A New Sinus Prosthesis for Aortic Valve-Sparing Surgery Maintaining the Shape of the Root at Systemic Pressure

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Purpose. **We describe a new prosthetic graft aiming to restore normal valve configuration in systemic circulation. In vitro evaluation data and first clinical results are presented.**

Description. **The aortic valve consists of three separate leaflets and sinuses of Valsalva interconnected through three straight interleaflet triangles. This shape has important implications on valve function.**

Evaluation. **In vitro tests showed nearly normal hemodynamics, although root distensibility was decreased and bending deformation of the leaflets was increased due to the nonflexibility of the graft material. However, the anatomical shape of the aortic root was well preserved in vitro and also in vivo without contact of leaflets to the prosthesis wall.**

Conclusions. **This new sinus prosthesis maintains normal configuration of the aortic root with three distinct sinuses of Valsalva and straight commissural pillars in systemic circulation. The noncompliant material induces abnormal leaflet bending during systole, but leaflets do not collide with the wall of prosthesis.**

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Aortic valve-sparing root reconstruction has emerged as an appealing procedure for patients with root aneurysm and macroscopically intact aortic valve leaflets, intending to overcome the shortcomings of prosthetic valve substitutes. Principally two techniques are applied, namely the remodeling method according to Sarsam and Yacoub [1], and the reimplantation technique according to David and Feindel [2], with certain modifications according to Miller [3]. In brief, the remodeling method implies the sole replacement of the sinuses of Valsalva by Dacron tissue from a tube prosthesis, whereas the reimplantation technique confines the aortic valve in a tube graft.

It is well known that the sinuses of Valsalva have a positive effect on leaflet stress reduction, [4] and if integrated in the prosthetic tube used for root replacement, the bulbed sinuses of Valsalva could prevent leaflets from contacting the prosthetic wall during systole [5]. Because naturally shaped separate sinuses are difficult to achieve in the reimplantation technique, modifications of the technique and special prostheses have been developed, providing some kind of sinus [3, 6]. However, these grafts have a tube-like configuration and may not completely resemble the shape of the aortic root. In this study, we introduce a new prosthesis type by incorporating separate sinuses and also straight pillars of the interleaflet triangles. In vitro and first clinical results are presented.

Technology

The commercially available sinus prosthesis (B/Braun AG, Tuttlingen, Germany) consists of a circular base annulus, three separate naturally shaped sinuses of Valsalva and 3 straight interleaflet triangles, followed by a tube graft for potential replacement of the ascending aorta (Fig 1).

Technique

The in-vitro experiments were performed as follows: After excision of the sinuses of Valsalva of a fresh pig heart, the aortic valve was reimplanted into a size-matched sinus prosthesis (diameter, 30 mm) using multiple subvalvular U-stitches with Teflon pledges and a continuous monofilament suture for attaching the valve

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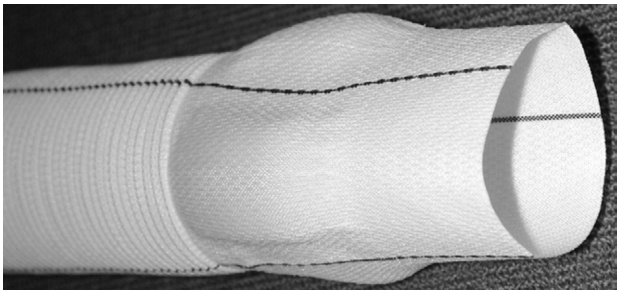

Fig 1. Photograph of the new sinus prosthesis demonstrating naturally shaped sinuses and straight commissural pillars.

to the prosthesis as routinely performed in clinical practice.

