EXPERT REVIEWS

The BridgePoint devices to facilitate recanalization of chronic total coronary occlusions through controlled subintimal reentry

Expert Rev. Med. Devices 8(1), 23–29 (2011)

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In view of the improved long-term patency with drug-eluting stents, the challenge with chronic total coronary occlusion remains a low primary success rate. Modes of failure to open a chronic total coronary occlusion are mainly related to the inability to pass a wire through the proximal occlusion cap, and the most difficult part of the procedure is to guide the wire into the distal true lumen. A frequent situation is a subintimal wire position. The BridgePoint (BridgePoint Medical, MN, USA) family of devices is designed to cope with both of these problems. First, the CrossBoss™ catheter aims at passing through the proximal cap by manual rotation of a blunt proximal tip, and second, in case of a subintimal position, the Stingray™ balloon enables guided reentry from the subintimal space into the true lumen. Certain features of an occlusion might favor the CrossBoss device, while the reentry approach may also be used as a standalone bailout method. The aim is to provide a means to resolve otherwise failed attempts and to make it unnecessary to resort to the more complex and time-consuming retrograde wire techniques through collateral channels with the associated potential higher procedural risks.

Keywords: chronic coronary occlusion • interventional technique • percutaneous coronary intervention • subintimal reentry

The rationale for recanalizing a chronic total coronary occlusion (CTO) is the relief of angina pectoris, the improvement of an impaired left ventricular (LV) function and a favorable effect on survival [1–5]. The percutaneous coronary intervention (PCI) in CTOs is hampered by two major problems: a higher rate of target vessel failure (TVF) than in nonocclusive lesions; and a low success rate [6]. The use of drug-eluting coronary stents (DESs) in CTOs overcame the first limitation of high TVF [7], whereas the low success rate remains a major setback in the routine approach to CTOs.

The main reason for a failed procedure is the inability of the guidewire to cross the occlusion into the distal true lumen, frequently ending up in a subintimal space. This has been documented by intravascular ultrasound [8]. A reentry into the true lumen from the subintimal space can be achieved by a forced subintimal tear with a wire, as described in the so-called subintimal tracking and reentry (STAR) technique, but the site of reentry is not controlled and side branches may be sheared off [9,10]. In the treatment of peripheral arterial occlusions of the superficial femoral artery, the same problem is faced and overcome by a directed penetration of the subintimal layer towards the true lumen with a needle [11,12]. In the smaller dimension of the coronary arterial system, no such dedicated device had been available until today.

The BridgePoint (BridgePoint Medical, MN, USA) devices, consisting of a blunt-tipped catheter to either pass the occlusion or at least create a subintimal entry (CrossBoss™), a flat-shaped balloon with side exit holes (Stingray™ catheter) and the appropriate small-diameter wire with an angled and sharpened tip (Stingray guidewire) to exit from these holes and reenter the true lumen, are the first set of tools specifically designed to facilitate the controlled subintimal reentry into the true lumen distal to a coronary

 10.1586/ERD.10.76 ISSN 1743-4440

occlusion. After an extensive series of *in vitro* evaluations and the first-in-man application to test this approach, the German and US Facilitated Antegrade Steering Technique for the treatment of Chronic Total Occlusions (FAST-CTO) studies were designed to show the feasibility of the device use in the hands of dedicated experts in the field of treating CTOs.

Market potential

The prevalence of CTOs is a much debated issue, with ranges from 20 to 35% but there is no doubt that the presence of a CTO is a major determinant to direct the subsequent therapeutic strategy away from a percutaneous intervention to bypass surgery, but also very often to medical therapy [13–16]. This has not changed even recently, when more advanced techniques improved the low primary success rate considerably [17–20]. In the recent Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX) trial of bypass surgery versus PCI, the presence of a complex CTO was one of the main reasons for ineligibility [21], as it had been the in the Bypass Angioplasty Revascularization Investigation (BARI) trial more than 10 years earlier [22]. The reason for this is that the improved success rate is highly dependent on experienced operators and the resource consumption, as well as laboratory time, is much higher than for PCI of nonocclusive lesions. Thus, in most countries with a high PCI volume, the number of PCIs for CTOs is only in the range of 5–7% [23,24].

