Cardiovasc Intervent Radiol (1992) 15:291–297

CardioVascular and Interventional Radiology

Stenting of the Iliac Arteries with the Palmaz Stent: Experience from a Multicenter Trial

Julio C. Palmaz, Jean C. Laborde, Frank J. Rivera, Carlos E. Encarnacion, James D. Lutz, and Jonathan G. Moss

Department of Radiology, The University of Texas Health Science Center at San Antonio, San Antonio, Texas, USA

Abstract. Balloon-expandable, intraluminal stenting of the iliac arteries with the Palmaz stent was the subject of a multicenter study for 4 years. A total of 486 patients underwent 587 procedures. Four hundred and five patients had unilateral and 81 had bilateral iliac stent placements. Follow-up ranged from 1 to 48 months (mean 13.3 ± 11 months). Sustained clinical benefit of the treated patients was obtained in 90.9% at 1 year, 84.1% at 2 years, and 68.6% at 43 months. Angiographic patency rate was 92%. Diabetes mellitus and poor runoff had significant negative influence on the clinical outcome. The 10% incidence of procedural complications was not altered by operator experience.

Key words: Atherosclerosis—Iliac arteries—Percutaneous balloon angioplasty—Intravascular stents

In August 1987 a trial was instituted to evaluate a balloon-expandable intraluminal stent in patients with iliac artery disease. Preliminary results from this trial were published previously [1–2]. Seventeen centers (see acknowledgment) were involved in phase II of the trial. The criteria for patient selection, the procedural guidelines, and the method of follow-up evaluation were performed under a protocol approved by the United States Food and Drug Administration (FDA) and the Institutional Review Boards and Ethics Committees of the institutions involved. Almost 5 years have elapsed since the beginning of this trial to the present but the patient accrual rate increased disproportionately with time. This caused an uneven distribution of the patient follow-up groups, with most of the patients having a relatively short period of follow-up. In order to obtain further data about safety and efficacy of this form of treatment in a significant number of patients, the evaluation will continue into the future. However limited, important information was elicited from the available data. The following is a statistical analysis of such data.

Address reprint requests to: Julio C. Palmaz, M.D., Department of Radiology, The University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Drive, San Antonio, TX 78284 USA

Material and Methods

The device under evaluation is a balloon-expandable stent manufactured by Johnson and Johnson Interventional Systems, Warren, NJ. This device is currently approved for the clinical treatment of iliac artery disease in the United States and most other countries. The protocol, patient selection, indications, contraindications, and procedural guidelines for the use of the device were previously described in detail [1–4]. The criteria for evaluation of the clinical results followed the guidelines proposed by Rutherford et al. [5].

Patient Population

The trial group was composed of 486 patients who underwent a total of 587 procedures. The patients' mean age was 62.9 ± 10 years, with patients in their 60s being the largest group. The risk profile of the patient population, composed of 75% males and 25% females, showed that 94.4% of the patients had a history of cigarette smoking, 22.9% suffered from diabetes mellitus, 50.4% had coronary artery disease, 18.2% had cerebrovascular disease, and 52% had high blood pressure (Fig. 1).

We used the following ranking system for lower extremity ischemia: stage 0 asymptomatic; stage 1 mild intermittent claudication (≥500 yards); stage 2 moderate intermittent claudication (500–50 yards); stage 3 severe claudication (<50 yards), stage 4 ischemic rest pain; stage 5 nonhealing ulcer, minor tissue loss; stage 6 major tissue loss, foot not viable. Two patients (0.4%) were in stage 0, 0.7% were in stage 1, 20.8% were in stage 2, 46% were in stage 3, 21.1% were in stage 4, 10.4% were in stage 5, and 0.5% were in stage 6 (Fig. 2). The 2 patients in stage 0 were

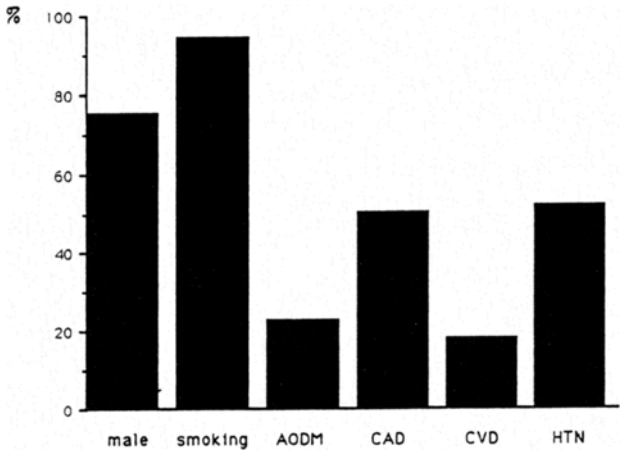

Fig. 1. Atherosclerotic profile as defined by the mean incidence of risk factors. AODM: Adult onset diabetes mellitus. CAD: Coronary artery disease, CVD: Cerebrovascular disease. HTN: Hypertension.

