Gait Analysis in the study of movement disorders and the plantar sensory stimulation device “Gondola” in the treatment of infantile cerebral palsy

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1. Gait analysis and its clinical use
2. The experience of G. Albertini Gait Analysis Lab of IRCCS San Raffaele Pisana.
3. The Automatic Mechanical Plantar Stimulation (Gondola) in cerebral palsy
San Raffaele Clinic and Research Institute dedicated to Rehabilitation.

Department for Rehabilitation of Developmental Disabilities:
Developmental Disabilities
Clinical conditions caused by early brain damages

- Prenatal
- Perinatal
- Postnatal
Developmental Disabilities

Clinical symptoms:
- motor problems
- intellectual disabilities
- both
Why a Movement Lab in such a Clinic?
Why a Movement Lab in such a Clinic?

Rehabilitation for both motor and cognitive problems
Movement: cognitive function
Posture, movement and functional limitation

In pathology:
1) Biomechanical problem
2) Alterations in the mechanism of task programming
The clinical needing

Integration of biomedical, physiological and educational aspects with a multidisciplinary approach (family and person oriented) in a life span prospective according to the principle of EBM
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Integration of biomedical, physiological and educational aspects with a multidisciplinary approach (family and person oriented) in a life span prospective according to the principle of EBM.

Instruments to quantify the outcomes of an educational and/or rehabilitative and therapeutically different type of treatment.
Gait analysis Lab

Optoelectronic system - kinematic

Platform - kinetic

Video cam – video analysis

EMG – muscular activity

Multifactorial quantitative evaluation of human movement
Data analysis
Characteristics of the measurements in rehabilitation

According to the Joint Commission on Accreditation of Health Care Organization (JCAHO) the tests and the equipment for the functional evaluation have to be:

“Practical, easy to use, insensitive to outside influences, inexpensive and designed for efficient administration”

To improve the decision making plan

To improve the treatment outcomes evaluation
TOOLS

Standard Tests
Clinical scales, Video analysis
Limits: subjective, not reliable, not consistent, not sensible

Instrumented evaluation
The advantages of movement quantification.

Flexion-Extension, internal external rotation abd-adduction of main joints.
Kinematic  Kinetics  EMG  Video

Multifactorial analysis
Gait analysis is a tool

- Understanding Biomechanics
- Diagnosis and Treatment Planning
- Assessing Outcome
Gait Analysis is a Tool (Gage, 2007)

Specifically it’s a measurement tool, like a carpenter’s measuring tape.

– The tape doesn’t tell the carpenter how to build a house – that knowledge lies within the carpenter
– But he can’t build a home without it!
Computerized gait analysis information modifies the surgical treatment recommendations for patients with CP in about half of the patients evaluated (DeLuca, 1997)
The introduction of Gait Analysis has radically changed the treatment of CP (Lee, 2000)

pre-treatment → More precise and complete evaluation of the pathology

post-treatment → Accurate analysis of the results
No other clinical evaluation is so able to evaluate the effectiveness of the treatment (Gage, 1991)

Without gait analysis, there is no way to assess accurately the results of a treatment (Novacheck, 1998)
The quantification of gait in CP

To monitor the patient locomotor alterations

To evaluate treatment outcome

To evaluate decision making
The experience of IRCCS SAN RAFFAELE Lab

IRCCS San Raffaele Pisana
Rome, Italy

Dipartimento di Scienze delle Disabilità Congenite ed Evolutive, Motorie e Sensoriali

1997

Dipartimento Elettronica, Informazione e Bioingegneria
Laboratorio di Analisi del movimento
“Luigi Divieti”
Gait Analysis lab of IRCCS San Raffaele Pisana

GA Database of 9700 GA sessions for clinics and research in a follow up of 20 years
Neurological and ethiological factors: IRCCS San Raffaele CP population

1975 subjs
(from 1997)
Neurological and ethiological factors: IRCCS San Raffaele CP population
Cerebral palsy:

Most common cause of physical disability in children (2.0 ±2.5 per 1000 live births).

