Aus der Klinik für Gefäß- und Endovaskularchirurgie
der Heinrich-Heine-Universität Düsseldorf
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Results after endovascular repair of the infrarenal abdominal aortic aneurysm with the ALTURA stentgraft

DISSERTATION

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Abstract

The aim of this study is to evaluate the durability, morphologic and anatomic changes after endovascular abdominal aortic repair using the ALTURA stentgraft system.

This is a retrospective computed tomography (CT) image analysis of patients treated with ALTURA stentgraft system at the Pauls Stradins Clinical University Hospital (Riga, Latvia) and at the University Hospital Düsseldorf (Germany). The follow-up CT scans were done one month, six months, one, two and three years after stentgraft implantation. Changes of the stentgraft length, aneurysm sac diameter and proximal and distal sealing zones were analysed using a centerline reconstruction.

From January 2014 to June 2017, 40 patients with a mean age 71±8.5 years, (range 51-84 years) with an infrarenal abdominal aortic aneurysm (AAA) were treated. The mean diameter was 5.6±1.0 cm. Image-based follow up was completed in all patients after 1 month, in 80% at 1 year, in 60% at 2 years, and in 20% of the patients at 3 years. Overall mean device shortening due to braided stent characteristics in the follow-up period in compare with first month follow-up was 4±3 mm after one year, 7±5 mm after two and 9±6mm after three years (p=.0001). There was a statistically significant stentgraft migration in compare with the first month follow-up. Aneurysm sac shrinkage more than 10 mm was seen one year after the treatment in 25% of patients, after two years in 38% of patients and after three years in 50% of patients. Clinical success (freedom from type I/III endoleak, graft thrombosis or conversion) one month after implantation was 97.5% (one type I endoleak) and 100% after one year. Seven patients had type II endoleak (17.5%) in first month follow-up, five of them (12.5%) underwent an embolisation. Three patients (7.5%) underwent PTA/Stent-implantation due stentgraftstenosis. After three years one stentgraft explantation due limb occlusion was needed. Ten secondary procedures in 8 patients in a three-year period were performed. No secondary aneurysm ruptures and no AAA-related deaths were observed. Midterm results showed significant morphological changes of stentgraft, aneurysm sac diameter and in sealing zones, but without clinical relevance after three years. The incidence of endoleaks and secondary procedures are acceptable, but a longer follow-up is needed to evaluate a durability of the Altura stentgraft system.

Zusammenfassung

Das Ziel dieser Studie ist die Dauerhaftigkeit, morphologische und anatomische Veränderungen nach endovaskulärer Versorgung des infrarenalen Bauchaortenaneurysma mit dem Altura Stentgraft-system zu untersuchen.
Dies ist eine retrospektive Computertomographie (CT) - Bildanalyse von Patienten, die mit dem Altura Stentgraft-system am Pauls Stradins Universitätsklinikum (Riga, Lettland) und am Universitätsklinikum Düsseldorf (Deutschland) behandelt wurden. Die Follow-up-CT-Scans wurden nach einem und sechs Monate, sowie nach einem, zwei und drei Jahren durchgeführt. Neben Längen- und Durchmesserveränderungen des Stentgrafts, sowie Durchmesserveränderungen des Aneurysmasacks wurden auch Längenveränderungen in den proximalen und distalen Abdichtungszonen untersucht.
Von Januar 2014 bis Juni 2017 wurden insgesamt 40 Patienten im Alter von 71±8,5 Jahren (51-84 Jahre) mit einem infrarenalen Bauchaortenaneurysma (BAA) behandelt. Der mittlere Durchmesser betrug 5,6±1,0 cm. Ein bildbasiertes Follow-up konnte nach 1 Monat bei 100% der Patienten, nach 1 Jahr bei 80%, nach 2 Jahren bei 60% und nach 3 Jahren bei 20% der Patienten durchgeführt werden. Die mittlere Verkürzung des Stentgrafts aufgrund der Eigenschaften des geflochtenen Stentgerüstes in der Nachbeobachtungszeit betrug im Vergleich zum Erstmonat 4±3 mm nach einem Jahr, 7±5 mm nach zwei und 9±6 mm nach drei Jahren (p=.0001). Es gab eine statistisch signifikante Migration des Stentgrafts nach kaudal im Vergleich mit dem ersten Follow-up Untersuchung nach einem Monat. Eine Schrumpfung des Aneurysmasackes von mehr als 10 mm wurde ein Jahr nach der Behandlung bei 25% der Patienten gesehen, nach zwei Jahren bei 38% der Patienten und nach drei Jahren bei 50% der Patienten. Der klinische Erfolg (Freiheit von Typ-I/III-Endoleaks, Stentgraft-Thrombose oder Konversion) betrug 97,5% einen Monat nach der Implantation (ein Typ-I-Endoleak) und 100% nach einem Jahr. Sieben Patienten hatten Typ-II-Endoleaks (17,5%) im ersten Follow-up nach einem Monat. Fünf (12,5%) davon wurden einer Embolisation unterzogen. Drei Patienten (7,5%) wurden mit einer PTA/Stent-Implantation aufgrund einer Stentgraftstenose behandelt. Nach drei Jahren musste ein Stentgraft aufgrund einer Thrombosierung explantiert werden. In den drei Jahren der Nachbeobachtungszeit wurden zehn sekundäre Interventionen bei 8 Patienten durchgeführt. Es gab keine Aneurysma-Ruptur und keine BAA-bedingten Todesfälle.
Das Altura-Stentgraftsystem zeigt signifikante morphologische Veränderungen des Stentgrafts, Aneurysmasackdurchmesser und Verankerungszonen nach drei Jahren. Diese sind jedoch ohne klinische Relevanz. Die Inzidenz von Endoleaks und sekundären Eingriffen ist akzeptabel, jedoch sind Studien mit längerer Nachbeobachtung erforderlich, um die Haltbarkeit des Altura-Stentgraft-Systems weiter zu bewerten.

Abbreviations

AAA - abdominal aortic aneurysm

ABI - ankle brachial index

BES – baloon expandable stent

CT - computed tomography

CTA - computed tomograhy angiography

DU – doppler ultrasound

EVAR - endovascular aneurysm repair

EVAS - endovascular aneurysm sealing

ICU - intensive care unit

IFU - intruction for use

MRI - magnetic resonance imaging

OR - open repair

rAAA ruptured abdomonal aortic aneurysm

SES - self expanding stent

BES – baloon expandable stent

SG - stentgraft

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1. INTRODUCTION

Abdominal aortic aneurysm (AAA), which is defined as an abdominal aortic dilation of 3.0 cm or greater, is an insidious condition with mortality up to 85% after rupture. In last decades the endovascular aneurysm repair has nearly replaced the classic open surgery. Currently, nearly 80% of all AAAs are treated by EVAR in United States and in Germany.[1,2,3]

There are many commercially devices and stentgraft systems available to treat patients with AAA. Each of them has some advantages in compare with other devices. During the last 30 years, much effort has been invested in improving our understanding of AAA and stentgrafts (SGs) biomechanics to prevent AAA rupture and optimize SG designs.[3,4] Each generation of EVAR devices has become more advanced than the last, and the indications for their use have steadily expanded to incorporate more and more complex anatomies.[5] However, long-term durability of EVAR remains an ongoing concern due to late complications of aneurysm enlargement, stentgraft migration, new-onset of endoleaks, need for secondary procedures, and aneurysm ruptures. Majority of currently available stentgrafts exploit self-expanding stent (SES) structures that exert radial force against the infrarenal aortic neck to provide fixation and seal. Most current-generation devices also incorporate suprarenal stent elements with penetrating hooks to enhance fixation.[6]

The evolution and diversification of stentgraft and delivery system designs have substantially improved the application rate and outcomes of endovascular treatment of AAAs, but further development is needed in order to treat larger spectrum of patients, reduce complications, improve device durability and the need for secondary procedures.

