Critical Design Elements of Self-Expanding Stents

The Cordis S.M.A.R.T.® Vascular Stent System is designed to provide longitudinal stability, scaffolding, and resistance to radial force.

BY CAROLYN RICE, MEM

The Cordis S.M.A.R.T.® Vascular Stent optimizes performance and outcomes through its unique design. In general, a self-expanding stent's performance is determined by its geometrical pattern, in conjunction with stent material properties. The S.M.A.R.T.® Vascular Stent, made of electropolished Nitinol, has a geometry that features 36 struts for each circumferential ring, with six alternating bridges connecting each ring to the next (Figure 1). This unique 36-strut, six-bridge design maximizes the stent's longitudinal stability, scaffolding, and resistance to radial force.

Stent longitudinal stability refers to the ability of the stent to resist stretching during deployment. Stent elongation occurs when the stent geometry distorts and stretches as the outer sheath of the delivery system is retracted. A stent with low longitudinal stability selected to match the length of a lesion may end up stretching past that lesion and providing less structural support than intended. This, in turn, will adversely impact stent performance associated with radial force.

Longitudinal stability was measured for various stent platforms by performing a tensile test along the stent axis, and measuring the force required to stretch the stent by 50% (Figure 2). A low tensile force corresponds with low longitudinal stability and vice versa. Stents with decreased longitudinal stability are more prone to deployment problems, reduced scaffolding, and decreased radial force (Figures 3–10).

The test results indicate that longitudinal stability of the S.M.A.R.T.® Vascular Stent far exceeds other stent platforms (Figure 11). In fact, it demonstrates up to 934% greater longitudinal stability than other stents, as reflected in the chart.

As discussed, stent elongation due to lack of longitudinal stability leads to a reduction in mechanical scaffolding and radial force. One stent manufacturer has demonstrated a correlation between the degree of stent elongation and primary patency. As Figure 12 demonstrates, a decrease in patency was observed when stents were deployed elongated. In a secondary analysis, the manufacturer found a greater amount of elongation correlated to a significant reduction in patency at 12 months. At 12 months, minimal to moderate elongation (11% to 40%) was shown to reduce

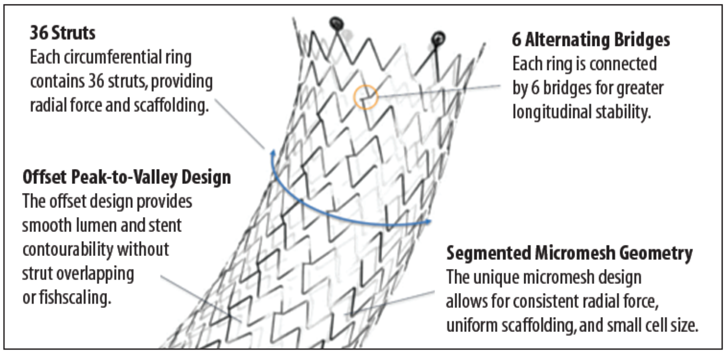

Figure 1. Key features of the S.M.A.R.T.® Vascular Stent design.

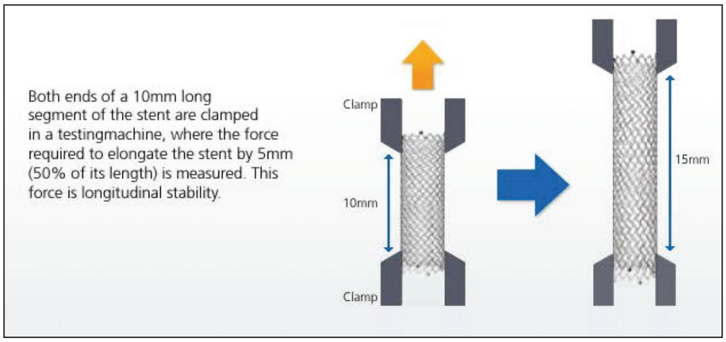

Figure 2. Test for stent longitudinal stability (Longitudinal Stability Test Method, data on file, Cordis Corporation 2013).[1]

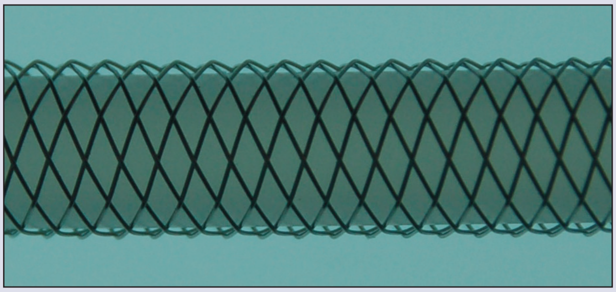

Figure 3. Woven wire stent design, nominal deployment.

