tional Institutes of Health and the Food and Drug Administration, already have taken the leadership in the development of these two areas of endeavor.

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Discussion

DR. FRANK J. VEITH (New York, New York): I would like to congratulate Dr. Moore on a most exciting presentation. There is little doubt in my mind that transluminally placed endovascular stented grafts will have a major impact on the way arterial lesions are treated.

Over the last year and a half, we have placed 51 endovascular stented grafts to treat a variety of arterial lesions in 40 patients. Unlike Dr. Moore's cases, most of our patients had major systemic or local contraindications to standard operative repair and many were too sick to undergo general or even regional anesthesia.

Since November, 1992, we have inserted via transfemoral routes seven stented grafts for aortic or aorto-iliac aneurysms. Results in some of these otherwise inoperable patients have been dramatic, with the patient leaving the hospital in 2 to 3 days with their aneurysm fully excluded.

However, we have had one death from multiorgan failure secondary to microembolization, a problem that Dr. Parodi, the father of this technique, has seen in three patients and one that we believe requires attention and care to prevent. I would like to ask Dr Moore if he has seen any evidence of this microembolization even though his patient population differed considerably from ours.

Aside from the aortic aneurysms, we have also used endovascular stented grafts to treat common iliac (2) and popliteal aneurysms (1) with uniform success and follow-up now extending over one year. Similarly with the eight traumatic arterial lesions, stented graft repair has been uniformly successful and our longest follow-up now extends to 16 months.

Finally, our most interesting early results with these endoluminal grafts have been in patients with arteriosclerotic occlusive disease at the aorto-iliac and/or the femoropopliteal levels. The aorto-iliac grafts have been particularly gratifying. Only 1 of the 17 patients with one or two grafts in this location has had a graft failure. Here also our follow-up exceeds 1 year.

We therefore believe these endovascular grafts may become quite important in the treatment of various arterial lesions. However, many of these procedures have been difficult and complex and their exact role and long-term effectiveness remain to be defined. Dr. Moore is to be commended for bringing this important new development to our attention.

DR. CALVIN B. ERNST (Detroit, Michigan): Clearly, endo-

vascular grafting appears to be a promising new treatment for localized abdominal aortic aneurysms. In the future, as this technique becomes further refined, we may be treating small aneurysms in relatively healthy, young patients. Identification through genetic screening of patients who are prone to develop aneurysms will permit placement of endovascular grafts in small aneurysms confined to the infrarenal aorta thereby precluding operating upon large 8 or 10 cm aneurysms that extend into the iliac arteries.

However, at the present time one of the problems we must deal with, in the patients currently encountered and to which Dr. Moore alluded, is identifying the aneurysm with a distal neck suitable for prosthesis fixation. At the Henry Ford Hospital we are participating in the Phase 2 trial evaluating this device. Over the past 2 months, of the many patients we see with abdominal aortic aneurysms, we have identified approximately ten with aneurysms confined to the infrarenal aorta but have yet to find one with an adequate distal neck. Too short a distal neck precludes fixation of the distal end of the graft because when one attempts to seat the hooks with the balloon, the balloon deploys partially in the common iliac artery and will not completely expand. So I would ask Dr. Moore whether he has solved this problem by using the kissing balloon technique whereby a second dilating balloon is passed through the contralateral iliac artery using two balloons to seat the distal graft.

Dr. Moore, I can foresee another potential problem that must be addressed, graft infection. Several years ago we reported that the bacterial colonization rate of abdominal aortic aneurysms was about 10%, primarily Staph Epidermidis. Several other investigators have confirmed these data. What are your views about deploying this type of prosthesis in a potentially infected field?

I think this is an exciting new technique and may well be the wave of the future, but I do not think it is going to put the vascular surgeon out of business because such a small number of patients, using current screening techniques, qualify for such treatment. On the contrary, such advances are going to expand our horizons for treating more and smaller aneurysms in the future.

DR. KEITH REEMTSMA (New York, New York): We are now entering a new era in vascular surgery with the use of endovascular prostheses, and we're indebted to Dr. Moore for sharing his experience with us. He and both of the discussants have pointed out the problems with the distal insertion of these grafts.

As Dr. Moore mentioned, only one out of seven patients that were screened had a suitable anatomic variant which permitted the use of this graft. Dr. Ernst has just called our attention to their study at Henry Ford in which none out of ten showed this.

For this reason I think it is imperative that we develop a method which includes the bifurcation, and I'd like to refer to the work of my colleague at Columbia Presbyterian, Dr. Tim Chuter, who has had experience now in 15 patients with the transluminal insertion of grafts with bilateral iliac implantation. In 15 patients they have had 13 successes.

I believe this type of approach will be essential in the future because of the frequency with which the iliacs are involved in aortic aneurysms.

DR. WILLIAM D. TURNIPSEED (Madison, Wisconsin): I would certainly commend this as an important technique that all of us are committed to follow. I have a technical question, regarding endovascular graft fixation and patient selection.

Since seating of the graft is based on hook fixation, is calcific plating in the aneurysm wall a contraindication? How do you identify plating? Is this an exclusion criteria or is it not?

