

Surgical Tourniquet Technology Adapted for Military and Prehospital Use

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ABSTRACT

In groundbased tactical situations and prehospital settings, the tourniquet is used as a life-saving hemorrhage control device. It must completely stop blood flow, must be fast and simple to self-apply, and must require minimal training. However, an improperly designed or used tourniquet can cause loss of the limb, compromised limb salvage, and systemic effects harmful to the patient; all may result from excess tourniquet pressure, excess tourniquet time, or a tourniquet that is too narrow. Most existing prehospital tourniquets use technology from the 1800's: mechanically tightened narrow bands that apply uncontrolled pressures (e.g. Spanish Windlass). In contrast, the modern pneumatic tourniquet is considered indispensable in common surgical procedures, and is now used thousands of times each day to completely occlude arterial blood flow in limbs continuously throughout surgeries lasting several minutes to several hours, and longer using appropriate techniques. Injury or compromise of limb recovery due to pneumatic tourniquet use in surgery is rare. The purpose of this study was to test a newly developed prehospital pneumatic tourniquet, which is based on proven surgical tourniquet designs. The new device has an inflatable bladder, a manual inflator, and a locking clamp. It weighs 220 g, packs to 570 cm³, and fits arms and thighs up to 85 cm circumference. To demonstrate effectiveness at safe pressures, the new tourniquet was applied to adult volunteers. Arterial occlusion (indicated by Doppler stethoscope) was reached at an average pressure of 229 mmHg (SD 32, range 165-302, n = 32) on the thigh and 140 mmHg (SD 17, range 106-175, n = 32) on the upper arm. The tourniquet was then used on thighs in 21 surgical procedures at the normally used pressures of 300-350 mmHg. Good hemostasis was maintained in all cases and there were no complications. Users found the tourniquet very easy to apply after a single demonstration. To demonstrate single-handed self-application after minimal training, volunteers were given one demonstration and then timed during self-application to the upper arm and thigh using their non-dominant hand only. First-time application and inflation averaged 29 seconds for the arm (range 22-40, SD 6.8, n = 7 volunteers) and 36 seconds for the thigh (range 24-62, SD 12.5, n = 7 volunteers). After 5 minutes of additional demonstration and practice, average times improved to 23 s (arm, range 12-47, SD 8.3, p = 0.035, n = 16 volunteers) and 26 s (thigh, range 18-36, SD 5.2, p = 0.042, n = 16). To demonstrate effectiveness when access over the distal end of the limb is impossible, volunteers unthreaded the tourniquet, passed it around the limb, and inflated to occlusion. Average times were 43 seconds (arm, range 26-63, SD 10.7, n = 16) and 43 seconds (thigh, range 23-82, SD 13.4, n = 16). The new prehospital pneumatic tourniquet studied proved safe, effective, and reliable in volunteer testing and in clinical evaluations. In contrast to most existing prehospital tourniquets, the new device occludes blood flow at safe pressures over adequate width, as has been proven safe in routine limb surgery. Manual and electronic controllers for the new prehospital pneumatic tourniquet are also described and discussed.

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1.0 INTRODUCTION

It is recorded that surgeons used constricting devices for amputation in Roman times, and in 1718 Jean Louis Petit developed a screw-type device (a ‘tourniquet’) which tightened a cloth band around the limb to achieve hemostasis. In 1864 tourniquets were first used for surgical procedures other than amputations. In 1904 Cushing introduced a pneumatic tourniquet for the surgical setting to provide more even and controllable pressure to the limb compared to previous mechanical tourniquets, thus allowing more reliable occlusion and reducing the chance of tourniquet-induced injuries. Pneumatic tourniquet systems (which include a tourniquet controller that supplies and/or regulates pressure and a pneumatic tourniquet cuff applied to the limb) have since been developed and refined. In 1982 the modern automated, microprocessor based tourniquet controller was introduced which featured greatly improved regulation of pressure, time display, warnings of various hazardous conditions, automatic self-test of calibration, and other patient safety related functions [18,21]. Wider, better fitting pneumatic tourniquet cuffs which include many other improvements in design have also been developed for better safety and performance, and to minimize the pressure required to maintain occlusion and thereby minimize the chance of injury [7, 19, 20, 24, 27, 28]. Due to these improvements in safety, efficacy, and reliability these modern tourniquet systems are now used in virtually all modern operating rooms in an estimated 20,000 procedures each day worldwide. Pneumatic tourniquet related complications are rare [23], and the pneumatic tourniquet has been placed in the lowest risk category for medical devices by the Food and Drug Administration (FDA), the US medical product regulatory body.

