

Long-term Reliability of Atrial Unipolar Screw-in Leads

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NAKAZATO ET AL.: Long-term Reliability of Atrial Unipolar Screw-in Leads. *Aims:* The purpose of this study is to clarify the long-term reliability of atrial unipolar screw-in leads. *Methods and Results:* We retrospectively studied the long-term reliability of atrial unipolar screw-in leads that were implanted from 1981 to 2000 at our hospital. Of the 385 leads used, fractures and/or insulation failures were observed in 10 leads (2.6%), all of which were implanted using the subclavian vein puncture approach. For leads implanted in the period from 1981 to 1985, the incidence of fracture was higher at 15.2%. The overall survival rate was 98.7% over 5 years, 95.9% over 10 years, and 93.3% over 15 years. Lead fractures were observed only in polyurethane leads but not in silicon leads. The polyurethane leads used in the early era of pacemaker implantation might affect the overall lead reliability results. *Conclusion:* The overall reliability of atrial unipolar screw-in leads is satisfactory, but the subclavian vein approach should be avoided because fracture is a major cause of lead failure. (*J HK Coll Cardiol* 2003;11:4-10)

Atrial screw-in lead, lead failure, longevity, reliability, unipolar

摘要

目的：旨在研究心房單極螺旋導線長期應用的可靠性。方法和結果：我們回顧性地研究自 1981 年至 2000 年我院放置的心房單極螺旋導線的長期應用的可靠性。在 385 例導線應用中，觀察到有 10 例折斷和/或絕緣失敗(2.6%)，所有這些病例均從鎖骨下靜脈穿刺途徑植入的。從 1981 年至1985年間植入的導線，發生折斷的比例高達 15.2%。總計的 5 年生存率為 98.7%，10 年生存率為 95.9%，15 年生存率為 93.3%。導線折斷僅發生在聚氨基甲酸乙酯導線中，而未發生於矽導線中。運用於早期心臟起搏器植入的聚氨基甲酸乙酯導線可能影響了總體的導線運用可靠性的結果。結論：總體上心房單極螺旋導線的可靠性是令人滿意的，但是鎖骨下靜脈途徑應當避免，原因在於導線折斷是引起導聯失敗的主要因素。

關鍵詞：心房螺旋導線 導線失敗 壽命 可靠性 單極

Introduction

Since the introduction of screw-in leads for clinical use, long-term atrial pacing has been feasible.¹ For reliable atrial pacing, the longevity of leads is the most important factor. However, lead fracture is still the main complication that affects lead longevity.² The

incidence of lead fracture is reported to be mostly influenced by the choice of venous approach and insulation materials.³ Few studies have been conducted that evaluate the long-term integrity of unipolar atrial screw-in leads. Thus, the purpose of this study is to investigate their long-term reliability.

Materials and Methods

We implanted 423 unipolar type atrial screw-in leads from 1981 to 2000 at our hospital and could retrospectively study 385 leads in order to trace the prognosis of lead failure. The remaining thirty-eight leads could not be followed up because of the change

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of patient's residence. Lead failure was defined as the point in time when the lead encountered some fracture, repair, or replacement. However, only verified lead fractures were included in the longevity study, and lead failures due to infection or other indirect causes were excluded because such factors did not directly relate to structural lead failure. Pacing was done in AAI mode in 88 patients and in DDD mode in 297 patients.

The implanted leads were divided into three groups on manufacturer (Guidant-CPI, Medtronic, Intermedics). The venous approach taken was either the cephalic vein cut-down method or the subclavian vein puncture method. Three operators were involved in the procedure and the technical skills were comparable among them. The insulation material of the implanted leads was either silicon or polyurethane. The survival rates in total and for each group of leads were analyzed using Kaplan-Meier methods. Differences between the lead survival curves according to the insulation material and venous approach were assessed via the Log-Rank test. Mean follow-up period in each group was verified using the unpaired Student's *t* test. If the *p*-value was <0.05, the result was considered statistically significant.

Results

Detailed lead profiles and number of complications were described in Table 1. By

manufacturer, the number of implanted leads was 149 for Guidant-CPI, 76 for Medtronic, and 160 for Intermedics. The insulation materials were silicon in 158 leads and polyurethane in 227 leads. As for venous route, the cephalic vein cut-down method was used for 61 leads, and the subclavian vein puncture method was used for 324 leads.

