Electromagnetic Determination of Blood Flow Through IMPRA (Expanded Polytetrafluoroethylene) Graft

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Abstract

The use of perivascular electromagnetic flow determination is an accepted diagnostic tool in reconstructive vascular surgery and like techniques are in widespread use in the laboratory. As yet, no prosthetic graft material has been available through which blood flow could be accurately determined in the acute setting. IMPRA,® an expanded polytetrafluoroethylene in the form of a vascular prosthesis does permit such determination when pretreated with minute amounts of absolute ethanol.

Graphic data is presented to show the quality of flow signal that may be obtained through IMPRA® as well as the accuracy of the signal with reference to flow determinations made through a fresh arterial segment under carefully controlled conditions.

Introduction

The technique of recording blood flow using electromagnetic flowmeters coupled with perivascular probes has become an accepted research method over the past three decades.[1,2,3] More recently, intraoperative evaluation of reconstructive vascular surgical procedures has become routine in some centers.[4,5,6] Simultaneously, a variety of prosthetic materials have come into common use in arterial reconstruction.

The capacity to measure blood flow directly from a vascular prosthesis has several advantages, yet no published work exists on the techniques employed and the problems involved with such measurements. There are in the world literature several articles which describe recording flows in newly implanted crimped dacron® prostheses despite general agreement that good quality signals cannot be obtained with such materials until tissue ingrowth has occurred. Examinations of the tracings in that literature verify the lack of high quality flow signals, and analysis of the numerical data in those cases where tracings are not available suggests problems with the flow determinations.[7] The single publication which describes flow measurement from an unspecified teflon® prosthesis includes a tracing which shows considerable artifact in the signal.[8]

The present study was undertaken to explore the possibility of obtaining high quality electromagnetic flow signals through IMPRA®[a] grafts. The material is expanded polytetrafluoroethylene that has been extruded in such a manner as to create wall arthitecture whose characteristics appear favorable for electroconductivity providing the graft has been appropriately pretreated with ethanol. (This pretreatment is not required for clinical use.) It is created by a mechanical elongation process that modifies the inherent internal structure into a series of solid polymer particles (called nodes) that are connected by a multitude of thin polytetrafluoroethylene fibrils. The particles are elliptically shaped with a minor axis of 10 microns and a major axis of random length oriented in the radial direction. The separation of the nodes is 30 to 40 microns on the average. This distance is also the fibril length and is known as "pore size". The resultant void space is approximately 85%, adequate for tissue ingrowth in this structural setting. As it is normally encountered, the graft is hydrophobic due to its strong negative charge. This high surface tension can be lowered so as to render the material hydrophilic by saturating it with com-

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[a]IMPRA®, IMPRA, Inc., Tempe, AZ 85281

pounds such as the small chain alcohols. The "wetting" of the graft permits water and electrolytes to then penetrate the material, creating a good conductive pathway through the polytetrafluoroethylene. Once electroconductivity is established, electromagnetic flow recording becomes feasible.

When blood flow is established in a graft that has been "wetted" there follows a several minute period during which the graft "weeps" serum until the minute amounts of alcohol and its effects are diluted. During this period serum proteins and platelets are apparently deposited, limiting the fluid loss but not diminishing conductivity. Should an alcohol treated graft be allowed to dry completely, it will again become hydrophobic. The combination of all these characteristics precludes the passage of red cells through the wall of the graft.[9]

Methods and Materials

A 10 centimeter portion of 5 millimeter I.D. IMPRA® was occluded at one end and three to four milliliters of absolute ethanol were introduced into the open end under a pressure of 50mm Hg until the ethanol had passed through the wall, appearing over the entire surface of the graft.

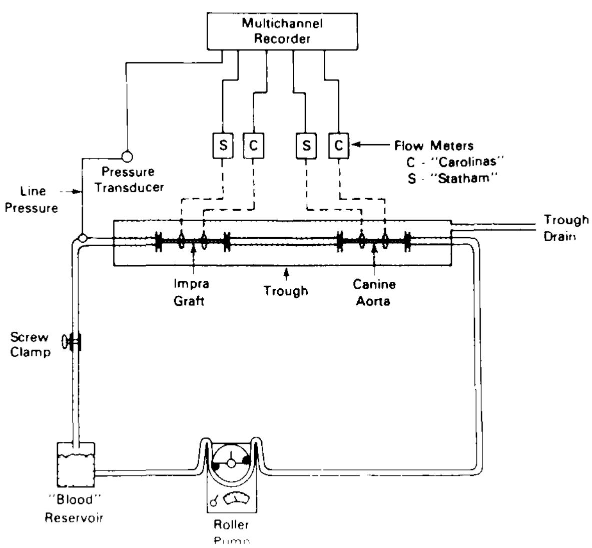

FIGURE 1: Schematic for comparative flow studies.

