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Lead insulation failure, a serious complication: risk factors and management

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INTRODUCTION

Endocardial leads are the most important parts of cardiovascular implantable electronic device systems. The endocardial lead parts are located in the tissue of the pocket, in the venous system, and finally in the right heart cavities. The three different microenvironments present different impacts on lead body parts, especially the outermost insulation. Lead design also concerns the outer insulation, which has been evaluated since implantation of the first pacemaker. In the current paper we present the different mechanisms of insulation failure of the leads available on the market, and of leads that have been withdrawn from the market but still exist in living patients.

The outer lead insulation may dictate the lead reliability. Silicone, polyurethane, fluoropolymers (PTFE, ETFE), and co-polymer silicone-polyurethane (Optim) are materials widely used as insulation of endocardial leads. Insulation breach and abrasions may occur anywhere along the lead. The lead parameters: abnormal sensing amplitudes, abnormal and variant pacing thresholds, and lead impedance abnormalities may be indicators of lead failure. The insulation characteristics of typical damage, lead failure symptoms, and lead management are crucial for patients, theirs doctors, scientists, and manufacturers.

SILICONE INSULATION OF ENDOCARDIAL LEADS: THE LONGEST EXPERIENCE

Silicone insulation has been used for more than 50 years. In spite of some disadvantages silicone is still present on the market. The main disadvantages include the fact that silicone tears, abrades, and cuts easily, is characterised by high friction in blood, and is more thrombogenic. Among its advantages doctors specify flexibility and excellent biostability [1].

"OUTSIDE-IN" ABRASIONS: A NEW PHENOMENA — MORE QUESTIONS THAN ANSWERS

We may divide abrasions according to mechanism into "outside-in" and "inside-out" abrasions. The "outside-in" abrasions are well known in the pocket as the result of friction between leads or between the lead and the device, as well as in the venous system, with tearing surfaces among leads, first rib, and clavicle. However, "outside-in" abrasions most frequently appear in the intracardiac part of the lead and are associated with infective endocarditis (IE) [2]. The outer insulation abrasion remains electrically signless unless concomitant inner insulation failure occurs and in the device control both oversensing and undersensing may be observed [3]. The Banacha classification was established to morphologically describe abrasions analysed with an optical microscope, and to facilitate comparison and analysis. The classification distinguishes three levels of silicone *in vivo* damage: mild, moderate, and severe, all in two subtypes: a and b [2]. A severe abrasion with conductor exposure may be assessed clinically (Fig. 1A) [4]. Insulation abrasion more often concerned patients with sub-pectorally or abdominally implanted devices. Risk factors of intracardiac abrasions are implantation of two or more leads in the heart cavities, and in the case of atrial leads: passive fixation, longer mean dwell time (time from implantation), and three or more procedures proceeding lead extraction [2]. Severe abrasions with conductor exposure were associated with the number of extracted leads, dwell time, location of the lead in the coronary sinus, and excessive lead length in the cardiac chambers [4]. The most important observation was that, irrespective of the abrasion level of degradation in the intracardiac part of the lead, they were associated with IE development [2]. The process of outside-in abrasion may be

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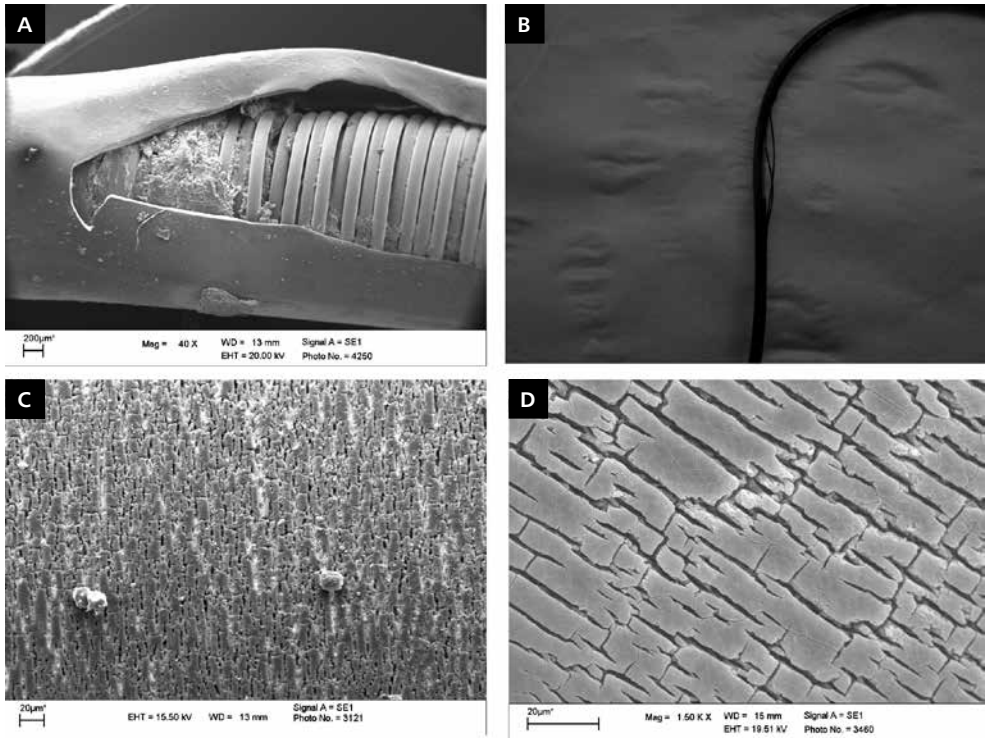

