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A physics-of-failure based reliability and maintenance modeling framework for stent deployment and operation

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Abstract

Reliability study of stents becomes extremely important due to the high demand on these devices to counteract the effects of atherosclerosis. Based on the physics-of-failure mechanisms, we propose a probabilistic reliability and maintenance modeling framework for stent deployment and operation. The fracture-mechanics-based approach in literature provides a rational basis for quantitative evaluation of damaging effects from two dominating failure modes of stents: (1) *delayed failures* or fatigue crack growth due to cyclic stresses, and (2) *instantaneous failures* due to single-event overloads. We develop the system reliability function using probabilistic degradation and random shock models. The developed system reliability model of stents is then incorporated in the optimization of a unique two-phase maintenance policy for achieving persistent patient outcomes. A numerical example is used to illustrate the results, where data in literature are used to analyze the reliability and optimize the maintenance schedule for stents. The developed reliability and maintenance models and analysis tools for stents provide fundamentally new perspectives on the application of reliability concepts to evolving medical devices.

Keywords

Stent reliability; Physics of failure; Fatigue crack growth; Single-event overloads; Degradation; Random shocks; Preventive maintenance

Figures and tables from this article:

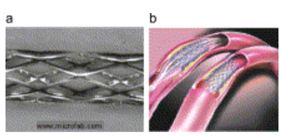

Fig. 1. (a) An example stent and (b) stents implanted within arteries [1].

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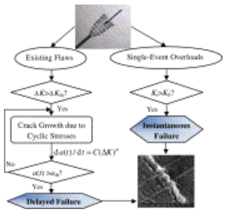

Fig. 2. Prominent failure modes of stents.

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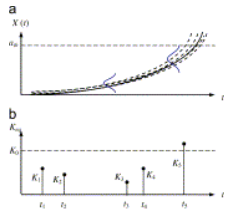

Fig. 3. Degradation and random shock modeling for two failure modes.

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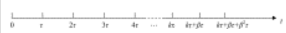

Fig. 4. Inspection model schema.

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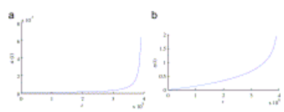

Fig. 5. (a) Fatigue crack growth and (b) mean degradation path.

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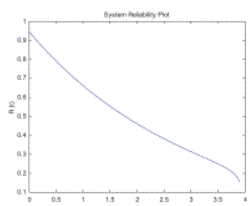

Fig. 6. System reliability function ($\Delta K'_{th} < a_{th}$).

Figure options

Table 1. Optimal solutions for two-phase maintenance model.

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