
Jules Flach

Coronary Artery Bypass Graft (CABG) Surgery is one of the most commonly performed procedures within Cardiac surgery, with over 700,000 new surgeries performed annually worldwide. Numerous studies describe the importance of verifying graft patency prior to chest closure, in order to improve outcome and to avoid or reduce the numbers of potential re-operations due to early graft failure.

D’Ancona et al. (2000) has shown TTFM findings indicating one or more grafts in 8% of all patients undergoing CABG, to be outside the normal ranges for a patent graft. Similar studies performed by Groom et al. (2001) and Walpoth et al. (1998), all show very comparable numbers. Furthermore, Jacob Bergsland et al. (Buffalo General Hospital, NY) has shown that in most cases where TTFM detected a non-patent graft, the surgeon did not expect any flow abnormality, stressing the fact that graft patency verification needs to be done on every graft in every patient undergoing CABG surgery. At the same time he found that if as a result of the TTFM indicating a non-patent / non-functioning graft, the surgeon decided to revise the graft, complete revascularization with all grafts patent, was achievable in almost all cases, confirmed by normal TTFM readings. Noteworthy reading is also the study from D’Ancona, G, et al. (2000) which shows how traditional methods such as finger palpation are not at all reliable in verifying graft patency, outlining the need for a quantitative measurement to reliably detect any graft issues before chest closure.

Eugene K.W. Sim, FRCS, University of Singapore concluded in his study published in the Annals of Thoracic Surgery (2005): [...] Transit-time flow measurements enables technical problems to be diagnosed accurately, allowing prompt revision of grafts. It should be mandatory in coronary artery bypass grafting to improve surgical outcomes...].

In summary there is strong evidence to support the need for an objective and accurate verification method prior to chest closure.

The above numbers are taken from the world leading institutions, and should be considered conservative when applied across all the institutions performing CABG surgery worldwide. Analysis from the current TTFM data on our VeriQ demo system, which contains 60 CABG surgery cases done in reputable hospitals in Hong Kong, Malaysia, Singapore, Macau and Thailand, suggest that the average number of patients with one or more grafts not patent is much higher than the number typically published, such as the ones above. 148 grafts were measured using the VeriQ TTFM system across the 60 patients. 20 patients or 30% of those 60 patients had a total of 25 grafts or 16.9% with TTFM outside the published normal values for graft patency (PI: <5 and DF: >50%).
Case example #1

Malaysian patient undergoing CABG surgery, the TTFM immediately before chest closure showed a non-functioning Radial to CX (fig. 1). Despite being a Radial Artery, a kink was detected on the back wall resulting in high flow resistance (Pl: 45.7) and predominant systolic flow (DF: 8%) with only 2ml/min of actual flow, while ECG did not show any changes. Fig. 2 shows a patent graft with Pl < 5, DF > 50% and mean flow improved from 2ml/min to 16ml/min after graft revision.

Case example #2

Fig. 3 In this Hong Kong patient, the TTFM on the SVG to OM graft showed virtually no flow, with a high flow resistance (Pl: 25.4) and predominant systolic flow (DF:15%) with very little actual flow (2ml/min). Fig. 4, shows the same graft after revision, now with low flow resistance (Pl: 2.2), predominantly diastolic flow (DF: 68%) and dramatically increased mean flow.

These measurements obtained during product demonstrations were taken within two minutes and information stored instantaneously for review.

Other Values of TTFM-QA

There are a wide range of compelling arguments that would support the implementation and use of TTFM-QA. These include providing the following benfits:

- An objective assessment to ensure all grafts are patent and functioning prior to chest closure, allowing for optimal revascularization. Thus, minimizing post-surgical complications including re-op.
- Build-in storage and reporting capabilities allow user to be in line with today’s evidence based medicine era. It easily caters for communication within department and referring physician cardiologist, insurance carriers, patient file and follow-up, education and research purposes etc.
- Better understanding of procedural complications.
- Ability to quantify and monitor the impact of procedural changes and new devices.
- Facilitate easy adoption to off-pump CABG, as well as training for junior surgeons.
- Ability to evaluate old graft performance in potential future re-CABG. Old graft performance can also be compared to previous graft patency measurements if available.
- Medical legal protection.
- Peace of mind.
- Patient’s best interest.
Graft Patency Verification using Transit Time Flow Measurement (TTFM)

