High-Cycle Flex Durability of a 16-Contact Coiled Spinal Cord Stimulation Lead

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BACKGROUND

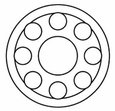
The overall incidence of lead fractures in the literature is reported to be between 4.3% and 10.2% over a two-year period.[1,2,3] This may lead to loss of therapy and impact the MRI conditionality of the system. Lead design plays a crucial role in establishing its durability. Two common lead design types are single-lumen and multi-lumen, where the latter is reported to be more durable.[4,5] One study reported zero fractures with multi-lumen leads out to 5 years, establishing them as a market-leading option.5. In this analysis, we evaluate the durability of a novel coiled lead design with 16-contacts compared to a market-leading 8-contact multi-lumen lead.

METHODS

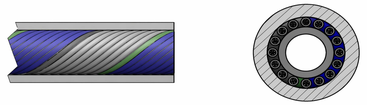
The test conditions were designed to accelerate and induce cable fractures beyond those expected in clinical use to demonstrate the lead body's integrity under high stress. The assessment involved flexing the lead body ±90°, with a bend radius measured from the Click Anchor, to accelerate failure. A monofilament was connected to an extension spring, which was sutured to a weight sufficient to conform to the bend radius. There were 22 samples for each lead type. Testing was stopped at the first contact failure on each sample, and MTTF (Mean Time to Failure) was censored at 2 million cycles if the test samples survived.

RESULTS

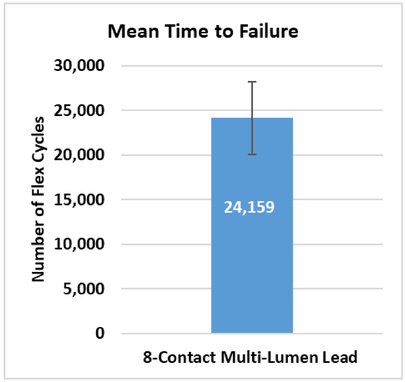
Market-Leading 8-Contact Multi-Lumen Lead Cross-Section

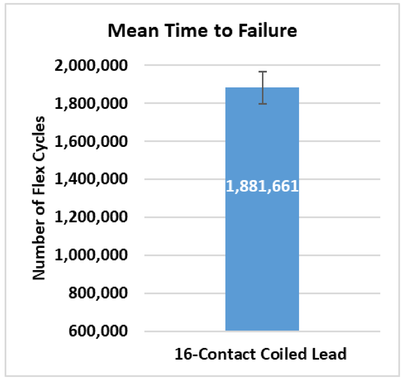


Infinion Pro 16-Contact Coiled Lead Cross-Section



Lead body construction schematics highlighting the design differences that contribute to each lead's durability.





The Infinion Pro 16-contact coiled lead had an MTTF of 1,881,661 ± 85,324, which was significantly greater than the MTTF of the market-leading 8-contact multi-lumen lead at 24,159 ± 4,060.

CONCLUSIONS

The new Infinion Pro 16–contact coiled lead design demonstrated its durability by significantly outlasting the market-leading 8-contact multi-lumen lead in this accelerated high-cycle flex testing.

- MTTF for Infinion PRO Lead: 1,881,661 cycles
- 18 of the 22 Infinion Pro leads did not suffer a fracture and survived the 2 million cycles tested.

REFERENCES

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DISCLOSURES

Study sponsored by Boston Scientific. David Kao and Karan Verma are employees of Boston Scientific.

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