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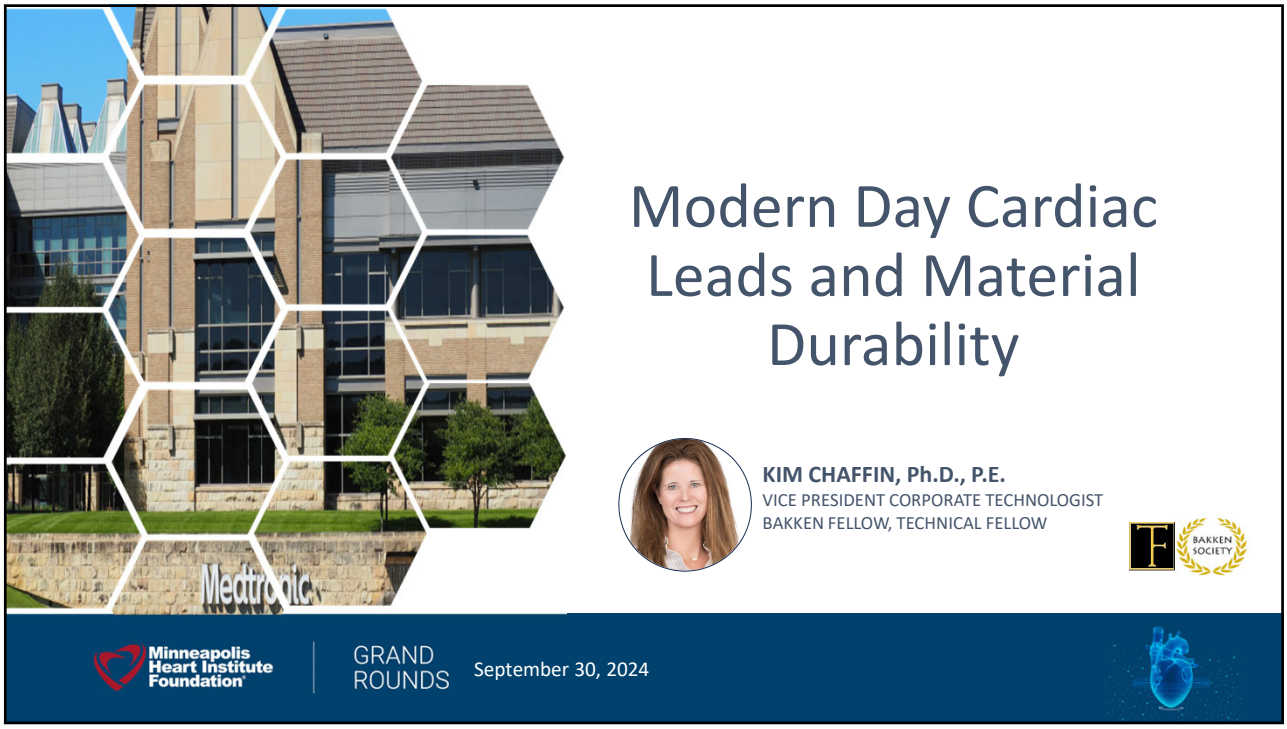
Modern Day Cardiac Leads and Material Durability
KIM CHAFFIN, Ph.D., P.E.
VICE PRESIDENT CORPORATE TECHNOLOGIST
BAKKEN FELLOW, TECHNICAL FELLOW
BAKKEN SOCIETY
Minneapolis Heart Institute Foundation
GRAND ROUNDS
September 30, 2024

2

Primary Cause of Class 1 Medical Device Recalls

40%

of Class 1 Recalls have a material of construction cited as the primary cause[1]

2/3

involve Polymers[2]

We face two challenges in accurately predicting FUTURE performance.

1. Prediction timeframes that exceed more than a decade.
2. Accurately accelerating concurrent mechanical and chemical attack.

[1] https://www.plasticstoday.com/medical/material-failure-root-cause-many-medical-device-recalls
[2] https://www.mddionline.com/materials/mitigating-risks-materials-failures-medical-devices

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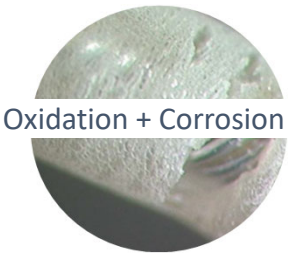
3

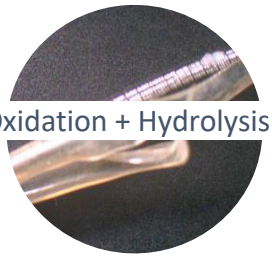
Material Failures in Medical Devices

Concurrent assault resulted in unexpected failures



Oxidation + Corrosion

Abrasion + Corrosion



Oxidation + Hydrolysis

1984: Metal Induced Oxidation

Corrosion of adjacent metal conductors catalyzed the polymer oxidation reaction, and in vitro studies **under predicted *in vivo* results**.

