



## Newer Stents: Materials and Designs

Rafael Beyar, MD, Ariel Roguin, MD

**ABSTRACT:** We aim to present here the experience with newer stents for coronary and peripheral interventions. Specifically, the design and technical considerations of the self-expanding nitinol coil stents for coronary and vascular indications, as well as the design and clinical experience with the tubular stainless steel balloon-expandable serpentine stents for coronary and peripheral interventions are discussed. The animal and clinical experience with both types of stent have shown that the mechanisms of deployment and expansion are different for these inherently different stents. The self-expanding coil stent, providing adequate scaffolding in various types of coronary lesions is deployed by self expansion, aided to a significant extent by balloon expansion. Long-term outside pressure on the wall may lead to further stent expansion as has been shown with this stent, which may be an important parameter in the restenosis process. The tubular balloon-expandable serpentine stent does not have the feature of long-term expansion, however, is characterized by superior scaffolding properties and unique features that allow its safe use in the most complex coronary diseases. Long-term clinical results are pending for these two families of stents.

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Stenting has recently been declared a “break-through technology”, changing the face of interventional cardiology.<sup>1</sup> The idea of arterial stenting is not new, going back to studies as early as 1969 by Dotter<sup>2</sup> who placed spring-shaped stents in arteries. However, only in the mid 80s was the idea of coronary stenting applied to patients. The first coronary stents were implanted in patients in 1986 by Dr. J. Peul (Toulouse) and Dr. U. Sigwart

(Lausanne).<sup>3,4</sup> In these early pioneering cases stents were implanted for prevention of restenosis, despite the absence of animal studies indicating an anti-restenosis action. The first 5 years of stenting were the “learning curve” of the medical community in using the proper technique of stent deployment and administering the proper adjunct pharmacological therapies. The first clinical experiences with the self-expanding Wallstent were under suboptimal anticoagulation treatment conditions and the complication rate of subacute thrombosis was as high as 20%.<sup>5</sup> Later, with more intense anticoagulation and the use of the Palmaz-Schatz<sup>6</sup> and Gianturco-Roubin<sup>7</sup> stents, the subacute thrombosis rate was reduced to 3–5%.

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From the Rambam Medical Center, the Rappoport Faculty of Medicine, and the Heart System Research Center, Technion-Israel Institute of Technology, Haifa, Israel.

Address reprint requests to: Rafael Beyar, MD, DSc, Director, Division of Invasive Cardiology, Rambam Medical Center, Bat Galim, Haifa, 31096 POB 9601 Israel.

The two major randomized trials<sup>8,9</sup> comparing primary stenting to balloon angioplasty in short lesions in native arteries, using the balloon expandable slotted-tube stent, showed a clear benefit in restenosis rate and late revascularization events at 6 months, thus establishing the concept of primary stenting for prevention of restenosis. Later, improvement in stent deployment using high pressure guided by IVUS<sup>10,11</sup> and the introduction of ticlopidine<sup>12,13</sup>, an effective anti-aggregant, into routine clinical use have further reduced stent thrombosis to the current rates of 1–2%.

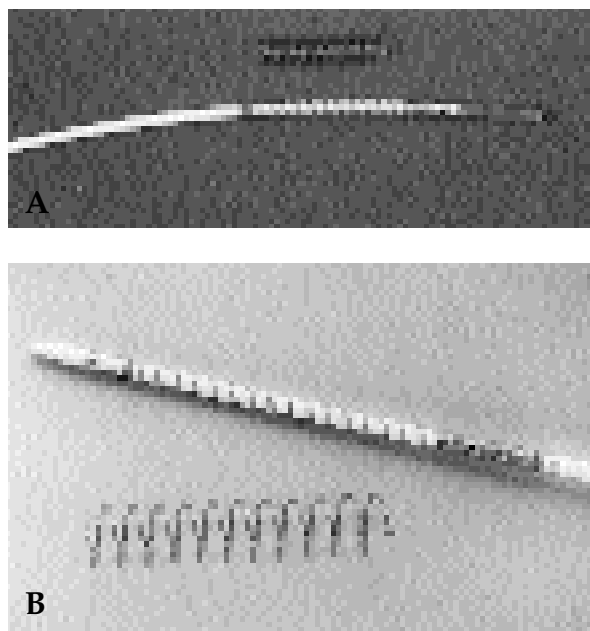
Among the various stents that have been developed for cardiovascular interventions we were involved in the development and evaluation of self-expanding coil stents (Cardiocoil, Vasucoil),<sup>14–20</sup> as well as stainless steel balloon-expandable stents<sup>21–23</sup> (beStent, V-Stent) which have been studied or are in a process of evaluation. The current paper reviews the design aspects and pilot clinical experience with these stents.

