

Endocardial lead insulation wear in a scanning and optical microscope

Mateusz Ulman^{1,A–D}, Krzysztof Boczar^{1,A–C,E}, Katarzyna Holcman^{2,3,B},
Magdalena Ziąbka^{4,B,C}, Maciej Dębski^{5,B–D}, Jacek Lelakowski^{1,3,F}, Andrzej Ząbek^{1,3,A,C,E,F}

¹ Department of Electrophysiology, The John Paul II Hospital, Cracow, Poland

² Department of Cardiac and Vascular Diseases, The John Paul II Hospital, Cracow, Poland

³ Institute of Cardiology, Jagiellonian University Medical College, Cracow, Poland

⁴ Department of Ceramics and Refractories, Faculty of Materials Science and Ceramics, AGH University, Cracow, Poland

⁵ Norwich Medical School, University of East Anglia, UK

A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation;

D – writing the article; E – critical revision of the article; F – final approval of the article

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Address for correspondence

Krzysztof Boczar

E-mail: krzysiek.boczar@gmail.com

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Abstract

Background. The path and interaction of leads within the cardiovascular system are influenced by various factors, including the implantation technique. Furthermore, the multifaceted composition of these leads, often comprising multiple materials, can contribute to their potential degradation and wear over time.

Objectives. Our aim was to investigate the wear of lead insulation following the removal of transvenous leads and pinpoint the regions of the lead most vulnerable to damage.

Materials and methods. We undertook a prospective analysis of patients from a single tertiary center who underwent transvenous lead explantation (TLE) between October 1, 2013, and July 31, 2015. Specifically, our examination focused on endocardial leads removed using simple screw-out and gentle traction techniques. Subsequent lead evaluations were conducted utilizing scanning electron and optical microscopes.

Results. Among the 86 patients who underwent the TLE procedure, 26 patients (30%) required the removal of 39 leads through simple traction. Inspection using scanning electron microscopy consistently indicated insulation damage across all leads. A total of 347 damaged sites were identified: 261 without lead unsealing and 86 exhibiting unsealing. Notably, the sections of the leads located within the intra-pocket area demonstrated the highest vulnerability to damage (odds ratio (OR): = 9.112, 95% confidence interval (95% CI): 3.326–24.960), whereas the intravenous regions displayed the lowest susceptibility (OR: 0.323, 95% CI: 0.151–0.694).

Conclusions. Our study reveals that all evaluated leads exhibited insulation damage, with the intra-pocket segments manifesting a notably higher prevalence of damage than the intravenous segments.

Key words: endocardial leads insulation, microscope analysis, simple traction, transvenous lead explantation, fatigue wear of endocardial leads

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Background

Endocardial leads are comprised of multiple components: an electrode, conductor, insulation, and connector pin. Functionally, these leads are classified into pacing (permanent pacemaker (PPM)) and defibrillating (implantable cardioverter-defibrillator (ICD)) categories.

The conductor, found universally in these leads, consists of 1 or more wires that can be coiled into helices or woven into cables. In current clinical lead models, the coil's filament count for a single electrode ranges from 1 to 8. Typically, these conductor coils and cables are made of a MP35N alloy (Fort Wayne Metals, Fort Wayne, USA), valued for its mechanical strength and resistance to chemical corrosion.¹

These conductor elements are encased in a polymer insulation layer that serves a dual role: It provides both physical and electrical isolation for the lead components. While the outer insulation shield protects against external tissue interactions, the internal insulation ensures inter-component isolation.^{2,3}

Additionally, the insulation layers play a crucial role in maintaining the lead's structural integrity. They also aid in transmitting torque and tension during lead implantation and subsequent explantation. Commonly used insulation materials include silicone (polydimethylsiloxane), polyurethane (often types 55D and 80A), fluoropolymers (typically ETFE), and silicone-polyurethane copolymers.^{4,5}

Medtronic (Medtronic, Dublin, Ireland) leads, like the CapSureFix Novus and Attain Ability+, demonstrate a layered insulation structure. They are comprised of an external layer of 55D polyurethane for tissue contact and an internal silicone layer for conductor isolation. In contrast, Medtronic DF leads, such as the Sprint Quattro, possess a more complex insulation system with multiple layers of ETFE and PTFE.⁶ Vitatron (Vitatron, Maastricht, the Netherlands) electrodes (Crystalline ICF 09B) are characterized by a single silicone insulation layer,⁷ while Biotronik (Biotronik, Berlin, Germany) offers dual-layer (Siello S, Solia S) or single-layer (Setrox S) insulation options.⁸

Previous studies have reported that around 25% of removed endocardial leads exhibit insulation damage.^{9,10} Additionally, isolated cases of insulation damage have been noted even in single-lead pacing systems without inter-lead interactions.¹¹

Material fatigue processes have been more widely researched since the 1960s.¹² While existing literature touches upon the wear of leads,^{3,9–11,13–18} there is a gap in understanding the specific types of damage to the outer insulation near the generator pocket. This study seeks to explore the role of fatigue mechanisms in shaping wear patterns on intracardiac electrodes.

