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Pre-Clinical Validation of a New Intra-Operative "Dual Beam Doppler" Blood Flowmeter in an Artificial Circuit

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ABSTRACT

Background: Intra-operative flow measurement during coronary or peripheral bypass operations is helpful for ruling out technical failures and for prediction of complication and patency rates. Preclinical validation of the flowmeters is required in order to rely on the intra-operatively measured results. The aim of this study is to evaluate a new "dual beam Doppler" blood flowmeter before clinical application and to compare it with the established "transit time flow measurement" technique in an artificial circuit.

Methods: Measurements were performed in an experimental flow model using pig blood and pig arteries. Three different flowmeters were used: Quantix OR (dual beam doppler flowmeter), CardioMed (transit time flowmeter), and Transonic (transit time flowmeter). Three validation tests were performed to assess correlation, precision, and repeatability of devices. (1) Correlation and agreement analysis was performed with various flow amounts (10-350 mL/min) (n = 160). (2) Device reproducibility and measurement stability were tested with a constant flow (flow amount = 300 mL/min) (n = 30). (3) A user accuracy test (intra- and inter-observer variability) was performed by 5 different observers with a constant flow (flow amount = 205 mL/min) (n = 75). Time collected true flow was used as a reference method in all steps and all tests were performed in a blind manner. Results are shown as mean values ± standard deviations. Pearson's correlation and Bland-Altman plot analyses were used to compare measurements.

Results: The mean flow was 167 ± 98 mL/min for true flow and 162 ± 94 mL/min, 165 ± 94 mL/min, and 166 ± 100 mL/min for Quantix OR, CardioMed, and Transonic, respectively. Correlation coefficients between Quantix OR, Medi-Stim, Transonic, and time collected true flow were over 0.98 (P = .01). Most of the measured results (> 90%) were between ±1.96 SD agreement limits in Bland and Altman plot analysis. All devices showed good results in the reproducibility test. During the user accuracy test, larger variance changes were observed between intra- and inter-observer results with the dual beam Doppler flowmeter compared to the 2 used transit time flowmeters when used for single sided vessel access without stabilization device (available from the manufacturer).

Conclusion: All 3 tested flowmeters showed an excellent correlation to the true flow in an artificial circuit and the accuracy of the tested devices was within agreement limits. Reproducibility of all devices was good and linear. The new dual beam Doppler flow measurement technique compares favorably to the classic transit time method. Clinical use may depend on operator, location, and condition, thus more studies may be required to ensure uniform results using the currently available blood flow measurement devices.

INTRODUCTION

Quality control is part of modern surgery today [Muratori 2001; Bonatti 2003]. During coronary or peripheral bypass operations, it is advisable to assess the quantity of blood flow through the graft to the revascularized area [Stirnemann 1994; Harder 2002]. Poor flow may be indicative of a technical failures and may lead to increased morbidity and mortality [Lundell 1993a; Walpoth 1998a; Ricci 1999; Alback 2000; Bauer 2002]. Transit time flow measurement is a validated and well established technique for this aim and its application has proven to rule out technical failures in previous studies [Walpoth 1998b; D'Ancona 2000].

"Dual beam Doppler" flow measurement is a newly-defined technique for intra-operative blood flow measurement [Skladany 1998; Soustiel 2002] with the advantage of not having to free the target vessel. Preclinical validation of medical devices such as flowmeters is required in order to rely on the intra-operative measured results. Thus, the aim of this study was to evaluate the new "dual beam Doppler"

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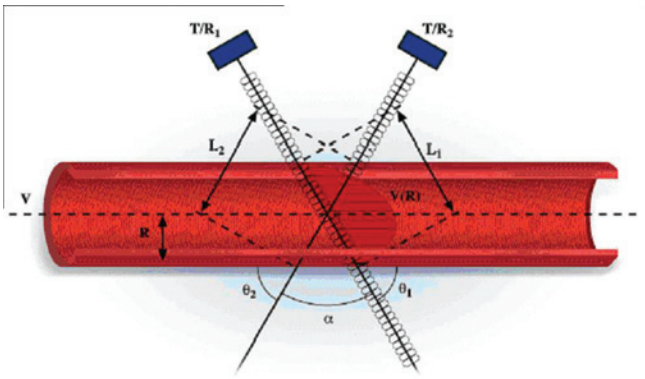

