

1 **Clinical Practice Guideline: Thoracic and Lumbar Orthoses**

2

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4

5 **Product: Specialty**

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20 **GUIDELINES**

21 American Specialty Health – Specialty (ASH) considers:

- 22 I. Use of thoraco-lumbar orthoses for the treatment of low back pain (LBP) are
 23 considered not medically necessary as the scientific literature is inconclusive
 24 regarding their clinical effectiveness.
- 25
- 26 II. Lumbar orthoses (LO) are considered not medically necessary as they are
 27 ineffective in the *prevention* of low back injury and any use is not supported by
 28 the available evidence.
- 29
- 30 III. Lumbar supports, if used in rare circumstances, should only be utilized upon
 31 failure of other conservative measures for low back pain and only in the short
 32 term as a bridge to active care.
- 33
- 34 IV. All uses of a thoracic-lumbar-sacral orthosis (TLSO) incorporating pneumatic
 35 inflation are considered unproven.

1 Bracing for scoliosis may be considered as a covered treatment option only when the
 2 following criteria are met:

- 3
- 4 1. A cervical-thoracic-lumbar-sacral (CTLS) or TLSO is considered medically
 5 necessary for the treatment of scoliosis in juvenile and adolescent members at high
 6 risk of progression and meets the following criteria:
- 7 • Idiopathic spinal curve angle between 25 and 40 degrees; **AND**
 - 8 • Spinal growth has not been completed (Risser grade 0-3; no more than 1 year
 9 after menarche in females).

10
 11 **OR**

- 12 • Idiopathic spinal curve angle greater than 20 degrees; **AND**
- 13 • There is documented increase in the curve angle; **AND**
- 14 • At least 2 years growth remain (Risser grade 0 or 1; premenarche in females).

- 15
 16
- 17 2. Use of an orthosis for the treatment of scoliosis that does not meet the criteria above
 18 is considered investigational.

19
 20 Note: A positive diagnosis of scoliosis is made based on a coronal curvature measured on
 21 a posterior-anterior radiograph of greater than 10 degrees. In general, a curve is considered
 22 significant if it is greater than 25 to 30 degrees. Curves exceeding 45 to 50 degrees are
 23 considered severe and often require more aggressive treatment.

24
 25 For Medicare recipients, per the Centers for Medicare & Medicaid Services (CMS) Local
 26 Coverage Determinations, a spinal orthosis (L0450 - L0651) is covered when it is ordered
 27 for one of the following indications by a medical physician:

- 28 • To reduce pain by restricting mobility of the trunk; or
- 29 • To facilitate healing following an injury to the spine or related soft tissues; or
- 30 • To facilitate healing following a surgical procedure on the spine or related soft
 31 tissue; or
- 32 • To otherwise support weak spinal muscles and/or a deformed spine.

33
 34 **HCPCS Codes and Descriptions**

HCPCS Code	HCPCS Code Description
L0450	TLSO, flexible, provides trunk support, upper thoracic region, produces intracavitary pressure to reduce load on the intervertebral disks with rigid stays or panel(s), includes shoulder straps and closures, prefabricated, off-the-shelf

HCPCS Code	HCPCS Code Description
L0452	TLSO, flexible, provides trunk support, upper thoracic region, produces intracavitary pressure to reduce load on the intervertebral disks with rigid stays or panel(s), includes shoulder straps and closures, custom fabricated
L0454	TLSO flexible, provides trunk support, extends from sacrococcygeal junction to above T-9 vertebra, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks with rigid stays or panel(s), includes shoulder straps and closures, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0455	TLSO, flexible, provides trunk support, extends from sacrococcygeal junction to above T-9 vertebra, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks with rigid stays or panel(s), includes shoulder straps and closures, prefabricated, off-the-shelf
L0456	TLSO, flexible, provides trunk support, thoracic region, rigid posterior panel and soft anterior apron, extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks, includes straps and closures, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0457	TLSO, flexible, provides trunk support, thoracic region, rigid posterior panel and soft anterior apron, extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks, includes straps and closures, prefabricated, off-the-shelf
L0458	TLSO, triplanar control, modular segmented spinal system, two rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the xiphoid, soft liner, restricts gross trunk motion in the sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment

HCPCS Code	HCPCS Code Description
L0460	TLSO, triplanar control, modular segmented spinal system, two rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the sternal notch, soft liner, restricts gross trunk motion in the sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0462	TLSO, triplanar control, modular segmented spinal system, three rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the sternal notch, soft liner, restricts gross trunk motion in the sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0464	TLSO, triplanar control, modular segmented spinal system, four rigid plastic shells, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to the sternal notch, soft liner, restricts gross trunk motion in sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0466	TLSO, sagittal control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, restricts gross trunk motion in sagittal plane, produces intracavitary pressure to reduce load on intervertebral disks, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0467	TLSO, sagittal control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, restricts gross trunk motion in sagittal plane, produces intracavitary pressure to reduce load on intervertebral disks, prefabricated, off-the-shelf