Stokes et al. *Journal of Biomaterials Applications*. 1986;1(3):411-448

2010: MoM Hip Implants

Mechanically based *in vitro* wear simulations **under predicted *in vivo* results** by 50x.

Sampson et al. *Ann Clin Biochem*. 2012 Mar;49(Pt 2):118-31.

2011: Hydrolysis of silicone-urethane

In vitro testing assumed oxidation and **under predicted *in vivo* results** when long term contact with water and mechanical loading occurred.

Chaffin et al. *Biomaterials*. 2013 Nov;34(33):8030-41

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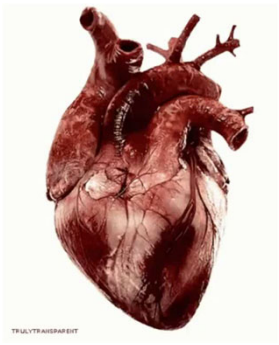
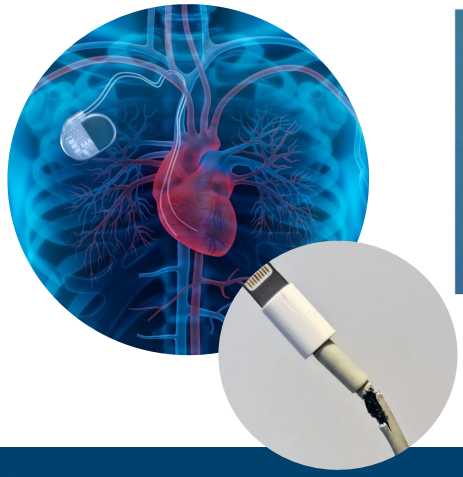
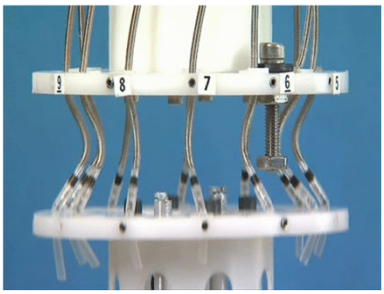
Concurrent Mechanical Load and Chemical Attack

Primary insulation integrity is critical to performance





40 Million Beats per Year



- 600 Million Beats
- 15-year device
- >95% Reliability

15 years of testing ~0.5 years

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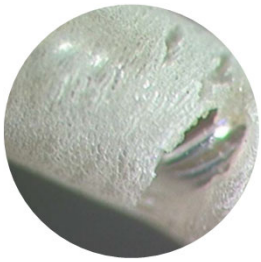
Insulation Integrity has a Long History

Evolution of lead coating materials to expand implant longevity

Silicone

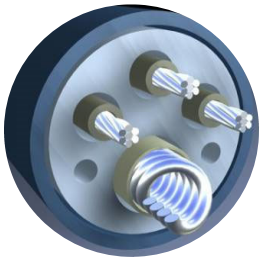
- Abrasion Failure
- Chemical resistant
- Soft/Flexible
- Large Diameter

Soft Polyurethane (80A)



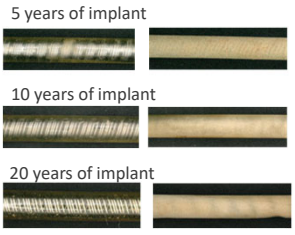
- Metal Ion Oxidation (MIO)
- Abrasion resistant/tough
- Soft/Flexible/Lubricious
- Small diameter

Metal Ion Barriers



- Environmental Stress Cracking (ESC)
- Abrasion resistant/tough
- Soft/Flexible
- Continued miniaturization

Environmental Stress Cracking (ESC)



- Oxidation
- Heterogeneous
- Superficial

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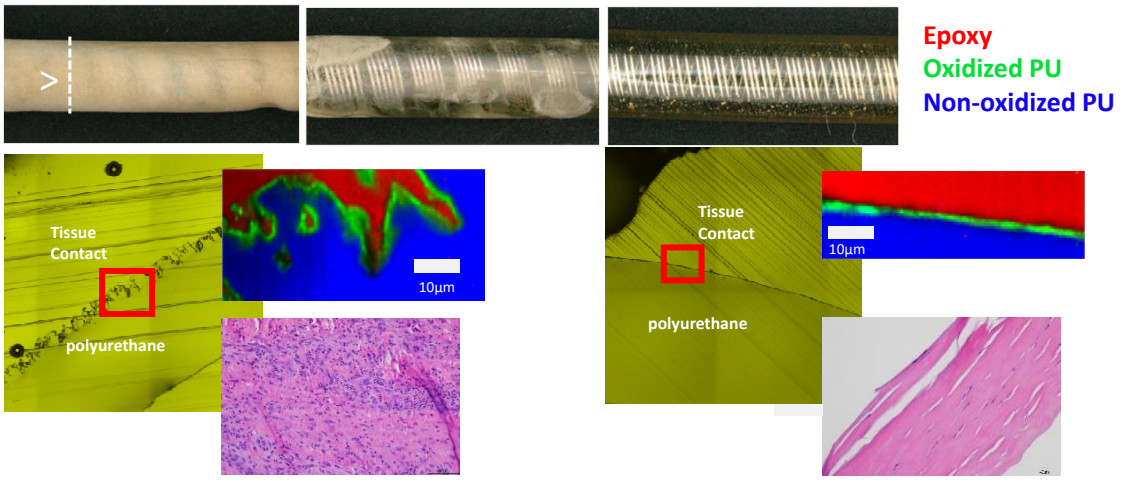
Environmental Stress Cracking (ESC)