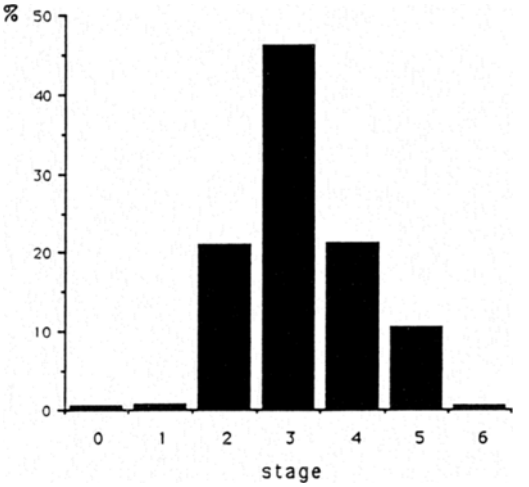

Fig. 2. Percent distribution of ischemic stages before treatment. Stage 0 = asymptomatic; stage 1 = mild intermittent claudication (≥500 yards); stage 2 = moderate intermittent claudication (500–50 yards); stage 3 = severe claudication (<50 yards); stage 4 = ischemic rest pain; stage 5 non-healing ulcer, minor tissue loss; stage 6 major tissue loss, foot not viable.

athletes, asymptomatic by stage grading but who had reduced exercise tolerance by a flow-limiting lesion in the iliac arteries.

Lesion Characteristics

In keeping with the trial goal to evaluate the device in relatively localized iliac artery disease, the average length of the iliac artery lesion treated was 3.2 ± 3.1 cm and 62.6% of the patients had a lesion equal or shorter than 3 cm. Longer lesions were present in fewer patiens, with 1.6% (8 patients) having lesions equal or longer than 15 cm (Fig. 3). The mean lesion stenosis was 82 ± 16%, and 13.5% of the lesions amounted to complete occlusion. The majority of the lesions (40.8%) were in the 80–99% range. Most of the patients with a less severe degree of stenosis were those with inflow and outflow disease in whom iliac revascularization was part of a combined treatment involving iliac stenting and lower extremity bypass surgery. Twenty-seven such patients accounted for 5.5% of the trial population. The mean intraluminal pressure gradient across the area to be treated was 39.1 ± 24 mm Hg.

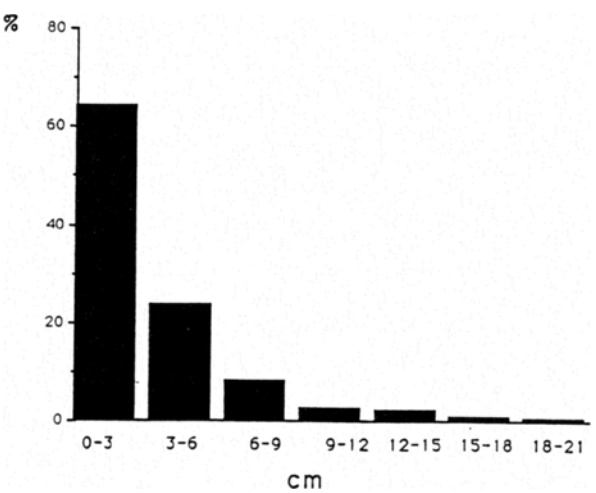

Fig. 3. Percent distribution of lesion length per patient.

Treatment and Follow-up Evaluation

Four hundred and five patients received stenting of one iliac artery and 81 patients had bilateral placements. Of these, 59 had both iliac arteries treated with stents at the same sitting and the other 22 patients had iliac stenting on two separate occasions. The common iliac artery was the site of stent placement in 66.5% and the external iliac artery in 19% of the patients. Both common and external iliac arteries were treated in 13.1% of the patients, and 1.4% received stents in the distal aortic lumen.

