Unsatisfactory Results in Hand Surgery

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The tourniquet

The pneumatic tourniquet is a device essential to modern hand surgery. The primary goals of operative hand surgery, namely precision and atramautic technique, cannot be achieved optimally without a bloodless surgical field. The use of such a device to temporarily arrest all circulation in the operative field is not without hazard. It is the responsibility of the surgeon to minimise the possibility of a tourniquet related complication. The surgeon should select a modern tourniquet system and be familiar with its operative characteristics and maintenance requirements. The guidelines for safe inflation time and pressure settings must be known and observed. It is possible that with continued research even safer methods of regional circulatory arrest for surgical procedures will be developed.

HISTORICAL REVIEW

The history of the use of non-pneumatic tourniquets in surgery has been reviewed extensively elsewhere (Klenerman 1962). The first record of the use of a tourniquet is by the Roman surgeon, Heliodoris, who in the second century A.D. wrote, 'I have been accustomed to apply a bandage above the part to be amputated so as to compress the vessels as far as possible' (Kessler 1966). Thus, the original tourniquet use was synonymous with the surgical procedure of amputation. In 1817, the French surgeon, Jean Louis Petit, described his device for hemostasis and named the instrument the 'tourniquet' (Klenerman 1962). Three advances were to follow in the evolution of bloodless field limb surgery: the introduction of the elastic

wrapped bandage for exsanguination in 1873 (Esmarch 1873) the introduction of a pneumatic tourniquet by Harvey Cushing in 1904 (Cushing 1904), and the introduction of microprocessorbased tourniquets (McEwen & McGraw 1979). The original 'Esmarch bandage' was a tube the thickness of a finger which was wound tightly around the limb after the blood had been expressed from it by bandaging. The flat rubber 'Esmarch bandage' used today was designed by von Langenbach. The Martin bandage, which is a similar device is made of cream coloured latex rubber. Cushing originally designed the pneumatic tourniquet to minimise bleeding during craniotomy. He also described the use of this tourniquet for 'cocaine operations' on the hand (Cushing 1904). Until recently, the pneumatic tourniquet underwent few if any significant modifications or improvements since its introduction by Cushing, except for the addition of a pressure gauge and the inclusion of mechanical pressure regulating mechanisms in the 1940s and 1950s. It was not until the late 1970s that the third significant advance occurred with the introduction by the authors of microprocessor-based tourniquets having improved safety and performance (McEwen & McGraw 1979, McEwen 1981).

HAZARDS OF TOURNIQUET USAGE

A 'tourniquet-related hazard' may be defined as a possible source of peril, danger, risk, or difficulty involving a tourniquet. In contrast, a 'tourniquetrelated incident' may be defined as an unexpected outcome associated with the use of a tourniquet in

which it is suspected that a possible malfunction, misuse or characteristic of the tourniquet may have contributed to the unexpected outcome. Table 2.1 contains a comprehensive summary of tourniquetrelated hazards, clinical signs and possible causes of injury which have been reported in the literature (McEwen & McGraw 1982, McEwen & Auchinleck 1982).

To assess the actual types and frequencies of tourniquet-related hazards, the authors initiated a programme of periodic inspections of 12 pneumatic tourniquets with mechanical pressure regulators (Kidde Model 400 Pneumatic Tourniquets) in two teaching hospitals over a 30-month period beginning in 1981 (McEwen & Auchinleck 1982). During this period, the 12 pneumatic tourniquets were given 84 safety and performance inspections at scheduled intervals by a hospital-based biomedical engineering department. In addition to sched-

uled inspections, the 12 pneumatic tourniquets were also given 71 unscheduled inspections as a result of reported incidents, hazards or malfunctions. The test results revealed an unexpectedly high frequency of occurrence of a variety of significant hazards. For example, in 49% of these tests a very large hysteresis (Johnson 1980, Mc-Ewen 1981) or error in the pressure-regulating mechanism, of 200 mmHg or more was observed. Significant physical deterioration of one or more major elements was observed in 45% of the tests. In 10% of the tests, an error in the pressure gauge of more than 10% was noted. In 5% of the tests, a maximum cuff pressure of over 1100 mmHg could be generated; in 5% of the tests, cuff pressure drifted more than 10% from the set value over a 15-minute period; in 5% of the tests, leaks were observed which were sufficiently large to cause visible depletion of the compressed-gas reservoir;

Table 2.1 Summary of tourniquet-related hazards, clinical signs and possible causes of injury which have been reported in the literature.