DR. ANTHONY M. IMPARATO (New York, New York): I'd like to congratulate Dr. Moore. I wonder if he might comment on how his technique differs from that of Dr. Parodi of Buenos Aires, who initiated transfemoral endovascular repair of AAA. Since Dr. Parodi, of Buenos Aires by this time has had considerable experience with this approach and has traveled extensively instructing other people on the use of this technique, would Dr. Moore perhaps give us a comment on some of Dr. Parodi's experience.

DR. DHIRAJ M. SHAH (Albany, New York): I, too, commend Dr. Moore and Dr. Veith for bringing this unique technique to our attention. I want to make a comment about the fluidity of the aneurysm around this graft placement. It may not be entirely due to a leak through the graft; it could be due to persistent collaterals. In our experience we've treated aneurysms with ligation, exclusion and extraluminal graft placement and a few of these aneurysms remain fluid a long time after ligation through the lumbar and inferior mesenteric collaterals. If that is so, then one may entertain embolizing those collateral arteries prior to graft placement. The collateral flow may cause expansion and even rupture of the excluded sac.

DR. WESLEY S. MOORE (Closing discussion): I would like to thank the discussants for their excellent and insightful comments. I will try to answer them in order.

Dr. Veith raises the possibility of inducing microembolization with the manipulation of this device in an aneurysm, containing laminated thrombus.

First of all, our experience is still very preliminary, if not in fact anecdotal. We are only reporting on ten implants. Another two were done prior to this meeting which brings our total to 12 patients to date. We have been lucky to this point; we have not encountered microembolization. However, it has been reported by Parodi in the Argentina experience.

Let me just skip briefly to the final question that Dr. Imparato asked, which was how does our technique differ from the Parodi device.

Dr. Parodi's device incorporates a stent that requires a balloon expansion. It is not self-expanding nor does it have any specific method for fixation of the device to the aortic wall other than the friction that is generated by expanding a rigid stent against the graft within the aorta. In contrast, the device we are reporting on contains hooks around the circumference of the abdominal system which engages the aortic wall.

Nonetheless, Dr. Parodi does indeed have the largest experience of endovascular aneurysm repair in the world and his cases now number in the forties. He has, however, encountered problems of embolization, as I recall, in about three patients who had major embolization as a consequence of placing his

graft. So whether or not we have been simply lucky and the next few are going to catch up with us, I really don't know.

We also look forward very much to Dr. Veith's further experience in the management of patients with occlusive disease using endovascular grafting. I think that this is an exciting new area. I believe that vascular surgeons need to become involved with these procedures since they clearly are going to be an important component of our surgical practice in the future.

Dr. Ernst raised several questions—first of all, the issue of patients with small aneurysms. I agree with him that if in fact this turns out to be a durable operation, we will be taking on patients with smaller aneurysms. I hope that this is going to have a significant impact in reducing the incidence of rupture that we currently see in this country. It might also be an impetus to begin to carry out ultrasound screening studies so that we can identify the patients with aortic aneurysms rather than finding them in a serendipitous manner.

Dr. Ernst also asked a technical question with regard to the seating of the distal anastomosis. The "kissing" balloon technique is simply putting in balloons from both sides so that they meet at the aortic bifurcation and simultaneous inflation serves to seat the distal attachment system. I used this technique in my last two patients, 2 days ago. It worked remarkably well and it is an important adjunct to the technical armamentarium.

Dr. Ernst and Dr. Reemtsma raised the question of applicability of this technique to the aneurysm population. There is no question that very few patients with abdominal aortic aneurysm are going to meet all of the anatomic criteria for the tube configuration of our graft replacement. Clearly, the absence of the distal neck is a most limiting feature.

We are aware, of course, of Dr. Chuter's work in the development of the bifurcated graft. There are also other bifurcated configurations that are currently in the development phase. We look forward to the time when a bifurcated graft receives FDA approval for investigation as all of us are anxious to know how they will perform in the context of a controlled clinical trial. There is no question in my mind that if the bifurcated graft were available right now, it would markedly increase the applicability of this technology to the patient population that we are serving.

Dr. Turnipseed asked a question about calcification and how we seat this graft particularly at the distal anastomosis. Remember, we have to penetrate calcification one way or the other, whether it's with a needle and thread or a hook. We have not turned down anyone because of calcification, but clearly we worry about it. In the context of a clinical trial, it is important to define the limitations of a new technology. To the best of my knowledge I have not failed because of calcification so far.

Dr. Shah raised the question about continued aneurysm activity due to back-bleeding from lumbar and mesenteric arteries. Obviously that is a concern. We have described two patients in the group showing continued contrast enhancement within the aneurysm sac by CT, that can either be caused by back-bleeding from lumbars or from an incomplete anastomotic seal. We believe that back-bleeding from lumbar arteries will be self limited. If the blood has no place to go, it will ultimately clot. The question is, when it clots will the aneurysm continue to be pressurized or not. Furthermore, if the aneurysm is pressurized, is there still the likelihood for rupture? These are all unanswered questions but they hopefully will be answered in this FDA monitored trial.