HCPCS Code	HCPCS Code Description
L0468	TLSO, sagittal-coronal control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, extends from sacrococcygeal junction over scapulae, lateral strength provided by pelvic, thoracic, and lateral frame pieces, restricts gross trunk motion in sagittal, and coronal planes, produces intracavitary pressure to reduce load on intervertebral disks, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0469	TLSO, sagittal-coronal control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, extends from sacrococcygeal junction over scapulae, lateral strength provided by pelvic, thoracic, and lateral frame pieces, restricts gross trunk motion in sagittal and coronal planes, produces intracavitary pressure to reduce load on intervertebral disks, prefabricated, off-the-shelf
L0470	TLSO, triplanar control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, extends from sacrococcygeal junction to scapula, lateral strength provided by pelvic, thoracic, and lateral frame pieces, rotational strength provided by subclavicular extensions, restricts gross trunk motion in sagittal, coronal, and transverse planes, provides intracavitary pressure to reduce load on the intervertebral disks, includes fitting and shaping the frame, prefabricated, includes fitting and adjustment
L0472	TLSO, triplanar control, hyperextension, rigid anterior and lateral frame extends from symphysis pubis to sternal notch with two anterior components (one pubic and one sternal), posterior and lateral pads with straps and closures, limits spinal flexion, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes fitting and shaping the frame, prefabricated, includes fitting and adjustment
L0480	TLSO, triplanar control, one-piece rigid plastic shell without interface liner, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, anterior or posterior opening, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes a carved plaster or cad-cam model, custom fabricated

HCPCS Code	HCPCS Code Description
L0482	TLSO, triplanar control, one-piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, anterior or posterior opening, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes a carved plaster or cad-cam model, custom fabricated
L0484	TLSO, triplanar control, two-piece rigid plastic shell without interface liner, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the sagittal, coronal, and transverse planes, includes a carved plaster or cad-cam model, custom fabricated
L0486	TLSO, triplanar control, two-piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the sagittal, coronal, and transverse planes, includes a carved plaster or cad-cam model, custom fabricated
L0488	TLSO, triplanar control, one-piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, anterior or posterior opening, restricts gross trunk motion in sagittal, coronal, and transverse planes, prefabricated, includes fitting and adjustment
L0490	TLSO, sagittal-coronal control, one-piece rigid plastic shell, with overlapping reinforced anterior, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates at or before the T-9 vertebra, anterior extends from symphysis pubis to xiphoid, anterior opening, restricts gross trunk motion in sagittal and coronal planes, prefabricated, includes fitting and adjustment
L0491	TLSO, sagittal-coronal control, modular segmented spinal system, two rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the xiphoid, soft liner, restricts gross trunk motion in the sagittal and coronal planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment

HCPCS Code	HCPCS Code Description
L0492	TLSO, sagittal-coronal control, modular segmented spinal system, three rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the xiphoid, soft liner, restricts gross trunk motion in the sagittal and coronal planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0621	Sacroiliac orthosis (SO), flexible, provides pelvic-sacral support, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, prefabricated, off-the-shelf
L0622	SO, flexible, provides pelvic-sacral support, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, custom fabricated
L0623	SO, provides pelvic-sacral support, with rigid or semi-rigid panels over the sacrum and abdomen, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, prefabricated, off-the-shelf
L0624	SO, provides pelvic-sacral support, with rigid or semi-rigid panels placed over the sacrum and abdomen, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, custom fabricated
L0625	LO, flexible, provides lumbar support, posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include pendulous abdomen design, shoulder straps, stays, prefabricated, off-the-shelf
L0626	LO, sagittal control, with rigid posterior panel(s), posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0627	LO, sagittal control, with rigid anterior and posterior panels, posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise

HCPCS Code	HCPCS Code Description
L0628	Lumbar-sacral orthosis (LSO), flexible, provides lumbo-sacral support, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include stays, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0629	LSO, flexible, provides lumbo-sacral support, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include stays, shoulder straps, pendulous abdomen design, custom fabricated
L0630	LSO, sagittal control, with rigid posterior panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0631	LSO, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0632	LSO, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, custom fabricated
L0633	LSO, sagittal-coronal control, with rigid posterior frame/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise

HCPCS Code	HCPCS Code Description
L0634	LSO, sagittal-coronal control, with rigid posterior frame/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, custom fabricated
L0635	LSO, sagittal-coronal control, lumbar flexion, rigid posterior frame/panel(s), lateral articulating design to flex the lumbar spine, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, anterior panel, pendulous abdomen design, prefabricated, includes fitting and adjustment
L0636	LSO, sagittal-coronal control, lumbar flexion, rigid posterior frame/panels, lateral articulating design to flex the lumbar spine, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, anterior panel, pendulous abdomen design, custom fabricated
L0637	LSO, sagittal-coronal control, with rigid anterior and posterior frame/panels, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0638	LSO, sagittal-coronal control, with rigid anterior and posterior frame/panels, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, custom fabricated

HCPCS Code	HCPCS Code Description
L0639	LSO, sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0640	LSO, sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, custom fabricated
L0641	LO, sagittal control, with rigid posterior panel(s), posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0642	LO, sagittal control, with rigid anterior and posterior panels, posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0643	LSO, sagittal control, with rigid posterior panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0648	LSO, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf

HCPCS Code	HCPCS Code Description
L0649	LSO, sagittal-coronal control, with rigid posterior frame/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0650	LSO, sagittal-coronal control, with rigid anterior and posterior frame/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0651	LSO, sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, prefabricated, off-the-shelf
L0970	TLSO, corset front
L0972	LSO, corset front
L0974	TLSO, full corset
L0976	LSO, full corset
L0980	Peroneal straps, prefabricated, off-the-shelf, pair
L0982	Stocking supporter grips, prefabricated, off-the-shelf, set of four (4)
L0984	Protective body sock, prefabricated, off-the-shelf, each
L0999	Addition to spinal orthosis, not otherwise specified
L1000	Cervical-thoracic-lumbar-sacral orthosis (CTLSO) (Milwaukee), inclusive of furnishing initial orthosis, including model
L1001	CTLSO, immobilizer, infant size, prefabricated, includes fitting and adjustment
L1005	Tension based scoliosis orthosis and accessory pads, includes fitting and adjustment
L1010	Addition to CTLSO or scoliosis orthosis, axilla sling
L1020	Addition to CTLSO or scoliosis orthosis, kyphosis pad
L1025	Addition to CTLSO or scoliosis orthosis, kyphosis pad, floating
L1030	Addition to CTLSO or scoliosis orthosis, lumbar bolster pad