1.1. Abdominal aortic aneurysms

The prevalence of AAA in general population is 4.8% (6.0% for males and 1.6% for females) and it increases with age. It is uncommon in persons younger than 50 years; however, 12.5% of men and 5.2% of women 74 to 84 years of age have AAA.[7,8,9,10,11]

Aneurysms develop as a result of degeneration of the arterial media and elastic tissues. Risk factors for AAA are similar to those of other cardiovascular disease: age, male gender, smoking, atherosclerosis, hypercholesterolemia and hypertension. Diagnosis of AAA is often made as an incidental finding on abdominal ultrasonography or computed tomography (CT). The natural history of AAA shows that as aneurysms increase in size, they expand at a greater rate (Table 1.) and the risk of rupture increases (Table 2.).[7,8,12]

Aneurysm diameter	Average annual expansion rate
3,0 to 3,9 cm	1 to 4 mm
4,0 to 6,0 cm	3 to 5 mm
>6,0 cm	7 top 8 mm

***Table 1**. Growth rates for abdominal aortic aneurysms.*[7]

Aneurysm diameter (mm)	Rupture risk
30-39	0%
40-49	1%
50-59	1-11%
60-69	10-22%
>70	30-33%

***Table 2.** 12-month abdominal aortic aneurysm rupture risk by diameter.*[8]

1.2. Endovascular aneurysm repair

Surgical treatment of AAA has been gold standard for many years. Nevertheless, endovascular techniques are replacing traditional surgery in the resent decade. Endovascular aneurysm repair (EVAR) is a minimally invasive

treatment for the exclusion of AAA based on the use of a stent graft. EVAR requires adequate aortic and iliac fixation sites for effective treatment to avoid stentgarft migration and endoleak formation.[2,8]

Potential advantages of EVAR over open repair (OR) include reduced operative time, avoidance of general anesthesia, less trauma and postoperative pain, reduced hospital length of stay and less need for intensive care unit (ICU), reduced blood loss and reduced perioperative mortality rates. Endovascular techniques may prove advantages in day care and emergency cases, if proper anatomy and devices are available.[2,5,13]

In the same time, potential disadvantages include the risk of device migration, incomplete AAA sealing and endoleak formation with potential risk of further aneurysm rupture. In addition, if EVAR is unsuccessful or complications arise during the primary endovascular procedure, conversion to open repair may be necessary, therefore a thorough patient evaluation should be completed prior to EVAR to assess the risk of both procedures.[8,14,15] A number of sealing site failure risk factors have been described, including the size mismatch between the stentgraft and the aorta, the presence of wall thrombus or calcification at the sealing zones and proximal neck (short length, increased angulation) and treatment out of instructions for use (IFU).[15,16,17,18] 10% to 30% of patients with AAA treated with EVAR require secondary intervention due to endoleaks, stentgraft migration, stent fracture, aortic neck dilatation and aneurysm expansion.[14,16,19]

1.3. Complications of EVAR

The main complications after EVAR are endoleaks, stentgraft migration, and stentgraft limb occlusion. Endoleaks are categorized into five different types, which differ in etiology as well as treatment.[2,20]

1.3.1. Endoleak

An endoleak is defined as persistent blood flow in the aneurysm sac following stentgraft implantation (Figure 1.). An endoleak may often resolve spontaneously, but some of them require immediate or delayed treatment to prevent aneurysm rupture. Endoleaks can develop months or years after EVAR. Thus, lifelong surveillance after EVAR is required. Management depends on endoleak type and risk of sac rupture.[2,20]

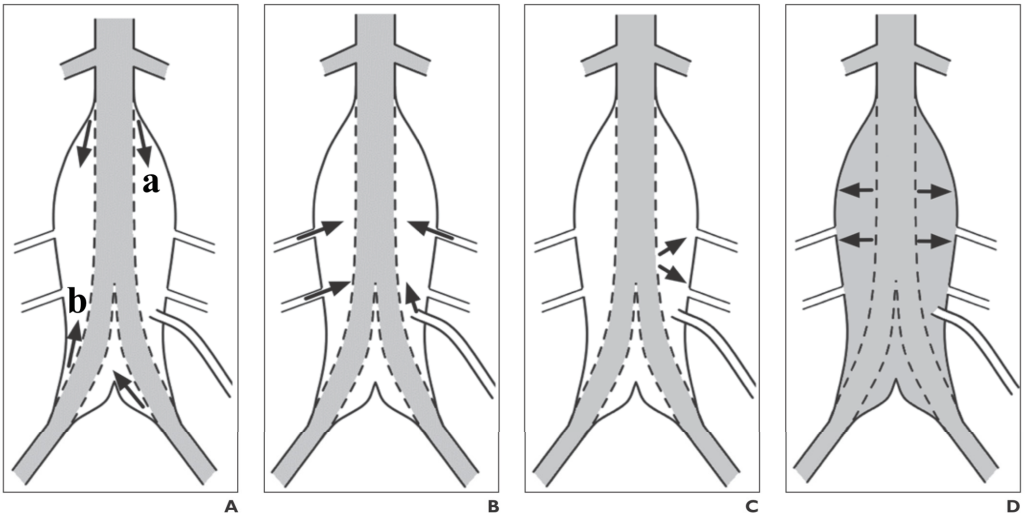

Figure 1. *Types of radiologically identifiable endoleaks. Arrows denote sites of leakage. A - Type Ia and Ib endoleaks, B - Type II endoleak, C - Type III endoleak, D - Type IV endoleak (modified from Bashir et al 2009).*[21]

A type I endoleak occurs when there is an incomplete seal at the ifrarenal aortic neck (type IA) or iliac artery (IB) and persistent blood flow into the aneurysm sack is seen. A type I endoleak is associated with elevated sac pressure and risk of aneurysm rupture.[2,20]

Type II endoleak is defined as persistent sac filling from back bleeding blood vessels (i.e., the inferior mesenteric artery, lumbar arteries, accessory renal or middle sacral artery). It is the most common endoleak. The decision to treat is based on the size and expansion of the aneurysm, endoleak cavity and the presence of symptoms.[2,20]

A type III endoleak is caused due fabric erosion, defect or a leak between stentgraft components. All type III endoleaks should be treated.[2,20]

Type IV endoleaks are related to porosity of the graft fabric, occur less frequently with current-generation stentgrafts, and are noted within 30 days of graft implantation. They usually resolve once graft interstices thrombose.[2,20]

Type V endoleak, or "endotension", is defined as elevated sac aneurysm pressure and enlargement without a demonstrable endoleak. It is generally believed that the etiology is an undetected endoleak or transmission of systemic pressure through thrombus.[2,20]

1.3.2. Stentgraft migration

Stentgraft migration after EVAR is defined as a movement of >10 mm relative to anatomic landmark or any migration leading to symptoms or requiring intervention. Migration has been described with all current stentgrafts including unibody design, modular configurations, infrarenal and suprarenal fixation and stentgrafts with a longitudinal columnar support. Most series evaluating the prevalence of device migration have reported an increase after 24 months. It can be asymptomatic and detected on CTA scan by the presence of a type I endoleak that can lead to rupture. Multiple factors affect stentgraft migration: aortic neck length and angulation, AAA morphology, accuracy of deployment, postoperative neck enlargement, proximal attachment failure, device oversizing and characteristics of stentgrafts. Nonparallel aortic neck (conical vs. straight) and the presence of calcium, thrombus in the aortic neck, have been also associated with an increased risk of distal migration.[8,20]

1.4. Imaging follow-up after EVAR and endoleak detection

Contrast-enhanced CT scan is the gold standard for detection of endoleaks. Type I and III endoleaks are detected on arterial phase images whereas type II

endoleaks are detected on delayed phase images. Usually post-procedure scan is done either 1 month after the index procedure or at patient discharge from the hospital. The follow-up CT-scans should be done 6 months and then annually after stentgraft implantation. In patients with no early endoleak, good component overlap and a stable or shrinking aneurysm sac, a yearly doppler ultrasound (DU) with or without contrast is recommended. A contrast-enhanced ultrasound may reduce need for frequent CT's and may be helpful in doubtful cases. It does not require nephrotoxic contrast administration and is not associated with radiation exposure, but its success depends greatly on the technologist, and it can be complicated by patient factors such as morbid obesity or presence of bowel gas. Any increasing aneurysm diameter or new endoleak, after prior imaging studies have suggested incomplete aneurysm sac exclusion, should prompt complete imaging with CTA. Alternative imaging method is magnetic resonance imaging (MRI). MRI is an expensive imaging modality, and caution must be used with stainless-steel devices.[20,22]

1.5. Altura stentgraft system

Altura (Lombard medical, Ltd., Oxford, UK) is a new low profile (14 French) stengraft system to treat patients with infrarenal aortic aneurysms. In compare with other stentgrafts, Altura has no main body, it contains two bilateral "D"-shaped proximal self-expanding braided stentgrafts with iliac extensions. It has long suprarenal bare springs with active fixation, a nitinol frame and a fabric polyester sleeve. Being able to place the aortic stents from the top down and the iliac portions from the bottom up gives precise landing below the renal arteries and above hypogastric arteries. The two aortic stentgrafts can be longitudinally aligned along the flat surface with an offset of up to 10 mm to accommodate the different anatomic positions of the left and right renal arteries (Figure 2.). There is no need for contralateral gate cannulation, which is needed for aortic stentgrafts with main body, for example, Medtronic Talent®, Cook Zenith® and Gore

