Characterization of Cardiac Lead Perforation Risk via a Dynamic Simulated Environment

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ABSTRACT

Delayed cardiac perforation is a serious medical condition where an implanted cardiac lead migrates through the heart wall, causing life-threatening complications. Where acute perforation occurs during implant, delayed perforation is not detected until after 30 days from implant and is frequently not diagnosed until complications are present. The phenomenon is particularly prevalent in cardiac leads with active helices. Detailed here is a test method that subjects leads to cyclic loading in an environment similar to that of the human heart. A test setup was developed; leads migrate through a degradable cardiac simulant for a fixed cycle count, after which the simulant is evaluated. Initial testing was conducted and improvements made to the device. Nineteen cardiac lead models were tested and ranked in three metrics related to perforation damage. Trends matched available medical knowledge on lead perforation risk. This experiment provides a framework for further investigation into lead perforation.

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Nomenclature

\[ \Delta E \] total energy difference
\[ \Delta T \] temperature difference
\( \alpha \) coefficient of linear thermal expansion
\( \delta \) phase angle
\( \delta_c \) coupling error
\( \delta_{\text{lead}} \) lead positioning error
\( \delta_{\text{tol}} \) tolerance error
\( \delta_{\text{steel}} \) displacement of steel baseplate bolt holes
\( \varepsilon \) error
\( \varepsilon_T \) thermal strain
\( \nu \) Poisson’s ratio
\( \rho \) density
\( \sigma_{\text{cr}} \) critical buckling strength
\( \varphi \) insertion angle
\( A \) peak-to-peak amplitude
\( A_t \) tip area
BSC Boston Scientific
\( C_E \) composite modulus
\( D \) diameter
\( D_{ic} \) outer diameter of inner coil
\( D_{oc} \) outer diameter of outer coil
\( E \) modulus
\( E_i \) modulus of inner insulation
\( E_{ic} \) modulus of inner coil
\( E_o \) modulus of outer insulation
\( E_{oc} \) modulus of outer coil
\( E_I \) total modulus of rigidity
\( E_{Ic} \) modulus of rigidity – inner coil
\( E_{Ioc} \) modulus of rigidity – outer coil
\( F \) load
\( G \) dynamic modulus
\( G' \) storage modulus
\( G'' \) loss modulus
\( H_t \) tissue hardness
\( I \) second moment of area
\( K \) buckling factor
\( L \) buckling/beam length
\( L_{\text{ext}} \) helix penetration depth
MDT Medtronic
\( P \) power
\( Q \) heat flow
\( R \) die radius
\( R_t \) tissue puncture resistance
SJM St. Jude Medical
\( V \) volume
a  radius of circular contact area
b  beam width
c  specific heat capacity
d  maximum initial deflection
d_i  outer diameter of inner insulation
d_{ic}  inner diameter of inner coil
d_o  outer diameter of outer insulation
d_{oc}  inner diameter of outer coil
f  load
g  gravitational acceleration
h  beam height
h_c  heat transfer coefficient
k_p  body stiffness
k_n  neck stiffness
l  heater length
l_h  helix length
m  mass
n  turn count
p  power flux
P_{tip}  tip pressure
r  radius
s  lead slack
t  tissue thickness
t_i  inner insulation thickness
t_{ic}  inner coil thickness
t_o  outer insulation thickness
t_{oc}  outer coil thickness
r  radius of gyration
u  displacement
x  distance between bolt holes
y  cyclic frequency
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1 Introduction

1.1 Motivation

Cardiac leads are among the most common implantable medical devices. Essentially a long, coiled electrode, leads connect the heart wall to the pulse generator, either a pacemaker (PM) that regulates the heartbeat to correct arrhythmias or the implantable cardioverter-defibrillator (ICD) that shocks the heart back to life during cardiac failure. Leads are designed to be flexible, tough enough to take years of abuse from the internal environment of the heart and corresponding veins, and most importantly, robust enough to deliver a well-regulated charge with millisecond precision.

However, one of the most serious risks of cardiac lead implantation is that of lead perforation. The perforation of a lead through the heart wall is a serious and recurring problem facing the medical device industry. The consequences of perforation can include everything from reduced therapy effectiveness to pericardial effusion, cardiac tamponade, and death. Such perforation can be acute, where penetration occurs during the initial placement of the lead in the heart with the guide stylet still in place; or chronic, where penetration occurs and/or is worsened through repetitive loading caused by the regular contractions of the heart itself. Acute perforations occur during implantation and thus are frequently noticeable to the operating physician, leading to immediate repair. Chronic perforations are not noticed during surgical procedure, and only become apparent much later, from weeks to months to years. There are documented cases of lead perforations detected as much as five years after the initial implantation. In total, these delayed perforations are estimated to account for less than 1% of all implants.

Currently, there is a lack of comprehensive knowledge of the mechanisms behind cardiac lead perforation. There is good evidence to show that the stiffness of the distal section of the lead contributes to perforation risk via pressure applied on the endocardium by the lead tip; however, there are other factors at play that remain unexamined. Because cardiac leads are designed for a useful lifetime of ten years, and due to the extreme harm that can be caused by perforation, understanding which design factors in a lead contribute to a high risk of perforation is paramount. No less important is considering the effect of non-design parameters on lead perforation – for example, the aggressive handling of a lead during implant could lead to complications further down the road. Investigation into these factors and others that influence perforation is necessary to describe the underlying mechanism.

1.2 Problem Statement

The goal of this work is to determine what factors contribute to the perforation of cardiac leads, with an emphasis on chronic or delayed perforation. In pursuit of this, the following tasks are necessary:

- **Analysis of lead design factors that may contribute to perforation risk.** These are lead-specific variables, potentially including distal tip mechanical properties, material composition, geometry, etc.
• Consideration of exogenous factors that may contribute to perforation risk. These are factors apart from the lead itself, and may include implant technique, patient age, heart abnormalities, etc.
• Designation of appropriate metrics to characterize a lead that is at high risk of perforation. These metrics will be used to rank tested leads in order of perforation risk.
• Design and manufacture of a prototype device to characterize leads based on the aforementioned metrics.

1.3 Scope

A complete analysis of the lead perforation phenomenon would include a number of topics that here are either treated lightly or not addressed at all. One of the most prominent is the mechanical and biological behavior of the cardiac tissue itself. There is certainly enough work in the tissue aspect of this project to merit a number of doctoral theses. Instead of diving headlong into the abyss, here a tissue phantom is selected and described in detail to simulate relevant properties of the cardiac wall. Because the true focus is the design of leads to resist perforation, it is more important for the phantom to be consistent and repeatable than for it to mimic the exact mechanical properties of the cardiac wall.

The scope of this project is limited to the tasks listed in the problem statement and tasks that may aid in their accomplishment – such as finite element analysis of the puncture resistance of various tip geometries. However, many external references, resources, and standard are relied upon, especially for issues of anatomy.

1.4 Thesis Structure

This thesis is comprised of six individual sections. Chapter 2 describes the characterization of cardiac perforation and includes a comprehensive review of the current literature on perforation events and rates. Chapter 3 lists factors relevant to cardiac lead perforation, and analytical models that govern their behavior. Chapter 4 details the design of experiments and fabrication of test devices and samples. Chapter 5 compiles experimental results and validates them against theoretical predictions and trends in recorded data. Finally, Chapter 6 summarizes the work accomplished in the thesis and concludes with suggestions for further practice.
2 Characterizing Cardiac Lead Perforation

2.1 Background

Though both acute and delayed cardiac lead perforation can incur life-threatening conditions, delayed perforation is potentially the more serious occurrence of the two for three reasons. Firstly, acute perforations occur either in the operating room, during recovery, or immediately thereafter during a period of close scrutiny, which allows for a physician to intervene to correct the condition. Delayed perforations can occur from weeks to months to years after the event, and are heretofore unpredictable. Secondly, after a successful implant, the post-operative reviews are frequent at first but then taper off as the patient resumes a normal schedule. Thus, delayed perforation events are rarely detected just after they occur; in some cases it appears as though the perforation had occurred years before detection. This leads to speculation over the cause of the initial perforation; because the incident was not observed, and body chemistry, tissue fibrosis, and other patient attributes may have changed in the meantime, there is rarely conclusive evidence as to the cause. Thirdly, the internal damage caused by delayed perforations can be significant. There is a documented study where a lead broke through the myocardium, the pericardial sac, and ended up in the subcutaneous fat of the chest[1]. Other studies describe a lead discovered in the process of boring through a rib[2]. Such cases are certainly not the norm, but suggest that fatigue may be an important factor in perforations occurring after lengthy time periods.

The heart is essentially a large pump divided into four cavities, each with an inflow and an outflow. Deoxygenated blood arrives from the superior vena cava into the right atrium (RA), where it then flows through the tricuspid valve into the right ventricle (RV). When full, the tricuspid valve closes to prevent backflow, an electrical pulse activates the compressive cardiac muscle and blood is forced into the pulmonary arteries, leading to the lungs. When oxygenated blood returns via the aorta, it repeats the process in the left atrium and left ventricle, separated by the mitral valve. When a full volume is achieved in the left ventricle, a similar electrical signal forces the blood into the pulmonary veins and throughout the body.

A cardiac lead usually arrives in the heart through the vena cava via a subcutaneous incision. If the lead is destined for the right atrium, it is tucked and fastened into the atrial wall. If the lead is to stimulate the right ventricle, it passes through the tricuspid valve and is fixated into either the right ventricular apex (RVA) the right ventricular free wall (RVFW), or the right ventricular outflow track (RVOT). RA and RV leads are thus distinguished by an additional lead length and the boundary condition imposed on the RV lead by the opening and closing of the tricuspid valve. In time, fibrotic growth from the cardiac tissue can fix the lead in different locations and alter the lead’s motion.

The contractions of the heart as it pumps cause the lead to buckle and compress. Anatomic measurement of the right ventricle is most often conducted as a volume, but several publications list approximate axial measurements. According to Tandri, the right ventricular end-diastolic long axis (RV LAX ED) dimension is 7.29 +/- 0.88 cm, while the end-diastolic short axis (RV LAX ED) dimension is 3.53 +/- 0.68 cm [3]. Mittal lists the end-systolic dimensions as well for both the long and short axes.
where the RV LAX ED is 5.68 +/- 0.75 cm, the RV LAX ES is 3.82 +/- 0.59, the RV SAX ED is 2.21 +/- 0.39 cm, and the RV SAX ES is 1.52 +/- 0.31 cm [4]. Mittal also provides wall thicknesses for various RV locations at diastole and systole; the measurements range from 2.5 +/- 0.6 mm for the RV anterior wall at end-diastole to 5.4 +/- 1.2 mm for the RV interior wall at end-systole. Foale estimates a general cardiac wall thickness of 3.0-4.0 mm [5]. An unpublished BSC study documented dimensions for a small, average, and large heart, where the RV LAX ED is given as 65.5 mm and the RV LAX SD is given as 50 mm for the small heart, leading to a displacement of 15.5 mm. For the average and large heart, the displacements are 19 and 23 mm, respectively, given these motions and accounting for the stiffness of the lead. Figure 1 diagrams the heart with inserted lead.

Figure 1 A diagram of a cardiac lead in the heart. This configuration shows entry through the right atrium, past the tricuspid valve, and into the right ventricular apex.

The force that the lead applies is slight in comparison to the contractile force of the heart. The buckling load for most bradycardia leads ranges from 0.1 - 0.5 N. Tachycardia leads, with larger diameters and thicker construction, can buckle at up to 4 N. The buckling load is the maximum force that a lead is capable of transferring to the tissue in which it is embedded and is measured as described in section 3.5. Therefore, leads are extremely compliant structures that do not generate high forces in buckling, but with repeated loading and the corkscrew geometry of the active tip, perforations become possible over time.
2.2 Literature Review

Perforation of a cardiac lead through the heart is a rarely-occurring but nonetheless well-documented phenomenon. Because acute perforation occurs in the operating room, where a physician can quickly remedy the situation, most of the published and peer-reviewed literature fits in one of two categories: case studies of individual delayed perforation victims, and reviews and compilations of perforation rates in databases by lead type or manufacture.

A literature review was conducted to retrieve as much knowledge on the delayed perforation phenomenon as possible, and also to search for trends among particular lead models, implant techniques, and patient types that might lend clues towards the mechanism of perforation. It is only recently that the majority of cardiac perforation literature has been published in medical journals; of the 105 journal articles and internal documents reviewed for this thesis, only a handful were published prior to the year 2000, and of those many were concerning subtopics such as cardiac anatomy and needle insertion models. Overall, the past ten years have seen an explosion in reported cases of delayed perforation — making this either a recent phenomenon or one that has been vastly underreported in clinical literature prior to the passing decade. Photos of the phenomenon appear in Figure 2.

![Figure 2 Cardiac lead perforation. Left A lead that has fully migrated through the cardiac wall and pericardial sac [6]. Right A lead that has migrated significantly past the right ventricular apex and into the pericardial sac [7].](image)

One heavily cited study predicts that perforation occurs in 0.1-0.8% of pacemaker lead implants and in 0.6-5.2% of implantable cardioverter defibrillator (ICD) lead implants[8]. However, perforation rates given for studies with more specific criteria are generally enveloped in a much closer distribution. Perforation rates in studies with large sample sizes (n > 1000) range from 0.31% (n = 7497) to 1.17% (n = 4280) [9, 10]. Perforation rates in smaller sample sizes (n < 1000) range from 0.02% (n = 92) to 4.83% (n = 62) [11, 12].
There are a number of noticeable trends that run through the majority of the literature. In the parlance of cardiac leads, a passive lead tip involves a small domed electrode at the distal end of the lead surrounded by angled tines that serve to anchor the lead in existing cardiac tissues or in the fibrotic growth resulting from implantation in the cardiac wall. An active tip is essentially a conductive helix that is fixated into the cardiac wall via an applied torque. Though the active tip achieves a better fixation, reducing the number of attempts needed to fixate a lead in the heart, the sharp tip of the helix can also cause damage during implant through the venous system. A simple solution involves a coating of soluble sugar that is molded around the helix to prevent scarring during implantation, which dissolves away to allow fixation. A more recent and common method involves an extendable helix mechanism, whereby a clinician can implant a lead with a retracted tip and then extend the helix in the spacious atrial or ventricular cavity for fixation.

In studies that compare perforation based on the method of lead fixation to the endocardium, active lead tips have had a significantly higher perforation rate than their passive counterparts. Porterfield reports a perforation rate of 0.45% for active lead tips as compared to 0.11% in passive lead tips among SJM Riata models; Hirschl evens the odds at 9.8% and 8.6% perforation rates for active and passive tips, respectively [13, 14]. In addition, of the 60 individual case studies reviewed here, only 10 include leads with passive tips.

Another trend is the size of the lead, measured in the French (Fr) catheter scale and corresponding to the effective lead diameter. Studies in which size was compared frequently reviewed perforation rates from 7 Fr and 8 Fr leads (corresponding to 2.33 mm and 2.66 mm effective diameters), and produce the suggestion that smaller leads have higher penetration rates, though not conclusively. Porterfield derives a 0.53% perforation rate for 7 Fr SJM Riata leads against a 0.37% rate for 8 Fr Riatas (n = 15387) [13]. Epstein comes to a similar conclusion with 0.52% against 0.26% (n = 7497) [9]. Corbisiero notes an even match in rate between 7 Fr and 8 Fr Riata leads, but the sample size in this study was far reduced (n = 714) [15].

In the literature, a significant number of case studies involve implantation into the right ventricular apex (RVA). Sterlinski notes a 0.63% perforation rate for RA implants as opposed to a 0.46% rate for RV implants (n = 2247, various leads)[16]. The RVA is noted in particular to be a problem spot for lead implantation, resulting in numerous repositionings among reported cases.

However, much caution must be taken while interpreting this data. In the course of this review, most of the published literature accounted for only a few repeated lead models. One could interpret this to mean that the leads studied here are particular candidates for perforation and that attention should be given to possible design flaws leading to the event. This line of thought seems promising, but it is not conclusively the case, due to a lack of published data on the vast remainder of cardiac leads. Also, the wide range in perforation rates between articles suggest other factors at play apart from the design of the lead itself – the effect of implant technique is something that cannot be gleaned from the literature but may be an extremely important contribution towards cardiac perforation. Laske published an article in 2005 to address instances of high pacing impedances post-implant which he posited were caused by an overtorquing of the active tip helix, causing damage to the myocardial tissue [17].
Because of the complexity of the issue and the contradictory nature of much of the published literature, it is impossible to state with certainty whether a lead that has been released into the field is at high risk of perforation. But while definitive conclusions cannot be drawn from the available information, it is possible to identify leads that have recurrently appeared in the literature for perforation risks and leads with higher than usual perforation rates in clinical studies. Here reasonable inferences of perforation risk were drawn from both sources and used to validate the test method results. If a lead serves as a negative (high perforation risk per the literature and reputation) or positive (few known perforation events in the literature or by reputation) control, it is indicated as such in Table 3 in Chapter 3.
3 Perforation Factors

While the mechanics of perforation are complex, a basic model of perforation serves to first elucidate the problem at hand, whereby more complex interactions can be considered subsequently. An object perforates a given material through a concentrated application of force, whether it be a consistent application that perforates directly or a cycled application that perforates over time. At a certain force limit, a material will begin to yield, crack, or otherwise fail, and from that point the applied force serves only to exacerbate the localized failure until a complete perforation is achieved. Therefore, the force applied to the material is our first consideration in constructing a model of perforation.