HCPCS Code	HCPCS Code Description
L1040	Addition to CTLSO or scoliosis orthosis, lumbar or lumbar rib pad
L1050	Addition to CTLSO or scoliosis orthosis, sternal pad
L1060	Addition to CTLSO or scoliosis orthosis, thoracic pad
L1070	Addition to CTLSO or scoliosis orthosis, trapezius sling
L1080	Addition to CTLSO or scoliosis orthosis, outrigger
L1085	Addition to CTLSO or scoliosis orthosis, outrigger, bilateral with vertical extensions
L1090	Addition to CTLSO or scoliosis orthosis, lumbar sling
L1100	Addition to CTLSO or scoliosis orthosis, ring flange, plastic or leather
L1110	Addition to CTLSO or scoliosis orthosis, ring flange, plastic or leather, molded to patient model
L1120	Addition to CTLSO, scoliosis orthosis, cover for upright, each
L1200	TLSO, inclusive of furnishing initial orthosis only
L1210	Addition to TLSO, (low profile), lateral thoracic extension
L1220	Addition to TLSO, (low profile), anterior thoracic extension
L1230	Addition to TLSO, (low profile), Milwaukee type superstructure
L1240	Addition to TLSO, (low profile), lumbar derotation pad
L1250	Addition to TLSO, (low profile), anterior ASIS pad
L1260	Addition to TLSO, (low profile), anterior thoracic derotation pad
L1270	Addition to TLSO, (low profile), abdominal pad
L1280	Addition to TLSO, (low profile), rib gusset (elastic), each
L1290	Addition to TLSO, (low profile), lateral trochanteric pad
L1300	Other scoliosis procedure, body jacket molded to patient model
L1310	Other scoliosis procedure, post-operative body jacket
L1499	Spinal orthosis, not otherwise specified
L4000	Replace girdle for spinal orthosis (CTLSO or SO)
L4002	Replacement strap, any orthosis, includes all components, any length, any type

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INTRODUCTION

Low back pain (LBP) is a major health problem in the United States with an estimate of 70-85% of the population suffering from this condition at some point in their life. Most patients recover quickly and 80-90% recover within three months. The group of patients

1 who do not recover within three months become a significant cost to the healthcare system
2 and make up a large proportion of time lost at work (Asche et al., 2007).

3
4 Lumbar supports are used in the management of low back pain and as a method to prevent
5 low back pain. They have been recommended for reducing pain, limiting spinal motion,
6 reducing mechanical load, and correcting deformity. Spinal orthoses for the mid and lower
7 back include thoracic orthoses (TO), thoracic-lumbar-sacral orthoses (TLSO), lumbar-
8 sacral orthoses (LSO), and lumbar orthoses (LO).

9
10 Spinal orthoses may be flexible, rigid, or semi-rigid. Flexible orthoses are generally used
11 for muscle support to reduce low back pain. They are used in cases of spinal instability or
12 arthritic conditions. Rigid orthoses are used post-fracture or postoperatively for spinal
13 immobilization. They are also used in the treatment of scoliosis. Orthoses may be
14 prefabricated or custom-fabricated.

15 **EVIDENCE REVIEW**

16 **Lumbar Supports and Pain Reduction**

17 A Cochrane Review by van Duijvenbode et al. (2008) assessed the effects of lumbar
18 supports for prevention and treatment of non-specific low back pain. Looking at the high
19 quality randomized controlled trials (RCTs), they concluded that there was moderate
20 evidence that lumbar supports were not more effective than training of lifting techniques,
21 or no intervention, in preventing low back pain. The outcomes measured back pain and
22 sick leave due to back pain. There was limited evidence that lumbar supports plus back
23 school reduced the number of workdays lost from back injury, but not in preventing
24 incidence of pain.
25

26
27 Further, the Cochrane Review noted that there was conflicting evidence as to whether
28 lumbar supports (are effective) in treating patients with low back pain. With return to work
29 and functional status as the outcomes, there was some evidence of efficacy for the lumbar
30 supports.
31

32 Bigos et al. (2009) did a systematic review of controlled trials to evaluate the effectiveness
33 of various interventions in preventing low back pain (LBP). They found 4 trials involving
34 lumbar supports that met their inclusion criteria and none of them reduced the incidence or
35 severity of LBP compared with controls.
36

37 Jensen et al. (2012) compared rest versus exercise as a treatment for patients with LBP and
38 Modic changes (pathological changes in the vertebrae). The resting group also used a
39 flexible lumbar belt and were instructed to use it up to 4 hours per day. Outcomes included
40 pain scales and sick leave, as well as the Back Depression Inventory. At the end of the 10
41 week trial, data was collected on 87 of the 100 patients. There was no statistically
42 significant difference in any of the outcomes.

1 A good quality systematic review on lumbar supports for low back pain consisting of 8
 2 trials determined that evidence was insufficient to determine the effects of a lumbar support
 3 for either acute or chronic LBP. Therefore, lumbar supports should only be utilized upon
 4 failure of other conservative measures for mechanical LBP (Chou et al., 2016):

- 5 • For acute or subacute low back pain, there was insufficient evidence to determine
 6 effects of lumbar supports versus no lumbar supports or an inactive treatment, due
 7 to methodological shortcomings and inconsistent results.
- 8 • For chronic low back pain, there was insufficient evidence to determine effects of
 9 lumbar supports versus no lumbar supports, due to methodological shortcomings
 10 and inconsistent results.
- 11 • For acute or subacute low back pain, no differences existed between a lumbar
 12 support plus an education program versus an education program alone in pain or
 13 function after 1 year.
- 14 • For chronic low back pain, no difference was found between a lumbar support plus
 15 exercise (muscle strengthening) versus exercise alone in short-term (8 weeks) or
 16 long-term (6 months) pain or function.
- 17 • There were no clear differences between lumbar supports versus other active
 18 treatments in pain or function.

