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Spinal orthoses — Guide to design

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Contents

Foreword

This British Standard has been prepared by Technical Committee CH/168. It supersedes BS 5473:1977, which is withdrawn.

While BS 5473:1977 specified requirements for spinal and abdominal fabric supports, this standard is limited to spinal orthoses excluding sacro-iliac orthoses and gives guidance on design and manufacture.

This standard deals separately with orthoses acting on the following regions of the spine:

a) lumbo-sacral;

b) thoraco-lumbo-sacral;

c) cervical; and

d) cervico-thoraco-lumbo-sacral.

For each of the above regions of the spine, information on the primary functions of the orthoses, methods by which these functions can be achieved and the form and extent of the control exerted by orthoses acting in these regions is given.

This standard is not intended to recommend particular designs of orthosis and, therefore, it only gives recommendations for particular designs if specific guidance is believed to be necessary to ensure the satisfactory functioning and quality of the design.

Attention is drawn to Annex 1 of the EC Council Directive 93/42/EEC which concerns medical devices as they apply to orthoses.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to ii, pages 1 to 10, an inside back cover and a back cover.

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1 Scope

This British Standard gives guidance on the design of spinal orthoses.

It is intended for designers of orthoses, clinicians prescribing orthoses for patients, orthotists, and manufacturers of both commercially available and custom made orthoses for individual patients.

The standard is not applicable to sacro-iliac orthoses (Sb), that is, orthoses that encompass the whole or a part of the sacro-iliac region of the trunk.

NOTE Guidance on the manufacture of the components of spinal orthoses is given in Annex A. Guidance on the marking, packaging and accompanying documentation for orthoses is given in Annex B.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN 1041:1998, *Information supplied by the manufacturer with medical devices.*

3 Terms and definitions

For the purposes of this British Standard, the following terms and definitions apply.

3.1
orthosis
externally applied device used to modify the structural and functional characteristics of the neuro-muscular and skeletal systems
[BS 7313-1.1:1990, definition **2.1.2**]

3.2
trunk
body excluding the head, the neck and the limbs
[BS 7313-1.1:1990, definition **2.2.14**]

3.3
thoracic region
that part of the trunk between the neck and the diaphragm, associated with the twelve thoracic vertebrae
[BS 7313-1.1:1990, definition **2.2.15**]

3.4
lumbar region
central part of the trunk between the ribs and the pelvis, associated with the five lumbar vertebrae
[BS 7313-1.1:1990, definition **2.2.16**]

3.5
sacro-iliac region
that part of the trunk lying caudal to the lumbar vertebrae, associated with the fused sacral vertebrae and their articulations with the os coxae
[BS 7313-1.1:1990, definition **2.2.17**]

3.6
distraction
application by an orthosis of an extending axial load

3.7
strut
compressive load bearing column
NOTE Struts can also transmit bending moments.

4 Categories of orthoses

A spinal orthosis is categorized according to the joint(s) or body region(s) it encompasses as follows.

a) *Cervical orthosis (CO)*
An orthosis that encompasses the whole or a part of the cervical region, including the atlanto-occipital joint.

b) *Cervico-thoracic orthosis (CTO)*
An orthosis that encompasses the whole or a part of the cervical and the thoracic regions, including the atlanto-occipital joint.

c) *Cervico-thoraco-lumbo-sacral orthosis (CTLSO)*
An orthosis that encompasses the whole or a part of the cervical, the thoracic, the lumbar and the sacro-iliac regions, including the atlanto-occipital joint.

d) *Thoraco-lumbo-sacral orthosis (TLSO)*
An orthosis that encompasses the whole or a part of the thoracic, the lumbar and the sacro-iliac regions of the trunk.

e) *Lumbo-sacral orthosis (LSO)*
An orthosis that encompasses the whole or a part of the lumbar and sacro-iliac regions of the trunk.

Hereafter in this standard the orthoses are referred to by the initials indicated.

NOTE Different parts of the spine are interconnected and act as an integrated unit. As a consequence some orthoses extend beyond the region(s) that they are intended to treat. For example a CTLSO might be prescribed to treat problems in the thoracic region only.

5 Design of orthoses

5.1 Lumbo sacral region

5.1.1 *Objectives and means of achievement*

The types of orthoses that can be used to treat the lumbo-sacral region of the spine include TLSOs and LSOs.

The primary function of an orthosis acting on the lumbo-sacral region of the spine is to provide relief of pain. This can be achieved through improved posture, which can be invoked by restricting motion, by supporting weak muscles, by increasing local body surface temperature or by sensory feedback.

