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CLINICAL EVALUATION OF TRANSIT-TIME FLOW MEASUREMENT AS A BIOMEDICAL ENGINEERING TOOL FOR INTRAOPERATIVE QUALITY ASSESSMENT DURING CORONARY ARTERY BYPASS GRAFTING

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ABSTRACT
Background: The accuracy intraoperatively measuring whether a bypass graft will function properly is vital in achieving a successful result for coronary artery bypass graft surgery. Traditional assessment of graft quality through visual and tactile examination is subjective and does not always disclose any technical problem until after the chest has been closed. Transit Time flowmetry (TTFM), an ultrasonic flow detection technique, provides an objective measurement of graft blood flow dynamics and has become a useful Biomedical Engineering technology in the assessment of quality during operations. But we are unaware if this technique is beneficial in a quantitative fashion for different left internal mammary artery (LIMA) harvesting methods during CABG.
Objective: To evaluate the effectiveness of Transit-Time Flow Measurement as a biomedical engineering technology for intraoperative graft quality assessment during isolated CABG and to determine its ability to objectively characterize graft hemodynamics.
Methods: The prospective observational study was carried out on 45 patients undergoing elective isolated CABG at Deptt of cardiovascular & thoracic surgery SKIMS Srinagar. Intrapoperative assessment of the graft was carried out immediately after finishing the coronary anastomosis by means of TTFM Transit Time Flow Measurement. Mean Graft flow, Pulseatility index, diastolioc Filling%, and waveform pattern were measured as objective indicators of graft performance. Statistical comparisons were done using unpaired students t-test &, when necessary, Fisher's exact test.
Results: Transit-Time Flow Measurement yielded meaningful intraoperative evaluation of all patients. The Skeletonized LIMA group experienced significantly higher Mean Graft Flow (46.8 ± 9.3 mL/min versus 37.4 ± 8.1 mL/min; $p = 0.001$), significantly lower Pulsatility Index (2.1 ± 0.5 versus 2.8 ± 0.7; $p = 0.002$) and significantly greater Diastolic Filling percentage (72.4 ± 6.8% versus 64.1 ± 7.5%; $p < 0.001$). The representative waveform analysis showed predictable and acceptable waveforms with consistent predominantly diastolic flow. The objective data generated by TTFM offered a real-time, real-world view of the conduit during surgery.
Conclusion: Transit-Time Flow Measurement is a practical biomedical technology for reliable intraoperative qualitative and quantitative evaluation of coronary bypass graft quality. Quantitative evaluation of Mean Graft Flow, Pulsatility Index and Diastolic Filling percentage provides a consistent objective tool that can be used by the surgeon to assist intraoperative assessment and improve quality assurance during CABG, laying the groundwork for an artificial intelligence approach.

KEYWORDS: Biomedical engineering; Transit-Time Flow Measurement; Ultrasound flowmetry; Coronary artery bypass grafting; Intraoperative monitoring; Medical instrumentation; Biosensors; Graft quality assessment.

1. INTRODUCTION

CABG remains a key procedure in the surgical management of patients with extensive coronary artery disease. Despite major advances in surgical techniques and perioperative care, perioperative graft failure may result in myocardial infarction, repeat revascularization, increased hospital length of stay, and mortality. [1-3] Therefore, objective assessment of bypass graft performance during surgery is essential in current cardiac practice.

Surgeons have relied on visual inspection, manual palpation, electrocardiography, and experience to assess the intraoperative functioning of bypass grafts.

However, these are qualitative, subjective assessments that do not exclude the possibility of anastomotic narrowing, conduit kinking, competitive flow, distal obstruction, or graft spasm. [3-5] Failure to detect such abnormalities prior to chest closure can compromise early and late graft performance. Modern biomedical engineering has made a significant impact on cardiovascular intraoperative monitoring through the development of sensitive, quantitative sensors providing real-time physiological information. Transit Time Flow Measurement (TTFM) has become a principal tool for intraoperative quality assurance in CABG. Rather than simply estimating flow velocity, TTFM utilizes an ultrasonic signal time-difference method, where differences in ultrasonic propagation times are used to determine blood volume flow within a vessel. [3-12]

This simple engineering concept provides a non-invasive method of directly measuring blood volume flow without altering the circulation. [13]

Existing TTFM devices utilize an ultrasonic probe containing upstream and downstream transducers, which emit and detect signals across the bypass graft or native artery, as well as complex signal processing algorithms that interpret time-differences in the signals. Data are collected over a specified period (typically in seconds) and used to generate quantitative measures of flow: Mean Graft Flow (MGF), Pulsatility Index (PI), Diastolic Filling percentage (DF%), and flow waveform contour. This quantitative physiological information has the capacity to demonstrate the patency of the conduit, distal vessel run-off, resistance to distal flow, and the presence of anastomotic disease. Surgeons have been able to utilize these data to readily identify technical problems and make immediate corrections during the procedure thereby improving the quality assurance. [13-17]