19
 20 According to the National Institute of Care and Excellence (NICE) guidelines (2017), belts
 21 or corsets for managing low back pain with or without sciatica should not be offered.
 22 Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical
 23 Practice Guideline from the American College of Physicians (2017) states that low-quality
 24 evidence showed no difference in pain or function between lumbar supports added to an
 25 educational program compared with an educational program alone or other active
 26 interventions in patients with acute or subacute low back pain.

27
 28 Gignoux et al. (2020) noted that clinical practice guidelines for non-specific low back pain
 29 do not recommend the use of non-rigid lumbar supports (NRLSs) despite the publication
 30 of several positive randomized controlled studies. Given this, they conducted a systematic
 31 review with meta-analysis to assess the efficacy of NRLSs in the treatment and prevention
 32 of non-specific low back pain. Of the 1,581 records retrieved, only 4 full-text articles were
 33 included, with 777 patients: 378 in the NRLS group, and 348 in the control group. NRLSs
 34 conferred greater amelioration of disability (effect size -0.54, 95% CI -0.90; -0.17) and
 35 pain (-0.29, -0.46; -0.12) than standard management. Insufficient data prevented a
 36 comparison of the efficiency for acute, subacute, and recurrent low back pain as well as
 37 meta-regression of responder phenotypes (sociodemographic and other patient
 38 characteristics). Authors concluded that despite the lack of support in guidelines, they
 39 demonstrated the overall efficacy of NRLSs for both disability and pain. However, further
 40 studies are needed to assess which patients can benefit the most from lumbar supports
 41 based on patient phenotype and the characteristics of low back pain. Lurati (2020)
 42 evaluates the evidence for use of lumbar supports for prevention or treatment of low back

1 pain. She summarizes that exercise continues to have the best evidence for prevention and
 2 treatment of low back pain, however in an occupation such as nursing and based on their
 3 case study, a lumbar belt could be used for certain activities to increase comfort.

4
 5 Annaswamy et al. (2021) evaluated the effect of back bracing to treat patients with chronic
 6 low back pain. This was a prospective, unblinded, randomized controlled trial of 61 adults
 7 with uncomplicated chronic low back pain (>12 wks) and imaging findings of degenerative
 8 spondylosis, to assess the effectiveness of a semirigid back brace. All study participants
 9 received back school instruction. The treatment group also received a lumbar orthosis and
 10 was instructed to wear it as needed for symptom relief. At baseline, 6 weeks, 12 weeks,
 11 and 6 months after intervention, the following was collected: Numerical Rating Scale to
 12 measure pain intensity, Pain Disability Questionnaire, Patient-Reported Outcome
 13 Measurement Information System, and EuroQol 5-Dimension (EQ-5D) to measure patient-
 14 reported function and quality of life. An interim analysis at the halfway point in enrollment
 15 (61 of 120 planned participants) revealed the Pain Disability Questionnaire, Patient-
 16 Reported Outcome Measurement Information System, and EQ-5D scores in the treatment
 17 group to be worse than in the control group, but no significant group differences in
 18 Numerical Rating Scale scores. Authors halted the study because continuation was unlikely
 19 to produce significant changes to the results. Authors concluded that in patients with
 20 uncomplicated chronic low back pain, a back brace when combined with education and
 21 exercise instruction did not provide any pain relief compared with education and exercise
 22 instruction alone.

23
 24 Wei et al. (2024) analyzed the effectiveness of lumbar braces in patients after lumbar spine
 25 surgery. Nine English papers and 1 Chinese paper were included in the present work,
 26 involving a total of 2,646 patients (2,181 in the experimental group and 465 in the control
 27 group). The differences in preoperative VAS, postoperative VAS, preoperative ODI,
 28 postoperative ODI, length of hospital stay, postoperative complications, and surgical
 29 comparison were not statistically significant. However, postoperative surgical site
 30 infection incidence was lower in the lumbar brace group than those without lumbar brace.

31 **Lumbar Supports and Spinal Motion**

32
 33 Kurd et al. (2007) looked at outcomes of patients with symptomatic isthmic spondylosis
 34 treated with a custom fit thoracic-lumbar-sacral orthoses (TLSO) and activity cessation for
 35 3 months. The TLSO was worn continuously for three months. The goal of the support is
 36 to limit motion and have an anti-lordotic effect. At the end of three months, 95% of patients
 37 achieved excellent results defined as all pretreatment symptoms being relieved. It is not
 38 clear how much limitation of movement the TLSO provided or if it just reinforced the
 39 cessation of activity.

40
 41 Giele et al. (2009) evaluated the effectiveness of bracing in patients with thoracolumbar
 42 fractures. The goals of bracing are to prevent failure of bone repair, facilitate

1 immobilization, and provide correct posture. These orthoses are designed to prevent
2 rotation and flexion of the spine. The studies included involved patients with
3 thoracolumbar compression fractures from T10-L5. Most of these fractures were at T12
4 and L1. The compression of the vertebrae at admission ranged from 11-25%. From the 7
5 retrospective studies included, there was no evidence for the effectiveness of bracing for
6 thoracolumbar fractures.

