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# Wire-Interwoven Nitinol

A new class of stents may expand treatment options for patients with peripheral arterial disease.

**BY CRAIG M. WALKER, MD**

Peripheral arterial disease affects more than 12 million people in the US. The superficial femoral artery (SFA) is commonly involved in this disease process, and stenosis or occlusion of the SFA is a common cause of claudication and is often part of critical limb ischemia. Interventional therapy of SFA disease using laser-cut nitinol tube stents is increasing as several reports show improved patency when compared with balloon angioplasty alone.[1-3] However, the SFA poses particular problems for stent placement because it elongates and foreshortens with movement, can be externally compressed, is subject to flexion, and often is affected with profound dystrophic calcification.

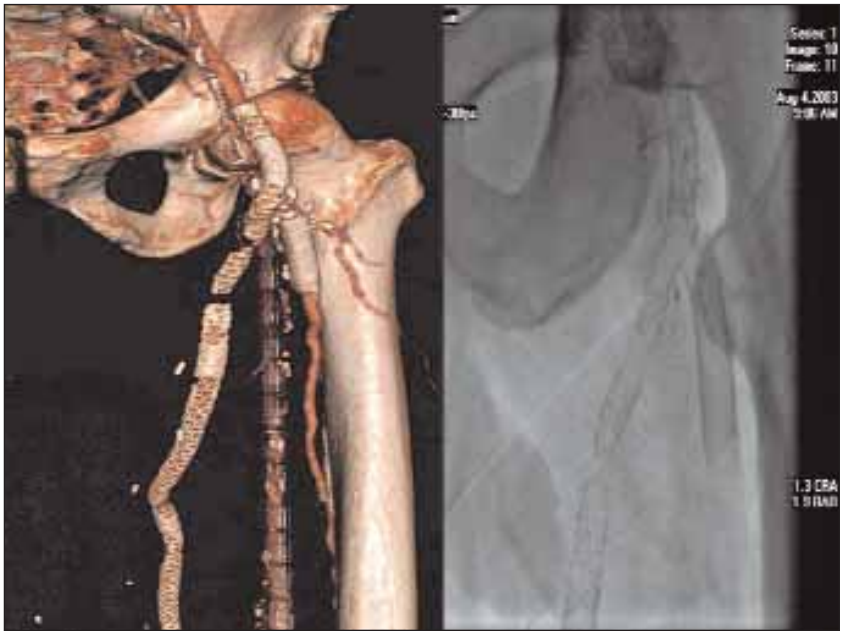

**Figure 1. Fractured laser-cut nitinol tube stent in the SFA.**

Limitations of present stent technology include insufficient radial force to withstand elastic recoil and external compression (in some cases), stent kinking, and stent fracture (Figure 1). Several generations of laser-cut nitinol tube stent technology are available, with newer generations showing improved flexibility and more fracture resistance, albeit with some decrease in radial force.[4]

A new class of stents made of wire-interwoven nitinol (WIN) has now been developed by IDev Technologies, Inc. (Houston, TX) and may address some of these issues. Bench testing of the WIN stents is showing increased radial force, increased flexibility, and *ex vivo* fracture resistance. Results from a series of three cyclical fatigue tests comparing the SUPERA™ wire-interwoven nitinol stent with several other commercially available laser-cut nitinol tube stent technologies show that the SUPERA self-expanding stent is likely to have superior radial force, flexibility, and durability.

## TESTING THE FATIGUE LIFE OF STENTS

A series of three fatigue tests was designed to compare the structural integrity and long-term durability of the new SUPERA WIN stent with several of the second-generation laser-cut nitinol tube stents. The fatigue failure modes were decoupled and isolated to assess the affect of each mode on stent performance. The tests were designed to simulate 10 years of use (approximately 1 million cycles/y) under forces associated with the peripheral vasculature: torsional fatigue, bending/extension fatigue, and compression fatigue. Four laser-cut nitinol tube stent designs currently commercially available were tested with the SUPERA wire-interwoven nitinol stent.

**Figure 2. Torsion fatigue test at 0° rotation of the 6-mm X 80-mm SUPERA™.**

**Figure 3. Torsion fatigue test at 45° rotation of the 6-mm X 80-mm SUPERA™.**

The laser-cut nitinol tube stents evaluated represent the most current stent technologies available.

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During each of the three fatigue tests, six SUPERA wire-interwoven nitinol stents were compared to two laser-cut nitinol tube stent products per brand of similar size and shape under the same test conditions. When an exact size could not be matched, the commercially available size that most closely matched the tested size of the SUPERA stent was used. All of the stents were visually inspected twice daily for possible failure during fatigue cycling. Testing continued and was stopped at daily inspection points until the stents either failed or had been subjected to at least 10 million cycles during each of the three tests. All tests were conducted at an independent testing lab.

