active and passive fixation CS leads is not known. Although our numbers are too small to draw a definitive comparison, a series of ten patients who underwent passive fixation CS lead extraction and subsequent CS venography reported only 50 % of the original target branches were occluded [16]. In that series of relatively short implant duration (3–59 months), an excimer laser was used in four of ten and was advanced into the CS in three of these patients; both figures considerably lower than in our experience of active fixation CS lead extraction.

Our case series is limited by its small size and retrospective nature. Furthermore, the procedures were performed at a high-volume referral center by experienced operators, which likely influenced the acute outcomes of the study and limited the extrapolation of our results to less experienced centers.

In conclusion, although we were able to successfully extract four of four Starfix leads, the active fixation mechanism of the lead added significant procedural complexity, with all leads demonstrating extensive fibrosis within the extendable lobes. Furthermore, a high rate of side branch and CS venous occlusion following extraction was noted, rendering reimplantation of a new lead in the same venous branch impossible. We suggest that other options be explored before the use of an active fixation CS lead is considered and that extraction of

these leads, even of short implant duration, should only be attempted by experienced operators.

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Editorial Commentary

Cronin et al. have presented data on the extraction of active fixation CS leads (Medtronic Starfix lead) from their center. The report is a retrospective review that highlights the difficulty in extraction as well as subsequent reimplantation in these patients. This information is important for implanters of CRT devices as well as for centers performing lead extraction. The report does not address the passive fixation lead extraction issues nor whether a lead could be reimplanted in the same branch where it was extracted from. This is an additional center experience in an area with limited reported data.