

MECHANICAL PROPERTIES OF THE GORE® TIGRIS® VASCULAR STENT





The nitinol frame makes it strong.

The fluoropolymers make it flexible.

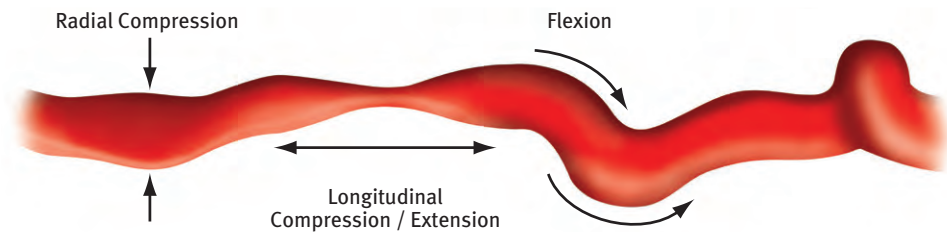
Together, they make it unique.

Purpose

The association of target vessel restenosis with stent fractures has led to an emergence of interest in the mechanical properties of nitinol stents¹. Reduction of these fractures requires an understanding of the biomechanical forces at the implantation site and the mechanical properties of the stent. Published comparisons between self-expanding stents have been sparse²⁻⁵, limiting the physician's ability to select the optimal stent for the intervention. The testing presented in this report is intended to provide a comparison of 6 mm diameter nitinol stents from various manufacturers (see *Table 1*) under relevant conditions: elongation, straightening force, longitudinal compression, radial compression, flexibility (*Figure 1*), and blood loop. The choice of stents was not intended to be comprehensive, but instead representative of commercially available devices. As standards for this testing do not exist, every attempt was made to design fair and relevant tests.

However, different tests are applicable to different applications and results may vary under other test conditions. No claim or evaluation with regard to product appropriateness for any indication is intended or implied.

FIGURE 1. Forces simulated in stent comparison.



Materials and Methods

Devices and Testing Equipment

The devices used in the study are presented in *Table 1*. Prior to testing, the devices were deployed.

TABLE 1.

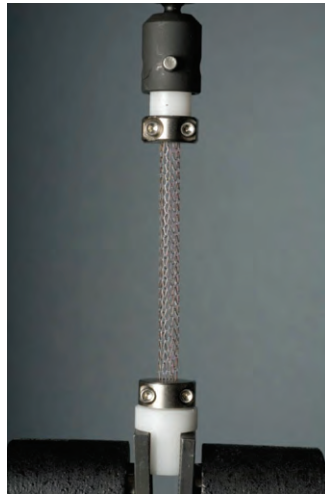
STENT	SIZE
GORE® TIGRIS® Vascular Stent	6 × 80 mm
BARD® LIFESTENT® Vascular Stent	6 × 80 mm
Cordis S.M.A.R.T.® CONTROL® Stent	6 × 80 mm
Covidien PROTEGE® EVERFLEX® Stent	6 × 80 mm
Abbott ABSOLUTE PRO LL Stent	6 × 80 mm
OptiMed SINUS-SUPERFLEX Stent	6 × 80 mm
COOK® ZILVER® PTX® Stent	6 × 80 mm
BARD® LUMINEXX® Stent	6 × 80 mm
IDEV® SUPERA® Stent	6 × 80 mm

Data Analysis

► Elongation

Stent samples were secured in custom longitudinal grips with a known distance between the attachment points and placed in the INSTRON® Tester (*Figure 2*). The top grip was advanced to elongate the stent until a load of 70 grams force was reached. The stent length at the target load was measured for each stent.

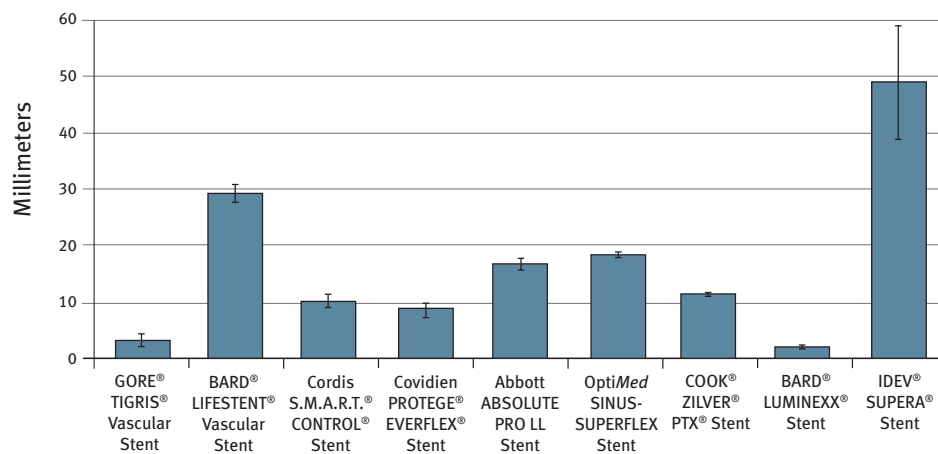
FIGURE 2.



