Review of Cardiac Pacemaker Lead Designs for Computational Models in a VR Environment

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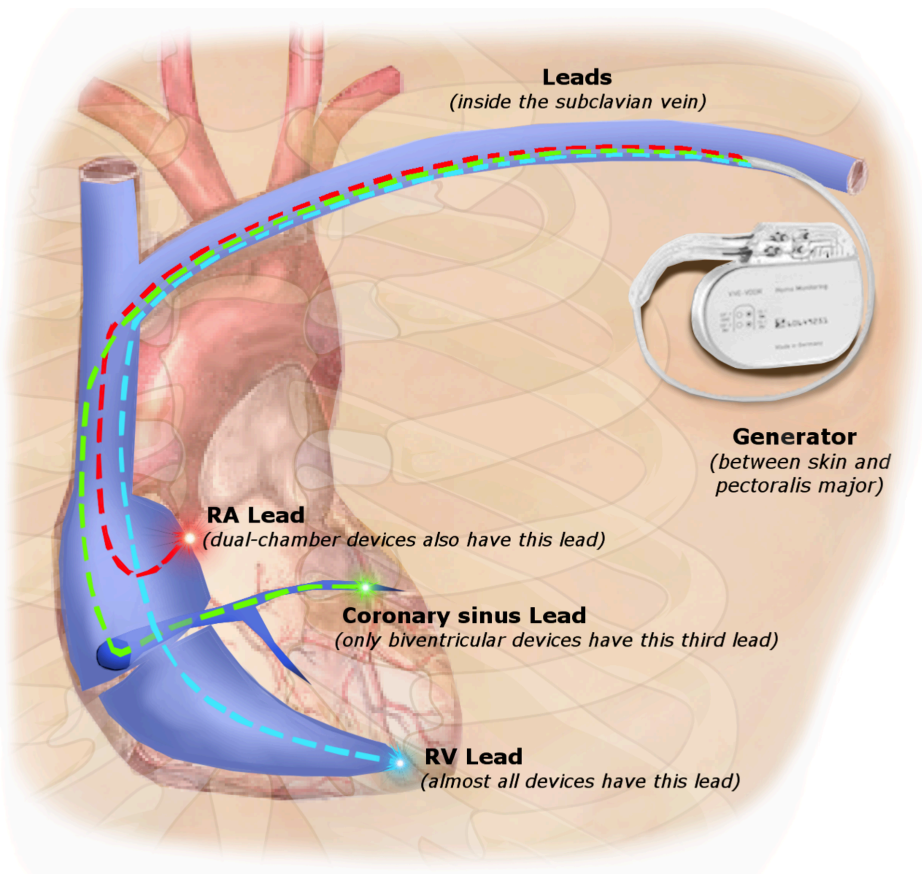
Background

Implantable cardiac pacemakers are used to modify and treat irregular heartbeats [1] and invented in 1958 [2].



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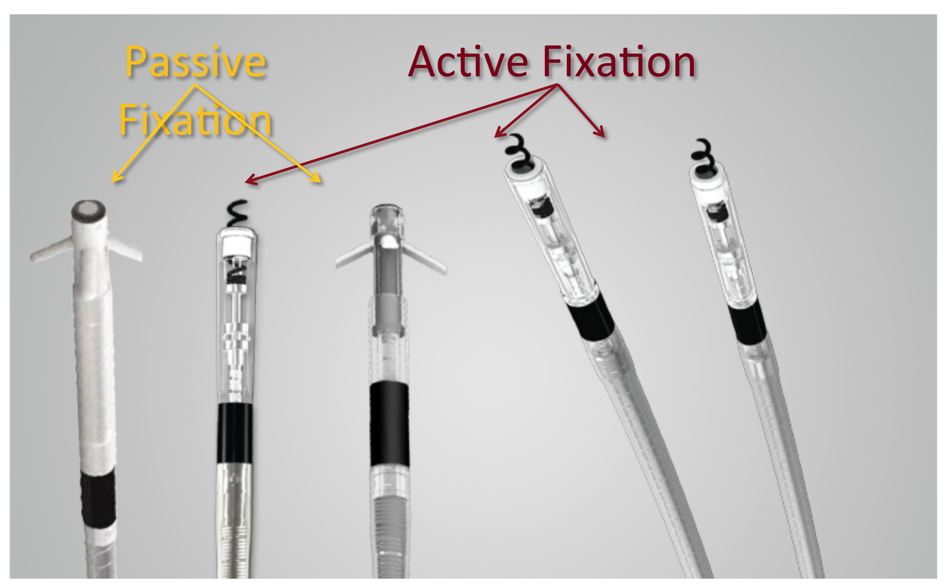
Devices have no fixation or fixed to the heart wall. No fixation leads lay in the bottom of heart cavities, while fixed leads have tines (passive) or a helix screw (active) to attach to the heart. Lead geometries and material properties vary between companies, with geometric sizing based primarily on the internal components of the lead.



