Failure Mode Analysis of the Endologix Endograft

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ABSTRACT

Objective: Type III endoleaks (T-III) following endovascular repair of aortic aneurysms (EVAR) remain a major concern. Our center experienced a recent concentration of T-III endoleaks requiring elective and emergency treatment and prompted our review of all EVAR implants over a 40 month period from April 2011 until August 2014. This report represents a single center experience with T-III endoleak management with analysis of factors leading to the T-III related failure of EVAR.

Methods: A retrospective review of all the operative reports, medical records and computed tomography scans were reviewed from practice surveillance. Using SVS aneurysm reporting standards, we analyzed the morphology of the aneurysms before and after EVAR implant using computed tomography (CT). Index procedure and frequency of reinterventions required to maintain aneurysm freedom from rupture were compared across all devices using SAS version 9.4 (SAS Institute, Inc. Cary, NC.). . Major adverse events requiring secondary interventions for aneurysm treatment beyond primary implant were analyzed for methods of failure. Aneurysm morphology of patients requiring EVAR was compared across all endograft devices used for repair. For purposes of major adverse event analysis, patients receiving Endologix (ELX) endograft were combined into Group 1 and Gore, Cook and Medtronic endograft patients were placed into Group 2.

Results: Overall technical success and discharge survival was achieved in 97.3% and 98% of patients regardless of device usage. There was no significant device related difference identified between patient survival or freedom from intervention. Major adverse events involving aneurysm treatment were over 7 fold more frequent with ELX (Group1) vs non-ELX (Group 2) endografts ($p<0.01$). Group 1 patients with aneurysm diameters larger than 65 mm were associated with a highly significant value for development of a T-III endoleak (OR=11.16, 95% CI (2.17, 57.27); p=0.0038).

Conclusions: While EVAR technical success and survival was similar across all devices, ELX devices exhibited an unusually high incidence of Type III endoleaks when implanted in AAA with a diameter of more than 65 mm. Frequent reinterventions were required for Endologix devices for prevention of aneurysm rupture due to T-III endoleaks.

INTRODUCTION: Endovascular management of abdominal aortic aneurysms (EVAR) has become an accepted form of repair since the initial report by Parodi[1]. In 2009, the Division of Vascular Surgery at Indiana University initiated a Level 1 Acute Aortic program designed to centralize rapid response, transport and treatment of aortic emergencies within the state of Indiana and surrounding area. All FDA approved and commercially available devices were used in our practice with preponderance of the use of Endologix endografts. In 2013, a concentration of reinterventions for Type III (T-III) endoleak treatment raised concern over device selection and prompted a review of all patients having EVAR repair with FDA approved endografts.

Methods: Using SVS/AAVS reporting standards, we obtained variables from the index procedure which included timing of repair, AAA neck and sac morphology, age, medical co-

morbidities, correlation of AAA repair with manufacturer's instructions for use, technical success and presence of endoleak at the completion of the procedure [2].

Indications for EVAR repair included all standard indications and specifically symptomatic or ruptured AAA; elective AAA size exceeding 5.5 cm in a male and > 5 cm in a female; saccular aneurysms regardless of size; enlarging aneurysms with size increase of > 0.5 cm in 6 months; atheroembolism attributed to aneurysmal disease and pre-transplant patients having AAA exceeding 3 cm (as per protocol). Technical success was defined as satisfactory endograft placement with exclusion of the aneurysm sac, maintaining patent renal vessels and absence of Type I or Type III endoleaks at the completion of the procedure. Mortalities were reviewed from medical records and from last known contact to determine if they were device related. For analysis, patients receiving an endograft from Endologix (Powerlink or AFX - Irvine, CA) were identified as Group 1. Patients receiving endografts from Gore (Excluder-Flagstaff, AZ), Cook (Zenith- Bloomington, IN) or Medtronic (Endurant- Minneapolis, MN) manufacturers were identified as Group 2. AAA freedom from re-intervention was assessed at any point of aneurysm reintervention as a binary numeral. Patient survival was documented at completion of the index procedure, at any re-intervention and from last available patient contact.

