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# Salvage of thrombosed dialysis access grafts with venous anastomosis stents

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**Salvage of thrombosed dialysis access grafts with venous anastomosis stents.**

*Background.* Thrombosis of arteriovenous (AV) grafts caused by stenosis at the venous anastomosis is a well-described problem. Surgical thrombectomy and conventional angioplasty with mechanical thrombectomy have provided good success rates in achieving immediate graft patency but with generally dismal graft survival rates in the range of 11% to 36% at 6 months' follow-up. The role of intravascular stents in patients who have failed angioplasty or surgical revision at the venous anastomosis has not been fully elucidated, particularly in older grafts that have previously undergone multiple procedures.

*Methods.* In this series, 34 patients had self-expanding nitinol stents placed at the venous anastomosis following graft thrombectomy and angioplasty procedures. Patients were selected for stent placement if conventional angioplasty alone was unsuccessful due to immediate elastic recoil or residual stenosis. All patients were followed after stent placement and evaluated for duration of graft patency and need for repeated endovascular procedures.

*Results.* The average graft age at the time of stent placement was 17.9 months. Eight-eight percent of grafts were functioning at 6 months' follow-up, and 63% of the entire group had survived without the need for additional procedures. Among those with need for repeat interventions, 81% had new lesions outside of the stent, and 57% had new lesions within the stent. In 38% of cases, new stenoses were located both outside and within the stent. Among grafts no longer being used, only 19% of the time was it due to disease recurring within the stent.

*Conclusion.* Polytetrafluoroethylene (PTFE) graft longevity is improved when venous anastomosis stenoses are treated with stents in selected cases of older grafts that would have normally undergone abandonment or surgical revision

Dialysis access failure caused by acute thrombosis is a common problem. In most scenarios of clotted arteriovenous (AV) grafts, a stenosis at the venous outlet of the graft will have precipitated the event by leading to diminished blood flow [1]. Attempts to reestablish circulation in the AV graft fail unless this stenosis, usually caused by hyperplasia of the vessel intima, is corrected. The literature abounds with a variety of approaches to handle an acutely thrombosed graft. These range from open surgical thrombectomy alone to surgical revision of the anastomosis between the graft and the native vein with patch angioplasty or jump grafts to more proximal veins. Percutaneous procedures for thrombectomy with angioplasty of severe stenoses have also gained much attention. Unfortunately, despite the many modalities used to treat AV grafts, the long-term graft survival rates after thrombosis remain dismally low, on the order of 11% to 36% at 6 months' follow-up, regardless of whether endovascular or surgical techniques were utilized [2–4]. Overall lifespan of grafts from creation to the final thrombosis event is also short, with estimates of unassisted patency of grafts at 2 years of only 24.6%, and graft survival (with additional procedures performed) at 59.8% at 2 years of follow-up [5]. Graft failure often occurs within 2 years of placement, requiring new vascular access to be obtained [6, 7].

Because the sites for definitive vascular access are limited, attempts to improve access patency and survival are essential. Salvage of grafts, rather than early abandonment and creation of new accesses, is important. In this regard, the exact role of different technologies, such as intravascular stents, has not been clearly defined. This observational study evaluates graft patency and survival in patients for whom intravascular stents have been placed to treat lesions at the anastomosis of the AV graft to the native vein following graft thrombosis.

## METHODS

All patients presenting with clotted AV grafts during an 18-month period were evaluated angiographically for the presence or absence of venous anastomosis lesions. In all patients in whom a significant lesion was found at the anastomosis (greater than 50%), conventional balloon angioplasty was performed. Mechanical thrombectomy followed angioplasty of the venous anastomosis. In those patients who had previously had angioplasty of the same

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lesion within 3 months who had lumens which collapsed immediately after angioplasty (elastic recoil), or had significant residual stenosis despite the use of angioplasty, intravascular stent placement at the venous anastomosis was performed prior to or immediately following mechanical thrombectomy of the graft and reestablishment of flow within the graft. Cutting balloon angioplasty was necessary in a small portion of cases to establish initial patency at the anastomosis.

