A Long-Term Clinical Experience with an Active Fixation Lead for Atrial Application

M.J.J.A. BOKERN, R. LECHNER, J. COEBERG
Waterland Hospital, Purmerend, The Netherlands

J.C.J. RES, R. ABELS, G. KROON
Zaans Medisch Centrum De Heel, Zaandam, The Netherlands

Summary

This article discusses our long-term clinical experience using the atrially implanted Elox active fixation lead, with respect to pacing and sensing issues. Unipolar and bipolar pacing and sensing values were monitored in 57 patients (mean age 74.6 ± 9.9 years, 28 female) for a period of 1 year. Implantation of an active fixation lead was not successful in one patient, who was consequently excluded from the study. Pacing threshold, P-wave amplitude, and lead impedance were measured at implantation, before hospital discharge, and at 6 weeks, 3 months, 6 months, and 1 year after implantation. In two patients, the threshold at implantation was higher than 2.0 V; in three others, it was between 1.5 V and 2.0 V. An initial increase in pacing threshold was observed at 6 weeks post-implantation. In individual cases, the peak value amounted to a factor of five, but after 3 months, the values had nearly fallen back to their initial values (1.0 ± 0.5 V). The overall results demonstrated that the Elox lead is easy to handle and provides favorable long-term pacing and sensing parameters.

Key Words

Screw-in lead, pacing and sensing parameters, long-term follow-up, atrial leads

Introduction

Atrial screw-in leads have recently gained popularity, especially for the treatment of patients who have undergone prior cardiac surgery, and for patients with planned implantable cardioverter-defibrillator (ICD) implantation [1]. The right atrial appendage is often removed at the time of cardiopulmonary bypass. Because of concerns regarding lead displacement, the use of active fixation atrial leads has been recommended for patients who require permanent atrial or dual-chamber pacing after open heart surgery. Furthermore, improved ease of handling, good pacing and sensing properties, and the lead's retractable characteristic (due to its isodiametric body) has increased the popularity of the atrial active fixation lead [2,3].
The present study is a report on an ongoing registry of the Elox lead (Biotronik, Germany). The Elox's fixation mechanism allowed the leads to be implanted at any location, resulting in high P-wave amplitudes and acceptably low pacing thresholds. Moreover, the absence of far-field signals of ventricular activation and phrenic nerve stimulation were examined during implantation. The objectives of this study were to evaluate the ease of implantation, and the short- and long-term pacing and sensing properties in a consecutive series of patients.

Materials and Methods

The Elox lead is a non-preshaped lead with an isodiametric lead body. The tip is fixated with an extendable (and retractable) fixation helix, which can be extended to a maximum of 1.8 mm (see Figure 1). The Elox lead has an electrically active fixation helix and a short interelectrode distance of 10 mm. For detailed specifications of the technical data, see Table 1. Turning the distal connector pin with a special clamp easily

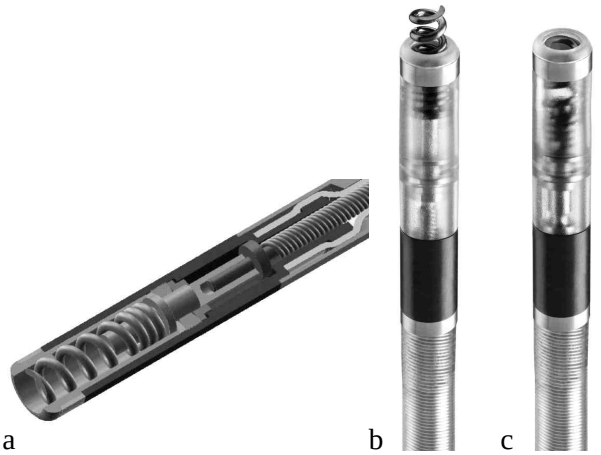

Figure 1. Technical drawing (a) and screw-out (b), screw-in picture (c) of the Elox lead tip (Biotronik, Germany). The helix is electrically active. Note the isodiametric lead body, which facilitates lead extraction.

