The effect of injectable biocompatible elastomer (PDMS) on the strength of the proximal fixation of endovascular aneurysm repair grafts: An in vitro study

Willem-Maarten P.F. Bosman, MD,[a] Tim J. van der Steenhoven, MD,[a,b] Daniel R. Suárez, MSc,[c,d] Edward R. Valstar, MSc, PhD,[c,e] Alexander C. de Vries, MD, PhD,[f] Hans L.F. Brom, MD, PhD,[g] Michael J. Jacobs, MD, PhD,[h] and **Jaap F. Hamming, MD, PhD,[a]** *Leiden, Tilburg, Delft, The Hague, Haarlem, and Maastricht, The Netherlands*

Purpose: **One of the major concerns in the long-term success of endovascular aneurysm repair (EVAR) is stent graft migration, which can cause type I endoleak and even aneurysm rupture. Fixation depends on the mechanical forces between the graft and both the aortic neck and the blood flow. Therefore, there are anatomical restrictions for EVAR, such as short and angulated necks. To improve the fixation of EVAR grafts, elastomer (PDMS) can be injected in the aneurysm sac. The support given by the elastomer might prevent dislocation and migration of the graft. The aim of this study was to measure the influence of an injectable biocompatible elastomer on the fixation strength of different EVAR grafts in an in vitro model.**

Methods: **The proximal part of three different stent grafts was inserted in a bovine artery with an attached latex aneurysm. The graft was connected to a tensile testing machine, applying force to the proximal fixation, while the artery with the aneurysm was fixated to the setup. The force to obtain graft dislodgement (DF) from the aorta was recorded in Newtons (N). Three different proximal seal lengths (5, 10, and 15 mm) were evaluated. The experiments were repeated after the space between the graft and the latex aneurysm was filled with the elastomer. Independent sample *t*tests were used for the comparison between the DF before and after elastomer treatment for each seal length.**

Results: **The mean DF (mean ± SD) of all grafts without elastomer sac filling for a proximal seal length of 5, 10, and 15 mm were respectively, 4.4 ± 3.1 N, 12.2 ± 10.6 N, and 15.1 ± 6.9 N. After elastomer sac filling, the dislodgement forces increased significantly ($P < .001$) to 20.9 ± 3.8 N, 31.8 ± 9.8 N, and 36.0 ± 14.1 N, respectively.**

Conclusions: **The present study shows that aneurysm sac filling may have a role as an adjuvant procedure to the present EVAR technique. The strength of the proximal fixation of three different stent grafts increases significantly in this in vitro setting. Further in vivo research must be done to see if this could facilitate the treatment of aneurysms with short infrarenal necks. (J Vasc Surg 2010;52:152-8.)**

Clinical Relevance: **Stent graft migration and endoleak due to suboptimal fixation are major drawbacks of currently available stent grafts. Optimizing the proximal fixation by peri-graft elastomer aneurysm sac filling may lead to lower incidence of graft migration and endoleak. It might make endovascular aneurysm repair available to larger group of patients with an abdominal aortic aneurysm.**

A major complication affecting the long-term success of endovascular aneurysm repair (EVAR) is stent graft migration, which can cause type I endoleak and even aneurysm rupture.[1-8] Fixation is dependent on the mechanical forces between the graft and the aortic neck, as well as the blood flow.[9] Therefore, EVAR has anatomical restrictions. Despite the manufacturers instructions for use, EVAR grafts are inserted in necks shorter than 15 mm, and sometimes significant angulation is accepted.[10,11] Zarins et al showed, in a prospective multicenter trial, that insufficient length of proximal seal will lead to stent migration.[8] Earlier studies have shown that, in up to 45% of abdominal aortic aneurysms (AAA), the anatomy of the proximal neck makes the AAA unsuitable for EVAR because of insufficient length, large diameter, or severe angulation.[12-14]

To overcome the disadvantages of current EVAR therapies, Aortic Customize was devised: a method of excluding the aortic aneurysm using endovascular techniques to inject a biocompatible elastomer into the aneurysm sac (Fig 1).[15] Filling the aneurysm sac with an injectable biocompatible elastomer reduces the wall stress and thereby the