Figure 1. Schematic presentation of "dual beam Doppler" technology (reproduced with the permission of Cardiosonix Ltd, Israel). T/R_1 indicates transmit beam; T/R_2, transmit beam; V, vessel centerline (velocity axis); L_1, vessel internal chord length 1; L_2, vessel internal chord length 2; V(R), velocity profile; R, vessel radius; α, beam angle (fixed); θ_1, probe transducer orientation angle; θ_2, probe transducer orientation angle 2.

blood flowmeter before clinical use and to compare it with 2 established "transit time flowmeters" in an artificial circuit.

MATERIALS AND METHODS

Measurement Systems

The following 3 flowmeters with their respective flow probes were used in the study: (1) Quantix-OR Flowmeter with flexible probe (dual beam Doppler flow measurement technology) [Cardiosonix, Ra'anana, Israel]); (2) CardioMed Flowmeter with 5 mm Quickfit probe (transit time flow measurement technology) [CM 4008, Medi-Stim AS; CardioMed, Oslo, Norway]); and (3) Transonic Flowmeter with 5 mm probe (transit time flow measurement technology) [T206; Transonic, Ithaca, NY, USA]).

Methodologic Principles of Flowmeters

Dual Beam Doppler Flow Measurement. This technology was designed to address the problems of Doppler angle dependency and time-dependent variations in the velocity profile and vascular diameter [Soustiel 2002]. Dual beam Doppler technology is based on the simultaneous use of 2 independent high resolution Doppler beams with a known geometric configuration. The angle of both beams is constant. Using digital Doppler technology, hundreds of sample volumes less than 200 µm in length at successive depths are simultaneously sampled along each ultrasound beam. Thus, the diameter of the insonated vessel can be calculated precisely from both beams. Due to the high-resolution beams several flow velocity profiles can be calculated within the insonated vessel. Thus a full-spectrum analysis of the laminar blood flow of each Doppler beam can be estimated. With the information about velocity and vessel diameter, blood flow amount is calculated by the following equation: Flow = mean velocity × CSA (Cross Sectional Area = [cap/pi] × r^2 (r = half diameter) (Figure 1). The probe does not need to surround the measured vessel. Since the technique is based on 2 Doppler signals, the beams have to be aligned in the central axis and greatest diameter of the vessel. As with all flow measurement devices, such measurements may be affected by vessel motion and the experience of the observer.

Transit Time Flow Measurement. As comparison, we used 2 flowmeters working on the transit time flow measurement principle (Medi-Stim; CardioMed and Transonic, Transonic Systems). These were validated in previous in-vitro and in-vivo studies [Lundell 1993b; Alback 1996; Beldi 2000].

The transit time flow measurement technique is based on the fact that ultrasound traveling against the bloodstream will take longer than when moving with the bloodstream [Karamanoukian 2003] (Figure 2). Transducers have 2 ultrasound crystals and are placed on one side of the vessel with a metal reflector on the opposite side. Therefore, it is necessary to free the vessel and surround it with the reflector/transducer. Both crystals transmit a Doppler pulse and each crystal is a receiver for the other one. The difference in transit time propagation depends on the volume blood flow. The difference in transit time is dependent only on the moving blood in the vessel, thus, good coupling of the vessel is important and makes the measurements independent of the inner diameter.

Artificial Flow Circuit

The validation tests were performed in an artifical circuit. The circuit included tubing sets, 1 roller pump, and 2 reservoirs. Pulsatile flow was obtained with the short length and small diameter of the tubes. Flow conditions were continously monitored during the procedure with invasive pressure and flow signals. A 6 cm–long pig carotid artery segment (freshly harvested) was inserted in the circuit (Figure 3). The artificial circuit was filled with pig blood (29 ± 3% Htc, ACD anticoagulation) and immersed in a 37[degree]C water bath. Time collected true flow amount was used as a reference during each