Type of tip		Retractable, electrically active
Extension screw		max. 1.8 mm
Electrode material	Tip	70 % Pt, 30 % Ir
	Ring	80 % Pt, 20 % Ir
Surface	Tip	Ir, fractal
	Ring	Ir, fractal
Polarity		bipolar
Interelectrode distance	10 mm	
Surface area	Tip	9.2 mm^2 (area of extended helix)
	Ring	37.6 mm^2
Resistance	Distal	0.22 Ω/cm
	Proximal	1.2 Ω/cm
Electrode diameter		2.4 mm (7.2 Fr)
Insulation material		Silicone

Table 1. Properties of the Elox lead (EX 53-BP, Biotronik, Germany). Pt = platinum, Ir = iridium.

extends the helix. This causes the helix to completely extend in six turns of the clamp after a short delay. Subsequent turns of the clamp will result in a backward revolution of the clamp. The helix will protrude out of the shaft of the lead body, which can easily be controlled by performing the procedure under fluoroscopy (see Figure 2). A third sign of adequate positioning is obtaining wall contact in the form of ST segment elevation directly after atrial deflection [4].

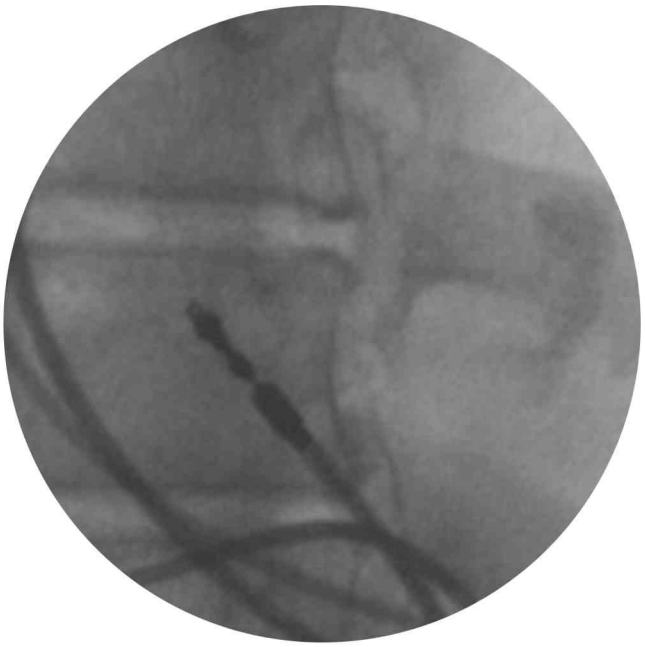

Figure 2. Fluoroscopy in the right atrial oblique view, when the lead tip is positioned in the right atrial appendage. Note that the helix protrudes from the shaft.

Acute pacing and sensing parameters are tested with the ERA 300B pacing system analyzer (Biotronik). A pacing threshold of 1.0 V or less, and a P-wave amplitude of at least 1.5 mV are generally accepted values. In some patients, a different position has to be sought due to high thresholds or low P-wave amplitudes. In one case, the lead was repositioned because of high far-field signals, potentially disabling adequate atrial sensing. The helix can easily be unscrewed by turning the clamp on the distal connector pin counter-clockwise. The lead tip can then be maneuvered with the guide wire to another position, and the final tests can be conducted. The procedure of extending and retracting the helix can be repeated up to ten times, if necessary. Once a lateral position was obtained, we investigated the threshold for phrenic nerve stimulation, up to a maximum of 10 V. When positioning of the tip was close to the right ventricle (right atrial appendage or anterolateral position), we tested the sensing of far-field signals. In several cases, higher pacing thresholds or lower P-wave amplitudes were accepted when all possible achievable positions had been attempted and rejected. In two cases, atrial fibrillation (AF) precluded adequate pacing threshold tests.