7
8 Jegede et al. (2011) evaluated the effects of three different lumbar orthoses on the range of
9 motion (ROM) of the lumbar spine during 15 activities of daily living (ADLs). Ten
10 asymptomatic subjects with a mean age of 26 years were measured. They were measured
11 without a brace, while wearing a corset, a semi-rigid lumbar-sacral orthoses (LSO), and a
12 rigid custom-molded LSO. Range of motion was measured with an electrogoniometer.
13 Although significant differences were seen in full ROM with the braces of varying rigidity,
14 there were no significant differences in functional ROM between rigid LSOs, and minimal
15 difference between values for the corset and the rigid LSOs. Functional ROM for 11 of the
16 15 activities was less than allowed by each brace. The ADLs that showed a significant
17 difference all involve flexion of the hips and lumbar spine. The authors conclude that
18 bracing serves as a proprioceptive guide that lets patients restrict their own motion.

19
20 Zarghooni et al. (2013) assessed the effectiveness and complications of orthotic treatment
21 of acute and chronic disease of the cervical and lumbar spine. They selected three relevant
22 systematic reviews and four controlled trials. Very few controlled trials have studied the
23 efficacy of orthotic treatment compared to other conservative treatments and surgery. They
24 concluded that no definitive evidence was found to support the use of orthoses after surgery
25 and in lumbar radiculopathy. Orthoses were not recommended for nonspecific low back
26 pain.

27 28 **Lumbar Belts and Lifting and Muscle Activity**

29 Zink et al. (2001) examined the effects of muscle activity and joint kinematics while using
30 a weight belt. Electromyography (EMG) activity was measured in 14 healthy men during
31 the squat exercise. The authors found there was no difference in muscle activity, but the
32 speed of the movement was significantly faster. Escamilla et al. (2002) examined two
33 different deadlift conditions, with and without a belt, and compared EMG activity.
34 Compared with the no belt condition, the belt condition produced significantly greater
35 activity in the rectus abdominis, and less activity in the external obliques. Kingma et al.
36 (2006) evaluated spinal compression forces in weightlifting with and without a belt. Spinal
37 compression was calculated using EMG, kinematics, and ground reaction forces. The belt
38 reduced compression forces by 10%, but only when inhaling before the lift. Walsh et al.
39 (2007) evaluated the use of a belt during the squat exercise. Forty-eight asymptomatic
40 athletes were measured using a three-dimensional (3D) motion analysis system. The use of
41 the support belt did not significantly alter spinal motion during the lift. The authors noted

1 that many of the athletes felt that the belt provided additional support during the lift
2 compared to the no belt condition.

3
4 Azadinia et al. (2020) aimed to evaluate available evidence in literature to determine
5 whether lumbosacral orthoses (LSO) results in trunk muscle weakness or atrophy in a
6 systematic review. Prospective studies published in peer-reviewed journals, with full text
7 available in English, investigating the effect of lumbar orthosis on trunk muscle activity,
8 muscle thickness, strength or endurance, spinal force, and intra-abdominal pressure in
9 healthy subjects or in patients with low back pain, were included. Thirty-five studies
10 fulfilled the eligibility criteria. Most studies investigating the effect of lumbar orthosis on
11 electromyographic activity (EMG) of trunk muscles demonstrated a decrease or no change
12 in the EMG parameters. A few studies reported increased muscle activity. Lumbosacral
13 orthosis was found to have no effect on muscle strength in some studies, whereas other
14 studies demonstrated increased muscle strength. Only one study, which included
15 ultrasound assessment of trunk muscle stabilizers, suggested reduced thickness of the
16 abdominal muscles, and reduced cross-sectional area of the multifidus muscles. Out of
17 eight studies that investigated spinal compression load, the load was reduced in four studies
18 and unchanged in three studies. One study showed that only elastic belts reduced
19 compression force compared to leather and fabric belts and ascribed this reduction to the
20 elastic property of the lumbar support. Authors concluded that this review showed that the
21 changes in outcome measures associated with muscle work demands were inconsistent in
22 their relation to the use of lumbar supports. This review did not find conclusive scientific
23 evidence to suggest that orthosis results in trunk muscle weakness.

24
25 Ludvig et al. (2019) noted that lumbar belts have been shown to increase lumbar stiffness,
26 but it is unclear if this is associated with trunk muscle co-contraction, which would increase
27 the compression on the spine. It has been hypothesized that lumbar belts increase lumbar
28 stiffness by increasing intra-abdominal pressure, which would increase spinal stability
29 without increasing the compressive load on the spine. Given this hypothesis, Ludvig et al.
30 (2019) measured trunk muscle activity and lumbar stiffness and damping in healthy and
31 low-back pain subjects during three conditions: no lumbar belt; wearing an extensible
32 lumbar belt; wearing a non-extensible lumbar belt. Muscle activity was measured while
33 subjects performed controlled forward and backward 20° trunk sways. Lumbar stiffness
34 and damping were measured by applying random continuous perturbation to the chest.
35 Findings noted the following: External oblique activity was decreased when wearing either
36 lumbar belt during all phases of movement, while rectus abdominis and iliocostalis activity
37 were decreased during the phase of movement where the muscles were maximally active
38 while wearing either belt. Trunk stiffness was greatly increased by wearing either belt.
39 There were no consistent differences in either lumbar stiffness or muscle activity between
40 the two belts. Wearing a lumbar belt had little to no effect on damping. There were no
41 group differences in any of the measures between healthy and low-back pain populations.
42 Authors interpreted these findings as consistent with the hypothesis that lumbar belts can

1 increase spinal stability by increasing intra-abdominal pressure, without any increase in the
2 compressive load on the spine. The findings can also be generalized, for the first time, to
3 subjects with low-back pain. Further research is needed to confirm findings.

4 **Bracing and Scoliosis**

5 Rigo et al. (2006) developed and distributed a questionnaire on braces for scoliosis to
6 specialists interested in the conservative treatment of adolescent idiopathic scoliosis (AIS).
7 There was not an agreement on the type of the brace that should be used or on pad
8 placement, but there was agreement on the importance of the three-point system
9 mechanism.