Clinical signs	Possible tourniquet-related causes
Hazard 1: Overpressurisation	
Tourniquet paralysis	Malfunctioning pressure regulator
Postoperative muscle weakness	Excessive hysteresis in pressure regulator
Pain at cuff site	Inaccurate pressure gauge or sensor
Other compression injuries to blood vessel, nerve, muscle, or skin.	Lack of audiovisual alarms
	Infrequent monitoring by staff
	Improper setting of tourniquet pressure
Hazard 2: Underpressurisation	
Blood in surgical field	Malfunctioning pressure regulator
Passive congestion of limb	Excessive hysteresis in pressure regulator
Shock	Inaccurate pressure gauge or sensor
Hemorrhagic infiltration of nerve	Lack of audiovisual alarms
	Infrequent monitoring by staff
	Improper setting of tourniquet pressure
	Kinking of hose to cuff
	Geometric mismatch of cuff and limb
	Cuff failure
	Loss of pressurised gas source
	Large leaks in cuff or hose
	Disconnection of cuff or hose
	Intraoperative increase in systolic pressure
Hazard 3: Excessive period of inflation	
Tourniquet paralysis	Infrequent monitoring of elapsed time
Postoperative muscle weakness	Lack of audiovisual alarms to warn of excessive inflation
Ischemic injury distal to cuff	periods
Excessive postoperative reactive hyperemia	
Hazard 4: Improper cuff application or perioper	ative procedures
Venous congestion	Improper preoperative extanguination
Soft tissue injuries (bruising, blistering,	Excessively slow inflation or deflation
pinching, necrosis of skin)	Incomplete or overly aggressive seal at cuff
Chemical burns at cuff	Pooling of preparation solutions

Cuff geometry or physical characteristics

and in 4% of the tests it was noted that the pressure gauge did not return to zero between uses, resulting in erroneous readings.

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Cuff-related hazards were examined in a second study initiated by the authors which involved the investigation of 55 tourniquet-related incidents over a 20-month period (McEwen 1983). Cuffrelated hazards which were identified include: undetected kinking between cuff and controller, resulting in non-regulation of cuff pressure; sudden depressurisation due to telescoping, pop-off or rupture of the cuff during use; sudden depressurisation due to disconnections of hosing; pinching and necrosis of soft tissue under an inflated cuff; mismatch of cuff and limb shapes leading to possible nerve injuries; chemical burns to skin due to seepage of fluids under the cuff; and overly tight or loose application of the cuff resulting in inappropriate cuff/limb interface.

As the design of modern tourniquet systems has improved, the relative significance of the hazards listed in Table 2.1 with regard to tourniquetrelated incidents has changed.

ELEMENTS AND CHARACTERISTICS OF MODERN TOURNIQUET SYSTEMS

The primary objective of a modern tourniquet system is to reliably maintain the minimum pressure necessary in a cuff which encircles a patient's limb to stop blood flow into the limb (Erlanger & Gasser 1937). Secondary objectives are to do so in a manner which minimises obstruction of the surgical field, and in a manner which minimises any tourniquet-related injury of the patient.

To accomplish these objectives, it is necessary that each component of a modern tourniquet system be effective and safe. The three basic elements of such systems are: 1. a cuff for encircling the patient's limb and pressurising to a pre-set value; 2. a pressure-regulating mechanism for initially pressurising the cuff, maintaining the pressure in the cuff at or near a pre-set value, and then depressurising the cuff; and 3. controls, indicators and alarms to provide the operator with means for controlling the function of the system, for displaying current values of parameters such as cuff pressure and elapsed time of cuff inflation, and for warning the operator of tourniquet-related hazards. Various suggestions regarding voluntary standards for desired characteristics of specific elements of modern tourniquet systems have been proposed (e.g. McEwen 1981, McEwen & Auchinleck 1982, AORN 1984, ECRI 1984) but no specific mandatory standards exist at present.

