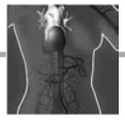
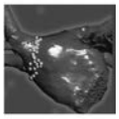
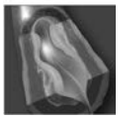

AngioSculpt® scoring balloon catheter: an atherotomy device for coronary and peripheral interventions

This article reviews the AngioSculpt® (AngioScore, CA, USA) scoring balloon catheter, one of the newest atherotomy-based systems used in the treatment of both coronary and peripheral vascular disease. We examine the clinically relevant aspects of the development of this technology and the current level of evidence for its use. We chronicle the role of the AngioSculpt device in the present-day era of drug-eluting stents and what may be in store for the future of the device.

KEYWORDS: angioplasty device ■ AngioScore ■ AngioSculpt® ■ atherotomy ■ coronary intervention ■ scoring balloon

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During the past three decades, the landscape of percutaneous cardiovascular interventions (PCIs) has dramatically changed. Improved technical experience coupled with a vast array of technologies to choose from has allowed the interventional cardiologist to tackle increasingly complex anatomy for revascularization. While stent implantation is undoubtedly the mainstay of the current percutaneous approach in the coronary vasculature, certain types of lesions remain a challenge for optimizing vessel patency, even in the modern stent era. There is significant heterogeneity in practice and controversy regarding the best approach to complex lesions involving the coronary ostia, vessel bifurcations, heavily calcified vessels, and chronic total occlusions. Even when stent implantation is planned, there are many potential strategies for lesion preparation, including direct stenting, balloon predilation, atheroablation (i.e., rotablator or excimer laser) and atherotomy or scoring systems (i.e., cutting and scoring balloons).

Challenges to conventional percutaneous angioplasty & stenting

Depending on the patient and lesion characteristics, conventional balloon angioplasty or plain-old balloon angioplasty (POBA) as a standalone strategy for coronary revascularization is beset with significant restenosis in 30–50% of cases – generally within the first 3 months following balloon dilation – and acute procedural complications such as occlusive dissection, myocardial infarction (MI) and the need for emergency bypass. There are several causes of restenosis after balloon angioplasty, which include both acute and late responses. Acute responses to balloon injury include arterial dissection, abrupt closure and elastic vascular recoil, while subacute to late effects include atherosclerotic remodeling and neointimal hyperplasia. Bare-metal stents (BMS) were established to reduce angiographic and clinical restenosis by virtually eliminating the problems of dissection, elastic recoil and remodeling [1,2]. However, 10–35% of these patients develop in-stent restenosis (ISR) within the first 6–8 months after stent placement [1,3–5], with clinically driven repeat coronary revascularization necessary in 50–80% of those cases [5–7]. The pathology behind ISR is linked to neointimal hyperplasia and the endovascular infiltration of inflammatory cells and myofibroblasts in a maladaptive response to the vascular injury induced by stenting [8].

With this pathophysiology of ISR in mind, drug-eluting stents (DES) – stents coated with antirestenotic agents – have led to a significant reduction in the incidence of ISR. However, even in the current DES era, ISR remains a significant clinical entity, with reported average restenosis rates of 5–10% but reaching as high as 19% in selected patient and lesion subsets [9]. In addition, both DES and, to a lesser extent, BMS carry a small but deadly risk of acute and late-stent thrombosis. While comorbid conditions and innate lesion characteristics contribute to one's risk for both ISR and stent thrombosis, the percutaneous technique employed, adequacy of lesion preparation, and adequacy of stent deployment may also affect patency rates in treated arteries.

By definition, adequate stent expansion means achieving its predefined reference area. Stent underexpansion has been associated with

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both ISR and stent thrombosis [10–12]. In intravascular ultrasound (IVUS) studies, failing to achieve a minimal stent lumen area (MLA) of 5 mm^2 or greater correlates with increased rates of early/subacute stent thrombosis [13,14]. In one study, approximately 80% of patients who experienced sirolimus-stent thrombosis showed evidence of underexpansion with an MLA of less than 5.0 mm [11]. Thus, the avoidance of stent underexpansion is considered a prerequisite to good PCI technique. Stent underexpansion can be decreased by matching the stent size appropriately with the vessel, performing adequate lesion preparation and post-treatment dilatation of the stent as needed, utilizing adjunctive IVUS as necessary.