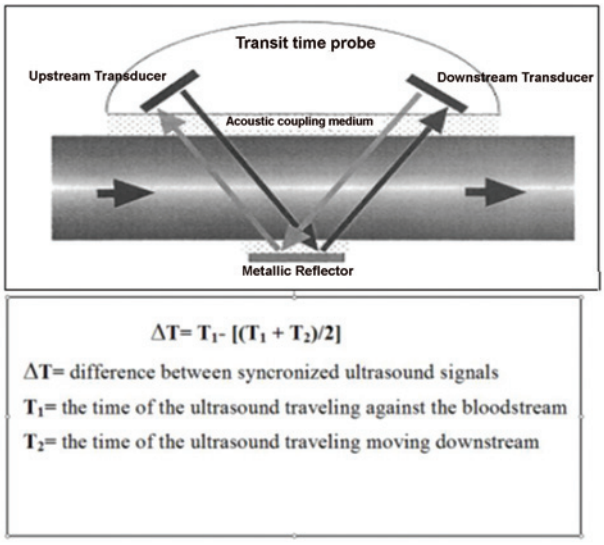

Figure 2. Probe design of a transit time flowmeter and measurement algorithm (reproduced with the permission of Medi-Stim SA, Norway).

Results of Correlation and Agreement Test

	True Flow	Quantix OR	CardioMed	Transonic
n	160	160	80	80
Mean flow, mL/min	167 ± 98	162 ± 94	165 ± 94	166 ± 100
Correlation (r) to the true flow		0.98*	0.98*	0.99*
Mean difference (True flow-flowmeter), mL/min		5 ± 12	5 ± 13	–2 ± 8

*P = .01

measurement. Blood was collected in a second reservoir during the measurement of 1 minute, then it was measured with the scaled glass cylinder. In order to stabilize and standardize the measurements, a steady state of 30 seconds was introduced to each run. All steps were performed in a blind manner.

Study Protocol and Validation Tests

Correlation and Agreement Analysis. The probes were fixed in a stable position by a holder (Figure 3). Flow was changed in steps from 10 until 350 mL/min. Blood pressure of the system was monitored with an invasive pressure transducer (Hewlett Packard, Palo Alto, CA, USA). Transit time flowmeters were tested separately to prevent ultrasonic interferences. First, a Quantix OR–CardioMed combination was tested with 80 measurements, and then the same measurements were repeated with a Quantix OR–Transonic combination (n = 80). Blood flow measurements were repeated twice for each of the pump flow settings and the probe's sequence was changed to prevent position artefacts.

Device Reproducibility and Measurement Stability Test. In this step, devices were tested separately with probes in a fixed position. The flow was held constant at 300 mL/min. After signal stabilization (first 30 seconds) measurements were taken 10 times at 20-second intervals.

User Accuracy Test (Intra- and Inter-Observer Variability). In this step, devices were tested separately, but probes were hand-held as in surgery. The flow was held constant at 205 mL/min. Five operators performed five repetitive measurements with each device in a blind manner. In addition, the ease of use and time required for each measurement was noted.

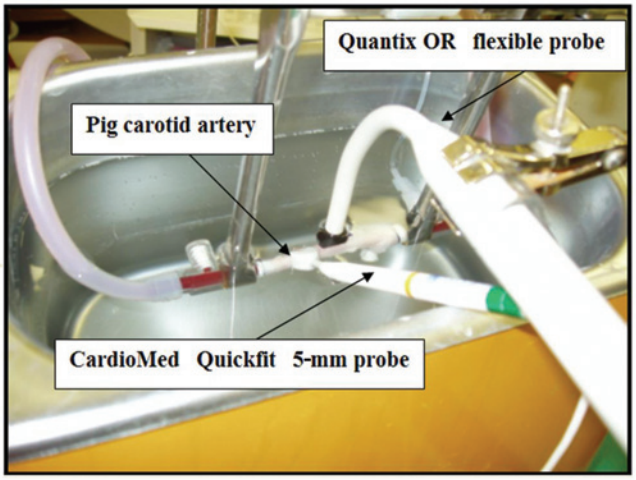

Figure 3. Position of the flow probes (CardioMed and Quantix OR) on a pig carotid artery in the artificial circuit and in the water bath.