This innovative technology also represents a successful example of the application of biomedical engineering in surgical practice where the concepts of ultrasound sensing, signal processing, and quantitative decision support have been implemented in the OR to improve patient care. Although there has been considerable clinical acceptance of TTFM in many centers, limited attention has been paid to the application of TTFM from a biomedical engineering point of view in the context of quantitative intraoperative parameters acquired during CABG procedures. [18-25] This study was conducted to investigate TTFM as a biomedical engineering tool for real-time intraoperative evaluation of bypass graft performance and to confirm its value in supplementing the standard visual and technical assessment of bypassed segments of the coronary vasculature.

2. MATERIALS AND METHODS

2.1 Study Design

A prospective observational study was carried out in the department of cardiovascular and thoracic surgery, Sher-i-Kashmir Institute of Medical Sciences (SKIMS), Soura, Srinagar, India. The purpose of the study was to determine the value of transit-time flow measurement (TTFM) as an instrument of bio-medical engineering, for intra-operative assessment of quality of bypass graft. To determine the role of TTFM to objectify coronary artery bypass grafts through quantitative analysis of their hemodynamics in patients undergoing isolated CABG.

The Institutional Ethics Committee reviewed the protocol of this study and gave their consent for conducting this study. Written informed consent for enrollment into the study was obtained from all patients before enrollment in this study.

2.2 Study Population

A total of **45 consecutive patients** undergoing elective isolated CABG were prospectively enrolled. Patients were allocated according to the institutional surgical schedule into:

- Skeletonized LIMA group (n = 24)
- Pedicled LIMA group (n = 21)

Only patients with complete intraoperative TTFM measurements were included in the final analysis.

2.3 Transit-Time Flow Measurement System

A commercial Transit-Time Flow Measurement (TTFM) system with sterile ultrasonic perivascular flow probes of appropriate size was used for intraoperative graft assessment. This TTFM system is based on transit-time ultrasound principles, in which ultrasonic pulses are emitted sequentially in the upstream and downstream directions across the vessel. Blood flow modifies transit time depending on flow direction, and the transit time difference (difference in the round-trip times for each direction) is directly proportional to the volumetric blood flow.

TTFM consoles translate these transit time differences into digital volumetric blood flow values with sophisticated signal processing algorithms and display flow waveforms and hemodynamic data in real time.

While Doppler ultrasound directly measures blood flow velocity, is subject to the insonation angle, and can be problematic in the presence of certain graft designs, transit time flow measurement directly calculates volumetric flow (mL/min), enabling highly reproducible and angle-independent intraoperative graft evaluation.

2.4 Biomedical Engineering Principles

- The TTFM system consists of these biomedical engineering elements:
- Ultrasonic piezoelectric transducers
- Digital signal acquisition circuitry
- Transit-time difference measurement
- Real-time digital signal processing
- Flow waveform reconstruction
- Quantitative hemodynamic analysis
- Data acquisition consists of real-time acquisition of ultrasound waveforms, electronic signal filtering, estimation of transit time difference, translation into volumetric blood flow and graphical representation of the pulsatile blood flow waveform.

2.5 Signal Acquisition
Measurements were taken following completion of distal coronary anastomoses and off the bypass pump. They were carried out under optimal physiological conditions in order to minimize physiological variation. These conditions were:
Sinus rhythm maintained throughout and at baseline for measurement

- Mean arterial pressure 60-80 mmHg
- Appropriate cardiac output
- No arrhythmias present
- No external compression or external tension on the graftThree measurements of blood flow were taken per graft and average recorded.

2.6 Hemodynamic Parameters
The following engineering-derived parameters were evaluated.
Mean Graft Flow (MGF)
Average volumetric blood flow through the graft.
Measured in:
mL/min
Higher values indicate improved graft perfusion.

Pulsatility Index (PI)
Calculated automatically using

$$\mathrm{PI} = \frac{Q_{max} - Q_{min}}{Q_{mean}}$$

where

- Q_{max}= Peak systolic flow
- Q_{min}= Minimum flow
- Q_{mean}= Mean graft flow

Lower PI values indicate lower vascular resistance and superior graft performance.

Diastolic Filling Percentage (DF%)
Calculated as

$$\mathrm{DF}(\%) = \frac{\text{Diastolic Flow}}{\text{Total Flow}} \times 100$$

Higher DF values indicate greater coronary perfusion during diastole.