Freedom from intervention was defined as the absence of any singular event required for aneurysm treatment and independent of the number of reinterventions encountered. Any indication for aneurysm treatment, timing of repair, repair method and procedural success was noted. Major Adverse Events (MAE) defined the cumulative sum of events involving any device related mortality + post-implant aneurysm rupture + any operative conversion and all aneurysm reinterventions required to maintain freedom from aneurysm rupture. Major adverse events were then tabulated for each group and independently for each patient.

The remainder of the study focused on the cohort of patients receiving an Endologix endograft (Group 1). IFU information was abstracted from Endologix manufacturer's "Instructions For Use" in the Powerlink XL pivotal US FDA trial in 2008 and later amended for AFX product update. An IFU Outlier was defined as any one of the following: aortic diameter < 18 or > 32 mm, aortic neck length of < 15mm, or aortic (Ao) neck angle > 60 degrees. AAA size, aneurysm neck angle change, measurements of centerline and device overlap and documentation of endoleak by computed tomography (CT) was monitored over time at all available follow up visits. Overlap was defined as the length of wireframe duplication observed between an aortic bifurcated unibody and the proximal aortic extension. Centerline change was defined as the length of the central flow lumen from lowest renal artery to aortic bifurcation occurring over time from the index procedure. Variables recorded from routine follow up included freedom from aneurysm re-intervention, AAA size, endoleak presence and centerline and overlap measurements.

Statistical Analysis: All information was stored in Redcap: a research electronic database capture provided by the Indiana Clinical and Translational Sciences Institute as a secure web application for managing surveys and databases[3]. This study met requirements for Indiana University IRB expedited review with patient consent waived. Statistical analysis was performed using SAS version 9.4 (SAS Institute, Inc. Cary, NC.). Odds Ratios for Type III endoleak occurrence, Chi square and Fischer's Exact test to account for low expected cell counts were used in univariate analysis of patient reinterventions. Pre-operative and procedural variables were submitted for ANOVA and multivariable-logistic regression analysis. Kaplan-Meier curve was used to plot patient survival. All analytic assumptions were verified to ensure results validity. A p value less than 0.05 was considered statistically significant.

RESULTS: There were a total of 151 patients, 83 having an ELX endograft (Group 1) while 68 received a Cook, Gore or Medtronic device (Group 2). **Table I** One hundred thirty two patients were alive at the completion of the study; Group 1= 71, Group 2 = 61 (p=0.3025). Technical success was achieved in 97.3% (147/151) for EVAR placement, with no difference between either group (p = 0.2525). Similarly, over 98% of patients were discharged alive following their EVAR procedure. There were four deaths that occurred during the index hospital stay: three from aneurysm rupture and one from operative conversion for an unresolved Type Ia endoleak. Over the course of the study, eighteen deaths were recorded with twelve in Group 1 and six in Group 2 (p=0.2451 overall). **Table II** Four mortalities were deemed device related (DR) which included one operative conversion during the index hospital stay and three deaths following emergent reintervention treatment, all in Group1 (p =0.1274).

No statistical significant difference was noted when the following variables were compared per group: sex, age, pre-op co-morbidity risk factors, and timing of repair, AAA size, or choice of endograft.

Survival analyses indicate that there were no significant differences in the time until death or re-intervention from surgery (p>0.05). **Figure 1** shows the Kaplan-Meier survival curve on time since surgery for mortality, with other survival analyses having similar KM curves. Group 1 centerline change greater than 10 mm from baseline proved non-significant also: OR = 3.64 (CI 0.81-16.33), p = 0.0910.

Major Adverse Event occurrences for Group 1 totaled thirty eight versus five in Group 1. **Table II** Categories of MAE in Group 1 (N= 38) include: DR mortality N = 4, AAA rupture N =8, OR conversion N = 2 and AAA reintervention N = 24. Twelve patients with T-III endoleaks accounted for 76% (29/38) of MAE's: (DR mortality = 2, post implant AAA rupture = 7, AAA reintervention = 20).

Statistical significance between groups was discovered in the following variables: aortic neck diameter (p= 0.0179), aortic neck length (p=0.0016), aortic neck angle (p=0.0101), AAA angle (p=0.0045), Major Adverse Event rate (<0.0001), post implant rupture rate (p = 0.0084) and total number of aneurysm re-interventions (p = 0.0008).