During follow-up, all measurements were performed by pacemaker telemetry (Biotronik Actros, Philos, or

Inos^{2+} CLS). The atrial pacing threshold was determined at 0.5 ms during implantation and at 0.4 ms during follow-up. A pacing impedance measurement was taken at 3.6 V. The minimum, mean, and maximum P-wave amplitudes were measured, but only the minimum values are given in this report. Patients were seen in the outpatient clinic before discharge (1 – 2 days after implantation), and at 6 weeks, 3 months, 6 months, and 1 year after implantation.

The Elox registry consists of 57 patients (28 female, 29 male; mean age 74.6 ± 9.9 years; range 37 – 91 years). Patient symptoms were recorded as dizzy spells (n = 25), syncope (n = 21), bradycardia (n = 2), and congestive heart failure with concomitant bradycardia (n = 9). Indications for pacing were high-degree or complete atrioventricular block in 35 patients, 12 of whom had paroxysmal AF, and sick sinus syndrome in 22 patients, 10 of whom had intermittent or paroxysmal atrial arrhythmias. Nine patients had undergone prior cardiac surgery with removal of the right atrial appendage. Eleven had coronary artery disease, three had severe chronic obstructive pulmonary disease, five had hypertension, four had diabetes mellitus, two had hyperthyroid disease, and one had hypothyroid disease. For two patients, the implantation of the Elox included a pacemaker upgrade from VVI to DDD, and one patient had to have a lead extracted before implantation of the Elox. In a subgroup consisting of 38 patients, P-wave amplitudes, pacing thresholds, and pacing impedances were measured in the unipolar configuration as well.

Data are reported as mean values ± standard deviation. Comparisons of paired and unpaired data were made by the paired and unpaired Student's *t* test, respectively. A p-value < 0.05 was considered significant.

Results

In all but one of the patients, the implantation of the Elox lead progressed without major complications. Extending and retracting the helix went smoothly. In cases of high pacing thresholds (1.0 V on the first attempt), very low P-wave amplitudes (less than 1.5 mV at the first position), phrenic nerve stimulation, or high far-field signals, other positions in the right atrium were explored. The Elox lead is straight, and the lead placement is most easily accomplished with the use of a manually curved stylet or a J-shaped stylet in order to find an optimal position in the atrium.

Case Reports

In two patients, the lead was introduced via the cephalic vein, and positioning was attempted without fluoroscopy. The tip of the lead was positioned blindly in the right atrial appendage. In both patients, this resulted in excellent positioning of the tip in the appendage, but only one patient exhibited good pacing and sensing parameters: atrial threshold was 0.7 V at 0.5 ms, P-wave amplitude was 3.1 mV, and pacing impedance was 720 W. In the other patient, the lead tip had to be repositioned because of a high pacing threshold (1.5 V at 0.5 ms).

The pacing threshold was immediately determined following helix extension, but the final measurements were made at least 10 min after fixation. A decrease in pacing threshold was always observed. Immediate measurements were performed for global approval of the position, i.e., the final position of the lead was approved according to pacing threshold, sensing values, stability during fluoroscopy, and ST-elevation as a sign of good contact between lead tip and myocardial tissue. Although attention has been given and time spent on obtaining a good final position, a position with less optimal characteristics has to be accepted. We tried to obtain atrial pacing thresholds below 1 V, lowest sensing values above 1.5 mV, and ST-elevation of at least 2 mV (preferably higher). Initial thresholds above 2.0 V were not accepted, except in two extraordinary cases. In one patient with almost continuous AF, the lead was positioned in the posterolateral wall of the right atrium during the third implantation procedure. Ten other positions of the lead tip were rejected because of non-capture at 5.0 V. During a short period of sinus rhythm the atrial pacing threshold was measured at 3.1 V, while sensing values were more or less "good," and the position was accepted. The pacing threshold remained high during follow-up, but non-capture during maximum pacemaker output was noticed only once during follow-up. In another problematic patient, the pacemaker and leads were implanted in the intensive care unit as an emergency procedure. The patient was in deep shock, under full respiratory support, and under complete anesthesia. She developed complete AV block, and a temporary pacemaker lead was dislocated. The implantation of the permanent pacemaker and follow-up were uneventful, but an initially high pacing threshold of 2.2 V was readily accepted. The pacing threshold later decreased to 1.5 V at 6 weeks post-implantation. In three other patients, pacing thresholds of above 1.5 V were

accepted after exploring many positions in the right atrium without success. None of those patients was excluded from this registry report.