Heterogenous and Superficial Oxidation of Polyurethane 80A

Cardiac Leads
20 year *in vivo*
Human exposure



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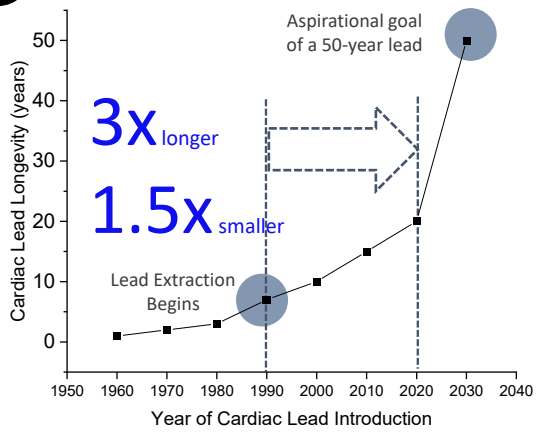
Reference: Theilacker, W., Spectroscopy Special Issues June 2020, Volume 35, Issue 2 Pages: 8–22, 40 (https://www.spectroscopyonline.com/view/applications-confocal-raman-spectroscopy-and-imaging-medical-device-industry)

7

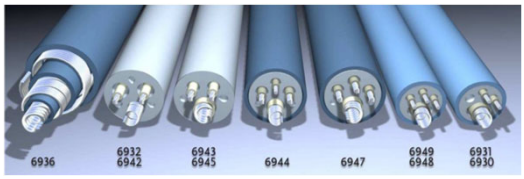
Miniaturization and Longevity Expansion

Material durability requirements are rapidly changing

1 Earlier diagnosis and modern therapies



2 Miniaturization pushes material to limits



10 Fr (3.3 mm diameter) → 6.6 Fr (2.2 mm diameter)

Industry seeking materials that perform better than Polyurethane (95% at 15 yrs)

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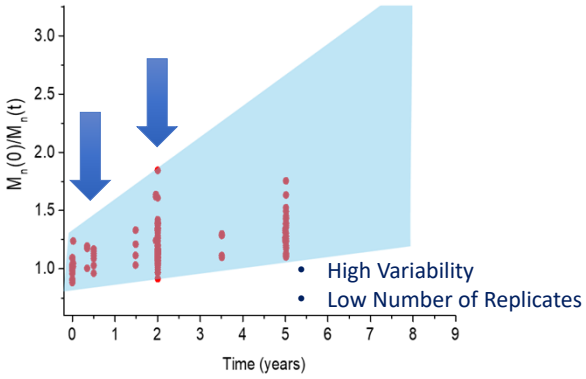
Preclinical Models are not Adequate for New Material Evaluation

Modern day longevity cannot be assessed in animal models

5-year Canine Implant
(cardiac leads with new insulation material)



Evaluation of Material Durability

FDA Guidance for Pacemaker Leads: 2000
- Focused on Polyurethane Oxidation
- 6 month *in vivo* (or 2 years without Oxidation challenge) to assess other reactions

ISO 10993: 2010
- 12-month in vivo OR
- 70 °C exposure for 60 days
- Defaults to 12-month preclinical

EU MDR: 2017
- 11 references to 'End of Life' performance.
- No guidance on methods to predict.

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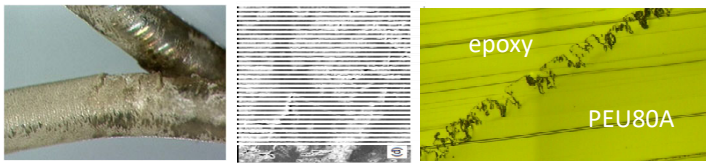
Evaluating Materials for Long-Term Performance

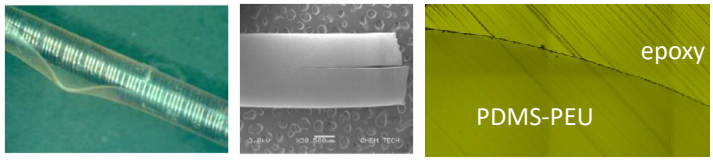
Accelerated material testing is necessary to predict the rate of change

Two primary *in vivo* reactions

Oxidation: Challenge Testing $CoCl_2 + H_2O_2$ (2000 Guidance)



Hydrolysis: Recently Qualified Medical Device Development Tool (2023 MDDT)



Simmons, et al. Biomaterials, Volume 25, Issue 20, **2004** pages 4887-4900, ISSN 0142-9612, https://doi.org/10.1016/j.biomaterials.2004.01.004.

