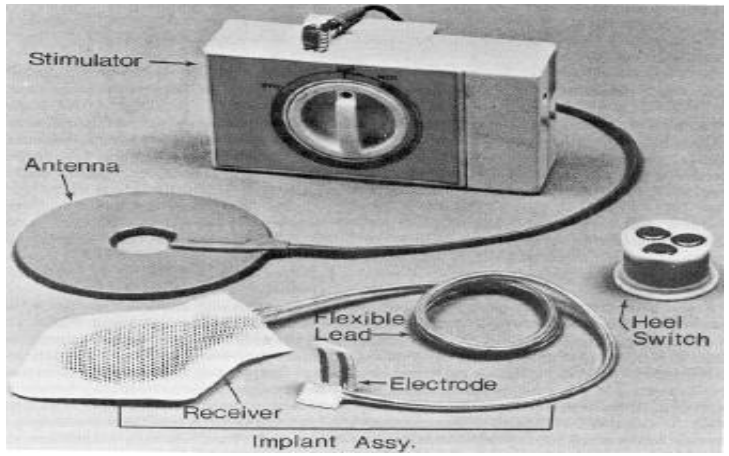
Functional Electrical Stimulation (FES) Treatment for Drop Foot

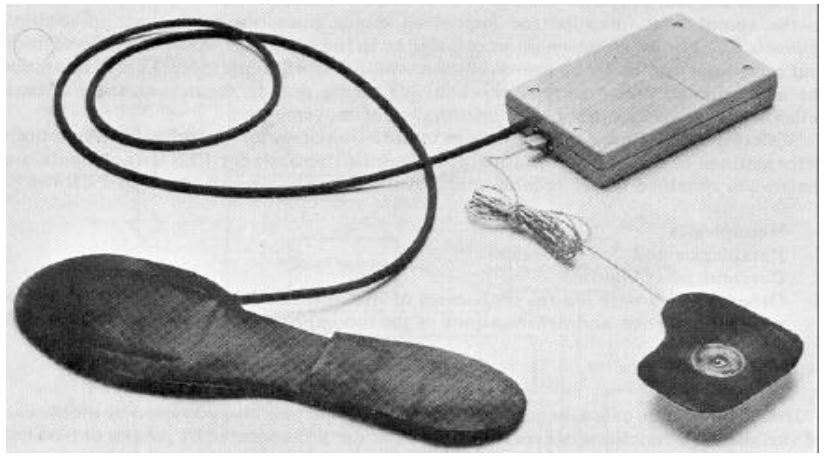
- History of FES and Support for FES
- Research Evidence
- FES Technologies for Drop Foot
- Therapeutic Effects and Use
- Clinical Use and Outcomes

History of Functional Electrical Stimulation (FES) & Support for Lower Extremity FES

FES - A Neuro Rehabilitation Tool for Decades

- Previously there were preferred conventional alternatives (i.e. AFO)
- Cost-benefit ratio was better for AFOs
- Reliability of FES was low
- Complexity of FES was high
- The devices were large and heavy; the electrodes messy and uncomfortable
- Cosmesis of FES was poor





FES - A Neuro Rehabilitation Tool for Decades

Reasons for Increased Clinical Use

- Changes in types of stimulation have improved comfort and performance.
  - Waveforms are more similar to physiologic electrical activity.
  - Stimulation is more comfortable and less fatiguing.
- Improvements with lower extremity FES systems have increased reliability and create custom gait programs for patients.
- A tremendous amount of engineering and platform enhancements have created technology that is efficacious, durable, comfortable, easy to use and safe.

Neuroplasticity

- CNS after injury has all the tools necessary to restore function, but no plans on how to do it.
- Plans have to be supplied.
  - They may be provided through:
    - Functional training
    - Tone management
    - Facilitation of proper movement synergies
- Plans have to be correct.
  - Training must be:
    - Functional
    - Task specific
    - Providing appropriate proprioceptive and kinesthetic cues
  - Passive support, PROM and mass activation of muscles with NMES are not sufficient.