Desired characteristics of tourniquet cuffs which have been suggested include the following: the cuff should conform closely to limbs of different shape; the cuff should be capable of being pressurised to pressures up to 500 mmHg without becoming detached from the limb or moving distally down the limb; the cuff should not obstruct the surgical field; the cuff should distribute pressure uniformly to underlying tissue; and the cuff should be constructed to minimise the probability of failure of any fasteners employed during use, and to facilitate cleaning, and re-use when intended. Any tubing and connectors intended for connecting the cuff to a controller should be designed and constructed to be resistant to kinking and inadvertent detachment.

Desired characteristics of a pressure-regulating mechanism for a modern tourniquet system include the following key requirements: it should regulate pressure to within 5% of a set value; it should maintain a stable pressure, remaining within 10% of the set value over at least a 60minute period; it should function reliably over long periods of operation; and it should not consume excessive amounts of supply gas in regulating pressure.

Desired characteristics of controls, indicators and alarms for tourniquet systems include the following: the controls should permit an operator to conveniently specify parameters for safe and desired functioning; indicators should provide the operator with accurate values of key parameters (such as cuff pressure and inflation time); and alarms should promptly advise the operator of any condition or malfunction which could be hazardous to the patient or operator. The indicators and alarms, combined with design characteristics of the tourniquet system, should assure that any malfunction or failure of a single component of the system will result in a situation 1. which is

immediately obvious to the operator, and 2. which is not hazardous to the patient.

The types of pneumatic tourniquets currently employed in hand surgery may be grouped into four general categories: 1. manual systems with operator-controlled regulation of pressure and monitoring; 2. mechanical systems with entirely non-electronic regulation of pressure, controls and displays; 3. hybrid systems incorporating mechanical pressure-regulating mechanisms with some degree of electronic displays or controls, and 4. digital systems with microprocessor-based pressure regulators, indicators and controls. All four groups of systems currently employ cuffs having similar characteristics. Manual approaches to maintaining occlusive pressure have largely been supplanted by other systems having reduced labour-intensiveness. Entirely mechanical systems as summarised above are currently being supplanted by other systems because many of the desired characteristics of modern tourniquet systems cannot be achieved cost-effectively (McEwen 1981, McEwen & McGraw 1982, ECRI 1984). Hybrid systems are an improvement over the earlier generation of purely mechanical systems, but still have inherent limitations in the accuracy and reliability of pressure regulation, as well as in alarms and indicators, which are not present in digital systems. Digital systems are now widely gaining in popularity in hand surgery because many of the desired characteristics can be achieved with acceptable accuracy, reliability, safety and cost.

COMPLICATIONS OF TOURNIQUET USE

The pneumatic tourniquet is regarded to be an essential device in modern limb surgery. Its everyday widespread usage has generated the erroneous notion that it is intrinsically safe. However, there continue to be reports in the recent literature of well documented and often unexplained nerve injury (Rorabeck & Kennedy 1980, Rudge 1974, Weingqarden et al 1979).

While the spectrum of complications associated with tourniquet usage is wide and generally subdivided into categories of cutaneous, vascular,

and muscular, the most serious is neurological The nerve palsies have the greatest potential for permanent disability. Moldaver has reported that the typical tourniquet paralysis syndrome consists of loss of light touch, light pressure, vibration and position sense appreciation together with a loss of motor power (Moldaver 1954). The effected function would most likely correspond to the large nerve fibres described by Erlanger & Gasser, the large A fibres (Erlanger & Gasser 1937). Temperature and pain appreciation and sympathetic function are less likely to be influenced. Therefore, pin testing is inappropriate in the postoperative period. Though a controversy persists as to whether the pathogenesis of the nerve injury is compression or ischemia, most investigators favour excessive local pressure (Danta et al 1971, Parkes 1973, Rorabeck 1980, Rudge 1974). Denny-Brown and Brenner suggested that ischemia due to compression of blood vessels supplying the nerve bundles was the primary cause of nerve damage. It has been confirmed experimentally that there is a localised conduction block as a result of mechanical deformation of nerve fibres (Ochoa et al 1972). These lesions have been shown with electron microscopy to be a type of intussusception within an axon in which a node of Ranvier is displaced away from the site of compression (Ochoa et al 1972). Large myelinated fibres only are so damaged and the nodes on the smaller myelinated fibres remain uninjured. This explains the sensory sparing of some modalities as reported by Gilliatt (1975). In addition to the effect of direct pressure on the nerve, ischemia distal to the compression site may contribute to impaired nerve function, particularly as the duration of the ischemia increases (Yates et al 1981). However, the relative importance of ischemia in relationship to the direct mechanical injury to the nerve compressed by the tourniquet in the pathogenesis of tourniquet paralysis in man has not yet been established. Recovery from tourniquet paralysis will depend on the absence of irreversible damage to the nerve tissue and vessels. Although experimental evidence is still lacking, it has been generally assumed that a high pressure would more likely produce irreversible damage in a short time than a low pressure for a longer period (Griffiths & Heywood 1973). Therefore, though a recovering lesion may not be explicable on the sole

