Eur J Vasc Endovasc Surg (2017) 53, 185-192

# Iliac Seal Zone Dynamics and Clinical Consequences After Endovascular Aneurysm Repair

F. Bastos Gonçalves <sup>a,b,\*,e</sup>, N.F. Oliveira <sup>a,c,e</sup>, M. Josee van Rijn <sup>a</sup>, K.H.J. Ultee <sup>a</sup>, S.E. Hoeks <sup>d</sup>, S. Ten Raa <sup>a</sup>, R.J. Stolker <sup>d</sup>, H.J.M. Verhagen <sup>a</sup>

<sup>a</sup> Department of Vascular Surgery, Erasmus University Medical Centre, Rotterdam, The Netherlands

<sup>b</sup> Department of Angiology and Vascular Surgery, Hospital de Santa Marta, Centro Hospitalar de Lisboa Central, Lisbon, Portugal

<sup>c</sup> Department of Angiology and Vascular Surgery, Hospital do Divino Espirito Santo, Ponta Delgada - Azores, Portugal

<sup>d</sup> Department of Anesthesiology, Erasmus University Medical Centre, Rotterdam, The Netherlands

#### WHAT THIS PAPER ADDS

Failure after EVAR is most often associated with loss of seal and consequent re-pressurisation of the aneurysm sac. This study explores the evolution of the iliac seal zones after implantation, showing that progressive dilatation and retraction are very common occurrences, which in turn have clinical consequences. Careful attention to planning to take full advantage of the potential iliac seal, avoidance of "bell-bottom" limbs whenever possible, and attention to signs of excessive dilatation and/or retraction over the course of follow-up are practical recommendations derived from the conclusions of this study that may improve outcomes.

**Objective:** To evaluate the dynamics of the iliac attachment zone after EVAR, and the association with clinical events.

**Methods:** A tertiary institution's prospective EVAR database was searched to identify common iliac arteries at risk. Internally validated measurements were made, using centre lumen line reconstructions. Iliac dilatation and endograft limb retraction were the main endpoints. Associations between dilatation, retraction, oversizing, and distal seal length were investigated. Association with clinical events (sealing or occlusion) was also explored. **Results:** Of 452 primary EVAR patients treated from 2004 to 2012, 341 were included (mean age 72 years, 12% female, 597 common iliac arteries). Median follow-up was 4.7 years. At 30 days, the mean iliac diameter increased from 14 mm to 15 mm (p < .001). Over follow-up, it increased to 18 mm (p < .001). Iliac dilatation  $\geq$ 20% occurred in 295 cases (49.4%) and exceeded the implanted endograft diameter in 170 (28.7%). Limb retraction  $\geq$ 5 mm was identified in 54 patients (9.1%) and was associated with iliac seal complications (p < 0.001). Iliac endograft extension diameter  $\geq$ 24 mm (OR 3.3, 95% Cl 1.7—6.4) and iliac artery dilatation beyond the endograft (OR 2.1, 95% Cl 1.2—3.8) were independent risk factors. Overall, there were 34 (5.7%) iliac seal complications. Retraction of the iliac endograft (OR 1.17 per mm, 95% Cl 1.10—1.24) and baseline AAA diameter (1.04 per mm, 95% Cl 1.01—1.07) were independent risk factors for seal related complications. Greater initial post-operative iliac seal length was protective (OR 0.94 per mm, 95% Cl 0.90—0.97).

**Conclusions:** Iliac dilatation and endograft retraction are common findings during follow-up, potentially leading to adverse clinical events. Optimisation of the iliac seal zone providing a long distal seal length and added attention to patients with large aneurysms or receiving  $\geq$ 24 mm diameter iliac extensions are recommended. Also, long-term surveillance including CTA is advised to reveal and correct loss of seal at the iliac attachments before adverse clinical events occur.

© 2016 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved.

Article history: Received 24 May 2016, Accepted 3 November 2016, Available online 24 December 2016 Keywords: Abdominal (MeSH), Blood vessel prosthesis implantation (MeSH), Iliac artery, Endoleak, Iliac occlusion, Risk factors, Aneurysm

*E-mail address:* f.bastosgoncalves@erasmusmc.nl (F. Bastos Gonçalves). <sup>e</sup> F. Bastos Gonçalves and N.F. Oliveira contributed equally to this paper.

1078-5884/ $^{\odot}$  2016 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved.

http://dx.doi.org/10.1016/j.ejvs.2016.11.003

#### **INTRODUCTION**

The importance of the iliac seal zones after endovascular aneurysm repair (EVAR) is not completely understood. The true incidence of iliac dilatation and retraction is largely unknown, and the potential consequences — loss of seal or occlusion — are undetermined.

While much attention over the years has focused on the hostile proximal neck, there is a lack of evidence regarding the risk of iliac complications that in turn may account for a

<sup>\*</sup> Corresponding author. Erasmus University Medical Centre, 's-Gravendijkwal 230, 3015 CE Rotterdam, The Netherlands.

growing proportion of EVAR related complications. Clarification of the significance and particularities of distal sealing zone dynamics after implantation may help reduce iliac related complications and consequently improve clinical success of EVAR.

There have been publications suggesting that adverse iliac anatomy increases the risk of complications.<sup>1–6</sup> However, difficulties in serial morphological assessment of iliac arteries have resulted in a gap in perception of post-implant iliac changes and possible complications.

