Measurement of hazardous pressure levels and gradients produced on human limbs by non-pneumatic tourniquets

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Abstract

This paper reports on existing and novel transducers for improved quantitative investigations of the levels of applied pressures and pressure gradients produced on human limbs by non-pneumatic tourniquet straps, and by non-pneumatic elastic bandages and elastic rolls when used as tourniquets, for comparison to benchmark data for pneumatic tourniquet cuffs commonly used in surgery at present.

Introduction

Pneumatic tourniquets are commonly used in surgery to safely establish a bloodless surgical field in a portion of a limb over a time period suitably long for the performance of a surgical procedure. It is estimated that at least 15,000 surgical procedures are performed each day on limbs with the benefit of pneumatic tourniquet systems. The introduction and widespread use of automatic tourniquet systems, with microcomputer control and improved pneumatic cuff designs, has greatly reduced the reported severity and number of tourniquet-related hazards and injuries [1-3]. It is well established in the medical literature that the probability of tourniquet-related injuries increases as tourniquet pressure increases, and as the pressure gradients near the edges of tourniquet cuffs increase eg [2, 4-8].

Pneumatic tourniquet cuffs have recently been developed for military and emergency use, based on surgical designs proven to be safe and effective over many years, and such pneumatic devices are deployed in Afghanistan and Iraq and in other pre-surgical emergency settings. At the same time, simple non-pneumatic tourniquet straps have also been deployed for use on the battlefield, for self-application by individual soldiers. While they may be effective in helping to stop potentially fatal arterial blood flow in combat, such non-pneumatic straps may produce hazardously high, inconsistent and uncontrolled pressures around limbs and may further produce high pressure gradients near the strap edges.

Very recently, it has been suggested that non-pneumatic tourniquets, including elastic bandages, elastic rings and non-elastic straps might again be employed in surgery, as they were in the 19th century. The uncritical acceptance and use of such non-pneumatic tourniquets in surgery for extended periods, without investigation of applied pressure levels and applied pressure gradients and with little evidence of their safety, may unnecessarily increase the incidence of tourniquet-related injuries in surgical patients to earlier levels, and may expose surgical staff in civilian settings to potential legal liability.

Measurement of applied pressures and pressure gradients using an existing transducer

Pressures underlying pneumatic tourniquet cuffs for surgery have been investigated and reported previously, eg [6-8]. Transducers useful in investigating applied pressure distributions underlying pneumatic tourniquet cuffs have also been described, eg [9,10].

For reference in the development of a novel transducer as described below, an existing type of transducer [9] was used to measure applied pressures and pressure gradients typically produced by (a) a modern pneumatic tourniquet cuff of 10 cm width commonly used in surgery [11], (b) a military non-pneumatic tourniquet strap designed for self-application by soldiers on the battlefield to stop arterial bleeding [12], and (c) a non-pneumatic elastic ring recently designed in an attempt to combine exsanguination and tourniquet functions for surgery [13]. Each device was selected and applied to a normal lower limb to stop arterial bloodflow according to each manufacturer's instructions. Applied pressures were then measured using the transducer, as described earlier [9,10]. The results are summarized in Fig. 1. As clearly shown in Fig. 1, the applied pressure levels and associated pressure gradients required to stop arterial bloodflow were substantially higher for the non-pneumatic strap and non-pneumatic ring, compared to the pneumatic surgical tourniquet cuff.

