# ZFEN Technology: Why It Works and What's in Its Future

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The following quote from David Hartley, FIR, remains true today: "It has become clear that not only the technology but also disease progression plays an important role in the durability of endovascular aortic therapy."[1] Endovascular aneurysm repair (EVAR) has changed the way we manage aortic aneurysms. Although the initial focus was on comparisons with open surgical repair, efforts have more recently been on how to expand the indications of EVAR to the 40% of patients who have inadequate landing zones or involvement of the visceral arteries. In these patients, there has been a push for more liberal indications outside the instructions for use and to shorten the minimum neck to 10 mm or less, including the use of parallel grafts or endoluminal stapling. Although some studies have shown favorable early outcomes with short neck indications, others caution higher rates of failure. Moreover, this change in paradigm is coming at a time when long-term results of the EVAR trials indicate a higher risk of aneurysm rupture for patients treated by EVAR compared to open repair.[2,3]

In the last decade, we observed a surge of innovative techniques to extend the indications of EVAR with fenestrations, branches, and parallel stent grafts. Fenestrated endografts have widely been used with increasing clinical experience in the last 2 decades. It is estimated that over 20,000 patients have been treated worldwide (Cook Medical, personal communication). In the United States, the Zenith Fenestrated (ZFEN) stent graft (Cook Medical) was approved by the US Food and Drug Administration for commercial use in April 2012. The device is designed with a maximum of three fenestrations and is indicated for patients who are not candidates for infrarenal EVAR because of short necks between 4 to 14 mm.

## WHY IT WORKS

Endovascular sealing is based on the principle that a close interaction between the stent graft and the aortic wall is needed to exclude the aneurysm sac. Thrombus, calcification, short length, and gutters violate this principle. Selection of the landing zone has significant ramifications on endovascular repair, because the aorta continues to enlarge adjacent to aneurysmal segments.

The implications of poor neck selection can be noted intraoperatively but are more often evident 3 to 5 years after the procedure.[2,3] Majewski et al observed that 60% of patients treated by open repair for juxtarenal aneurysms had enlargement of the aorta above the graft anastomosis.[4] Neck dilatation is more prominent with self-expandable stent grafts, which are typically oversized to the normal aortic diameter. Enlargement is > 10 to 15 mm below the renal artery origin and in patients who have proximal necks > 30 mm in diameter.[5-7] Neck enlargement continues to progress even in patients who experience a decreasing aneurysm sac and have no evidence of endoleaks.[8] This process continues beyond 5 years after the initial procedure.[9]

The problem of using short neck indications is that treatment of a failed EVAR remains a challenge with significant morbidity and mortality. Several studies have shown that open surgical explantation for failed EVAR is associated with higher morbidity and mortality.[10] Salvage endovascular procedures (eg, placement of cuff extensions) or chimney grafts are not as effective and may potentially lead to more reinterventions, added cost, and loss of renal function. As for salvage with fenestrated grafts, these are technically more demanding and are associated with lower technical success.[11] For these reasons, the first repair needs to be planned with the goal of long-term durability for the lifespan of the patient.

## ZFEN AND FUTURE PERSPECTIVES

The United States Zenith Fenestrated trial has shown that the procedure is safe and effective.[12] Mortality was low (1.5%) with no conversion, aneurysm rupture, and with a low rate of renal artery occlusion (4%). Secondary renal stent patency was high (97%). Type Ia endoleak occurred in only one patient at 3 years due to enlargement of the aortic neck. These results have been replicated by systematic reviews, as well as multicenter and single-center experiences.[13-16]

Two-thirds of patients with complex abdominal aortic aneurysms are not candidates for the ZFEN device due to its design constraints. The maximum of three fenestrations (one nonreinforced) and the use of single-diameter scallops limit the ability to achieve sealing zones above

the superior mesenteric artery or celiac axis, making it impractical to treat suprarenal aneurysms while maintaining the very principle of long, healthy sealing zones.

The next generation of ZFEN devices is being designed to address these limitations and will include features that help to facilitate technical aspects of the procedure. These improvements in device design will also allow for extending the repair to the supraceliac aorta, even for short-necked infrarenal aneurysms, if there is concern with progression of aortic disease. Recent clinical experience with three- or four-vessel fenestrations demonstrates high technical success and low morbidity and mortality, with lower rates of type Ia endoleaks long term as compared to one- or two-vessel fenestrated endografts.[12-16]

## SUMMARY

The ZFEN device represents an initial step forward in achieving durable sealing zones in patients with what has been considered "unfavorable" neck anatomy for infrarenal EVAR. The articles in this supplement aim to further illustrate how far the fenestrated EVAR concept has evolved, with excellent and durable outcomes throughout the years of its commercial use. Cook continues to advance this technology forward with improvements in device design, implantation techniques, and adjunctive maneuvers to decrease mortality and morbidity, with the long-term goal of achieving the most durable repair possible.

We greatly appreciate the efforts of the authors who have contributed to this edition, and we hope you will find the following articles to be informative and valuable in your practice. ■

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