**In vitro investigation of a novel elastic vascular prosthesis for valve-sparing aortic root and ascending aorta replacement**

Michael Scharfschwerdt\(^a\), Moritz Leonhard\(^a\), Judith Lehmann\(^a\), Doreen Richardt\(^a\), Helmut Goldmann\(^a\) and Hans-Hinrich Sievers\(^a,b,*\)

\(^a\) Department of Cardiac Surgery, University Clinic of Schleswig-Holstein, Lübeck, Germany
\(^b\) Department of Cardiac and Thoracic Vascular Surgery, University of Lübeck, Lübeck, Germany

* Corresponding author. Department of Cardiac and Thoracic Vascular Surgery, University of Lübeck, Campus Lübeck, Ratzeburger Allee 160, Lübeck 23538, Germany. Tel: +49-451-5002108; fax: +49-451-5002051; e-mail: hans-hinrich.sievers@uksh.de (H.-H. Sievers).

Received 23 July 2015; received in revised form 28 September 2015; accepted 15 October 2015

**Abstract**

**OBJECTIVES:** Prosthetic replacement of the thoracic aorta with common Dacron prostheses impairs the aortic ‘windkessel’ and, in valve-sparing procedures, also aortic valve function. Elastic graft material may overcome these deficiencies.

**METHODS:** Fresh porcine aortas including the root were set up in a mock circulation before and after replacement of the ascending part with a novel vascular prosthesis providing elastic behaviours. In a first series (\(n = 14\)), haemodynamics and leaflet motions of the aortic valve were investigated and also cyclic changes of aortic dimensions at different levels of the root. In a second series (\(n = 7\)), intravascular pressure and dimensions of the proximal descending aorta were measured and the corresponding wall tension was calculated.

**RESULTS:** Haemodynamics of the aortic valve remain comparable after replacement. Though the novel prosthesis does not feature such high distensibility as the native aorta, the dynamic of the root was significantly increased compared with common Dacron prostheses at the commissural level, preserving ‘windkessel’ function. Thus, wall tension of the residual aorta remained unchanged; nevertheless, maximum pressure–time differential \(dp/\text{dt}\) increased by 13%.

**CONCLUSIONS:** The use of the novel elastic prosthesis for replacement of the ascending aorta seems to be beneficial, especially with regard to the preservation of the aortic windkessel. Further studies will be needed to clarify long-term utilization of the material in vivo.

**Keywords:** Aorta, thoracic • Blood pressure • Blood vessel prosthesis • Blood vessel prosthesis implantation • Elasticity • Polyurethane

**INTRODUCTION**

Certain pathologies, such as the idiopathic cystic medial degeneration, atherosclerosis or the Marfan syndrome, lead to aortic aneurysms or dissections, which, in severe cases, require the replacement of the related parts of the aorta. Rebuilding aortic surgery with artificial grafts, including valve-sparing procedures, was performed for many years [1–3], providing satisfactory long-term results [4, 5].

Though the acute problem of the patient is solved by such procedures, commonly applied woven Dacron grafts do not reconstitute functional properties of the natural aorta such as the aortic ‘windkessel’. The lack of distensibility of the prostheses used for aortic replacement impairs aortic valve function (in valve-sparing procedures) [6] as well as the pressure load of the residual aorta [7–9] and the left ventricle [10]. The non-compliant material causes a local loss of the vessel’s volume storage capacity, which results in an augmentation of systolic pressure. Also, a significant increase of maximum pressure–time differential \((dp/\text{dt})\) could be observed [7, 9] while the blood passes the stiff region. Regarding the post-procedural aortic valve performance in valve-sparing techniques, valve opening was restricted by a stiff prosthesis, increasing transvalvular pressure gradients and bending deformation of the leaflets [6].

One might assume that reconstruction of the aorta with an elastic material would overcome these deficiencies. In this manner, results from, for example, homograft aortic treatment were encouraging [11, 12], but durability was questionable. Artificial materials, on the other hand, often do not provide haemocompatibility (e.g. latex rubber or silicone) or adequate mechanical properties [13, 14]. In this study, a novel vascular prosthesis made of biocompatible polyurethane with suitable elastic properties was introduced, at which *in vitro* haemodynamics, aortic valve function and aortic pressures in valve-sparing aortic replacement were evaluated.

