

T400-Series Surgical Protocol

Vascular Graft Prosthesis: Blood Flow Measurement with Perivascular Flowprobes

Introduction

Early investigations conducted by Transonic® indicated that perivascular Probes could not be used on expanded polytetra-fluoroethylene (ePTFE, GORTEX®) and Dacron® vascular graft prostheses. Without pretreatment, these materials greatly attenuate acoustical signal strength. The cause for this attenuation is thought to be air trapped in the interstices of the ePTFE and between the fibers of Dacron.

Despite this problem, we received reports of our Flowprobes operating properly on chronically implanted prosthetic grafts. This is only possible if the air was removed. We learned that there has been considerable research on methods for removing air from these materials because the entrapped air causes other side effects such as increased thrombogenicity and slower endothelialization.

VAD Development

The revolution in VAD (ventricular assist device) size and development has increased their clinical use and the use of Transonic Flowprobes on VAD outlet grafts. When VADs are implanted, the grafts must be pre-clotted and sealed to avoid leakage and sucking of air into the device during the VAD implant transition and weaning from CP bypass. While these de-airing procedures are required for proper venting of the device, sealing the grafts also enables flow measurement with Transonic® transit-time ultrasound Flowprobes to confirm pump output during the implant procedure. Flowprobe signal coupling is also hastened post-operatively in clinical efficacy research studies, allowing pump performance flow measurements in the critical time period post-implant.

(Continued on next page)

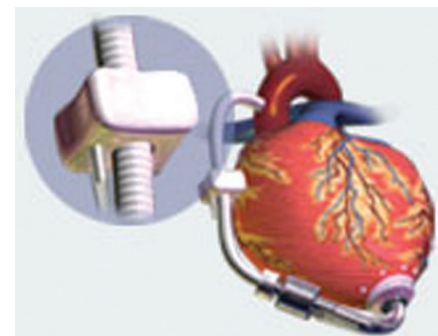


Fig. 1: Custom Transonic transit-time Flowprobe mounted on the GELSEAL® polyester outflow cannula of a MicroMed HeartAssist 5™ Pediatric Ventricular Assist Device (formerly DeBakey VAD® Child).

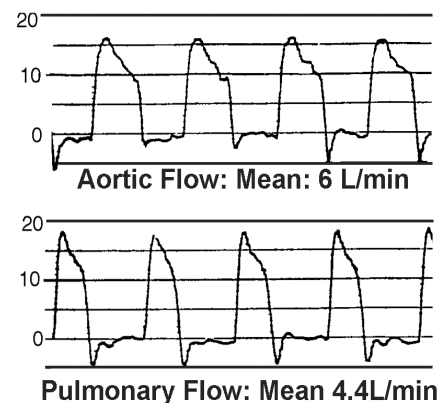


Fig. 2: Aortic and pulmonary arterial flows recorded with 24 mm perivascular Flowprobes on pre-clotted Dacron grafts anastomosed to natural vessels on a University of Utah Total Artificial Heart.

Vascular Graft Prosthesis: Blood Flow Measurement with Perivascular Flowprobes cont.

Dacron

Dacron prosthetic grafts, composed of knitted or woven fibers, rely upon clotting to maintain graft integrity. As clotting fills the spaces between the fibers, air is displaced. This reduces ultrasonic attenuation and allows successful transit-time flow measurements. One technique recommended is to clot the graft by soaking the grafts in blood before implantation.

New techniques have employed a react-in-place fibrin sealant (Tisseel® or CoSeal® from Baxter Healthcare Corp.) to de-aerate and seal grafts. There are also several types of woven and knitted Dacron polyester grafts (under Vascutek trade names GelSeal™, GelSoft™, and GelSoft™ Plus) which are presealed with gelatin or albumen coating. Because air in these materials has been removed, the ultrasonic signal coupling for Transonic Flowprobes is enhanced and intraoperative flow measurements are possible.

ePFTE

Expanded polytetrafluoroethylene grafts (GORTEx® and IMPRAFLEX®), are somewhat more difficult to work with. Early technique for the removal of air required special equipment for pressurization.

The following procedure with easily obtainable materials may be implemented.

1. Remove the rubber stopper from a blood collection tube.
2. Place the graft in the tube and fill the tube with ethanol.
3. Place a needle (22 ga.) through the stopper and replace the stopper allowing fluid to exit through the needle.
4. Evacuate as much air as possible by withdrawing with a 20 cc syringe on the needle.
5. Repeat this procedure with several tubes of sterile saline.
6. Rinse the graft 20 minutes later with the prepared saline. The alcohol has less surface tension and aids in the replacement of air spaces with fluid. The graft should change from opaque white to translucent if sufficient air has been removed.

Care (frequent irrigation) must be taken to prevent air from re-entering the graft upon implantation. In vivo results have shown frequent agreement between flow measured in the native vessel and the adjacent prosthetic graft.

Testing Quality Signal

One good indicator of the effectiveness of an air removal procedure is to use the Test Mode on the Flowmeter to access the amplitude of the received signal on the graft compared with that of a native vessel or in a water bath. If the signal strength is significantly lower on the graft, the air is not sufficiently removed. We also recommend that the flow in the graft be validated by comparing it to that of the connecting native vessel or by performing an in vivo calibration at the end of the experiment.

Transonic® also offers signal optimization and custom calibration service for use on prosthetic graft since the signal may be lower on some grafts than on a native vessel. A sample of the graft (6" minimum length) is required for this evaluation and service at the factory.