## The Self-Expanding Nitinol Coil Stents

### Stent material and design

**The mechanical behavior of nitinol.** Nitinol, a thermal shape memory alloy, is composed of equiatomic nickel and titanium elements. Nitinol has a transition temperature; upon heating it transforms from a martensite crystalline state, characterized by a low modulus of elasticity (low stiffness), to an austenite state characterized by a higher modulus of elasticity (high stiffness). The thermal shape memory allows this material to “remember” its original shape by a special heat treatment. Therefore, if the stent is plastically deformed at a temperature lower than the transition temperature, it will resume its original shape by transforming to the austenite state upon re-heating.<sup>24</sup> In addition, nitinol has a unique pseudoelastic property which allows it to undergo large nonplastic deformations of up to 6% (versus an elastic range of only 2% for stainless steel). This property, known also as super-elasticity, caused by stress-induced martensitic transformation, implies that stress remains nearly constant despite large changes in strain due to gradual changes between the martensitic and austenitic crystalline phases.

**The nitinol coil stent.** The nitinol coil<sup>14–18</sup> is a self-expanding stent that is restrained on a delivery catheter in a compressed state and deployed by a

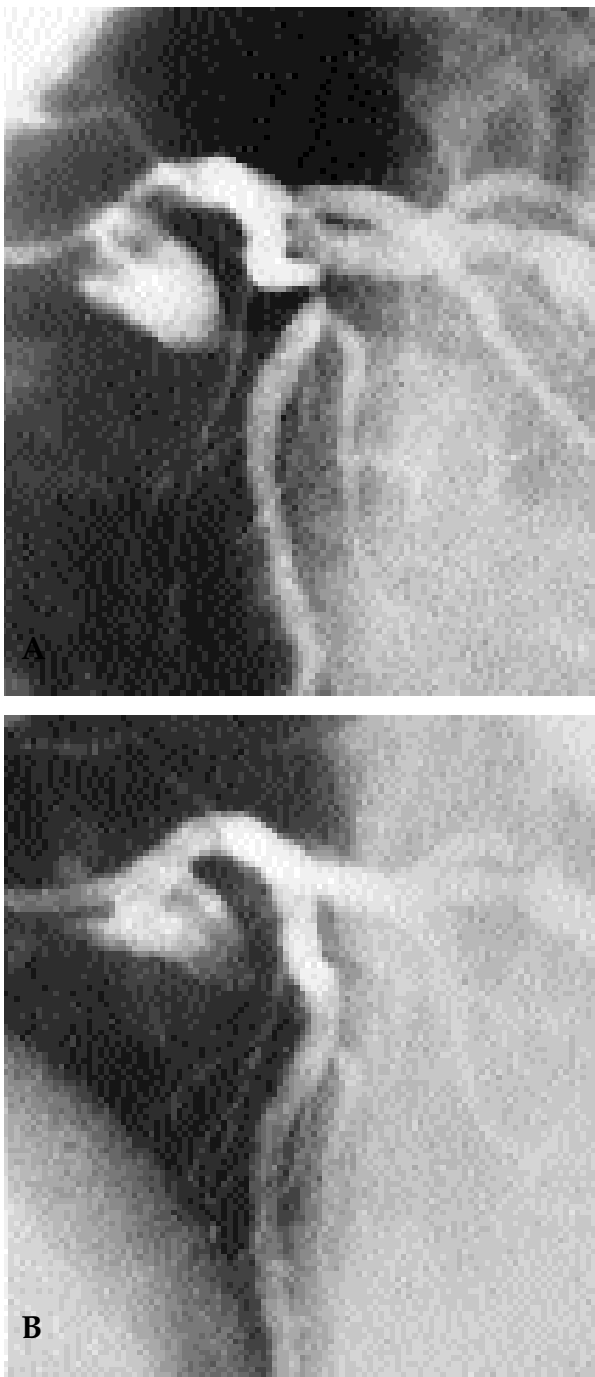


**Figure 1.** The nitinol coil stent on the delivery catheter and in its expanded free form. The Cardiocoil (A) is attached both proximally and distally and is released from distal to proximal, where the tightly wound portion of the catheter shortens proximally. The Vasucoil (Fixed-tip model, B) has two release wires and is released from proximal to distal part of the catheter, so that the stent end at the distal portion is fixed and shortening of the proximal part of the stent towards the catheter tip occurs.

wire-based release mechanism (Figure 1). The coronary stent (Cardiocoil) has a final diameter of 3.0–5.0 mm and 15 and 20 mm in length. The vascular stent (Vasucoil) is available in diameters ranging from 5 to 10 mm at a length of 40 mm. Both stents are designed as helical coils with terminal balls for mounting. The stent is visible on fluoroscopy, highly resistant to compression and applies gentle radial force upon release. By being self-expanding, this stent does not recoil and will continue to apply force on the wall until it reaches its nominal diameter. The Cardiocoil as well as the Vasucoil are designed from round wires. A flat wire design of the Cardiocoil, exhibiting better scaffolding and lower profile has been designed as well. The stents are characterized by high longitudinal flexibility in both its open and wound configuration. Yet, the longitudinal flexibility of the stent-delivery system is determined to a large extent by the delivery catheter.

