



ISPO Scientific Committee

Recommendation for Defining Orthotic Dataset for Research Study

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Introduction

An understanding of research participant characteristics and orthoses used is essential for interpreting results in the scientific and consumer literature. In the field of orthotics, these characteristics are often under-reported, or inconsistently presented, leaving the reader to make assumptions on the study design and clinical application of the results. Orthotic studies require not only typical personal information, such as height, weight, and gender, but also descriptions of the orthotic components and other assistive devices.

For the researchers, the decision on participant information data collection is made during the study design phase. It is typically difficult or impossible to obtain after data collection has been completed and the results are being disseminated. A participant information minimum data set would be used when planning orthotic studies, to collect appropriate participant data during the participant encounters, and assist study reviewers by providing a set of criteria that could be adopted for publication assessment.

This document is a recommendation for an ISPO-sanctioned data set for reporting participant and orthotic characteristics in orthotic research and development publications. While this recommendation will have direct benefits for typical scientific publications, such as the journal of Prosthetics and Orthotics International, the data set can also improve how technical and clinical reports are designed and reported to the orthotic community and help reviewer reviewing papers on orthotics.

The data set includes a comprehensive list of items, descriptions, and formats for all possible descriptors. Researchers might not use the complete data set to describe study participants due to time and resource constraint.

Data set should include:

- overall considerations,
- participants and
- orthotic characteristics.

Overall Considerations

- Characteristics that apply to all participants should be mentioned in the manuscript text (e.g., all subjects were males with spinal cord injury, all orthoses were hip-knee-ankle-foot (HKAF) orthoses, etc.).
- The appropriate professional that assessed the participant and fabricated/fit the orthosis prior to inclusion and the person who performed the tests/measurements in the study should be noted in the manuscript text (i.e., orthotist [ISPO Category or certification], medical doctor and his/her speciality, physical therapist, occupational therapist, orthotic technician and their experience).
- For group data, the mean and standard deviation, range and median for quantitative measures should be reported.
- Detailed description of function of each component, trim lines, material, and manufacturer should be included for orthotic components to help define iterative product updates that can affect the relevant function.
- Information about Ethics approval should be mentioned.

- For all questionnaires used for assessing outcome translation procedure and validation of the original version and translated version have to be mentioned.
- For all clinical tests used for assessing outcomes report their psychometric properties, Minimal Detectable Change for the diagnosis/es included and Minimal Clinical Important Difference if is known for diagnosis/es included.

The following are the recommended **Orthotics Data Set**:

Section	Item
SECTION 1 - Overall Description	1.1. General information about the participant <ul style="list-style-type: none"> • Age • Height • Weight
SECTION 2 - Health condition and functional deficiencies	2.1. Description of the Participant <ul style="list-style-type: none"> • Clinical condition to be treated with orthosis – functioning limitations • Significant medical history • Reference to the anatomical segment • Motivation and personal needs 2.2. Clinical Objectives 2.3. Functional Requirement of orthoses
SECTION 3 - Definition of Orthosis characteristics	3.1. Definition of the category (ISO 8549-3:1989) 3.2. Definition of the sub-category, related to the disease 3.3. Description of the product itself and its functions
SECTION 4 – Description of data collection method	4.1. Description of procedures and tests 4.2. Data analysis

SECTION 1 – Overall Description

1.1. General information about the participant

- Characteristics that apply to all participants should be mentioned in the manuscript text (e.g., age, height, weight, etc.), or presented in the table.
- For group data, report mean and standard deviation, confidence interval and effect size (all that apply based on the chosen statistical test) for quantitative measures.
- Ethics approval number and statement about the informed consent
- Inclusion/exclusion criteria

SECTION 2 – Health Condition and Functional Deficiencies

2.1 Description of the Participant

a. Clinical Condition to be Treated – Functional Limitations

Item	Description	Format
Reasons	Primary medical diagnosis	ICD-10, When appropriate refer to the scale being use and cut-point
Comorbidities	Comorbidities at first data collection session	ICD-10, Refer to the scale being use (MMSE, Comorbidity questionnaire) and cut-point
Functional problem	Describe (e.g., drop foot, knee instability)	ICF, Refer to the scale being use and cut-point
Time since onset	Time since clinical condition occurs	Days, Months, Years
Assessment of involved anatomical parts	Report all relevant (muscle testing, ROM, limb discrepancy, sensation, gait assessment, hand function, Cobb angle, etc.)	Refer to the scale being use or use SI measurement units