Orthoses can achieve these objectives by:

a) restricting motion;

NOTE This will depend on the incorporation of an effective system of three point loading. None of these devices is capable of achieving immobilization and their effect is to reduce inter-regional motion thereby reducing the total range of motion.

b) providing sensory feedback;

c) increasing intra-abdominal pressure by supporting weak muscles;

d) retaining body heat; and

e) creating a total contact system by means of components which maximize the areas of body contact.

5.1.2 *Form and means of control*

The form and extent of the control exerted by the orthosis depend on one or more of the following:

a) the material from which it is made;

b) the length of the orthosis and its anterior/posterior and lateral dimensions;

c) the accuracy of placement and/or shaping of the stiffeners or reinforcing components incorporated into it;

d) the effectiveness of the fastenings;

e) the security of the orthosis-patient interface in respect of location, load transmission and comfort.

Controls applied in the lumbo-sacral region have an effect on the pelvis and other areas of the spine generating increased control or limiting movement ranges within the higher regions of the body. The orthosis design should take account of these considerations.

5.1.3 *Loading and strength requirements*

Due to the large amount of surrounding tissue it is not possible to apply significant direct forces to the spine via orthotic devices. The loads have to be transmitted through the surrounding tissue. It is necessary to consider the effects of the increased pressures which are generated in order to transmit the required forces, both on the immediately surrounding tissue and that which is distant from the spinal region.

If an appropriate stable location can not be provided for the orthosis, migration of the orthosis from its desired location might occur. Additional strapping arrangements might be necessary to prevent this migration from compromising the intended effect.

Although cyclic loadings will be applied to these orthoses, the limited values of the dynamic loads means there is only a small likelihood of fatigue failure. Nevertheless, care should be taken with highly loaded components to minimize stress concentrations by ensuring they have a smooth surface finish and no abrupt changes of cross-section.

5.2 Thoraco-lumbo-sacral region

5.2.1 *Objectives and means of achievement*

The types of orthoses that can be used to treat the thoraco-lumbo-sacral region of the spine include CTLSOs, TLSOs and LSOs.

The primary functions of an orthosis acting on the thoraco-lumbo-sacral region of the spine are:

a) to support, control and/or correct pathological curvatures of the spine in the sagittal and/or coronal planes;

b) to control instability; and

c) to relieve pain.

Orthoses can achieve these objectives by:

1) restricting motion;

2) applying corrective forces;

3) promoting improved alignment;

4) increasing intra-abdominal pressure;

5) providing sensory feedback; and

6) creating a total contact system.

5.2.2 *Form and means of control*

The form and extent of the control exerted by the orthosis depend on one or more of the following:

a) the material from which it is made;

b) the length of the orthosis and its anterior/posterior and lateral dimensions;

c) the accuracy of the shaping of the orthosis;

d) the security of the fastenings;

e) the comfort and stability of the orthosis-patient interface.

When designing these orthoses consideration should be given to the restriction of movement which is required and/or can be tolerated by the patient, the functional capability of the patient and the degree of functional loss that an orthosis might cause to the patient, and the body mass and underlying pathology of the patient to be treated. The interface between the patient and orthosis should be designed to transmit the loads generated. The shape and skin condition of the trunk and the characteristics of the underlying tissue at the patient-orthosis interface should be taken into account, with particular reference to areas of high sensitivity, as should be the integrity of the underlying structures through which loads might need to be applied.

These orthoses normally achieve their objectives by the method of loading at three or more points for each spinal curve through adjacent structures and by promoting improved alignment through muscular activity.

The larger the angle of the spinal curves the smaller will be the moment arms through which these loads can be applied, and the moments which can be generated will be constrained by the limit of patient tolerance of the contact forces.

Improved alignment needs to be "self generated" by the patient because the externally applied loads necessary to achieve this are so great that they would damage the delicate structures through which they would need to be applied (e.g. the chin). Mechanical structures placed adjacent to these areas are normally expected to act as "reminders" to the patient to stretch upwards to achieve improved alignment.

These orthoses might also be required to control or reduce rotational deformities of the spine. This requires a torque to be generated about the main axis of the spine. To be effective this demands a reactive element which is firmly located on the pelvis with de-rotational forces applied tangentially above the rotational deformity. In both regions there should be a minimum of two opposing de-rotational forces to apply torque whilst minimizing translational bending effects.

