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Long-term reliability of sweet-tip type screw-in leads

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ABSTRACT

Background: Active fixation leads have provided stable atrial and ventricular pacing; however, long-term follow-up data have not been satisfactory. The purpose of this study was to investigate the long-term reliability of active fixation leads and their electrical characteristic stability.

Methods: A total of 1196 pacing leads were implanted in 830 patients consecutively between 2002 and 2013. In this retrospective study, we were able to trace 1092 leads in 750 patients to investigate the prognosis of implanted leads. The measurement values (including pacing thresholds, sensing amplitudes, and lead impedances of both the atrial and ventricular leads) were obtained from medical records at the time of implantation and during follow up at the outpatient device clinic. All pacing leads were FINELINE II Sterox EZ Leads (Boston Scientific, MN, USA), which are sweet-tip type screw-in active fixation leads, except for the shock leads in patients with implantable cardioverter defibrillator.

Results: The mean follow-up period was 51.3 ± 29.2 months (median, 48 months). A total of 1092 leads were implanted in either the atrium (682 leads) or the ventricle (410 leads). Venous access was achieved through cephalic vein cut down (CVC) method (914 leads) or the subclavian vein puncture (SVP) method (178 leads). The overall lead survival rate was 99.6% at both 5 and 10 years. Lead fracture was observed in 4 of 1092 leads (0.37%), all of which were implanted by the SVP method. No lead fracture occurred among patients wherein CVC method was applied ($p < 0.01$). Device-related infection was observed in four patients (0.53%).

Conclusions: The overall reliability and stability of sweet-tip type screw-in leads were satisfactory throughout the long-term follow-up period (median, 4 years). Because it was associated with less lead fractures, cut-down access from the cephalic vein may be recommended as the first-line approach when considering the importance of long-term durability of pacing leads.

1. Introduction

In recent years, the number of patients with cardiac implantable devices (CID) has increased, including those with pacemakers and implantable cardioverter defibrillators (ICD). CID and pacing leads have been developed as advancements in medical technology. The current generation of CID has already achieved favorable longevity, greater variety, and smaller size compared with previously available devices. Although CIDs still need to be changed every 5–10 years due to battery drain, exchanging pacing leads easily is impossible. Therefore, long-term reliability is essential for pacing leads. It is well known that the longevity of pacing leads is associated with venous approach, insulation materials, and lead structures [1,2]. FINELINE II Sterox EZ Leads (Boston Scientific, Minneapolis, MN, USA), which are sweet-tip type screw-in active-fixation leads, have been used worldwide since 2001. More than one million of these pacing leads have been implanted, and the number is expected to increase because these leads are compatible with magnetic resonance imaging (MRI). The purpose of this study was to investigate the long-term reliability and stability of electrical characteristics in sweet-tip type active fixation leads.

2. Materials and methods

Between June 2002 and July 2013, a total of 1196 leads were implanted in 830 patients at our hospital. Among these cases, 1092

leads implanted in 750 patients were available for our investigation of lead prognosis. Pacing thresholds, sensing amplitudes of the atrial or ventricular activities, and lead impedances were obtained from the medical records collected at the implantation and from the outpatient device clinic.

2.1. Lead Model

The FINELINE II Sterox EZ Lead (Boston Scientific) is an active fixation screw-in bipolar lead that is one of the thinnest leads as MRI conditional pacing leads. The structure is parallel and incorporates an electrically insulated nickel–cobalt alloy screw-tip with polyethylene glycol capsule coating, titanium-ring electrode tip with oxidized iridium coating, and platinum–iridium sleeve. The distance between the distal and proximal electrodes is 16 mm. Furthermore, mannitol is coated on the top of the helix, and is melted away when the pacing lead is inserted in the blood vessels. Thus, considerable skill is required when the pacing lead is fixed to the myocardial tissue. Six models of these leads are marketed, which differ in length and insulation materials used for their bodies (polyurethane, 4469, 4470, and 4471; silicone rubber, 4472, 4473, and 4474). The lead models were chosen depending on the patient's height or lead positions.

