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# Aortic Customize: An *In Vivo* Feasibility Study of a Percutaneous Technique for the Repair of Aortic Aneurysms Using Injectable Elastomer

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#### **KEYWORDS**

Abdominal aortic aneurysm; Aneurysm-sac filling; Endovascular aneurysm repair; In vivo study; Polydimethylsiloxane **Abstract** *Objective:* This study aimed to test a percutaneous technique for aneurysm-sac filling by means of *in situ* polymerisation in an *in vivo* model.

*Design*: Aortic Customize is a new endovascular treatment concept for aortic aneurysms: a non-cross-linked liquid elastomer is injected to fill the aneurysm sac around a balloon-catheter. With this method, a compliant elastomer mould with a patent lumen is created.

*Material*: The formulation used in the experiments consisted of a two-component additioncure liquid-silicone formulation, based on vinyl-terminated polydimethylsiloxane (PDMS).

*Methods:* The concept of aneurysm-sac filling was tested *in vivo* in porcine experiments (n = 3). *Results:* In vivo porcine experiments with the sac-filling application showed successful exclusion of the created aneurysms with patent lumens and absence of endoleaks. The aneurysms were excluded successfully in the *in vivo* model, injecting elastomer through a 7-French catheter, filling up the entire aneurysm sac.

*Conclusions*: These *in vivo* experiments demonstrate that the principle of aneurysm-sac filling by means of *in situ* curing is feasible, excluding the aneurysm and creating a new lumen. Further long-term animal experiments must be done prior to consideration of clinical application. © 2010 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved.

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Endovascular repair of aortic aneurysms has evolved into a widely used technique. Large multicentre studies have shown clear advantages of this less invasive technique over conventional open repair.<sup>1,2</sup> However, with the more widespread use, disadvantages have also become more evident. Complications and re-interventions caused mainly by endoleaks, endotension, stent-graft migration and device failure are of major concern.<sup>3,4</sup> Due to anatomical restrictions, endovascular aneurysm repair (EVAR) is not available for each patient with an abdominal aortic aneurysm (AAA). Manufacturers of commercially available EVARgrafts state that an infra-renal aneurysm neck of at least 15 mm is needed to ensure a strong proximal seal, and tortuous anatomy is a (relative) contraindication. A study from Timaran et al. has shown that, with 27% of AAAs, the anatomy of the aneurysm makes it unsuitable for EVAR because of insufficient neck length, large neck diameter or severe angulation.<sup>5</sup> These problems are less manifest with fenestrated or branched EVAR-grafts, although the use of these grafts is not always possible.

Often, arterial cut-down of the femoral arteries is necessary, as bulky delivery devices with an external diameter of 12–16 French (Fr) have difficulties passing the stent through arteriosclerotic, stenotic and, often, elongated iliac vessels. The inguinal incisions can cause seroma, haematoma or wound infection, adding morbidity to the procedure.<sup>6,7</sup>

To overcome these disadvantages, 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). The non-cross-linked liquid elastomer is used to fill the aneurysm sac around a balloon-catheter. An endoluminal mould fills up the aneurysm sac after *in situ* polymerisation. With this method, an elastomer cuff with a patent lumen is created.

An earlier study in an *in vitro* circulation model by our group has shown that filling an aneurysm sac with an injectable biocompatible elastomer brings about a reduction in the wall stress.<sup>8</sup> With this reduction in wall stress, a reduction in rupture risk is achieved, since aneurysm rupture occurs when the local wall stress exceeds the local wall strength.<sup>9,10</sup>

This study aimed to test the treatment concept of aneurysm-sac filling in an *in vivo* porcine model.

