

Evaluation of the Merox Lead: Good Grades for Handling During Implantation, Lead Design, and Low Rate of Complications

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Summary

The quality of pacemaker leads determines the efficiency of modern pacemaker systems. The Merox bipolar pacemaker lead (Biotronik, Germany) has fractally coated, electrically active surface areas. One section is divided into four segments, which are part of the geometric surface covering an area of 1.3 mm². This design's goal is to create a balance between tissue contact and stability, thus reducing the incidence of intracardiac tissue irritation and microdislocation. The current post-marketing surveillance, the Merox Register, will study 160 Merox leads over a period of 6 months. Besides the usual electrical lead parameters (amplitude, pacing threshold, and impedance), the collection of data will focus especially on the investigator's evaluation of implantation handling and lead design as well as on gathering information about possible complications. Up to now, we have gathered implantation data on 77 atrial (15) and ventricular (62) Merox leads; we already have data for 49 of these leads, including the 6-month follow-up. The intraoperative measurements yielded the following results for the ventricular (v) and atrial (a) leads: impedance = 853 ± 196 Ω (v) and 622 ± 260 Ω (a); threshold, bipolar = 0.4 ± 0.2 V (v) and 0.5 ± 0.2 V (a), unipolar = 0.4 ± 0.1 V (v) and 0.5 ± 0.2 V (a); amplitude, bipolar = 13.1 ± 6.1 V (v) and 4.4 ± 1.8 V (a), unipolar = 14.2 ± 5.8 V (v) and 5.4 ± 4.7 V (a). On average, the investigators awarded the Merox handling during implantation the following grades: 17 ± 3 (22%) leads were "very good," 59 ± 3 (77%) "normal," and 1 ± 1 (2%) "difficult" (N = 77 evaluated leads). The final investigators' evaluation of lead design yielded the following results for Merox: 16 ± 4 (34%) leads were "very good," 30 ± 3 (66%) "average," and none "difficult" (N = 49 evaluated leads). Based on the data presented up to the 6-month follow-up for 49 leads, a Merox lead positioned in the atrium might have produced a microdislocation. In comparison with other pacemaker leads, the interim analysis yielded positive results for the intraoperative measurements of the electrical parameters; however, with respect to chronic values, we do not have sufficient data yet. On average, the investigators awarded the Merox good grades for handling during implantation and lead design. Considering its low rate of complications, the Merox lead can be rated as a good quality standard lead that contributes to a modern pacemaker system.

Key Words

Small surface electrode, handling during implantation, lead design, complications, fractal coating

Introduction

The performance of modern pacemaker systems is not only determined by multiple, efficient therapy options but also significantly by the quality of the leads used [1]. The general requirements for a successful lead design are ease of handling during implantation, optimal func-

tional and electrical qualities, and a minimal complication rate [1,2]. Post-marketing surveillances facilitate the study of clinically relevant features of medical products that are usually not obvious before the actual use of the device. The same holds true for the design of cardiac

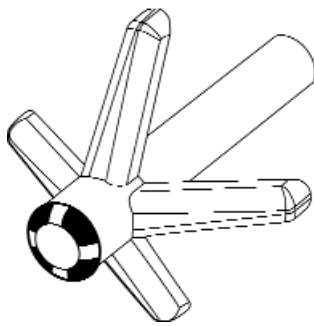


Figure 1. Lead tip of the Merox lead (Biotronik, Germany).

leads for pacemakers and defibrillators. The Merox bipolar pacemaker lead has fractally coated, electrically active surface areas. They are partitioned into four segments and are part of the entire geometric surface area of 1.3 mm². This design aims at creating a balance between tissue contact and stability (Figure 1). Therefore, the incidence of intracardiac tissue irritation and microdislocation compared to common leads is reduced. The fractal structure of the lead increases the electrically active area more than a thousand times [3]. The fixation tines of the Merox lead are positioned in such a way that both straight and J-shaped leads can be implanted with 8 F introducers. This design facilitates handling during implantation. The technical information of the Merox lead is listed in Table 1.