### Animal experiments

**Canine model.** The nitinol stents were implanted in 23 mongrel dogs.<sup>15</sup> Coronary



**Figure 2.** An example of a patient treated with the Cardiaccoil for an angulated mid-LAD lesion. The lesion is shown before treatment (A) and after stenting (B). Note that in spite of the acute angle a beautiful angiographic result with preservation of the diagonal branch is achieved.

angiography was performed at the end of the follow-up and all dogs were sacrificed. Sixteen dogs were available for follow-up from 1 week to 1 year. It was seen that the immediate response to stent implantation may be partial denudation of the

artery due to endothelial damage. At 1 week, signs of lateral compression of the stent on the internal elastic lamina and tunica media start to appear. Evident proliferative response was seen 2 weeks after implantation, comprising of focal proliferation of fibroblasts in proximity to the stent wires.

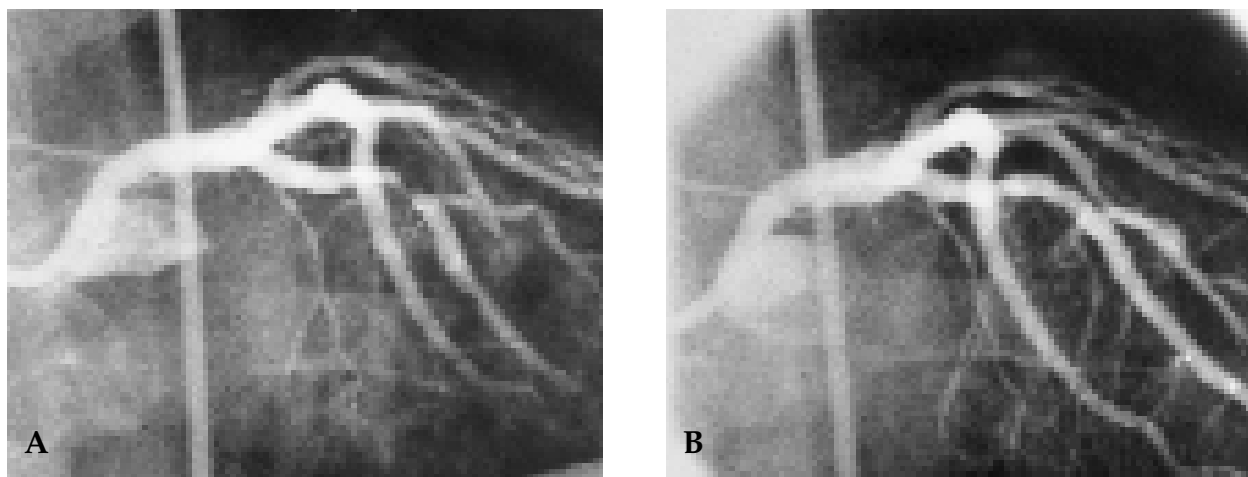
By 1 month a mild proliferative response was present in all dogs and the stent was already covered with neo-intima. At 3 months mild to moderate intimal hyperplastic process with smooth muscle proliferation was present in all dogs. Chronic inflammatory response could also be seen. The histological picture at 6 months was very similar to that of 3 months. At 12 months the above findings were present, but the response seemed less severe.

The average measurements of intimal thickness showed a typical increase in intimal thickness from 1 week to 3 months. However, after 3 months the intimal thickness did not increase, and at 12 months a tendency to a decrease in thickness was seen. The peak proliferative response occurred at 3 months and was 247  $\mu$ .

**Swine model.** The stent was evaluated in 12 pigs which were serially sacrificed up to 6 months after implantation.<sup>19</sup> Neointimal response was favorable (less than 200 microns), starting at one week after implantation, with evidence of continuing self-expansion over time. The majority of stent struts were found in the adventitia by 6 months. This represents a dissociation between deep vessel injury and neointimal reaction, which is for this type of stent.