Results

To mimic the potential for stents to elongate during deployment, all stents underwent an extension force of 70 grams and the stent elongation was measured (*Graph 1*).

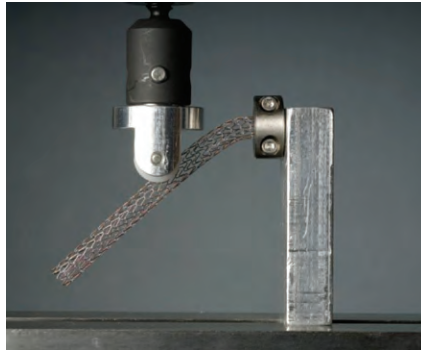
GRAPH 1.



► Straightening Force

Stent samples were secured on one end in a fixture with a load cell fixture set to just touch the stent at a known distance from the secured end (Figure 3). The load cell pushes down 15 mm on the free ends of the stent and the resulting force acting to straighten the stent is measured for each stent.

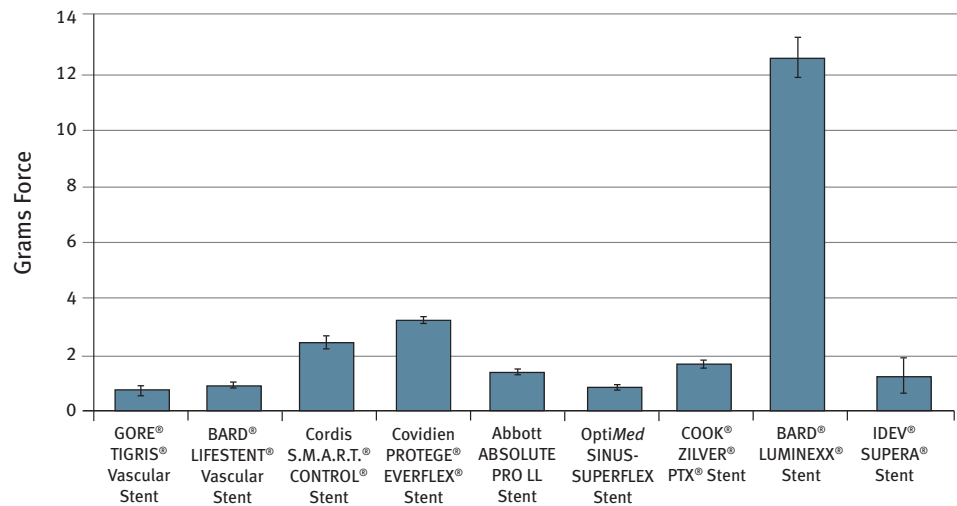
FIGURE 3.



Results

To quantify the tendency of a stent to straighten tortuous anatomy *in vivo*, the free end of all stents were displaced and the resulting straightening force measured (Graph 2).

GRAPH 2.



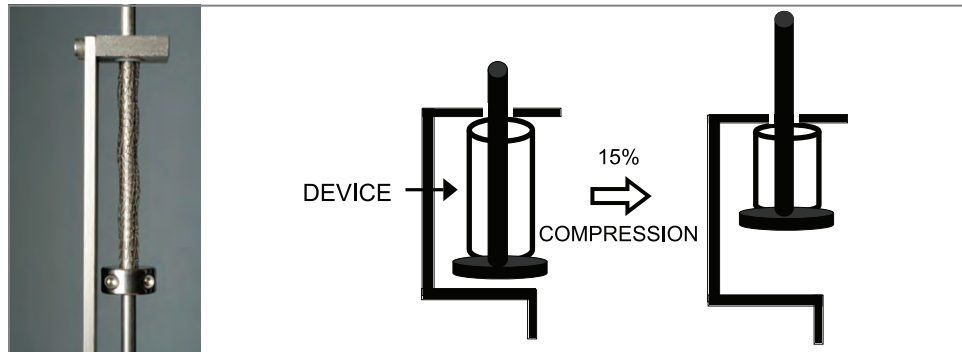
▶ Longitudinal Compression

Stent samples were placed in a custom longitudinal grip and placed in the INSTRON® Tester (*Figure 4*). The grip has a central rod, a flat surface attached to the rod, and an upper flat surface with an opening to allow the rod (but not the stent) to move freely through the surface. The stent is placed on the rod and rests on the bottom flat surface. As the rod is advanced up through the upper flat plate, the stent contacts the upper flat plate and is compressed.

