

## Regular Papers

# An Adaptive Tourniquet for Improved Safety in Surgery

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**Abstract**—The increasingly recognized inability of the current generation of pneumatic tourniquets to control pressure with adequate accuracy, reliability, and stability has been associated with continuing reports of tourniquet-related injuries, incidents, and hazards. Moreover, the labor-intensiveness and operating costs associated with the use of current types of pneumatic tourniquets have significant cost implications for hospitals. To a large extent, the recent development of a microprocessor-based tourniquet capable of safely and accurately maintaining a desired pressure, and capable of simultaneously performing other functions such as detection of alarm conditions, has reduced these hazards and operating-cost implications. Furthermore, the availability of a microprocessor-based tourniquet has facilitated the development of the adaptive tourniquet described in this paper, in which the pressure in a tourniquet cuff is changed throughout a surgical procedure as a function of the patient's changing intraoperative systolic pressure, thus approximating the minimum safe pressure necessary to maintain a bloodless field for surgery. While the use of an adaptive tourniquet, rather than just a microprocessor-based tourniquet set at a constant pressure may not be necessary in most cases, it promises to have significant value in certain surgical procedures and for patients who may be at greater risk of tourniquet-induced complications. Also, the lower average pressures possible through the use of an adaptive tourniquet may permit the evolution of surgical techniques of longer duration without a concomitant increase in the risk of tourniquet-induced complications. Finally, despite the increased safety of the adaptive tourniquet, it is estimated that the operating costs will be lower than for conventional pneumatic tourniquets due to elimination of the need for compressed gas and reduced labor-intensiveness.

### INTRODUCTION

CURRENTLY available types of surgical tourniquets consist of three basic components: a source of pressurized gas, a pressure-regulating mechanism with pressure gauge, and a pneumatic cuff which is applied to the proximal portion of a patient's limb and inflated to a suprasystolic pressure in order to maintain a bloodless surgical field in the distal portion of the limb. In properly employing a pneumatic tourniquet for surgery of the extremities, the pressure in the cuff should be maintained at the minimum pressure necessary to assure a bloodless field distal to the cuff. Maintaining a bloodless field in the limb for surgery makes dissection easier, surgical tech-

niques less traumatic, and the time required for operations shorter [1]. Moreover, maintaining a bloodless field while simultaneously minimizing the pressure in the pneumatic tourniquet cuff will minimize the probability of pressure-related injury associated with tourniquet usage [2], [3].

Because of its usefulness, the pneumatic tourniquet is widely employed. Information obtained from manufacturers and regulatory agencies suggests that in North America at least ten thousand pneumatic tourniquets are used in more than one million surgical procedures annually. However, none of these pneumatic tourniquets are capable of safely and automatically maintaining the minimum pressure necessary to assure a bloodless field throughout surgery due to factors associated with their design and construction (e.g., see [4]–[7]) and they cannot be modified readily to achieve significantly greater levels of safety, accuracy, stability, and reliability. Accordingly, it is perhaps not surprising that the widespread use of pneumatic tourniquets has been accompanied by continuing reports of injuries, e.g., [4]–[6], [8]–[11]. It has been suggested that the true incidence of tourniquet-induced complications may be significantly underestimated, and that each use of a pneumatic tourniquet may in fact lead to some damage, although such damage is generally short-term and reversible [11], [12].

Many, but not all, tourniquet-related injuries are pressure-related. Tourniquet-related complications may result not only from excessive pressure leading to nerve compression or other injuries at the site of the cuff [2], [13], [14], [16], but also from insufficient pressure leading to surgical complications, passive congestion, and hemorrhagic nerve infiltration [14], from excessive periods of tourniquet application [9], [15], [16], or from application of the cuff without due consideration of the underlying anatomy [11], [17], [18]. To a large extent, the risk of injury associated with these factors has been significantly reduced by the recent development of a microprocessor-based tourniquet having a much higher degree of safety, accuracy, and reliability [4]. The objective of the work described in this paper was to determine whether the already developed microprocessor-based tourniquet could be modified and used effectively to further reduce the probability of injury by adaptively adjusting the pressure in the tourniquet cuff intraoperatively, as a function of the patient's changing systolic pressure, in order to minimize the pressure necessary to maintain a bloodless field during surgery.