None of the external mechanical corrective effects on the orthosis can be achieved through direct application to the spine of all the required forces. Care should be taken to ensure that irreversible damage is not caused to the skeletal structures and other tissues through which loads are applied. Interface pressures should be minimized by spreading loads over the maximum areas available in practice. Interface materials used should allow compliance to the intricate patient shapes through which the structures apply the loads. Metal superstructures should be shaped so that they do not apply damaging forces to tissue or otherwise impinge upon the patient during any normal functional activity of the patient.

Controls applied in the thoraco-lumbo-sacral region can influence the pelvis and the head. This effect might generate increased control or limitations of movement and the design should take account of these considerations. The effects on respiratory function should be taken into account.

5.2.3 *Loading and strength requirements*

Plastics moulded structures provide opportunities for applying loads over the maximum area, combining good cosmesis with acceptable structural rigidity. To achieve these objectives the positive moulds should be carefully rectified to achieve the desired effects, particularly when the pelvis is to be used as a reaction region. Whilst the general pattern of moulded plastics spinal orthoses has the potential for good structural rigidity this inevitably is diminished by the need for an opening to allow putting on and taking off, which compromises the structural integrity of the essentially tubular shape. Rigid fastenings across the opening should be used to counteract this effect and prevent the two adjacent edges of the moulding sliding relative to each other as bending and torsion are applied to the structure. Close fitting moulded structures can generate excessive perspiration in the patient, and ventilation should be provided to counteract this.

Considerable forces can be applied to the structures of these orthoses and the possibility of overload should be borne in mind. The use of brittle materials should be avoided since they might fracture at low energy input levels and result in jagged edge fractures.

In use cyclic loadings are applied to TLSOs but the limited values of dynamic stresses mean that there is small potential for fatigue failure. Nevertheless care should be taken to minimize stress concentrations in highly loaded components by ensuring they have a smooth surface finish and no sudden changes of cross-section, so as to further reduce the risk of mechanical failures of components adjacent to delicate tissue.

5.3 Cervical region

5.3.1 *Objectives and means of achievement*

The types of orthoses that can be used to treat the cervical region of the spine include COs, CTOs and CTLSOs.

The primary functions of an orthosis acting on the cervical region of the spine are:

a) to restrict movement of the cervical spine;

b) to relieve pain; and

c) to control instability.

Orthoses can achieve these objectives by:

1) restricting motion;

2) applying corrective forces;

3) promoting improved alignment;

4) providing sensory feedback; and

5) applying distraction.

5.3.2 *Form and means of control*

The form and extent of control exerted by the orthosis will depend on one or more of the following:

a) the material from which it is made;

b) the length of the orthosis and its anterior/posterior and lateral dimensions;

c) the accuracy of the shaping of the orthosis;

d) the security of the fastenings;

e) the effectiveness of the skeletal anchorage; and

f) the comfort and stability of the orthosis-patient interface.

These orthoses generally apply forces to provide support or control to the cervical region of the spine. Where limited support is required the orthosis normally takes the form of a collar to cushion movements of the head. More comprehensive control demands an orthosis with a structure linking the skull to the thoracic region of the patient.

A collar needs to achieve the degree of cushioning required by the pathological condition. Stiffness is the crucial factor and the appropriate compromise for patient comfort and function will be determined by the choice of materials and/or structural elements.

Where fuller control is required than is possible with the use of a collar, a structure linking the skull to the shoulder or thoracic region of the patient becomes a necessity. In these circumstances the structural elements need to be strong enough to cope with the bending loads which can occur, particularly during dynamic activities where the mass of the head produces inertial reaction forces within the structure. Where distraction is to be applied the structure will also be required to take the compressive axial loads which this generates within the orthosis. Where adjustable struts are incorporated into the structure, struts with appropriate cross-sections should be used to ensure that buckling cannot occur due to the axial or bending loads they are required to support. Care should be taken to ensure that the required forces are transmitted through suitable areas of the skull and that, in particular, the more delicate areas (e.g. the chin) are protected from high loads and interface pressures.

If direct skeletal fixation is necessary there are clear biological implications in the selection of suitable locations on the skull where screws can be attached and the design should take account of this.

NOTE It is essential that the application of these devices be managed by clinically qualified staff.

The screws should be of appropriate material and cross-section to accommodate the large bending and shear loads which will inevitably be applied.

In providing cervical support or control, the design of the orthosis should be such as to avoid constriction of the patient's airway.

5.3.3 *Loading and strength requirements*

Orthoses which are intended to control the cervical spine will be subjected to cyclic loading. The limited range of dynamic stresses makes it unlikely that fatigue will be a problem in orthoses which have adequate safety margins. The avoidance of abrupt changes in cross-section in load bearing elements, surface scratches and unnecessary holes can further reduce the risk of failure.