**Torsion Fatigue Test**

The torsion fatigue test applied a uniform angular displacement to 6-mm X 80-mm stents subjected to 45° of angular displacement. Initially, all stents were mounted without angular displacement, noted as 0° (Figure 2). Angular displacement was then applied to the lower end of the stent by turning the lower fixation point 45° while the upper end of the stent remained stationary (Figure 3). All five brands of stents survived the initial 10 million cycles. As a result, a more aggressive torsion fatigue test using the same test samples was initiated whereby the angle of displacement was changed from 0° to 45° to an angle of -90° to 90°. As shown in Table 1, only Product A-1 failed shortly after the 90° angular displacement was initiated (approximately 300,000 cycles). The remaining stents survived an additional 10 million cycles, thereby successfully completing 20.3 million cycles, at which time the test was stopped.

**Flexion/Extension Fatigue Test**

The flexion/extension fatigue test simulated the anatomical geometry and displacement associated with the knee. Stents were mounted on the bending test fixture so that each stent was loaded with an initial 25-g tensile load when straight (0° of deflection) (Figure 4), and then each stent was bent to a 120° angle (Figure 5). As the fixture rotated, the tension was relieved, and the stent was allowed to bend freely at a radius that most naturally fit the particular stent design. The test was designed to induce large bending forces near the center of the stents without subjecting the ends of the stents to the bending forces. The tension that was applied to the stent was distributed along the entire length of the stent. Figure 5 shows that the laser-cut nitinol tube stents that were evaluated buckled when bent to a 120° deflection. As shown in Figure 6, no laser-cut nitinol tube stents remained unfractured at 100,000 cycles in the test. All

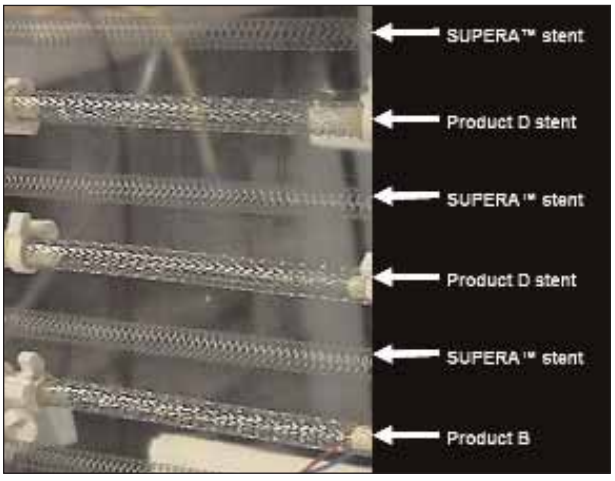


**Figure 4. Flexion/extension fatigue test at 0º flexion with tension.**

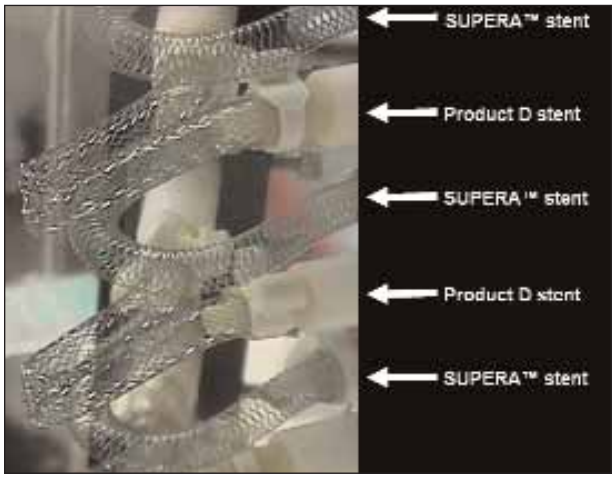


**Figure 5. Flexion/extension fatigue test at 120º flexion.**

laser-cut nitinol tube stents failed by an evaluation point 21,087 cycles, with the exception of one Product B stent, which subsequently failed by the 92,415-cycle-count evaluation point (Table 1). The SUPERA wire-interwoven nitinol stents, on the other hand, were unaffected at the completion of 10 million cycles.

### Compression Fatigue Test

The compression fatigue test comprised two different test conditions used to determine the radial strength of the stents at their center. Similar to the flexion/extension fatigue test, the length of the tested stents was not expected to affect the results of this test provided the stents eval-

**TABLE 1. SUMMARY OF FATIGUE TEST RESULTS**

| Test Method | Quantity Tested | Stent (mm) | Final Cycle Count* |
|---|---|---|---|
| Torsion | 6 | SUPERA (6 X 80) | 20.3 M - Passed |
| | 2 | Product A-1 (6 X 80) | 10.3 M - Failed |
| | 2 | Product B (6 X 80) | 20.3 M - Passed |
| | 2 | Product C (6 X 80) | 20.3 M - Passed |
| | 2 | Product D (6 X 80) | 20.3 M - Passed |
| Flexion/Extension | 6 | SUPERA (6 X 90) | 10 M - Passed |
| | 2 | Product A (6 X 100) | 21,087 - Failed |
| | 2 | Product B (6 X 80) (1 and 2) | 1 – 21,087 - Failed<br>2 – 92,415 - Failed |
| | 2 | Product C (6 X 80) | 1,738 - Failed |
| | 2 | Product D (6 X 80) | 21,087 - Failed |
| Compression at 4 lbs | 6 | SUPERA (6 X 90) | 10 M - Passed |
| | 2 | Product A (6 X 100) | 1 M - Failed |
| | 2 | Product B (6 X 80) | 1 M - Failed |
| | 2 | Product C (6 X 80) | 1 M - Failed |
| | 2 | Product D (6 X 80) | 1 M - Failed |