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## ADAPTIVE TOURNIQUET

At present, pressures in pneumatic tourniquets are commonly set at constant, preestablished levels: for example, pressures of approximately 300 mmHg for upper limbs and 500 mmHg for lower limbs are widely employed [1], [13]. Such pressures are clearly much higher than normal systolic pressures, but have been used traditionally to accommodate hysteresis in pressure-regulating mechanisms, errors in pressure gauges, suboptimal cuff geometries, leaks, and intraoperative increases in systolic pressure. It has been suggested that improved safety would result from setting tourniquet pressure  $P_T$  to some constant threshold  $K$  above a patient's preoperative systolic pressure  $P_S(t_0)$ , rather than to some arbitrary and unnecessarily high level [2], i.e.,

$$P_T = P_S(t_0) + K. \quad (1)$$

It has been suggested specifically that 30-75 mmHg might be appropriate values of  $K$  for upper limbs [2], [3], [9], and that  $K$  might be set to  $P_S(t_0)$  for lower limbs, provided the patient was normotensive and did not have grossly hypertrophied or obese thighs [19]. However, the above-noted limitations in the accuracy and reliability of widely used types of pneumatic tourniquets makes their use either hazardous or labor-intensive because constant monitoring would be needed. In contrast, the lower pressures which have been advocated have been implemented through the use of the previously mentioned microprocessor-based tourniquet, resulting in reductions in tourniquet pressure by as much as 40 percent in comparison to traditional levels, with a simultaneous reduction in labor-intensiveness and increased safety [4]. Thus, a minimum constant pressure can be achieved through the use of such a device. In certain cases, however, a dynamically changing pressure in the tourniquet cuff may be warranted to further reduce the mean pressure and thereby increase safety for certain patients at greater risk of tourniquet-induced complications, e.g., those who have thin limbs with little protective musculature such as infants, small children, and certain adults. Particularly for these patients and perhaps for others, a tourniquet capable of adaptively minimizing its cuff pressure throughout a surgical procedure promises to be safer than one which is only capable of maintaining a constant pressure.

Because the patient's systolic pressure  $P_S$  can vary throughout the time  $t$  of a surgical procedure as a function of variables such as changes in anesthetic technique or physiologic status, tourniquet pressure  $P_T$  should also be a time-varying function in order to minimize the pressure necessary to maintain a bloodless field and (1) should be expressed as

$$P_T(t) = P_S(t) + K. \quad (2)$$

Also, the threshold  $K$  in (2) should be set according to other variables, i.e.,

$$K = e_H + e_S + f_T(w_T, c_T, g_T) \quad (3)$$

where  $e_H$  is inherent error due to hysteresis in the pressure-regulating mechanism,  $e_S$  is the error in the pressure-sensing means, and  $f_T$  is a function of tourniquet cuff width  $w_T$ , limb circumference  $c_T$ , and considerations related to the shape and geometry of the limb and cuff  $g_T$  [9], [11], [17], [18], [20].

The patient's true systolic pressure  $P_S(t)$  is related to the measured systolic pressure  $P_{SM}(t)$  as determined by an indirect method such as oscillometry or Korotkoff-sound analysis in the following manner:

$$P_S(t) = f_M \cdot P_{SM}(t) + e_P \quad (4)$$

where

$$f_M = f_M(w_M, c_M, g_M) \quad (5)$$

and where  $w_M$  is the width of the pneumatic cuff used for blood pressure measurement,  $c_M$  is the circumference of the limb,  $g_M$  is a factor associated with the anatomy, geometry, and shape of the limb site at which blood pressure is measured, and  $e_P$  is some error associated with the indirect measurement technique [20]-[24].

If tourniquet pressure is set at  $(N+1)$  discrete times  $\{t_i\}$ ,  $i = 0, 1, \dots, N$ , during a procedure rather than continuously, then (2) becomes

$$P_T(t) = P_S(t_i) + K + e_A(t - t_i) \quad t_i < t \leq t_{i+1} \quad (6)$$

where  $e_A$  represents the maximum increase in the patient's systolic pressure which may have arisen since the last measurement because of changes in the patient's cardiovascular status or for other reasons. Combining (4) and (6) yields

$$P_T(t) = f_M \cdot P_{SM}(t_i) + e \quad (7)$$

where

$$e = f_T + e_P + e_H + e_S + e_A(t - t_i) \quad (8)$$

for

$$t_i < t \leq t_{i+1}, \quad i = 0, 1, \dots, N.$$

To reduce the magnitude of short-term changes in tourniquet pressure as a function of the variability in successive determinations of  $P_{SM}$ , a moving average value could be employed, e.g., a three-point moving average

$$\widehat{P_{SM}} = \frac{1}{3} \sum_{j=1}^3 P_{SM}(t_{i-3+j}) \quad (9)$$

could be substituted for  $P_{SM}$  in (7).