Flow Waveform Analysis
Waveforms morphology was inspected for;
smooth systolic upstroke , predominant diastolic flow , lack of signal noise , lack of waveform distortion and steady rhythm . A variety of representative waveforms were digitized for data recording.

2.7 Engineering Performance Assessment
TTFM performance was evaluated according to:

- Ability to provide real-time measurements
- Reproducibility of flow values
- Quantitative discrimination between grafts
- Ease of intraoperative interpretation
- Clinical usefulness for immediate quality assurance

2.8 Statistical Analysis
IBM SPSS Statistics, software version 25 was utilized for data analysis. Continuous data are expressed as mean±SD and analyzed by independent Student's t-test. Categorical data were described as frequency (%) and were analyzed using Chi-when indicated. Statistical significance was set at p<.05 for a two-sided test.

3. RESULTS
3.1 Patient Characteristics
Forty-five patients selected for elective isolated CABG were prospectively included. Skeletonized LIMA harvesting was performed in 24 patients, whereas Pedicled LIMA harvesting was performed in 21 patients. All the included patients completed the protocol, and Transit-Time Flow Measurement (TTFM) was successfully recorded from all the grafts, leading to an intraoperative measurement success rate of 100%. Baseline demographics and clinical features, including age, sex ratio, body mass index, cardiovascular risk factors, and pre-operative left ventricular ejection fraction, were

comparable in both study groups, suggesting that the hemodynamic parameters reported subsequently were not altered by pre-operative confounding variables.

Table 1. Baseline Characteristics of the Study Population

Variable	Skeletonized LIMA (n = 24)	Pedicled LIMA (n = 21)	p-value
Age (years), Mean ± SD	58.7 ± 7.4	59.9 ± 8.1	0.58
Male, n (%)	20 (83.3)	19 (90.5)	0.49
Female, n (%)	4 (16.7)	2 (9.5)	0.49
Body Mass Index (kg/m²), Mean ± SD	26.4 ± 2.8	26.8 ± 3.1	0.64
Diabetes Mellitus, n (%)	13 (54.2)	12 (57.1)	1.000
Hypertension, n (%)	16 (66.7)	17 (81.0)	0.329
Smoking, n (%)	14 (58.3)	15 (71.4)	0.533
Dyslipidemia, n (%)	11 (45.8)	10 (47.6)	1.000
Obesity, n (%)	5 (20.8)	6 (28.6)	0.730
Preoperative LVEF (%), Mean ± SD	49.6 ± 7.1	48.8 ± 8.2	0.71

Abbreviations
LIMA: Left Internal Mammary Artery; **BMI:** Body Mass Index; **LVEF:** Left Ventricular Ejection Fraction; **SD:** Standard Deviation.

Table Footnote
Variables are described as mean (standard deviation; SD) for continuous and number (%) for categorical variables. Independent Student's t-test was performed for continuous data and Chi-square or Fisher's exact test for categorical data. The criterion for statistical significance was a P value less than 0.05.