This study aimed to identify the dynamics of the distal sealing zone over time and its association with clinical events.

## **METHODS**

#### Sample

A retrospective study was conducted based on a prospectively kept database of AAA patients treated by EVAR in a single tertiary institution from 2004 to 2012. Inclusion criteria were treatment with an endovascular device with landing zone in the common iliac arteries and surveillance using computed tomography angiography (CTA). Patients with infected or anastomotic aneurysms were excluded from the analysis. Implants with extension to the external iliac artery were not included in the analysis. If a patient had both common and external iliac artery sealing zones, only the common iliac limb was considered.

## Measurements

All measurements were performed by two observers trained in image analysis (FBG, NO), after manual centre lumen line (CLL) reconstruction using dedicated post-processing software (3Mensio, Bilthoven, The Netherlands). According to local practice, pre-operative CTA had to be performed no more than 3 months before operation, and the first postoperative CTA was performed within 30 days (typically at day 2 or 3, before hospital discharge). The local surveillance protocol during the study period included annual CTA, although a shift towards more duplex ultrasound based surveillance was noted during the last few years.

To assess iliac dilatation in a standardised fashion, the iliac bifurcation was used as landmark and the iliac diameter measured a fixed distance from this landmark. The first postoperative CTA was used as reference and the iliac diameter was measured 10 mm proximal to the distal edge of the implanted stent graft. The distance to the iliac bifurcation was recorded and the pre-implantation iliac diameter was measured at the same level. Using the same technique, the last available post-operative iliac diameter was obtained (Fig. 1). To assess endograft limb retraction over time, the distance from the most distal portion of the stent graft to the iliac bifurcation was measured at the first and last available exams. Validation of this technique was performed on a random sample of 30 patients. Inter-observer agreement was high (Spearman's Rho 0.969 for iliac diameter and 0.989 for distance from graft to iliac bifurcation, Fig. 2).

Iliac seal length measuring was performed according to previously reported methods.<sup>7</sup> In summary, the length of circumferential apposition between the iliac endograft and the iliac artery wall was measured in a CLL reconstruction (Fig. 3).

#### Definitions

Iliac dilatation was defined as an increase greater than 2 mm or 10% of the outer to outer iliac diameter. Dilatation

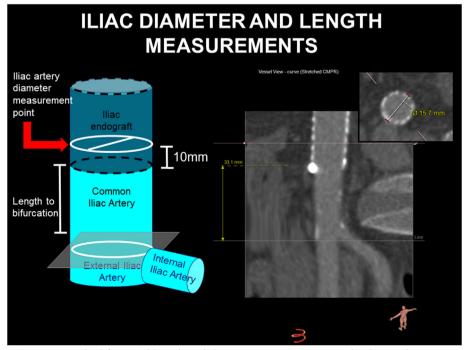


Figure 1. Method for serial length and diameter measurements at the iliac sealing zone.

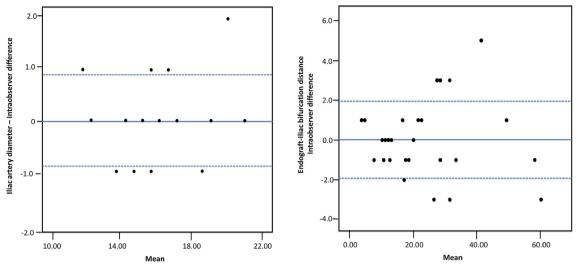


Figure 2. Bland-Altman plots for inter-observer variability for iliac artery diameter (left) and distance between the distal end of the endograft and iliac artery bifurcation (right).

beyond implanted graft diameter was considered if the outer to outer iliac diameter exceeded the implanted graft diameter by 2 mm (mean wall thickness among 20 random cases from the study population was 1.2 mm,  $\pm 0.88$ ). Endograft retraction was considered present if the distance between the iliac bifurcation and the distal edge of the last stent had increased  $\geq 5$  mm. Oversizing was calculated using the following formula: (implanted limb diameter — native iliac diameter)/native iliac diameter. Iliac seal complications were considered if one of the following occurred: type Ib endoleak or need for iliac limb extension (preemptive). Iliac artery tortuosity was classified into  $\geq 90^{\circ}$  or  $<90^{\circ}$  based on evaluation of the pre-operative imaging.

# Endpoints

The primary endpoints for this study were dilatation of the common iliac arteries and endograft limb retraction. Additionally, the associations among iliac dilatation, limb retraction, oversizing, and distal seal length at implant were investigated. Lastly, the potential clinical consequences of iliac dilatation and limb retraction were investigated.