Cases with lead trouble during the follow-up period were summarized in Table 2. Lead infections were observed in 5 out of 385 leads (1%) and all such leads were replaced with new ones. Verified lead fractures were observed in 10 out of 385 leads (2.6%), all of which were implanted via the subclavian vein puncture method. Lead fractures observed when the subclavian puncture approach was chosen were 10 out of 314 (3%), whereas no fractures were seen in the cephalic vein access group. Fractures were observed at the entry site of puncture in 9 leads and distal to the sleeve fixation in 1 lead. The onset of fracture varied from 1.6 to 16.6 years after implantation. The survival rate by different venous routes was compared in Figure 1. The overall cumulative survival rates with respect to verified lead fracture were $98.7 \pm 0.9\%$ over 5 years, $95.9 \pm 2.1\%$ over 10 years, and $93.3 \pm 5.8\%$ over 15 years (Figure 2). Comparison of 5-year and 10-year longevity in each era is shown in Table 3. For leads implanted during the period between 1981 and 1985, 5-year and 10-year survival was 93.4% and 89.9%, respectively. It was contemporaneously calculated every 5 years, and

Table 1. Lead profile and complications

Manufacturer	Model	Material	Diameter (mm ²)	Implanted (N)	Infection	Fracture
Guidant-CPI (n=149)	4143	Silicon	2.2	15	0	0
	4144	Silicon	2.2	68	1	0
	4145	Silicon	2.2	4	0	0
	4165	Silicon	2.2	5	0	0
	4166	Silicon	2.2	16	1	0
	4169	Silicon	1.5	41	0	0
Medtronic (n=76)	4057	Polyurethane	2.2	18	1	2
	5067	Silicon	2.2	9	0	0
	6957	Polyurethane	2.2	49	2	7
Intermedics (n=160)	435-02	Polyurethane	1.7	35	0	0
	435-05	Polyurethane	1.7	45	0	0
	435-07	Polyurethane	1.7	65	0	1
	479-01	Polyurethane	1.7	14	0	0
	438-10	Polyurethane	1.7	1	0	0

Table 2. Cases with lead failure during follow-up period

Case	Company	Model	Onset*	Trouble	Mode	Approach	Therapy
1	Med	6957	14.7	fracture	DDD	P	new lead
2	Med	6957	7.4	fracture/insulation failure	AAI	P	repair
3	Med	6957	16.3	infection	DDD	CD	new lead
4	Med	6957	3.3	fracture	AAI	P	new lead
5	Med	6957	8.9	infection	DDD	P	new lead
6	Med	6957	6.4	fracture/insulation failure	AAI	P	new lead
7	Med	6957	16.6	fracture/insulation failure	AAI	P	new lead
8	Med	6957	7.8	fracture	DDD	P	new lead
9	Med	6957	7.4	fracture/insulation failure	AAI	P	new lead
10	CPI	4166	6.1	infection	DDD	P	new lead
11	Med	4057	3.8	fracture	DDD	P	repair
12	Med	4057	2.2	infection	DDD	CD	new lead
13	CPI	4144	2.3	infection	DDD	P	new lead
14	Med	4057	9.8	fracture	DDD	P	repair
15	IM	435-07	1.6	fracture	DDD	P	new lead

