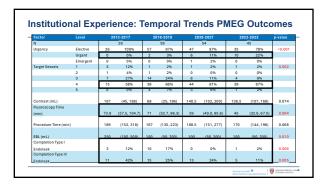


Institutional Experience

- Data from 2012 – 2023, stratified into four time periods (less cases in the first years):
- 2012-2017
- 2018-2019
- 2020-2021
- 2020-2021
- 2022-2023

- Includes data from:
- Ongoing PMEG IDE trial (NCT #04746677)
- Cases performed urgently/emergently, and patients with prior aortic surgery
- ZFEN cases for comparison

- Trend tests to assess changes in operative characteristics of PMEGs over time and Kaplan-Meier methods to compare survival and reintervention in PMEG vs ZFEN in a 5-year period.



## How do results vary with vs. without an IDE? Trend toward decreased fluoroscopy time and decreased rate of completion type I and type III endoleaks (all p < .05). Stable perioperative outcomes and perioperative mortality of 4.9% (includes urgent/emergent cases). Learning curve, increase in patient experience. Increased complexity of cases. All TAAA/CAAA PMEG patients go into IDE. FDA Mandate. Need Emergency approval from FDA and IRB for any implant outside of inclusion/Exclusion