Statistical Analysis

The data were analyzed by statistical package SPSS version 10.0. Results show mean ± standard deviation. Pearson's correlation and Bland-Altman plot analyses were used to compare measurements [Bland 1986].

RESULTS

Correlation and Agreement Analysis

A total of 160 flow measurements were performed during the correlation and agreement analysis test (true flow, n=160: Quantix OR and Cardio-Med, 80 measurements; Quantix OR and Transonic, 80 measurements). The mean flow amount was 167 ± 98 mL/min for true flow and 162 ± 94 mL/min for Quantix OR, 165 ± 94 mL/min for CardioMed, and 166 ± 100 mL/min for Transonic, respectively (Table). Correlation coefficients between Quantix OR, Medi-Stim, Transonic, and time collected true flow were over 0.98 (P = .01) (Figure 4). Most of the measured results (> 90%) were between ±1.96 SD (standard deviation) agreement limits with the Bland-Altman plot analysis test as seen in Figure 5.

Device Reproducibility and Measurement Stability Test

All devices showed good results in the reproducibility test. Measured results were between ±10% agreement limits (Figure 6).

User Accuracy Test (Intra- and Inter-Observer Variability)

During intra- and inter-observer variance analysis tests, larger changes were observed with the dual beam Doppler flowmeter compared to the transit time flowmeters. All of the measured results (> 90%) were between agreement limits for the transit time flowmeters, whereas results of Quantix OR showed larger variances (Figure 7). All the systems were user-friendly and fast (12 ± 2 sec, 10 ± 2 sec, and 13 ± 4 sec for Quantix OR, Medi-Stim, and Transonic, respectively). There was not a statistically significant difference in measurement time.

DISCUSSION

The dual beam Doppler principle for flow measurement is an old technology which was described originally by Daigle in 1974 [Skladany 1998]. Validation of medical devices before clinical introduction is required to prevent device-related complications and misleading results. In this validation study using a new intra-operative flowmeter based on dual beam Doppler (Quantix OR), a good correlation and agreement were found

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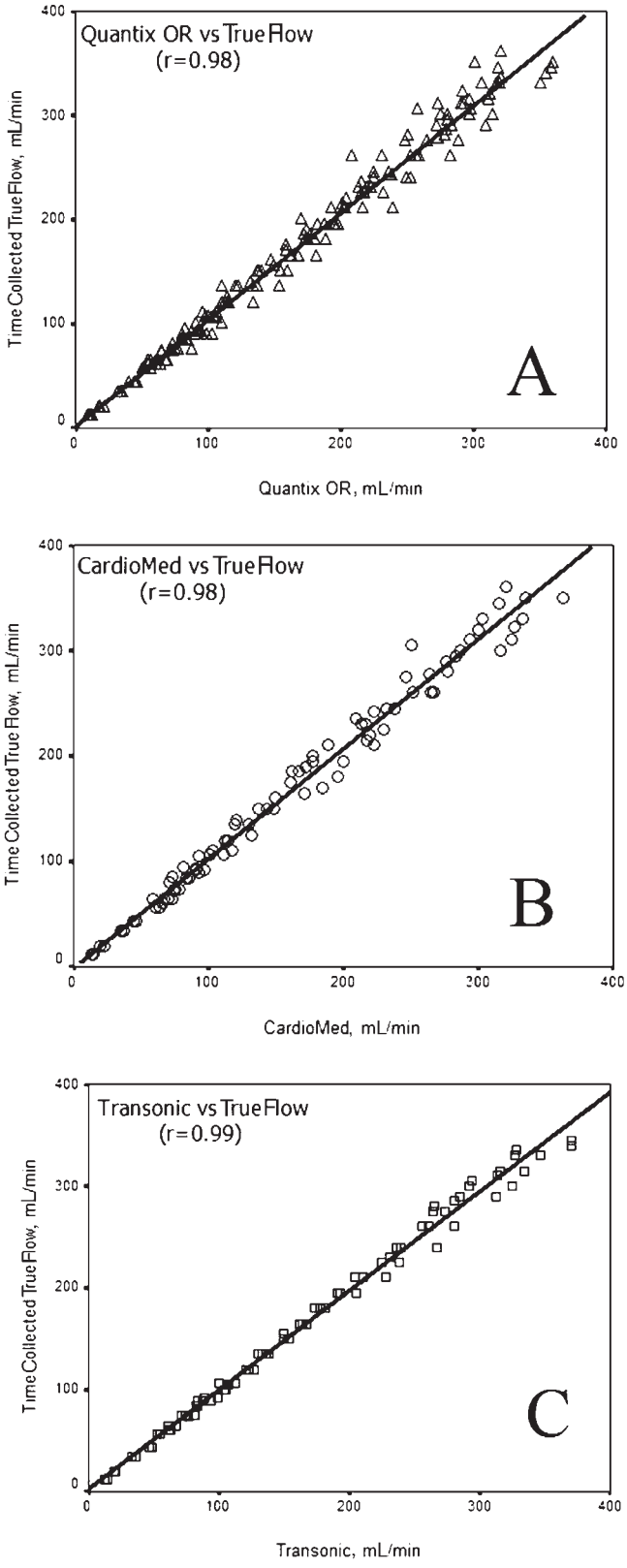