However in the pre-hospital, emergency, and military settings, established tourniquet techniques still employ a non-pneumatic constricting band and a mechanical device (such as a windlass, buckle, or ratchet mechanism) to allow the user to generate the high tension required to occlude blood flow. For example, most emergency medicine guidelines describe a windlass technique wherein the user ties a strap or cloth band around the limb, inserts a stick or rod under the band, and twists the stick to tighten the band until blood flow stops. In the surgical literature, it has been shown that narrow tourniquets must apply very high pressures to the limb to occlude blood flow [10]. High pressures have been shown to cause nerve, muscle and soft tissue damage, and in particular the resulting steep pressure gradients developed in the limb are thought to be the primary mechanism of nerve injury [11, 25, 26]. Applications of high pressure, even for a brief period, can cause limb paralysis [1, 30].

Due to these hazards, most emergency medicine guidelines have specified the non-pneumatic tourniquet as a ‘last resort’ method to control life-threatening bleeding [2, 4, 6, 15, 17, 29, 31], although the life-saving value of an effective tourniquet is recognized [12, 17, 32]. Current commercially available tourniquets for emergency settings (MacMillan Tourniquet, CMC Rescue Inc., Santa Barbara, CA; Prämeta Emergency Tourniquet 910A, Prämeta, Cologne, Germany) and some tourniquets under development [3, 5] utilize narrow, non-pneumatic constricting bands. Various non-pneumatic strap-type tourniquets and commercially available venous tourniquets (designed to assist in intravenous catheter placement) have been shown to be ineffective for occluding arterial blood flow [5]. In emergency situations where life-threatening bleeding from an extremity must be controlled quickly and pressure bandages cannot be used effectively, an effective tourniquet may save the victim’s life. However, such a strap or cloth-and-stick type emergency tourniquet may not be effective, and if it can be applied tightly enough to be effective it may reduce the chance of successful limb salvage.

A pneumatic emergency tourniquet, a new manual pneumatic tourniquet system, and a prototype miniature electronic tourniquet monitor, all based on modern pneumatic surgical tourniquet technology, have been developed by tourniquet specialists Delfi Medical Innovations Inc. (Vancouver BC, Canada; www.delfimedical.com) for emergency and pre-hospital use. These new tourniquets have designs that are

closely based on the proven designs of pneumatic surgical tourniquets that are widely used in hospital settings (see US patents 5312431, 5454831, 5578055; US Patent Application 20030139766), and thus have similar safety and reliability to modern surgical tourniquet systems, but are adapted for portability and use in settings without external power sources. In this article we report on the development of the new pneumatic emergency tourniquet, manual tourniquet system, and electronic tourniquet monitor, results of volunteer testing, and results of use in surgery. Essential tourniquet design details from proven commercial surgical tourniquets that have been incorporated in the new devices are described below.

