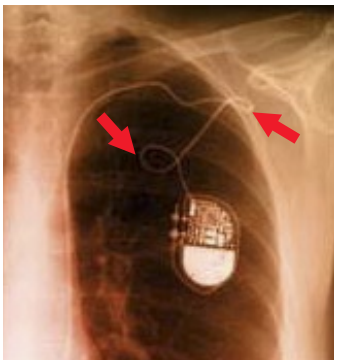
A VEXTEC CASE STUDY:

Virtual Life Management for Medical Implant Wires

OVERVIEW

There are few operating environments harsher than the human body. Medical implants have to endure violent, unpredictable stress and strain, and constant exposure to corrosive chemicals, all while facilitating life-dependent reliability, day after day. In addition, no two bodies are alike, and installation procedures vary with the surgeon performing them. To complicate matters even further, material, vendor and manufacturing variability all play interconnecting roles that affect device durability.



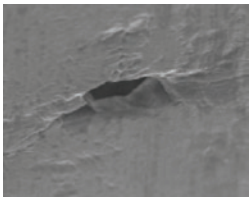
Pacing device lead coils subjected to numerous sources of variability ranging from:

- *Coil kinks, bends and twists due to implantation methods*
- *Material vendor and part manufacturer variability*
- *Various patient activity levels leading to varying loads*

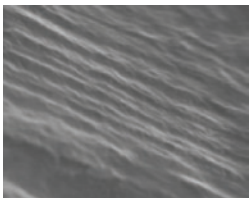
To ensure patient safety, medical device manufacturers spend billions on testing to make sure their products will work under the broadest possible set of conditions. Even so, it's practically impossible to physically test for every one of these conditions, let alone all their various combinations. Medical device manufacturers simply need more information—about how their products react to unpredictable stress, installation anomalies, and manufacturing and material variances—than they're able to get with traditional methods.

THE PROBLEM

Medical device manufacturers are always on a quest to make their devices more reliable. Unfortunately, it's not always readily apparent as to just how that might be accomplished, nor is it always possible to measure the effects certain changes may have, or how those changes will in turn affect other characteristics of the component's makeup. For instance, upon examination, seemingly identical lead wires in a random sample were found to have up to a 10X variation in durability. Manufacturers would like to know how much of that variation is caused by the manufacturing process itself (which is quite complex), how much is caused by variations in the material, and how much is caused by the arrangement of the material's microstructure. Residual stress, induced when the wire is spooled, introduces yet another level of variability; it makes the wire stronger at some locations and weaker in others. Furthermore, if all of the above factors could be controlled, in what way should they be adjusted to deliver a more consistent, durable lead wire? Finding the answers to these questions involves a level of complexity that trial-and-error, physical testing simply cannot approach. Even if the answers could be arrived at with the most sophisticated testing regime, the cost would be prohibitive and the lead wire in question obsolete by the time it was completed.

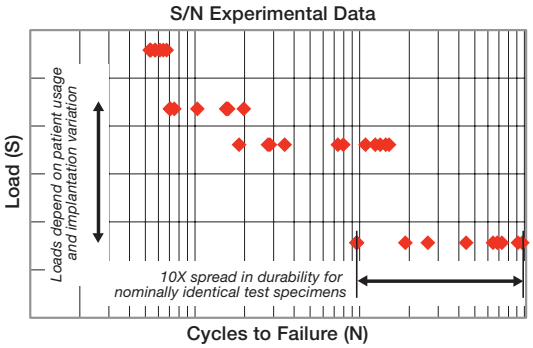


Surface particle driven failure

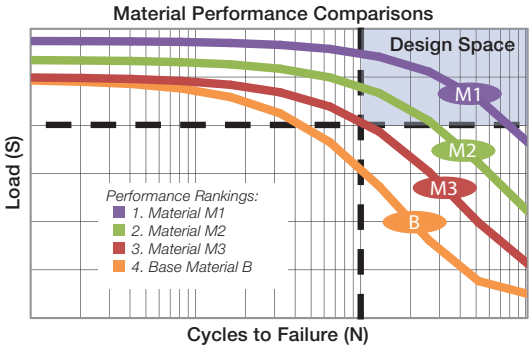


Surface grain slip band driven failure

MORE >



Design for high reliability lead coils is complex. Material variations alone can cause up to a 10X spread in durability. Multiple failure mechanisms are present



What materials will meet design requirements? VEXTEC leverages VLM technology to answer this question and more in a matter of days. Physical testing for the same information would take years.

THE SOLUTION

Typically, the knowledge a company gets about its products from its testing lab is supplemented by prior experience, anecdotal evidence and conventional wisdom. But all of that evidence is deterministic in nature, in that it merely describes what happened in the past, not what is going to happen in the future. And none of that information is a match for the intricacies of complex new products, or the extreme variability of the world in which those products are expected to perform.

VEXTEC Virtual Life Management (VLM) simulation technology models that variability by using a combination of material science, probabilistic methods and loading parameters to predict the behavior of materials in the physical world. Unlike FEA models that only measure where stress occurs, VLM simulates how materials respond to that stress at the microstructural level. Modeling the component at this level provides a more accurate picture of how stress, transformed into energy, moves through the microstructure creating damage. Once these models are built, as in this example of the lead wire, they can be interrogated in ways that are simply not possible or practical with physical testing.

THE RESULTS

The power of VLM simulations is shown in the results that are delivered. The simple question, "What material specification will meet design requirements?" is impossible to answer without years of testing and untold millions of dollars in research. Yet VLM technology not only provides the answers in a matter of days, it also shows the impact of the key parameters—material characteristics, processing effects, and usage variability—and how adjusting the interplay among them can produce lead wires that fit comfortably within the design criteria. This kind of detailed information about product composition and behavior is simply beyond the capability of traditional R&D methods, and its importance to the company cannot be overstated. With this new knowledge, a company can reduce product development and physical testing time, and begin focusing attention on creating a sustainable competitive advantage. Having this capability can accelerate time to market, cut new product development costs and schedules, and provide management, for perhaps the very first time, with a clear and confident picture of expected product performance in the field.

ABOUT VEXTEC

VEXTEC accurately, efficiently and economically predicts the performance, durability and true lifetime cost of a single component or an entire fleet—before they're ever built. Founded in 2000, VEXTEC has pioneered and patented innovations in material science and probability theory to form the foundation of its Virtual Life Management (VLM) technology. Manufacturing companies from such diverse industries as aerospace, heavy equipment, automotive, electronics and medical implants can all benefit from VEXTEC's unique ability to predict product life cycles and failure, and most importantly, their financial consequences. To learn more, visit www.vextec.com.