As an example of the application of (7) above, one might consider the case where indirect determination of blood pressure is being performed on one upper limb by some system meeting the requirements of the draft AAMI standards [23]-[24], and where such information is used to manually reset the pressure in a commercially available pneumatic tourniquet applied to the other upper limb at intervals of 30 min or more. In such a case, setting  $e_P$  to 16 mmHg should be adequate for values of  $P_{SM}$  within two standard deviations of  $P_S$ . Other typical values are

$$f_M = 1$$

$$f_T = 10 \text{ mmHg}$$

$$e_S = 20 \text{ mmHg}$$

$$e_A(30 \text{ min}) = 50 \text{ mmHg}$$

and assuming  $e_H$  is only 50 mmHg, (7) becomes

$$P_T(t) = P_{SM}(t_i) + 146 \text{ mmHg} \quad t_i < t \leq t_{i+1}$$

$$i = 0, 1, \dots, N. \quad (10)$$

Thus, in this example, tourniquet pressure should be set at 146 mmHg above the patient's intraoperative systolic pressure for safe operation. In practice, this threshold might be much larger, e.g., typical values of 150 mmHg for  $e_H$  have been reported [7]. Therefore, although it might be desirable in principle to use suggested lower pressures of as little as 30–75 mmHg above the preoperative systolic level [2], [3], [9], implementation of such suggestions with commonly used tourniquets would be hazardous.

The projected use of the previously mentioned microprocessor-based tourniquet in the above example is instructive. Assuming that tourniquet pressure could be adaptively set on the basis of automatic determinations of systolic blood pressure made at 1-min intervals, the equivalent values for (8) would be as follows:

$$f_T = 10 \text{ mmHg}$$

$$e_P = 16 \text{ mmHg}$$

$$e_H = 6 \text{ mmHg}$$

$$e_S = 3 \text{ mmHg}$$

$$e_A(1 \text{ min}) = 15 \text{ mmHg}$$

and (7) would become

$$P_T(t) = P_{SM}(t_i) + 50 \text{ mmHg}, \quad t_i < t \leq t_{i+1}$$

$$i = 0, 1, \dots, N, \quad (11)$$

resulting in considerably lower pressure in the tourniquet cuff.

For blood pressure measurements employing a nonstandard system, cuff, or anatomical location,  $f_M$  would be a function of the variables indicated in (5) rather than a constant. Similarly,  $f_T$  is generally a function of corresponding variables, as suggested by (3).

#### DESCRIPTION OF SYSTEM

Fig. 1 shows a block diagram of the prototype of the tourniquet which was initially developed in order to determine whether it would be possible to adaptively adjust tourniquet pressure as a function of intraoperative systolic pressure. With the exception of the pressure-measuring module, printer, and blood pressure cuff depicted in Fig. 1, all components are similar to those in the prototype of the microprocessor-based tourniquet described previously elsewhere [4]. The micro-computer employs an Intel 8085A microprocessor with 2K byte RAM and 8K byte PROM. The hardware was based on an STD bus with card cage and PROLOG 7801 CPU board, PROLOG 7000 motherboard, PROLOG 7604 TTL I/O board, custom analog I/O board, and power-supply board. As suggested by Fig. 1, pressure in the cuff is controlled by a combination of pressure-generating element and pressure-release valve. The pressure-generating element is an electrical pump with appropriate control circuitry and modifications to limit the maximum pressure to 500 mmHg. Data obtained from the pressure transducer/processor are used in the regulation of pressure in the cuff to within  $\pm 6$  mmHg. The regulation of

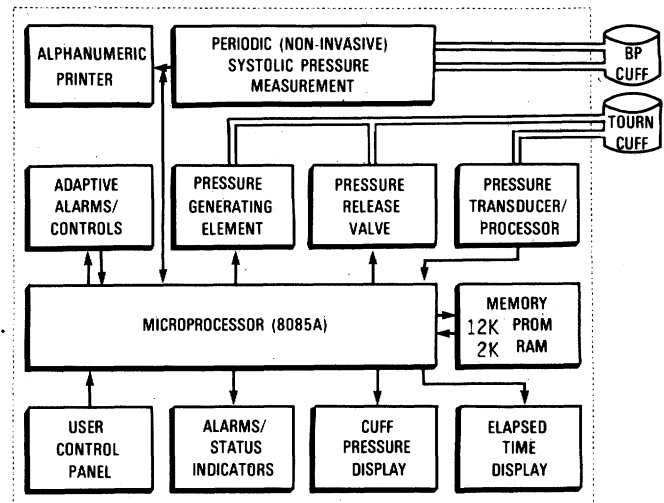


Fig. 1. Block diagram of the prototype of the adaptive tourniquet.

pressure thus achieved is an order of magnitude better than that of pneumatic tourniquets which are widely used at present. Use of an electrical pressure-generating element not only permits better control of pressure, but also reduces operating costs by eliminating the requirement of conventional tourniquets for compressed gas.

The configuration of the control/display panel of the tourniquet depicted in Fig. 1 can be seen in Fig. 2. The panel contains an elapsed-time display to indicate the period of cuff inflation, a display to indicate cuff pressure, and a variety of audiovisual alarms to warn of hazardous conditions such as overpressurization, underpressurization, excessive periods of inflation, kinking of the cuff lines, and internal malfunctions such as failure of a pressure transducer. Fig. 2 also shows the alphanumeric printer and the device employed in the prototype for periodically measuring systolic pressure  $P_{SM}$ . This pressure-measuring device was a DINAMAP Model 845 non-invasive blood pressure monitor which estimates systolic pressure by means of an oscillometric algorithm [25]. Controls on the pressure-measuring device were set so that values of  $P_{SM}$  would normally be generated at 1-min intervals. The printer employed was a DINAMAP Model 950 printer, which is compatible with the pressure-measuring device and which can accept other serial input through a system connector.