2.0 MATERIALS AND METHODS

2.1 Emergency Tourniquet

The new emergency tourniquet consists of a pneumatic bladder having similar width (3.5") to many commonly used surgical tourniquets, a securing clamp, and a manual hand-bulb type inflator and deflation valve (Fig. 1). Many crucial features are closely based on the proven, patented designs of surgical tourniquets, as described below. The tourniquet weighs 210 grams (7.5 ounces) and is about 4" x 3" x 3" when packed. The securing clamp allows the user to self-apply the tourniquet using one hand only and allows adjustment to fit limbs from 8 to 85 cm (3 to 34") in circumference, encompassing over 97.5% of arms, thighs, and lower legs encountered in the population. The bladder is formed from sheets of urethane-backed nylon radio-frequency sealed together; this material and assembly technique are used in surgical tourniquet cuffs which normally last for hundreds of surgical procedures over several years. The selected width of the pneumatic bladder provides a width/limb circumference ratio greater than 0.10, allowing occlusion at pressures similar to those used in surgery [10]. Unlike a blood pressure cuff, the tourniquet bladder completely encircles the limb and applies inward radial pressure evenly around the entire limb circumference, which is essential for complete occlusion. To prevent the tourniquet from rolling down the limb as it is inflated, selected areas along the edges of the bladder are non-inflating. The bladder design allows sufficient inward expansion upon inflation to provide occlusion in most cases when the tourniquet is applied over clothing, is not applied snugly as directed, or is applied to an obese limb. The tourniquet is packed with both ends of the bladder threaded through the clamp to form a loop which can be passed over the distal end of the injured limb, moved proximally into position, pulled snug and clamped, then inflated. If access over the distal end of the limb is restricted, one end of the bladder can be unthreaded from the clamp, passed around the limb at the desired location, and rethreaded through the clamp.

2.1.1 Volunteer Test Method

A convenience sample of 16 volunteers was recruited among research center staff members (15 male, median age 27, age range 19-50). All volunteers were civilians with no prior training in emergency medicine. Two volunteers had previous experience with the tourniquet, and the remaining 14 had not seen the tourniquet in use before the test. Each volunteer was timed from the moment of picking up the tourniquet until locking the clamp with the tourniquet snugly applied around the limb under the following conditions:

- First attempt passing the looped tourniquet over the distal end of the limb, after a 30 second demonstration by the investigator.
- Second attempt as above, after up to 5 minutes of additional demonstration of optimal techniques and practice (up to two applications).
- Third attempt in which the volunteer unthreaded the tourniquet bladder, wrapped it around their limb, rethreaded the bladder through the clamp, tightened the bladder around the limb, and locked the clamp. Volunteers were shown the optimal technique and allowed up to two practice applications before their timed attempt.

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The above sequence of tests was performed on each volunteer's dominant arm and on one thigh. Note that volunteers were considered 'experienced' after their first attempt on either the arm or thigh, therefore there are only 7 true 'first attempts' for each limb. Limb occlusion pressure (LOP, the tourniquet pressure at which the distal pulse was no longer audible) was measured after the first and second attempts on each limb by gradually inflating the tourniquet and monitoring the distal pulse in the limb using a Doppler stethoscope. After their third attempt, the time required for each volunteer to manually inflate the tourniquet approximately to their LOP was measured. For each attempt, the sum of the application time and the inflation time is taken as the total time to occlusion. In all tests, volunteers used their non-dominant hand only and attempted to limit movement of the affected limb. All tests were done with the volunteer sitting on a flat surface. The tourniquet was applied over the volunteer's clothing; full length single layer fabric trousers on all thighs and up to two layers of clothing on arms. At the beginning of each application the tourniquet was rolled up as packaged, but was not sealed in its plastic pouch; time required to rip open the pouch is not included in the results. All LOP measurements were taken at the posterior tibial and radial arteries by a single experienced technician using a Doppler stethoscope (Versatone D-9, Medsonics, Mountain View CA USA). A hand operated pressure regulator (Inflatomatic 3000, Zimmer, Dover OH USA) was used to inflate and increase tourniquet pressure during the LOP measurements, and pressures were monitored using a digital gauge with 1 mmHg resolution (Cecomp Electronics, USA).