1. The material must have a fast degradation reaction giving a large and detectable signal in the preclinical (animal) model.
2. The measurement method must be precise enough to accurately measure small changes.
3. The reaction must be accelerated to measure changes precisely enough to support extrapolation

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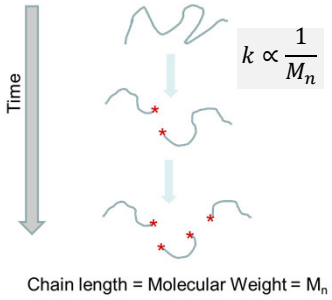
MDDT: Method to Quantitively Accelerate and Predict Performance

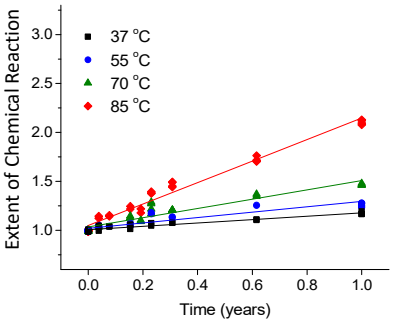
Utilized the Arrhenius relationship to deduce the kinetics of reaction

1. Measure the rate
(reactions per time)



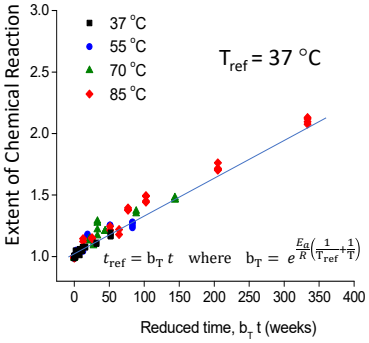
The number of chemical reactions is inversely proportional to chain length

2. Accelerate the reaction
(the same reaction as at 37 °C)



Determine the effect of temperature on rate (i.e. the activation energy (E_A))

3. Reduced Time
(1 year predicts ~ 7 year performance)



Chaffin *et al. Macromolecules* **2012**, 45, 22, 9110-9120

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Medical Device Development Tool (MDDT)

FDA Program (est. 2017): Expedite guidance for regulatory submissions

The FDA has qualified 17 MDDTs to-date

Accelerated Testing to Prove Long-Term Biostability

August 9, 2023

FDA Announces a New Qualification through the Medical Device Development Tools Program

Today, the U.S. Food and Drug Administration (FDA) announced the qualification of a new tool through the voluntary Medical Device Development Tools (MDDT) program: ***Accelerated Testing to Prove Long-Term Material Biostability***.

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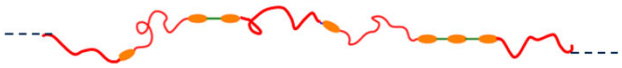
The Oxidation Susceptibility Spurred New Material Introduction

Soft Segment in Polyurethane is the susceptible linkage in the oxidation failure mode

The Polyurethane Soft Segments (red) were oxidized



Substitute new Soft segment

Silicone-Polyurethane (PDMS-PU)

Optim™

Silicone
- Flexibility
- Biostability

Polyurethane
- Lubricity
- Toughness

50x the abrasion Resistance of silicone
(no long-term in vivo exposure)

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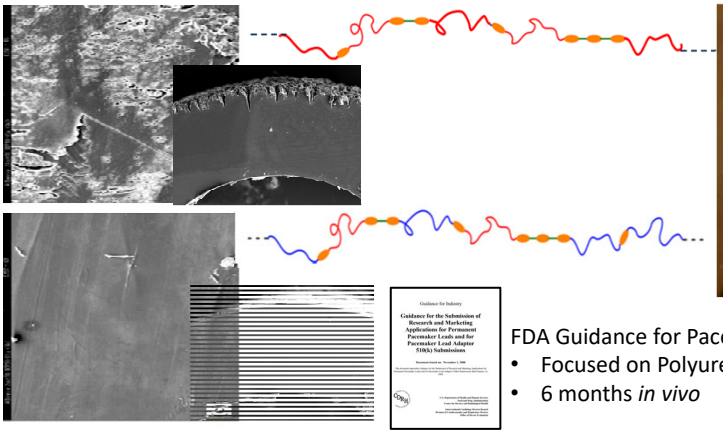
PDMS Substitution Improved Oxidative Stability