Specifically, access to the clotted AV graft was obtained by placement of 7 French Brite-Tip™ sheaths (Cordis International, Miami, FL, USA) at the arterial aspect of the graft in a direction toward the venous outflow. The sheaths were placed via modified Seldinger technique. The venous anastomosis and the clotted graft itself were traversed with a guide wire, usually a floppy 0.035-in Bentson™ (Cook, Inc., Bloomington, IN, USA), a hydrophilic Glidewire™ (Boston Scientific Corporation, Boston, MA, USA), or comparable stiffer guide wire, depending on the specific needs of the individual case. Angiography of the venous anastomosis was performed through a guide catheter that had been inserted over the wire and beyond the anastomosis, and pulled back through the anastomosis as iodinated contrast was released.

Angioplasty was usually performed with a Powerflex™ balloon (Cordis International). These balloons had diameters of 7 to 10 mm and lengths of 40 mm to 80 mm depending upon the lesion size. Balloons were inflated to maximal capacity, usually up to 15 atmospheres of pressure. High-pressure balloons, namely the Conquest™ balloon (Bard, Inc., Murray Hill, NJ, USA), were employed in a few cases in which the Powerflex™ balloon achieved suboptimal results. These balloons had maximal burst pressures of 25 to 30 atmospheres of pressure. The Sci-Med cutting balloon (Boston Scientific) was employed in those cases where the stenosis was particularly unable to be resolved with either of the conventional balloons.

Intravascular stent deployment took place with nitinol self-expanding S.M.A.R.T.™ stents (Cordis International). The stent was delivered under angiographic guidance over the guide wire that had traversed the venous anastomosis. Stent sizes approximated the angioplasty balloon sizes used in the particular case, and ranged from 8 mm to 12 mm in diameter and 20 mm to 80 mm in length. The median length was 40 mm. The stent's diameter size utilized exceeded the maximal vessel diameter by 1 to 2 mm in each case. The length of the stent used was determined by the length of the lesion to be covered, allowing for approximately 10 mm of the edge of the stent to cover normal-appearing vessel.

Mechanical thrombectomy was performed with the HELIX™ Clot Buster thrombectomy device (Microvena Corporation, White Bear Lake, MN, USA) with intragraft administration of heparin. An additional Brite Tip™ sheath at the opposite limb of the graft was necessary in all cases to complete mechanical thrombectomy and evaluate for arterial lesions. Repeat angiography was performed through the sheaths once the procedure was completed.

Percutaneous treatment of the venous anastomosis was avoided if the guide wire could not safely traverse the lesion, or if the thrombosis occurred in the immediate postoperative period of graft creation or revision (less than 10 days). Intravascular stent deployment was not used in lesions for which angioplasty alone remedied the problem, and no recent (less than 3 months) percutaneous or surgical procedure was necessary on the graft. Stent deployment was also avoided if there were resistant central venous stenoses that could not be remedied by usual percutaneous techniques, including central venous stent placement.

Patients received clopidrogel 300 mg immediately after stent placement, and 75 mg daily for at least 4 weeks after the procedure. Only patients with stent placement received clopidrogel.

Patients were followed for graft patency, survival, and the need for repeat percutaneous procedures. If repeat percutaneous procedures were performed for thrombosis or poor flows, the location of lesions, including intrastent and central venous lesions, was noted and treated appropriately with angioplasty and additional stent placement if needed.

The study is not a randomized controlled trial, but an observational study. In addition to the above for patients who received stents, we collected data on patients during the current study period that received thrombectomy and percutaneous intervention without stent placement at our institution. Due to the nature of the referral network for vascular interventions at our institution, only patients at the dialysis facility adjacent to the university hospital were available for full follow-up after thrombectomy without stent placement.

Descriptive statistics were performed for the patient demographics. Frequencies (percentages) were utilized for nominal level characteristics, and measures of central tendency and variability were utilized for continuous level characteristics. Comparison of the duration of graft survival between secondary unassisted patency with primary patency was assessed using Kaplan-Meier analysis.

## RESULTS

Two hundred eleven patients were evaluated for clotted AV grafts. Thirty-four patients had intravascular stent placement at the venous anastomosis. Among these, all except one were available for follow-up analysis at one month. This one patient expired from unrelated causes.