Figure 1: Emergency tourniquet in use (left) and packed (right)

2.1.2 Surgical Evaluation Method

To confirm that blood flow could be reliably occluded at pressures similar to those used in surgery, the emergency tourniquet was used in surgical procedures to the knee and lower leg. This technique of evaluation on surgical patients is not possible for unproven strap-type tourniquets, because of concerns about possible tourniquet-related injuries, but was possible for the emergency tourniquet because the design was closely based on proven surgical tourniquets. The tourniquet was applied to the thigh and inflated to 300 mmHg (for small and average sized thighs) or 350 mmHg (for large thighs) for each case (the typical range of thigh tourniquet pressures used in standard surgical tourniquets [13]). The surgeon in charge noted the quality of the bloodless field throughout the procedure. For these clinical cases the hand-bulb inflator was removed and the emergency tourniquet was connected to the standard automatic tourniquet instrument normally used in the operating room.

2.2 Manual Tourniquet System

A new manual tourniquet system has been developed for applications where the self-application ability and extreme compactness and light weight of the emergency tourniquet are not essential (e.g. medic kits, far-forward surgical teams, ground and air ambulances, and other applications such as industrial and marine medical aid kits). The manual tourniquet system requires no batteries or external power sources. It consists of a 4" wide by 34" long pneumatic bladder, hook-and-loop fasteners to secure the bladder around the limb, a manual hand-bulb type inflator with deflation valve, a pressure gauge, and a quick-release locking connector to allow connection to a hospital-type or portable automatic tourniquet system at any time during use. The bladder includes a plastic stiffener having a selected width and stiffness to prevent the bladder from rolling down the limb and to direct expansion of bladder radially inwards upon inflation. The design of the cuff is closely based on the proven design of surgical tourniquet cuffs that are used safely and effectively many times each day in hospital operating rooms around the world.

2.2.1 Evaluation Method

Extensive testing was not required for the manual tourniquet system because the bladder design has been well proven in surgery and its performance on typical thighs and lower legs has been reported in the literature [19, 20]. The system was tested on the upper arms of two volunteers for LOP. The system was also applied to one volunteer's arm, thigh, lower leg, and ankle to check for movement down the limb.

2.3 Electronic Tourniquet Monitor

The prototype electronic tourniquet monitor is a portable, self-contained, water-resistant unit weighing 90 grams (3.2 ounces) that may be used with the emergency tourniquet (described above) or with other pneumatic tourniquet cuffs to monitor tourniquet pressure and time (Fig. 2).

