The Effectiveness of Serial Casting & Ankle Foot Orthoses in Treating Children with Autism Spectrum Disorder

IRB & CTSC GRANT
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Acknowledgements

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Timeline

1st Case Report

2nd IRB

3rd Grant

4th Research project

5th Alternative Funding Opportunities
Gait deviations in children with autism spectrum disorders: a review

Kindregan, D., Gallagher, L., & Gormley, J. (2015)

Reduced:
- Stride length
- Peak ankle PF and hip flexion moments
- Knee flexion-extension at toe-off
- Step length
- Ground reaction forces
- Ankle DF and knee extension at initial contact

Increased:
- Wide base of support
- Stance time
- Step width
- Cadence
- Variability in stride length (especially when using visual cues) and stride time
- Hip flexion at toe-off
Comparative gait analysis between children with autism and age-matched controls: analysis with temporal-spatial and foot pressure variables

Lim, B. O., O’Sullivan, D., Choi, B. G., & Kim, M. Y. (2016)

- 15 children with ASD matched with 15 children not diagnosed with ASD
- Average age of 11

Results:

- Reduced cadence, gait velocity, and step length in ASD
- Increased step width in ASD
- Decreased active pressure areas in hindfoot in ASD
  - Due to characteristics of a flat foot that is often associated with ASD
Background

- Toe walking – Absence of heel strike during initial contact of gait cycle & inability to obtain full contact during the stance phase of gait cycle (Van Kuijk AAA, 2014)

- Toe walking is often associated with a variety of neurological disorders including: Cerebral Palsy, myopathy, neuropathy and ASD (Shulman LH, 1997)

- Furthermore, 68% of children with ASD in this study exhibited some type of gait abnormality (Shetreat-Klein M, 2014)

- Incidence of persistent toe walking lasting longer than 3 months is reported to be 20.1% in children with ASD (Barrow, W. J., Jaworski, M., & Accardo, P. J. (2011))

- Clinical care guideline exclude non-idiopathic causes of toe walking (Le Cras S, 2011)
No consensus regarding most effective treatment for this population

Interventions include: observation, orthoses, serial casting, motor control interventions and augment auditory feedback

Serial casting is a safer and less costly intervention than surgery

Serial casting has been found to be effective in increasing passive ankle dorsiflexion range and improving EMG gait variables in children with idiopathic toe walking (ITW) (Le Cras S, 2011).
Kinematic Gait Changes Following Serial Casting and Bracing to Treat Toe Walking in a Child with Autism: A Retrospective Case-Report (Barkocy, 2017)

- 7 y/o male, non-verbal and diagnosed with ASD
- Intervention: Serial casting & AFOs
- Baseline measurements:
  - Walked on his toes
  - -23 degrees of DF on the right and -18 degrees DF on the left
  - Navigated stairs side-ways with two hands on rails at all times
  - Could not perform backward or side stepping without falling
Before Intervention

After Intervention

Increase of passive DF from -23 to -6 on left and -18 to -8 on right
IRB
What is an IRB?

- Institutional review board
- A type of committee used in research in the United States that has been formally designated to approve, monitor and review biomedical and behavioral research including humans
- Often conduct some form risk-benefit analysis
- Purpose: To assure steps are taken to protect the rights and welfare of humans participating as subjects in a research study
How to Write an IRB Application

** Citi training certification**

- Purpose of investigation and procedures
- Anticipated risks and benefits for participants
- Steps taken to protect participants
- Manner of obtaining participants
  - Flyer
- Informed consent
  - Consent form
- Edits: All changes to IRB must be tracked
  - 6 versions before being approved
Objective

- To determine the effectiveness of serial casting and ankle foot orthoses (AFOs) on gait patterns for children with Autism Spectrum Disorder (ASD) who toe walk.
- 3-D gait analysis will be used to assess improvements of ankle rocker range of motion during gait.
Hypothesis

That a series of interventions (serial casting and AFOs) will improve clinical outcomes as well as create functional ankle rocker during gait through increased range of motion of ankle dorsiflexion in children with ASD
Serial Casting/AFOs

- A conservative treatment for muscle elongation
- Low load, long duration stretch to tight gastrocnemius muscle
- Increased ankle dorsiflexion range of motion
- Need to be followed by braces, including AFOs to maintain over time
3D Gait and Motion Analysis