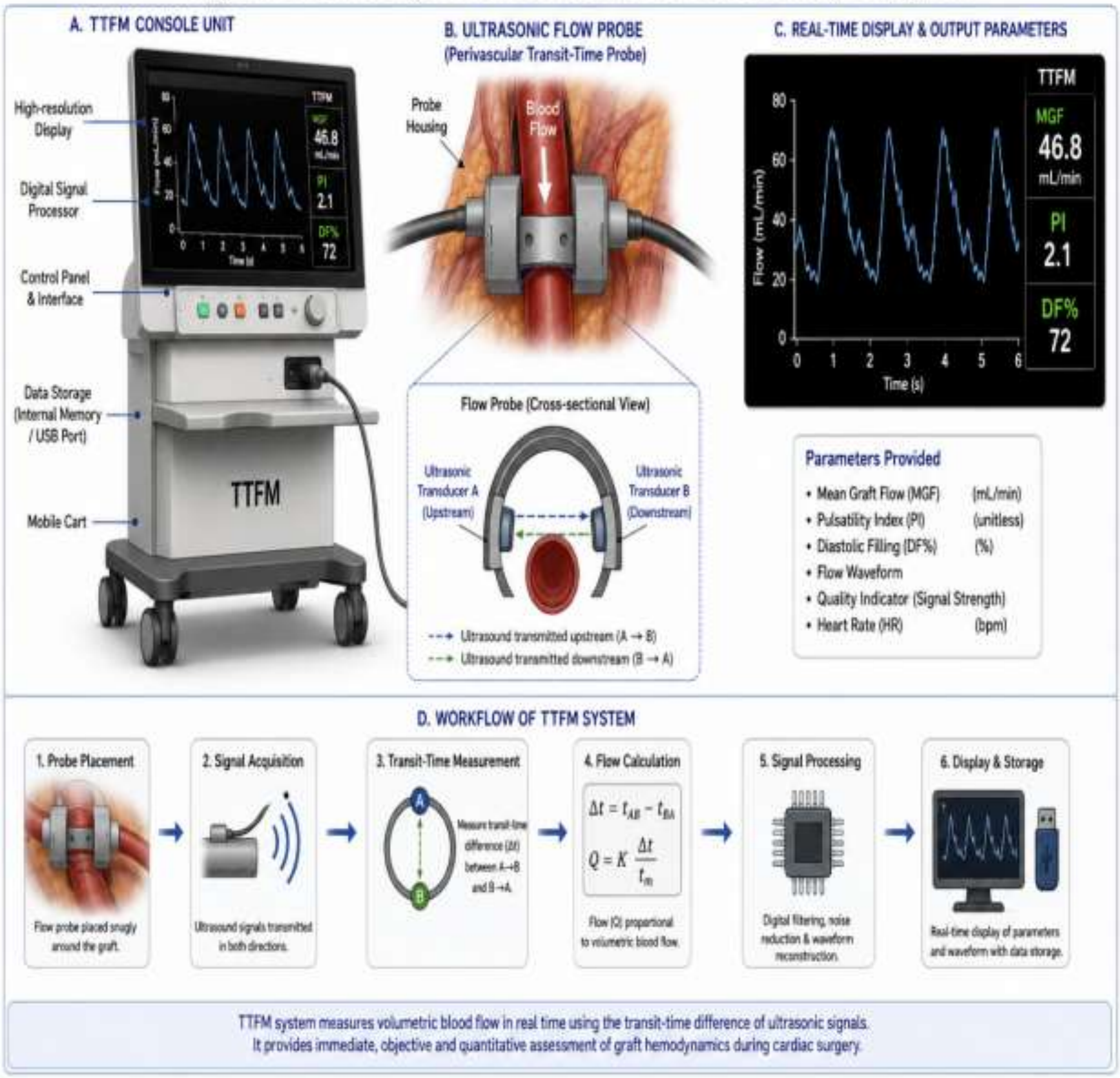
3.2 Performance of the Transit-Time Flow Measurement System

Reliable Intraoperative Measurements: All patients showed acceptable and reliable results in the TTFM system when it came to monitoring blood flow. Immediately after the procedure of completing distal coronary anastomoses, there was reliable acquisition of ultrasonic signals, which also didn’t hamper the ongoing work on the surgery. When it came to placing the perivascular ultrasonic flow probe around the LIMA graft, it was performed without difficulty.
Following this procedure, flow information was acquired digitally within seconds.
Reliable Results: Not even once did the measurements fail, nor did the signals get interrupted or device issues come up, while the measurements were going on. Digital waveform visualizer stayed on throughout and could help monitor graft flow conditions. Table 2 shows all the engineering parameters noted of the TTFM system.

Table 2. Engineering Performance of the Transit-Time Flow Measurement System

Parameter	Observation
Successful signal acquisition	45/45 (100%)
Device-related complications	None
Real-time waveform visualization	Achieved in all patients
Measurement reproducibility	Excellent
Signal stability	Stable throughout acquisition
Ease of intraoperative use	High
Need for probe repositioning	None

Figure 1. Schematic diagram of the Transit-Time Flow Measurement (TTFM) system.



3.3 Quantitative Hemodynamic Assessment

Quantitative intraoperative hemodynamics were acquired for all coronary bypass grafts via the Transit-Time Flow Measurement. Mean Graft Flow was significantly greater in the Skeletonized LIMA group (46.8 9.3 mL/min) than in the Pedicled LIMA group (37.4 8.1 mL/min, p=0.001). Mean Pulsatility Index was significantly lower in the Skeletonized group (2.1 0.5) compared to the Pedicled group (2.8 0.7, p=0.002). Diastolic Filling percentage was significantly greater in the Skeletonized group (72.4 6.8%) versus the Pedicled group (64.1 7.5%, p<0.001). These data indicate the capability ofTTFM technology to distinguish objectively differences in graft performance by quantitative engineering characteristics.