## Statistical analysis

Discrete variables are presented as counts and percentages, and continuous variables as mean  $\pm$  standard deviation if normally distributed, or median (interquartile range [IQR]) if

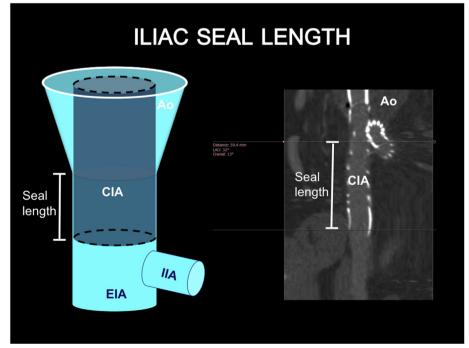


Figure 3. Method for serial measurement of iliac sealing length. CIA = common iliac artery; EIA = external iliac artery, IIA = internal iliac artery.

non-normally distributed. Individual differences in length and diameter over time were tested using related samples Wilcoxon signed rank test. Associations between iliac artery dilatation, endograft limb retraction, and distal seal complications (type-Ib endoleaks, loss of seal without endoleak, or need for iliac extension) and morphological and device related variables were tested using Mann-Whitney U statistics for continuous non-normal data or with the Pearson's chi-square for categorical variables. Multivariate logistic regression models were created for each outcome with variables with an  $\alpha$  value <.1 after excluding multicollinearity among the included variables. Time was included as a covariate in the models to adjust for the differences in timing of last available CT imaging. An  $\alpha$  value <.05 was considered to be statistically significant. All statistical analyses were performed using SPSS software v20.

#### RESULTS

Four-hundred and fifty two patients were treated with EVAR from 2004 to 2012 at the Erasmus Medical Centre. Of these, eight had infected aneurysms, 38 had anastomotic aneurysms and one was a traumatic aneurysm. From the remaining 405 patients, another 64 were excluded because they did not have two post-operative CTAs of which one within 30 days of operation for comparison of iliac morphology. Three hundred and forty one patients (26 aortic-uni-iliac devices, 656 iliac arteries overall) followed for a median of 4.7 years (IQR 2.8–6.2) were included. Among these, there were 59 cases of endograft extensions ending in the external iliac artery that were excluded, leaving 597 common iliac arteries available for analysis.

### **Baseline characteristics**

The mean age of the study population was 72.3  $\pm$  7.5 years, and there were 41 (11%) females. The median pre-operative AAA diameter was 61 mm (IQR 56–71), and the median iliac diameter was 14 mm (IQR 12–16). The median iliac oversizing chosen for device implantation was 20% (IQR 9–33). A variety of devices were used in this patient cohort, with predominance of the Medtronic Endurant (189/341, 55.4%) and Gore Excluder (130/341, 38.1%) devices. AUI devices were used in 26/341 (7.6%) patients. Baseline characteristics are summarised in Table 1.

## Iliac dilatation and limb retraction

At the 30 day CTA, the median distance from the distal edge of the endograft to the iliac bifurcation was 21 mm (IQR 14–31), and the median iliac seal length was 28 mm (IQR 19–38). The median iliac diameter, measured 10 mm proximal to the distal edge of the implant, increased from 14 mm to 15 mm (p < .001) at 30 day imaging and to 18 mm (p < .001) at the last available CT (Table 2). At the last available imaging, iliac dilatation was  $\ge 20\%$  in 295 cases (49.4%) and had exceeded the implanted endograft diameter at the measuring point in 170 cases (28.7%). Among patients treated with  $\ge 24$  mm diameter endografts, median iliac dilatation was 4.0 mm (17.8%) (IQR 7.6–

Table 1. Baseline patient and device related c	characteristics.
--	------------------

Table 1. Dasenne patient and device related t	
Age, years	72.3 (±7.5)
Female gender	42 (11)
Pre-operative AAA maximum	61.0 (56.0–71.0)
diameter, mm	
Common iliac diameter, mm	14.0 (12.0—16.0)
Endografts used	
Medtronic Endurant	322 (53.9)
Gore Excluder	238 (39.9)
Medtronic Talent	22 (3.7)
Cook Zenith	5 (0.8)
Others	12 (2.0)
AUI configuration, N (%)	26 (4.3)
Implanted diameter, mm (593/597)	16.0 (14.0-20.0)
Percentage iliac oversizing (590/597)	20.0 (9.0-33.3)
Common iliac seal length @30 days	28.0 (19.0–38.0)
(597/597)	

Continuous data are presented as mean ( $\pm$ standard deviation) or median (IQR), dichotomous data as count (percentage).

37.0%) while for the remaining patients it was 3.0 mm (19.9%) (IQR 6.7–33.3%) (p = .96). Follow-up time (OR 1.69, 95% CI 1.53–1.86) and oversizing >20% (OR 2.61, 95% CI 1.77–3.86, Table 3) were identified in multivariate regression analysis as independent risk factors for dilatation  $\geq$ 20%. In multivariate analysis, the chance of the iliac artery diameter exceeding the diameter of the implanted endograft increased over time (OR 1.42 per year, 95% CI 1.30–1.56, p < .001) and was higher among patients with iliac limb retraction  $\geq$ 5 mm (OR 2.02, 95% CI 1.07–3.80, p = .03). On the other hand, endograft oversizing  $\geq$ 15% was protective for excessive dilatation (OR 0.52, 95% CI 0.35–0.77, p = .001).

Retraction  $\geq$ 5 mm was observed in 54 (9.1%) cases. Implantation of a  $\geq$ 24 mm endograft limb (OR 2.80, 95% CI 1.44–5.46) and iliac artery dilatation (OR 1.09 per mm, 95% CI 1.01–1.18) were found to be independent risk factors for retraction  $\geq$ 5 mm (Table 4).

The endograft model was significantly associated with retraction  $\geq 5$  mm, occurring in 41 cases (11.9%) with Medtronic devices and in 13 cases (5.5%) with Gore devices (p = .008). No association was found regarding dilatation.