From the Department of Surgery, Leiden University Medical Center,[a] the Department of Surgery, St. Elisabeth Hospital,[b] the Biomechanics and Imaging Group, Department of Orthopaedics, Leiden University Medical Center,[c] the Department of Precision and Microsystems Engineering,[d] Faculty of Mechanical, Maritime, and Material Engineering, Delft University of Technology,[e] the Department of Surgery, Medisch Centrum Haaglanden,[f] the Department of Surgery, Kennemer Gasthuis,[g] and the Department of Surgery, Maastricht University Medical Center.[h]

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Competition of interest: Drs de Vries, Brom, and Jacobs have developed and patented the elastomer used in the experiment. The other authors have no financial or other competing interests in the experiments.

Reprint requests: W.M.P.F. Bosman, MD, Department of Surgery, K6-R, Leiden University Medical Center, Postbox 9600, 2300 RC Leiden, The Netherlands (e-mail: W.M.P.F.Bosman@lumc.nl).

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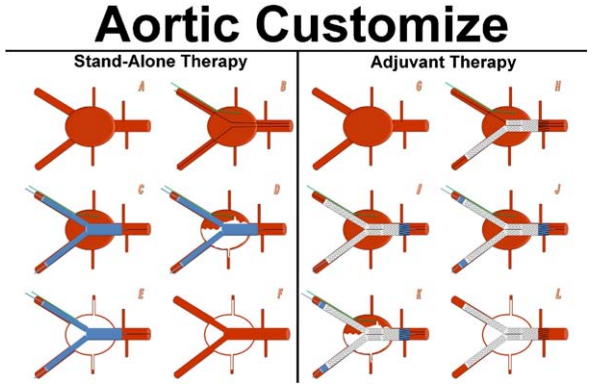

Fig. 1. Aortic Customize, the treatment concept. Left side depicts the stand-alone therapy (**A**-**F**), while the right side depicts the therapy as adjuvance to current EVAR-therapy (**G**-**L**). Guide wires are inserted to the aneurysm (**B**), over which endovascular balloons are inserted to exclude the aneurysm sac from the circulation (**C**). A fill catheter was inserted next to the balloon, through which the liquid elastomer is injected (**D**). The elastomer fills every cavity in the aneurysm sac and obliterates lumbar arteries, thereby preventing potential endoleaks (**E**). When the elastomer has cured (<5 minutes), the endovascular balloon is deflated, leaving the aneurysm excluded with a new lumen (**F**). As adjuvant therapy (**G**-**I**), the process is very similar, whereby the cavities between the graft in an aneurysm sac are filled with the elastomer (**J, K**), fixating the graft in an elastomer mould of the sac.

rupture risk,[15] since aneurysm rupture occurs when the local wall stress exceeds the local wall strength.[16,17]

This treatment concept can function as a standalone treatment, but might also play a role as an adjuvant procedure to the current EVAR treatment (Fig 1). The elastomer can be injected next to the inserted EVAR graft and will cure around the graft, taking on its form. The support of the elastomer could prevent dislocation and migration of the graft. With this technology, aortic aneurysms with less favorable proximal neck anatomy could be made suitable for EVAR.

Our hypothesis is that filling the spaces between the graft and the aneurysm sac will increase the proximal fixation as it increases the supporting areas of the graft. The aim of this study is to measure the influence of aneurysm sac filling with an injectable biocompatible elastomer on the strength of the proximal fixation and the necessary aneurysm neck length in an in vitro model.

MATERIALS AND METHODS

Setup. Fresh bovine aortas were obtained from an abattoir. The abdominal portion of the aorta was retained and all non-vascular tissue was removed. Three to four samples with a length of 45 mm were selected from each aorta with a mean diameter of 19.5 mm (±1.0 mm). The samples of bovine artery were fixated in an experimental setup (Fig 2). The distal part of the artery was stitched with 4.0 prolene stitches (Ethicon, Somerville, Mass) to a latex sphere, resembling an AAA. Side branches of the aorta were ligated with the same 4.0 prolene stitches.