- Tool utilized to assess kinematic and kinetic gait parameters in children who exhibit gait deviations
- Compare gait parameters pre and post intervention
- Ten camera Vicon Gait Analysis System using Vicon Nexus Software
Subjects

Inclusion

- 5-16 years old
- Diagnosis of ASD per parent report
- Demonstrate toe-walking (have limitation in ankle dorsiflexion range of motion)
- Able to walk independently without assistive device
- Able to follow commands
- Consent from parents/legal guardians

Exclusion

- History of surgery for toe walking
- Previously or currently being treated for toe walking
- Unable to walk minimum of 500 yards independently
Subjects Cont’d

- Recruitment: Sample of convenience
  - Flyer
  - Word of mouth
- Total number = 6
  - Avoid Type II errors
  - General attrition rate in a clinical trial, approximately 20%, was applied
Research Setting/Resources

- Research will be performed on the UNM HSC campus in the UNM Center for Gait and Motion Analysis lab.
- Treatment will take place at Explor Abilities for serial casting and Advanced Prosthetics and Orthotics for orthotics fabrication and fitting.
- All treatment interventions will be billed through patient’s third party payers.
- The patient is responsible for any deductibles or co-pays for these interventions if necessary.
Outcome Measures

- Anthropomorphic (height, weight, leg girth, and bony landmark distance measurements needed for computer calculations)
- Goniometric measurement (ankle, knee and hip passive range of motion)
- Pediatric Outcomes Data Collection Instrument (PODCI) Pediatric or PODCI Adolescent
  - Questionnaire that assess parent/child perception of mobility
  - PODCI Pediatric 2-10 y/o & PODCI Adolescent 11-18 y/o
- Functional Mobility Scale
  - Walking ability over progressively longer distances
- Patient Specific Function Scale
  - Scale to assess change
Study Timeline

Total of 1 year

Phase I: 4-6 weeks for enrollment

Phase II: Consent and screening
- Outcomes & Gait capture: Baseline 1
- Gait capture: Baseline 2 - 2 weeks post baseline 1

Phase III: Casting 2-6 weeks (will vary based on degree of contracture and responsiveness to casting)
- Gait capture

Phase IV: Orthoses 6 months
- Outcomes & Gait capture

Phase V: Analyze data 1 month
Data Analysis

- Repeated ANOVA
  - Hypothesize our primary outcomes (range of motion, kinematics and kinetics of ankle during gait) will show a normal distribution
- Alpha level of 0.05
- **Non-parametric tests if data show heterogeneous**
Grant
The Clinical and Translational Science Center (CTSC) of the University of New Mexico (UNM) Health Sciences Center (HSC) grant will support pilot projects that utilize CTSC infrastructure to produce preliminary data for competitive National Institutes of Health (NIH) grant proposals in clinical and translational research.

- Applied in January
- Denied in March
Focus Areas

- Abstract
- Generalizability
- Translational Research
- Research Plan
Grant Feedback

- Uncertain of the long term negative significance of toe walking as a medical problem
- No control group: “a major flaw”
- Inadequate sample size
- Possibility of external funding is limited
- Scoring Breakdown:
  - Innovation: 10%
  - Significance: 10%
  - Approach, Environment, and Investigator: 30%
  - Plan for and probability of extramural funding: 30%
  - Utilization of CTSC Resources: 20%.
Possible Alternative Funding

- RAC Grant
- Autism Speaks Grants
- APTA Grants
- Foundation for Physical Therapy: Pediatric Research Grant
Where is the Study Now?

- Continuing to recruit subjects
- Start casting in Summer 2017
- Proceed without funding but will apply for future grants
What We Learned

- How to perform literature review
- Coordination with other team members
- How to utilize feedback to improve future research
- How to write, edit and submit an IRB & grant
- The process of possibly developing a clinical practice guideline (CPG)
- Participating in research is very rewarding
References

- Barkocy, M., Dexter, J., Petronovich, C. Kinematic Gait Changes Following Serial Casting and Bracing in a Child with Autism who Exhibits Toe Walking- A Chart Review Case Report (Accepted for publication spring 2017 in Pediatric Physical Therapy)


Questions?