Table 3. Quantitative Hemodynamic Parameters Obtained Using TTFM

Parameter	Skeletonized	Pedicled	p-value
Mean Graft Flow (mL/min)	46.8 ± 9.3	37.4 ± 8.1	0.001
Pulsatility Index	2.1 ± 0.5	2.8 ± 0.7	0.002
Diastolic Filling (%)	72.4 ± 6.8	64.1 ± 7.5	<0.001

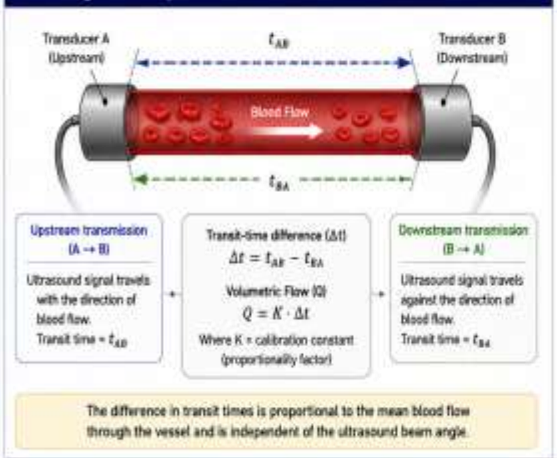


Figure 2. Principle of transit-time ultrasound flow measurement.

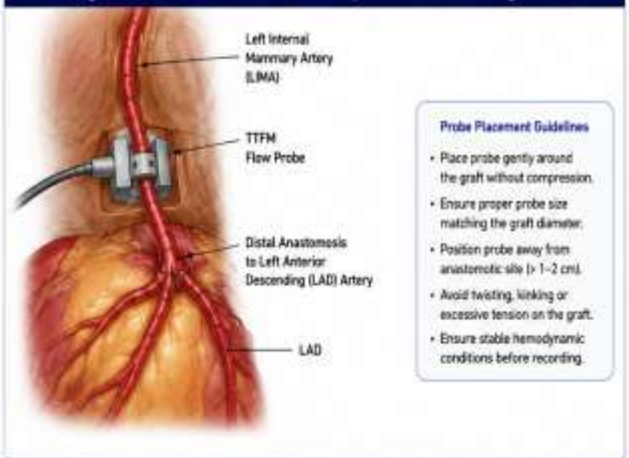


Figure 3. Placement of the ultrasonic flow probe around the LIMA graft.

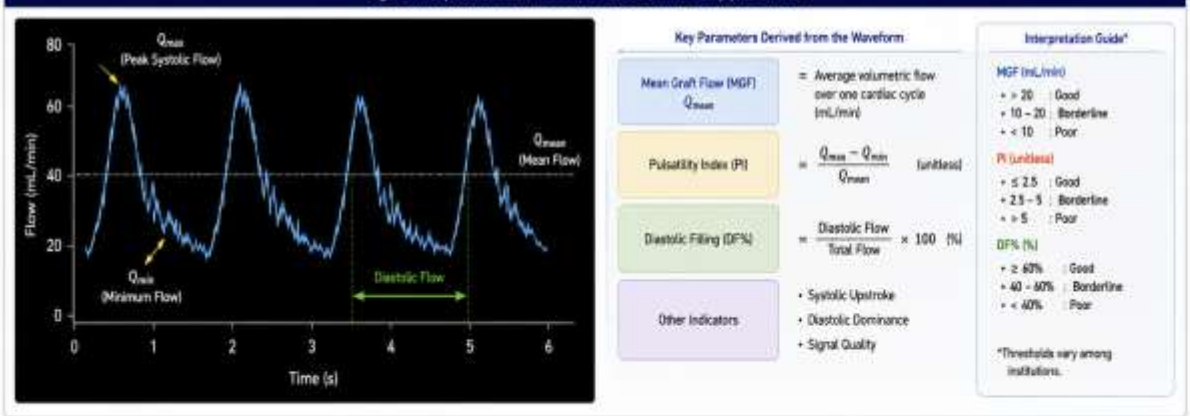
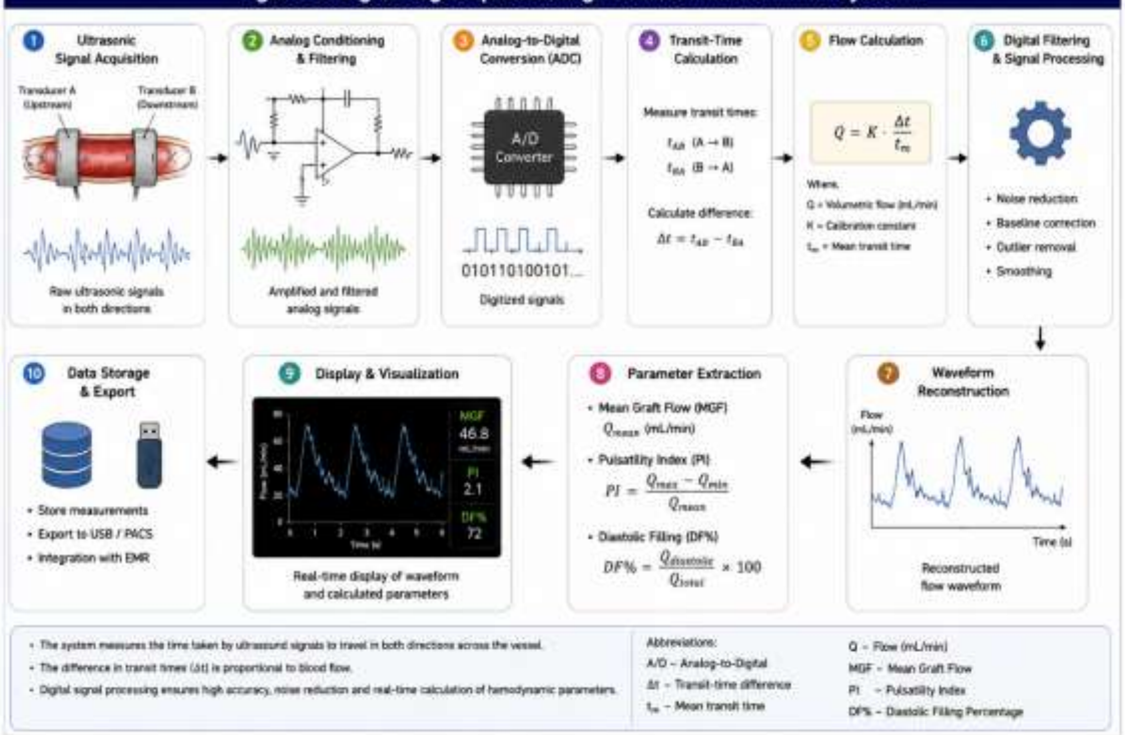