As a separate but related concept, incomplete stent apposition occurs in approximately 10–20% of patients receiving DES and is defined as a lack of contact between the stent struts and the underlying vessel wall [15]. Stent malapposition has been correlated with higher rates of late-stent thrombosis, typically when malapposition occurs in the presence of stent underexpansion [16,17]. Stent malapposition is conjectured to occur by one of the following mechanisms [16]:

- Acute – during stent deployment when the mechanics of a heavily calcified or fibrosed lesion prevent adequate and homogeneous stent expansion;
- Subacute – migration or disruption of intimal thrombus, leaving stent struts partially exposed;
- Late – secondary to positive remodeling of the artery.

Thus, a number of revascularization failures secondary to stent malapposition may be preventable by the techniques used at the time of the intervention.

One of the ways to prevent stent underexpansion or malapposition is by adequate lesion preparation. Whether tackling percutaneous revascularization in the coronary arteries or the peripheral vasculature, standard balloon angioplasty is the most prevalent technique for lesion preparation prior to stenting. While POBA is successful in most vascular stenoses with good angiographic and clinical outcomes, complex lesion subsets remain where POBA alone may be at a considerable risk of failing. In calcified or fibrosed lesions, POBA can frequently leave significant residual stenosis with inadequate stent expansion secondary to elastic recoil. Plaque shifting is common, and the risk of dissection and/or rupture is not insignificant, particularly in resistant lesions in which issues of differential compliance along the surface of the lesion become manifest. Balloon slippage, also known as 'watermelon seeding', remains a concern with POBA, causing damage to additional, unintended segments of the artery. In select lesions, angioplasty alone can lead to an unacceptably high restenosis rate of 50% or greater [18].

In addition to lesion preparation before stenting, clinical scenarios remain where stenting itself is not optimal or appropriate. Clinically significant stenosis can exist in vessels with diameters of less than 2.5 mm – nonetheless, there remains controversy regarding whether small arteries are better treated with stenting or POBA. Moreover, stenting in certain distal branches (i.e., posterior descending coronary artery, distal left anterior descending coronary artery or distal obtuse marginals) can preclude the future option of coronary artery bypass grafting. In addition, some patients with clinically compromising stenosis may not be good candidates for dual antiplatelet therapy, owing to either a higher risk of bleeding or concerns about noncompliance. Bifurcation lesions, which occur in 20–25% of PCI cases, pose a unique set of technical considerations. Plaque shifting and elastic recoil during angioplasty can lead to compromise and/or loss of side branches. Created dissections from POBA may sometimes necessitate the placement of a second stent in the side branch, which exposes the patient to an increased risk of ISR and/or stent thrombosis. Overall, bifurcation lesions have higher rates of stent thrombosis and ISR compared with nonbifurcation lesions, and recent studies such as the Nordic and the Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents (CACTUS) studies suggest that a single stent approach may be the preferred initial strategy to treat such lesions [19–21]. Thus, alternative technologies are necessary to achieve durable patency of the side branch.

Treatment options for ISR have been aplenty over the past several decades; however, the ISR saga has been checkered with moments of great hope followed by disappointment. Modalities such as repeat angioplasty, laser ablation and atherectomy devices are all minimally successful in preventing ISR recurrence and affecting the clinical course. The Restenosis Intra-Stent Balloon Angioplasty Versus Elective Stenting (RIBS) trial, which assessed balloon angioplasty versus BMS for the treatment of ISR, followed patients for up to 1 year with statistically similar rates of recurrent ISR [22]. While intravascular

brachytherapy demonstrated considerable promise in trials such as Gamma-1 [23] and Intimal Hyperplasia Inhibition with Beta In-stent Trial (INHIBIT) [24], the technique has fallen out of clinical use owing to inconsistency in real-world experience, difficult logistics and late catch-up. However, with the advent of DES, there finally appears to be a successful therapy for most cases of ISR. The RIBS-2 trial, which compared BMS with DES, found DES to be superior, reducing recurrent ISR from 39 to 11% [25]. However, it is not always possible or prudent to use DES to treat ISR, especially when there are multiple layers of stents, smaller caliber vessels or contraindications to dual antiplatelet therapy. There remains a clinical need for non-stent-based solutions in the treatment of ISR.