Objectives

This study aims to conduct a comprehensive qualitative and quantitative assessment of fatigue wear on lead

insulation, focusing specifically on the 4 distinct anatomical regions of leads explanted via simple traction.

Materials and methods

Study design and setting

This study adopted a prospective approach, focusing on patients who underwent transvenous lead extraction (TLE) at a tertiary cardiac center (Department of Electrophysiology at St. John Paul II Hospital, Cracow, Poland) between October 1, 2013, and July 31, 2015. The study specifically targeted patients whose leads were removed using only simple screw-out methods and gentle traction to ensure no inadvertent damage to the lead.

Participants

Ethical clearance was secured from the Research and Ethics Committee of the Jagiellonian University, Cracow, Poland (decision No. KBET/259/B/2011). Every participant provided written informed consent for the use of their anonymized data in this study. The research strictly adhered to the 1975 Declaration of Helsinki and World Health Organization (WHO) Good Clinical Practice guidelines.

Data collection

The dataset incorporated:

- Patient's baseline information: birth date and gender.
- Clinical profile: information on diabetes mellitus, height, weight, and age during the TLE.
- Lead specifications: dwell-time, lead model, manufacturer (Medtronic, Vitatron and Biotronik), and specific model details.
- Lead performance parameters: threshold, sensing and impedance.

The study contrasted the patterns of insulation damage among 4 indications for TLE: lead dysfunction, dislocation, lead-dependent infective endocarditis (LDIE), and pocket infections.

Evaluation techniques

Electrode positioning was determined pre-extraction using chest X-rays (CXR). Lead lengths across the intracardiac, intravenous, subclavian, and intra-pocket regions were derived from these X-rays. Post-extraction, leads underwent detailed microscopic analysis. Lead segments were sectioned into 2-cm intervals and examined under an optical microscope (Nikon Corp., Tokyo, Japan). Further evaluations utilized a scanning electron microscope (SEM; Nova Nano SEM 200; FEI Europe B.V., Eindhoven, the Netherlands) combined with an energy dispersive X-ray (EDX) detector for microstructural and chemical assessments.