### Materials and methods

#### The elastomer

The formulation used in the experiments consisted of a two-component room-temperature addition-cure liquidsilicone formulation, obtained from Viazym BV (ViaZym BV; Delft, the Netherlands). The two components consist of:

• A platinum containing vinyl-terminated polydimethylsiloxane (PDMS) with an optimised molecular weight with regard to viscosity versus mechanical properties of the cured end-product (elongation to break, modulus). This component further contains surface-treated amorphous silica and a sesquisiloxanelike material known as Vinyl Q, which is known to increase tear-strength of the final cured elastomer without much increase in viscosity

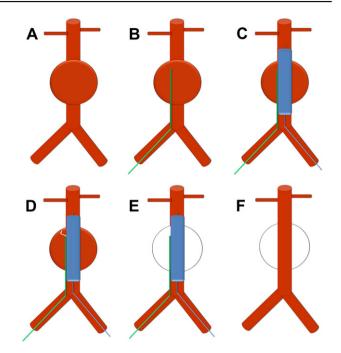


Figure 1 Aortic Customize, the treatment concept: (A) A schematic drawing of an abdominal aortic aneurysm, (B) A fill catheter is inserted through a femoral artery, (C) An endovascular balloon excludes the aneurysm from the circulation, (D) The two components of the elastomer are pumped in the excluded aneurysm. Excess blood is pushed out alongside the balloon, (E) After the aneurysm is filled, the elastomer takes 5 min to cure, (F) When the elastomer has cured, the endovascular balloon is deflated, leaving the aneurysm excluded with a new lumen.

 A methylhydro-dimethyl-siloxane co-polymer containing vinyl-terminated PDMS. This component further contains surface-treated amorphous silica and Vinyl Q.

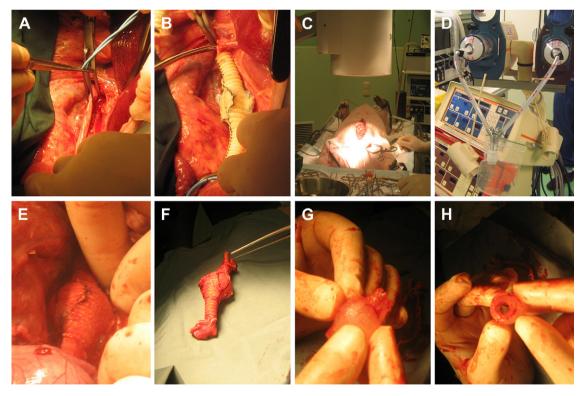
Silicone-based elastomers meet the requirements of blood compatibility and have been successfully used in intra-vascular applications by others.<sup>11–16</sup> The material is non-toxic and cross-links isothermically in the presence of blood, without the release of toxic by-products. The viscosity of the compound allowed infusion rates of up to 2 mL s<sup>-1</sup> using a standard angiographic pump with an injection pressure of up to 1200 pounds per square inch. The substance has an average polymerisation time of ~5 min. After curing, the material had a yield-stress of ~400 kiloPascal (kPa), failing at >20% elongation. The density of the cured elastomer is 1.0167 g cm<sup>-3</sup>.

A cast of the material with the added cross-linker and filler has been subjected to fatigue tests at 21 cycles  $s^{-1}$  with stresses comparable to the stresses in the human aorta. No signs of material failure or tear have been observed after 1 month, which is comparable to an exposure of 18 years in a circulation with a mean frequency of 70 beats min<sup>-1</sup>.

### In vivo porcine experiment

After selection of the ideal composition of the elastomer, the concept of sac filling through a small-calibre catheter was tested. Earlier experiments in a circulation set-up had shown the feasibility of the treatment concept in a dynamic *in vitro* set-up.<sup>8</sup>