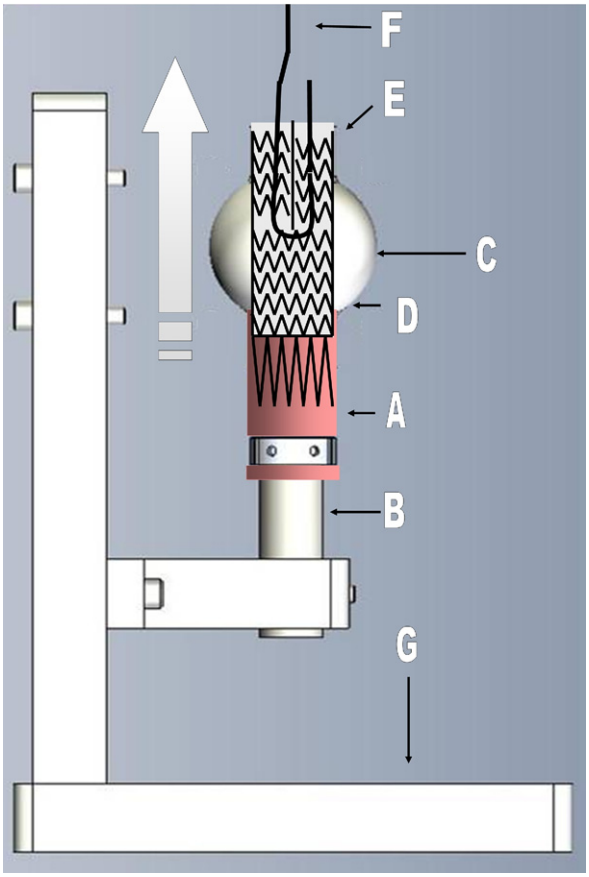

Fig. 2. Schematic drawing of experimental set-up: (**A**) Sample of bovine artery (45 mm long). (**B**) Distal fixation plug on which the bovine artery is attached. (**C**) Artificial aneurysm made of latex (neck 19 mm; widest part 40 mm), which is sutured to the bovine artery (**D**) A stent-graft inserted in the bovine neck of the aneurysm. (**E**) Rigid rod with anchor through the endograft, connecting it to the tensile testing machine. (**F**) Plugs for fixation of the set-up on tensile testing machine.

Stent grafts. Three types of commercial endografts of different manufacturers were used and compared in this experimental study (Fig 3): An Excluder AAA Endoprothesis (WL Gore and Associates, Inc, Flagstaff, Ariz), an Anaconda AAA Endovascular Graft (Vascutek, Inchinnan, Scotland), and an Endurant AAA Stent Graft (Medtronic, Minneapolis, Minn). The diameter of all grafts was 23 mm.

Method of excluding the aneurysm. The proximal part of the stent graft was inserted in the bovine artery and fixated by inflating a Reliant endovascular balloon (Medtronic) with a diameter of 30 mm. Using 23 mm stents in arteries of 19.5 mm, a mean 13% oversizing was applied. The neck length was measured from the start of the aortic segment to the lowest covered part of the proximal site of the stent graft. With the Endurant, this meant that the suprarenal fixation stent was inserted further down in the aortic neck.

Measurements. After insertion in the artery, a rigid hook was used to connect the graft to a tensile testing