The patients were followed up clinically, hemodynamically, and angiographically following a routine previously described [1–2]. The average clinical and hemodynamic follow-up was over 1 year (13.3 ± 11 months), with the largest group of patients followed up to 6 months. Sixty-nine (16.3%) of the patients had more than 24 months of follow-up evaluation.

Two hundred and one patients had an angiographic follow-up study at an average of 8.7 ± 5.7 months (range 1–35 months). For the purpose of establishing angiographic patency, a stented lumen equal to or smaller than 50% was considered stenotic. The clinical outcome of the procedure was evaluated by the Kaplan-Meier product-limit method (BMDP statistical software. Los Angeles, CA). Validity of an observation was set at a standard error ≤0.1. Statistical evaluation between categories was assessed by the Wilcoxon test and significance level was set at $P \leq 0.05$.

Results

An average of 1.9 ± 1.3 stents were used per patient (range 1–8). Because the most frequent lesion length was shorter than 3 cm (Fig. 4), most patients received just one stent (52.4% = 1; 28.7% = 2; 9.2% = 3; 4.6% = 4; 2.7% = 5; 1% = 6; and 0.8% = 7 stents) (Fig. 4). Following stenting the

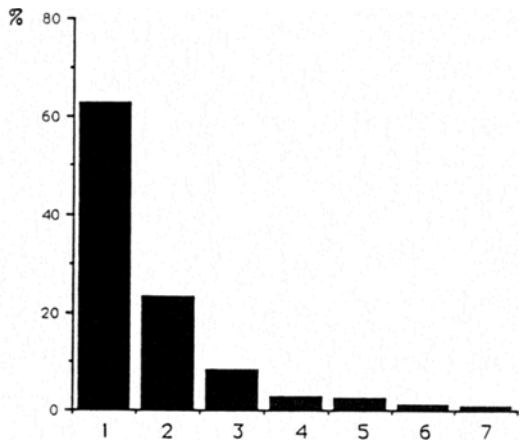

Fig. 4. Percent distribution of number of stents per patient.

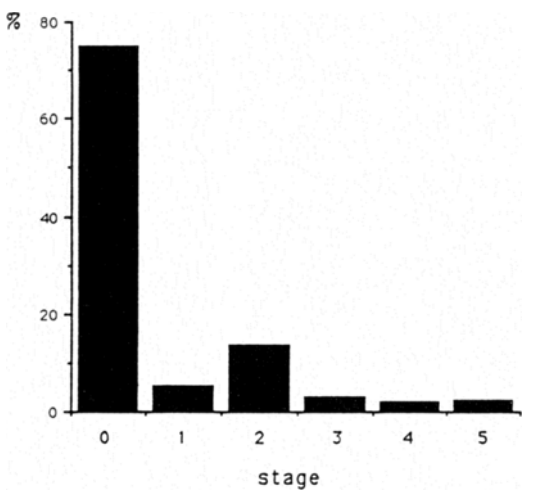

Fig. 5. Percent distribution of ischemic stages soon after treatment. Stage 0 = asymptomatic; stage 1 = mild intermittent claudication (≥500 yards); stage 2 = moderate intermittent claudication (500–50 yards); stage 3 = severe claudication (<50 yards), stage 4 = ischemic rest pain; stage 5 non-healing ulcer, minor tissue loss; stage 6 major tissue loss, foot not viable.

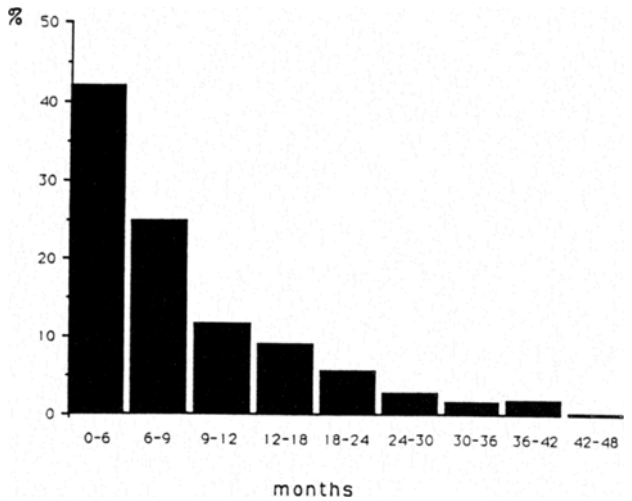

Fig. 6. Percent distribution of time intervals at the latest follow-up examination.