Figure 4. Correlations between flowmeters and time collected true flow. A, Quantix OR versus true flow. B, CardioMed versus true flow. C, Transonic versus true flow. Pearson correlation coefficients were perfect for all systems and all were significant (P = .01).

to the time collected true flow in an artificial circuit. Measuring performance of the new device was stable and linear.

In Vivo and In Vitro Models for Flow Validation

There are 2 possibilities to validate flowmeters, namely the in vivo and in vitro tests. Comparison of measured flow with time collected blood volume is a standard for both models. Experimental animal models or human grafts can be used during in vivo validation studies with the advantage of having real circulatory parameters [Lundell 1993b; Alback 1996]. Time collection is normally obtained with exsanguination during in vivo validation studies. This may cause some errors during animal studies and ethical problems during human studies. The use of native tissues (arteries and veins), real blood, and physiologic hemodynamics may help to mimic in vivo conditions for in vitro validation models [Soustiel 2002; Beldi 2000]. In the present study, a phantom model was designed to simulate circulation and all physiologic parameters.

Validation Tests

Validation of new medical devices in unbiased academic centers is an important step for medical standards. The following 3 tests have been used for this aim: (1) correlation and agreement analysis with true flow; (2) device reproducibility and measurement stability test; and (3) user accuracy test to see intra- and inter-observer variabilities. Correlation means the correct increase or decrease of measured results with time collected true flow. Good agreement means good matching of the measured results with time collected true flow. Ideally, a device should have a high correlation and agreement with time collected flow. By medical standards, results are acceptable if values fall between ±1.96 SD of difference, as described by Bland and Altman [Bland 1986]. Although good agreement always means a good correlation, a good correlation does not always mean good agreement. Device reproducibility and measurement stability means reproducible, linear and stable function over time. The last property of good flowmeter is to have closely matching results for the same operator as well as for different operators (intra- and inter-observer stability). This implies that the system is not affected by the person using it. The ideal system should give similar results. In our test, the transit time flowmeter systems had very little variance, but the Quantix OR showed more variability (Figure 7). This reflects the difficulty of single sided access to a free vessel segment without the use of hooks or stabilizers.

Importance of Quality Control in Cardiovascular Surgery

Because surgical technical failures have a major impact on patency, morbidity, and mortality rates, intra-operative quality control is important for the patient and for the surgical team. Although there is no consensus concerning which is the best method for intra-operative assessment of bypass grafts, several techniques, such as angiography, flow measurement, distal peripheral resistance measurement, and Doppler ultrasonographic velocity measurement, have been used as methods of quality control [Johnson 2000; Bonatti 2003; Schmitz 2003]. Such intra-operative quality control methods should have good accuracy and precision (error ± <10%), be easy to