For quantitative analysis, the central rod was advanced until the device had compressed 15% longitudinally (12 mm for 80 mm length stents) between the upper and lower surfaces. The force required to achieve this compression was measured for each stent. Data was normalized to account for differences in resting stent length.

As a qualitative assessment of the performance of these stents under longitudinal compression conditions without axial constraint, a 25% compression level was used. Pins were set such that the stent would be compressed 25% when positioned between them (*Figure 4*). To further challenge the GORE® TIGRIS® Vascular Stent, it was compressed > 25%. A central guidewire was used to keep the stents between the pins.

FIGURE 4. Photo and schematic of longitudinal compression testing fixture.



Results

To mimic potential *in vivo* longitudinal compression forces^{6,7}, all stents were compressed longitudinally by 15% and the corresponding force measured (*Graph 3*).

GRAPH 3. Force (grams-force) required for 15% longitudinal compression.

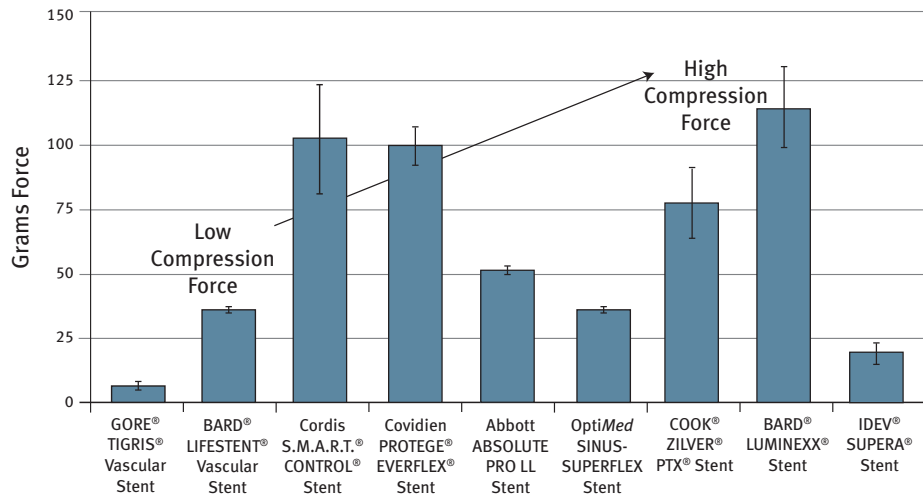
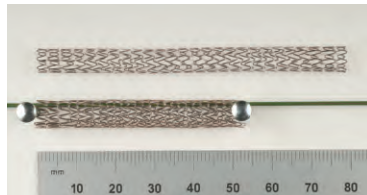
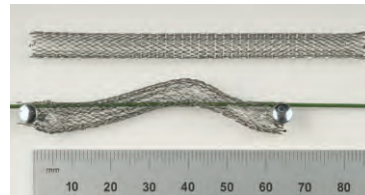


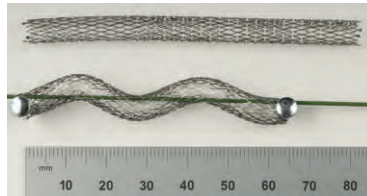
FIGURE 5. Note that the GORE® TIGRIS® Vascular Stent was compressed more than the other stents and was still able to absorb the longitudinal compression without moving out of plane.