Figure 1. **A**. "Outside-in" abrasion, severe type 3a, with conductor exposure; the lead transvenously removed because of infective endocarditis; **B**. "Inside-out" abrasion, typical cables extrusion due to their relative motion; the lead transvenously removed because of its electrical dysfunction; **C**. Optim insulation failure probably due to environmental stress cracking strengthened by *in vivo* mechanical damage in a 71-year-old patient who underwent lead extraction due to infective endocarditis; **D**. Outer polyurethane lead overlay damage due to environmental stress cracking; lead removed due to its electrical dysfunction

aggravated by macrophages and pathogens: in *in vitro* experiments macrophages and *Staphylococcus* (*S.*) *aureus* strains separately and especially in the co-cultures initiated silicone biodegradation. *S. aureus* strains presented different biodegradation potential [5]. Anderson [6] described the sequence of host reactions following implantation of medical devices that cover the following: injury, blood-material interaction, provisional matrix formation, acute inflammation, chronic inflammation, granulation tissue, foreign body reaction, and fibrosis/fibrous capsule development. *In vivo* mechanical work and interaction among leads, aggravated by cell/tissue response to injury and foreign body reactions, seems to be strategic for the longevity not only of silicone leads [7]. Future studies need to evaluate the population of patients at highest risk of outer silicone lead insulation abrasion. The new diagnostic method for *in vivo* abrasion evaluation may prevent IE development. Nowadays the first symptom of abrasion is cardiovascular implantable electronic device IE (CIED-IE). Management of CIED-IE according to the guidelines involve complete hardware removal [8]. Sometimes in older patients with a wide range of comorbidities conservative therapy may be taken into consideration; however, its efficiency in the light of abrasion-related knowledge seems to be questionable.

"INSIDE-OUT" ABRASIONS: A RELATIVELY NEW PHENOMENON — MORE ANSWERS, NEW QUESTIONS

Lead insulation failure in the mechanism of inside-out abrasions (Fig. 1B) because of relative movements of conductor cables in the multi-lumen silicone implantable cardioverter-defibrillator (ICD) leads with secondary conductor cables externalisation has been described for St. Jude Medical Riata leads. Riata leads were available for eight years and were finally withdrawn from the market by the manufacturer in 2010, followed by a class I recall by the United States Food and Drug Administration (FDA) in December 2011 (Medical SJ Medical device advisory). The inside-out abrasion may concern electrically active cables or filler cables [9]. The incidence of insulation damage reaches from 0.21% to 27.4% [10]. Steinberg et al. [11] indicated that the incidence of insulation breach in Riata leads is much higher than quoted by the manufacturer or reported by most of the literature, with a total frequency of 24.3% when systematic use of postero-anterior (PA) and lateral chest X-ray (CXR) with magnification up to factor 7.5 was applied in 284 unselected living patients. Abnormalities were more common in 8 F leads, concerned more often 1582 single-coil (41.2%) and 1580 dual-coil (31.4%) models, with longer dwell time (6.7 vs. 5.9 years) and higher pacing