2.2. Implant procedure

Before the implant procedure, we first performed cephalic vein venography on the implanted side, except for patients who had considerable renal failure. The operation began after we had confirmed the patency or running of the cephalic and subclavian veins. Three experienced operators performed the procedure under local anesthesia. We used a primary approach for lead implantation from the cephalic vein. The approach was changed to subclavian vein puncture (SVP), if necessary. Extrathoracic puncture of the axillary vein method was not performed in this study. Second, we cut the skin of the left or right pectoral region and created pacemaker pockets below the fascia of the pectoralis major muscle after administration of local anesthesia. We exposed the cephalic vein and ligated the distal side with silk thread. Subsequently, we inserted a sheath introducer, followed by the guide wire. It was necessary to insert two leads for a dual-chamber device. Hence, we preferred to use leads with different insulation materials between the atrium and ventricle due to the smoothing operation. Moreover, in each implantation, we attempted to fix the lead at the right atrial septum (for the right atrial lead) and the right ventricular mid-septum (for the right ventricular lead), which were our first choices for the locations. If the septum location was considered unacceptable, the right atrial appendage or free wall was chosen for the right atrial leads, and the right ventricular apex or outflow tract (high septum) was also chosen for the right ventricular leads. After lead fixation, we measured the sensing of atrial and ventricular activities, as well as pacing thresholds in volts (V) at a pulse width of 0.4 ms. Atrial and ventricular lead impedances were measured with a pulse width and amplitude of 0.4 ms and 5 V, respectively. Intra-operative measurements were performed using a pacing system analyzer (Biotronik ERA-300; Biotronik Inc., Berlin, Germany). After confirming all electrical measurements were within permissible range, we ligated the pacing leads alongside the cephalic vein and tissues. Finally, we sutured the subcutaneous and skin after the devices and the leads had been connected.

2.3. Statistical analysis

The overall lead survival rate was estimated by using the Kaplan–Meier method. The log-rank test was used to assess

Table 1
Study characteristics.

Patients ($n=750$)	Study characteristics
Age	68.8 ± 13.0 years
Sex	464 Males, 286 females
Pacemaker indication	
Sick sinus syndrome (%)	279 (37%)
AV block (%)	253 (34%)
AF with bradycardia (%)	47 (6%)
Others (NMS, HOCM, and CHF) (%)	4 (1%)
ICD indication	
Ventricular tachycardia (%)	167 (22%)

Table 2
The number of pacing leads.

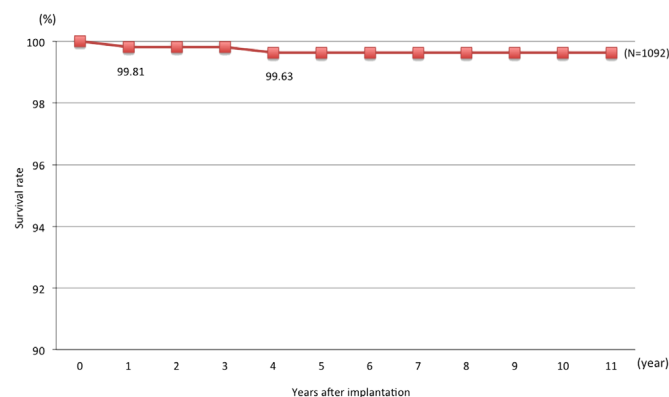| Leads ($n=1092$)	Atrial lead	Ventricular lead
4469 (polyurethane, 45 cm)	97	0
4470 (polyurethane, 52 cm)	166	153
4471 (polyurethane, 58 cm)	3	246
4472 (silicone, 45 cm)	159	0
4473 (silicone, 52 cm)	257	5
4474 (silicone, 58 cm)	0	6
Approach		
Cephalic vein (%)	554 (81%)	360 (88%)
Subclavian vein (%)	128 (19%)	50 (12%)

Fig. 1. The overall survival rate of FINELINE II Sterox EZ Leads with verified lead fracture.

differences in lead survival, based on the use of the venous approach. Data on electrical characteristics are expressed as mean ± standard deviation (SD). The Student t-test was used to compare the measurements of pacing, sensing, and lead impedance. Values of $p < 0.05$ were considered statistically significant. Data were collected, and the statistical analyses were performed by using JMP® 11 (SAS Institute Inc., Cary, NC, USA).