Excluder®. The stentgrafts are introduced into the femoral artery over a guidewire. (Figure 2.).[23]

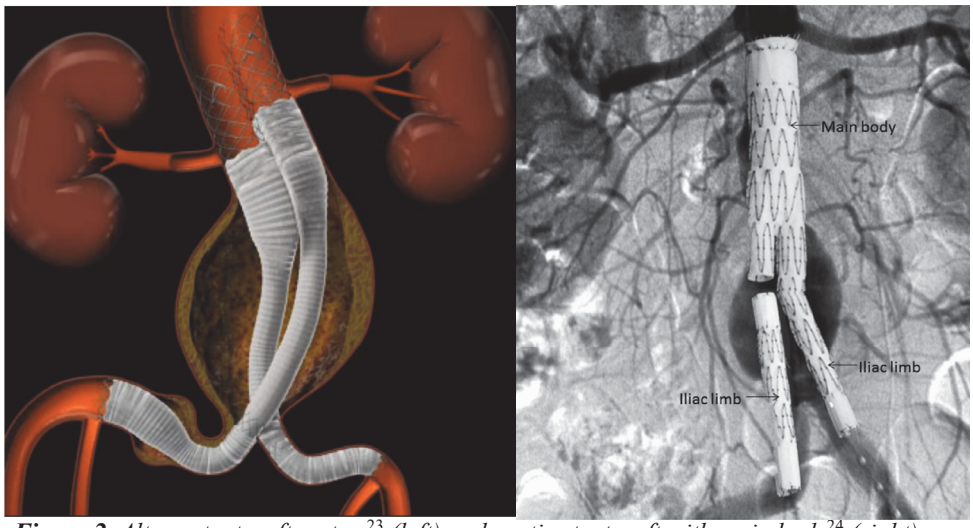

***Figure 2**. Altura stentgraft system[23] (left) and aortic stentgraft with main body[24] (right).*

1.6. Altura and other parallel graft devices

There is only one more commercially available parallel graft device to treat patients with abdominal aortic aneurysms - Nellix device (Endologix, Irvine, California). The Nellix uses polymer-filled endobags surrounding balloon-expandable stents covered with expanded polytetrafluoroethylene and stabilizes the aneurysm sac by completely filling and sealing the blood flow lumen, hence the name EndoVascular Aneurysm Sealing (EVAS) system.[25] Complications, including migration and proximal endoleak formation have been recognized and recently the IFU has been changed to further optimize outcome.[26,27]

1.7. Aim of the study

In this retrospective study were included patients with asymptomatic infrarenal aortic aneurysms, who underwent elective treatment from January 2014

to June 2017 with the Altura stentgraft system in Pauls Stradins Clinical University Hospital (Riga, Latvia) and University Hospital Düsseldorf (Düsseldorf, Germany).

The aims of this study are:

1. To evaluate the durability of AAA treatment with Altura stentgraft, regarding:
    - Freedom from endoleaks,
    - Freedom from secondary procedures,
    - Freedom from aneurysm rupture and aneurysm related death.

2. To evaluate morphological and anatomic changes after EVAR with Altura stentgraft:
    - Changes of aneurysm diameter,
    - Changes in the proximal and distal sealing zone,
    - Length-changes of Altura stentgraft,
    - Stentgraft migration.

2. MATERIALS AND METHODS

2.1. Study design

This is a retrospective computed tomography image analysis of patients with infrarenal abdominal aortic aneurysms treated with the Altura stentgraft system (Lombard, Ltd., UK) at the Pauls Stradins Clinical University Hospital (Riga, Latvia) and at the University Hospital Düsseldorf (Düsseldorf, Germany). The study protocol was approved by the local ethic comittees at each site (Study Nr: 6033R, PSKUS-3218725).

2.2. Study population

The study population included patients with asymptomatic infrarenal abdominal aortic aneurysms who underwent elective treatment from January 2014 to June 2017. Patients who had pre-implant and post-implant computed tomography scans and follow-up contrast CT imaging studies were included in the study.

The inclusion criteria in the study was:

- Patients with asymptomatic infrarenal aortic aneurysms, which were elective treated from January 2014 to June 2017 with Altura stentgraft system,
- The treatment were done in two clinical sites: University Hospital Düsseldorf (Düsseldorf, Germany) or Pauls Stradins Clinical University Hospital (Riga, Latvia),
- Patient age over 18 years.

The exclusion criteria in the study was:

- Patients who mismatch the inclusion criteria,
- Patients with symptomatic or ruptured infrarenal aortic aneurysms,

- Not elective treated patients,
- Mycotic or systemic disorders associated infrarenal abdominal aneurysms,
- Preoperative renal failure, which may influence patient follow-up with CTA.

2.3. Quantitative morphometric analysis

Patients with pre-implant and post-implant CT scans underwent a quantitative morphometric assessment. Measurements were done on using Osirix v.5.8.2 (Pixmeo SARL, Bernex, Switzerland) CT scans were performed using 256-slice scanners with an axial slice thickness of 1 mm.

All analyses were based on multi-planar aortic reconstructions with measurements taken perpendicular to the vessel or stent-graft centerline.

Central lines of D-shaped stentgrafts with iliac extensions were reconstructed to measure a migration. The migration of stentgraft and changes in proximal sealing zone were measured from first slice caudal of lowermost renal artery to stentgraft renal artery radiopaque marker (Figure 3.).

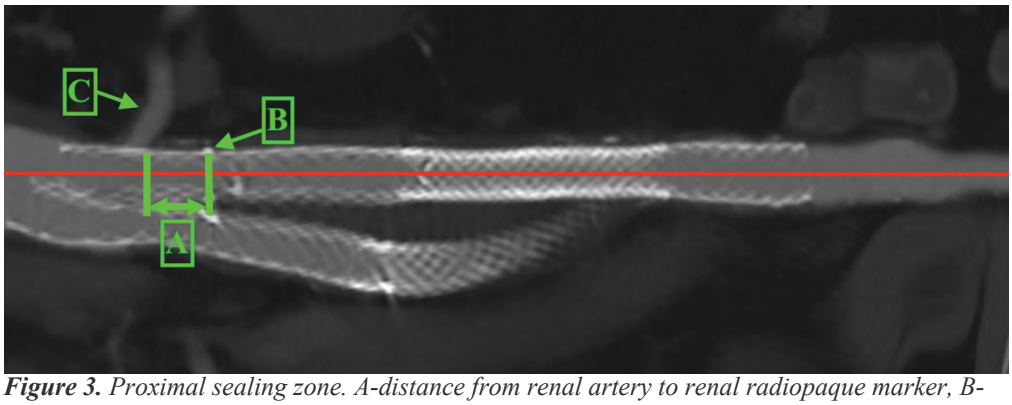

Figure 3. *Proximal sealing zone. A-distance from renal artery to renal radiopaque marker, B-renal artery radiopaque marker, C-renal artery.*

The migration of the stentgraft in iliac arteries and changes in distal sealing zone were measured from external iliac artery to the distal end of the stentgraft (Figure 4.).

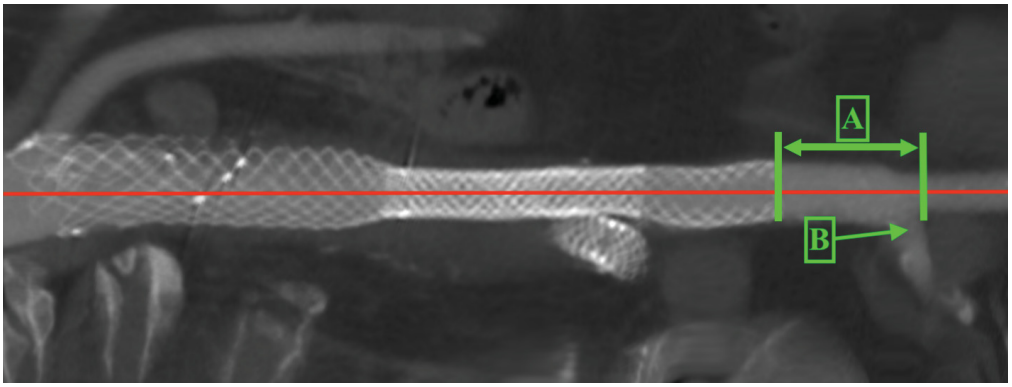

Figure 4. *Distal sealing zone: A-distance from end of the stentgraft to external iliac artery, B - internal iliac artery.*

The total length of the stentgraft, the length of the proximal part of D-shaped stentgraft, aortic stentgraft, overlapping zone, iliac stentgraft and the length of iliac extension distal part were measured. The length of migration was defined as shortening or prolongation in these lengths over the time (Figure 5.).

