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ORIGINAL ARTICLE

Comparative study of the corrosion behavior of peripheral stents in an accelerated corrosion model: experimental *in vitro* study of 28 metallic vascular endoprostheses

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PURPOSE

Clinical cases of stent-fractures show that corrosion behavior might play a role in these fractures. Implanted *in vivo*, especially in combination with other implanted foreign materials, these metallic products are exposed to special conditions, which can cause a process of corrosion. Here, we aimed to test the corrosion potential of stents made of different materials in an *in vitro* setting.

METHODS

A total of 28 peripheral stents of different materials (nitinol, cobalt-chromium-nickel, tantalum, V4A) and surface treatments (electropolish, mechanical polish, no polish) were tested *in vitro*. Corrosion was accelerated by applying a constant voltage of 3.5 V and amperage of 1.16 mA in 0.9% NaCl.

RESULTS

Nitinol stents showed the lowest susceptibility to corrosion and the longest period without damage. The Memotherm II[®] (BARD Angiomed[®]) was the only stent that showed neither macroscopic nor microscopic damages. The worst performing material was cobalt-chromium-nickel, which showed corrosion damages about ten times earlier compared to nitinol. Considering the reasons for termination of the test, nitinol stents primarily showed length deficits, while V4A and tantalum stents showed fractures. Cobalt-chromium-nickel stents had multiple fractures or a complete lysis in equal proportions. When placed in direct contact, nitinol stents showed best corrosion resistance, regardless of what material they were combined with. In terms of polishing treatments, electropolished stents performed the best, mechanical-polished stents and those without polishing treatment followed.

CONCLUSION

The analysis of corrosion behavior may be useful to select the right stent fulfilling the individual needs of the patient within a large number of different stents.

ongenital stenosis or volume decreasing processes due to accumulation of tissues or by outside pressures are the most common indications for vascular interventional therapies. After the initial "cardiac catheterization" by Forssmann et al. (1) in 1929, percutaneous interventional techniques for treatment of vasoconstricting processes was continued constantly, whereby the use of permanent mechanical stents has gained an increasingly important role.

Stents used in clinical practice should fulfill certain conditions to achieve an unproblematic application as well as an optimal result. The following properties apply to this ideal: good biocompatibility, low shortening, high-density in X-ray, high patency rates, low thrombogenicity, rapid endothelialization without excessive intimal hyperplasia, high flexibility and longitudinal elasticity, sufficient pressure stability at high centrifugal force, technical ability to secure application and exact positioning, and good expansion ratio for safe percutaneous application also with larger prostheses (2, 3). With the approval of stents for clinical use in 1986, the use of stents in peripheral vessels was also practiced on human patients. Palmaz et al. (4) published the first results of the clinical use in 1988 in one of the first multicenter trials on the use of stents in stenosed atherosclerotic iliac arteries. After the successful development of Palmaz[®] stents and Wallstents[®] as prototypes of balloon-expandable and self-expanding stents, a variety of new stents have been developed.

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Published online 10 August 2015 DOI 10.5152/dir.2015.15062 The stents used today are made of different materials. These include nickel titanium alloys (nitinol), surgical stainless steel (V4A), tantalum, and cobalt compounds. Implanted in the human body, especially in combination with other implanted foreign materials, these metallic products are exposed to special conditions causing a process of corrosion. The higher the ionic conductivity of a liquid is, the faster the reaction. For this reason, liquids that contain a high proportion of electrolytes, such as blood with its high proportion of NaCl, cause much faster corrosion of materials (5).

We aimed to perform a comparative study regarding the corrosion behavior of peripheral stents, to reflect the behavior of implanted stents in patients and contribute to find a safer indication in the selection of vascular prostheses. Likewise, we tested the hypothesis that the polishing process influences their corrosion behavior.

Methods

From August 2009 to April 2010, 28 different kind of vascular endoprotheses were tested regarding their corrosion behavior.

