

Evolution Not Revolution: The Altura Stent Graft

Taking EVAR to new heights.

BY PAUL HAYES, MD

Evolution is the gradual, progressive development of an entity that is driven forward by a pressure for change. It often occurs over a prolonged time span, during which some developmental steps improve the entity, but others fail. The effects may be gradual, but the impact of a successful evolutionary change can have profound and long-lasting effects on the status quo of those around them.

Revolution is often very abrupt and dramatic, and it may have profound consequences far beyond what those driving the change ever thought possible. Those unforeseen consequences sometimes lead back to a less advantageous position than before the revolution. These sudden changes are often short lived, and can lead back to the starting position. It should be noted that evolution has won far more Nobel prizes than revolution.

So, is the Altura endograft system (Lombard Medical, Inc.) (Figure 1) evolutionary or revolutionary? At first sight it might seem revolutionary, but in most senses, Altura is a conventional endovascular stent graft. It has long suprarenal bare springs with active fixation, a nitinol frame, a fabric polyester sleeve, and the flexibility of a modular system (Figure 2). The evolutionary step was to split the main infrarenal body into two sections, which has had several profound and beneficial consequences.

DEVICE DEPLOYMENT

Altura has simplified the critical first step in all endovascular aneurysm repair (EVAR) procedures—planning. Diameters of the proximal and distal landing zones are measured like usual, but the flexibility of the Altura system's total length means that there is a good degree of latitude in terms of length planning, which is often the more involved planning stage. The top and bottom stents are placed first, and if the stent overlap is too small, a simple universal bridging piece is placed to bridge the central portion.

Deployment is very simple. First, the two aortic com-

ponents are introduced bilaterally, opening one delivery system 1 cm to 2 cm and injecting contrast through the partially open sheaths to visualize the renal arteries. Working stepwise, the proximal parts of both stent grafts' "D" portions are released while retaining the bare stents in the top caps of the delivery systems. The flat faces of the "Ds" are easily aligned in a medial position with three clear markers (Figure 3). A single lateral marker is used for aligning height wise with the renal arteries. After rotation and alignment, both stents are expanded to be a snug fit in the aorta. If the position of the stents isn't optimal, the expansion can be reversed, repositioned, and reexpanded until optimal positioning is achieved (Figure 4). Next, the two top caps are pushed off to release the long suprarenal bare stents and anchors, and the remainder of each

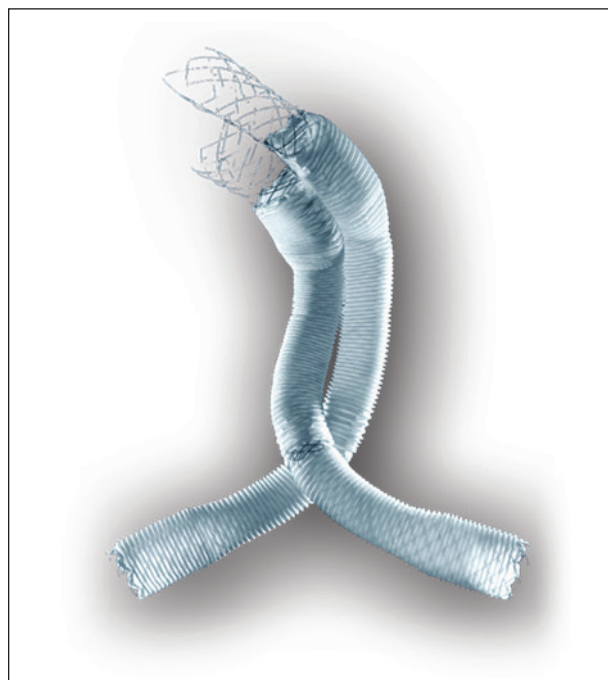


Figure 1. The Altura stent graft.

aortic stent graft is unsheathed. The delivery systems are then removed.

There is no need for contralateral limb cannulation here, as both iliac limbs are simply inserted over the preexisting stiff wires. The distal end of the limb is placed at the approximate location of the iliac bifurcation and about 1 cm of sheath is deployed to allow injection of contrast. This shows the internal iliac and allows the distal end of the stent graft to be placed accurately at the bifurcation of the common iliac. Keep deploying the sheath, and the limb will be deployed from distal to proximal (Figure 5).

