PhD Dissertation Defense

Stent Reliability and Maintenance: Integrating Probabilistic and Physics-of-Failure Models

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The rapid advancement of biomedical implant devices has raised new challenges to the failure analysis and reliability study of such new devices. More than one million stents are implanted in human arteries each year. These devices are subject to a wide range of stress due to biological and procedural factors. Fatigue and structural damage can occur to stents that may lead to tumor formation, allergies or even death. For this reason, reliability study of stents, which remains in its immaturity, becomes an urgent call.

The physics-of-failure mechanisms of stents are investigated and analyzed based on fracture mechanics study in biomaterial and medical fields. We then propose a probabilistic modeling framework to study reliability and maintenance strategies for stent deployment and operation through two dominating failure processes: *delayed failures* or crack growth due to cyclic stresses and *instantaneous failures* due to single-event overloads. We develop the reliability model using probabilistic degradation and random shock models, by first assuming these two failure processes are independent. The reliability model is then used to optimize a new two-phase maintenance policy to minimize patient risks.

Subsequently, the dynamic nature of human systems is incorporated in developing the reliability models given that patient activities can alter the shock magnitude, leading to dependent failure processes for patients with a high activity level. Reliability models for dependent competing failure processes are then derived according to stochastic processes. The results are embedded in an aperiodic maintenance policy to optimize the long-run maintenance cost rate for different patient groups.

The research is extended by developing reliability models for multi-stent systems, motivated by thorough analysis of related medical study. An experimental study on stent materials is then conducted using top-notch testing and inspection facilities. A mathematical relationship between crack length and cyclic counts is established, and a probabilistic interpretation of material fracture is made.

This dissertation represents new research in the area of applying reliability methodology to evolving medical devices. It is expected to add another dimension to the design, development and application of small biomaterials implanted in human bodies, and therefore, enhance their performance and sustain patient outcomes.