This international, post-marketing surveillance studies 160 Merox leads over a period of 6 months. Besides the electrical lead parameters (amplitude, pacing threshold, and impedance), data collection focuses especially on the investigators' evaluation of handling during implantation and lead design, as well as on gathering information about possible complications. The first interim results of 77 implanted Merox leads within the Merox Register are presented in this study.

Materials and Methods

The Merox Register is a prospective, multicenter, international, post-marketing surveillance. The inclusion of patients started in September 2001, and will be completed by the end of 2003. Data on a total of 160 Merox leads will be collected in total within the framework of the Merox Register. All four Merox types can be used: MEX 53-BP, MEX 60-BP, MEX 45-JBP, and MEX 53-JBP (J = J-shaped). Each patient will participate in the Merox Register for 6 months; the timing for

Connection System	IS-1	
Polarity	Bipolar	
Tip electrode		
Form	Segmented	
Area	1.3 mm ²	
Material	80% Pt, 20% Ir	
Surface, structure	Ir, fractal	
Ring electrode		
Active area	22.6 mm ²	
Material	80% Pt, 20% Ir	
Surface, structure	Ir, fractal	
Insulation	Silicone	
Tip-to-ring distance	15 mm	
Conductor	Distal	Proximal
Coil material	MP 35 N	MP 35 N
Resistance (straight leads)	1.16 Ω/cm	1.05 Ω/cm
Resistance (J-shaped leads)	0.55 Ω/cm	1.05 Ω/cm
Connector material	Medical grade, stainless steel	
Lead lengths	45/53/60 cm	
Catheter diameter	2.4 mm (7.2 F)	
Suitable lead introducer	8 F	

Table 1. Technical data of the Merox lead.

follow-up will be scheduled in accordance with the usual regulations for pacemaker therapy [4]: implantation; pre-hospital discharge, as well as 1-month, 3-month, and 6-month follow-up visits. Patients in the Merox Register have a pacemaker indication according to the usual regulations [4,5], and they have been or will be implanted with a Merox lead in the right atrium and/or ventricle. There are no exclusion criteria. Furthermore, there are no prerequisites with respect to pacemaker type; possibly, an additional lead and the programming device will be used for follow-ups. The pacemakers are programmed according to the needs of the patients: no guidelines are provided in the context of this post-marketing surveillance. The following data will be collected within the Merox Register:

- Inclusion: date of birth, gender, weight, heart condition, NYHA class, ejection fraction (facultative), symptom(s), ECG indication(s), etiology(ies), medication.

- Implantation: implantation/revision, date, duration, pacemaker (model, manufacturer, location), focus lead (model, manufacturer, location, access), intraoperative measurements (duration, amplitude, pacing threshold, impedance), evaluation of lead handling (intravenous passage, tricuspid valve passage, lead placement).
- Discharge, 1-, 3-, 6-month follow-ups: date, duration, NYHA class, ejection fraction (facultative), change of medication, measurements of the focus lead (amplitude, pacing threshold, impedance), complications (dislocation, tissue irritation, revision, other), evaluation of lead design (diameter, isodiametric construction, flexibility, four-part surface, tine structure, lead introducer set, stylet, other).

Results

Inclusion Rate

Within the Merox Register, 77 Merox leads have been implanted up to now in the atrium and/or ventricle of 63 patients, in 14 clinics, in 5 different countries (Table 2).

Country	Clinics	Patients	Leads
Spain	5	20	27
Brazil	5	19	19
Belgium	2	14	14
Czech Republic	1	2	2
Slovak Republic	1	8	15

Table 2. Number of participating clinics, included patients, and implanted leads per country.

Patient Data

Regarding gender, 52% of the included patients are male and 48% female. The average age at the time of implantation is 71 ± 14 years (male: 72 ± 13 years; female: 69 ± 14 years). The average weight is 72 ± 12 kg. The left ventricular ejection fraction has been measured in 20 patients (32%), and its average value is $54\% \pm 15\%$. The following indications for pacemaker therapy have been recorded for patients in accordance with the codes of the European Pacemaker Registration Card (Version 7, 1996. Nine patients were mentioned several times): In the category of ECG indication, 62% of the patients exhibited a conduction disturbance (59% AV block, 3% bundle-branch block), and 41% present-

ed with sick sinus syndrome. The most frequent symptom was syncope (53%) or presyncope (38%). In the etiology category, 65% of the patients were classified with the code "unspecified" or "unknown."