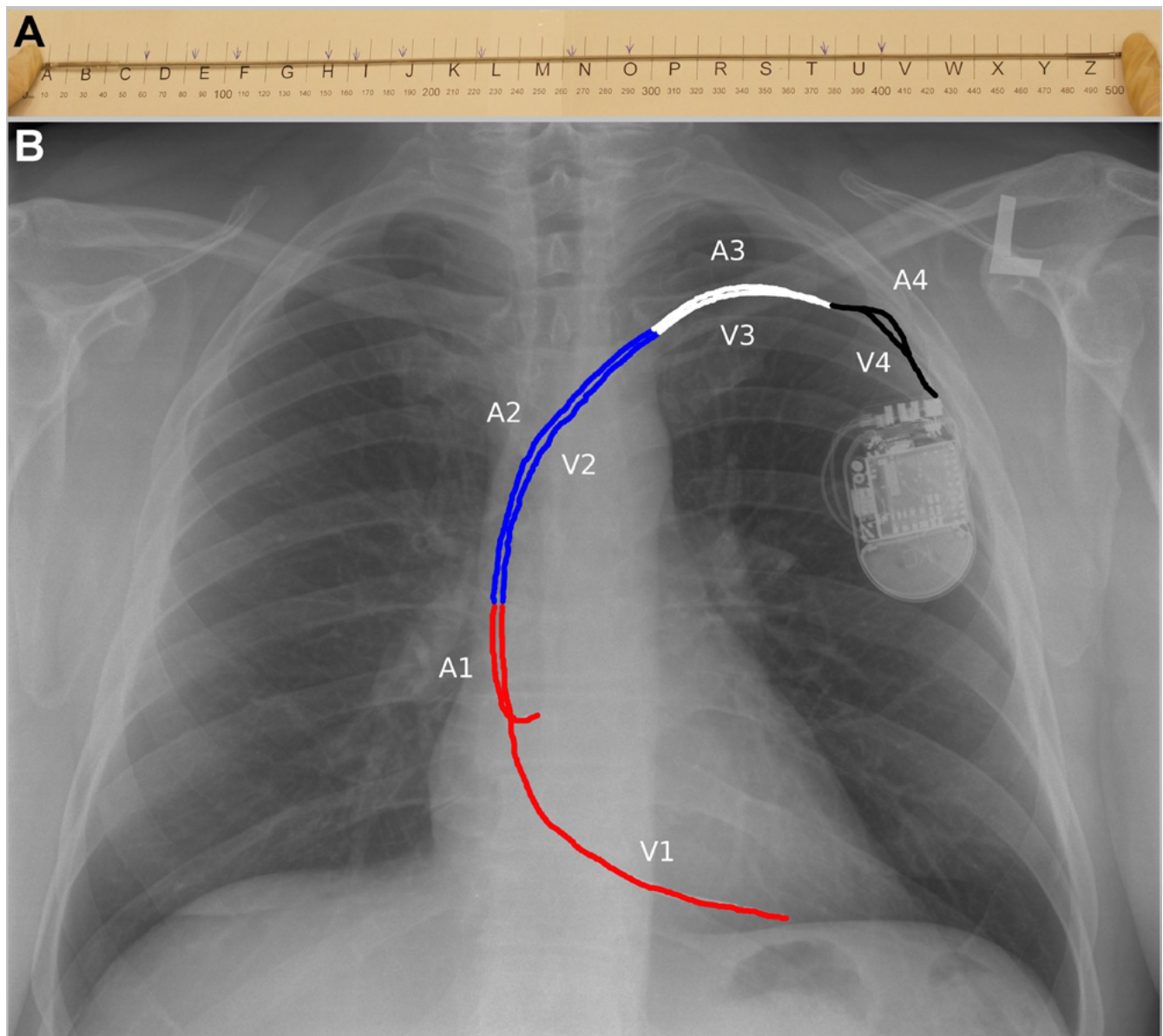


Fig. 1. Measuring the location of the lesion. A. The analyzed leads were divided into 2-cm sections. The small arrows at the top of the ruler indicate the locations of destruction; B. Chest X-ray – posteroanterior projection; A – atrial lead; V – ventricular lead; 1 – the intracardiac region, 2 – the intravenous region, 3 – the subclavian region, 4 – the intra-pocket region; the section length measurement was made using the Digital Imaging and Communications in Medicine (DICOM) system; the invisible part of the electrode belongs to the intra-pocket region

(Fig. 1). A comparative analysis was also conducted using brand-new lead models.

The study methodically assessed outer lead insulation wear across these anatomical regions, categorizing damage types based on lead unsealing. Additionally, correlations between damage pattern variables like lead make, manufacturer and insulation material were explored.

Statistical analyses

Data were analyzed using IBM SPSS Statistics v. 24.0 (IBM Corp., Armonk, USA). Descriptive statistics depicted data distributions, while appropriate tests determined comparisons between continuous and categorical variables. Continuous variables were tested for normal

distribution with the use of the Kolmogorov–Smirnov test and compared using Student’s t-test or the Mann–Whitney U test, depending on the data distribution. Spearman’s rank correlations assessed relationships, and uni- and multivariable logistic regression models unveiled predictors of lead damage, represented as odds ratios (ORs) with a 95% confidence interval (95% CI). A p-value <0.05 was deemed significant for all analyses.

Results

A total of 86 consecutive patients underwent the TLE procedure. Among these, 26 patients (30%) had 39 leads extracted using simple traction, with 11 (42%) being female.

Table 1. Types of the leads

Manufacturer	Model	Localization	Outer insulation material	Number of leads
Medtronic	CapSureFix Novus 52 cm	atrial	polyurethane 55D	11
Medtronic	CapSureFix Novus 58 cm	ventricular	polyurethane 55D	6
Medtronic	Sprint Quattro 65 cm	ventricular, ICD	polyurethane 55D, 80A	2
Medtronic	Attain Ability+ 88 cm	coronary sinus	polyurethane 55D	2
Biotronik	Selox JT	atrial	silicone	2
Biotronik	Selox ST	ventricular	silicone	1
Biotronik	Setrox S53	atrial	silicone	1
Biotronik	Setrox S60	ventricular	silicone	5
Biotronik	Siello S53	atrial	polyurethane	1
Biotronik	Siello S60	ventricular	polyurethane	1
Biotronik	Solia S53	atrial	polyurethane	1
Biotronik	Solia S60	ventricular	polyurethane	1
Vitatron	Crystalline 52 cm	atrial	silicone MED 4719	3
Vitatron	Crystalline 58 cm	ventricular	silicone MED 4719	2

ICD – implantable cardioverter-defibrillator.

