Novel interface pressure transducers for tourniquets and other medical devices.

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Abstract

Novel MEMS transducers have been developed and tested for the measurement of interface pressure in biomedical tourniquet applications. On-body transducer performance was evaluated by reference to tourniquet inflation pressure for pneumatic tourniquets. Excellent correlation between transducer indicated peak pressure and tourniquet inflation pressure was observed. In addition, the transducer, in the form of an array, provides real-time pressure-gradient data. Transducer performance with non-pneumatic tourniquets was also evaluated.

Introduction

Many clinical and emergency procedures would benefit from the availability of a reliable, real-time indicator of the actual interface pressure arising between a limb or tissue and medical tourniquets. Specifically, it would be useful to have quantitative data relating to peak interface pressure as well as interface pressure gradients as an information channel to inform safety and efficacy of procedures and treatments. Systems are available that provide such data within clinical and research environments[1] but cost effective solutions are not available for treatment environments such as home, sub-acute and emergency.

MEMS pressure sensor device technology is now mature and offers low cost, reliable, durable solutions for gas and liquid pressure sensing. However, it has proven difficult to exploit this technology for non-invasive biomedical interface pressure applications where the sensor must interface to a spectrum of tissue and medical media such as bandages and tourniquets. All such materials will support shear forces and the presence of such forces greatly complicates the measurement environment. Satisfactory calibration of pressure sensors depends critically on the existence of a well defined sensor contact area. Rigid sensor housings and general sensor intrusiveness makes it difficult to realize stable contact areas in biomedical application environments.

We present results obtained with a novel biomedical interface pressure (IFP) transducer incorporating MEMS pressure sensors, and designed to overcome some of the problems outlined above.

Tourniquet application environment.

Medical tourniquets may be grouped into two broad categories, tensional and pneumatic, according to their primary mechanism of pressure application. Each category presents distinctive challenges from an interface pressure measurement perspective.

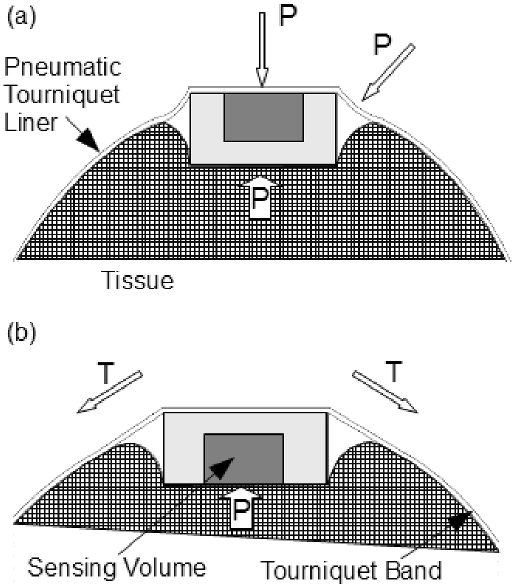

Figure 1 Schematic representation of an interface pressure sensor between a pneumatic tourniquet (a) and a tensional (band) tourniquet (b) and a supporting limb.

A schematic representation of a generic MEMS open package sensor with rigid housing, deployed at the tourniquet tissue interface for both tourniquet categories is shown in Figure 1. The 'sensor volume' transmits the pressure to a sensing element (not shown) on the package floor. Pneumatic tourniquets are generally wider than tensional tourniquets, use lower operating pressures[2] and since the mechanism of pressure application is primarily hydrostatic, Figure 1a, associated shear stresses, while present, are not as pronounced as for tensional devices. Tensional tourniquets generate local pressures which in routine operation can exceed 500 mmHg and produce very pronounced tissue deformation leading to relatively large local tensile and shear stresses[3], Figure 1b.

In the case of tensional tourniquets, the sensing volume must face the supporting tissue in order to offer some prospect for pressure measurement. If facing the tourniquet band, the sensor housing would shunt the tension/pressure away from the sensor volume. Use of a ‘bump’ top extension to the sensing volume, would couple some of the tensional force to the sensor but since the sensor changes the local curvature of the tourniquet (see Eqn 1 below), this can not be expected to be a reliable representation of the tourniquet applied pressure. The sensing volume may be directed either towards the tissue or towards the tourniquet for pneumatic devices. The sensor housing does not shunt the applied pressure provided the sensing volume surface is flush with the top of the housing and its volume does not change under load.