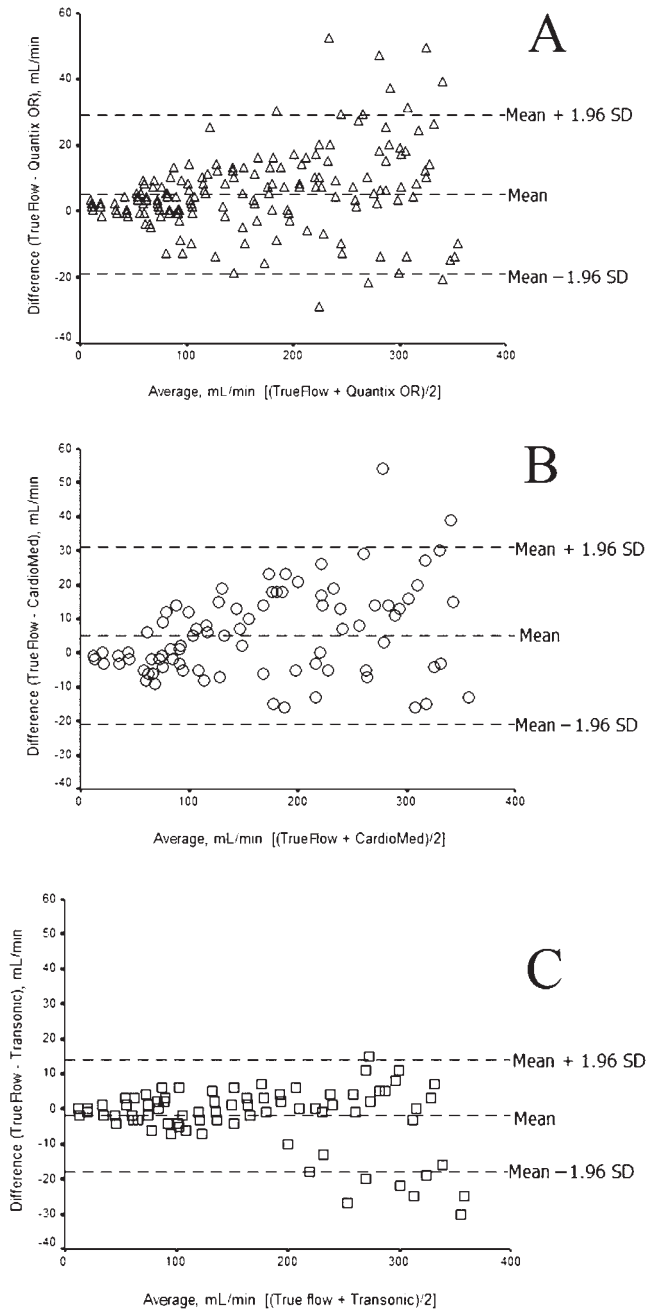

Figure 5. Agreement analysis with Bland-Altman Plot between flowmeters and time collected true flow. A, Quantix OR versus true flow. B, CardioMed versus true flow. C, Transonic versus true flow. More than 90% of results were between ± 1.96 SD agreement limits.

learn and use, be economical, be fast and repeatable, be non-invasive, and have no adverse effects for the patient [Cikirikcioglu 2005]. All 3 tested blood flowmeters share all of the above parameters.

Quality Control Methods in Bypass Surgery: Pros and Cons

Intra-operative arteriography is accepted as the gold standard for determination of technical adequacy of bypass operations, including anastomoses, conduit, and out-flow arteries. However, this intervention provides only anatomic information, typically in one plane. Thus, clinical outcomes have not always correlated well with intra-operative angiography [Hol 2002]. On the other hand, it is an invasive procedure and may have some complications related with the intervention itself or the use of radiopaque contrast media [Walsh 2000]. Today, noninvasive techniques, such as intra-operative Doppler ultrasonography and transit time or dual beam Doppler graft flow measurement, are preferred to detect technical failure at the anastomotic site early, and to identify low-flow situations resulting from vasospasm or poor runoff [Schmitz 2003]. Intra-operative Doppler ultrasonography is a well-established method but it requires having experienced personnel and a device readily available in the operating room [Rasmussen 2003].