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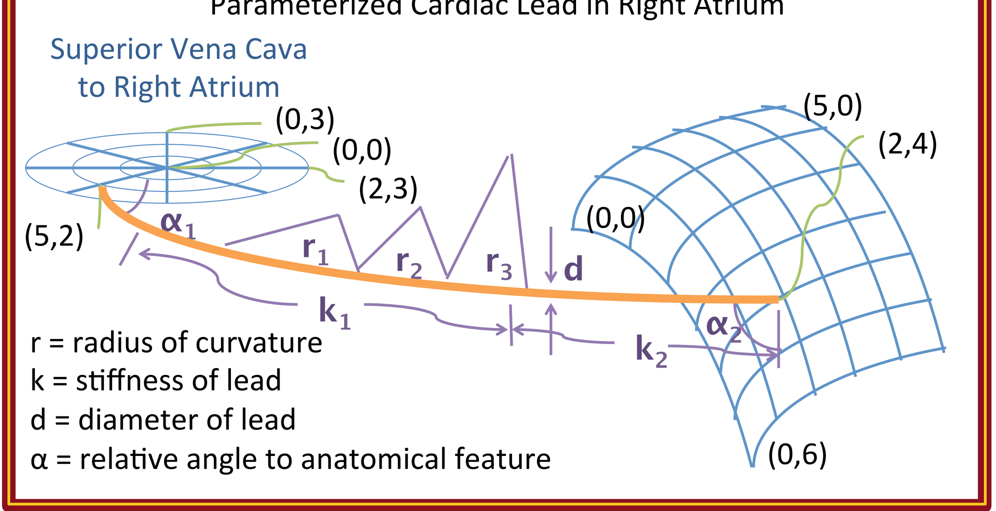
Finite element analysis (FEA), computational fluid dynamics (CFD) and bench-top simulations are used to evaluate cardiac leads. These simulations analyze only one lead and struggle to compare and test variations in lead designs. Advanced computational resources can run many computer simulations of anatomical environments, however model complexity increases the time to run each simulation.

To address this issue, we present a simplified parameterized design space for cardiac pacemaker leads in the right atrium. This information will be used to run multiple simulations of leads in blood flow, for visualization in a single virtual reality (VR) environment and allow the designer to iterate through many design variations (See Figure 1).