basis of either the pressure level or its duration, a permanent paralysis will almost certainly be solely due to an excessive pressure (Flatt 1972).

Muscle injury

Patterson & Klenerman showed that the damage to muscle ultrastructure was more severe as a result of direct tourniquet pressure than that seen in the ischemic muscle distal to the tourniquet (Patterson & Klenerman 1979). The degree of muscle injury was related to the duration of tourniquet application. In Patterson & Klenerman's experiment it was found that a 5-hour period of ischemia invariably produced severe muscle damage, whereas a 3-hour period caused similar changes in only a quarter of the monkeys examined. There is no obvious reason not to believe that these findings would be similar to man.

Venous thrombosis

Whether the use of a pneumatic tourniquet increases or for that matter decreases the likelihood of the formation of venous thrombosis is controversial and in fact unknown. Kroese & Stiris (1974, 1975) carried out venography on patients undergoing surgery of the lower limb under tourniquet within 48 hours of operation. In the first series 10% showed radiographic evidence of thrombosis while a 17% incidence was noted in the second series. The authors reported that these figures were low compared to other reports of postoperative thrombosis and therefore concluded that the tourniquet did not seem to increase the incidence of thrombosis formation. Kroese & Stiris concluded by recommending that the use of a tourniquet should be avoided in patients who are in a high risk category for thrombus formation.

Cutaneous

Minor skin problems are seen usually due to the improper application of the tourniquet. Burns may occur due to the seepage of skin preparation materials beneath the tourniquet.

Fat

On occasion fat necrosis following the routine and apparently appropriate application of a pneumatic tourniquet has been observed.

CONTRAINDICATIONS TO TOURNIQUET USE

The use of a tourniquet in patients with known peripheral vascular disease carries an increased risk and therefore should be avoided if at all possible. Patients who have vasculitis also may be at risk, not only from the use of the tourniquet, but also the actual procedure being employed. The use of a tourniquet in an infected limb is not contraindicated but exsanguination by stripping should probably be avoided to prevent bacteriemia and possible septicemia. This same principle should apply to the surgical management of neuromusculoskeletal malignancies when a pneumatic tourniquet is employed. The application of a pneumatic tourniquet to the calf or forearm is considered contraindicated if the appropriate thigh or upper arm is available for application. The compression of clearly defined fascial compartments is to be avoided if possible.

EXSANGUINATION AND THE TOURNIQUET

Some form of exsanguination is generally practiced in association with pneumatic tourniquet use. The application of an Esmarch or Martin's bandage (latex) immediately prior to inflation of the tourniquet is an acceptable method of preventing engorgement of tissues. Simple elevation of the limb for 2 minutes prior to elevation of the tourniquet is regarded by many to be equally effective. Exsanguination of a limb results in an effective increase in circulating blood volume of up to 800 ml (Bradford 1969). It would therefore be unwise to exsanguinate more than one limb at one time in an individual with poor cardiac reserve (Klenerman & Hulands 1979). It is recommended that the tourniquet be deflated prior to the application of any rigid dressing as exsanguination

and pneumatic tourniquet inflation may result in up to a 20% reduction in limb volume.

