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Corrosion in Pacemakers: Mechanisms, Implications and Advances in Prevention

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Abstract - Corrosion of pacemaker and its leads presents a significant concern in cardiac device management, potentially leading to device malfunction and patient harm. This paper reviews the current understanding of corrosion mechanisms in pacemaker leads, including the effects of physiological conditions, material properties, and environmental factors. Various prevention techniques for corrosion and types of corrosion resistant pacemakers are discussed, along with emerging technologies and types of pacemakers. The metals/alloys suitable for pacemakers are also noted. By addressing these issues, researchers and clinicians can improve the reliability and longevity of pacemaker leads, enhancing patient safety and device performance.

Key Words: pacemaker leads, corrosion, prevention techniques, mitigation strategies

1.INTRODUCTION

Pacemakers are small devices implanted in the chest to regulate abnormal heart rhythms. They consist of a generator and lead connecting to the heart. By monitoring the heart's electrical activity, they deliver electrical impulses to maintain a normal heartbeat. Pacemakers treat conditions like bradycardia, heart block, and certain arrhythmias. Corrosion of pacemakers, primarily due to exposure to bodily fluids and the metallic components within the device, can lead to serious health risks. Over time, corrosion may compromise the structural integrity of the pacemaker, potentially causing malfunction or failure. This poses significant risks to patients reliant on these devices for maintaining proper heart function. In some cases, corrosion can result in device breakage or release of toxic materials into the body, leading to inflammation, tissue damage, or even systemic complications. Therefore, ensuring the materials used in pacemakers are resistant to corrosion and regularly monitoring patients for signs of device degradation are crucial steps in minimizing these risks and safeguarding patient health.

2. Pacemaker Corrosion: Mechanisms, Risks and Real-world Implications

Lead pacemakers, with their pulse generators and leads, have long been the standard for cardiac rhythm management, offering reliability but carrying risks like lead-related complications. In contrast, leadless pacemakers, implanted directly into the heart, provide a minimally invasive alternative with reduced risk of complications. While traditional pacemakers offer proven versatility, leadless pacemakers signify a promising shift towards innovative, less invasive cardiac care.

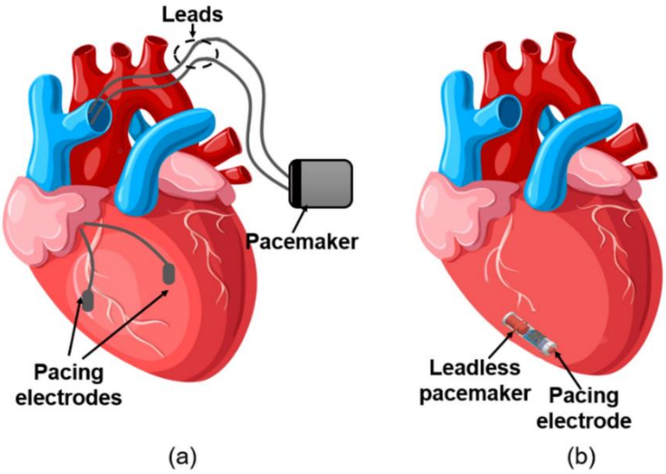

Fig -1: Schematic of the conventional pacemaker vs leadless cardiac Trans catheter Pacing (TCP) system (a) conventional pacemaker with pacing leads (b) leadless cardiac TCP implanted inside human heart with pacing electrode at the tip.

Lead Pacemakers:

1. Conventional pacemakers consist of a pulse generator and one or more leads (wires).
2. The pulse generator is typically implanted beneath the skin near the collarbone, while the leads are threaded through a vein into the heart.
3. These leads transmit electrical impulses from the pulse generator to regulate the heartbeat.

4. However, they can be prone to issues such as displacement, breakage, or infection.
5. Moreover, the extended use of traditional pacemakers can lead to corrosion of the leads over time, potentially compromising the device's effectiveness and leading to malfunctions.

Leadless Pacemakers:

1. Leadless pacemakers, on the other hand, are compact devices that eliminate the need for leads.

2. They are implanted directly into the heart through a minimally invasive procedure involving a catheter inserted into a groin vein.
3. This design reduces the risk of complications associated with leads.
4. Leadless pacemakers are particularly suitable for patients requiring single-chamber pacing.

In summary, while traditional pacemakers have been a mainstay, they are not without drawbacks, including the potential for lead corrosion over time. Leadless pacemakers offer a promising alternative, especially for patients at higher risk of lead-related complications.