thresholds (1.1 ± 0.8 V vs. 0.9 ± 0.4 V) followed by noise [11]. Systematic fluoroscopic screening also was conducted for active Riata ICD leads in 31 centres in the Netherlands, with concomitant device interrogation to assess the electrical integrity of the lead. The study revealed 147/1029 (14.3%) externalised conductors with abnormal electrical parameters (abnormal impedance) in just 10.9% of cases. The rates of externalised conductors were 6.9% (95% CI 5.3–8.9%) and 36.6% (95% CI 30.6–43.4%) at five and eight years after implantation, respectively. 77% of insulation defects were located near the annulus of the tricuspid valve [12]. Steinberg et al. [11] showed that the total radiation dose of a standard PA and lateral CXR in theirs centre is 0.09 milliSievert (mSv), three-view fluoroscopy (PA, right-anterior and left-anterior oblique 20–45°) at 15 Fr/s and 15 cm magnification 0.23 mSv, and a cine fluoroscopy generating a 2–3-fold higher dose indicated the method as effective and safe. However, even cine-fluoroscopy may underestimate the number and extent of cable extrusions [10]. Plain chest radiographs are not sensitive for detecting cable externalisation.

Liu et al. [13] also indicated 8 Fr Riata lead as more prone to failure. Theuns et al. [12] presented that the proportion of externalised conductors was higher in 8-F Riata compared with 7-F Riata ST (21.4% vs. 8.0%, $p < 0.001$). Moorman et al. [14] analysed a patient population with a larger proportion of 7-F Riata ST leads that were all dual coiled. Cable externalisation was observed in 10/48 patients (21%), and an additional five (10%) had abnormal cable spacing; all showed normal electrical parameters. Patients with lead failure had more implanted leads *in situ* (2.5 ± 0.7 vs. 1.6 ± 0.8 leads, $p = 0.002$) and a higher rate of non-ischaemic cardiomyopathy (80% vs. 24%, $p = 0.03$). The authors did not recommend routine lead replacement but rather watchful waiting; all patients with Riata and Riata ST lead were placed on home monitoring, and programming changes were made as recommended by the company [14].

The obvious consequences of lead damage are inappropriate shocks and failure of therapy delivery in case of electrically active cables while extrusion of filler cables is totally electrically silent [9]. Lakshmanadoss et al. [15] presented two cases where the ICD failed to deliver shock therapy due to Riata lead failure near the can with no abnormalities on interrogation and intact fluoroscopy. The authors indicated that insulation breach near the generator may be difficult to identify, especially without electrical and fluoroscopic abnormalities, and so all Riata leads should have defibrillation threshold testing (DFT) at the time of pulse generator replacement [15].

Electrical dysfunction of the low-voltage circuts could lead to oversensing, inappropriate shock, and loss of capture. High-voltage circuit failure could lead to short circuit with failure to defibrillate. On the other hand, an externalised conductor may mechanically irritate the endocardium provoking ventricular tachyarrhythmias [12]. Ricciardi et al. [16] presented the thrombotic abilities of externalised cables in a 67-year-old man with Riata lead model 7020. Device dysfunction seems to be related to underestimated complication and diseases. Riata leads may have multiple defects along lead body, and externalised cables may be the one manifestation of interior insulation damage [17]. Externalised conductors more frequently concern patients with a higher left ventricular ejection fraction (47 ± 13% vs. 33 ± 12%, $p = 0.04$) and progressive decrease (≥ 30% of the initial value) in amplitude of ventricular electrogram (9/12 [75%] vs. 4/24 [17%], $p = 0.03$) [18]. Shen et al. [10] established predictors of lead extrusion that included longer time from defibrillator lead implantation, and multiple right ventricular leads. The possible role of "outside-in" abrasion as a consequence of lead-lead interaction in cables externalisation was indicated.

Any Riata and Riata ST lead advisory concerning lead extraction or replacement should be considered carefully, especially bearing in mind the results of analysis of the Accufix (Teletronics) lead advisory that resulted in a higher complication rate when leads were extracted in comparison to ones left in place [19]. The FDA does not recommend replacement of leads with externalised cables, but states that the decision should be individualised based upon patient history and the severity of the fluoroscopic abnormality. Thrombogenic properties of externalised conductors increase the range of possible complications. Leaky insulation creates the perfect location for biofilm formation, which raises the question of the risk of late CIED infective complications. The possibility of non-arrhythmic consequences of cable externalisation makes decision making difficult in elderly patients with multiple co-morbidities, and shows home monitoring as an insufficient method. The extraction procedure in cases with looped extruding cables may be difficult. Rubenstein et al. [9] presented a technique allowing safe extraction of the leads.