A little downward traction once the distal end of the stent has opened will allow it to sit into the bifurcation, utilizing all the iliac vessel length. If the iliac vessels are stenotic or there is a narrow distal aorta, it can be very helpful to pull the delivery system slightly distally during deployment as this will dilate the stent graft and give it quite significant radial strength. Once deployed, the delivery systems are removed, the device is ballooned, and the procedure is complete (Figure 6).

EVOLUTION IN DESIGN

The diameter of conventional stent graft delivery systems is driven by the need to contain the metalwork and fabric for the whole main body in a single delivery system. There has been pressure from both physicians and patients to lower delivery system profiles to reduce vessel trauma and facilitate shorter length of stays. This has driven manufacturers to reduce the density of their graft fabrics and to make thinner wire frames, while simultaneously packing these potentially less robust materials more tightly into smaller delivery systems. Some consequences of these changes have become apparent recently with unexpected reports of short-term durability issues. The longer-term consequences of using less robust structures remain to be seen.

The simple division of the main aortic body has many important consequences:

- EVAR planning is further simplified
- Very low-profile delivery without compromising resilience
- Procedures are shortened and more predictable
- Retrograde iliac deployment maximizes sealing in short iliac vessels
- Proximal stent off setting utilizes the full potential of the aortic neck
- Early clinical data support these apparent benefits
- The 1,000-patient ALTITUDE registry will begin enrollment very soon

Two features of Altura have allowed for a significant reduction in delivery system diameters without compromising the construction materials in any way. The most obvious is the fact that splitting the main body into two pieces physically requires less space in which to pack the materials (Figure 7). The less obvious feature is the fact that the braided nature of the Altura nitinol frame allows the diameter to be reduced further by simply stretching it out as it is packed in the delivery system. The volume of material used remains the same but unlike conventional Z-stents, its diameter can be reduced by elongating the cylinder it is constrained in. These features allow a robustly constructed stent graft to be delivered through a 14-F system. Such low profiles can drive changes in practice, such as day case EVAR using percutaneous access or a simple cut down in the SFA under local anesthetic.

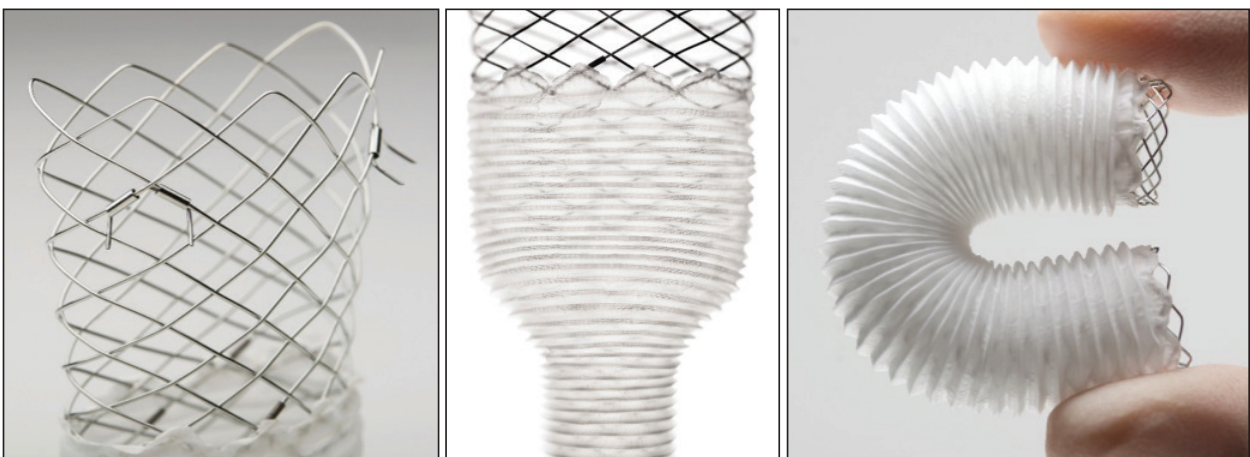


Figure 2. [PLEASE PROVIDE CAPTION]

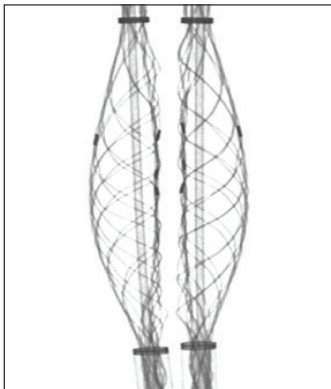


Figure 3. [PLEASE PROVIDE CAPTION]