*:years, Med: Medtronic, IM: Intermedics, P: Puncture, CD: Cut-down

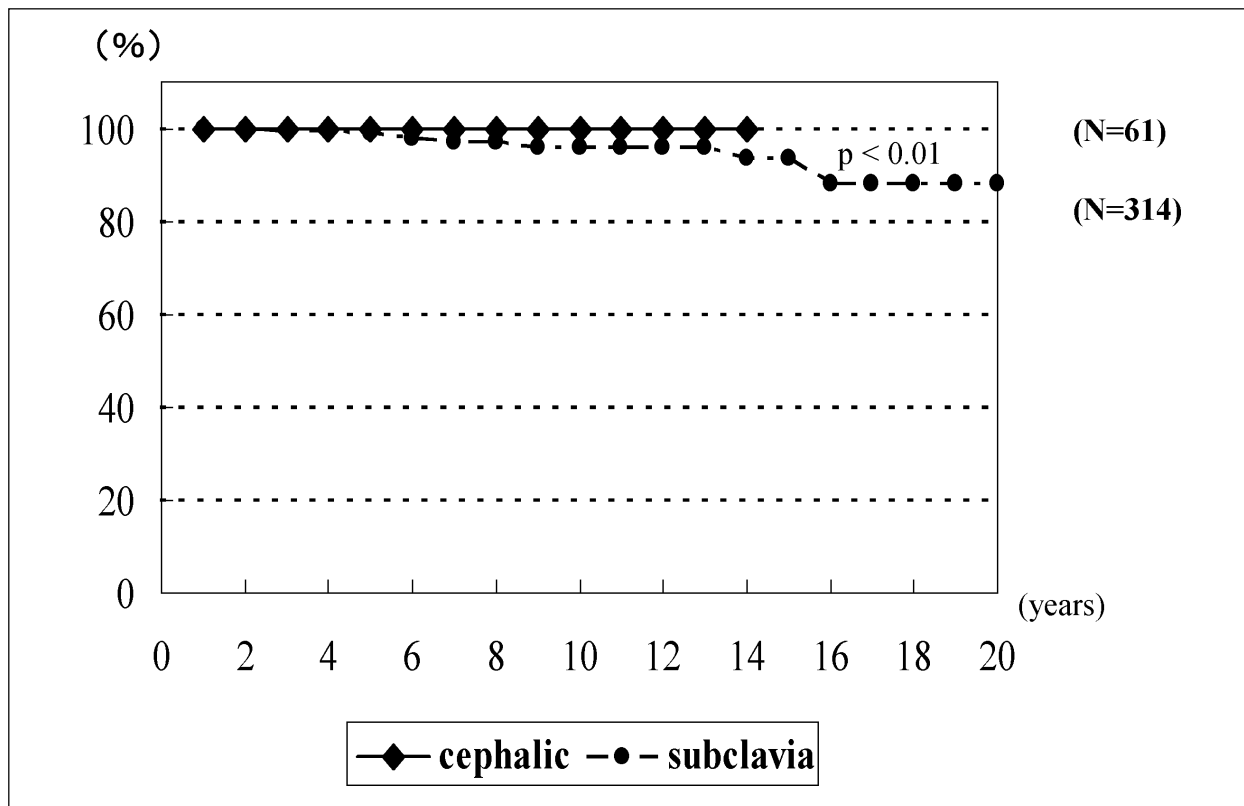


Figure 1. Comparison of survival rate between cephalic vein cut-down and subclavian vein puncture methods.