The schematic for this study is depicted in Figure 1. Ten centimeter segments of IMPRA® and freshly harvested distal canine aorta were connected in series with Tygon® tubing[b] to create a perfusion circuit through which flow was directed using a calibrated roller pump (Model 3500 Travenol).[c] Four cuffed-type perivascular flow probes carefully chosen for fit were placed so that a Carolina Medical probe of the EP-400 series[d] and a Statham 7500 series probe[e] each were placed on the segment of canine aorta and on the IMPRA® graft. The probes were connected to the appropriate flowmeters, Carolina Model 501[d] and Statham SP-2202.[e] The phasic and mean outputs of the flowmeters were recorded on an eight channel Brush Model 481 Accuchart recorder.[f]

A single screw clamp was placed on the circuit well distal to the recording sites to permit control of the pressure in the system. This made it possible to control the amount of distention of the arterial and graft segments so that "best fit", or the probe fit that gave good null and electrical zero settings, could be maintained constantly. Line pressure was monitored at a point in the circuit just proximal to the screw clamp and mean pressure was continuously displayed on the Brush recorder.

The use of the roller pump in this minimal compliance circuit clearly results in "pulsatile-like" flow (Figure 2). The characteristics of the flow cycle could be varied by changing tubing

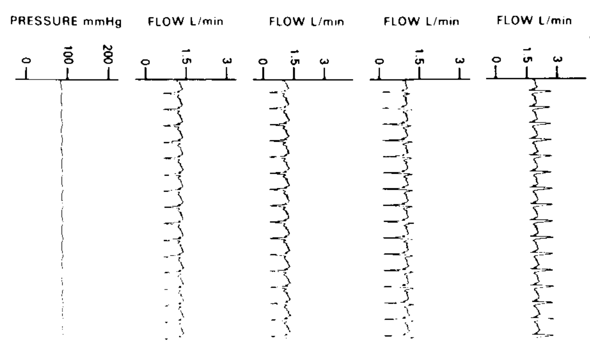

FIGURE 2: Representative simultaneous tracings of electromagnetic flowmeters employed as in Figure 1. Known flow is 1000cc/min.

[b]Tygon® Norton Laboratories, Akron, OH 44309

[c]Travenol Laboratories, Deerfield, IL 60015

[d]Carolina Medical Electronics, Inc., King, NC 27021

[e]Gould Inc., Medical Products Division, Oxnard, CA 93030

[f]Gould Inc., Instrument Systems Division, Cleveland, OH 44114

diameter or roller head occlusion. Line pressures in this study were permitted to range between 20 and 60mm Hg, depending on the degree of roller head occlusion and the line occlusion set by the screw clamp.

To allow the recording to be done in an environment similar to that in which the manufacturers[10] calibrated the probes, the artery, graft and probes were placed in a non-conductive trough which was filled with 0.9% saline. The circuit was perfused with a mixture of outdated human red cells, pooled human plasma, and lactated Ringer's solution which had a resultant packed cell volume of 39%.

Null and electrical zero settings were determined repeatedly during the study by simultaneously halting the pump with its off-on switch and occluding the circuit distal to the recording sites. This method was important for two reasons. First, identical flow rates could be regained each time and second, mechanical and electrical zeroes could be obtained with artery and graft under pressure so the "best fit" was assured and the fit during zeroing was as close to the fit during flow as could possibly be obtained in a pulsatile system. The actual flow rates in the circuit were determined by instantaneous diversion of flow to a graduated collecting bottle whose filling was timed with an electrical stopwatch. Flow could be repeatedly adjusted in this system until the desired rate was obtained since the measured blood could be returned to the reservoir at the experimenter's convenience without altering flow in the circuit.

Results

To compare the quality of flow signals obtained from artery and prosthesis, the tracings of a single flow rate are presented in Figure 2. Similar quality tracings were obtained at flow rates ranging from 500cc/min. to 2000cc/min. With the frequency response of all flowmeters set at 20-30 Hertz (Hz), the tracings were essentially free of noise and all were symmetrical throughout the entire pulse wave-form.

Values obtained from the tracings were reproduced with consistency after each of the multiple cessations of flow for mechanical and electrical zeroing. Like values were obtained after several repositionings of each probe, provided satisfactory nulls and zeroes could be again established.

The data points in Figure 3 are the means of three determinations where each was one of a set of values taken as the flow was continually increased from 500 to 2000cc/min. The flow was reduced to zero and the process repeated twice more.