b. Significant Medical History

Item	Description	Format
Disease	Primary medical diagnosis	ICD-10
Trauma	Describe remaining problems due to previous trauma (Limb discrepancy, decreased ROM, muscle strength, cognitive problems, etc.)	ICF, Refer to the scale being use (e.g., MMSE) and cut-point
Functional problem	Describe (e.g., drop foot, knee instability, etc.)	ICF, Refer to the scale being use and cut-point

c. Reference to the Anatomical Segment

Item	Description	Format
Body part	Upper limb, lower limb, spinal	Upper limb, lower limb, spinal
Side	Limb side(s)	Left, right, bilateral, full trunk
Dominance when relevant	Upper and/or lower limb dominance	Self reported by participant or refer to the scale being use

d. Motivation and Personal Needs

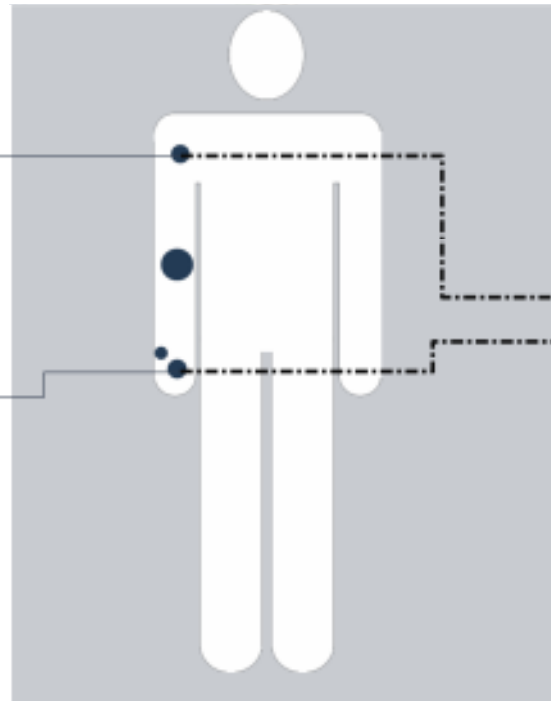
Item	Description	Format
Patient's expectations	What does patient expect from the treatment – is it realistic?	Describe
Treatment duration	The first treatment, participants already had orthosis, previous orthoses	Days, Months, Years
Follow-up time	Time between the first and last assessment	Days, Months, Years

2.2 Clinical Objectives

Define and select the objectives from a list

- ☐ To relieve pain
- ☐ To manage deformities
- ☐ To prevent an excessive range of joint motion
- ☐ To increase the range of joint motion
- ☐ To compensate for abnormalities of segment length or shape
- ☐ To manage abnormal neuromuscular function (e.g., weakness or hyperactivity)
- ☐ To protect tissues
- ☐ To promote healing
- ☐ To provide other effects (e.g., placebo, warmth, postural feedback)

