

From the Western Vascular Society

Adjunctive primary stenting of Zenith endograft limbs during endovascular abdominal aortic aneurysm repair: Implications for limb patency

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Objective: Endograft limb occlusion is an infrequent but serious complication of endovascular abdominal aortic aneurysm (AAA) repair. The insertion of additional stents within the endograft limb may prevent future occlusion. This study evaluates limb patency with and without adjunctive stenting of endograft limbs at the time of endovascular AAA repair.

Methods: We performed a retrospective review of 248 patients who underwent endovascular abdominal aortic aneurysm repair with the Zenith AAA endovascular graft between 1999 and 2004. Among these patients, two groups were identified: 64 patients with adjunctive stents placed in 85 limbs and 184 patients without additional bare stent placement in endograft limbs at the time of endovascular AAA repair.

Results: Women comprised 23% of stented and 11% of unstented patients ($P = .02$). The mean length of follow-up in the stented and unstented groups was 2.0 years. There were 13 instances of limb thrombosis in 13 patients (5.2% of patients, 2.7% of limbs), all in the unstented group. No limb occlusions occurred in the presence of adjunctive bare metal stents. Seventy-three percent of the occlusions occurred ≤ 6 months of endovascular AAA repair. Two patients (15%) had no symptoms of lower-extremity ischemia despite graft limb occlusion and did not undergo intervention. The others underwent thrombectomy ($n = 2$), thrombectomy with bare stent placement ($n = 3$), femoral-femoral bypass ($n = 4$), thrombolysis ($n = 1$), and thrombolysis with bare stent placement ($n = 1$). Of the seven who underwent thrombectomy or thrombolysis, three had no additional stents placed at the secondary procedure, and two of these three went on to rethrombose. By life-table analysis, primary patency at 3 years in the stented and nonstented limbs was $100\% \pm 0\%$ and $94\% \pm 3\%$, respectively ($P = .05$).

Conclusions: The intraoperative insertion of additional bare metal stents appeared to eliminate the risk of thrombosis and was without complication. Of the 85 stented limbs in this series, not one occluded. The overall rate of limb thrombosis was low, with most limb occlusions occurring ≤ 6 months of stent-graft insertion, and would probably have been even lower had we been able to identify all high-risk cases for prophylactic adjunctive stenting. Limb occlusion denotes an underlying problem with the graft, which if left untreated after thrombectomy or thrombolysis will lead to rethrombosis. Postoperative imaging was of little value in detecting impending limb occlusion. Based on these findings, we believe one should identify and stent any limbs that appear to be at risk for thrombosis, but this study lacks the data to predict which limbs need stenting. (*J Vasc Surg* 2006;43:662-70.)

Endovascular aneurysm repair has many short-term advantages over open surgery,^{1,2} but long-term durability is marred by late complications, many of which require reintervention.^{3,4} The rates of graft limb thrombosis vary according to the design of the stent-graft, with unsupported limbs showing the highest rates.^{3,5-9} Fully stented limbs fare better, but the most widely used systems still have reported limb thrombosis rates of 3% to 5%.

Much has been written on the treatment of graft limb thrombosis,^{3,7,10,11} but little regarding its prevention.⁵

The goal of this study was to evaluate the role of adjunctive bare stenting of endograft limbs in the prevention of graft limb occlusion.

METHODS

We performed a retrospective review of patients at University of California, San Francisco (UCSF) Medical Center who underwent endovascular abdominal aortic aneurysm (AAA) repair with the standard bifurcated Zenith AAA endovascular graft (Cook Inc, Bloomington, Ind) between February 1999 and June 2004. This study was approved by the UCSF Institutional Review Board.

We identified 323 patients. Of these, 75 lacked sufficient imaging and were excluded, and 248 patients had sufficient intraoperative and postoperative imaging to show additional stents within the limbs, identify the probable indications for stenting, and determine subsequent limb patency. Two groups were identified: patients with and without additional bare stent placement in endograft limbs at the time of endovascular AAA repair. We collected information on demographics, existing comorbid condi-

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tions, primary treatment, limb patency, and secondary interventions.

After standard deployment of the Zenith AAA endovascular graft, we removed all guidewires and performed multiplanar angiography to assess device placement, aneurysm exclusion, limb angulation, and patency. Cases of possible luminal compromise were generally investigated further by injecting contrast into one limb at a time in the ipsilateral anterior oblique view.

When we saw narrowing of the graft limb in association with angulation (kinking), we implanted a Wallstent (Boston Scientific Co, Natick, Mass), dilated the area by using an angioplasty balloon, and repeated the angiography. When we saw narrowing of the graft limb in association with external compression at the aortic bifurcation, we implanted one (or more) Palmaz stents (Cordis Co, Miami, Fla). Under these circumstances, the two limbs often overlapped, and angiographic evaluation was performed one limb at a time. When we saw narrowing of the graft limb in association with external compression or angulation within the proximal external iliac artery, we implanted a Wallstent.

Less concrete indications for adjunctive stenting emerged as the study progressed. These included angulation of the proximal common iliac artery on preoperative imaging, angulation of the graft limb in the absence of narrowing, and external iliac artery implantation. In cases of angulation at or close to the end of the graft, the additional Wallstent stent extended into the downstream artery.