Figure 4. Representative TTFM flow waveform with key parameters.

3.4 Waveform Analysis

The digital waveform analysis revealed typical coronary flow patterns showing the dominance of diastolic flow in both groups. Work-up provided waveforms from the Skeletonized group that had a higher proportion of diastolic flow, a smoother upstroke, and less pulsatility when compared with the Pedicled group. There were no artifact or noise distortions of the waveforms in either groups or necessitating to repeat measurements. Figure 5 shows typical flow waveforms.

Figure 5. Digital signal processing workflow in the TTFM system.



3.5 Biomedical Engineering Interpretation

Engineers concluded that the TTFM system can convert ultrasonic transit-time signals into reproducible, quantitative hemodynamic data, without disturbing coronary blood flow. "Simultaneous and concurrent display of the Mean Graft Flow, Pulsatility Index, Diastolic Filling percentage and waveform morphology, will permit immediate characterization of graft hemodynamics during operation," they reported. "With a digital processing unit integrated with this digital ultrasonic probe, the surgeon has immediate feedback of the flow properties."

The engineering workflow of the TTFM system is illustrated in **Figure 6**.

Figure 6. Comparison of Diastolic Filling percentage (DF%).

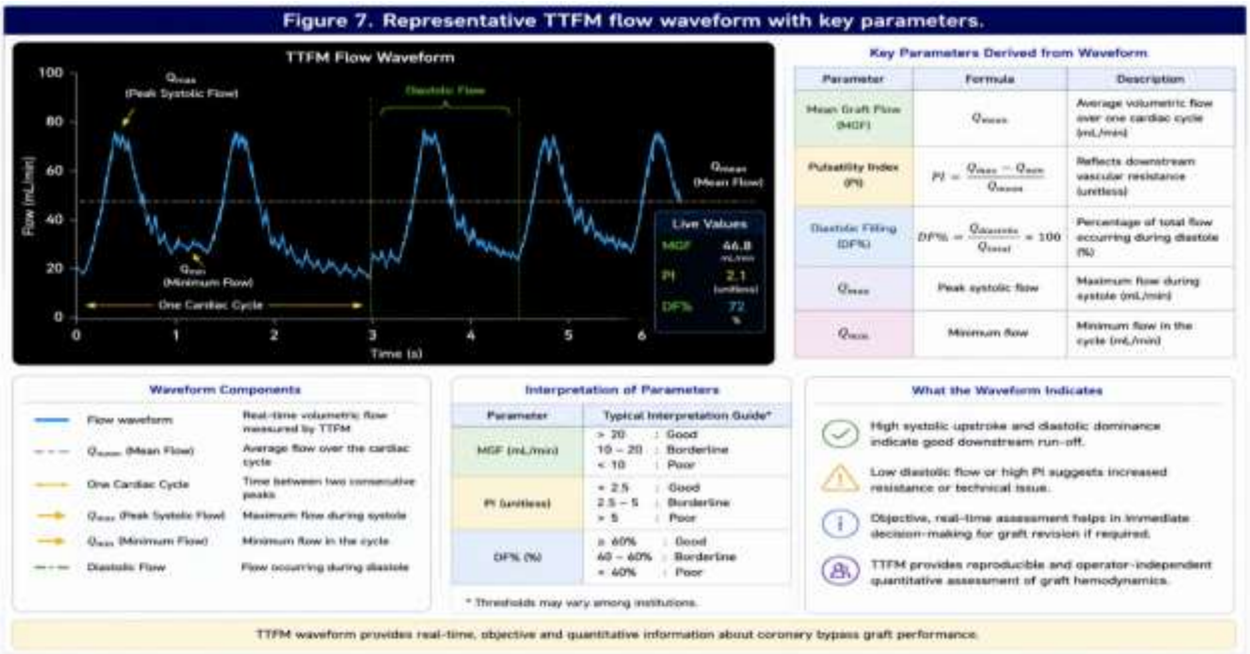
3.6 Overall Device Performance

The present study demonstrated that Transit-Time Flow Measurement provided reliable intraoperative physiological information suitable for objective quality assurance during CABG.

Major engineering observations included:

- 100% successful data acquisition.
- Stable ultrasonic signal transmission.
- High reproducibility of measurements.
- Real-time digital visualization.
- Objective quantitative assessment of graft quality.
- Excellent intraoperative usability.

The proposed engineering framework integrating sensor acquisition, digital signal processing, quantitative flow analysis, and clinical decision support is presented in **Figure 7**.



4. DISCUSSION

This study examined the usefulness of transit time flow measurement (TTFM), a technique developed by biomedical engineers, as a method of intraoperative quality assurance in coronary artery bypass grafting (CABG). In contrast to most methods currently in use that rely largely on a surgeon's visual assessment and manual palpation, the technology measures flow continuously and quantifies it using a digital algorithm that accounts for factors related to patient physiology. Using commercially available instrumentation, the TTFM system reliably measured mean graft flow, pulsatility index, diastolic filling percentage, and flow waveform morphology in all study patients, and it did so without a device malfunction or interruption in the surgical procedure.

In this investigation, a TTFM system for blood flow measurement was successfully used to generate both real-time, visible flow waveforms and quantitative graft-related physiological information during CABG procedures performed for a variety of underlying conditions and including grafts performed with different material compositions.