In an experimental *in vitro* model, the metallic stents were inserted into a device for corrosion acceleration and continuously exposed to a current of 1.16 A at a voltage of 3.5 V in a parallel circuit. The individual stents were examined at defined time points for corrosion-related damage, such as filament breakdown or loss of length. To carry out the experimental series, two different *in vitro* exper-

Main points

- Cases of clinical stent fractures *in vivo* caused by corrosion showed that corrosion behavior and resistance should play a role in the selection of stents.
- Implanted in the human body, especially in combination with other implanted foreign materials, vascular endoprotheses are exposed to special conditions causing a process of corrosion (galvanic corrosion).
- Testing the influence of polishing treatments on corrosion, electropolished stents performed best, followed by mechanical polished and unpolished stents.
- In terms of stent material, nitinol stents showed the highest resistance against corrosion while CoCrNi stents performed the worst.

imental setups were used. The method of induction and acceleration of corrosion applied in our study was compliant with the current ASTM standards as well as the currently practiced methods of many research groups.

As peripheral stents are made of different materials with specific physical and material properties, they show different types and timings of corrosion. The materials used in the test series are those that currently predominate the market: nitinol (17 of 28 stents), surgical stainless steel/V4A/316L (eight stents), tantalum (one stent), and cobalt-chromium-nickel (three stents).

A total of three experiments were conducted with 28 different stents produced by the leading companies of Europe and USA that are currently used in clinical practice (Table 1). In each experiment, twenty different kinds of stents were tested. To ensure the representativeness of the experiment, 10 models previously tested in experiment 1, were again tested in experiment 2 together with 10 new stent models. In the third experiment, nine of 28 investigated stent models (representative of all four material groups) were tested in individual runs to determine the influence of contact of different or same materials on time and type of corrosion.

Experiments 1 and 2

The examined stents were removed from their original packaging and, with the help of the respective introducer, set into provided positions for each model. For this purpose, each of 20 tested stents was placed on a metal stent bridge, in a way that every stent had full contact with the metal. Balloon-expandable stents were expanded using dilatation catheter, while self-expanding stents were released by pulling back the lock catheter to give their final configuration. Since the individual stents have different lengths, they were arranged in a way that the downward facing part of each vascular endoprosthesis had an identical distance to the bridge. After placement, the stent was mounted on a glass container and filled with physiological NaCl solution. The level of the liquid was identical for each stent and chosen so that there was no contact between the NaCl solution and the metal of the stent-bridge.

The NaCl-filled glass container was placed in a corroder designed especially

for this experiment, an apparatus for accelerating corrosion using electric power. The device contained a transformer producing AC voltage. One end was connected to the stent bridge and the other to two graphite electrodes. This type of experiment ensured that all stents had the same potential and the circuit was closed by the NaCl solution.

The level of the NaCl solution was monitored continuously to ensure that the stents were always surrounded by the same level of solution during the entire experiment. The voltage was monitored continuously by a voltmeter on the display of the corroder for a permanent voltage at 3.5 V. During the experiment, two blinded radiologists examined the stents for corrosion damage by macroscopic and microscopic observation at predefined pointsof-time, and documented the different types of damages (Table 2). The stents were taken out of the experiment when showing predefined irreversible damages. Visual inspection of morphological changes in the stent was performed at the following time points: 15 min, 45 min, 75 min, 100 min, 150 min, 200 min, 260 min, 320 min, 380 min, 440 min, 500 min, 560 min, 620 min, 680 min, 740 min, 800 min, 860 min, 980 min, 1100 min, 1320 min, 1440 min, 1560 min, 1680 min, 1820 min, 2100 min, 2300 min. If there was no sign of corrosion after 2300 min, the experiment was finished and the stent was evaluated as a noncorroded stent.

Experiment 3

In this experiment, the arrangement of the first two experiments was used with the difference that the stents were in contact. This was achieved by placing one of the investigated prostheses in the lumen of the other. We tested following stents: four nitinol stents (Memotherm Prostatic stent[®], sinus Flex[®], Dynalink[®], sinus[®]); one cobalt-chromium-nickel stent (Wallstent[®]); three V4A stents (Jostent[®], Cardiologic Diamond[®], Palmaz[®]); one tantalum stent (Strecker[®]).