Parameterized Cardiac Lead in Right Atrium



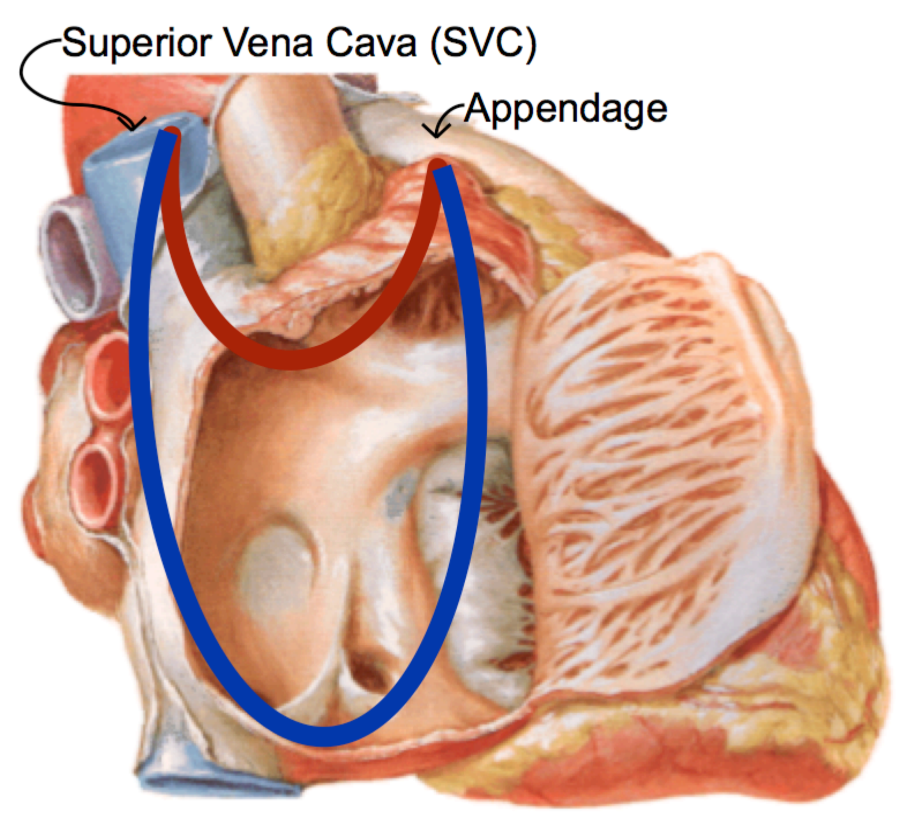
Methods

Cardiac leads on the market are designed to treat specific heart conditions. To demonstrate the value of a large scale user driven exploration of many design variations, a design space was developed for use cases use full to engineers and medical professionals.

First, nine engineers and medical professionals were interviewed to determine the opportunities for an anatomical, fluid-structure-interaction computational model of implanted cardiac lead to help with future cardiac lead device designs.

Second, the design space of a cardiac lead was defined and simplified. A survey of cardiac pacemaker leads was conducted of the major manufactures in the United States. These companies included Medtronic [3], Boston Scientific [4] and St. Jude Medical [5], who manufactured 93.1% of pacemakers in 2015 [6]. Published information was collected from their respective websites to document variations in designs and included external lead geometry, fixation locations and materials used in the leads, but did not include information about overall stiffness of the leads.

Human anatomy was evaluated to determine minimum and maximum distances from the Superior Vena Cava (SVC) to the appendage attachment point. Four DICOM stacks of human heart anatomies from the University of Minnesota (UMN), Visible Heart Laboratory (VHL), Atlas of Human Cardiac Anatomy [7] were uploaded into Mimics [8]. Splines were generated to define the lead pathways.



https://www.slideshare.net/Abomustafa/anatomy-of-the-heart-42723933

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Results

Interviewees agreed that a VR based simulation of lead variations within the heart and with fluid flow would be valuable to their analysis and design of new leads. Designers wish to compare cardiac leads within one simulated environment and discriminate between device and blood flow simulations. They also want to prepare guidance documents for doctors implanting devices that recommend the lead length left in the heart based on anatomical characteristics and management of multiple leads in a heart.

Implant specialists want to understand the blood flow with respect to lead placement, evaluate the interaction between multiple leads in a heart, select a lead for a specific patient's anatomy and predict the fibrosis growth impact on lead movement and extraction procedures.

Twenty cardiac leads were evaluated from manufacturer's product information. Use cases focused on external lead geometry and lead placement. Parameters were narrowed to include lead length in the heart cavity, lead diameter, lead stiffness and attachment location. Internal lead geometry is integrated to create a lead stiffness.

Company	Model		Active Fixation	Passive Fixation	Pacing	Defibrillator
Boston Scientific	Accuity™ X4	4671, 4672		X	X	
	Ingevity™ MRI	7740, 7741, 7742, 7731, 7732, 7735, 7736	X	X	X	
Medtronic	CapSure Sense MRI™ SureScan™	4074, 4574		X	X	
	CapSureFix Novus MRI™ SureScan™	4076, 5076	X		X	
	SelectSecure	3830	X		X	
	Sprint Quattro Secure™	6946M		X	X	X
	Spring Quattro Secure S™	6935, 6935M, 6947, 6947M	X		X	X
	Spring Quattro Secure S MRI™ SureScan™	6935, 6935M, 6947, 6947M	X		X	X
St. Jude	Durata™	7120, 7121, 7122	X			X
	IsoFlex®	1944T, 1948T		X	X	
	OptiSense®	1999	X		X	
	QuickFlex®	1258T		X		
	Tendril® ST	1888TC	X		X	
	Tendril® SDX	1688T/TC	X		X	
	Tendril MRI™	LPA 1200M	X		X	

