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**Gelweave Valsalva™**

The world's first anatomically designed aortic root graft

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www.terumo-cvgroup.com

Manufactured by:
VASCUTEK, a TERUMO Company
Newmains Avenue, Inchinnan
Renfrewshire PA4 9RR Scotland, UK
Tel: +44.141.812.5555
Fax: +44.141.812.7170
www.vascutek.com
Vascutek, a Terumo company, is a world leader in the design and manufacture of products that address the needs of vascular and cardiovascular clinicians throughout the world.

For almost 30 years, Vascutek has applied advanced and innovative technologies to develop a wide portfolio of products which include an extensive range of sealed woven and knitted polyester grafts for peripheral, abdominal and cardiothoracic surgery. Additionally, Vascutek offers an extensive range of sealed and unsealed ePTFE grafts for peripheral and vascular access applications.

History of Gelweave Valsalva™ Grafts

1982 - Vascutek Ltd. founded
1983 - Development of gelatin sealant begins
1992 - First Gelweave™ grafts produced
2001 - Gelweave Valsalva™ graft launched outside USA*
2002 - Vascutek becomes part of Terumo Corporation
2010 - Gelweave Valsalva™ long-term follow-up published†

*510(k) clearance granted in 2002
Gelweave Valsalva™ Graft

- FDA 510(k) clearance granted June 2002
- First on the market and available for over 10 years
- Approved worldwide and used in 50 countries
- Over 20,000 patients treated
- Over 30 articles and papers published

"The ability of the Valsalva™ graft to provide 3 independent sinuses of normal shape and dimension makes the reimplantation procedure applicable to virtually every patient. This in turn will result in improved standardization and greater reproducibility of results."¹

The Graft Design
- mimics sinus geometry on implantation¹ and enables valve leaflet motion similar to normal individuals¹,⁴
- relieves tension on the coronary anastomoses may reduce postoperative bleeding and late pseudoaneurysm formation⁵
- may provide potential for increased valve longevity⁴,⁶

Stress Charts
Von Mises charts showing stress (in red) around the coronary ostia on a straight graft model compared to reduced stress on a graft model with sinuses of Valsalva present in Gelweave Valsalva™ graft.

Published literature demonstrates that the graft design enables:
- a more physiological flow pattern⁶
- relieves tension on the coronary anastomoses with the opportunity of reduced postoperative bleeding and incidence of pseudoaneurysm formation⁵
- stentless and stented biological valve conduits¹,²,³
OBJECTIVE

The Valsalva graft is a specifically designed Dacron graft that, on implantation and pressurization, generates pseudosinuses of Valsalva. We reviewed a multicenter experience of the reimplantation procedure with the Valsalva graft in patients with aneurysms involving the aortic root.

METHODS

A total of 278 patients underwent valve-sparing aortic root replacement using the Valsalva graft at 4 different Italian cardiac surgery centers and were studied by clinical assessment and echocardiography. Of the 278 patients, 220 were men (79%), with a mean age of 56 ± 15 years. Of the patients, 42 (15%) had Marfan syndrome, 31 (11%) had a bicuspid aortic valve, 13 (5%) had acute aortic dissection, and 136 (49%) had grade 3 or 4+ aortic insufficiency. Concomitant cardiac procedures were performed in 78 patients (28%). Additional aortic leaflet repair was necessary in 25 patients (9%). The mean crossclamp time was 120 ± 27 minutes.

RESULTS

There were 5 (1.8%) operative and 5 (1.8%) late deaths. The mean follow-up was 52 ± 28 months (range, 2–112 months) and was 100% complete. The cumulative actuarial survival was 95.2% (268 patients). A total of 32 patients (11%) had grade 3 to 4+ aortic insufficiency, and 17 of these required late aortic valve replacement (range 3–78 months). At 10 years of follow-up, the freedom from aortic valve reoperation rate was 91%, and the rate of freedom from residual aortic insufficiency not needing reoperation was 88%.

CONCLUSIONS

The reimplantation type of valve-sparing procedure can be facilitated by the use of the Valsalva graft and can be performed with satisfactory perioperative and midterm results. How an optimal root reconstruction will affect the second decade of follow-up has yet to be determined.
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**Bore**

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**Collar**

**Skirt**

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Newmains Avenue, Inchinnan Renfrewshire PA4 9RR Scotland, UK
Tel: +44.141.812.5555
Fax: +44.141.812.7170
www.vascutek.com

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