In this case, the application of force is not acute but chronic. From fatigue studies it becomes apparent that many cycles at low stress (and below the elastic limit of the material) can cause material failure similar to that caused by few cycles at high stress. Some materials such as steel and other heavily ferritic alloys have a perceived endurance limit - a stress equal to some fraction of the material yield stress below which life is "infinite" and failure does not occur. Most materials, however, do not possess such a limit, and even very low stresses at many cycles are capable of causing failure over long time spans.

The mechanics of human cardiac tissue are complex. In addition to the tissue degradation that can be caused by repeated stress, such stresses can also cause swelling in the tissue; fibrotic growth; temperature effects; and other nonlinearities. To comprehensively model such behavior could occupy the pages of many doctoral theses, so here a representative mechanical approach is taken.

The cardiac wall is composed of three structural layers - the endocardium, myocardium, and epicardium. The endo- and epicardium are stiff, and comprise the inner and outer layers of the heart wall, respectively. The more compliant myocardium comprises the middle layer, and is much thicker than either of the other two layers. Because cardiac tissue is fibrotic, penetration involves the initial puncture and then splitting of fibers along their axis of alignment - as opposed to a linear elastic isotropic material, where failure consists of displacement of crystalline lattices on the atomic scale, tissue failure usually occurs as a parting of two macro-scale adjacent fibers [18].

Because the larger motivation for this project is to reduce the perforation of cardiac leads through the heart, it is important to analyze all of the component factors that contribute to a perforation. There are two classes of factors that affect the likelihood of a given lead to perforate during an implant - endogenous factors that are intrinsic to the lead, whether by design or manufacture; and exogenous factors that are beyond the control of the lead manufacturer.

3.1 Endogenous Factors

The lead itself possesses mechanical characteristics that affect the likelihood of perforation. All of the endogenous factors discussed in this section are specified by the designer in the development phase of
the lead and as such can be altered by the device manufacturer. In the initial stages of this research, a list of possible endogenous factors was compiled, shown here in Table 1. By first principles, each perforation factor was examined, and bench-level experiments performed where appropriate to determine the factor effect.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body stiffness</td>
<td>$k_b$</td>
<td>Distal end stiffness of the lead from tip to constraint</td>
</tr>
<tr>
<td>Buckling strength</td>
<td>$\sigma_{cr}$</td>
<td>Stress at which the lead will buckle</td>
</tr>
<tr>
<td>Tip area</td>
<td>$A_t$</td>
<td>Contact area of the distal tip with the cardiac tissue</td>
</tr>
<tr>
<td>Tip geometry</td>
<td></td>
<td>3D profile of tip</td>
</tr>
<tr>
<td>Tip modulus</td>
<td>$E$</td>
<td>Elastic modulus of tip</td>
</tr>
<tr>
<td>Fixation mechanism</td>
<td></td>
<td>Active or passive</td>
</tr>
<tr>
<td>Tip pressure</td>
<td>$P_{tip}$</td>
<td>Pressure tip exerts on tissue</td>
</tr>
<tr>
<td>Neck stiffness</td>
<td>$k_n$</td>
<td>Bending stiffness of the neck section</td>
</tr>
<tr>
<td>Helix length (active)</td>
<td>$l_n$</td>
<td>Total unscrewed length of helix</td>
</tr>
</tbody>
</table>

Within this framework, there are two subcategories – the creation of force in the lead, which relies on stiffness and buckling mechanics; and the transmission of force to the tissue, which relies on contact mechanics. These two areas involve distinctly different factors that are addressed here.

3.1.1 Stiffness and Buckling Properties

The stiffness of the lead governs the critical load that causes the lead to buckle. The contraction of the heart wall against the lead increased the load experienced until that critical load is reached and buckling occurs in a particular unconstrained length of the lead. After buckling, the transmitted load decreases, and the cycle continues. Therefore, the stiffness of the lead determines the maximum load caused by heart motion. A simplified diagram of the lead being compressed by the heart can be seen in Figure 3.
The body stiffness of the lead can be defined as a measure of the force generated by the lead divided by the magnitude of an imposed displacement. For a thin elastic homogenous column, the buckling load can be idealized with the Euler buckling equation

\[ P_{cr} = \frac{\pi^2 EI}{(KL)^2} \]  

where \( E \) is the elastic modulus, \( I \) is the second moment of area, \( L \) is the buckling length, and \( K \) is a buckling faction dependent upon boundary conditions. This load is the maximum load that the member experiences, and therefore, is the maximum force that a lead can generate into a medium. The buckling strength of a column is then

\[ \sigma = \frac{C \pi^2 E}{(L/r)^2} \]  

where \( C \) is a constraint coefficient between 1 (round ends) and 4 (fixed ends) and \( r \) is the radius of gyration. However, Eqs. (1) and (2) assume a perfectly straight column, which for a lead is never the case. With a slight initial curvature, the strength becomes
where \( d \) is the maximum initial deflection, \( c \) is the distance from the vertical axis to the furthest fiber on the concave side of the column, and \( r \) is the radius of gyration with respect to the vertical axis [19].

The neck stiffness of the lead is an additional parameter that should be considered in stiffness analysis. A thin overmolded plastic neck is an “anti-perforation” feature included in some leads, designed to buckle at a lower critical load than the complete lead body. This preserves the structural integrity of the lead while reducing the critical buckling load at the helix, thereby mitigating the force applied to the tissue.

However, the lead is not a homogenous structural member, but rather an assemblage of multiple layers of polymer tubing and metal coils. For a typical bipolar pacing lead, the least complex cross-section of the lead body is likely to have at least five layers of tubing and coils that are sized and specified for each individual lead model. A typical defibrillation lead can also include cables, typically in non-symmetric tubing with multiple lumens. In addition, the conductors are composite materials themselves, comprised of medical alloys and rare metals for biocompatibility. Thus different lead types and models will respond very differently to flexural stimuli, applied torsion, and simple buckling based simply on the differences in composition.

For a simple model of a bipolar pacing lead, a generic and simplified lead cross section is presented. In this model we assume an inner coil, an outer coil, and an inner and outer sheath to prevent electrical contact between the two and with the body. A representative cross-section is shown in Figure 4. In this case, the modulus of rigidity (the composite of modulus and moment of inertia) would amount to

\[
EI = \frac{\pi}{64}(E_ot_o^4 + E_it_i^4) + EI_{oc} + EI_{lc}
\]

where \( E_o \) is the modulus of the outer insulation layer, \( t_0 \) is the thickness of the outer insulation layer, \( E_i \) is the modulus of the inner insulation layer, \( t_i \) is the thickness of the inner insulation layer, and \( EI_{oc} \) and \( EI_{lc} \) are the moduli of rigidity for the outer and inner coils, respectively. The last two terms can be calculated using coil bending equations depending on the particular coil structure and filar count [20-22].
With all terms in the critical buckling load defined, dividing by the total cross-sectional area yields the buckling strength of the lead for a perfectly vertical configuration

\[ \sigma_{cr} = \frac{\pi^3 (E_o t_o^4 + E_i t_i^4) + E_{loc} + E_{lic}}{64(KL)^2 d_0^2} \]  

Figure 4 Cross-section of generic lead, with one inner coil, one outer coil, and an inner and out layer of insulation.

an expression for the bending strength in an initially curved configuration would follow as Eq. (3) with

\[ EA = \frac{\pi}{4} (E_o t_o^2 + E_{oc} t_{oc}^2 + E_i t_i^2 + E_{ic} t_{ic}^2) \]

There is a similar issue with the neck stiffness of the lead, which is a parameter that should be considered simply due to leads with “anti-perforation” features designed to buckle early and mitigate the force transmitted through the lead towards the tissue. Such features include “hinge” joints formed using a thin overmolded plastic sections or transitions to softer materials.

3.1.2 Lead Tip Construction

Much of the burrowing capability of a lead through tissue depends on the geometry and size of the lead tip. Sharp features tend to penetrate more easily than blunt features; square corners work their way through tissue more easily than filleted corners. The size of the lead tip is expected to have an effect
as well similar to that of a needle point; the larger the needle, the more force required to force it through the cloth. Because the heart applies a relatively constant force irrespective of the lead employed, it is predicted that with all other factors equal, smaller diameter lead tips will tend to perforate more than larger diameter lead tips. However, because stiffness is typically proportional to size as well, many smaller diameter lead bodies tend to buckle under a much smaller load and therefore do not apply as much force at the lead-tissue interface.

The modulus, or hardness, of the lead tip is typically much greater than that of the tissue, so this is typically not a distinguishing factor except in the case of a drastic material change – for example, a collar of soft silicone instead of hard PEEK [23].

The interaction between the lead tip and the tissue can be modeled using contact mechanics [19]. Hertz contact theory describes the interaction between two elastic bodies and is useful as a first-pass estimate of the contact stress in the tissue. Lead tip geometry is usually roughly cylindrical with an edge that is either filleted or square. Because the tissue is much more compliant than the lead tip shell materials, we can assume a rigid cylindrical die. If that die (lead tip) interfaces with a flat elastic semi-infinite body (tissue surface), and a load \( F \) is applied to the die, the static deflection is given by

\[
y = \frac{F(1 - \nu^2)}{2RE}
\]

where \( \nu \) is the Poisson’s ratio of the tissue, \( E \) is the elastic modulus of the tissue, and \( R \) is the radius of the die. The stress at any point on the contact surface can be described by

\[
\sigma = \frac{F}{2\pi R \sqrt{R^2 - r^2}}
\]

where \( r \) is the radius at the point of interest. The stress at the center of the cylinder is shown to be

\[
\sigma_c = \frac{F}{2\pi R^2}
\]

The stress at the outer edge will increase will theoretically approach infinity, but in reality can be controlled with the addition of a chamfer or fillet.

Varied geometry can lead to a different result. If we assume a completely rounded lead tip, the contact problem becomes point contact, and the modeling equations change. Again assuming a rigid sphere, the maximum deflection for a given load \( F \) becomes
\[ y = 1.040 \sqrt[3]{\frac{F^2 C_E^2}{D}} \]  

(10)

where \( D \) is the diameter of the sphere, and \( C_E \) is a composite modulus, and for a rigid sphere, is equal to

\[ C_E = \frac{1 - \nu^2}{E} \]  

(11)

The maximum stress is then

\[ \sigma_{max} = 0.918 \sqrt[3]{\frac{F}{D^2 C_E}} \]  

(12)

and the radius of circular contact area is

\[ a = 0.721 \sqrt[3]{FD C_E} \]  

(13)

Eqs. (7)-(9) provide a decent first pass toward modeling the contact problem of cardiac tissue with a cylindrical lead tip, and Eqs. (10)-(13) do the same for a spherical lead tip.

Active leads, or leads with an extendable and retractable helix to anchor them to the cardiac tissue, are now the most common lead implanted in the U.S. They are much less prone to dislodgment and thereby avoid many of the complications and health risks associated with a loose lead. However, they are significantly more likely than passive leads to perforate through the cardiac wall according to the literature, and it is suspected that the geometry of the helix has much to do with that probability. The helix length, pitch (fixed or variable), diameter, coating are all factors to be considered. Helix length can cause penetration by extending past the heart upon insertion; pitch can pull tissue into the helix and cause damage, or create a higher contact force on the tissue; the diameter of the helix can increase the contact force on the tissue, and the coating can increase the friction between the helix and tissue causing irritation and damage. A multifilar helix design could also have effects on anchoring and stability in the tissue.

It must be stated that the above factors address the perforation issue from a design standpoint and, more importantly, from a mechanical standpoint. There are a host of biological interactions that significantly influence the performance of an implanted lead, and some of these also affect the mechanical properties listed above. Several of these biological factors are included in the list of exogenous factors in the next section. However, to avoid a never-ending list of possible lead configurations and interactions, it was necessary in this project to limit or exclude biological factors in testing; this will be further explored in a later section.
3.2 Exogenous Factors

Though the lead possesses characteristics that affect perforation, there are a number of factors that are unaccounted for in the design of the lead and are beyond the control of the device manufacturer. Such factors are exogenous, and design changes have no direct influence on their occurrence and effects. These factors can be further divided into characteristics of the target heart and the technique of the clinician during implantation. A list of possible exogenous factors was compiled and appears in Table 2.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue thickness</td>
<td>$t$</td>
<td>Absolute thickness of heart wall</td>
</tr>
<tr>
<td>Tissue hardness</td>
<td>$H_t$</td>
<td>Hardness of local tissue</td>
</tr>
<tr>
<td>Tissue puncture resistance</td>
<td>$R_t$</td>
<td>Puncture resistance of local tissue</td>
</tr>
<tr>
<td>Patient age</td>
<td>$\eta$</td>
<td>Age of the patient</td>
</tr>
<tr>
<td>Medical condition</td>
<td></td>
<td>Any heart diagnoses, history of problems</td>
</tr>
<tr>
<td>Turn count</td>
<td>$n$</td>
<td>Number of turns used to extend helix</td>
</tr>
<tr>
<td>Helix penetration depth</td>
<td>$L_{ext}$</td>
<td>Actual depth helix punctures into tissue (not design depth)</td>
</tr>
<tr>
<td>Lead slack</td>
<td>$s$</td>
<td>Lead length between tricuspid valve and implantation site</td>
</tr>
<tr>
<td>Insertion angle</td>
<td>$\varphi$</td>
<td>Angle from the normal at which the lead is attached</td>
</tr>
</tbody>
</table>

The thickness of the cardiac wall at the lead-tissue interface is obviously of great importance. A greater thickness provides more material through which a lead must burrow, and therefore requires a greater force or length of time for a lead to perforate. The stiffness of the tissue is also expected to have an effect—a softer tissue structure will dissipate more of the cycling energy, whereby a more rigid interface will have less energy dissipation. The puncture resistance of the tissue is simply a measure of how well an object can force its way through the tissue, and has much to do with hardness; however, because the tissue is not homogenous, non-linear, and not static, it is difficult to characterize the average puncture resistance, or the average hardness, both across a physical sample and with time.

There are also factors that tend to affect the physical and biological factors distinctly, even though they may only be correlations. It has been observed that the older the patient during implant, the more likelihood of a complication. This is because the heart wall tends to grow thinner and also weaker with age, and therefore becomes more susceptible to perforation. The medical condition of the patient may also have a significant influence; for example, if the patient experiences a condition that slows the
regeneration of heart tissue, a lead may burrow through the cardiac wall much more easily (and therefore, in less time) than would otherwise be possible.

The implant technique also has an effect on the likelihood of perforation. Because both the lead and the cardiac tissue are compliant, it is possible for a physician to press and secure a lead into compressed cardiac tissue, or while the lead is already buckled. Because the process is inexact, the lead or tissue can be left with residual stresses that create tensile or compressive forces at the lead-tissue interface. Tensile forces typically result in dislodgement over time; compressive forces result in perforation. However, since the composition of the tissue changes over time, especially to external stimuli, it is difficult to predict the effect of too much or too little pressure on the lead tip. Another aspect of implant is the penetration depth of the helix. A lead helix is designed to be fully extended to anchor the lead to the tissue securely; a helix that is not fully extended can become dislodged and then start burrowing into the tissue from a loose position. In addition, if the extended helix length is greater than the thickness of the heart wall, a fully extended helix will already have punctured through the heart wall, forming a crack that can potentially lead to perforation.

Finally, the orientation of the lead during implant can significantly affect the amount of force transferred during systole. If one assumes a fixation point at the tricuspid valve (due to fibrotic growth at the valve interface), then the total lead length in the ventricle dictates the lead shape, which can have an effect on the maximum force applied at the lead-tip interface. Also, the incident angle between the lead distal segment and the cardiac tissue can affect the magnitude and direction of forces and moments generated at the interface, and therefore the likelihoods of dislodgement and perforation.

### 3.3 Biological Factors

The biology of the cardiac environment can help or hinder a lead against perforation. Like elsewhere in the body, cardiac cells react to foreign objects with rapid fibrotic growth around the intruder. For a lead in a cardiac cavity, this fibrosis can fixate a lead to a section of the cardiac wall. For a lead implanted in the right ventricle of the heart, fibrotic growth frequently occurs in two places: at the lead-tissue interface, and at the tricuspid valve through which the lead must pass. Both of these growths can effectively anchor the lead to the cardiac wall. Passive leads rely on this growth mechanism to eventually anchor them to the lead-tissue interface. These fixation points create boundary conditions for the buckling of the lead, and thus have concrete mechanical effects.

The fibrotic growth on the tip of the lead is known as a thrombosis, and starts as a cluster of cells which then, with time, works its way along the distal tip of the lead. This growth creates another material layer that affects the mechanical properties of the lead, especially with regards to buckling. Depending on the design of the lead, the fibrotic growth can also work its way into complex features of the lead such the filars of a shocking coil, gaps around an electrode, or into the internal components. Many leads use design features and specialized manufacturing processes to avoid this complication, as it severely inhibits lead removal.
The composition of the cardiac tissue beneath the lead-tip interface also changes upon implant and thereafter, as shown in Figure 5. Fibroplasia progresses around the area of helix insertion, sometimes leaving distinct fibrotic traces throughout the myocardium. Fibroplasia changes the mechanical properties of the heart wall and can additionally cause muscular contraction around the helix, altering how the tissue responds to the implanted lead. It is worth remembering that the biological issues here are extremely complex and have a significant role to play in perforation risk, but are not accounted for in this thesis.

Figure 5 Cross-sectioned cardiac tissue showing a regular lead implantation at 90 days. Fibroplasia in green and viable myocardium in red. Notice the holes where the helix was nested in the wall.