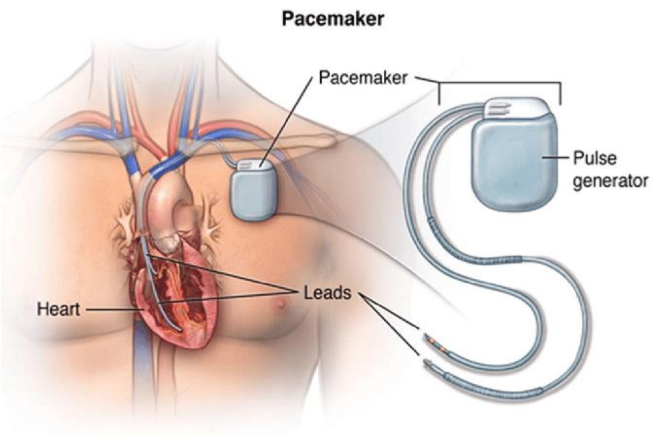

Fig -2: Pacemaker

2.1 Critical Components Prone to Corrosion in Pacemakers

There are several parts of a pacemaker that can potentially undergo corrosion due to exposure to bodily fluids and the harsh environment inside the human body. These include:

1. Pacemaker casing/housing: The outer casing or housing of the pacemaker, typically made of titanium or titanium alloys, is likely to go under corrosion if the protective oxide layer is compromised or if the casing is not hermetically sealed.

2. Electrodes: The electrodes, responsible for delivering electrical impulses to the heart, are made of conductive metals like platinum, platinum-iridium alloys, or other metal of group 8. These electrodes can undergo corrosion due to electrochemical reactions and exposure to bodily fluids.

3. Leads: Pivotal part of Pacemaker is leading the wires that connect the pacemaker to the electrodes in the heart. They are often made of metals like MP35N (a nickel-cobalt alloy), stainless steel, or other alloys. The leads can corrode due to galvanic corrosion, crevice corrosion, or pitting corrosion, especially at the junction between different materials.

4. Feedthroughs: Feedthroughs are the hermetic seals that allow the leads to pass through the pacemaker casing while maintaining a tight seal. If the feedthroughs are not properly sealed or if the insulating materials degrade, corrosion can occur at these sites.

5. Batteries: Some types of batteries used in pacemakers, such as lithium-iodide batteries, can undergo corrosion if the electrolyte leaks or oozes out or if the battery casing is not properly manufactured.

6. Interconnects and circuit boards: The metallic interconnects, circuit boards, and other electronic components inside the pacemaker can corrode if bodily fluids or moisture penetrate the casing.
Therefore, corrosion resistance is a critical factor in the design and material selection of pacemakers to ensure their longevity and reliable performance.

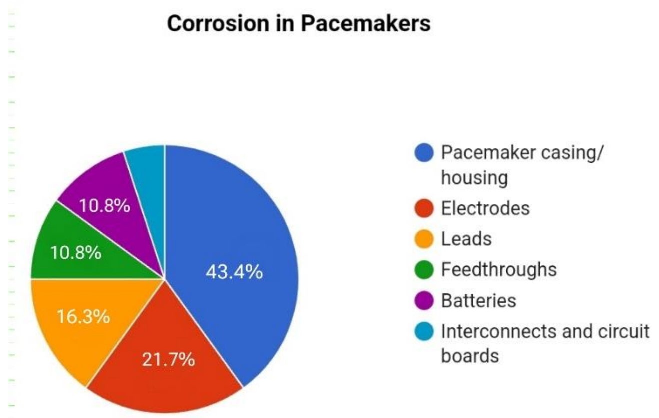

Fig-3 : Percentage Contribution of Corrosion Factors in Pacemakers

2.2 Mechanism of Corrosion in Pacemakers:

Electrochemical corrosion, galvanic corrosion, and pitting corrosion are common challenges in pacemaker longevity. These processes, driven by reactions between metallic components and bodily fluids, can compromise device integrity. Environmental factors such as pH, temperature, and ion concentration further influence corrosion rates. Managing these phenomena is vital for extending pacemaker lifespan and ensuring patient safety.

1. Electrochemical corrosion: The electrochemical reactions between the metallic components of the pacemaker and the surrounding body fluids can lead to the formation of oxide layers, metal dissolution, and pitting corrosion.
2. Galvanic corrosion: When dissimilar metals are in contact within the pacemaker system, a galvanic cell is formed, accelerating corrosion of the less noble metal.
3. Pitting corrosion: Pitting corrosion creates small holes in metals due to local passive film breakdown by aggressive ions like chlorides.