The cuff inflation pressure is easily measured with pneumatic tourniquets and such data is very useful in guiding the development and improvement of interface pressure transducers for this tourniquet category. Tourniquet tension may be measured directly, but not conveniently, and since the applied pressure is also dependent on the local curvature, the use of this parameter to guide IFP transducer improvements in tensional tourniquets is less common.

Measurement of pneumatic tourniquet interface pressures

Gel filled MEMS sensors were surface mounted onto a flexible circuit substrate with standard termination. The sensor was then inserted into a specially machined Teflon ring which served as an anti-hammocking guard, Figure 2. The transducer was connected directly to a National Instruments USB DAQ which in turn was connected to a laptop running a dedicated LabView VI. The interface pressure (IFP) transducers were calibrated using zero and 150 mmHg air pressure set-points.

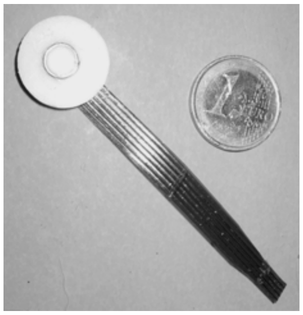

Figure 2 MEMS interface pressure (IFP) transducer with 2cm diameter Teflon anti-hammocking guard.

In the case of pneumatic tourniquets, best results were achieved with the IFP transducer placed centrally under the cuff and facing it with stockinette holding it in place. Figure 3 shows results obtained on the upper arm using a 100mm wide Zimmer cuff. The initial pressure rise on the first inflate cycle is due to the hand tightening of the un-inflated cuff onto the arm which may be eliminated by re-zeroing the transducer while the cuff is deflated but in place on the limb, see second cycle, Figure 3.

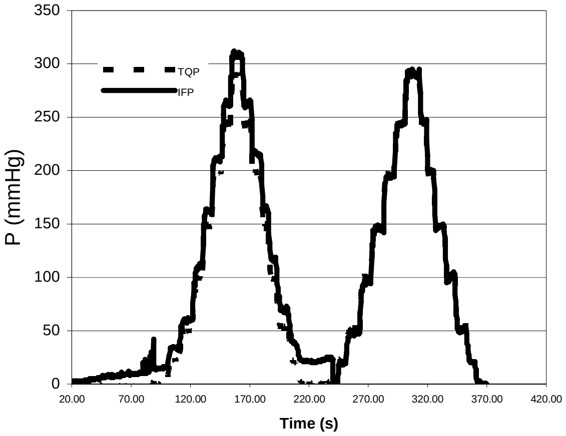

Figure 3 Tourniquet inflation pressure (TQP) and measured interface pressure (IFP) for Zimmer tourniquet on upper arm, two inflate/deflate cycles.

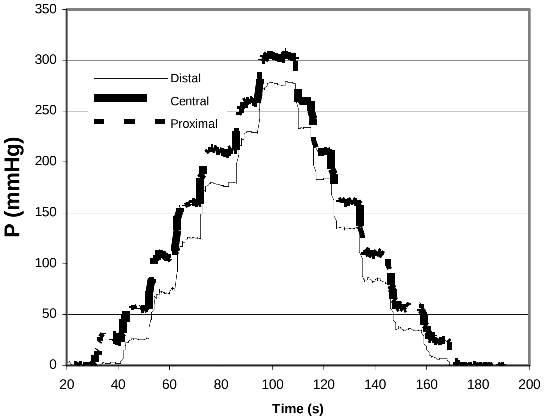

Figure 4 Three sensor array placed at interface between Zimmer tourniquet and upper arm inflate/deflate cycle: 0, 20, 50, 100 ….300, 250,…50, 20, 0 mmHg).

A 3-sensor linear array transducer (sensor spacing 12mm, array extent 3cm) was also assembled and tested under the Zimmer tourniquet. Very little difference in indicated pressure was found between the three sensors when the array was placed centrally under the cuff. Figure 4 shows pressure data obtained from the array axially aligned to the limb and located close to one edge of the cuff (distal edge). The sensor closest to the edge of the cuff indicates reduced pressure as expected.

Measurement of tensional tourniquet interface pressures

Combat Application Tourniquets (CAT®, Composite Resources Inc.) were selected to test the suitability of the IFP transducer for the second general category of tourniquets, i.e. tensional devices. The CAT comprises a 4cm wide self adhering Velcro band with internal 2.5cm wide tensioning strap connected to a windlass rod, Figure 5. The band is wrapped around the limb and threaded through a friction buckle and secured either using the buckle or by folding the band back onto itself. A rod locking clip is used to secure the windlass handle.