While in the hospital, patients underwent multiplanar abdominal radiography and contrast-enhanced computed tomography (CT) scans. Patients were then followed-up at 1 month, 6 months, and 1 year, and yearly thereafter with a physical exam, contrast-enhanced CT, and multiplanar abdominal radiography. Patients with postoperative evidence of endograft limb compression, kinking, angulation, or limb thrombosis underwent angiography and catheter-based intervention. After thrombectomy or thrombolysis, angiographically identifiable stenosis, kink, or angulation were usually treated by using additional bare metal stents, and the patient was followed-up according to the routine imaging protocol.

Statistical analysis. Measured values are reported as percentages or means \pm SD. The Student's *t* test and Fisher's exact test were used to determine differences between groups. $P \leq .05$ was considered significant. Survival, primary patency, and patient freedom from limb thrombosis were calculated by using life-table analysis and reported with standard errors. The log rank test determined differences between life tables. Analyses were performed with JMP software (version 5.0.1) (SAS Institute, Cary, NC).

RESULTS

Between 1999 and June 2004, 248 of the patients treated with the Zenith AAA stent-graft had sufficient imaging for inclusion in this retrospective review, and 64 had additional bare stent placement in endograft limbs at the time of endovascular AAA repair. The remaining 184

Table I. Patient demographics

	Adjunctive stents (n = 64) (%)	No stents (n = 184) (%)
Age (mean, years)	79 \pm 8	79 \pm 5
Female sex*	15 (23)	21 (11)
Risk factors		
Smoking	33 (52)	108 (59)
COPD	16 (25)	57 (31)
Myocardial infarction	24 (38)	68 (37)
Congestive heart failure	12 (19)	35 (19)
Coronary artery disease	42 (66)	120 (65)
Hypertension	46 (72)	127 (69)
Diabetes mellitus	7 (11)	26 (14)
Cerebrovascular disease	12 (19)	40 (22)
Hyperlipidemia	33 (52)	101 (55)
Renal insufficiency	12 (19)	36 (20)
Coagulopathy	4 (6)	14 (8)
Previous vascular surgery	21 (33)	66 (36)
Mean maximum aneurysm diameter (mm)	58 \pm 13	59 \pm 10

COPD, Chronic obstructive pulmonary disease.

* $P = .02$.

patients had no additional bare stents. The standard three-component bifurcated Zenith stent-graft was used in 238 patients. Three patients in the stented group and seven patients in the nonstented group underwent aneurysm repair with a custom-made uniiliac version of the Zenith stent-graft.

There were no limb occlusions in the stented group and 13 limb occlusions in 13 patients in the unstented group. Thirty-eight percent of thrombosed limbs involved the contralateral limb, and 62% involved the ipsilateral limb. The overall rate of limb thrombosis in the total population of 486 limbs was 2.7%. Mean follow up was 2.0 \pm 1.3 years in the stented group and 2.0 \pm 1.4 years in the nonstented group.

Patient demographics and risk factors for atherosclerosis are listed in Table I. There were 15 women (23%) and 49 men in the stented group, compared with 21 women (11%) and 163 men in the unstented group ($P = .02$). By life-table analysis, survival at 6 months, 1 year, and 3 years was 95% \pm 3%, 87% \pm 4%, and 61% \pm 12%, respectively, in the stented group compared with 98% \pm 1%, 95% \pm 2%, and 76% \pm 4% in the unstented group ($P = \text{NS}$) (Fig 1). Four of the 13 patients with limb thrombosis died during follow-up. One death was secondary to infection of a femorofemoral bypass 4 months after placement for a thrombosed endograft limb. The other three deaths were unrelated to graft occlusion and caused by aneurysm rupture (secondary to a type II endoleak), cardiac disease, and pulmonary disease.

At the initial operation, 64 patients had adjunctive stents inserted in 85 endograft limbs. On retrospective review of perioperative imaging, the primary indications for adjunctive bare stent placement appear to have been endograft limb angulation (34%), compression (41%), and kinking (25%). Details of stent placement are listed in Table II. The nominal diameter of the bare stent used was ≥ 10 mm.