Implanted Devices

All patients had the pacemaker system implanted for the first time. The entire implantation procedure lasted on average 60 ± 20 min. Sixty (95%) of the 63 patients received a Biotronik pacemaker: 38 Philos (DR, D, SR), 13 Actros (DR, D, SR, S), 6 Axios (DR, S), 1 Kairos DR, 1 Pikos 01, and 1 Triplos LV. The remaining 3 patients received 1 Pulsar Max SR (Guidant), 1 Kappa (Medtronic), and 1 Microny 2 SR (Pacesetter), respectively. Forty-four devices (70%) have a dual-chamber system, 18 (29%) a single-chamber system, and 1 (2%) a triple-chamber system. Among the 77 Merox leads, 15 have been implanted in the atrium (19%; all MEX-53BP) and 62 in the ventricle (81%; 42 MEX-60BP and 20 MEX-53BP). The atrial Merox leads were inserted into the vascular system via the vena subclavia (N = 9; 60%) or vena cephalica (N = 6; 40%), whereas the ventricular Merox leads were inserted via the vena subclavia (N = 42; 68%), the vena cephalica (N = 17; 27%), or the vena jugularis interna (N = 1; 2%); the rest (N = 2; 3%) have

	Impedance (Ω)	Threshold (V)	Amplitude (mV)
Ventricle	853 \pm 196 at 4.2 \pm 1.1 V and 0.5 \pm 0.0 ms (N = 62)	0.4 \pm 0.2	13.1 \pm 6.1
		bipolar	bipolar
		at 0.5 \pm 0.0 ms (N = 34)	(N = 39)
		0.4 \pm 0.1	14.2 \pm 5.8
Atrium	622 \pm 260 at 3.8 \pm 0.6 V and 0.4 \pm 0.0 ms (N = 14)	unipolar	unipolar
		at 0.5 \pm 0.0 ms (N = 26)	(N = 20)
		0.5 \pm 0.2	4.4 \pm 1.8
		bipolar	bipolar
Atrium	622 \pm 260 at 3.8 \pm 0.6 V and 0.4 \pm 0.0 ms (N = 14)	at 0.5 \pm 0.1 ms (N = 6)	(N = 7)
		0.5 \pm 0.2	5.4 \pm 4.7
		unipolar	unipolar
		at 0.8 \pm 0.6 ms (N = 6)	(N = 6)

Table 3. Intraoperative measurements; N = Number of available measurements.

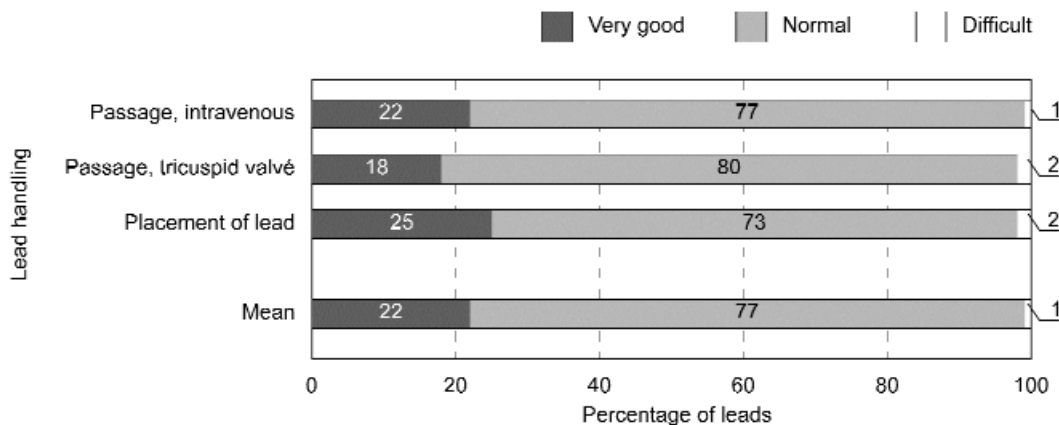


Figure 2. Evaluation in percentage of subjective investigators' evaluation of the Merox lead's handling during implantation. Missing evaluation ("no evaluations") will not be considered. Number of evaluated Merox leads: $N = 77$; evaluation by 14 investigators in 5 countries. For the basis of data, see Table 4.

