Aorfix Flexible Endograft for Endovascular Aneurysm Repair: What Can It Do that Other Grafts Cannot, Based on 3-Year Clinical Results?

Brian R. Hopkinson, ChM, FRCS, Nottingham, UK

As a result of our early experiences with the Chuter graft in 1994, it soon became clear that the straight-sided Gianturco stent and polyester graft combination had limitations as far as fixation and seal were concerned in angulated necks or curly iliacs. The straight-sided Gianturco stents simply do not conform to the curves and therefore allow endoleak, and our subsequent experience confirmed a fairly high slippage rate with downward migration of the top stent and upward migration of the iliac stents. In addition, on bench testing, it became quite clear that the junction where the contralateral limb is plugged into the stump on modular grafts using straight-sided Gianturco stents again provides a very weak pull-out strength and a stronger join was therefore required. The original research work was supported by a MedLink grant from the United Kingdom Department of Health and Department of Trade & Industry so that we could develop an embroidered graft using Nitinol embroidered onto the cloth of the graft to create a tube that will go around corners without kinking and also form a sounder fixation in the iliacs and the junctions of the stent grafts, such as at the plug-in leg junction.

We explored many different patterns of embroidering the wire onto the cloth and came up with a ladder pattern that was folded longitudinally so as to form the tube with circumferential rings of Nitinol on the outside of the graft. These rings enabled the tube to bend quite nicely up to 90° or more without kinking, and on bench testing, proved to be very much more leak resistant than the equivalent Gianturco stent at angulation above 40°. The first grafts were made by Pearsall Sutures in Taunton, UK, and were a uni-iliac pattern. They were tested appropriately in animals and the first ones were inserted into patients in December 2001. Since then the uni-iliac graft has been used in some 13 patients, most of whom have had difficult, angulated necks that were thought to be impossible to deal with by conventional Gianturco stent grafts. None of them have had postoperative type I endoleaks or migration of the top or bottom of the stent graft. The longest survivor is one who had his graft put in during March 2002, and the situation as of May 2005, is that he has no endoleak and no expansion of the graft. All the others seem to have done well despite having very angulated necks and iliacs.

We then went on to make a bifurcated graft with a plug-in contralateral leg. Bench testing showed that the circular wires interlocked at the junction of the plug-in to provide a very strong pull out strength of the order of 20 to 25 N, as opposed to the 4 or 5 N required to pull out a Gianturco stent combination plug-in leg. After extensive animal testing for the regulatory bodies we inserted the first bifurcation graft in October 2003 and since then have inserted over 60 bifurcated grafts in different centers throughout the world. The initial clinical trial, called the Arbiter trial, was conducted in Professor Gerasimides unit in Thessaloniki, Greece, in Professor Schmidt's unit in Warsaw, Poland, and Professor Trojanowska's unit in Lublin, Poland. All these centers had the appropriate ethics committee approval, and results have been excellent with no post-implantation problems. There are no endoleaks at the top, bottom, or junctions to date, and there is no evidence of migration of the top, bottom, or joints. This is despite putting an Aorfix graft into cases with difficult, short angulated necks that the local surgeons at the centers where the grafts were implanted thought they would not be coped with by the commercially available Gianturco stent and polyester graft combinations that are currently available.

We have also developed a stapling device that works endovascularly and that has been tested in animals and cadavers and have showed it to work extremely well, to be accurately deployed, and to provide good fixation between the graft and aorta. At the time of writing this abstract, we are hoping to get a CE mark for this endo-stapler shortly. It will be available to fix migrating stent grafts firmly back to the aorta and, if necessary, to fix extension pieces above or below the areas of migration so as to recover the area required for seal.