On average ($\pm$ standard deviation ($\pm$ SD)) the examined patients had 2.15 (0.6) electrodes implanted prior to the TLE procedure. Distribution among lead manufacturers was as follows: Medtronic 54%, Biotronik 33% and Vitatron 13%.

The average ($\pm$ SD) age at initial cardiac implantable electronic device (CIED) implantation was 68.2 ($\pm$ 10.4) years, with a median of 70.6 and an interquartile range (IQR) of 17.0. By the time of the TLE procedure, the patient's mean ($\pm$ SD) age was 71.2 ($\pm$ 10.0) years, with a median of 75.3 and an IQR of 19.3. The lead's mean age was 35.8 ($\pm$ 21.4) months, with a median of 27.8 and an IQR of 37.1. The range for lead dwell-time spanned from 18 days to 76.9 months. The mean body mass index (BMI) recorded was 29.8 ($\pm$ 4.4), with a median identical to the mean and an IQR of 7.6. Diabetes mellitus was present in 12 patients (46.2%).

Among the leads extracted, 18 (46.2%) were for malfunctioning, 7 (17.9%) were dislocated, 4 (10.3%) were due to LDIE, and 10 (25.6%) were due to local infections. A detailed division is provided in Table 1. All analyzed leads were bipolar, categorized as 19 (48.7%) atrial leads, 16 (41%) right ventricular pacing leads, 2 (5.1%) implantable cardioverter defibrillator leads, and 2 (5.1%) left ventricular leads.

Scanning electron microscopy examinations identified lead insulation damage across all samples (Fig. 2,3). A total of 347 instances of lead damage were recorded: 261 (75.2%) without unsealing and 86 (24.8%) with unsealing. Damage was predominantly observed at the intra-pocket (56.2%) and subclavian (18.2%) regions, while the intracardiac (17.0%) and intravenous (8.6%) regions showed lesser damage. A detailed division of electrode defects is outlined in Table 2.

Table 3 presents the correlation between selected variables and lead damage, with or without unsealing. The univariable analysis incorporated factors such as lead region, type, age of the patient and electrode, gender, diabetes

Table 2. Localization and types of damage of endocardial leads

Localization of damage	Damage of lead insulation with the absence of unsealing	Damage of lead insulation with the presence of unsealing
Number of damage over the entire length of all electrodes*, n (%)	261 (75.2)	86 (24.8)
Intracardiac region, n (number of damage/cm)	49 (0.0864)	10 (0.0176)
Intravenous region, n (number of damage/cm)	27 (0.0372)	3 (0.0041)
Subclavian region, n (number of damage/cm)	46 (0.1474)	17 (0.0545)
Intra-pocket region, n (number of damage/cm)	139 (0.1463)	56 (0.0589)

*excluding anchoring sleeve location.

status, BMI, insulation material, TLE indications, and manufacturer. Significantly, the intra-pocket region of the lead (OR: 9.112, 95% CI: 3.326–24.960), use of Vitatron leads (OR: 2.913, 95% CI: 1.002–8.463) and an extended dwell-time (OR: 1.018 per 1-month, 95% CI: 1.002–1.034) were notable predictors for lead damage without unsealing.

During multivariable analysis, these predictors remained significant. The intra-pocket lead region (OR: 9.740, 95% CI: 2.856–33.219), Vitatron leads (OR 3.438, 95% CI: 1.111–10.641) and older electrode age (OR: 1.031 per 1-month, 95% CI: 1.010–1.054) were especially noteworthy. The amount of lead damage over time is presented in Fig. 4.

While the intravenous region showed minimal damage during the univariable analysis (OR: 0.323, 95% CI: 0.151–0.694), its significance waned during the multivariable assessment.

