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## Can Diastat Grafts Meet the Challenges of Daily Punctures?

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**T**o determine whether Diastat grafts can meet the challenges of daily needle punctures required for home hemodialysis (HD), a retrospective analysis was performed on the experience with 47 grafts placed in 44 patients receiving HD three times a week. The control group consisted of 17 patients who received 17 stretch polytetrafluoroethylene (s-PTFE) grafts. Apart from their ability to better contain bleeding after needle withdrawal, in all measures of longevity the Diastat grafts were outperformed by the s-PTFE grafts. No more direct data exist to address the original challenge.

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### Key words

Arteriovenous fistula, hemodialysis blood access, Diastat, stretch polytetrafluoroethylene

### Introduction

Daily home hemodialysis (HD) has been proposed as a modality with augmented efficacy and convenience (1). However, one of the significant impediments to this form of therapy has been the unavailability of a viable access to the blood stream, other than an indwelling central venous catheter. This retrospective, nonrandomized analysis examines whether Diastat grafts can meet the challenges of needle punctures required for daily home HD.

Diastat grafts are a product of W.L. Gore & Associates, Inc., Phoenix, AZ, and became available in the United States in 1993. They differ from stretch polytetrafluoroethylene (s-PTFE) synthetic grafts in that Diastats have an additional three layers, which surround the s-PTFE grafts (2). Diastat grafts have the advantage that they can be used immediately, unlike

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the s-PTFE grafts, which cannot be used until a 14-day waiting period has elapsed. This is because Diastat grafts have been shown to take a shorter time to stop bleeding after the HD needles have been withdrawn (3). The need for an interim HD access such as a central venous catheter (with its accompanying long-term complications) can thus be avoided. However, whether or not Diastat grafts can withstand more frequent needling remains to be seen. No direct data support or refute the tenacity of Diastat grafts.

### Material and methods

From January 1994 to July 1996, 47 Diastat grafts were surgically placed in 44 patients with end-stage renal disease. The control group consisted of 17 patients who received 17 s-PTFE grafts. All grafts were 7 mm in diameter, and all were placed in the forearm. The mean age of patients was 65 years, and they received HD 3 days a week. Males and females were equal in number, while Whites outnumbered Blacks. Diabetic nephropathy was the most common cause of renal failure. All grafts were carefully monitored with regard to functionality and complications. In order to support graft function and survival, preemptive intervention in the form of either timely angioplasty or pseudoaneurysm repair or revision was used. The indications for angioplasty were graft stenosis of >50% or >20% gradient (peripheral vein/graft) or >8 mm (central vein, upstream), in association with >20% recirculation or >200 mm venous pressure on HD.

Survival of each type of graft was analyzed using software written for life-table analysis using the Kaplan–Meier method (Prism, Graphpad, San Diego, CA).

### Results

The mean duration from placement to cannulation was 15 days for Diastat grafts and 21 days for s-PTFE grafts. Only 23% of Diastat grafts were used within 3 days, in conjunction with a single-needle device. No

grafts sustained initial hematoma, but one s-PTFE graft developed a hematoma associated with failure. Exclusively in the Diastat group, there were two episodes of graft infection with *Staphylococcus aureus* and two instances of "steal." Four instances of dissection occurred in the Diastat group due to separation of the layers from improper needle placement and depth, leading to development of intragraft hematoma. Thanks to highly skilled interventional radiological help, sufficient graft function was restored in all four instances.

The novelty of Diastat grafts indeed posed a learning curve. Because of the graft thickness and because the thrill was often impalpable, they were harder to needle. During placement, the cut fibers tended to soil the operating field. The risk of both graft kinking and intussusception was thought to be high if the tunnel length was less than that of the graft. After placement, there was more of a tendency for edema and tissue reaction from the Diastat grafts than from the s-PTFE grafts. Nonsteroidal anti-inflammatory agents helped to reduce this.

Event-free patency was defined as the duration of undeterred function, the end point being any maneuver on the graft other than needling for HD. At 3 and 12 months, both groups of grafts performed equally; however, at 6 and 9 months the s-PTFE grafts did better; see Figure 1 [the ordinate depicts survival (percentage), and the abscissa depicts the time interval (in months)].

Assisted primary patency was defined as the duration of function assisted by preemptive intervention such as angioplasty or revision, the end point being clotting. Performance of the s-PTFE grafts was superior to that of the Diastat grafts (Figure 2). Secondary patency was defined as the span of function after thrombectomy. Stretch-PTFE grafts outperformed Diastat grafts (Figure 3). Cumulative primary patency was the length of function from placement to first thrombosis. Here again, the s-PTFE grafts outperformed the Diastat grafts (Figure 4).