Vascular Graft Prosthesis: Blood Flow Measurement with Perivascular Flowprobes cont.

ACKNOWLEDGEMENTS

DACRON: George Pantalos, PhD, Univ. of Utah Artificial Heart Lab, Salt Lake City, Utah.

ePTFE: Bruce Klitzman, MD, Duke University Medical Center Durham, NC.

REFERENCES: PROSTHETIC GRAFT TREATMENT

Trundell, LA et al, "Alcohol Treated PTFE Vascular Grafts," *Trans Artificial Internal Organs* 1979;22:320-23.

Madras, PN et al, "Enhancement of Thrombus Formation by Vascular Prosthesis," *Can J Surg* 1980; 23: 544-46.

Ward, CA, "Reduction in Platelet Adherence to Biomaterials by Removal of Gas Nuclei," *Trans Artificial Internal Organs* 1974; 20: 77-84.

Demos, CP et al, "Decreased Thrombogenicity of Vascular Prosthesis Following Gas Denucleation by Hydrostatic Pressure," *Plastic & Reconstructive Surg* 1988; 88: 1042-45.

Ritter, EF et al, "Hydrostatic Pressure Reduces Thrombogenicity of PTFE Vascular Grafts," *AJP* 257: H1076-81.

REFERENCES: PROSTHETIC GRAFT FLOW

(Selected from over 100 publications.)

Voigt O, Benkowski RJ, Morello GF. Suction detection for the MicroMed DeBakey Left Ventricular Assist Device. *ASAIO J.* 2005 Jul-Aug;51(4):321-8. MicroMed Technology, Inc., Houston, TX. (7077A)

Noon GP, Lynch BE et al, Clinical experience with the MicroMed DeBakey ventricular assist device. *Ann Thorac Surg.* 2001 Mar;71(3 Suppl):S133-8; discussion S144-6. Dept. of Surgery, Baylor College of Medicine, Houston, TX. (1779AH)

Litwak KN, Pantalos, GM et al, Effects of left ventricular assist device support and outflow graft location upon aortic blood flow. *ASAIO J.* 2004 Sep-Oct;50(5):432-7. Jewish Hospital Heart and Lung Institute, Univ. of Louisville, Dept. of Surgery, Louisville, KY. (3061A)

Slaughter MS Pantalos, GM et al, Intraoperative evaluation of the HeartMate II flow estimator. *J Heart Lung Transplant.* 2009 Jan;28(1):39-43. Cardiovascular Innovation Institute, Univ. of Louisville, KY. (7727AH)

Russell S et al, HeartMate II LVAS: Patient Management Guidelines HM II Guidelines Page 1 of 75. Revision O 2006. http://www.fda.gov/ohrms/DOCKETS/ac/07/briefing/2007-4333b2-20-%209_4%20HM%20II%20Patient%20Management%20Guidelines.pdf

Radovancevic B, Frazier OH et al, Biventricular support with the Jarvik 2000 axial flow pump: a feasibility study. *ASAIO J.* 2003 Sep-Oct;49(5):604-7. Texas Heart Institute, Houston, TX.(2677A)

Tuzun E, Kadipasaoglu KA et al, Myocardial hemodynamics, physiology, and perfusion with an axial flow left ventricular assist device in the calf. *ASAIO J.* 2004 Jan-Feb;50(1):47-53. Texas Heart Institute, Houston, TX. (2837A)

Ootaki Y, Fukamachi K et al, Initial In Vivo Evaluation of the DexAide Right Ventricular Assist Device. *ASAIO J.* 2005. Nov-Dec;51(6):739-42. The Cleveland Clinic Foundation, Cleveland, OH. (7171A)

Lukic B, Weiss WJ et al, The effect of left ventricular function and drive pressures on the filling and ejection of a pulsatile pediatric ventricular assist device in an acute animal model. *ASAIO J.* 2007 May-Jun;53(3):379-84. Penn State College of Medicine, Penn State Children's Hospital, Hershey, PA. (7404A)

Slaughter, MS, LaRose J et al, HeartWare Miniature Axial-Flow Ventricular Assist Device Design and Initial Feasibility Test *Tex Heart Inst J.* 2009; 36(1): 12-16. (7874A)



Transonic Systems Inc. is a global manufacturer of innovative biomedical measurement equipment. Founded in 1983, Transonic sells "gold standard" transit-time ultrasound flowmeters and monitors for surgical, hemodialysis, pediatric critical care, perfusion, interventional radiology and research applications. In addition, Transonic provides pressure and pressure volume systems, laser Doppler flowmeters and telemetry systems.

AMERICAS

Transonic Systems Inc.
34 Dutch Mill Rd
Ithaca, NY 14850
U.S.A.
Tel: +1 607-257-5300
Fax: +1 607-257-7256
support@transonic.com

EUROPE

Transonic Europe B.V.
Business Park Stein 205
6181 MB Elsloo
The Netherlands
Tel: +31 43-407-7200
Fax: +31 43-407-7201
europe@transonic.com

ASIA/PACIFIC

Transonic Asia Inc.
6F-3 No 5 Hangsiang Rd
Dayuan, Taoyuan County
33747 Taiwan, R.O.C.
Tel: +886 3399-5806
Fax: +886 3399-5805
support@transoniasia.com

JAPAN

Transonic Japan Inc.
KS Bldg 201, 735-4 Kita-Akitsu
Tokorozawa Saitama
359-0038 Japan
Tel: +81 04-2946-8541
Fax: +81 04-2946-8542
info@transonic.jp