For leads exhibiting unsealing, only the intra-pocket region (OR: 4.844, 95% CI: 1.595–14.708) and lead dysfunction (OR: 6.096, 95% CI: 1.386–26.819) retained significance during multivariable analysis. Vitatron's influence approached significance (OR: 2.454, 95% CI: 0.937–6.427). Notably, the intravenous region emerged with the least amount of damage in the context of unsealing (OR: 0.186, 95% CI: 0.044–0.771). Further details are available in Table 3.

Discussion

One of the principal observations of our investigation is the pronounced onset of fatigue wear in endocardial leads. This wear manifests remarkably early, emerging within the initial weeks following the implantation of CIEDs, and is consistently evident across all evaluated leads. The initiation and propagation of lead cracks are not confined to specific locations but extend throughout the entire length of the endocardial lead wherever it interfaces with the valve apparatus, veins, connective tissue, or the device itself. The wear progression initiates with fatigue wear, primarily targeting the lead's insulation. A critical consideration is the insulation's thickness; inadequately robust or excessively thin insulations can precipitate lead unsealing due to cyclic stress. This fatigue wear is instigated by the repeated bending of the pacing lead external insulation layer by the surrounding tissues.^{19–21} Notably, the genesis of initial electrode impairment is localized at the Bielayev's point, a region subjected to maximal stresses. This phenomenon is further accentuated when the lead's surface remains unblemished. Over time, these microscopic fissures have the propensity to amalgamate, culminating in the emergence of a “macro crack”, which can subsequently propagate, resulting in the stratification and disintegration of the polymer insulation.²¹

In our investigation, a statistically significant predominance of damage was discerned within the intra-pocket region, juxtaposed with diminished damage

