Randomized comparison of the magnetic navigation system vs. standard wires in the treatment of bifurcations

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Aims
Randomly compare the magnetic navigation system (MNS) to standard guidewire techniques in managing bifurcating lesions.

Methods and results
Thirty-one consecutive patients with bifurcating lesions were randomized to cross the bifurcating vessels prior to treatment and thereafter the struts of deployed stents with either magnetic or standard guidewires. Crossing success, crossing/fluoroscopy times, and contrast media usage were directly compared. Similar times were noted in both the magnetic wire crossings (median, IQR; 68 s, 45–138 s vs. 59 s, 32–133 s) and fluoroscopic times (median, IQR; 62 s, 44–135 s vs. 55 s, 27–133 s) when compared with standard conventional wires passage through the deployed struts. The MNS successful crossings were 30/31 (96.8%) compared with 28/31 (90.0%) observed with the standard wires. Two previously failed standard wire cases were successfully crossed with magnetic guidewires.

Conclusion
In contemporary stented bifurcations, the MNS achieved equivalent crossing/fluoroscopy times through deployed stents struts and may be useful in salvaging failed standard wire cases.

Keywords
Bifurcations • Coronary artery disease • Magnetic navigation • Three-dimensional reconstruction and contrast media usage

Introduction
Drug eluting stents have radically changed the management of coronary bifurcations. To improve outcome kissing balloon dilatation, post-stenting is desirable. In the ‘crush’ bifurcation technique, two layers of stents are crossed in order to access the side branch. In others (T-stent, provisional, or culotte), recrossing of a single layer is required. Gaining access to the side branch can be challenging and give rise to the more dedicated stents.1,2 We have previously reported that magnetic navigation system (MNS) successfully steered a guidewire through layers of a crushed stent into a side branch that failed with standard conventional wires.3 This is because this system can offer precise distal control at the wire tip to avoid tracking a false lumen in a dissected vessel. We therefore evaluated feasibility of the MNS in the recrossing overlying stent struts in bifurcations and randomly compared its performance to conventional wire approaches.

Methods
Patient selection and definitions
In a 12 months period, 31 consecutive stable or unstable angina patients with bifurcating lesions on angiography were managed with the MNS (Stereotaxis, St Louis, MO, USA). All patients were single blindly randomized to cross both limbs of the bifurcation twice, either using a standard/conventional or a magnetically enabled guidewire. This was done by choosing sealed envelopes instructing the operator to use either the standard/conventional or the magnetized wire as the first choice for crossing the vessel. Having crossed and acquired the necessary data for the first choice wire, the data for
the comparative wire were acquired for each limb of the untreated bifurcated vessel.

Following a pre-specified treatment strategy for the bifurcation as determined by the operator, the layer of stent(s) covering the ostium of the vessel was then recrossed to allow kissing balloon dilatation. This crossing of the overlying stent struts was again randomized as described earlier to be recrossed twice either by using a standard/conventional or a magnetically enabled guidewire as a first choice. The crossing success, crossing/fluoroscopy times (s), and contrast media usage (mL) for both techniques were determined from the transit of the guidewire at the tip of a guide catheter engaged at the ostium to a pre-defined point in a distal vessel. Inability to cross within 6 min with either wire was defined as a failure in accordance to previously published studies. Within the 6 min, conventional wires could be removed from the catheter, reshaped, and exchanged to improve success. Operators were senior interventional cardiologists trained with the MNS and had unrestricted access to both guidewire types. The study was locally approved; patients were appropriately informed and gave written consent to the procedure. Haemodynamically unstable or patients with contraindications for the MNS were excluded.

The magnetic navigation system

The Niobe™ II MNS (Figure 1) is now well described. Briefly, it orientates a small (2–3 mm long) magnet embedded at the tip of the guide wire or catheter through a predetermined rapidly updated external magnetic field. The software (Navigant™) directly incorporates two-dimensional angiographic films or a three-dimensional reconstruction (3DRC) of the vessel using another dedicated software (CardioOp-B, Paieon Medical Inc., Rosh Ha’ayin, Israel) to create a navigational pathway depicted as a centre-line through a virtual vessel (Figure 2A). Steering via a virtually created lumen (Figure 2B) is also possible after co-registration with the live fluoroscopic image (Figure 2C). To guide the procedure, both the vectors and navigational centre-line are displayed on the live fluoroscopic X-ray image (Figure 2D). Vectors are automatically updated but can be manually modified via the touch sensitive monitor situated at arm’s length from the operating table.

