The Renu Device: A New System for Endovascular Rescue of Stent Grafts That Have Migrated, or Other Proximal Fixation Problems

Samuel R. Money, MD, New Orleans, LA

The risk of proximal fixation failures such as migration remains a concern for patients treated endovascularly for abdominal aortic aneurysms (AAAs). Migration in which the graft moves caudally can lead to a type I endoleak. The rates of migration are clearly graft specific; however, migration may occur with any type of graft. When significant migration occurs, the renewed risk of aneurysm rupture is present. Many of these patients who have had previous endovascular aortic aneurysm repair in the past are in worse health than they were for their original procedure. Therefore, they are not good candidates for surgical conversion. In the past, these patients were treated either by conversion to open repair, which has a significantly greater risk of morbidity and mortality, or by using a variety of available extension cuffs. Most of these extension cuffs have the same proximal fixation mechanism (radial force) as the failed primary graft. Although the intervention with a cuff may be successful in treating the existing endoleak, the question of long-term success is present. It is obvious that the radial force used as the proximal fixation mechanism in the original graft has already failed.

The Zenith Renu system is indicated for secondary endovascular interventions in patients having received prior endovascular infrarenal aortic aneurysm or aortoiliac aneurysm repair in which there is inadequate proximal fixation or seal. There are two different types of the Renu graft system.

The Renu converter configuration (Figure 1) is intended for use in short-bodied preexisting grafts. It is deployed with the proximal portion of the graft above the preexisting graft bifurcation and below the lowest renal artery. The distal portion of the graft is deployed within an iliac leg of the existing graft. It may commonly be used in conjunction with an additional iliac graft to land in the iliac artery, and it also may require a contralateral iliac occluder. A femoral-femoral bypass will be necessary to provide flow to both iliac/femoral arteries. The Renu main body extension (Figure 2) is intended for use in longer body grafts. This graft is deployed above the bifurcation of the existing graft and allows blood to flow into both iliac arteries without additional surgical procedures. The advantage of both types of Renu grafts is that they both contain the proximal _fixation characteristics of the Zenith Flex AAA grafts. These include a suprarenal stent with caudally oriented barbs. They both should be oversized by approximately 10 to 20% compared with the native aortic diameter directly below the renal arteries.

The anatomic criteria required for the Zenith Renu ancillary grafts vary based on which one of the two devices will be used. Clearly, there must be adequate access compatible with the required French size to deliver the device (18 or 20F.). The minimal fixation site that is acceptable for the converter system is 37 mm from the lowest renal artery to the bifurcation of the previously placed endograft. For the main body extension, a minimum of 43 mm from the lowest renal artery to the bifurcation is required. The outer wall of the native aorta must measure between 18 and 28 mm, with angulation of less than 60° relative to the long axis of the aneurysm and 45° relative to the axis of the suprarenal aorta. The distal fixation site for the main body extension, which lies within the main body of the primary endograft, must be greater than 17 mm in length and not larger than 30 mm in diameter. For the converter, the distal fixation site without an iliac limb must be greater than 17 mm in length and less than 12 mm in diameter. However, it must be noted that the converter can be used in combination with a Cook iliac extension or iliac limb, and distal fixation sites of up to 20 mm in diameter may be used.

Recently, the Zenith Renu AAA ancillary graft devices have received US Food and Drug Administration (FDA) approval. In an interesting approach to FDA approval, Cook Inc. has proposed and has received permission for the release of these grafts based on global clinical experience and on the proviso that a registry is prospectively pursued. This Renu registry is a nonrandomized, single-arm, prospective, postmarket registry of cases involving the Zenith Renu grafts. There is no limit to the number of institutions that may participate. This is because this device is being marketed as a "bail-out device." The use of the Renu device is anticipated to be infrequent and spread across many institutions, therefore, not lending itself to a traditional study format.

In summary, this new family of ancillary AAA grafts will serve a purpose in patients who have previously placed endografts with subsequent caudal migration or other proximal fixation failures of the endograft. The new systems provide a potential solution to the problem by the two following approaches: bridging the area below the renals and into the old graft using an extension cuff, or converting a bi-iliac to an aorto-uni-iliac graft using a converter.