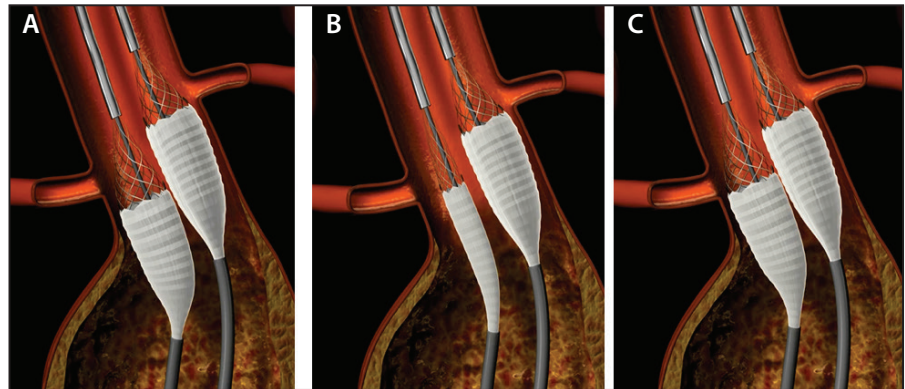


Figure 4. Suboptimal initial position (deployed low) (A). Low device reconstrained and moved proximally (un-deployed) (B). Optimal aortic neck landing zone created (repositioned) (C).

At a time when physicians are looking to maximize the durability of EVAR, maximizing aortic coverage has gained increased importance. This is based on the concept that the more the stent graft is in contact with healthy aortic wall, the better the longer-term outcomes are, and this seems to be borne out by the available evidence.^{1,2} It is not unusual to leave healthy aortic neck unused in many cases, and this is where the top of the covered stent graft is deployed at the lowest renal. Sometimes the offset between renal arteries is quite small, but it is relatively common to have differences in height where clinically useful aortic neck is not being utilized.³ The “D” faces of Altura are 25 mm long, allowing one stent to be placed up to 10 mm further into healthy aortic neck while still leaving a 15-mm flat sealing zone between the stents. The ability to maneuver the tops of the stent grafts individually can be particularly useful where some neck angulation exists because in this setting, the top of conventional stents tends to fall away from the outer curve, losing valuable neck length.

On occasion, physicians unintentionally end up with a device that is deployed a bit lower than they intended, although we don't all admit it. A second feature of the Altura system that aides maximal use of the healthy aortic neck is the ability to fully expand the “D” sections of the graft, check the seal and position of the renal vessels, and then if needed, can reconstrain the device and move it into a better position. This can be repeated until an optimal position, utilizing all the available neck, is achieved (Figure 8).

As well as achieving a durable proximal seal, it is equally as important to maximize the seal in the iliac vessels.⁴ Traditionally, all standard limbs deploy from the top down, and although they are often planned to land at the

iliac bifurcation, it is a common and frustrating occurrence to watch the distal end of the limb pop northwards as it is finally released. When conventional devices are packed, there is an inherent residual tension in the graft fabric, and because they are fixed proximally first, the only direction for the distal end to move is upwards. In a 5-cm iliac, this is of little consequence, but when there is only 25 mm to land in, this can clearly impact long-term durability. To adapt to this problem, Altura has simply turned limb deployment around and deploys from its distal position proximally. The iliac bifurcation can be identified by an angiogram through the limb sheath, and a small amount of the stent is deployed. Once this has flared out, it can be snugged back to the common iliac bifurcation and, because it is larger than the external or internal iliac arteries, it will stop when it reaches them. This evolution from conventional grafts makes it almost impossible for the distal end of the stent to suddenly end up longer than planned, with the patient inadvertently losing an internal iliac artery. The device is then deployed proximally, keeping a little backward tension into the iliac system to achieve maximal coverage and long-term seal in the common iliac artery (CIA) (Figure 9).

CONSEQUENCES OF DESIGN EVOLUTION

The simple step of dividing the main body has further benefits for surgeons and patients. The independent nature of the stents means that no contralateral limb cannulation is required. Although cannulation of the contralateral gate is sometimes straightforward, there are always cases where it proves to be more difficult than anticipated. The improved design of Altura makes the procedure predictable in terms of steps and time and has the overall effect of reducing the time required to complete EVAR.