Therapeutic Effects - AFO vs. FES Neuroprosthesis

	AFO	FES
Improve stability	●	●
Improve mobility	●	●
Improve strength & endurance		●
Reduce/delay/reverse muscle atrophy		●
Increase circulation		●
Reduce hypertonicity		●
Maintain/increase range of motion		●
Maintain/increase bone density		●
Muscle re-education & facilitation		●
Treat entire neuro musculoskeletal system		●

Support for Lower Extremity FES Outcomes

FDA listing for possible benefits of FES:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

Outcomes Noted in the Literature

- Decrease in Abnormal Tone
  - Measured by physiologic measures of spasticity (EMG, H Reflex and M Wave Ratio) and by clinical measures (MAS, Fugel Myer Score)
- Neuroplastic Changes
  - Measured by changes in motor evoked potentials, cortical activation, and spinal reflex activity
- Changes in Other Systems
  - Cardiovascular function, bone density, muscular atrophy

Support for FES Outcomes
Improved Gait Outcomes Post FES

- Increased gait speed
  - Support is strongest for this outcome.
  - Speed changes have been seen in all populations over ground, on treadmill, and with subjects' preferred speed.
  - Speed improvements have been noted over short distances (10 and 25 meter tests) and over longer distances (3 and 6 minute walk tests) suggesting that the improvements are functional and relate to greater endurance as well.
- Increased symmetry of swing and stance phases
  - Changes seen most often are increased step and stride length.
  - Outcomes with less support include stride width variability, stride time measures and inter limb coordination scores.

Support for FES Outcomes
Improved Gait Outcomes Post FES

- Improved balance/functional ambulation
  - Balance is rarely investigated directly.
  - Three studies have used Timed Up and Go (2 used the TUG component of the Modified Emory Functional Ambulation Profile); other indirect measures used were Barthel Index and gait component of the Tinetti gait scale.
- Increased endurance/decreased physiological cost
  - Moderate support is in the literature for this outcome.
  - Several studies have found a decrease in the Physiological Cost Index, an indirect measure of gait "effort".
  - One MS study used true respiratory measures and found a decrease in oxygen uptake per unit distance walked with FES.
  - Several studies have found improved distances in the 6 Minute and 3 Minute Walk tests.
  - Several studies have indicated better compliance, increased wearing times, enhanced QOL measure and a preference to FES over an AFO.

Support for FES Outcomes
Facilitation of Neuroplastic Changes

- Carry over effects post FES
  - These have been noted since the original peroneal nerve stimulation study was done in 1961.
  - No “dose-response” trends have been found due to the wide ranges in study protocols.
- Improved motor evoked potentials
  - There are two studies that directly document cortical changes in patients post peroneal nerve FES (measured with transcranial magnetic stimulation).
- Normalized spinal reflexes
  - Two studies have shown normalization of spinal reflexes (most notably restored Reciprocal Inhibition) after FES. These studies suggest that the spinal cord’s plasticity and its role in gait are stronger than previously thought.
- Normalization of cortical activation patterns
  - Transcranial magnetic stimulation has documented cortical changes, specifically re-activation of areas lost post brain insult.

Support for FES Outcomes

- Complete clinical study summations, bibliographies and clinical research are available upon request.
- The clinical data supporting FES outcomes is especially compelling and consistent with regard to faster walking speeds at a reduced cost of effort. This creates a strong foundation for using FES as a treatment with patients having drop foot and/or gait dysfunction caused by CNS injury or disease.

Research Evidence

Research Evidence

A Multicenter Trial of a Foot Drop Stimulator Controlled by a Tilt Sensor

30 subjects with drop foot caused by CNS disorders were studied before and after using a drop foot stimulator for 3-12 months; 20 subjects had generally progressive conditions (i.e multiple sclerosis) and 10 had non-progressive conditions (i.e. stroke, spinal cord injury).

- Results showed increases in gait velocity both with and without the FES (Therapeutic Effect).
  - 3 mo 16%
  - 6 mo 27%
  - 12 mo 51%
- Physiologic Cost Index (PCI) decreased 25%.
- Voluntary drive and muscle strength improved.