Given these numbers of 5–10% of all PCIs being performed for CTOs and the prevalence of at least 20% in patients with symptomatic coronary artery disease, probably more, approximately 10% of CTOs remain untreated by PCI. There may be a reasonable number of patients with multivessel disease including one or more CTOs who should be transferred to surgery but we can safely assume that at least 10% of CTOs who do not receive this treatment today would be candidates for PCI. In Germany, for example, this would constitute an additional volume of 30,000 PCIs per year. It should be noted that these PCIs would require the use of DESs, as it is unanimously accepted that DESs are mandatory in CTOs to prevent lesion recurrence [25,26]. As the lesions are longer and more complex, often more than two DESs are required, highlighting the potential impact on the DES market if more CTOs were treated.

A major argument against revascularization of CTOs is based on the lack of a randomized trial to support this. However, the same arguments should apply for any other lesion subset in stable angina patients. If there are symptoms, and/or at least 10% of total myocardium ischemic, the indication is supported by the new European guideline on myocardial revascularization [27].

Device description

The CrossBoss catheter (Figure 1) is a single-use over-the-wire disposable percutaneous catheter designed for facilitating crossing of occlusions in the coronary vasculature. This is achieved by steering the 1-mm diameter distal tip of the device to the occlusion site within the native blood vessel lumen, and then rotating and advancing the catheter as necessary to facilitate advancement past the stenotic lesion. The distal portion of the CrossBoss is hydrophilic coated to enhance lubricity. A torque device, coaxially positioned over the proximal portion of the CrossBoss catheter, provides a comfortable user interface for device manipulation. The device delivers a guidewire beyond the diseased segment. Subsequent to conventional guidewire placement, PTCA catheters and stents may be used to provide therapeutic benefit. The BridgePoint Medical CrossBoss device in itself does not provide any therapeutic effect or benefit beyond simple facilitation of guidewire crossing.

The potential benefit of the CrossBoss could be the security against perforation for passing the proximal cap and the body of a CTO. The channel created could lead from true lumen to true lumen. If it goes subintimal, then this channel facilitates the advancement of the Stingray reentry catheter without extending the subintimal space. One concern for the device is that it may tend to enter into side branches, which requires careful attention, especially during the passage in the body of the occlusion, where side branches may not be visualized.

The Stingray catheter is a sterile, single-use, disposable catheter designed to further facilitate placement of a guidewire across a CTO lesion by enabling reentry into the true vessel lumen in cases where a conventional guidewire or the CrossBoss has been advanced into the subintimal plane (Figure 2). This is accomplished through the use of a distal inflatable element, which, when inflated with radiopaque contrast medium, provides visibility and intra-arterial stability. The distal inflatable element consists of two small-caliber inflatable balloons positioned adjacent to a guidewire lumen. When inflated, these small-caliber balloons, along with the lumen, generally define a planar geometry where the width of the construction is approximately three-times its height (3 mm and 1 mm, respectively). Within the inflatable element, the distal portion of the catheter includes two oppositely facing lateral ports that communicate with the central guidewire lumen. These ports allow the operator to direct a guidewire from the wire lumen at an angle to the catheter shaft (Figure 3). The inflatable