The prototype of the adaptive tourniquet was fabricated from the conventional pressure-measuring device and from the previously described microprocessor-based tourniquet by means of three basic changes in hardware. First, a MICRO/SYS dual serial interface card was added to the card cage and STD bus; and an EIA-to-TTL converter chip was removed from the serial board to generate compatible data levels for the printer. Second, as depicted in Fig. 1, auxiliary connectors and cables were installed to connect the serial line between pressure-measuring device and printer to the serial board of the tourniquet as well; this change permitted the development of software in the tourniquet to scan the alphanumeric data being passed to the printer in order to easily extract successive determinations of the patient's systolic pressure. The third hardware change consisted of the provision of an extra control and display panel, which can be seen in Fig. 2, to permit the oper-

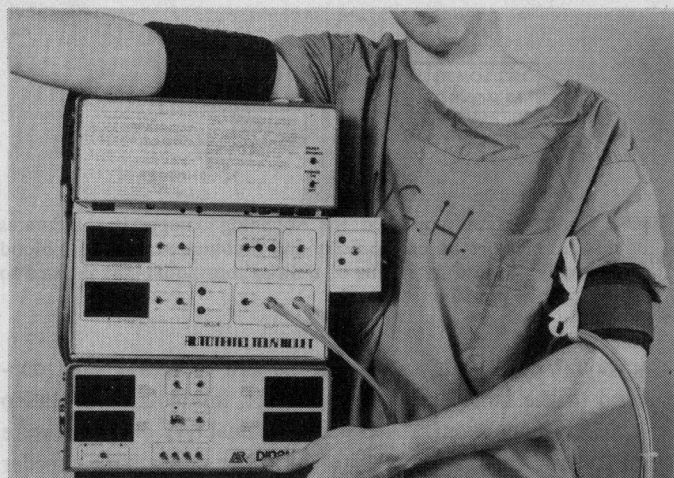


Fig. 2. Physical configuration of the prototype of the adaptive tourniquet in which the printer, noninvasive pressure-measuring module, and cuff, as well as microprocessor-based tourniquet and cuff, can be seen.

ator to select either an adaptive pressure or a constant pressure for the tourniquet.

Following hardware modifications, changes to existing software were made to permit it to function as part of an adaptive prototype in the following manner. As part of the preoperative preparation of a patient, the pneumatic cuff for the pressure-measuring device and the tourniquet cuff are applied to the patient, as illustrated in Fig. 2. The pressure-measuring module and printer are then activated, and the printer is checked to assure that reasonable measurements of systolic pressure are being generated. Following induction of anesthesia and exsanguination of the limb for surgery, the tourniquet is activated in the "constant pressure" state. The tourniquet can then be changed to an adaptive state when desired by momentarily depressing the appropriate switch (see Fig. 2). LED indicators display the current state. In the adaptive state, values of  $P_{SM}$  are normally obtained at 1-min intervals by analyzing the character string generated by the pressure-measuring module. In the presence of excessive artifact or other problems, the generation of values of  $P_{SM}$  is automatically suspended by the pressure-measuring module and the previously obtained value is substituted by the tourniquet. Successive values of  $P_{SM}(t_i)$ ,  $i = 0, 1, \dots, N$ , which are thus obtained are checked for compliance with the following three criteria:

$$80 < P_{SM}(t_i) < 160;$$

$$\Delta t \leq 3 \text{ min}$$

for successive estimates

$$P_{SM}(t_i - \Delta t), \quad P_{SM}(t_i);$$

and

$$|P_{SM}(t_i) - P_{SM}(t_i - \Delta t)| \leq 32 \text{ mmHg}.$$

Failure to satisfy the first of the above-noted criteria indicates that the patient's systolic pressure falls outside generally accepted limits, and therapeutic action may be required. Failure to satisfy the second criterion may indicate the presence of excessive artifact or other problems requiring operator intervention. Failure to satisfy the third criterion indicates a fluctuating