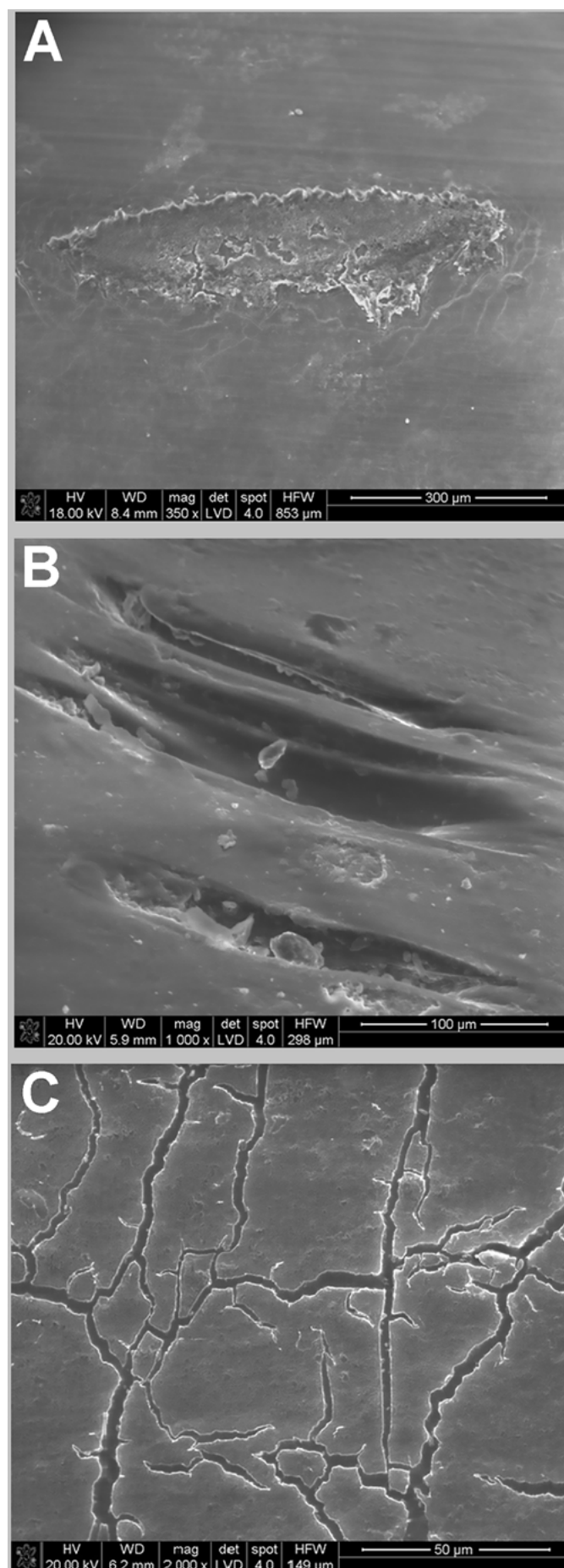


Fig. 2. Scanning electron microscopy (SEM) images. Examples of damage to the lead insulation with the absence of unsealing. Visible polishing of the insulation surface resulting from friction contact. A. Bipolar active-fixation atrial Medtronic CapSureFix Novus lead (lead insulation composed of 2 layers: outer – polyurethane 55D, contacting the surrounding tissues, and inner – silicone, adhering to the metal wire) with a 1-year dwell time in the defibrillator with cardiac resynchronization therapy (CRT-D) device. Indication for removal: dislocation of lead. Destruction at the right atrium level near the entrance to the tricuspid valve; B. Bipolar active-fixation ventricular Biotronik Setrox lead (insulation: only silicone) with a 5-year dwell time in the dual-chamber atrioventricular pacing (DDD) pacemaker device. Indication for removal: lead damage. Destruction at the level of the subclavian region; C. Bipolar active-fixation atrial Biotronik Setrox lead with a 2-year dwell time in the DDD pacemaker device. Indication for removal: pocket infection. Destruction at the level of the intra-pocket region

