CryoVein® Femoral Vein Allograft Hemodialysis Access Clinical Experience

CryoVein cryopreserved femoral vein allografts are clinically used as access grafts for hemodialysis. From the first implant in September 1996 through July 2001, there have been 1,177 documented implants of CryoVein femoral vein for dialysis access in the United States. The graft has been used by more than 250 surgeons at 204 hospitals.

The clinical results presented below were compiled from retrospective data collected from three implant centers in Atlanta GA, Wichita KS, and Springfield MA, representing the experience of seven surgeons and 148 patients. The primary indications for implantation of CryoVein were failed primary fistula (6%), failed previous graft (69%), and infection of a previous graft or patient sepsis or bacteremia (35%). The following analysis includes a summary of the entire cohort, as well as stratification by primary indication for surgery into prior infection and failed previous graft subgroups.

In 66% of the patients, the length of a single allograft was adequate for graft formation. If a single allograft was not of sufficient length, a composite of two allograft segments sewn end-to-end was utilized (34%). The following analysis includes a comparison of single versus composite grafts within the failed previous graft group. Patient demographic information for all patients, and the prior infection and failed previous graft subgroups are presented in Table 1.

	All Patients (n=148)	Prior Infection (n=52)	Failed Single (n=35)	Previous Graft Composite (n=33)
Age (mean)	59 yr.	54 yr.	58 yr.	60 yr.
Sex	50% male	52% male	43% male	52% male
Medical History*				
Diabetes	47%	57%	47%	44%
Hypertension	83%	86%	89%	79%
Peripheral Vascular Disease	30%	40%	27%	18%
Coronary Artery Disease	38%	48%	40%	18%
Smoking History	28%	45%	26%	9%
Years of Hemodialysis (mean)	2.2 yr.	2.1 yr.	2.6 yr.	2.4 yr.
Anastomoses				
Arm Vessels	83%	90%	91%	59%
Leg Vessels	17%	10%	9%	41%
Graft Type				
Single Allograft	66%	81%	100%	0%
Composite Allograft	34%	19%	0%	100%

Table 1. Patient Demographics (*more than one answer per patient may be reported)

Patient charts were reviewed for postoperative graft-related events. Graft performance was determined by evaluating primary patency, secondary patency, and freedom from mortality. Non-thrombotic complications such as graft infection, aneurysms, steal syndrome, and bleeding complications were recorded. A summary of study endpoints for the entire cohort and the two subgroups is provided below. Performance data are reported up to 24 months after implant with a mean follow-up time of 326 ± 49 days.

Entire Cohort (n=148)

Primary patency was calculated as the time from graft implant to the first intervention performed to restore lost or reduced patency. Secondary patency was calculated as the time from graft implant to final loss of graft function. Figure 1 contains the actuarial curves of the primary and secondary patency for this patient population. At 12 months, the primary patency was 40% and the secondary patency was 80%. After 24 months, the primary and secondary patency was 32% and 72%, respectively.

There were 45 reported deaths in this patient population. The cause of death in 17 patients was unknown. For the patients with known cause of death, no death was reported to be related to the CryoVein femoral vein. The actuarial freedom from mortality at 12 months and 24 months was 72% and 54%, respectively.

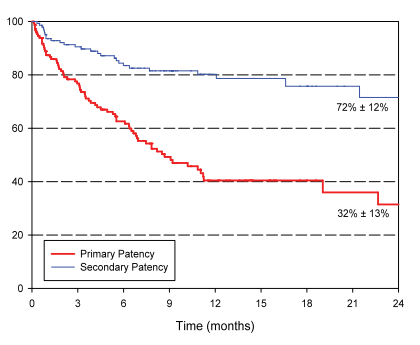

Figure 1. All Grafts, Primary and Secondary Patency.

In this patient population there were 19 reported non-thrombotic complications including nine cases of steal syndrome, two graft infections, three aneurysms, and five instances of bleeding complications.

Prior Infection Subgroup (n=52)

Fifty-two patients (35%) in the overall cohort required CryoVein placement due to an existing graft infection or a systemic infection. The primary patency was 37% at 12 months and 28% at 24 months. Secondary patency of the prior infection subgroup was 69% at 12 months and 63% at 24 months. The actuarial curves are shown in Figure 2.

There was only one recurrence of infection in the subgroup, corresponding to a 97% freedom from infection at two years.

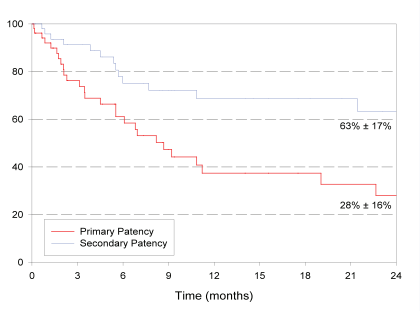

Figure 2. Prior Infection, Primary and Secondary Patency.

Failed Previous Graft Subgroup (n=68)

A subgroup of patients receiving a CryoVein due to a failed previous graft was utilized to compare single segment grafts to composite grafts.

Primary patency actuarial curves of single and composite grafts are shown in Figure 3. At 12 months, primary patency was 39% for single grafts and 53% for composite grafts (NS). Secondary patency actuarial curves of single and composite grafts are shown in Figure 4. At 12 months, secondary patency was 83% for single grafts and 87% for composite grafts (NS).

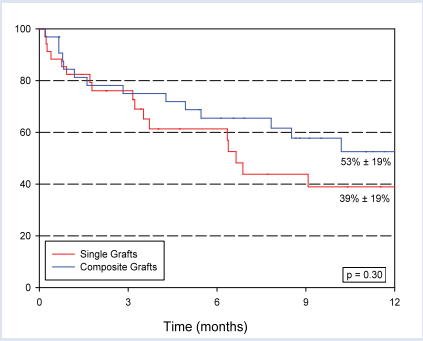

Figure 3. Failed Previous Graft, Single vs. Composite, Primary Patency.

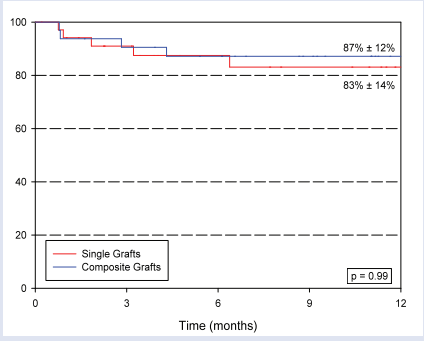

Figure 4. Failed Previous Graft, Single vs. Composite, Secondary Patency.

Summary

- For the entire cohort (n=148), secondary patency is 80% at one year and 72% at two years.
- For the prior infection subgroup, secondary patency is 69% at one year and 63% at two years. Freedom from graft infection is 97% at two years.
- For the failed previous graft subgroup, primary and secondary patency of single and composites grafts are not statistically different at one year. Secondary patency at one year is 87% for composite grafts and 83% for single segment grafts.

CryoLife®
1655 Roberts Boulevard, NW • Kennesaw • Georgia 30144 • USA • Tel: 770 419 3355 • 800 438 8285 • Fax: 770 590 3753 • www.cryolife.com
ML0101.000 (09/2001)