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A multicenter study of permanent hemodialysis access patency: Beneficial effect of clipped vascular anastomotic technique

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Objective: **There is an urgent and compelling need to reduce the morbidity and expense of maintaining hemodialysis vascular access patency. This large, long-term, retrospective, multicenter study, which compared access patency of autogenous arteriovenous fistulas (AVF) and synthetic bridge grafts (AVG) created with conventional sutures or nonpenetrating clips, was undertaken to resolve conflicting results from previous smaller studies.**

Design: **Patency data for 1385 vascular access anastomoses (clipped or sutured) was obtained from 17 hospitals and dialysis centers (Appendix). Five hundred eighteen AVF (242 clip, 276 suture) and 827 AVG (440 clip, 384 suture) were analyzed. Statistical comparisons were made with Kaplan-Meier survival analysis, log-rank test, two-sample *t* test, and X^2 test. The Cox proportional hazards model was used to confirm Kaplan-Meier analysis.**

Results: **Access patency (primary, secondary, overall, and intention to treat) was significantly improved in access anastomoses constructed with clips. In the intention-to-treat group, primary patency at 24 months was 0.54 for clipped AVF and 0.34 for sutured AVF, and was 0.36 for clipped AVG and 0.17 for sutured AVG. At 24 months, primary patency rate for AVF successfully used for dialysis was 0.67 for clips and 0.48 for sutures, and for AVG was 0.39 for clips and 0.19 for sutured constructs. Interventions necessary to maintain patency were significantly fewer in clipped anastomoses.**

Conclusion: **Replacing conventional suture with clips significantly reduces morbidity associated with maintaining permanent hemodialysis vascular access. This beneficial effect may be due to the biologic superiority of interrupted, nonpenetrating vascular anastomoses. (J Vasc Surg 2003;38:229-35.)**

The population with end-stage renal disease (ESRD) is increasing at a rate of 6% per annum, and more than a billion dollars is expended annually to maintain vascular access patency and manage access-related complications.[1-5] Anastomotic neointimal hyperplasia (ANH) resulting in stenosis and eventual access occlusion remains the leading cause of access failure.[6,7] Interventions targeted at reducing ANH by changing anastomotic hemodynamics with vein cuffs, patches, and anastomotic angle, all based on conventional suturing, have failed to improve patency.[3,4] Thus, despite a need to improve access patency, reduce morbidity, and relieve a growing financial burden, there have been no significant technical improvements since inception of the procedure.[3,5]

Nonpenetrating arcuate legged clips that enable an everted, elastomeric, flanged "blood-tight" anastomosis with streamlined blood flow and improved hemodynamics have recently been introduced into clinical practice (VCS; US Surgical Corp/Tyco Inc).[8] Experimental studies and preliminary clinical reports have demonstrated the superiority of clips for end-to-side and end-to-end vascular anastomosis, with reduced ANH, improved patency, and appreciated cost savings.[9-12] Although improved long-term patency of both clipped autogenous arteriovenous fistulas (AVF) and synthetic bridge-graft fistulas (AVG) have been reported,[13,14] other single-institution studies have not confirmed patency differences.[15,16]

To resolve this important question, a long-term multicenter retrospective study was undertaken to determine whether clips have a beneficial effect on fistula patency compared with conventional sutures. This report describes the superior outcome of clipped vascular anastomoses on vascular access patency.

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Competition of interest: The VCS clip is manufactured and sold by US Surgical Corp/Tyco Inc, New York. The patent for the clip is assigned to the University of New Mexico Medical Center and licensed to US Surgical Corp. Dr Kirsch receives a royalty from US Surgical Corp in accordance with the regulations and bylaws of the University of New Mexico Medical Center. Dr Kirsch has no financial interest in the company or its competitor that makes the product (the VCS clip) described in this article.

Dr Stewart has been paid a speaking fee by US Surgical Corp/Tyco, which markets the VCS clip.

