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Standard Guide for Selection and Use for Pelvic Ring Circumferential Compression Stabilization Devices (PRCCSD)[1]

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1. Scope

1.1 This guide establishes minimum standards for devices designated here as pelvic ring circumferential compression stabilization devices(s) (PRCCSD), commonly known as pelvic slings, belts, or binders. The PRCCSD is used as the initial pelvic ring stabilization device on patients suspected of having sustained traumatic disruptions of the pelvic ring. It is used during patient transport by emergency personnel and before definitive treatment.

1.2 This guide addresses the recognized need to reduce and stabilize pelvic ring disruptions through the use of circumferential compression devices.

1.3 Peer-reviewed medical literature does describe specific testing methods used to determine the range of effective compression force, efficacy in reduction, stability, and safety for a particular (PRCCSD). This guide, however, does not identify specific testing methods as it is recognized such methods could vary according to device configuration and study design.

1.4 This guide does not address individual quantitative performance standards for any particular device, but does address general performance standards and good practice characteristics for all devices using circumferential compression to reduce and stabilize disruptions of the pelvic ring.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.*

2. Terminology

2.1 *Definitions:*

2.1.1 *circumferential compression force, n*—influence that deforms an object by shortening its circumference.

2.1.2 *compression force, n*—influence that deforms an object by making it smaller or shorter.

2.1.3 *controlled level of force, n*—force confined within certain defined limits.

2.1.4 *disruption of the pelvic ring, n*—any traumatic alteration of the normal anatomic relationships of the bony structures forming the pelvic ring. Included in these disruptions are fractures, dislocations, subluxation, and diastasis.

2.1.5 *effective level of force, n*—that range of quantified force required by the particular pelvic ring circumferential compression stabilization device (PRCCSD) to reduce and stabilize disruptions of the pelvic ring in the 95th percentile of adult American males.[2]

2.1.6 *immobilization, n*—limitation of motion.

2.1.7 *pelvic ring, n*—normal anatomic ring-shaped structure formed by three bones: two innominate bones (each made up of the ilium, ischium, and pubis) and the sacrum.

2.1.8 *reduction, n*—returning anatomic structures to their normal anatomic position.

2.1.9 *retention system, n*—an adjunct to or an integral part of the primary platform that allows the patient to be securely attached to that platform, used in whatever configuration and size necessary to accomplish the goal, while still allowing reasonable and necessary access to the patient.

2.1.10 *safe level of circumferential compression force, n*—that range of quantified force producing a resultant effect in which no undue alteration of the normal anatomic relationship of the pelvic ring occurs.

2.1.11 *stabilize, v*—maintaining in a firm, constant, or fixed state.

2.1.12 *spinal immobilization system, n*—device(s) that immobilize the spine and contiguous structures, the pelvis, and the skull.

[1] This guide is under the jurisdiction of ASTM Committee F30 on Emergency Medical Services and is the direct responsibility of Subcommittee F30.01 on EMS Equipment.

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[2] *The Handbook of Adult Anthropometric and Strength Measurements Data for Design Safety, University of Nottingham, University Park, Nottingham NG7 2RD United Kingdom.*

3. Significance and Use

3.1 The intent of this guide is to identify the general performance and good practice standards that a pelvic ring circumferential compression stabilization device (PRCCSD) should possess.

3.2 Currently, a number of base platforms such as full-body spinal immobilization devices (long boards) are used to immobilize patients during transport and before definitive treatment. These platforms limit gross movements of the spine and pelvis but do not specifically reduce and stabilize disruptions of the pelvic ring. The PRCCSD applied circumferentially about the patient exerts a compressive force to reduce and stabilize disruptions of the pelvic ring.

3.3 The PRCCSD may be used alone but, according to clinical situations, will commonly be used in conjunction with different supporting base platforms during transport and before definitive treatment.

3.4 The PRCCSD, when circumferentially applied, should be centered at the level of the greater trochanters and symphsis pubis.[3]

3.5 A device intended for use with adult patients shall accommodate the 95th percentile adult American male.[2]

3.6 The device should be able to be applied by a single practitioner.

4. Characteristics

4.1 When applied, the PRCCSD shall accommodate the 95th percentile adult American male patient.[2]

4.2 The PRCCSD should be configured to allow ease of application by a single practitioner.

4.3 The PRCCSD should be sufficiently radiolucent to allow good quality X-rays.

4.4 The PRCCSD, when affixed about a patient, shall be capable of applying a controlled level of circumferential compression force.

4.5 The PRCCSD, when affixed about a patient, shall be capable of applying an effective level of circumferential compression force.

4.6 The controlled level of circumferential compression force applied by the PRCCSD to the pelvic ring should not exceed a safe level of circumferential compression force.

4.7 The design of the PRCCSD should allow access for urinary catheterization.

4.8 The design of the PRCCSD should allow access to the femoral vessels.

4.9 The design of the PRCCSD should allow access to the pelvic ring for purposes of external fixation.

4.10 The design of the PRCCSD should facilitate and not impede movement of the patient across the surface of support platforms such as spine boards or stretchers.

4.11 The design of the PRCCSD should not impede the use of other spinal immobilization systems.

4.12 The PRCCSD, when applied, shall not alter the position of the patient's spine.

4.13 The PRCCSD should be packaged with instructions describing application and removal protocols.

4.14 When the PRCCSD is applied on a patient, the pressure exerted by the PRCCSD on the patient's skin shall not exceed 32 mm Hg.[4]

4.15 When a PRCCSD is applied for an extended period, a regular skin inspection protocol should be used.

4.16 The PRCCSD should support reasonable air and moisture transmission.

5. Durability

5.1 The PRCCSD should be functional over the extreme range of normal ambient temperatures.

5.2 The function of the PRCCSD should not be affected by changes in altitude.

6. Maintenance

6.1 The PRCCSD shall be disposable or easily cleaned, consistent with Center for Disease Control (CDC) and Occupational Safety & Health Administration (OSHA) decontamination procedures, without deterioration of the product or retention of cleaning agents that may be harmful to the patient.

7. Capability

7.1 The PRCCSD should, when affixed about the patient, be capable of applying a controlled, effective, and safe range of circumferential compression force to the pelvic ring.

7.2 The efficacy and safety of the controlled level of circumferential compression force provided by the PRCCSD should be supported by scientific testing.

7.3 Though peer-reviewed medical literature does describe the controlled, effective, and safe range of circumferential compression force provided by a particular PRCCSD, this guide does not identify any specific range of force or testing methods as it is recognized that the range of force and testing methods could vary according to device configuration and study design.

8. Keywords

8.1 diastasis symphysis pubis; open book fracture; pelvic fracture

[3] Bottlang, M., Krieg, J. C., Mohr, M., Simpson, T. S., and Madey, S. M., "Emergent Management of Pelvic Ring Fractures with Use of Circumferential Compression," *Journal of Bone and Joint Surgery*, Vol 84-A (Supplement 2), 2002, pp. 43-47.

[4] Landis, E.M., "Micro-Injection Studies of Capillary Blood Pressure in Human Skin," *Heart*, Vol 18, 1929, pp. 209-228.