LETTERS TO THE EDITOR

Regarding "Comparison of endovascular and conventional vascular prostheses in an experimental infection model"

To the Editors:

With great interest we read the article by Parsons et al. (J Vasc Surg 1996;24:920-6), which suggested that endovascular prostheses have a higher rate of infection than vascular prostheses implanted in conventional surgery in an experimental model. Our clinical and experimental studies do not confirm completely their conclusion.[1,2] Therefore, we would like to add our experience with endoluminal repair of infrarenal aortic aneurysms.

Since September 1994 we have performed endoluminal repair for exclusion of infrarenal aneurysm with use of a polyester textile–covered nitinol stent.[1,2] In a series of 83 patients treated endoluminally, no graft infection occurred. The mean follow-up period is 18 months, ranging from 8 days to 32 months. Our follow-up protocol includes clinical examination, intraarterial angiography, and spiral computed tomography.

However, there is an inflammatory response in all patients after endoluminal stent graft implantation. With a delay of 6 hours after aortic endografting, elevation of C-reactive protein (range, 8.4 to 24.8 mg/dl) and leukocytosis (range, 8.4 to 27.8 $\times$ 10^3/mm^3) developed in all patients. Elevated body temperature (range, 38.0° to 39.8° C) developed in half of the patients. There was no evidence of bacteremia.[2]

Our experimental and immunologic studies showed a significant and uniform elevation of interleukin 6, which is suspected to be responsible for proinflammatory reaction. The graft material acts most likely as a foreign body. This reaction is self-limiting, with laboratory findings becoming normal within 8 days.

According to these clinical and experimental data, our current policy includes the following regimen for endoluminal repair of infrarenal aneurysms: (1) administration of a single dose of broad-spectrum antibiotics (cephalosporin) periprocedurally; and (2) only symptomatic antiinflammatory treatment.

Christian Schlensak
Ulrich Blum
Gerhard Spillner
Friedhelm Beyersdorf
Department of Cardiovascular Surgery
University of Freiburg
Hugstetterstr. 55
Freiburg 79106
Germany

REFERENCES

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2. Schlensak C, Weinbeck M, Blum U, Walter S, Spillner G, Langer M, Beyersdorf F. Clinical experience with transfemoral endovascular aortic stent-graft placement for infrarenal aortic aneurysm (AAA). Cardiovasc Surg 1996;4(suppl):1.

24/41/84840

Reply

To the Editors:

We read with interest the letter by Schlensak, Blum, Spillner, and Beyersdorf, which refers to their experience excluding infrarenal aneurysms with the use of a polyester textile–covered nitinol stent. In their series of 83 patients, they have noted a significant inflammatory response with the endoluminal graft implantation but have noted no significant infection. We congratulate them for their good results in this group of patients. We have noted similar findings in our 62 patients who have undergone endoluminal repair of aortoiliac aneurysms. This inflammatory response has also been noted in our series of 55 patients who have undergone placement of an endoluminal graft for aortoiliac occlusive disease. We have not observed any significant graft infection in any of these patients, either.

However, these observations are irrelevant to our article. The article in question documents that if an experimental endovascular prosthesis gets infected, the infection is more virulent than after a standard repair. This article does not attempt to discuss the incidence of infection after endovascular grafting. The world's experience with endovascular grafts is in its infancy, and the rate of infection is still not clear. Our paper merely suggests that if an infection develops in an endoluminal graft, the infection is likely to be more virulent than that encountered after placement of a standard prosthetic arterial graft.

Luis A. Sanchez, MD
Division of Vascular Surgery
Montefiore Medical Center
111 East 210th St.
New York, NY 10467-2490

24/41/84839

Regarding "Stent deformation and intimal hyperplasia complicating treatment of a post–carotid endarterectomy intimal flap with a Palmaz stent"

To the Editors:

In the article by recently published by Johnson, Fujitani, Leyendecker, and Joseph (J Vasc Surg 1997;25:764-8), several questions arise in the endovascular management of this particular patient.

The choice of a JJIS 294 stent in a cervical segment, common carotid lesion may not have been the most logical choice. In the IDE-sponsored registry for carotid occlusive

disease, the JJIS stent is indicated in only bifurcational and internal carotid lesions. The 294 stent was unreasonably long in this segment of the carotid artery, which is directly exposed to external compression. If for some reason, and I cannot imagine why, the JJIS stent was the only option, then that stent should have been the much shorter JJIS 154. After all, the illustrated angiogram demonstrates a quite focal lesion, and the short stent would have been quite adequate.