**Final cycle count refers to the cycle number at which an observation was performed. Therefore, the number of cycles reported for failed stents were less than or equal to the cycle count shown.*

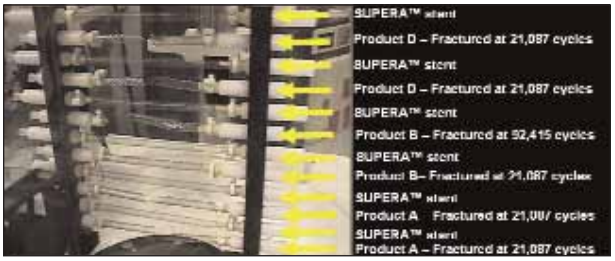


**Figure 6. Flexion/extension fatigue test at 21,087 flexion/tension cycles.**


**Figure 7. Compression test setup.**

uated were longer than the compression mandrel. The compression test fixture is shown in Figure 7. Before testing began, all of the stents were first subjected to a common force, measured in pounds, and measured for displacement. This first test better characterized the compressive stress/strain curves for each of the devices tested. As shown in Figure 8, approximately 4 lbs of compressive force were

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required to produce a .2-inch displacement for the laser-cut nitinol tube stents, whereas the same 4 lbs of loading resulted in only a .03-inch displacement for the SUPERA wire-interwoven nitinol stent. Similarly, at a compression of .2 inches (5 mm), the SUPERA wire-interwoven nitinol stent had 360% greater radial strength (>18 lbs) than all of the other laser-cut nitinol tube stents tested. From these data, a common force (4 lbs) was translated into displacements for both the laser-cut nitinol tube stents and the SUPERA wire-interwoven nitinol stents. After determining this common

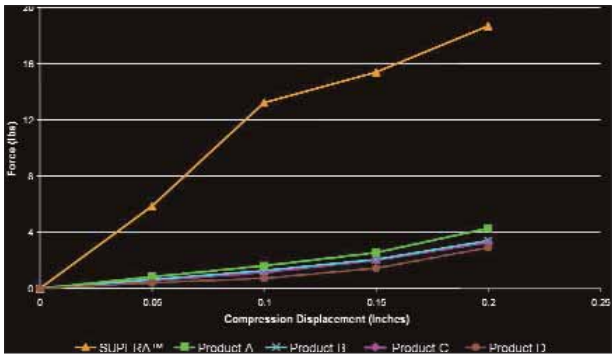


**Figure 8. Baseline crush compression test outcomes.**

force, all stents were then subjected to a fixed displacement to simulate an approximate 4 lbs of external/compressive force. Although all laser-cut nitinol tube stents failed by 1 million cycles, the SUPERA wire-interwoven nitinol stents completed the full 10 million cycles without failure.

## CONCLUSION

The complexity of motion and the variable forces experienced by stents placed in SFA or femoropopliteal arteries have limited the ability to treat many common vascular conditions effectively with stents. The SUPERA wire-interwoven nitinol stent is a new generation of self-expanding (WIN) design stents that may fill a need for patients with SFA disease, as bench testing has demonstrated improved flexibility, radial force, and fracture resistance. Additional tests of the SUPERA stent in the clinical setting are needed to determine if these bench tests will correspond with improved clinical outcomes. ■

*Craig M. Walker, MD, is Medical Director and Founder, Cardiovascular Institute of the South in Houma, Louisiana. He has disclosed that he is a stockholder in Cardiva, CV Therapeutics, IDev, and Spectranetics; a consultant to Boston Scientific, Cardiva, CV Therapeutics, ev3, FlowMedica, IDev, Possis, and Spectranetics; serves on the speaker's bureau for Abbott, AstraZeneca, Boston Scientific, Cardiva, Cordis, CV Therapeutics, FlowMedica, Possis, Spectranetics, and Toshiba; and is on the medical/scientific advisory board for Cardiva, Edwards Lifesciences, FlowMedica, Philips, Spectranetics, and The Medicine Company. Dr. Walker may be reached at (800) 445-9676; craig.walker@cardio.com.*

1. Schillinger M, Sabeti S, Dick P, et al. Sustained benefit at 2 years of primary femoropopliteal stenting compared with balloon angioplasty with optional stenting. Circulation. 2007;115:2745-2749.
2. Schillinger M, Sabeti S, Loewe C, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. N Engl J Med. 2006;354:1879-1888.
3. Cho L, Roffi M, Mukherjee D, et al. Superficial femoral artery occlusion: nitinol stents achieve flow and reduce the need for medications better than balloon angioplasty alone. J Invas Cardiol. 2003;15:198-200.
4. Schlager O, Dick P, Sabeti S, et al. Long-segment SFA stenting—the dark sides: in-stent restenosis, clinical deterioration, and stent fractures. J Endovasc Ther. 2005;12:676-684.