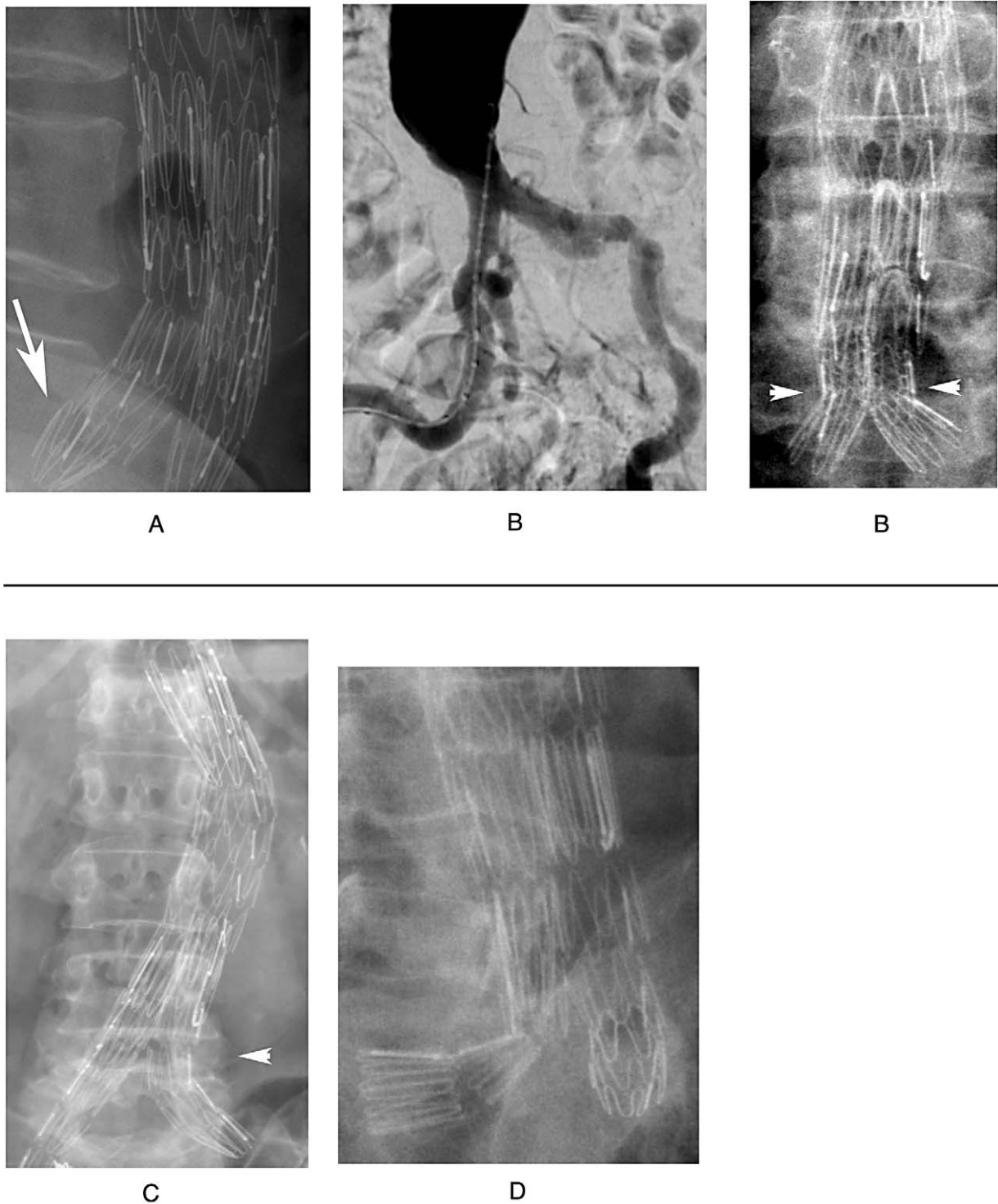


Fig 1. Plain abdominal radiographs of a stent-graft show indications for adjunctive stent placement. A, Limb stenosis (arrow) in the distal aspect of the stent graft limb. B (left panel), Preoperative angiography illustrates narrow distal aorta and bifurcation. B (right panel), Palmaz stents (arrow) were placed in both stent graft limbs at the level of the narrow distal aorta to maintain patency. C, Limb angulation (arrow). D, Limb kinking: combination of limb angulation with reduction of luminal diameter.

Table II. Procedural characteristics

	Adjunctive stent (n = 85) (%)	No stent (n = 361) (%)
Distal endograft limb fixation		
Common iliac artery	65 (89)	347 (96)
External iliac artery*	8 (11)	14 (4)
Predeployment endograft limb diameter (mm)*	13 ± 3	16 ± 4
Narrowest endograft limb diameter (mm) postdeployment	9.4 ± 2	
Stent type (64 patients; 85 limbs)		
Palmaz	16 (25); 25 (29)	
Wallstent	51 (80); 64 (75)	
Bilateral	20 (31); 40 (47)	
Mean stent diameter (mm)	12 ± 2	
Mean stent length (mm)	60 ± 20	
Mean balloon diameter (mm)	11 ± 2	
Mean number of stents	1.4 ± 0.6	

**P* < .01.

Twenty-two graft limbs (in 22 patients) were implanted in the external iliac artery. This includes eight (11%) of 85 stented limbs and 14 (4%) of 361 unstented limbs (*P* < .01). Two of 14 unstented limbs subsequently occluded, but all of the stented limbs remained patent.

Although no limbs in the stented group have occluded, two patients have undergone additional treatment for threatened occlusion. In one patient, kinking developed at an unstented site, and another patient was found to have a dissection of the external iliac artery. Both problems were treated with Wallstents. No complications have been attributable to adjunctive stents.

