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JUNCTIONAL TOURNIQUET EFFECTOR HEAD: MINIMAL FORCES AND PRESSURES PRODUCING OCCLUSION.

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INTRODUCTION

Junctional tourniquets such as the Combat Ready Clamp (CRoC)[1], Abdominal Aortic Tourniquet (AAT)[2] SAM Junctional Tourniquet[3]) have been developed recently, with the objective of saving lives in prehospital and emergency settings by controlling or eliminating extremity haemorrhage. In general junctional tourniquets produce artery occlusion by applying localised pressure at truncal sites over a target artery using a mechanical (see Figure 1) or pneumatic effector head. Safe operation demands an effective pressure applicator technology combined with medical expertise to locate and deploy the applicator at the appropriate anatomical site to affect extremity haemorrhage control in minimal time[4] and at minimal applied force and pressure. However, such medical expertise may not be present in pre-hospital and emergency settings. Incorrect location and application of the effector head could result in failure to produce timely occlusion and/or organ and tissue damage.

Data are presented here relating to the pressures and forces that are likely to arise at truncal sites used by junctional tourniquets with mechanical effector heads to affect extremity artery occlusion. One commercially available junctional tourniquet, the Combat Medical Systems, Combat Ready Clamp[5] (CRoC) was used in this study along with improvised semi-oval (half-egg shaped) effector heads. The study was motivated by a need to explore the operational force/pressure parameter space for such devices in order to provide some guidance on the safety of the device category. A further motive for the study was to investigate the prospects for improving the effectiveness of such devices in the hands of non-medical experts through the use of a simple integrated Doppler guidance system.

Experimental Details

The CRoC used in this work was manufactured by Combat Medical Systems. An RTV silicone mold was used to form semi-ovate (half-egg shaped) effector heads (see inset to Figure 7) from fastcast polyurethane resin (Maragon Arts & Crafts, UK).

Figure 1: Combat Ready Clamp (CRoC) with hemispherical (3.75 cm [1.5 in] radius) effector head.

Pressure data were obtained using low profile Biomedical Interface Pressure Transducers[6] (BIPTs) which were either implanted in the effector heads or were embedded in flexible polydimethylsiloxane (PDMS) pads which could be placed between the pressure applying effector head and the target body site. The PDMS pads were approximately 4 mm thick and were flexible enough to conform to the effector head profile when in use. Data logging was carried out using a LabView platform (National Instruments DAQ card and LabView VI). In the case of the

improvised devices, an axial force dynamometer with rotation decoupling linkage was used to measure directly the force being applied to the effector head via the effector head shaft/handle. Provision was made to insert a Hi-Dop BT-200 vascular Doppler probe into one of the effector heads to facilitate artery location. Artery occlusion was established using a Contec Medical Systems model CMS-50B pulse oximeter placed on a toe or finger as appropriate. The subject (55 year old male) was in a supine position for all tests.

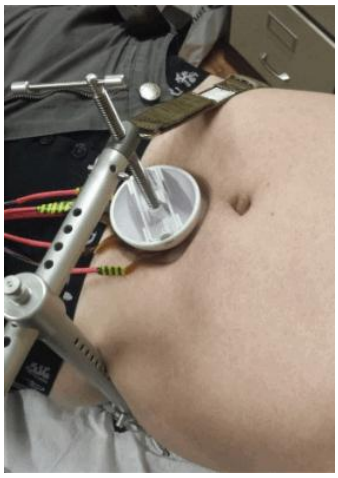

Figure 2: CRoC with BIPT disc in place between effector head and target site.

RESULTS

Combat Ready Clamp (CRoC)

The CRoC was used, in accordance with the manufacturer's instructions, at three junctional artery sites, the proximal iliac area, inguinal area (mid way between the pubic tubercle and the anterior superior iliac spine), and axilla area (deltopectoral groove). The hemispherical CRoC head was used for iliac and inguinal locations. The rectangular head (detachable from the hemispherical effector head) was used at the axilla area. Tightening of the clamp was advanced in half turns of the handle until the pulse disappeared. The CRoC was unclamped immediately if occlusion was not achieved by 20 full turns of the handle or if the subject became uncomfortable. Occlusion was deemed stable once a pulse was absent for more than 10 s. Interface pressure was measured using the BIPT disc pad in the case of the hemispherical CRoC (see inset to Figure **3**). Occlusion with the CRoC was comfortably achieved at both iliac and inguinal sites using the CRoC hemispherical effector head.

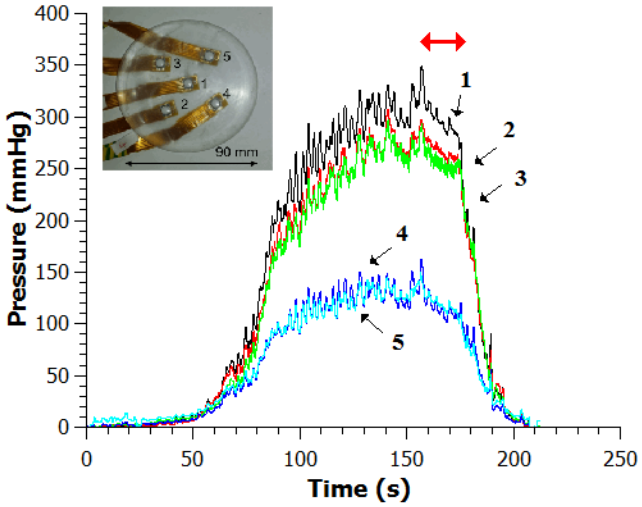

Figure 3: Sub CRoC pressure data for application to the proximal iliac area. The red arrow indicates a region of stable occlusion. Inset: BIPT disc pad.