Reducing the soft segment concentration slows the oxidation failure mode

Material Screening *in vitro* (Oxidative Challenge)



Extended 5-year Canine Pre-clinical

FDA Guidance for Pacemaker Leads: 2000
- Focused on Polyurethane Oxidation
- 6 months *in vivo*

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Insulation Integrity and Performance

Publications suggest high voltage performance is impacted to a greater extent

Europace. 2013 Feb; 15(2): 278–283. PMCID: PMC3549219
Published online 2012 Aug 21. doi: 10.1093/europace/eus245 PMID: 22915789

Failure of a n
implantable c

Robert G. Hauser,

Author informatio

Comparative Study > Heart Rhythm. 2019 Apr;16(4):572-578. doi: 10.1016/j.hrthm.2018.10.024. Epub 2018 Oct 24.

Long-term performance of a pacing lead family: A single-cente

Mikhael F El
Patrick Zakk
David Delur
Faisal M Me

> Heart Rhythm. 2019 Dec;16(12):1855-1861. doi: 10.1016/j.hrthm.2019.05.020. Epub 2019 May 21.

Detection of high-frequency artifact as a function of pulse gene material

Ryohsul
Eun-Jeo
Christop

Affiliations + expa
PMID: 31125674

Heart Rhythm O2. 2023 Jul; 4(7): 417–426. PMCID: PMC10373148
Published online 2023 May 20. doi: 10.1016/j.hroo.2023.05.002 PMID: 37520017

Prevalence and management of electrical lead abnormalities in cardiac implantable electronic device leads

Hilary Roberts, BSc,* Kara Matheson, MSc,† John Sapp, MD,‡ Martin Gardner, MD,‡ Chris Gray, MD,‡ Amir AbdelWahab, MD,‡ David Lee, MD,‡ Ciorsti MacIntyre, MD,§ and Ratika Parkash, MD, MSc‡*

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10+ years

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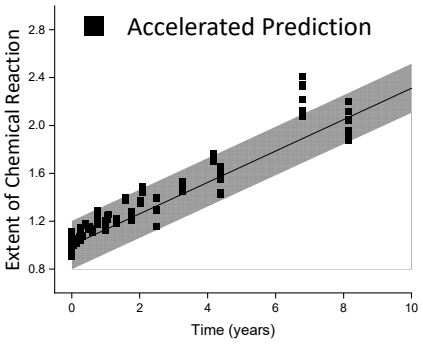
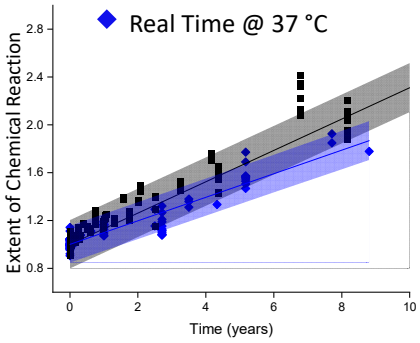
Validating the Accelerated Prediction

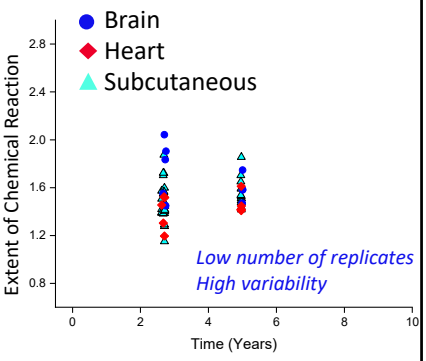
Real-time testing to demonstrate that accelerated in vivo conditions could simulate the in vivo environment



Chaffin *et al. Macromolecules* **2012**, 45, 22, 9110-9120



Chaffin, *ACS Macro Letters*. **2020** 9. 1793-1798.



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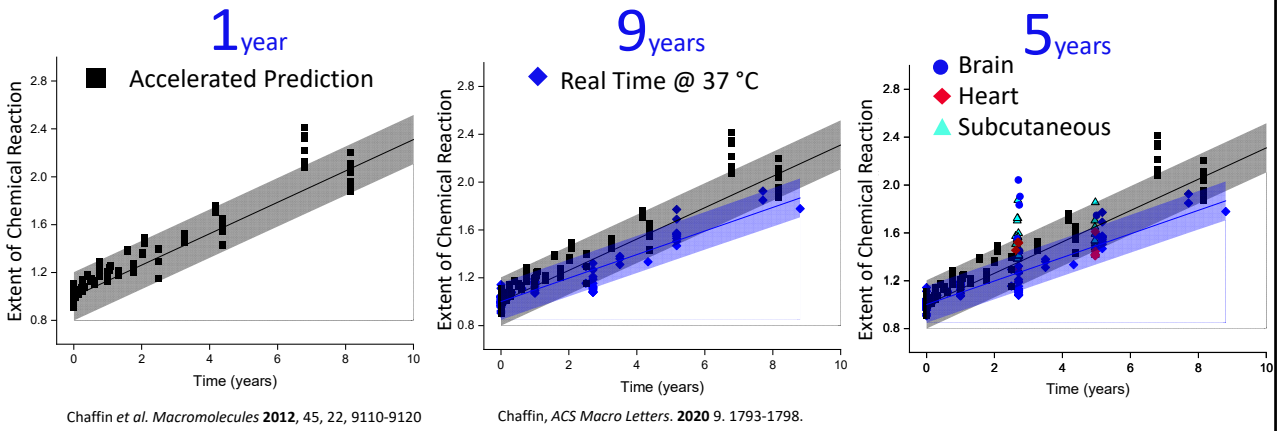
16