In the unstented population, 73% of occlusions occurred ≤6 months of endovascular AAA repair. The mean time to occlusion was 0.68 ± 1.3 years. Reasons for occlusion included angulation in 7 (54%), kinking in 3 (23%), compression in 1, heparin-induced thrombocytopenia in 1, and external iliac dissection in 1. Two patients had no intervention because they were asymptomatic. Interventions to restore perfusion in 11 patients included thrombectomy in 2, thrombectomy with bare stent placement in 3, femorofemoral bypass in 4, thrombolysis in 1, and thrombolysis with bare stent placement in 1 (Table III). Of the seven who underwent thrombectomy or thrombolysis, three had no additional stents placed at the secondary procedure. Two of these three went on to rethrombose, one at 4 months and the other at 2 years after the secondary intervention to restore perfusion. Both then underwent femorofemoral bypass.

By life-table analysis, primary patency was 100% ± 0% at 6 months, 1 year, and 3 years in stented limbs, compared with 97% ± 1%, 96% ± 1%, and 94% ± 3% in unstented limbs (*P* = .05) (Fig 2). By life-table analysis, patient freedom from any limb thrombosis was 100% ± 0% at 6 months, 1 year, and 3 years in the stented patients, compared with 94% ± 2%, 92% ± 4%, and 88% ± 5% in unstented patients (*P* = .05) (Fig 2).

DISCUSSION

We found adjunctive bare metal stents to be safe and effective for the prevention of limb thrombosis following endovascular AAA repair with a Zenith stent-graft. No stented limb thrombosed and no complications occurred as a result of adjunctive stenting. All of these stents were inserted to treat findings such as kinking and external compression that are known to predispose to limb thrombosis.⁹ We conclude, for lack of an alternative explanation, that the absence of subsequent thrombosis in these high-risk patients was attributable to the presence of the additional stent.

What this retrospective review lacks is a control group. We cannot say what the thrombosis rate would have been had no patients been stented, or had stenting been applied randomly. In this study we used the unstented patients for comparison, but they were certainly not an unselected group. Indeed, they were left unstented at the time of operation because they were not thought to be at high-risk for limb thrombosis. We assume that this process of selection eliminated the particularly high-risk patients and probably reduced the overall thrombosis rate observed in the unstented group in much the same way that the availability of endovascular repair improves the results of open surgery.

We recognize that the lack of a control group limits our ability to interpret provocative findings such as the high proportion of women among the stented group. We believe that unfavorable anatomy in women produced high rates of kinking or stent-graft compression, which were identified at operation and treated with adjunctive bare metal stents. Other authors have attributed gender-related differences in the outcomes of endovascular aneurysm repair, including high rates of limb thrombosis,¹² to a higher prevalence of unfavorable anatomy in women. The absence of any difference between men and women in overall thrombosis rate in our study may be a consequence of the observed difference in the rate of adjunctive stenting or of some previously unreported characteristic of the Zenith stent-graft.

The disproportionate number of external iliac limbs in the stented group probably represents our response to the observation that a disproportionate number of external iliac graft limbs thrombose⁷ in the absence of stents. Again, the selective insertion of adjunctive stents has limited our ability to interpret the findings of this study. Nevertheless, we now routinely insert Wallstents in cases of external iliac artery implantation.

The current study provides no indication of what findings warrant a stent and what affect such a policy would have on overall thrombosis rates. From our findings, however, one can say that the additional stents are unlikely to cause additional problems. It is only a question of time and expense; hence, our current liberal approach to adjunctive stenting.

Had we been able to identify and stent all at-risk limbs, we would probably have had even less to report,

Table III. Outcome of thrombosed limbs

No.	Side	Distal implant	Narrowest limb diameter (mm)	Time to thrombosis (yr)	Cause thrombosis	Intervention	Initial outcome	Secondary intervention
1	C	CIA	8	3.94	A	T/stent	+	
2	I	CIA	11	0	HIT	T	+	T/fem-fem
3	I	CIA	10	.01	A	Fem-fem	+	
4	I	EIA	8	.12	A	Fem-fem	+	
5	I	CIA	9	0	S	T	+	
6	I	CIA	8	1.05	A	None	None	
7	C	CIA	7	.04	K	T/stent	+	
8	C	CIA	11	.01	K	Fem-fem	+	
9	I	EIA	9	.04	K	L/stent	+	Fem-fem
10	I	CIA	11	.6	A	Fem-fem	+	
11	C	CIA	5	3.03	A	None	None	
12	C	CIA	10	.01	D	T/stent	+	
13	I	CIA	11	.3	A	L	+	

C, contralateral limb; I, ipsilateral limb; CIA, common iliac artery; EIA, external iliac artery; A, severe angulation; K, kink; S, stenosis; D, dissection; T, thrombectomy; Fem-fem, femorofemoral bypass; L, thrombolysis; HIT, heparin-induced thrombocytopenia.