5.4 Cervico-thoraco-lumbo-sacral region

5.4.1 *Objectives and means of achievement*

The type of orthosis that can be used to treat the cervico-thoraco-lumbo-sacral region of the spine is a CTLSO.

The primary functions of an orthosis acting on the cervico-thoraco-lumbo-sacral region of the spine are:

a) to support, control and/or correct pathological curvatures of the spine in the sagittal and/or coronal planes;

b) to control instability; and

c) to relieve pain.

5.4.2 *Form and means of control*

Control of sacral, lumbar, thoracic and cervical regions of the spine can be achieved by combining all of the elements described in **5.1**, **5.2**, and **5.3**. The design principles for each of these elements should be as described in **5.1**, **5.2** and **5.3**. When combining separate elements together in the same orthosis, care should be taken to ensure appropriate structural integrity and that the connecting components do not constitute a danger to the patient by failing mechanically ensuring that mechanical components have the required mechanical strength and do not have sharp edges. Where control of the spine from sacral to cervical levels is required, a structure connecting the pelvis and head, which allows adjustable and controlled distraction, is an option. When this is done care should be taken to ensure that the loads produced are applied to the appropriate skeletal structures. In particular only very small traction forces can be applied through the jaw and occipital areas. Additionally there are important mechanical features which need to be incorporated. The structure should be such that the compressive loads it is required to sustain do not cause buckling in the possibly long slender columns which contain the adjustable elements. Any bends in the supporting structures will increase the likelihood of buckling. Care should be taken to ensure that the support structure is clear of the patient, thus reducing the chances of it causing injury. Since these orthoses may be used in a variety of environments, possible problems of corrosion should be avoided by appropriate choices of material. Although load variations are likely to be minimal, stress concentrations should be avoided by the use of smooth changes of cross-section and good scratch free surface finishes to further reduce risk.

5.4.3 *Loading and strength requirements*

The type of construction necessary for this category of orthosis makes them susceptible to overload, particularly when long struts are employed. Ductile materials should be employed in all structural elements so as to prevent sudden catastrophic brittle failure, should uncontrolled loading lead to excessive stresses.

6 Reuse, decontamination and disposal

For devices that can be reused it is essential that they are decontaminated each time they are reused and suitably labelled to indicate that they are ready for reuse.

To avoid cross contamination it is essential that approved decontamination procedures are followed when a device is removed from service for maintenance, adjustment or scrap.

It is essential that spinal orthoses are disposed of as clinical waste unless suitable decontamination procedures have been applied.

Annex A (informative)
Manufacture of plastics components

A.1 General

It is essential in the manufacture of orthoses that the following recommendations are adhered to.

a) All edges should be smooth and free from burrs.

b) Edges and other friction points (i.e. at extremities of the orthosis) should be chamfered away or flared as necessary.

c) Peripheral contours should be smooth flowing (i.e. free from discontinuities), particularly in high stress areas.

d) Unlined orthoses should be free from coarse stockinette or similar imprints.

e) Linings, when fitted, should closely follow the contours of the orthosis.

f) Mouldings should be free from folds and creases.

g) Holes for strap fixings should be a minimum distance of 15 mm from the edge.

h) Rivets for straps should be the correct length for the combined thicknesses of materials to be secured.

WARNING The handling of mouldable thermoplastics materials is potentially hazardous because potentially toxic fumes and/or dust can be created. Attention is drawn to the Health and Safety at Work etc. Act 1974 [1] and to the Control of Substances Hazardous to Health Regulations 1988 [2].

A.2 General methods for using sheet plastics

The general method of manufacture of components is similar for all sheet plastics, and is as follows.

Initially a positive mould of the patient is produced and rectified according to clinical requirements. If the mould is still damp or moist, it should be covered with a layer of absorbent material to ensure that, when the hot plastics sheet is moulded, steam is not generated from the cast as this could cause the plastics material to distort or bubble up.

Any padding or lining required should be attached at this stage.

The plastics sheet material type and thickness (typically between 3 mm and 6 mm) should be selected depending on the function to be performed by the component, and the age, activity level and body mass of the patient.

The mould should be measured to determine the approximate size and shape of the material required and a piece of material should be cut to that size and shape, allowing an extra 25 mm to 50 mm in each direction for working the material.