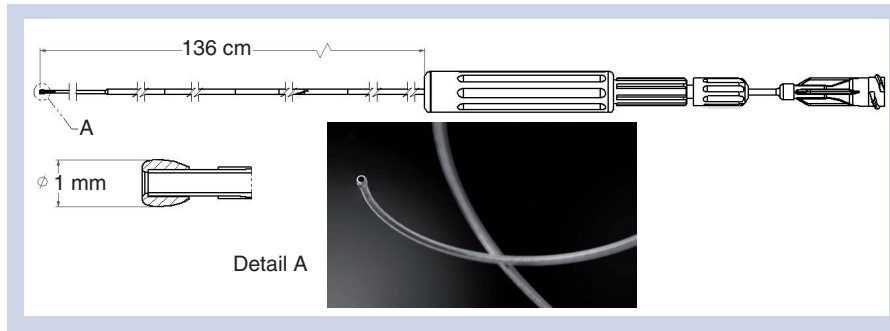

Figure 1. The CrossBoss™ catheter design features with a blunt tip (detail A) that is rotated by manual rotation of the proximal handle with a guidewire inserted (but not advanced out of the distal central lumen). The wire is held fixed by a torque.

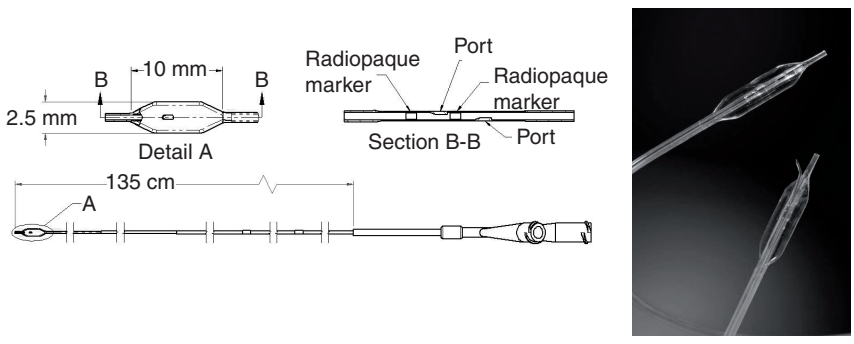

Figure 2. The Stingray™ balloon catheter design features. The balloon has a central wire lumen and a side port that is connected to the distal balloon. Because of the small balloon volume the balloon is preferably filled with pure contrast to achieve a faint contrast fill on fluoroscopy.

element, along with the lateral ports, make it possible to accurately position the distal tip of a guidewire in such a way as to allow entry back through the internal subintimal tissue without harm to the adventitia and external vessel wall. In this manner, the device provides a pathway for the advancement of a guidewire back into the true vessel lumen distal to the CTO.

The Stingray guidewire (Figure 3) is a single-use disposable 0.014-inch diameter wire designed to enhance wire reentry into the true vessel lumen with the use of the Stingray catheter. The distal portion also includes a platinum coil for visibility. The distal tip of the guidewire includes an angled geometry that transitions to a rounded tip. A short protrusion (~0.0025-inch) extends from the tip to help facilitate reentry back through the internal subintimal tissue without harm to the adventitia and external vessel wall.

Initial clinical experience

The first-in-man experience was carried out in early 2008 by a small group of US physicians (among them Lombardi, Thompson and Whitlow) in Chile treating consecutive CTO patients. Further clinical experience was gained in a European study using the devices in refractory CTOs after initial conventional wire attempts. The device success rate in these refractory cases from Europe was 67%. These studies had not been reported in full except for presentations at various medical conventions. This author gained experience with the device during the European study. Currently, the US FAST-CTO study is going to be concluded under US FDA regulations to obtain FDA approval of these devices. A CE approval for the European market had been granted in 2009. The results from the US study recently communicated during Transcatheter Cardiovascular Therapeutics 2010, held on September 21–25, 2010 (Washington, DC, USA), on refractory cases are summarized as follows. Refractoriness was established either by a previously failed attempt to cross, a concurrent attempt to cross within 10–15 min of fluoroscopy time with guidewires of the operators' choice, or entry into the subintimal space during this 10–15 min of fluoroscopy time. The primary effectiveness end point was technical success, defined as BridgePoint Medical System facilitation of placing a guidewire in the true lumen distal to the CTO. Technical success was 77%, with a 30-day cardiac death, lesion-related acute myocardial infarction and emergency bypass surgery involving the treated segment (MACE) rate of 4.8%, mean procedure time was 105 min (median: 96 min) and mean fluoroscopy time was 44 min (median: 41 min).

