ISO Performance Standards for Postural Support Devices
What should I know?

Kelly Waugh, PT, MAPT, ATP
Assistive Technology Partners
University of Colorado

Terms....
- ISO = International Organization of Standardization
- RESNA = Rehabilitation Engineering and Assistive Technology Society of North America
- PSD = Postural support device

A postural support device is a component of a body support system in a wheelchair that has a surface intended to contact the wheelchair occupant's body.

I. Introduction

Goal
Problem
Solution

What is “product performance”?

Regardless of your role, we all want to achieve:

- Quality outcomes
  - Improved health, comfort and function for the individuals we serve
  - Happy, satisfied customers
- Value = quality outcomes at a reasonable cost
ISO Performance Standards for Postural Support Devices: What should I know?

Problem

A trial and error approach to seating intervention dominates our industry

- How frequently do you find yourself replacing a postural support component within a year after delivery because it is “not working”?

Solution

To move away from this approach, need to make product decisions based on better information

- What is the crucial information that you need to make better choices about the products and strategies that will lead to improved outcomes and value for your clients?

Better data → Better choices → Better outcomes

- Don’t need MORE data, but BETTER data
  - About the person
  - About the products

- Need to know that chosen products will perform as expected

What is “product performance”?

- Product performance = how well does the product do what it was intended to do?

- What determines product performance?

Design, Quality and Application

- **Product design (features)**
  - Materials, shape, dimensions

- **Product quality**
  - Effected by design and construction
  - Goal is durability and safety

- **Product application**
  - Appropriate feature match to person’s needs
  - Appropriate sizing to match user’s body dimensions
  - Appropriate set up/configuration in wheelchair

Design, Quality and Application
ISO Performance Standards for Postural Support Devices:
What should I know?

ISO seating standards related to PSD performance and application:

**Body and Seat Measures:**
“Vocabulary, reference axis convention and measures for body segments, posture and postural support surfaces”

**PSD Performance:**
“Determination of static, impact and repetitive load strengths for postural support devices”

ISO Performance Standards for Postural Support Devices

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Lateral trunk support failure

Have you ever experienced failure of a postural support device – bending, breaking, slipping, tearing?

Lateral trunk support failure

How did this failure affect:
• Quality outcomes?
• Consumer satisfaction?
• Costs?

Pelvic belt slippage and need for frequent readjustment

• Constant hip extensor thrusting and movement
• Belt slips
• Being evaluated for power mobility using head array
• Wants to be more secure and stable

Improper set up of critical seating angles and dimensions

What happened??

Desired postural alignment achieved during shape capture

Poor postural alignment in new wheelchair and custom seating
Wouldn’t it be nice if you had known……

- That the lateral trunk support ordered would withstand the client’s high tone?
- That the belt you provided would not slip?
- That when the wheelchair was ready for delivery it was set up correctly to fit the client according to specifications determined at the evaluation?

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Current perceptions

What do you think of when you hear the word “standards” in the context of wheelchairs or wheelchair seating?

Wheelchair Seating Standards

Current perceptions

1. Standardized assessment process/methodology? NOT TRUE!!
2. Standardized prescription? YES!!
3. Standardized outcomes?
4. Standardized terminology to describe features? YES!!
5. Standardized testing for product performance/safety? YES!!

Standards development process

International cooperation

Standards development occurs at international and national level; goal is harmonization

International
- ISO = International Organisation of Standardization

National (examples)
- ANSI = American National Standards Institute
- BSI = British Standards Institution
- JISC = Japanese Industrial Standards Committee
- SAI = Standards Australia
ISO Performance Standards for Postural Support Devices: What should I know?

