Orthotic Management of Patients Post-Stroke: A Systematic Review of the Literature

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Stroke

- Fourth leading cause of death in United States (CDC, 2012)
- $18.8 billion in the United States for care
  - Additional $15.5 billion attributed to lost productivity and premature mortality (CDC, 2012)

Stroke - Treatment

- Medical Management
- Rehabilitation

Stroke - Rehabilitation

- Multifactorial: many different objectives
  - Prevent deformity
  - Improve function
    - Walking
    - Balance
    - Transfers
    - Reaching / grasping
- Orthotic management of patients post-stroke address many of these objectives

Orthoses

- Minimize contractures
- Improve joint position
- Increase joint stability
- Maximize functional movement
- Prevent/compensate for limb deformities

Objective

- While reports in the literature describe orthotic interventions, there is little agreement as to the best course of application of these treatments. It is the purpose of this systematic review to address the effectiveness of orthotic interventions for patients post stroke.

What is a *Systematic* Review?

- Search for research reports
  - Focus this search to include the most relevant research
- Grade the quality of the research methods
  - Assess the included studies for risk of bias
- Extract the information from included studies
- Synthesize this information to draw conclusions

Methods

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Data Sources

- RECAL Legacy database
- Cochrane Systematic Reviews and Clinical Trials
- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- MEDLINE (NLM database)
- Scopus

Search Terms

- Stroke
- CVA
- Cerebrovascular Accident
- Cerebral Vascular Accident
- Cerebrovascular Disorders
- Orthosis(es)
- Orthotic
- Orthotic devices
- Brace / Bracing
- Splint

Sample Search - MEDLINE

Searches	Query	Results
1	exp Cerebrovascular Disorders/ or cva.mp.	257199
2	exp Stroke/	74430
3	exp Splints/	7138
4	orthosis.mp.	1975
5	orthoses.mp. or exp Orthotic Devices/	9239
6	exp Braces/ or orthotic.mp.	9198
7	1 or 2	257199
8	3 or 4 or 5 or 6	17063
9	7 and 8	330

Study Selection: Inclusion Criteria

- Studies in peer-reviewed journals
- Published 1998 or later (last 15 years)
- English
- Included a population post-stroke
- Included an orthotic intervention

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Assessing Methodological Quality

- How well was the study designed?
  - Note: this is NOT the same as "How well did the intervention work?"
- We used the PEDro Scale
  - Based on the Delphi list developed by Verhagen (Verhagen et al. 1998)
  - This list is based on consensus, not empirical data

PEDro Scale

- Addresses both internal validity and interpretability of results
  - Internal validity: questions 2 - 9
  - Ability to interpret the results: questions 10 – 11
- Not necessarily a measure of the validity of the study's conclusion

PEDro Questions (yes/no)

1. Eligibility criteria were specified
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)
3. Allocation was concealed
4. The groups were similar at baseline regarding the most important prognostic indicators
5. There was blinding of all subjects
6. There was blinding of all therapists who administered the therapy
7. There was blinding of all assessors who measured at least one key outcome
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"
10. The results of between-group statistical comparisons are reported for at least one key outcome
11. The study provides both point measures and measures of variability for at least one key outcome

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Scoring on the PEDro Scale

- One point for every "yes" for questions 2-11
- Maximum score of 10
  - 9 – 10: "excellent"
  - 6 – 8: "good"
  - 4 – 5: "fair"
  - < 4: "poor"

- Each study scored independently by 2 raters

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Data Extraction

- Number of subjects
- Relevant inclusion and exclusion criteria
- Intervention being assessed
- Outcome measures used to assess the intervention
- Results found

Data Extraction

- Results were tabulated to assist in organization
- Separate tables were created to address different orthotic interventions and outcomes.

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Synthesis

- After all studies were tabulated, an overall conclusion based on the evidence was proposed.
- These conclusions were based on the Levels of Evidence initially proposed by the United States Agency for Health Care Policy and Research (AHCPR, now AHRQ, the Agency for Healthcare Research and Quality) as modified and described in the Evidence-Based Review of Stroke Rehabilitation (EBRSR, Teasell, 2012)

AHRQ Levels of Evidence

Level 1a (Strong)	Findings supported by meta-analysis if available, or by at least 2 RCTs of "fair" quality or better.
Level 1b (Moderate)	Findings supported by a single RCT of "fair" quality or better.
Level 2 (Limited)	Findings supported by at least one controlled trial with at least 10 subjects
Level 3 (Consensus)	In the absence of evidence, agreement by a group of experts on the appropriate course of treatment
Level 4 (Conflicting)	Disagreement between the findings of 2 or more RCTs.