Specify the anatomical part for each objective

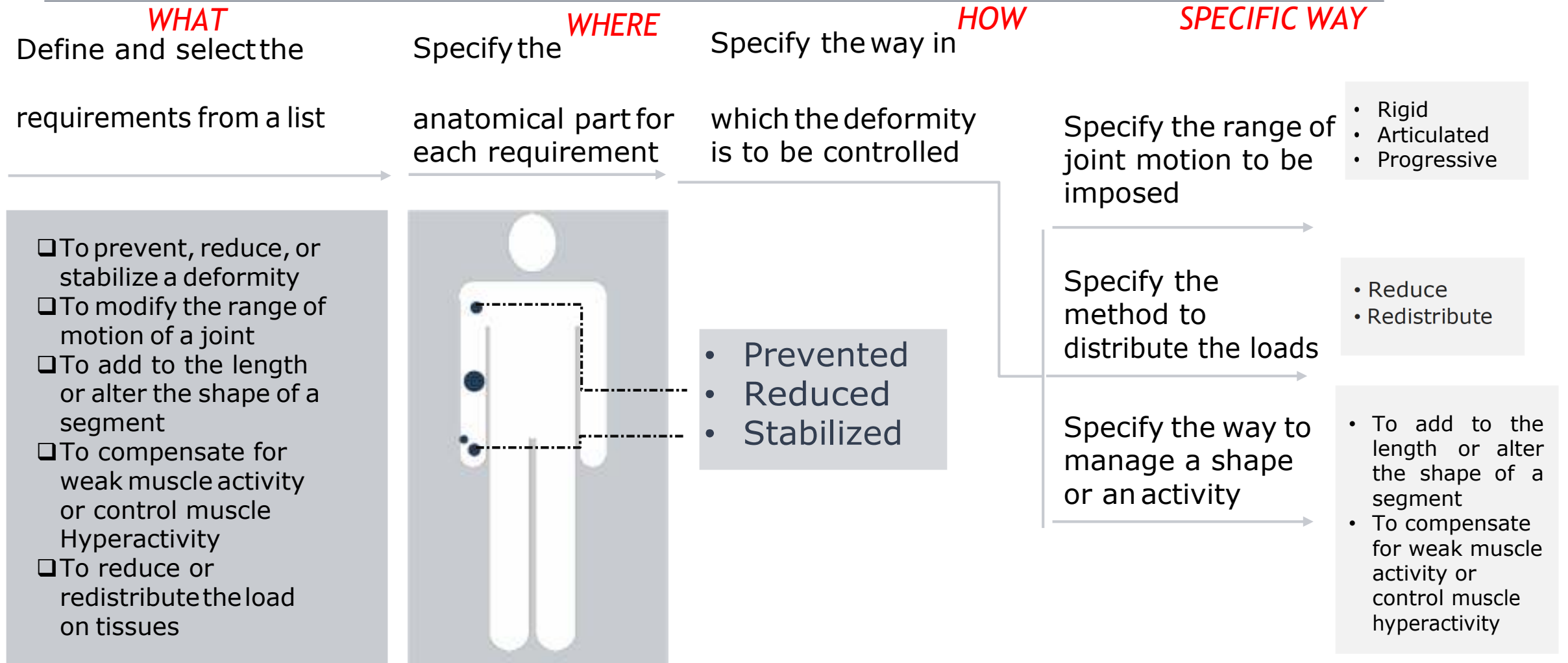


Specify the expected outcomes

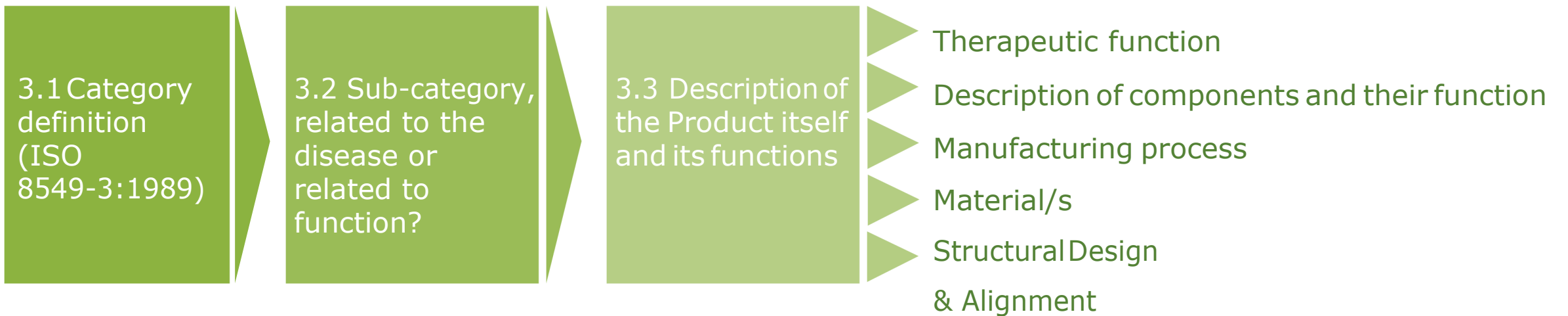
- Preventable
- Reducible
- Irreducible

2.3 Functional Requirement of orthoses

Necessary to achieve the previously defined clinical objectives



SECTION 3-Definition of Orthosis Characteristics



SECTION 3 - Definition of Orthotics' characteristics

3.1 Category definition (ISO 8549-3:1989)

Use of ISO terminology, which describes the involved part that needs to be treated by the Orthotic device

Spinal Orthoses

- Sacroiliac orthosis(SIO)
- Cervical orthosis(CO)
- Cervicothoracicorthosis(CTO)
- Cervicothoracolumbosacral orthosis (CTLSO)
- Thoracolumbosacral orthosis (TLSO)
- Lumbosacralorthosis(LSO)

Upper limb Orthoses

- Wrist–handorthosis(WHO)
- Finger orthosis(FO)
- Wrist–hand–finger orthosis (WHFO)
- Hand orthosis(HdO)
- Elbow orthosis(EO)
- Elbow–wrist–hand orthosis (EWHO)
- Shoulder–elboworthosis(SEO)
- Shoulder–elbow–wrist–hand orthosis (SEWHO)
- Shoulder orthosis(SO)