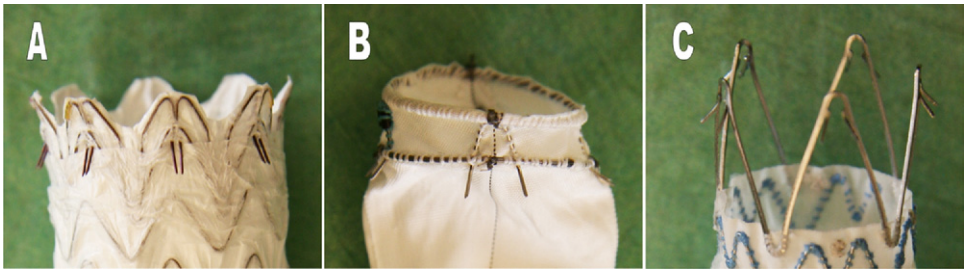

Fig. 3. The endoprotheses used in this study: (**A**) Gore Excluder, (**B**) Vascutek Anaconda, and (**C**) Medtronic Endurant.

machine (Lloyd's LR5K; Ametek, Paoli, Pa). Uniaxial traction was applied to the stent graft and quantified using a ZFA 250N load cell (Scaime, Annemasse, France). The retrieved data was digitized and stored using a voltmeter (Voltcraft, Oldenzaal, The Netherlands) and a personal computer. Traction was gradually increased, as the traction bar moved upward at a speed of 1 mm/s. The dislodgement force (DF) was the force needed to dislodge the stent graft from the aorta. The DF was noted on visual inspection and was confirmed by analysis of the force/displacement graph. The DF of each graft was measured at different lengths of proximal seal: 5, 10, and 15 mm. The test was repeated five times for each type graft at each length of proximal seal. The Anaconda was only tested for the 10 and 15 mm proximal seal, as its fixation rings and hooks take more than 5 mm of the proximal side of the graft when positioned in the aorta. The same stent and same sample of artery were used, only if there was no extensive damage or deformation on visual inspection. The intimal layer was considered damaged if there was macroscopic disruption of the tissue. At least two segments were used per graft to prevent differences in measurements due to different aorta characteristics.

Sac-filling. After the measurements of the DF of the grafts for each length of proximal seal, the experiments were repeated after the aneurysm was filled with the biocompatible elastomer. We used a low viscous elastomer, polydimethylsiloxane (PDMS; ViaZym BV, Delft, The Netherlands).[18] PDMS is a silicone rubber composed of two components. It is widely used in vivo because of its physiological inert properties.[19-21] PDMS cures without exothermic heat; there is no release or formation of by products as it hardens (curing and cross linking) in a watery environment at 37° C.

The aneurysm was filled through the space between the AAA sac and the legs of the graft, directly after graft insertion with the endovascular balloon still in place. The elastomer needed 5 minutes to cure, after which the balloon was deflated and the graft was attached to the tensile testing machine.

After the experiments, the arteries and the latex aneurysms were dissected to see if the entire peri-graft area in the aneurysm sac was filled with elastomer.

Statistics. Independent sample *t* tests were used for the comparison of the DF before and after elastomer filling with all grafts at each seal length (SPSS 16.0; SPSS Inc, Chicago, Ill). This was also done for each separate type of graft.

RESULTS

For a proximal seal length of 5, 10, and 15 mm, the mean dislodgement forces of all grafts combined, without elastomer sac filling, were 4.4 ± 3.1 N, 12.2 ± 10.6 N, and 15.1 ± 6.9 N (Fig 4 and Table). After elastomer sac filling, the DF increased significantly ($P < .001$) to 20.9 ± 3.8 N, 31.8 ± 9.8 N, and 36.0 ± 14.1 N, respectively. The fixation strength improved with, respectively, 376%, 161%, and 139% (Table). There was no clear trend in difference (increase or decrease) between the first and the following measurements. There were no signs of weakening of the grafts or the arteries.

The dislodgement forces per graft (Excluder, Anaconda, and Endurant) at each proximal seal length are shown in Fig 4 and the Table.

An identical elastomer cast of the aneurysm sac was created with all grafts (Fig 5).

DISCUSSION

The long-term success of EVAR depends on secure stent graft fixation. Complications such as stent graft migration, endoleaks, and graft kinks have been reported by many investigators.[8-10,22-33] Earlier research has shown the importance of proximal neck length on forces needed for dislocation.[28] The present study demonstrates clearly that the proximal fixation of an endovascular graft can be enhanced by filling the aneurysm sac with a biocompatible elastomer. There was a clear increase in DF, independently of the graft used (Fig 4 and Table). The increment of DF ranged from 76% to 1015%.