Rationale behind atherotomy devices & experience with the cutting balloon

The challenges posed by these difficult-to-treat lesion subsets have engendered a myriad of devices to optimize vessel patency both in preparation for stenting and as standalone treatments. While technologies using atherectomy and atheroablation have an important niche, their discussion is outside the scope of this article. This article instead focuses on an adaptation of conventional balloon angioplasty through the use of atherotomy (balloon with metal blades) and/or scoring balloons (where a standard balloon is encased in one or more metallic wires). When the balloon is inflated, the metallic components of these devices anchor into the tunica intima, thereby preventing balloon slippage and any geographic misplacement. Atherotomes or wires are able to 'cut into' areas of fibrosis or calcification better, allowing for a more uniform balloon expansion and potentially more predictable results. This advantage is particularly desirable with complex lesions such as type B2 or C lesions based on the American College of Cardiology (ACC) lesion classification system [26], and may be beneficial in both *de novo* stenosis and recurrent ISR. Better lesion preparation can facilitate fuller stent expansion at lower atmospheres and can correlate with potentially fewer procedural complications. In the revascularization of bifurcation or ostial lesions, scoring balloons are believed to decrease elastic recoil and plaque shifting, potentially reducing the need for two stents in the case of bifurcations.

The first of the atherotomy (scoring) devices to be developed was the cutting balloon (Flextome® Cutting Balloon, Boston Scientific, MA, USA). Developed in the early 1990s, the cutting balloon has had considerable clinical application over the past two decades. It consists of a noncompliant balloon surrounded by three to four longitudinal microtomes (or microsurgical blades) deliverable via a standard over-the-wire (OTW) and rapid exchange approach. Several IVUS studies have suggested that the cutting balloon achieves greater plaque reduction with less elastic recoil compared with standalone POBA [27,28]. Animal experiments have demonstrated decreased neutrophilic infiltration and fibrinolytic activation using cutting compared with standard balloons – these markers of inflammation contribute to ISR development [29–31].

In initial randomized control trials (RCTs), vascular stenosis treated with cutting balloons were found to have less evidence of ISR than lesions treated with standard balloons [32,33]. Despite initial optimism, cutting balloons have not represented a major advance in improving outcomes with coronary revascularization. The largest multicenter RCT that compared cutting balloons with standard angioplasty in 1238 patients with focal *de novo* coronary lesions did not find any difference in 6-month angiographic restenosis rates [34]. In this trial, cutting balloons also had higher rates of coronary perforation (five vs zero events), MI (4.7 vs 2.4%) and death (1.3 vs 0.3%).

Some technical concerns specific to the cutting balloon also exist. The cutting balloon has a relatively large crossing profile ranging from 0.041 to 0.046 inches, depending on the number of atherotomes and the selected balloon size. Its diameter and inherent rigidity can create difficulty in crossing certain lesions (i.e., the jailed side branches of bifurcations). Given these concerns regarding deliverability and the possibly heightened perforation risk, cutting balloons are reserved for niche indications, rather than for most cases of conventional PCI. However, the potential technical advantages of cutting balloons over conventional POBA have engendered the development of other atherotomy devices. The FX miniRAIL™ (Abbott Vascular, CA, USA) uses a dual wire platform of external stainless steel wires that score the plaque with balloon inflation [35]. However, despite achieving US FDA approval in 2003, this device is not being actively marketed in the USA. A single-blade cutting balloon device has also been described, although there are not many published data at present. The most popular and successful new iteration of the atherotomy/scoring balloon technology in the USA has been the AngioSculpt® (AngioScore, CA, USA) system.

AngioSculpt® scoring devices

The AngioSculpt scoring balloon consists of a double lumen catheter with a semicompliant, nylon balloon surrounded by an external nitinol-based helical scoring edge (Figure 1A). The expansion properties of the three rectangular spiral struts (four struts in devices ≥4 mm in diameter) are influenced by a fixed distal end and a semiconstrained proximal end in relation to the balloon (Figure 1B). This design allows for a controlled and uniform expansion of the balloon and nitinol cage, potentially preventing significant device slippage while scoring the plaque and maximizing luminal expansion. Compared with the cutting balloon, the AngioSculpt is designed to be more flexible and ideally more deliverable across complex coronary lesions. However, the AngioSculpt tries to retain the advantages of cutting balloons including decreased incidence of balloon slippage, more uniform balloon expansion, reduced elastic recoil and an optimal postinflation minimal lumen diameter (MLD) even in fibrotic/calcified lesions (Figure 2).