**Table 1.** Patient demographics

| | Frequency (%) |
|---|---|
| Gender | |
| Male | 18 (53%) |
| Female | 16 (47%) |
| Race | |
| Caucasian | 4 (12%) |
| African American | 29 (85%) |
| Asian/Pacific Islander | 1 (3%) |
| Age (placement of stent) *years* | |
| Median (min-max) | 59 (29–87) |
| Reason for renal failure | |
| DM | 6 (18%) |
| HTN | 13 (39%) |
| Diabetes and hypertension | 7 (21%) |
| Lupus | 2 (5%) |
| Heroin abuse | 1 (3%) |
| Nephrectomy | 1 (3%) |
| Obstructive neuropathy | 1 (3%) |
| Renal cell cancer | 1 (3%) |
| Unknown | 2 (5%) |
| Location of access | |
| Upper arm | 19 (56%) |
| Forearm | 13 (38%) |
| Leg | 2 (6%) |
| Reason stent placed | |
| Residual stenosis | 20 (58%) |
| Elastic recoil | 7 (21%) |
| Multiple previous angioplasties | 7 (21%) |

Thirty-two were available for follow-up analysis at six months, and 14 were available for follow up at 12 months. Variable numbers available for follow-up are a reflection of the variable times during the 18 months of study that individuals had their individual percutaneous procedures performed.

Demographic information available among the population studied suggests that the average age at the time of stent deployment was 59 years, and the average duration of time with end-stage renal disease was 4.8 years. Eighty-five percent was African American. Forty-seven percent was female. Forty-five percent was diabetic. The average age of the grafts studied was 17.9 months (range 2 months to 72 months). Fifty-six percent of grafts were in the upper arm, 38% in the lower arm, and 6% in the leg. Eighty-four percent of patients had one or more endovascular or surgical procedures for graft malfunction prior to this episode of thrombectomy and stent placement (Table 1).

Figure 1 demonstrates the life table analysis of grafts after stent placement. Notably, continued graft survival 6 months after stent placement was 88%, and 86% at 12 months**.** This is overall graft survival, otherwise known as assisted patency or secondary patency. Survival without the need for an additional procedure (referred to as unassisted patency or event-free survival or primary patency) was 63% at 6 months and 36% at 12 months.

Among those patients requiring repeat procedures for graft survival after stent placement [21], the majority

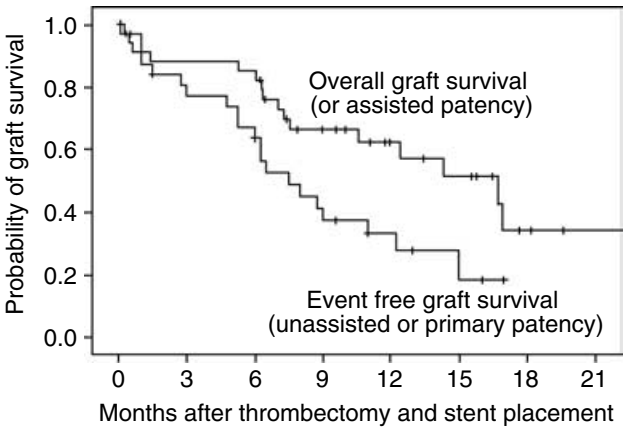


**Fig. 1. Life table analysis of probability of graft patency.**

(81%) had new lesions found outside of the stent at the time of repeat angiography. In 38% of cases, lesions were found both outside of the stent and within the stent. In 43% of cases of repeat procedures, the original lesion at the venous anastomosis (intra-stent) was not implicated as the cause of graft dysfunction because the stent had remained patent. In these patients, new lesions were found only outside of the stent. Among those patients requiring additional interventions after stent placement to maintain graft function, only one required multiple procedures at 6 months of follow-up. The rate of repeat procedures among surviving grafts was 0.72 per graft year post-thrombectomy and stent placement.

Evaluation of the 16 grafts no longer in use at the end of follow-up revealed that they fell into distinct groups. Four grafts were removed because of infection unrelated to any percutaneous endovascular procedures. Two patients died with functioning grafts. Two grafts were abandoned while functioning because multiple aneurysms in the graft led the surgeon to make the judgment that abandonment was better than surgical intervention in treating the aneurysms. The grafts were, however, functioning well at the venous anastomosis stent sites. In five patients, severe stenoses within the graft hampered adequate dialysis flow and new graft placement was necessary. In three patients, spontaneous thrombosis and patient and nephrologist desire for new graft placement dictated abandonment.