All T-III events occurred in Group 1 (ELX). **Table III** Regression analysis identified AAA diameter > 65 mm as a predictor for Type III endoleak (OR=11.16, 95% CI (2.17, 57.27); p=0.0038). While differences were seen between groups for aortic neck measurements as noted above, only AAA diameter achieved significance for T-III endoleaks in Group 1 only.

DISCUSSION: Since EVAR's inception, stent-graft design modifications have made EVAR a safe and durable procedure for AAA repair. Safety profiles of the eight FDA approved endovascular stent grafts are well established [4, 5, 6, and 14]. Surveillance monitoring for EVARs remain a critical part of AAA care to maintain freedom from rupture. One recognized method of EVAR failure is development of a Type III endoleak which can return aortic sac pressures to systemic levels. Endovascular repair for component separation (T-IIIa) of a modular endograft can often be accomplished by bridging the gap with an additional iliac limb extension, while a fabric tear (T-IIIb) may require relining an

involved limb or the entire device to avoid need for open conversion. ELX device T-IIIa endoleaks are unique in that separation involves aortic components requiring bridging of additional aortic extension(s) and their inherent larger sheaths to complete a repair. ELX device T-IIIb endoleaks are more commonly attributed to the bifurcated unibody device which occurs near the saddle of the endograft. Relining the entire endograft is recommended given the difficulty in pinpointing the exact location and extent of the defect. In contrast to all other endograft designs, the ELX endoskeleton can prove challenging with reinterventions to avoid wireframe entrapment. Currently no evidence exists as to whether repair of T-III endoleaks should be accomplished with like (similar) devices or with alternative endograft products. Both techniques were utilized in this series and similar outcomes were noted.

The Endologix endoskeletal design for both Powerlink and AFX stent grafts provide maximum flexibility in conforming to AAA morphology. The bifurcated unibody design, ease of length adjustment for overlap at the time of implant and rapid deployment system allow for elective, urgent and emergent AAA repair with one sheath delivery. Several reports have documented its safety record in longitudinal AAA care [7, 8, and 9]. Flexibility in the endoskeletal design, however, may be detrimental to lateral stability especially when a large diameter aneurysm is treated as distraction forces impact component overlap to a greater degree than caudal or cephalad migration of aortic and iliac seal zones. We hypothesize that fabric billowing of the proximal aortic extension may provide a reverse windsock effect that increases distraction forces between the bifurcated unibody stent graft and the proximal aortic extension by cephalad displacement that can ultimately cause an uncoupling of the two components. This appears more pronounced with aneurysms of

larger size (65mm) and may be accentuated when diameters of the bifurcated unibody stent graft and the aortic extension differ significantly. The mean AAA size for patients with T-IIIa endoleak in this study was 80.5 mm. All six patients experiencing T-IIIa in this report had a 25 or 28 mm diameter bifurcated unibody stent graft coupled with a 34 mm proximal aortic extension.

Similar to prior reports, we found no difference between patient survival and freedom from any intervention between the two groups [4, 10, 11, 12]. Significant differences were noted between Groups for Aortic Neck diameter ($p = 0.0179$), Aortic neck length ($p = 0.0016$), Aortic neck angle ($p = 0.0101$) and Aneurysm angle ($p = 0.0045$) measurements. All of these values are well within the IFU recommendations of all devices used, so clinical relevance of these values is uncertain. While there was no difference between Groups in freedom from reintervention , we found a large difference in MAE's not previously reported as several of our patients experienced more than one MAE at different episodes of treatment (range 0-5) ($p < 0.0001$). Post implant rupture rate and AAA reintervention proved to be also highly significant between Groups.

While not statistically significant, all T-IIIa patients in this series did develop increasing centerline measurements and decreasing component overlap prior to IIIa endoleak discovery. This is likely due to the extended length of follow up imaging obtained during routine surveillance for stable aneurysms. Our 7.2% (6/83) incidence of T-IIIa is more than double that reported by Endologix Core Lab analysis of 3.1% (4/127). Based on post-market report findings, Endologix now recommends: 1) maximizing component overlap greater than previously recommended 40 mm, 2) avoidance of excessively oversized extension relative to the bifurcated unibody stent graft and 3) use of a third overlapping component to increase columnar strength in AAA larger than 70 mm.

