The importance of infrarenal sealing zone assessment in endovascular aneurysm repair

Zuidema, Roy

DOI:
10.33612/diss.904121558

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Chapters 2 and 3 – Defining the infrarenal sealing zone

In **Chapter 2**, the European expert group of vascular surgeons emphasised the need to distinguish the preoperative sealing zone from the postoperative sealing zone. They defined the preoperative target anticipated sealing zone (TASZ) as “the length starting just inferior to the distal renal artery and ending at the most proximal slice at which the endograft is anticipated to no longer be in proper apposition to the aortic wall,” and the postoperative real achieved sealing zone (RASZ) as “the length starting at the proximal end of the endograft fabric over which the endograft material is in proper apposition to the aortic wall.”

The TASZ and RASZ should be measured on a computed tomography angiography (CTA), and in patients with challenging anatomies, they emphasised that the shortest length (i.e., the shortest apposition length [SAL]) should be measured between the reference points. Four parameters were identified that are most relevant for the preoperative TASZ: aortic neck length, neck diameter, neck shape, and infrarenal angulation. Lastly, a clinical decision algorithm was developed to determine when and whether adjunctive procedures or reinterventions could be considered, based on the presence of neck-related complications (type 1a endoleak or migration) or insufficient/suboptimal postoperative RASZ. They advised considering adjunctive procedures or reinterventions in the presence of neck-related complications (strong consensus) or in the case of an insufficient/suboptimal sealing zone (weak consensus) on the completion angiography or postoperative CTA. In the case of negative evolution of the RASZ over time, considering a reintervention was advised (strong consensus).

The systematic review and meta-analysis in **Chapter 3** revealed that the risk of developing a type 1a during both early and late follow-up was higher in patients with a larger aortic neck diameter. An angulated aortic neck mainly increased the risk of a late type 1a endoleak. Qualitative analysis showed that the aortic neck length and the length of the RASZ are risk factors for type 1a endoleak and migration as well. However, only a limited number of studies, with serious risk of bias and heterogeneity, were available. Thus, a proposal for standardisation of preoperative and postoperative definitions and measurement methods was provided. This can be used to standardise infrarenal sealing zone assessment and to enhance uniformity in endovascular aneurysm repair (EVAR) research, to ultimately improve data transparency and reusability.

Chapters 4 and 5 – Risk stratification for type 1a endoleak

In these chapters, patients with a late type 1a endoleak were matched to uncomplicated control patients without a type 1a endoleak to assess whether the SAL could be used to determine the risk for type 1a endoleak after EVAR. The cohort of patients evaluated in both chapters was almost the same. In **Chapter 4**, we showed that patients with a late type 1a endoleak had a significantly shorter SAL at the first postoperative CTA compared with uncomplicated control patients. A SAL of <10 mm at the first postoperative CTA was an independent predictor for a late type 1a endoleak.

The results of **Chapter 5** added that most patients with a late type 1a endoleak also had decreasing SAL during follow-up, whereas uncomplicated patients had an increasing SAL. Almost two-thirds of patients with a late type 1a endoleak had a SAL of <10 mm on the last uncomplicated CTA before the endoleak was detected. In addition, three mechanisms of decreasing sealing zone were identified: (1) distal migration of the endograft, (2) decreasing apposition at the distal sealing zone in the aortic neck, and (3) decreasing apposition at the proximal sealing zone in the aortic neck. These mechanisms can be used to identify the underlying cause of a decrease in the sealing zone, and ultimately, they might help to determine the optimal reintervention strategy.

Chapters 6 and 7 – Assessment of a novel conformable endograft

In **Chapter 6,** we performed a prospective single-centre study to assess the short-term position and apposition results of the Gore Excluder Conformable Endoprosthesis with active control system (CEXC). These geometric parameters were again investigated in **Chapter 7**, this time in a multicentre prospective registry. The results presented in these chapters show that the CEXC reaches ≥10 mm SAL in most patients, even in most patients with challenging aortic neck anatomy. The acquired SAL remained stable during 1 year of follow-up. The postoperative shortest fabric distance (SFD) was relatively low; thus, it is possible to position the CEXC device close to the lowest renal artery. We found no difference in SAL or SFD at the 30-day CTA for patients treated inside vs outside the instructions for use. These results might offer new opportunities for endovascular treatment of patients with a challenging aortic neck anatomy.