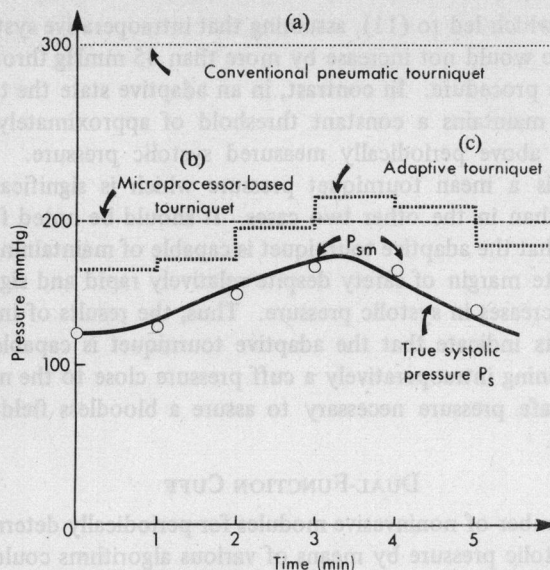


Fig. 3. Comparative tourniquet pressures  $P_T$  in upper-limb cuff for a patient with rapidly fluctuating systolic pressure  $P_S(t)$  for (a) conventional pneumatic device with  $P_T$  set at 300 mmHg, (b) microprocessor-based device with  $P_T$  set at approximately 80 mmHg above the patient's preoperative systolic level (see text), and (c) adaptive device with  $P_T$  set as described in the example given in the text. Note that the adaptive tourniquet in this case would achieve the lowest mean cuff pressure while still maintaining a safe margin between cuff pressure and intraoperative systolic pressure.

uating systolic pressure which again may require operator intervention. In the event that one or more of these criteria are not satisfied, the prototype is programmed to revert from an adaptive state to a constant-pressure state, at the initially set pressure, while simultaneously activating an audiovisual alarm to indicate the change of states. The alarm can be suppressed by momentarily depressing an "alarms reset" switch on the tourniquet (see Fig. 2) which will leave the device in a constant-pressure state; the operator can change back to the adaptive state by activating the appropriate switch after any remedial action has been taken. In the event that successive values of  $P_{SM}$  satisfy all of the above-noted criteria, pressure in the tourniquet cuff is adaptively changed by the prototype in accordance with (7), (8), and (9), assuming standard blood pressure and tourniquet cuffs are employed on opposite upper limbs. For cases of lower-limb surgery, or for other cases such as those involving use of nonstandard cuffs as described below, the same equations can be used with  $f_M$  and  $f_T$  specified appropriately as functions of their variables.

Fig. 3 illustrates comparative cuff pressures arising from the use of a conventional pneumatic tourniquet set at a traditional level, the microprocessor-based device set at a constant pressure based on a determination of the patient's preoperative systolic pressure, and the microprocessor-based device in an adaptive mode. According to common practice, the conventional tourniquet would be set at approximately 300 mmHg for upper-limb surgery; this value is roughly consistent with the level suggested by the nominal values given in the example above which led to (10). In a constant-pressure state the microprocessor-based tourniquet could safely be set at approximately 80 mmHg above the preoperative systolic level, as suggested in the literature (e.g., [2], [9]) and by the nominal

values which led to (11), assuming that intraoperative systolic pressure would not increase by more than 45 mmHg throughout the procedure. In contrast, in an adaptive state the tourniquet maintains a constant threshold of approximately 50 mmHg above periodically measured systolic pressure. The result is a mean tourniquet pressure which is significantly lower than in the other two cases. It should be noted from Fig. 3 that the adaptive tourniquet is capable of maintaining an adequate margin of safety despite relatively rapid and significant increases in systolic pressure. Thus, the results of initial lab tests indicate that the adaptive tourniquet is capable of maintaining intraoperatively a cuff pressure close to the minimum safe pressure necessary to assure a bloodless field for surgery.

#### DUAL-FUNCTION CUFF

A number of noninvasive modules for periodically determining systolic pressure by means of various algorithms could be employed in the prototype. This is because in a configuration such as the one illustrated in Figs. 1 and 2, systolic pressure is measured through the use of a separate cuff applied to an upper limb not involved in the surgical procedure, i.e., tourniquet cuff and blood pressure cuffs are applied to separate limbs. It would be preferable to employ one dual-function cuff for both purposes: for example, an upper (proximal) segment of such a cuff could be employed for measuring systolic pressure periodically and a lower (distal) segment could be maintained at a suprasystolic pressure. The use of one dual-function cuff in conjunction with the adaptive tourniquet might be desirable for a variety of reasons, e.g., occlusive cuffs on both upper limbs might affect intravenous administration of fluids and medications [25]. A separate blood pressure cuff could be applied to a lower limb not involved with the surgical procedure, but application of two cuffs would still be more labor-intensive, cumbersome, and physically obstructive. The development of a combined dual-purpose cuff, however, is clearly dependent upon the use in the adaptive tourniquet of a noninvasive pressure-measuring module employing an algorithm capable of accurately measuring pressure with greatly reduced blood flow at the measurement site.