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Table I. Patient distribution

	AVG		*AVF*	
Location	*Suture (N = 384)*	*Clip (N = 443)*	*Suture (N = 276)*	*Clip (N = 242)*
St Louis, Mo	76 (4)	104 (1)	63 (6)	60 (2)
Miami, Fla	55 (1)	44	47 (5)	57
Stockton, Calif	28 (1)	35	2	1
Tucson, Ariz	40	19	2	1
Portland, Ore	29	21	5 (1)	0
Detroit, Mich	24 (1)	27	8	5
Riverside, Calif	23 (1)	14 (1)	32	17 (1)
Baltimore, Md	24	19	15	10
Florence, SC	16	74	32 (1)	13 (1)
Opelousas, La	18	37	3	4
Hartford, Conn	9	18	5	8 (1)
Boston, Mass	1	0	0	8
Easton, Pa	7 (1)	4	19	12 (1)
Natick, Mass	4	1	32	35 (1)
Pittsburgh, Pa	9	10	2 (1)	0
Dallas, Tex	9	10 (3)	1 (1)	0
New Bedford, Mass	11	6	8	11

Thirty six of 40 excluded procedures appear in parenthesis. The other four were procedures without details on technique (Riverside, Calif, 3; Dallas, Tex, 1). *AVG,* Arteriovenous graft; *AVF,* arteriovenous fistula.

Table II. Demographic data and risk factors

	AVF				*AVG*			
	Clip (n = 199)		*Suture (n = 199)*		*Clip (n = 401)*		*Suture (n = 344)*	
Variable	*n*	*%*	*n*	*%*	*n*	*%*	*n*	*%*
Demographic data								
Age, mean ± SD	55.9 ± 16.2		57.5 ± 14.8		60.8 ± 14.9		58.9 ± 16.2	
Gender								
Male	146	73.3	126	63.3	157	39.1	149	43.3
Female	53	26.7	73	36.7	244	60.9	195	56.7
Race								
White	77	38.7	93	46.7	106	26.4	102	29.7
African American	96	48.2	86	43.2	261	65.1*	189	54.9
Other	79	39.7	18	9	30	7.5*	45	13.1
Uncertain	7	3.5	2	1.0	4	1.0	8	2.3
Renal disease								
Intrinsic	19	9.5	26	13.1	24	6.0	27	7.8
Congenital	6	3.0	8	4.0	6	1.5	3	0.9
Systemic	138	69.3	131	65.8	317	79.1	271	78.8
Uncertain	36	18.1	34	17.1	54	13.5	43	12.5
Access location								
Radiocephalic	114	57.3	96	48.2	174	43.4	148	43.0
Brachiocephalic or basilic	51	25.6	69	34.6	81	20.2	68	19.8
Thigh	9	4.5	24	12.1	23	5.7	14	4.1
Uncertain	25	12.6	10	5.0	123	30.7	114	33.1
Risk Factors								
Diabetes								
Yes	81	40.7	77	38.7	216	53.9	165	48.0
No	113	56.8	113	56.8	168	41.9	153	44.5
Uncertain	5	2.5	9	4.5	17	4.2	26	7.6
Erythropoietin therapy								
Yes	102	51.3	95	47.7	200	49.9	149	43.3
No	85	42.7	94	47.2	178	44.4	168	48.8
Uncertain	12	6	10	5.0	23	5.7	27	7.8
Albumin <3 g/L								
Yes	18	9	17	8.5	16	4	20	5.8
No	153	76.9	157	78.9	335	83.5	274	79.7
Uncertain	28	14.1	25	12.6	50	12.5	50	14.5

AVF, Arteriovenous fistula; *AVG,* arteriovenous graft.
**P* = .01; all others nonsignificant (within access type).

Table III. Exclusions

	*AVF (n = 541)**				*AVG (n = 844)**			
	Clip		*Suture*		*Clip*		*Suture*	
	n	*%*	*n*	*%*	*n*	*%*	*n*	*%*
Recruited	249		291		445		396	
Exclusions								
Occluded	31	12.4	46	15.8	39	8.8	43	10.8
Failed to mature or not used	12	4.8	31	10.7†	0		0	
Follow-up data incomplete‡	5	2.0	11	3.8	5	1.1	9	2.3
Date of placement unknown‡	2	0.08	4	1.4	0		0	
Remaining for Analysis	199	79.9	199	68.4	401	90.1	344	86.9

AVF, Arteriovenous fistula; *AVG,* arteriovenous graft.
*Attachment method unknown for 1 AVF and 3 AVG.
†$P < .05$.
‡Excluded from intention-to-treat analyses.