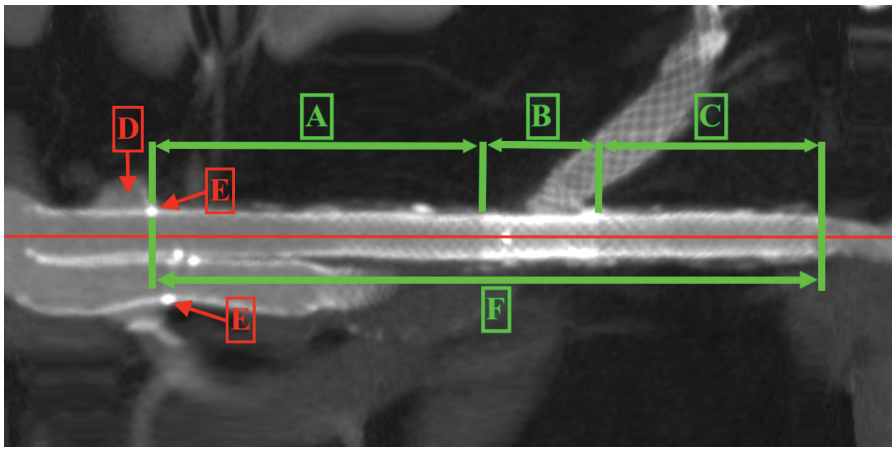

Figure 5. *Altura stentgraft parts and segments: A-proximal part of aortic stentgraft, B-overlapping zone of aortic stentgraft and iliac extension, A and B - aortic stentgraft, C-distal part of iliac extension, B and C - iliac extension, D-renal artery, E-renal artery radiopaque marker F-total length of stentgraft.*

The maximal aneurysm sac diameter was calculated from the cross-sectional area (Figure 6.) using the standard equation.

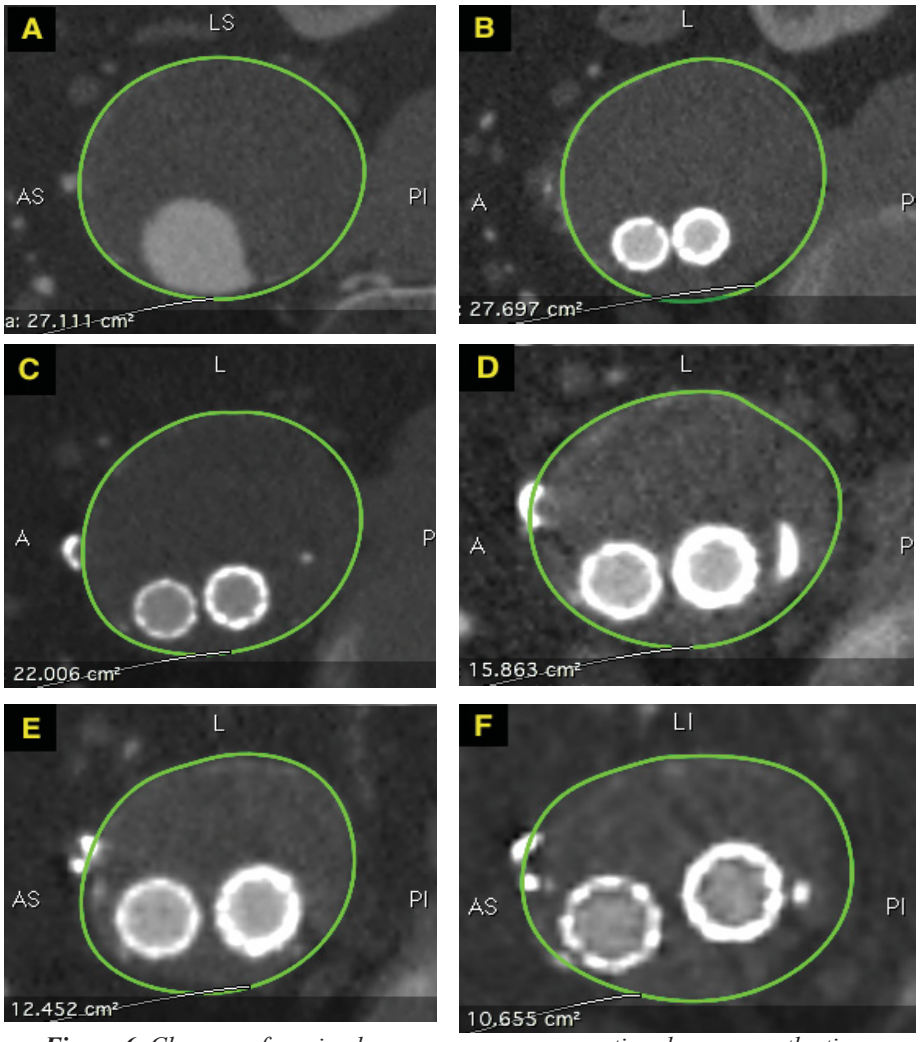

Figure 6. *Changes of maximal aneurysm sac cross sectional area over the time. A-before treatment, B-1st month follow-up, C-6th month follow-up, D-1st year follow-up, E-2nd year follow-up, F-3rd year follow-up.*

All data were entered into an electronic database (Microsoft Excel; Microsoft Corporation, Redding, Washington). Statistical analysis was performed using SPSS 20.0 (SPSS Inc. Chicago, III). Continuous variables are presented as mean±SD, and categorical variables as n(%). Nonparametric data were compared with the Kruskal-Wallis-Test. The Kaplan-Meier survival analysis was used to estimate the freedom from endoleaks and secondary procedures. Statistical significance was assumed at $p<.05$.

3. RESULTS

3.1. Patient population

From January 2014 to June 2017, 40 patients were treated with a mean age of 70±8.5 years (range 47-84) years. Most of the patients were males (34 men, 6 women). All patients were treated at two clinical sites: University Hospital Düsseldorf (Düsseldorf, Germany) and Pauls Stradins Clinical University Hospital (Riga, Latvia).

The mean AAA diameter was 5.6±1.0 cm (range 4.4-8.1 cm). There were no patients with symptomatic or ruptured AAA. 95% of implantations were done percutaneous. The mean operating time was 86±26 minutes (range 34-210 minutes). The mean hospital stay was 3±1.5 days (range 2-8 days). Overview of study population is summarized in Table 3.

Age (mean ± SD)	70.4±8.5 years
Male gender (n,%)	34 (85%)
Maximum AAA diameter (mean ± SD)	5.6±1.0 cm
Smokers (n,%)	10 (25%)
Diabetes mellitus (n,%)	5 (13%)
Concomitant cardiac disease (n,%)	24 (60%)
Dialysis (n,%)	0 (0%)
Previous cerebral infarction/TIA (n,%)	2 (5%)
Arterial hypertension (n,%)	30 (75%)
Known pulmonary disease (n,%)	1 (3%)
length of stay (days)	3±1.5 days
Operation time (minutes)	86±26 minutes

***Table 3**. Patient description. AAA - abdominal aortic aneurysm.*

Follow-up was complete in all patients at 1 month (Table 4.). Image-based follow up was 80% at 1 year (32 patients), 60% at 2 years (24 patients), 20% at 3 years (8 patients). There were no perioperative deaths observed.

	1st month	6th month	1st year	2nd year	3rd year
Patients	40	30	32	24	8
Percentage	100 %	75 %	80 %	60%	20%

***Table 4**. Overview of patient follow-up.*

3.2. Aneurysm sac changes

The first month follow-up was done for 40 patients. Image-based follow up was at 1 year available for 32 patients, at 2 years for 24 patients and at 3 years for 8 patients.

Aneurysm sac shrinkage greater than 10 mm one year after treatment in compare with pretreatment aneurysm diameter was seen in 8 of 32 patients (25%, n=8/32). There was one patient with aneurysm sac growth 5 mm in first year follow-up. This patient had a type II endoleak, which thrombosed spontaneously 6 months after the stentgraft implantation.

After two years the aneurysm sac shrinkage greater than 10 mm was seen in 9 from 24 patients (38%, n=9/24). The maximal aneurysm sac growth was 6 mm and it was seen in 12% of the patients (n=3/24). All of these patients had a type II endoleak, which was diagnosed in first month follow-up. One patient underwent an embolisation after the first month follow-up, two of them were treated with embolisation after second year follow-up.

