GORE® ACUSEAL
Vascular Graft

ECONOMIC VALUE OF PREVENTING CENTRAL VENOUS CATHETER SEPSIS INFECTIONS WITH EARLY CANNULATION ARTERIOVENOUS GRAFTS (ecAVGs) COMPARED TO NON-ecAVGs

Background:

Approximately 80% of hemodialysis patients in the U.S. initiate dialysis with a central venous catheter (CVC) despite their high incidence of infections compared to other vascular access modalities.[1]

End-stage renal disease (ESRD) patients with CVCs have a higher rate of sepsis infections of 2.32 per patient year compared to arteriovenous grafts (AVGs) at .61 per patient year.[1]

Sepsis hospitalizations have been cited as the costliest condition to treat in the U.S.[2]

ESRD patients hospitalized for sepsis related to CVCs cost an average of $27,088 per admission and have an in-hospital mortality rate of 7.6%.[3]

Objective:

We compare CVC sepsis costs for patients implanted with the early cannulation GORE® ACUSEAL Vascular Graft to patients with non-early cannulation AVGs (ecAVGs).

Methods:

An economic cost model was estimated using the GORE® ACUSEAL Vascular Graft clinical study,[4] clinical literature for the non-ecAVG, and publicly available cost sources.

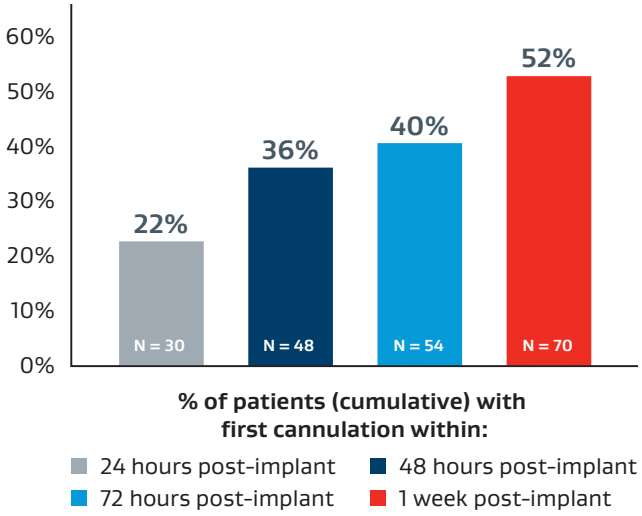
The GORE® ACUSEAL Vascular Graft clinical study was a prospective, multi-center, single-arm study to establish the safety and efficacy of the GORE® ACUSEAL Vascular Graft for use in hemodialysis access (Table 1).

Table 1: Evaluation of the GORE® ACUSEAL Vascular Graft for Hemodialysis Access Study

Objective	To establish the safety and efficacy of the GORE® ACUSEAL Vascular Graft for use in hemodialysis at any time post-implantation.
Design	Non-randomized, multi-center, prospective GORE® ACUSEAL Vascular Graft compared to historical control.
Patient population	ESRD patients either currently receiving hemodialysis or expected to require hemodialysis through a prosthetic vascular access graft within 30 days.
Primary efficacy endpoint	Cumulative patency at six months — Percentage of subjects free from complete loss of access for hemodialysis at the study access site.
Sample size	N = 138
Follow-up	One year

The GORE® ACUSEAL Vascular Graft can be cannulated within 24 hours of implantation. Approximately 22% of the GORE® ACUSEAL Vascular Grafts were cannulated within 24 hours, and 52% of the GORE® ACUSEAL Vascular Grafts were cannulated within one week of the implant procedure (Figure 1).

Figure 1: Time to first cannulation



Note: Estimates calculated from 135 subjects.

The study collected data on the first three consecutive hemodialysis sessions as a surrogate endpoint for time to potential CVC removal.

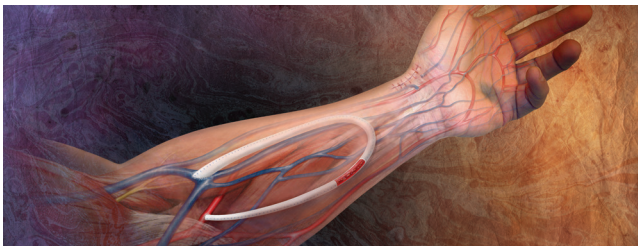
The median days to potential CVC removal was 15.5 in the study compared to a combined average of 34 days for non-ecAVGs from Quinn et al and Shingarev et al which is an increase of 18.5 catheter-dependent days as compared to GORE® ACUSEAL Vascular Grafts.[5,6]