Validating the Accelerated Prediction

Real-time testing to demonstrate that accelerated in vitro conditions could simulate the in vivo environment



Chaffin *et al. Macromolecules* **2012**, 45, 22, 9110-9120

Chaffin, *ACS Macro Letters*. **2020** 9. 1793-1798.

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Unpublished Medtronic data - 5-year canine study

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Human Cardiac Lead Explants

Molar mass as a function of insulation material type

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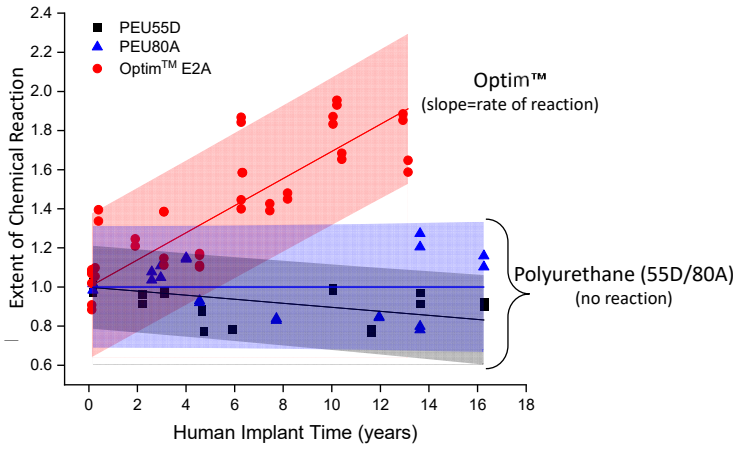
ASSOCIATE PROFESSOR
MEDICAL DIRECTOR
CARDIAC ELECTROPHYSIOLOGY
EMORY UNIVERSITY



Ibrahim *et al*. Heart Rhythm. 2024 21(8):1334-1341.

100 leads representing all manufacturers were explanted from humans with implant times from 3 months to 16 years.

FTIR was employed to confirmed materials of construction and separate leads as a function of material.

Poly(ether)urethane and Optim™ materials comprising the outer insulation were evaluated at Jordi Labs for molar mass

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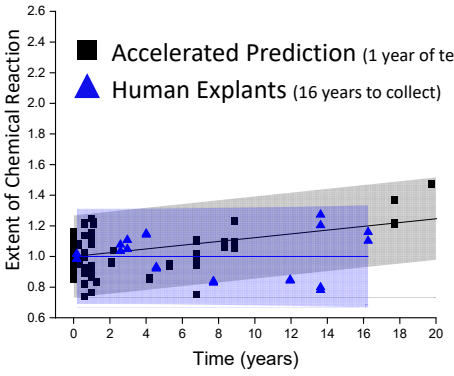
Accelerated Prediction vs. Human Explant

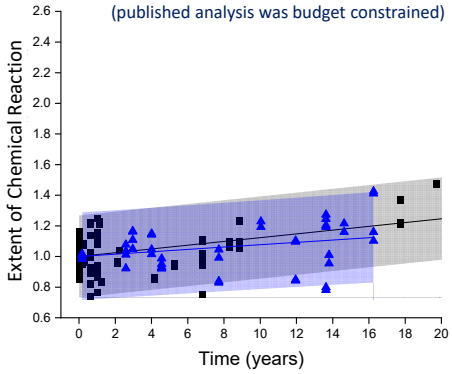
Human cardiac lead explants: Explant analysis has lower statistical power

Polyurethane 80A



Expanding the Analysis to include all Polyurethane 80A leads collected

(published analysis was budget constrained)



Ibrahim *et al*. Heart Rhythm. **2024,** 21(8):1334-1341.
Chaffin *et al. Macromolecules* **2014**, 47 (15): 5220-5226.