Figure 5. [PLEASE PROVIDE CAPTION]

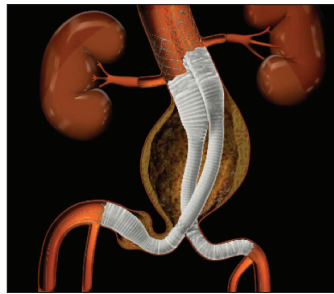


Figure 6. [PLEASE PROVIDE CAPTION]

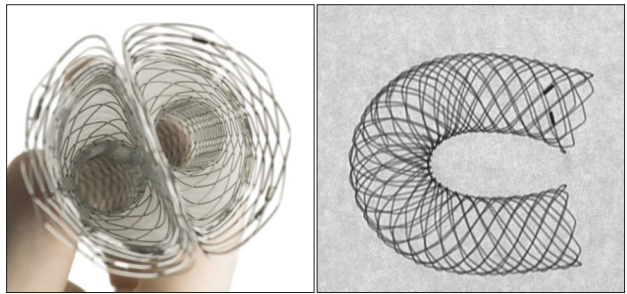


Figure 7. [PLEASE PROVIDE CAPTION]

As the number of EVAR procedures increases, there is a growing awareness of the levels of radiation that physicians are exposing themselves to in the process.^{5,6} Fluoroscopic screening during contralateral gate cannulation significantly adds to the burden of radiation. The ability of Altura to negate the need for cannulation will reduce radiation dose for both patients and physicians who choose to adopt this technique.

The Altura system has a braided stent, providing several advantages over conventional stents. The deployed stent is highly flexible and exerts a relatively high radial force. It is also possible to compress the stent without kinking. This combination of factors allows the device to be used in narrow aortic bifurcations and reduces the risk of one limb dominating the other and causing a limb occlusion when the bifurcation is narrow (Figure 10).

As conventional stent graft systems evolve, there is a tendency for the number of device component and size options to increase. This can make fully stocking devices more problematic and increases the complexity of planning. Being able to place the aortic stents from the top down and the iliac portions from the bottom up gives great flexibility in terms of length planning, which in turn greatly reduces planning time. The simplicity of the Altura system's independent stents means only six pieces are required to treat the full range of AAAs in its instructions for use, making stocking and planning more straightforward than with conventional stent grafts.

The combination of relatively simple, rapid planning and predictable procedure times makes the Altura system an attractive potential option for treating ruptured aneurysms, too. Like all surgical procedures, familiarity with the system in the elective setting is going to significantly improve performance in the pressured setting of a rupture. Not needing contralateral limb cannulation in a potentially unstable patient is a clear benefit. The bifurcated Altura system can be deployed in a similar timeframe to a uni-iliac device and iliac plug, avoids the need for a crossover graft, and improves durability of the repair.

The low profile of the delivery system means that a local anesthetic for access is possible, and this has been proven to be of benefit in ruptured AAA.⁷

THE OUTCOMES OF EVOLUTION

Altura's graft adaptations from a conventional unibody aortic graft to a two-part body with active suprarenal fixation have the potential to simplify EVAR for the benefit of patients and healthcare systems. There are already indications that this aspiration is being met from early implant data. [AU: IS THERE A REFERENCE AVAILABLE FOR THIS STATEMENT? DOES LOMBARD HAVE THIS ON FILE?]

The first-in-human studies along with the ELEVATE registry, conducted by Dainis Krevins, MD, PhD, in Riga, Latvia and Dr. Albrecht Kramer from Santiago, Chile, generated data on 103 patients treated with Altura some of whom now have data out to 4 years. [AU: REFERENCE AVAILABLE?] Only 20% of patients required general anesthesia for their implant. This potentially shortens overall procedure time, and it may reduce patient morbidity and hospital stay.

A recent publication from Liverpool⁸ comparing implant times for conventional EVAR versus endovascular aneurysm sealing (EVAS) showed that the operating time was shorter for EVAS at 121 minutes versus 162 minutes for EVAR ($P < .001$). In the first 103 Altura cases, the com-

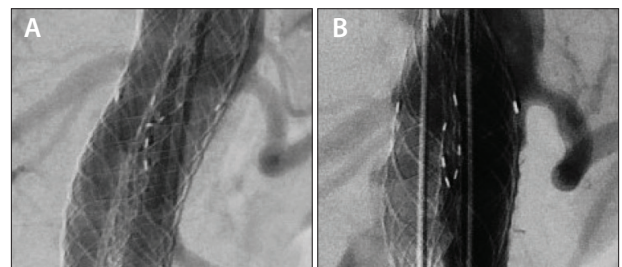


Figure 8. Initial graft deployment was too low, so the device was recaptured (A). Tight positioning on the renal artery to utilize all available aortic neck (B).