Implantation of the Elox was attempted in another female patient, but the results were not entered in the registry because there were no pacing and sensing parameters. The implantation was halted due to acute chest pain, which started as soon the helix was screwed into the lateral wall. Relocating the tip to a different position (right atrial appendage) led to a repetition of the symptom: pain in the chest. Subsequently, a passive fixation lead was implanted successfully.

Electrophysiologic Results

The mean pacing threshold at implantation was 0.8 ± 0.5 V at 0.5 ms and increased directly to 1.5 ± 1.0 V at 0.4 ms (p-value = 0.00042) during pre-discharge measurements. However, after 6 weeks there was a steep decrease in the threshold from 1.6 ± 0.9 V; at 3 months it was 1.2 ± 0.6 (p-value = 0.019). At 6 months and 1 year, there was an insignificant decrease in the threshold (see Figure 3). The pacing impedance was high at implantation due to a few measurements with very high impedances above 1000 Ω. The mean impedance decreased from 493 ± 182 Ω to 380 ± 64 Ω (p-value = 0.00018) at pre-discharge, but stabilized thereafter (see Figure 4). The P-wave amplitudes are given as the lowest measured values during implantation or follow-up (see Figure 5): at implantation it was 2.3 ± 1.4 mV (n = 48), and it did not change significantly over time; at 1 year it was 2.2 ± 1.2 mV (n = 15). The range of measurements was wide, which was partly the result of AF or other atrial arrhythmias occurring during the measurements. Four patients with P-waves below 1.0 mV at implantation experienced AF. Those patients were not excluded from this registry. A P-wave of 0.7 mV during AF changed to 2.5 and 2.4 mV,

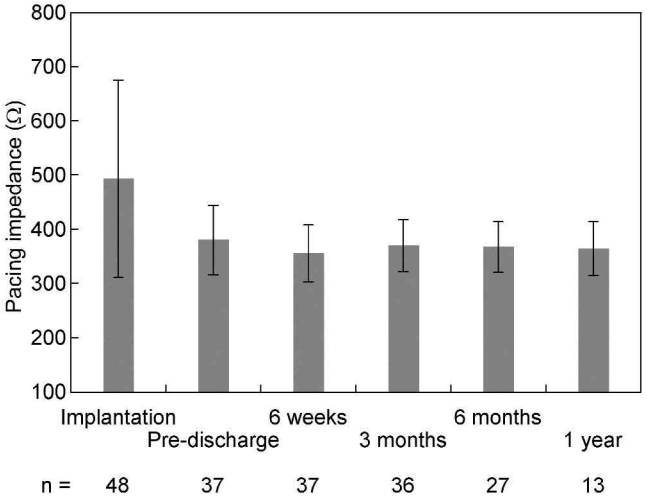

Figure 4. Bipolar pacing impedance measured at 3.6 V and 0.4 ms. The pacing impedance was low but stable throughout the follow-up period, except for a high impedance measured during implantation. See also Table 2 for unipolar and bipolar measurements.