10
11
12 Schiller et al. (2010) did a review of the history of AIS and other factors, as well as the
13 types of braces available for treatment. One challenge was the definition of “success” in
14 treating the scoliotic patient. The majority of the literature defines success as a progression
15 of less than 5 degrees. Some authors use a curve progression of 10 degrees, and others use
16 a total curve value of 45 degrees. Many studies are compromised by poor compliance of
17 the patients as braces need to be worn 18-23 hours per day. There is no prospective,
18 randomized study to determine the effectiveness of bracing.

19
20 Aulisa et al. (2012) reviewed the progressive action short brace (PASB) for scoliosis. The
21 results of a case series of 110 patients were presented. The average decrease in rotation
22 was from 15.8 degrees to 8.3 degrees. They had similar success for lateral flexion. The
23 methodology of their study was weak. Data was extracted from their database, and they
24 only included patients who were fully compliant; they did not describe the criteria for
25 compliance.

26
27 Weinstein et al. (2013) conducted a multicenter study that included patients with typical
28 indications for bracing due to their age, skeletal immaturity, and degree of scoliosis. Of
29 242 patients included in the analysis, 116 were randomly assigned to bracing or
30 observation, and 126 chose between bracing and observation. Patients in the bracing group
31 were instructed to wear the brace at least 18 hours per day. The primary outcomes were
32 curve progression to 50 degrees or more (treatment failure) and skeletal maturity without
33 this degree of curve progression (treatment success). The trial was stopped early owing to
34 the efficacy of bracing. Based on analysis, the rate of treatment success was 72% after
35 bracing, as compared with 48% after observation. In the intention-to-treat analysis, the rate
36 of treatment success was 75% among patients randomly assigned to bracing, as compared
37 with 42% among those randomly assigned to observation. There was a significant positive
38 association between hours of brace wear and rate of treatment success. According to
39 authors, bracing significantly decreased the progression of high-risk curves to the threshold
40 for surgery in patients with adolescent idiopathic scoliosis. The benefit increased with
41 longer hours of brace wear.

1 Negrini et al. (2015) authored a Cochrane Review on bracing for idiopathic scoliosis in
2 adolescents. They evaluated the efficacy of bracing for adolescents with scoliosis vs. no
3 treatment or other treatments on quality of life, disability, pulmonary disorders, progression
4 of curve and psychological issues. They included 7 studies (662 participants). The authors
5 determined that due to the important clinical differences among the studies, it was not
6 possible to perform a meta-analysis. Two low quality studies showed that bracing did not
7 change quality of life during treatment, back pain, and psychological and cosmetic issues
8 in the long term (16 years). All included papers consistently showed that bracing prevented
9 curve progression (secondary outcome). However, given the low quality of evidence,
10 confidence in the findings is limited and further research is needed. The high rate of failure
11 of RCTs demonstrates the significant difficulties in performing RCTs in a field where
12 parents reject randomization of their children. This will challenge the ability to perform
13 higher quality research in the future.

14
15 The U.S. Preventive Services Task Force (USPSTF) (2018) has published conclusions for
16 scoliosis treatments: “The USPSTF found inadequate evidence on treatment with exercise
17 and surgery. It found adequate evidence that treatment with bracing may slow curvature
18 progression in adolescents with mild or moderate curvature severity (Cobb angle $<40^{\circ}$ to
19 50°); however, evidence on the association between reduction in spinal curvature in
20 adolescence and long-term health outcomes in adulthood is inadequate. The USPSTF
21 found inadequate evidence on the harms of treatment.”

22
23 Schoutens et al. (2020) evaluated the effectiveness of nonsurgical treatments in
24 symptomatic adult degenerative scoliosis (ADS) in a systematic review. Six studies were
25 included. Of these, four focused specifically on injections, bracing, or yoga; two involved
26 multiple treatments. Two single-group retrospective cohort studies lent support for bracing
27 to slow curve progression. Evidence for bracing was rated as very low quality. Authors
28 concluded that the quantity and quality of the evidence regarding bracing was insufficient
29 to advise for or against the use of bracing to improve outcomes in symptomatic ADS.

30
31 Costa et al. (2021) investigated whether there is a difference in effectiveness between brace
32 types/concepts. All studies on brace treatment for AIS were searched for in PubMed and
33 EMBASE up to January 2021. Articles that did not report on maturity of the study
34 population were excluded. Critical appraisal was performed using the Methodological
35 Index for Non-Randomized Studies tool (MINORS). Brace concepts were distinguished in
36 prescribed wearing time and rigidity of the brace: full-time, part-time, and night-time, rigid
37 braces and soft braces. In the meta-analysis, success was defined as $\leq 5^{\circ}$ curve progression
38 during follow-up. Of the 33 selected studies, 11 papers showed high risk of bias. The rigid
39 full-time brace had on average a success rate of 73.2% (95% CI 61-86%), night-time of
40 78.7% (72-85%), soft braces of 62.4% (55-70%), observation only of 50% (44-56%). There
41 was insufficient evidence on part-time wear for the meta-analysis. The majority of brace
42 studies have significant risk of bias. No significant difference in outcome between the

1 night-time or full-time concepts could be identified. Soft braces have a lower success rate
2 compared to rigid braces. Bracing for scoliosis in Risser 0-2 and 0-3 stage of maturation
3 appeared most effective.