Apart from these, there are other factors that can lead to corrosion of pacemakers,
Corrosion of pacemakers after implantation can occur due to various environmental factors, including:

1.Moisture: Exposure to moisture can accelerate the rate of corrosion of the metallic components and alloys used in pacemakers. Sweat, condensation, or immersion in water can lead to corrosion over time.
2.Chemicals: Direct or indirect contact with chemicals, such as those found in cleaning agents, body fluids, or medications, can cause corrosion of pacemaker materials. Some chemicals may react with the metallic surfaces, thereby leading to degradation.
3.Temperature: Extreme temperatures, especially high temperatures, can promote corrosion of pacemakers. Heat can accelerate chemical reactions, leading to increased corrosion rates in hearts.
4.Electric and Magnetic Fields: Exposure to strong electric or magnetic fields, such as those from electrical appliances, power lines, or medical imaging devices like MRI machines, can induce currents in the pacemaker leads or casing, potentially leading to corrosion and thereby degradation.
5.Biological Environment: The body's biological environment can also contribute to corrosion. Factors such as pH levels, presence of electrolytes, and immune responses that is Antigen-Antibody reactions can influence corrosion rates.

Overall, proper device selection, implantation techniques, and post-implantation care are essential to minimize the impact of environmental factors on pacemaker corrosion and ensure the longevity and effectiveness of the device.

2.3 Consequences of Corrosion:

Corrosion in pacemakers triggers several critical issues. It accelerates battery depletion, compromises lead integrity, leading to pacing failures, and can cause electromagnetic interference, risking device malfunctions. Moreover, corrosion products may incite biocompatibility issues, eliciting inflammatory responses or tissue toxicity. Addressing these concerns is crucial to ensure pacemaker longevity and patient safety.
1. Premature battery depletion: Corrosion can lead to increased self-discharge of the battery, reducing the pacemaker's lifespan.
2. Lead fracture or insulation breach: Corrosion of the lead components can cause mechanical failure, resulting in loss of pacing or sensing capabilities.
3. Electromagnetic interference: Corrosion products can alter the electrical properties of the pacemaker system, leading to electromagnetic interference and potential malfunctions.
4. Biocompatibility issues: The release of corrosion products can trigger inflammatory responses or toxicity in surrounding tissues.

2.4 Case Study:

In 2011, a case report published in the journal Circulation: Arrhythmia and Electrophysiology described a 70-year-old woman who had experienced multiple episodes of syncope (fainting) and palpitations. She had a dual-chamber pacemaker implanted in 2006 due to sick sinus syndrome (abnormally slow heart rate).
During a routine follow-up appointment in 2010, it was discovered that her pacemaker was not functioning properly. The device was unable to capture the heart's electrical activity, and the patient's symptoms had worsened. The pacemaker was subsequently explanted (removed) and sent for analysis.
Examination of the explanted device revealed significant corrosion of the metal components, particularly the titanium casing and the electrical connections. The corrosion had disrupted electrical connections and eventual failure of the pacemaker. The root cause of the corrosion was traced to a small defect in the epoxy header (the part where the pacemaker leads connect to the device), which allowed bodily fluids to seep in and corrode the metal components over time. This defect was likely introduced during the manufacturing process or as a result of mechanical stress during implantation. The patient's pacemaker was replaced with a new device, and her symptoms resolved after the successful implantation.

Table – 1 : Comparative analysis of metals used in pacemakers

Metals	*Availability*	*Cost Effectiveness*	*Corrosion Resistance*	*Future Scope*	*Efficiency*
Titanium	Abundantly available	Moderate	Excellent	Continued use due to biocompatibility	Biocompatible, lightweight, corrosion-resistant
Stainless Steel	Widely available	Cost-effective	Good	Remains a staple for durability and flexibility	Durable, flexible, cost-effective
Platinum	Relatively rare	Expensive	Excellent	Continued use due to electrical conductivity	Excellent electrical conductivity, biocompatible
Cobalt-Chromium Alloy	Readily available	Moderate	Good	Advancements may improve properties	Balance of strength and biocompatibility
Tantalum	Commercially Available	Expensive	Excellent	Biocompatibility and corrosion resistance may lead to specialized use	Corrosion-resistant, biocompatible
Nitinol (Ni-Ti Alloy)	Commercially available	Expensive	Good	Unique properties may offer innovative solutions	Shape memory, super elasticity, flexible
Gold	Readily available	Expensive	Excellent	Continued use in critical components	Excellent electrical conductivity, corrosion-resistant
Ruthenium	Commercially available	Expensive	Excellent	Continued use in specialized applications	Corrosion-resistant, biocompatible
Iridium	Rare but commercially available	Expensive	Excellent	Continued use in specialized applications	Corrosion-resistant, stable

2.5 Types of Pacemakers which are corrosion resistant.

1.Titanium-cased pacemakers: Titanium is a highly corrosion-resistant metal that is widely used for the casings of pacemakers. Its natural oxide layer provides excellent protection against corrosion in the body's environment. Many pacemakers from major manufacturers like Medtronic, Boston Scientific, and Abbott (St. Jude Medical) use hermetically sealed titanium casings.