Flow Measurement in Bypass Operations

Intra-operative flow measurement after bypass surgery allows functional evaluation of grafts and may be predictive of patients' immediate and late outcome after coronary or peripheral bypass surgery. With the advent of minimally invasive coronary artery bypass grafting, including multivessel revascularization on the beating heart, quality control of the anastomoses becomes particularly important [Ricci 1999; D'Ancona 2000]. Early recognition of low bypass flow and technical failures is cost effective and may prevent hemodynamic instability and perioperative myocardial infarction, reducing the length of stay in the intensive care unit and improving patient outcome after coronary bypass surgery [Walpoth 1998b; Ricci 1999; D'Ancona 2000; Bauer 2002]. Similarly, there is an increasing number of patients operated on for peripheral bypass procedures with difficult pathologies. The importance of intra-operative flow measurement for the prediction of graft function and limb salvage has been reported after peripheral bypass operations [Lundell 1993a; Stirnemann 1994; Alback 1996; Harder 2002].

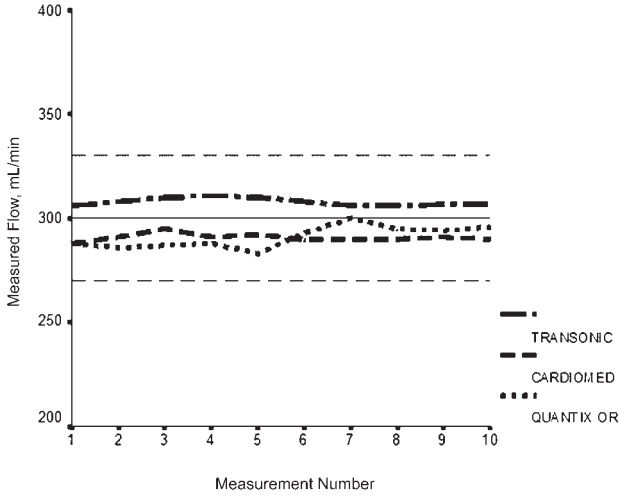

Figure 6. Device reproducibility and measurement stability test. All systems worked linear without big alterations.

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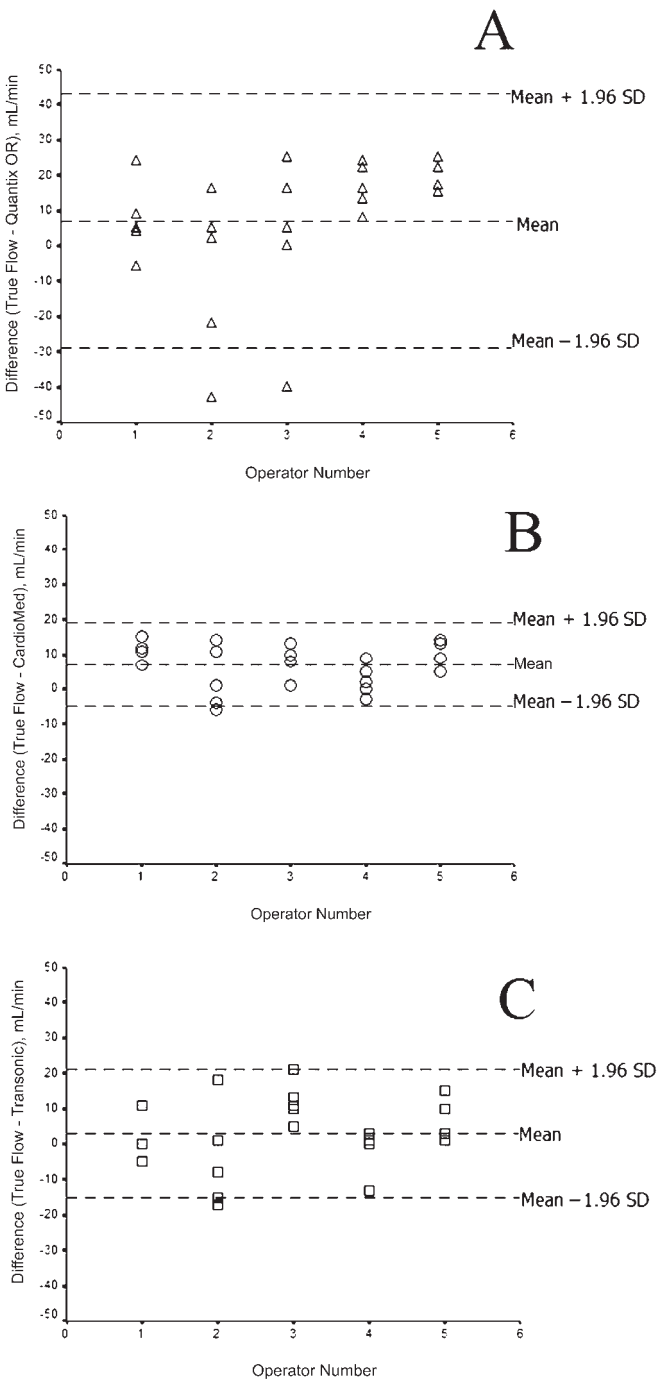