#### Predictors of iliac seal complications

Iliac seal complications occurred in 34 (5.7%) of the cases (Table 5): there were 16 (2.7%) type 1B endoleaks of which seven had retraction  $\geq$ 5 mm, and a single case of a type 3

		<i>p</i> -Value
Pre-operative iliac diameter, mm	14.0 (12.0–16.0)	
Iliac diameter at 30 days, mm	15.0 (13.0–17.0)	<.001
Iliac diameter at last CTA, mm	18.0 (15.0-21.0)	<.001
Iliac dilatation, mm	3.0 (1.0-5.0)	<.001
$\geq$ 4 mm	235 (39.3)	
Iliac limb retraction (mm)	0.0 (-2.0 to 2.0)	<.001
≥5 mm	54 (9.1)	

Continuous data are presented as median (IQR), dichotomous data as count (percentage).

Risk factor	Univariate			Multivariate			
	Dilatation $\geq$ 20% ( $N =$ 295)	Controls ( $N = 302$ )	<i>p</i> -Value	OR	95% CI	<i>p</i> -Value	
CT follow-up, years	4.4 (2.9—5.5)	1.8 (0.2-3.6)	<.001	1.69	1.53 - 1.86	<.001	
Pre-operative AAA diameter	60.0 (55.0-72.0)	62.0 (56.0-71.0)	.237				
Pre-operative iliac artery diameter	14.0 (12.0-16.0)	14.0 (12.0-16.0)	.376				
Pre-operative iliac artery tortuosity $\geq$ 90°	57 (19.3)	34 (11.3)	.007	1.39	0.81-2.38	.235	
Endograft diameter $\geq$ 24	35 (11.9)	39 (12.9)	.664				
Oversizing >20%	165 (56.5)	124 (41.1)	<.001	2.61	1.77-3.86	<.001	
lliac seal @30 days $\leq$ 20 mm	82 (27.8)	97 (32.4)	.217	0.83	0.55-1.26	.384	
Distance to iliac bifurcation @30 days	20.0 (13.0-30.0)	22.0 (15.0–33.0)	.070				
Iliac limb retraction $\geq$ 5 mm	29 (9.8)	25 (8.3)	.553	1.26	0.65-2.43	.489	

Table 3. Uni and multivariate associations for iliac artery dilatation  $\geq$  20%.

Continuous data are presented as median (IQR), dichotomous data as count (percentage).

endoleak. No patient left the operating room with a detectable type IB or III endoleak. In two cases the endoleak was present at the 30 day CTA, all the rest developed later. Aneurysm rupture occurred in a patient with bilateral type 1B endoleaks and who was later found to have also developed a type 1A endoleak. The patient was considered unfit for open conversion, and the anatomy was very unfavourable for endovascular treatment, so no elective correction was proposed. The patient subsequently died because of rupture. In 17 patients (2.9%) a pre-emptive limb extension was performed because of loss of seal, without a visible endoleak. No model of endograft was associated with an increased rate of seal complications.

There were 75 iliac arteries implanted with a  $\geq$ 24 mm iliac endograft. Seal related complications developed in eight of these (10.7%) while there were 26 events in the remaining 522 iliac limbs receiving an endograft <24 mm of diameter (5.0%, p = .047). Iliac limb occlusion occurred in one case among the  $\geq$ 24 mm iliac limb group (1.3%) while it developed in nine cases among the <24 mm iliac limb group (1.9%, p = .17).

Among patients with iliac seal complications, median iliac dilatation 3.5 mm (1–6.1) and median retraction was 3.5 mm (0–8.5). Dilatation beyond the graft diameter was present in 11 (32%) cases, and retraction >5 mm in 13 (38.2%, Table 5).

Table
5.
Iliac
seal
complications
and
related
secondary

interventions.

</

Complications	N (%)
Type 1B endoleak	16 (2.7)
Type 3 endoleak	1 (0.2)
Sac growth without visible endoleak	7 (1.2)
Secondary interventions	
Iliac limb extensions	29 (4.9)
Pre-emptive limb extension because of loss of	17 (2.9)
seal but without type 1B endoleak	

Univariate analysis of possible risk factors for iliac seal complications revealed baseline AAA diameter (p = .018), baseline iliac diameter (p = .037), iliac endograft diameter  $\geq 24 \text{ mm}$  (p = .047), iliac seal length at 30 days (p < .001), distance from the distal end of the iliac limb to the iliac artery bifurcation (p = .01), and iliac limb retraction (p < .001) as significant (Table 6).

The degree of oversizing was not associated with seal complications in this cohort. Multivariate analysis, adjusted for duration of follow-up, confirmed pre-operative AAA diameter (1.04 per mm increase, 95% CI 1.01–1.07) and iliac limb retraction (OR 1.17 per mm increase, 95% CI 1.10–1.24) as independent risk factors for iliac seal complications. Iliac seal length on 30 day imaging was a protective factor

Table 4. U	Uni- and	multivariate	associations	for I	limb	retraction	>5	mm.