Three years after Altura implantation aneurysm sac shrinkage greater than 10 mm was achieved in 50% of the patients (n=4/8). One patient from this follow-up group had aneurysm sac growth of 10 mm. This patient had a persistent type II endoleak after unsuccessful embolisation two years after stentgraft implantation.

The mean aneurysm sac shrinkage one year after EVAR in compare with pre-treatment aneurysm diameter was 6±7.4 mm, after two years 7±10.7 mm and after three years 10±14.1 mm (Table 5.). There was statistically significant aneurysm sac shrinkage one year after stentgraft implantation ($p<0.05$).

	1st year	**2nd year**	**3rd year**
Shrinkage in mm	6±7.4 mm *p=.017*	7±10.7 mm *p=.164*	10±14.1 mm *p=.108*
Shrinkage in %	11%	13%	18%
Shrinkage >5 mm	n=15/32 (47%)	n=13/24 (54%)	n=6/8 (75%)
Shrinkage >10 mm	n=8/32 (25%)	n=9/24 (38%)	n=4/8 (50%)
Growth > 5 mm	n=1/32 (3%)	n=3/24 (12%)	n=1/8 (12%)

Table 5*. Aneurysm sac changes in compare with pretreatment aneurysm sac diameter.*

Figure 7. shows aneurysm sac shrinkage of one of the study patient in follow-up period. Before EVAR the maximal aneurysm sac diameter was 6.5 cm, in first month follow-up it was 6.4 cm, one year after implantation it was 4.3 cm, after two years 3.6 cm and three years after EVAR 3.2 cm.

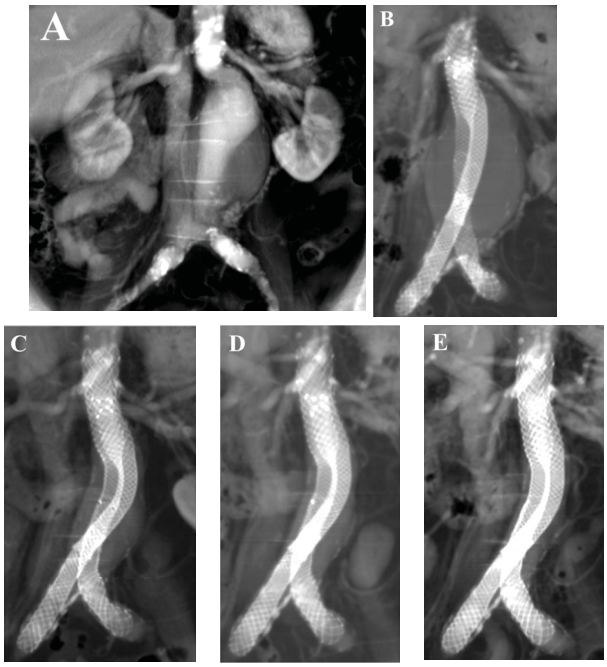

Figure 7. *Aneurysm sac shrinkage in follow-up period. A - before EVAR, B - first month follow-up, C - first year follow-up, D - second year follow-up, E - third year follow-up.*

3.3. Stentgraft migration

In total 174 (40 pre- and 134 postoperative) CT-scans were analyzed. As every patient had two separate parallel stent grafts, each side was evaluated separately and so 268 multi-planar stentgraft reconstructions were done.

The mean changes of the stentgraft length due to the braided stent characteristics in the first year follow-up in compare with first month follow-up was 4±3 mm. After two years of follow-up it was 7±5 mm and after three years 9±6 mm retrospectively (Table 6.).

Stentgraft shortening >10 mm in first year follow up in one or both stentgrafts in compare with first month follow-up were seen in 3% of stentgrafts (n=2/63), after two years 27% of stentgrafts (n=13/48), after three years 50% of stentgrafts (n=8/16).

	Shortening of proximal part (mm)	**Shortening of overlapping zone (mm)**	**Shortening of distal part (mm)**	**Shortening of stentgraft (mm)**
1st year	0,2±2 *p=.201*	1±2 *p=.0001*	3±3 *p=.0001*	4±3 *p=.0001*
2nd year	0,3±3 *p=.201*	2±2 *p=.0001*	4±3 *p=.0001*	7±5 *p=.0001*
3rd year	1,0±4 *p=.201*	3±3 *p=.0001*	4±4 *p=.0001*	9±6 *p=.0001*

Table 6. *Shortening of Stentgraft in compare with first month follow-up.*

The shortening of Altura stentgraft one, two and three years after implantation was statistically significant in compare with first month follow-up ($p<.05$). In Figure 8. is showed stengraft reconstructions of one of the patient with length changes of stentgraft over the study period. For this patient the shortening of stentgraft three years after implantation was 1.6 cm.

There was a statistically significant shortening of distal part of the stentgraft and overlapping zone after one, two and three years in compare with first month follow-up ($p<.05$). In Figure 5. parts and segments of Altura stentgraft are showed. Changes of the proximal part of the stentgraft were not statistically significant.

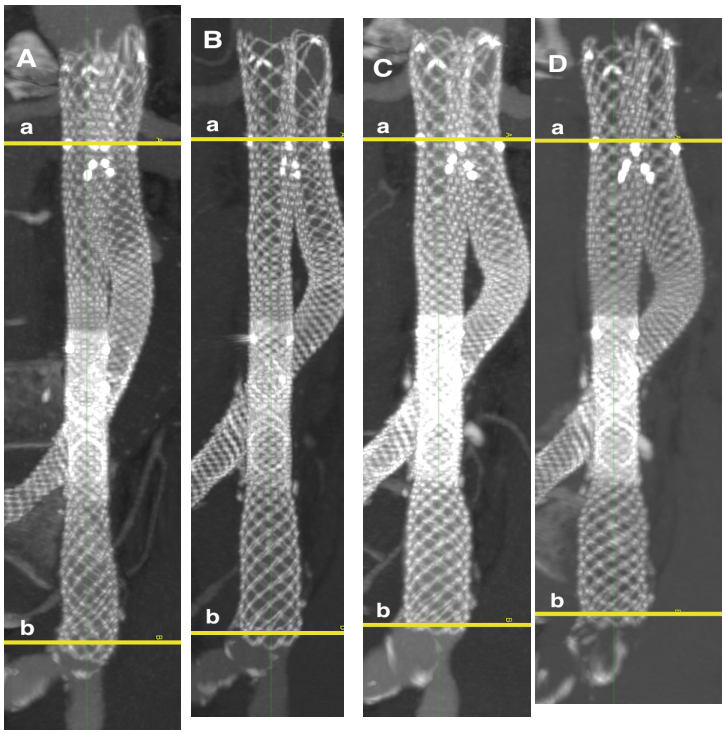

Figure 8. *Shortening of Altura stentgraft. A-1st month follow-up with stentgraft length 17.3 cm, B-1st year - 16.6 cm, C-2nd year - 15.9 cm D-3rd year - 15.7 cm, a- aortic stentgraft renal artery radiopaque marker, b-end of the iliac stentgraft.*

There was a statistically significant shortening of distal part of the stentgraft and overlapping zone after one, two and three years in compare with first month follow-up ($p<.05$). Changes of the proximal part of the stentgraft were not statisticallee significant.

The shortening of the aortic stentgraft in the first year follow-up in compare with first month follow-up was 1±3 mm. After two years it was 2±4 mm and after three years – 4±4 mm. The shortening of iliac extensions in in first year follow-up was 4±3 mm, in second year - 6±4 mm and in third year 8±4 mm (Table 8.).

There was a statistically significant shortening of the "D"-shaped stentgraft and iliac extension over the time in compare with the first month follow-up ($p<.05$).

	Shortening of aortic stentgraft (mm)	Shortening of iliac extension (mm)
1st year	1±3 *p=.0001*	4±3 *p=.0001*
2nd year	2±4 *p=.0001*	6±4 *p=.0001*
3rd year	4±4 *p=.0001*	8±4 *p=.0001*

Table 8. *Shortening of "D"-shaped aortic stentgraft and iliac stentgraft.*

The shortening of the distal sealing zone and stengraft upward migration from the end of the stentgraft to the external iliac artery after one year in compare with first month follow-up was 3±3 mm. In the second year 5±5 mm, in the third year follow-up it was 7±7mm (Table 9.).

The loss of the distal sealing zone and upward migration >10mm after the first year follow-up was seen in 5% of the stentgrafts, after second year in 26%, and after third years in 25% of the stentgrafts. The loss of the distal sealing zone and upward migration was statistically significant over the time in compare with first month follow-up ($p<0.05$).