It is difficult to assess the potential of new devices for CTOs because a major factor of the primary success rate is the operator's experience and skill, as well as the inherent learning curve with a new device (Figure 4). The device success in the European FAST-CTO study was only assessed for a small group of operators but the interoperator comparison already showed distinct differences most likely attributable to selection differences, as the overall success rate in CTO procedures among these operators was not in line with the success rate within this study. Furthermore, the learning curve is certainly relevant for such a new device approach, which is reflected by the current experience in the ongoing US trial where a higher level of experience led to higher success rates.

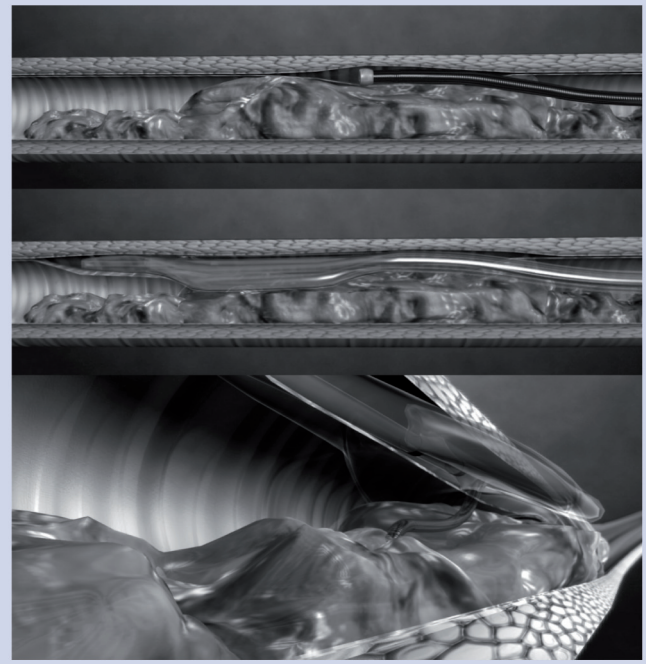

Figure 3. Schematic presentation of the advancement of the CrossBoss™ catheter through rotational movement. In this example, the catheter is entering the subintimal space. After exchange of the CrossBoss catheter over-the-wire for the Stingray™ balloon catheter, this balloon is inflated in the subintimal space at the level of the distal true lumen. One side port is then pointing towards the outer vessel wall, the other inside towards the true lumen. The Apollo reentry wire is then turned in such a way that it leaves the balloon lumen towards the inside and then immediately twisted by 180° to avoid exit on the opposite vessel wall and alignment downstream within the true lumen.

Figure 4. Case example of an occluded left anterior descending artery occlusion treated with a combined approach by the CrossBoss™ and Stingray™ catheters. (A) Approximately 20-mm long occlusion of the left anterior descending artery (between arrows). **(B)** A CrossBoss catheter is positioned at the entry into the occlusion (arrow) with the wire retracted. **(C)** With spinning movements the CrossBoss is easily advanced towards the distal cap of the occlusion. The distal morphology is unfavorable, with a diagonal side branch and several small septal branches. **(D)** Contralateral filling shows the CrossBoss tip beyond the occlusion between the branches – that is, subintimal (arrow). **(E)** A floppy polytetrafluoroethylene wire is advanced and the CrossBoss exchanged. The tip of the wire loops where the channel created by the CrossBoss ends (arrow). **(F)** Then the Stingray balloon is advanced towards the tip of the wire (arrowheads indicate the two distal markers). **(G)** The Stingray balloon is positioned approximately 1 cm beyond the distal occlusion, with seemingly overlap with the contrast filled distal vessel in the right anterior oblique projection, the arrowheads indicate the distal markers. The Stingray wire is already advanced close to the first side port. **(H)** The left anterior oblique projection reveals the position beside of the distal vessel. So both projections let the operator now direct the advancement of the Stingray wire. **(I)** The wire is directed in left anterior oblique towards the vessel lumen and punctures the true lumen; this is achieved by exit from the proximal side port proximal to the first marker. The side port that is directing towards the lumen needs to be probed gently by the operator. **(J)** After the puncture of the true lumen the wire is turned approximately 90° downstream and gently advanced under contralateral contrast visualization (arrow). Subsequently, the Stingray balloon is exchanged for a microcatheter, which is advanced into the distal vessel to then replace the stiff reentry wire for a floppy wire. **(K)** Final angiogram after drug-eluting stent placement (between arrows).
Courtesy of Etsuo Tsuchikane.