Stein, 2006

Research Evidence

Long Term Therapeutic and Orthotic Effects of a Foot Drop Stimulator on Walking Performance in Progressive and Non-progressive Neurological Disorders

Orthotic and therapeutic effects on walking performance were noted when individuals having progressive and non-progressive conditions used a drop foot stimulator.

- Immediate change in gait with FES as compared to without; noted in subjects with progressive and non-progressive disorders through 11 months (orthotic effect).
- Change in walking performance over time due to FES peaked for the progressive group at 3 months but continued to increase for the non-progressive group through 11 months (therapeutic effect).
- The combined effects were significant in both groups.

Stein, 2010

Research Evidence

Acceptability and Potential Effectiveness of a Foot Drop Stimulator in Children and Adolescents with Cerebral Palsy

This FES device was well accepted and effective for foot drop in those with mild gait impairments from CP.

At both self-selected and fast walking speeds with the FES, significant changes were noted.

- Dorsiflexion increased significantly during swing.
- Initial contact improved.
- Plantarflexion at toe off was preserved.
- 19 of 21 subjects chose to continue wearing the FES for the next part of the study (treatment phase).

Prosser, 2011

Research Evidence

Muscle Plasticity and Ankle Control After Repetitive Use of a Functional Electrical Stimulation Device for Foot Drop in Cerebral Palsy

This FES device produced evidence of use-dependent muscle plasticity in CP, although permanent improvements in voluntary ankle control after repetitive stimulation were not demonstrated.

- Anatomic cross-sectional area, tibialis anterior muscle thickness and pennation angle increased with FES as compared to baseline and were maintained at the 3-month follow-up.
- Maximum ankle dorsiflexion improved or was maintained during the intervention phase.

Damiano, 2012

Research Evidence

Effects of a WalkAide® Home Assessment Program on Walking Ability and Quality of Life in People with Multiple Sclerosis: A Preliminary Report

Use of the WalkAide® FES System as a neuroprosthesis over a period of time as short as 2 weeks can significantly improve gait speed, decrease the impact of MS on walking ability and improve Quality of Life.

Downing, 2014

Research Evidence

The Effects of Peroneal Nerve Functional Electrical Stimulation Versus Ankle-foot Orthosis in Patients with Chronic Stroke: A Randomized Controlled Trial.

Use of FES is equivalent to an AFO.

- Subjects that wore the WalkAide and those that wore an AFO had significant improvements in gait speed at 6 and 12 months.
- WalkAide group improved significantly for total and some Modified Emory Functional Ambulation Profile (mEFAP) scale sub-scores at 6 and 12 months.
- WalkAide group improved significantly on 6 MWT at 12 months.
- There was no significant difference between groups.

Bethoux, 2014

Research Evidence

Effectiveness of Functional Electrical Stimulation for Foot Drop on Walking Abilities and Balance Performance in Saudi Individuals with Chronic Stroke

This randomized controlled trial found that FES therapy of the tibialis anterior muscle with the use of the FES foot drop stimulator was effective in improving walking and balance abilities in Saudi patients with stroke.

- Significant improvements were noted between pre and post-treatment measures in subjects that used the FES and had conventional therapy and those that only had conventional therapy.
- The FES group showed more favorable, statistically significant values for gait velocity, overall stability index, and overall directional control index post-treatment.

El-Fiky, 2016

Research Evidence

WalkAide Efficacy on Gait and Energy Expenditure in Children with Hemiplegic Cerebral Palsy: A Randomized Controlled Trial

WalkAide functional electrical stimulation may be a useful tool for improving gait pattern and energy expenditure in children with hemiplegic cerebral palsy.

El-Shamy, 2016

Research Evidence

Wireless, Accelerometry-Triggered Peroneal Nerve Stimulation in Spastic Paraparesis: A Randomized, Controlled Pilot.

- Over 10 weeks, gait training using FES improved ankle and knee kinematics and reduced plantar flexor spasticity compared with conservative physical therapy.
- Kinematic and spasticity improvements occurred in the FES group only.