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Unpublished Medtronic data - 5-year canine study

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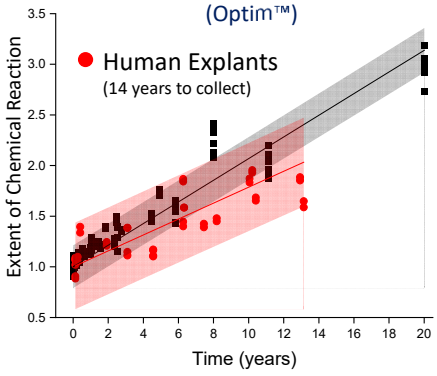
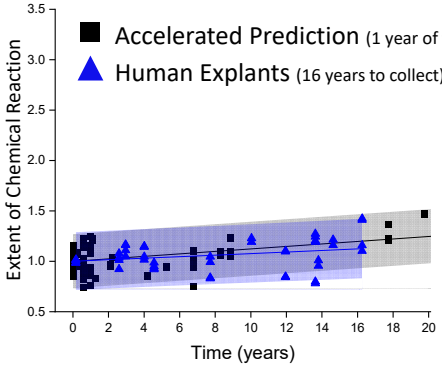
Accelerated Prediction vs. Human Explant

Accelerated testing predicted human performance in less than 1 year

PDMS-Polyurethane (Optim™)



Polyurethane 80A



Ibrahim *et al*. Heart Rhythm. **2024,** 21(8):1334-1341.
Chaffin *et al. Macromolecules* **2012**, 45(22): 9110-9120.

Chaffin *et al. Macromolecules* **2014**, 47 (15): 5220-5226.

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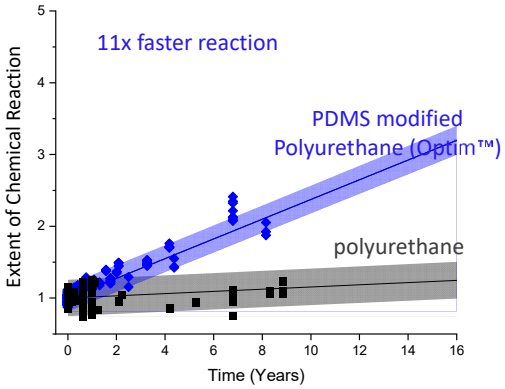
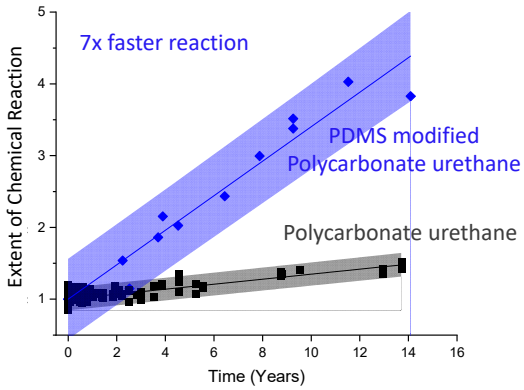
Accelerated Testing for New Materials

PDMS modification appears to accelerate hydrolysis

Polyurethane 80A



Polycarbonate Urethane 95A



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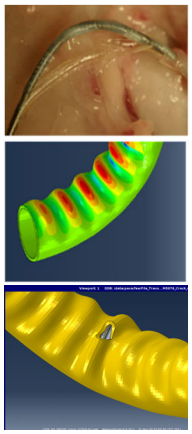
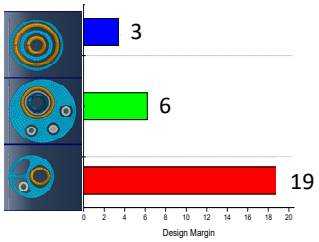
Accelerated Testing Allows for End-of-Life Device Evaluation

EU MDR requires End-of-Life performance testing



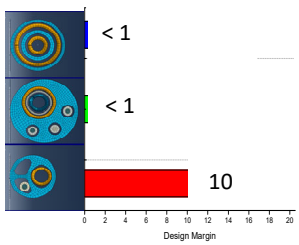
Mechanical Performance
without considering
chemistry changes in the insulation

Design Margin Calculated with Initial Material Properties



Mechanical Performance
for the insulation material after
5 years of *in vivo* reaction

Design Margin Calculated with 5-year Material Properties



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Summary: Modern day Cardiac Leads and Insulation Durability

1. The recently qualified MDDT fills a gap in the current guidance which only accelerates the OXIDATION reaction, leaving the rate of HYDOLYSIS reaction to be resolved in SHORT real time exposures. Endorses ACCELERATED predictive testing.