GENERAL DISCUSSION AND FUTURE PERSPECTIVES

One of the most important factors for the success of endovascular aneurysm repair (EVAR) is achieving a sufficient and sustainable sealing zone in the infrarenal aortic neck to prevent migration and/or type 1a endoleak.[1] This thesis emphasised the importance of infrarenal sealing zone assessment before and after EVAR. Incorporating this assessment in standard EVAR care might contribute to the prevention of sealing zone failures and subsequent aneurysm rupture. The sealing zone assessment could be used during the preoperative, postoperative, and possibly also during the intraoperative phase. In every phase, there are advantages as well as challenges concerning the implementation, which are discussed in this chapter.

Preoperative sealing zone assessment

Adequate preoperative planning is crucial in determining the most suitable surgical treatment method for patients with an abdominal aortic aneurysm (AAA).[2] Treatment options include EVAR, open surgical repair, or complex endovascular options such as fenestrated, branched, or chimney EVAR.[3] To determine the adequacy of the proximal neck, several two-dimensional measurements are performed on a vascular workstation. These measurements include neck length, neck diameter, infrarenal angulation, suprarenal angulation, neck shape, and the amount of thrombus and/or calcification.[4–6] These measurements are then compared with the instructions for use (IFU) for the endovascular devices so the most suitable treatment method can be chosen.

For a successful EVAR procedure, it is important to aim for a minimum postoperative real achieved sealing zone (RASZ) length of ≥10 mm to prevent sealing zone failures.[7,8] However, determining the RASZ preoperatively is not possible; rather, an estimate of the target anticipated sealing zone (TASZ) is made. Using the infrarenal aortic neck length as a measure for the TASZ appears to be straightforward; however, the two-dimensional neck measurements have a reciprocal influence. For example, in a patient with a >90° infrarenal angulation, a 15-mm neck length, and a conical neck shape, the TASZ will be less than the TASZ in a patient with almost no angulation, a 15-mm neck length, and a straight neck shape. Additionally, one should appreciate that the sealing zone length is not of equal length along the entire circumference of the infrarenal neck, especially in patients with challenging aortic neck anatomy.

The current thesis provided definitions for TASZ and RASZ. However, estimating the TASZ is still difficult and depends on many factors. How individual neck characteristics influence the TASZ is unclear, especially in patients with multiple challenging neck characteristics. It is possible to estimate the TASZ over the centre lumen line (CLL) or to compute the anticipated neck surface. Unfortunately, only the actual shortest apposition length (SAL) can be assessed postoperatively. This assessment is important to confirm procedural success and to establish a baseline SAL value for follow-up. A method to evaluate the three-dimensional anatomy of the aorta and to estimate the preoperative TASZ in terms of the SAL would be superior; however, this is not yet possible.

Future perspectives: preoperative application of sealing zone assessment

The use of a grading score would be a possible solution to account for multiple neck characteristics. Van Schaik et al. demonstrated that a composite aneurysm severity grading neck score was able to predict proximal endograft failure during long-term follow-up after EVAR.[9] This score, which ranges from 0 to 11, includes the neck length, neck diameter, infrarenal angulation, and presence of calcification and/or thrombus. A score of ≥5 indicates unfavourable aortic neck anatomy.[9] This score provides valuable insight in the composite risk of neck characteristics for predicting proximal endograft failure. However, the key issue, which is achieving sufficient sealing zone, is not addressed. Preoperative quantification of TASZ is important, because it not only provides the endovascular specialist with the possibility of risk stratification but could also be used to consider multiple operation methods.