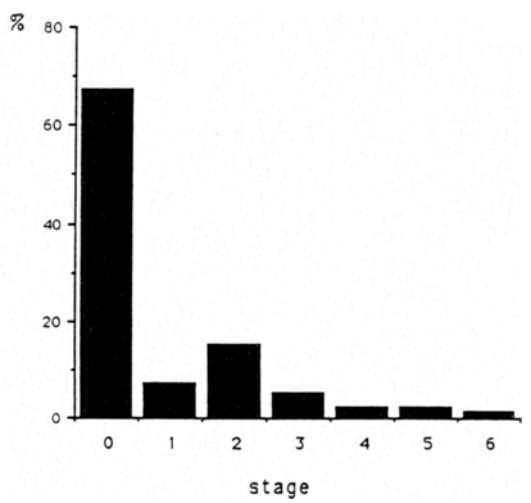

Fig. 7. Percent distribution of ischemic stages at latest follow-up examination. Stage 0 = asymptomatic; stage 1 = mild intermittent claudication (≥500 yards); stage 2 = moderate intermittent claudication (500–50 yards); stage 3 = severe claudication (<50 yards), stage 4 = ischemic rest pain; stage 5 non-healing ulcer, minor tissue loss; stage 6 major tissue loss, foot not viable.

mean pressure gradient across the treated area was reduced to 1.3 ± 2.9 mm Hg. The clinical status at the time of hospital discharge following treatment of the iliac artery stenosis with stents as the only procedure or in combination with bypass surgery of the lower extremity was graded with the same ranking system as before treatment. Three hundred and fifty-seven (74.7%) patients were asymptomatic, 5% had stage 1, 13.4% stage 2, 2.9% stage 3, 1.9% stage 4, and 2.1% had stage 5 lower extremity ischemia (Fig. 5). The patients were evaluated by clinical examination and segmental, lower extremity cuff-pressure measurements at regular intervals [1–2]. The longest time of follow-up averaged 13.3 ± 11 months (range 1–39) (Fig. 6). At the latest follow-up, the clinical status of the lower extremity in 67.1% of the patients was asymptomatic, 7.1% were in stage 1, 15% stage 2, 5% stage 3, 2.3% stage 4, 2.3% stage 5, and 1.2% were in stage 6 (Fig. 7). The mean ankle-brachial index increased from 0.62 ± 0.2 prior to the treatment to 0.8 ± 0.2 soon after and it was 0.8 ± 0.2 at the latest follow-up examination.

The evaluation of clinical success by the product limit method, as defined by the retention of at least one stage improvement in the ischemic ranking system, indicated a success rate of 99.2% immediately after treatment, 90.9% at 12 months, 84.1% at 24, and 68.6% at 43 months (Fig. 8). Comparison of

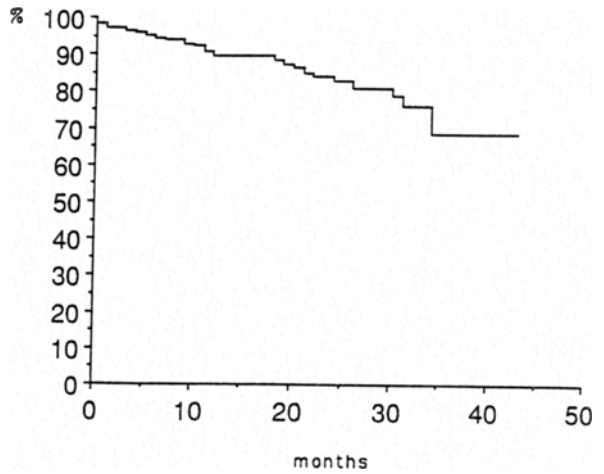

Fig. 8. Product limit statistics on overall success of the treatment.

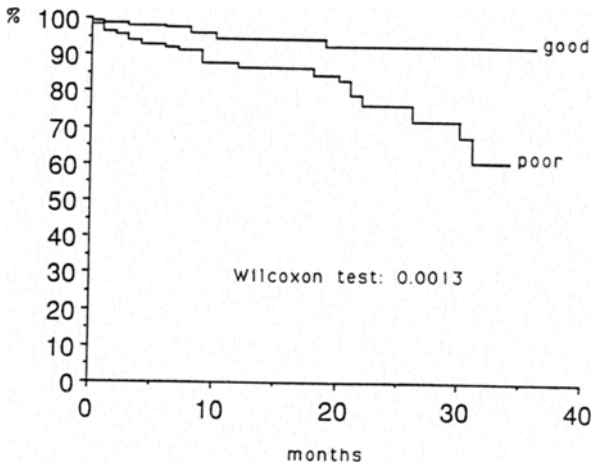

Fig. 10. Product limit statistics of clinical success in patient with and without poor runoff.