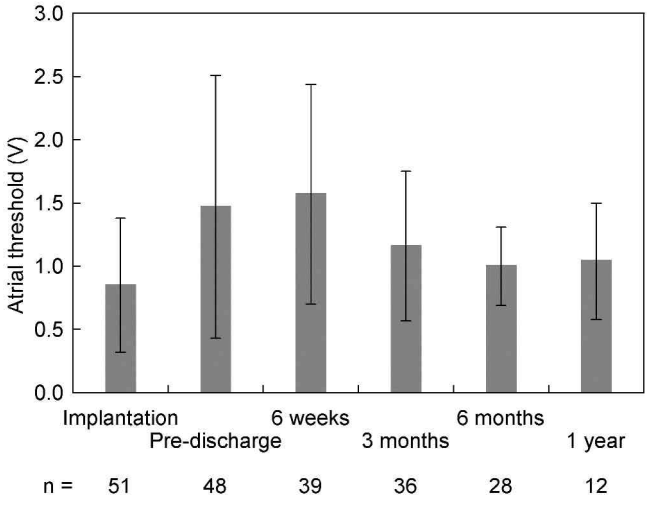

Figure 3. Bipolar pacing threshold at 0.5 ms at implantation and at 0.4 ms during follow-up.

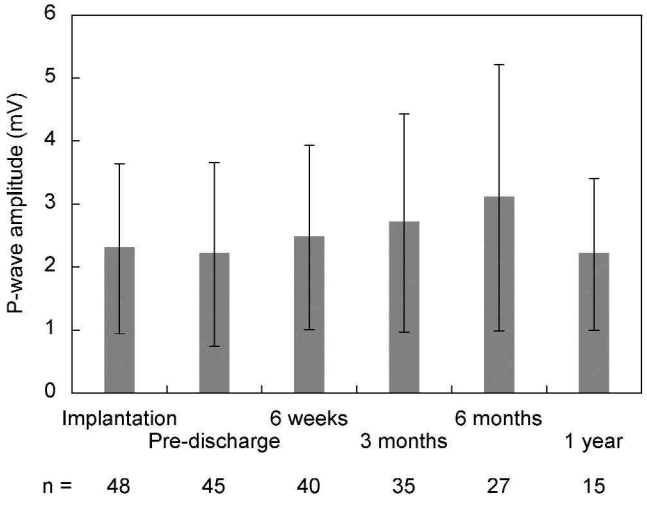

Figure 5. Bipolar P-wave amplitudes for all measurements from implantation through 1 year of follow-up. There were no significant differences observed over the course of this period.

		Unipolar	No.	Bipolar	No.	P-value
Threshold	Implantation	0.8 ± 0.5 V	34	0.8 ± 0.5 V	51	NS
	6 weeks follow-up	1.3 ± 0.7 V	28	1.6 ± 0.9 V	39	NS
Impedance	Implantation	541 ± 231 Ω	34	493 ± 182 Ω	48	NS
	6 weeks follow-up	291 ± 52 Ω	33	355 ± 52 Ω	37	< 0.0001
P-wave amplitude	Implantation	1.8 ± 1.0 mV	32	2.3 ± 1.4 mV	48	NS
	6 weeks follow-up	1.9 ± 1.4 mV	29	2.5 ± 1.5 mV	40	NS

Table 2. Pacing and sensing parameters at implantation and at the 6-week follow-up. NS = not significant.

respectively during sinus rhythm in two patients. The range of the P-wave amplitudes was 0.7 to 5.8 mV, with the wide range still being present at 6 months and 1 year post-implantation: 0.5 to 8.2 mV.

Unipolar and bipolar measurements of the pacing and sensing parameters are shown in Table 2. There were no large differences between the two groups, except for an insignificant tendency towards a lower P-wave amplitude and higher pacing threshold at 6 weeks in the unipolar configuration. Only the pacing impedance showed significantly higher impedance in the bipolar configuration at 6 weeks.

Discussion

There are still controversies surrounding the use of atrial leads with respect to unipolar systems and passive versus active fixation. European pacemaker and ICD surveys have indicated sizeable differences among countries regarding the use of active and passive fixation [1]. In some countries, atrial fixation is 100% active, while in others it may be less then 1%. Unipolar leads are less frequently applied in the atrium, possibly due to high ventricular far-field signals in unipolar recordings, and reduced or minimized far-field signals in bipolar recordings [4]. However, another survey on leads implanted in the U.S. indicated a higher rate of early and late-stage lead problems with bipolar versus unipolar leads. For example, there were 0.08% unipolar lead problems (for active as well as passive fixation), versus 0.87% and 0.84% for bipolar leads with active and passive fixation (p-values = 0.029 and < 0.0001, respectively). An explanation for this phenomenon was not given in this survey [5].