Ghedira, 2017

Research Evidence

Functional Electrical Stimulation for Foot Drop in Multiple Sclerosis: A Systematic Review and Meta-Analysis of the Effect on Gait Speed

FES used for foot drop has a positive initial and ongoing effect on gait speed in short walking tests.

Miller, 2017

Research Evidence

A Clinically Meaningful Training Effect in Walking Speed Using Functional Electrical Stimulation for Motor-Incomplete Spinal Cord Injury

Daily independent use of FES may produce clinically meaningful changes in walking speed which are significant for motor-incomplete spinal cord injury.

Street, 2018

FES Technologies for Drop Foot

Indications for FES Drop Foot Stimulators

Individuals with upper motor neuron (UMN) lesions may be candidates, for example:

- Incomplete Spinal Cord Injury (iSCI)
- Traumatic Brain Injury (TBI)
- Stroke (CVA)
- Multiple Sclerosis (MS)
- Cerebral Palsy (CP)
- Familial Hereditary Spastic Parapelgia (FSP)

Contraindications, Warnings & Precautions

- **Contraindications, Warnings and Precautions:**
  - Lower motor neuron (LMN) lesions (ie. peripheral nerve damage from injury, disease or surgery; GB, CMT and Polio)
  - * Pacemakers
  - * Seizures
  - * Pregnancy
  - Malignant tumors in the leg
  - Deep vein thrombosis
  - Inappropriate response to stimulation
  - Chronic skin conditions or poor skin integrity

** Insufficient evidence exists to confirm or deny that FES is contraindicated in these circumstances. Medical clearance from a physician is necessary for considering use of FES with these conditions.*

Other Considerations

- **Other Considerations:**
  - Presence of other electrically controlled devices (i.e. Baclofen pumps, deep brain stimulators or indwelling pain control devices)
  - Morbid obesity (fat tissue is too insulating for stimulation to be effective)
  - Unstable cardiovascular status/HTN
  - Severe balance deficits/vestibular issues
  - Severe sensory deficits
  - Chronic infectious disease
  - Neurogenic pain syndromes

FES Technologies for Drop Foot

Bioness L300Go

FES Technologies for Drop Foot

XFT – G3

FES Technologies for Drop Foot

ODFS® Pace XL

FES Technologies for Drop Foot

WalkAide® System

FES Technologies for Drop Foot

WalkAide® II

Therapeutic Effects and Use

Theories Regarding Therapeutic Effects
Effect of FES on Sensorimotor Function

- Stimulation of motor nerves creates feedback.
- Proprioceptive and kinesthetic feedback is sent from muscle spindles, GTOs and joint receptors as the muscle contracts.
- This intrinsic feedback goes to the cerebellum and basal ganglia allowing the brain to make better motor decisions and to produce better quality movement.
- Stimulation of spinal interneurons affects the contractile state of muscles and antagonists.
- Stimulation adds to sensory feedback (i.e. to the intrinsic information in the system) and allows for a better balance of muscle effort/tone across the joint.
- FES affects muscles grouped in synergistic patterns; as sensory info is improved, the brain “remembers” how to effectively group muscles in normal synergies to increase efficiency of movement.