Results

There was a big difference between the corrosion behaviors of the products based on different reasons. While the Smart[®] stent showed obvious signs of

Table 1. All 28 stent models tested in this study with technical and corrosion data							
Stent	Company	Material	Polishing treatment	Time to corrosion (min)	Kind of corrosion	Type of expansion	Radiopaque spoons
Chromaxx®	BARD Angiomed	Co-Cr	Mechanical	100	LX	BE	+
Expander®	Bolton Medical	Co-Cr-Ni	-	100	KT2	SE	-
Wallstent®	Boston Scientific	Co-Cr-Ni	Mechanical	85	LX, KT2	SE	-
Lifestent®	BARD Angiomed	Nitinol	Mechanical	1070	L05	SE	+
Memotherm I®	BARD Angiomed	Nitinol	-	650	BX, L02	SE	-
Memotherm II®	BARD Angiomed	Nitinol	Mechanical	2300	-	SE	+
Memotherm Prostatic®	BARD Angiomed	Nitinol	-	100	KTX	SE	-
Epic®	Boston Scientific	Nitinol	Electropolishing	1640	L05	SE	+
Dynalink®	Boston Scientific	Nitinol	Mechanical	560	L05	SE	+
Sentinol®	Boston Scientific	Nitinol	-	200	L05	SE	-
Vascuflex [®]	Braun	Nitinol	Mechanical	1280	L05	SE	+
Za®	Cook	Nitinol	-	45	KT2	SE	-
Resistant®	Eucatech	Nitinol	Mechanical	1640	BX	SE	+
Cordis smart®	Johnson & Johnson	Nitinol	Mechanical	915	KT2, L05	SE	+
Self-X®	Jomed	Nitinol	Mechanical	800	L05	SE	-
Cragg®	Mintech	Nitinol	-	45	KT2	SE	-
Sinus 535®	Optimed	Nitinol	Electropolishing	1870	L05	SE	+
Sinusflex®	Optimed	Nitinol	Mechanical	1250	L05	SE	+
Sinus Repo®	Optimed	Nitinol	Electropolishing	320	L05	SE	+
Strecker®	Boston Scientific	Tantal	-	560	BX	BE	-
Express Vascular®	Boston Scientific	V4A	Mechanical	700	LX, KT2	BE	+
Palmaz large®	Johnson & Johnson	V4A	Mechanical	100	KT2	BE	-
Palmaz XL®	Johnson & Johnson	V4A	Mechanical	260	KT2	BE	-
Corinthian®	Johnson & Johnson	V4A	Mechanical	150	KT2	BE	-
Devon Saxx®	BARD Angiomed	V4A	Mechanical	75	LX, KT2	BE	-
Cardiologic Diameond®	Plasma Chem	V4A	Electropolishing	380	KT2	BE	-
Driver [®]	Medtronic	V4A	-	260	KT2	BE	-
Josent®	Jomed	V4A	Mechanical	150	L05, B01	BE	

Co-Cr, cobalt chromium; LX, complete lysis; BE, balloon expansion; Co-Cr-Ni, Cobalt, chromium, nickel; KT2, stent broken into two pieces; SE, self expansion; L01–05, length reduction of 1–5 mm; BX, break of ≥4 filaments; KTX, stent broken into X pieces; V4A, surgical stainless steel; B01, break of one filament.

corrosion damages after 15 min necessitating termination of the test, the Memotherm II® (BARD Angiomed) made of nitinol had no defects until the predefined end of the experiment after 2300 min. Except for Memotherm II®, all other stents had to be taken out from the experiment before the determined end after 2300 min, mainly due to a loss of length greater than 5 mm.

Considering the results obtained for the nitinol stents, we could observe that only four nitinol stents had to be withdrawn prematurely from the experiment, showing damages defined as irreversible (Cordis Smart[®] after 15 min, Cragg stent and Memotherm prostatic stent after 100 min and the Cook Za[®] after 45 min). Almost all other nitinol stents showed damages due to corrosion, but not in a way that made it necessary to remove them out of the experiment. The only stent with no macroscopic or microscopic traces of corrosion after the whole 2300 min was the Memotherm II[®], followed by the Sinusflex[®] with only microscopic detectable spoon corrosion after 2100 min in the second run. Cobalt-chromium-nickel stents showed signs of corrosion starting at a very early stage. After 75 to 100 min the first damages were visible. These defects were of the kind that required immediate removal of the endoprosthesis from the test series. Termination of the test for stents made of cobalt-chromium-nickel was mainly caused by loss of length or a break into two pieces after about 150 min.

Another large group of the investigated vascular endoprotheses comprised stents made of surgical stainless steel.