Seven of these reconstructed roots were tested in a pulse duplicator and were compared with the native aortic roots as previously described [7]. In brief, a special visco-elastic resistance module in the pulse duplicator serves to closely imitate the natural pulse wave form. Hemodynamic measurements were made in pulsatile conditions ejecting 58 mL of saline water with a pulse rate of 64 beats per minute for a systemic pressure of 125/80 mm Hg. Pressure gradients were measured between the left ventricular outflow tract and three diameters distal to the aortic valve using Envec Ceracore M pressure transducers (Endress + Hauser, Maulburg, Germany). Flow was determined with a TS-410 ultrasonic flow-meter (Transonic Systems Inc, Ithaca, NY) for closing and leakage volumes. The diameters of the aortic root were measured at the sinotubular junction, the sinuses, and the commissures using ultrasonic micrometric crystals (Sonometrics Corp, London, Ontario, Canada). From digitized high-speed video data, which recorded the movement of the cusps with a Motionscope HR-1000 (Redlake Imaging Corp, Morgan Hill, CA), the bending deformation index in the leaflets was calculated by following a protocol, which have been previously described in detail [8].

Statistical Analysis

Data were expressed as means ± standard deviation. Comparisons between the groups were performed using the student's *t* test for independent samples.

In Vitro Results

The results of the measurements are presented in Tables 1 and 2. Compared to the native aortic root, mean and peak pressure gradients are close to normal, the closing volume is decreased, and the bending deformation index is increased in the new sinus prosthesis. The compliance is decreased at all three levels of the root. The shape of the root with three separate sinuses of Valsalva and the straight interleaflet triangles is preserved (Fig 2). Contact of leaflets with the prosthesis wall was not observed in any case.

Clinical Experience

After approval of the Ethics Committee and after obtaining the patient's consent, the new prosthesis was implanted in a 20-year-old patient with Marfan syndrome and an aortic root aneurysm (diameter, 5 cm). The prosthesis size was 30 mm. This was determined from the distance between the stretched commissures in which the proper leaflet coaptation was achieved. The annulus was tailored to leave a short rim of 3 mm, which was sutured using subvalvular Teflon felt-pledgeted sutures in the left ventricular outflow tract after the dilated native sinuses had been excised, taking care to fix the prosthesis congruently to the native root anatomy. While knotting the subvalvular sutures a Heger dilatator was inserted into the left ventricular outflow tract warranting a nonrestricted annulus diameter. No incisions in the proximal part of the prosthesis were made to prevent possible future dilatation of the annulus. Thereafter the commissures were stretched under some tension and fixed inside the prosthesis with Teflon pledgeted mattress sutures (Serag Wiesner, Naila, Germany). This procedure was followed by adaptation of the sinus tissue rims to the prosthesis using a continuous suture in overcast fashion. After reimplantation of the coronary arteries, the proximal anastomosis was performed using a continuous suture.

The intraoperative transesophageal echocardiography in longitudinal section revealed the root configuration with the sinus of Valsalva and the straight interleaflet triangle. The leaflets did not touch the wall of the prosthesis in the fully open position during systole (Fig 3). In a computed tomographic cross section, the configuration of the new prosthetic root is also outlined (Fig 4).

Comment

Aortic insufficiency caused by root aneurysm can be treated in different ways. The conventional technique is to replace the aortic valve and root by a valve-bearing conduit. The results are excellent; however, lifelong anticoagulation is necessary if a mechanical valve is used with the known risks of thrombembolism and bleeding [9]. Furthermore, if this technique is applied in aortic dissections, remodeling of the distal dissection layers may be impaired by anticoagulation. If a

Table 1. Hemodynamics and Bending Deformation Index of the New Sinus Prosthesis

	Pressure Gradient (mm Hg)		Closing Volume (mL/cycle)	Bending Deformation Index
	Mean	Peak		
New sinus prosthesis	3.8 ± 0.7	8.9 ± 1.1	−2.8 ± 1.1	0.57 ± 0.13
Native aortic valve	3.34 ± 0.9	9.3 ± 2.5	−5.3 ± 1.0	0.17 ± 0.01
	NS	NS	$p = 0.0003$	$p = 0.0001$

NS = nonsignificant.