**METHODS**

The novel vascular prosthesis was designed in cooperation with Aesculap AG, Tuttingen, Germany. The prosthesis was built of a company’s polyester–urethane polymer (PUR), which is currently applied in reconstructive patch angioplasty of, for example, the carotid artery, providing haemocompatibility, long-term stability.
and present elastic properties which can be forced to a vessel-like behaviour. Prosthesis diameters were 26, 28 and 30 mm, adapted to the size of the porcine roots and aortas. Prostheses were used both straight tubular and with incorporated bulbed sinuses for aortic root replacement (Fig. 1). Wall thickness of the prostheses ranged from 0.46 to 0.49 mm.

**Experimental set-up**

Haemodynamic investigations were performed in a flow simulator, details of which have been described previously [15]. Two different set-ups were used. In a first series, aortic valve behaviours after prosthetic root replacement were investigated following a protocol described by Erasmi et al. [6]. In brief, aortic roots were dissected from fresh porcine hearts leaving a short rim of ventricular muscle at which a piece of Dacron prosthesis was sutured for fixation of the root to the inflow spigot. The aorta was cut at the height of the first supra-aortic branch, the outflow spigot was fixed distally and the root was mounted inside the test circuit for primary haemodynamic measurements. Afterwards, the aorta and sinuses were resected, aortic replacement was performed with the PUR prosthesis using the reimplantation technique and measurements were repeated. Figure 2 shows a photograph of such set-up. For comparison, some roots were also replaced with common Dacron prostheses.

In the second series, aortic pressure, dynamic aortic diameter and residual aortic wall tension were investigated. For this purpose, the porcine aortas were left entirely, including the arch and descending aorta, shortened to a length of ~15 cm distal to the left subclavian artery. Supra-aortic branches were ligated. The aortas were prepared for mounting as described above and placed inside the test circuit in a fluid reservoir to keep it moist. Measurements were performed as specified in a former investigation [9]. After the ascending aorta was cut and replaced with the novel prosthesis using the reimplantation technique, the graft was distally connected to the aortic arch and measurements were run again.

**Data acquisition and analysis**

For the first series, pressure measurements were performed using Envec Ceracore M pressure transducers (Endress + Hauser, Maulburg, Germany) at the inflow and outflow spigots. The flow through the valves was measured with a ME13PXN ultrasonic flow probe (Transonic Systems, Inc., Ithaca, NY, USA). Data were collected digitally at a rate of 500 samples per second, and transvalvular pressure gradients as well as regurgitant volumes were determined as required in the ISO 5840 [16]. Ultrasonic micrometric transceiver/receiver crystals (Sonometrics Corp., London, ON, Canada) were used to measure root diameters at the sinotubular junction (STJ), commissural (COM) and mid-sinus level (SIN), respectively, at peak systolic and end-diastolic pressures representing roughly maximal and minimal diameter. Root distensibility was presented as the total percentage diameter change referenced to the value at end-diastole. Aortic valve opening and closing were recorded with a Motionscope HR-1000 high-speed camera (Redlake Imaging Corp., Morgan Hill, CA, USA) positioned straight above the valve at a rate of 500 frames per second. Video data were digitized and analysed using a custom-made motion evaluation software. Open cusp-bending deformations were quantified from the largest observed fold at which the ratio of the fold depth and the shortest fold edge was used as a cusp-bending deformation index [6].

In the second series, aortic diameters were measured by the ultrasonic micrometers placed around the proximal descending aorta 1 cm distal to the left subclavian artery. At the same position, a microtip catheter pressure transducer (Millar Instruments, Inc., Houston, TX, USA) was inserted into the central lumen of the vessel to determine aortic pressures. From the recordings, wall tension was calculated using the Laplace’s law ($T = p \cdot d/2 \cdot w$, where $T$ is wall tension, $p$ pressure, $d$ diameter and $w$ wall thickness).