Figure 1. Mean times to start of corrosion were: nitinol, 908 min; cobalt-chromium-nickel, 94 min; stainless steel (VA4), 325 min; and tantal, 560 min. The end of the experiment depending on the different stent materials was established as: nitinol, 1880 min; cobalt-chromium-nickel, 190 min; stainless steel, 893 min; and tantal, 2300 min.



Figure 2. Reasons for removing the stents out of the experiments due to damages defined as irreversible. LX, complete lysis; BX, break in >4 filaments; KTX, stent broken into X pieces; SP, structural changes; KS, corrosion of radiopaque spoons.

The Corinthian[®] stent showed the worst result of the V4A stents. It was the first endoprothesis that had to be taken out of the test, because of irreversible corrosion damages after 150 min. Within the stainless steel group the BSI Express Vascular[®] showed the best performance with an overall survival of about 2000 min. Strecker[®] stent, the only stent made of tantal to be tested, showed the first sign of corrosion-related damage after 560 min, as breakdown of one filament, with further damage occurring during the remainder of the experiment. Shortly before the end of the experiment a length deficit of the tantalum stent could be seen.

For better comparability of the individual materials, stents were examined with regard to the time of the first detectable corrosion and the time it took each stent to be removed from the experiment due to corrosion-induced damages (Fig. 1). The nitinol stents remained in good condition the longest until the first corrosion defects appeared (average 908 min). The worst result was observed for stents made of cobalt-chromium-nickel, where initial damages already occurred approximately after 94 min. Tantalum stent showed damages after about 560 min. The earliest defects occurred in surgical stainless steel models (average 325 min). Stents followed a similar order in terms of durability, which was measured as time to corrosion-induced termination of the experiment. The tantalum stent showed the greatest durability, followed by nitinol stents with approximately 1880 min (but including the only stent with no detectable defect - Memotherm II[®]). Stents made of surgical stainless steel had to be removed from the experiment at approximately 893 min, while stents made of cobalt-chromium-nickel were removed very early, at about 190 min.

We analyzed the main reason for corrosion-related termination of the test for different materials (Fig. 2). For nitinol stents (e.g., Sinus Repo[®] in Fig. 3) the main cause for termination was complete lysis (65.2%), followed by stent breaking into several pieces (17.5%), and various fractures in the filaments (8.7%). Only one stent had partial loss of structure or corrosion of the spoons (both 4.3%). The stents made of cobalt-chromium-nickel showed multiple fractures or lysis of the material. Vascular endoprostheses made of V4A were mainly removed from the experiment due to a break into several pieces (e.g., Palmaz[®] stent in Fig. 4). The tantalum stent was removed from the experiment after showing several fractures. In summary, most stents had to be removed from the test either because of a complete lysis or being broken into several pieces.

As it is possible to have a direct stent contact *in vivo*, we examined whether the corrosion of the individual stents is accelerated by contact, which of the two materials corrode first, and what combination of materials is therefore the best. Nitinol stents had the longest survival without cor-



Figure 3. a, b. Macroscopic (a) and microscopic (b) corrosion damages of the Sinus Repo. (Optimed.) after 320 min. Complete lysis of the radiopaque spoons, a thinning of the filaments, and corrosion of all the stent filaments can be observed.



Figure 4. a, b. Microscopic pictures of Palmaz[®] stent after the test (a). The stent had to be removed from the experiment after 620 min, when the stent finally broke into two parts. Microscopic picture of the breaking point (b).

rosion damage, regardless of the material with which they were combined. The presence of a cobalt-chromium-nickel stent appeared to accelerate the corrosion of the other stents regardless of the material they were produced from. For example, when Sinusflex[®] (nitinol) was in contact with the Wallstent[®] (cobalt-chromium-nickel) the first corrosion-related damage appeared on the nitinol stent after 45 min, whereas when two nitinol stents (Prostatic® stent and Sinus® stent) were combined, first signs of corrosion appeared after 860 min. Contact of two stents made of the same material did not accelerate corrosion significantly (e.g., nitinol without contact 908 min vs. 860 min with contact).