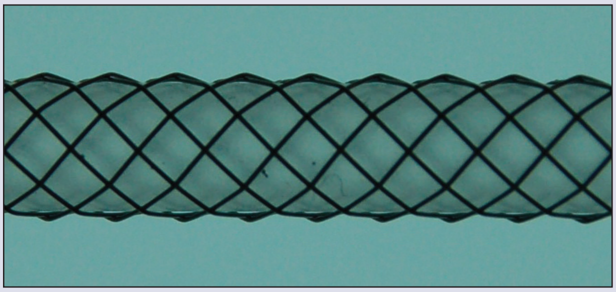

Figure 4. Woven wire stent design, 1 N of force.

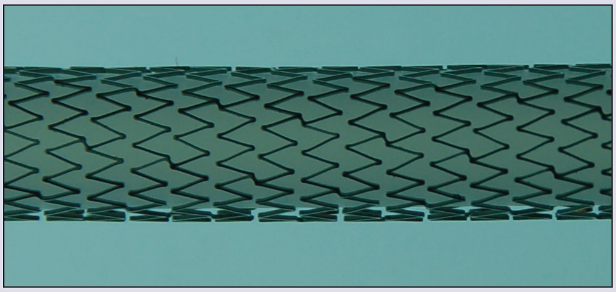

Figure 5. Stent design with fewer connecting bridges, nominal deployment.

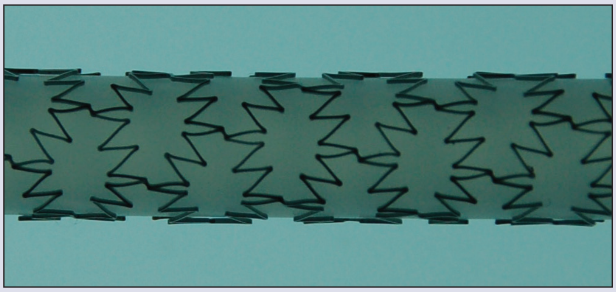

Figure 6. Stent design with fewer connecting bridges, 1 N of force.

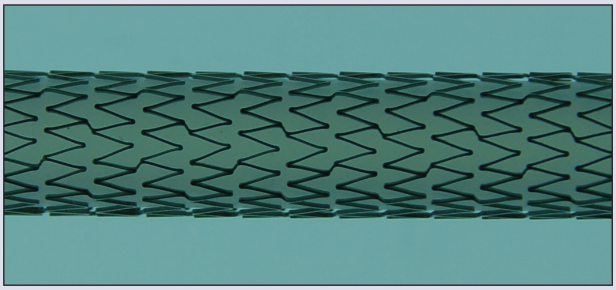

Figure 7. Cordis S.M.A.R.T.® Stent, nominal deployment.

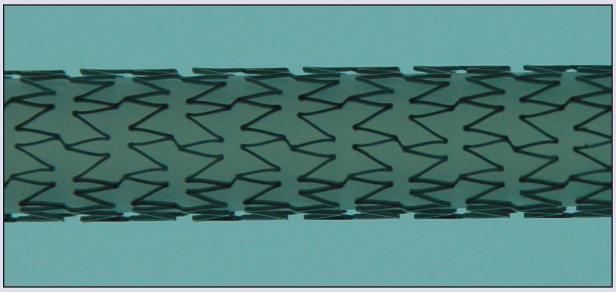

Figure 8. Cordis S.M.A.R.T.® Stent, 1 N of force.

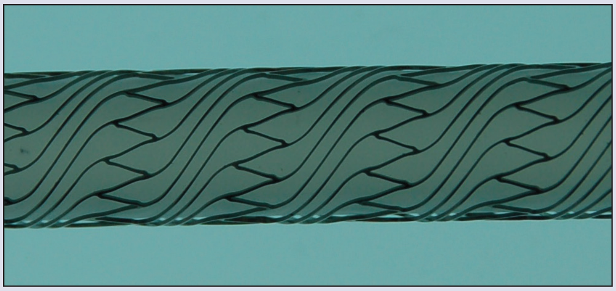

Figure 9. Cordis S.M.A.R.T.® Flex Stent, nominal deployment.

