Medtronic

Fatigue Test Method to Evaluate the 50-Year Durability of Venous Stents

Clinical Paper Review
Prepared by PVH Scientific Communications *for Health Care Professionals*

Authors Vogel J, Cheng C, Murphy E, Black S, Desai K
Citation *Eur J Vasc Endovasc Surg.* 2024;68(4):521-528. doi: 10.1016/j.ejvs.2024.06.024.

Purpose

To describe an in vitro 50-year stent fatigue test method designed to assess durability against dynamic stress-induced stent fracture for venous stents (Abre™ venous self-expanding stent system).

Methods

Study Design

The fatigue test method was developed in four stages: a literature review to determine the frequency and amplitude of hip flexion activities, cadaver study to quantify stent deformation, a determination of test parameters to replicate stent deformations and reliably produce stent fractures in off-label stents, and fatigue testing of stents designed for iliofemoral venous use.

Literature Review Methodology

A review of published research was conducted to determine hip motion frequencies and ranges of hip motion for walking, stair climbing, and sit-to-stand activities. This involved screening 3,430 reports and selecting 88 eligible sources, with five deemed most appropriate for inclusion.

Cadaver Study Methodology

Cadaver studies were conducted to quantify stent deformation using donated human tissue. One Abre venous self-expanding stent system (14 mm x 100 mm) and one modified Abre (14 mm x 200 mm) open cell venous nitinol stents were deployed with 2-3 cm overlap in each of the left legs of four cadavers (two men and two women). The stents were deployed extending caudally from the iliocaval confluence to the confluence of the femoral and deep femoral veins and infused with warmed saline to ensure full deployment of the nitinol stents.

Cadavers were imaged with computed tomography at various hip flexion angles to analyze stent and vessel geometries. Stent deformations were assessed at flexion angles corresponding to walking, stair climbing, and sit-to-stand activities.

Medtronic

Methods (continued)

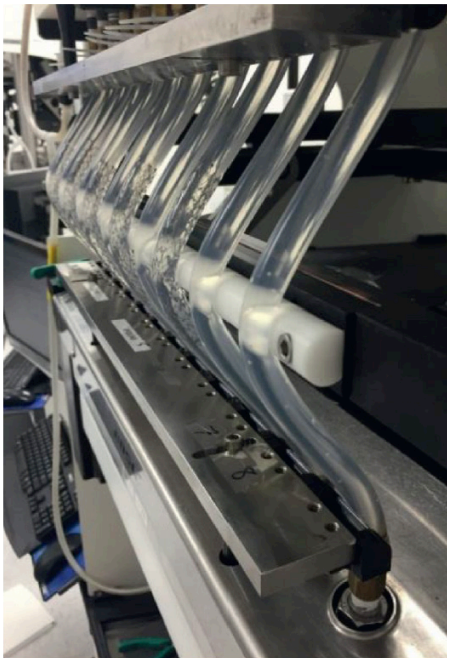
Test Parameter Methodology

Test parameters were determined by photographing a nitinol stent in multi-axis peripheral stent (MAPS) fatigue test equipment to measure curvature amplitude. The test configuration that best matched the curvature amplitude from the worst-case cadaver bending conditions (0˚ to 90˚ hip flexion) was chosen.

For the final validation step, the fatigue test method was applied to 40 self-expanding nitinol off-label 14 mm x 60 mm and 14 mm x 80 mm stents for 100,000 simulated hip flexion cycles.

Fifty-Year Fatigue Testing Methodology

A calibrated MAPS tester was used for fatigue testing 20 Abre stents of 14 mm x 150 mm, simulating 50 years of hip flexion cycles (Fig. 1).



Stents were deployed into custom extruded silicone tubing of 2 mm inner diameter less than the stent nominal diameter. The tubing was filled with phosphate-buffered saline and was set to circulate at 768 mL/min at 41˚C, yielding 37 ± 2˚ C within the tubing. The duty cycles were run at 2 Hz until 50 years of equivalent life with periodic monitoring for fractures and tears in the silicone tubing caused by wear.

Upon completion of the test, the stents were carefully removed from the test tubing, examined under a microscope, and any observed fractures were classified according to the stent fracture characterization scheme.