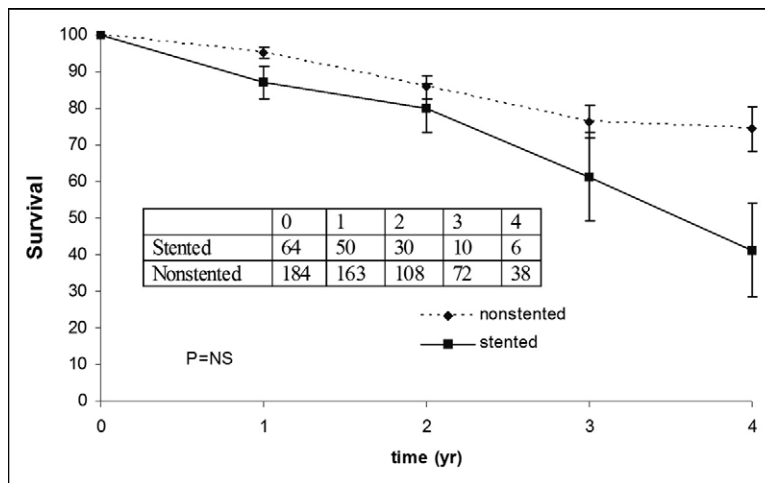


Fig 2. Life-table analysis for survival of stented and nonstented patients. The number of patients in each interval is given in the table within the graph. Values are the mean ± SE for all data points.

with a thrombosis rate of zero in both groups. Since that was not the case, it is clear that we still need a better way to identify limbs that might benefit from additional stents. For a variety of reasons, we were not able to analyze the predictive value of preoperative CT, preoperative angiography, or intraoperative angiography as determinants of thrombosis risk. Most preoperative CT scans were not represented in three-dimensions but only as a series of slices. Many patients did not have preoperative angiography. The intraoperative angiograms were not all saved to a file, and those that were saved were not of uniform quality. The criteria for stenting varied between operators and evolved as the study progressed.

Even if we had been able to stratify risk according to the findings of high-quality preoperative and intraoperative imaging, it is possible that other tests would still be needed to further refine patient selection. Pullback pressure measurements, for example, can help identify hemo-

dynamically significant lesions,⁵ but they are relatively insensitive, even after flow through the femoral arteries has been restored. Ultrasound may be more sensitive,¹³ but the test is expensive, time consuming, and of unknown predictive value.

The current routine follow-up regimen appeared to play little role in the prevention of limb thrombosis. We identified and treated only two cases of impending limb thrombosis, both in already-stented patients. The explanation may lie in the timing of routine follow-up. Most cases of graft thrombosis occurred ≤6 months of stent-graft insertion, during which time the patients underwent routine imaging only once at 1 month.

CONCLUSION

Limb thrombosis is a rare, but preventable, source of morbidity following endovascular aneurysm repair with the Zenith stent-graft. Adjunctive stenting is effective prophy-

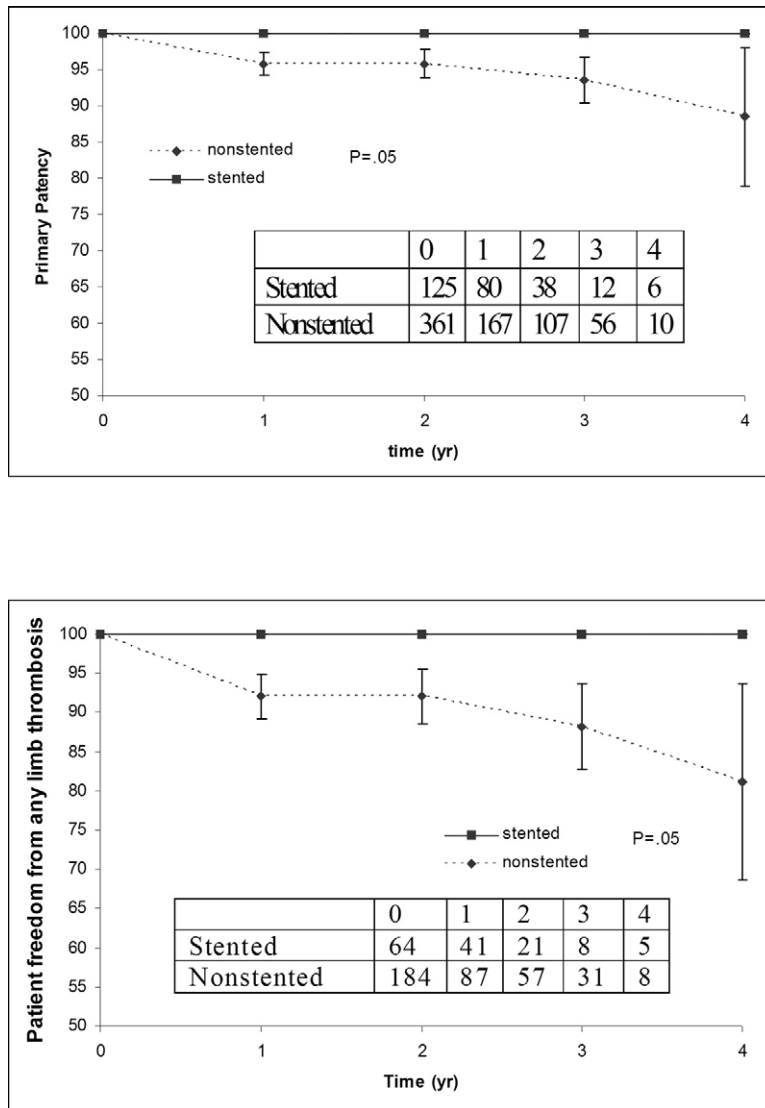


Fig 3. Top, Life-table analysis for the primary patency of all limbs in the stented and non-stented patients. Bottom, Life-table analysis of patient freedom from any limb thrombosis. The number of patients or limbs in each interval is given in the table within the graph. Values are the mean \pm SE for all data points.

laxis for selected high-risk limbs, yet their identification remains problematic. Fig 3).