The AngioSculpt percutaneous transluminal coronary angioplasty (PTCA) scoring balloon catheter is available in balloon lengths of 10, 15 and 20 mm; balloon diameters of 2.0, 2.5, 3.0 and 3.5 mm; and a catheter length of 137 cm. The crossing profile of the smallest devices is approximately 0.036 inches. The balloon inflation range is listed as 2–20 atm with a nominal pressure of 8 atm and a reported burst pressure ranging between 16 and 20 atm depending on the diameter chosen. Worldwide delivery platforms include rapid exchange, easy exchange or OTW using a standard 0.014-inch guidewire. In addition to the difference in delivery platform, the easy exchange catheter has a longer and more tapered distal tip and a nitinol support wire incorporated in the distal catheter shaft to improve pushability and deliverability. Also available in a version for peripheral interventions, the AngioSculpt percutaneous transluminal angioplasty (PTA) scoring balloon catheter uses the same design, materials and technology as the AngioSculpt PTCA scoring balloon catheter. With a catheter length of 50–137 cm, it is available in a larger spectrum of sizes suitable for peripheral interventions, including balloon lengths of 10–40 mm and balloon diameters of 2–6 mm. The AngioSculpt PTA scoring balloon uses an OTW platform with a 0.014-inch wire if the balloon diameter is less than or equal to 3.5 mm and a 0.018-inch wire if the diameter is 4.0 mm or greater.

All AngioSculpt catheters are intended for single use only with manufactured compatibility with 6-Fr guide catheters (or 5-Fr sheaths) for balloon diameter sizes of 3.5 mm or less and 7-Fr guide catheters (or 6-Fr sheaths) for balloon diameter sizes greater than 4.0 mm. Radiopaque markers demarcate the proximal and distal edge of the balloon for fluoroscopic visualization. During balloon deflation, the nitinol cage is believed to play an active role in the device deflation. The FDA has approved the AngioSculpt PTCA scoring balloon catheter for the treatment of coronary artery stenosis, including complex type C lesions and in-stent restenosis. The AngioSculpt PTA scoring balloon is approved for the treatment of native and artificial arteriovenous dialysis fistulae and the dilation of peripheral and renal vascular disease, excluding the neurovasculature.

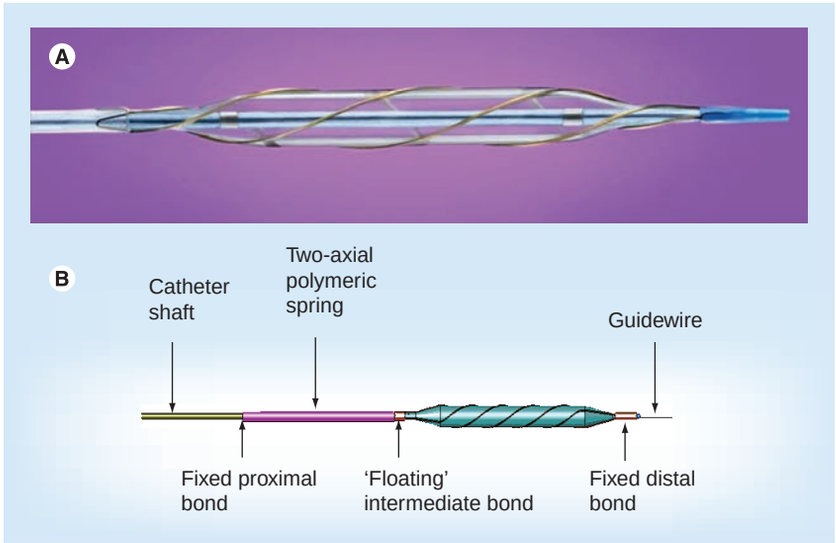

Figure 1. AngioSculpt® scoring balloon catheter. (A) AngioSculpt scoring balloon catheter – close-up picture featuring the inflated balloon encased by a nitinol wire cage. **(B)** Nitinol cage design with fixed distal end and a semiconstrained proximal end that allows for expansion and disengagement properties.

Clinical evidence for AngioSculpt®: coronary

The first-in-man experience using AngioSculpt was an international registry of 45 patients with both ISR and *de novo* coronary lesions. These data were reported to the FDA as part of the device's approval application, although at the time of the data's publication in 2008, the series had been expanded to 60 patients [36]. This feasibility trial, which analyzed the use of the AngioSculpt with routine BMS for *de novo* lesions and AngioSculpt as a standalone