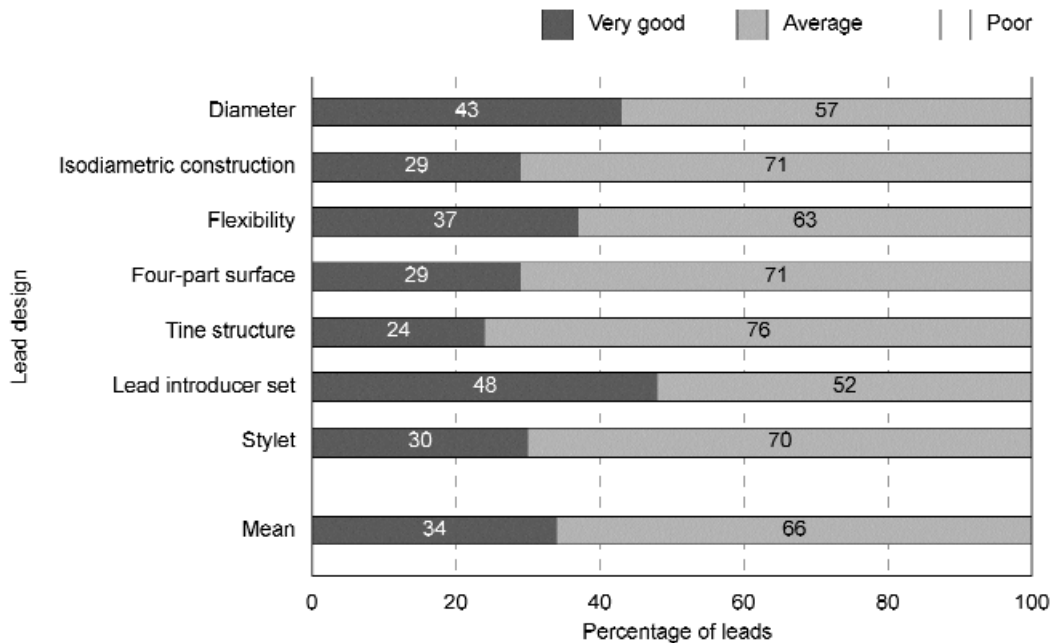


Figure 3. Evaluation in percentages of the final subjective investigators' evaluation of the Merox lead design. Missing evaluation ("no evaluations") will not be considered. Evaluation period: From implantation to 6-month follow-up; number of evaluated Merox leads: $N = 49$; evaluation conducted by 10 investigators in 4 countries. For basis of data, see Table 5.

not been defined. The lead was positioned in the auricula cordis ($N = 12$; 80%) in the atrium, or the location has not been recorded ($N = 3$; 20%). In most cases, the apex cordis ($N = 56$; 90%) has been selected for the ventricular position; in one case (2%), the subtricuspidal location was chosen, and 5 (8%) cases were without information. The Merox focus lead was the only one about which data has been collected.

Intraoperative Measurements

The intraoperative measurements have been completed for more than 50% of the leads with the ERA 300 ($N = 41$; 53%) from Biotronik. The following intraoperative measuring devices have also been used: PSA ($N = 10$; 13%; Cordis), ERA 20 ($N = 8$; 10%; Biotronik), EPR 1000 ($N = 6$; 8%; Biotronik), or no information ($N = 12$; 16%; 2 times Medtronic). The results of intraoperative measurements are listed in Table 3.

		Evaluation			
		"Very good"	"Normal"	"Difficult"	No evaluation
Lead handling	Passage, intravenous	17	59	1	0
	Passage, tricuspid valve	14	61	1	1
	Placement of lead	19	56	2	0
	Mean \pm standard deviation	17 \pm 3	59 \pm 3	1 \pm 1	0 \pm 0

Table 4. Subjective investigators' evaluation of the Merox lead's handling during implantation. Number of Merox leads evaluated: $N = 77$; evaluation conducted by 14 investigators in 5 countries.