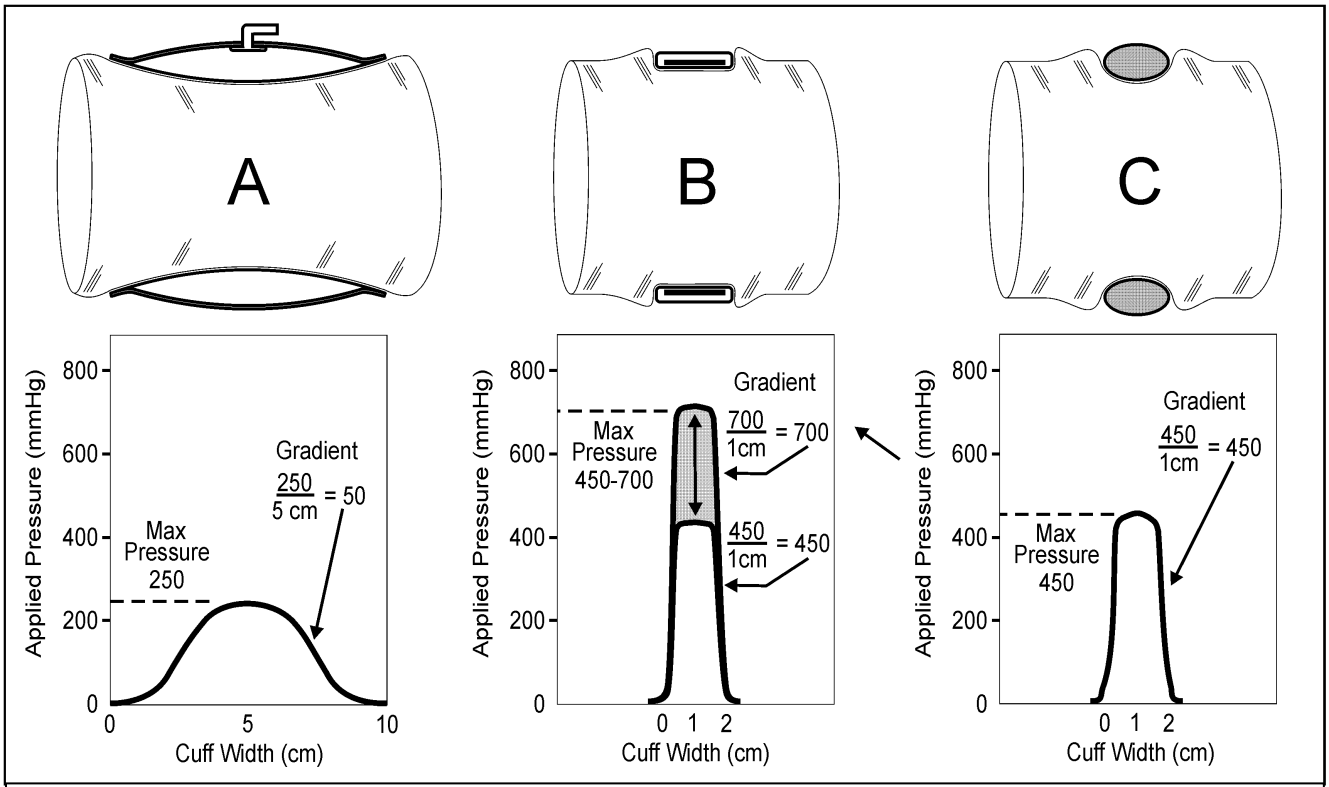

Fig. 1 Applied pressures and pressure gradients typically produced by (a) a modern pneumatic surgical tourniquet cuff, (b) a non-pneumatic, non-surgical military tourniquet designed for self-application on the battlefield, and (c) a non-pneumatic elastic ring designed in an attempt to combine exsanguination and tourniquet functions. Higher levels of pressure and higher pressure gradients are associated with higher probabilities of patient injuries, eg [2,4-8].

Novel transducer development and issues

To further investigate applied pressure levels and pressure gradients produced by non-pneumatic tourniquet devices in comparison to surgical pneumatic tourniquet cuffs as shown in Fig 1, and to assist in the potential development of improved devices for stopping arterial bloodflow at lower maximum applied pressures and at lower pressure gradients, a novel transducer able to accurately measure an array of applied pressures without distorting the local interface measurement environment would be helpful. Such a novel interface pressure transducer incorporates a MEMS transducer which has been developed under the guidance of recent experimental and modeling studies. Some preliminary data is presented. For the purpose of units conversion, 1 Pa =1 N/m^2, 1 MPa =1 N/mm^2 and 40 kPa ≈ 300 mmHg.