Generally, the neck length is used in clinical practice to estimate the TASZ. However, this method overestimates the TASZ because it does not incorporate prosthesis- and procedure-related parameters and assumes ideal placement of the endograft, regardless of challenging anatomy. In 2022, van Veldhuizen et al. developed a statistical shape model (SSM) that captured the three-dimensional geometry of the infrarenal aortic neck.[10] This SSM describes the shape variation of the infrarenal aortic neck in unique principal shape components in a population of EVAR patients and could predict the risk for postoperative type 1a endoleaks.[11] Moreover, this SSM is currently used to create a machine learning-based preoperative decision tool that accurately predicts the preoperative TASZ in a binary fashion (SAL ≥10 mm or <10 mm).[12] Eventually, this model could be further developed and expanded to create a patient-specific virtual stenting tool that could be used in clinical practice to predict TASZ length based on the three-dimensional aortic neck anatomy, endograft type, and preferred intended oversizing. To truly develop a simulation tool for EVAR, such a model should be validated with postoperative endograft position and apposition.

Intraoperative sealing zone assessment

At the end of an EVAR procedure, a completion angiography is made to assess the technical success of the procedure and to detect (and potentially treat) endoleaks. Considering adjunctive procedures is advised if a type 1a endoleak is diagnosed intraoperatively, or in selected patients, a conservative approach could be considered, because some endoleaks might seal spontaneously.[13,14] In addition, one could consider adjunctive procedures if the sealing zone is insufficient or suboptimal. Unfortunately, assessing the infrarenal sealing zone is not possible on a two-dimensional completion angiography because only the distance between the lowest renal artery and the endograft fabric can be assessed. Intraoperative sealing zone assessment was not investigated in the current thesis; however, several relevant developments offer possibilities for the implementation of sealing zone assessment intraoperatively.

Future perspectives: intraoperative application of sealing zone assessment

Kappe et al. developed a deep learning-based endograft segmentation method for analysis of the completion angiography.[15] This method offers possibilities for assessing endograft position and enhanced detection of endoleaks. However, assessing the sealing zone remains impossible on a completion angiography. Another promising imaging method is a completion contrast-enhanced cone beam CT, which can be reconstructed during the EVAR procedure.

Cone beam CTs are most commonly known from dentistry; yet, they are also used for intraoperative guidance during complex fenestrated EVAR.[16,17] The use of cone beam CT during an EVAR procedure has been shown to detect clinically relevant endoleaks and might reduce late endograft-related complications.[18,19] Ultimately, Vascular Image Analysis (VIA) software could be applied to the intraoperative cone beam CT to assess the RASZ during the EVAR procedure. This would offer the possibility to perform adjunctive procedures if a SAL of <10 mm is found or to create a personalised follow-up scheme. On the other hand, this should be applied with caution to avoid overtreatment, because some small low-flow type 1a endoleaks might also disappear spontaneously.[13,14] Future research could investigate whether this intraoperative assessment method is feasible and whether performing adjunct procedures in patients with insufficient intraoperative RASZ without a visible type 1a endoleak is worthwhile.

Postoperative sealing zone assessment

Regular computed tomography angiographies (CTAs) are performed after EVAR to detect postoperative complications such as endoleaks and endograft migration. The current Society for Vascular Surgery (SVS) guidelines recommend CTA imaging at 1 month, after which annual duplex ultrasound (or CTA) is advised if no endoleak or sac growth is found. In addition, a CTA should be made at least every 5 years.[6] The European Society for Vascular Surgery (ESVS) guidelines recommend a more personalized follow-up scheme with a 1-month CTA, after which delayed CTA imaging is possible up to 5 years, based on risk factors such as endoleaks, sac shrinkage/growth, treatment within/outside IFU, and the RASZ (≥10 mm or <10 mm).[5] Nevertheless, in 2023 Antoniou et al. published a meta-analysis of 22,762 EVAR patients in which they compared patients who were and were not compliant with the EVAR follow-up.[20] They concluded that no difference in survival was found between the groups.[20] This could mean that regular EVAR follow-up is redundant or that not all relevant information is currently being extracted from follow-up CTAs.[21] The latter was suggested by Andersson et al., who stated that structured CTA analysis can identify most precursors of post-EVAR rupture.[22]