Univariate				Multivariate		
Limb retraction	Without complication	<i>p</i> -Value	OR	95% CI	<i>p</i> -Value	
≥5 mm ( <i>N</i> = 54)	(N = 543)					
3.1 (1.5-5.0)	3.1 (1.2-5.0)	.429				
62.0 (56.0–76.3)	61.0 (55.0—71.0)	.352				
15.5 (13.0–17.5)	14.0 (12.0-16.0)	.001 <sup>a</sup>	_	_	-	
12 (22.2)	80 (14.7)	.146				
15 (27.8)	60 (11.0)	<.001	3.31	1.71-6.44	.003	
17.7 (12.4–28.9)	21.7 (9.1–33.3)	.597				
28.5 (20.0-41.3)	28.0 (18.0-38.0)	.211				
21.0 (11.8-30.3)	21.0 (14.0-32.0)	.477				
23 (42.6)	147 (27.3)	.018	2.14	1.20-3.84	.010	
0 (0.0)	10 (1.8)	.315				
	Limb retraction $\geq$ 5 mm (N = 54) 3.1 (1.5-5.0) 62.0 (56.0-76.3) 15.5 (13.0-17.5) 12 (22.2) 15 (27.8) 17.7 (12.4-28.9) 28.5 (20.0-41.3) 21.0 (11.8-30.3) 23 (42.6)	Limb retractionWithout complication $\geq$ 5 mm (N = 54)(N = 543)3.1 (1.5-5.0)3.1 (1.2-5.0)62.0 (56.0-76.3)61.0 (55.0-71.0)15.5 (13.0-17.5)14.0 (12.0-16.0)12 (22.2)80 (14.7)15 (27.8)60 (11.0)17.7 (12.4-28.9)21.7 (9.1-33.3)28.5 (20.0-41.3)28.0 (18.0-38.0)21.0 (11.8-30.3)21.0 (14.0-32.0)23 (42.6)147 (27.3)	Limb retractionWithout complication $p$ -Value $\geq 5 \text{ mm } (N = 54)$ $(N = 543)$ $3.1 (1.5-5.0)$ $3.1 (1.2-5.0)$ .429 $62.0 (56.0-76.3)$ $61.0 (55.0-71.0)$ .352 $15.5 (13.0-17.5)$ $14.0 (12.0-16.0)$ .001 <sup>a</sup> $12 (22.2)$ $80 (14.7)$ .146 $15 (27.8)$ $60 (11.0)$ <.001	Limb retractionWithout complication $p$ -ValueOR $\geq 5 \text{ mm } (N = 54)$ $(N = 543)$ .429 $3.1 (1.5-5.0)$ $3.1 (1.2-5.0)$ .429 $62.0 (56.0-76.3)$ $61.0 (55.0-71.0)$ .352 $15.5 (13.0-17.5)$ $14.0 (12.0-16.0)$ .001 <sup>a</sup> $12 (22.2)$ $80 (14.7)$ .146 $15 (27.8)$ $60 (11.0)$ <.001	Limb retractionWithout complication $p$ -ValueOR95% Cl $\geq 5 \text{ mm } (N = 54)$ $(N = 543)$ .429.429 $3.1 (1.5-5.0)$ $3.1 (1.2-5.0)$ .429.429 $62.0 (56.0-76.3)$ $61.0 (55.0-71.0)$ .352.429 $15.5 (13.0-17.5)$ $14.0 (12.0-16.0)$ .001 <sup>a</sup> . $12 (22.2)$ $80 (14.7)$ .146 $15 (27.8)$ $60 (11.0)$ <.001	

Continuous data are presented as median (IQR), dichotomous data as count (percentage).

<sup>a</sup> Multicollinearity was detected between pre-operative iliac diameter and device size (Pearson's correlation R = .737, p < .001), consequently the former variable was excluded from the multivariate model.

Among the 34 cases of seal complications, 29 of these underwent a limb extension of which 17 were performed pre-emptively. In five cases, a type 1A endoleak developed subsequently either before treatment (2 cases, same patient) or after successful intervention (limb extension, 3 cases). Additional proximal seal related endovascular procedures were performed in the latter three cases.

## DISCUSSION

After EVAR, the iliac sealing zone remains dynamic and is a possible source of morbidity and, ultimately, treatment failure. Although attention has focused on the proximal seal, the present study suggests that iliac dilatation and endograft limb retraction are common occurrences and are associated with clinical consequences.

Much of the difficulty in reporting iliac related complications is related to the capacity for accurately assessing and reproducing measurements. Reporting measurements on the proximal attachment site can be done using wellstandardised methods. In contrast, the complexity of the iliac sealing zones probably explains the lack of standardisation for reporting and consequently the paucity and conflicting nature of published data.<sup>8</sup> In this study, a technique is proposed, based on centre lumen line measurements and anatomical landmarks, which allows for consecutive measurements of the distal iliac seal zone at exactly the same location, as well as quantification of the retraction of iliac components of endografts. Using this tool, it was possible to demonstrate that both iliac dilatation and endograft limb retraction are common and related events. Moreover, limb retraction is a risk factor for iliac seal complications. Importantly, the length of the initial iliac seal achieved during endograft implantation is the only protective factor for seal complications.