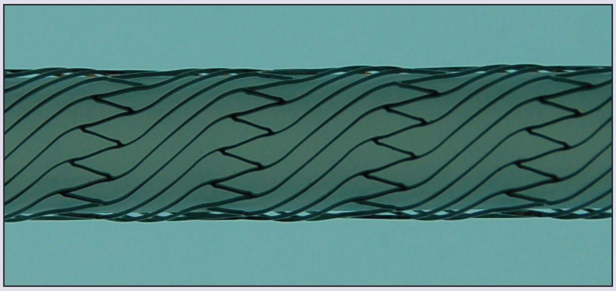

Figure 10. Cordis S.M.A.R.T.® Flex Stent, 1 N of force.

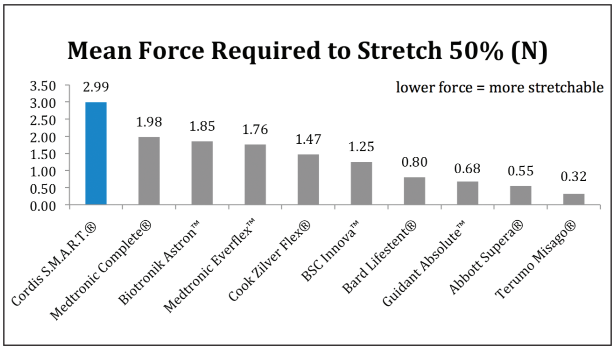

Figure 11. Longitudinal stability of the S.M.A.R.T.® Vascular Stent (S.M.A.R.T. and S.M.A.R.T. Flex Competitive Testing Analysis, data on file, Cordis Corporation 2015).[2]

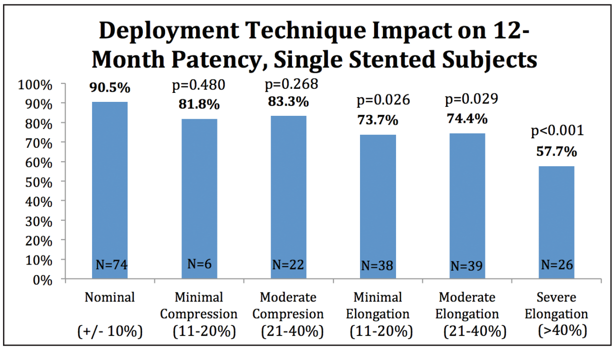

Figure 12. The relationship of stent elongation to primary vessel patency at 12 months (ITT, Single Stented Subjects).[3]

primary patency by 19%. Severe elongation (> 41%) was shown to reduce primary patency by 36%. For this particular stent design, internal bench testing demonstrated an 18% decrease in crush resistance when the stent elongates by 25% and a 31% decrease in crush resistance when elongated by 50%.[3]

Additionally, stent elongation upon deployment has been linked to stent integrity and the occurrence of fractures by another stent manufacturer's investigational device exemption study.[2] Six out of 12 fractures were classified as type IV (complete transverse fracture) at the 18-month analysis. It was observed that in those patients where type IV fractures occurred, all six were elongated at deployment. Nearly 40% of patients with > 10% elongation went on to develop type IV fractures within 1 year.[4]

The S.M.A.R.T.® Vascular Stent offers a unique balance of strut length, number of struts, and bridge connections to maximize longitudinal stability and decrease stretching upon deployment. This results in consistent and predictable scaffolding, as well as resistance to radial force.

The next-generation self-expanding stent platform from Cordis—the S.M.A.R.T.® Flex Self-Expanding Stent System—is currently under clinical investigation in the United States for vascular use. The S.M.A.R.T.® Flex Stent is an evolution of S.M.A.R.T.® Stent technology, building on the performance attributes of the S.M.A.R.T.® Stent design, while adding fully connected helical struts designed to provide longitudinal stability, flexibility, and structural integrity. ■

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1. Longitudinal Stability Test Method, data on file, Cordis Corporation 2013.
2. SMART and SMART Flex Competitive Testing Analysis, data on file, Cordis Corporation 2015.
3. SUPERB Study analysis, Abbott Supera® Peripheral Stent System IFU, PPL00038, March 21, 2014.
4. RESILIENT Study Analysis, Bard Lifestent® Solo™ Vascular Stent System IFU, B05692 Vers.4/09-11.