The small size and high performance to cost ratio of MEMS pressure transducers make them very attractive for biomedical applications. For instance MEMS based disposable blood pressure transducers sell by the millions. There is no agreed functional specification for an applied pressure transducer for surgical tourniquets, IVRA systems and other biomedical applications but an optimal transducer for such applications should conform to the general specification prescribed by Paris-Seeley [10]. Its basic function must be to measure the pressure applied by any one of a specified number of medical devices to a portion of a human body surface, tissue or organ, in the pressure range 0 − 500 mmHg (0 − 70 kPa). Amongst many other desirable qualities the transducer design must permit fast, convenient and intuitive calibration checking in the target application environment. Ideally, simultaneous measurement of an array of pressures should be possible.

MEMS pressure transducers commonly comprise a thin walled diaphragm as the primary sensing element. A dielectric gel on the front side of the diaphragm isolates the diaphragm and integrated electronics from the fluidic measurement environment yet couples the fluid pressure to the diaphragm. The rear side of the diaphragm may face a sealed vacuum enclosure or may be ported to facilitate application of a reference pressure. A differential pressure across the diaphragm causes the diaphragm to deflect and the deflection is converted into an electrical signal proportional to the pressure difference. Since the area over which the fluid pressure acts is well

defined, calibration is easy and reliable for fluids. The major challenge for biomedical applications relates to the transducer package which must facilitate MEMS transducer operation often in harsh corrosive and mechanically aggressive environments.

For non-invasive biomedical interface pressure measurement the transducer may be sited remote from the interface. A small balloon with a fixed volume of fluid sited at the interface is coupled to the transducer via a fluid filled line. However, this approach is subject to a range of problems such as poor frequency response, errors due to variability of the fluid head, kinking and twisting of the fluid lines. In addition it involves complicated set-up and measurement protocols and presents a leakage hazard.

As an alternative to fluid line systems, the transducer may be modified to provide a contact plate which translates the applied pressure to the sensing diaphragm via a localized fluid link in a load-cell type arrangement. The transducer and packaging for this type of arrangement is necessarily rigid and intrusive for interface pressure measurement applications. In practice, indicated pressures are often far in excess of the actual applied pressures and calibration is difficult and unreliable. These problems are attributable to the so called *hammocking* effect [14,15] where the tourniquet membrane or non-pneumatic strap or elastic ring drapes over the transducer and lifts away from the supporting tissue. The hammocking effect has been studied experimentally [16] and modeled for a rigid disc on a cylinder [15]. The hammocking effect results in an increase in the effective active area of the transducer, i.e. the area over which it integrates the applied pressure. In simple terms, the tourniquet device applies pressure to the plate area (now the calibration area) where it is in conformal contact with it. However, the pressure acting on the tourniquet membrane in the lift-off area is also coupled to the edge of the plate by the cuff-membrane, producing an increase in indicated pressure which can be multiples of the actual pressure [14-16]. The indicated pressures will therefore be larger than the actual pressure. Calibration difficulties arise since the operation of load-cell type transducers requires a well defined constant contact area. Guard rings can alleviate this effect but the inherent accuracy of the MEMS transducer with these precautions is compromised.