To investigate the *in vivo* feasibility of the treatment concept, three *in vivo* porcine experiments were conducted. The animal experiment has been approved by the animal ethical committee of the Maastricht University Medical Centre. Three separate aneurysms were created by stitching ellipse-formed polyester patches in longitudinal incisions in polyester-tube grafts. The aneurysms were 75-mm long and had a neck and sac diameter of 8 mm and 25 mm, respectively. In the adult pigs (weight range: 45-55 kg), general anaesthesia was induced and, following this, the abdomen was prepared in a sterile manner and opened through a midline incision. The aorta was exposed from the renal arteries to the trifurcation. Heparin was not administered. Non-traumatic vascular clamps were used to clamp the aorta below the renal arteries and above the trifurcation. The aorta was transected and a 7-cm segment was excised. The polyester aneurysm was sewn end-to-end into the defect with 4/ 0 running prolene sutures (Ethicon, Somerville, NJ, USA) (Fig. 2A and B). Circulation was restored and haemostasis was achieved. The abdomen was not closed, allowing direct observation of the treatment concept (Fig. 2D). Following this, bilateral incisions were made in the groin and the femoral arteries were exposed. Through an arteriotomy in the left femoral artery, a 7-Fr catheter (Boston Scientific, Natick, USA) was placed in the aneurysm sac and a control angiogram was made with standard radiographic contrast (Omnipague, GE Healthcare, Fairfield, USA), showing no leakages from the sac or the attachment sites. Through the contralateral femoral artery, a 7-Fr catheter with an 8  $\times$  100 mm endovascular balloon (Cordis Corporation, New Brunswick, USA) was inserted and placed in the aneurysm, just below the renal arteries. The balloon was inflated with a mixture of saline solution and radiographic contrast (Omnipaque, GE Healthcare, Fairfield, USA), thereby excluding the aneurysm from the circulation. A standard angiographic pump, containing a cassette with the elastomer, was connected to the catheter in the left femoral artery (Fig. 2C). The excluded aneurysm was filled with the elastomer, replacing the contrast in the aneurysm. The aneurysms were filled with  $\pm 6.1$  mL of elastomer [= (volume aneurysm sac - volume of the balloon) + 5%]. The elastomer was given 5 min to cure, after which the balloon was deflated and circulation was restored. We considered the treatment successful if the sac was excluded from the circulation, while the peripheral arteries were still perfused. Control angiograms were carried out to see that the aneurysms were treated successfully and were free from contrast. After the experiments, the pigs were observed for 30 min, following which they were sacrificed and the aneurysms were retrieved and inspected.



**Figure 2** The porcine experiments: a porcine aorta was ligated (A) and replaced by a hand made polyester aneurysm (B). After placing the aneurysm, a fill catheter and an endovascular balloon were inserted through an entrance in the femoral arteries (C), The aneurysm sac was excluded from the circulation by pumping up the endovascular balloon. The two components were loaded in an angiographic pump (D), which was attached to the 7 Fr fill catheter. The excluded aneurysm sac was filled with the elastomer, which cured in less then 5 min (E). After the successful exclusion the specimen was terminated and the excluded aneurysm was harvested (F). From the polyester aneurysm sac a perfect elastomer mould was harvested (G), with a patent lumen at the place of the endovascular balloon (H).

## Results

The polyester aneurysms were inserted successfully in the porcine aortae (Fig. 2A and B). Pre-treatment angiograms showed no leakages from the aneurysm (Fig. 3) or its anastamoses. The aneurysms were successfully excluded from the circulation with the balloon, after which the sacs were filled with the elastomer through the 7-Fr catheter (Figs. 2 and 3).

After 5 min, the elastomer had cured and the balloon was deflated, leaving a patent lumen. Control angiograms showed a straight, patent lumen. The aneurysm sac was excluded as there was no contrast or palpable pulsations in the former aneurysm sac. Pulsations, however, were present in the pigs' hind legs.

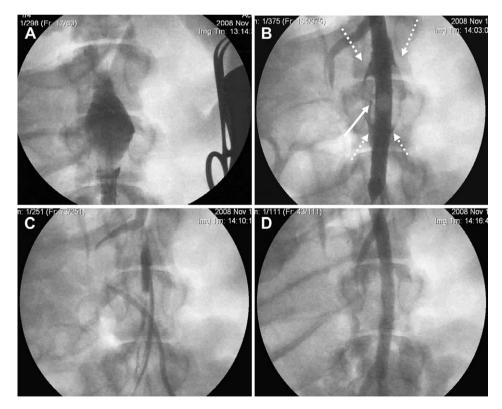
Dissection of the aneurysms, after euthanisation of the animals, showed that the sac was completely filled by the elastomer, with a patent lumen at the site of the balloon (Fig. 2E-H).