Iliac dilatation over time has been demonstrated before. Kaladji et al. studied the evolution of 179 patients over a mean of 24 months, and found iliac dilatation to be very common (mean increase 2-3 mm, depending on level). Although they could not find a correlation with clinical events, the authors sent a word of caution.<sup>2</sup> Previously. Falkensammer et al. had shown that dilatation was more pronounced in patients with previously existing iliac dilatation,<sup>9</sup> and both Hobo et al. and Albertini et al. reported a higher risk of complications in patients requiring bellbottom ( $\geq$ 24 mm) iliac limbs, a finding corroborated by the present study.<sup>6,10</sup> Similarly, Schanzer et al. reported a greater chance of sac enlargement in patients with larger (20 mm or greater) iliac diameter endografts.<sup>11</sup> In the present study, although iliac arteries receiving a bell-bottom endograft did not dilate more than the remaining cases, significantly more limb retraction was observed among this group, which is, in the authors' opinion, the preceding step to development of a seal complication. Furthermore, the present study suggests that progressive iliac dilatation, which starts immediately following EVAR, precedes limb retraction, which in turn is a risk factor for clinically significant iliac seal loss, thus establishing a temporal line between these events. According to the present results, iliac dilatation follows two stages, one acute immediately postimplant and another gradually occurring over time. This reproduces the phenomenon already well characterised at the proximal aneurysm neck, following implantation of oversized self expanding nitinol based devices.<sup>12</sup> Although uncommon at the proximal neck, expansion beyond the diameter of the implanted endograft is not a rare event in the iliac arteries during follow-up, as shown by Adiseshiah et al.<sup>13</sup> and confirmed in this study. Although the present study reports a high rate (28.7%) of iliac artery dilatation greater than the diameter of the endograft, iliac seal complications were only noted in 5.7%, as the iliac seal was still conserved over some of the remaining length of the iliac artery. Of note, excessive oversizing did increase the risk of excessive dilatation over time, which is a logical finding because of the self expanding nature of the implanted nitinol material. However, excessive oversizing

Table 6. Uni- and multivariate associations for sealing cor	mplications.
---	--------------

Risk factor	Univariate			Multi	variate	
	With seal	Without seal	<i>p</i> -Value	OR	95% CI	<i>p</i> -Value
	complication ( $N = 34$ )	complication ( $N = 563$ )				
Follow-up time, years	6.8 (5.0—9.0)	4.6 (2.7-6.1)	<.001	1.49	1.26-1.77	<.001
Pre-operative AAA diameter, mm	70 (58.5—83.5)	61 (55—71)	.018	1.04	1.01 - 1.07	.006
Pre-operative iliac diameter, mm <sup>a</sup>	18.0 (16.0-24.0)	14.0 (12.0-16.0)	.037 <sup>a</sup>	-	_	-
Pre-operative iliac artery tortuosity $\geq$ 90 $^{\circ}$	13 (38.2)	79 (13.2)	<.001	1.44	0.59-3.52	.428
lliac endograft diameter $\geq$ 24 mm	8 (23.5)	67 (11.9)	.047	2.54	0.89-7.27	.081
Oversizing (%)	20.0 (9.0-41.0)	20.0 (9.0–33.0)	.908			
Iliac seal @30 days, mm	17.5 (5.0—26.0)	29.0 (20.0–38.0)	<.001	0.94	0.90-0.97	<.001
Distance between graft and iliac bifurcation	29.0 (16.8–38.5)	21.0 (13.0-31.0)	.01	1.02	0.99-1.05	.119
@ 30 days, mm						
Iliac artery dilatation beyond endograft	11 (32.4)	159 (28.4)	.625			
Iliac limb retraction, mm	3.5 (0-8.3)	0.0 (-2.0 to 2.0)	<.001	1.17	1.10-1.24	<.001
Iliac limb occlusion	0 (0)	10 (1.8)	.433			

Continuous data are presented as median (IQR), dichotomous data as count (percentage).

<sup>a</sup> Multicollinearity was detected between pre-operative iliac diameter and device size (Pearson's correlation R = .737, p < .001), consequently the former variable was excluded from the multivariate model.

did not, in the present series, result in further or accelerated degeneration beyond the implanted diameter, which explains why this is not a predictor of complications. Nevertheless, the iliac seal zone will most likely remain dynamic over time, possibly leading to complete loss of seal and the development of a type 1B endoleak and leaving a significant number of patients at increased chance of rupture. Consequently, the present authors recommend that increasing the distal seal length at the original implantation may be an adequate preventive measure.

Iliac limb retraction is an interesting and relevant finding of this study. Sideways displacement of endograft limbs within the aneurysm sac has been associated with adverse events after EVAR.<sup>14</sup> This observation may be a surrogate finding of limb retraction (in the absence of endograft migration in the proximal aneurysm neck and inadequate component overlap). In fact, Waasdorp et al.<sup>14</sup> found that patients with limb displacement had larger aneurysms and shorter iliac fixation zones, findings consistent with the results of the present study. This study demonstrates that iliac retraction is a common event, associated with iliac dilatation, which is likely to reduce the resistance to displacement resulting from the endografts' radial force. This effect had been suggested before by Arko et al., in an in vitro study evaluating the importance of iliac fixation in preventing longitudinal displacement of a stent graft.<sup>15</sup> Moreover, the present study suggests that iliac arteries requiring a bellbottom endograft are more prone to develop limb retraction, which in turn increases the risk of developing an iliac seal related complication. And despite reaching only a statistical trend on multivariate modelling for iliac seal complication prediction, the observed rate of iliac seal complications was double among bell-bottom iliac limbs when compared with the remaining cases, and, as previously stated, the risk of endograft retraction was threefold in these cases, when compared with the smaller diameter arteries. Benharash et al. later found, in a study analysing 92 patients treated between 2000 and 2004, that shorter iliac fixation length was associated with the risk of proximal device migration, and suggested coverage of the entire length of the common iliac artery as a protective factor.<sup>16</sup> Others have also linked the chance of retraction to insufficient distal seal.<sup>17,18</sup> Although most of the studied endografts in these studies had a high columnar force (AneuRx), which had previously been regarded to be more prone to presenting iliac seal complications, these events have also been reported among devices with highly flexible limbs other than in the present report.<sup>19</sup> Consequently, it is recommended to increase the length of iliac seal to reduce the risk of iliac seal complications, regardless of the specific endograft model.