In summary, patients with Riata and Riata ST leads should be identified, and watchfully controlled, preferably with home monitoring. Cine monitoring seems to be relatively safe and efficient in finding patients with silent "inside-out" abrasions. All leads with electrical dysfunction should be carefully qualified to transvenous lead removal. The decision to remove a lead should be based on the individual patient and the physician's experience. The lead extraction procedure carries significant risk of injury or even death, especially in the case of leads with long dwell time. Prophylactic lead extraction may be considered during generator exchange in patients at highest risk. New lead implantation and abandoning a damaged ICD lead is feasible but poses a high risk of complications. All extraction procedures in cases of failed leads should be preceded by transoesophageal echocardiography because of the risk of thromboembolic events due to lead-attached thrombus. Generator exchange should be followed by DFT.

OPTIM INSULATION — A NEW HOPE

Optim™, also known as SJM SPC™, is a silicone-polyurethane copolymer approved by the FDA as an overlay for Riata ST™ Optim and Durata St. Jude Medical (Sylmar, CA, USA) ICD leads in 2006 and 2007, respectively. It was developed by AorTech International, Inc. (Rogers, MN, USA). It is a thin (0.09 mm) overlay that covers the lead silicone body except for the part beneath the shocking coils. Optim is 50 times more abrasion-resistant than silicone with > 2,500,000 cycles to failure in comparison to > 125,000 cycles to failure high-performance silicone, on a custom bench test, with superior tear and tensile strengths [20]. Optim also revealed significantly more biostable than Pellethane 55D and Pellethane 80A in animal tests. Optim insulated leads are available worldwide and more than 300,000 have been released onto the market. Systematic fluoroscopic review of Optim coated leads revealed normal appearance in all 234 patients (413 leads) [21]. Reports from different medical centres have been optimistic. Cairns et al. [22] analysed a population of 10,835 patients with 11,016 Optim insulated leads that were included into three prospective registries: Optimum, Score, and SJ4. There were reported 51 mechanical failures during the median follow-up of 3.2 years. Freedom from conductor fracture was identified in 99.4% and from all-cause abrasion in 99.8% of leads [22]. Wilkoff et al. [23] analysed over 96,000 Optim high-voltage leads and 138,000 silicone ICD leads, and presented a significant reduction of full-thickness abrasion-related failures at 44 months post implant — no cases of externalised conductors were noticed. The first acknowledgement of Optim insulated leads from 2008 concerned 1093 ICD leads observed for 22 months without insulation failure or conductor externalisation [24]. Hauser et al. [25] searched the FDA's Manufacturers and User Device Experience (MAUDE) for Optim insulated lead abrasion and found 52 reports documenting that Optim does not prevent insulation abrasions developing as a result of friction with an ICD can or another device. In Riata ST Optim the dwell time was 29.1 ± 11.7 months, and 15 abrasions were observed (can abrasion, abrasion as the result of friction with another device, outer and inner insulation abrasion). Durata lead dwell time was 22.2 ± 10.6 months, and 37 of them presented features of abrasion [25]. Riata ST Optim model 7070 showed evidence of conductor externalisation proximal to a distal coil over 1 cm length but in the silicone-insulated segment of the lead, visible in chest X-ray [26]. We presented the Optim insulation failure in the mechanism of abrasion, silicone biodegradation, and environmental stress cracking in the intracardiac, intravenous, and pocket part of the leads. The abnormalities were observed simultaneously in the same lead, and insulation failures were most frequently observed in the intracardiac part of the leads (Fig. 1C) [27]. Wilkoff et al. [28] compared Optim insulated, Pellethane 55D, and silicone elastomers from cardiac leads that were implanted for up to five years. Surface cracking was not observed in Optim and silicone probes but was seen in 41% of Pellethane 55D leads. Optim molecular weight and tensile strength were decreased modestly (~20% and 25%, respectively) at two–three years. In the study the intracardiac parts of the leads were not analysed [28]. Bennett et al. [29] presented the Canadian experience with Durata and Riata ST Optim ICD leads; the annual rate of lead failure was 0.24% and 0.27%/year, respectively, without instances of conductor externalisation, and two patients experienced inappropriate shocks because of lead failure. Similarly systematic fluoroscopic and electrical assessment of Optim insulated leads (both ICD and low-voltage leads) did not revealed any structural defects after an average of 31 months post-implant in high-resolution cine-fluoroscopy. There were seven Optim coated lead failures due to electrical malfunction (threshold changes, inadequate sensing, pacing and impedance abnormalities) resulting in lead replacement [21]. In an *in vitro* study Chafflin et al. [30] tested long-term performance of a polyurethane polymer after immersion in buffered water for up to 52 weeks at temperatures ranging from 37°C to 85°C. A reduction of the molecular mass and degradation of the ultimate tensile properties were observed, suggesting that polymer might not be reliable in the long term. An additional study revealed that reduction in molar mass also was associated with a reduction in the abrasion and fatigue resistance [31].