	1st year	2nd year	3rd year
Stengraft upward migration in iliacs and loss of distal sealing zone (mm)	3±3 *p=.0001*	5±5 *p=.0001*	7±7 *p=.0001*
Stentgraft upward migration in iliacs and loss of distal sealing zone >10 mm	5%, (3/63)	26%, (12/47)	25%, (4/16)
Maximal stentgraft upward migration in iliacs and loss of distal sealing zone (mm)	15	18	25

Table 9*. Loss of distal sealing zone in compare with first month follow-up.*

Most significant stentgraft upward migration in iliacs and loss of distal sealing zone was seen in patients with aneurysmatic common iliac artery (Figure 9.).

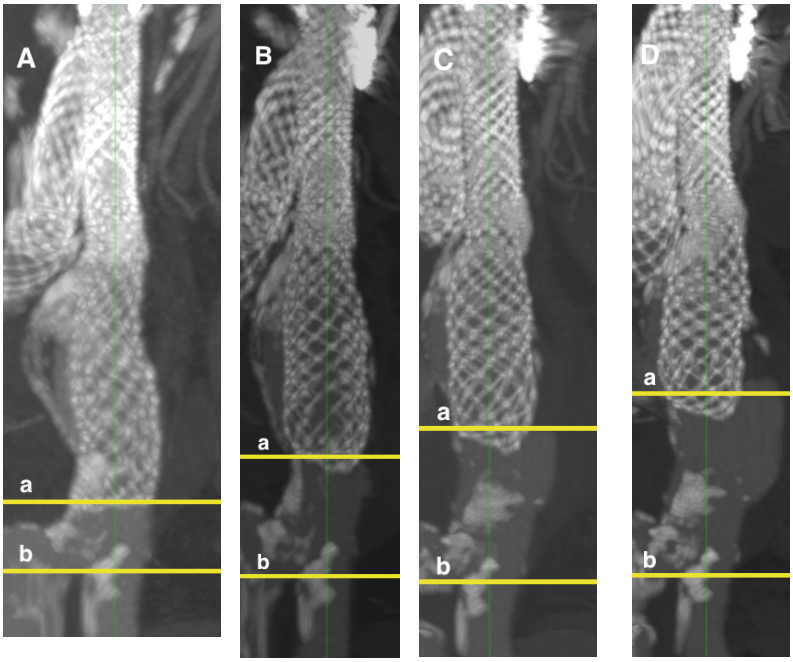

Figure 9. *Stentgraft upward migration in iliacs and loss of distal sealing zone in patient with aneurysmatic common iliac artery. A-1st month follow-up B-1st year with stentgraft upward migration 0.5 cm, C-2nd year - 1.0 cm D-3rd year - 2.5 cm, a- end of the iliac stentgraft, b-external iliac artery.*

The stentgraft downward migration and loss of proximal sealing zone from the lowermost renal artery to the renal artery radiopaque marker after one year in compare with first month follow-up was 1±2 mm. After second year 2±2 mm and after third year it was 3±3 mm. The maximal downward migration was 7 mm in all follow-ups (Table 10.). The stentgraft downward migration in aortic neck and loss of proximal sealing zone was statistically significant over the time in compare with first month follow-up ($p<.05$).

	1st year	**2nd year**	**3rd year**
Stentgraft downward migration and loss of proximal sealing zone (mm)	1±2 *p=.0001*	2±2 *p=.0001*	3±3 *p=.0001*
Maximal stentgraft downward migration and loss of proximal sealing zone (mm)	7	7	6

Table 10. *Stentgraft downward migration and loss of proximal sealing zone in compare with first month follow up.*

In Figure 10. stentgraft downward migration and loss of proximal sealing zone in infrarenal aortic neck of one of the study patients is showed.

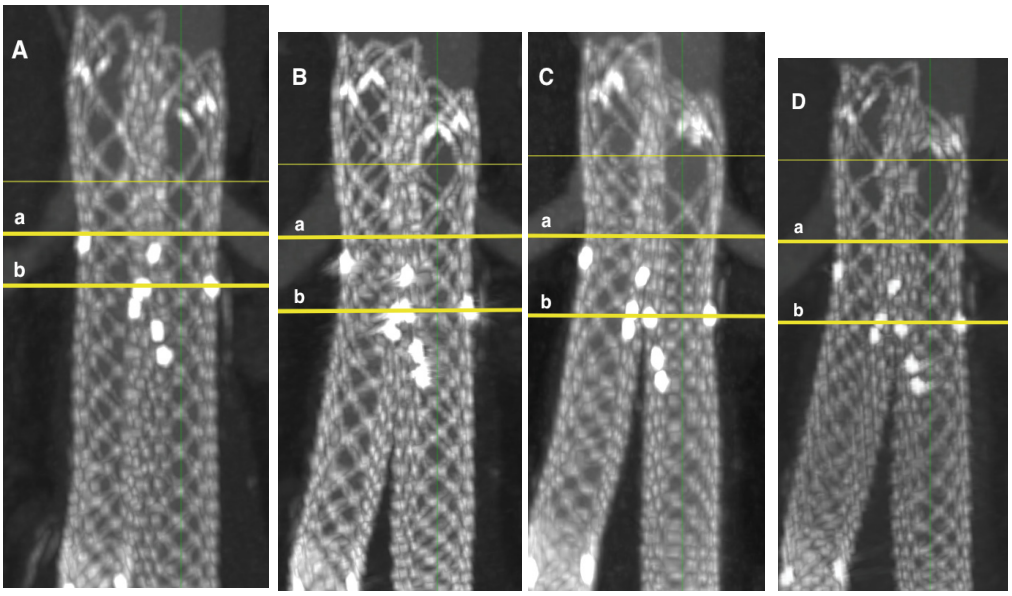

Figure 10. *Stentgraft downward migration in infrarenal aortic neck and loss of proximal sealing zone. A-1st month follow-up B-1st year with stentgraft downward migration 4 mm, C-2nd year - 5 mm D-3rd year - 6 mm, a-lowermost renal artery, b-aortic stentgraft renal artery radiopaque marker.*

3.4. Complications and secondary procedures

During the follow-up period, a total of 10 secondary procedures were performed in 8 patients, resulting in an incidence of any secondary procedure 20%. The causes of re-intervention included type I endoleak type, type II endoleak with aneurysm sac growth or large endoleak cavity, stentgraft stenosis and limb occlusion.

Endoleak (n=6, 60%) was the leading cause for reintervention, followed by stentgraft stenosis (n=3, 30%) and stentgraft thrombosis (n=1, 10%). Secondary procedures were catheter-based in 9 cases (90%) including embolisation (n=6, 67%) and PTA/Stent (n=3, 33%). Open procedure included conventional aortic graft replacement.

Endoleak. We had one patient with a type Ia endoleak, who was treated with coil and glue embolisation after first month follow-up. Seven patients had type II endoleak. All of them were diagnosed in first month follow-up. Five

patients with type II endoleak underwent glue embolisation with or without coil embolization. In one patient the endoleak resolved spontaneously six months after stentgraft implantation. One patient, who underwent embolisation, showed persistent type II endoleak during the follow-up with aneurysm sac growth of 10 mm after 3 years. Summary of endoleaks by period is showed in Table 11.

	1 month *(n=40), No. (%)*	**1 year** *(n=32) No. (%)*	**2 years** *(n=24),No. (%)*	**3 years** *(n=8)No. (%)*
Any endoleak	8 (20.0)	5 (15.6)	5 (20.8)	1 (12.5)
Type I	1 (2,5)	0 (0.0)	0 (0.0)	0 (0.0)
Type II	7 (17.5)	5 (15.6)	5 (20.8)	1 (12.5)
Type III	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
No endoleak	32 (80.0)	27 (84.4)	19 (79.2)	7 (87.5)

Table 11. *Summary of endoleaks by period.*

Clinical success (freedom from Type I/III endoleaks, graft thrombosis or conversion) was 97.5% at 30 days (n=1/40) and 100% after first and second year of follow-up. Freedom from type I and type III endoleaks one, two and three years after stentgraft implantation was 99.2% (Figure 9.).