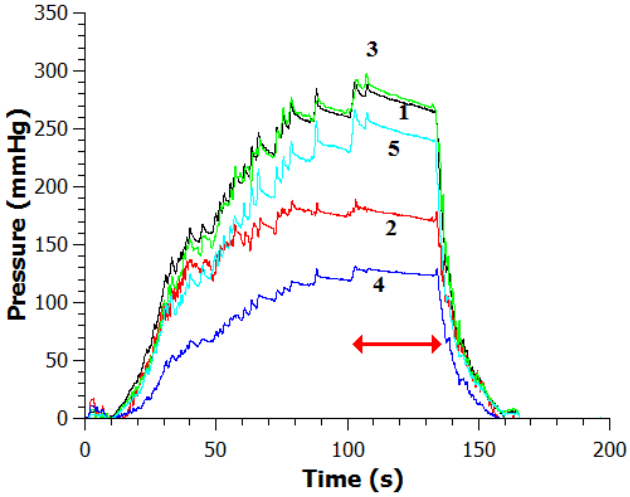

Figure 4: BIPT disc pressure data for CRoC used to occlude the upper femoral artery (inguinal area). The red arrow indicates the region of stable occlusion.

However, it was not possible to achieve occlusion of the axilla using the rectangular head (surface contact area 15 cm^2) at the deltopectoral grove due to subject discomfort[7]. Stable iliac occlusion occurred for a central peak pressure (BIPT 1) of

approximately 325 mmHg (43 kPa), see Figure 3. Only partial contact between the CRoC effector head curved surface and tissue (see Figure 2) occurred at pressures required to produce occlusion. Therefore, there is a large spread in the pressures indicated by the BIPTs under the hemispherical CRoC effector head: BIPTs 4 and 5 indicate considerably lower pressures than BIPTs 1-3. However, variation in the compliance of the sub CRoC tissue may also contribute to this variation. This variability of interface pressure is also evident in the data shown in Figure 4 for CRoC application (hemispherical effector head) to the inguinal area to produce femoral artery occlusion.

It is difficult to calculate the total force produced by the CRoC to affect occlusion because of the variability of contact area and contact pressures. However, an estimate may be made using the average BIPT pressures and the estimated CRoC-tissue contact area (half the hemispherical surface area judged from photographs). The CRoC compression forces required to produce occlusion in the iliac and femoral arteries, using the hemispherical head, are thus estimated to be in the region of 130 N and 125 N respectively.

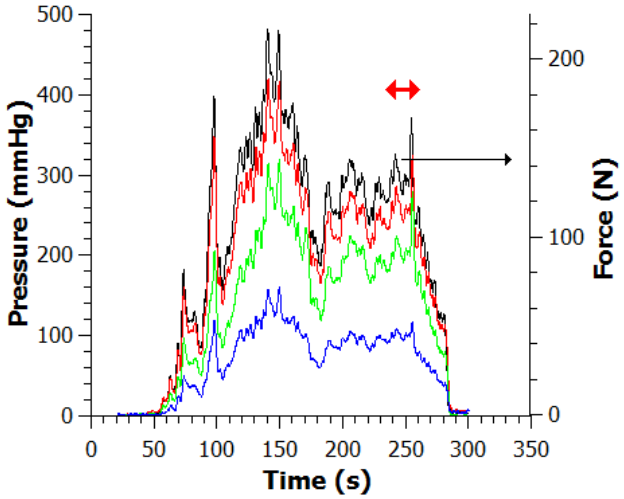

Figure 5: Clamped semi-oval effector head used to occlude the iliac artery (linear BIPT array). Force is indicated using the black trace.

Semi-oval Effectors

The semi-oval effectors were used either as hand held devices or in a CRoC like clamp. The curved surface area of these devices (35 cm^2) was less than half the surface area of the CRoC hemispherical effector (88 cm^2) and over twice the area of the CRoC rectangular effector (front surface only).

Pressure and force data for a clamped semi-oval effector head are shown in Figure 7. The high force/pressures in the 100-170 s region did not produce occlusion. However, the clamp was then released and the oval effector head was rotated such that its major axis was roughly transverse to the line of the iliac artery. A stable occlusion was achieved at a peak pressure of 300 mmHg and corresponding force of 140 N. In the case of the femoral artery, the oval effector head produced occlusion at a peak pressure of 310 mmHg and corresponding peak force of 160 N, see Figure 6.

