

Endografts and the Aortic Arch: Zenith TX2 With Pro-Form

Control of endografts in the distal arch was difficult due to issues with conformability and accuracy—advances in graft technology may ensure a higher degree of technical success.

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Endovascular repair of the thoracic aorta has rapidly become the first-line therapy for many thoracic diseases, including thoracic aneurysms, acute complicated type B dissections, and traumatic aortic injuries. The success and rapid adoption of endovascular techniques in these areas is remarkable given the hemodynamic and anatomical challenges that occur in the distal aortic arch and proximal descending thoracic aorta, as well as the fact that most thoracic endografts have evolved from abdominal prostheses, which are designed for an anatomy that poses considerably fewer technical challenges.

CHALLENGES IN TREATING THE DISTAL AORTIC ARCH

The pathologies suitable for endovascular therapy mandate that a large proportion of thoracic endografts

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have a proximal sealing zone in the proximity of the left subclavian artery.^{1,2} There are considerable anatomical difficulties in this area due to the curvature of the aortic arch, which may be steep and make conformity of the graft to the aortic surface tenuous. In early experience, at least 2 cm of proximal sealing zone was required on the inner curvature of the aortic arch to effect an adequate seal. In many cases, this proved difficult, with the necessity to overstent the left subclavian artery to achieve an adequate landing zone. Overstenting the left subclavian artery has significant implications for stroke and spinal cord ischemia,^{3,4} and a prophylactic bypass was often required.

Conformation of a thoracic endograft to the distal aortic arch sealing zone is a key parameter in thoracic endografting; this property may influence technical success of the procedure, because poor conformity may result in a type 1 endoleak through the inner curvature of the arch (Figure 1). Similarly, the difficulties with graft conformability in this zone may influence late migration of endografts through an angulated sealing zone and the high hemodynamic forces present in this area of the thoracic aorta (Figure 2). Type 1 endoleaks and migration have been problematic throughout the early experience of thoracic endografting and often necessitate insertion of additional stents or the deployment of balloon-expandable stents

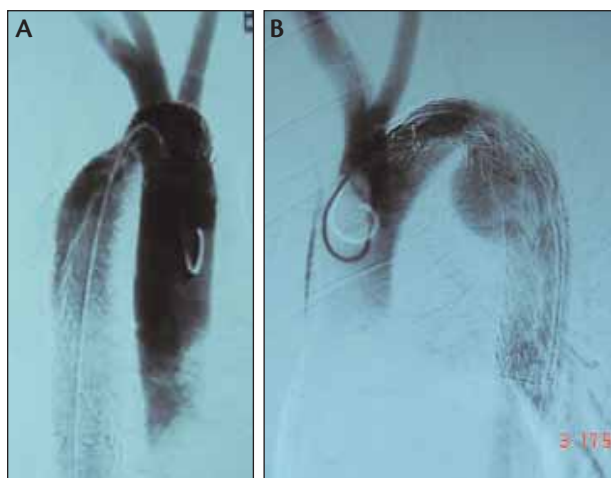


Figure 1. Two views of proximal type 1 endoleak after deployment of a thoracic endograft.