- **Standards development process**
  - National (U.S. example)
  - RESNA is accredited by ANSI to develop voluntary, national consensus standards related to Assistive Technology
    - Called RESNA American National Standards
  - As a general rule, initial and primary work done at ISO level
  - Then ISO standard is adopted as an American National Standard (after review, revision and voting)

- **Overview of relevant standards**
  - ISO Standards
    - ISO 7176 series, Wheelchair
    - ISO 16840 series, Wheelchair Seating
    - Wheelchair Transportation Safety
  - RESNA Wheelchair Standards
    - RESNA WC-1 & WC-2 (performance testing for manual & power wheelchairs)
    - RESNA WC-3 (Wheelchair Seating)
    - RESNA WC-4 (Wheelchairs and Transportation)

- **General characteristics of standards**
  - Developed to insure the safety and quality of products
  - Contain specific performance tests, or define terminology
  - Performance standards specify test methods that measure either product performance or product characteristics
  - All performance standards have disclosure requirements
    - what test results must be disclosed to the public?
  - Different types of tests and disclosure requirements

- **Types of performance tests**
  1. Tests that define minimum performance criteria (Pass/Fail)
    - Example: static and impact strength tests for wheelchair frame components
  2. Tests that produce quantifiable information
    - No minimum performance criteria
    - Test result is disclosed as a "performance value"
    - Example: wheelchair static stability test
  3. Destructive testing, or "load to failure"

- **More characteristics of standards**
  - VOLUNTARY!
  - They are regularly reviewed and revised
  - They allow comparison of products with respect to a specific feature or performance criteria
  - Often establish and define terms
  - They do not dictate a standard evaluation process or prescription outcome

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How tippy is the wheelchair?
ISO Performance Standards for Postural Support Devices: What should I know?

What we learned from the WC-19 standard

- Standard published first in the U.S. by RESNA, and then by ISO
  - RESNA Wheelchair Standards Volume 1, Section 19: Wheelchairs Used as Seats in Motor Vehicles

- WC19 is a voluntary industry standard for designing, testing and labeling a wheelchair that is ready to be used as a seat in a motor vehicle.

What we learned from the WC-19 standard

- Great example of a voluntary industry standard that evolved to become universally adopted by wheelchair manufacturers
  - Why? MARKETING PRESSURE
- Resulted in increased safety for wheelchair occupants

The POWER of wheelchair standards!

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ISO 16840 Series: Wheelchair Seating

- ISO 16840-1: Wheelchair Seating, Part 1: Vocabulary, reference axis convention and measures for body segments, posture and postural support surfaces
  - Part 1: Body and Seat Measures
- ISO 16840-3: Wheelchair Seating, Part 3: Determination of static, impact and repetitive load strengths for postural support devices
  - Part 3: Postural Support Device Performance

ISO 16840 Seating Standards

- Part 1: Body and Seat Measures
- Part 3: Postural Support Device Performance

Part 1: Body and Seat Measures

- Defines standardized terms for measurements of the seated person’s body, and for the wheelchair’s seating support surfaces
- Includes both angular and linear measures
- Supports a more accurate translation of body measures into seating prescription
- Improved communication – less errors
- Increased accuracy and efficiency
ISO Performance Standards for Postural Support Devices: What should I know?

**Part 1: Body and Seat Measures**

- Part 1: Vocabulary, reference axis convention and measures for body segments, posture and postural support surfaces
- ISO 16840-1 currently under revision

- Section 1: Vocabulary, reference axis convention and measures for body posture and postural support surfaces


**Examples of Body Measures**

- Thigh to Trunk Angle
- Frontal Sternal Angle

**Examples of seating measures**

- SEAT TO BACK SUPPORT ANGLE
- SEAT TO LOWER LEG SUPPORT ANGLE

**Improper set up of critical seating angles and dimensions**

Desired postural alignment achieved during shape capture

Poor postural alignment in new wheelchair and custom seating

What happened??

**Communication of key seating angles and dimensions is critical to successful outcomes, increased efficiency and reduced costs**

Effective seat depth = 18”
Seat to BS angle = 105
Seat to LLS angle = 75

Effective seat depth = 21”
Seat to BS angle = 105
Seat to LLS angle = 90
Improper set up of critical seating angles and dimensions

Costs:
- Client discomfort/complaint
- Day program disruption
- Early skin breakdown coccyx
- $3/hr client/caregiver time and travel costs
- $3/hr clinician time
- $2/hr RTS time
- $1/hr tech time
- Cost to replace posterior calf pad hardware

Let's get it right the first time!