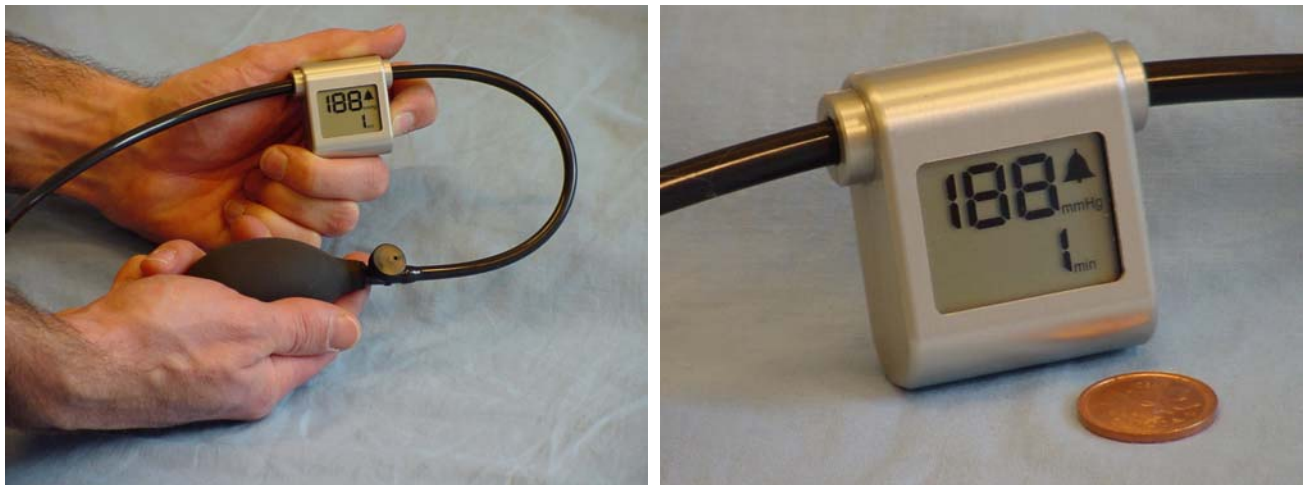


Figure 2: Electronic tourniquet monitor

The monitor has a field-replaceable battery (shelf life 5 years and service life of 100 two-hour uses) and a hand-bulb type inflator. Like modern surgical tourniquet controllers, the monitor accurately displays tourniquet pressure, allows the user to set a desired pressure set point, and gives audio and visual warnings if the tourniquet pressure drifts outside of a tolerance zone around the set point. Elapsed tourniquet time is also

displayed, and audio and visual warnings are triggered if tourniquet time exceeds a selected limit. The monitor powers up automatically upon tourniquet inflation and shuts down automatically after being deflated for a pre-set period. An audio-visual low battery alarm is activated when there is still sufficient battery life for several uses.

3.0 RESULTS

3.1 Emergency Tourniquet

3.1.1 Volunteer Test

Volunteers with no previous experience were able to pass the tourniquet over the distal end of the limb, slide it proximally into position, then lock and inflate it to occlusion pressure in an average of 29 seconds for the arm (range 22-40, SD 6.8, n = 7 volunteers) and 36 seconds for the thigh (range 24-62, SD 12.5, n = 7 volunteers). After up to 5 minutes additional demonstration and two practice applications (and including results from two additional volunteers with previous experience with the tourniquet), average times improved to 23 s for the arm (range 12-47, SD 8.3, p = 0.035, n = 16) and 26 s for the thigh (range 18-36, SD 5.2, p = 0.042, n = 16). Volunteers were also able to unthread the emergency tourniquet, pass it around the limb, rethread it, then lock and inflate it to occlusion pressure in an average time of 43 seconds for the arm (range 26-63, SD 10.7, n = 16) and 43 seconds for the thigh (range 23-82, SD 13.4, n = 16) after up to two practice applications. In all 96 timed applications, 3 took longer than 60 seconds; one volunteer required 62 seconds to complete a thigh application on their first attempt and two other volunteers required 63 and 82 seconds to unthread, wrap, and apply the tourniquet to the arm and thigh respectively (see Figs. 3 and 4). Occlusion was achieved at an average pressure of 229 mmHg (SD 32, range 165-302, n = 32) on the thigh and 140 mmHg (SD 17, range 106-175, n = 32) on the arm.

3.1.2 Surgical Evaluation

The new tourniquet was used in 22 surgical cases. One surgeon performed 6 arthroscopic anterior cruciate ligament reconstructions and 12 other knee arthroscopic procedures, and a second surgeon performed 4 below knee open surgeries using the emergency tourniquet. A satisfactory bloodless field was achieved in all cases. Eight thighs were noted to be large or obese, and on 4 of these patients 350 mmHg was used. In the remaining 18 cases 300 mmHg was used. Pressure was not increased during the procedure in any of the cases. Both surgeons noted that there was no difference in occlusion compared to the surgical tourniquet cuffs normally used at the clinic, and that no problems of fit or function of the tourniquet were encountered. In several cases staff noted that the new tourniquet was easier to apply than standard surgical tourniquet cuffs, particularly on large limbs.