2.Ceramic-cased pacemakers: Some pacemakers have casings made of ceramic materials, such as zirconia or alumina ceramics. These materials are highly resistant to corrosion and are also biocompatible. Biotronic, a German manufacturer, is known for its ceramic-cased pacemakers.

3.Hermetically sealed pacemakers: Hermetic sealing involves enclosing the pacemaker's internal components in a sealed metal casing, typically made of titanium or a titanium alloy. This prevents bodily fluids from entering and causing corrosion. Many modern pacemakers from major manufacturers employ hermetic sealing techniques.

4.Polymer-cased pacemakers: While less common, some pacemakers have casings made of corrosion-resistant polymers, such as polyurethane or epoxy resins. These materials are generally resistant to corrosion but may be more susceptible to degradation over time compared to metals or ceramics.

5.Hybrid pacemakers: Some pacemakers combine different materials to maximize corrosion resistance. For example, they may have a titanium casing with ceramic components or a ceramic casing with titanium components. Using different metals in combination would relatively decrease the pace and rate of corrosion.

2.6 Titanium cased Hermetic sealed Pacemakers, The Future of Pacemakers?

Based on current trends and research, the pacemaker type that is likely to be in highest demand in the future due to its superior corrosion resistance is titanium-cased pacemakers with hermetic sealing. Here are the key reasons why these pacemakers are expected to be highly sought after:
1. Titanium casing: Titanium is an excellent choice for pacemaker casings due to its high corrosion resistance and biocompatibility. Titanium forms a stable, protective oxide layer that prevents corrosion in the body's environment. Many major manufacturers like Medtronic, Boston Scientific, and Abbott already use titanium casings for their pacemakers.

2.Hermetic sealing: Hermetic sealing involves enclosing the pacemaker's internal components in a sealed, impermeable metal casing, typically made of titanium or a titanium alloy. This sealing prevents bodily fluids from entering the device and causing corrosion of internal components. Hermetic sealing is widely adopted by leading pacemaker manufacturers for its proven ability to prevent moisture ingress and corrosion.

3. Proven track record: Titanium-cased, hermetically sealed pacemakers have a long history of reliable performance and corrosion resistance in clinical use. Their durability and corrosion resistance have been well-established through extensive research and real-world experience.

4.Continuous improvements: Manufacturers are continuously refining the hermetic sealing techniques, improving gasket materials, and optimizing the manufacturing processes to further enhance the corrosion resistance of these pacemakers.

5. Regulatory acceptance: Titanium-cased, hermetically sealed pacemakers have a well-established regulatory acceptance and approval pathway, as they are based on proven materials and technologies. This streamlines the regulatory process and facilitates their adoption compared to newer, unproven technologies. While other materials and technologies, such as ceramic casings, polymer-based pacemakers, and alloplastic (biological) pacemakers, are also being explored for their corrosion resistance, the titanium-cased, hermetically sealed pacemakers are likely to remain the gold standard and in highest demand due to their established track record, continuous improvements, and regulatory acceptance. Titanium cased hermetically sealed pacemakers are expected to remain a prominent choice for their proven corrosion resistance and reliability.

2.7 Future trends and prospects in Corrosion resistant Pacemakers:

The use of pacemakers is poised to grow substantially in the future due to several factors. An aging population, coupled with advancements in cardiac care and diagnostic technologies, will increase the prevalence of cardiovascular conditions pacemaker therapy. Furthermore, ongoing innovation in pacemaker technology, including smaller sizes, longer battery life, and wireless connectivity, will make these devices more compact, attractive and accessible to a wider range of patients. As a result, pacemakers are expected to play an increasingly crucial role in managing cardiac rhythm disorders and improving patient outcomes worldwide. Improving it is vital for the future of healthcare due to various reasons. With an aging population and increasing prevalence of cardiovascular diseases, advanced pacemakers tailored to individual needs and manufacturing it to increase its effectiveness can optimize patient care. By enhancing reliability, incorporating remote monitoring, and fostering innovation, healthcare burdens/threats can be minimized, while global accessibility and patient empowerment are maximized. Overall, improving pacemakers is essential for advancing cardiovascular medicine, improving patient outcomes, and shaping a more inclusive and effective healthcare landscape for all. The future trends and prospects in developing more corrosion-resistant pacemakers are promising, driven by advancements in materials science, manufacturing techniques.