Figure 1 The magnetic navigation system. (A) The Niobe™ II magnetic navigation system showing the magnets in the tilting position and (B) the touch sensitive screen monitor situated at arm’s length that is used to re-orientate the magnetic wire without the need to remove it from the patient.

The guidewires, bifurcation classification, and treatment strategies

The following standard/conventional wires and magnetic guidewires were used in this study: PT Graphix™ Intermediate, Choice™ PT Floppy (Boston Scientific Corp., Miami, FL, USA), Whisper, Pilot 50, and high torque BMV (Abbott Vascular Devices, Redwood, CA, USA), 2 mm angled or 3 mm straight magnetic tips Titan™ Soft Support (Stereotaxis, St Louis, MO, USA). Bifurcations were managed with contemporary one or two stent bifurcation strategies involving the ‘crush’, ‘T-stent’, ‘culotte’, provisional, and the Tryton™ Side Branch Stent. Crossing of a single layer of stent (T-stent, culotte, provisional, and the Tryton Side Branch Stent) was directly compared with the ‘crush’ (two stent layers) technique. Drug eluting stents were used in all the treatment strategies either on their own or in combination with the Tryton Side Branch Stent strategy.

Statistical analysis

Non-normally distributed variables were observed for both the crossing/fluoroscopic times (s) and contrast media usage (mL) and are therefore presented as median and 25–75% interquartile ranges (IQR).

Results

In a population consisting of mainly stable angina patients (25 patients, 81%), the treated bifurcations involved mostly the left anterior descending (LAD)/diagonal (D) (25 patients, 81%). Others were found in left circumflex (LCX)/obtuse marginal (OM) arteries (5 patients, 16%) and the right coronary/posterior descending artery (PDA) (1 patient, 3%). Using the Medina classification, 74% (23 cases) had diseased proximal main vessel, 87% (27 cases) diseased distal main vessel, and 81% (25 cases) diseased side branch.

Success in wire crossing native bifurcation

In all cases, both the conventional and the magnetically enabled wire successfully crossed both branches of the non-stented pre-treated bifurcation within 6 min. The magnetic wire was, however, observably slower (Table 1). Relatively less contrast media was used (Table 2) in crossing both limbs of the bifurcation with magnetic wires (median, 25–75% IQR; 2 mL, 0–5 mL vs. 4.5 mL, 0–7 mL).

Success in wire crossing stented bifurcations

Overall the magnetic wires appeared better in crossing the stented bifurcations [(30/31) 96.8% vs. (28/31) 90%]. The only failed magnetic case (LCX/OM, Medina classification of 1,1,1) involved ‘crushed’ Taxus™ stents and a 3 mm long magnetic tip that ‘bucked’ as the wire got caught between the strut layers. By employing software that increased the angular gain at the wires’ tip, it was possible to negotiate through an alternative set of overlying stent struts after 8 min. One of the failed standard/conventional wire cases (LAD/D, Medina 1,1,1) also involved two crushed Taxus stents and a Pilot 50 guidewire (Abbott Vascular Devices) caught between the struts that could not be advance distally. By manually creating a different angulated bend, a Graphix™ Intermediate guidewire was able to engage an alternative cell to
enable a successful crossing. In the two other failed standard/con-
ventional wire cases, procedural success was a direct consequence
of the magnetic wire. Both cases involved the LAD/D with diseased
side branches (Medina 1,0,1 and 0,1,1) and treated with ‘crushed’
Taxus (3.5 × 24 and 2.25 × 16 mm) and Taxus (3.0 × 16 and
2.5 × 12 mm) stents, respectively. False lumens created by the
conventional Graphix Intermediate guidewire dissecting between
the layers of the vessel and the underlying stent prevented a
standard/conventional wire to engage the true ostium (Figure 3).

By circumnavigating away from the dissected false lumen, the
magnetic guidewire was able to successfully track into the true
lumen to complete the procedure.

### Assessment of crossing and fluoroscopic times
Equivalent times were recorded for both the magnetic and stan-
dard/conventional wires for recrossing (median, IQR: 68 s, 45–
138 s vs. 59 s, 32–133 s) and fluoroscopy (median, IQR: 62 s,
Comparable data were observed in recrossing a single layer of stent (Median, 25–75% IQR (crossing times: 50 s, 37–103 s vs. 49 s, 30–109 s) and (fluoroscopy times: 48 s, 36–109 s vs. 37 s, 27–101 s)), but longer times were observed with double stent layers as in the crush technique [(crossing time: 109 s, 55–155 s vs. 72 s, 41–108 s) and (fluoroscopic time: 90 s, 55–150 s vs. 71 s, 41–173 s)] for the magnetic and standard/conventional wires, respectively (Table 1). No differences were noted in the use of contrast media with respect to single/double stent layers crossed (Table 2); however, the overall contrast media usage was observably less with the magnetic wire.