3.4 Perforation Mechanics

The exact mechanism of perforation is still under debate. It is also possible that, due to the low incidence of perforation overall and the notable variability in associated conditions, there are multiple mechanisms by which a lead can perforate. This project does not address those mechanisms directly, but instead uses first principles to create a simple model of lead perforation to elucidate the phenomenon.

Perforation here is considered as a hard object breaking through a compliant membrane of finite thickness. In order for any puncture to occur, there must be a transmitted force that causes a fracture mode in the membrane. In this case, that force is generated by a displacement that forces a thin member into buckling. So, at the simplest level, one can generalize lead perforation as a slender object in buckling pressing against a compliant membrane. For simplicity, we say that the lead is homogenous with an
effective modulus and that the buckling can be idealized with an Euler mode. This is the force transfer model.

However, force is not the only factor involved in perforation. With an extended helix that is assumed rigid, any rotational motion about the lead axis can cause an unthreading effect (like a bolt in a threaded hole), or a compressive effect (like an overtorked bolt). Because the tissue is so compliant relative to the helix metal, the overtorking is of particular concern to perforation.

3.5 Previous Testing

This project is not the first effort to address the perforation phenomenon from a design standpoint. Prior to this dynamic perforation test, a static tip pressure test was developed in accordance with recommended test 10 on page 8 of FDA’s Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions (Issue date of January 14, 2000). This specification was developed with the understanding that the tip pressure of the lead – the force a lead applies during cycling across its projected area at the tip – contributed heavily to the risk of perforation [24].

Using an MTS servo-mechanical tensile tester, a force was slowly applied to a lead secured in to concentric pin vises. Testing was performed with the lead initially straightened and a free gage length of 7 cm between the vise grips. Additionally, the exposed section of the lead (between the vises) was submerged in saline solution held at the biological temperature of 37°C. A picture of the submerged setup appears in Figure 6.

Figure 6 A submerged lead in the static tip pressure test. On the left, a straightened lead in the initial position; on the right, a compressed lead in the bucked position.

Several leads were tested in this setup and the full force-displacement response curves were recorded for first loading cycle. Average force was calculated during the last 1 mm of motion and then
normalized by the projected area of the lead tip at the lead-tissue interface to result in a pressure value. The resulting summary data for a sampling of non-commercialized prototype test leads and commercially available lead products appear in Figure 7. A specification for lead tip pressure was devised from the distribution of the test results based on an understanding of the tested devices’ performance in human clinical use and pre-clinical animal studies. Using this test method, a lead which generated more than the pressure specification during the test would have the potential to perforate in human clinical use.

Figure 7 Chronic tip pressure results (tested with no stylet). Results are grouped by manufacturer.
3.6 Leads Tested

A full complement of cardiac leads was tested for this project. Three manufacturers' products were used – Boston Scientific (BSC), St. Jude Medical (SJM), and Medtronic (MDT). A full list of leads tested and their characteristics and quantities appears in Table 3. Lead families which are listed as positive controls have acceptable field performance with low perforation rates. Lead families which are listed as negative controls have data or field reports which may indicate marginally acceptable or potentially unacceptable field performance. Images of the leads and their distal ends are displayed in Figure 8, Figure 9, and Figure 10.

Table 3 Leads tested.

<table>
<thead>
<tr>
<th>Leads</th>
<th>Model No.</th>
<th>Manufacturer</th>
<th>Lead Type</th>
<th>Polarity</th>
<th>Insulation</th>
<th>Fixation</th>
<th>No. Tested</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endotak Reliance G</td>
<td>0186</td>
<td>BSC</td>
<td>Tachy</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>6</td>
<td>Positive</td>
</tr>
<tr>
<td>Fineline II EZ Sterox</td>
<td>4469</td>
<td>BSC</td>
<td>Brady</td>
<td>Bi</td>
<td>Poly</td>
<td>Fixed</td>
<td>6</td>
<td>Positive</td>
</tr>
<tr>
<td>Flextend</td>
<td>4086</td>
<td>BSC</td>
<td>Brady</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>6</td>
<td>Negative</td>
</tr>
<tr>
<td>Dextrus</td>
<td>4137</td>
<td>BSC</td>
<td>Brady</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>6</td>
<td>Positive</td>
</tr>
<tr>
<td>Selute</td>
<td>4185</td>
<td>BSC</td>
<td>Brady</td>
<td>Bi</td>
<td>Silicone</td>
<td>Passive</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Sweet Tip</td>
<td>4143</td>
<td>BSC</td>
<td>Brady</td>
<td>Bi</td>
<td>Uni Silicone</td>
<td>Fixed</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>CapsureFix Novus - Polyurethane</td>
<td>4076</td>
<td>MDT</td>
<td>Brady</td>
<td>Bi</td>
<td>Poly</td>
<td>Active</td>
<td>6</td>
<td>Positive</td>
</tr>
<tr>
<td>CapsureFix Novus - Silicone</td>
<td>5076</td>
<td>MDT</td>
<td>Brady</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>6</td>
<td>Positive</td>
</tr>
<tr>
<td>CapsureFix MRI SureScan</td>
<td>5086</td>
<td>MDT</td>
<td>Brady</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Tendril SDX</td>
<td>1688T</td>
<td>SJM</td>
<td>Brady</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Tendril ST</td>
<td>1788T</td>
<td>SJM</td>
<td>Brady</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Tendril ST Optim</td>
<td>1888T</td>
<td>SJM</td>
<td>Brady</td>
<td>Bi</td>
<td>Optim</td>
<td>Active</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Tendril STS</td>
<td>2088T</td>
<td>SJM</td>
<td>Brady</td>
<td>Bi</td>
<td>Optim</td>
<td>Active</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>Durata</td>
<td>7120Q</td>
<td>SJM</td>
<td>Tachy</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>1</td>
<td>Negative</td>
</tr>
<tr>
<td>Test Lead G - Poly</td>
<td>-</td>
<td>BSC</td>
<td>Brady</td>
<td>Bi</td>
<td>Poly</td>
<td>Active</td>
<td>4</td>
<td>Negative</td>
</tr>
<tr>
<td>Test Lead G - Silicone</td>
<td>-</td>
<td>BSC</td>
<td>Brady</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>4</td>
<td>Negative</td>
</tr>
<tr>
<td>Test Lead 1</td>
<td>-</td>
<td>BSC</td>
<td>Brady</td>
<td>Bi</td>
<td>Poly</td>
<td>Active</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>Test Lead S - Silicone</td>
<td>-</td>
<td>BSC</td>
<td>Brady</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>3</td>
<td>Negative</td>
</tr>
<tr>
<td>Test Lead T</td>
<td>-</td>
<td>BSC</td>
<td>Tachy</td>
<td>Bi</td>
<td>Silicone</td>
<td>Active</td>
<td>4</td>
<td>-</td>
</tr>
</tbody>
</table>
Figure 8 Commercialized BSC cardiac leads tested.

Figure 9 MDT cardiac leads tested.
Figure 10 SJM cardiac leads tested.
4 Test Development

4.1 Test Design

The desired objective of this project is a physiologically appropriate simulation that mirrors the conditions of the lead in the heart as closely as possible. However, there is much variation between individual implants, which can significantly impact the likelihood of a perforation. Because we are interested in ranking the leads, the test must be a standard protocol to which each lead can be subjected. The more controlled variables in the test, the more any differences in the results can be attributed to the individual leads. With that in mind, a set of standard parameters for heart anatomy and conditions were developed.

Yet before parameters could be determined, it was necessary to decide on the lead implant scenario to be considered. The literature shows that the vast majority of perforations occur with bradycardia leads in the right ventricle at or near the apex. It is thought that the conical geometry of the apex creates wall boundaries that do not allow the lead to buckle freely, and instead produce a force-funneling effect. However, perforations have occurred not only at the apex but also at the cardiac wall surrounding the apex; and along the cardiac wall not near the apex at all. The cardiac wall is typically thinner at and around the apex, which may contribute to the higher incidence of perforation. In addition, the geometry of the apex varies widely from person to person, with some hearts possessing a very acute angle and some possessing a larger space in which the lead can move. For this project, it was decided to instead use a flat segment to simulate pure buckling against a cardiac wall rather than a constrained buckling.

From the above, and due to the large selection of bradycardia leads from the top three lead manufacturers (Boston Scientific, Medtronic, and St. Jude), it was decided that the test would primarily focus on bradycardia leads. However, the test must still be capable of handling other leads as well, provided they had a helix and fell within a certain diameter range. The majority of the leads commonly used have a diameter of 6-8 Fr (where Fr is the French catheter scale, and 1 Fr = 0.33 mm). However, larger leads, like Boston Scientific’s Endotak Reliance, approach 10 Fr, and smaller leads, like Boston Scientific’s Fineline, approach 5 Fr. For this reason it was decided that the test should have the capability to test leads from 4 to 10 Fr in diameter.

A study analyzing lead motion in the right ventricle was conducted and included three models of the right ventricular geometry. The models are for a small heart, and average heart, and a large heart – the parameters for each of which are displayed in Table 4. The small heart model was used here for purposes of conservatism – because buckling of the lead is the main phenomenon, Euler’s theory indicates that a shorter buckling length requires a greater load for the same lead stiffness. Therefore, the small heart model will deliver the largest load from a buckled lead by creating a shorter free buckling length. A diagram of the template appears in Figure 11.
Figure 11 Right ventricular heart motion template alongside a tilted view of the heart for reference [25].

Table 4 Anatomical parameters for heart models[25].

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Small Heart</th>
<th>Average Heart</th>
<th>Large Heart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Distance [PD] (mm)</td>
<td>70</td>
<td>84</td>
<td>98</td>
</tr>
<tr>
<td>Diastolic Distance [A1L1] (mm)</td>
<td>65.5</td>
<td>79</td>
<td>92</td>
</tr>
<tr>
<td>Systolic Distance [A2L2] (mm)</td>
<td>50</td>
<td>60</td>
<td>69</td>
</tr>
<tr>
<td>Stroke (mm)</td>
<td>15.5</td>
<td>19</td>
<td>23</td>
</tr>
</tbody>
</table>

The small heart model provides distances for parameters of interest. For this test, we are primarily interested in the major axis length of the right ventricle at diastole, and the major axis length of the right ventricle at systole. This axis length runs from the tricuspid valve to the right ventricular apex. From those two distances the distance which the heart compresses during systole can be calculated, known here as stroke length.

The last assumptions that must be made are the boundary conditions for the lead. The distal end lead will be fixated at the apex, but another fixation point is needed to establish a buckling mode. For this study, it is assumed to be the tricuspid valve, based on the fibrotic growth that frequently anchors the lead at that point. This location is a conservative but realistic decision. A fixation point at the tricuspid valve is a known phenomenon and creates a shorter lead length subject to buckling. If the lead was not fixated at the tricuspid valve, then the second boundary condition would be at a location proximal to the valve either on the cardiac wall or vascular wall, typically up in the superior vena cava. This condition
would create a longer lead length subjected to buckling. Since the shorter lead length will transmit higher
force by the buckling analysis presented earlier, the tricuspid valve was selected as a conservative
condition.

Therefore, the complete anatomical model has the lead fixated by its helix at the apex of the small
heart model, and constrained via fibrotic growth at the tricuspid valve (the two end points of the major
axis length). The stroke length is the displacement of the apex upon systole, and serves to provide the
force to buckle the lead. To emulate a constant and repeatable stroke, a fixed-displacement test is
required, whereby one end of the lead is displaced relative to the other by a fixed amount. A fixed-force
test would be inappropriate, as more compliant leads would experience much greater deflections than
stiffer leads, which from the anatomy is not the case. The heart stroke length is approximately constant
regardless of the presence of a lead. This assumption is sound because the contractile strength of the heart
wall is much greater than the buckling strength of a lead.

With the geometry considered, there are other conditions in the heart that can significantly affect the
mechanical performance of a lead. Because leads are comprised of several polymers, their mechanical
properties are governed not just by proportion and size but also by temperature, humidity, and strain rate.
It would be well beyond the scope of this thesis to analyze the response for each individual lead under a
variety of conditions; however, because the aim is to mirror the internal physiology, the test must be
conducted under physiologically similar conditions. The lead is implanted in a cavity that regularly fills
with blood at human body temperature at a given interval. Therefore, the test is conducted in a saline bath
at 37°C to mirror the temperature of circulating human blood. The heartbeat rate translates into a stroke
frequency. If an average heart, beating at 60 bpm, contracts over a period of 0.3s (the systolic period), that
motion can be transformed into a cyclic rate by doubling the stroke period and taking its reciprocal,
resulting in a 1.666 Hz cycle rate. Though not precisely the acceleration profile of the heart, a sinusoidal
motion was selected to avoid the hard stop of the sawtooth profile on the mechanical tester used here,
which caused jerking overcompensation motions in the sensitive lead. A more physiologically appropriate
motion profile could likely be achieved with different profile software.

Table 5 summarizes the test parameters and Figure 12 gives a visual depiction.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment</td>
<td>37 deg C, saline or air</td>
</tr>
<tr>
<td>Tissue Phantom</td>
<td>Perma-Gel</td>
</tr>
<tr>
<td>Boundary Conditions</td>
<td>Clamped at tricuspid; fixated at tip</td>
</tr>
<tr>
<td>Cycle Rate</td>
<td>1.666 Hz (0.3 s systole)</td>
</tr>
<tr>
<td>Test Method</td>
<td>Fixed displacement</td>
</tr>
</tbody>
</table>
The length of the test was another factor to be considered. Ideally, the test would run in fresh cardiac tissue at the biological heart rate for as long as necessary to perforate. However, that method would take months, if not years, to draw conclusions, and is impractical for this work. With a slightly accelerated cyclic displacement, the true accelerated parameter in the test is the degradation of the cardiac simulant, discussed in Section 4.2. Because the simulant degrades readily, tests were conducted on three leads for first just under three hours (16,000 cycles), and then eight hours (48,000 cycles). The eight hour test results showed a greater degree of differentiation between leads while still allowing for high test throughput in a limited amount of time. Therefore, 48,000 cycles was selected as the test cutoff length.

Another consideration is the inclusion of failure criteria during the test. With failure criteria, the test would cycle until a certain parameter was achieved. Without failure criteria, the test would run for a fixed number of cycles and then the result would be characterized. For this project, a failure criterion of perforation was initially considered where a lead would be repeatedly cycled against a cardiac wall or simulant until it broke though. Then the cycle count at the time of perforation would serve as a ranking system by which leads could be compared. Though physiologically appropriate, there was no guarantee that every lead would eventually perforate through the medium. In addition, creating multiple simulant samples at a tightly controlled thickness would be a difficult endeavor, and accurately detecting a breakthrough would be even more challenging. Therefore, it was decided that a fixed cycle test would be used here.

With each lead running to a fixed number of cycles, the damage done to the cardiac wall or simulant would be characterized at the conclusion of the test and used to rank the leads. This is more intensive in the sense that metrics must be developed to characterize the damage done, but it also provides a fixed amount of time during which the samples can run which was appropriate for the limited resources and time available for the large roster of test samples.
4.2 Cardiac Simulant

In order to decide how long the test should run, it was necessary to choose a cardiac simulant with consistency, repeatability, and degradability. Actual post-mortem cardiac tissue does not possess any of these properties. The thickness of cardiac tissue can range from 2mm to 6mm, its patterning can be erratic, and it is not a smooth, repeatable surface, so every test sample of cardiac tissue will possess different thickness and potentially different mechanical properties. In addition, it takes days to months to years for leads to fully perforate through the heart in the delayed case. Because of the finite length of this project and the number of leads to be tested, a large cycle count was not possible. These factors certainly attribute to variation within clinical perforation cases, and for the same reason, cardiac tissue is not an appropriate material for a controlled test.

However, if cardiac tissue were used, other test parameters could be adjusted to “accelerate” the test. Such acceleration could involve a faster cycle rate, a large stroke, or a smaller grip length as means of applying more force to the sample and creating degradation in a short time period. However, because both the cardiac tissue and the lead materials are not linear elastic isotropic, and each lead has a different sensitivity to temperature, strain-rate, and other environmental conditions, it becomes impossible to change the test parameters without changing the material behavior of the test. Dynamic modulus data on polymers employed in lead construction show that changes in material behavior begin as low as 10Hz, the effect of which would be compounded by the number of cycles. Because each polymer responds differently and each lead is constructed of different polymers, it was not reasonable to increase the cycle rate of the test without conducting a lengthy analysis on the effects of that increase.

Acceptable consistency of a given material requires that the mechanical properties and appearance of the material are the same spatially throughout a sample. The properties at the top of the sample should be identical to the properties at the bottom of the sample. Acceptable repeatability requires that every batch of samples maintains the same mechanical properties when tested, so that one sample is not more compliant than another based on how the sample was melted or mixed. Acceptable degradability requires that each lead be able to create measurable damage in the simulant in a reasonable amount of time, so that variable data on each lead can be measured without months of testing.

With that in mind, a number of materials were considered, displayed below in Table 6. Each of these materials was evaluated for the three aforementioned traits. Consistency was evaluated either by changes in color and durometer in solid samples and inspection for bubbles in cast samples for the gelatins and plastics, within an individual sample. Repeatability was evaluated by comparing those traits among multiple samples of the same material. Degradability was tested by cycling a probe into the material and inspecting the divot created.
Table 6 List of materials considered for cardiac simulant.