All in all, 6 of 16 grafts (37%) were abandoned due to unrelated infections or patient death and not due to graft failure. Seven of 16 grafts (44%) were abandoned secondary to disease that occurred in an area distinct from the venous anastomosis. Finally, in only 3 of 16 grafts (19%) could the venous anastomosis lesion be implicated as the cause of graft abandonment.

Table 2 demonstrates the 6-month total survival and event-free survival rates based upon the location of the graft.

**Table 2.** Survival data based upon graft location in 6-month follow-up group

| | Overall ($N = 32$) | Upper arm ($N = 18$) | Lower arm ($N = 13$) | Leg ($N = 1$) |
|---|---|---|---|---|
| Survival | 28 (88%) | 15 (83%) | 12 (92%) | 1 (100%) |
| Event free | 20 (63%) | 12 (67%) | 7 (54%) | 1 (100%) |

There were 35 patients from the dialysis unit adjacent to the university hospital available for full follow-up after thrombectomy without stent placement during the same time period. The three months' unassisted patency (event-free survival) was 40%, and the assisted patency rate (overall survival) was 46% after thrombectomy. Six-month event-free survival (unassisted patency) was 12%, and 12-month event-free survival was 0%. Assisted patency was 29% at 6 months and 3% at 12 months. Mean graft survival after thrombectomy was 4.2 months (range 0 days to 13 months) in these patients with thrombectomies and no stents.

## DISCUSSION

These data suggest that when intravascular stents are placed at the venous anastomosis of clotted PTFE grafts, patency and longevity may be improved, but this improvement depends upon repeated percutaneous procedures. The underlying process of vascular intimal hyperplasia continues unabated in other areas of the graft or native vein, and in some cases recurs in the stent as well. To interpret these findings in light of the previously published literature regarding intravascular stents and dialysis AV grafts, care should be taken to note the type of stents and the adjunctive means utilized—surgical, percutaneous, and medical for re-establishing flow.

Multiple reports note that primary patency of PTFE dialysis grafts is low. Average grafts maintain patency from 1 to 3 years, and most patients can expect multiple procedures to maintain the patency. Some have reported that in the natural history of PTFE grafts, 1.22 interventions per graft year are necessary for maintaining access patency [8]. Initial studies regarding salvage of AV grafts had focused on the varying successes of endovascular approaches compared with surgical approaches. Multiple studies in the late 1980s and early 1990s compared the efficacy of surgical and percutaneous approaches in dealing with thrombosed PTFE grafts [9]. A meta-analysis by Mehta et al [10] revealed that the life expectancy of radiologically revised grafts was not shorter than those treated surgically. Later, Gray [11] reported that the available literature indicated that "percutaneous treatments are at least as effective as surgery."

Intravascular stents have been tried previously. Table 3 provides a summary of some trials involving stents and dialysis grafts. Of note, only two previous trials consistently evaluated thrombosed AV grafts requiring salvage procedures [16, 17]. In the other trials, stents were placed in grafts that had not yet clotted or had not previously undergone interventions. It is difficult to compare previous stent trials that include patients with nonthrombosed accesses because it has been well described that graft patency after thrombosis is significantly worse than patency after elective percutaneous intervention. Similarly, it can be presumed that trials in which stents were placed without scrutiny to try evaluating a high-risk population for graft abandonment (previous thromboses, previous procedures, current thrombosis) also would be less likely to show a benefit in graft survival with stent placement, and may not be comparable with the current study.

Turmel-Rodrigues et al [16] retrospectively evaluated 52 stents (Wallstents and Craggstents) placed in their institution in stenoses associated with PTFE grafts and AV fistulas: 26 of these stents were placed in patients with PTFE grafts and a graft thrombosis at the time of stent placement. The indications for use of a stent were very similar to the present study and included elastic recoil, restenosis within 6 months, or iatrogenic vessel rupture. They achieved impressive secondary patency rates for the PTFE grafts of 100% at 6 months and 88% at 1 year. Interestingly, they calculated the mean interval between radiologic interventions before and after the stent was placed. This interval increased to 2.1 times its pre-stent duration, suggesting that the stent may have delayed the need for repeat endovascular intervention.

Patel et al [17] report the utility of Wallstents in settings with acute angioplasty failure, rapid restenosis, and vessel perforation has occurred during treatment of graft thrombosis and venous anastomotic stenoses. Among 26 lesions studied, technical success was 100%, and primary and secondary patency rates were 27% and 72% at 6 months, respectively. The secondary patency rate was 50% at 12 months.