The large number of T-IIIb endoleaks (N=8) found in Group 1 ELX patients is unique and at odds with reported rates of 0.22% worldwide (Endologix Clinical Update June 2, 2015.). No relationship could be found between device implantation, surgeon, completion balloon angioplasty, or AAA morphology except for size greater than 65 mm. Time to T-IIIb presentation varied between 6 and 51 months (**Table III**). Most of the IIIb endoleaks appeared to involve the bifurcated unibody stent graft although post hoc analysis proved difficult to assign an exact location as can be seen in **Figure 2**. All surveillance CT scans evaluated before IIIb presentation by the treating vascular surgeon were interpreted as unremarkable and demonstrated stable or shrinking aneurysm sacs over time.

In an October 2014 product update, Endologix announced a change in their ePTFE fabric from Strata® to Duraply®, citing "a high density multilayered design to bolster strength characteristics". All patients in this study received devices of Powerlink or AFX system having Strata® fabric predating Duraply®. It remains unclear if the change in fabric design to Duraply will provide greater security in preventing T-IIIb endoleaks.

We found the cobalt chromium wireframe visualization of the ELX stent grafts assessment challenging in comparison CT studies for overlap determination. Plain film radiographs are a better choice than CT scans to monitor this change. Observations from our study will strengthen the need for further design modification requirements required for the device in order to monitor the overlap between components. Similarly, we believe a conventional duplex scan exam to monitor sac morphology during the post implant period may not help predict impending T-IIIA endoleak. We propose that combinations of CTA with plain radiograph films are required during the surveillance period.

This study has several limitations. It is retrospective and from a single center experience. A small sample size may have prevented observed trends to demonstrate statistical significance. EVAR monitoring was at the discretion of the treating vascular surgeon. Selection bias may have occurred with endograft selection although no difference in patient survival or freedom from reintervention could be identified between elective vs emergent procedures. In contrast to open repair, EVAR monitoring requires continued surveillance for endoleak detection and to verify device integrity to maintain freedom from AAA rupture. The practitioner's role in surveillance remains critical. Practice variation can produce disparate EVAR outcomes among providers with like stent graft devices. Most notable in this review were differences in CT scan technique from multiple imaging centers and a lack of uniform time in follow up surveillance imaging. This decreased the strength of centerline and overlap end points as several imaging studies lacked the capability for reformatting acquired images (slice thickness equal or exceeding 4 mm).

Several observations can be made based on our scrutiny of imaging studies from initial EVAR repair to all available surveillance scans. First, our ELX cohort represented approximately 55% (83/151) of all EVAR procedures performed at our institution between April 2011 and August 2014. Device selection was at the vascular surgeons' discretion. No selection bias was discovered between ELX and alternative stent graft use with regards to AAA morphology, calcification or neck anatomy. Our freedom from reintervention rate for (non-ELX patients) of 7.3% is not significantly different from the 14.4% incidence for the ELX group. Nonetheless, repeated interventions (N =20) were necessary in the ELX group of patients exhibiting T-III complications who required multiple procedures to prevent aneurysm rupture while no additional procedures were necessary in the non-ELX group. Second, appropriate "like" sized ELX device

selection is critical in large aneurysms as T-IIIa risk appears increased when there are marked differences in diameter between the unibody and aortic extension components. Maximizing device overlap beyond 40 mm and adding a third device as a multilayer component for larger size AAA appears logical to potentially minimize both lateral and cephalad distraction forces that predispose to T-IIIa development. Obtaining bimodal imaging at the time of EVAR repair with AP and oblique views may also help to identify those patients with extreme endograft angulation. Currently, the largest bifurcated unibody device diameter is 28 mm. All patients with T-IIIA separation in this series received a 34 mm diameter aortic extension necessary for proximal aortic neck diameters. This combination continues to prove challenging in patients with large aneurysms. Third, protocol surveillance with CT imaging appears preferable over ultrasound to monitor changes in centerline length and device overlap observed over time, potentially identifying those patients at risk for T-IIIa development. We currently have treated two patients for centerline changes electively to avoid potential T-IIIa development. Fourth, our large concentration of IIIb endoleaks in this cohort remains unexplained and unpredictable as to onset and incidence. It is our belief that Endologix patients treated before October 2014 remain at risk for fabric deterioration and specifically those with AAA greater than 65mm should have regularly scheduled CT imaging to continue verifying endograft stability. As Hertzer implies, "Results mean everything", so it is incumbent on us to remain good stewards to AAA care with EVAR device use[13].