Optim abrasion may develop less than four years after implantation, a fact which made us aware that ideal lead insulation still constitutes a challenge, as well as the fact that more data are needed to single out patients in danger of device related complications.

POLYURETHANE OVERLAID LEAD FAILURE: A WELL KNOWN PHENOMENON

A polyurethane (PEU) outer coating covering a silicone core was used in Sprint Fidelis (SF) leads (Medtronic Corporation, Minneapolis, MN, USA) from 2004 until October 2007, when lead was withdrawn from the market due to reports of elevated failure rates and the subsequent death of five patients [32]. Insulation failure and conductor fracture are indicated as a cause of lead failure and lead dependent late complications. The outer insulation damage with deep cracks and insulation breaches occurs in the mechanism of environmental stress cracking at the interface between the polymer and host phagocytic cells. The degradation requires mechanical or endogenous stress on the material and contact with adherent phagocytic cells [33, 34]. In an *in vitro* study exposure of the PEU to activated human neutrophils, hypochlorous acid, and peroxynitrate led to polymer structure modification and marked reduction in molecular weight due to oxidation of the urethane-aliphatic ester and aliphatic ether groups with morphology similar to that observed *in vivo* (Fig. 1D) [35]. On the other hand, PEU cannot be significantly degraded by phagocytic cell products like cationic proteins,

proteases, superoxide, or hydrogen peroxide [33]. However, a large number of neutrophils convert substantial amounts of hydrogen peroxide to the more potent oxidant, hypochlorous acid, a likely cause of PEU *in vivo* degradation [35, 36].

In coaxial bipolar pacemaker leads with PEU inner and outer insulation, as well as environmental stress cracking degradation developing in direct contact with tissue, metal ion oxidation (MIO) was observed. The MIO is a mechanism of PEU degradation in direct contact with metal ions from conductor coils that interact with hydrogen peroxide (a product of inflammatory cells) that permeate through the outer insulation. MIO concerns both the inner surface of the outer insulation, and generally the outer and inner surfaces of the inner insulation. Wiggins et al. [37] analysed bipolar coaxial pacemaker leads composed of a silicone outer and a PEU inner insulation, explanted because of clinical evidence of electrical dysfunction. Physical damage was observed in five leads with different levels of degradation from shallow pitting and slight discolouration to significant discolouration and complete loss of integrity of the insulation. There was also a strong correlation between physical damage and chemical degradation. Intact outer silicone insulation led to the hypothesis that inner insulation degradation is caused by permeation of extracellular hydrogen peroxide from outside the lead body through the silicone insulation. Inhomogeneous PEU degradation results from a high concentration of hydrogen peroxide from local cellular activity and depends on the type and density of encapsulating lead tissue [37].

Polyether polyurethane elastomers offer superior mechanical properties and are biocompatible, so, despite the fact that they are not biostable, they have not been abandoned, because of progress in understanding and controlling their degradation mechanisms. Clinical studies have evaluated the risk factors of lead damage, lead failure presentation, and proposed management.