The recorded numerical values for known pump flow of 1000cc/min. were as follows: Statham/IMPRA® - 1350cc/min., Statham/Artery - 950cc/min., Carolina/IMPRA® - 945cc/min., Carolina/Artery - 985cc/min. The recorded values for flows over the entire range of 500 to 2000cc/min. are graphically displayed in Figure 3. Although the graphs indicate the performance of the systems to be linear over this range, it is really apparent that no two slopes are identical. There is also crossover of the plots. Linear regression analysis of the data points in Figure 3 yielded the following slopes: Carolina/Artery - 0.96, Carolina/IMPRA® - 1.08, Statham/Artery - 1.457, Statham/IMPRA® - 1.39. No y-intercept was at zero. For each of the four experimental designs, the correlation coefficients for the data points at each observation with reference to the slope (line) were greater than 0.995. Analysis of the slopes shows that the Carolina measurements are equivalent for both graft and artery at the 90% confidence level. At the same confidence level these slopes are statistically equivalent to the slope of 1.0. Statham meters also show the flows from graft and artery to be equivalent at the 90% confidence level, although neither was equivalent to the ideal slope. These observations, coupled with the absence of any tendency to higher or lower values from either type flowmeter suggests that any explanation for the variance is a complex one.

Discussion

The ability to record blood flow through a prosthetic material using perivascular electromagnetic flow recording techniques has several distinct advantages for both the clinician and the researcher. Such a capability in the setting of reconstructive vascular surgery could allow assessment of the reconstruction without additional dissection either proximal or distal to the anastamoses for placement of flow probes. It would also be possible to measure flows in shunts or bypasses where the anatomy of the inflow and the runoff preclude measurement of the flow unless multiple probes are employed.

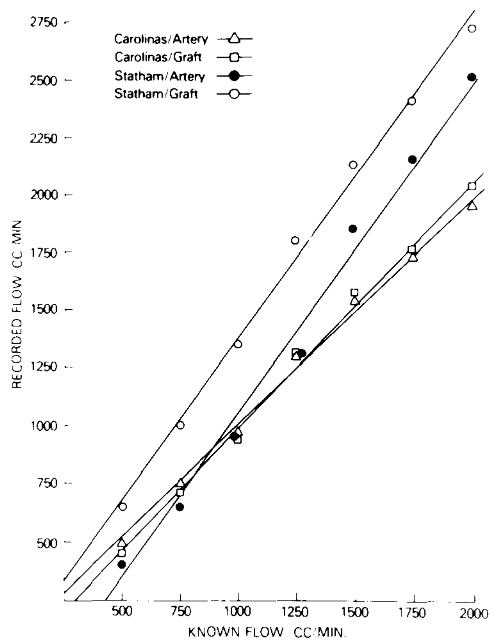

FIGURE 3: Performance of flowmeters/probes over a range of known flows.

Two of the most common situations in which such direct measurement might be advantageous are the arteriovenous shunt for vascular access and the systemic to pulmonary shunt. Both exemplify the difficulties that would be encountered in attempting to accurately determine flow, even if exposure of some of the involved vessels could be accomplished.[11]

Examination of the results obtained in this study indicate the quality and accuracy of the electromagnetic flow signals obtained through IMPRA® to be equal to those obtained through a segment of freshly harvested artery. Measurement of blood flow in this arterial prosthesis even when newly implanted is therefore a reality and the accuracy can be expected to equal that obtained when these flowmeters are used on arterial or venous structures. It should be added that although this capability is unique in the acute setting, electromagnetic flows can be determined through a number of chronically implanted porous prostheses including crimped dacron. This should be possible in any material where tissue ingrowth has occurred and provided a conductive pathway from probe to blood in a manner like that of any vascular structure.

The variances in the recorded flows encountered in this study remain without certain explanation. Since each of the four data sets has a different slope and y-intercept, and there is a crossover of the plots, no one aspect of the system could be responsible. Neither the conduit (canine artery or IMPRA® graft) nor the type of recording system (Statham or Carolina Medical) can be implicated as a single explanation for the differences in recorded flow. Attention might then be directed to the interface of probe with conduit. Because there are probes of two different manufacturers interfacing with two very different types of conduit, small differences in fit between all four interfaces is quite possible. The effects of such differences may be further exaggerated by the "pulsatile-like" nature of flow as seen in this study, since fit may be expected to change continuously throughout each cycle of pressure and flow when the conduit is known to have some elasticity. This effect would not be predictable because the probes were not calibrated in a pulsatile system, and in fact, no conclusive information exists as to the accuracy of such electromagnetic flow determination systems when applied to a closed, pressured expansile circuit in which there is pulsatile flow.[12] This problem is currently under study at this institution.

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