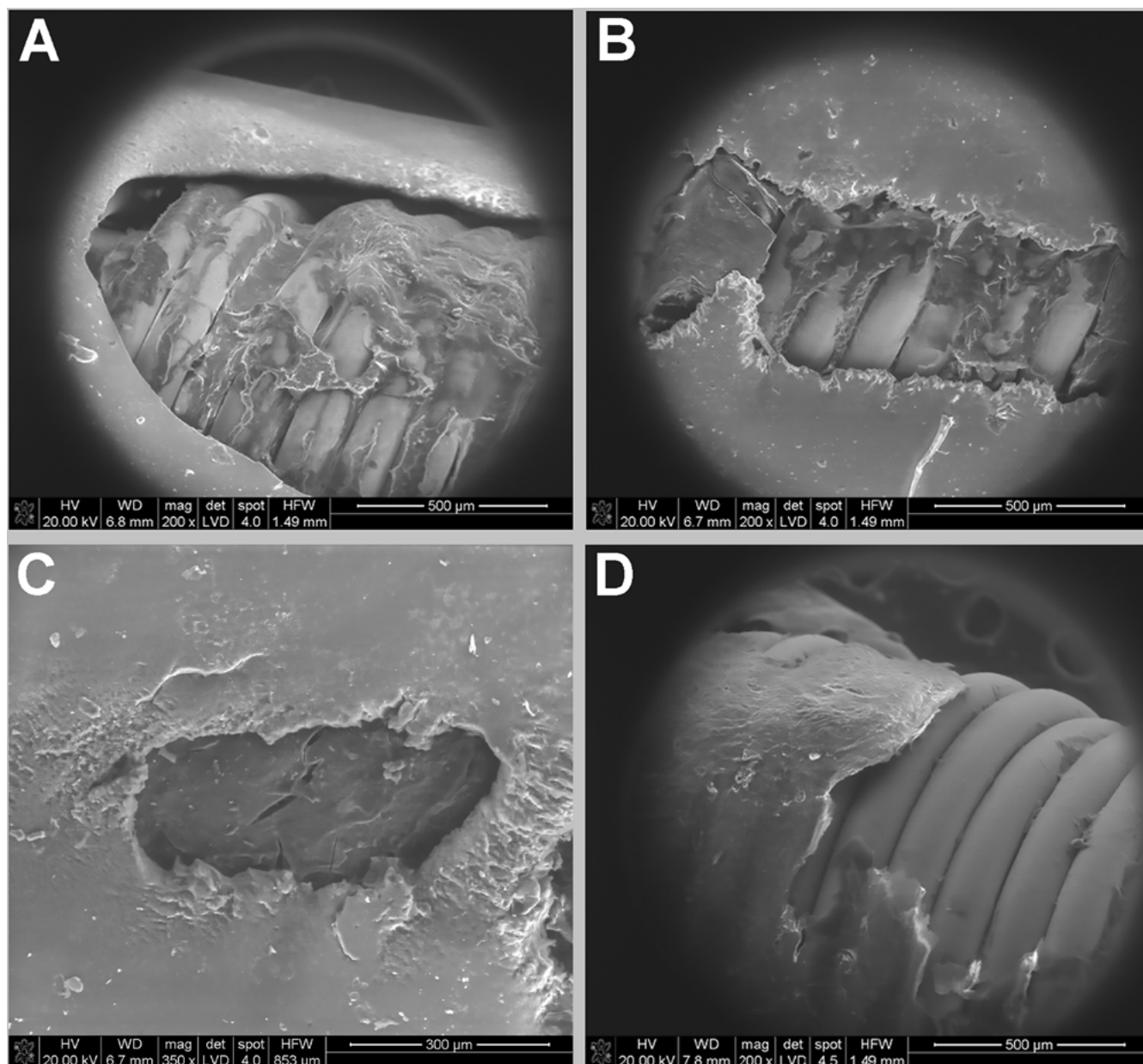


Fig. 3. Scanning electron microscopy (SEM) images. Examples of damage to lead insulation with the presence of unsealing. View of the worn-out lead insulation and silicone shift on the metal wire visible in the abraded opening. A, B. Bipolar active-fixation ventricular Medtronic CapSureFix Novus lead (lead insulation composed of 2 layers: outer – polyurethane 55D, contacting the surrounding tissues, and inner – silicone, adhering to the metal wire) with 4-year dwell time in the dual-chamber atrioventricular pacing (DDD) pacemaker device. Indication for removal: lead-dependent infective endocarditis. Destruction at the level of intra-pocket region (A) and subclavian region (B); C, D. Bipolar active-fixation atrial Biotronik Setrox lead (insulation: only silicone) with 5-year dwell time in the DDD pacemaker device. Indication for removal: lead damage. Destruction at the level of the intra-pocket region

in the intravenous region, irrespective of the presence or absence of lead unsealing. This observation diverges from the findings of Małecka et al., who, in their study of 22 leads spanning an age range of 3–25 years with a mean duration of 8.3 years, reported a proclivity towards increased damage in the intra-cardiac region.³ Similarly, Kolodzinska et al., in their assessment of 212 leads with an age range of 6–276 months and a mean age of 83.6 months, presented contrasting outcomes.¹⁵ The observed disparities might emanate from