<table>
<thead>
<tr>
<th>Material</th>
<th>Model</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular liquid plastic</td>
<td>2132LP</td>
<td>M-F Manufacturing Co.</td>
</tr>
<tr>
<td>Cardiac muscle</td>
<td>T-MUS-C-1020</td>
<td>Syndaver</td>
</tr>
<tr>
<td>Derma-Sol</td>
<td>-</td>
<td>California Medical Innovations</td>
</tr>
<tr>
<td>Poly Vinyl Alcohol (PVA)</td>
<td>Mowiol 10-98</td>
<td>Sigma-Aldrich</td>
</tr>
<tr>
<td>Simulated tissue</td>
<td>TSS-10</td>
<td>SimuLab</td>
</tr>
<tr>
<td>Ballistics gel</td>
<td>Professional Grade Ballistic &amp; Ordnance Gelatin</td>
<td>Vyse</td>
</tr>
<tr>
<td>Hydrogels</td>
<td>-</td>
<td>Cambridge Polymer Group</td>
</tr>
<tr>
<td>Perma-Gel</td>
<td>Product #: 315783</td>
<td>Perma-Gel</td>
</tr>
</tbody>
</table>

Almost all of the materials were consistent when appropriate preparation was conducted. The least consistent of all materials were the casted gelatins and plastics, which sometimes captured air bubbles during the cooling process, creating an inconsistent medium. However, using controlled conditions it was possible to dissipate the bubbles from the gelatins, rendering them consistent. The most consistent were the pre-packed simulants, such as the Syndaver cardiac tissue. All materials were decently repeatable – the gelatins and cast materials had surprisingly good consistency between batches. The true distinction came at degradability of the materials. The solid cardiac simulants were too tough for the lead helix to penetrate, and showed only elastic deformation during probe testing, leaving no mark. The gelatins were softer and easily degradable, as were the silicones. Overall, the Perma-Gel offered the best combination of consistency, repeatability, and degradability as well as ease of use. In addition, the gel was able to be re-melted numerous times without significant change in mechanical properties. Table 7 lists the ratings and rankings.
Table 7 Material ratings for the three necessary cardiac simulant metrics.

<table>
<thead>
<tr>
<th>Material</th>
<th>Consistency</th>
<th>Repeatability</th>
<th>Degradability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular liquid plastic</td>
<td>Consistent</td>
<td>Highly variable</td>
<td>Degradable</td>
</tr>
<tr>
<td>Cardiac muscle</td>
<td>Very consistent</td>
<td>Very repeatable</td>
<td>Not degradable</td>
</tr>
<tr>
<td>Simulated tissue</td>
<td>Very consistent</td>
<td>Very repeatable</td>
<td>Not degradable</td>
</tr>
<tr>
<td>Ballistics gel</td>
<td>Very consistent</td>
<td>Repeatable</td>
<td>Very degradable</td>
</tr>
<tr>
<td>Perma-Gel</td>
<td>Very consistent</td>
<td>Very repeatable</td>
<td>Very degradable</td>
</tr>
</tbody>
</table>

Because a perforation test depends so much upon the material being perforated, a deeper analysis of the Perma-Gel was necessary. There were several questions that needed to be addressed. What is the effective modulus of the material and how does it compare to the modulus of cardiac tissue? How does the material respond to repeated cycling? Does the material experience stress relaxation or creep? How do the mechanical properties vary with temperature? Is it possible for the material to absorb aqueous solutions? It was necessary for all of these questions to be answered before incorporating the material into the test.

Establishing a modulus estimate was the first order of business. Fresh porcine cardiac tissue (no more than four hours postmortem) was obtained and a tension test was conducted. Various loads were applied to the strip and the extension measured via caliper. A strip of Perma-Gel was tested in an identical manner. Both materials are highly nonlinear, but the initial stress-strain curve was quickly ascertained, displayed here in Figure 13, and a linear modulus was estimated from a least squares fit of the first three data points for each test, respectively, as shown in Figure 14. The estimated moduli for the Perma-Gel and cardiac tissue were 54.8 kPa and 17.3 kPa, respectively. It became clear that, in tension, the materials demonstrated distinct stress-strain curves. The porcine tissue becomes stiffer with increasing strain, while the Perma-Gel becomes more compliant. So the tissue is strain-hardening, and the Perma-Gel strain softening. This quick bench-test verified that there are certainly differences in the material behavior between the tissue and Perma-Gel, but also established that the Perma-Gel is not an order of magnitude stiffer than the tissue and therefore could still be used as an acceptable simulant.
Figure 13 Quick stress-strain measurements of porcine tissue and Perma-Gel.

Figure 14 Quick modulus measurements of porcine tissue and Perma-Gel.
Viscoelastic materials are modeled with a dynamic modulus, a complex term designed to represent both the amount of energy stored in the material during cycling and the amount dissipated. For a purely elastic material, stress and strain are always in phase. For a purely viscous material, the strain lags the stress by 90 degrees of phase. A viscoelastic material has elements of both behaviors, and therefore has a phase lag somewhere between zero and 90 degrees. The dynamic modulus can be modeled as

\[ G = G' + iG'' \]  

where \( G' \) is the storage modulus and \( G'' \) is the loss modulus. These terms reflect the relationship between the amplitude of an applied oscillatory stress and the resulting strain and the phase lag between the two quantities according to

\[ G' = \frac{\sigma_0}{\varepsilon_0} \cos \delta \] 

\[ G'' = \frac{\sigma_0}{\varepsilon_0} \sin \delta \]

To obtain a comprehensive picture of the material behavior during the test, a dynamic mechanical analysis (DMA) was performed on the gel. Using a 25 mm parallel plate fixture, a sample 25 mm in diameter by 12 mm thick was tested in compression on a Thermal Analysis RSA G2. The dynamic mechanical analyzer is capable of examining the effect of temperature and strain rate on a material, as well as computing a dynamic modulus for viscoelastic materials such as polymers. The analysis conducted addressed creep, stress relaxation, and temperature effects on the material.

Tests were conducted at room temperature (23 deg C), test temperature (37 deg C), and 50 deg C and 60 deg C to analyze the gel response if temperatures were to rise above 37 deg C during the heating process. Time sweeps were conducted at the aforementioned temperatures to test for stress relaxation at 5% strain. There is no significant change from room temperature to test temperature, but there are distinct changes in the material behavior at the higher temperatures. It was important to clarify exactly where these changes were taking place, so a full scan was compiled to find the transition point.

The full plot determines that there is a transition that begins around 42 deg C where the dynamic modulus begins to change rapidly. The storage modulus rapidly drops at 42 deg C, and the loss modulus increases significantly — so a large amount of energy previously stored per cycle is now dissipated in the cycling process. Therefore, it is important not to heat the Perma-Gel much beyond the 37 deg C test temperature. Three-dimensional plots of the storage modulus, loss modulus, and phase angle appear in Figure 15, Figure 16, and Figure 17.
Figure 15 Perma-Gel storage modulus plotted against temperature and step time.

Figure 16 Perma-Gel loss modulus plotted against temperature and step time.
A DSC test was performed as well to verify the above findings. It was confirmed that the Perma-Gel began a phase change at approximately 128 deg C, as shown in Figure 18.
Figure 18 Modulated differential scanning calorimetry results for the Perma-Gel sample. The blue plot is the reversible heat flow, and the steep drop confirms that a phase change (melting) begins at the melt temperature of 128 deg C.

4.3 Fixturing Design

The overall concept of the test environment was a custom tank that fit into a dynamic tester. Multiple leads were to be tested at once, and the tank would need to have the flexibility to test one lead or many with equal precision and accuracy. In addition, the variables mentioned in the previous section needed to be controlled and each lead positioned precisely. Figure 19 displays the CAD model and actual test setup.
In order to install multiple leads into a test setup, it was necessary to devise a modular system whereby the lead and gel could be aligned outside of the system, inserted into the system, and then secured. There were unique constraints on the degrees of freedom for the various modules according to their function, and this informed their design.

For design simplicity, it was necessary to develop a system with the minimum amount of modules that fulfilled the functional requirements of the system. Because one end of the lead must displace relative to another during the buckling motion, two modules are necessary at a minimum. However, to align them, a third removable module is required to connect to each. The three modules serve the purposes of constraining the proximal end of the lead; constraining the distal end of the lead; and locating the first two modules in three dimensions. These modules are the lead grip, gel holder, and setup fixture, respectively, and combine to form the lead assembly.

The design process for the lead assembly involved first determining the required constraints and allowed degrees of freedom for each module, and then determining the most robust connection scheme. It is important to note that connections must be made to the dynamic tester as well; the lead grip does not only have to connect to the setup fixture for alignment, but also connect to the crosshead while aligned. In addition, the setup fixture must be removed from the aligned lead grip and gel holder while in place in the tester. In addition, this process must be repeated multiple times and in a space-constrained environment.
Of prime concern is the accuracy required in the placement of the lead. We know that by Euler’s theorem the buckling load of a column goes as the inverse of the length squared. However, for a thin and very compliant lead structure, errors in length as well as in concentricity may have a significant effect on the forces and moments at the lead-tissue interface. This and the preceding factors inform the design of the modules, which is covered in the next section.

An annotated model of the test tank appears in Figure 20, followed by an annotated picture of the full system in Figure 21.

Figure 20 Annotated model of full tank assembly.
4.3.1 Setup Fixture

The setup fixture is designed to precisely align the lead grip and the gel holder in three dimensions. The gel holder and grip must be parallel in plane, centered, and a set distance apart. Additionally, the distance must be adjustable to one of three specifications. With that in mind, a two-part setup fixture was designed with three couplings—one for the lead grip, a second for the gel holder, and a third for the three positions required of the setup fixture. Figure 22 demonstrates the interfaces between the components.
The lead mount is a stage that can be positioned on the backbone at three intervals—corresponding to small, average, and large heart distances of 70, 84, and 98 mm between the tip of the lead grip and the top of the gel surface. A pin alignment scheme here would become difficult due to the three positions necessary, and angular misalignment becomes a major concern since the lead follows the groove path down to the gel. Therefore, a three-groove kinematic coupling was used (three of them, actually), to precisely locate the stage. The coupling uses three vee-grooves mated with balls spaced equally about a coupling circle. The balls form the vertices of a coupling triangle, within which the coupling is stable[26]. For this application, gravity would be acting in a direction perpendicular to the direction of coupling, resulting in slippage. The solution is a securing bolt in the interior of the coupling triangle that preloads the coupling to ensure that the effect of gravity is minimized. The precision of a three-groove coupling with these materials and a screw preload can easily be on the order of microns; here such precision is not needed but may very well be achieved. Figure 23 shows the coupling design and the Hertzian contact between the spheres and vee-grooves, and Figure 24 shows the setup fixture and its design features.
Figure 23 *Left* The vee-groove coupling with coupling triangle outlined. The stable region lies inside the triangle, and the unstable region outside. The preload bolt lies inside the triangle to ensure stability in any configuration. *Right* Hertzian contact mechanics ensure that six points of contact constrain six degrees of freedom for a deterministic system.

Figure 24 Setup fixture design with relevant features.
4.3.2 Lead Grip

A novel lead grip was required to simulate the effect of a fibrotically-enclosed tricuspid valve on the lead body. The completed lead grip design appears in Figure 25.

![Lead grip design with relevant features.](image)

The current grip fixture for lead compression testing is a pin vise with an exit port; the grip consists of four flexural members that are deflected into the lead with the tightening of an external nut with an internal taper. However, the members contact the lead across a very short length, and as such the force is barely distributed and can cause damage to the lead coils. In addition, the concentrated force can axially fix the inner lead body components and increase the buckling load. The new grip design is adapted from an existing grip for long cycle testing. A wider clamp length is used to distribute the applied force and avoid damage to the lead. X-ray imaging of the two grip designs show deformation in the pin vise and no deformation in the new grip (Figure 26).
Figure 26 Radiographs of a lead in the standard pin vise (left) and the lead grip designed for this project (right). Coil crushing is observable in the old grip, but not the new grip.

It was also necessary to connect the lead grip to both the setup fixture (for alignment) and the crosshead (for attachment). As such, there are two coupling planes on the lead grip that must be addressed; the top plane against the crosshead and the back plate against the setup fixture.

The function of the back coupling plane is simply alignment; there does not need to be a permanent connection, but all six degrees of freedom must be constrained to a certain positional tolerance in order for the grip to align with the crosshead. A planar kinematic coupling is used for the back alignment plane for simplicity of design. Three alignment pins constrain the grip in three degrees of freedom; a spring plunger supplies a nesting force to ensure that sufficient contact is made between all three pins. The design for the lead grip appears in Figure 27 with a diagram of contact forces that constrain its degrees of freedom, and Figure 28 shows a 3D annotated model of the interface.
Figure 27 Constraint forces and moments for the lead grip/setup fixture interface. *Top* The three kinematic constraints and nesting force. *Bottom left* Force balance for the grip in equilibrium with allowed motion. *Bottom right* Moment balance for the grip in equilibrium.

Figure 28 Annotated 3D model of the lead grip/setup fixture interface.
The top coupling plane is a semi-permanent connection—that is, it is necessary for the lead grip to connect in a manner where no motion is allowed during the test, but where the grip can be easily removed after the test has concluded. However, due to the planar kinematic back connection to the setup fixture, the top coupling must couple the grip and the crosshead without the gross rotation of the lead grip. For this, a floating adapter was designed with a female thread to affix to a male threaded adapter on the crosshead. The female adapter threads onto the male adapter until contact is made between the end of the male adapter and an internal shoulder bolt on which the floating adapter rides; then additional tightening stretches the threads and provides a secure fit. The completed lead grip design appears in Figure 25.

Because it was desirable to minimize mass and high absolute stiffness was not required due to the high compliance of the lead, the lead grips were manufactured in Ultem 1000 plastic.

4.3.3 Gel Holder

A fixture was required to contain the cardiac simulant gel. The diameter of an average lead falls between 6 Fr and 8 Fr, or 2-2.66 mm—with that in mind, to avoid boundary effects from an elastic gel, the gel container was designed with a minimum radius to exceed five times the 8 Fr diameter. In the final design, the minimum radius is 0.75 in, about 7 times the 8 Fr diameter. The gel cavity was initially designed to be round, but was changed to a square design in order to reduce refraction through the gel during optical inspection. The outer shape of the holder is also square instead of round to make for simple alignment on the baseplate.

It was also desired to clamp a thin film or tissue sample in the gel holder, and as such the design is flexible enough to allow that. With the addition of a threaded hole on one of the three non-mating sides of the holder, the cavity can draw a vacuum or be pressurized. With the combination of the thin film and pressurization, it is possible to displacement a simulant sample without moving the gel holder. These corollary applications were taken into account for the final design, which appears in Figure 29.
It was also necessary for the gel holder fixture to connect to the setup fixture on the backbone plane and the baseplate on the bottom plane. Thus the gel holder also has two coupling planes. The baseplate coupling is the simpler of the two – a three pin alignment scheme locates the gel holder and a magnet in the bottom plane retains the fixture. The rear coupling plane for the setup fixture has similar requirements to the lead grip/setup fixture coupling – the release must be made cleanly in a single direction. Another planar kinematic coupling is used, this time with two pins. One pin rests on a vee-groove, providing two points of contact, while the third rests on the flat shelf for a total of three points of contact (Figure 30). The nesting force is provided by two spring plungers that also oppose the weight of the setup fixture when the gel holder is aligned in the fixture. The spring plungers have rolling ball tips that allow the gel holder to slide freely off of the setup fixture during removal. Due to the weight of the setup fixture, a magnet coupling was forgone in favor of a quick release pin with four spring-loaded balls that ride against an inner bored surface. A deep groove is machined to intersect with the bore and provide a locking location for the quick release pin. A disc spring is used on the quick release spring pin to preload the connection and avoid any linear play in the pin coupling. A 3D CAD model appears in Figure 31.

![Figure 30 Constraint forces and moments acting on the gel holder. Left The three kinematic constraints and nesting forces. Right Horizontal and vertical force balances for the gel holder in equilibrium. The force pairs that create the moment balance are seen in this diagram as well due to symmetry.](image)

56
Figure 31 Annotated 3D model of the gel holder/setup fixture interface.

The gel holder needed to withstand the elevated temperatures of the gel melt processes (128 deg C) while maintaining shape so most plastics were excluded from the material construction. The holder also needed to survive in the saline environment without heavy corrosion, and so many metals were excluded. Finally, cost was considered and many of the specialized alloys were excluded. The final material choice was 316 SS.

4.3.4 Tank Design

Because of the mechanical dependence of cardiac leads upon temperature and humidity and the size requirements of testing multiple leads in the same setup, it was decided that designing a custom tank was the simplest way to achieve the above objectives instead of attempting to design fixturing around an existing tank setup.

Primary concerns for the design of the tank included material selection to prevent corrosion; design of the thermal system to ensure a steady 37 deg C with minimal thermal losses; design of the draining system to fill and empty the tank; and sealant selection to prevent leaks at the joints and at the access door.

For purposes of lightweight construction and also the ability to see inside the test chamber as it runs, transparent plastics were desired for bulk construction. Polycarbonate was selected for the walls, door, and lid segments.
For the design of the thermal system, the main question to be answered was where to place the heaters. Several options were considered - hanging placement in the water akin to a fish-tank heater; circulating fan heaters to be mounted in the rear of the tank; submerged heaters on the bottom surface; and heaters incorporated into the actual bottom surface, which would then function as a platen for the entire tank. Hanging heaters were the simplest and cheapest option, but because the tank was designed to have a capability to run in air as well, fish-tank heaters would not give off the required amount of heat to maintain the entire tank at 37 deg C without a massive power draw. Circulating flow heat sources are appropriate for tests in dry air and in humidity, but inappropriate for heating up a 25-liter tank of saline solution, and as such that potential solution was discarded as well. Placing a submersible heat source on the inside bottom surface of the tank seemed a reasonable option, but would take up necessary space from alignment features for fixturing. By process of elimination, the heated baseplate concept was selected for further development.