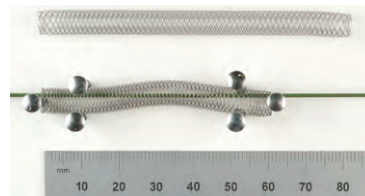
GORE® TIGRIS® Vascular Stent



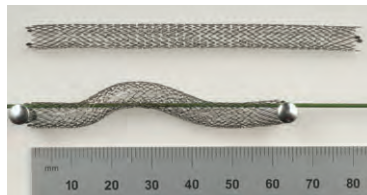
Cordis S.M.A.R.T.® CONTROL® Stent



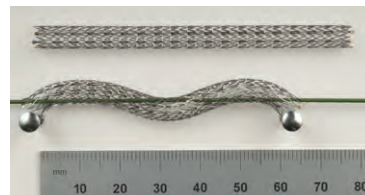
Covidien PROTEGE® EVERFLEX® Stent



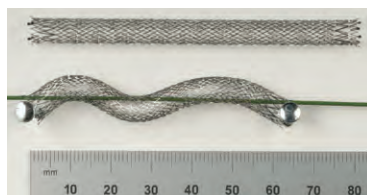
IDEV® SUPERA® Stent



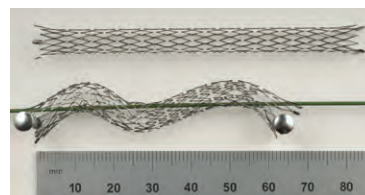
OptiMed SINUS-SUPERFLEX Stent



COOK® ZILVER® PTX Stent



BARD® LIFESTENT® Vascular Stent

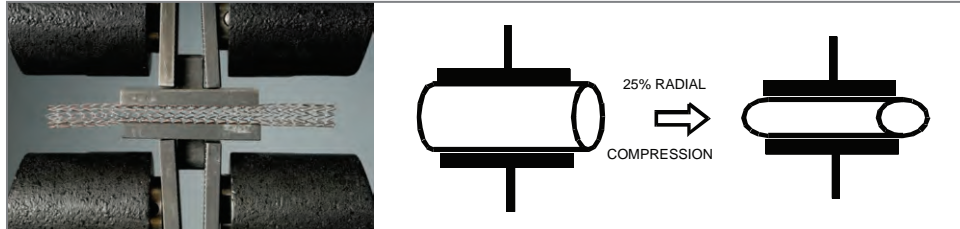


BARD® LUMINEXX® Stent

Radial Compression

Each stent was placed between two flat plates (2" wide) attached to the INSTRON® Tester and the plates were advanced toward each other (Figure 6). The force required to compress the stent radially by 25% (1.5 mm) was measured. Data was normalized to account for differences in resting stent diameter.

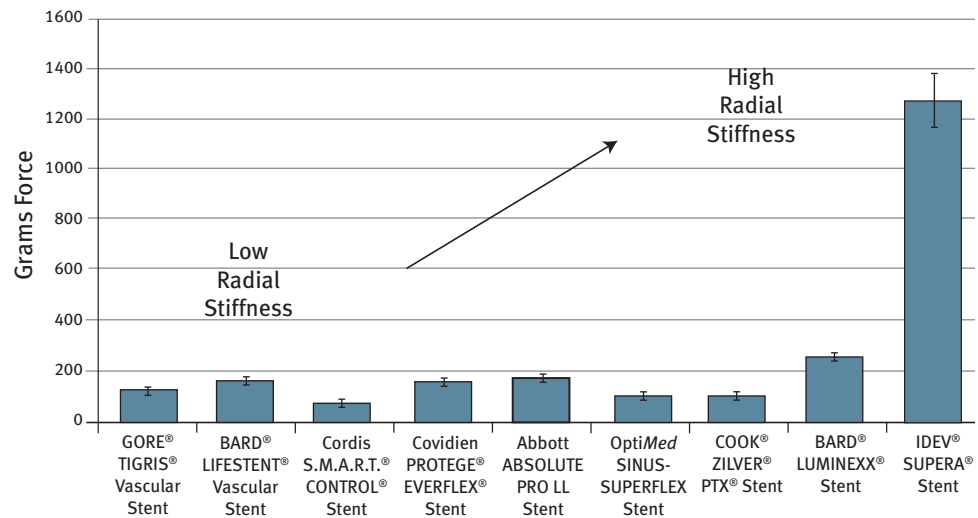
FIGURE 6. Photo and schematic of radial compression testing.



Results

To test radial compressive strength, all stents were placed between two flat plates and the force to compress the devices radially by 25% was measured (Graph 4).

GRAPH 4. Force (grams-force) required for 25% radial compression.



Flexibility

To obtain a visual representation of the stent samples in extreme bending configurations, the stents were bent around pins and photographed (Figure 7 and Figure 8).

FIGURE 7.