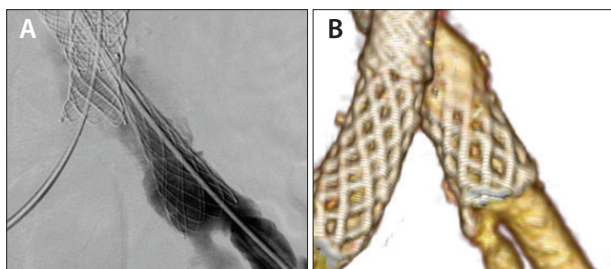


Figure 9. Short 2.4-cm CIA. [AU: THIS PANEL WAS MISSING FROM FILE. DO YOU WANT TO ADD?] Retrograde deployment with gentle retrograde traction to utilize all the CIA landing zone (A). Follow-up at 30 days demonstrating perfect placement (B).

parable time was only 107 mins, despite many cases representing the site's early learning curve. In the Liverpool data, there was a statistically significant correlation between radiation dose and operating time ($P < .001$). It seems reasonable to assume that physicians using Altura will reduce their radiation exposure because of the short and predictable operating times associated with the device's simplicity. The team from Manchester recently presented their early experiences with Altura at VEITH 2016. In addition to reporting very low screening times, they managed to discharge 75% of their cases within 24 hours of treatment. [AU: REFERENCE AVAILABLE?]

The initial data relating to Altura's durability is very encouraging. Despite representing the first cases undertaken, the first-in-human studies and ELEVATE registry had a technical implant success rate of 99%, with a clinical success rate of 97.3% at 12 months. The 12-month type 1 endoleak rate was only 1%. There are now 30 Altura cases with 2-year follow-up and all are free from type 1 endoleak, as are the 12 patients with 3-year follow-up.

Migration has recently become an important issue again in EVAR. With its long suprarenal bare stents, active fixation, and positive neck radial force, the Altura system has retained those features that have served conventional endografts well in preventing distal migration. Accordingly, at 12 months there are no cases of migration of more than 10 mm in the 74 patients with appropriate imaging. By 3 years, this remains true for the smaller number of cases with longer-term follow-up.

Of course, the effects of evolution can only truly be assessed with data using large numbers of patients gathered over a longer period. Lombard Medical has recognized this need and instituted the 1,000 patient ALTITUDE registry. Once complete, this will be the second largest EVAR registry and will allow Lombard to evaluate the impact of the graft adaptations on its long-term success. ALTITUDE will commence enrol-

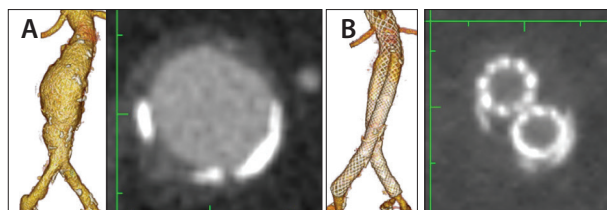


Figure 10. Standard AAA with a 14-mm bifurcation (A). Braided Altura stents equally expanded to 7 mm each (B).

ment in spring 2017, with the first sites being based in Europe and then rolling out to become a global effort later in the year. For information about the trial please see www.altituderegistry.com.

CONCLUSION

Technology can be disruptive or sustaining. Disruptive technology is one that changes or replaces the accepted way of doing things. It can lead to rapid change but with an associated risk. Sustaining technology enhances an existing product or service by refining it or making its creation and delivery more efficient.

Altura has not been designed to fix a niche in the EVAR market—it has developed in response to the pressures and demands that most EVAR users will recognize. It has kept many tried and trusted features such as active suprarenal fixation, a fabric graft and a robust nitinol stent. The flexibility produced by the division of the main body has the potential to significantly improve many facets of EVAR performance. ■

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Disclosures: [PH: PLEASE PROVIDE ANY RELEVANT FINANCIAL INTERESTS]