OCCLUSION TIME AND PRESSURE

There is a wide variety of opinion with regard to the optimum inflation pressure in the upper and lower extremities. It has been traditional for manufacturers of tourniquets in North America to recommend a pressure of 300 mmHg for the arm and 500 mmHg for the leg (Instruction Manual for Kidde Pneumatic Tourniquet (Model 400)). These figures and similar figures suggested in the literature and by tourniquet manufacturers appear to be entirely arbitrary and have no scientific basis. They presumably arose historically as 'safe' pressures necessary to assure a supersystolic pressure on the limb while at the same time compensating for typical errors in the tourniquet regulators, gauges and cuffs (McEwen 1981, McEwen & McGraw 1982, Sanders 1973). It has been shown that the slowing in conduction velocity and time required for it to return to normal after release of the tourniquet varies directly with the amount and duration of the pressure applied (Rorabeck 1980). Sanders has recommended that the tourniquet pressure for upper limbs ideally should be only 70 mmHg above systolic pressure (Sanders 1973). Klenerman & Hulands advise that the occlusive pressure for the lower limbs be estimated by doubling the systolic pressure taken in the arm, thereby providing the lowest effective occlusive pressure and allowing for fluctuation in blood pressure which might occur during the course of a normal operation provided the patient is normotensive and does not have a grossly hypertrophied or obese limb (Klenerman & Hulands 1979). These recommendations for the upper and lower extremity are considered safe and practical.

Most reports in the literature recommend that the period of time of tourniquet application should not exceed 90–120 minutes (Bruner 1970, Flatt 1972, Wilgis 1972) although some authors feel that up to 3 hours of tourniquet application is safe (Klenerman 1980, Parkes 1973). For practical purposes a duration of a 150 minutes in normal individuals should not be exceeded if possible.

CONCLUSION

A number of possible tourniquet-related complications have been reported in the literature. The two most frequent problems of concern are tourniquet paralysis (or paresis) and intraoperative bleeding. Regardless of whether a potential tourniquet-related complication is considered to be major or minor when it is identified, each such incident should be investigated promptly and thoroughly by appropriately qualified staff, in order to minimise both the probability of similar incidents in future and potential legal liability. To assist in the thorough and consistent investigation of such incidents, the questionnaire shown in Table 2.2 has been developed. In employing the questionnaire to investigate a potential incident involving a tourniquet, the surgeon and any assisting nurse or technologist who might have been involved in the operation of the tourniquet should attempt to answer the clinical questions which are posed in Table 2.2. An experienced biomedical engineer or similarly qualified individual should attempt to respond to the technical questions posed. The authors have found that a thorough review of the responses to the set of questions posed in Table 2.2, in conjunction with a review of the literature on reported tourniquetrelated complications which was cited earlier in this chapter, is of significant value in the satisfactory and prompt resolution of such incidents. A brief elaboration of the content of Table 2.2 for the two most frequent problems of concern, tourniquet paralysis (or paresis), and intraoperative bleeding, is given below.

Tourniquet paralysis

In the event of postoperative tourniquet paralysis or paresis there is no definite treatment unless there is a co-existent compartment syndrome. Therefore the principal concern is one of prevention. Accordingly, a tourniquet incident such as postoperative weakness with sensory change must be promptly investigated. As suggested by Table 2.2, one should quickly ascertain that this is indeed an isolated event and not one incident of a yet unrecognised series related to faulty equipment or procedural errors. The time and pressure values Table 2.2 Questionnaire for use in the event of possible tourniquet-related complications

A. Event

- What was the nature of the complication? 1.
 - -What extremity?
 - -Paralysis or paresthesia, intraoperative bleeding, soft-tissue injury, or other? -If bleeding was observed, was the blood dark in colour?
- Was more than one patient involved?
 - -If so, over what period of time did the cases occur?
 - -If so, did the complication seem associated with a particular anesthetic technique?
 - -If not, how many patients had been treated previously with the same complete tourniquet system?
- Approximately how many minutes after cuff inflation was the complication first observed? 3. -If the complication was not observed during the procedure what was the total duration of tourniquet application?
- 4. What was the status of the patient?
 - -Did the patient have any pertinent abnormal conditions (e.g. atrophied or hypertrophied limbs, calcified blood vessels, steroid treatment, hypertension)?
 - What were the limb circumferences at the proximal and distal cuff edges?
 - -What was the patient's systolic pressure throughout the procedure?
 - -If bleeding was observed, was the patient's systolic pressure recorded at the time?
 - -If a paralysis or paresthesia was observed, was a post-op EMG study done to identify and localise any possible lesion? Results?

B. Equipment

- 1. What tourniquet system was used?
 - -Cuff: manufacturer, model number, length, width, dual or single bladder? -Connector and tubing: type and length?