Table IV. Postoperative complications

	AVF		*AVG*	
	Clip (n = 199)	*Suture (n = 199)*	*Clip (n = 401)*	*Suture (n = 244)*
Steal	5	4	11	9
Infection	4	7	13	26*
Bleeding	0	9†	6	7
Nerve injury	0	0	1	1

AVF, Arteriovenous fistula; *AVG,* arteriovenous graft.
*$P < .05$.
†$P < .01$.

METHODS

Patency, morbidity, and demographic data were analyzed for 1385 fistulas (541 AVF, 844 AVG) placed in 1110 patients at 17 institutions by 21 different surgeons between January 1996 and June 1999 (Table I). Individual cases were tracked with examination of hospital, office, and dialysis center records to acquire duration of primary, assisted primary, secondary, and overall patency.[17] Fistulas with both arterial and venous anastomoses, or the venous anastomosis of the AVG, constructed with clips, comprised the clip cohort. Renal disease and factors that affect fistula survival, eg, diabetes, erythropoietin (EPO) therapy, and serum albumin concentration, were also documented (Table II).

Primary patency duration is defined as time from fistula placement to first intervention or occlusion. Assisted primary patency duration is time from fistula placement to first occlusion in fistulas with previous surgical or endovascular interventions. Secondary patency duration is defined as time from fistula placement to fistula abandonment because of nonfunction or occlusion, for fistulas with previous successful interventions to treat thrombosis. Overall patency duration is defined as total number of fistulas in use for dialysis at the end of the study. Patency comparisons were performed only for fistulas used successfully for dialysis (five consecutive treatments). Excluded from patency comparisons were fistulas with uncertain placement date or anastomotic technique, fistulas with incomplete follow-up data, fistulas that failed to mature, fistulas that were patent but not used, and fistulas that occluded before use. To eliminate exclusion bias, intention-to-treat analysis was also performed for all fistulas with complete data (Table III). Intention to treat was defined as all AVF or AVG procedures intended to be used for successful dialysis, in essence, all graft or fistula procedures. All cases with complete follow-up data were included in intention-to-treat patency analysis. The biostatistical group at a nonparticipating center (Center for Health Research, Loma Linda University School of Public Health) performed data collation and analysis. Data entered were verified at each participating center by the respective investigator. A different reviewer at the four centers that performed most procedures again verified accuracy of data collection.

Statistical methods. Patency of AVF and AVG (clipped versus sutured) were compared with Kaplan-Meier survival analysis and log-rank test. Demographic data and risk factors were compared with an independent two-sample *t* test for continuous variables and X^2 test for nominal variables. Differences resulting in $P < .05$ were considered significant. A Cox proportional hazards model was used to confirm the results of Kaplan-Meier analysis for primary patency alone, because there were too few cases for the multivariate Cox model to be appropriate for other patency data.

RESULTS

Comparative patency: AVF. Three hundred ninety-eight AVF (199 clip, 199 suture) in 382 patients (derived from 541 access procedures in 488 patients) qualified for patency analysis over the 40-month study period. One hundred forty-three AVF (50 clip, 92 suture, 1 uncertain anastomotic technique) were excluded: 77 became (14%) occluded before maturation, 43 (8%) remained patent but were not used for dialysis, and 23 (4%) lacked complete follow-up data (Table III). Demographic data, cause of renal disease, and risk factors for thrombosis were similar

Table V. Patency survival: Clip vs suture for AVF and AVG access

	Clip		*Suture*		
Patency	*n*	*Mean survival (mo)*	*n*	*Mean survival (mo)*	P*
AVF					
Primary	199	28	199	24	.0072
Primary ITT	242	23	276	18	.0003
Primary assisted	11	34	22	22	.26
Primary assisted ITT	15	25	24	20	NS
Secondary	12	24	13	29	.0673
Secondary ITT	14	24	20	20	NS
Overall	199	34	199	29	.024
Overall ITT	242	29	276	21	.0002
AVG					
Primary	401	20	344	14	.0001
Primary ITT	443	19	384	13	.0001
Primary assisted	70	22	50	20	NS
Primary assisted ITT	72	22	58	17	.067
Secondary	95	27	119	20	.0067
Secondary ITT	106	24	128	19	.0304
Overall	401	31	344	24	<.0001
Overall ITT	443	29	384	22	<.0001

AVF, Arteriovenous fistula; *AVG,* arteriovenous graft; *ITT,* intention to treat; *NS,* not significant.
*Log-rank test.