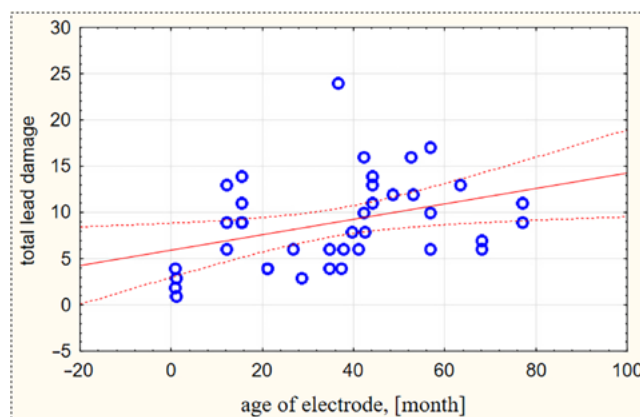


Fig. 4. The amount of lead damage over time; Spearman's R-value 0.3669

Table 3. Predictors of all-cause lead damage

Variable	Univariable				Multivariable			
	OR	95% CI		p-value	OR	95% CI		p-value
Lead damage with the absence of unsealing								
Intracardiac region vs other	0.662	0.319	1.371	0.2673	–	–	–	–
Intravenous region vs other	0.323	0.151	0.694	0.0037	0.465	0.171	1.269	0.1352
Subclavian region vs other	0.760	0.367	1.570	0.4588	–	–	–	–
Intra-pocket region vs other	9.112	3.326	24.960	<0.001	9.740	2.856	33.219	0.0002
ICD/PM leads	1.456	0.336	6.314	0.6160	–	–	–	–
Manufacturer (Biotronik vs other)	0.891	0.457	1.735	0.7334	–	–	–	–
Manufacturer (Medtronic vs other)	0.714	0.378	1.347	0.2985	–	–	–	–
Manufacturer (Vitatron vs other)	2.913	1.002	8.463	0.0494	3.438	1.111	10.641	0.0321
Silicone leads vs other	1.093	0.517	2.312	0.8145	–	–	–	–
Age of electrode (1 month decrease)	1.018	1.002	1.034	0.0236	1.031	1.010	1.054	0.0050
Female sex	1.231	0.637	2.378	0.5367	–	–	–	–
Diabetes mellitus	0.980	1.008	0.537	1.8920	–	–	–	–
BMI (1 kg/m² decrease)	0.999	0.930	1.073	0.9706	–	–	–	–
Age of patient during TLE (1 year decrease)	1.003	0.971	1.035	0.8678	–	–	–	–
Lead dysfunction	1.462	0.767	2.785	0.2471	–	–	–	–
Lead dislocation	0.665	0.259	1.709	0.3961	–	–	–	–
LDIE	0.842	0.299	2.370	0.7449	–	–	–	–
Pocket infection	0.813	0.396	1.669	0.5718	–	–	–	–
Lead damage with the presence of unsealing								
Intracardiac region vs other	0.492	0.198	1.219	0.1256	–	–	–	–
Intravenous region vs other	0.160	0.046	0.553	0.0038	0.186	0.044	0.771	0.0204
Subclavian region vs other	1.043	0.465	2.339	0.9176	–	–	–	–
Intra-pocket region vs other	5.915	2.685	13.030	<0.001	4.844	1.595	14.708	0.0050
ICD/PM leads	1.620	0.370	7.093	0.5219	–	–	–	–
Manufacturer (Biotronik vs other)	0.706	0.327	1.526	0.3763	–	–	–	–
Manufacturer (Medtronic vs other)	0.861	0.426	1.741	0.6784	–	–	–	–
Manufacturer (Vitatron vs other)	2.454	0.937	6.427	0.0675	2.088	0.671	6.500	0.2040
Silicone leads vs other	0.843	0.359	1.977	0.6948	–	–	–	–
Age of electrode (1 month decrease)	1.019	1.002	1.037	0.0290	1.027	0.987	1.068	0.1895
Female sex	0.941	0.451	1.962	0.8707	–	–	–	–
Diabetes mellitus	1.145	0.567	2.311	0.7064	–	–	–	–
BMI (1 kg/m² decrease)	0.949	0.877	1.028	0.2015	–	–	–	–
Age of patient during TLE (1 year decrease)	0.998	0.964	1.035	0.9329	–	–	–	–
Lead dysfunction	2.305	1.128	4.711	0.0220	6.096	1.386	26.819	0.0170
Lead dislocation	0.665	0.259	1.709	0.9972	–	–	–	–
LDIE	0.577	0.156	2.134	0.4098	–	–	–	–
Pocket infection	1.380	0.632	3.015	0.4189	–	–	–	–

95% CI – 95% confidence interval; ICD – implantable cardioverter-defibrillator; OR – odds ratio; PM – pacemaker; TLE – transvenous lead extraction; LDIE – lead-dependent infective endocarditis; BMI – body mass index.

the inclusion of leads extracted using mechanical methodologies, variances in electrode regional categorization, or extended lead dwell times.

Furthermore, a salient observation from our investigation underscores the statistically significant correlation

between prolonged dwell times of endocardial leads and associated damage, regardless of the presence of lead unsealing. This finding aligns harmoniously with extant literature emphasizing the implications of extended lead duration on their overall performance.²²

Limitations

While our investigation provides critical insights into the fatigue wear of endocardial leads, several limitations warrant acknowledgment. Primarily, the modest sample size may restrict the broader applicability of our results. Additionally, our study's focus on leads extracted using gentle traction and screw-out techniques potentially excluded cases with iatrogenic lead damage, limiting the comprehensiveness of our findings. Furthermore, the predominant inclusion of dual-chamber systems in our cohort diminishes our ability to definitively assess the impact of lead number variations on damage outcomes. A more diverse representation, particularly of single-chamber pacemakers and defibrillator with cardiac resynchronization therapy (CRT-D) systems, would have provided a more comprehensive perspective on this subject.

Conclusions

The endocardial leads exhibited greater susceptibility to insulation damage in the intra-pocket region than in the intravenous segment, irrespective of lead unsealing. Extended lead dwell time and the utilization of Vitatron leads were identified as key predictors of damage, regardless of lead seal status. There is a critical need for ongoing monitoring and re-evaluation of lead designs and materials to bolster their durability and safety in clinical applications.

Data availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

ORCID iDs

Mateusz Ulman  <https://orcid.org/0009-0007-2709-9302>
 Krzysztof Boczar  <https://orcid.org/0000-0002-1833-2404>
 Katarzyna Holcman  <https://orcid.org/0000-0002-6895-4076>
 Magdalena Ziabka  <https://orcid.org/0000-0003-0702-7137>
 Maciej Dębski  <https://orcid.org/0000-0002-3669-3916>
 Jacek Lelakowski  <https://orcid.org/0000-0003-0301-8946>
 Andrzej Ząbek  <https://orcid.org/0000-0001-8331-3210>

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