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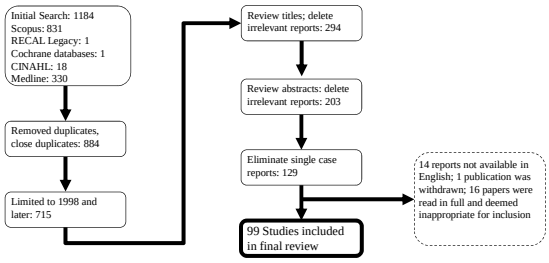
Results

Selection of Studies for Inclusion



Methodological Quality

- 85 studies scored on PEDro scale
  - None "excellent" (9-10)
  - 40 "good" (6-8)
  - 36 "fair" (4-5)
  - 9 "poor" (<4)
- Systematic Reviews cannot be scored on PEDro

What we found (finally!)

Lower Extremity Interventions

- Ankle Foot Orthosis (AFO)
- Functional Electrical Stimulation (FES)
- Knee Brace
- Hip-Knee-Ankle-Foot Orthosis (HKAFO)

Ankle Foot Orthosis

- 4 Systematic Reviews
- 3 Randomized Controlled Trials
- 43 Crossover Design Trials
- 1 "Methods" paper

Ankle Foot Orthosis – Gait

- 31 papers (3 RCTs) assessed gait with and without AFOs
- **There is *strong* (1a) evidence to support the use of AFOs to improve gait in patients post-stroke.**

Ankle Foot Orthosis – Balance

- 11 papers (1 RCT) assessed some measure of balance with and without AFOs
- **There is *conflicting* evidence on the use of AFOs to improve balance in patients post-stroke.**
  - 1 high-quality RCT found no difference in FRT or TUG scores
  - Several of the crossover studies (with good PEDro scores) found improvements in BBS, TUG and instrumented balance measures (e.g., BalanceMaster)

Ankle Foot Orthosis – Energy

- 10 papers (1 RCT) assessed some measure of energy expenditure with and without AFOs for patients post-stroke
- **There is *moderate* evidence to support the use of AFOs to decrease energy cost of walking post-stroke.**

Ankle Foot Orthosis - Muscle Activity

- 6 papers assessed muscle activity related to tone or spasticity
- **There is *limited* evidence that AFO use**
  - **decreases tibialis anterior muscle activity during swing.**
  - **decreases plantar flexion during swing.**
  - **has no effect on measures of spasticity.**

Ankle Foot Orthosis – Type of AFO

- **There is *limited* evidence that the type of AFO (anterior vs. posterior; dynamic vs. not dynamic) has no effect on gait (walking speed, endurance, energy consumption).**
- We'll discuss this in a few minutes…

Functional Electrical Stimulation (FES)

- 2 Systematic Reviews
- 1 Randomized Controlled Trial
- 9 Crossover Design Trials
- 1 Descriptive Study

FES – Gait

- 12 papers (1 SRL, 1 RCT) assessed gait with and without FES; all used peroneal nerve stimulation.
- **There is *strong* (1a) evidence that FES improves gait speed.**
- **There is *moderate* evidence that FES improves cadence.**
- **There is *limited* evidence that FES improves gait symmetry.**

FES – Energy Consumption

- **There is *insufficient* evidence to assess the effect of FES on energy consumption in patients post-stroke**
  - Some crossover studies found an effect, but populations in those studies were a mixture of CVA and non-CVA
  - Other studies found no effect

FES – Overall function

- **There is *limited* evidence that FES improves overall function (e.g., SF-36 scores, SIS scores) in patients post-stroke.**

Knee Bracing

- 1 study assessed gait with and without a knee brace
- **There is *limited* evidence that bracing the knee may increase walking speed in patients post-stroke.**

Hip-Knee-Ankle-Foot Orthosis

- 2 studies assessed gait with and without an HKAFO
- **There is *limited* evidence to support the use of a hip flexion assist orthosis to increase walking speed in patients post-stroke.**

Upper Extremity Interventions

- Wrist-Hand Orthosis (WHO)
- Shoulder Orthosis / Strapping
- Compression Garments
- Arm Sling
- Functional Electrical Stimulation (FES)

Upper Extremity Orthoses

- 5 Systematic Reviews
- 10 Randomized Controlled Trials
- 5 Crossover Design Trials
- 2 Pre-post Cohort studies
- 1 Case Series

Hand Splinting

- **There is *strong* (1a) evidence that hand splinting:**
  - **does not improve impairment nor reduce disability.**
  - **does not reduce the development of contracture nor reduce spasticity.**
- **There is *moderate* evidence that hand splints have no effect on balance in patients post-stroke.**

Shoulder Orthosis / Strapping

- **There is moderate evidence that a shoulder orthosis may decrease Shoulder-Hand Syndrome in patients with subluxation of the shoulder.**
- **There is conflicting evidence that strapping the hemiplegic shoulder reduces the development of pain.**
- **There is moderate evidence that strapping does not improve upper limb function or ROM.**

Compression Garments

- **There is limited evidence to support the use of compression garments during exercise to decrease distal swelling and improve wrist posture in patients post-stroke.**