It is important to keep in mind that all self-expanding metallic stents are not similar in efficacy. This will limit the ability to compare the present results with those of earlier studies in which different types of stents were used. The shape of the stent, the exact component materials, and efficacy in adherence to the vessel wall are different among the various stents (Wallstent, Cragg, Gianturco, S.M.A.R.T.). This idea is reflected in animal studies, which demonstrate some differences, although clinical trials comparing various stents and their rates of restenosis have not been published with regard to the venous anastomosis. Treotola et al [18] compared Gianturco Z stents with Wallstents in a canine model. These authors found the Gianturco Z stent to have longer primary patency but more likelihood of stent fracture and necrotizing inflammation.

Use of similar materials but adding covering to the stent can also change the effects of the stent on the local vessel wall. Dacron-covered nitinol stents (covered

**Table 3.** Summary of previous stent trials (uncovered stents)

| Study | Stent type | No. of PTFE grafts stented | % at venous anasto-mosis | Salvage grafts selected | Graft thrombosis | Clopidgel with stent | Immediate technical success | 6-month patency advantage |
|---|---|---|---|---|---|---|---|---|
| Beathard [12] (1995) | Gianturco | 28 | 100% | No | No | No | Yes | No |
| Hood [13] (1994) | Not specified | 20 | 35% | Yes | Not specified | No | Yes | Yes |
| Gallego [14] (2000) | Not specified | 19 | 89% | No | No | No | Yes | No |
| Hoffer [15] (1997) | Wallstent | 17 | 70% | Yes | Yes (27%) | No | Yes | No |
| Turmel-Rodrigues [16] (1997) | Wallstent Craggstent | 26 | 100% | Yes | Yes | No | Yes | Yes |
| Patel [17] (1998) | Wallstent | 26 | 100% | Yes | Yes | No | Yes | Yes |

Cragg stents) used to treat angioplasty-related vessel perforations have not been demonstrated in small series to prevent intimal hyperplasia, and actually cause increased inflammatory reaction at the venous anastomosis compared with Wallstents. [19] Recently, however, Ross [20] demonstrated the clinical utility of a nitinol stent covered with PTFE graft material at the venous anastomosis, adapting a strategy that has been used to treat aortoiliac occlusive disease. Donaldson et al [21] reported primary patency rates of 54% at 6 months and secondary patency of 72% in a group of 12 patients (14 stents) using the same product.

There has been no prior use of heparin and clopidrogel in conjunction with endovascular stents. Clopidrogel was utilized in the current study to conform to other interventionalists in the institution who utilize the medications with arterial stents in the coronary and peripheral vascular systems. It is unclear whether this provided an advantage in preventing in-stent restenosis and maintaining graft patency.

At this point, the previously published literature does not support the routine use of stents in venous anastomotic lesions in nonthrombosed grafts referred for angiogram by various intradialytic monitoring schemes (Table 3). In the present study, stents were restricted to patients who had immediate angioplasty failure or repeated angioplasties with recurrent thrombosis, and likely to have their grafts abandoned. Eighty-four percent of patients had a previous percutaneous or surgical procedure on the graft prior to thrombectomy and stent placement, and most of these occurred in the two months prior to stent placement.

While primary and secondary patency rates are important, especially in comparison to natural history of grafts that would have been abandoned or undergone surgical correction, it cannot be overemphasized that immediate patency achieved by stents, even if for a few weeks or months, can help avoid temporary or long-term tunneled dialysis catheter insertion while the patient waits for a new surgically placed access to mature.

There is some concern that stent placement may jeopardize future vascular access surgery. The need to place a jump graft between the existing graft and a more proximal vein, thereby bypassing the diseased venous anastomosis, has specifically been touted by some as the reason to avoid stent placement. Carefully sized stents that do not extend much beyond the diseased anastomosis can prevent this problem and preserve the native vein for surgery. In the present study, stents covered the entire diseased segment of vein and encroached into the healthy venous segment by no more than 10 mm.