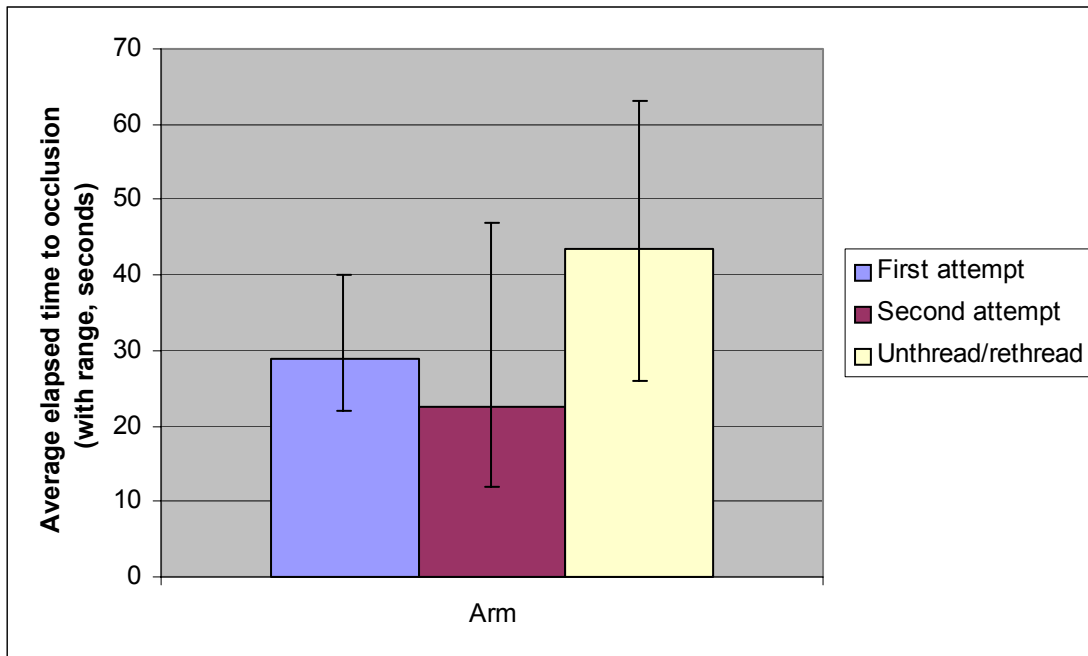


Figure 3: Average time to self-apply with non-dominant hand only, arm

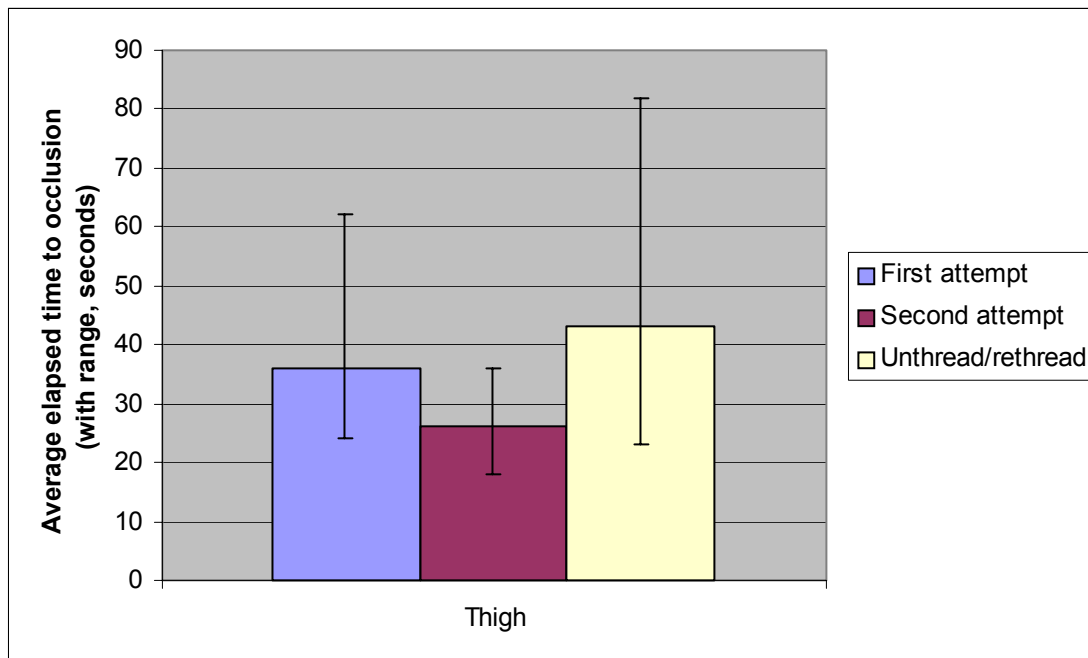


Figure 4: Average time to self-apply with non-dominant hand only, thigh

3.2 Manual Tourniquet System

On two volunteers with 25-28 cm (10-11") circumference upper arms, the system occluded blood flow at 140 mmHg, which is well below the 200 to 250 mmHg that is typically used on upper arms in surgery. In additional thigh, lower leg, and ankle applications on one volunteer the tourniquet remained stable and did not slide down the limb. The bladder design has previously been shown to be stable and effective in surgery on a wide variety of patients.