The design of the fluid circulation system involved few components and was relatively simple. The dynamic tester sat on a table at waist height; a large saline reservoir sat below that, slightly elevated from the ground. A drain pipe from the bottom of the baseplate ran from a drainage port to the top of the saline reservoir and emptied saline via gravity. The saline reservoir outlet was connected to a centrifugal pump with polypropylene impeller (to avoid corrosion) that would pump saline back up to the tank through a fill port raised eight inches from the baseplate surface. Valves at the tank inlet, the tank outlet, and the saline reservoir outlet ensured that the tank and saline reservoir were fully separable in the event of any leaks. All tubing was PVC, designed to handle fluid at temperatures of 130 F (54.4 deg C) - well above the heated temperature for the test - and also for corrosion resistance against saline flow. Valving was polypropylene, PVC, or stainless steel.

Leakage from the tank was a prime concern, especially given a test that involved 25 liters of saline surrounded by power lines, electronics, and other expensive test equipment. Because the baseplate would contain the thermal system, it would expand due to heating from the cool condition to warmed condition. Differences in linear thermal expansion was a concern in sealing a plastic wall to a metal baseplate with sealant compound alone. The additional displacement due to thermal effects can be estimated by

\[ \varepsilon_T = \alpha \Delta T \]  

(17)

where \( \alpha \) is the linear coefficient of thermal expansion and \( \Delta T \) is the change in temperature. If we assume that \( \alpha_{\text{steel}} = 11 \times 10^{-6} \text{1/deg C} \) and \( \alpha_{\text{polycarb}} = 70 \times 10^{-6} \text{1/deg C} \), then the displacement of the steel is

\[ \delta_{\text{steel}} = x \alpha_{\text{steel}} \Delta T \]  

(18)

where \( x \) is distance between two aligned bolt holes on the baseplate, equal to the distance between the bolt holes across the largest dimension of the tank, 20 in (50.8 cm). Though the stable temperature is 37 deg
C, the baseplate can reach up to 100 deg C at the heater locations. The diffusivity of the steel as well as the saline aids in distributing the temperature, but it would not be too conservative to estimate a maximum bulk plate temperature of 60 deg C for a maximum $\Delta T = 60 - 23 = 37$ deg C. The thermal expansion of the steel is 0.0094 in (0.24 mm) along $L$. The thermal expansion of the polycarbonate across the same dimension is 0.052 in (1.32 mm). Therefore the total opposed displacement would be $0.052 - 0.011 = 0.043$ in across a 20 in substrate, or a strain of 0.22%. This is a relatively small amount that would not lead to failure mechanisms in the polycarbonate and would be taken up through elastic expansion of the silicone sealant. It is highly unlikely that stress in the sealant would cause a crack at such a low strain level.

Instead of the typical butt joint found in many aquarium tanks, more comprehensive measures were taken to ensure a leak-free tank. Flanges were added to the polycarbonate wall segments, and a linear bolt pattern spaced evenly around the tank perimeter. The flanges were melted directly to the plastic wall, forming a strong seal. The walls were bonded to the baseplate with silicone sealant and then secured further with bolted joints on the flanges to compress the sealant and create a strong bolted joint.

The design of the door was borrowed from a separate tank in the Boston Scientific test labs. A removable polycarbonate panel with a recessed O-ring was secured to the front wall with toggle clamps. Originally designed with two clamps pressing against the side, a third was added to address a moment applied about the clamps by the hydrostatic pressure at the bottom of the tank, which in turn created a leak at the bottom of the door seal. The third clamp remedied this issue. The tank design is shown in Figure 32.

![Figure 32 Design of tank and baseplate. Inset. Detailed baseplate features for thermal control.](image-url)
4.3.5 Baseplate

The baseplate was designed to provide a mounting surface to the gel holders and also to provide a uniform heat gradient across the tank to ensure that all lead components are experiencing a similar temperature. The connection to the phantom gel holders is a three-pin location scheme that constrains the planar degrees of freedom of the holders. A magnet is mounted in the center of the intended holder placement to provide a securing force.

It was necessary to design the size of the baseplate to accommodate as many test samples as possible while still meeting space requirements and ease of use considerations. The daylight aperture of the Instron (the maximum open dimension from one post to the other) determined the maximum width of the baseplate; the length was constrained by location of the tester and center of gravity considerations for the flooded tank. The crosshead of the tester was adjustable to a significant height, and it was only necessary to fill the tank to a level which would submerge the active section of the lead.

In the planar space, the number of samples tested depended on the geometric constraints of the walls and reasonable amounts of access space to manipulate the fixturing. Not only the lead assembly, but the load cell assemblies as well must be considered. Based on the available space, six samples were chosen to fit into the assembly, as demonstrated in Figure 33.

Figure 33 Six setup fixtures mounted on the baseplate. Six was the maximum number of samples that could be comfortably nested on the baseplate while allowing individual sample removal.
The material choice was another important consideration. Because the material will be in a heated saline bath, and will be the conductor that transfers the heat into the bath, it was necessary to account for thermal conductivity, thermal diffusivity, and corrosion resistance. Stainless steel has high thermal conductivity, decent thermal diffusivity, and high corrosion resistance in some grades. SAE grade 316 was chosen as the best combination of the aforementioned properties.

For heat source selection, it was necessary to consider heat transfer type, power needed, and ease of installation and use to raise the tank to 37 deg C from room temperature in a reasonable amount of time. Based on the dimensions of the tank and the fill height, a filled tank would possess approximately 26 liters of saline solution. To bring that mass to temperature, we can approximate the water as a bulk mass and estimate the amount of energy necessary with

$$\Delta E = \rho V c \Delta T$$  \hspace{1cm} (19)

where $\rho$ is the density of the saline, $V$ is the volume of the saline, $c$ is the specific heat capacity of the saline, and $\Delta T$ is the change in temperature. Assuming the density of 0.9% saline solution to be approximately 1 kg/L, the specific heat capacity of the saline to be 4181 J/g-K, and again knowing room temperature is 23 deg C, the total energy amounts to 1.52 MJ. To provide that change in temperature in one hour, it would take 422 W under ideal circumstances with no thermal losses. However, thermal losses are prevalent in the system.

With the objective being saline heating, thermal losses were estimated from the water surface to the air above and from the sides and exposed bottom of the baseplate. Convective heat transfer can be estimated by

$$Q = h_c A \Delta T$$  \hspace{1cm} (20)

where $h_c$ is the heat transfer coefficient, and $A$ is the area of transfer. Assuming natural convection between the baseplate and the saline (where $h_c = 50$ W/m$^2$-K), and a bulk temperature of 60 deg C, the heat flow $Q$ is 212 W. Assuming a heat transfer coefficient of 20 W/m$^2$-K for the sides and bottom of the tank, with a total exposed area of 51 in$^2$ (sides) + 272 in$^2$ (bottom) = 323 in$^2$ (0.208 m$^2$), the heat flow is estimated at 145 W.

Thermal inefficiency in the cartridge hole gap must also be accounted for. Here thermal grease was employed to maximize heat transfer in the mounting hole, but the energy transfer is not perfect, and there are energy conversion losses inherent to the cartridge heater itself. Here the total conversion efficiency (the amount of energy transferred into the plate over the total amount of energy drawn) is estimated at 0.5.

To be realistic and incorporate all of these effects into an efficiency of 0.20 (an estimate based on thermal losses between the cartridge and the fitting hole, convective and radiant losses from the baseplate itself, and inefficiency of power transfer), it would require five times the original figure, or 2110 W.
Based on this, four cartridge heaters were selected for the baseplate, each providing 300 W/in². Geometric constraints allowed for heater lengths of up to six inches. An appropriate length was selected by

\[ l = \frac{P}{np\pi D} \]  

(21)

where \( P \) is the total power desired, \( n \) is the number of heaters, \( p \) is the power per unit area provided by the heaters, and \( D \) is the diameter of the heaters. By this calculation, the heaters would need a minimum length of 2.24 inches. There is an additional buffer zone of 0.25 inches on either side of the heater, bringing the total heater body length to 2.75 in for a one-hour heat-up. To better distribute the generated heat and allow for a shorter warm-up time while avoiding an extreme hole depth that would require specialized machining, four inch long heaters were selected. After assembly, testing showed that a full tank was brought to temperature in approximately 40 minutes with the above parameters, as expected.

4.3.6 Crosshead Fixture

The purpose of the crosshead fixture was to provide connections to each of the lead grips and also a general connection to the dynamic tester crosshead. There were two important considerations for this design – low mass and high stiffness. This informed the material choice and geometric design of the crosshead fixture.

6061 aluminum alloy and 316 stainless steel alloy have approximately the same specific modulus, but because in cantilevered beam bending the stiffness goes as the thickness of the beam cubed, aluminum was selected to have a higher thickness per unit mass. An anodization process was performed on the crosshead to reduce corrosion. The crosshead fixture is shown with annotations in Figure 34.
The deflection of each mount point on the crosshead fixture can be estimated with the superposition of simple beam bending equations. However, because the cross-bracing of the structure renders it statically indeterminate, one can best solve for the deflections under load with linear algebra. If one considers the vertical displacements of the six connection points as unknown degrees of freedom, the connection points themselves as nodes in a network, and the braces as edges in that network, one can establish a matrix equation governing their displacements in response to a given load. By establishing a stiffness matrix, a load vector can be applied to determine the displacements of the individual nodes. A graph of the nodal network is presented in Figure 35. Here the central node (node 7) is fixed and relative displacements are analyzed.
Figure 35 Spider fixture and its associated graph. Here the nodes represent the connection points for the six load cells and the crosshead adapter, which is fixed.

The vertical displacements of the fixture are related to the applied forces by the bending stiffnesses of the beams according to

\[ F = KU \]  \hspace{1cm} (22)

or, solving for the displacements,

\[ U = K^{-1}F \]  \hspace{1cm} (23)

where \( U \) is the displacement vector, \( K \) is the stiffness matrix, and \( F \) is the load vector. For this geometry, the stiffness matrix was calculated with graph theory methods [27], and amounts to
where \( c \) represents the stiffness of the individual beam element according to

\[
c = \frac{3EI}{L^3}
\]  

(25)

where \( E \) is the modulus of the material, \( I \) is the bending moment of inertia, and \( L \) is the length of the beam. The bending moment can be calculated for a simple cantilever beam by

\[
I = \frac{bh^3}{12}
\]  

(26)

where \( b \) is the beam width and \( h \) is the beam thickness. The displacement and force vectors are, respectively,

\[
U = \begin{bmatrix}
u_1 \\
u_2 \\
u_3 \\
u_4 \\
u_5 \\
u_6 \\
\end{bmatrix} \quad F = \begin{bmatrix}
f_1 \\
f_2 \\
f_3 \\
f_4 \\
f_5 \\
f_6 \\
\end{bmatrix}
\]

(27)

representing the displacements and loads applied to the six nodal elements not fixed in space.

From these equations, beam dimensions for each brace were chosen and assigned. The expected loads applied in the test are identical and account for both the gravitational acceleration and the maximum dynamic acceleration from the sinusoidal motion of the crosshead. The loads can be modeled by

\[
(28)
\]
\[ f = m \left( g + (2\pi y)^2 \left( \frac{A}{2} \right) \right) \]

where \( m \) is the mass of the load cell assembly and lead grip, \( g \) is the gravitational acceleration constant, \( y \) is the cyclic frequency, and \( A \) is the peak-to-peak amplitude of the waveform. Plugging in all values and solving for \( U \), the total displacements corresponding to a dynamic load resulting from a sinusoid with amplitude of 15.5 mm and frequency of 1.666 Hz is

\[
U = 10^{-5} \begin{bmatrix} 4.64 \\ 4.64 \\ 0.27 \\ 0.27 \\ 4.64 \\ 4.64 \end{bmatrix} m
\]

The maximum displacement is 46.4 \( \mu \)m, and the maximum error displacement is 43.7 \( \mu \)m between the greatest nodal displacement and the smallest. Finite element analysis with identical parameters yielded a maximum vertical displacement of 69.9 \( \mu \)m, and a maximum error displacement of 63.8 \( \mu \)m. A visual depiction of the vertical displacement can be seen in Figure 36. The discrepancy between the pure calculation and the finite element method is attributed to asymmetric beam geometry, but both results are negligible quantities.
4.4 Structural Loop

With all the components of the test assembly identified and designed, the structural loop was considered in order to calculate the error budget for the assembly. A diagram of the structural loop for the complete assembly appears in Figure 37.

Figure 37 Left Structural loop for the test assembly. The loop runs down the tester crosshead and into the fixturing stem before passing through the lead, into the gel, and into the tester base. Right Loop section relevant for error budget.

The error budget is only of concern as it affects the dimensions and position of the constrained lead section. Though absolute accuracy for all samples is obviously a priority, of potentially more importance is the precision among the six samples, since lead results will be compared to each other across tests and each lead is to have undergone the same test procedure. With that in mind, it was necessary to calculate the maximum precision error between any two samples in the test.

Because the lead is the most compliant element by orders of magnitude compared to the other elements in the loop, positional tolerances outweigh stiffness concerns (of most components) in calculating the error for each sample. Additionally, the tolerances on the dynamic tester structure apply to
each sample, and therefore have no effect on the relative error between samples. The focus is solely on
the loop section beginning at the spider fixture and concluding at the baseplate surface.

Because all of the elements are in series, the tolerance stack up is linear from one component to
the next. Sources of error include the flexural stiffness of the spider fixture, the positional error from the
lead grip/load cell coupling, positional tolerances in the lead (which is laid by hand between the lead grip
and gel, and dimensional tolerances of each component. Mathematically, this amounts to

\[ \varepsilon = u + \delta_c + \delta_{lead} + \delta_{tot} \]  

From the previous section, \( u \) is 43.7 um (the maximum relative displacement). \( \delta_c \) is determined
by the tolerance of the male thread adapter on the load cell, which is +/- 0.005\( ^\prime \) (0.127 mm) or 0.010\( ^\prime \)
(0.254 mm). \( \delta_{lead} \) is also positioned by hand and is likely accurate to 0.5 mm. The tolerances on the
vertical dimension of each component are +/- 0.005\( ^\prime \) (0.127 mm), and there are three additional
components – the load cell adapter, the shoulder bolt that constrains the captive female thread adapter on
the lead grip, and the lead grip body. Adding the tolerances, the complete stack up amounts to 1.559 mm
of potential error from one subassembly to the next. Holding extremely close manufacturing tolerances
would be an expensive solution to this problem, so the two-nut vertical adjustment connection between
the subassembly and the spider fixture was devised to allow physical vertical adjustment to reduce any
positional error.

Because the distal tip of the lead is fixated by hand into the gel, human error can easily allow for
a millimeter or so of displacement in a given direction. Though, based on machining tolerances and the
precision of the coupling mechanisms mentioned previously, the concentricity tolerance stack-up is less
than this figure, even a large offset has a minimal effect on buckling force. A concentricity offset simply
creates an initial buckling imperfection in the lead, which would have a significant effect if the lead were
to begin in a perfectly straight configuration. However, the lead is already initially bent simply due to its
own weight and high compliance (a perfectly straight lead would cause tensile forces at the lead-tissue
interface), and the buckling mechanism occurs at very low strains (and therefore very small
displacements), leading to a buckled plateau. This plateau also corresponds with the maximum force
imparted by the lead. The lead simply starts already buckled, further along on this plateau, and therefore
impacts the same maximum force for a slightly longer duration. Angular error in the structural loop would
create a similar scenario. A plot of this phenomenon can be seen in Figure 38.
4.5 Data Recording

To record the force measurement and the elapsed cycles, load cells were rigged to a National Instruments data acquisition module (NI-DAQ) along with an analog output from the dynamic tester to represent the displacement of the crosshead. NI LabVIEW was used to create a test program that records the force output from the six load cells and correlates them to the measured displacement. There were a number of challenges to be addressed with the data recording; namely, setting up a system of triggers to automatically record the force data at assigned periods, developing an automatic cycle counting algorithm, and calculating relevant extrema from recorded sample periods.

The load cells used were Honeywell Model 31 1000g capacity load cells with stainless steel and welded construction to prevent corrosion and allow submersion. These were then spliced to a TJ-50 connector and plugged into TEDS modules for the NI-DAQ 9239 chassis, which would allow calibration data to be uploaded automatically. The analog displacement output was fed into a 9219 module.

A tare function was developed by the use of a conditional case structure subtracting the current load cell readings upon a button press. A delay feature was also developed using a similar case structure, whereby a counter on a shift register would increase to a certain integer. When that counter equaled a delay integer, here the number of sample periods in the delay, the remainder of the program would be triggered. A graphic user interface (GUI) was developed with three panels to allow for test setup, live data display, and recorded data display. Figure 39, Figure 40, and Figure 41 display screenshots from the virtual instrument (VI) panels.
Figure 39 Setup panel for the dynamic perforation test data recorder VI. Note the uncalibrated and calibrated signals to provide visual cues when the load cells are approaching capacity regardless of when they were tared. All manual data entry was conducted from this page.