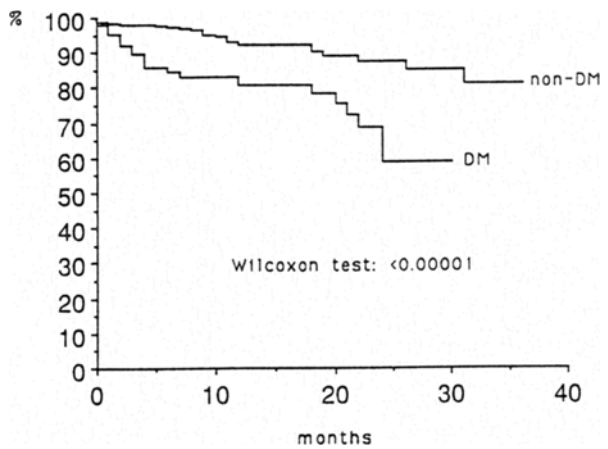

Fig. 9. Product limit statistics of clinical success in patients with and without diabetes mellitus. (DM: diabetes mellitus).

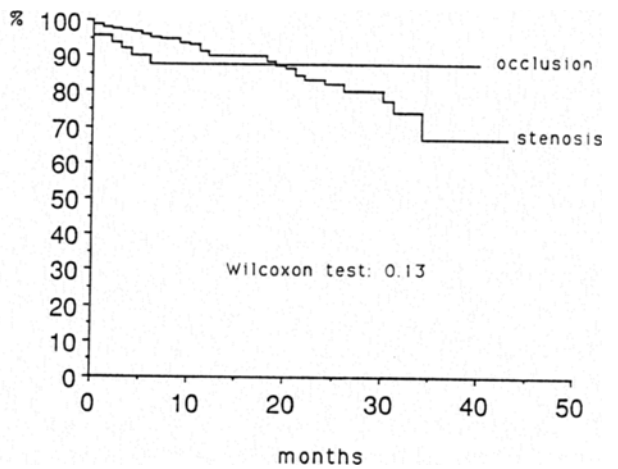

Fig. 11. Product limit statistics of clinical success in patient with and without iliac artery occlusion prior to stenting.

survival curves between patients with and without diabetes mellitus indicated a statistical significant difference in retention of improvement at 3 years (Wilcoxon test $P < 0.00001$) (Fig. 9). Likewise, patients with poor runoff vessels had poorer results (Wilcoxon test $P = 0.0013$) (Fig. 10). Patients with recanalized complete iliac artery occlusion did better than those with stenosis as 87.8% of the patients with stented occlusion were classified as successful compared with 66.6% of those with stenosis, at 40 months. The statistical comparison did not, however, achieve significance (Wilcoxon test $P = 0.13$) (Fig. 11).

Evaluation of the angiographic data available yielded an angiographic patency rate of 91.9%. Including the complete occlusions, the mean loss of luminal diameter was 15 ± 16%. Restenosis occurred in 15 common iliac and one external iliac artery stents. In 2 patients, restenosis occurred in both common and external iliac artery stents. Restenosis was diagnosed at 1 month or sooner in 7 patients (1.4%) and after 1 month in 8 patients (1.8%). Angiography detected progression of atherosclerotic disease at a site distant to the stent in 4.5% of the patients during the first year, in 5.5% of the patients during the second year, and in 5.8% during the third year after treatment. The overall limb loss was 1.9%. Five below-knee amputations occurred at 15 days and 1, 2, 4, and 4 months, respectively. Four additional above-knee amputations occurred at 1, 6, 15, and 16 months, respectively. No stent thrombosis was present in any of the amputees.