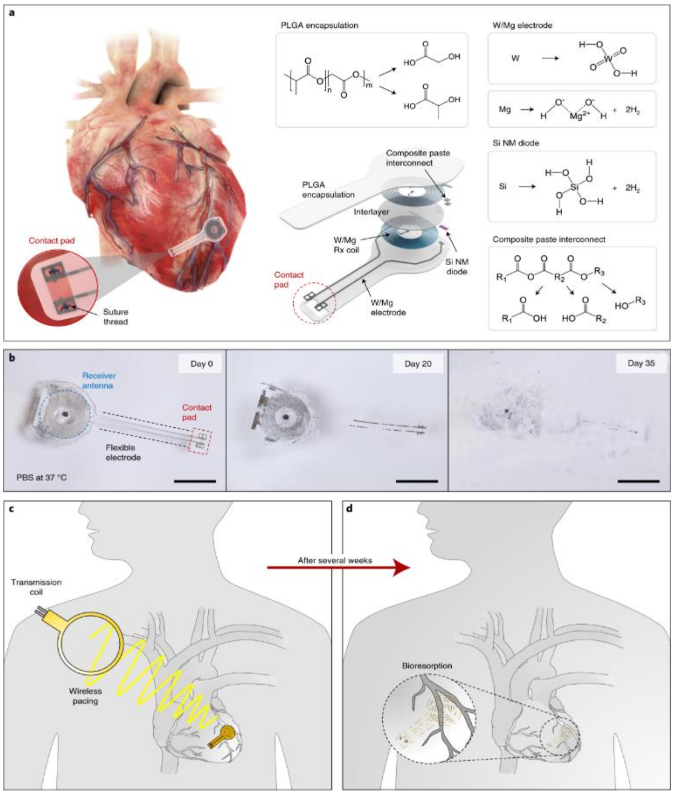

Fig -4 : Bioresorbable cardiac Pacemakers. [Ref: https://www.nature.com/articles/s41587-021-00948-x.jpej]

1. Advanced alloys and coatings: Researchers are exploring the use of advanced titanium alloys, such as titanium-niobium alloys, which offer superior corrosion resistance and biocompatibility compared to traditional titanium alloys.

2. Nanostructured materials: Nanostructured materials, including nanocrystal line metals and Nano composites, are being investigated for their potential to improve corrosion resistance and mechanical properties of pacemaker components. These materials can exhibit enhanced and effective resistance to stress corrosion cracking and pitting corrosion.

3. Improved hermetic sealing techniques: Manufacturers are continuously refining hermetic sealing techniques to ensure better protection against moisture and corrosion.

4. Bioresorbable materials: There is ongoing research into the use of bioresorbable materials for certain pacemaker components, such as leads or fixation devices. These materials would gradually degrade and be absorbed by the body, reducing the risk of long-term corrosion or adverse reactions.

5. Alloplastic pacemakers: Also known as biological pacemakers, are an emerging concept in cardiac pacing technology. Unlike traditional pacemakers that rely on electronic components, alloplastic pacemakers aim to create a biological pacing system within the heart itself, potentially offering a more long-lasting and corrosion-resistant solution.

3. CONCLUSION

Biomaterials corrosion remains a serious clinical concern. Indeed though the freely corroding implant accoutrements used in the history have been replaced with ultramodern erosion- resistant super blends, injurious erosion processes have been observed in certain clinical settings. There's a reason to believe that attention to variables related to metallurgical processing, forbearance of modular connections, face- processing modalities and applicable selection of accoutrements could drop the rate of erosion and minimize the eventuality for adverse clinical issues. The mechanical-electrochemical relations of unresistant essence oxide shells must be delved further. The stresses and stir that are demanded to fracture passivating oxide flicks as well as the goods of repeated oxide bruise on the electrochemical behaviour of the interface and eventually the implant are areas of active disquisition. The part of particulate erosion products in adverse original towel responses also needs to be delved further. The clinical ramifications of increase in essence content in body fluids and remote organs of cases who have a essence implant need to be explained.

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