4
5 Dufvenberg et al. (2021) aimed to explore patient adherence and secondary outcomes
6 during the first 6 months in an ongoing randomized controlled trial of three treatment
7 interventions. Interventions consisted of physical activity combined with either
8 hypercorrective Boston brace night shift (NB), scoliosis-specific exercise (SSE), or
9 physical activity alone (PA). Measures at baseline and 6 months included angle of trunk
10 rotation (ATR), Cobb angle, International Physical Activity Questionnaire short form
11 (IPAQ-SF), pictorial Spinal Appearance Questionnaire (pSAQ), Scoliosis Research
12 Society (SRS-22r), EuroQol 5-Dimensions Youth (EQ-5D-Y) and Visual Analogue Scale
13 (EQ-VAS). Patient adherence, motivation, and capability in performing the intervention
14 were reported at 6 months. The study included 135 patients (111 females) with AIS and
15 >1-year estimated remaining growth, mean age 12.7 (1.4) years, and mean Cobb angle 31
16 (± 5.3). At 6 months, the proportion of patients in the groups reporting high to very high
17 adherence ranged between 72 and 95%, while motivation ranged between 65 and 92%,
18 with the highest proportion seen in the NB group. IPAQ-SF displayed significant between
19 group main effects regarding moderate activity, with a medium-sized increase favoring the
20 SSE group compared to NB. From baseline to 6 months, ATR showed significant between
21 group medium-sized main effects favoring the NB group compared to PA, but not reaching
22 a clinically relevant level. In conclusion, patients reported high adherence and motivation
23 to treatment, especially in the NB group. Patients in the SSE and PA groups increased their
24 physical activity levels without other clinically relevant differences between groups in
25 other clinical measures or patient-reported outcomes. The results suggest that the
26 prescribed treatments are viable first-step options during the first 6 months.

27
28 Guy et al. (2022) biomechanically analyzed and compared various passive correction
29 features of braces, designed by several centers with diverse practices, for 3D correction of
30 adolescent idiopathic scoliosis. A wide variety of brace designs exist, but their
31 biomechanical effectiveness is not clearly understood. Many studies have reported brace
32 treatment correction potential with various degrees of control, making the objective
33 comparison of correction mechanisms difficult. A Finite Element Model (FEM) simulating
34 the immediate in-brace corrective effects has been developed and allows to
35 comprehensively assess the biomechanics of different brace designs. For this study, expert
36 clinical teams (one orthotist and one orthopedist) from 6 centers in 5 countries participated
37 in the study. For 6 scoliosis cases with different curve types respecting SRS criteria, the
38 teams designed 2 braces according to their treatment protocol. FEM simulations were
39 performed to compute immediate in-brace 3D correction and skin-to-brace pressures. All
40 braces were randomized and labelled according to 21 design features derived from
41 SOSORT proposed descriptors, including positioning of pressure points, orientation of
42 push vectors, and sagittal design. Simulated in-brace 3D corrections were compared for

1 each design feature class using ANOVAs and linear regressions (significance $p < 0.05$).
2 Seventy-two braces were tested, with significant variety in the design approaches. Pressure
3 points at the apical vertebra level corrected the main thoracic curve better than more caudal
4 locations. Braces with ventral support flattened the lumbar lordosis. Lateral and ventral
5 skin-to-brace pressures were correlated with changes in thoracolumbar/lumbar Cobb and
6 lumbar lordosis. Upper straps positioned above T10 corrected the main thoracic Cobb
7 better than those placed lower.

8
9 Duarte et al. (2022) tested the hypothesis that anterior vertebral body growth modulation
10 (AVBGM) achieves 3D deformity correction after 2-year follow-up while brace treatment
11 limits curve progression for moderate idiopathic scoliosis ($30\text{-}50^\circ$). For idiopathic
12 scoliosis, bracing and AVBGM have overlapping indications in skeletally immature
13 patients with moderate scoliosis curve angles, creating a grey zone in clinical practice
14 between them. The relative 3D deformity control performance over a 2-year period
15 between these fusionless treatments is still uncertain. A retrospective review of a
16 prospective idiopathic scoliosis patients database, recruited between 2013 and 2018 was
17 performed. Inclusion criteria were skeletally immature patients (Risser 0-2), with Cobb
18 angles between $30\text{-}50^\circ$ and a 2-year follow-up after bracing or AVBGM. 3D radiological
19 parameters and Health Related Quality of Life (HRQoL) scores were evaluated. Thirty-
20 nine patients (12.7 ± 1.3 y.o.) with Cobb angles $\geq 30^\circ$ treated with brace and 41 patients
21 (11.8 ± 1.2 y.o.) with presenting Cobb angles $\leq 50^\circ$ who received AVBGM were reviewed.
22 The statistical analysis of 3D deformity measurements showed that at 2-year follow-up,
23 only the 3D spine length and both sides apical vertebral heights changed significantly with
24 brace treatment. While AVBGM treatment achieved statistically significant correction
25 differences in thoracic and lumbar Cobb angles, TrueKyphosis, 3D spine length and
26 selective left apical vertebra height ($p < 0.05$). 35% of brace patients had a curve
27 progression of $>5^\circ$ at final follow-up while it was 0% for AVBGM. HRQoL assessment
28 showed no statistically significant differences between pre and post SRS total scores for
29 each group ($p > 0.05$). Authors concluded that even though these 2 cohorts are not fully
30 comparable, bracing seems to control progression for a significant portion of patients with
31 moderate scoliosis curves, while AVBGM significantly corrected and maintained 3D
32 deformity parameters at 2-year follow-up.