Published data indicate that measurement of systolic pressure under such conditions using a manual sphygmomanometric technique based on *K*-sound analysis is possible [21], [26]. However, it was anticipated at the outset that automatic measurement under such conditions might be less accurate and less reliable with an algorithm based on *K*-sound analysis than with an algorithm based on oscillometry, primarily because it was thought that *K*-sound algorithms would be more dependent than oscillometric algorithms on flow-related phenomena [21], [25]. To initially test this hypothesis, an experiment was conducted with the configuration of devices illustrated in Fig. 4. Each subject was first connected to a Vitastat Model 900-S blood pressure monitor with the cuff located proximally on an upper limb; the Vitastat Model 900-S normally measures blood pressure by an algorithm based on analysis of *K*-sounds, but automatically switches to a second algorithm based on oscillometry if a microphone in the cuff is deliberately deactivated. As suggested by Fig. 4, a standard Kidde pneumatic

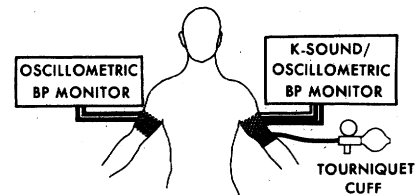


Fig. 4. Configuration employed for obtaining comparative estimates of systolic pressure by oscillometry and *K*-sound analysis with blood flow greatly reduced by means of a distal tourniquet cuff inflated to a suprasystolic pressure (see text).

tourniquet cuff with aneroid gauge and bulb was then connected to the same limb of the subject, immediately distal to the blood-pressure cuff. A Dinamap Model 845 blood pressure monitor was then connected to the other upper limb in order to obtain reference values of systolic pressure by oscillometry. In the experiment, both pressure-measuring devices were activated simultaneously at 1-min intervals to obtain comparable estimates of systolic pressure. By successively activating and deactivating the Vitastat microphone during this period, alternating measurements based on oscillometry and *K*-sound analysis were obtained from one limb for comparison with oscillometric measurements from the other limb. The tourniquet cuff was then quickly inflated to a suprasystolic pressure (approximately 250 mmHg) and measurements of systolic pressure continued in the same manner for another 4 min. The cuffs were then switched to corresponding positions on opposite limbs and the same experiment was repeated. The results from the first six subjects tested are given in Table I. The results show that in all six subjects either an oscillometric algorithm or a *K*-sound algorithm could be employed to measure systolic pressure at the measurement site, despite greatly reduced blood flow at the site due to an inflated tourniquet cuff. Table I also indicates for each subject and experimental condition the maximum difference between simultaneous measurement of systolic pressure on the test limb and at the reference site. The results summarized in Table I emphasize the variation in indirect measurements of systolic pressure which can be anticipated when measuring over short periods at the same site, when measuring simultaneously on opposite limbs, or when measuring with devices employing different algorithms or even different implementations of the same algorithm. In these respects, the results of the initial experiment tended to agree with previous findings of others arising from extensive studies, e.g., [21], [24], [25]. A blood pressure monitor employing an oscillometric algorithm (see Fig. 2) was chosen for incorporation into the prototype of an adaptive tourniquet intended for use with a dual-function cuff because the use of an oscillometric module for this application has the advantage that it eliminates the need for a microphone in the dual-function cuff, it reduces the precision required in positioning the cuff on the limb, and it may permit measurements of systolic pressure to be made in situations where measurement by *K*-sound analysis would be difficult. Although a discrete commercially available oscillometric device was employed initially, an oscillometric module or a module based on a *K*-sound algorithm could clearly be incorporated into the prototype of adaptive tourniquet in the future if warranted.

TABLE I  
MEAN SYSTOLIC PRESSURES OBTAINED SIMULTANEOUSLY FROM A TEST LIMB AND A REFERENCE LIMB, BEFORE AND AFTER INFLATION OF A TOURNIQUET CUFF ON THE TEST LIMB. RESULTS ARE GIVEN FOR SIX SUBJECTS AND FOR CONTRALATERAL UPPER LIMBS SUCCESSIVELY SERVING AS TEST LIMBS FOR EACH SUBJECT. SEE TEXT FOR FURTHER EXPLANATION

PRE-INFLATION					POST-INFLATION				
Mean Pressures (mmHg)					Mean Pressure (mmHg)				
Subject/ Test Limb	Test Limb: K-Sounds	Test Limb: Oscillometry	Reference Limb: Oscillometry	Maximum Difference- Simultaneous Msmts	Subject/ Test Limb	Test Limb: K-Sounds	Test Limb: Oscillometry	Reference Limb: Oscillometry	Maximum Difference- Simultaneous Msmts
J/Left	134	140	139	-8	J/Left	117	130	132	-20
J/Right	129	134	145	-17	J/Right	111	138	136	-23
R/Left	136	133	139	-9	R/Left	144	129	139	-11
R/Right	146	123	140	-23	R/Right	146	129	140	-15
W/Left	136	138	141	-13	W/Left	131	130	137	-11
W/Right	136	141	144	-14	W/Right	136	137	138	+9
K/Left	105	103	119	-23	K/Left	112	102	114	-13
K/Right	102	109	116	-16	K/Right	110	102	115	-16
E/Left	110	127	138	-29	E/Left	108	124	134	-29
E/Right	133	124	130	-12	E/Right	141	130	126	+22
M/Left	127	131	136	-16	M/Left	130	120	130	-18
M/Right	118	131	126	-11	M/Right	132	118	125	+8