Conclusion: Patients with AAA diameter > 65 mm may have an increased risk for T-III complications with the ELX graft. CT imaging is recommended over ultrasound to monitor device overlap and centerline changes that may occur over time to avoid Type IIIa endoleak. While freedom from intervention remains similar between endograft groups, major adverse

events are frequent and markedly increased in ELX patients that require further aneurysm treatment. Type IIIb endoleak development was found unrelated to AAA morphology yet appears linked to AAA size and to fabric design. Our results call for continued surveillance in patients treated with ELX devices especially in those treated prior to October 2014 with CT imaging recommended as the primary imaging modality.

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Table I

Patient Demographics and Pre-op Variables

Variable	Group 1 (ELX) n=83	Group 2 (non-ELX) n=68	P-value
Age	71.0 (9.60)	72.14 (8.64)	0.4485
Male	71 (56.4%)	55 (43.7%)	0.4434
Cardiac status			
0-2	56 (67.4)	54 (79.4)	0.3379
3-4	27 (32.5)	13 (20.5)	
Pulmonary			
0-2	72 (86.7)	60 (88.2)	0.1514
3-4	7 (8.4)	8 (11.8)	
Renal			
0-2	77 (92.7)	65 (95.6)	0.8259
3-4	5 (6.0)	3 (4.4)	
Hypertension			
0-2	44 (53.0)	35 (51.5)	0.7754
3-4	39 (46.9)	33 (48.5)	
Ao Neck diameter	25.58 (4.19)	24.01 (3.50)	0.0179
Ao Neck Length	25.22 (14.32)	33.69 (16.82)	0.0016
Ao Neck angle	19.11 (16.20)	26.30 (15.48)	0.0101
AAA angle	38.38 (20.27)	47.74 (16.48)	0.0045
IFU Outlier	10 (13.3)	3 (4.7)	0.0810
AAA size	62.56 (15.07)	60.79 (12.30)	0.4254
Timing			
Elective	55 (66.3)	43 (63.2)	0.6297
Urgent	8 (9.6)	10 (14.7)	
Emergent	20 (24.1)	15 (22.1)	
Technical Success	79 (95.2)	67 (98.5)	0.2525
Procedure Survival	79 (95.2)	68 (100)	0.1111

Overall Survival	71 (85.5)	61 (91.0)	0.3025
Freedom from Int (No)	12 (14.5)	5 (7.4)[1]	0.2025
Major Adverse Events total	38	5	<0.0001
Patient MAE mean/range	0 (0-5)	0 (0-1)	
Type III endoleak			
IIIa	6	0	<0.0001
IIIb	8	0	

[1]One patient declined treatment in Group 2.

Freedom from Int (No) = Patient requiring post implant AAA treatment.

Table II

Major Adverse Events

Event Type	Group 1(n)	Group 2(n)	p-value
Device Related Mortality	4	0	0.1274
Post Implant Rupture	8 (T-III = 7)	0	0.0084 (.0166)

OR Conversion	2	0	0.5016
AAA Reintervention	24 (T-III =20)	5	0.0008 (.0076)
Total	38	5	

Legend: AAA Reinterventions include: Limb extension for aneurysmal disease; Limb occlusion; Endoleak treatment; Centerline increase with concern for IIIA endoleak; Renal artery treatment. (T-III patients accounted for 7/8 post implant ruptures and 20/24 AAA reinterventions). Second p-value is for T-III only frequencies.

Table III

Reinterventions in Patients with Type III Endoleak

Pt Number	AAA (mm)	Ao Neck Angle	Case Type	Event Interval (Months)	Event	Event survival
70	80.2	55	Urgent	18	IIIa	Y
72	79	39	Emergent	16	IIIb	Y
			Elective	20	Ib	Y
98	54	6	Emergent	12	IIIb	Y
101	53	67	Elective	46	IIIa	Y
			Emergent	51	IIIb	Y

102	80	NA	Emergent	32	IIIa	Y
			Emergent	35	IIIb	Y
			Emergent	35	ALI	N
105	111	24	Elective	3	Ib	Y
			Urgent	16	Ia	Y
			Emergent	25	IIIa	Y
			Emergent	42	IIIb	N
107	88	45	Urgent	11	IIIb	Y
114	91	51	Elective	3	Iliac	Y
			Elective	20	CL	Y
142	41	19	Elective	6	IIIb	Y
150	78	10	Urgent	26	IIIa	Y
151	81	30	Elective	36	IIIa	Y
152	52	8	Elective	36	IIIb	Y

Legend: Endoleak = Ia, Ib, IIIa, IIIb; ALI = Acute Limb, Ischemia; Iliac = Limb extension;
CL = Centerline Increase
AAA diameter > 65mm association with T-III endoleak: (OR=11.16, 95% CI (2.17, 57.27) p = 0.0038).