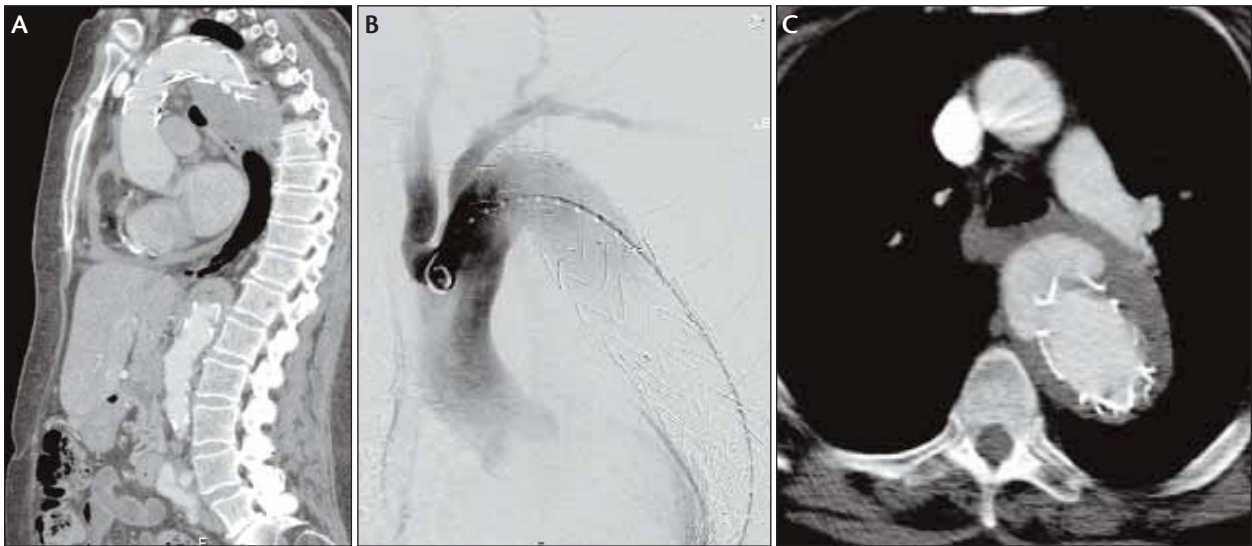


Figure 2. A well-placed thoracic endograft (A) has migrated (B) leading to a large proximal type 1 endoleak (C).

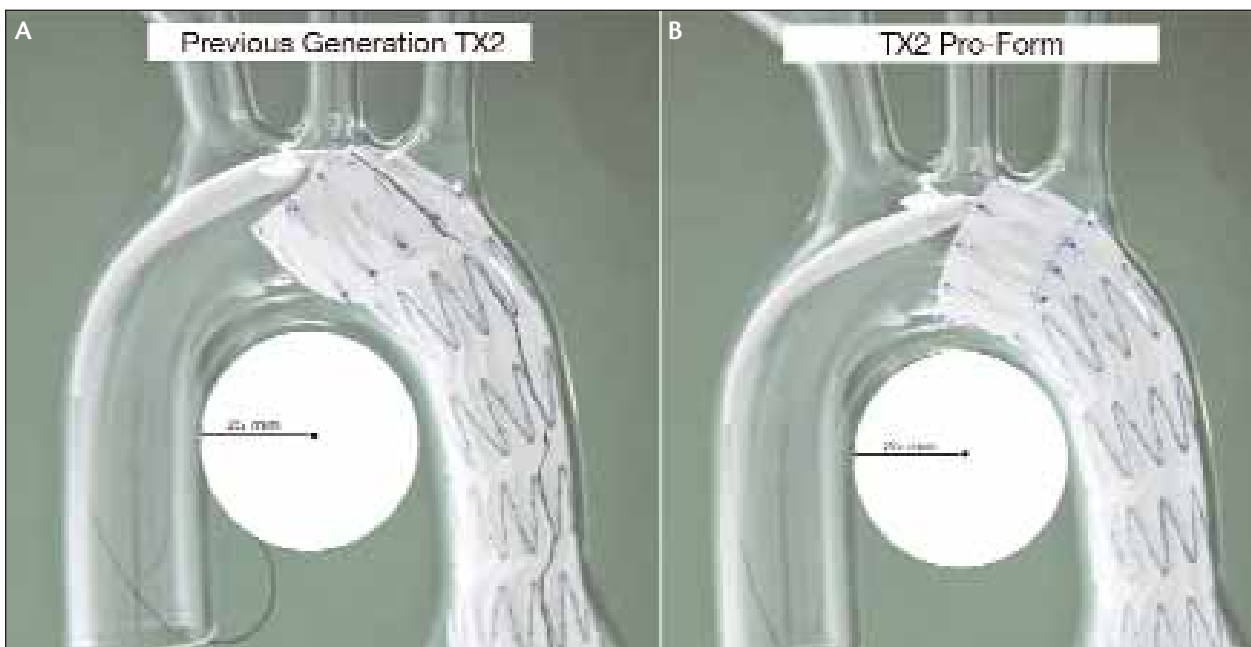


Figure 3. Standard (A) and Pro-Form (B) modification of the TX2 thoracic proximal component (Cook Medical, Bloomington, IN) showing better apposition to the lesser curve in the modified endograft.

to force the endograft to appose the aortic wall.

In addition to the challenges posed by the angulation of the distal arch, the hemodynamic forces in this zone should not be underestimated. High hemodynamic forces may cause inaccuracy in deployment or distal movement of the endograft.