Table 1. Complication of stent placement for iliac artery disease in 486 patients (587 procedures)

Procedure related		Stent related	
Groin hematoma	8	Acute thrombosis	5
Distal embolization	6		
Groin pseudoaneurysm	4	Pseudoaneurysm	2
Iliac artery pseudoaneurysm	1	Dislodgement	4
Aortic extravasation	1		
Groin arteriovenous fistula	1		
Retroperitoneal hematoma	2		
Surgical arteriotomy bleed	1		
Puncture site thrombosis	2		
Puncture site laceration	4		
Angioplasty site rupture	4		
Subintimal dissection	5		
Contrast-induced renal failure	4		
Death (contrast reaction)	2		

Complications

The overall complication rate was 9.9%. Eight percent of the complications were related to the stent delivery procedure and largely localized to the vessel entry site (Table 1). The remaining 1.9% were related to the stent itself. Acute thrombosis shortly after stent placement occurred in five instances. Two pseudoaneurysms adjacent to the stented site developed in 2 patients who had laser recanalization of complete chronic occlusions followed by stent placement. One of them, small in size, was treated conservatively. The other one was treated by distal ligation of the iliac artery and femoro-femoral bypass. Four stent thromboses were recanalized with thrombolysis and balloon angioplasty. One patient underwent aortofemoral bypass.

Analysis of the incidence of complications by investigational site failed to indicate a relationship between number of complications and number of procedures performed at each site. Therefore, the incidence of complications was similar in all sites. Among the centers with the largest number of cases performed, the incidence of complications per year did not change significantly through the duration of the study. Nine patients (1.9%) died within 30 days and 27 patients (6.2%) died beyond 30 days of the treatment. One year after treatment, the overall mortality was 6.1%. Cardiovascular causes were responsible for 63% of deaths. Neoplasm was the reason for demise in 19.4%, infection in 8.3%, and miscellaneous causes in an additional 8.3% of the patients.

Discussion

During the past 6 years, a sizable clinical experience with the use of stents in the iliac arteries has been reported. In a randomized comparison between balloon-expandable stents and percutaneous balloon angioplasty of the iliac arteries, Richter et al. [6] demonstrated that stenting may improve upon the results of iliac angioplasty, but longer follow-up is needed to confirm this preliminary conclusion. Stents suitable for use in iliac artery disease such as the Cook "Z" stent (Bloomington, IN), the Schneider Wallstent (Minneapolis, MN), the Medi-tech, Strecker stent (Watertown, MA), and the Johnson and Johnson Palmaz stent (Warren, NJ) are commercially available in Europe, Australia, Asia, and South America. The Palmaz stent is currently the only one approved for iliac artery stenting in the United States. As no clinical registry of the use of iliac stents is available, systematic information regarding patients, devices, and treatment outcome is lacking. The iliac stent data published in the literature probably represents a small fraction of the global experience in the use of iliac stents, and the reporting methods are not standardized for comparative analysis. In order to evaluate the safety and efficacy of an intravascular stent in any clinical application, minimal information must include acute occlusion rate, patency, and complications. Data on acute occlusion is important because of the inherent thrombogenicity of these devices and, in this respect, most investigators agree that a thrombotic event occurring within 3 weeks after stent placement should be considered acute. Stent patency may be expressed as minimal luminal diameter or mean percentage stenosis, however, it is most commonly reported as percentage of stents with a lumen less than or equal to 50% of the immediate postplacement diameter. Sectional imaging may provide enough information to evaluate patency but conventional or digital angiography provide additional information about the vessels proximal and distal to the stent that is essential for a complete evaluation. Six months after initial stent placement is the most commonly reported period of time for establishing patency or restenosis rate. Longer periods of time may be more meaningful, as would be serial angiographic evaluations. However, this is an unrealistic expectation as asymptomatic patients tend to refuse even a single, scheduled follow-up arteriogram.

Noncontrolled comparison between series of patients who received different stents is marred by biased patient selection. Examples of such selection biases are the operators' tendency to select patients with long iliac lesions to receive equally long stents or patients with disease-free common femoral arteries for those stents with large delivery systems. The first would influence negatively and the second positively the procedure outcome. Considering all the limitations, analysis of reports containing enough

Table 2. Clinical experience in iliac artery stenting

Stent	No. patients	Acute occlusion %	Patency %	Complication %
Palmaz				
US Multicenter [7]	401	1	94.1	11
European multicenter [6]	159	1.3	93.1	3.1
Henry et al. [8]	56	0	97	3.5
Average	616[a]	1	94.1	8.5
Wallstent				
Vorwerk and Guenter [9]	68	3	93.3	12
Guenter et al. [10]	91	2.2	83.5	20
Zollikofer et al. [11]	26	0	96	7.8
Average	185[a]	2.2	88.6	9.2
Gianturco "Z"				
Kichikawa et al. [12]	10[a]	0	100	0

Stents and authors are listed by number of cases reported
[a] Values representing total number of patients

data for comparative analysis is detailed in Table 2. Acute thrombosis, patency, and complications are reasonably similar among the three devices under comparison, even taking into consideration possible bias in the patient selection and interpretation of the results [6–12].