Lower limb Orthoses

- Foot orthosis(FO)
- Ankle–foot orthosis(AFO)
- Knee–ankle–footorthosis (KAFO)
- Hip orthosis(HpO)
- Knee orthosis(KO)
- Hip–knee orthosis(HKO)
- Hip–knee–ankle–foot orthosis (HKAFO)

3.2 Sub-category, related to the function

Use of ISO terminology, which describes the involved part that needs to be treated by the Orthotic device

Example:

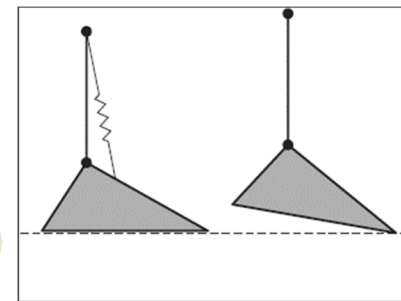
If selected category 3.1 is an Ankle-Foot Orthosis AFO



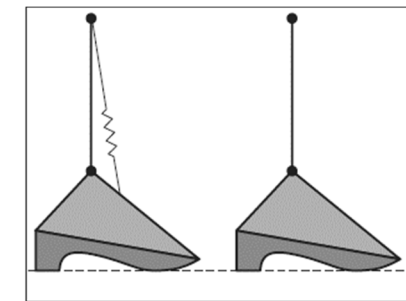
Sub-category depends on desired function

- foot drop
 - equinovarus
 - equinovalgus
 - poliomyelitis
- flaccid equinus
 - gastrocnemius-soleus trauma or dysfunction
 - Charcot-Marie-Tooth disease
 - cerebrovascular accidents (mild residual symptoms, muscular dystrophy, peroneal palsies)

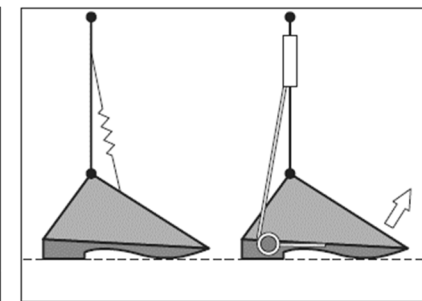
Orthotic AFO options to compensate the selected problem



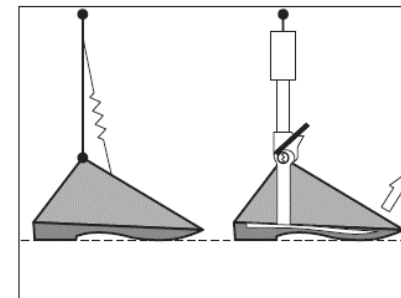
Biomechanical deficit:
flaccid equinus



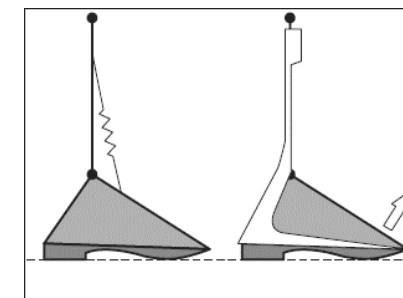
Bilateral 2-inch Heel Lifts, to
accommodate equinus position



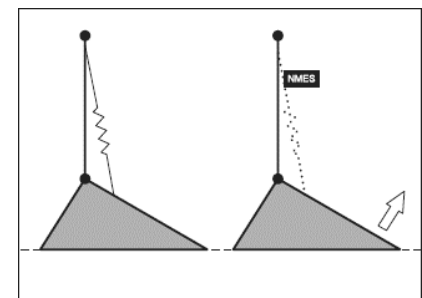
Piano wire AFO Spring Wire
AFO for Dorsiflexion Assist



Klenzak AFO for Dorsiflexion
Assist



Molded Plastic AFO for
Dorsiflexion Assist



Peroneal NEMS: Functional
Electrical Stimulation for
Dorsiflexion Assist

Example:

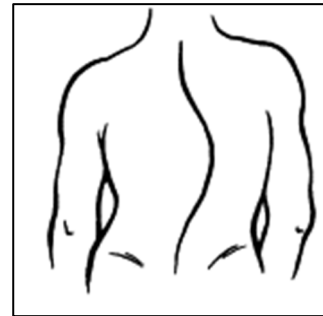
If selected category 3.1 is a
Thoracolumbosacral orthosis
(TLSO)