3. Results

The mean follow-up period was 51.3 ± 29.2 months (median, 48 months). Seven hundred fifty patients (464 men and 286 women) were included in this study. The mean age of the patients was 68.8 ± 13.0 years (range, 11–94 years). The indications for pacemaker or ICD implantation are provided in Table 1, which included sick sinus syndrome, atrioventricular (AV) block, ventricular tachycardia, atrial fibrillation (AF) with bradycardia, and other conditions (neurally mediated syncope, hypertrophic obstructive cardiomyopathy, or congestive heart failure) in 279 (37%), 253 (34%), 167 (22%), 47 (6%), and 4 patients (1%), respectively. A total of 1092 leads could be traced for investigation in this

Table 3
Cases with lead issues during the follow-up period.

| Case	Age	Sex	Model	Onset	Mode	Approach	Troubule	Therapy
1	76	M	4473	< 1 (8 months)	DDD	Subclavian puncture	Fracture (subclavian crush)	Changed mode VVI
2	82	F	4472	4 years	DDD	Subclavian puncture	Fracture	New lead
3	59	F	4469	1 year	DDD (ICD)	Subclavian puncture	Fracture (subclavian crush)	New lead
4	12	F	4469	8 years	DDD (ICD)	Subclavian puncture	Incomplete fracture	–
5	66	M	4470	4 years	DDD (ICD)	Cephalic vein cut down	High threshold	New lead
6	88	M	–	6 years	VVI	Subclavian puncture	Infection	New lead
7	76	F	–	< 1 (6 months)	DDD	Subclavian puncture	Infection	New lead
8	76	M	–	< 1 (6 months)	DDD	Cephalic vein cut down	Infection	New lead
9	66	M	–	1 year	DDD (ICD)	Cephalic vein cut down	Infection	New lead
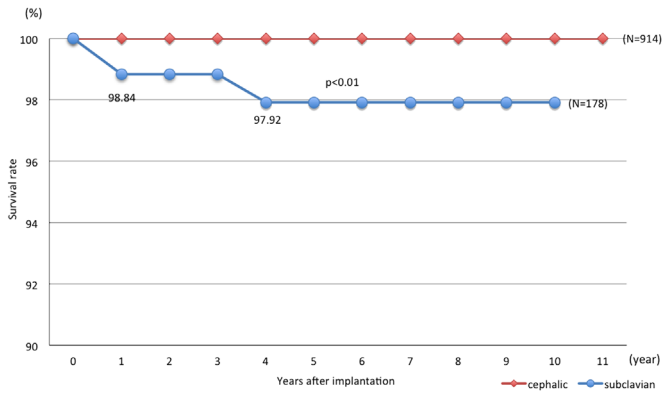
Fig. 2. Comparison of the survival rates observed for the cephalic vein cut-down and subclavian vein puncture methods.
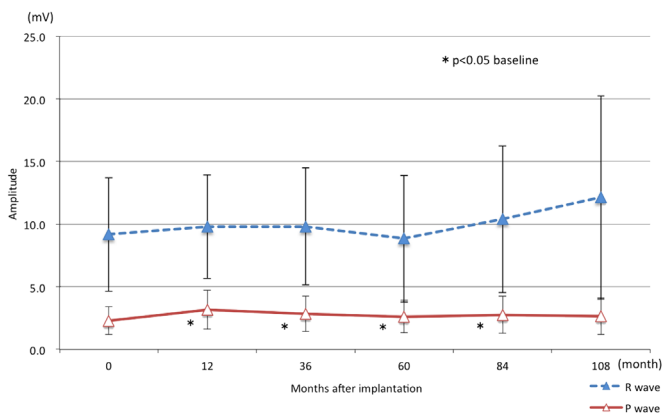

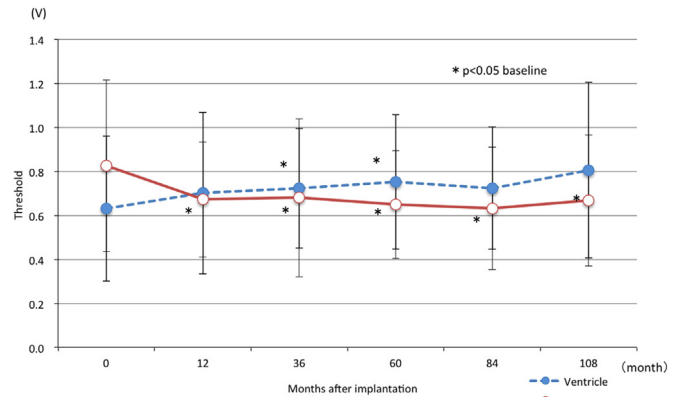**Fig. 3.** P- and R-wave amplitudes during the follow-up period.