Fig. 1. MAPS testing equipment setup to simulate bending caused by hip flexion

Results

Literature Review Outcomes

The literature review results are summarized in the table below:

Activity	Change in hip angle (◦)	Max/min flexion	Annual frequency
Walking	43.2 ± 6.9	+31.2 / -12.0	N/A
Stair climbing	71.5 ± 6.0	+74.6 / +3.2	45,990 ± 34,675
Sit-to-stand	99.3 ± 9.2	+96.5 / -2.8	21,915 ± 8,036

Data are presented as mean ± standard deviation. N/A = not applicable.

Results (continued)

Cadaver Study Outcomes

- Vein greatly curved in standing position; vein straightens as hip transitions to sitting angle.
- The location of greatest curvature change during hip flexion was found to be in the vicinity of the inguinal ligament.
- Since curvature change amplitude during walking was too small to be measured, walking cycles should not be included in the total loading cycles for fatigue testing related to hip flexion.
- The sit-to-stand bending test was demonstrated to be the most challenging compared to measured twisting and axial compression and, therefore, the most important loading condition for durability testing of the venous stent.
- One of the female cadavers produced the highest hip flexion curvature amplitudes and provided the greatest challenge to stent durability; therefore, it was selected from the group for all subsequent analyses.

Test Parameter Outcomes

- For the 14 mm stents, a 9.5 mm radius bend bar and a 71.5° bend angle best matched the cadaver curvature in the bench method.
- Among the 40 off-label nitinol stents tested, fractures were observed in 14 (35%), suggesting the test is more challenging than the average venous stent-bearing patient.

Fatigue Testing Outcomes

Results from the fatigue testing are summarized in the table below:

Stent type	Stent fracture rate	Test duration
Abre stent	15% (3/20)	50 years
Non-venous	35% (14/40)	1.4 years

- Two Abre stents suffered a single strut fracture and one stent suffered two strut fractures.

Discussion

- Venous stent placement will likely continue to increase as the clinical benefits are increasingly well documented. With the increase in procedure volume, number of stents placed, and given the young ages of many of these patients, improved standards for long-term durability testing of these stents are required to ensure long-term risk to patients is reduced.
- The study found that the challenge parameters for hip flexion reliably caused fractures in non-venous nitinol stents, with 15% of dedicated venous stents experiencing fractures at 50 years compared to 35% of non-venous stents tested at 1.4 years.
- This study presents a paradigm for testing venous stents indicating that 50-year durability is an attainable goal based on these results.

Medtronic

Discussion (continued)

- The study acknowledges limitations such as small cadaver sample size and lack of data on the incorporation of the stent into the vein wall, advocating for further research to improve long-term stent durability. Another minor limitation of the cadaver study was that it did not explore what happens to the stent during hip extension, which is present in walking.

Authors' Conclusion

This study presented a fatigue test method for evaluating the durability of stents intended for venous use. Dedicated venous stents demonstrated superior fatigue resistance to non-venous stents via in vitro hip flexion testing.

Funding Source

Medtronic

Abre™ venous self-expanding stent system
Brief Statement

Intended Use/Indications: The Abre™ venous self-expanding stent system (Abre™ stent system) is indicated for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.

Contraindications: Do not use the Abre™ stent system with patients with known hypersensitivity to nickel titanium (nitinol), with patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system, and with patients in whom anticoagulant or antiplatelet therapy is contraindicated.

Potential Adverse Effects of the Device on Health: The potential adverse effects (e.g., complications) associated with the use of the Abre™ stent system include, but are not limited to, access failure, access site infection, allergic reaction to contrast medium or procedure medications; aneurysm; AV fistula; bleeding; bruising; death; device breakage; device maldeployment; edema; embolization; fever; hematoma; hypertension; hypotension, nausea, or other vasovagal response; infection; myocardial infarction, arrhythmia, or other cardiovascular insufficiency; open surgical repair; pain; pseudoaneurysm; renal insufficiency or renal failure (new or worsening); respiratory distress or pulmonary embolism; sepsis; stent fracture; stent malapposition; stent malposition; stent migration; stroke, paradoxical embolism, transient ischemic attack, or intracerebral hemorrhage; tissue necrosis; venous occlusion, restenosis, or thrombosis, within or outside of stented segment; and vessel damage, including intimal injury, dissection, perforation, or rupture.

Warnings, precautions, and instructions for use can be found in the product labeling at http://manuals.medtronic.com.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.