Figure 40 Live data panel. All six load cell channels are represented and updated with each sample period.
Figure 41 Recorded data panel. Data was collected infrequently; these graphs provided visual plots of the last sample period recorded.

Load cell readings were passed through the VI as dynamic data, down-sampled to reduce the size of data files, and then accumulated and written to a spreadsheet file for post-processing.

A cycle counting algorithm was also developed to provide an estimate of the test progress and completion time. Because tests were run around the clock and in close succession, it was helpful to have a count automatically displayed so the available time on the tester could be used efficiently. Because the Instron Electropuls 1000 could not provide a cycle count in digital form, the analog displacement signal was measured and the frequency of the waveform calculated. From there, the expected number of cycles until test completion was known and so a progress percentage could be calculated. The peak-to-peak amplitude and offset were also measured. Because it was desired to have the data recording trigger with the beginning of the cycle count, it was necessary to create a noise threshold so that the VI could differentiate between random noise of random frequency and the controlled motion of the desired frequency. A noise threshold was applied as a minimum amplitude limit; any motion of less than amplitude 0.1 mm was neglected. The display for the cycle counting module appears in Figure 42.

Figure 42 Cycle counting module.
A separate VI was created to measure the individual temperatures of the gel during a test. Type T thermocouples were inserted into the gel during a test, and connected to a data acquisition system that was then connected to a computer via GPIB. The low heat diffusion through the stainless steel baseplate gave rise to concerns that some gel samples might end up hotter than others during the warm-up period, which could potentially have an effect on the gel mechanical properties. The thermocouple probes were inserted approximately 0.5 inches into the gel top surface (the maximum depth at which a lead could conceivably penetrate during an 8 hour test). A full warm-up was conducted and the temperatures of each gel sample measured. Then the test was allowed to hold at steady state to observe the finalized gel temperatures. The results appear in Figure 43. The maximum error between the hottest gel sample and the coldest gel sample was 1.8 deg C during the first heating attempt; during the next heating attempt to maintain steady state, that error was reduced to 0.6 deg C, and during steady state heating the error was 0.2 deg C, as displayed in Figure 44. Based on the modulus v. temperature plot for the Perma-Gel presented previously, the small temperature error from the diffusion effect was negligible.

Figure 43 Individual gel temperatures during the autotune warm-up procedure of the thermal control. The peak temperature is indicated in the figure.
4.6 Gel Fill Procedure

Because such trouble was taken to establish positional accuracy with the lead fixturing, it was necessary to ensure high accuracy in gel sample dimensions as well. It was discovered early in the project that simply pouring molten gel into containers led to dimensional errors based on the meniscus effect. Surface tension causes the molten gel to adhere closely to the sides of the container, and gravity pushes down the mass of gel in the unconstrained center, forming a “bowl” feature and creating an unpredictable feature height in the center of the gel sample. In addition, air bubbles caught in the gelatin from the pour would establish themselves prominently in the gel, making it both less optically transparent and increasing the probability that a lead would find an air pocket that would distort the results. Because the lead is to be placed directly in the center of the sample and no bubbles close to the surface could be tolerated, a complete-fill procedure was devised.

The gel was melted at a temperature of 128 deg C.

First attempts simply filled the gel holder to top level, allowed the gel to cool, and then bolted the holder to a plate and flipped it upside down. The gel would be replaced in the oven and subjected to another heating-cooling cycle to establish a flat surface against the plate. When cooling was complete, the holder would be flipped again and the gel sample thus attained a flat, bubble-free surface for the lead. While this created a dimensionally accurate top surface, it also pushed the air bubbles to the bottom of the gel holder where they would conglomerate into a large bubble. Oftentimes this bubble proved large enough to remove contact from the bottom surface of the gel and the bottom “floor” of the gel holder.
This, in turn, raised concerns that only adhesion with the walls was holding the gel in place, and that the unpredictability of the size or location of the air bubble could cause variation in mechanical behavior.

The final solution involved the drilling of riser ports into the bottom of the gel holders to allow gelatin to be poured directly into the bottom of the holders. Like in casting processes, the risers were filled to the brim and the cooled gelatin was allowed to settle at a level that eliminated the large air bubble at the base. The shrinkage of the gelatin from molten to room temperature was so high that the 0.75" deep, 0.250" diameter risers proved too short to prevent small air bubbles forming at their base, but their size was such that their mechanical effect was inconsequential to the sample.

In order to facilitate this process for twelve samples at once (two tests' worth of samples), a 0.25" aluminum plate was drilled with twelve square mounting patterns to fit the gel holders and then the contact surface sanded down with 320-grit sandpaper and sterilized with isopropanol. See Figure 45 for the gel melting fixturing.

![Figure 45 Gel melting apparatus. Top left The aluminum mounting plate (bare). Bottom left The aluminum mounting plate (full). Top right An original gel holder, filled, with depressed surface in bold. Bottom right Six well-formed gel samples.](image)

The final heating/cooling process took approximately five hours – 30 minutes of gel preparation, 45 minutes of gel melting, 15 minutes of pouring, 30 minutes of heating, final pour and then three hours of cooling before flipping to bring the gel down to ambient temperature and avoid the meniscus effect.
4.7 Test Fabrication and Assembly

The complete CAD assembly, including the tank, crosshead fixture, setup fixtures, lead grips, gel holders, and miscellaneous hardware was designed and thoroughly checked for compatibility. The assembly was comprised of 50+ individual components (including sourced hardware). Components which could not be bought off the shelf were custom designed. Prints, including bills of materials, were generated for the complete assembly and tolerated. Final prints were generated by Boston Scientific and then checked for errors and intent. The complete assembly was subcontracted to external machine shops for part production via the Boston Scientific model shop.

The gel holders, lead grips, and setup fixtures did not require assembly. The tank assembly was conducted over the course of one day and involved the application of sealant to the flanged surfaces (which were then subsequently bolted down) and to the butt joints between the walls. O-ring stock for the tank door was sourced and also sealed (on the non-contact side) with RTV.

The crosshead fixture was assembled and the load cells installed. The large cables for the load cell were secured via zip-tie to the central column supporting the crosshead so as to avoid interference with the tank lid during cycling.

4.8 Improvements

An initial round of testing was conducted with high variability in results. The large deviations from one sample to the next prompted a review of the test procedure. With the intent to reduce variability, several potential improvements were determined, and a number implemented.

The original load cell adjustment method was unwieldy and thus not used during initial testing. Consisting of two nuts securing a threaded stud in a thru hole, they required a miniature wrench to release the bottom nut, an arduous task when the crosshead fixture was below the top plane of the tank and the wall would interfere with the wrench motion. New large profile threaded nuts were used on the bottom to allow hand tightening, and large diameter knurled threaded knobs were machined from shaped aluminum stock to allow for fine vertical adjustment. UNC #6-32 threads were used, leading to a 0.031" vertical adjustment for each complete rotation of the threaded knob. The adjustment mechanism can be seen in Figure 46.
Figure 46 Vertical displacement adjustments. Left Original dual machine nut locking interface. Right Improved dual nut locking interface with large diameter knob for greater control.

The original kinematic coupling configuration for the setup fixture/gel holder interface had two pins supporting the weight of the gel holder (due to the force of gravity in the vertical configuration) and a nesting force supplied by a single spring plunger at the midpoint of the gel holder edge. This configuration functioned well when the setup fixture was supporting the gel holder (during transport, for instance), but not when the gel holder was supporting the setup fixture during tank loading. After the quick-release pin was removed, the spring plunger could not provide sufficient force to balance the weight of the setup fixture, and because it was located at the midpoint, it allowed rotational motion in the plane, leading to significant Abbe error at the lead grip/crosshead interface. This design error was remedied with the removal of the original spring plunger and its mount and the addition of two stiffer spring plungers spaced equidistant from the midpoint secured in a new mount.

The design of the test tank specified an epoxy coating over the magnets to prevent exposure to the saline and resultant corrosion. This was not completed upon tank delivery, and due to time constraints the initial round of testing was conducted with exposed magnets. Corrosion proved to be a very large nuisance, causing coatings of rust particles on tested leads, contaminating the saline in the tank, and necessitating the refilling of the saline reservoir every couple of tests to maintain the purity of the saline. Prior to the later round of testing, the magnets were ground down and a high-temperature epoxy was cemented over the exposed surface. This reduced corrosion significantly from the baseplate. Figure 47 displays the before and after results of the epoxy coating.
A couple of components on the crosshead fixture were fabricated out of a regular steel alloy instead of stainless steel, and also began to corrode during testing. The load cell threaded adapters were all replaced by stainless steel components; the male threaded adapters to connect the load cells to the lead grips were thoroughly cleaned and the threads re-cut with a die to insure a stable threaded fit. These components were intermittently dipped in saline during cycling or splashed during the tank fill procedure, so the corrosion from the crosshead did not have a significant influence on the saline quality as compared to the baseplate magnets.

The lead grips were also redesigned between the first and second rounds of testing. The original lead grip was causing kinking in the larger diameter leads due to the small bend radius behind the grip door. This problem was exacerbated by an exit port angle that was too shallow, resulting in a complete 90 degree lead bend angle from entrance to exit of the lead grip. In the revision, the bend radius at the top of the grip door was enlarged and the exit port angle was increased by 45 degrees to allow a smooth exit. There were no problems with kinking with the new grips. The floating female threaded adapter at the top of the lead grip was also redesigned to address grip issues prior to and after the test. The smooth cylindrical surface proved difficult to tighten against its male counterpart, so hex flats were added to the female adapter to allow for a better grip and the ability to torque with a wrench if necessary.

4.9 Test Procedure

Six samples can fit into the test tank at one time, and for the vast majority of the tests conducted, six samples were loaded. Prior to loading, the setup fixture was assembled with lead grip and gel holder, and the lead was inserted through the rear aperture of the lead grip and adjusted until the distal tip made light contact with the gel. The lead grip door was clamped and secured and torque applied to the terminal pin of the proximal end of the lead to extend the helix into the gel. Once the appropriate number of turns
was completed, the complete setup fixture was placed into the test tank at an available location. Setup fixtures were loaded from the rear forward.

Once all setup fixtures were loaded in the tank, the crosshead was brought down to make light contact with the lead grips. The female connector on the lead grip was threaded to the male connector on the load cells and tightened. At this point, the quick-release pin securing the gel holder to the setup fixture was pulled and the full weight of the fixture transferred to the spring plungers above the gel holder. The setup fixtures were then rolled off the gel holders and removed from the tank. Lead grips and gel holders were double-checked for any misalignment, and then the test door was sealed and lids placed. The complete operator instructions for test setup can be found in the Appendix.

With the test-tank sealed, the drain valve was closed, the inlet valve opened and the tank flooded. A foot switch triggered a pump that would draw saline from a large reservoir into the tank. The tank was filled to the shoulder of the lead grips to ensure complete submersion of the lead body. Once fill was complete, the inlet valve was closed to completely seal the tank. The process thermocouple was inserted into the tank from the top mounting holes and the thermal system activated.

It took approximately 45 minutes for the filled tank to reach test temperature from ambient temperature. Upon reaching 37 deg C, the test program was activated and the leads cycled.

The test was split into three phases – the ramp to start, cycling, and ramp to finish. The ramp to start slowly compressed the leads over four seconds to half of the amplitude of the sine wave, or 7.750 mm below the initial level. The cycling program was split into sixteen identical blocks, each consisting of 3000 cycles of physiological cycling at 1.666 Hz (approximately 30 minutes’ worth) followed by five slow cycles at 0.50 Hz for measurement. The cycle rate was slowed down to negate inertial effects and drag effects on the lead grip. The complete cycling procedure took just over eight hours to complete. The ramp to finish drew the leads back up into their original extended position over four seconds, the same timing as the ramp to start.

Upon test completion, the tank was drained, helixes retracted, and gel holders and lead grips removed. The individual leads were dried and returned to packaging, while the gel holders were dried and the caps removed. The gel samples were pulled from the holders and placed for CT scan.
5 Results

5.1 Gel Characterization

Several methods were pursued to develop metrics for characterizing the gel samples returned from the test. Because of the small size of the divots created by the cycled lead compared to the overall volume of gel, and the relatively minute differences from sample to sample, high resolution in measurement was extremely important. The desired measurement quantities were ascertained by first principles analysis of the forces generated at the tip.

The distal tip of the lead begins the buckling cycle at a near-right angle to the surface of the gel. As a displacement is applied to the proximal end of the lead, the distal tip begins to press down on the gel surface and also rotate like a pinned connection. This rotation continues until the full displacement is applied, and then the tip rotates back towards the normal direction to the gel surface.

If one were to apply the same cyclic displacement to a stiff wire, the wire would puncture through and create a divot in a direction normal to the gel surface. Each lead tested here enters into the compliant buckling mode and therefore changes the angle of penetration. However, it stands to reason that the stiffer the lead, the more towards the normal direction the divot will be, and therefore the more compliant, the shallower the angle of penetration. Thus the angle gives a decent estimate of the lead resistance to the buckling shape, or the flexural stiffness of the lead.

In addition to the burrowing angle, the depth of the lead penetration normal to the gel surface provides perhaps the most telling estimate on how far a lead would burrow in an actual insertion. Though the heart wall is of finite thickness compared to the semi-infinite gel block, in a perforation the lead is forced to work its way through the wall and not simply along it. So it is possible for a lead to do significant damage to the endocardium and myocardium without passing through the cardiac wall, but such damage will not be a perforation and will not cause more serious consequences such as cardiac tamponade.

In addition to the force applied at the tip, a measure of the area affected by the lead is needed. The divots all share the same general shape, detailed in Figure 48. As seen from an aerial view, the major axis of the divot runs along the direction in which the lead buckles and provides a measure of the lead-affected area. This divot length is the final metric by which the divots are characterized.
Other metrics considered included the volume of the divot, the mass displaced, the perimeter of the divot, and various other linear parameters that could be devised by the current metrics. The volume of the divot would be a very useful metric—comparing the leads on the basis of how much material they remove from the gel block might illuminate some of the field reputations and, at the very least, validate the other metrics used. A couple of methods were attempted in bench-testing to return a high-precision volume measurement.

The first involved filling the cavity with fluid of a known density and then measuring the mass on a scale to back out the total volume. This approach was attempted with water and with oil. The accuracy of the technique was under question since it was unknown whether the gel could absorb minute quantities of the measuring fluid, and whether that effect depended on the surface area of the divot (so that a larger divot would absorb more fluid). In addition, the fill technique was done by hand and to the “brim” of the divot, which led to the amount of fluid per pour being inexact. In addition, surface tension effects caused some of the fluid to remain in cavities within the divot, so that all of the fluid input was not necessarily all of the fluid output to be weighed. With the stack-up of these effects considered, this approach was deemed too imprecise for a meaningful measurement.

A similar approach involved the measurement of the mass displaced by the lead during the process. The filled gel holder was weighed prior to testing and then weighed again after testing. The difficulties here involved finding a high-precision scale that also had sufficient capacity to weigh the full stainless steel gel holder. To address the large mass of the gel holder, one could simply remove the gel block from the holder and weigh it first, and then reinsert it; however to reinsert the gel block to its initial flat level in a gel holder is cumbersome at best and impossible at worst. In initial bench testing with an artificially created divot, the difference in mass between the full gel block and the gel block with a sizeable divot (on the larger end of those produced during the test) was approximately 12 mg. There was additionally a concern that residual saline solution could possibly be absorbed into the gel during the test or remain in small cavities. This could be addressed by waiting for the samples to dry thoroughly before
they were measured to avoid the effects of absorption. However, the inability to locate a precise and high-capacity scale eventually undermined this effort.

Volume estimation was also pursued through reconstruction software. By scanning a gel sample, one could create a mapped surface along the surface of the divot, and then export that surface to a stereolithography file where it could be measured in a CAD program. However, the quality of the surface depended heavily on the quality of the scan, and time would not permit a full high-resolution scan to be taken of every sample. Even if such a high-resolution reconstruction was completed an accurate surface reconstruction was not guaranteed; the surface mapping software was extremely sensitive to changes in the iso value (which essentially determined how much of the scanned volume to count as solid and how much to remove from the reconstruction). Therefore, simulated volume reconstruction was not pursued due to time constraints and technical drawbacks.

There were a number of methods considered for the measurement of the three metrics discussed previously. First, optical measurement was attempted through the square sides of the transparent gelatin. A Keyence microscope was used to image the gel sample, and Keyence software to take the measurements. This did not produce high-quality results for two reasons - the borders of the divot were highly dependent on the focus of the optical lens (which was focused on a level near the center of the divot) and also the lighting conditions reflecting on the specific geometry of the gel. These two effects, combined with viewing through a few centimeters of transparent gel, created an invariably blurry image. Thus the accuracy of the measurement was called into question. The second reason is that the major axis of the divot need not run parallel with one of the gel block sides, and fixturing for the gel sample became a problem. Because so much depended on the accuracy and repeatability of user manipulation of the gel block, this approach was eventually abandoned.