Despite the influence of a learning curve, the technical feasibility and applicability of the device concept was proven in the current study of initially failed cases. As the operators were selected experienced physicians, it may be assumed that the devices were indeed only used after a thorough attempt with conventional wires. The median refractory time with dedicated wires was 10 min, but ranged up to 90 min. The median time may appear low compared with previous studies of new devices [28–30], but in those studies soft wires were often only used for the initial probing of the occlusion, and almost never new dedicated wires of the Miracle and Confianza type, which have a much higher success rate of passing the occlusion [20].

Expert commentary

The CrossBoss device is designed for crossing the proximal cap

In its design, the CrossBoss catheter resembles the Magnum recanalization wire with a blunt ball-type tip [31]. The advancement should be performed with mechanical fast rotation to reduce friction and enable the forward push into the proximal cap. As the device is not steerable by itself, ideally it would work with an occlusion with a well-defined entry, blunt or tapered, but without a larger side branch at the site of the occlusion. The rigid design to enable the transfer of push force limits the passage through tortuous segments proximal to the occlusion. In the absence of these limitations, the device may even be able to pass the occlusion from true lumen to true lumen. A potential application might also be its use in occluded stents.

As the CrossBoss catheter has an over-the-wire design, guidewires can be exchanged during the procedure. Often a Miracle wire is used for the advancement of the device, and if the device cannot be advanced with the wire pushed back inside, the wire can be used to find an initial pathway into the proximal cap to facilitate the device advancement. In case of an inability to further advance the rounded tip, a sort of limited STAR technique could be tried with a soft lubricious wire to enlarge the subintimal space.

Severely calcified lesions may be resistant to the advancement of the catheter and the company discouraged its use in such situations, but with increasing experience these types of lesions may be attempted. The CrossBoss tip is likely to leave the true lumen into the subintimal space, especially at vessel bends, where it tends to be directed towards the outer curvature; however, to date there are no reports that the rounded tip of the device ever exited the adventitia. Therefore, it appears safe with respect to vessel perforations, if every caution is administered to avoid passage of the device into a side branch at the proximal entry into the occlusion.

The morphology of CTOs is manifold and it is unlikely that a single device design may serve all possible situations. However, it appears that if the CrossBoss device is used upfront after a conventional wire failure, the procedure can be shortened compared with the combined use, with a reentry attempt. It remains to be established with further experience which morphologies are likely candidates for an early use of this specific device.

Guided subintimal reentry using the Stingray catheter & reentry wire

The major problem in reopening a CTO from the antegrade approach is the deviation of the recanalization wire into the subintimal space, and the inability to redirect it back into the true lumen. A guided reentry, such as that applied in interventions for peripheral artery disease, is a logical step, but the dimension of the coronary artery system requires a miniaturization. This is achieved with the design of the Stingray balloon. This balloon, with its flat shape, is intended to be inflated in the subintimal space and to orient itself within this space along the course of the vessel so that one of its side port holes is directing towards the true lumen. The problem is the advancement of this balloon distal along the occluded segment towards a position where a fluoroscopic controlled advancement of the Stingray reentry wire can be executed. The creation of a subintimal space with the CrossBoss catheter is often sufficient to enable the advancement of the Stingray balloon. In cases without prior use of the CrossBoss catheter, small-diameter balloon inflation within the subintimal space may be required to create enough space for the Stingray balloon.