For an initial assessment of the feasibility of a dual-function cuff, a commercially available two-chamber tourniquet cuff (Zimmer Inflatomatic Dual Cuff) normally used for intravenous regional anesthesia was connected to the adaptive tourniquet. This cuff functioned satisfactorily in lab tests, with the proximal section employed for periodic determinations of systolic pressure and the distal section maintained at suprasystolic pressure. As expected, values of systolic pressure determined in this manner were high in comparison to simultaneous determinations on the contralateral limb, likely due to the fact that the cuff was much narrower than conventional blood pressure cuffs and was of nonstandard design [20], [23]. On the basis of these initial results, samples of a dual-function cuff specifically intended for evaluation with the prototype have been fabricated by a manufacturer of conventional tourniquet cuffs. The proximal (upper) section of the dual-function cuff has dual ports for connection to the pressure-measuring module of the adaptive tourniquet, but has a narrower width and other physical differences which necessitate that  $f_M$  in (4) be specified. The distal (lower) section of the cuff also has dual ports for connection to the pressure-controlling portion of the tourniquet (see Fig. 1), so that it can be adaptively inflated to the minimum pressure necessary to maintain a bloodless field. As with the pressure-measuring section, the width and other physical characteristics of the pressure-control section of the cuff have been changed, necessitating a determination of  $f_T$  for use in (8). The primary reason for reducing the width of both sections in relation to conventional cuffs was to minimize surgical obstruction. An evaluation of these new dual-function cuffs must be made to determine their reliability and define  $f_M$  and  $f_T$  prior to employing them in clinical trials. If the results of the trials of these cuffs are

promising, other sizes and shapes of dual-function cuffs will be fabricated for evaluation on upper and lower limbs having a variety of shapes and sizes.

#### DISCUSSION

Further work is being carried out in connection with the development and clinical evaluation of the prototype of the adaptive tourniquet and various cuffs such as the dual-function cuff described above. Following completion of a technical evaluation of the adaptive prototype and cuffs by biomedical engineering staff to assure that they perform to expectations, that they comply as much as possible with pertinent standards, and that an adequate level of reliability has been achieved, a clinical evaluation will be completed. In the clinical evaluation as in past clinical trials of the microprocessor-based tourniquet, the prototype will only be used with a biomedical engineer in constant attendance and with a conventional tourniquet available immediately as backup in the event of unforeseen problems. Other work will be carried out to determine whether or not  $f_T$  and  $f_M$  in (3) and (5) can be set automatically and whether or not changes should be made to the adaptive software to accommodate lower-limb surgery with and without dual-function cuffs. Also, if the results of the initial clinical evaluation are promising, the hardware and software will be revised and an oscillometric pressure-measuring module may be physically incorporated into the prototype so that it can be clinically evaluated in a wide variety of surgical procedures over an extended period.

The widely recognized inability of the current generation of pneumatic tourniquets to control pressure with adequate accuracy, reliability, and stability has clearly been associated with continuing reports of tourniquet-related injuries, incidents,

and hazards. Moreover, the labor-intensiveness and operating costs associated with the use of current types of pneumatic tourniquets have significant cost implications for hospitals. To a large extent the advent of a microprocessor-based tourniquet capable of safely and accurately maintaining a desired pressure and capable of simultaneously performing other functions such as detection of alarm conditions has reduced these hazards and operating-cost implications. Furthermore, the availability of a microprocessor-based tourniquet has facilitated the development of an adaptive tourniquet in which the pressure in the tourniquet cuff is changed throughout a surgical procedure as a function of the patient's changing intraoperative systolic pressure, thus approximately the minimum safe pressure necessary to maintain a bloodless field for surgery. While the use of an adaptive tourniquet, rather than just a microprocessor-based tourniquet set at a constant pressure may not be necessary in most cases, it promises to have significant value in certain surgical procedures and for patients who may be at greater risk of tourniquet-induced complications, e.g., patients with little protective musculature. The adaptive tourniquet may also permit a safer pressure to be employed with hypertrophied limbs (having a suboptimal ratio of cuff width to circumference) if appropriate values of  $f_T$  and  $f_M$  can be determined automatically or entered manually for such patients. Also, the lower average pressures possible through the use of an adaptive tourniquet may permit the evolution of surgical techniques of longer duration without a concomitant increase in the risk of tourniquet-induced complications. Finally, despite the increased complexity of the adaptive tourniquet, it is estimated that the difference between the projected capital cost of the adaptive device and a commonly used type of pneumatic tourniquet may be offset after two years of normal usage due to reduced operating costs arising from elimination of the need for compressed gas and reduced labor-intensiveness.