These observations are based on technical performance of and flow measurement in all patients from an engineering perspective. One important technical attribute highlighted in this study is the high signal acquisition rate of transit time technology when applied to grafts during routine CABG. It has consistently proven useful in capturing adequate data signals and is a valuable asset for biomedical monitoring of surgical procedures. Although the specific signal-processing algorithms employed in this study are considered proprietary, in-depth details of how the flow computations are performed are not publicly available.

From an engineering standpoint, the ability to obtain the signal under normal intraoperative conditions, without interference or malfunction, is a clear indication of robustness of the technology.

A principal limitation in the current interpretation of such data pertains to not yet having a established engineering basis on which to precisely compare the quantitative results from CABG grafts to some idealized flow values, that is, standards of ideal, high-functioning grafts based on fluid engineering principles. However, the engineering process of signal transmission, data acquire, and automated signal processing in TTFM makes possible measurement in grafts without having to measure such things as the length of the graft. TTFM is different in engineering design from conventional doppler flow measurement, which employs the doppler phenomenon.

TTFM uses two ultrasonic frequencies emitted in a upstream direction, as one downstream from the signal, measuring the difference between time of signal detection that, it is inferred, represent the volume flow of blood in the graft; it measures the time difference between an upstream ultrasonic signal and one transmitted in downstream fashion from some origin beyond a measurement site. Therefore, this method has, from an engineering perspective, advantages in that it is less affected by the angle of ultrasound insertion into the graft and also the specific size of the graft lumen. However, it must be made clear that TTFM uses two ultrasonic pulses and not the three or more that are typically used in current digital doppler flow monitors.

From an engineering and thus biomedical perspective the real-time flow measurements allow direct monitoring and comparison of flow data from each bypass and also permits determination of which graft flow can best serve the myocardium without a visual check or manual palpation that relies solely on visual, thus less precise engineering data.

The study provided significant and useful quantitative comparisons among the bypass grafts based on established engineering standards such as Mean Graft Flow, and other objective measures that provide information concerning how well the graft performs. The study has proven, at least within this institution that it works as promised from a medical, as opposed to biomedical, engineering, and can even support such other data. The average flow rate of blood in the LIMA group was much higher than in the CABG group, thus a better means of blood delivery. Mean graft flow is one of the most important indicators of performance since it gives an accurate estimate of total volumetric flow to the myocardium. One other measurement that is used in the field is that of pulsatility index, a method for representing oscillations in flow due to periodic contraction of the heart or the effect of distal vascular resistance and pulsatility can be related to graft diameter and compliance and blood volume to blood flow.