The plastics sheet should be heated slowly and evenly until it reaches a mouldable temperature. Low Density Polyethylene (LDPE) and polypropylene sheets normally become transparent when their moulding temperature is reached, while further heating causes them to flow and become unmouldable. Particular care should be taken with High Density Polyethylene (HDPE) and High Molecular Weight Polyethylene (HMWPE) during heating as it might be difficult to see when these products are ready to mould due to their poor flow characteristics which make it easy to overheat them and burn or scorch the surface.

The hot material should then be formed to the contours of the mould and held in place until cold. Then it should be carefully cut from the mould and finished off to leave rounded edges.

The strength of the orthosis may be altered by introducing reinforcement (such as laminations) or corrugations. Straps and other fittings to secure the orthosis to the patient should be added as necessary.

A.3 Methods for the use of two-part rigid materials

These materials differ significantly from sheet materials in that they are applied as a gel directly onto a cotton fabric undergarment worn by the patient, and then harden in situ as a chemical reaction occurs to produce a rigid orthosis.

Once hardened, the material can be trimmed to the desired shape in situ using an oscillating plaster saw or shears.

In the case of some products the cotton fabric and gel are supplied in bandage form.

NOTE 1 Since a chemical reaction is occurring in close proximity to the patient it is essential that the manufacturer's safety instructions are followed when using these materials.

NOTE 2 Attention is drawn to the Health and Safety at Work etc. Act 1974 [1].

A.4 Methods for the use of plastics moulded directly onto the body

These plastics include the following:

a) foamed plastics;

b) foamed plastics liner in conjunction with a plastics sheet; and

c) low temperature mouldable plastics (sheet or mesh).

In these instances less care should be taken to ensure that the patient is sufficiently protected from the hot material during the moulding process.

A.5 Ventilation holes

Ventilation holes may be added to the completed orthoses if clinically required. Particular care should be taken to ensure that these holes are not positioned in such a way as to weaken the orthosis (e.g. either too near to an edge or too close to a point of flexure) or to introduce undesirable pressure effects on body tissue. The edges of all ventilation holes should be smooth and free from cracks.

The location of ventilation holes might require some judgement with regard to the nature of the orthosis, including its cosmetic appearance.

Annex B (informative)
Marking, packaging and accompanying documentation

NOTE Attention is drawn to the labelling requirements given in the EC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

B.1 Marking of orthoses

B.1.1 *General*

The marking should not affect the structural strength or integrity of the orthosis.

Marking may be achieved by means of:

a) etching information onto a thin metal plate fixed by rivets in a position where it will not affect the strength or function of the orthosis;

b) adhesive labels conforming to BS 4781;

c) imprinting with heated dies, for plastics orthoses;

d) surface identification, by stamping blocked leather parts or metal in an area of minimum stress.

B.1.2 *Custom made orthoses*

Custom made orthoses should be clearly and indelibly marked with at least the following information.

a) The manufacturer's name or recognized trade mark or logo.

b) A unique identification code, by which the month and year of supply to the patient can be traced.

c) The patient's name.

B.1.3 *Standard size orthoses*

Standard size orthoses should be clearly and indelibly marked with at least the following information.

a) The manufacturer's name or recognized trade mark or logo.

b) The manufacturer's catalogue number or code.

c) The production date or batch number of the orthosis.

d) The size of the orthosis.

B.2 Packaging

Orthoses should be packaged to protect them from abuse, damage or deterioration during storage and transit.

The preferred manner of packaging is for orthoses to be packaged individually in rigid or semi-rigid containers and protected within the containers by shock-resistant material, such as expanded polystyrene or plastics foam material.

Alternatively, orthoses may be wrapped in corrugated cardboard or similar material and covered with a heavyweight polythene bag. Protruding parts should be further protected with suitable material, such as expanded polystyrene blocks.

B.3 Marking of packaging

B.3.1 *Custom made orthoses*

The packaging of custom made orthoses should be marked with at least the following information, together with the information listed in **B.1.2**.

a) The address for delivery.

b) The patient's name.

B.3.2 *Standard size orthoses*

The packaging of standard size orthoses should be marked with at least the following information together with the information listed in **B.1.3**.

a) The name of the manufacturer of the orthosis.

b) The manufacturer's catalogue number or code.

c) The production date or batch number of the orthosis.

d) The size of the orthosis.

B.4 Accompanying documentation

Orthoses should be accompanied by documentation giving advice on maintenance and including information on components to which the skin of some patients might be sensitive. This advice should indicate the frequency with which the patient should report to the prescribing orthotist.

Any information supplied by the manufacturer should conform to BS EN 1041.

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