In this thesis, we showed that a SAL of <10 mm on the first postoperative CTA was an independent predictor for developing a late type 1a endoleak. These high-risk patients should at least be monitored closely, with frequent sealing zone assessment performed on CTAs. These results confirm evidence from previous studies by Baderkhan et al. and Bastos Gonçalves et al. that investigated sealing zone length over the CLL, which were the foundation for the ESVS guidelines.[7,8] In addition, we demonstrated that diminishing SAL is an important indicator for a future type 1a endoleak, especially if the SAL decreases <10 mm. These results are in line with a previous study by Schuurmann et al.[23] Interestingly, most patients with uncomplicated follow-up had an increasing SAL during follow-up combined with a decreasing aneurysm sac diameter. A decreasing sac diameter seems to lead to an increase in SAL, probably due to convergence of the aortic wall toward the endograft at the distal part of the infrarenal neck. Sac regression has been associated with decreased adverse events and lower mortality and morbidity rates after EVAR.[24,25] Moreover, even a stable sac is associated with higher long-term mortality.[26] Absence of sac shrinkage may be caused by undetected endoleaks or an inadequate RASZ. In addition, in the Delphi consensus that was conducted in this thesis, the European advisory board suggested reintervention be considered in patients with an insufficient or suboptimal sealing zone at the postoperative CTA and in patients with negative evolution of the sealing zone over time.

Figure 1 provides a proposed CTA assessment algorithm, based on the ESVS and SVS guidelines, the algorithm provided by Schuurmann et al., the results from this thesis, and the referred recent literature.[5,6,27] In general, each EVAR patient without contraindications (e.g., renal insufficiency) should receive a 30-day CTA and a CTA at least every 5 years to determine eventual changes in the geometry of the aortic neck and proximal part of the endograft. Each CTA should be carefully evaluated to detect endoleaks and to assess apposition (SAL), position (shortest fabric distance [SFD]), SAL/neck length ratio, aneurysm sac diameter, aortic neck diameter, and postoperative oversizing. We advise an additional 1-year CTA to assess changes in SAL, SFD, and aneurysm sac size early on and to enhance the reliability of risk stratification. For example, if a patient has sac shrinkage with increasing SAL at 1 year, future CTA follow-up could be further delayed. In patients with concerns (sac growth, SAL of <10 mm, or decreasing SAL) an additional CTA could be made to assess whether this concern remains stable or worsens and might require treatment. Also important to assess is the (change in) proximity of the endograft to the lowest renal artery, expressed as the SFD, which indicates endograft migration. If no serious concerns are present or only a type 2 endoleak is detected, annual duplex ultrasound could be used to observe aneurysm sac dynamics.