Theories Regarding Therapeutic Effects

Effect of FES on CNS Tone Management

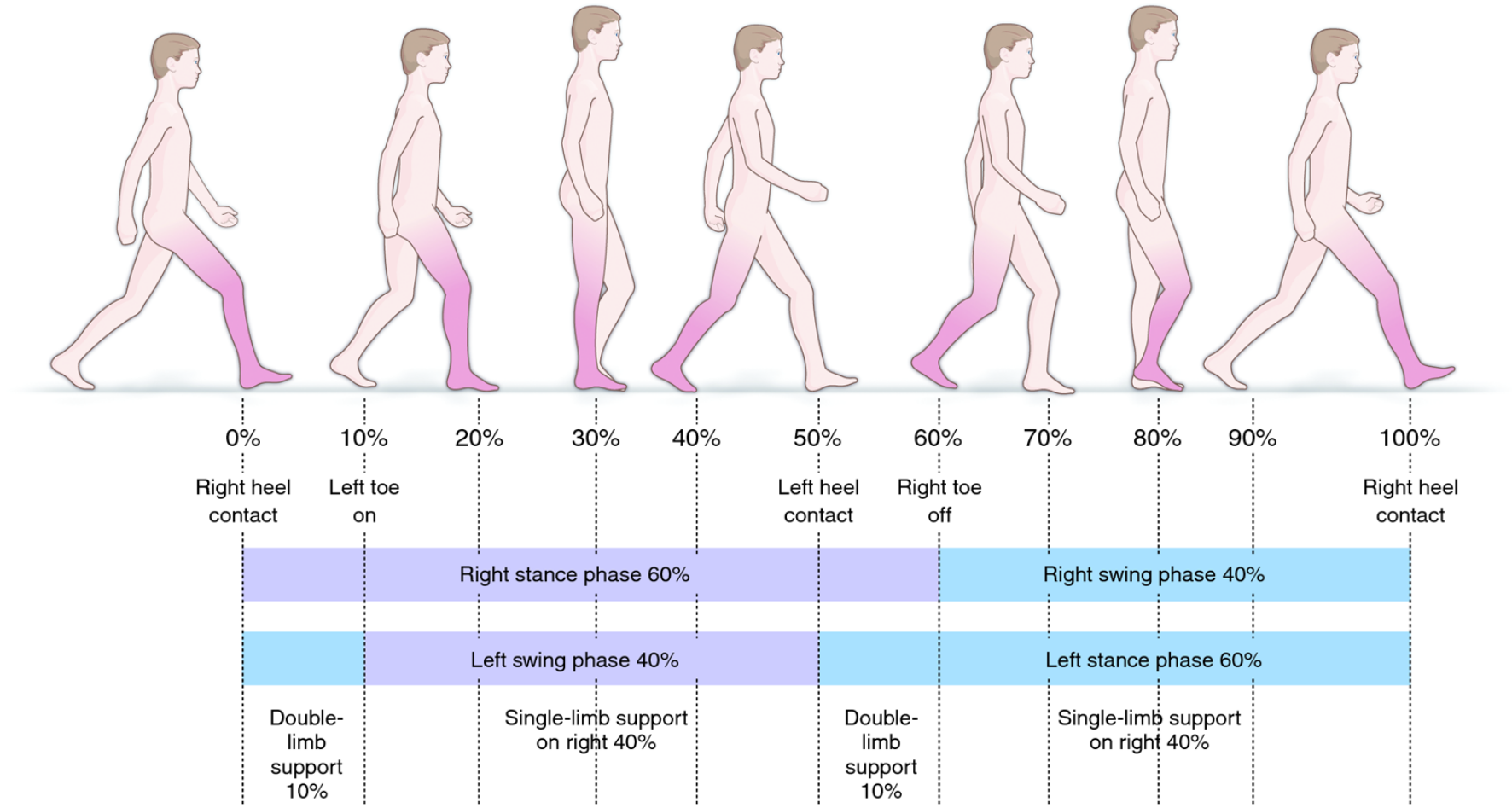
- The restoration of the reciprocal inhibition reflex is key. Contraction of the anterior tibialis and peroneal muscles leads to inhibition of the spastic gastroc-soleus and invertor muscle groups.
- A normal balance of muscle effort facilitates normal synergistic grouping of muscles.
- Improved sensory input leads to improved quality of motor output and improved motor planning.
- Functionally, tone will decrease as movement improves: Improved gait → decreased effort → decreased tone.