Table 2. Diameters of the Aortic Root at Different Anatomic Levels During Cardiac Cycle[a]

	New Sinus Prosthesis			Native Aortic Valve		
Level	Systole (mm)	Diastole (mm)	Δ (%)	Systole (mm)	Diastole (mm)	Δ (%)
Sinotubular junction	27.9 ± 2.7	26.9 ± 2.5	3.2 ± 1.3	30.4 ± 3.2	27.0 ± 2.5	12.5 ± 3.3
Commissures	28.1 ± 2.3	27.5 ± 2.2	1.9 ± 1.1	34.1 ± 2.9	28.6 ± 2.4	19.1 ± 2.8
Sinuses of Valsalva	34.6 ± 2.8	33.7 ± 2.8	2.8 ± 1.1	39.6 ± 4.6	36.4 ± 4.1	8.6 ± 1.9

[a] Diameters are measured maximal during systole and minimal during diastole.

$p < 0.001$ at all levels

bioprosthesis is used, reoperation especially in young aged patients is foreseeable. Thus, the alternative of sparing the patient's own valve is theoretically appealing, providing the advantage of autologous tissue without the need for anticoagulation and the prospect of lifelong function.

However, there is a certain risk of reoperation caused by different mechanisms. In the remodeling technique, which shows physiological sound hemodynamics, leaflet motion, and root distensibility, as well as some kind of a sinus of Valsalva [4], reoperation may be necessary, especially in patients with a large flaccid aortic annulus, which is typical for Marfan syndrome. In the reimplanation technique, there is no sinus of Valsalva if a straight tube is used, sometimes leading to a collision of the cusps with the wall of the prosthetic tube, with uncertain impact on structural integrity of the leaflets [5, 8]. A special modification of the Stanford group using a larger root prosthesis that is tailored at the sinotubular junction and gets rid of this problem, also provides some kind of sinuses [3]. Special prostheses were also developed [6]. However, these grafts have a basically tubular configuration that may not completely resemble the shape of the aortic root after reimplantation. This potentially may cause a decrease of leaflet coaptation area because the commissures tend to be displaced outwards. Whether these mechanisms have an influence on aortic insufficiency over time remains to be determined.

In the new sinus prosthesis presented in this study, the typical configuration of the aortic root with separate sinuses and straight pillars for the interleaflet triangles and commissures in between is preserved. The postoperative computed tomographic scan shows the anatomical root configuration with three distinct sinuses of Valsalva (Fig 4), and the intraoperative echocardiogram demonstrates that the leaflets do not touch the wall of the prosthesis (Fig 3) that may occur in straight tube grafts [5]. Computational studies also provide some evidence that a sinus configuration may have a positive effect on stress reduction of the leaflets [8] as well as coronary flow [10].

The configuration of the new prosthesis adapts well to symmetric aortic valves. Whether the pre-formatted shape of the new prosthesis will be consistent with all geometric conditions remains to be evaluated. In some cases (ie, bicuspid aortic valves), prostheses with no constructional constrains may be beneficial. On the other hand the commissural pillars are straight in line with the annulus and distal tube graft allowing for fixation of the commissures at optional distances from the annulus, and thus may be advantageous according to the naturally given variety of commissural length in patients.

However, the distensibility of the prosthetic root is reduced compared with the native root, which is caused by the noncompliant prosthetic material leading to an increased bending deformation index of the leaflets. Whether this has an impact of long-term durability of the valve is speculative; nevertheless, physiologically compliant material of the sinus prosthesis would be clearly beneficial.