		Evaluation			
		"Very good"	"Normal"	"Difficult"	No evaluation
Lead design	Diameter	21	28	0	0
	Isodiametric construction	13	32	0	4
	Flexibility	18	31	0	0
	Four-part surface	13	32	0	4
	Tine structure	11	34	0	4
	Lead introducer set	22	24	0	3
	Stylet	13	30	0	6
	Mean \pm standard deviation	16 \pm 4	30 \pm 3	0 \pm 0	3 \pm 2

Table 5. Final subjective investigators' evaluation of the Merox' lead design. Evaluation period: From implantation to 6-month follow-up; number of Merox' leads evaluated: $N = 49$; evaluation conducted by 10 investigators in 4 countries.

Lead Handling

The investigators have currently documented the implantation handling of 77 implanted Merox leads. The individual results are listed in Table 4. With respect to the different implantation steps, the Merox lead received an average evaluation of 17 ± 3 with "very good," 59 ± 3 with "normal," and 1 ± 1 with "difficult." The three implantation steps in the survey showed a balance in all three evaluation grades. Figure 2 displays the results of Table 4 in a graphic with the evaluation in percentages. Missing evaluation ("no evaluation") will not be considered. On average, the Merox lead has been evaluated in 22% of the cases with "very good," in 77% with "normal," and in 1% with "difficult."

Lead Design

The lead design has been assessed at the end of the survey period of each patient (6-month follow-up); results have been reported by now for 49 leads. Table 5 displays the results of the final subjective investigators' assessment of the Merox lead design. With respect to the design, the average assessment of all parameters of

the Merox lead has been 16 ± 4 times "very good" and 30 ± 3 times "normal." The lead design has never received the a grade of "difficult." On average, 3 ± 2 times the investigators gave no evaluation. Figure 3 displays the results of Table 4 in a graphic with the evaluation in percentages. Missing evaluations ("no evaluation") will not be considered. On average, the Merox lead design has been evaluated for 34% with a grade of "very good," and for 66% with "average." Three of the 7 design parameters received a grade of "very good" in more than a third of the cases: lead introducer set (48%), diameter (43%), and flexibility (37%).

Complications

Complications occurred among 49 atrial and ventricular leads (for which we have the entire data up to the 6-month follow-up) in 0% to 2% of the cases. Tissue irritation (0%) never occurred; however, in an atrial positioned Merox lead, probable dislocation occurred (2%) with stable sensing during follow-up. Another patient with an atrial lead exhibited paroxysmal atrial fibrillation (2%) during the 6-month follow-up.

Altogether, a revision of one ventricular lead (2%) was necessary; however, further information about timing and the reasons for the revision are not available.

Discussion

The clinical characteristics of patients in this study correspond mostly with those from patients of other post-marketing surveillances [6]. Supposedly, small surface electrodes (1 – 2 mm²) require more delicate handling during implantation than standard electrodes (5 – 8 mm²). They may also be associated with an increased complication rate caused by electrode positional instability and early or late lead dislodgement [3,7-12]. In the past, this has resulted in a limited acceptance in clinical practice, despite the favorable findings of several large clinical trials [2,13-17]. However, these limitations of small surface electrodes, which are discussed in several medical publications and compared to standard electrodes, cannot be confirmed by the data collected in this post-marketing surveillance. Up to now, we have just found a minimal complication rate (below 2%), and the investigators have graded the Merox lead's performance predominately as "average" or "very good."

Despite the theoretically higher risk of clinical complications in small surface electrodes [17], a complication rate between 0% and 2% among the 49 Merox leads up to the 6-month follow-up is very low. No incidence of intracardiac tissue irritation occurred during the study. One incidence of microdislocation was reported; however, the sensing remained stable during the follow-up. The special design of the Merox lead might have caused this minimal complication rate. The ideal balance between tissue contact and stability is due to the distribution of the fractally coated, electrically active area into four segments on a large geometric surface. Small surface electrodes do not have to be associated necessarily with a higher complication rate, since similarly low complication rates have also been reported for other small surface electrodes. For example, a 4-year study of Synox leads (1.3 mm² surface, 8 F introducer, Biotronik) demonstrated that only 2 leads (3%) among 74 required invasive interventions (microdislocation and insulation defect) [17]. Complication rates to this extent are in line with the results obtained with quality state-of-the-art pacemaker leads [16,18].