Analysis of the patient population of the present study yields valuable information about the nature of iliac artery disease and how it can be affected by intraluminal stent placement. This group of patients reflects that atherosclerotic disease of the iliac artery predominately affects male smokers in their 60s. Half of the patients have hypertension or coronary artery disease and about one-fifth have cerebrovascular disease or diabetes mellitus. Severe intermittent claudication at 50 yards or less is present in almost half of the patients. The most common lesion treated was a short (≤3 cm), high-grade (82 ± 16%), common iliac artery stenosis causing a large intraluminal pressure gradient (39 ± 24 mm Hg). Recanalization of such obstructions by stent placement was effective in relieving symptoms as 75% of the patients were rendered asymptomatic after treatment. Survival statistics of clinical success showed a steady decline in the cumulative success, with only 67% of the patients retaining benefit 43 months after treatment. This was shown to be related to progression of atherosclerotic disease proximal or distal to the treated site which developed at an approximate rate of 5%/year. Clinical failure was caused by the development of these new lesions rather than restenosis of the treated site which remained patent in 92% of the patients. The observation that all amputations occurred in patients with patent stents also suggests that distal progression of the disease is the most common cause of failure. As expected, diabetes mellitus and poor runoff had a negative influence on the long-term outcome.

The higher treatment success among patients with recanalized occlusions as opposed to those with stenoses is not conclusive until a larger number of patients allows for more accurate statistical evaluation. However, there is a trend to indicate that all clinical failures among recanalized occlusions occurred within 8 months, with no failures thereafter. This suggests that reendothelialization may take this long to be complete after stenting of occluded arteries, which are obviously devoid of endothelial lining immediately after treatment. A period of risk of stent failure exists before endothelialization finally protects the treated segment from low-flow thrombosis. The sustained clinical success beyond the first 8 months confirms the notion that "protected" vessels distal to iliac occlusions may be relatively free of disease and that these patients derive maximum benefit from proximal revascularization.

The iliac stent complication rate of 10% compares well with the complication rate of iliac balloon angioplasty averaging 9% [13–16]. Most of the complications are related to the puncture site and the relatively large size of the delivery system (9 French). It is expected that these complications will be reduced with the use of new balloon-expandable stents of smaller diameter, that may be crimped over 5F angioplasty balloons and introduced through 7F sheaths. Serious complications directly related to the stent, such as pseudoaneurysm, should be avoided by refraining to place stents after recanalization of chronic iliac occlusion by any method that may cause wall perforation, such as laser or atherectomy. Stent placement in these circumstances may intensify bleeding by stretching open a defect in the

wall that may have been partially or completely closed by elastic recoil. The fact that the incidence of complications is not higher among investigators accruing a small number of cases indicates a short or absent specific "learning curve." The technique is closely related to percutaneous balloon angioplasty, and all testing sites involved in this trial had a large expertise in this procedure. Therefore, this may have reflected positively on the incidence of complications, which remained at a relatively low, constant level as the experience increased.

As expected in this patient population, most deaths were related to myocardial infarction and stroke. This emphasizes the need for aggressive screening of the coronary and carotid vessels among patients with iliac artery disease. Longer follow-up and further analysis of this cohort is under way and may increase in the future our understanding of the natural history of the disease.

In conclusion, the present study supports the use of balloon-expandable stenting as safe and effective for the treatment of atherosclerotic iliac artery disease.

Acknowledgment. The authors gratefully acknowledge the thorough and painstaking data collection by the following centers involved in the trial (listed in alphabetical order):
Alexandria Hospital, Alexandria, Virginia
Arizona Heart Institute, Phoenix Arizona
Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania
Incor, Sao Paulo, Brazil
Indiana University Hospitals, Indianapolis, Indiana
Miami Vascular Institute, Miami, Florida
Scripps Clinic, San Diego, California
Shadyside Hospital, Pittsburgh, Pennsylvania
St. Vincent's Hospital, Indianapolis, Indiana
Thomas Jefferson University Hospital, Philadelphia, Pennsylvania
Terrebone Hospital, Houma, Louisiana
University of Freiburg Hospital, Freiburg, Germany
University of Minnesota Hospital, Minneapolis, Minnesota
University of Mainz, Mainz, Germany
University of Texas Health Science Center, San Antonio, Texas
Washington Hospital, Washington, DC
Western Pennsylvania Hospital, Pittsburgh, Pennsylvania