Arm Sling

- **There is limited evidence to support the use of an arm sling to increase walking speed and improve gait symmetry in patients post-stroke.**

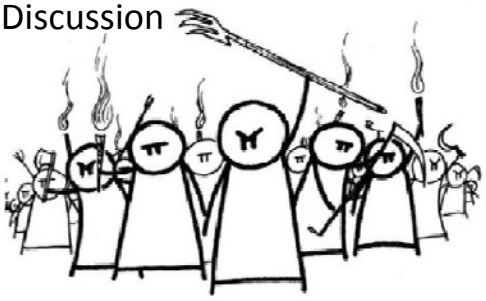
Upper Extremity FES

- 2 Systematic Reviews
- 2 Randomized Controlled Trials
- 3 Pre-post Cohort studies
- 1 Crossover Trial

Upper Extremity FES

- **There is *strong* (1a) evidence to support the use of FES at the shoulder to reduce subluxation.**
- **There is *moderate* (1b) evidence that UE FES:**
  - **can reduce spasticity and improve motor function.**
  - **is not effective for preventing contractures.**
  - **may improve functional performance in the upper extremity.**

Discussion



Before you rush the podium…

A lack of definitive evidence ≠ A treatment does not work

A return to slide 37: What does this mean?

Ankle Foot Orthosis – Type of AFO

- **There is *limited* evidence that the type of AFO (anterior vs. posterior; dynamic vs. not dynamic) has no effect on gait (walking speed, endurance, energy consumption).**
- **We'll discuss this in a few minutes…**

What it means:

- Limited evidence: "Findings supported by at least one controlled trial with at least 10 subjects" (that is, not an RCT).
  - In this case, exactly 1 comparing anterior and posterior AFOs
- In all other studies, compared with and without an AFO (whatever type they were looking at) – no "head-to-head" comparison

The impetus for this review:

- To inform a Working Group developing clinical practice guidelines for the use of orthotic interventions post-stroke.
- To best accomplish this task, we have to start with the highest quality evidence regarding the effectiveness of these interventions.

Comprehensive Search for Evidence

- Comprehensiveness check: we independently identified almost all of the relevant individual studies that had been included in previously published systematic reviews.
- We are confident that the studies included in this review comprehensively cover orthotic management of the patient post-stroke.
- 14 identified studies were not available in English, and obtaining translations was not feasible.
- We recognize that there are studies that have not been included here.

Limitations regarding inclusion criteria

- Our search was limited to those studies published since 1998, and did not consider case reports or case studies.
- Consequences
  - Well-established clinical practice may be excluded.
  - Newly developed interventions may not appear yet.
  - "Foundational" papers older than 15 years excluded.

Assessment of methodological quality: the PEDro scale

- The scale was originally developed to assess RCTs. In this case, we also applied it to case-control and crossover studies.
  - The scale has been adapted to fit these cases – e.g.: to answer the question "Were subjects randomly assigned to groups?", one is instructed to answer yes if, for a crossover study, the order in which treatments were applied was randomly assigned.
  - However, for a pre-/post-test trial, where a subject is evaluated before and after treatment, this criterion cannot be met.
  - The vast majority of the studies included in this review were not randomized controlled trials; thus, PEDro scores will be lower.

Assessment of methodological quality: the PEDro scale

- Blinding:
  - Orthotic interventions tend to be obvious; it is difficult to blind either the subject wearing the orthosis or the clinician/therapist evaluating performance.
  - Three of the 10 points on the PEDro scale are awarded for blinding; this is why almost no studies in our review scored higher than a 7.

Variety of Outcome Measures

- A plethora of outcome measures are used to assess the effects of orthotic interventions.
  - They run the gamut from the electrophysiologic (H-reflex) to walking velocity to muscle activation patterns to energy consumption to participation in activities of daily living.
- Goals such as prevention of disability (skin breakdown, contractures, falls) are difficult to measure without a control group and a long study duration.

Variety of Outcome Measures

- There is no general agreement on the most relevant outcome measures, or those clinically measureable parameters which best correlate to function and community integration.
  - Even in an area as specific as "gait", there are dozens of parameters included as outcome measures in the studies included in this review.
- No attempt was made in this review to identify the most relevant/sensitive/meaningful outcome measures.

What does "strong" mean?

- Terms such as "strong evidence" and "limited evidence" are qualitative, subjective assessments of the body of knowledge.
  - This review has attempted, in certain cases, to qualify statements regarding effectiveness.
- According to the AHCQR guidelines used in this review, non-randomized studies can provide at best "limited" evidence.
  - One might consider a preponderance of non-randomized clinical trials which all show agreement in outcomes as providing more than "limited" evidence.

Conclusion

- We aren't at the conclusion yet.
- This review serves to identify the current evidence regarding orthotic interventions
  - Effectiveness of interventions in some areas has been demonstrated
  - Helps to identify areas where future studies are needed

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QUESTIONS?