4.0 DISCUSSION

Current emergency tourniquet techniques and devices are based on centuries-old narrow constricting strap approaches, and narrow tourniquets have been shown to require high pressures to occlude blood flow [10]. These high pressures are developed by increasing the tension in the strap during application, and accordingly most non-pneumatic devices include a windlass, ratchet, or other mechanical arrangement to assist the user in tightening the strap. Wider tourniquets occlude blood flow at lower pressures and have been found to transmit pressure more effectively to deep tissues [7, 22], but increasing the width of the strap in a non-pneumatic tourniquet greatly increases the tensioning effort required as a greater area of tissue must be compressed. In a recent study of a variety of commercially available and custom self-applied tourniquets, Calkins found that all of the non-pneumatic, strap-type devices tested (typically 1-1.5 inches wide and including several ratchet-assisted devices) failed to occlude blood flow in a substantial number of trials [5]. Furthermore, pressures are difficult to measure and regulate with strap-type tourniquets and although a strap tension indicator has been suggested (U.S. Patent No. 4,243,039), strap tension has not been shown to be a reliable indicator of pressure applied to a limb around its circumference. High, uncontrolled tourniquet pressures increase the chance of further injury to the limb [1, 25, 26, 30] and therefore will likely decrease the chance of successful limb salvage. Due to these hazards, narrow, non-pneumatic strap-type tourniquets cannot be ethically tested on healthy volunteers in the civilian and medical setting. In contrast, surgical pneumatic tourniquets are routinely used on healthy volunteers in studies.

Some references specify that a wide material should be used to encircle the limb and warn against using rope, cord, or twine [2, 4, 6, 29]. However wide cloth bands or similar materials tightened using a windlass tend to concentrate the pressure applied to the limb along the midline of the band; a similar effect has been observed under elastic bandages used as tourniquets [22].

Another hazard of tourniquet use is excessive continuous tourniquet occlusion time, which can result from attendants forgetting or not being aware that a tourniquet is in place, not knowing when it was applied, or leaving tourniquets in place continuously during a long evacuation to hospital care [8, 33]. Although most emergency medicine guidelines warn of the hazards of excessive continuous tourniquet time, the user is typically advised to leave the tourniquet in place until hospital care is available [2, 6, 15, 29, 31].

Due to the hazards associated with currently known emergency tourniquets and techniques, their use is typically recommended only as a 'last resort' [2, 4, 6, 15, 17, 29, 31]. Using a blood pressure cuff as an emergency tourniquet is suggested in some emergency medicine references [2, 4, 15], but these cuffs are typically not designed to completely occlude all arterial flow, have inflatable bladders that do not completely encircle the limb, are generally too wide, are not intended to be pressurized for extended periods of time, and can fail under typical prehospital conditions [9]. Despite these limitations and risks inherent in current emergency tourniquets and techniques, the life-saving potential of an effective tourniquet has been recognized in military [5, 12, 16] and some emergency medicine literature [4, 17, 32]. One civilian emergency medicine guideline states that a tourniquet can be extremely useful when applied properly, but recommends only wide, pneumatic types providing even pressure distribution around the limb [17].