Motor problems:

Primary:
directly related to the lesion in the CNS influencing muscle tone, balance, strength, and selectivity

Secondary:
static muscle contractures and bony deformities develop slowly over time in response to the primary problems and to growth (Gage, 2004).
Walking rehabilitation of cerebral palsy:

• Physiotherapy (including stretching, strengthening, and motor training)
• Orthoses,
• Serial casting,
• Electrical stimulation,
• Intramuscular injections of botulinum toxin type A (BTX-A) or phenol,
• Orthopedic surgery.
Walking rehabilitation of cerebral palsy:

Recently, non-invasive rehabilitation strategies for children with CP are developed and used to improve motor function, based on peripheral stimulation of the sensory-motor system and neuroplasticity.
From manual to automated treatment

**MANUAL**

- unprecise stimulated areas,
- variable stimulation pressure,
- irregular stimulation time

**AUTOMATED**

- precise stimulated areas,
- reproducible stimulation pressure,
- controlled stimulation times, cycle
- designed for regular home use

Dynamometer used in the proof of concept study (Barbic et al 2014)
Automated Mechanical Peripheral Stimulation (AMPS) treatment.
Automated Mechanical Peripheral Stimulation (AMPS) treatment.
What’s “Automated Mechanical Peripheral Stimulation” (AMPS)

AMPS is a peripheral – plantar – stimulation delivered by a dedicated device, known as Gondola (Gondola Medical Technologies SA, Switzerland).
“Automated Mechanical Peripheral Stimulation” (AMPS)

Data from literature
“Automated Mechanical Peripheral Stimulation” (AMPS)

Data from literature: Gondola and Parkinson Disease
<table>
<thead>
<tr>
<th>Authors</th>
<th>Title</th>
<th>Journal, year</th>
<th>Main results</th>
</tr>
</thead>
<tbody>
<tr>
<td>M. Galli, A.F.R. Kleiner, M. Gaglione, P. Sale, G. Albertini, F. Stocchi, M. F. De Pandis</td>
<td>Timed Up and Go test and wearable inertial sensor: a new combining tool to assess change in subject with Parkinson’s disease after automated mechanical peripheral stimulation treatment</td>
<td>International Journal of Engineering and Innovative Technology (IJEIT), 2015</td>
<td>Improvement in <strong>TUG test</strong>, in the <strong>duration of the going phase and returning phase</strong>, in the <strong>velocity of the sub-movements performed during the test</strong></td>
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<td>A.F.R. Kleiner, M. Galli, M. Gaglione, D. Hildebrand, P. Sale, G. Albertini, F. Stocchi, M. F. De Pandis</td>
<td>The Parkinsonian Gait Spatiotemporal Parameters Quantified by a Single Sensor before and after Automated Mechanical Peripheral Stimulation Treatment</td>
<td>Parkinson’s Disease, 2015</td>
<td>Improvement of <strong>gait velocity, stride length, propulsion. The worse is the clinical status, the bigger is the improvement of stride length</strong></td>
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Clinical Study

The Parkinsonian Gait Spatiotemporal Parameters Quantified by a Single Inertial Sensor before and after Automated Mechanical Peripheral Stimulation Treatment

Ana Kleiner,° Manuela Galli,° Maria Gaglione,® Daniela Hildebrand,® Patrizio Sale,® Giorgio Albertini,® Fabrizio Stocchi,® and Maria Francesca De Pandis®
Clinical Study

The Parkinsonian Gait Spatiotemporal Parameters Quantified by a Single Inertial Sensor before and after Automated Mechanical Peripheral Stimulation Treatment

Ana Kleiner,1,2 Manuela Galli,1,3 Maria Gaglione,4 Daniela Hildebrand,5 Patrizio Sale,3 Giorgio Albertini,3 Fabrizio Stocchi,3 and Maria Francesca De Pandis4

Figure 3: Correlation observed between the PD clinical status (H&Y) and the stride length percentage of improvement (stride length %) after AMPS.
Gondola and the Brain (in Parkinson Disease)

RESEARCH ARTICLE

Acute Modulation of Brain Connectivity in Parkinson Disease after Automatic Mechanical Peripheral Stimulation: A Pilot Study