33
34 Liu et al. (2023) investigated actual orthosis-wearing compliance and evaluate the
35 effectiveness of orthotic treatment in controlling scoliotic curvature and preventing surgery
36 for patients with AIS under various levels of orthosis-wearing compliance. This study
37 systematically reviewed 17 of 1,799 identified studies, including 1,981 subjects. The actual
38 compliance was inconsistent and ranged from 7.0 to 18.8 hours daily. The proportion of
39 compliant subjects in each study varied from 16.0% to 78.6% due to the heterogeneity of
40 calculation period, measurement methods, and orthosis prescription time. Thirteen studies
41 were investigated to determine the effectiveness of orthotic treatment in controlling curve
42 deformity under different compliance groups, and 2 studies compared the compliance

1 under different treatment outcomes. The rate of curve progression, defined as surpassing
 2 the measurement error threshold of 5° or 6° after orthotic treatment, varied from 1.8% to
 3 91.7% across the studies. Ten studies defined the treatment failure, surgery, or surgery
 4 indication as Cobb angle progressing to a certain degree (e.g., 40°, 45°, or 50°) and reported
 5 failure/surgery/surgery indication rates ranging from 0.0% to 91.7% among different
 6 compliance level groups. This review found that the actual compliance with orthotic
 7 treatment was generally lower than the prescribed wearing time and exhibited wide
 8 variation among different studies. The electronic compliance monitors show promise in
 9 regular orthotic treatment practice. More importantly, the group with higher and consistent
 10 compliance has significantly less curve progression and lower surgery or failure rate than
 11 the group with lower and inconsistent compliance. Further studies are proposed to
 12 investigate the minimal orthosis-wearing compliance in patients with AIS treated with
 13 different types of orthoses.

14
 15 Zapata et al. (2024) determined brace wear adherence for patients treated with nighttime
 16 braces and evaluated the effect of brace adherence on curve progression. One hundred
 17 twenty-two patients with AIS ages 10-16 years, Risser stages 0-2, major curves 20°-40°
 18 treated with Providence nighttime braces prescribed to be worn at least 8 h per night were
 19 prospectively enrolled and followed until skeletal maturity or surgery. Brace adherence
 20 was measured using iButton temperature sensors after 3 months of brace initiation and at
 21 brace discharge. Curve types were single thoracolumbar/lumbar (62%, $n = 76$), double
 22 (36%, $n = 44$), and single thoracic (2%, $n = 2$). Brace adherence averaged 7.8 ± 2.3 h after
 23 3 months (98% adherence) and 6.7 ± 2.6 h at brace discharge (84% adherence). Curves that
 24 progressed $\geq 6^\circ$ had decreased brace adherence than non-progressive curves after 3 months
 25 (7.0 h vs. 8.1 h, $p = 0.010$) and at brace discharge (5.9 h vs. 7.1 h, $p = 0.017$). Multivariate
 26 logistic regression analysis showed that increased hours of brace wear, single curves, and
 27 curves $< 25^\circ$ were associated with non-progression at brace discharge. Authors concluded
 28 that patients treated with nighttime bracing have a high rate of brace adherence. Lack of
 29 curve progression is associated with increased brace wear. Nighttime bracing is effective
 30 at limiting curve progression in AIS single thoracolumbar/lumbar and double curves.

31
 32 Lee et al. (2024) compared the Boston brace and European braces using a standardized
 33 Scoliosis Research Society (SRS) inclusion criteria for brace treatment as well as
 34 consensus recommendations for treatment outcome. All studies that were included in this
 35 review had applied fully/partially the SRS inclusion criteria for brace wear. Outcome
 36 measures were divided into primary and secondary outcome measures. Of these 1176
 37 studies, only 15 had fulfilled the eligibility criteria and were included in the study. The
 38 percentage of patients who avoided surgery for European braces ranged from 88 to 100%,
 39 whereas for Boston brace ranged from 70 to 94%. When treatment success was assessed
 40 based on the final Cobb angle $> 45^\circ$, approximately 15% of patients treated with European
 41 braces had treatment failure. In contrast, 20-63% of patients treated with Boston brace had
 42 curves $> 45^\circ$ at skeletal maturity. Curve correction was not achieved in most patients (24-

1 51% of patients) who were treated with the Chêneau brace and its derivatives. However,
 2 none of the patients treated with Boston brace achieved curve correction. Authors
 3 concluded that the Boston brace and European braces were effective in the prevention of
 4 surgery. In addition, curve stabilization was achieved in most studies. Limitation in current
 5 literature included lack of studies providing high level of evidence and lack of
 6 standardization in terms of compliance to brace as well as multidisciplinary management
 7 of brace wear.

9 **PRACTITIONER SCOPE AND TRAINING**

10 Practitioners should practice only in the areas in which they are competent based on their
 11 education training, and experience. Levels of education, experience, and proficiency may
 12 vary among individual practitioners. It is ethically and legally incumbent on a practitioner
 13 to determine where they have the knowledge and skills necessary to perform such services.

14
 15 It is best practice for the practitioner to appropriately render services to a patient only if
 16 they are trained, equally skilled, and adequately competent to deliver a service compared
 17 to others trained to perform the same procedure. If the service would be most competently
 18 delivered by another health care practitioner who has more skill and expert training, it
 19 would be best practice to refer the patient to the more expert practitioner.

20
 21 Best practice can be defined as a clinical, scientific, or professional technique, method, or
 22 process that is typically evidence-based and consensus driven and is recognized by a
 23 majority of professionals in a particular field as more effective at delivering a particular
 24 outcome than any other practice (Joint Commission International Accreditation Standards
 25 for Hospitals, 2020).

26
 27 Depending on the practitioner’s scope of practice, training, and experience, a member’s
 28 condition and/or symptoms during examination or the course of treatment may indicate the
 29 need for referral to another practitioner or even emergency care. In such cases it is prudent
 30 for the practitioner to refer the member for appropriate co-management (e.g., to their
 31 primary care physician) or if immediate emergency care is warranted, to contact 911 as
 32 appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* policy for
 33 information.

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