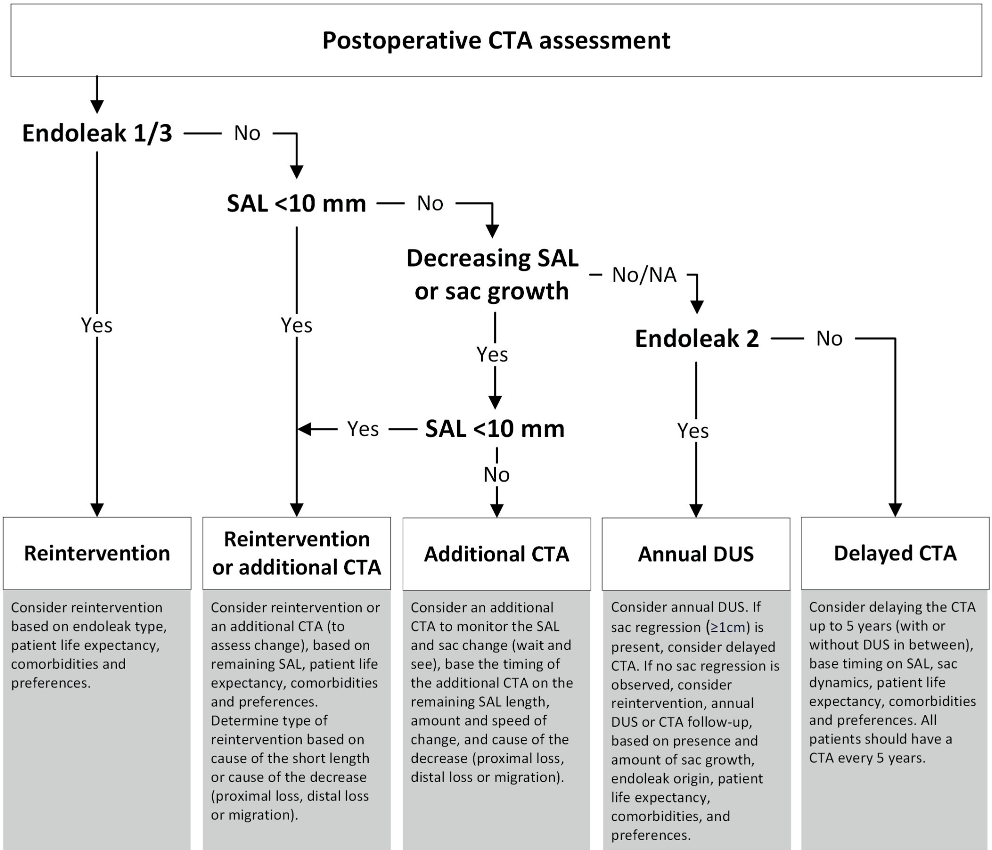

Figure 1. Proposed flowchart for postoperative computed tomography angiography (CTA) assessment, based on endoleak presence, shortest apposition length (SAL), and aneurysm sac regression. All patients without contraindications (e.g., renal insufficiency) should receive a 30-day postoperative CTA and a CTA at least every 5 years. NA = not applicable (in case of the 30-day postoperative CTA); DUS = duplex ultrasound.

There are, of course, some challenges and complexities involved in the interpretation and implementation of the flowchart in Figure 1. First, the SAL can only be calculated by using VIA software, which is not yet Conformité Européenne (CE) marked, and therefore not widely available. The best temporary solution would be to use the sealing zone length measured over the CLL, although this might overestimate the sealing zone length. A future study comparing SAL with the CLL sealing zone length could offer valuable insight regarding the added value of the SAL. Second, the cutoff value for SAL (<10 mm) is not yet evidence-based because it is based on previous studies that investigated the sealing zone length over the CLL, and device IFU. A consecutive study should be performed to determine the cutoff value for SAL, based on the risk for type 1a endoleak development. Third, performing reinterventions or intensifying follow-up based on the SAL might induce overimaging, overdiagnosis, and overtreatment of EVAR patients, which also increases health care costs, because EVAR reinterventions are relatively costly.[28] Future research should determine whether reintervention, after strict patient selection, would be beneficial in complications, mortality, morbidity, and cost-effectiveness.

As mentioned, infrarenal sealing zone assessment could be used to stratify the risk for type 1a endoleak for individual patients. Additionally, it could also be used to investigate the performance of endografts. By doing so, we showed that the Gore Excluder Conformable AAA Endoprosthesis with active control system (CEXC; W.L. Gore and Associates, Flagstaff, AZ, USA) reached adequate endograft apposition and position, which remained practically stable during short-term follow-up, even in patients with challenging aortic neck anatomy. Before conclusions can be drawn, the stability of the apposition and position should be investigated in a cohort with long-term follow-up. If reasonable long-term results are found, selected patients with challenging anatomy and multiple comorbidities might be eligible for EVAR with the CEXC. When patients with challenging neck anatomy are treated with EVAR instead of open surgical repair or fenestrated or branched EVAR, the benefits and risks for each treatment should be thoroughly considered, and patients should be well-informed about the risks. A comparative analysis of geometric factors in different endografts could help to determine the optimal endograft choice in these patients. For example, it would be interesting to compare the Excluder with the Endurant (Medtronic Cardiovascular, Santa Rosa, CA, USA), for which the forthcoming Endurant Stent Graft System vs. Excluder Endoprosthesis (ADVANCE) trial presents a promising opportunity.[29]