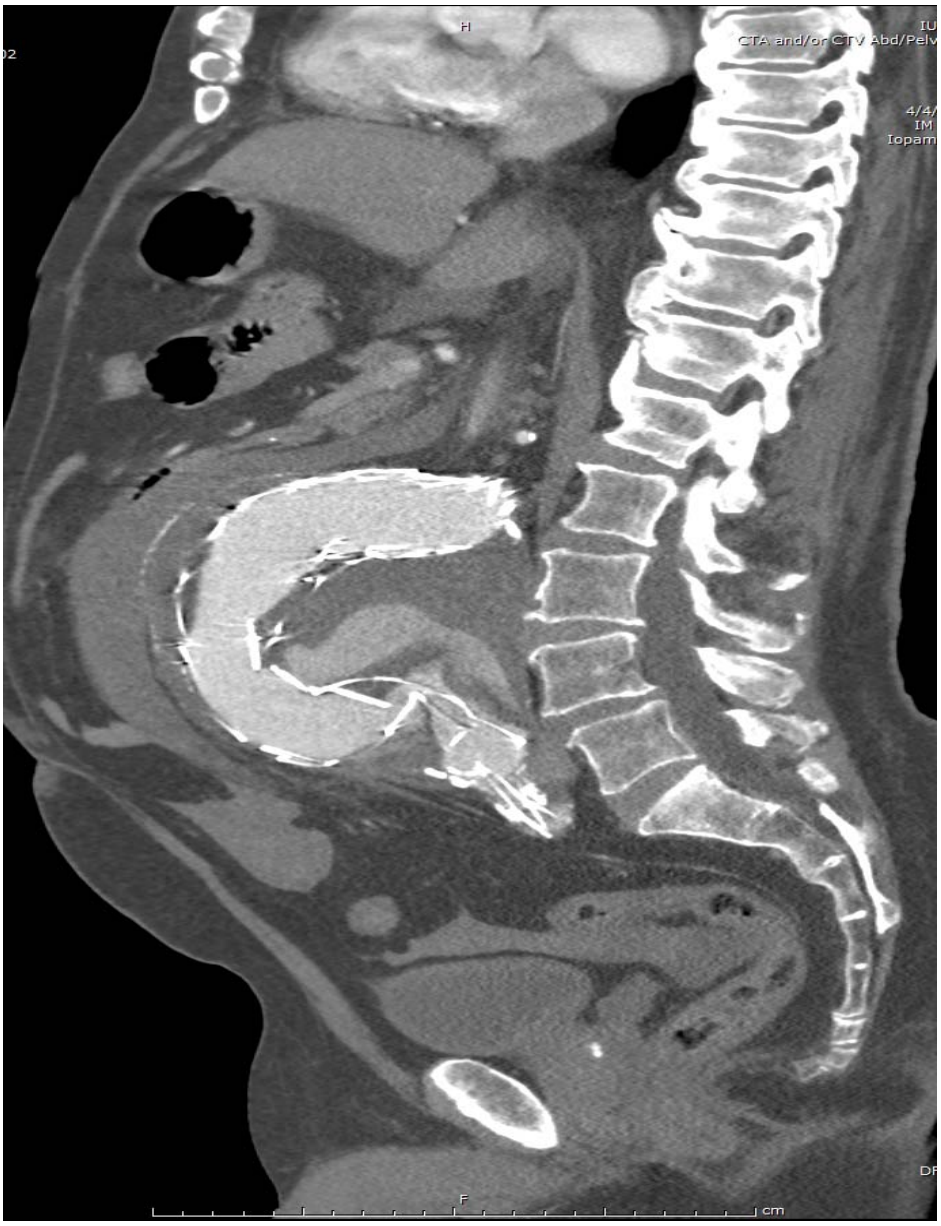

Figure 2: 111 mm Ruptured Aneurysm with consecutive emergent T-IIIa and T-IIIb events. Open conversion required after 4 Major Adverse Events

