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Multiaxial Fatigue in Verification & Validation Testing of NiTi Medical Devices

Nitinol medical devices are subject to complex in-vivo loading conditions. For many decades, most products were approved by notified bodies based on fatigue-to-success test data in single-mode fatigue at a representative physiological load level. This data can prove that a selected device will survive at this one loading condition for a given number of cycles, typically equivalent to 10 years of service life in the patient. However, as devices have become more complex and were implanted in increasingly challenging indications with higher cycle numbers, the amount of physiological papers about clinically encountered device fractures has led to more awareness about the limitations of this approach during submission testing of new implants and devices.

The normative landscape began to address the issue with heavy involvement of regulatory agencies, resulting in new standards, such as ASTM F3211-17[1] and the most recent revisions of the ISO 5840 series[2], ISO 25539-2:2020[3], ASTM F2477-23[4], and ASTM F2942[5]. The combined approach of using established fatigue-to-success, fatigue-to-fracture, finite element analysis, and in silico methods to better understand and predict the mechanical behavior in-vivo and to improve patient safety is gaining track in the medical device community. Therefore, the testing of devices in additional fatigue modes or the combination thereof is expected to become a submission requirement soon.

This paper describes recent developments in medical device fatigue testing providing examples of cardiovascular implants and components of active implants for cardiac and rhythm management.

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