

Use of logistic regression to evaluate all-cause readmission and acute renal failure rates from an infrarenal fixation device family with ePTFE (GORE® EXCLUDER® Device family*) versus two suprarenal fixation devices with PET (polyethylene terephthalate) material

M. NAKUM^a, B. BAIDOO^b
a. Department of Health Economics and Outcomes Research, W. L. Gore & Associates, London, U.K.
b. Department of Health Economics and Outcomes Research, W. L. Gore & Associates, Phoenix, AZ, U.S.

INTRODUCTION

This study aims to evaluate the clinical outcomes of three different fixation devices used in patients with renal disease, specifically assessing the differences in outcomes associated with an infrarenal fixation device made of expanded polytetrafluoroethylene (ePTFE) (GORE® EXCLUDER® Device family*) and two suprarenal fixation devices made of PET (polyethylene terephthalate) (ENDURANT Device[†] and ZENITH Device[‡]).

The primary focus is on examining how the choice of device influences post-operative complications such as the incidence of acute renal failure and 30-day all-cause readmission rates.

OBJECTIVE

The objective of this study is to determine the relationship between the selection of fixation devices and postoperative complications in patients with pre-existing renal conditions.

Specifically, the study aims to compare the impact of three different devices on:

- The 30-day all-cause readmission rates, with a focus on patients with baseline renal failure.
- The 30-day acute renal failure rates in relation to the type of fixation device used.

METHOD

This research is based on a retrospective, real-world analysis of data extracted from the Premier Healthcare (PINC AI) Database, covering the period from 2020 to 2023.

The study included 978 patients who were implanted with one of the fixation devices (EXCLUDER Device family, ENDURANT Device and ZENITH Device).

Logistic regression analysis was performed to assess key outcomes, including 30-day all-cause readmission rates and 30-day acute renal failure rates. The analysis controlled for potential confounding variables to ensure accurate assessment of the impact of device selection on patient outcomes.

RESULTS

The results indicated that patients with baseline renal failure had more than twice the risk of 30-day all-cause readmission compared to patients without baseline renal failure, regardless of the device used.

Patients who were implanted with the EXCLUDER Device family demonstrated a 25% reduction in the odds of developing acute renal failure within 30 days compared to those who received ENDURANT Device and ZENITH Device.

Furthermore, when the EXCLUDER Device family was compared to ZENITH Device, patients with the EXCLUDER Device family had 80% lower odds of developing acute renal failure within 30 days, highlighting the potential advantage of the EXCLUDER Device family in preventing renal complications.

RESULTS

DEPENDENT VARIABLE: 30-DAY ALL CAUSE READMISSION				
Parameters	Odds ratio estimate	95% confidence limits		P-value
Baseline acute renal disease — EXCLUDER Device family vs. ENDURANT Device	2.649	1.281	5.478	0.0086

DEPENDENT VARIABLE: 30-DAY ACUTE RENAL FAILURE				
Parameters	Odds ratio estimate	95% confidence limits		P-value
EXCLUDER Device family vs. ENDURANT Device	0.742	0.292	1.885	0.5303

DEPENDENT VARIABLE: 30-DAY ALL CAUSE READMISSION				
Parameters	Odds ratio estimate	95% confidence limits		P-value
Baseline acute renal disease — EXCLUDER Device family vs. ZENITH Device	2.270	0.923	5.581	0.0741

DEPENDENT VARIABLE: 30-DAY ACUTE RENAL FAILURE				
Parameters	Odds ratio estimate	95% confidence limits		P-value
EXCLUDER Device family vs. ZENITH Device	0.200	0.037	1.089	0.0627


* EXCLUDER Device family refers to GORE® EXCLUDER® AAA Endoprosthesis, GORE® EXCLUDER® Conformable AAA Endoprosthesis.
† ENDURANT Device refers to MEDTRONIC® ENDURANT® II AAA Stent Graft System/MEDTRONIC® ENDURANT® IIs AAA Stent Graft System.
‡ ZENITH Device refers to COOK® ZENITH ALPHA® Abdominal Endovascular Graft, COOK® ZENITH FLEX® AAA STENT Graft System.

CONCLUSIONS

- The findings of this study suggest that the EXCLUDER Device family is associated with the lowest rates of acute renal failure of the studied devices within 30 days, making it a promising option for patients at higher risk of renal complications.
- Additionally, the EXCLUDER Device family appears to contribute to a lower likelihood of readmission due to renal failure, potentially improving patient outcomes and reducing hospital readmissions.
- These results support the viability of the EXCLUDER Device family in clinical practice, particularly for patients with pre-existing renal disease and warrant further investigation to explore its long-term benefits across broader patient populations.

CONTACT INFORMATION

mnakum@wlgore.com



Consult Instructions
for Use
eifu.goremedical.com

Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. Rx only

Products listed may not be available in all markets.

COOK, ZENITH ALPHA and ZENITH FLEX are trademarks of Cook Medical, Inc. MEDTRONIC is a trademark of Medtronic, Inc. ENDURANT is a trademark of Medtronic Vascular, Inc.

GORE, *Together, improving life*, EXCLUDER and designs are trademarks of W. L. Gore & Associates. © 2025 W. L. Gore & Associates GmbH 25AR2006-EN01 APRIL 2025