It proved difficult to obtain reproducible results with the IFP transducer when deployed under the CAT with its sensing volume facing the CAT even when soft gel cushioning layers were used between the CAT and the transducer. However, it was possible to get reproducible data from the transducer when it was facing the supporting limb and when very carefully centered under the tensioning strap of the CAT.

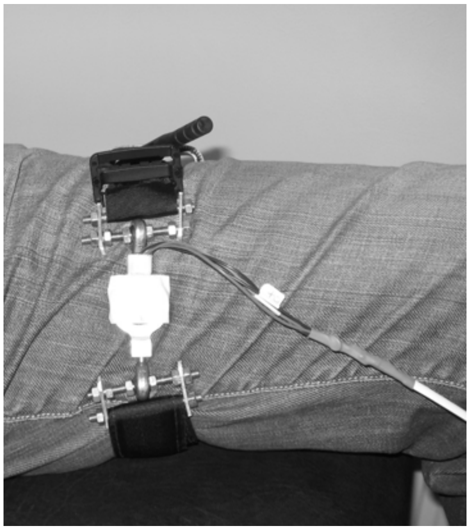

Figure 5 CAT on thigh with ring dynamometer replacing CAT buckle.

In an effort to identify a suitable transducer profile for these devices and verify IFP transducer indicated pressures, a ring dynamometer was constructed which would allow the direct measurement of the tension load in the CAT. This in turn may be used to obtain an independent dynamic estimate of the average CAT applied pressure.

The dynamometer[4] comprises an elastic ring shaped element with two integral bosses diametrically opposed, Figure 6. The bosses are threaded to accept bearing joints which in turn support buckle type couplers centered on the longitudinal dynamometer axis and designed to accept the CAT, Figure 5. The dynamometer is made from Aluminium 2024-T6. The circular ring is of square section with four single element 120ohm strain gauges located on the inner and outer ring surfaces on the horizontal diameter. This configuration ensures maximum tensile load sensitivity (full-bridge) while minimizing and compensating for temperature and out-of-plane moments. The dynamometer is conveniently calibrated using a Monsanto Tensometer.

The sensor is placed centrally under the CAT and faces the limb. The dynamometer indicated load, $F(N)$ is converted to pressure $P(mmHg)$ using

$$P = T\kappa = 7.5\times10^{-3}\frac{F}{wr} \qquad (1)$$

where $T = F/w$ is the CAT tension and w is the width of the tensioning strap in the CAT. A regular cylindrical geometry is assumed for the leg thereby allowing a simple curvature, κ, calculation using $\kappa = 1/r$ where r is the radius of curvature derived from the leg circumference under the CAT.

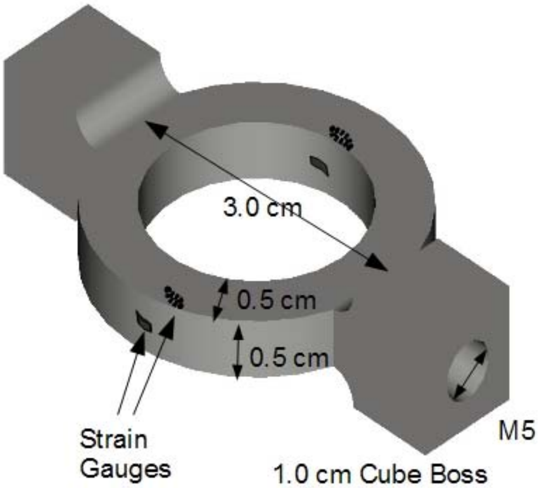

Figure 6 Ring dynamometer designed to measure tensional loads in CATs while on-body.

Typical results are plotted in Figure 7. The first spike and plateau region of the curves corresponds to the initial tightening and securing of the Velcro strap. Subsequent steps in pressure are due to complete turns of the windlass handle. The pressure spikes at the leading edge of these step increases arise, in part, because the windlass handle must be turned until it passes the opening of the securing bracket. Once in the securing bracket, it untwists slightly thereby reducing the tension. However, tissue dynamics may also contribute to this initial steep pressure rise. In general a disparity of between 20-50mmHg may arise between the stable interface transducer indicated pressure and the dynamometer derived pressure. Out of plane deformation of the dynamometer is one possible source of this discrepancy. Nevertheless, considering the relatively large size of both the sensor and the dynamometer, the dynamometer provides a useful indication of the upper bounds pressure for transducers with guard diameters of 2-2.5cm which is useful in guiding further sensor improvements.