As an alternative to *constant area* pressure transducer configurations for biomedical interfacial pressure measurement, we are developing a prototype *constant volume* interface pressure transducer which incorporates a MEMS pressure transducer (Motorola MPX2000 transducer with package top removed and side walls reduced) in a constant volume arrangement which does not involve fluid lines. The reference port of the MEMS transducer is sealed at ambient atmospheric pressure and the entire assembly is then encapsulated in a two gel package of well defined shape and volume. A soft inner dielectric gel, compatible with IC circuitry is formed over the front side of the MEMS transducer diaphragm. An outer gel is then molded into a contoured form around the MEMS plus inner gel and cured to provide a malleable but durable and touch-dry package. Lead wires or flexible printed circuit cable protrude from the molded gel pack. The gel pack forms an air-tight housing for the MEMS. The contoured shape of the pack ensures that there is no hammocking; the inner soft gel ensures that shear forces are not coupled to the sensing diaphragm; the incompressibility of the gels reduces hysteresis and provides a constant volume even with changing pressure. Calibration is done in a sealed pressurized chamber, and clinical calibration-checking is done with a specifically designed calibrator [11].

With this design the MEMS transducer is in theory operating under optimal conditions - no shear force or flexural force coupling to the diaphragm. Thus the measured level of applied pressure level is anticipated to be an accurate representation of the pressure at the interface averaged over the transducer pack footprint. It does not integrate the pressure over the footprint area. The design may smooth out local variations due to buckling and folding of tissue and the tourniquet surface.

Two limitations have been identified in prototypes and testing to date. First, a prototype transducer under a pneumatic cuff did not respond accurately until the pneumatic pressure exceeded 50 mmHg. Also, the maximum applied pressure was lower than pneumatic cuff pressure by about 40 mmHg. Despite these limitations, initial test results indicate that the transducer is potentially useful for estimating pressure levels under non-pneumatic tourniquet devices and for estimating pressure gradients at the edges of non-pneumatic devices. Both limitations may be attributable to the large size of the prototype transducer relative to that of the tourniquet cuff, strap or ring. Further, both limitations may be reduced or eliminated for practical purposes by a physically scaled-down implementation of the transducer under development. If so, it will prove useful in future studies of pressure levels beneath non-pneumatic tourniquet devices, and particularly in rigorous studies of pressure gradients near the edges of non-pneumatic tourniquet straps, elastic bandages and elastic rings.

Results and Discussion

The widespread adoption and use of such automatic tourniquets employing microprocessor technology,

together with improved designs of pneumatic tourniquet cuffs, has greatly improved the safety, accuracy and reliability of tourniquets in surgery. The resulting decrease in the number of reported hazards and incidents was accompanied by a reduction in risk class by the (US) FDA: in 1996, the FDA classified pneumatic tourniquets as Class I medical devices (indicating that they present minimal harm to the user and do not present a reasonable source of injury through normal use), and the FDA thereafter exempted pneumatic tourniquets from its (510k) pre-market notification and clearance procedures. Modern pneumatic tourniquets are now similarly classified in other western countries, and are used in an estimated 15,000 orthopaedic and non-orthopaedic surgical procedures daily in the US and elsewhere, facilitating surgery by reliably establishing a bloodless surgical field with relative safety.

However, non-pneumatic tourniquet devices for stopping arterial bleeding may not be similarly safe. As shown in Fig. 1, non-pneumatic tourniquet straps and non-pneumatic elastic rings produce substantially higher applied pressures and higher pressure gradients when selected and used to stop arterial bloodflow according to manufacturer's instructions. Such higher pressure levels and higher pressure gradients are associated in the clinical literature with higher probabilities of patient injuries. Thus further investigation is warranted before uncritical acceptance and use of such non-pneumatic devices for extended periods of time increases the incidence of tourniquet-related injuries to surgical patients and unnecessarily exposes users in surgical and civilian settings to potential legal liability.

To measure potentially hazardous levels of pressure and pressure gradients produced on limbs, an existing type of transducer has been found to be adequate. Further, a novel transducer now being developed appears to have potential to allow such measurements to be made with improved accuracy, reproducibility and spatial resolution. Finally, the unique constraints of this measurement environment suggest that ample opportunities exist for other biomedical engineers to develop other improved transducers and implementations to address and investigate this important problem and need.

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