Transit Time Probes are available in various sizes to cover the typical graft diameters in CABG surgery, ranging from 1.5mm for small IMA grafts, up to 5mm for large vein grafts. To ensure good acoustical contact with the vessel, the correct size probe provides a close fit, and a bit of saline or patient blood is recommended (fig. 5). The probes are connected to the VeriQ system (MediStim, Oslo, Norway). ECG signal for the VeriQ system is received via an interface cable from the existing patient physiological monitor in the operating theatre. Fig. 6 shows the real time color-coded TTFM tracing. Blue section indicates flow during diastole and red section indicates flow during systole. A patent graft is expected to show predominant diastolic flow. The DF number indicates the percentage of diastolic flow. The Pulsatility Index PI, is an indicator of flow resistance. Typically PI is less than 5 in a patent graft. PI and DF together form a very solid indicator of graft patency, DF>50% and PI<5 indicates a patent graft. The VeriQ system also provides mean-flow in ml/min. While it is interesting to understand the amount of flow through the graft, it is greatly affected by the vascular run off, the size of the graft, the heart rate and blood pressure and therefore cannot alone be used as a reliable indicator for graft patency.

TTFM has shown to be reliable and accurate and without the need for calibration. It is easy to use and provides an objective, instant quantification with a sensitive and reliable graft patency verification.

Cost saving projection with the use of TTFM-QA

In addition to the obvious benefits of using a graft patency verification process as described above, there are economical benefits in the form of cost savings by eliminating or reducing costs for re-operations due to early graft failure.

The below table gives an indication of the potential cost-savings. Costs for re-op may vary from country to country, hospital to hospital. For this model we assumed a re-op cost of US$ 9,000 (fees for surgical team, OR time, disposables, extended stay in ICU etc).

<table>
<thead>
<tr>
<th># of CABG/year</th>
<th>VeriQ cost (probes) @ US$ 85 /case</th>
<th>4% Re-ops due to early graft failure</th>
<th>Re-op cost @ US$ 9,000 / case</th>
<th>Hospital savings Year 1</th>
<th>Hospital savings Year 3</th>
<th>Hospital savings Year 5</th>
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<tr>
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Above includes the cost of a VeriQ System (basic Configuration) with its cost written off over an 8-year period. The VeriQ cost per procedure has been calculated at US$ / procedure, assuming an average of 1.7 probe uses / case.

Above model would indicate that even a relatively low volume surgery (50 CABG / Year) would be able to save money by applying a graft patency verification process/system. Considering the publications by D’Ancona et al, the 4% Re-ops used in the above cost saving model may be considered conservative. Reviewing 60 patients in our demo system's archive, 4% seems very low. In fact it appears the less CABG surgeries performed in a given institution the higher the percentage re-ops.
To realize the projected savings TTFM-QA of each and every single graft in every patient undergoing CABG surgery is required. As Dr. Jacob Bergsland described, most of the time when TTFM-QA detected a non-patent graft, the surgeon did not expect anything to be wrong with the graft, thus TTFM-QA should not be used on indication but routinely on all grafts.

Other costs / risks which can be eliminated or dramatically reduced by the use of a TTFM-QA graft patency verification include potential legal exposures as a result of early graft failure and a reduction of post surgical complications, including AF/VF leading to reduced ICU stays. A recent publication by the Heart Institute Lahr / Baden (2005), involving almost 8000 patients, concludes: Routine use of TTFM significantly reduced the incidents of postoperative VF, postoperative CK/CK-MB fraction, and angiographically detected bypass malfunction. A simultaneously implemented algorithm reduced the mortality with VF after CABG. The consequent use of TTFM intra-operatively reduced the incidence of postoperative anastomosis and technically related complications of bypass surgery and led to a significant reduction of postoperative mortality in CABG procedures. This publication came at the same time as the Lusine Abrahamyan’s publication in the Asian Annals “Determinants of Morbidity and Intensive Care Unit Stay after Coronary Surgery”, indicating arrhythmia being the main post-surgical cause for extended ICU stay and death.

**Conclusion**

Strong evidence supports the need for an Objective and Accurate Verification method before chest closure. TTFM-QA is easy to use, accurate, highly reproducible and relatively inexpensive. It has shown that TTFM-QA improved outcome in numerous publications and case presentations. With the routine use of TTFM-QA, cost savings are realized from the elimination or dramatic reduction of potential re-ops and reduction in ICU stays. Furthermore, TTFM-QA provides excellent documentation of the surgical outcome and allows for better understanding of procedural complications. It gives a quantitative measurement of the impact of procedural changes and facilitates training for junior surgeons and off-pump procedures. It provides an excellent tool to evaluate old graft performance in the cases for potential CABG re-dos. TTFM-QA should be mandatory in coronary bypass surgery.

**References:**