---

**Figure 1:** Photograph of the novel prosthesis, demonstrating a sinus configuration for valve-sparing aortic root and ascending aortic replacement.

**Figure 2:** Photograph of the novel prosthesis on a porcine aortic root, mounted inside the test apparatus and pressurized. SL: suture line of the aortic valve reimplantation; UM: position of the ultrasonic micrometers.
Measurements and statistical analysis

In the first series, 14 aortic roots were investigated and 7 aortas in the second series. Tests were done either native and after prosthetic replacement of the ascending aorta at a heart rate of 64 cycles per minute with a stroke volume of 65 ml for a systemic pressure of 125/80 mmHg. Peripheral resistance and remote vascular compliance were set to physiological values. Data were collected from 10 consecutive cycles each and expressed as mean ± the standard deviation of the mean. Statistical analysis was performed by comparison of the means using the paired t-test, except for root distensibility comparison between polyurethane and common prostheses, which was performed by the independent samples t-test. P-values of <0.05 were considered to be significant. Statistical power analysis was performed to prove significance of the test; value was 0.97–0.98 for the first series and 0.72 for the second series.

RESULTS

Table 1 depicts the results of the haemodynamic measurements from the first series. After prosthetic replacement with the novel PUR prosthesis, haemodynamics of the aortic valve remained unchanged in comparison with the native condition, except for the valve’s closing volume, which was slightly decreased. Root distensibility decreased with the novel prosthesis and common prostheses likewise (Table 2) at all levels compared with the native root, but remained twice as much at the COM level with the PUR prosthesis (5.5 vs 2.1% with common prostheses, P < 0.001). With regard to the minor systolic expansion, cusp-bending deformation increased, but less pronounced as observed in classical reimplantation procedures [6].

Peak systolic pressure and thus residual aortic diameter and calculated aortic wall tension showed no significant changes after PUR replacement; nevertheless, the pressure-time differential still increased by ~13% (Table 3).

DISCUSSION

In the study, a novel aortic prosthesis with elastic behaviours was demonstrated, which can be applied in aortic replacement procedures and thus may be an alternative to common vascular prostheses.

There is no doubt that the present aortic repair with the usually applied Dacron or PTFE grafts was state of the art, providing satisfactory long-term results in patients [4, 5]. Nevertheless, some deficiencies have to be taken into account. Commonly applied grafts do not reconstitute the functional properties of the natural aorta due to the lack of distensibility of the prostheses. The resulting local loss of the ‘windkessel’ function (in explanation, the volume storage and distribution capacity of the particular vessel’s segment) provokes an additional pressure load to the residual aorta [7–9] and the left ventricle [10]. In valve-sparing procedures, also aortic valve function is impaired, depending on the degree of prosthetic bondage of the aortic root [6]. In this regard, preservation of aortic elasticity should be recommended in rebuilding surgery, but appropriate materials are difficult to find. Most of the elastic polymers do not feature blood compatibility and mechanical properties are also not adequate. The prosthesis used in this study was made of a specific polyester-urethane, which provides both haemocompatibility and suitable elastic behaviours. To investigate the utility of the prosthesis, in vitro measurements were performed in different set-ups which were applied in former investigation of the subjects [6, 9].

Haemodynamics of the aortic valve remained mostly unchanged after ascending aorta and aortic root replacement with the novel prosthesis. This result favourably indicated a less restriction of systolic valve outward movement compared with common woven or knitted Dacron prosthesis, due to the elastic properties of the polyurethane. In the study, a basic reimplantation technique was used for root replacement, because of its ability to well stabilize the aortic annulus [17], also ordinary prosthesis diameters were applied; in such a configuration, post-procedural pressure gradients are usually elevated [6]. Only closing volume was slightly decreased, which can be observed for most valve-sparing aortic replacement procedures, but it seems to be without clinical relevance.

With the polyurethane prosthesis, the aortic ‘windkessel’ function could be well preserved. While in the wake of standard

<table>
<thead>
<tr>
<th>Table 2: Root distensibility in native state and after replacement with the novel polyurethane prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native (n = 14)</td>
</tr>
<tr>
<td>STJ</td>
</tr>
<tr>
<td>COM</td>
</tr>
<tr>
<td>SIN</td>
</tr>
</tbody>
</table>

The right column shows values from a common prosthesis for comparison.