The CVC sepsis rate of 2.32 per patient year was obtained from the U.S. Renal Data System.[1]

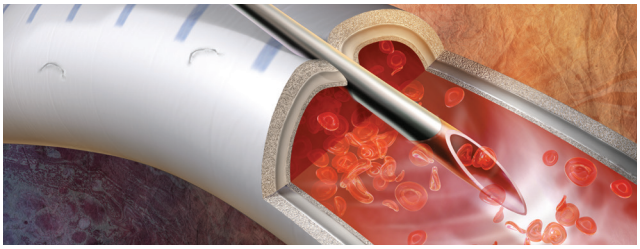
The CVC sepsis hospitalization cost was calculated as $27,088 from the Healthcare Cost and Utilization Project 2010 Nationwide Inpatient Sample and converted to 2014 dollars using the Medical Consumer Price Index.[3,7]

- Hospitalization costs were estimated using a combination of ICD-9-CM diagnosis codes to determine the costs for hospitalization of specific ESRD CVC patients with sepsis.
- Hospital admissions with a primary diagnosis code of 999.31-infection due to CVC with secondary diagnosis codes, 585.6-ESRD, and 995.91-sepsis and/or 995.92-severe sepsis, were used to determine the appropriate patient population.

Forearm loop arteriovenous graft for hemodialysis access



Cannulation of an arteriovenous graft



Results:

Assuming 100 patients in each group, the GORE® ACUSEAL Vascular Graft group was estimated to have 9.9 CVC sepsis episodes compared to 21.6 in the non-ecAVG group, with estimated total sepsis hospitalization costs of $268,171 versus $585,101, respectively, due to the extended time with the CVC (Table 2).

Table 2: Cost savings

GORE® ACUSEAL Vascular Graft	Non-ecAVG
100 CVC patients receive implant	100 CVC patients receive implant
2.32 CVC sepsis infection rate per patient year	2.32 CVC sepsis infection rate per patient year
15.5 days to potential CVC removal	34 days to potential CVC removal
= 9.9 potential CVC sepsis infections	= 21.6 potential CVC sepsis infections
× $27,088 / CVC sepsis infection	× $27,088 / CVC sepsis infection
= $268,171 total CVC sepsis costs	= $585,101 total CVC sepsis costs
and $2,682 CVC sepsis costs per patient	and $5,851 CVC sepsis costs per patient

On average, the GORE® ACUSEAL Vascular Graft was estimated to reduce the number of CVC sepsis episodes by 11.7 since it reduces the number of catheter-dependent days by 18.5 compared to a non-ecAVG.

The estimated average CVC sepsis costs in the GORE® ACUSEAL Vascular Graft group were $2,682 per patient versus $5,851 per patient in the non-ecAVG group, resulting in a cost savings of $3,169 per patient (Figure 2).

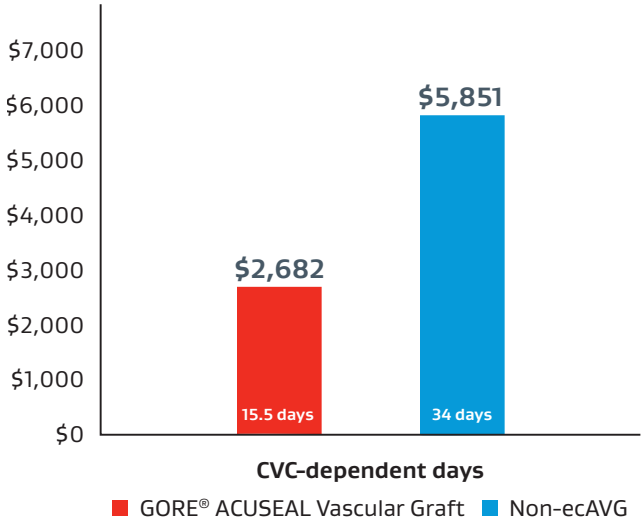
Conclusion:

It is estimated the GORE® ACUSEAL Vascular Graft reduces the overall incidence of CVC sepsis and related costs compared to non-ecAVGs due to fewer CVC-dependent days.

As clinicians become more accustomed to cannulating the GORE® ACUSEAL Vascular Graft within 24 hours, the cost savings could potentially be higher than what is currently estimated.

Cost savings of $3,169 per patient with avoidance of 18.5 CVC-dependent days

Figure 2: Average sepsis costs per patient



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   The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government.

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