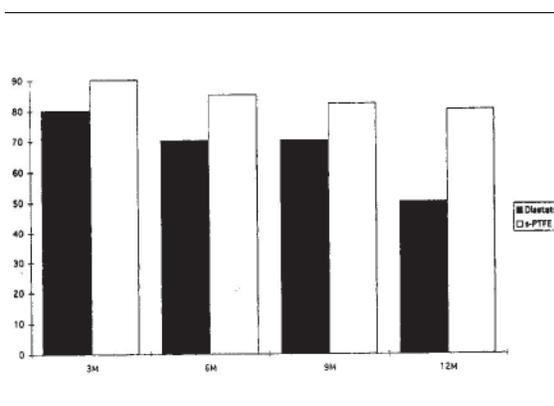


FIGURE 2 Assisted primary patency. The ordinate depicts survival (percentage), and the abscissa depicts the time interval (in months). s-PTFE = stretch polytetrafluoroethylene; Pub-Diastats = the results with Diastat grafts published in the literature.

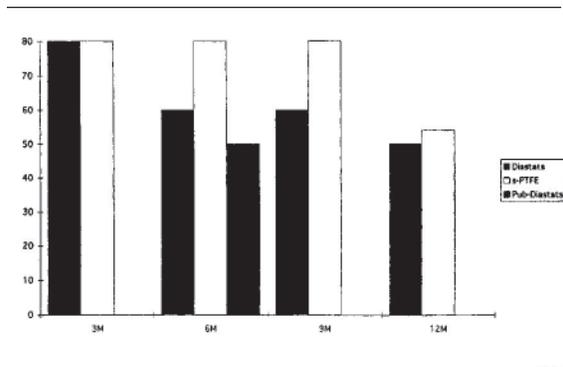


FIGURE 1 Event-free patency of Diastat and stretch polytetrafluoroethylene (s-PTFE) grafts in our center compared to the results with Diastat grafts published in the literature (Pub-Diastats). The ordinate depicts survival (percentage), and the abscissa depicts the time interval (in months).

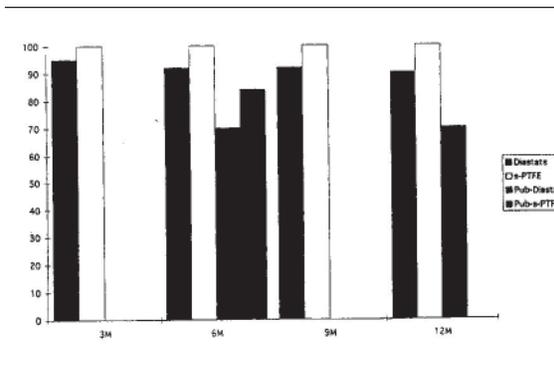


FIGURE 3 Secondary patency. The ordinate depicts survival (percentage), and the abscissa depicts the time interval (in months). s-PTFE = stretch polytetrafluoroethylene; Pub-s-PTFE = published results with s-PTFE grafts; Pub-Diastats = the results with Diastat grafts published in the literature.

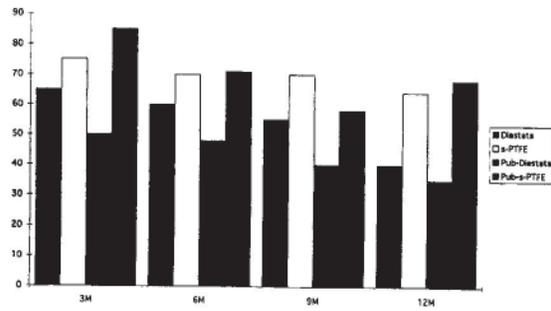


FIGURE 4 Cumulative primary patency. The ordinate depicts survival (percentage), and the abscissa depicts the time interval (in months). s-PTFE = stretch polytetrafluoroethylene; Pub-s-PTFE = published results with s-PTFE grafts; Pub-Diastats = the results with Diastat grafts published in the literature.

### Discussion

Several centers have published their experiences with Diastat grafts (4–7). Whenever possible, such collective information is represented in Figures 1 through 4, despite our observation of a lack of consistency in definitions in published reports. Although our single center's experience with Diastat and s-PTFE grafts may seem to be better than the average graft performance in published reports, a definite pattern emerged. Both in our center and elsewhere, s-PTFE grafts offered more longevity than the Diastat grafts at a graft puncture frequency of 6/week. This indeed is very significant, also given the fact that there is a 47% price differential for Diastat grafts versus s-PTFE grafts in the 7-mm size; in the 6-mm size, the price differential is 52%.

For the surgeon, s-PTFE grafts may be easier to place than Diastat grafts. For the HD nurse and techni-

cian, Diastat grafts may be more difficult to needle, at least initially. The multiplicity of layers to help stop the bleeding after needle withdrawal may also lead to dissection and intragraft hematoma formation. But with more experience these considerations may become less relevant. It is debatable whether the situation may be any easier for the patient who self-needles, even though most patients exercise great care in needle placement.

Given the aforementioned outcome of our retrospective analysis, in our opinion, the only advantages Diastat grafts may offer toward daily home HD may be the fact that they can be used sooner and their ability to cause less bleeding following the needle removal.

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