Fig. 4. Atrial and ventricular pacing thresholds during the follow-up period.
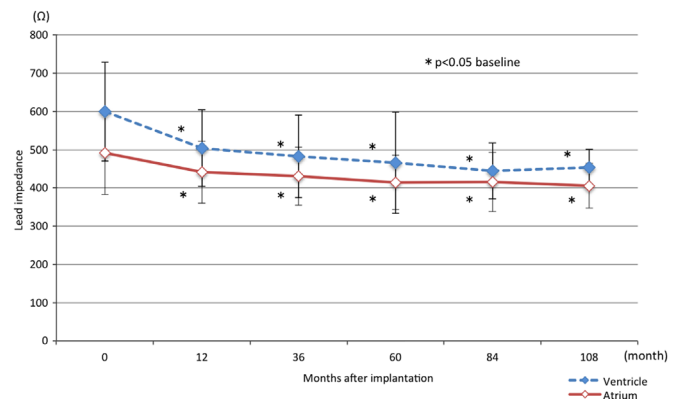

Fig. 5. Atrial and ventricular lead impedances during the follow-up period.

study. The details of the implanted lead models are shown in Table 2. Among these, 682 and 410 leads were implanted in the atrium and ventricle, respectively. Regarding venous access, the cephalic vein cut down (CVC) and SVP methods were used for 914 (84%) and 178 leads (16%), respectively. The overall lead survival rate was 99.6% at both 5 and 10 years (median, 4 years) (Fig. 1). The details of the issues with implanted leads during the follow-up period are summarized in Table 3.

Lead fracture was observed in 4 of 1092 leads (0.37%); verified and incomplete lead fractures were observed in three (0.27%) and one lead (0.09%), respectively. All these fractures occurred in leads implanted by the SVP method; no fractures were observed in leads implanted by the CVC method ($p < 0.01$) (Fig. 2). An excessive elevation of the atrial pacing threshold occurred in one lead for which the CVC method had been used. The details of the

problematic cases are as follows. Case 1 was a 76-year-old man who was implanted with a DDD pacemaker for bradycardia–tachycardia syndrome. When we found the atrial lead fracture, his AF became chronic. Therefore, we changed the pacing mode from DDD to VVI. In cases 2 and 3, a DDD device was implanted; we added an atrial new pacing lead. Case 4 was a 12-year-old girl who was implanted with a dual-chamber ICD for long-QT syndrome. Her atrial lead showed incomplete fracture with the lead impedance increasing from 450 to 2000 Ω after 8 years of implantation. We changed the pacing mode from DDD to AAI back up to prevent unnecessary ventricular pacing following atrial noise sensing. Case 5 was in 66-year-old man who was implanted with a dual-chamber ICD. We observed an excessively high atrial pacing threshold a year after implantation. Therefore, a new atrial pacing lead was implanted when he required an ICD exchange.

Device-related infection was observed in four patients (0.53%). All devices and leads were removed, and then another device system was re-implanted.

3.1. Electrical characteristics of the right atrial and ventricular leads

The P-wave amplitude was elevated significantly from implantation (2.3 ± 1.1 mV) to 1, 5, and 7 years after implantation (3.2 ± 1.6 mV, 2.6 ± 1.3 mV, and 2.8 ± 1.5 mV, respectively; $p < 0.05$) (Fig. 3). The atrial pacing threshold was also significantly improved from 0.82 ± 0.39 V at implantation to 0.67 ± 0.26 V, 0.68 ± 0.36 V, 0.65 ± 0.25 V, and 0.63 ± 0.28 V after 1, 3, 5, and 7 years, respectively ($p < 0.05$) (Fig. 4).

Atrial lead impedance decreased continuously from $492 \pm 108 \, \Omega$ at implantation to $406 \pm 58.6 \, \Omega$ after 9 years ($p < 0.05$) (Fig. 5).

The R-wave amplitude was slightly increased, but the change was not significant (Fig. 3). The ventricular pacing threshold was slightly elevated from 0.63 ± 0.33 V at implantation to 0.72 ± 0.27 V ($p < 0.05$) and 0.75 ± 0.31 V ($p < 0.05$) 3 and 5 years after implantation, respectively. However, the change was not significant at 7 and 9 years after implantation (Fig. 4). Ventricular lead impedance significantly decreased from $560 \pm 129 \, \Omega$ at implantation to $504 \pm 100 \, \Omega$ ($p < 0.05$) 1 year after implantation, and continuously decreased until 7 years after implantation, and becoming stable thereafter (Fig. 5).

No clinical lead issues occurred during the follow-up period, except for lead fracture and infection.

4. Discussion

The main findings of our study are the following:

1. The overall longevity of the FINELINE II Sterox EZ Lead was satisfactory, with a high lead survival rate during the follow-up period (99.6% at both 5 and 10 years).
2. Lead fracture was observed in 4 of 1092 leads (0.37%). All these fractures occurred in leads implanted by the SVP method, and no fractures were observed in leads implanted by the CVC method ($p < 0.01$).
3. All electrical characteristics of the implanted leads were clinically acceptable during the follow-up period.