Table VI. Revisions

	AVF		*AVG*	
	Clip (n = 199)	*Suture (n = 199)*	*Clip (n = 401)*	*Suture (n = 344)*
Fistula-years	127	146	312	212
Revisions	28	54	268	367
Revisions per fistula-year	0.22*	0.37	0.86†	1.73

AVF, Arteriovenous fistula; *AVG,* arteriovenous graft.
*$P < .05$.
†$P < .001$.

for both groups (Table II). Postoperative bleeding occurred more frequently with sutures ($P < .01$) (Table IV).

Primary patency was significantly improved in the clip group ($P = .007$; Fig 1, *A*). Assisted primary patency between the groups did not reach statistical significance ($P = .26$), but the number of fistulas that required interventions was small (Table V). Secondary patency ($P = .07$) was marginally better in the suture anastomosis group (Fig 2, *A*). Overall patency of the clip AVF cohort was significantly improved ($P = .02$; Table V).

To maintain patency during the study period, 82 secondary procedures were performed in 53 AVF (28 clip, 54 suture). The number of secondary procedures per fistula ranged between one (n = 38) and five (n = 1). Clipped AVF required 0.22 procedures per fistula-year to maintain patency, compared with 0.37 procedures per fistula-year for sutured AVF ($P < .001$) (Table VI).

Of 541 AVF, 518 (276 suture, 242 clip) qualified for intention-to-treat analysis. Twenty-three AVF (7 clip, 15 suture, 1 uncertain) with incomplete data were excluded (Table III). A significantly improved primary patency rate ($P = .0003$; Fig 3, *A*) and overall patency rate ($P = .0002$; Table V was found for clip AVF. No difference was observed in secondary intention-to-treat patency, because of small numbers (Fig 4, *A*).

AVF were performed by 22 different surgeons; 6 surgeons performed 15 or more procedures. Sets of indicator variables were created to test for surgeon effect and location effect. A Cox model was created, with sex, age, surgeon, clip or suture, and location included as independent variables. This model was used to analyze primary patency data. After controlling for the above-mentioned covariates, clips continued to be significantly protective over sutures (odds ratio, 0.58; $P = .008$).

Comparative patency: AVG. Seven hundred forty-five AVG (401 clip, 344 suture) of 844 procedures qualified for patency comparisons. Ninety-nine AVG (44 clip, 52 suture, 3 uncertain) were excluded: 82 AVG (39 clip, 43 suture) became occluded or were abandoned within 2 months after placement, and follow-up data were incomplete for 14 (Table III). Demographic data, cause of renal disease, and risk factors were similar for patients in both groups, except for a difference in racial distribution (Table II). There were more African American and nonwhite patients in the clip group. Seventy-four complications were encountered, with significantly lower infections in the clipped cohort (Table IV).

Primary, secondary (Figs 1, *B*, and 3, *B*), and overall patency rates were significantly improved in the clip AVG group ($P = .0001$, $P = .007$, and $P = .001$, respectively; Table V). To maintain patency, 635 secondary procedures were performed in 293 AVG during the study. Procedures per fistula ranged between one (n = 149) and 15 (n = 1).