The DFs of the grafts alone, without elastomer aneurysm sac filling, have been published earlier.[34] The recorded forces of the grafts alone compare well to other in vitro studies with comparable setups.[9,27-32,34]

Previous in vitro experiments have shown that injecting the AAA sac with elastomer is a new potential treatment of abdominal aneurysms.[15] This experiment has been set up to see if there is also a role for this sac filling technology as an adjuvant procedure to the present EVAR technology. The presented results show that aneurysm sac filling has a positive effect on the strength of the proximal fixation of an

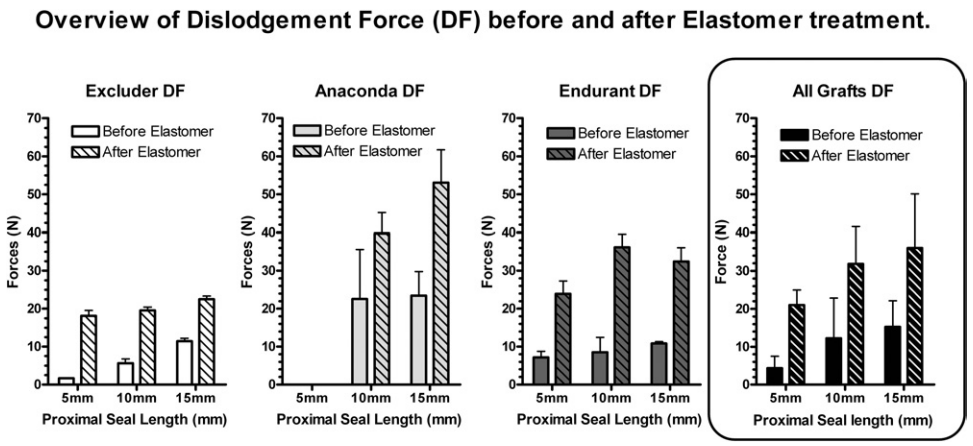

Fig. 4. The dislodgement forces (DF) for the different kinds of stent grafts. The bars show mean dislodgement force (n = 5) for the seal length, while the error bars depict the standard deviation (SD). The empty bars show the force needed to dislodge the graft when the aneurysm sac was empty; the striped bars show the forces needed after filling the sac with elastomer. The graph at the right shows that all grafts benefit from the elastomer augmentation.

Table. Dislodgement force before and after elastomer injection

		DF (Graft only)		*DF (Elastomer)*			
Graft	*Proximal seal*	*Mean*	*SD*	*Mean*	*SD*	P	*% Gain*
All grafts	5 mm	4.39	3.10	20.89	3.82	<.001	376
	10 mm	12.16	10.59	31.77	9.75	<.001	161
	15 mm	15.08	6.99	35.98	14.10	<.001	139
Excluder	5 mm	1.62	0.03	18.08	1.44	<.001	1015
	10 mm	5.58	1.02	19.51	0.86	<.001	250
	15 mm	11.40	0.79	22.45	0.78	<.001	97
Anaconda	10 mm	22.50	13.07	39.71	5.50	.039	76
	15 mm	23.38	6.35	53.05	8.58	<.001	127
Endurant	5 mm	7.15	1.60	23.69	3.34	<.001	231
	10 mm	8.42	3.90	36.10	3.45	<.001	329
	15 mm	10.46	0.63	32.43	3.55	<.001	210

DF, Dislodgement force.
Independent sample *t* tests were used to compare the dislodgement forces.
The percentage that the fixation at that proximal seal length was increased is shown under the header % gain.
The % gain was obtained by the following equation: (DFafter – DFbefore)/DFbefore*100.