#### The Cardiaccoil: Clinical experience

The major clinical experience is from the Rambam Medical Center (Haifa, Israel), where most of the clinical experience originated.<sup>25</sup> Between January 1995 and January 1996, 71 stents were deployed in 51 patients, undergoing elective angioplasty. There were 40 *de novo* and 11 restenotic lesions, and total occlusion in seven cases. The stents were 15 or 20 mm long and 3.0 (n=18), 3.5 (n=35), 4.0 (n=17) and 4.5 mm (n=1) in diameter. Aspirin and calcium channel blockers were given before stent deployment with post procedural heparin coverage for additional 12–24 hours. All patient received aspirin and ticlopidine for one month, starting immediately after the procedure, while the first 8 patients also received warfarin for 3 months. Stent deployment was preceded by complete predilatation to the reference diameter. The indications for stenting were exces-



**Figure 3.** An example of a patient treated with the Cardiocoil for a tight calcified LAD lesion just prior to a diagonal branch. The lesion is shown before treatment (A) and after stenting (B). Note that the diagonal branch patency is maintained within the stent.

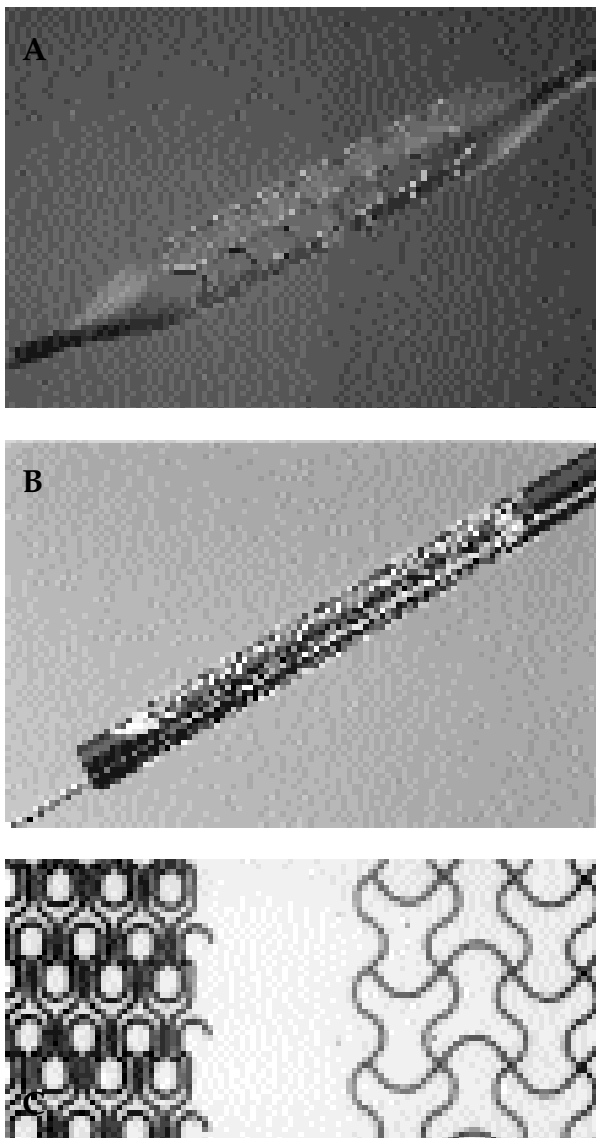
sive recoil or suboptimal results. The stent was positioned with its distal shortening portion in a non-stenosed portion distal to the lesion and released. The delivery catheter was withdrawn and stent post-dilatation at 12 to 16 atm was performed in all cases.

Quantitative computerized-assisted analysis was performed using selected views demonstrating the stenosis in its most severe and non-foreshortened projection. The cine-images were optically magnified and digitized using a cine-video converter. Using the external diameter of contrast-filled guiding catheter as the calibration standard, reference, average and minimal lumen diameters and percent diameter stenosis were determined before, after balloon angioplasty, after stent deployment and after in-stent high pressure balloon inflation.

The majority of the lesions were class B2 or C (55%) with some 20% total occlusions. Only 21 (41%) of the lesions were short with a substantial number of lesions with tubular (n=19, 37%) and diffuse disease morphology (n=11, 22%). A total of 71 stents were implanted. Multiple stents required to treat tandem lesions or long lesions that could not be treated with one stent were implanted in 15 of 51 patients (31%). An example of a patient treated with the Cardiocoil for an angulated mid-LAD lesion is shown in Figure 2. Note that in spite of the acute angle an adequate angiographic result with preservation of the diagonal branch was achieved. Another patient treated for a calcified mid LAD with a diagonal branch originated distal to the lesion, spanned by the stent is shown in Figure 3.