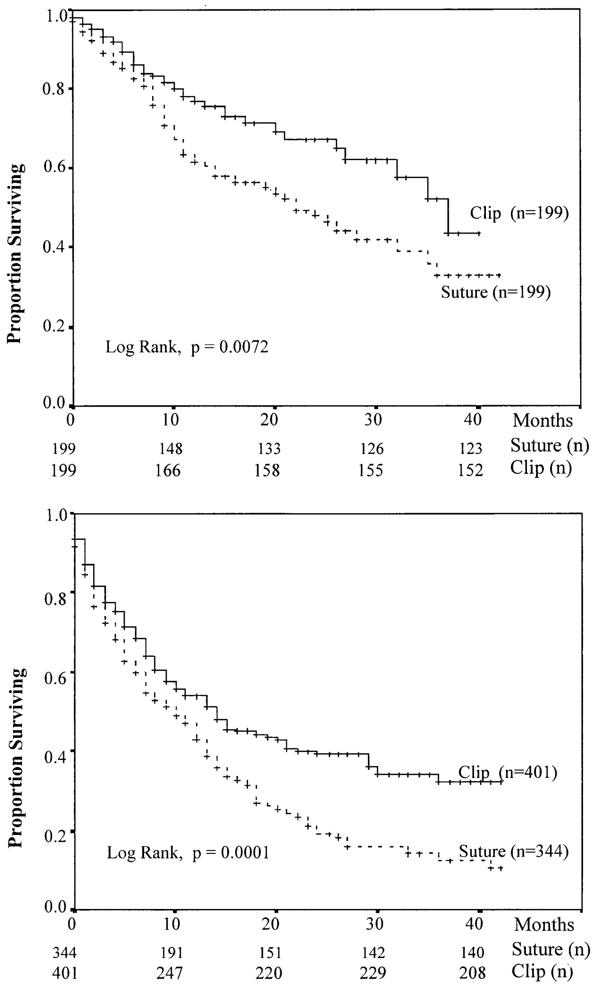

Fig 1. Kaplan-Meier analysis of primary patency for AVF (**A**) and AVG (**B**), with numbers remaining at risk.

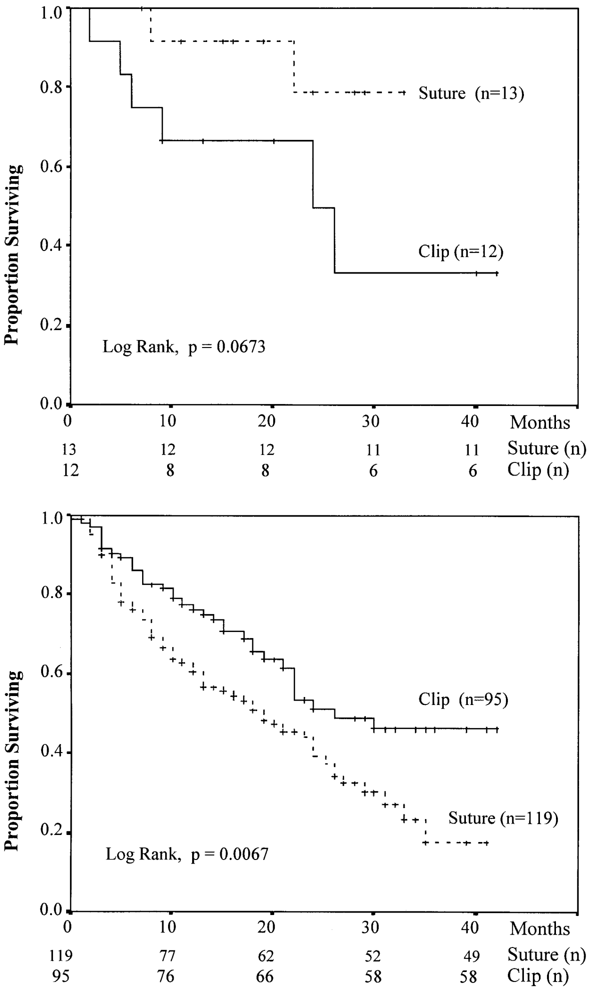

Fig 2. Kaplan-Meier analysis of secondary patency for AVF (**A**) and AVG (**B**), with numbers remaining at risk.

Sixty-eight AVG required two revisions, 38 required three revisions and 15 required four revisions. Clipped AVG required 0.86 procedures per fistula-year, compared with 1.73 for sutured constructs, to maintain patency ($P < .05$; Table VI).

Intention-to-treat analysis was performed for 827 (443 clip, 384 suture) of 844 AVG; 17 were excluded because of incomplete technical or follow-up data (Table III). Primary ($P = .0001$; Fig 3, *B*), secondary ($P = .03$; Fig 4, *B*), and overall patency ($P < .0001$; Table V) rates were significantly improved in the clip group.

Six of 21 surgeons involved in AVG construction performed more than 20 procedures each. Sets of indicator variables were created to test surgeon and location effect. A Cox model was created, with sex, age, surgeon, clip or suture, and location included as independent variables. This model, when applied to primary patency rate, showed a significant benefit for clips over sutures (odds ratio, 0.67; $P < .001$).