EVAR graft. Filling the cavities around the graft increased the mechanical support of the graft's body and kept it in place. With this technique, it can be expected that a smaller proximal seal will be needed to withstand physiological forces (ie, shear forces due to blood flow and others). These forces will not only be exerted on the proximal seal, but also on the iliac bifurcation. Not only distal migration but also lateral migration and kinking can theoretically be prevented as the graft is entirely fixated.

Besides the stronger fixation, filling the peri-graft cavities with biocompatible elastomer has some other potential benefits. The technique might lead to a more optimal seal between the graft and the artery wall as the elastomer will fill every cavity in its fluid state. This will diminish the chance of type I endoleaks. Another benefit might be that proximal necks with severe angulation could be treated endovascularly. Anatomical variations in the morphology of the aneurysms neck can be customized to the form needed for good graft fixation and seal. Type II endoleaks are less likely to occur as the elastomer will fill the lumbar arteries as well. Barnett et al showed, in an in vitro setup, that the peri-graft area can be filled with a liquid polymer, thereby successfully treating or preventing type II endoleaks.[35]

Further research will be focused on these and other potential benefits.

Limitations of the study. The setup obviously differs from the in vivo situation, where grafts are dislodged by repetitive dislodgement forces due to blood flow. However, the use of a fixated animal aorta and uniaxial dislodgement by a tensile testing machine is a validated method to investigate proximal fixation of EVAR grafts.[9,28-30,32,33] Furthermore, we wanted an accurate as possible recording of the dislocation forces of the different grafts. This was