With the average reference vessel diameter increasing from  $2.79 \pm 0.88$  mm at baseline to  $3.24 \pm 0.66$  mm at the end of the procedure, the minimal lumen diameter increased from  $1.02 \pm 0.73$  mm to  $2.86 \pm 0.61$  mm and the mean artery percent stenosis decreased from  $65 \pm 26\%$  to  $12 \pm 37\%$ , respectively. The absolute angioplasty gain was  $1.18 \pm 0.67$  mm, the self-expanding gain  $0.39 \pm 0.47$  mm, and the high-pressure dilatation gain  $0.33 \pm 0.47$  mm. Note that 64% of the total gain was due to balloon dilatation, 19% due to the self-expansion properties of the stent and 17% due to post-stenting high pressure balloon dilatation.

The angiographic success was 100%. There were no procedural complications or mortality associated with stent implantation. Stent thrombosis occurred in three patients. In one patient with a long total occlusion incompletely covered with two stents, subacute thrombosis occurred on day four after stent implantation, several hours after discontinuation of heparin. The artery was redilated with good angiographic patency. In two other patients, both with two sequential stents in the proximal LAD, stent thrombosis occurred on day 1 and 4 and the patients underwent repeat angioplasty. In one patient retroperitoneal bleeding with profound shock was treated with blood transfusion and surgical suture. Tamponade due to wire exit in a total occlusion patient was successfully treated with pericardial drainage. The long-term results are currently evaluated and will be available in mid 1997. Therefore, of the 51 patients treated, 3 had major events leading



**Figure 4.** The beStent in its non-expanded (A) and expanded (B) configurations. The serpentine design and the gold markers are visible. The stent mesh before (C, left) and after (C, right) expansion show the principle of rotational junctions and orthogonal locking.

to MI death or early repeat revascularization, making the clinical success 47/51 (94%).

#### The Vasucoil: Clinical experience

Most of the experience in peripheral arteries is by Dr. Henry<sup>20,26</sup> (Nancy, France) where 82 stents were placed in 73 patients for indications of sub-optimal results, dissection or restenosis. The stents were placed in femoral (n = 45), iliac (n = 9), popliteal arteries (n = 19) and bypass grafts (n = 3). All implants were successful with adequate

angiographic adherence to the arterial wall. There were three stent thrombosis: A patient with stage IV peripheral vascular disease which was treated with three femoral stents for femoral occlusion with a very poor run-off; a patient with cardiac transplant and a long occlusion of the superficial femoral artery treated with two stents; and a patient treated for popliteal occlusion after a thrombosis of a femoro-popliteal bypass graft. Two patients were treated medically and one surgically. Angiographic follow-up between 4-6 months is available for 54 patients. At the iliac level, all stents remained patent at follow-up without restenosis. At the femoral level 2/45 (4.2%) patients had restenosis at 6 months (with one treated by surgery, one by new PTA) and 2/45 (4.2%) had restenosis at 1 year (1-surgery, 1 new PTA). This gives a primary and secondary patency of 86% and 90%, respectively, for all lesions. Primary patency was 100%, 80% and 92% for the iliac, femoral and popliteal arteries, respectively. Secondary patency was 100%, 89% and 92%, respectively.

Therefore, based on the limited experience with this stent in peripheral arteries it can be stated that the stent can be easily implanted in peripheral arteries both below and above the inguinal ligament. The stent provides adequate arterial support in most cases and performs well, particularly in arteries that are subjected to external compression (SFA, femoral, popliteal) as well as in frequent flexing arterial portions (popliteal, femoral). A very low restenosis rate in spite of unfavorable lesions makes this stent particularly attractive for stenotic or occlusive lesions below the inguinal ligament.

#### The Balloon Expandable Mesh Stents

The stent is made of 316 L stainless steel tube cut into a unique serpentine design (Figure 4). The stent utilizes the principles of rotational non-stress junctions and orthogonal locking upon expansion. The stent has no shortening and two radiopaque end-markers for adequate visibility allowing precise positioning. The stent lengths used in this study were 15, 25 and 35 mm, available in both a small diameter (BES series) which are intended for reference artery diameters arteries between 2.5 and 3.0 mm and large diameter ranges (BEL series) intended for reference artery diameters between 3.0 and 5.5 mm. The stent has a strut thickness of 0.8 mm, is characterized by recoil of 3-5%, and is relatively resistant to external compression, being close in its radial strength to