As stents with different polishing treatments are offered in order to improve the surface properties, we calculated the mean value of the onset of corrosion-related defects due to their polishing treatment. Our results showed that stents with electropolishing had the longest time without corrosion (1052 min), followed by mechanical polished stents (752 min). Stents without any polishing had a significantly earlier onset of corrosion with a mean time of 243 min (Fig. 5). Among nitinol stents corrosion onset was approximately five times earlier in stents with no polishing treatment compared with polished stents; similarly, surgical stainless steel endoprostheses with no polish showed earlier corrosion defects compared with polished ones. Only on stents made of cobalt-chromium-nickel no significant difference was observed between different polishing treatments.

Discussion

Our results showed that nitinol stents that underwent electropolishing procedures have the highest resistance against corrosion. With regard to corrosion-related stent fractures of in vivo implanted endoprostheses, an in vitro comparison model for studying the corrosion behavior of today's commercially available peripheral stents seems indispensable. Although many research groups investigated the corrosion behavior of different have been no studies that investigated the currently available stents in clinical use regarding their susceptibility for corrosion and directly compare them by

naming time and type of corrosion. Also there are no actual data showing the influence of material contact of different stents or the influence of a combination of different stent materials.

Several research groups used both electric power to accelerate the corrosion process (5–9) and physiological NaCl solution (8, 9, 11) to ensure that the conditions of the human body are imitated in a realistic manner. In a comparison of the corrosion behavior of mechanically and electrically polished nickel-titanium stents physiologic saline solution was used as a medium and voltage was applied for accelerating the corrosion (11). Pound et al. (11) proved that NaCl is a much more realistic medium in comparison with other buffered solutions, which means it clearly simulates the predominating conditions of the human organism better than other available solutions. NaCl 0.9% solution is also named in the ASTM F746 standard as an appropriate electrolyte for metallic surgical implants. Shih et al. (6) tested the cytotoxicity of corrosion products of nitinol stents in smooth muscle cells by corroding the endoprostheses in NaCl under constant voltage. Corrosion was induced by a three-electrode system using a potential that is higher than the predicted "breakdown" potential of nickel-titanium alloy.

The surface treatment of nitinol is the subject of many recent studies where optimization of the corrosion behavior and biocompatibility is sought by elimination of nickel ions. It was detected that surface modification by means of electropolishing improves the durability and resistance against local corrosion of nitinol stents (12, 13). Thierry et al. (12) compared the effect of electropolishing to mechanical polishing on breakdown behavior in Hank's solution. Mechanically polished stents showed corrosion damages at a potential of 0.53 V, whereas electrically polished stents showed corrosion induced damages above a value of 0.99 V (12). In previous studies, Venugopalan et al. (14) showed that nitinol stents have a mean breakdown potential of 0.88 V in Hank's solution. A similar value is specified for physiological NaCl solution. The breakdown potential of mechanically polished nitinol stents varied in different studies. Endo et al. (5) observed that mechanically polished nitinol shows no cor-



Figure 5. a, **b**. First signs of corrosion depending on different polishing treatments (**a**). Mean time until first corrosion-related damages appear is 1052 min in stents with electropolishing treatment, 752 min in mechanical polished stents, and 243 min in stents with no treatment. First corrosion-related damages depending on polishing treatment and stent material are shown in panel (**b**).

rosion damages in 0.9% NaCl solution at 1.2 V. Speck and Fraker (16) showed that mechanically polished nitinol and cobalt were resistant to defects in Hank's solution up to a potential of 1.14 V. Pound et al. (11) also studied the behavior of mechanical and electropolished stents in NaCl solution and compared it with the behavior of vascular endoprotheses in phosphate-buffered solution. Pound et al. (11) showed that using an electropolishing surface treatment a higher breakdown potential was reached. Electropolished nitinol showed corrosion damages at 1 V, whereas mechanically polished stents showed corrosion defects much earlier. The observed higher resistance of electropolished stents to corrosion was explained with a stent surface that is richer of titanium when that kind of polishing treatment is used. Our test results are in accordance with Pound et al. (11) in showing that electropolishing treatments greatly improve the breakdown potential of nitinol stents and their resistance to corrosion. Similarly, Wiskirchen et al. (10) reported that the homogeneous surface of the electropolished nitinol stents results in higher corrosion resistance. Shabalovskaya et al. (17) showed that mechanically polished stents are less susceptible to corrosion compared with stents that undergo no polishing process. Significant differences were found in local corrosion of untreated and polished nickel-titanium stents. Thus, various studies confirm that any type of surface treatment of nitinol stents, improve their resistance to corrosion (18).