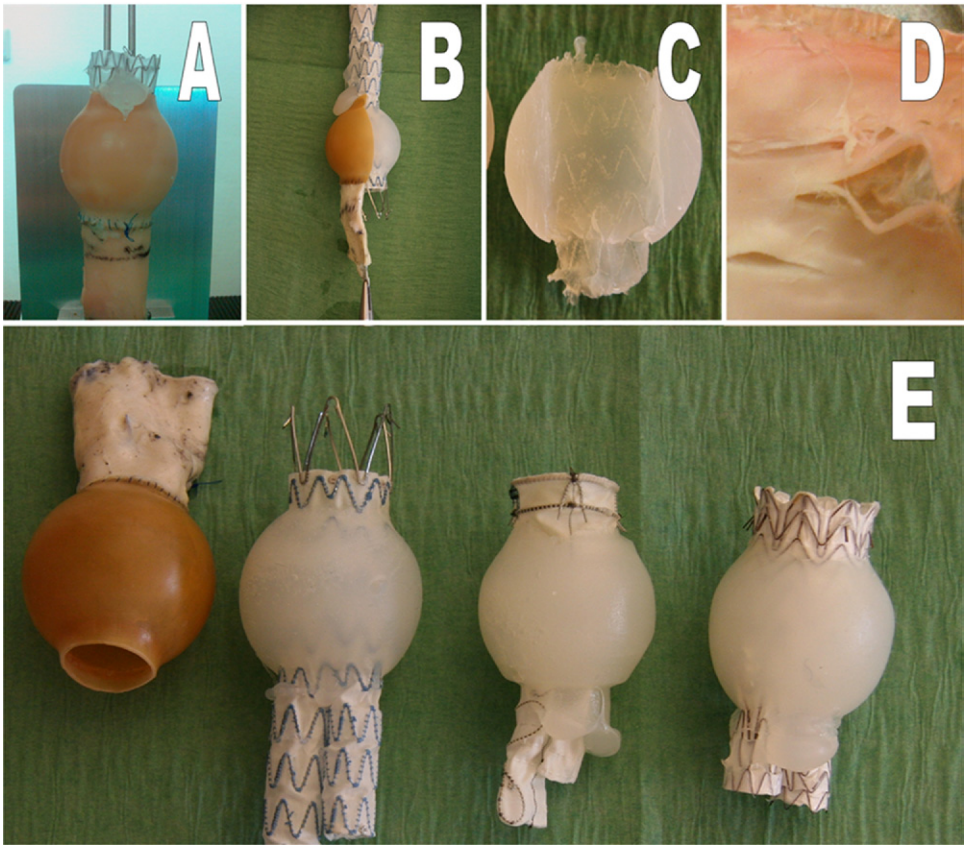

Fig. 5. Overview of the setup, the specimens, the grafts, and the elastomer. Inset **A** shows the setup with a bovine artery with the sutured latex aneurysm. In the artery, a Gore Excluder is placed, which is fixated by elastomer sac-filling. On the top of inset **A**, the rigid hook is visible on which the graft is attached. The elastomer filling has taken on the exact form of the latex aneurysm with the graft in place (**B, E**). When the endograft is removed from the elastomer mould, it becomes clear that the elastomer had filled every cavity between graft and sac, leaving casts of the struts of the graft (**C**). The sharp, rigid hooks for proximal fixation of the Anaconda left distinctive damage to aortic wall, when applying high extraction forces (**D**).

possible with a tensile testing machine, in which the dislocation velocity can be programmed and with an accurate load cell (accuracy, 0.25-2.5 N), which recorded the force exerted on the graft.

The aortic specimens were harvested from healthy young animals. There was no sign of calcification or thrombus. This might have lead to higher dislodgement forces in comparison to the in vivo situation, when there often are extensive atherosclerotic plaques.[23] However, the use of healthy animal arteries is an accepted method for examining proximal fixation.[27,31-33]

Furthermore, we only tested the effect of the proximal fixation of each graft. With many graft designs, the distal iliac seal is thought to provide additional graft fixation.[33] As the scope of our research was to see if it was possible to enhance the strength of the proximal fixation, we decided to only fixate the proximal part of the stent graft. It is possible that larger forces are needed to dislocate a stent graft in vivo, as the stent-graft (without elastomer aneurysm sac filling) would have a stronger fixation due to the iliac seal and columnar strength of the graft body.

Another potential difference with the in vivo situation is that the specimens were straight segments of an artery, and there was no angulation. Earlier studies have shown that (severe) angulation of the proximal neck may lead to suboptimal fixation and postoperative stent graft migration.[36,37]

Potential limitations of treatment method. Before this technique can be used in vivo, a few hurdles have to be taken. When working with arterial embolic agents, there is always the risk of developing an embolus. An embolus in the lumbar arteries or in the inferior mesenteric artery might lead to paraplegia or colonic ischemia. However, we expect that the elastomer will not travel far in the inferior mesenteric artery or lumbar arteries. In our extensive studies developing the elastomer and the treatment concept, emboli were not noted. The elastomer is more viscous and heavier then blood. The elastomer will press the organized thrombus against the aneurysm wall and the residual blood out of the sac as the elastomer fills up the AAA. Due to the smaller diameter of the arteries, there will be a higher pressure in the side branches. Therefore, the side branches will fill up when the whole sac is filled. At that moment, the

curing process of the elastomer is in full progress, the substance becomes even more viscous, and it will be very difficult for it to travel far in a pressurized small diameter vessel. Furthermore, it should be noted that with the current EVAR treatment of infrarenal AAAs, by which the inferior mesenteric artery is excluded as well, complications such as colon ischemia are seen seldom.

CONCLUSIONS

Earlier research has shown that the concept of filling an aneurysm with a biocompatible elastomer may be a potential new treatment option of abdominal aortic aneurysms.[15] The present study shows that elastomer aneurysm sac filling may have a role as a complementary procedure to the present EVAR technique. The strength of the proximal fixation of different stent grafts increases significantly after elastomer aneurysm sac filling. In vivo research must be done to see if this could facilitate the treatment of aneurysms with short infrarenal necks.

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AUTHOR CONTRIBUTIONS

Conception and design: WB, TS, DS, EV, AV, HB, MJ, JH
Analysis and interpretation: WB, TS, DS, EV
Data collection: WB, TS, DS
Writing the article: WB
Critical revision of the article: TS, DS, EV, AV, HB, MJ, JH
Final approval of the article: TS, DS, EV, AV, HB, MJ, JH
Statistical analysis: WB, DS
Obtained funding: WB, JH
Overall responsibility: WB, JH

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