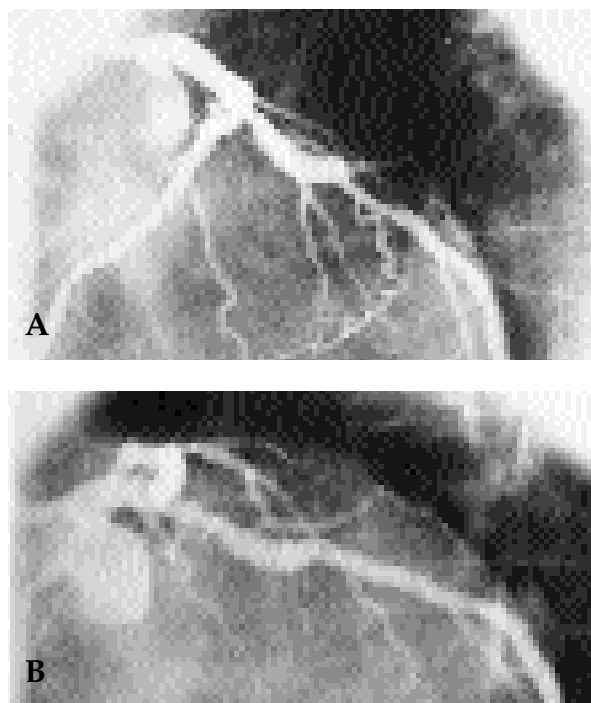
the PS-153 Palmaz-Schatz stent. The endoluminal metal surface coverage ranges between 14% and 18% at the expansion ranges achieved clinically.

Pilot data of 217 patients treated in 8 centers in Israel and Europe were recently published.<sup>27,28</sup> Treatment with 284 stents was initiated for 266 lesions. Inclusion criteria were both native and vein graft vessels of 2.5 mm or larger. Both *de novo* and restenotic lesions were allowed. Primary stenting, as well as stenting for bailout or suboptimal results conditions were included. Short, as well as long lesions, were also allowed and included in the study.

All patients received aspirin before stent deployment. A bolus of 10,000 units of heparin was given after sheath insertion. The patients were maintained on daily 100 mg of aspirin indefinitely, unless contraindicated. Ticlopidine 500 mg daily was started on the day of procedure and continued for 1 month. In two centers (Institute of Cardiology, University of Milan, Italy; Panorama Heart Institute, Capetown, SA; Total number of patients = 61) only aspirin without ticlopidine was given after the procedure.

The implantation of the beStent is similar in principles to implantation of other unmounted balloon-expandable stents. The stent was mounted on the appropriate balloon for delivery (a 15 mm stent is mounted on a 20 mm balloon, a 25 mm stent on a 30 mm balloon and a 35 mm stent is mounted on a 40 mm balloon). If possible, a semi-compliant or a non-compliant balloon was generally used so that the same balloon can be used for the high (14 atm or higher) pressure inflation, thus optimizing balloon usage. Once the lesion was crossed the stent was positioned using its end markers. Since there is no stent shortening, the markers precisely define the stent final deployment position. Initial deployment was done at a pressure of 8 atm. After complete balloon expansion, 10-30 seconds were allowed for equilibration before the balloon was deflated. The balloon was then re-positioned so that it did not protrude distal to the stent and re-inflated to a pressure of 14 atm or higher. If the delivery balloon could not be used at high pressure, further dilatation with a high pressure balloon was employed. In case of planned multiple stenting, it was our approach to start with the implantation of the distal stent, followed by the more proximal stent.

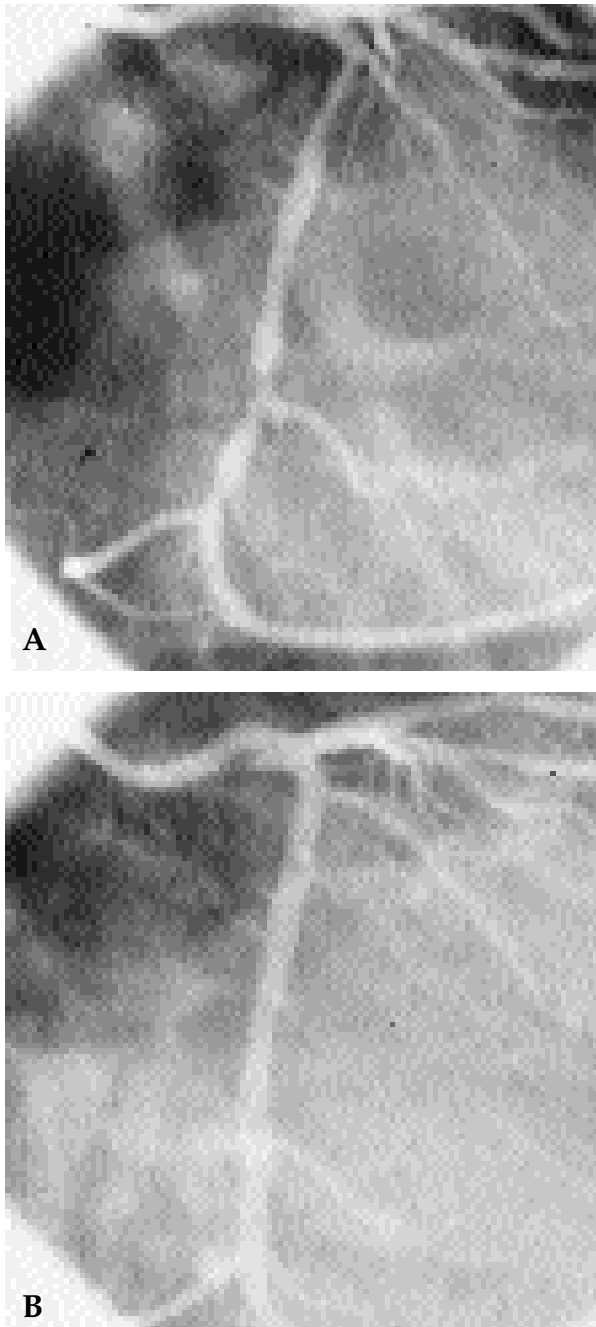
An example of treatment of a lesion distal to a circumflex artery aneurysm is shown in Figure 5. This is aided to a large extent by the stent markers, which aid in precise positioning of the stent.