3D optical profilometry was pursued next in order to map profile and depth measurements. The same Keyence microscope was employed, this time with a motorized head to conduct incremental two-dimensional scans at various linearly increasing foci, then interpolated to create a fully three-dimensional surface. Because the measurement was taken from the top-down instead of through the side of the gelatin, the blurriness of the image was not an issue here. However, the same sensitivity to lighting conditions did apply, and perhaps more so since the scanning software reconstructed depth information based on the reflected light. With good lighting and a smooth divot, the end result was a relatively consistent scan, but slight imperfections could cause glares that would then significantly distort the depth information. Because of the prevalence of these glares and the roughness of the divot surface in some samples, the accuracy of the depth and profile measurements was not accepted. In addition, in some cases the large takeoff angle of the divot created an undercut that could not be imaged from a top-down view. Figure 49 displays a characteristic optical scan.
A two-dimensional X-ray scan was attempted for measurement purposes as well. The main advantage of the X-ray is its non-invasiveness; however, its two disadvantages imaging the gel samples were a lack of contrast and a lack of internal measurement system. For a 2D scan to return accurate results, one would need to place a calibration standard directly in the imaging plane of the divot and then estimate the depth from that standard reference. However, that exact plane was difficult to determine because the contrast in the machine used was unable to clearly resolve the divot borders without saturating the scan.

The final measurement technique turned out to be a computed tomography scan of the divot area (see apparatus in Figure 50). A sample was placed upon Styrofoam supports, centered on the rotating stage in front of the X-ray source, and images were taken as the stage rotated a full revolution in finite steps. This was a more complex measurement system than those previously considered, but ended up yielding the most complete and versatile results due to high-quality reconstruction software.
Radiographs from the CT scan were loaded, along with the calibration radiographs, into North Star Imaging’s efX-ct reconstruction software. A preview reconstruction, a cubical aperture of the full scanning range, was displayed on the screen. This preview could then be sized down in three-dimensions to form a more intimate reconstruction range around the divot. Image alignment could be performed automatically or manually, but was done automatically for this procedure. Finally, the complete reconstruction could be performed, the results of which can be viewed in Figure 51.
The metrics were measured by creating a two-dimensional slice of the 3D reconstructed volume. This slice was positioned by the user to fall along the major axis of the divot so that it would include the maximum lead penetration depth. At that plane, a 2D screen capture was taken, measurements were overlaid on the photo and the relevant dimensions were calculated by the software and displayed in real time. A capture of one of the samples appears in Figure 52.
It must be mentioned that there are a pair of error sources that could affect the results via this measurement system. The first is the autofocus of the reconstruction process; during the build-up of the 3D model from individual 2D slices, mismatch could result in boundary blurring errors on the order of 0.1mm. The second is the user-operated measurement layout, where a human must drop and drag the angular and linear scales that display the measurements. Even in a perfect picture, there would be small errors attributed to this fact, but because the divots themselves are irregular shapes and do not perfectly conform to the idealized shape upon which the metrics were derived, the errors become larger. The placement procedure is done as carefully as possible and to the user’s best estimation of the beginnings and endings of divot features. It is impossible to know for certain, but an estimate of the combined error from both of these sources does not exceed 0.5mm on the linear scale and is frequently very much less.

5.2 Force Measurement

The lead forces were also measured via load cell. The force data was transmitted through the NI 9237 chassis and logged to the LabVIEW VI. Force data was also recorded for an empty test (with no lead in the lead holder) to measure the effect of lead grip buoyancy on the force readings for reference.

The buoyancy force was significant, and overshadowed the natural force response on the more compliant leads. Thus it was necessary to subtract the buoyancy effect from the force responses recorded for all leads. The resulting waveform was analyzed with a MATLAB script that calculated the mean waveform value (the cycle offset), the maxima and minima of the waveform, and the range. A typical force response graph for the six channels of the test appear in Figure 53. All leads were measured and the results are listed in Table 8 and plotted in Figure 54.
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Figure 53 Typical force response patterns. Shown here are the six channels of the MDT 5076 test, edited to show only active recording time (data was recorded for five cycles every 30 minutes).
5.3 Analysis

Two rounds of testing were completed for this project. The first round involved a 48,000 cycle test where force data was taken at fixed intervals at the 1.666 Hz cycle rate. Three lead types were tested. The second, and final, round involved the test procedure outlined in this thesis run with the aforementioned improvements, and all available lead types were tested. The first round of testing returned samples that were measured via 3D optical profilometry, a technique which was later replaced by a 3D CT scan as detailed in the measurement section.

The state-of-the-art perforation test prior to this project was the static tip pressure test, a controlled compression test that subjected the lead to parameters similar to those used in this test. However, there were significant differences between the two methods. The static test required that a lead be secured by means of two pin vises, one at the distal tip, and the other at the proximal end. This caused a fixed-fixed buckling condition where by the boundary conditions of the lead require that the lead be vertical at the interfaces; this significantly changes the buckling structure and therefore the buckling strength from the fixed-pinned approximation in the dynamic perforation test detailed here. In addition, because the distal clamp provided the lower boundary condition, the lead helix was not incorporated into the testing. Therefore the static tip pressure test was more of a measure of the flexural stiffness of the lead than of its perforation potential.

This is not to say that the results are not useful. Flexural stiffness is a large factor in the amount of force applied at the lead-tissue interface, and as such it is important to compare the results of the static tip pressure test to the results achieved here with the dynamic perforation test.

A baseline for acceptable tip pressure was created based on the results of this test. A chart of the static tip pressure for a variety of leads tested without stylets appears in Figure 7 in Section 3.5.

Gel sample results were compiled and each metric averaged across the number of leads tested. Six samples were tested of most leads, but in cases of product shortage or other inability to procure lead samples, fewer were tested. Results are presented first by rank order of average value plotted with standard deviation in Figure 55, Figure 56, Figure 57, and also in order of manufacturer with individual value plots in Figure 58, Figure 59, and Figure 60. All test results are compiled in Table 9.
Table 8 Average force and force range values for all leads tested.

<table>
<thead>
<tr>
<th>Name</th>
<th>Average Force (gf)</th>
<th>Force Range (gf)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTRUS</td>
<td>-0.51</td>
<td>17.99</td>
</tr>
<tr>
<td>FINELINE II EZ STEROX</td>
<td>0.79</td>
<td>15.66</td>
</tr>
<tr>
<td>FLEXTEND</td>
<td>-0.13</td>
<td>20.21</td>
</tr>
<tr>
<td>TEST LEAD G - SILICONE</td>
<td>1.37</td>
<td>18.44</td>
</tr>
<tr>
<td>TEST LEAD G - POLY</td>
<td>6.98</td>
<td>21.19</td>
</tr>
<tr>
<td>TEST LEAD I</td>
<td>-1.03</td>
<td>20.39</td>
</tr>
<tr>
<td>ENDOTAK RELIANCE G</td>
<td>-3.26</td>
<td>21.40</td>
</tr>
<tr>
<td>SELUTE</td>
<td>-1.10</td>
<td>12.49</td>
</tr>
<tr>
<td>TEST LEAD T</td>
<td>6.61</td>
<td>19.16</td>
</tr>
<tr>
<td>TEST LEAD S - SILICONE</td>
<td>1.08</td>
<td>17.26</td>
</tr>
<tr>
<td>SWEET TIP</td>
<td>-0.31</td>
<td>13.93</td>
</tr>
<tr>
<td>TENDRIL SDX</td>
<td>0.66</td>
<td>20.51</td>
</tr>
<tr>
<td>TENDRIL ST</td>
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<td>19.21</td>
</tr>
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<td>DURATA</td>
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<td>17.73</td>
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<tr>
<td>CAPSURE FIX MRI SURESCAN</td>
<td>4.27</td>
<td>20.55</td>
</tr>
</tbody>
</table>

Figure 54 Mean and range recorded force values.
Figure 57 Insertion angle results in rank order. The average value is displayed in blue while the standard deviation is displayed in red.
Table 9 Averaged metrics for all leads tested with standard deviations.

<table>
<thead>
<tr>
<th>Name</th>
<th>Length (mm)</th>
<th>$\sigma$ (mm)</th>
<th>Depth (mm)</th>
<th>$\sigma$ (mm)</th>
<th>Angle (deg)</th>
<th>$\sigma$ (mm)</th>
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</thead>
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<tr>
<td>DEXTRUS</td>
<td>8.49</td>
<td>1.55</td>
<td>3.86</td>
<td>0.62</td>
<td>35.60</td>
<td>10.09</td>
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<td>FINELINE EZ</td>
<td>6.34</td>
<td>0.79</td>
<td>2.62</td>
<td>0.27</td>
<td>31.34</td>
<td>2.81</td>
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<tr>
<td>STEROX II</td>
<td>6.34</td>
<td>0.79</td>
<td>2.62</td>
<td>0.27</td>
<td>31.34</td>
<td>2.81</td>
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<tr>
<td>FLEXTEK G - SILICONE</td>
<td>10.34</td>
<td>0.88</td>
<td>5.90</td>
<td>0.25</td>
<td>47.14</td>
<td>4.85</td>
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<tr>
<td>TEST LEAD G - SILICONE</td>
<td>8.81</td>
<td>1.88</td>
<td>5.00</td>
<td>0.58</td>
<td>43.60</td>
<td>3.10</td>
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<tr>
<td>TEST LEAD G - POLY</td>
<td>8.57</td>
<td>0.53</td>
<td>7.72</td>
<td>1.07</td>
<td>50.65</td>
<td>4.49</td>
</tr>
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<td>TEST LEAD I</td>
<td>9.16</td>
<td>0.51</td>
<td>6.09</td>
<td>0.56</td>
<td>41.43</td>
<td>1.96</td>
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<td>11.96</td>
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<td>4.25</td>
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<td></td>
<td>0.60</td>
<td></td>
<td>20.32</td>
<td></td>
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<td>1.48</td>
<td>3.58</td>
<td>0.93</td>
<td>33.45</td>
<td>8.51</td>
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<td>TEST LEAD S - SILICONE</td>
<td>7.84</td>
<td>0.46</td>
<td>3.84</td>
<td>0.27</td>
<td>34.94</td>
<td>3.61</td>
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<tr>
<td>SWEET TIP</td>
<td>6.52</td>
<td>0.66</td>
<td>2.28</td>
<td>0.14</td>
<td>25.46</td>
<td>0.85</td>
</tr>
<tr>
<td>TENDRIL SDX</td>
<td>8.15</td>
<td>1.62</td>
<td>5.84</td>
<td>0.66</td>
<td>47.60</td>
<td>2.68</td>
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<tr>
<td>TENDRIL ST</td>
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<td>4.68</td>
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<tr>
<td>TENDRIL ST OPTIM</td>
<td>8.84</td>
<td>1.25</td>
<td>4.58</td>
<td>0.32</td>
<td>48.69</td>
<td>5.42</td>
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<tr>
<td>TENDRIL STS</td>
<td>7.17</td>
<td>0.76</td>
<td>4.24</td>
<td>0.81</td>
<td>37.03</td>
<td>5.60</td>
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<tr>
<td>DURATA</td>
<td>9.65</td>
<td></td>
<td>9.61</td>
<td></td>
<td>54.06</td>
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<tr>
<td>CAPSUREFIX NOVUS - POLY</td>
<td>8.74</td>
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<td>6.27</td>
<td>1.32</td>
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<td>CAPSUREFIX NOVUS - SILICONE</td>
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<td>0.62</td>
<td>5.25</td>
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<td>CAPSUREFIX MRI SURESCAN</td>
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<td></td>
<td>5.52</td>
<td></td>
<td>49.60</td>
<td></td>
</tr>
</tbody>
</table>
Figure 58 Crater major axis length values for all leads tested. Average values in blue, with individual sample values in red.

Figure 59 Crater normal depth values for all leads tested. Average values in blue, with individual sample values in red.
Trends are apparent in the rankings. The BSC Selute lead (n=1) was tested as verification that a passive lead would not create a large divot, and the results clearly show that Selute ranked at the bottom of both the depth \((d = 0.60 \text{ mm})\) and angle \((a = 20.32 \text{ deg})\) categories, low values of both which indicate a very low likelihood of perforation. The BSC Sweet Tip (n=3), a fixed helix lead with no known perforation issues, also ranks at the bottom of the order \((d = 2.28 +/- 0.14 \text{ mm}, a = 25.46 +/- 0.85 \text{ deg})\) above Selute. Likewise, BSC Fineline II EZ Sterox (n=6), another lead with no history of perforation, rounds out the bottom three for both depth \((d = 2.62 +/- 0.27 \text{ mm})\) and angle \((a = 31.34 +/- 2.81 \text{ deg})\).

The highest ranking lead for the depth and angle categories is the SJM Durata (n=1), which was tested at the same time as BSC Test Lead I leads and clearly burrowed much deeper \((d = 9.61 \text{ mm})\) and at a steeper angle \((a = 54.06 \text{ deg})\) than any other lead. The second ranking lead for both depth \((d = 7.72 +/- 1.07 \text{ mm})\) and angle \((a = 50.65 +/- 4.49 \text{ deg})\) was the BSC Test Lead G Polyurethane lead (n=4), another lead with unacceptable perforation data. After Durata and Test Lead G Polyurethane, there is a sharp decrease in depth of penetration, and the next grouping is the MDT CapsureFix Novus - Polyurethane (n=6), BSC Test Lead I (n=5), BSC Flextend (n=6), and SJM Tendril SDX (n=6). For the angle of penetration, that order is MDT CapsureFix MRI SureScan (n=1), SJM Tendril ST (n=1), MDT CapsureFix Novus - Silicone (n=6), SJM Tendril SDX (n=6), and BSC Flextend (n=6).

The remainder of the leads tested all fall into the middle of the pack for depth, from \(d = 3.58 \text{ mm}\) to \(d = 5.52 \text{ mm}\). For angle as well, the middle of the pack ranges from a lower rating of \(a = 33.45 +/- 8.51\) to \(a = 45.54 +/- 4.97\). Thus there are clear outliers in the depth and angle category that have established records of perforation.

It must be mentioned that the number of leads tested is not equal for all lead types, and this significantly contributes to the uncertainty associated with these measurements. Unfortunately, it was not possible to procure more than one test article for some of the lead types on the roster, but the results are still published here for comparison.

From the above analysis, a baseline value for the metrics can be drawn by separating the top offenders from the remainder. Statistical methods are not entirely appropriate based on the somewhat unverifiable nature of lead perforation data. However, the data does show a few clear outliers for the depth metric which do have a reputation for perforation, separated from the normal population that does not have that negative reputation. The suggested specification is therefore 7.0 mm of normal depth penetration, as seen in Figure 61. The barrier is less distinct for the angle metric, where the greatest angles are associated with known perforators but the difference between the highest values and the next-highest values is not as distinct. The recommended specification is 50 degrees, shown in Figure 62. For the major axis length metric, the higher the value the less likely a lead is to perforate as the cycling force is spread out across a greater area. Neither the lowest or the highest length values are associated with leads known to perforate, and therefore a recommendation cannot be made on that metric.

![Figure 61 Linear ranking of depth values with suggested baseline specification.](image)
5.4 Error

There are a number of error sources that contributed to uncertainty present in this experiment. The error sources are categorized as mechanical error and measurement error and discussed separately. Mechanical error involves any error that affects the mechanical components of the lead as they relate to the perforation test. All of the controlled sources in the test have some form of error — the temperature, saline fill level, crosshead height, and spatial positioning of both the setup fixture on the baseplate and the lead in the setup fixture. Measurement error involves difficulties or limits in obtaining measurement values that are precise, accurate, and consistent among a highly variable sample population.

Apart from the tolerance stack-up reviewed in an earlier chapter, there were other factors that contributed to mechanical error in this setup. The extension of the helix was not verified during set-up apart from a light touch to verify that it had extended into the gel. A standard turn-count was used to apply torque from the terminal pin; this turn count was empirically determined by extending and retracting the helix in the open prior to test insertion. One of each lead type was tested in this manner. However, there is no verification that the helix buried completely in the gel at the specific number of
turns, leaving open the possibility that some helices were only partially extended, which could affect lead penetration through the gel.

In addition, the straight shape of the lead was variable and dependent on the lead manufacturer, lead stiffness, and whether the lead had been tested prior to the dynamic perforation test. Fresh leads tended to show no signs of kinking or bending (unless slight bending is intended, as in the case of the Test Lead I lead). Tested leads, however, often defaulted to positions that were slightly bent or curved. Some of the larger leads would take a permanent set after testing – while initially straight, after 48,000 cycles the leads showed a permanent bend in the shape of the buckling mode. This bend was problematic for two reasons – it meant the effective properties of the lead were changing mid-test, and it also shortened the effective vertical dimension of the lead. Because the lead became vertically shorter, and the crosshead moved at a fixed displacement, the lead is put into tension on the upstroke. This tension would reverse the direction of force at the lead-gel interface, and in extreme cases would cause leads to become dislodged from the gel entirely and skip across the surface. Divots from skipping leads are highly distorted from the average divot geometry, and increase the variability in each metric. Figure 63 demonstrates this phenomenon.

Figure 63  Left A normal Dextrus divot (48k cycles).  Right A Dextrus divot where the lead skipped across the surface (48k cycles).

There was also an error source associated with the load cells used for force measurement. Even when the crosshead was at a standstill, the load cells experienced noise with a maximum peak-to-peak amplitude of approximately 2 gf (0.02 N). Load cells 3 and 4, located in the middle of the crosshead fixture, regularly experienced an error close to this maximum, whereas the noise in the remaining load cells was more typically less than 1 gf (0.01N) peak-to-peak.