DISCUSSION

This 40-month, multicenter retrospective study shows significantly improved patency and reduced revision rates for clipped AVF and AVG compared with conventionally sutured constructs. These data emphasize the importance of the vascular anastomotic technique on vascular access patency. This single modification of a standard surgical procedure enables a significant reduction in morbidity, and could result in decreased financial burden on third-party payors such as Medicare. This benefit is apparent when overall patency rates of clipped and sutured AVG ($P = < .0001$) are compared. Other studies have reported 30% to 50% secondary patency rate for AVG at 2 years despite extensive salvage procedures, a patency rate that is consistent with our suture group.[4] In this study, clipped AVG had a secondary patency rate of nearly 60% at 2 years.

The uniformly improved access patency rate observed with an interrupted anastomosis performed with nonpenetrating clips confirms the positive trend reported earlier

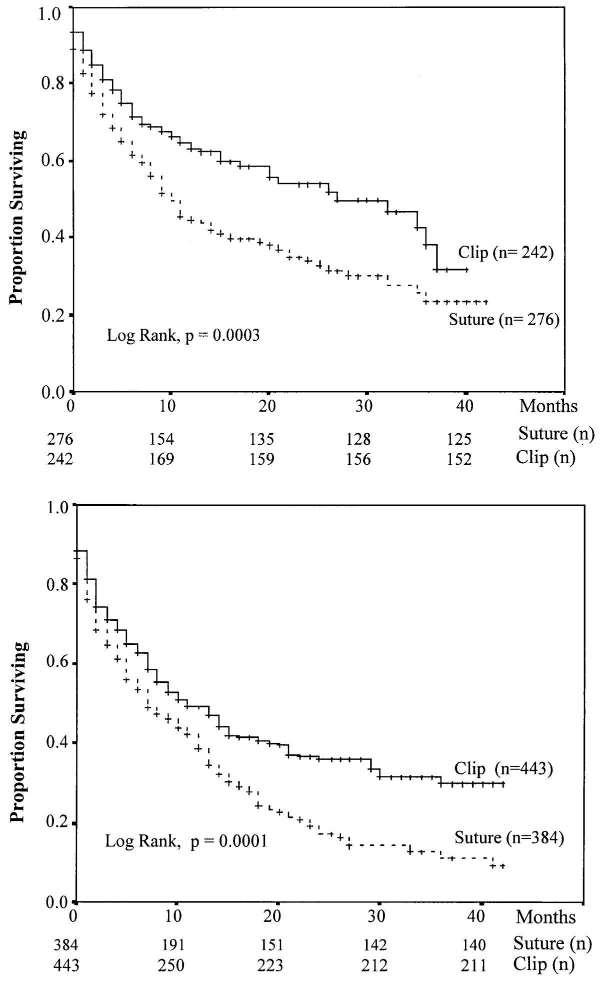

Fig 3. Kaplan-Meier analysis of primary patency for AVF (**A**) and AVG (**B**) intention-to-treat cohorts, with numbers remaining at risk.