Girerd et al. [38], among 269 SF leads, observed 33 (12.3%) lead failures with five-year survival of 65.6 ± 7.5%; age was indicated as single predictor of lead damage. Patients with median age < 62.5 years had significantly higher risk of lead failure, and the annual incidence of lead failure was 11.6 ± 4.9% during the fourth year and 22.9 ± 13.2% during the fifth year after implantation [38]. The estimated five-year lead survival was low and few other reports showed that the risk of SF continuously decreased with time [39, 40]. Morrison et al. [41] documented 18 SF, and six Sprint Quattro fractures in an analysis of 1314 patients indicated that patients < 50 years old are at increased risk of lead failure compared to those > 50 years old. In the studies by Hauser et al. [42] younger age was also mentioned as a variable that predisposed to lead failure. Higher or preserved left ventricular ejection fraction, female gender, non-cephalic venous access, a generator exchange (in 60% of cases within three months), biventricular defibrillator, and previous lead failure were also associated with Medtronic ICD lead failure [40, 42–47]. Arias et al. [43] reported a lead survival of 96.15% at 36 months. Researchers also presented the procedure-related risk factor of insulation damage [43]. Electrocautery is routinely used during cardiac device implantation and pulse generator replacement for local haemostasis or tissue dissection. Transvenous endocardial leads insulated with PU55D are extremely vulnerable to damage, and the copolymer of polyurethane and silicone is not resistant to thermal damage by cautery-cut mode [48]. Most commonly the lead failure is related to electrical findings during a device check/control visit, and it is usually defined as an increase or decrease in lead impedance, decrease in signal amplitude, or frequent short sensed intervals. Sometimes the X-ray presents morphology of pace-sense or high voltage conductor fracture. Lead failure rarely relates to an insulation defect in clinical research. The basic cause of lead damage in most reported series is unknown. The population in danger of adverse events related to lead failure is characterised only according to a symptomatic key.

MEDTRONIC LEAD MANAGEMENT

Prophylactic lead replacement with or without lead extraction was not recommended in 2007 by an independent physician quality panel from Medtronic due to the high rate of procedural complications [32]. Parkash et al. [49] indicated that lead replacement in favour of prevention of adverse events associated with an SF malfunction can be carried out, but that it is associated with a high complication rate (14.5%). The risk in patients with lead removal was 19.8% vs. 8.6% when compared to those with abandoned leads. However, Girerd et al. [38] indicated that sufficient data supporting the fact that lead failure is more common in young patients led to the conviction that prophylactic a new lead placement at the time of generator replacement should be recommended. Nonetheless, other studies should determine if damaged leads should be abandoned or explanted. The lead replacement may be considered in patients with Fidelis leads who are pacemaker-dependent, of young age (< 50 years old), physically active, and have preserved ejection fractions or secondary prevention indications for defibrillator therapy [41]. Kalahasty and Ellenbogen [50] presented short- and long-term management of ICD lead failure. Inappropriate shocks require immediate device interrogation and reprogramming. A donut magnet placed directly over the device secured to the skin by type, disable detection but not alter the bradycardia pacing. In most cases of lead failure a new lead needs to be implanted. In older patients, patients with multiple comorbidities, and patients for whom lead extraction is prohibitively high risk a new pace/sense lead alone can be added if there is an isolated fracture of the ring electrode conductor. Implantation of a new ICD lead, abandoning the previously failed lead, may be considered. However, an increased number of leads in the heart poses the risk of complication related

to lead-lead and lead-tissue interaction, also the complexity and risks of lead extraction would be higher. To decrease the risk of inappropriate shocks the lead-integrity algorithm, downloadable RAMware, was designed (Medtronic Inc.). It uses a combination of changes in lead impedances and short V-V intervals. Decisions concerning Fidelis lead extraction must be made on a case-by-case basis [50].

FUTURE DIRECTIONS

The perfect lead is still our aim. Aurichio et al. [51] showed that a leadless endocardial ultrasound-based cardiac stimulation pacing system may be safely applied and effective. The WiCS®-LV system (EBR Systems Inc.) converts ultrasound energy to electrical energy and may be added to an existing pacing or ICD system. The WiCS®-LV system may be helpful in patients qualified as non-responders, or for whom implantation of a third lead is challenging due to a lack of vessel potency with risk of mechanical trauma to the pre-existing leads or when the existing left ventricle lead develops exit block. Reddy et al. [52] presented a novel leadless cardiac pacemaker that was designed to be implanted to the right ventricle and function in a VVIR capacity with a battery life of around eight years. A leadless cardiac pacemaker was implanted via femoral venous access through an 18 Fr sheath under X-ray guidance, which may be repositioned when necessary. Pre-clinical studies with implanted defibrillator leads have also demonstrated the capability for the technology to evolve to include: dual chamber, cardiac resynchronisation therapy, and bi-ventricular pacing.

All insulation materials present advantages and disadvantages when applied for cardiovascular usage. Investigators are searching for a new, more reliable insulation material, but maybe the future is in electrodes wirelessly connected to the device since the present leads are intended to survive in an extremely unfriendly environment-human organism.

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