The reentry into the distal true lumen with the Stingray reentry wire from the subintimally advanced Stingray balloon catheter requires good visualization of the distal target lumen, most often through a simultaneous contralateral injection. The reentry wire is extremely rigid and needs to be exchanged as soon as possible for a softer wire through an exchange catheter before one progresses to balloon dilatation and stent placement. The major cause of a failed reentry would be the loss of distal contrast filling because of the extension of the subintimal space and compression of the distal true lumen. Another problem could be a failure to direct the reentry wire towards a very small distal target lumen. Thus, an early decision to use the reentry balloon before the loss of the distal target by wire manipulations that are too extensive could be a key to success.

To sum up the features of this new family of devices, one can state that the mode of action, particularly of the Stingray balloon, is certainly unique among the specific devices designed for use in chronically occluded coronary arteries. Previous devices aimed at facilitating the passage of the occlusion with more or less refined designs (Frontrunner®, Crosser, SafeCross® and Ovalum). In the preliminary studies, it was shown that the BridgePoint device allows a guided subintimal reentry if a distal target artery can be visualized by contralateral contrast filling. The upfront use of the CrossBoss catheter may cross the occlusion from true lumen to true lumen in some cases, but it certainly facilitates the advancement of the Stingray balloon within the subintimal space. Further experience will also highlight the potential of these devices and may define lesion morphologies that may be suitable for an upfront use of the CrossBoss instead of the use in bailout situations after failed wire attempts.

Five-year view

Of the many attempts to make the recanalization of CTOs more successful and/or reduce the procedure time with the development of dedicated devices, none of them is of relevance for

clinical practice and many disappeared despite gaining FDA approval. This highlights the problematic market situation and specific complexity of the task to improve the success of the interventional treatment of CTOs. The only advancements with considerable impact of the procedural success rate were related to improved wire technology and wire strategies, most notably the highly torquable wires of ASAHI Intecc (Nagoya, Aichi, Japan) with their high range of penetration power. Following this, the retrograde approach supporting the antegrade wire passage through wires advanced via the tiny collateral connections from contralateral vessels brought a decisive further improvement, making success rates of more than 90% possible. However, with these new strategies, the broad application in daily practice became even more difficult, as limited resources, laboratory time and the need for specific training, restrict the wider use. Currently, it does not appear that these improvements of procedural success in expert hands changes the situation in the daily routine approach towards CTOs.

The BridgePoint device family bears the potential to change this current development, as it helps to solve one of the major modes of failure of the antegrade wire approach, the subintimal wire exit by a guided reentry. If this can be achieved without the need for the retrograde techniques, operators without the specific expertise in the retrograde approach will be able to resolve complex and potentially failed CTO attempts by use of the BridgePoint devices. Even experts may use these devices more frequently as restrictions and regulations on radiation exposure require shorter procedures, and this appears to be possible with the BridgePoint devices.

Financial & competing interests disclosure

The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

Key issues

- The BridgePoint catheters are the first devices for the treatment of chronic total coronary occlusions (CTOs) to allow a guided reentry from a subintimal wire position into the true distal vessel lumen.
- The CrossBoss catheter also facilitates a rapid true lumen to true lumen passage of the proximal occlusion cap in relative straight segments, in case of subintimal exit of the catheter tip with low risk of perforation, it creates a space for the reentry balloon catheter.
- A prerequisite for the successful application is the preserved contrast filling of the distal target lumen, which requires contralateral injection in most cases.
- The reentry wire is a stiff wire with a fixed bend, which requires careful and gentle advancement after the lumen reentry, as it may re-exit on the opposite wall.
- With increasing experience these devices may help to reduce the need for complex retrograde techniques for failed antegrade recanalization attempts.
- In the quest for an increased primary success rate in even complex CTOs, these devices provide a new option that was not available previously.

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