

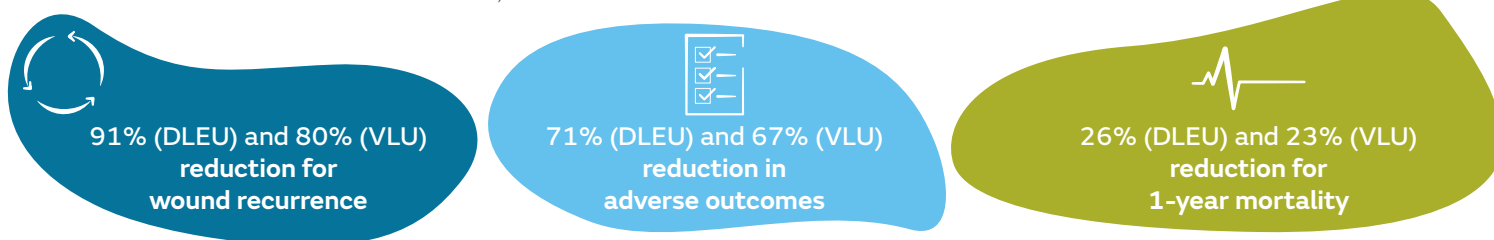
GRAFIX[®] PL PRIME and GRAFIX PRIME are associated with lower wound recurrence, adverse outcomes, and 1-year mortality for patients with diabetic lower extremity ulcers (DLEU) and venous leg ulcers (VLU), compared to standard care

Padula WV, Ramanathan S, Cohen BG. Comparative effectiveness of placental allografts in the treatment of diabetic lower extremity ulcers and venous leg ulcers in U.S. Medicare beneficiaries: a retrospective observational cohort study using real-world evidence. *Advances in Wound Care*. 2024 Mar 5. [Epub ahead of print]

Available at: [Advances in Wound Care](#)  

Key points

Treatment with GRAFIX PL PRIME for DLEUs, and GRAFIX PL PRIME or GRAFIX PRIME for VLUs resulted in:



Overview

- Retrospective, observational, cohort study of Medicare beneficiaries for DLEUs and VLUs between 2016–2020
 - 333,362 DLEU episodes among 261,101 beneficiaries
 - 122,012 VLU episodes among 80,415 beneficiaries
- Three cohorts of patients were evaluated:
 - Viable cryopreserved placental membrane (vCPM) or viable lyopreserved placental membrane (vLPM)
 - Other cellular tissue products (CTP)
 - Standard of care (SOC)
- Patients that received vCPM or vLPM were treated with GRAFIX PRIME or GRAFIX PL PRIME, respectively
- The following outcomes were assessed:
 - Recurrence
 - Adverse outcomes
 - 1-year mortality

Results

- For patients with DLEUs (Table), GRAFIX PL PRIME was associated with:
 - A relative risk ratio (RRR) reduction of 91% for wound recurrence versus SOC, and a RRR reduction of 49% for wound recurrence versus other CTPs
 - An odds ratio (OR) of 2.42 (70.8% reduction) for adverse outcome prevention compared to SOC
 - A RRR of 0.74 for reduced 1-year mortality versus SOC
- For patients with VLUs (Table):
 - GRAFIX PL PRIME was associated with a relative risk reduction for wound recurrence compared to SOC (80%) and other CTPs (73%)
 - GRAFIX PL PRIME or GRAFIX PRIME were associated with a 67% reduction in adverse outcomes compared to SOC
 - GRAFIX PL PRIME or GRAFIX PRIME was associated with a RRR of 77% for 1-year mortality compared to SOC

Table. Outcomes assessed for DLEU and VLU cohorts.	DLEU cohort		VLU cohort	
	GRAFIX PL PRIME vs CTPs	GRAFIX PL PRIME vs SOC	GRAFIX PL PRIME and GRAFIX PRIME vs CTPs	GRAFIX PL PRIME and GRAFIX PRIME vs SOC
Wound recurrence	0.51 RRR	0.09 RRR	0.27 RRR	0.20 RRR
Adverse outcome prevention	0.99 OR	2.42 OR	0.88 OR	2.01 OR
1-year mortality	1.07 RRR	0.74 RRR	1.21 RRR	0.77 RRR

Conclusions

Diabetic lower extremity ulcers and venous leg ulcers treated with GRAFIX PL PRIME and GRAFIX PRIME allografts are associated with lowered wound recurrence, adverse outcomes, and 1-year mortality compared to standard care.

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