Summary: ISO 16840 - Part 1
Body and Seat Measures

Incorporating standardized body and seating measurements into your practice can:
- Provide you with better information about your client and their seating support needs
- Help you to communicate critical seating parameters more accurately with your team
- Help you to get it right the first time

ISO 16840 Seating Standards

- Part 1: Body and Seat Measures
- Part 3: Postural Support Device Performance

- Part 3: Determination of static, impact and repetitive load strengths for postural support devices

Part 3: PSD Performance Standard

- Three types of tests: static, impact, repetitive load
- Specifies test methods for nine types of PSDs

<table>
<thead>
<tr>
<th>Static Strength Test</th>
<th>Impact Strength Test</th>
<th>Repetitive Load Test</th>
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<tbody>
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<td>Lateral supports</td>
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Part 3: PSD Performance What is it?

- Specifies test methods that provide information on the ability of a Postural Support Device (PSD) to withstand static, impact and repeated loads
- Establishes performance criteria for some tests; in other tests no minimum requirements currently specified

Part 3: PSD Performance Standard

- Three types of tests: static, impact, repetitive load
- Specifies test methods for nine types of PSDs

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<td>A specified load is applied one time for X seconds (load based on size of intended user)</td>
<td>A higher load is applied one time with a pendulum</td>
<td>A smaller load is applied repetitively, for 1000 cycles</td>
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Part 3: PSD Performance Standard

- Three types of tests: static, impact, repetitive load
- Specifies test methods for nine types of PSDs

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Basic concepts:
1. Tests designed to reflect a ‘worst case situation’, that is repeatable, and doesn’t destroy numerous wheelchairs in process
2. PSDs mounted on rigid test fixtures
   - To simulate mounting on a wheelchair
3. Static, impact and repeated loads applied to simulate normal usage
4. Test types: Pass/Fail; Disclose results; Destructive

Anterior pelvic/trunk support tests

Tests for anterior pelvic and trunk supports tell you whether or not a product meets defined performance criteria when subjected to loads during intended use.

- Pass/Fail

Set-up for static and repetitive load test
Anterior pelvic support

Set-up for static and repetitive load test
Anterior trunk support
Anterior pelvic/trunk support tests
Test process for static and repetitive loads

1. Set up
2. Apply pre-load
3. Measure position of loading pad as starting ref
4. Apply a specified test load (force/torque)
   - 1x for static, 1000 cycles for repetitive
5. Record type of failures, and force/torque at which it occurred
6. If no failure, record max displacement of loading pad (linear or angular)

7. Allow recovery (no load for 30 min)
8. Re-apply pre-load, and re-measure the “starting” position of loading pad
   - Difference indicates any displacement that has occurred from permanent deformation of product

Padded pelvic belt repetitive load test

Marking belt pre-testing

Measuring for slippage: PASS
ISO Performance Standards for Postural Support Devices: What should I know?

Flexible anterior trunk support repetitive load test

Anterior pelvic/trunk support tests

Failures

Examples of failure:
- Cracks, tears, broken stitches
- Slippage in position or adjustment of PSD more than 10mm
- Inability to achieve maximum load under specified test conditions

What can cause failures:
- Product quality or design
- Attachment points too wide
- Inappropriate sizing of product to the loading pad

Examples of failures

Failures will prompt manufacturer to make design improvements to improve product performance... The power of standards!

56mm of slippage

Grommet failure

Anterior pelvic/trunk support tests

Data

Information reported:
- Any failures and force/torque at which it occurred
- If no failure:
  - Maximum force/torque applied during testing
  - Maximum displacement of the loading pad under test load
  - Displacement resulting from permanent deformation of product (difference in position of loading pad pre and post)

What does the data tell you?
- Whether or not a product meets defined performance criteria when subjected to loads that mimic intended use
- Also provides quantifiable information that describes the elastic range of a product - helping with appropriate selection and application

Anterior pelvic/trunk support tests

Sample Test Report

To give you an idea of what a test report looks like, here is a sample test report for an anterior pelvic support from Bodypoint

Here is a sample test report for an anterior trunk support from Bodypoint

Pelvic belt slippage and need for frequent readjustment
ISO Performance Standards for Postural Support Devices: What should I know?