There are important limitations to this study that must be considered. Firstly, there is a bias in patient and graft selection that limits the extrapolation of these results to all EVAR populations. In particular, there is a paucity of patients treated with devices with stiffer iliac components. These may yield different results in terms of the chance of retraction and/or occlusion, and change the results significantly. This study used predominantly Medtronic and Gore devices, and although a higher risk was found for retraction with the use of Medtronic devices, this is most likely explained by the selection bias introduced with larger device diameters being available for that specific manufacturer. The exclusion of patients with extension to the external iliac also restricts the applicability of the results, but allowed for a more homogeneous sample and methodology. Another limitation is the relatively few clinical events in the present series, which limits the capacity for discriminating risk factors and therefore to make stronger recommendations on minimal seal or ideal oversizing to reduce the rate of adverse clinical events. Also, the retrospective design of the study has the potential risk of selection bias. Finally, the method used to determine iliac morphology and dynamics, although highly reproducible, is relatively complex and may not be practical for use in a clinical setting.

Despite the limitations, three recommendations can be made based on these results. Firstly, the authors suggest maximisation of the iliac seal zone by adapting the planning to increase the wall-graft contact length and extending the iliac components as close as possible to the iliac bifurcation. This recommendation which was made in the era of much stiffer endografts seems to remain valid for the current flexible ones. This is particularly important, in patients with large AAA (>65 mm diameter) or patients requiring iliac endograft extensions with >24 mm diameters. An increase in seal may be achieved by simply extending the larger diameter limb length, instead of sealing only at the final stent component of the graft. In patients where an adequate iliac seal (>15 mm) cannot be achieved, extension to the external iliac artery may be considered, possibly with preservation of the internal iliac artery (with an iliac bifurcated device or other revascularisation methods) when technically feasible and clinically justified. While technical success is generally very high when extending to the external iliac artery (with or without hypogastric side branch), this increases the risk of occlusion by over 50% especially if the vessel diameter is <10 mm.<sup>20</sup> Moreover, hypogastric branch devices occlude frequently, both early and at midterm.<sup>21,22</sup> In the absence of clear recommendations, clinical judgement should consider the risk of endoleak by sub-optimal seal at the common iliac artery and balance this with the increased risk of occlusion when extending to the external iliac artery.

Secondly, the present data suggest that oversizing by 15% or greater at the distal component is recommended for prevention of seal complications. However, excessive oversizing is a known risk factor for occlusion and this endpoint was not considered in this study,<sup>23,24</sup> therefore, a maximum safe oversizing cannot be recommended.

Thirdly, extra attention should be given to surveillance of patients with large aneurysms and endograft limbs  $\geq$ 24 mm, especially in the long term. As CT is necessary to determine progressive loss of seal and/or retraction, it is suggested that these patients should have a surveillance programme that includes CT scanning at least occasionally.

As dilatation and retraction is a late phenomenon, CT scans cannot be waived completely over time.

In conclusion, this study demonstrates that the iliac seal zone remains dynamic after EVAR implantation. Iliac dilatation and endograft limb retraction are common findings during follow-up, which may lead to clinically relevant loss of iliac seal. Optimisation of the iliac seal zone providing long distal seal length and added attention to patients with large aneurysms and those receiving  $\geq$ 24 mm diameter iliac endograft extensions are recommended. Also, long-term surveillance including CTA is advised to reveal and correct loss of seal at the iliac attachments before adverse clinical events occur.

# **CONFLICT OF INTEREST**

H.J.M. Verhagen discloses that he is a consultant for Medtronic, WL Gore, Endologix Arsenal AAA, and Philips.

## FUNDING

N.F. Oliveira and S.E. Hoeks receive an unrestricted educational research grant from the Lijf en Leven Foundation.