The pulse in the dorsalis pedis artery was monitored by palpation during CAT application to the upper thigh. It disappeared at about 320 mmHg as indicated on the IFP transducer (confirmed using an Omeda 3800 Pulse Oximeter applied to the toe). This is significantly higher than the systolic pressure of 120 mmHg determined using a sphygmomanometer (120/85 mmHg) on the arm of the subject. However, the surface applied pressure necessary to produce occlusion in an artery increases with arterial depth[5] and also increases as the width of the pressure applying band/tourniquet is reduced[6].

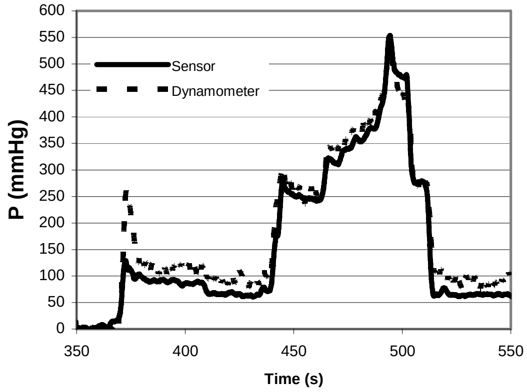

Figure 7 Pressure traces for interface sensor located under CAT (medial anterior position on thigh of healthy male subject) and Dynamometer replacing CAT buckle.

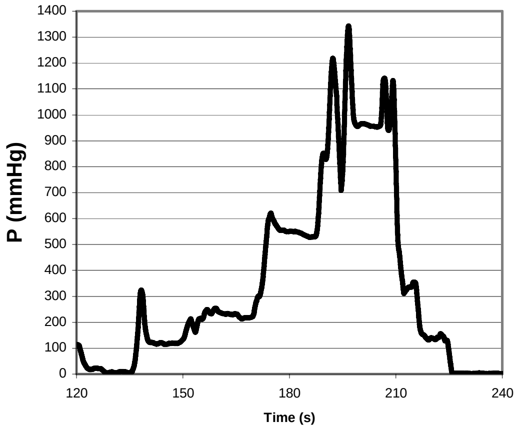

Figure 8 Small footprint IFP transducer (1.5cm diameter) under CAT on upper arm.

Transducer indicated pressures increased markedly for devices with guard rings less than 2cm, Figure 8. Since the dynamometer measures the load applied across the width of the tensioning strap, it is not surprising that better agreement is found for IFP transducers with footprints close to this width. While the pressures indicated for the smaller devices may be closer to the peak pressure at the centre of the tensioning strap, there may be significant contributions from shear force artifacts and hammocking[7,8]. MEMS sensor device size is shrinking[9] in response to demands for watch type altimeters and depth gauges and so it should be possible to develop less intrusive IFP transducers with improved spatial resolution.

Conclusions

A novel MEMS based interface pressure transducer has been tested under pneumatic and tensional tourniquets. Results indicate that the device is likely to prove useful in clinical applications in the case of pneumatic tourniquets but may require further scale reduction for tensional tourniquet applications.

Acknowledgements

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References

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[1] Candy H.Y. Lai, Cecilia W.P. Li-Tsang, Validation of the Pliance X System in measuring interface pressure generated by pressure garment. Burns, 2009;35:845-851.

[2] Noordin S, McEwen JA, Kragh J F, Eisen A, Masri, BA, Surgical Tourniquets in Orthopaedics. J Bone Joint Surg Am 2009; 91: 2958-2967.

[3] Fay TF, Brienza DA, What is Interface Pressure? Proc. 22nd EMBS International Conference, July 2000, Chicago, 2254-2255.

[4] Bray A., Barbato G. and Levi R., Theory and Practice of Force Measurement. Academic Press, London, 1990.

[5] Shaw J, Murray D. The relationship between tourniquet pressure and underlying soft tissue pressure in the thigh. J Bone Joint Surg 1982;64A(8):1148-52.

[6] Hargens A R. et al. Local compression patterns beneath pneumatic tourniquets applied to arms and thighs of human cadavera. Journal of Orthopedic Research 1987; 5(2):247-252.

[7] O'Brien SBG, Casey V. Numerical and asymptotic solutions for hammocking. Quart J Mech App Math 2002;55:409-420.

[8] Casey V, Griffin S and O'Brien SBG. An investigation of the hammocking effect associated with interface pressure measurements using pneumatic tourniquet cuffs. Medical Engineering and Physics, 2001;23:511-517.

[9] See 'World's smallest barometric sensor'; http://www.epcos.com.