The deformation of the stent that did occur as found on the follow-up study appears to be less than 40%. The intimal hyperplasia, however, and the restenosis at the target site were quite significant and approached at least 80%. The preliminary data from seven U.S. centers that are involved in the carotid stent registry have described stent deformation occurring in fewer than 2% of cases and a restenosis rate at 6 months of less than 5%.

The authors' initial decision to use a self-expanding flexible Wallstent (Schneider, Minneapolis, Minn.) was quite appropriate, realizing that the Wallstent has a flexibility feature and is "noncrushable" and would have been quite satisfactory for this segment of the carotid artery. Discovering, however, that they did not have the adequate-length stent after they had initiated the procedure and were ready for deployment was difficult to explain. The procedure should have been terminated at this point. Furthermore, the authors chose a polyethylene terephthalate balloon for stent deployment with a 0.035 inch wire passed across the target lesion and left within the internal carotid artery during the deployment process.

Although the authors discuss the widespread use of "off-label applications of endovascular stents," the question occurs whether this particular procedure was performed under an approved Investigational Device Exemption protocol?

Endovascular stenting for carotid occlusive disease is evolving as an alternative to the "gold-standard" of carotid endarterectomy, but until significant registry data or randomized controls establish its efficacy and safety, this procedure should be confined to experienced centers.

Mark H. Wholey, MD
Chairman
Pittsburgh Vascular Institute
5230 Centre Ave.
Pittsburgh, PA 15232

24/41/85094

Reply

To the Editors:

The authors appreciate Dr. Wholey's comments on our article and would like to respond. While we recognize that stent technology and deployment techniques are continually evolving, it should be noted that this case was performed in 1994, using techniques considered optimal at that time. In addition, we would like to point out that the placement of the stent occurred without complication. As Roubin et al. stated in their symposium on carotid stenting at the Society for Cardiovascular and Interventional Radiology's (SCVIR) 22nd Meeting, "the optimal technique for carotid stent placement has not been determined," and "optimal wire guides, delivery sheaths, balloons, and stents have not yet been determined."[1]

Dr. Wholey states that he "cannot imagine why a Palmaz stent" was the only option. We would like to clarify that the reason the Wallstent was not placed was because the deployment delivery device was not long enough, not because we did not have an adequate-length stent. At the time of this procedure, the Wallstent was only available in a usable *delivery* length of 75 cm, which was not long enough for adequate deployment from a femoral approach. It currently is available in several deployment lengths, including a 135 cm usable delivery system that easily allows placement from a femoral approach. Therefore, with the possible exception of using a 7F brachial approach, the Palmaz stent was the only choice in this patient. The flap and intimal irregularity extended over a 1 cm area, and this is the reason for the choice of stent length. Furthermore, both the 154 and 294 stents are equally prone to deformation because they have the same radial hoop strength.

The point of this case was to illustrate the theoretical but previously unpublished concern of placing a deformable stent in the cervical carotid system. Except in the situation of a high bifurcation of the carotid artery, the distal common carotid artery, bifurcation, and proximal internal carotid artery are all located in exposed, potentially compressible locations. It should be noted that in Dr. Wholey's abstract from this year's SCVIR meeting entitled "Endovascular stents for carotid occlusive disease," seven of the 58 patients in his subject group who underwent carotid stenting had a Palmaz stent placed in the common carotid artery.[2]

Dr. Wholey cites data on 58 patients from seven centers in the carotid stent registry, noting only a 2% deformation rate. Other investigators have noted a significantly higher rate of Palmaz stent deformation in the carotid artery. Vitek et al.,[3] who probably have the largest experience in the United States, noted a 13% rate of stent deformation at 6-month follow-up in the 203 patients they treated with balloon-expandable stents. They concluded "because of the risk of stent deformation of balloon-expandable stents, it is more appropriate to use the self-expandable stents".[3]

In 1994, this procedure was performed as an off-label use of a FDA-approved device for compassionate reasons. The FDA has since clarified clinical research of carotid stenting, and we agree with Dr. Wholey that any current placements in the United States should be done under IRB- and IDE-approved protocols. We are not currently performing carotid procedures because we are not satisfied