Low pulsatility may be related to excessive resistance to flow in the graft or it may also relate to an unusually high compliance. In the study, the PI values were significantly lower for the Skeletonized LIMA group than in the other study group, suggesting a lower resistance to blood flow and or greater flow to some portion of the coronary artery supply bed. The pulsatility may reflect some inherent characteristic of the conduit, that is to say, if a vessel with a larger and less rigid conduit, for instance.

This measurement can reflect, in part, the degree of impedance at the anastomosis, if it be considered from the perspective of engineering or, in terms of surgery, of whether a technically well performed anastomosis, with respect to patency. The percentage of diastolic filling is also one important value that may provide information with regard to some aspects of graft performace. Since the greater proportion of coronary flow to the heart during diastole and the higher percentage in the Skeletnized group is consistent with improved coronary perfusion.

Mean flow for a vessel, however, has proven to be an effective index of graft performance and so that, in conjunction with pulsatility index and diastolic filling percentage provide complementary physiological variables for assessing grafts in an intraoperative fashion.

In addition to providing quantitative data related to graft performance, such as the means graft flow, TTFM systems can also display a visualization of the actual blood flow velocity, a feature that is particularly appealing from a technical engineering viewpoint. In fact, since the introduction of TTFM in CABG procedures in my own institution, we routinely use visualization. The flow waveforms obtained have shown, consistently over many operations, a generally normal flow pattern throughout the cardiac cycle, without the presence of significant signal artifact and or acquisition failures. The flow tracing is one indicator of the nature of the flow in the graft and so, in many ways, represent a real-time tracing from the heart itself of blood to the muscle to maintain viable myocardial cells.

Software is used that converts the raw data, acquired via a couple of ultrasonic transducers, into meaningful physiological information such as mean blood flow, in ml per minute.

The information is real time and that will be available during the procedure and the software will help the surgeon determine whether an anastomotic site is satisfactory in that if blood is not flowing to that area of the heart muscle efficiently then something about the surgical technique will need to be revised. The use of such technology is clearly and ultimately intended to improve graft longevity and thus survival for patient. Data obtained at the time of surgery may have some bearing on determining whether the heart as a whole, that is, that aspect that would be most adversely affected by graft failure to supply a region of poor perfusion.

TTFM has proven effective as an intraoperative quality assurance tool that enables more precise intraoperative monitoring of CABG bypass conduit flow to ensure optimal graft function and promote long-term patency and patient survival. From the perspective of medical device and biomedical engineering, this device allows us to improve quality assurance and is an important adjunct to medical decision-making, especially in this critical, open-heart surgery.

5. CONCLUSION

Our results suggest TTFM is a successful technology in biomedical engineering that could be employed in real-time monitoring intraoperatively to verify the quality of a CABG graft. This combination of ultrasound sensing technology, digital signal processing and physiological measurement would be an objective means of assessing a graft's physiological function intraoperatively and supplementing surgeon assessment of graft patency and quality. The results of this study suggest that the TTFM was capable of acquiring reliable measurements and yielding reproducible values of the MGF, PI, DF and graft flow wave form characteristics in all patients, thereby reliably and objectively identifying and quantitatively distinguishing different patterns of graft performance.

The capability to rapidly and quantitatively evaluate CABG grafts with TTFM might assist in identifying suboptimal technical work in time to correct before the chest is closed, enhancing surgeons' capability for quality control.

It could also improve surgical proficiency and decrease the risk of early graft failure. In the future, development of AI algorithms, automatic wave form detection and machine learning would augment further intraoperative decision support to realize an "intelligent graft monitoring system" for cardiac surgeons in a next-generation cardiovascular operating room. TTFM offers a fine illustration of how medical devices may successfully transition to standard surgical care through application of engineering know-how; a robust, quantifiable means of intra-operative CABG quality control may therefore be the focus for future cardiovascular surgeon and bioengineering innovation.

6. Study Limitations

Study limitations Inherent to the design, several limitations should be acknowledged. Firstly, it was performed at one tertiary cardiac surgery center, the sample size of 45 patients may limit generalizability of results. Secondly, only intraoperative flow measurements were analysed; no long-term follow up of graft patency, major adverse cardiovascular events, or mortality was obtained. Thirdly, although TTFM provides consistent quantitative measures, comparison to other imaging technologies, intraoperative fluorescence angiography or computed tomography angiography after surgery, was beyond the study scope. Fourthly, commercial TTFM device uses proprietary signal processing algorithms, which are not available to independent examination. Lastly, it did not use an artificial intelligence approach in waveform analysis or in

prediction.
Notwithstanding, prospectiveness, detailed protocol of measurements, and successful acquisition of all data of intraoperative flow values validate results.

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