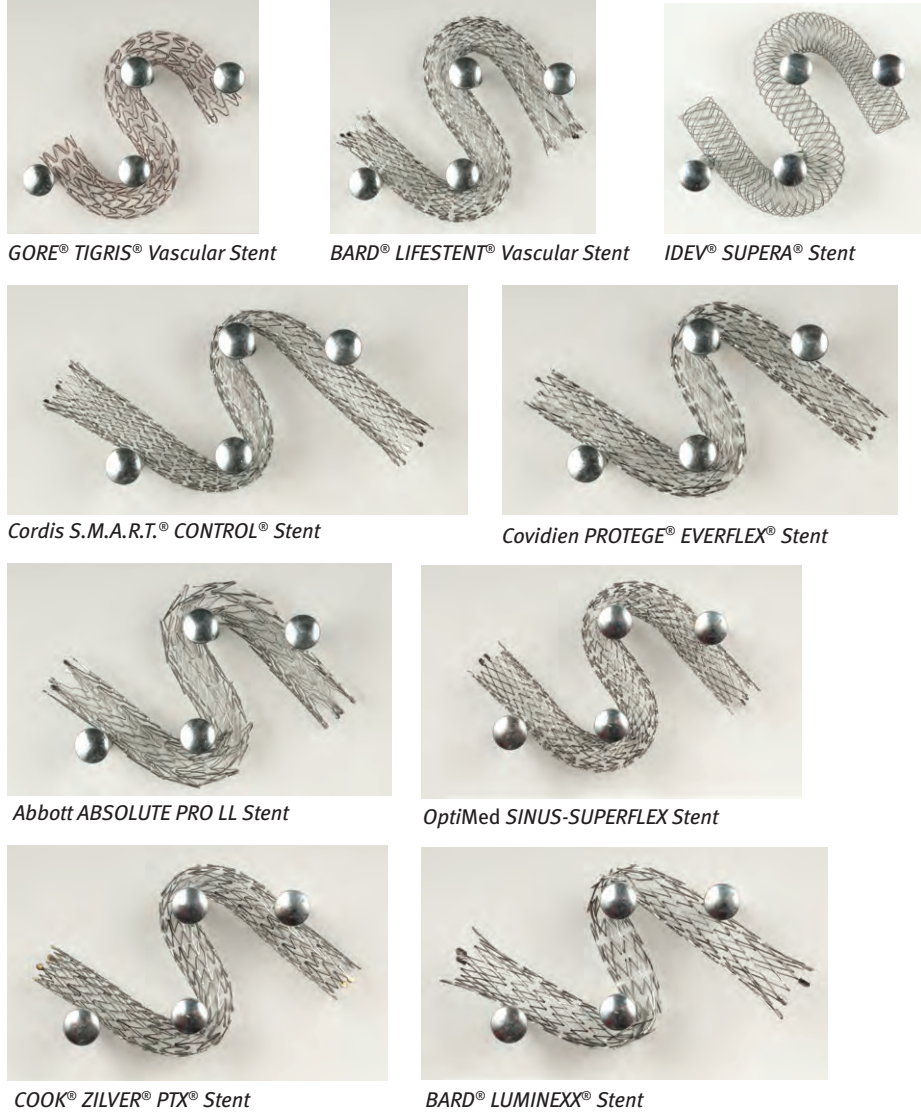
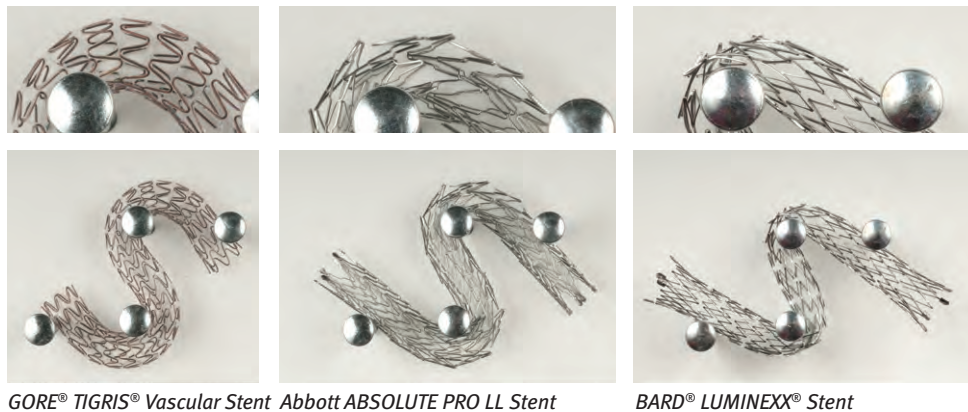


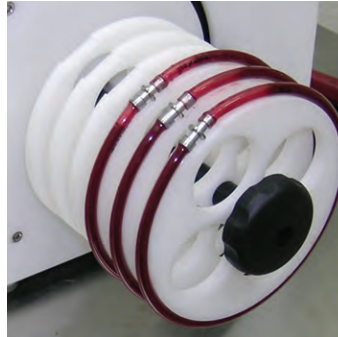
FIGURE 8.