The lead insertion process is also vulnerable to mechanical error. The setup fixture was designed to make it as simple as possible to align a lead precisely between the lead grip and the gel surface;
however, the compliance of the lead and the gel makes a perfect alignment a challenge. The lead is not a stiff structure, and therefore is susceptible to bending and buckling under its own weight. The guide structure on the setup fixture aids in ensuring proper alignment, but it is very difficult to insert a lead in a perfectly straight configuration. In addition, when sliding the lead towards the gel surface, the intended hard stop is truly more of a compliant stop; there is a slight amount of play in the gel surface. This is usually not an issue since the gel is highly elastic as well, and bounces the lead back; yet helix fixation requires mild contact between the lead distal tip and the gel surface, and positioning is only accurate to a millimeter or so. This does not necessarily alter the characteristics of the resulting divot, but can exacerbate issues such as pre-buckled lead configurations, permanent sets, and skipping during the test.

The setup fixture/lead grip coupling allows for 0.050" of vertical motion to prevent overloading of the load cell upon contact. However, all load cells must be in contact with all lead grips before any pair can be mated. The z-adjustment modules on the crosshead fixture aid in ensuring all of the load cells make contact at the same time, but there is error in the lead buckling length associated with the compression of the nesting spring plunger. The crosshead is lowered by hand until contact occurs, but always displaces slightly below the lead grip starting height, reducing the lead buckling length by a couple of thousandths of an inch. Because the lead is so compliant, this almost guarantees a pre-buckling configuration. This is not entirely inappropriate for the test, since it is extremely difficult to begin a lead at a perfectly neutral position without putting it into tension, and since the displacement is applied to all leads equally. However, it does result in a slight change from the intended parameters of the test and must be noted.

The final source of error is inherent to the lead itself. The stack-up of manufacturing tolerances, especially in a multilayered and compliant product, can cause differences in mechanical behavior from two nominally identical leads. There was no attempt to quantify the amount of manufacturing variation present in the leads tested here — such an effort would be exhaustive — but it should be mentioned that some fraction of the variability seen in the testing results is on account of the physical parameters of the leads themselves.

5.5 Helix Effects

One topic not completely addressed in this work is the effect of helix geometry on lead perforation. Because every lead has a different helix was varied geometry, it was not plausible to examine the component effects of helix design on perforation. However, initial work was completed on the theory of the interaction between the extendable/retractable helix and cardiac tissue.

A major concern for lead manufacturers is the backdriveability of the lead helix. The extendable/retractable helix is almost universal in current cardiac leads because it avoids two major issues during implant — the snagging or scarring of vascular tissue during the lead insertion process, and the need to torque the entire lead to fasten a fixed helix into the heart. Previously, a lead was either inserted bare, with significant risk to the vascular structure, or a hard dissolvable coating was molded into a smooth cast over the helix to prevent damage. The coating would dissolve in minutes in the bloodstream, and after its
removal, the physician could continue the implant. On the other hand, an active helix can be retracted
during implant so as not to interfere with the vascular structure, and then once implanted, torque is
applied only to the lead terminal pin and transmitted through the inner coil to extend the helix without
rotating the entire lead body.

From a design perspective, the active helix is a significant advance over previous methods.
However, the literature clearly shows that active helices have a higher rate of perforation than passive (or
tined) leads, and it is undeniable that the structure of the helix must have something to do with that
increase. The motion of the heart during systole, though modeled here as a pure compression, is actually
an imperfect combination of translation and rotation by which the heart wall compresses and torques the
lead at the same time. The degree to which a given lead will be torqued by a given heart is inexact, but it
is known that both motions to contribute. Because an active helix is not fixed in space and is capable of
retraction with the application of torque, there is a concern that the right torque application at the distal tip
of the lead, rather than the proximal tip, might cause the helix to partially or fully retract in the heart post
implant.

From a patient perspective, this is undesirable because the chances of dislodgment are either high
or certain, and without fixation at the distal end, the lead is free to wiggle throughout the cardiac wall,
improperly sensing and pacing. Though not directly linked to death, it is not hard to imagine how the
wrong pacing at the wrong spot could easily lead to complications. From an electrical perspective, the
lead is now seeing very high pacing impedances due to the low contact area, and pacing is therefore less
effective. And from a mechanical perspective, the lead is now not fully secured and capable of
dislodgement, potentially with a sharp helix point still protruding and moving about the interior of the
cavity.

Helices are not standardized among leads, even within the same class of lead by the same
manufacturer. A close view of the Dextrus helix is displayed in Figure 64, and a schematic of the Fineline
helix in Figure 65 to illustrate some of the differences in helix design.
Figure 64 Helix grinds. A Biotronik helix with undercut. B SJM helix with three-facet grind. C MDT helix with flat grind. D BSC Dextrus with three-facet grind.

Figure 65 Left Various lead helices and coatings. Right BSC Fineline helix print.

The complexities of the helix-tissue interaction are beyond the scope of this work, and no experiments have been performed to more fully analyze the issue; however future work should consider this issue in detail.
6 Conclusions

6.1 Suggested Improvements and Continued Work

The initial dynamic lead perforation bench test described in this work was an appropriate step towards unraveling the mysteries of the lead perforation phenomenon, but the results generated here are not the final word on the subject. There are a number of improvements that can be made to the test setup that would allow for greater insight into the phenomenon and potentially reduce some of the variability noted in the results. Some of these suggestions are mechanical improvements to the test rig design, and others are procedural improvements to the test method.

The test tank was originally designed to run both saline and air. Though air tests are possible, the heater placement on the baseplate makes it impractical because the gel temperature during warm-up was significantly different between positions 1, 2, 5, 6 and 3, 4. In addition, the process thermocouple that measures the temperature was sensing the air at a point level to the top of the gel surface; however conduction from the baseplate caused the gel temperature to be hotter than the surrounding air. Because the heat transfer coefficient of air is less than that of saline, the conductive heat is not easily dissipated into the environment as it was for saline, and therefore causes a temperature difference.

With an aluminum baseplate of increased thickness, the heat would be distributed evenly on the top surface so that no temperature differences would exist among the gel holders. In addition, an alternative baseplate design could have been employed where the SS plate sat in the center of a larger polycarbonate plate with a small perimeter gap – instead of joining the SS to the polycarbonate via sealant and bolts and designing against the thermal stresses between the two dissimilar materials, the thermal expansion would be taken up by the gap to prevent stresses in the plate or tank walls.

It would have also been prudent to rearrange the test setup to place the load cells on the bottom surface, submerged in water. The buoyancy of the lead grip assembly altered the force readings in a way that overwhelmed the lead force response curve; the crosshead-mounted sensors also allowed an inertial affect from the acceleration of the crosshead. Both of these effects would have been avoided with a different mounting location. The fixture design would need to be altered as well, since an 1000 gf load cell does not have the capacity to hold the current stainless steel gel holder without damaging the sensor.

It would be beneficial to investigate a test method where the boundary conditions involve contact between the lead and hard boundaries instead of a clamped condition at the tricuspid valve. Also, the differences between the porcine tissue tested and the Perma-Gel are not conclusive but indicate that, with further effort, it may be possible to find a more suitable cardiac simulant.
6.2 Conclusion

Delayed cardiac perforation is a serious complication of lead implant and a phenomenon that is not well-understood within the medical community. Though there are no complications at first implant, the contraction of the heart wall causes a cyclic loading of the cardiac lead that can sometimes force the lead into or through the cardiac tissue. The phenomenon is particularly well-noted in leads with active helices, leading to the hypothesis that the geometry of the lead helix has a significant effect on the likelihood of perforation, in addition to other design factors.

Here a dynamic perforation test was developed to address the need for a characterization method for cardiac leads that reflects the full mechanism of perforation in the heart. Emphasis was made on physiological similarity between the test environment and the conditions inside the human heart. Lead design factors, exogenous factors, and biological interactions were all considered in the behavior of the lead inside the body, and informed the development of a physiologically appropriate test to simulate a lead perforating through the heart tissue. Bench-level experimentation was conducted to verify basic principles and further inform the design of the test. A complete bench-level test was devised, designed, and constructed to subject multiple leads to cyclic loading into a cardiac simulant. The resulting gel samples were characterized and the metrics were shown to have followed known patterns for lead perforation performance.

With further development and refined methods, this bench-test can provide the foundation for a standardized industry specification to estimate the risk of lead perforation in an environment that is physiologically similar to the human heart. This study provides insight into delayed cardiac perforation and provides a framework to unravel the details of this complex medical challenge.
References

A Appendix

MATLAB Script for Crosshead Fixture Displacements

% Spider Fixture Matrix Equations

clear all
close all
clc

E = 70*10^9; % modulus (Pa)

% beam dimensions
b1 = 0.50; h1 = 0.25; L1 = 5.00;
b2 = 0.25; h2 = 0.25; L2 = 5.50;
b3 = 0.25; h3 = 0.25; L3 = 4.45;
b4 = 0.75; h4 = 0.25; L4 = 1.45;

% nodal forces
m = 0.2; % mass (kg)
g = 9.8016; % gravitational acceleration (m/s^2)
freq = 1.666; % cycle rate (Hz)
A = 7.75*10^-3; % amplitude (m)
omega = 2*3.1415*freq;
a = omega^2*A; % maximum acceleration (m/s^2)
F = m*a;

f = m*g + F;
f1 = f; f2 = f; f3 = f; f4 = f; f5 = f; f6 = f;

q = 0.0254; % in to m conversion
b1 = b1*q; h1 = h1*q; L1 = L1*q;
b2 = b2*q; h2 = h2*q; L2 = L2*q;
b3 = b3*q; h3 = h3*q; L3 = L3*q;
b4 = b4*q; h4 = h4*q; L4 = L4*q;

% bending moments of inertia
I1 = b1*h1^3/12;
I2 = b2*h2^3/12;
I3 = b3*h3^3/12;
I4 = b4*h4^3/12;

% bending stiffnesses
c1 = 3*E*I1/(L1^3);
c2 = 3*E*I2/(L2^3);
\[ c_3 = \frac{3 \times E \times 13(L_3^3)}{}; \]
\[ c_4 = \frac{3 \times E \times 14(L_4^3)}{}; \]

\[ K = \begin{bmatrix} c_1 + c_2 + c_3 & -c_2 & -c_1 & 0 & 0 & 0 \\
-c_2 & c_1 + c_2 + c_3 & 0 & -c_1 & 0 & 0 \\
-c_1 & 0 & c_1 + c_4 & 0 & -c_1 & 0 \\
0 & -c_1 & 0 & c_1 + c_4 & 0 & -c_1 \\
0 & 0 & -c_1 & 0 & c_1 + c_2 + c_3 & -c_2 \\
0 & 0 & 0 & -c_1 & -c_2 & c_1 + c_2 + c_3 \end{bmatrix}; \]

\[ f = [f_1 \ f_2 \ f_3 \ f_4 \ f_5 \ f_6]' \]

\[ u = Kf \]
Instructions for Test Setup and Execution

Configurator Instructions

The WATLOW EZ-Zone Configurator program requires an EIA-485 serial connection to communicate with the RMC control module. The connector cable is a series connection consisting of a USB-to-Serial (RS232) connector and a RS232 to RS485 converter. The RS485 converter is then connected to the RMC control module via a wired interface. The wired connections made are common (GND) to CF, D+ to CE, and D- to CD.

The cable should be connected to the control module already, so turn on the control box, and then insert the USB plug into the port. After the connector is in place and connected at both ends, one can open the Configurator to make changes to the program. Open Programs\WATLOW\EZ-Zone Configurator\EZ-Zone Configurator and select “Configure a device while communicating with it.” Select COM3 (this is the assigned COM port to the bottom USB hub on the front of the PC), and allow the Configurator to detect the EZ-Zone RM equipment. Four modules should appear – one RUI/Gateway, two Control modules, and one Expansion module. Select the Control module using Zone 1 (RMC5B1A1A1NAAAA). The program should appear and edits can now be made.

The configurator will display a split screen explorer that shows the file tree on the left and any editable parameters on the right. The maximum temperature limit for the heaters is found in Math Block 2 under the Math section of the file tree. The high limit is an input value in deg F, which is then converted and displayed in deg C on the RUI in the thermal box. The current high limits for saline and air are 212 F (100 C) and 140 F (60 C), respectively.

After all desired changes are made, a configurator settings file can be saved for later upload.

There are two PID controller loops in the thermal control; one feeds into the other in an arrangement called “Cascade Control.” The first loop governs the heater temperatures – the setpoint is the desired heater temperature and the controlled input is the power to the four cartridge heaters. The second loop is the tank temperature – the setpoint is the desired tank temperature and the controlled input is the heater temperature. The system is currently tuned for approximately 4 gallons of 0.9% saline solution and remains precise to +/- 2C.

Data Measurement and Logging

Force measurements, displacement measurements, cycle counting, and data logging are all accomplished via a LabView VI.

Hardware

The hardware used in measurement includes six (6) Model 31 1000 g Load Cells by Honeywell, each connected via RJ-50 cable to an NI 9237 module and read in as an analog signal via an NI cDAQ-9178 chassis. In addition, an analog voltage is output through the Instron console and is read through an NI 9219 module in the same chassis. The chassis is connected to the computer via USB.
Of no small importance to data accuracy are the sampling rate limits of each piece of hardware. The cDAQ-9178 and the 9237 module have a minimum sampling rate of 1.613 kHz, while the 9219 has a maximum sample rate of 100 Hz. The sampling rate used here is 2 kHz, 20 times faster than the 9219 can handle. For compatibility, the 9219 has an adjustment mechanism that fills in the missing samples by repeating the last sample value — therefore, for a forced sampling rate of 2 kHz, the 9219 will still sample at 100 Hz and because the ratio of sampling rates is 20:1, output 20 identical values to match the one actual value sampled. This can lead to strange waveforms, but here, it only affects the analog displacement voltage, and that in turn is primarily used for cycle counting, so the immediate effect is negligible.

**DPT Environment**

The data logging VI is comprised of four sections. Setup & Calibration controls the majority of the test inputs, including the sample rate, length samples, scan time, and headers for the data files. Live Channels displays the six individual load cell signals; Data Channels displays the data from the last scan recorded and the calculated maxima and range. The auxiliary display at the bottom of the screen displays the crosshead displacement and controls cycle counting parameters.

The VI is configured to automatically begin data logging when the first displacement cycle is detected, provided that three things are true: the load cells must be tared, the ‘All Systems Ready’ Boolean switch must be active, and amplitude of the displacement waveform must exceed the noise threshold.

The VI logs data to two files; the first is raw data, and the second is data with a filter applied. Only the raw data includes maxima and range measurements. The filter is a low-pass to eliminate high-frequency noise from the load cell signal, and the lower cut-off frequency can be controlled from the Setup & Calibration tab.

**Test Procedure**

When a test is ready to run, the header information on the Setup & Calibration tab should first be completed — the filenames of the raw and filtered data must be supplied, as well as any comments about the test to be conducted, and the IDs of the leads being tested. If the samples are loaded, the tank is filled (for a wet test), and heated, the load cells can be tared by pressing the blue Tare button. If a delay is desired, make sure that the Delay @ Start button is active. Verify that all parameters are correct, and then press the All Systems Ready button. At this point, the VI is waiting on the first displacement cycle from the Instron, and data logging will begin (after any delay) when that first cycle is detected.

**Sample Mounting**

*Components Needed:*

[E71804-104] Lead Grip (x6)

[E71804-105] Setup Fixture (x6)
**General Setup**

1. Place Setup Fixture into Setup Fixture Table.

2. Insert Lead Grip into pin constraints by gently pushing down until the spring plunger retracts. Let go and allow the spring plunger to nest the Lead Grip against the pins.

3. Insert the Gel Holder into the Setup Fixture by angling the holder and then pushing the spring plunger upwards until the quick release pin is seated in the corresponding hole on the holder.
   a. Depress the plunger on the quick release pin and press the holder into the Setup Fixture.
   b. Grabbing the flange of the quick release pin and the top of the Gel Holder with both hands, press the pin firmly into the setup fixture until you hear a click.

4. Unscrew the nut on the Lead Grip, open the door, and slide a lead into the grip and out the rear groove on the Setup Fixture.

5. Align the lead in the front groove running down towards the gel, and ensure that the lead tip touches the gel surface.

6. Close the door and tighten the nut by hand until you feel resistance. Check to make sure that the lead is secured and that it is aligned in the groove.

7. Using the terminal pin tool, extend the helix of the lead by rotating the pin until the helix is fully deployed.

8. Remove the completed Setup Fixture from the Setup Fixture table.

9. Align the gel holder with the three alignment pins on the baseboard of the Tank. Slide the holder into place and ensure that it is fully contacting all three pins.
10. Repeat steps 1-9 with all Setup Fixtures.

Test Setup

11. Lower the crosshead on the Instron. The E1000 must be in Position Control and Low Power mode in order for the coarse crosshead adjustment to function. Ensure that the crosshead clamps are both loosened before attempting to move the crosshead.

12. When the crosshead approaches the tops of the Lead Grips, use the crosshead jog buttons to touch the Lead Grips. It is okay to depress the Lead Grips slightly.

13. Fasten the Lead Grips to the Load Cells via the female thread adapters.

14. Remove the quick release pin from the back of the Setup Fixture and slowly separate the fixture from the Lead Grip and Gel Holder.

15. Ensure that the Lead Grip is tight on the Load Cell.

Adjusting the Lead Grip Mount on the Setup Fixture

16. The lead grip mount can be removed and replaced at one of three designated heights. To remove the mount, unscrew the #8-32 center bolt with a 9/64” Allen wrench. Remove the bolt.

17. Lift the magnet mount and seat it in one of three kinematic couplings. The ball-groove interaction is designed for precision position repeatability. The heights corresponding to each groove set are 7cm, 8.4cm, and 9.8cm (small, average, and large heart sizes).

18. Reinsert the bolt and fasten the mount to the fixture.