STJ: sinotubular junction; COM: commissural; SIN: mid-sinus level.

<table>
<thead>
<tr>
<th>Table 3: Systolic aortic pressure (AP sys), maximum pressure-time differential (dp/dt max) and calculated descending aortic wall tension in native state and after replacement with the new polyurethane prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native (n = 7)</td>
</tr>
<tr>
<td>AP sys (mmHg)</td>
</tr>
<tr>
<td>dp/dt max (mmHg/s)</td>
</tr>
<tr>
<td>Wall tension (kPa)</td>
</tr>
</tbody>
</table>

TVP: transvalvular pressure gradient; BDI: bending deformation index.
replacement of the ascending aorta, a significant augmentation of systolic aortic pressure amplitude can be observed which increases residual aortic wall tension [7, 9] and pressure load of the left ventricle [10], values remained unchanged with the elastic prosthesis. However, a slightly increase in pressure-time differential was found, but much less than observed in standard applications (13 vs 36 and 43%, respectively) [7, 9]. These findings may be beneficial especially for patients with residual aortic pathologies.

Indeed, the novel prosthesis did not completely replicate native aortic properties. Root distensibility significantly decreased at STJ, COM and sinus level. This was an expected finding regarding the rather sigmoid pressure-strain relationship of the prosthesis compared with the exponential course of the native aorta, which of course implies a stiffer behaviour of the prosthesis at standard physiological pressures. Nevertheless, prosthetic root dynamics were superior to common prostheses at STJ and particular COM level at which systolic expansion was twice as much with the PUR prosthesis. Thus, valve-opening characteristics would be less influenced than that observed in other procedures. In fact, changes in leaflet cyclic motions are frequently described with root replacement [18–20] and also leaflet distortion, which was associated with root stiffening [6, 20]. In a healthy native root, COM distance increases by ~14% or more during systole, providing sufficient space to keep the leaflet free edges smooth in open position. By the application of a Dacron prosthesis, the outward movement of the leaflet attachment was reduced down to 2% with the classical reimplantation technique and the redundant leaflet tissue provokes wrinkling and folding the leaflet's edge which may elevate bending stress. Because distensibility of the root was somewhat preserved with the novel prosthesis, cusp-bending deformation was reduced in comparison with a common reimplantation [6].

An interesting finding during the experiments was that the integrated bulbed sinuses had proved to be essential for such elastic roots. In preliminary measurements with cylindrical grafts, some kind of leaflet trapping could be observed in 2 of 5 cases, which was that one of the leaflets was closely attached to the prosthesis wall during systole and thus valve closure was delayed. This phenomenon does not occur in non-compliant grafts. In such case, the leaflets free edge length always overestimates the circumference of the tube between the commissures, whereby the leaflets touch the prosthesis wall in folds, thus leaving sufficient space behind. In the new prosthesis, an adequate distance between leaflet and prosthesis wall is well preserved by the sinus configuration.

There are some limitations to this study. Experiments were performed in an in vitro set-up which may not completely reproduce the physiological conditions. The tissue of the porcine roots and aortas has functional characteristics that differ from those of diseased tissue of a patient, which could alter measurements. Also, we did not use blood but saline water whose different viscosity features may have influenced valve motions and bending deformation. However, former investigations with this set-up demonstrated good accordance with findings in vivo. At least, tissue interactions of the prosthesis material, which might diminish distensibility of the prosthesis in vivo, are actually not investigated. Further animal studies will provide more information about this item and the like.

In conclusion, the application of the novel elastic prosthesis for replacement of the ascending aorta is a feasible option and seems to be beneficial, especially with regard to the preservation of the aortic ‘windkessel’. Further studies are ongoing to clarify long-term utilization of the material in vivo.

Funding
This project was supported by the German Federal Ministry of Education and Research (grant no. 13EZ1110).

Conflict of interest: none declared.

REFERENCES