***Additional leads are available on the market.
Information about these leads are not available on company websites.

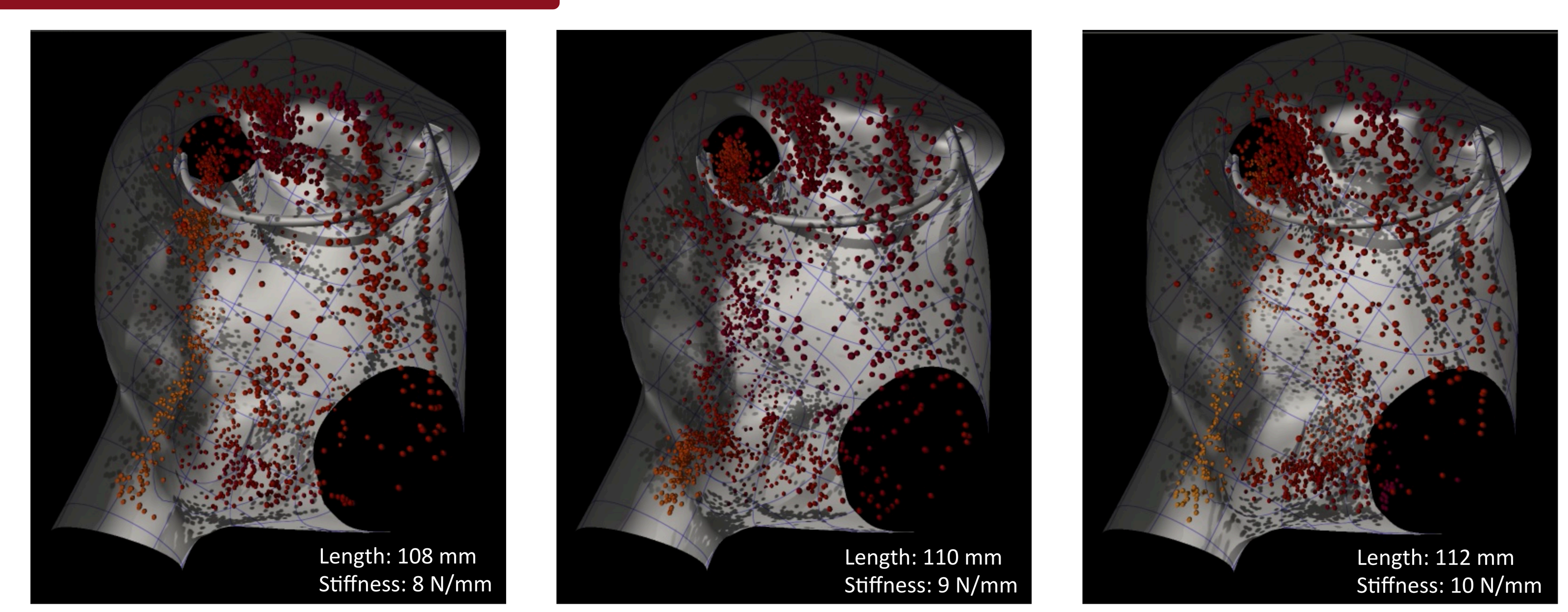
Results (continued)

The first parameter studied was the lead length inside the right atrium. The lead travels into the right atrium through the SVC and must bend around the anatomy to attach to the appendage tip. Manufactured leads vary from 35 cm (Medtronic, CapSureFix Novus MRI SureScan 5076) to 100 cm (Medtronic, Sprint Quattro 6947 and 6944) in length. The four anatomies were studied from the University of Minnesota Visible Heart Laboratory. The hearts had an average minimum distance of 96.6 mm from SVC to appendage tip, while the average maximum distance was 195.7mm. Minimal interaction with heart walls is desired to reduce fibrous adhesion. The second parameter studied was diameter of the lead. Diameters varied from 4.1 Fr (1.36 mm) for a pediatric pacing lead to 8.6 Fr (2.87 mm) for defibrillator leads.

The third parameter was stiffness of the lead and was difficult to define. During our interviews, engineers discussed targeting specific overall lead stiffness, however these values are not published in the literature. Many articles discuss the results of lead stiffness testing [10], without quantifying the stiffness of leads studied. One publication from Dassault Systemes, quantified the axial behavior of a lead to be 9 N/mm [11] (See Table 1). One study compared the distal stiffness of a series of leads, concluding that polyurethane leads are stiffer than silicone rubber leads [10].

The fourth parameter is attachment location of the lead's distal end. Most leads are attached to the appendage in the right atrium, while research is showing the benefits of His-Bundle pacing. His-Bundle pacing paces the top of the septum to transmit signal through the natural electrical conduction system [12].