treatment for BMS ISR lesions, examined the 1- and 6-month composite safety end point of device-related complications – in particular major adverse cardiac events (MACEs) including death, MI and target lesion revascularization (TLR). The complication rate was reported to be 0% at 1 month and 10.2% (five patients) at 6 months, consisting entirely of TLR. There were no deaths or MIs reported in this study period. Procedural success, defined as achieving less than 50% residual stenosis following the intervention, was reported at 100%. In the *de novo* lesion subgroup using quantitative coronary angiography and IVUS, the MLD increased on average from 0.89 to 1.6 mm ($p < 0.001$), while the MLA increased from 2.7 to 6.6 mm^2 ($p < 0.001$). In the 17 patients treated for ISR, the MLD initially increased from 0.9 to 2.6 mm postprocedure with minimal regression noted at 6 months to 2.0 mm. The postprocedure MLA increased from 2.0 to 4.6 mm^2 with IVUS at 6 months showing a MLA of 3.7 mm^2 ($p < 0.001$). There were two type A coronary dissections noted after the AngioSculpt that were successfully sealed after stenting; there were no coronary perforations.

The first US trial of the AngioSculpt device was a multicenter, nonrandomized, single-arm study of 200 patients and 219 treated arteries with both *de novo* lesions (84%) and ISR (16%) [101]. The distribution of treated arteries mostly included native coronaries with moderate complexity including 76.1% ACC type B2 or C, 29% bifurcation lesions, 27% eccentric plaques and approximately 35% with at least moderate calcification. Angiographic success (again defined as achieving <50% residual stenosis) was attained in 100% of patients with adjunctive stenting performed in 97.7% of lesions. The clinical MACE rate at 21 days was 2.5%, consisting of five post-procedural MIs, two of which required further TLR. The post-AngioSculpt dissection rate was reported to be 13.6% and reduced to 0.5% post-stenting. There were no coronary perforations or deaths and 0% slippage during balloon inflation as assessed by angiographic core laboratory analysis. The largest published registry experience with AngioSculpt in complex coronary lesions has been presented in abstract form [37]. Treating 521 patients (745 lesions) with at least moderate calcification in 75% and an average reference vessel diameter of 2.48 mm, Grenadier *et al.* reported 30-day MACE of 2.9% with 97.9% procedural success. Almost 3 years after the revascularization procedure, there was a 7.1% MACE rate, including 0.4% death and 5.9% TLR. The cumulative rate of stent thrombosis at a mean follow-up of 33.7 months was only 0.9%, despite the predominant use of DES [37].

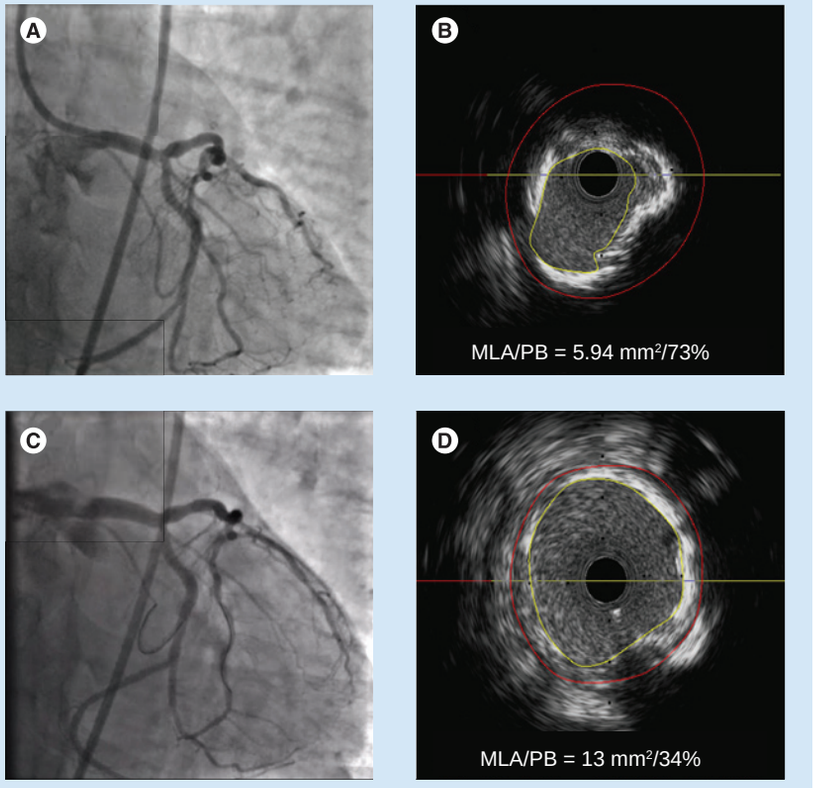

Figure 2. Angiographic and ultrasound example of an AngioSculpt®-treated lesion. (A & B) Preintervention angiogram and intravascular ultrasound of calcified distal left main artery stenosis (>50%). MLA is measured to be 5.94 mm^2. The overall PB is calculated to be 73%. **(C & D)** Post-AngioSculpt intervention of the distal left main stenosis. Angiogram documents good postintervention expansion with intravascular ultrasound MLA of 13 mm^2 and residual PB of 34%. MLA: Minimal lumen area; PB: Plaque burden.