Blood Loop

Stent samples were deployed in 5 mm diameter tubing incorporated into a 33 cm circumference closed loop (Figure 9). Human blood was circulated through the loop at 37°C for two hours. Samples were removed from test loop, gently rinsed and photographed (Figure 10).

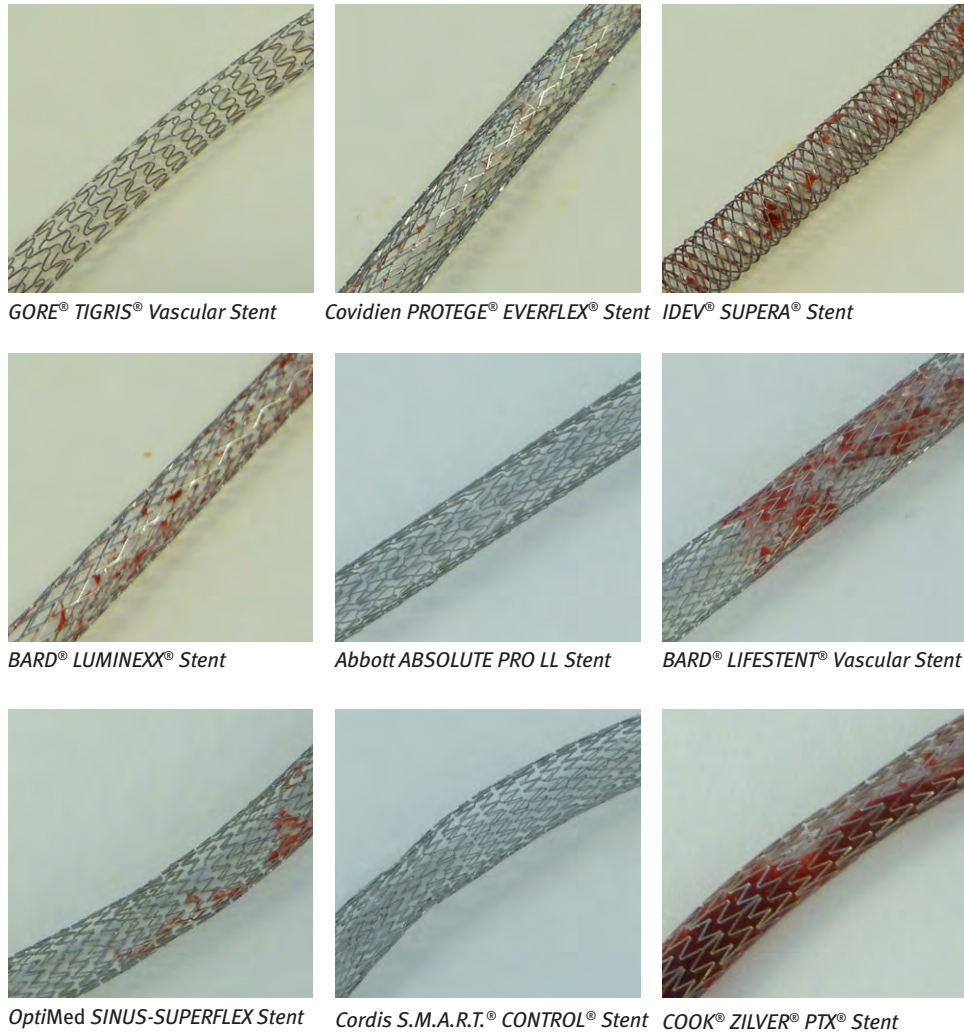
FIGURE 9.



Results

To document the potential for thrombus to form on the stents *in vivo*, stents were exposed to human blood at 37°C for two hours, rinsed and photographed (Figure 10).

FIGURE 10.



References

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Disclaimers

Please consult the *Instructions for Use* supplied with each device for a list of indications, contraindications, warnings, precautions, and adverse events



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