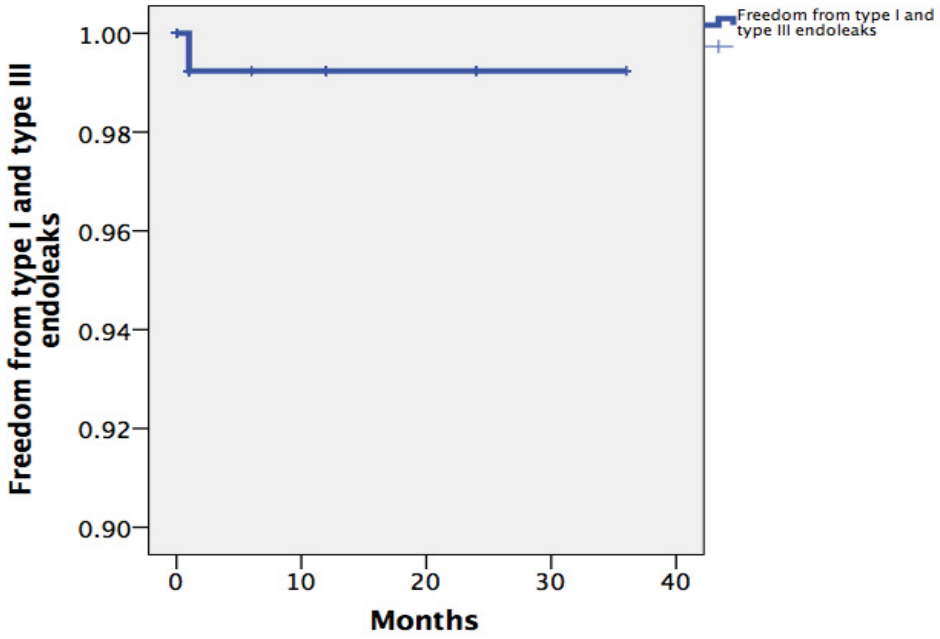

Figure 9. *Freedom from type I and type III endoleaks.*

Freedom from all endoleaks one, two and three years after EVAR with Altura stentgraft was 92.6% (Figure 10).

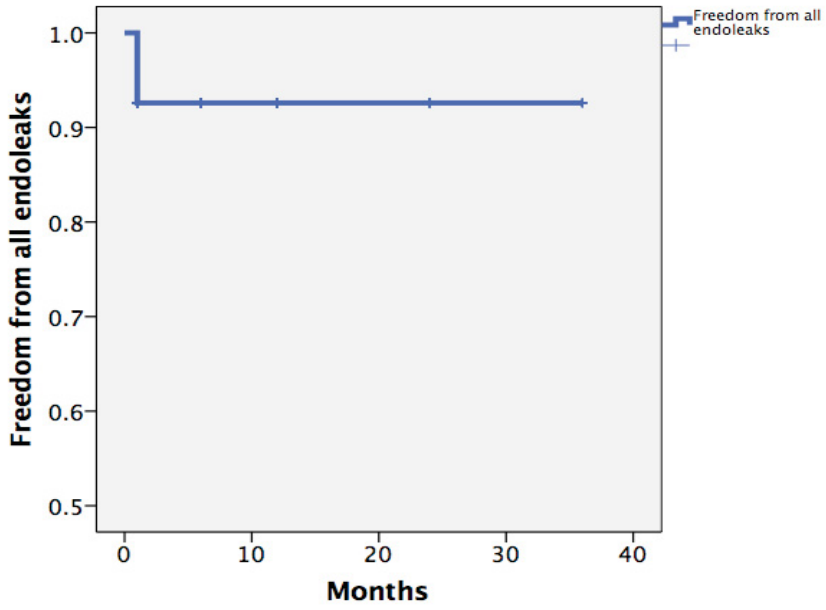

Figure 10. *Freedom from all endoleaks.*

Stentgraft stenosis. There were three patients with stenosis in the stentgraft at first month follow-up. Two patients were treated with PTA and one patient underwent PTA and stent implantation. One of the patients with iliac stent stenosis had on the same side a stentgraft thrombosis at third year follow-up. This patient underwent stentgraft explantation and open conversion. Complications and secondary procedures are summarized in Table 12.

Complication	Patients and overall incidence of complications	Secondary procedure	Overall incidence of secondary procedures
Type Ia endoleak	1 patient (2.5 %)	Coil and glue embolization	2.5%
Type II endoleak	7 patients (17.5 %)	5 embolisations, 1 resolved spontaneously during follow-up, 1 patient was treated conservatively	12,5%
Stentgraft stenosis	3 patients (7.5 %)	2 PTA (1 explantation due to limb occlusion), 1 PTA + Stent,	7,5%
Stentgraft thrombosis	1 Patient (2.5%)	Conversion, stentgraft explantation	2.5%

Table 12*. Complications and secondary procedures after EVAR.*

Freedom from secondary procedures after EVAR with the Altura stentgraft system one and two years after implantation was 91.1%, after three years - 56.9% (Figure 11.).

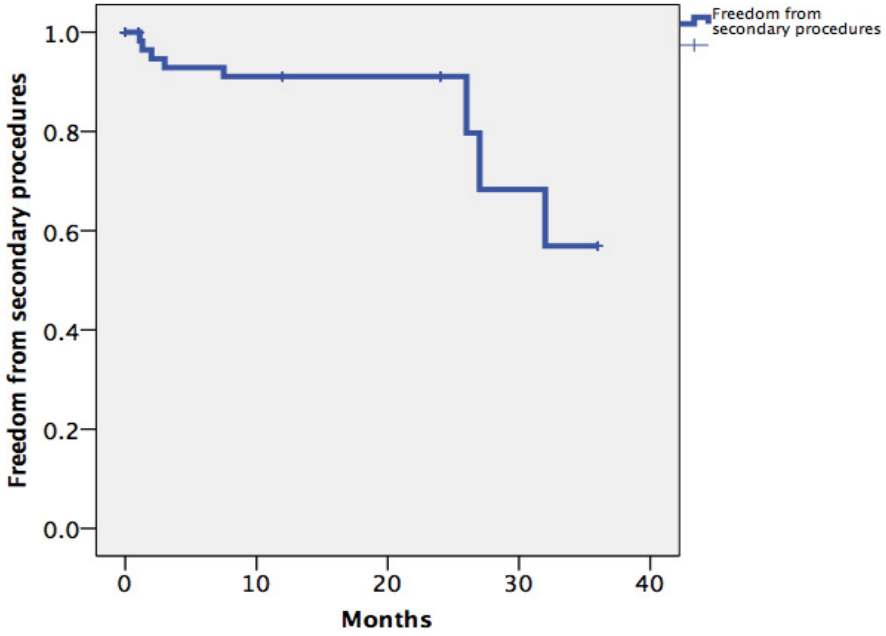

Figure 11. *Freedom from secondary procedures.*

During the study period there were no aneurysm related deaths or aneurysm ruptures.

4. DISCUSSION

4.1. Altura stentgraft system

At the beginning of our study there were no published clinical data about durability of the Altura stentgraft system. Altura is a new low profile stengraft system, which contains two D-shaped proximal self-expanding braided stentgrafts with iliac extensions. It has long suprarenal bare springs with active fixation, a nitinol frame and a fabric polyester sleeve.[23]

In this study 40 patients after EVAR with the Altura stentgraft system were analysed. The maximal follow-up period was up to three years after the device implantation.

The first-in-human studies and the ELEVATE registry included 103 patients treated with Altura stentgraft with maximal follow-up period 4 years. The technical implant success rate was 99%. One year after index procedure 1% of patients had type I endoleak. [23]

4.2. Aneurysm sac changes

Aneurysm sac shrinkage after EVAR with Altura stentgraft system was statistically significant in compare with first month follow-up. Patients with endoleak showed stable aneurysm sac diameter or growth of it.

In the ENGAGE registry 1262 patients were included, which were treated with the Endurant stentgraft. One year after stentgraft implantation 2.8% of patients had aneurysm sac enlargement more than 5 mm, in our study it was observed in 3% of patients: 55.9% of patients the aneurysm size was stable and 41.3% of patients had aneurysm sac shrinkage more than 5 mm. After EVAR with Altura the aneurysm shrinkage greater than 5 mm was observed in 47% of patients.[28]

In the Italian Excluder registry 872 patients were treated with Gore Excluder stentgraft. One year after stentgraft implantation, the aneurysm sac was stable or decreased in 94.8% of patients, whereas growth of aneurysm sac was observed in 5.2%.[29]

In a study from *Verzini et al* 610 patients underwent elective EVAR using the Zenith stentgraft (Cook Inc, Bloomington, Ind) with maximal follow-up 14 years. Aneurysm sac growth more than 5 mm occurred in 6.7% of patients. In our study aneurysm sac growth more than 5 mm one year after stentgraft implantation was 3% of patients, after two and three years -12%.[30]

Aneurysm sac shrinkage one year after Altura implantation was observed in 25% of patients. In cohort from *Bastos Goncalves et al* the aneurysm sac shrinkage more than 10 mm one year after EVAR with other devices was seen in 28.6% of patients. He conclude, that early change in aneurysm sac diameter is a strong predictor of late complications after EVAR and patients with major sac shrinkage have a very low risk of complications for up to 5 years.[31] Our data showed similar shrinkage rate in compare with other stentgrafts.