There is only one study to date comparing AngioSculpt with other revascularization options; a nonrandomized cohort study of 299 consecutive patients (299 lesions) undergoing IVUS-guided coronary DES implantation [38]. This study compared the following three stent strategies: direct stenting, predilation with a standard balloon or predilation with the AngioSculpt in *de novo* native coronary lesions with visually assessed diameters of greater than or equal to 2.5 mm. Participants were excluded if post-stent dilation was performed with balloons other than the stent balloon. Patient characteristics were comparable across the groups and 54.1% of treated lesions were classified as ACC type B2 or C. There was a higher percentage of treated right coronary arteries (51%) among the AngioScore group compared with

the direct stenting and standard balloon predilation groups (21 and 29%, respectively). The overall plaque morphology, degree of calcification and predilation MLA as assessed by IVUS were similar in all groups. While the preintervention MLAs of treated lesions were similar across all patients, the AngioScore subgroup had a postintervention MLA improvement to 6.8 mm^2 compared with 6.0 mm^2 for direct stenting and 5.9 mm^2 for standard balloon dilation ($p = 0.02$). Among the direct stenting and standard balloon dilation groups, 74% of lesions achieved a final MLA of greater than or equal to 5 mm^2 compared with 89% of lesions pretreated with AngioSculpt.

Two prospective single-arm studies assessing the AngioSculpt device in coronary bifurcation lesions are presently enrolling patients at the time of writing this article; the AngioSculpt Scoring Balloon Catheter for Bifurcation Coronary Lesions (ABC) study based in Israel and the AngioSculpt Coronary Bifurcation Study (AGILITY) study based in USA [102,103]. Of these two studies, the AGILITY trial recruited 93 participants from nine medical centers. This trial evaluates an initial single stent strategy in treating bifurcation lesions with more than 50% stenosis involving the side branch ostium, designated by the Medina classification system as (x,x,1). The AngioSculpt scoring balloon is the planned primary therapy for the side branch while DES is planned for the main branch. The trial's primary end point is in-hospital procedural success including successful use of the single-stent strategy for treating the main and side branch. Secondary end points include freedom from MACEs, stent thrombosis and TLR at 30 days and 9 months. Additional end points are rates of dissection, balloon slippage and crossover to a two-stent strategy. The study investigators plan to then compare these data with historical controls (where POBA was used as the primary side branch treatment) to infer device effectiveness. The initial results will be available in September 2010.

One of the potential concerns with scoring balloon catheters has always been the risk of device entrapment during inflation. Over the past 15 years, there have been few published reports of device entrapment during inflation occurring with cutting balloons [39]. Outside of FDA reporting, there is one published case report of an AngioSculpt catheter getting entrapped in a heavily calcified coronary – after multiple attempts at withdrawal, the patient was taken to surgery for catheter removal [40]. Otherwise, there remain few other published adverse events in the past 5 years of clinical use.

Based on the aforementioned evidence, the AngioSculpt PTCA scoring balloon catheter has been approved for the treatment of coronary artery stenosis, including complex type C lesions and in-stent restenosis. In our opinion, the AngioSculpt catheter's advantage remains in the preparation of calcified and fibrotic lesions prior to stenting in addition to the treatment of ISR in lesions not amenable to further DES. It is prudent to await the results of the AGILITY trial and ABC study prior to advocating routine use of the AngioSculpt in bifurcation lesions.

Clinical evidence for AngioSculpt: peripheral

Another situation in need of lasting percutaneous options is peripheral artery disease (PAD). While PTA is effective in treating focal (TransAtlantic InterSociety Consensus classification A or B) lesions of the iliac system, the evidence for using PTA compared with bypass surgery in infrainguinal disease is more controversial. However, in patients who have high perioperative risk, PTA even in infrainguinal arteries remains a viable option – especially in clinical scenarios such as critical limb ischemia (CLI) [41]. The use of concomitant stents in PAD is not nearly as well supported as in CAD – thus, nonstent options such as POBA or atherectomy are often the principle means of revascularization. Similarly to coronary stenosis, PTA alone is challenging in lesions with heavy calcification, fibrosis, chronic occlusions or poor distal run-off. Complication rates from POBA are reported to be high as 30%, including high rates of uncontrolled dissection.