Figure 7. User accuracy test (intra- and inter-observer variability). Variance changes were larger for Quantix OR compared to CardioMed and Transonic. Most of the results were between ± 1.96 SD agreement limits.

Advantages and Disadvantages of Transit Time and Dual Beam Doppler Flow Measurement Techniques

After the comparison of the 2 tested flow measurement technologies in the artificial circuit, we have the following remarks. Flow measurement with transit time flowmeters yields fast and accurate results. However, it requires skeletonized vessels, and, to obtain correct results, it is necessary to use the correct probe size. The graft should fill at least 75% of the lumen of the probe [Drost 2002]. In contrast, dual beam Doppler enables measurement by single-sided vessel access using one probe for all vessel sizes. Thus, flow measurement is possible on the native vessel in situ. Like transit time, this technology is motion sensitive. Reduced inter- and intra-observer variance is obtained with the training and experience of the user. We expect the results to be comparable when used with the vessel stabilizer.

Flow measurement of synthetic grafts (such as ePTFE) during surgery is the Achilles heel of all quality control devices using the ultrasonographic principle (transit time or dual beam Doppler). These type of grafts have residual air trapped in the wall. Ultrasonographic waves can not cross through the graft because of the air barrier. However, flow measurement is possible on native arteries or veins.

In conclusion, all 3 tested flowmeters showed an excellent correlation to the true flow in an artificial circuit, and the accuracy of the tested devices was within the agreement limits. Working performances of all devices were stable and linear. The new dual beam Doppler flowmeter compares favorably to the classical transit time flowmeters. However, it should be kept in mind that results may depend on operator, location, and conditions, thus more measurements may be required, especially in the clinical setting.

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The Quantix OR flowmeter and probes were provided free of charge by the company (Cardiosonix, Ra'anana, Israel), whereas the 2 other flowmeters (transit time technique) are used routinely in our laboratory. The study was partially supported by the Swiss National Science Foundation (SNF 3100-56728 "Artificial bypass grafts and vascular gene therapy") and the Swiss Heart Foundation ("Anti-angiogenic gene therapy for prevention of intimal hyperplasia in synthetic vascular grafts"). No other financial support was granted.

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REVIEW AND COMMENTARY

Editorial Board Member SC389 writes:

(a) Would the flow be different in a live model where there is tissue underneath the vessel? Would this affect the readings?

(b) How do the authors propose surgeon training to prevent operator error with the Cardiosonix device?

Author's Response from Mustafa Cirkirikcioglu, MD:

(a) Since the technology is based on a Doppler beam, surrounding tissue of a vessel is theoretically no problem. However, additional motion artefacts or acoustic signal coupling might become a problem. It is always advisable to free the vessel on the measuring part since, for using the dual beam Doppler technology, it is essential that the probe is precisely aligned in the direction of flow and that the user moves the probe along the vessel until he hits the largest diameter that is indicated on the device. However, using this technology does not require freeing the vessel; thus tissue underneath the vessel should not affect the readings.

(b) There is certainly some more training required to use this technology than other flow meters based on transit-time techniques, since it is based on a Doppler signal. This is particularly true if used without a clip-on vessel hook since a precise application is then required. With the clip, the technique loses its advantage of not requiring to free the vessel, thus it gains in user-friendliness, but is then comparable with all the other flow measuring techniques.

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