These results may have important implications for individualization of postoperative surveillance. For patients with aneurysm sac shrinkage and no endoleak or other technical failures, a yearly doppler ultrasound may be sufficient and recommended. The CT-scan with intravenous contrast is a gold standard for observation after EVAR and still need to be done for patients with an endoleak or aneurysm sac growth. This strategy would be more cost-effective and would simplify the follow-up after EVAR.

4.3. Stentgraft length changes and migration

To evaluate stentgraft changes and migration, length changes of different parts of stentgraft and length changes in proximal and distal sealing zones were measured. Our data showed statistically significant shortening of whole stentgraft in different parts of it. Significant shortening of Endurant stentgraft main body,

with mean shortening of 22±4 mm, and native aorta have been described in patients with severe aortoiliac tortuosity.[32]

The stentgraft upward migration in iliacs one year after EVAR have been described with other stentgrafts: Zenith endovascular graft and Gore Excluder. The mean length of shortening with consequent migration was 1.2±1.7 mm. There was a significant difference in the length of the landing zone between the migration more than 3 mm and the migration less than 3 mm with both stentgrafts. The migration more than 3mm was seen in 7.4% of stentgrafts with distal landing zone more than 15 mm and 16.7% with distal sealing zone less than 15 mm.[33] All patients in our study were treated within IFU and the distal landing zone was over 20 mm. The stentgraft upward migration in iliacs one year after EVAR was 3±3 mm, after three years it was 7±7 mm. Too short distal landing zone can provoke formation of type Ib endoleak. Considering the significant stentgraft upward migration, loss of distal sealing zone and shortening of the Altura stentgraft system, it would be advisable to treat patients within IFU (distal sealing zone 20 mm or even more) to avoid type Ib endoleak formation. The advantage of the Altura stentgraft system is that the iliac stentgraft is deployed from distal to proximal, which allows exceptionally accurate iliac placement.

The downward migration in aortic neck and loss of proximal sealing zone with Altura stentgraft system was statistically significant in compare with first month follow-up, but not clinically relevant. However, the migration was relatively small, which may be explained with active suprarenal fixation mechanisms and bare stent good incorporation into aortic wall within time. We had one patient with type I endoleak, which was seen intraoperatively and embolised one month after stentgraft implantation. There were no late type Ia endoleaks observed during the study follow-up period.

Older generation stentgrafts with no active suprarenal fixation like Talent or AneuRx are in higher risk for stentgraft migration and formation of type Ia endoleak.[18] One year after Endurant stentgraft implantation there was no stentgraft migration (>5mm) observed.[28] Stentgraft migration after EVAR with Zenith stentgraft occurred in seven patients (n=7/610, 1.1%), only two of them the

migration was more than 10 mm and required secondary intervention with proximal stentgraft extension.[30] After EVAR with Gore Excluder 0.5% of patients (n=4/872) underwent secondary intervention due to stentgraft migration.[29] In multicenter IRENE study 335 patients from 2013 to 2015 were treated with Nellix device. The stentgraft caudal migration with secondary intervention were in 0.6% of patients observed.[34] The stentgraft migration 5-10 mm after introduction of new IFU criteria in 2016 was 8.3% of patients in compare with 14.9% of patients, which were treated within the IFU of 2013.[35]

In three year follow-up period after Altura implantation significant stengraft shortening and migration were observed, but there were no new type Ia, Ib, and III endoleaks.

4.4. Complications and secondary procedures

The overall incidence of type Ia endoleak in our study was 2.5% (one patient). The incidence of type I endoleaks after EVAR with other devices been observed up to 4.4%, after EVAS with Nellix device in a multicenter study with 1851 patients up to 3% in short term with increased numbers in longer follow-up period.[27,36] The incidence of type I endoleak 30 days after index procedure with Endurant and Gore Excluder stentgarfts was 1.4% and 1.6%.[28,29]

The overall incidence of type II endoleak after EVAR with Altura was 17.5% (7 patients). There was no late type II endoleaks during the study follow-up period. This is in accordance with observations in other EVAR studies. The incidence of type II endoleaks after EVAR using other devices been observed in up to 20-22%.[36,37] After EVAS the incidence was only 4%, because the stentgrafts has a endobags which are filled with polymer in aneurysm sac, thus protecting from type II endoleak formation.[25] After EVAR with Endurant and Gore Excluder stentgrafts the incidence of type II endoleak 30 days after implantation was 9.9% and 7.8% of patients.[28,29]

In the study from *Pineda et al* were observed 462 patients after EVAR in a

17-year period. 75% of patients with early type II endoleak had resolution of the endoleak without treatment compared with only 29% in the late group. Patients with late type II endoleak (develop 1 year after EVAR or later) required more frequent interventions due to enlargement of aneurysm sac.[38] In our study there were no late type II endoleaks observed.

We had three patients (7.5%) with stentgraft stenosis, who underwent PTA with or without stent implantation. All these stenoses were seen at the first month follow-up. Stentgraft stenosis 30 days after EVAR with Nellix device and Endurant stentgraft was observed in 3% and 1.4% of patients (in 0.6% cases with Endurant stentgraft was endovascular intervention for graft occlusion, stenosis or kinking required).[28,25] The incidence of secondary intervention due to stentgraft stenosis after EVAR with Gore Excluder was in 0.5% of patients observed.[29] In our study there is comparatively high incidence of stengtarft stenosis in compare with other devices. Most of the stenosis were located in proximal stentgraft overlapping zone. To avoid formation of stentgrat stenosis between aortic stentgrafts and iliac extensions more aggressive dilation of stentgrafts during implantation is needed.

Endovascular stentgrafts are at a higher risk for limb occlusion than bifurcated surgical grafts, as observed in the EVAR 1 trial.[2] Stentgraft stenosis can be provoked by a calcified narrow aortic bifurcation or by tortuous, angulated and diseased iliac arteries. The incidence of limb occlusion after EVAR is approximately 4%, with the majority of occlusions presenting within 2 months and nearly all within the first year after EVAR.[2] In our study the incidence of limb occlusion was 2.5% (one patient) and it was observed in third year follow-up; a stentgraft explantation was needed. This patient had a stentgraft stenosis at the time of implantation. After Nellix, Gore Excluder and Endurant stentgraft implantation the incidence of limb occlusion was 5.0%, 1.1% and 2.0%[25,28,29]

In our study from 40 patients in a three-year period 8 of them had a secondary procedure due to endoleaks, stentgraft stenosis or limb occlusion with overall incidence of 20%. The review from *de la Motte et al* included twenty-three studies with 83307 patients after EVAR, where re-intervention rates after EVAR

were analysed. Secondary procedures for type I endoleaks were reported in 0.6%-13% and type III endoleaks in 0.9-2.1% with a significant improvement for newer devices. Migration rates varied between 0-4%. Type II endoleak was the most common indication for reintervention ranging from 14-25.3% although the majority resolved without intervention. Rupture rates ranged from 0-5.4% and carried a high mortality (60-67%).[39] There were no aneurysm ruptures or aneurysm related deaths during our study period. Freedom from all endoleaks in three-year follow-up period was 92.6%. Estimated freedom from endoleaks with Gore Excluder was 82.5% at 1 year and 75.8% at 3 years.[29] Freedom from secondary procedures one and two years after Altura implantation was 91.1%, after three years - 56.9%. Freedom from reintervention with Gore Excluder at 1 and 3 years of follow-up were 98.6% and 94.6%. After EVAR with Endurant stentgraft freedom from reinterventions at 1 year was 95.1%.[28,29] The incidence of endoleaks and secondary procedures after EVAR with Altura stentgraft system is similar with other devices.

4.5. Limitations

The main limitation of this study is a relatively small study population. In the study only 40 patients from two clinical sites were included. Three-year follow-up data are only available for 20% of the patients. Longer follow-up with more patients is needed to evaluate changes of Altura stentgraft system and clinical results.

5. CONCLUSION

Midterm results after EVAR with Altura stentgraft system showed significant morphological changes of stentgraft, aneurysm sac diameter and sealing zones, but with no clinical relevance after three years. The incidence of endoleaks and secondary procedures are acceptable, but studies with longer follow-up are needed to evaluate a durability of the Altura stentgraft system.

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