Future perspectives: postoperative application of sealing zone assessment

Analysis of the infrarenal sealing zone using VIA offers promising opportunities in visualizing the infrarenal sealing zone. However, implementing this software in clinical practice encounters some challenges. As mentioned, the software is not yet CE-marked, and there are still some knowledge gaps that need to be filled in. In addition, current analysis with VIA is still semiautomatic and somewhat time consuming, which might discourage vascular surgeons. The complete analysis of apposition and position by a trained observer, including preprocessing, takes approximately 10 to 15 minutes. Artificial intelligence and machine learning offer future possibilities to refine this process.[30] For example, artificial intelligence is already used to detect bone fractures or body composition on a CT scan.[31,32] Eventually, it might be possible to provide a geometric analysis on a vascular workstation with a single click of a button, but this is still a vision for the future. Another more practical solution would be to include dedicated technical physicians in the EVAR outpatient clinic or during multidisciplinary consultation to perform and interpret the analysis.

The (visual) VIA outcomes could also be used to further promote shared decision making in the consultation process before and after EVAR, especially because the choice between a wait-and-see policy or reintervention is often not clear-cut. Ubbink et al. showed that there is still room for improvement regarding shared decision making in vascular surgery and that decision support tools have been shown to improve the level of shared decision making.[33,34] The visual output of VIA could be used in the consultation room to guide the patient through the postoperative results. Ideally, a simplified infographic, combined with their own visual VIA output, could be available for patients to take into consideration.

In patients with a decreasing SAL and/or an increasing aneurysm sac diameter, the origin of this process should be investigated. This could be done by classifying the mechanism of decrease in the infrarenal neck (distal loss, proximal loss, or migration) or by identifying an endoleak on the CTA. However, in some of these patients, no endoleak is detected on regular static CTA follow-up. An explanation might be that the aortic diameter differs slightly during the cardiac cycle.[35] This aortic pulsation influences the proximal (and distal) sealing zone and results in changes in apposition during the cardiac cycle, which are not detected on static CTA images.[36] In these patients, electrocardiogram-gated or dynamic CTA might offer possibilities to accurately detect and classify endoleaks.[37,38] In addition, it would be interesting to measure SAL on dynamic CTAs to determine whether and how much the SAL changes during the cardiac cycle. Adding a dynamic CTA to the follow-up algorithm, after strict patient selection, might offer additional information to determine optimal reintervention strategies.

The current thesis focused on assessment of the infrarenal sealing zone. However, this assessment could be used beyond the scope of the infrarenal neck. The sealing zone assessment at the distal sealing zone at the iliac arteries was investigated by Goudeketting et al. and Kooijman et al. and might be equally important.[39,40] Van der Riet et al. described the assessment of the proximal sealing zone after fenestrated EVAR, as well as the geometric analysis of balloon-expandable covered stents in fenestrated EVAR.[41,42] Lastly, Van Noort et al., and Dieleman et al. demonstrated the applicability in thoracic endovascular aortic repair.[43,44] These studies show the potential future benefit of sealing zone assessment in the entire trajectory of the aorta, from the aortic arch to the iliac arteries.

CONCLUSION

This thesis emphasised the importance of careful determination of both the preoperative target anticipated sealing zone (TASZ) and the postoperative real achieved sealing zone (RASZ) in the infrarenal aortic neck. Meticulous estimation of the TASZ is important to choose the most suitable patient-tailored treatment option and to prevent complications. The RASZ can help identify patients at risk for endoleaks and potentially determine the best reintervention strategy. Therefore, the RASZ serves as a quality outcome measure that should be evaluated at each postoperative CTA. It plays a critical role in risk assessment for complications, perhaps even more so than the preoperative neck characteristics. Although there are still several challenges to overcome, the time is ripe to incorporate a structured sealing zone assessment into clinical EVAR practice.

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