Qualified Medical Device Development Tools (MDDTs)

Accelerated Testing to Prove Long-Term Biostability
August 9, 2023

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Unpublished Medtronic data - 5-year canine study

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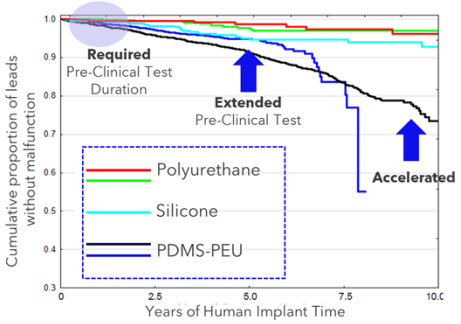
Summary: Modern day Cardiac Leads and Insulation Durability

1. The recently qualified MDDT fills a gap in the current guidance which only accelerates the OXIDATION reaction, leaving the rate of HYDOLYSIS reaction to be resolved in SHORT real time exposures.

2. Modern day biostable materials require accelerated testing to resolve degradation reactions that could compromise patient safety

Electrical Performance
8,000 Cardiac Leads



El -Chami, et al *Heart Rhythm* **2019**, 16, 572-578

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Unpublished Medtronic data - 5-year canine study

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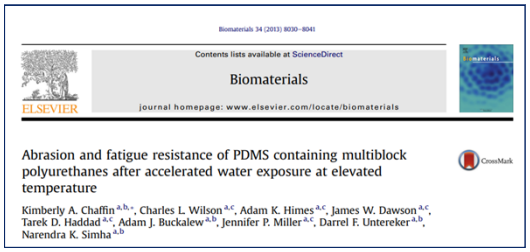
Summary: Modern day Cardiac Leads and Insulation Durability

1. The recently qualified MDDT fills a gap in the current guidance which only accelerates the OXIDATION reaction, leaving the rate of HYDROLYSIS reaction to be resolved in SHORT real time exposures.

2. Modern day biostable materials require accelerated testing to resolve degradation reactions that could compromise patient safety

3. The accelerated testing scheme provides a recipe for taking a material to a simulated future time and evaluating it for performance.


Biomaterials 34 (2013) 8030–8041

Contents lists available at ScienceDirect

Biomaterials

journal homepage: www.elsevier.com/locate/biomaterials

Abrasion and fatigue resistance of PDMS containing multiblock polyurethanes after accelerated water exposure at elevated temperature

Kimberly A. Chaffin [a,b,*], Charles L. Wilson [a,c], Adam K. Himes [a,c], James W. Dawson [a,c], Tarek D. Haddad [a,c], Adam J. Buckalew [a,b], Jennifer P. Miller [a,c], Darrel F. Untereker [a,b], Narendra K. Simha [a,b]

Chaffin et al. Biomaterials **2013**; 34(33):8030-8041

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Modern day Cardiac Leads and Insulation Durability

Backup Slides

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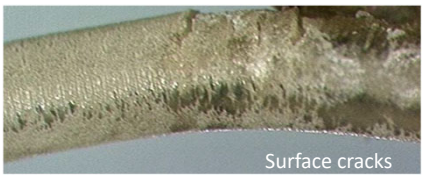
Two primary in vivo Reactions: Oxidation and Hydrolysis

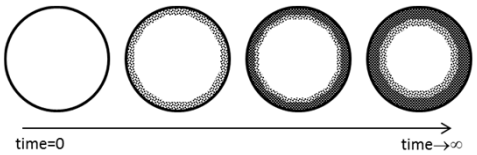
Only oxidation will show surface cracking. Hydrolysis must be measured in the bulk with molar mass

Oxidation results in surface damage

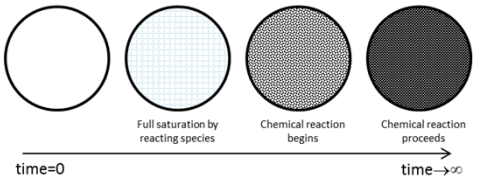


Hydrolysis results in bulk damage

Oxidation
- Mass transport limited



Hydrolysis
- Reaction limited



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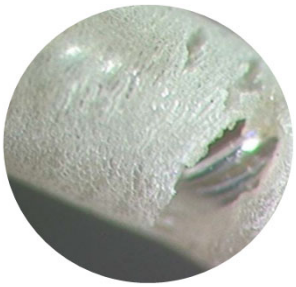
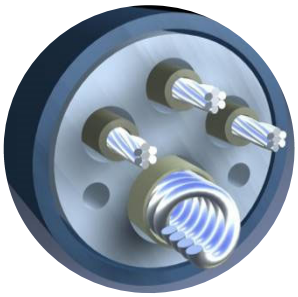
Screening New Materials for Long Term Durability

Understanding the oxidation reaction: Most consequential recall for my company circa 1983





- 80% survival at 3 years end of life
- 30,123 leads
- Company size: $750 M annual revenue

New Design Rules

1. Metal Ion Barriers (PTFE and ETFE)
2. Material Screening with Oxidative Challenge **0.1M $CoCl_2$/20% H_2O_2** @ 37°C; 16 weeks
3. Minimum Wall Thickness
4. Longer Preclinical Screening for New Material Introduction

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