Parameter	Minimum	Maximum	Interval	Variations
Length	100 mm	140 mm	2 mm	20
Diameter	5 Fr (1.67 mm)	8 Fr (2.67 mm)	0.04 mm	25
Stiffness	8 N/mm	10 N/mm	1 N/mm	3
	Location 1		Location 2	Variations
Attachment	Appendage		His-Bundle	2
			Total Variations	3000

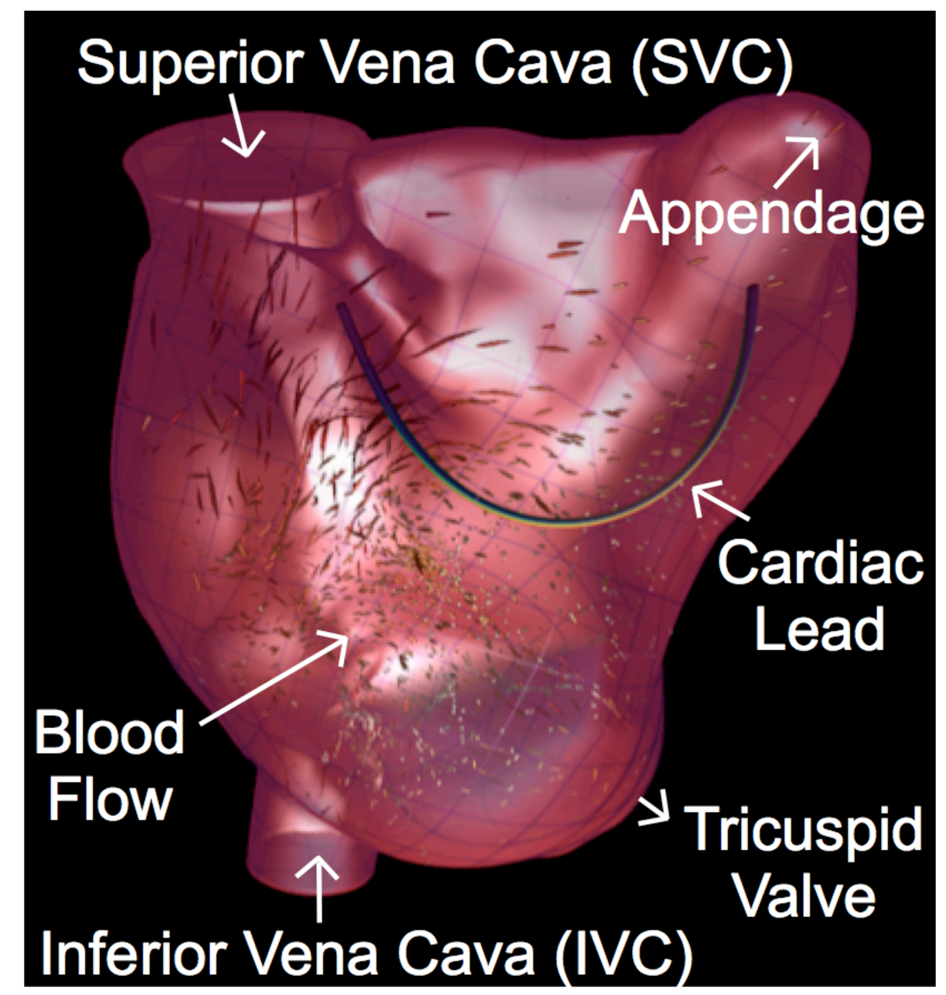


Interpretation

Leads are manufactured in a series of lengths and the recommendation is to coil excess lead length under the pacemaker housing in the pocket. This simulation would allow manufactures to recommend how much lead should be left in the heart cavity and how to manage multiple leads.

Defining the design space, enables using computational resources to generate hundreds of design instances. These design instances within the VR environment will reveal how the lead impacts blood flow. The visualized continuous design space can be used to identify a lead design for a specific patient's anatomy.

Simplifying the parameters for a computational model is important to efficiently compute hundreds of simulations in a reasonable time frame for create a continuous design space to complete understanding of the design options. However, waiting days, weeks or even months for a complete design space is unrealistic in todays fast paced design process. Simplified design models open the opportunity for real time generation of computation models. As a designer is iterating through design options, the software could be generating models fill in the design space based on the direction of the designer. This process will reduce the number of pre-generated models that are geometrically and visually out of spec, but could have seemed numerically feasible.



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