**Figure 5.** An example of treatment of a lesion distal to a circumflex artery aneurysm. The lesion is shown before (A) and after (B) treatment. Stent positioning is aided to a large extent by the stent markers which aid in precise positioning of the stent.

Another case with two circumflex lesions is shown in Figure 6. The distal circumflex lesion that has a side-branch was treated with a Cardiocoil, whereas the proximal lesion, close to the ostium of the artery in proximity to the left main stem was treated with a 25 mm beStent, taking advantage of the markers for precise stent positioning after the left main bifurcation.

The majority of lesions (160/266) were types B2 and C. Lesion length was distributed between short lesions and long diffuse disease, with the majority of lesions being in the tubular length range and with an average length of  $16.9 \pm 8.6$  mm. While the majority of patients required one stent for treatment, a substantial number of patients required two or more stents ( $n=60$ ) for treatment of long lesions and diffuse disease. Implantation was successful in 97% of patients, with failure to implant a stent in 6 (2.8%) patients. Failure to reach the lesion was encountered in 7 patients, most of them (6/7) with long stents facing tortuous calcified vessel. In one patient, treated for a moderately calcified vessel with 99% stenosis, the (35 mm) stent was lost after it could not cross the lesion. It was then successfully retrieved. In three patients, 25 mm stents could not cross the lesion and were successfully



**Figure 6.** A patient with two circumflex lesions (A). The distal circumflex lesion that has a side branch was treated with a Cardiocoil, whereas the proximal lesion close to the ostium of the artery in proximity to the left main was treated with a 25 mm beStent taking advantage of the markers to assure precise stenting after the bifurcation of the left main. The final results with preservation of the side-branch in the distal vessel and smooth results in the proximal vessel is shown (B).

retrieved. In two cases, peripheral stent embolization occurred after failed retrieval techniques. In one of these cases, another beStent was successfully implanted. In one patient, a 15 mm stent

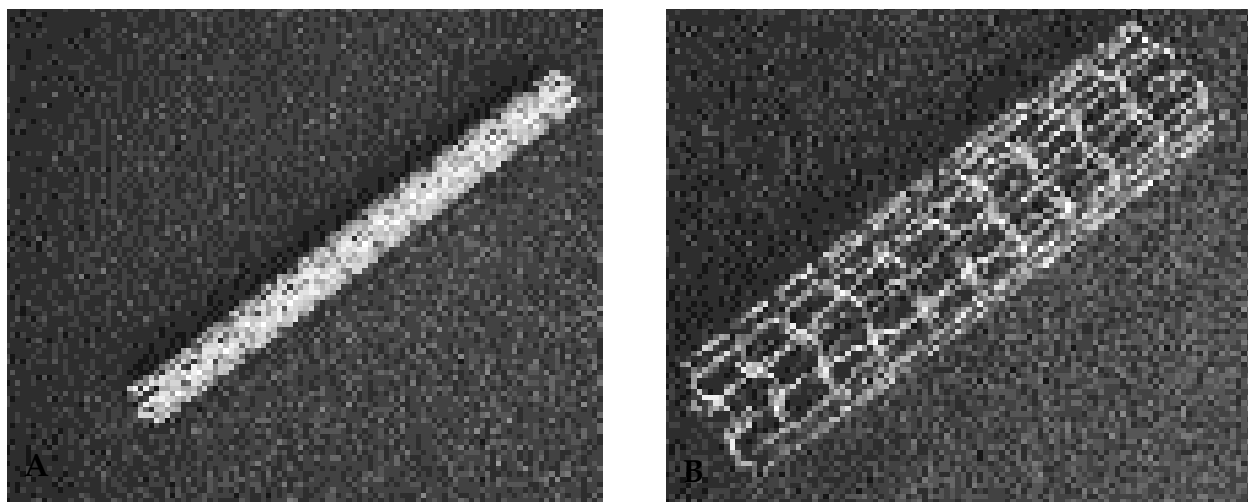
could not reach the lesion due to excessive tortuosity; it was successfully retrieved. None of the above patients, including the two patients with stent loss, had any sequelae following the technical failures.