In this setting, the AngioSculpt PTA catheter received FDA approval in 2005, as an adjunctive scoring balloon catheter in the treatment of PAD and arteriovenous fistulae. The potential benefits of the scoring balloon compared with POBA remain the same in the peripheral vasculature as with the coronaries. The scoring device concentrates the dilatory force, thus assisting in the dilation of calcified/fibrotic lesions and potentially allowing for a more uniform balloon inflation at lower atmospheres without balloon slippage. The end goal is to achieve a more lasting revascularization while minimizing the risk of dissection.

Two published single-arm nonrandomized studies have evaluated the AngioSculpt in treating infrapopliteal PAD. The first human

experience with AngioSculpt PTA examined 42 patients, 38 of whom presented with CLI, across five European centers [42]. Treated lesions had moderate-to-severe calcification (73%) with an average MLD of 0.7 mm and reference vessel diameter of 2.8 mm. This feasibility and safety trial demonstrated 98% procedural success with AngioSculpt, although four lesions required initial upsizing using a smaller balloon (presumably to facilitate device delivery). A total of 11% of patients experienced minor dissections, all of whom were successfully treated with stents. There were no perforations or angiographically assessed balloon slippage. A second study from Belgium reported 1-year clinical follow-up in 31 patients (average age 76 years) with high rates of diabetes (45%) and all of whom presented with CLI [43]. In total, 37 infrapopliteal lesions were treated with the AngioSculpt PTA catheter, with 36% of patients receiving additional stent placement (10% owing to minor dissections and 26% in order to achieve optimal patency). At 1 year, primary patency rates were 61%, with limb salvage of 86%. Overall, the 1-year survival rate was 84%.

The first and only study to date examining the safety and efficacy of using the AngioSculpt PTA device for femoral-popliteal disease is the Femoropopliteal AngioSculpt Scoring Balloon Catheter (MASCOT) trial [104]. This prospective, single-arm trial is examining 30-day complication-free survival (including freedom from above-the-ankle amputations, death or TLR) in patients presenting with claudication symptoms. The secondary end point is the 1-year patency of the treated vessel (i.e., freedom from TLR or significant stenosis on B-mode Doppler). Results of the study were recently reported at the Cardiovascular Research Technologies 2010 meeting, including 96% of patients free of complications at 30 days and a 74% vessel patency rate at 12 months [44]. The complete data from the trial and manuscript have yet to be published.

At this juncture, there is suitable safety and efficacy evidence to support using the AngioSculpt PTA scoring balloon catheter in the treatment of infrapopliteal PAD. With the recent presentation of the MASCOT trial, we believe that AngioSculpt PTA may also carve out a niche in the revascularization of femoral-popliteal disease. The AngioSculpt PTA is also FDA approved in the treatment of native or synthetic arteriovenous dialysis fistulae. As of March 2010, the FDA granted the AngioSculpt PTA balloon catheter with 510(k) clearance in the treatment of renal artery stenosis (RAS). This 510(k) clearance for RAS is predicated on the AngioSculpt PTA catheter being 'equivalent' in safety and efficacy to its use in other forms of PAD previously approved by the FDA. This clearance allows AngioScore to market the device for this additional indication, and in the future, we can expect studies examining the use of AngioSculpt in RAS.

Conclusion

The AngioSculpt represents an important device adaption/iteration from its predecessor the cutting balloon, and it may continue to have an expanded role in both the pretreatment of lesions prior to stenting and as a primary treatment in select situations. Challenging coronary and peripheral cases with significant fibrosis and calcium, lesions involving a bifurcation or ISR all represent potential uses of the device. The published registries and trials represent moderate-to-severe complex lesions and patient comorbidites well in line with the device's target population. While the positive attributes of the device's design in addition to promising initial studies are encouraging, there are no published RCTs to date comparing this device with other treatment modalities; indeed, this lack of comparative trials remains a significant problem with many of our interventional devices. What we can presently say is that the AngioSculpt device's efficacy and safety profile seems on a par with that of other commonly used devices such as the cutting balloon. It is highly encouraging that all the published experiences in sum have documented dissection rates similar to or lower than those of POBA and no reported coronary perforations to date. The scoring balloon technique remains intuitively similar to standard balloon angioplasty – this may prove to be advantageous as it fits within the interventionist's comfort zone, especially in comparison with atherectomy or atheroablation devices. With emerging applications, the AngioSculpt device may carve out a significant niche in the percutaneous treatment of coronary and vascular disease in the future.