Also, this objection, raised mostly in the surgical literature, may not be applicable to the patients studied in the present series. Placement of a jump graft to preserve access function implies that both the PTFE graft and the proximal vein are healthy and only the anastomosis is severely diseased. The observations noted among patients who required repeat interventions in the present study suggest that the likelihood of this scenario is rather limited. The majority of patients who needed repeat percutaneous procedures had stenoses in areas outside of the stent.

Another potential criticism of stent placement at the venous anastomosis is that it prevents direct surgery of the venous anastomosis. This type of surgery is known as patch angioplasty. However, in many of the publications regarding techniques of surgical correction of the venous anastomosis and comparison of techniques of surgical treatment of thrombosed grafts to endovascular treatment, for unclear reasons patch angioplasty is limited to a minority of salvage operations (12–18%) [22–24]. Also, there is no data showing its superiority over any other techniques, surgical or endovascular.

Finally, some have argued that stent placement may preclude native AV fistula creation. Creation of fistulas, usually in upper arm veins after forearm graft thrombosis, is an innovative approach to increase the prevalence of fistulas. However, this requires a healthy venous segment. In the present group of patients, great care was taken to minimally encroach on the healthy venous segment, and not preclude the creation of a fistula at another point in time. However, our data suggest that the venous disease is progressive and not limited just to the venous anastomosis. How this would affect the creation and patency of native vein fistula in this population remains to be determined.

With regard to evaluating the long-term results in the stented patients in this study, care should be taken to compare with the available literature regarding the two distinct variables "graft patency" and "graft survival." In many articles, secondary patency rate refers to graft survival with additional procedures being performed after the study treatment (surgery or endovascular procedure). Primary patency refers to unassisted patency after the study treatment has been utilized. This is certainly not consistent, especially in previous literature.

What generally appears true is that overall graft survival is in the range of 1 to 3 years, and that multiple procedures are necessary to maintain the full lifespan of the graft. If the definitions are relied upon in the older literature, the best case scenario for conventional therapy of thrombosed grafts would give survival of 36% at 6 months after thrombosis [2–4]. If the definition of survival is flawed (based upon the portion of patients who had surgical revisions, jump grafts, or secondary conversion to fistulas), the best case scenario for assessing the conventional therapy is to utilize the secondary patency rates for grafts of 59.8% at 2 years [5]. This figure comes from a large retrospective analysis of patients in the United States Renal Data System Dialysis Morbidity and Mortality Study. Even if the latter number is used to compare conventional therapy (surgical or angioplasty alone), the present study suggests that intravascular stents offer a survival advantage for older grafts. The average age of grafts in the study was 17.9 months, and the data indicated 88% and 86% survival at 6 and 12 months after stent placement. These survival numbers well exceed the expected 2-year survival numbers.

Again, we would emphasize that the current study was not a randomized controlled study. However, our findings in the 35 nonstented population of patients with thrombectomies echo the dismal outcomes noted for graft survival in the post-thrombectomy period with conventional means of surgery and endovascular treatment in the literature.

The Dialysis Outcome Quality Improvement (DOQI) Guidelines recommend in guideline 21 that at 3 months after a thrombectomy and angioplasty, unassisted patency rates (corresponding to event-free survival) should exceed 50%. Similarly, the guidelines call for 50% unassisted patency at 6 months and 40% unassisted patency at 1 year if surgical thrombectomy with revision is performed. This recommendation is listed as evidence-based for the angioplasty guideline and opinion-based for the surgical revision guideline. In those patients with stents, these recommended values of patency are markedly surpassed at the 3, 6, and 12 month follow-up periods. Figure 1 demonstrates this. Our patient population that had thrombectomies but did not have stents at the venous anastomosis failed to meet these criteria; however, this outcome is not dissimilar from the outcomes listed in the current literature for post-thrombectomy graft survival.

This study is interesting because it demonstrates that patients who required repeated procedures often had stenoses in areas outside of the intravascular stent, rather than within the stent. This suggests that placement of the stent did not affect the underlying disease process, causing graft or native vein disease. Equally important, it suggests that treatment of the venous anastomosis lesion may prolong graft life in significantly diseased grafts, provided additional percutaneous procedures are utilized.

## CONCLUSION

Indeed, intravascular stent placement may play a specific role in prolonging the lifespan of older dialysis grafts that have already undergone previous percutaneous or surgical procedures. This type of information is vital as the dialysis population begins to outlive vascular access sites and more importance is placed on graft salvage rather than abandonment and fresh access creation.

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