## Discussion

The concept of filling the sac of an abdominal aneurysm with a biocompatible elastomer is a new treatment option, offering several advantages over conventional and endovascular techniques. These *in vivo* experiments show that it is feasible to achieve complete exclusion of the aneurysm with our new technique, using only a 7-Fr catheter and sheath.

In a recent in vitro study, Barnett et al. also described a treatment concept in which the aneurysm sac is filled with a liquid polymer.<sup>17</sup> In their *in vitro* study, they use hydrogels such as EmboGel and UltraGel to fill the aneurvsm sac around an endovascular stent. EmboGel is a mixture of iohexol and alginate, while UltraGel consists of Irgacure, iohexol and polyethylene glycol diacrylate. In the search for a polymer solution for aneurysm-sac filling, we considered the use of alginates and acrylates. However, these substances did not meet our specifications with regard to durability; both materials are applied in the form of a biodegradable hydrogel,<sup>18,19</sup> which is undesirable as the implant is expected to stay in place for many years. In addition to the unfavourable bio-stability of the hydrogelbased solutions, these materials possess insufficient inherent strength and, therefore, need an additional endovascular stent to stabilise the aneurysm wall when used as sac-filling. This will still necessitates a bulky device in order to insert the graft in the aneurysm sac, thereby losing the advantage of a percutaneous approach.

Low elastic modulus of the implant, preferably matching that of a healthy aorta  $(1.18 \pm 0.21 \text{ MPa})$ ,<sup>20</sup> is only possible with a small number of elastomers, PDMS being among the most versatile, the most biocompatible, non-biodegradable



**Figure 3** Angiographic recordings of the porcine experiment. Adding contrast to the circulation shows the successfully inserted polyester aneurysm (A). After placing a 7 Fr fill catheter, the aneurysm was excluded by an  $\bigotimes$  8 mm contrast filled endovascular balloon. Through the 7 Fr catheter (arrow), the viscose elastomer was pumped in the aneurysm sac, pushing away the present contrast (dotted arrows) (B), When the aneurysm sac was entirely filled and the elastomer had cured, the endovascular balloon was deflated and extracted (C), Control angiography showed an excluded aneurysm sac with a patent straight lumen (D), No endoleaks or elastomer embolisms were detected.

and most documented examples used in (bio-)medical applications.  $^{\rm 11-16}$ 

#### Benefits of new technique

Although the results are quite preliminary, the concept of aneurysm-sac filling has a number of hypothetical advantages compared to the current EVAR-techniques. The major complication of EVAR is endoleak after the placement of the EVAR graft. We expect that the sac-filling technique is free of type II endoleaks (branch-vessel leakage) because, similar to the aneurysm sac, branch-vessels will be occluded by the elastomer. Type III endoleaks are not likely to occur as the mould is cast in one piece and there is no graft material in which tears can occur. As the material is non-porous, type IV endoleak is not likely to occur.

With the current generation of EVAR-grafts, angulation of the AAA neck is an important excluding factor for treatment. When endovascular balloons will be available in different kinds of form and configuration, in theory, any AAA with a deviant anatomy will become treatable. With current EVAR-techniques, severe angulation may lead to endoleaks<sup>21–23</sup> and to kinking of the graft material and eventually to migration of the graft.<sup>23–25</sup> The fluidity of the non-polymerised elastomer inherently causes adjustment to the geometry of the aneurysm, not only by filling the large aneurysm sac but also by diffusing into all irregularities and side-holes. The elastomer mould will fixate itself as it customizes itself to the form of the AAA sac.