AUTHOR CONTRIBUTIONS

Conception and design: TAMC
 Analysis and interpretation: NS, DBS, LMR, JHR, TAMC
 Data collection: NS, HSS, TAMC
 Writing the article: NS, TAMC
 Critical revision of the article: NS, TAMC, LMR, JHR, DBS
 Final approval of the article: TAMC
 Statistical analysis: NS, TAMC
 Obtained funding: TAMC
 Overall responsibility: TAMC

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DISCUSSION

Dr Farber. I would like to congratulate Dr. Sivamurthy on an excellent presentation and thank the UCSF group for their provocative paper. In this retrospective analysis 248 abdominal aortic aneurysm patients treated with the Zenith endograft were evaluated. Those patients, who had underwent intraoperative adjunctive bare metal stent placement to treat limb abnormalities, were compared to those in whom stents were not used. Reasons to stent included limb angulation, compression, and kinking. There were significantly more women in the stented group. A significant proportion of the grafts that extended to the external iliac artery were stented. Two external iliac artery limbs that were not stented eventually occluded. During follow up there were no limb occlusions in the stented group and 13 limb occlusions in the non-stented group.

The major strength of this paper is that it brings up a topic that has not been fully explored: Intraoperative management of an endograft limb. Most of us would treat an obvious graft limb deformity with angioplasty and possible stenting. But what about minor limb deformities? It is not uncommon to see a minor luminal abnormality on a completion angiogram in an endograft limb and yet its treatment is not always obvious. This paper demonstrates that use of bare-metal stents to treat limb abnormalities is effective and safe.

The major weakness of this paper, which is well acknowledged in the manuscript, is that the cohort in which bare-metal stents were used lacked an adequate control group. Therefore some conclusions drawn from this study may be difficult to interpret. Clearly there are situations in which placement of a stent is appropriate. The lack of limb thrombosis in the stented group only underscores the correct decision on the part of the surgeons to stent when a limb abnormality was noted. What then can be said about the non-stented limbs which went on to thrombose? Could these events have been possibly prevented by stent placement? It is clear that angiography is not completely accurate in predicting which endograft limbs need to be stented. Should other intraoperative imaging techniques be routinely used? This paper brings up these provocative issues and challenges us to design prospective studies in an attempt to answer them.

I have several questions:

Dr Farber. 1. What exactly affected your decision to place a stent? Was it only the obvious limb abnormalities? Did you stent any minor limb irregularities? What is your advice regarding management of an endograft limb which is noted on a completion angiogram to have a minor non flow limiting stenosis or angulation?

Dr Sivamurthy. The decision to stent varied from operator to operator, and study period to study period. At the outset of the study different surgeons applied different criteria. Since then we have seen a convergence of views. We recognize that the subjective nature of the decision to stent is one of the weaknesses of this

paper. Initially, our indications as a group to place stents in endograft limbs were for limb stenosis, limb kinking, and narrow aortic bifurcations. Over time, our indications have evolved and we have become more liberal in our indications for stenting to include limb angulation. The decision to place a stent was based predominantly on completion angiography after all stiff guidewires were removed. Minor limb irregularities seen on completion angiography were selectively stented based on preoperative imaging. For the endograft limb which has a minor non flow limiting stenosis or angulation on completion angiogram, we would base our decision to stent based on the preoperative imaging. If the iliac arteries had significant tortuosity or disease preoperatively, we would stent the limb with a minor limb irregularity. Furthermore, iliac artery tortuosity and stenosis tends to reassert itself in the postoperative period so that a mild irregularity seen on completion angiogram may actually become more severe leading to limb thrombosis in the postoperative period. Remember, most limb thromboses occurred early within 6 months in this study and our current imaging protocol at 1 month, 6 month, and yearly missed these impending limb thromboses.

Dr Farber. 2. Intravascular Ultrasound (IVUS) has been shown to identify endograft limb abnormalities that were missed during angiography in Ancure endografts. Have you used IVUS in your patients? Do you think IVUS should be used routinely?

We have not used IVUS in our patients. Although IVUS may be more sensitive, we do not feel that it needs to be used routinely. IVUS is expensive, time consuming, and of unknown predictive value in trying to identify such a small population of limbs at risk for thrombosis with "abnormalities missed during angiography." Furthermore, this study illustrates bare stenting is simple, safe, and effective when employing our liberal indications.

Dr Farber. 3. You identified two potentially high risk groups for limb thrombosis: women and patients in whom endograft limbs were extended into the external iliac artery. Is it your recommendation that patients in these groups ought to be stented routinely?