 - -Was a non-standard connector or adapter employed to match the cuff connector to the tubing or pressure controller?
 - Tourniquet pressure controller : manufacturer, model, serial number?
 - -What was the configuration of equipment (sketch)?
 - -Was a dual-cuff switch employed in a Bier's block mode?

2 What safety and performance-assurance testing of the equipment was performed?

- -At what time prior to the incident were specific, documented tests last performed on each element of the system involved (cuff, tubing and controller)?
- What standards were employed?
- -What written test procedures were followed?
- -What were the qualifications and experience of whoever performed these tests?
- At what time following the incident were each of the above-noted elements of the tourniquet system again tested?
- Standards? Procedures?
- Who did the testing? Documented results? Abnormal results?

C. Procedure

- 1. What application procedures were followed?
 - Who applied the cuff to the patient?
 - What was the experience of the applicator with that specific cuff?
 - -How tightly was the cuff applied?
 - -Was a soft bandage applied beneath the cuff? -Was a tape seal employed at the distal edge?

 - -How was the limb exsanguinated?
 - -If it was exsanguinated by elevation, how long was the limb elevated? At what angle?
 - -If it was exsanguinated by rubber bandage, how tightly was the bandage wrapped? By whom? Experience?
 - -What pressure settings were used?
- What was the nature and extent of training of each of the staff who were involved in the testing and operation of the tourniquet system?
 - -e.g., was training received by review of labelling and operating instructions, operating manual, audio-visual aids, vendor's presentation, institutional seminars, etc?

associated with the incident must be reviewed and compared to the acknowledged safe ranges. If the values of these parameters were recorded with acceptable accuracy and frequency, and if commonly accepted limits were not exceeded, the possibilities of faulty equipment, cuff-related problems or procedural errors must be considered. Table 2.2 offers guidance in this regard. For example, when any of the older mechanical types of tourniquet systems are used, the pressure gauge and the pressure regulator should be tested frequently to identify errors and possible malfunctions; a structured investigation will help determine whether the device met standards and whether pre-incident tests were adequately performed. Inaccurate pressure gauges and defective pressure regulators permitting excessive hysteresis were common causes of tourniquet injury in the past. In contrast, inaccurate pressure indicators and defective pressure regulators are much less likely to occur in digital tourniquet systems, and are much less likely to exist undetected by the operator when they do occur in such systems. Again, this can be confirmed by structured investigations of all pertinent incidents.

Intraoperative bleeding

Intraoperative bleeding in the presence of a pneumatic tourniquet is an annoying occurrence which unnecessarily delays the procedure. With rare exception, it is, of course, preventable. If bleeding occurs it is usually wise to stop the procedure, deflate the tourniquet and evaluate a number of factors prior to re-exsanguination and re-inflation: 1. the patient's systolic blood pressure should be re-assessed in relation to the patient's limb circumference and cuff size, and the tourniquet pressure selected accordingly; 2. if the patient's limb is hypertrophied or if the possibility

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of major vessel calcification exists, a higher pressure might be considered; 3. the tubing and connections should be checked; and 4. in older mechanical systems containing an integral gas cartridge, the gas source must be determined to be adequate. If consideration of these factors does not permit identification and resolution of the problem, the possibility of device-related factors should be considered. As in the case of tourniquet paralysis, device malfunctions such as defective gauges and pressure regulators can be responsible for intraoperative failure of mechanical tourniquets. However, modern digital tourniquet systems generally have audio and visual alarms which alert the operator to unintended and significant alterations in tourniquet pressure, as well as excessive periods of inflation, making these factors much less significant. Inappropriate exsanguination procedures can cause minor oozing with a properly functioning tourniquet system. Alternatively, Furlow's 'tourniquet ooze' syndrome may be responsible (Furlow 1971). Any of a variety of cuff-related problems, as outlined earlier in the chapter, may also be factors. This emphasises the need for systematic and prompt investigation of all incidents of possible tourniquet-related complications along the lines suggested in Table 2.2.

In the latest generation of computer-based tourniquet systems now being developed and introduced, the tourniquet has the capability of constantly adapting the cuff pressure to the patient's ever-fluctuating occlusion pressure in the limb, so that the minimum effective pressure can routinely be employed.

In future, it is possible that tourniquet injury might be eliminated entirely by a combination of thorough investigation of pertinent incidents, improved design of digital tourniquets, improved design of occlusive cuffs, and adoption of safe and effective operating procedures.

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