Another important exclusion criterion for the current EVAR therapy is strong tortuosity or occlusive disease of the iliac arteries. Many stent-grafts need a minimal diameter of 12-16 Fr for access of the bulky delivery sheath. To fill the sac with the biocompatible elastomer, a fill catheter with minimal diameter of 7 Fr needs to be introduced into the aneurysm sac through the femoral or brachial artery.

In addition to the treatment concept as depicted in Fig. 1, the elastomer and injection-technique are more broadly applicable. The elastomer can already be used as an adjuvant with current stent-grafts when problems of endoleak or migration occur. In these cases, the elastomer can be used to fill-up the aneurysm sac and secure the endovascular stent-graft.<sup>26</sup>

## Potential limitations of technique

Despite the potential benefits, the treatment option might have other shortcomings. Although we did not observe this in our *in vivo* and *in vitro* experiments, type I endoleaks may still occur at the junction-sites of the elastomer mould and the native vessel-wall. However, the addition of conventional stents might still be an option to repair this. Furthermore, it is not desirable to have leakage of the fluid elastomer (before the cross-linking) to the peripheral vessels (e.g., renal arteries), as this might act as an arterial embolus. During the filling procedure, the aneurysm sac is excluded from the circulation, below the renal arteries. In the various *in vitro* and *in vivo* experiments we conducted, there was no visible sign of leakage of the elastomer to distal areas, along the side of the balloon.<sup>8</sup> However, it could still be possible that small invisible fragments, indeed, leaked away. Intensive *in vivo* animal experiments will have to be done to exclude this potential disadvantage. The amount of elastomer which has to be used can be calculated from preoperative computerised tomography (CT) scan volume measurements, thereby preventing potential 'overfilling' of the sac, which may lead to leakage.

Another theoretical disadvantage is that, during the filling of the sac, the pressure may increase in such a way that the AAA sac is at risk of rupture. If, indeed, such a rupture does occur, it will in all probability be sealed directly by the curing elastomer. The potential rupture might then not be relevant anymore, as it is directly treated and excluded from the circulation.

Animal experiments are necessary to prove the longterm success of the treatment concept. At this moment, we do not yet know how the aneurysm sac will react to the elastomer filling *in vivo*. It is not clear if the sac will continue to dilate after elastomer filling or that the present thrombus will break down, creating new open spaces in the aneurysm sac. Experimenters will have to investigate whether this might lead to clinically relevant problems.

All these hypothetical benefits and potential shortcomings will have to be investigated before clinical application can be considered.

#### Perspective

In earlier *in vitro* research, we have shown that filling the aneurysm sac with elastomer clearly decreases the amount of wall stress. In a circulation model, a latex aneurysm was successfully treated with elastomer, reducing the wall stress from 15.6 N cm<sup>-2</sup> before sac-filling to 1.1 N cm<sup>-2</sup>after sac-filling.<sup>8</sup>

Prior to its clinical application, the focus will have to be on the long-term results of the aneurysm exclusion and on the development of new endovascular balloons. For example, to treat aneurysms of all different morphologies, it will be necessary to be able to place kissing balloons with a perfect seal between each other.

Following these successful *in vivo* experiments, we will conduct further animal and *in vitro* experiments, testing this novel treatment concept, eventually leading to its clinical use in treating aortic aneurysms.

## Conclusion

The technique of aortic customizing offers a whole new approach to treating aneurysmatic disease of the abdominal aorta. Advantages are the percutaneous approach, absence of (types II–IV) endoleaks and impossibility of kinking or migration of the graft. Therefore, it circumvents most major problems associated with currently available stent-grafts. This *in vivo* study shows that treatment concept is feasible and it potentially offers a custom-made treatment for the majority of arterial aneurysms. However, clinical application of this sac-filling technique is still an unproven modality and long-term animal research needs to be done.

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## Conflict of interest

A.C. de Vries, H.L. Brom and M.J. Jacobs are patent holders of the elastomer formula used in the experiments. All other authors have no conflict of interest to report.

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