The evaluation of handling during implantation and lead design of the Merox lead varied among investiga-

tors; in summary, they evaluated the lead as being better than normal or average. The ratio between the grades "normal" to "very good" for lead handling during implantation is approximately 3:1. The three evaluated implantation phases returned a grade of "difficult" for only 1 or 2 leads. The final evaluation of the lead design, 6 months after the implantation, assigned a grade of "very good" even more frequently. Depending on the design parameter evaluated, the ratio between "average" and "very good" was between approximately 3:1 (tine structure) and 1:1 (lead introducer set). The design parameters have not been awarded a grade of "poor" at all. Due to the limited amount of data, we are currently unable to state the reasons for the differences in the evaluation of the Merox lead. Different causes might have influenced the evaluation process. Not only the type of vascular access, but also anatomic characteristics of the individual patient could have played a role in the evaluation of the lead's handling. This aspect is supported by the fact that some investigators rated the handling and the design sometimes as "very good" and at other times as "normal" or "average." On the other hand, there are also investigators who rated the lead with respect to handling and design most of the time as "very good" or as "normal/average." The collected data does not support the assumption that the Merox lead requires a learning curve. Final results can only be assessed after all data on all 160 Merox leads are available.

As stated above, the evaluation of the electrical lead parameters (amplitude, pacing threshold, impedance) is also limited, since data about chronic values are insufficient. The intermediate analysis for intraoperative measurements returned favorable results compared to published evaluations; data available in the medical literature focus predominately on ventricular leads [1,19-23]: Depending on the type of publication, the evaluation of the intraoperatively measured medium pacing threshold of ventricular leads varied between 0.3 and 0.5 V at 0.5 ms. The current measurement results from the Merox Register yielded an average value of 0.4V at 0.5 ms (N = 60 ventricular leads, bipolar, and unipolar measurement). This value overlaps with the average value found in reference articles. In medical publications, the average values of intraoperatively measured R-wave amplitudes vary between 12.4 and 16.6 mV. The R-wave amplitude values assessed in the current study, 13.1 (bipolar, N = 39) or 14.2 (unipolar, N = 20), coincide with the

average values in the reference material. The measurements of intraoperative impedance vary greatly in the medical literature. There are several reasons for this situation: a large difference in the electrically active area between standard leads and high impedance leads, variations in measurement conditions that return mean impedances of between 441 and 1089 Ω (at 4.8 to 5 V). This post-marketing surveillance returned a mean, intraoperative impedance of 853 Ω (at 4.2 V and 0.5 ms) for the ventricular Merox leads. This value overlaps with the measurement of higher quality standard leads and almost reaches impedance values found in some high impedance leads [7].

The interim results of the data collected during this Merox Register already confirm the successful performance of the Merox lead. The low complication rate, the good grades on average for handling during implantation, and lead design prove that the disadvantages of small surface electrodes listed in medical publications do not include the Merox lead. In addition, the positive intraoperative values signify that the Merox lead fulfills the requirements of a state-of-the-art lead with respect to the basic electrical parameters (amplitude, pacing threshold, impedance). Therefore, the Merox lead can be evaluated as a solid standard lead that contributes to the performance of any modern pacemaker system.

Conclusion

The results of the interim analysis of the current post-marketing surveillance, the Merox Register, for 77 implanted Merox leads (we have collected data up to the 6-month follow-up for 49 of the 77 leads) are as follows:

- positive intraoperative values for amplitude, pacing threshold, and impedance;
- an overall positive summary of the lead's handling during implantation;
- an overall positive summary of the lead's design; and
- a currently rather low complication rate.

These results confirm an overall successful performance of the Merox lead. The lead conforms to the expectations of a high quality, state-of-the-art lead without the disadvantages frequently indicated in the literature.

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