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Gondola and the Brain (in Parkinson Disease)

Flowchart of the experimental protocol of the pilot interventional study (approved by the LEC)
Results show a consistent effect of AMPS on increasing Resting State Functional Connectivity (RSFC) of brain regions involved in

- visuo-spatial integration and processing
- sensory-motor integration
- anticipation of body position during movements

Fig 3. Z-statistic images showing clusters of significantly increased RSFC (p < 0.05, cluster-level FWE corrected) after one session of effective AMPS of the primary sensory motor cortex (a), the nuclei striati (c) and the cerebellum (d), overlaid onto a MNI-registered anatomical 3D-T1 volume. Seed regions of interest are red-coloured in the panels on the left. MNI coordinates (x, y, z) of the maximal Z-scores are presented in *Table 2*. Coronal and axial views follow the neurological convention.
The Gondola Treatment Rationale in Cerebral Palsy

Several clinical studies have documented that AMPS therapy is effective in improving motor skills in Parkinson’s: slowness of movement, small steps and balance problems.

Our hypothesis is that this treatment, which is not invasive and it has been demonstrated to be useful to reorganize the motor control, could be effective also in children with CP.
The treatment consists in the application of a pressure via rounded stimulation tips in four specific target areas in patient’s feet.
• device adjusted to patient’s feet
• feet supports (L – R)
• electrical motors for two 2 mm actuated steel bars
• the motor-activated stimulators apply a mechanical pressure in two specific areas of each foot.
The pressure of stimulation, always applied in a range of 0.3–0.9 N/mm², is set for each subject upon appearance of the reflex in the Tibialis Anterior muscle by the detection of a liminaris contraction while applying pressure in the contact areas.
**STIMULATION POINTS:**
the head of the hallux, the base of the hallux (between the sesamoid bones).
Gondola in Infantile Cerebral Palsy: the San Raffaele Research Project

A first goal of this project is to investigate the changes after AMPS treatment, in terms of the walking ability and functional recovery through spatio-temporal parameters, 3D joints kinematics, kinetics and traditional clinical scales in Cerebral Palsy.

Specifically, in this study we will compare the biomechanical parameters of gait of children with CP who were treated with AMPS associated to traditional rehabilitative program (AMPS Group) versus a group of children with CP who received a traditional rehabilitative program (Control Group).
Gondola in Infantile Cerebral Palsy: the San Raffaele Research Project

Primary Outcome Measures: change in the walking velocity between AMPS Group and Control Group.

Secondary Outcome Measures: stride length; cadence; Gait Profile Score
Gondola in Infantile Cerebral Palsy: the San Raffaele Research Project

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Measured by Gait Analysis
Gondola in Infantile Cerebral Palsy:
the San Raffaele Research Project

Inclusion criteria:
Diagnosis of CP
Male/Female;
Age: 9-18 years;
Written informed consent.
Able to walk 10 meters unassisted or with minimal assistance
Shoe size higher than 37
Had not had botulinum toxin injected into the lower limbs within 6 months prior to the assessment or casts on these levels
No previous selective dorsal rhizotomy or Baclofen pump
Cooperative for Gait analysis acquisition.
Gondola in Infantile Cerebral Palsy:
the San Raffaele Research Project

Exclusion criteria:
Skin abrasions on the feet
Sensitive skin of the feet
Strong feet deformations
Shoe size lower than 37
Gondola in Infantile Cerebral Palsy: the San Raffaele Research Project

Workplan:

WP1 patients’ recruitment (month 1 to 5)
WP2 T1 assessment with clinical scales and gait analysis (month 1 to 6)
WP3 patients’ treatment (month 2 to 7)
WP4 T2 assessment with clinical scales and gait analysis (month 3 to 8)
WP5 T3 assessment with clinical scales and gait analysis (month 4 to 9)
WP6 data elaboration and analysis (month 4 to 11)
WP7 statistical analysis (month 9 to 11)
WP8 Final report (month 11 to 12)
Gondola in Infantile Cerebral Palsy: the San Raffaele Research Project

...ready to go
Thank you for your attention