Figure 1

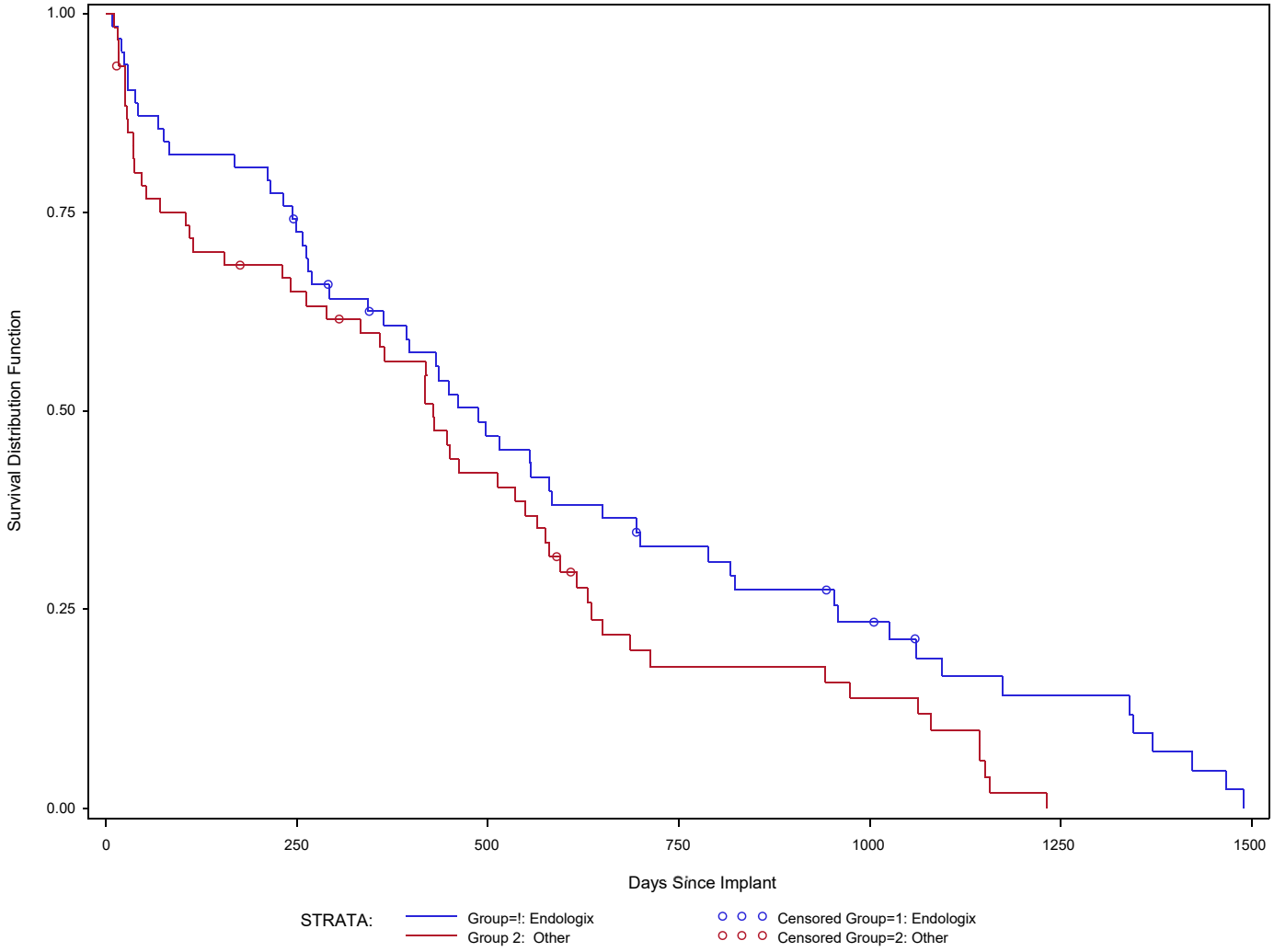

Figure 3: Kaplan-Meier survival curve for mortality over time since surgery, showing no difference between strata (ELX vs. others); p=0.1354.