## REFERENCES

- 1 England A, Butterfield JS, McCollum CN, Ashleigh RJ. Endovascular aortic aneurysm repair with the talent stent graft: outcomes in patients with large iliac arteries. *Cardiovasc Intervent Radiol* 2008;**31**:723–7.
- 2 Kaladji A, Cardon A, Laviolle B, Heautot JF, Pinel G, Lucas A. Evolution of the upper and lower landing site after endovascular aortic aneurysm repair. J Vasc Surg 2012;55:24–32.
- 3 McDonnell CO, Semmens JB, Allen YB, Jansen SJ, Brooks DM, Lawrence-Brown MM. Large iliac arteries: a high-risk group for endovascular aortic aneurysm repair. J Endovasc Ther 2007;14: 625–9.
- 4 Parlani G, Zannetti S, Verzini F, De Rango P, Carlini G, Lenti M, et al. Does the presence of an iliac aneurysm affect outcome of endoluminal aaa repair? An analysis of 336 cases. *Eur J Vasc Endovasc Surg* 2002;**24**:134–8.
- 5 Timaran CH, Lipsitz EC, Veith FJ, Chuter T, Greenberg RK, Ohki T, et al. Endovascular aortic aneurysm repair with the zenith endograft in patients with ectatic iliac arteries. *Ann Vasc Surg* 2005;**19**:161–6.
- **6** Hobo R, Sybrandy JE, Harris PL, Buth J. Endovascular repair of abdominal aortic aneurysms with concomitant common iliac artery aneurysm: outcome analysis of the eurostar experience. *J Endovasc Ther* 2008;**15**:12–22.
- 7 Bastos Goncalves F, van de Luijtgaarden KM, Hoeks SE, Hendriks JM, ten Raa S, Rouwet EV, et al. Adequate seal and no endoleak on the first postoperative computed tomography angiography as criteria for no additional imaging up to 5 years after endovascular aneurysm repair. J Vasc Surg 2013;57: 1503–11.
- 8 Diehm N, Dick F, Katzen BT, Schmidli J, Kalka C, Baumgartner I. Aortic neck dilatation after endovascular abdominal aortic aneurysm repair: a word of caution. J Vasc Surg 2008;47:886–92.
- 9 Falkensammer J, Hakaim AG, Andrew Oldenburg W, Neuhauser B, Paz-Fumagalli R, McKinney JM, et al. Natural history of the iliac arteries after endovascular abdominal aortic

aneurysm repair and suitability of ectatic iliac arteries as a distal sealing zone. *J Endovasc Ther* 2007;**14**:619–24.

- 10 Albertini JN, Favre JP, Bouziane Z, Haase C, Nourrissat G, Barral X. Aneurysmal extension to the iliac bifurcation increases the risk of complications and secondary procedures after endovascular repair of abdominal aortic aneurysms. *Ann Vasc Surg* 2010;24:663–9.
- 11 Schanzer A, Greenberg RK, Hevelone N, Robinson WP, Eslami MH, Goldberg RJ, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. *Circulation* 2011;123:2848-55.
- 12 Sampaio SM, Panneton JM, Mozes G, Andrews JC, Noel AA, Kalra M, et al. Aneurx device migration: incidence, risk factors, and consequences. *Ann Vasc Surg* 2005;19:178–85.
- 13 Adiseshiah M, Boardley D, Raphael MJ. Late iliac artery aneurysm formation: implications for the lower landing site after evar. J Endovasc Ther 2008;15:246-7.
- 14 Waasdorp EJ, Gorrepati ML, Rafii BY, de Vries JP, Zarins CK. Sideways displacement of the endograft within the aneurysm sac is associated with late adverse events after endovascular aneurysm repair. J Vasc Sur 2012;55:947–55.
- 15 Arko FR, Heikkinen M, Lee ES, Bass A, Alsac JM, Zarins CK. Iliac fixation length and resistance to in-vivo stent-graft displacement. J Vasc Surg 2005;41:664–71.
- 16 Benharash P, Lee JT, Abilez OJ, Crabtree T, Bloch DA, Zarins CK. Iliac fixation inhibits migration of both suprarenal and infrarenal aortic endografts. J Vasc Surg 2007;45:250–7.
- 17 Heikkinen MA, Alsac JM, Arko FR, Metsanoja R, Zvaigzne A, Zarins CK. The importance of iliac fixation in prevention of stent graft migration. J Vasc Surg 2006;43:1130–7. discussion 1137.
- 18 Waasdorp EJ, de Vries JP, Sterkenburg A, Vos JA, Kelder HJ, Moll FL, et al. The association between iliac fixation and proximal stent-graft migration during evar follow-up: mid-term results of 154 talent devices. *Eur J Vasc Endovasc Surg* 2009;37: 681–7.
- 19 Karkos CD, Kapetanios DM, Anastasiadis PT, Grigoropoulou FS, Kalogirou TE, Giagtzidis IT, et al. Endovascular repair of abdominal aortic aneurysms with the anaconda stent graft: mid-term results from a single center. *Cardiovasc Intervent Radiol* 2015;**38**:1416–24.
- 20 Faure EM, Becquemin JP, Cochennec F. ENGAGE collaborators. Predictive factors for limb occlusions after endovascular aneurysm repair. J Vasc Surg 2015;61:1138–1145 e1132.
- 21 Mylonas SN, Rumenapf G, Schelzig H, Heckenkamp J, Youssef M, Schafer JP, et al. A multicenter 12-month experience with a new iliac side-branched device for revascularization of hypogastric arteries. J Vasc Surg 2016;64(6): 1652-9.
- 22 Karthikesalingam A, Hinchliffe RJ, Holt PJ, Boyle JR, Loftus IM, Thompson MM. Endovascular aneurysm repair with preservation of the internal iliac artery using the iliac branch graft device. *Eur J Vasc Endovasc Surg* 2010;**39**:285–94.
- 23 Mantas GK, Antonopoulos CN, Sfyroeras GS, Moulakakis KG, Kakisis JD, Mylonas SN, et al. Factors predisposing to endograft limb occlusion after endovascular aortic repair. *Eur J Vasc Endovasc Surg* 2015;49:39–44.
- 24 van Zeggeren L, Bastos Goncalves F, van Herwaarden JA, Zandvoort HJ, Werson DA, Vos JA, et al. Incidence and treatment results of endurant endograft occlusion. *J Vasc Surg* 2013;57:1246-54. discussion 1254.