COOK'S ZENITH TX2 THORACIC ENDOGRAFT

Like many endografts, the TX2 proximal component often required a long landing zone to compensate for

the relatively poor conformability to distal arch anatomy. In an attempt to increase conformability and deployment accuracy in such anatomy, the Pro-Form modification was developed (Figure 3). Pro-Form is an adaptation to the TX2 proximal components that uses the existing trigger wires to “diameter reduce” the back end of the sealing stent. When the sheath is pulled back, the trigger wires that previously held only the proximal end in the trifold now also hold down the back end of the sealing stent. The effect of restraining the back end is that on a tight curve, the advancing

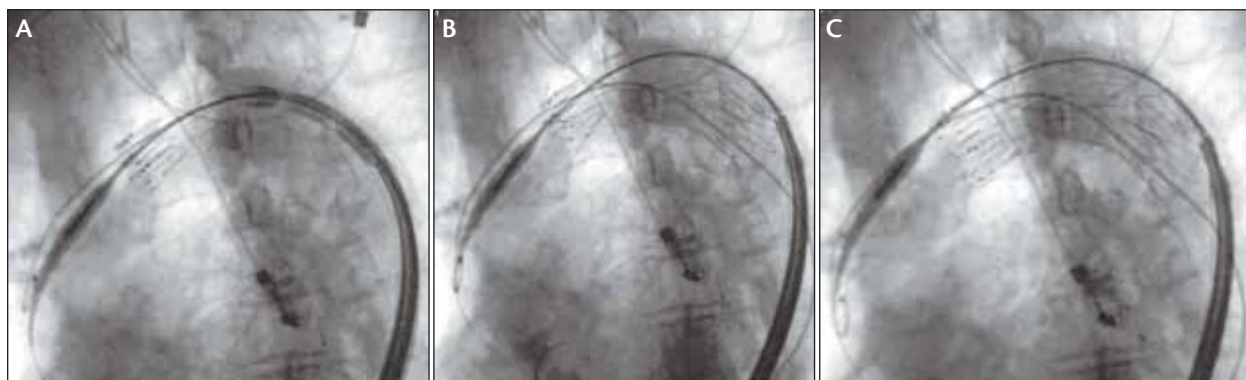


Figure 4. The deployment of the TX2 Pro-Form in the distal arch (A, B). The graft is completely deployed in the last figure (C), which shows the appearance of the graft when the trigger wire is removed.

graft travels more parallel to the aortic lumen. It is less apt to orient toward the top of the arch. Upon release of the trigger wires, the graft material stretches along the top but becomes pleated on the underside to conform to the inner curvature. Simultaneously, the lead stent overlaps the second stent. At the inner curvature, both the first and second stents are brought into contact with the aortic wall.

The engineering behind this modification involves so-called trigger wires that remotely connect the operator's hands to the graft. With the current TX2 proximal component, four small-diameter wires travel up through the introducer and tether to the graft to hold onto it. The Pro-Form modification, while still featuring the familiar trifold proximal configuration, uses these same wires to also capture the distal end of the sealing stent. At the distal stent level, wires pull both the graft and stent inward in diameter. This is accomplished by the use of a circumferentially sewn suture on the outside of the graft, the eyelets of which are pulled internally, looped, then captured by the lengthwise-running trigger wires.

EARLY CLINICAL EXPERIENCE WITH ZENITH TX2 WITH PRO-FORM

In our early experience with the Pro-Form TX2, there appear to be significant advantages to the modified system. Deployment in the distal arch appears more reliable due to the graft not contacting the upper curvature of the arch early in the deployment sequence. This, allied to the restraining nature of the trigger wires, facilitates a more accurate deployment. Additionally, the Pro-Form appears to result in overlapping of the first two stents, which allows an apparent greater conformability (Figure 4). Clearly, the performance of this device will be evaluated qualitatively, because any quantitative evidence of improved performance is unlikely.

CONCLUSION

The conformability of endovascular stent grafts in the distal arch is a key performance indicator and will be the subject of much research in design. The conformability and accuracy of deployment will be governed by several factors that will include stent design, stent length, distance between adjacent stents, and the type of fabric employed. One valuable lesson from the development of the Pro-Form is that the delivery system plays a crucial role in the behavior of thoracic endografts. ■

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