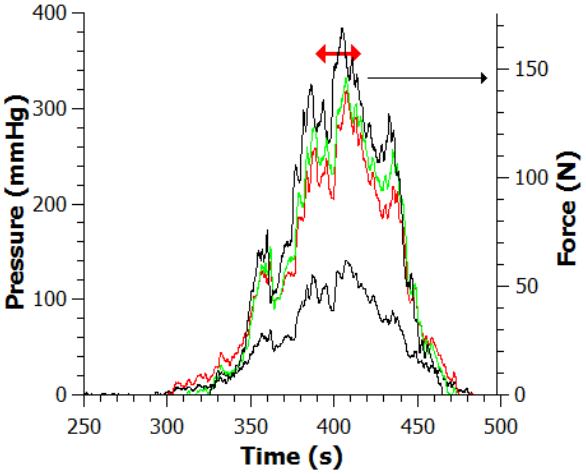

Figure 6 Clamped semi-oval effector head on upper femoral artery (linear BIPT array).

A Doppler probe was integrated with BIPTs in a semi-oval effector head (see inset to Figure 7b) which in turn was controlled using a handle with integrated dynamometer, in order to improve tourniquet placement. The effector head was coated with aquagel before being pressed against the target tissue site. The Doppler probe provided audio feedback to indicate the strength of the Doppler signal and thereby guided manipulation of the effector head to position it over the target artery.

Force and pressure data for iliac occlusion using the Doppler guided effector head are shown in Figure 7a. There was a significant reduction in the force required (90 N compared

to 140 N without Doppler) once the effector was located directly over the artery. Similar reductions were achieved for inguinal occlusion of the femoral artery. The absence of a BIPT at the central Doppler probe location does not allow comparison between unguided and Doppler guided pressure data since the pressure profile for all occlusions shows highly localized concentration even for the relatively small area oval effector heads.

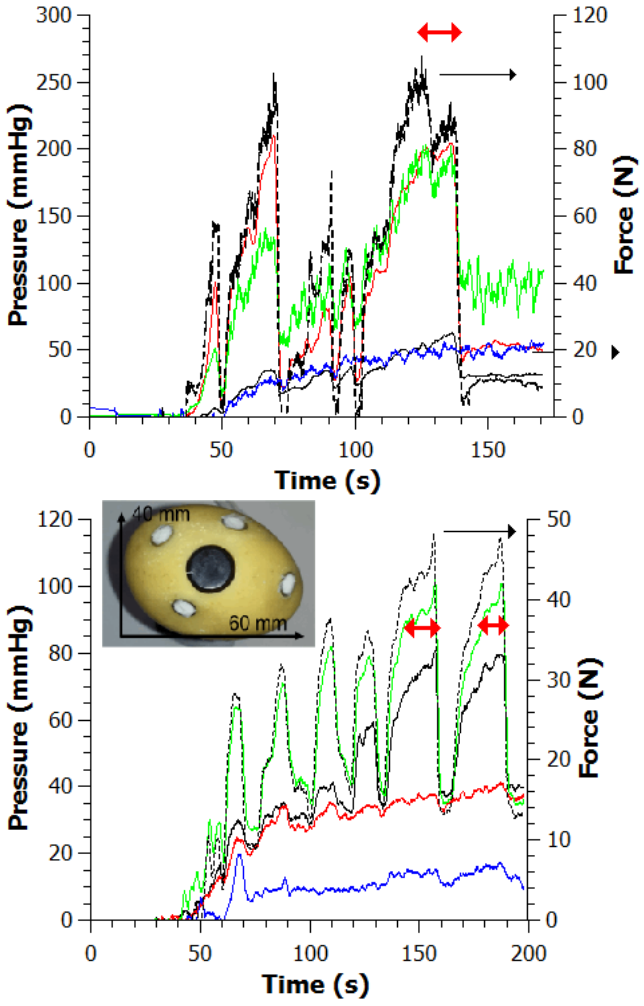

Figure 7: Plot of force (black dashed trace, right axis) and pressures for handheld Doppler effector head for (a) iliac and (b) axilla artery.

To further illustrate this, pressure force data for occlusion of the axilla artery, using an under arm site, are shown in Figure 7b. Peak pressure values at occlusion range from 15 mmHg (very little contact) to 100 mmHg (strong contact). Subject blood pressure was determined as 120/80 so clearly the element of the effector head producing occlusion was highly localized and probably centered on the Doppler probe where pressures would have to be in excess of 120 mmHg.

CONCLUSIONS

Junctional tourniquets must, in the hands of non-medical experts, affect occlusion in the target artery within a very short action window. They should achieve this without causing injury to tissue and organs. Preliminary data presented here indicates that the effective contact area producing occlusion with mechanical effector heads may be less than half the curved surface area of the head. The forces required to produce occlusion are likely to be in the range 100-150 N (roughly equivalent to dead weights of 10 -15 kg). A simple guidance system, such as a Doppler probe, could facilitate fast, effective tourniquet location and function. Correct location of the effector head can produce junctional artery occlusion at interface pressure levels which are well within the pressure ranges commonly encountered in routine medical practice.

ACKNOWLEDGEMENTS

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