4.1. Method of venous access: cephalic vein cut-down versus subclavian vein puncture

The reliability of the pacing leads has long-term importance because they cannot be removed easily after implantation. The long-term reliability of pacing leads is associated with lead structure, material, and venous access [1–3]. The implantation methods for a transvenous lead are classified as CVC or SVP. It is well known that the SVP access is often used because it is more convenient than the alternative. However, the SVP method may cause some complications, such as pneumothorax, hemopneumothorax, and inadvertent artery puncture. The CVC method is the first choice for endocardial pacing lead implantation in our institution. In this study, we demonstrated that the long-term reliability of the pacing leads was better with the CVC method than the SVP method. Lead fracture occurred in only four leads (0.37%) with the SVP method, and no lead fractures occurred with the CVC method, except for one excessive increase of the atrial pacing threshold. All these lead fractures were observed only in atrial pacing leads. The reason we considered is that majority of atrial pacing leads was implanted by using the SVP method due to priority of ventricular pacing lead insertion by using the CVC method; hence, some differences of procedural situation were found between atrial and ventricular pacing leads. This may cause bias between atrial and ventricular pacing leads.

4.2. Comparison between unipolar and bipolar leads

Compared with bipolar leads, unipolar leads had superior long-term reliability because of their simple structure and smaller diameter in the previous generation. A smaller diameter lead may be subject to a little fracture damage between the clavicle and the first rib, where the main site of the lead fractures occurred. A previous study has shown that unipolar leads have better long-term reliability than bipolar leads [4]. We previously reported that the survival rate of unipolar leads was 98.7% and 95.9% at 5 and 10 years, respectively [1]. Helguera et al. [2] studied 1253 unipolar and 1358 bipolar leads. The survival rate of unipolar leads was observed to be 98.6% and 98.6% at 5 and 10 years, respectively. Although the survival rate of bipolar leads was similar (98.1% and 93.8% at 5 and 10 years, respectively), lead fracture occurred in 12 bipolar leads (0.9%). Therefore, the results of their study indicated that unipolar leads were superior to bipolar leads [2]. However, the survival rate of bipolar leads was excellent (99.6% at both 5 and 10 years) in our study. These results are almost similar as those noted in the Boston Scientific product performance report (polyurethane insulation leads, 99.4% and 98.7% at 5 and 10 years, respectively; silicon insulation leads, 98.8% and 97.0% at 5 and 10 years, respectively). Some studies have examined changes in the electrical characteristics of the pacing lead in acute and chronic stages [5,6]. However, the long-term status of the FINELINE II Sterox EZ Lead has not been reported to date. In this study, we demonstrated that the electrical characteristics of the FINELINE II Sterox EZ bipolar lead have long-term stability. As medical technology has progressed, the bipolar lead diameters have become smaller. One of the bipolar leads with a small diameter is the FINELINE II Sterox EZ Lead, which has the same size as the unipolar leads. Bipolar leads offer lesser malfunction rates for undersensing and pectoralis major muscle stimulation. In the future, bipolar leads will take on indispensable roles for CID. However, the structure of the bipolar lead is more complicated than that of the unipolar lead; thus, lead malfunction and fracture may be issues of concern. Therefore, further research on the long-term reliability of FINELINE II Sterox EZ Lead is necessary in the future.

4.3. Study limitations

Limitations of this study include its retrospective design and the absence of any randomization, which leave our results susceptible to selection bias. In addition, most (more than 80%) leads were implanted by using the CVC method. Second, the FINELINE II Sterox EZ Lead is a bipolar screw-in lead. No comparison with a tined lead was performed in this study. Third, electrical characteristics were measured using the same pacing system analyzer (Biotronik ERA-300) during implantation. However, follow-up measurements after implantation were obtained using different programmers for each implanted device manufacturers. This might have resulted in some inconsistencies between the implantation and follow-up data, which we previously reported [7].

5. Conclusions

The overall reliability of the sweet-tip type screw-in leads (FINELINE II Sterox EZ) is satisfactory: the 10-year survival rate was 99.6%, and its electrical characteristics were clinically acceptable throughout the long-term follow-up period. To prevent lead fractures, cut-down access from the cephalic vein may be considered as the first-line approach.

A. Takano et al. / Journal of Arrhythmia 33 (2017) 12–16

Conflict of interest

The authors declare no conflict of interest related to this study.

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