We recommend bare stenting of all endograft limbs extended into the external iliac artery. This represents our response to the observation that a disproportionate number of external iliac graft limbs thrombose in the absence of stents. We do not recommend routinely stenting all women. This should be performed on a case by case basis based on preoperative and intraoperative anatomy. Unfavorable anatomy (smaller, tortuous vessels) in women probably lead to higher rates of kinking or stent graft compression and explains our higher rate of stenting in this group.

Dr Farber. 4. Did you evaluate whether there was a correlation between limb thrombosis and quantitative anatomical factors such as minimal iliac diameter, iliac angulation, and degree of iliac calcification?

Our prospective data collection did include an assessment of iliac tortuosity. Unfortunately, this was rather subjective and in-

tended to assess ease of delivery system insertion, not stent-graft angulation. We are not in a position to make these measurements retrospectively because most of the CT scans were represented by hard copy transaxial slices and many of the patients lacked preoperative angiograms. We cannot assess intraoperative findings, because the recorded completion angiograms are often limited to a single AP view, especially in unstented cases. Intraoperative imaging tended to be better in stented cases, because the additional angiograms formed the basis for the decision to insert adjunctive stents.

Even if we could measure these factors we would be unable to correlate most of the highest risk cases with outcome because these were the very ones that received additional stents, which may have prevented thrombosis. We are unable to offer any specific recommendations as to which limbs require adjunctive stenting. Based on the findings of this study we can say that adjunctive stenting appears to be safe and effective prophylaxis against graft limb thrombosis, but we cannot say which patients are most at risk, or how to apply a policy of selective stenting.

Dr Farber. 5. Finally, twelve out of the thirteen limb occlusions appeared to have had an anatomical abnormality on postoperative imaging. Did you compare these studies with your intraoperative angiography studies to see if in retrospect the offending lesion could be identified and the need to stent predicted?

Attempts were made to review the intraoperative angiography studies to see if the offending lesion could be identified. Unfortunately, these images were inadequate. Because a decision was made not to place stents in these patients, the imaging was limited to an AP view. Typically, when a decision is made to place a stent, multiple oblique views are performed to define the anatomy. Therefore, the offending lesion may have been present, but unidentified at the time of operation. Another consideration is that the lesions developed later as tortuosity of the native system overwhelmed the stiffness of the limb. Furthermore, it would be easy to miss subtle shifts in stent graft position on the one month postoperative images that might progress slowly to produce thrombosis before the six month interval when most limb thrombosis presented in this study.

Dr William Quinones. (Los Angeles, CA) I enjoyed your presentation very much because I think this is an important problem. Given that the graft that you are using, the endograft that you are using, is fully supported, we at UCLA have taken the position that when we finish these grafts with angioplasty the limbs liberally, not just as recommended by the company at the junctions and so on, and our incidence of long-term limb thrombosis has been extremely low. I mean I think we have maybe 3 or 4 over the last 10 years. My first question is, do you angioplasty these areas that you see either a kink or a defect before you stent or do you stent primarily?

Dr Nayan Sivamurthy. (San Francisco, CA) We stented primarily in all cases and then balloon angioplastied. From our experience, stenting is required to correct the anatomic defect. Initially, angioplasty alone may alleviate the defect. However, iliac tortuosity tends to reassert itself and may predispose graft limbs to develop kinking, angulation, or stenosis and subsequent limb thrombosis on follow up. Therefore, we feel primary stenting is indicated in the majority of cases.

Dr Quinones. So you haven't tried just angioplastying the process, because I can tell you that in our hands works very well. It resolves 95% of the instances.

My second question is, it is curious to me that even in the cases that you had long-term limb thrombosis in the unstented group, even when you did thrombectomy or lysis in some of those cases you did not stent. You just left it alone, so the question is would having stented that limb initially prevented the thrombosis or how do you explain the fact that you treated the thrombosis and didn't have to stent?

Dr Sivamurthy. At the time, the operating surgeon's impression was that there was no anatomic lesion to treat. 7 of 13 patients with limb thrombosis had no stent placed after interventions to

treat the occlusion. 4 of the 7 patients with limb thrombosis underwent extranatomic bypass which is a viable alternative. 2 of 7 patients had thrombectomy alone. One of these patients required reintervention and extraanatomic bypass. One patient underwent thrombolysis alone. Retrospective review of those incidences of graft thrombosis where we did not place a stent during reintervention (7 of 13) an anatomic lesion could be appreciated. These seven cases may have been amenable to a stent. However, the difficulty of a retrospective review is trying to identify the operating surgeon's thought process.

Dr Ben Starnes. (Tacoma, WA) Two questions--one technical question and one philosophical question.

The technical question is, when you do your completion angiography, do you do that with stiff wires in place or with soft wires in place to allow for the tortuosity?

My second question is, you used 80% Wallstents to stent these graft limbs and my question is why? There are better self-expanding stents in my opinion. The Wallstent has frayed edges on the end. I'm wondering if you've seen graft complications or erosions into the graft material from the Wallstents. Do you use self-expanding stents at the aortic bifurcation only and Wallstents in the tortuous portions? I was just wondering if you'd comment on that.

Dr Sivamurthy. Regarding the first question, we remove all stiff guidewires before completion angiography.

