Cardiac Pacemakers: A Closer Look at Technological Innovations

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Abstract

The use of technology in medical sciences, specifically the use of embedded technology to correct dysfunctional organs closer to their natural state, found its place with the great cardiac surgeons from the early 1900’s like [Dr. Vivien Thomas](https://en.wikipedia.org/wiki/Vivien_Thomas) and [Dr. Christiaan Barnard](https://en.wikipedia.org/wiki/Christiaan_Barnard). The consistent leaps in the treatment of diverse, more frequent, or rare heart conditions enabled other fields of science and technology to partner and collaborate to build diverse solutions achieving long-term survival for patients of all ages.

The early century pioneering of [Dr. Albert S. Hyman](https://en.wikipedia.org/wiki/Albert_Hyman) (Harvard trained cardiologist from New York) to late century ingenuity of [Dr. Jose Carlos Pachón-Mateos](https://www.teses.usp.br/teses/disponiveis/98/98131/tde-12062012-074413/publico/TeseJuanPachon_Corrigida.pdf) (University of São Paulo – USP trained cardiologist) who designed and built cardiac pacing and defibrillation devices themselves, to [Biotronik SE & CO., KG](https://www.biotronik.com/) and [Medtronic plc](https://www.medtronic.com/), in the vanguard of researching, designing and providing state of the art pacemakers for more than fifty years, accelerating and expanding the adoption of cardiac pacemaker devices even in high-risk patients (with the incidence of various cardiovascular diseases rising across the globe.

In the todays day and age, the ubiquity of pacemakers is likely to pique the interest of many who, with a quick search on the internet, will find information on websites like the great medical school Johns Hopkins University School of Medicine, popular online medical like Medicine Plus, or even Wikipedia, all of them telling us that pacemakers are devices that are surgically implanted to sustain our hearts’ electrical system.

In this article, we will briefly navigate the recent history of pacemakers and respective changes in manufacturing and materials and will illustrate the incredible significance of these devices and their makers. The goal of this text is to draw the profile of the fast-paced innovations included in this famous yet misunderstood device, as well as the changes in risk and the consequences faced in the near future.

Keywords: biotech, pacemakers, cardiac pacing, cardiac defibrillation

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World’s current affairs are difficult to position without considering the post COVID19 pandemic accommodations. This once-in-a-century event accelerated changes in daily practices in the most diverse fields of business, education, government and, not differently, the practice of medicine across the globe (Daida, Kagiyama, Kasai, & Takahashi, 2022).

While the general public perception of pacemaker devices and of the use of these devices as long term treatment of different heart conditions emanates from “word-of-mouth”, “hearsay”, and social interactions when storytelling about a recent occurrence in a relative’s or common friend’s health condition, the official assessment of the quality of life for patients pre and post pacemaker implantation (Weheida, Gebril, Mohamed, & Fathy, 2021), even if shared anecdotally, is likely to be on the top of the list of the factors or reasons a random member of the public would have any level of understanding about the need and use of these devices.

For this article, it is assumed that, at least superficially, a random person understands that a pacemaker is a lifesaving artificial device used procedures of a treatment of a given heart condition and has become widely used worldwide. This electronic device is implantable and uses electrical impulses to motivate the heart to adapt when of its compartments is not working properly (Snegalatha, Amnand, Seetharaman, & John, 2019).

# Permanent Pacemaker Therapy

According to Beurskens (Beurskens, 2022) “Permanent transvenous pacemaker therapy is an essential management option in patients with symptomatic bradyarrhythmia (including, but not limited to low blood pressure, pulmonary edema, and congestion, abnormal rhythm, chest discomfort, shortness of breath, lightheadedness, confusion), but harbors a concomitant risk of serious complications”. These complications are usually related to the use of lead as one of the raw materials to manufacture the different models of the device.

However, the current annual rate of pacemaker implantation worldwide is estimated to be one million devices per year (Beurskens, 2022), discounting existing regional differences in the use and adoption rate for different countries, the treatment with this family of devices is not going anywhere, rather, it has become ubiquitous. At the same time researchers look for improvement in existing therapies, new or renovated therapies, and even therapies that will cover conditions yet not reached by the pacemaker ecosystem. Innovative solutions will introduce their specific roadmaps (including risk assessment, known possible collateral effects), but changing existing therapies (or the construct of the devices used in these therapies), will open a new and important necessity to understand if the adoption of leadless devices would surface other complications.

## Leadless cardiac pacemaker devices

While we might raise the question about the development of new models of pacemaker, and the respective efforts and investments to focus on microelectronics, solid state physics, remote programming, wireless analytics, and cloud connectivity, the manufacturing of the device and its different components, considering for the purposes of this text the fact that the device will be part of the living body of a patient, the use of different metal alloys for example has an important significance on the potential effect it might have on patients and other unknown risk factors.

Today, an alloy of nickel (Ni) and titanium (Ti) named nitinol is the most commonly used material in the making of intracardiac devices (Edlinger, et al., 2022), even though there are records of patients experiencing allergy to both elements, to which gold (Au) coating may be a viable alternative.

From my own early experiences as a research and development engineer for pacemaker management and control devices (including programming without any physical connection to the device), I dedicated a comprehensive amount of time understanding the potential and feasibility of using Titanium (Ti) and Stainless Steel 316L as the main material for the pacemaker external shell.

Again, according to Edlinger (Edlinger, et al., 2022) “the vast majority of devices are made of a material that is both safe to implant and nontoxic in long-term treatment according to the current knowledge”.

### Background

The motivation for the design of leadless intracardiac pacing devices was to avoid the need for a pacemaker pocket and transvenous lead, meeting its safety and efficacy goals. For more than fifty years, the used pacemaker device treatment systems. These systems consisted surgically implanted subcutaneous electrical generator connected to one or more transvenous leads. These devices were, indeed, effective, with one in eight patients demonstrating early complications (Reynolds, et al., 2016).

### Conclusion

Current generation of leadless pacemaker devices is a welcomed innovation with safe and efficient single chamber pacing therapy (and without the need for transvenous pacemaker leads) (Beurskens, 2022). However, the implantation of such devices will be more challenging, requiring more precision than single chamber devices. Also, these innovative technologies placed interventional therapies at a crossroads (Hauser, Katsiyiannis, Gornick, Sengupta, & Abdelhadi, 2022).

The challenges (limitations) of the leadless devices hinder the broad implementation of this recent technology, that also include end-of-life management and the above-mentioned single chamber pacing indication (Beurskens, 2022).

There is advanced research and already existing advanced VLSI (Very Large-Scale Integration) technologies deeply applied into the wide variety of pacemaker devices and pacemaker-based treatment systems. The introduction of contemporary designs and the use of the newer technologies to improve proven well-functioning devices will always be the focus of attention when thinking of innovations in the world of pacemaker devices. There are innovations, as much as important as any, related to engineering of materials and the mechanical aspects of the devices that represent relevance to enable an even broader availability and use of this important health-saving device to the public in general.

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