It is almost impossible to combine two metals without a transfer of metals taking

place with the result of galvanic corrosion. When the transferred metal is different from the metal to which it has been transferred, this leads to voltage differences, which can induce a corrosion process, apart from the injury of the superficial protective film. Brussatis et al. (19) and Mueller et al. (20) mention the use of mixed metals as one of the most common causes of corrosion in the human body.

Most of the stents showed primarily two patterns of corrosion-induced material failure. In one pattern the integrity and functionality of the endoprosthesis was destroyed by a complete lysis. In the second pattern stents had to be removed from the experiment due to breaking into several pieces or due to several fractures of the wire filaments. For nitinol stents, the end of the experiment in our tests was mainly caused by a complete lysis of the endoprosthesis (65.2%), followed by a stent facture in several parts (17.5%), and various fractures (8.7%). Only one stent had a partial loss of structure or corrosion of the radiopague spoons (both 4.3%). Major et al. (21) studied the mechanism of material failure on stents for endovascular treatment of abdominal aortic aneurysm. They observed that vascular endoprostheses made of nickel titanium showed various fractures in individual wire filaments of the stent and subsequently showed complete stent fractures. The causes and consequences of the corrosion-induced ion loss were the subject of numerous in vitro and in vivo studies, where a steady loss of individual nickel or titanium ions were shown to cause a decrease in the diameter of the wire filaments at first sight, followed by a progressive lysis of the medical implants (22-26). The stents made of cobalt-chromium-nickel were either fractured in multiple parts (50%) or showed a complete lysis (50%). Lam et al. (24) studied the macroscopic and microscopic structure of medical implants made of cobalt-chromium alloys, and showed that in 75% of the studied implants, corrosion caused material defects or irreversible damage in the form of implant fatigue. In our test series endoprostheses made of V4A were mainly removed from the experiment due to multiple fractures. Wang et al. (9) studied coronary stents made of surgical stainless steel with the help of accelerated corrosion tests and determined that the material failure was primarily caused by corrosion-induced filament fractures. Similarly Venugopalan et al. (14) showed that, due to their special geometry, vascular endoprostheses made of nitinol and V4A were susceptible to corrosion on the entire area of the stent and thus resulted in material fractures.

Studying corrosion in simulated and physiological conditions, Virtanen et al. (26) found that implants made of surgical stainless steel should not come into contact with cobalt-based implants because of the relatively poor corrosion resistance of surgical stainless steel in accelerated galvanic corrosion. They also described that the contact between cobalt chromium and titanium surfaces is a material combination extremely susceptible to induction of galvanic corrosion (27). It can be said that a precise choice of stent materials, especially when used in combination with other implanted metallic devices, is a big opportunity to influence the future stent behavior in the sense of reducing the rate of corrosion induction and the extent of resulting damage. Knowledge of already implanted materials is important in the choice of a new stent implantation.

There are some limitations to our study. We had to construct an in vitro model instead of an in vivo model, so our stent corrosion data may not reflect real life conditions. Moreover, it was necessary to accelerate the process of corrosion by using electric power and thus we are not able to indicate a reasonable and appropriate conversion factor to predict in vivo durability of the stents based on the measured time to corrosion. Nevertheless, the use of NaCl solution is an adequate and accepted method to simulate conditions of the human blood in the most realistic way. Further studies should be conducted to investigate the impact of the ion composition of human blood and to study the influence of the presence of other implanted intracorporeal foreign materials on the corrosion behavior of stents. Another topic that requires further study is the cytotoxicity of corrosion products circulating in the blood.

In conclusion, the perfect stent, combining all desired properties such as low thrombogenicity, high elasticity, and a high corrosion resistance, is not available yet. Commercially available stents are so far a compromise on advantages and disadvantages. Several clinical cases of stent fractures caused by in vivo corrosion make clear that stent implantation should be performed only when strictly indicated and that corrosion behavior should also play a role in the choice of the stent. This comprehensive analysis of corrosion behavior may provide a necessary basis to choose within a large number of different stent designs and models to fulfill the individual needs of the patients.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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