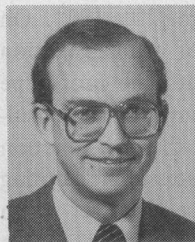
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#### REFERENCES

- [1] H. Smith "Surgical technique," in *Campbell's Operative Orthopaedics*, 5th ed. St. Louis, MO: Mosby, 1971, p. 58.
- [2] R. Sanders, "The tourniquet: Instrument or weapon?" *Hand*, vol. 5, pp. 119-123, 1973.
- [3] J. C. Adams, *Standard Orthopaedic Operations*. New York: Churchill and Livingston, 1976, pp. 4-5.
- [4] J. A. McEwen, "Complications of and improvements in pneumatic tourniquets used in surgery," *Med. Instrum.*, vol. 15, pp. 253-257, 1981.
- [5] D. Fry, "Inaccurate tourniquet gauges," *Brit. Med. J.*, vol. 1, p. 511, 1972.
- [6] S. J. Prevoznik, "Injury from use of pneumatic tourniquets," *Anesthesiol.*, vol. 32, p. 177, 1970.
- [7] D. L. Johnson, P. D. Neufeld, and R. G. Hussey, "Hazards in single-stage regulation of pressure cuffs," *J. Clin. Eng.*, vol. 5, pp. 59-62, 1980.
- [8] "Malfunction of the Kidde automatic tourniquet," in *Medical Devices Alert No. 16*, Health Protection Branch, Canada, Dec. 13, 1978.

- [9] L. Klenerman, "Tourniquet time—How long?" *Hand*, vol. 12, pp. 231-234, 1980.
- [10] S. I. Weingarden, D. L. Louis, and G. W. Waylonis, "Electromyographic tourniquet," *J. Amer. Med. Ass.*, vol. 241, pp. 1248-1250, 1979.
- [11] C. H. Rorabeck and J. C. Kennedy, "Tourniquet-induced nerve ischemia complicating knee ligament surgery," *Amer. J. Sports Med.*, vol. 8, pp. 98-102, 1980.
- [12] C. H. Rorabeck, "Tourniquet-induced nerve ischemia: An experimental investigation," *J. Trauma*, vol. 20, pp. 280-286, 1980.
- [13] E. H. Flewelling and B. Jarem, "Pneumatic tourniquets," *Anesthesiol. Rev.*, vol. 5, pp. 31-34, 1978.
- [14] D. J. Arenson and L. S. Weil, "The uses and abuses of tourniquets in bloodless field foot surgery," *J. Amer. Pod. Ass.*, vol. 66, pp. 854-861, 1976.
- [15] A. E. Flatt, "Tourniquet time in hand surgery," *Arch. Surg.*, vol. 104, pp. 190-192, 1972.
- [16] J. M. Bruner, "Time, pressure and temperature factors in the safe use of the tourniquet," *Hand*, vol. 2, pp. 39-42, 1970.
- [17] J. C. Griffiths and O. B. Heywood, "Bio-mechanical aspects of the tourniquet," *Hand*, vol. 5, pp. 113-117, 1973.
- [18] A. Parkes, "Ischaemic effects of external and internal pressure on the upper limb," *Hand*, vol. 5, pp. 105-112, 1973.
- [19] L. Klenerman and G. H. Hulands, "Tourniquet pressures for the lower limb" (Abstract), *J. Bone Joint Surg.*, vol. 61B, p. 124, 1979.
- [20] L. A. Geddes and S. J. Whistler, "The error in indirect blood pressure measurement with the incorrect size of cuff," *Amer. Heart J.*, vol. 96, pp. 4-8, 1978.
- [21] J. M. R. Bruner *et al.*, "Comparison of direct and indirect methods of measuring arterial blood pressure, Part I," *Med. Instrum.*, vol. 15, pp. 11-21, 1981.
- [22] —, "Comparison of direct and indirect methods of measuring arterial blood pressure, Part II," vol. 15, pp. 97-101, 1981.
- [23] (Proposed) Standard for Non-Automated Sphygmomanometers, *Ass. Advancement Med. Instrum.*, Arlington, VA, Aug. 1980.
- [24] (Proposed) Standard for Electronic or Automated Sphygmomanometers, *Ass. Advancement Med. Instrum.*, Arlington, VA, Aug. 1980.
- [25] D. P. Paulus, "Noninvasive blood pressure measurements," *Med. Instrum.*, vol. 15, pp. 91-94, 1981.
- [26] F. H. Vanbergen *et al.*, "Comparison of direct and indirect methods of measuring arterial blood pressure," *Circulation*, vol. 10, pp. 481-490, 1954.



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