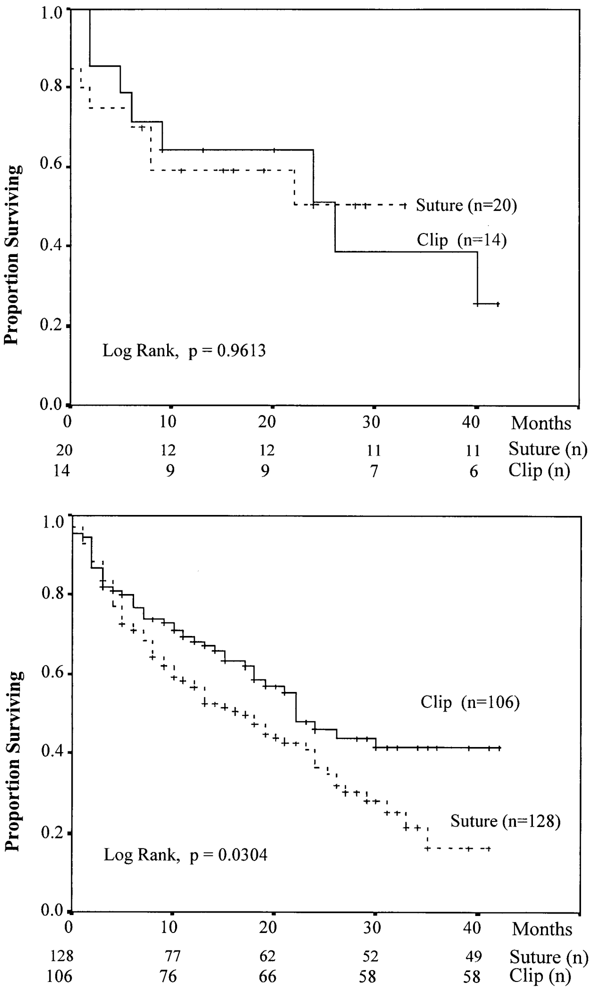

Fig 4. Kaplan-Meier analysis of secondary patency for AVF (**A**) and AVG (**B**) intention-to-treat cohorts, with numbers remaining at risk.

from smaller, single-institution studies.[14,15] A significant difference in patency outcome between clipped and sutured access was not apparent in other single-center studies with smaller numbers of cases and shorter follow-up.[15,16] Data from one of the these centers are included in this analysis.[15]

Fistula failure, though most frequently due to ANH, is multifactorial. Repeated needle sticks, tissue infiltration, hemorrhage and hematoma, dialysis-related hypotension, cytokine release, and local compression at needle stick sites contribute to loss of patency.[5] ANH, the common cause for access failure, is difficult to evaluate with direct tissue examination, because this requires biopsy of the anastomotic region. Indirect evidence for ANH is loss of access patency. It is postulated that the unique nonpenetrating quality of the vascular clip enables rapid healing, reduces compliance mismatch, and provides a "blood-tight" interrupted anastomosis.[9,18,19] Unlike sutured anastomoses, no intraluminal material is present at the clipped anastomotic line, minimizing endothelial and vessel wall trauma and inflammatory tissue response. These biologic and hemodynamic differences between clip and suture anastomoses, particularly the end-to-side construct, may account for the beneficial effects of clips.

Data acquisition and analysis for hemodialysis access outcomes is problematic with regard to accuracy and reliability, because the surgeon is only part of the multidisciplinary team that cares for patients with ESRD. Follow-up, particularly in large institutions, is often fragmented, and until recently there were no universally accepted definitions and reporting standards for data analysis.[17] To ensure accuracy and reliability of our analysis, a number of safeguards were instituted during data collection and entry. The number of procedures excluded because of inaccurate information and incomplete follow-up was small (AVF, 5.8%; AVG, 2.7%). Exclusions because of early occlusion were 14% for AVF and 9% for AVG, an incidence consistent with previously reported studies.[20,21] Fistulas (AVF, 8%; AVG, 0%) patent at data analysis but not yet used for dialysis were also excluded. The positive results in the intention-to-treat analysis of the entire cohort of AVF and AVG provide further validation of these results.

This large retrospective study of consecutive access procedures over a 40-month period is a reasonable alternative to the ideal double-blind prospective, randomized trial. In agreement with our results, previous smaller randomized prospective studies have also demonstrated superior patency for clipped vascular access.[11,13]

Three factors can influence the validity of our results: center effects, surgeon effects, and time effects. Although two academic centers (University of Miami Medical Center and Washington University School of Medicine) contributed most cases (35%), the distribution of access procedures over the course of the study shows an equivalent number of evaluable sutured and clipped anastomoses. Thus no clustering of clipped or sutured procedures occurred at any of the 17 centers. Although dialysis methods vary among centers, the distribution of cases among academic and private dialysis units was similar. Data for this study were extracted from centers distributed throughout the United States, correcting for recognized regional diversity of access management.[22]

Results can be biased by a surgeon effect, in which degree of familiarity with technique has a role. In this study, all surgeons were more experienced with sutures than with clips; thus bias is weighted against clipped procedures. Clips were generally introduced later in the individual series as experience with the device was accrued; thus a clip learning phase was inevitable. The same surgeons performed both sutured and clipped procedures. During the study period (January 1996 to June 1999) there were no significant changes in dialysis techniques or vascular access techniques (other than the clip itself) that would be likely to substantially improve vascular access patency, thus obviating a time effect.

In conclusion, this multicenter study provides convincing evidence that use of vascular clips rather than conventional suture improves patency rate of vascular access for hemodialysis. Clip usage results in significant cost savings in management of ESRD, with reduction in surgical morbidity. These results suggest that use of the clip in other cardiovascular surgeries may have similar long-term beneficial effects.

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APPENDIX, online only

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