Pelvic belt tested to ISO/RESNA standard was provided

- No more belt slippage
- Stable pelvic position
- Increased comfort
- Increased functional control of head movements

Anterior pelvic/trunk support tests

What can you do?

1. Ask the manufacturer:
   “I want to make sure the pelvic belt I prescribe will not slip and is sized correctly for maximum performance. Are any of your belts tested to the ISO 16840- Part 3 standard?”

2. Understand the test results

3. Look for a label on products

Part 3: PSD Performance Standard

Tests for seats, back supports, lateral/medial supports, and arm/foot supports

These tests tell you how much force a PSD can withstand before it fails, such as how much force a lateral trunk support can withstand before bending or breaking.

Destructive/load to failure tests

Part 3: PSD Performance Standard

Tests for seats, back supports, lateral/medial supports, and arm/foot supports

Set up components

- Rigid test fixture

- Loading pads of specified shape and dimensions
  - Seat loading pad
  - Convex loading pad
  - Concave loading pad
  - Convex hemispherical loading pad

- Loading device (static, impact or repetitive)
ISO Performance Standards for Postural Support Devices: What should I know?

Tests for seats, back supports, lateral/medial supports, and arm/foot supports

**Test process for static, impact and repetitive loads**

- There are no minimum performance requirements, because we don’t know how much force people exert on these PSDs
- Increasing loads are applied until failure
- Disclose type of failure, and the load at which it occurred

**Head support static strength test**

Pre-load  Max load  Remove load

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**Tests for seats, back supports, lateral/medial supports, and arm/foot supports**

**Data**

Information reported:

- Maximum displacement of the loading pad
- Maximum force/torque applied
- Failures and force/torque at which it occurred

**What does the data tell you?**

- Can compare results between similar products
- Difficult to apply clinically, as we don’t yet know normal forces applied to these supports

**Tests for seats, back supports, lateral/medial supports, and arm/foot supports**

**What can you do?**

1. **Ask the manufacturer:**
   - “I need a lateral trunk support that withstands high forces. Are any of your lateral trunk support assemblies tested to the ISO 16840-3 standard?”
   - “What are the maximum forces that can be applied to your LTS assembly before failure?”
   - “Which one of your products will withstand a greater force?”

2. **Compare products**

**Summary: ISO 16840 Part 3**

**PSD Performance**

PSDs that meet minimum performance criteria and that hold up over time to different loads can

- Reduce cost of product replacement, repairs, and additional visits for adjustments
- Increase client safety
- Increase client/therapist/supplier satisfaction
- Improve outcomes and value

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Benefits of standards

• Terminology and measurement standards improve accuracy of product prescription and product application, as well as service delivery efficiency
• Performance standards help manufacturers design better products, because testing informs design (testing shows what can go wrong, how product performs best)
• Performance standards enable us to compare products wrt specific features
• Elevate level of professionalism in our field
• Encourage research

Seating standards can help to:

- Improve the design, quality and application of PSDs
- Improve product performance
- Improve overall client outcomes (the first time!)
- Improve value of products and services we provide

JOIN THE STANDARDS MOVEMENT!

- Become knowledgeable about standards.
- Spread the word about standards with your colleagues
- Volunteer to participate on a standards committee!

BE EMPOWERED!

- Go to courses to learn more about standardized body and seating measurement
- Ask manufacturers if they test their PSDs to the ISO 16840-3 standard
- Look for a label on products, such as this

Web Resources

http://www.iso.org/iso/home/standards.htm
http://www.resna.org/atStandards/
www.bodypoint.com/standards.aspx
ISO Performance Standards for Postural Support Devices:
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References


Questions/Discussion

Contact Info:
Kelly Waugh, PT, MAPT, ATP
Clinic Coordinator | Senior Research Instructor
Assistive Technology Partners
Department of Bioengineering | University of Colorado Anschutz Medical Campus
303-315-1951 / Kelly.Waugh@ucdenver.edu

Assistive Technology Partners
601 East 18th Avenue • Suite 130 • Denver, CO 80203
303-315-1280 • TTY 303-837-8964 • Fax 303-837-1208
www.assistivetechnologypartners.org • generalinfo@at-partners.org

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