Angiographic success was similar to the technical success, since in all patients with successful stent delivery smooth angiographic results with less than 30% residual stenosis were obtained. Major adverse clinical events occurred in five patients. There were two in-hospital non-cardiac deaths. In one case, retroperitoneal bleeding with shock on Day-2 led to sepsis and death due to disseminated intravascular coagulopathy on Day-14. There were no ECG changes throughout the stormy course leading to the patient's death. In another case, a patient with an optimal stent results in the LAD died suddenly on Day-3 due to massive pulmonary embolism without evidence of a cardiac ischemic event. Two patients had stent thrombosis (Day-1 and 2) which led to MI. In both these cases the stent was successfully recrossed and dilated. Therefore the in-hospital clinical success rate was 95.2%. During 30 day follow-up there were two additional events. One patient was referred for CABG and died after surgery. Another patient with a 35 mm stent in the LAD and treated with aspirin alone, developed stent thrombosis with subsequent MI on Day-5. The 30 day cumulative event-free survival was 97.2%.

These data show that the beStent can be used safely to treat simple and complex lesions, as well as long lesions of unfavorable anatomy. A high success with a relatively low rate of complications characterizes the initial pilot evaluation of this stent in spite of unfavorable lesion anatomy in a significant portion of the patients. The long-term results of these patients using the beStent, in these varying lesion subsets is yet to be determined.

### V-Stent

The V-Stent is similar in its design to the beStent, however, it is manufactured to cover arterial sizes of 5 to 10 mm. The stent is shown in Figure 7. The same principles that apply to the coronary stent are also applicable to this stent. The rotation junctions and orthogonal locking assure the longitudinal flexibility, the radial strength and the no-shortening, a feature of high importance, especially for treatment of ostial lesions and where precise positioning is required. Animal experiments which are underway have shown a typical proliferative response not differ-



**Figure 7.** The V-Stent before (A) and after (B) expansion. The design is similar to the beStent and is scaled up to span vessels between 6 and 10 mm.

ent than the coronary stents. Clinical studies with this stent are currently underway.

## DISCUSSION

The design characteristics and first clinical results with new self- and balloon-expandable stents have been reviewed. The self-expanding coil stents,<sup>14-20</sup> constructed of a nitinol coil are unique in their design and are characterized by high longitudinal flexibility, high resistance to collapse and excellent conformability to arterial curvatures, both in the peripheral and coronary circulation. Results with the coronary stent have shown the feasibility of this stent and have documented its unique feature to further expand during follow-up due to its long-term shape memory. This has also been documented in animal experiments.<sup>19</sup> The animal and clinical experience have proven that this stent can be easily deployed without excessive vessel trauma, and that favorable acute and short-term results may be achieved with this stent.<sup>25</sup> The coil design has been associated with adequate scaffolding properties, preserving side-branches, yet tubular stent of various designs may provide smoother angiographic results than a coil stent. Longer follow-up with this stent in peripheral arteries below the inguinal ligament have shown high patency rates at difficult and unfavorable locations such as the popliteal and the femoral arteries.<sup>26</sup>

The balloon-expandable, stainless-steel serpentine stent<sup>21-23</sup> is completely different in its deployment and post-deployment principles than the self-expanding stent. It is mounted on a balloon,

can be expanded to the required diameter within the allowed range of the stent, and does not continue to expand beyond the final implantation result. It provides a smoother angiographic results than a coil stent and can be used to treat long and diffuse disease with a relatively low rate of complications. The special features of this stent are its longitudinal flexibility due to its unique design, with the rotational junctions assuring both the orthogonal lock mechanism and no shortening upon expansion. Precise positioning is possible due to the no-shortening feature and the end-gold-markers, that aid in stent delineation. The experience in tandem stenting and treatment of complex anatomy with this stent have proven its versatility in a wide range of disease.<sup>27,28</sup> Long-term clinical results with the pilot registry for simple and complex coronary disease will be available toward the middle of 1997. Studies to test its long-term angiographic restenosis rate (ROSE, Cardialysis, Rotterdam) have recently completed recruitment of patients and the results are expected towards the end of 1997. A similar design for the peripheral arteries is currently being studied.

In summary, the design aspects and clinical characteristics of new self- and balloon-expandable stents have been reviewed and showed the inherent differences between these type of stents. Further and longer experience is required in order to understand the implications of the difference between these stents on their clinical use in various lesion and clinical subset conditions.

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