These limitations and risks have largely been addressed in the surgical setting, and the pneumatic tourniquet has become standard equipment in the modern operating room [14]. Pressure on the limb is generated by inflation pressure rather than circumferential tension, and is therefore more easily controlled and more evenly applied around the circumference of the limb. The required pressure can be generated in a tourniquet of any size, and modern tourniquet bladders have been developed to fit various limb sizes. Pneumatic pressure can be accurately regulated and both elapsed time and pressure can be monitored and displayed. Alarms and other safety features are often incorporated to prevent hazardous conditions such as excessive tourniquet pressure and time. Bladder width is typically 3 – 5 inches for adult limbs, providing a sufficiently high width/circumference ratio to occlude most limbs at less than 350 mmHg. Modern bladder designs completely encircle the limb, allow sufficient inward radial expansion, produce acceptable pressure gradients at the tourniquet edges, and include stiffeners or other means to direct expansion of the bladder radially inward and to prevent rolling and sliding of the tourniquet down the limb. Bladder materials are durable enough to withstand daily use and hundreds of inflation cycles. However until now this modern surgical tourniquet technology has not been adapted to the emergency and pre-hospital setting. Surgical tourniquet systems generally require an external power source and are not portable or rugged (with the exception of the P.T.S. Portable Tourniquet System, Delfi Medical Innovations Inc., Vancouver BC, Canada www.delfimedical.com). A variety of surgical tourniquet bladder sizes are normally required to fit all limbs of all patients, and they are not well suited for self-application.

The new pneumatic emergency tourniquet described in this study offers significant improvements in safety and efficacy over existing emergency tourniquets. The design of this new pneumatic emergency tourniquet was closely based on the proven design of surgical tourniquets that are used safely and effectively many times each day in hospital operating rooms around the world. This resulted in reliable occlusion at pressure levels that are routinely used in surgery without complications. To allow the emergency tourniquet to be rolled up to a small packed size, the bladder design has been adapted to eliminate the stiffener used in most surgical tourniquets. The new tourniquet utilizes a clamp rather than hook-and-loop type fasteners to secure the bladder snugly around the limb; this allows the tourniquet to fit the majority of limbs likely to be encountered, enables one-handed application, and improves reliability in wet or dirty conditions. In the current study, most untrained volunteers were able to successfully apply the new emergency tourniquet within a minute, and application times improved after about 5 minutes of additional demonstration and practice. Blood flow was occluded on all volunteers at pressures similar to those used routinely in surgery [13]. These application times are comparable to those recorded by Calkins, although the Calkins study did not investigate untrained volunteers and scenarios where access over the distal end of the injured limb was impossible [5]. In surgery, the new emergency tourniquet maintained occlusion at 300-350 mmHg throughout typical surgical procedures, which included repositioning and manipulation of the limb. Such evaluation on surgical patients, and demonstration of the low pressures required to stop blood flow, was only possible for the emergency tourniquet because the design was closely based on proven surgical tourniquets. Such evaluations would not generally be possible for non-pneumatic strap-type tourniquets, because of concerns about reliability and about the risk of tourniquet-related injuries to the underlying limb due to high pressures and high pressure gradients.

The new manual tourniquet system described in this study provides a surgically-equivalent pneumatic bladder designed in a size that will fit the great majority of limbs and a completely self-contained manual inflator, valve, and pressure gauge. It is portable, does not require any batteries, external power, or compressed air, and can also be used with automatic tourniquet systems.

The new electronic tourniquet monitor is the first portable, self-contained device that provides tourniquet pressure and time monitoring and safety alarm functions similar to those of modern surgical tourniquet

systems. It is a more sophisticated alternative to the pressure gauge used with the manual tourniquet system described above and can also be used with the new emergency tourniquet or with other pneumatic tourniquet cuffs. Safety is improved by assisting the user in maintaining safe tourniquet pressures and times; as tourniquet pressure changes due to changing conditions such as ambient temperature or movement of the limb, audio-visual alarms indicate if the pressure deviates excessively from the selected pressure. The user may then manually inflate or deflate the tourniquet back to the selected level. The elapsed time monitor, display, and alarms reduce the risk of excessive continuous tourniquet time. The automatic power-on, power-off, and low battery indicator features minimize the user inputs required to operate the device and help ensure that the monitors and alarms function at all times when the tourniquet is inflated. The device does not require external power or compressed gas sources.

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