Disclosures and Freedom of Investigation

This novel vascular prosthesis was developed by the authors in collaboration with partial support for the in vitro study by B/Braun AG, Tuttlingen, Germany. The authors had full and independent control of the design of

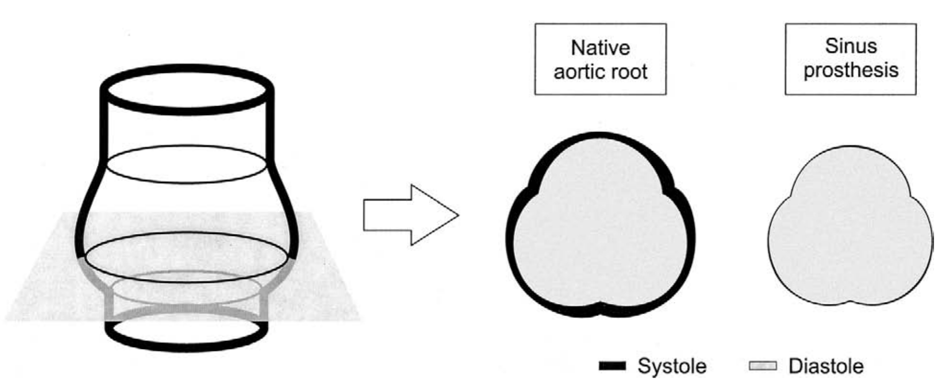

Fig 2. Schematic illustration of the root cross section of the sinus level in the native state and after root replacement with the new sinus prosthesis obtained from in vitro test data. Light and dark areas depict diastolic and systolic dimensions, respectively.

NEW TECHNOLOGY

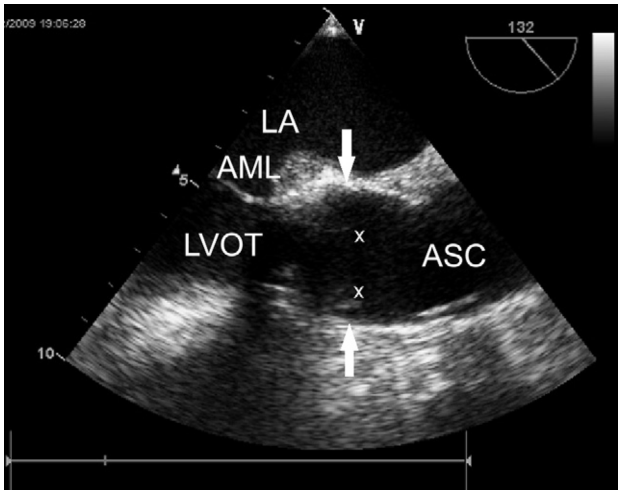

Fig 3. Long-axis view of transesophageal echocardiography of the new sinus prosthesis after implantation in a patient. The sinus configuration (upper arrow) and the straight interleaflet triangle (lower arrow) are illustrated. The leaflets (x) do not collide with the wall of the prosthesis. AML = anterior mitral leaflet; ASC = ascending aorta; LA = left atrium; LVOT = left ventricular outflow tract.

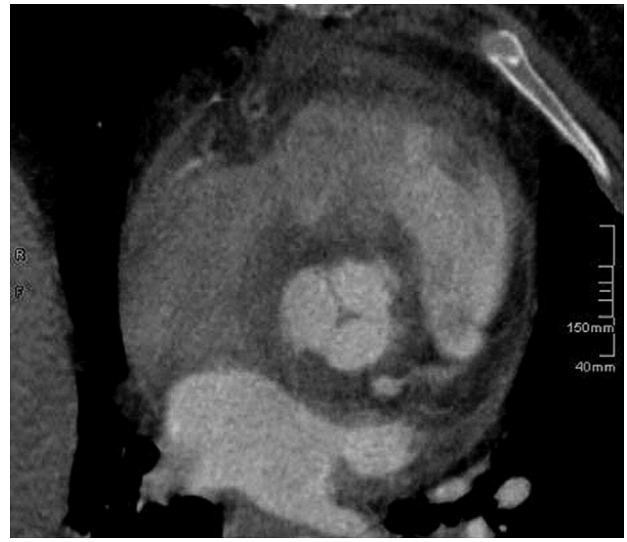

Fig 4. Tomographic cross-sectional view of the patient 14 days postoperatively, showing the normal configuration of the root with distinct separate sinuses of Valsalva. The slice image was taken from the mid-sinus level.

the study, methods used, outcome measurements, data analysis, and production of the written report.

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