Sub-category depends on
the disease/pain/trauma

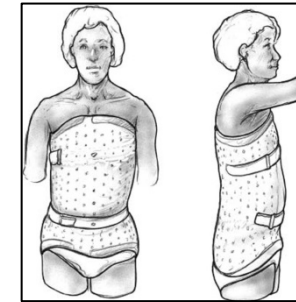
- Hyperkyphosis
- Burst fracture
- Scheuermann's kyphosis
- Ankylosing Spondylitis
- Scoliosis



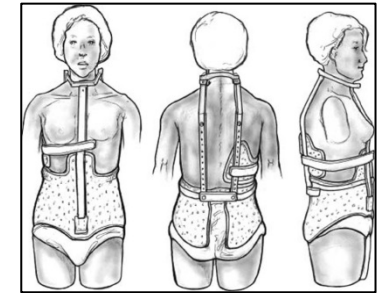
Orthotic options to compensate the selected problem



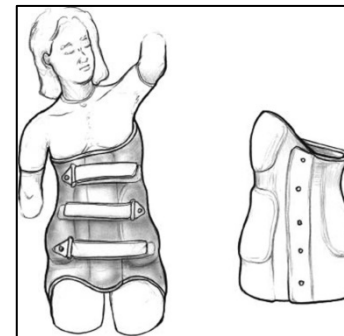
Lateral curvature of
the spine



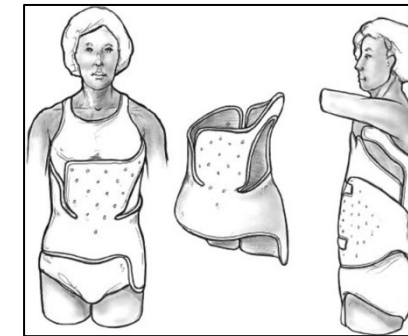
TLSO: Boston brace



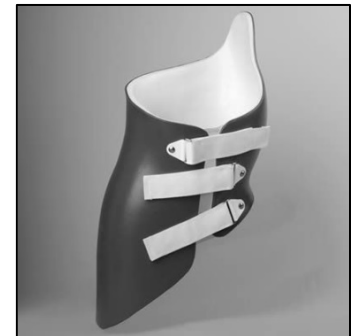
CTLSO: Milwaukee brace



TLSO: Charleston bending
brace



TLSO: Wilmington brace



TLSO: Providence brace

3.3 Description of the Product

Therapeutic function

- Control of motion
- Correction of deformity
- Compensation for weakness.

Example: Motion control

Biomechanical control in the sagittal and coronal planes

Description of components, their function and alignment

- Interface components
- Articulating components
- Structural components

Material/s

Manufacturing process

Structural Design

- (e.g. pendulous abdomen design)
- Brand/Orthopedic Lab name
- Manufacturer year
- Manufacturer version number

Control of motion based on the therapeutic function

	Icon	Metal System	Plastic System	Biomechanical Control
FREE Motion				Coronal plane HOLD fixes Inversion/eversion; Sagittal plane = Free plantar/dorsiflexion
Dorsiflexion ASSIST				Coronal plane = HOLD if articulated; RESIST if non-articulated plastic; Sagittal plane = Dorsiflexion ASSIST
Plantarflexion STOP				Coronal plane = HOLD if articulated; RESIST if non-articulated plastic; Sagittal plane = Plantarflexion STOP
Dorsiflexion STOP				Coronal plane = HOLD if articulated; RESIST if non-articulated plastic; Sagittal plane = dorsiflexion STOP
Fixed Ankle				Coronal plane HOLD fixes inversion/eversion; Sagittal plane HOLD fixes plantar/dorsiflexion; Sagittal plane may be VARIABLE HOLD, if PF/DF attitude is adjustable

SECTION 4 – Description of data collection method

4.1 Description of procedures and tests

Describe data collection methods in details so they can be reproduced by any other researcher. Impression taking technique & measurements (e.g. plaster casting, scanning, 3D printing)

- Data collection instruments (e.g. questionnaire, motion analysis system, camera, measuring tape, stop watch)
- Data collection environment (e.g. indoor vs. outdoor, walkway, virtual simulator)
- Rationales for choosing these methods, instruments, etc.

4.2 Data analysis

- Data analysis instruments, tests & the rationales for choosing them
 - How prepared the data before analyzing (e.g. checking for missing data, removing outliers, transforming variables)
 - The software used to analyze the data (e.g. SPSS, Stata)
 - The statistical methods used (e.g. two-tailed t-test, simple linear regression)