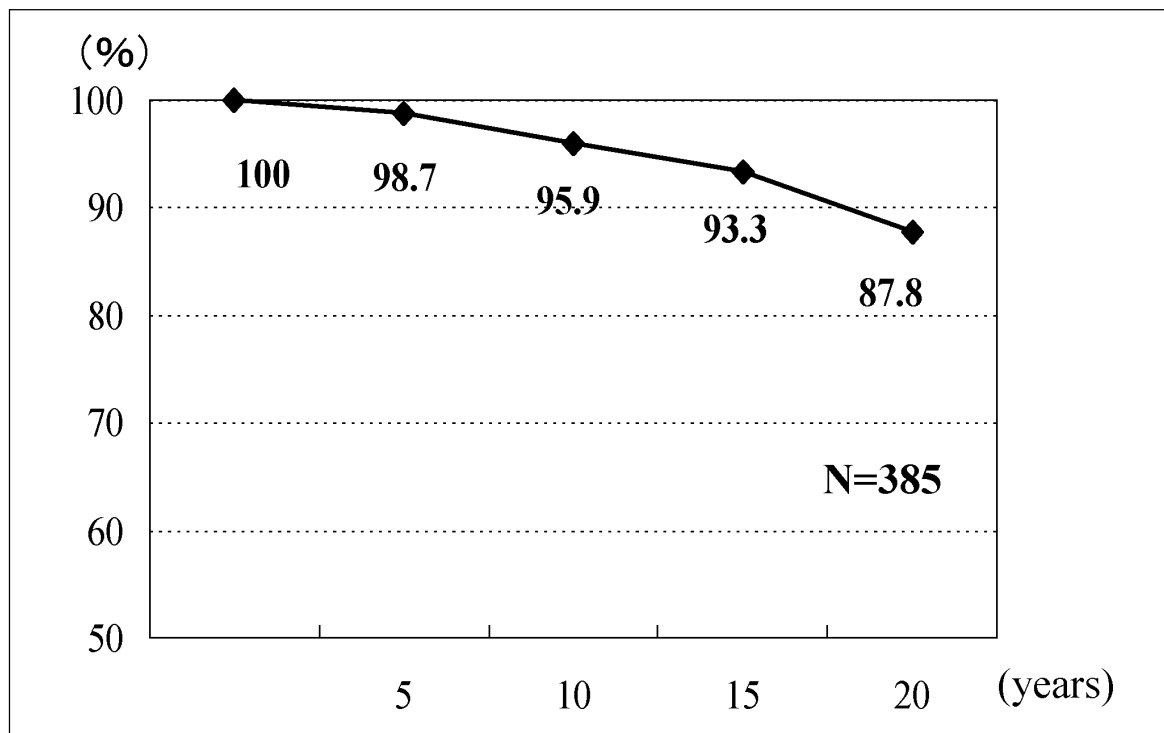


Figure 2. The overall survival rate of atrial unipolar screw-in leads with verified lead fractures.

Table 3. Comparison of 5 and 10-year lead longevity in each period

Period	Implanted lead	Fracture		Survival Rates (Mean±SE)	
	(N)	(N)	(%)	5 years	10 years
1981-1985	33	5	15.2	93.4±4.5	89.8±5.5
1986-1990	57	1	1.8	100	97.9±2.1
1991-1995	82	3	3.6	98.7±1.3	95.6±9.6
1996-2000	213	1	0.5	99.5±0.3	—

the incidence of fracture was found to be higher in the initial 5 years than in the later period ($p<0.05$). According to the manufacturer subdivision, the ten-year survival rate was 100% for Guidant-CPI leads, 99.4% for Intermedics leads, and 96.2% for Medtronic leads (Figure 3). Although the median follow-up period of the Medtronic leads was significantly longer (11.2 years, $p<0.01$) than that of the others (3.8 years, each), 9 out of 10 fractured leads were Medtronic polyurethane product. In these 9 leads, 7 were Medtronic model 6957 and the remaining 2 leads were model 4057. The

incidence of fracture of those leads was 14% (7 out of 49 leads) in model 6957 and 11% (2 out of 18 leads) in model 4057.

With regard to the insulation material, the silicon lead longevity was 100% even after 15 years of follow-up whereas the polyurethane lead longevity was 92% at 10 years, 88% at 15 years, and 81% at 20 years. Statistical significance was seen between the longevity of silicon and polyurethane leads ($p<0.01$). Comparison of the survival rate between silicon and polyurethane leads is presented in Figure 4.