Theories Regarding Therapeutic Effects
Summary

- At the least, FES can:
  - Decrease compensations during gait training
  - Facilitate swing appropriately and consistently without distal handling
- At most, FES can:
  - Inhibit abnormal tone
  - Facilitate normal synergistic motion
  - Improve sensory feedback to the brain and spinal cord
  - Encourage motor effort, improved motor planning and improved motor coordination
  - **Stimulate neuroplasticity like nothing else can**

Clinical Use and Outcomes

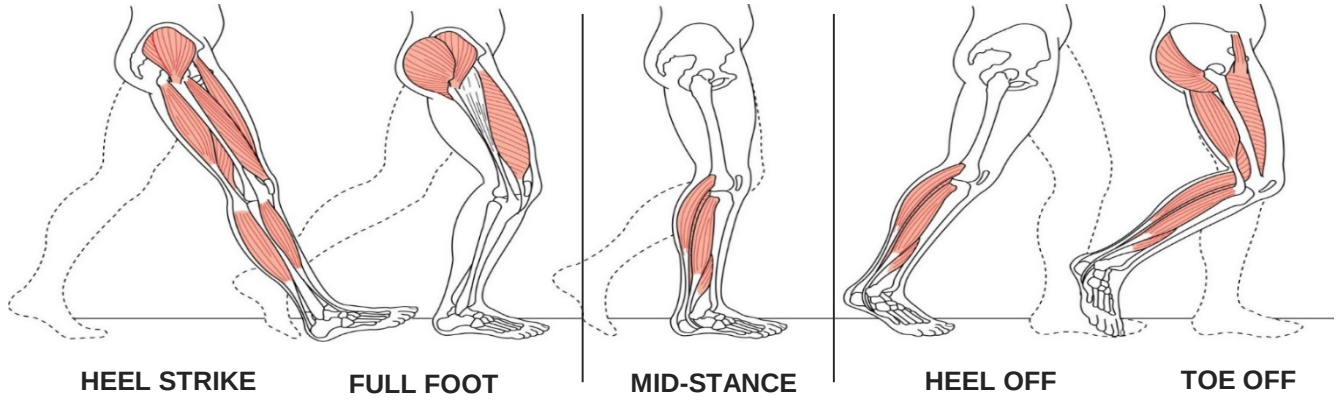
Normal Gait



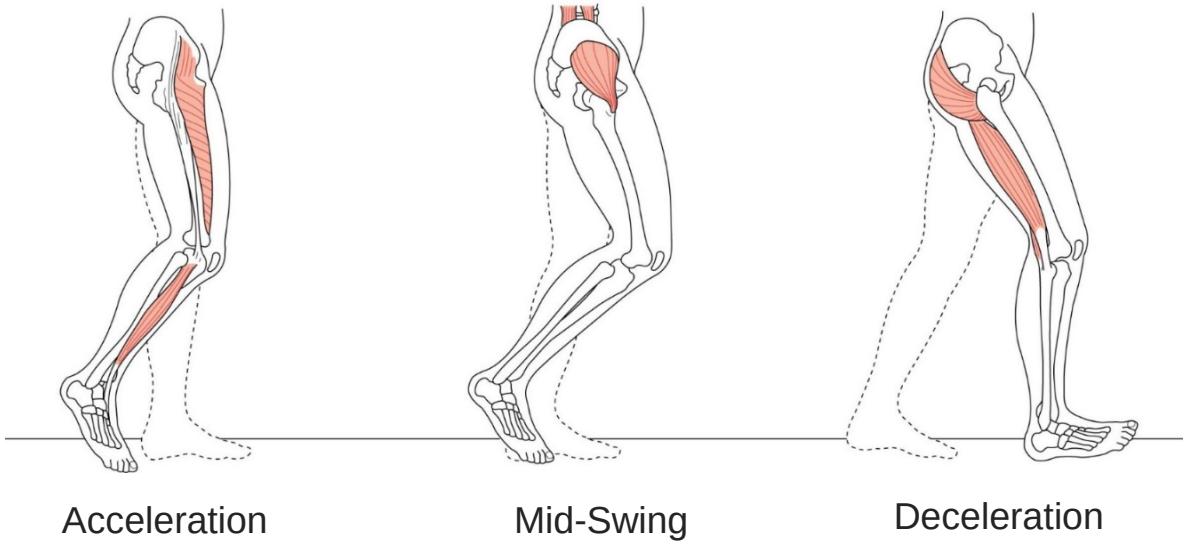
Source: Mark Dutton: *Dutton's Orthopaedic Examination, Evaluation, and Intervention*, 4th Edition: www.accessphysiotherapy.com