References

1. Palmaz JC, Richter GM, Noeldge G, Schatz RA, Robison PD, Gardiner GA, Becker GJ, McLean GK, Denny DF, Lammer J, Paolini RM, Rees CR, Alvarado R, Heiss WH, Root HD, Rogers W (1988) Intraluminal stents in atherosclerotic iliac artery stenosis: Preliminary report of a multicenter study. Radiology 168:727–731
2. Palmaz JC, Garcia OJ, Schatz RA, Rees CR, Roeren T, Richter GM, Noeldge G, Gardiner GA, Becker GJ, Walker C, Stagg J, Katzen BT, Lammer J, Schwarten D, Tio FO, Root HD, Rogers W (1990) Placement of balloon-expandable intraluminal stents in iliac arteries: First 171 procedures. Radiology 174:969–975
3. Rees CR, Palmaz JC, Garcia OJ, Roeren T, Richter GM, Gardiner G Jr, Schwarten D, Schatz RA, Root HD, Rogers W (1989) Angioplasty and stenting of completely occluded iliac arteries. Radiology 172:953–959
4. Palmaz JC, Encarnacion C, Garcia OJ, Schatz RA, Rivera FJ, Laborde JC, Dougherty SP (1991) Aortic bifurcation stenosis: Treatment with intravascular stents. JVIR 2:319–323
5. Rutherford RB, Flanigan PD, Gupta SK, Johnston WK, Karmody A, Whittmore AD, Baker JD, Ernst CB, Jamieson C, Mehta S (1986) Suggested standards for reports dealing with lower extremity ischemia. J Vasc Surg 4:80–94
6. Richter GM, Noeldge G, Roeren T, Landwehr P, Brambs HJ, Kauffmann GW, Palmaz JC (1990) First long-term results of a randomized multicenter trial: Iliac balloon-expandable stent placement versus regular percutaneous transluminal angioplasty (abstract) Radiology 177(P):152
7. Palmaz JC (1991) Update on clinical experience with peripheral vascular stents. Presented at the annual meeting of the Arizona Heart Institute (International Congress IV), Phoenix, February 13, 1991
8. Henry M, Beron R, Amicabile C, Voiriot P, Chastel A (1991) Palmaz-Schatz stents in the treatment of peripheral vascular diseases (abstract) J Am Coll Cardiol 17:302A
9. Vorwerk D, Guenther RW (1990) Mechanical revascularization of occluded iliac arteries with use of self-expandable endoprostheses. Radiology 175:411–415
10. Guenther RW, Vorwerk D, Antonucci F, Beysen B, Essinger A, Gaux JC, Joffre F, Raynaud A, Rousseau H, Zollikofer Ch L (1991) Iliac artery stenosis or obstruction after unsuccessful balloon angioplasty: Treatment with a self-expandable stent. AJR 156:389–393
11. Zollikofer CL, Antonucci F, Pfyffer M, Redha F, Salomonowitz E, Stuckmann G, Largiadèr J, Marty AH (1991) Arterial stent placement with use of the Wallstent. Mid-term results of clinical experience. Radiology 179:449–456
12. Kichikawa K, Uchida H, Yoshioka T, Maeda M, Nishimine K, Kubota Y, Sakaguchi S, Ohishi H, Iwasaki S (1990) Iliac artery stenosis and occlusion: Preliminary results of treatment with Gianturco expandable metallic stents. Radiology 177:799–802
13. Borozan PG, Schuler JJ, Spigos DG, Flanigan DP (1985) Long-term hemodynamic evaluation of lower extremity percutaneous transluminal angioplasty. J Vasc Surg 2:785–793
14. Johnston KW, Rae M, Hogg-Johnston SA, Colapinto RF, Walker PM, Baird RJ, Sniderman KW, Kalman P (1987) 5-year results of a prospective study of percutaneous transluminal angioplasty. Ann Surg 206:403–413
15. Waltman AC, Greenfield AJ, Novelline RA, Abbott WM, Brewster DC, Darling RC, Moncure AC, Ottinger LW, Athanasoulis CA (1982) Transluminal angioplasty of the iliac and femoropopliteal arteries. Arch Surg 117:1218–1221
16. Gallino A, Mahler F, Probst P, Nachbur B (1984) Percutaneous transluminal angioplasty of the arteries of the lower limbs: A 5-year follow-up. Circulation 70:619–623