Regarding the second question we primarily use the Wallstent. We have not seen any graft complications or erosions into the graft material from the Wallstents. We feel the Wallstent has no sharp points along its length to injure the body of the graft except at the proximal and distal ends. We tend to place the wall stent so that the top starts a little above the aortic bifurcation and the bottom of the stent ends in native artery to minimize this part of the stent in contact with the graft. We use the balloon expandable Palmaz stent specifically when more radial force is required. An example would be distal aortic narrowing due to calcification or prior aortic surgery. We have not used any other self expanding stents

Discussion Audience: I just want to make some comments. First of all it was a nice presentation. But we always tend to dwell on the negatives of looking at limb thrombosis, but if you look at it the other way you are talking about 500 limbs that were placed at risk in 3 to 4 years and you had 13 limbs that are occluded. You are talking about a very low limb thrombosis rate and I think that is something that when we started, especially when I started doing endografting years ago that I thought our limb thrombosis was going to be much higher and I also thought that the external iliac artery was going to be a problem as we put in this large device into the external iliac artery. This was proven not to be the case in your series and our series at Harvard. I mean the same thing, the external iliac artery tolerates actually this manipulation very well. I think what we are doing is we are _____ this vessel. Actually we are improving our patency. In our patient population 25% of them end up having an increase in their ABIs in the postoperative period, so I think that is something that arises from it.

With regards to women, they continue to be a problem with endografting. Being from the other spectrum of using intravascular ultrasound in every case, what I find it is not so much the angulation but the diameter. The vessels tend to be smaller. It may be that is really an oversizing on the limbs rather than angulation.

The other comment I have is that I thought that when we did have limb thrombosis that thrombolysis would be ideal for them and that has not been the case. We end up doing a lot more crossover fem-fem or mechanical thrombectomy in that area. This is something that you also pointed out too.

My question though is when you get limb thrombosis late one of the things that has been very useful—the group in Sidney has pointed this out—is just looking at the x-rays before you submit somebody to an angiogram and see those limb angulations. Could you speculate, in the limb thromboses that occur late, was that due in some way to the collapse of the aneurysm, reshaping the limb entry into the limb and that might be the failure mode.

Thank you very much.

Dr Sivamurthy. We do find the plain abdominal xrays very useful in displaying the limb anatomy and determining the cause for limb thrombosis. This was our primary mode for identifying the cause for limb thrombosis. Our postoperative surveillance includes CT and plain films at 1 month, 6 month, 1 year, and then yearly afterwards. Two patients developed limb angulation and subsequent thrombosis late that was not apparent on earlier imaging. Retrospective review allowed us to appreciate this over time. You can speculate that it may be secondary to aneurysm remodeling, but I can not make that conclusion with certainty. More likely, thrombosis is a result of iliac tortuosity reasserting itself in the postoperative period. Remember, the majority of limb thrombosis occurred early with 73% occluding within 6 months of endograft placement. Limb thrombosis appears to be an early event. Postoperative imaging based on our protocol was not useful in detecting early impending occlusion. Imaging may detect late impending occlusions. However, late thrombosis appears to be a rare event and involved only two patients in this study.

Dr Chuter. I'd like to just kind of clarify a couple of things, what-was-in-the-mind-of-the-attending kind of things. One of them relates to the use of the Wallstents. If you look at the big European experience with earlier stent graft designs, you find that some stents make holes in grafts and the bit of the stent that makes the hole is the apex of the zigzag, and all of the stent alternatives that are out there essentially consist of a series of zigzags. When you put them around a corner, those little zigzags present outwards. They have sharp apices and they are potentially injurious to grafts. The Wallstent doesn't have any of those. It is continuous wire from end to end. The only bits you have to worry about are

the top and the bottom. If you put the top sticking up a little bit into the bifurcation and the bottom sticking a little bit down into the artery, you don't have any of that in contact with graft wall. There are a couple of reports in the literature of the old EBT, the Ancure device, getting injured by Wallstents but it's very, very rare. Wallstent is quite a benign object. Our experience tends to bear that out.

One of the other things relates to the late occurrence of thrombosis. What we've tended to find is that anatomy reasserts itself, that if you put a stiff stent graft, which the _____ stent graft is rather stiff, through a tortuous limb, you can straighten it out. Unfortunately, when you come back a month later the anatomy if it was very tortuous has reasserted itself and now there is a kink. So we have taken preoperative anatomy as something of an indication of what postoperative anatomy maybe is not like in the OR but will be like a little bit later, so we are more aggressive on that point of view.

Just one comment that relates back to the data. One of the most interesting findings I think Nayan dug up relates to the limbs that weren't stented in patients who had other stented limbs, so the unstented side of a stented patient. Those limbs never thrombosed. They had no stents in them and they never clotted off. The question is why. I suggest that the answer is that the presence of a stent in one limb is a marker for the surgeon and the surgeon who is placing stents in one limb is going to perhaps be more likely to place stents in another limb if that limb needs it, so perhaps we're seeing there what happens with a slightly more aggressive approach. I'll tell you what happens, you don't get any limb thrombosis. I'll put that out as a hypothesis.