We did not encounter major complications in this Elox registry. Dislocation did not occur, though this may still be a clinical problem, even with active fixation, as has been reported elsewhere in a small number of patients who have undergone prior open heart surgery [6,7]. Pericarditis is an imminent and major problem, causing acute hemodynamic failure due to acute exudative pericarditis; it leads to subsequent heart tamponade and shock [8-10]. The implanting physician should be aware of the possible risk of pericardial irritation. We aborted the implantation of the Elox because of acute chest pain.

The acute pacing threshold measurements performed at implantation were in keeping with the reports on active screws. For P-wave amplitudes, no significant differences were observed between steroid and non-steroid active fixation leads: P-wave amplitudes of 3.3 ± 1.8 mV in the non-steroid group versus 3.2 ± 1.2 mV in the steroid group (p-value = 0.91) [11]. It must be stressed that the other authors did not record the minimal P-wave amplitudes in their study, as we did in this registry. In other studies, [6,7,12] similar findings or somewhat lower values were reported at implantation. Pacing thresholds showed a similar pattern at implantation; the atrial screw with electrically active helix showed identical or slightly higher thresholds: 0.91 ± 0.48 V at 0.5 ms [11], 0.9 ± 0.3 V [6], or 1.1 ± 0.2 V [8]. The results of this registry are also in keeping with the results achieved with active fixation and porous tips: 0.84 ± 0.59 V [13] or with steroid and active fixation: 0.83 ± 0.39 V [11]. The pacing impedance was somewhat lower than in other lead designs. Improvements could possibly be made by isolating the helix, which has no contact with the myocardium.

Long-term reports on pacing thresholds and active fixation are scarce. Wiegand et al. [11] reported on a 6-week observation of steroid and non-steroid active fixation. On average, the pacing threshold of the non-steroid lead increased to 2.06 ± 0.45 V, and even the steroid leads with active fixation showed a small

increase from 0.83 ± 0.39 to 1.08 ± 0.53 V. The long-term reports (≥ 1 year of follow-up) exist on the porous tip; one report on the Accufix (St. Jude Medical, USA) showed an increase of the pacing threshold to 1.85 ± 0.36 V after a mean follow-up period of 16 months [14]. The same report indicated that the threshold of a non-steroid active fixation increased to an even higher level: 1.93 ± 0.95 V. In another report on porous tips, the peak threshold was reported to be 0.99 ± 0.74 V, determined at the mean follow-up of 18.3 months [13]. However, these two reports did not provide the results for 6-week and 3-month follow-ups, which are associated with the highest peak threshold; they simply missed it. The long-term results show that chronic pacing thresholds are close to the implantation values. The Elox lead offers very good chronic thresholds after the initial increase during the first 6 – 8 weeks.

Conclusion

Active fixation is a feasible implantation option for every type of patient, whether they have undergone prior surgery or have paroxysmal AF. It can even be performed without fluoroscopy. In principle, each pacing site can be selected when certain precautions have been taken for the final acceptance of the position: low pacing threshold, high P-wave amplitudes, no far-field sensing, and no phrenic nerve stimulation. Lead handling and the active fixation mechanism do not present any problems. Pacing and sensing properties are very good; the higher pacing impedance of the active fixation lead may make it the ideal pacing lead.

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Contact
Dr. J.C.J. Res
Zaans Medisch Centrum "De Heel"
P.O. Box 210
1500 EE Zaandam
The Netherlands
Telephone: +31 72 581 7030
Fax: +31 72 581 7031
E-mail: janres@tref.nl