### Discussion

Having established a role in some electrophysiological procedures, the MNS is being extended to percutaneous coronary interventions. Early reports appear promising for failed complex conventional cases and in crossing tortuous vessels. Randomized direct comparisons with conventional wire techniques are scarce, as current technical limitations curtail the system’s potential advantage over conventional wires approaches in all but rather than a selective PCI patient population. The rigid 2–3 mm magnetic tip limits flexibility when compared with the smoother transition of the tip and shaft observed with standard conventional wires. Furthermore, the ‘ocular-hand coordination’ of the ‘seasoned’ conventional PCI operator seems currently unbeatable as time is lost in moving the large external magnets to realign with the desired vectors. It is also an expensive technology requiring a learning curve for both the operator and the technical staff.

In this first randomized study directly comparing the performances of magnetic and standard conventional wires in managing routine bifurcating lesions, the MNS had a higher procedural success. But this could be due to chance since the study is small and operator bias could not be entirely excluded. The MNS took longer to cross pre-treated bifurcating vessels than the conventional wires because time was lost as software available at that time required manual updates of the navigational vectors on the touch screen monitor. Even though equivalent times were observed with respect to the overall stent struts (one and two layers) being crossed, the minor benefits observed in contrast media reduction with the magnetic wires suggest that at present the MNS offers no significant advantage over conventional guidewire procedures.

The MNS salvaged failed standard wire cases by avoiding the wire entering false lumens of dissected vessels. This is because of the system’s ability to orient the wire tip within the proximity of the carina so as to engage an alternative set of cells without causing vascular trauma. This is unlike the standard wire where in two of the failed cases the operator unknowingly forced the wire between the struts and the vascular wall creating a false lumen. Future multi-magnet tips having gentler transition with the shaft may alleviate some of the current problems in recrossing,

### Table 2  Contrast media used in crossing the untreated and treated bifurcating lesions

<table>
<thead>
<tr>
<th></th>
<th>Native untreated bifurcation, n = 31</th>
<th>Overall treated bifurcation, n = 31</th>
<th>One layer of struts, n = 14 (45%)</th>
<th>Crush/two layers of struts, n = 17 (55%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contrast (mL) used with magnet wire</td>
<td>2 mL, 0–5 mL</td>
<td>0 mL, 0–5 mL</td>
<td>0 mL, 0–3 mL</td>
<td>2 mL, 0–5 mL</td>
</tr>
<tr>
<td>Contrast (mL) used with standard wire</td>
<td>4.5 mL, 0–7 mL</td>
<td>5 mL, 0–9 mL</td>
<td>4.5 mL, 0–6.8 mL</td>
<td>5 mL, 0–15 mL</td>
</tr>
</tbody>
</table>

Values are given as median, 25–75% interquartile range (IQR).
but at present the system offers no clear advantage over conventional wire techniques.

The paper, however, demonstrates that the MNS is a unique technology that gives the operator precision control at the point of intervention. It also recognizes the system’s ability to co-integrate computer modelled 3DRC of the vessel. This 3-dimensional precision guidance either via modelling or directly though computer tomography integration can offer a further niche for adopting the MNS in managing more complex anatomies such as occluded vessels, anomalous coronary arteries, and highly angulated vasculature. With over 150 systems installed globally, it is anticipated that a network could be established in the near future for operators to plan and exchange these difficult cases.

Limitations

Only a relatively small number of patients with bifurcating lesions were admitted into the magnetic room over the study period. The 3DRC was time-consuming (up to 30 min) and required angiography of a suitable standard that was not always possible from standard views due to foreshortening or overlapping. The static road map created from the 3DRC image was superimposed on a dynamic real-time image for magnetic navigation, and hence only in one phase, the wire tip was perfectly aligned. There were a number of operators and types of wires and this, together with no selection of the target vessel segment, may have led to heterogeneity. Also as the operators were not blinded to the wiring technique, the possibility of operator bias as a major limitation of the study could not be excluded in this study. At present, without data on clinical efficacy or cost-effectiveness, it may be difficult to justify initial investment in this novel technology. We also appreciate that this technology is limited thus far to only a few institutions.

Conclusion

In this small study population, the MNS had comparable crossing/fluoroscopic times to those achieved with conventional wiring techniques and may successfully salvage failed conventional cases. A larger patient population in additional centres is warranted. Moreover, the potential enhancement in magnetic techniques is eagerly anticipated.

Conflict of interest: none declared.

References