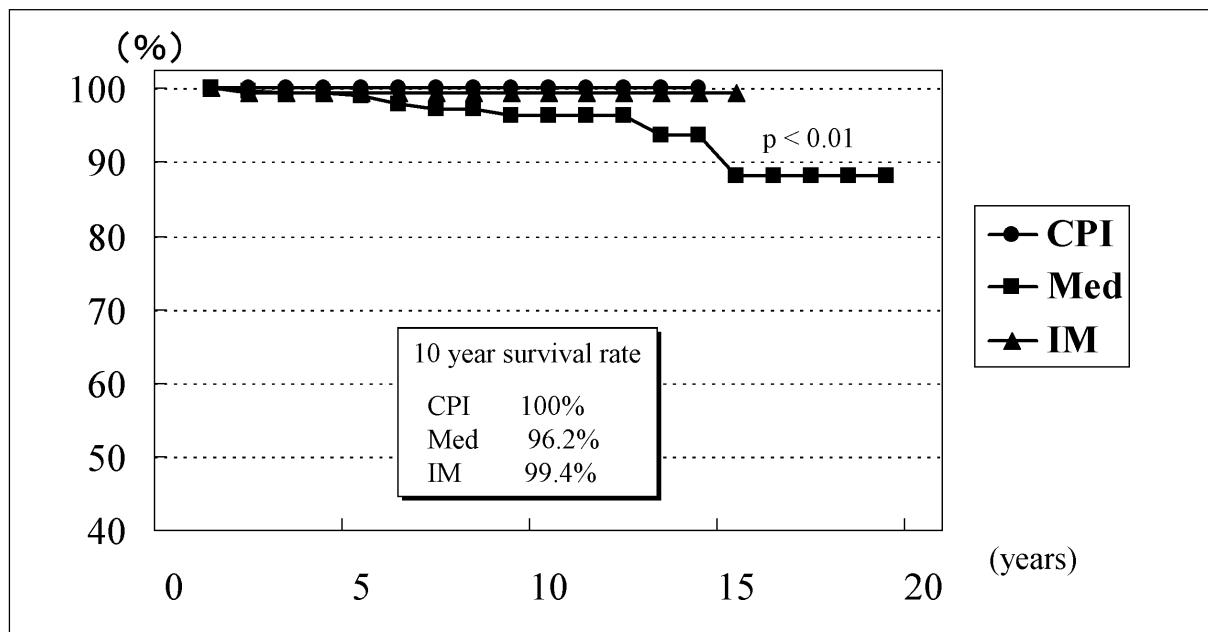


Figure 3. The survival rate by lead manufacturer.

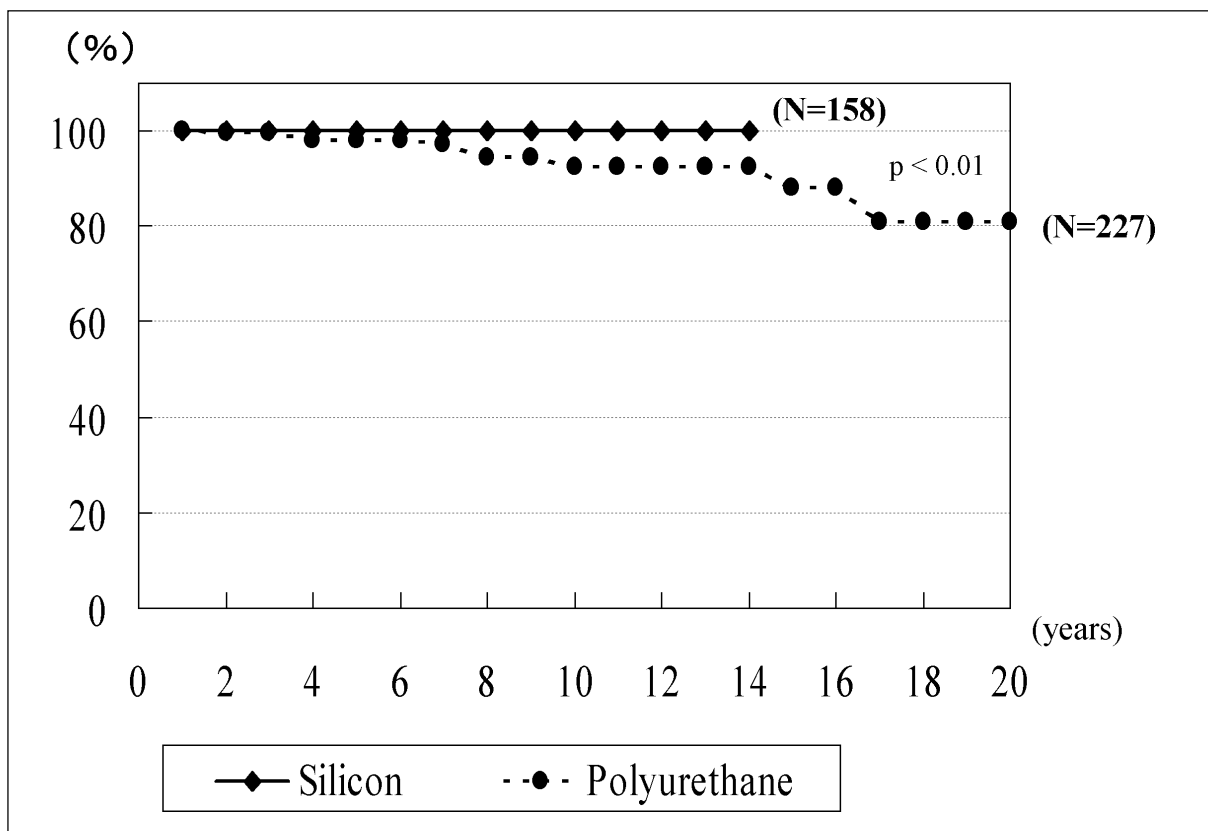


Figure 4. Comparison of survival rate between silicon and polyurethane leads.