Future perspective

The current data on AngioSculpt catheters demonstrate that this device represents a safe and viable option in the interventional armamentarium. While the current level of evidence consists only of small and mostly noncomparative

studies, it is clinically reasonable to use this device in the treatment of complex lesions with significant calcification and fibrosis both in the coronary arteries and peripheral vasculature. As with everything in clinical medicine, our end goal is to improve clinical outcomes while minimizing risk, and no device is a substitute for the technical experience of the operator. As the experience with standard balloons has proven to be safe and effective in the majority of lesions, we believe that in the absence of comparative data demonstrating superiority of the AngioSculpt balloon catheter, standard balloon angioplasty will remain the first option for lesion preparation prior to stenting. The indications for scoring balloons such as the AngioSculpt are expected to grow, but this device will probably remain reserved for complex vessels, select cases of ISR and the treatment of side branches in bifurcation lesions. Future adaptations of the AngioSculpt PTA system should allow longer length (60–100 mm) and diameter (≥6.0 mm) balloons to be used in peripheral interventions, but larger balloons will also necessitate additional nitinol scoring wires to be integrated into the device. Further improvements in the crossing profile and distal deliverability of the next-generation catheter, as well as the addition of hydrophilic coatings and catheter tip enhancements, may be expected to facilitate access to more difficult-to-approach lesions.

Adaptations of the scoring balloon concept may also hold great promise with both balloon valvuloplasty and drug-covered balloon technologies. In the cases of mitral, aortic and pulmonic stenosis, percutaneous balloon valvuloplasty remains a valid therapeutic option in select patients (e.g., those with a significant degree of commissural calcification). While this hypothesis remains to be proven, the goal of valvuloplasty is to achieve resolution of stenosis/gradient while maintaining low rates of valvular regurgitation and other complications; in this way, a scoring balloon has the potential to achieve technical success at lower pressures than standard valvuloplasty balloons. In addition, there have been several studies suggesting that balloons covered with antiproliferative drugs (i.e., paclitaxel) may adequately prevent the neointimal hyperplasia response typical after vascular damage and thus abrogate the need for stenting, thereby decreasing the risk of stent thrombosis or ISR. A catheter combining the technical benefits of scoring balloons with a drug-coated balloon would be a logical application for the next generation of AngioSculpt devices.

Executive summary

Device name

- The AngioSculpt® percutaneous transluminal coronary angioplasty scoring balloon (AngioScore, CA, USA) is used for coronary interventions.
- The AngioSculpt percutaneous transluminal angioplasty scoring balloon is used for peripheral vascular interventions.

Device description

- Semicompliant balloon surrounded by a nitinol helical cage:
  – Available balloon lengths of 10–40 mm and balloon diameters of 2–6 mm;
  – Available in both over-the-wire and rapid exchange systems.

Indications

- The AngioSculpt percutaneous transluminal coronary angioplasty scoring balloon catheter is used for the treatment of coronary artery stenosis, including complex type C lesions and in-stent restenosis.
- The AngioSculpt percutaneous transluminal angioplasty scoring balloon is used for the treatment of arteriovenous dialysis fistulae and the dilation of peripheral and renal vascular disease, excluding the neurovasculature.

Potential design benefits

- Compared with standard balloon angioplasty, the benefits are decreased balloon slippage, more uniform balloon expansion, reduced elastic recoil and improved dilation in heavily fibrotic or calcified lesions.
- Compared with a cutting balloon, the benefits are improved deliverability given smaller crossing profile and flexibility; theoretically, there is a decreased risk of coronary perforation (microtomes vs scoring wires).

Level of current evidence

- Supporting evidence only consists of registries and single-arm nonrandomized trials. Supporting studies using clinical, angiographic and intravascular ultrasound:
  – Coronary: moderately complex lesions, *de novo* lesions and in-stent restenosis; pending trials with bifurcation lesions;
  – Peripheral: infrapopliteal disease and femoral-popliteal disease.

Future studies

- Two prospective single-arm studies exist for assessing the AngioSculpt device in coronary bifurcation lesions are presently enrolling patients at the time of writing this article: the AngioSculpt Scoring Balloon Catheter for Bifurcation Coronary Lesions (ABC) study based in Israel and the AngioSculpt Coronary Bifurcation Study (AGILITY) study based in USA.

Financial & competing interests disclosure

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