Discussion

Main Findings

In this study, we investigated the long-term reliability of atrial unipolar screw-in leads. Overall longevity was observed to be favorable and a high survival rate was seen. Lead survival was 98.7% at 5 years, 95.9% at 10 years, and 93.3% at 15 years. The major factor affecting lead longevity was the incidence of lead fracture. All of the cases of fracture were those where the implant approach chosen was subclavian venous puncture. With regard to the insulation material, silicon leads showed significantly better performance than polyurethane lead ($p < 0.01$).

Lead Longevity and Related Factors

Helguera, et al. surveyed 1131 atrial leads, including bipolar and unipolar types, and found that only 3 leads (0.2%) showed fracture. The survival rates of atrial leads at 5 and 10 years were reported to be 99.6% and 98.9%, respectively.⁴ In our study, the overall longevity of atrial unipolar screw-in leads was observed to be satisfactory and comparable to their report.

There are several factors affecting lead longevity. Non-structural lead failure including infection, dislodgement, and patient death could also be included with this category. However, to confirm the reliability of unipolar screw-in leads, we focused on verified structural lead fractures because they had a more direct relation to lead longevity. We also discussed several factors causing lead fracture.

The method of venous approach is a well-known factor for lead fracture. Generally, the approach using the subclavian vein is easy and widely used. However, it has the disadvantage of a high incidence of fracture, particularly at the site of narrow passage between the first rib and clavicle.^{5,6} To avoid this complication, the lateral approach has recently been recommended if subclavian puncture is going to be the method applied.^{5,7} Helguera, et al. emphasized the incidence of lead fracture was not different between the subclavian puncture (0.8%) and cut-down approaches (0.7%).⁴ Irwin et al. also commented that the incidence of insulation failure was not different based on venous route.⁸ However, many reports support using the cephalic vein cut-down approach rather than subclavian puncture because of its more reliable results.^{2,9} In our study, all of the fractured lead had been implanted via

the subclavian vein using the puncture method. No fracture was observed in leads implanted using the cephalic vein cut-down approach. Therefore, the cephalic vein cut-down approach should always be considered in order to avoid unwanted complication.

From the beginning of the era of pacemaker implantation, we used unipolar screw-in leads for all atrial pacing. There are few studies describing the long-term reliability of leads that are focused solely on unipolar atrial screw-in leads. Moller et al. reported that the survival rate at 5 years for atrial pacing leads was 97% in unipolar leads and 86% in bipolar leads.⁹ They emphasized the superiority of unipolar leads. According to Helguera et al, unipolar leads showed better performance than bipolar leads in both atrial and ventricular pacing, although statistical significance was not seen.⁴ Our results also indicated the better long-term prognosis of unipolar leads.

Insulation material is another important factor influencing lead fracture.¹⁰ To compare the overall longevity, the majority of studies clarified that silicon leads have a better prognosis than polyurethane leads. Antonelli et al experienced no lead failures in 116 silicon leads implanted either using the cephalic vein or subclavian approaches.² In our study, there was no fracture in silicon leads but 10 fractures (2.6%) in polyurethane leads. The survival rate with polyurethane leads was 92% at 10 years and 88% at 15 years. Thus, statistical significance in survival rate was observed between silicon and polyurethane leads. The majority of fractures were observed in the Medtronic model 6957 and 4057 leads. The insulation material of these leads was polyurethane classified as Pellethane 80A. This type of polyurethane lead demonstrated susceptibility to environmental stress cracking and metal-induced oxidation, which is an oxidative degeneration.^{11,12} On the other hand, currently available polyurethane-insulated leads are composed of Pellethane 55D. This material is much stiffer and harder than Pellethane 80A, and it has shown better long-term biostability.^{13,14} In the manufacturer classification, the difference of survival rates after 10-year between Medtronic and other companies' leads could be explained by the difference of polyurethane material used, and it may also explain why the incidence of lead fracture in the early '80s was higher than in the latter 10-year period despite the fact that the period of mean follow-up was significantly different. Further observation is necessary to verify the

long-term performance between currently available polyurethane and silicon leads.

The limitation of this study is that the comparison of venous approach and the leads performance in different manufacturers were only done retrospectively and no randomizations were performed. It might be the cause of selection bias. In addition, we studied solely the prognosis of unipolar screw-in leads, therefore, no comparative data to bipolar lead could not be obtained in this study.

In conclusion, the overall reliability of atrial unipolar screw-in leads is satisfactory. However, the subclavian venous approach should be avoided to prevent lead fracture since it is a major cause affecting lead longevity.

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