Phases of Walking

- **Stance Phase** = the entire period during which the foot is on the ground



- **Swing Phase** = the time when the foot is in the air for limb advancement; beginning as soon as the toe is lifted from the floor (toe-off) and ending with initial contact of the foot (heel strike)



Pathological Gait

Examples of common pathological gait patterns resulting from dysfunction caused UMN lesions and/or created as compensations for those dysfunctions:

- Short single limb stance on the involved side
- Short step or stride with the uninvolved limb
- Inability to clear the toes from the floor may cause compensations, such as:
  - Circumduction – the stiff involved leg is rotated away from the body then back towards it in a semicircle
  - Hip hike – elevation of the pelvis on the involved side during swing
  - Vaulting – rising onto the toes of the uninvolved limb while swinging the involved limb anteriorly
  - External rotation at the hip - rotation of the involved limb to turn the toes outward
  - Lateral lean – lean the trunk to the uninvolved side, helping to elevate the involved limb

Treatment Recommendations

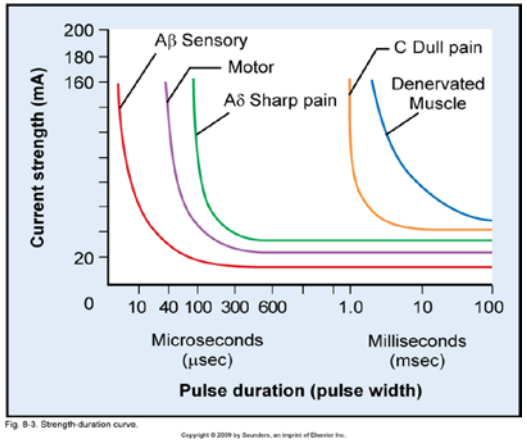
- Integrate FES into each patient's unique treatment plan based on their needs, functional levels and goals.
- Start with NMES for ROM, strength and/or endurance if the patient is not ready for FES during walking.
- Use FES for weight shifting exercises and other pre-gait training.
- Use FES for walking.
  - Hand trigger for low level function
  - Foot switch for low-high level function
  - Tilt sensor for mid-high level function
- Progress from flat surfaces to walking on unenven surfaces, around/over obstacles or on stairs.
- Progress from slow to faster walking speeds.
- Incorporate NMES for strength and endurance to promote increased durations or distances walked.

Clinical Use and Outcomes

- FES is not an instant cure.
- Optimal clinical outcomes are attained over time in conjunction with physical therapy.
- Kinematic and physiological changes occur with time and repetition.
- Three possible patient scenarios are typical.
    1. Immediate dramatic improvements in gait occur when FES is first applied.
    2. The patient does not tolerate stimulation, lacks ROM or is not a candidate… at least not yet.
    3. Most commonly, slow and profound improvements in gait occur with use over time.

Stimulus Settings

- Stimulus – a series of pulses
- Pulse Width – the duration of each pulse within a stimulus; an increase or decrease affects power and functional response
- Intensity – the amplitude of the stimulus; has a direct corolation with pulse width that affects the net amount of energy sent from the device to the patient
  - If the intensity is high with a small motor response, increase the pulse width
  - If the intensity is low and the patient cannot tolerate the stimulation, decrease the pulse width
- Frequency – the speed at which the pulses occur; an increase enhances comfort, controls functional response and increase the net energy delivered



Advanced Settings

Adjust the stimulation parameters for comfort and function as needed:

- Ramp on: When stimulation starts, intensity slowly increases to full power.
- Ramp off: Stimulation intensity gradually diminishes at the end of a step.

Use or customize an exercise program to enhance strength and/or endurance or to manage spasticity:

- Stimulation is ON for a duration to facilitate nerve and muscle function.
- Stimulation is OFF for a period of recovery between each stimulation.
- The exercise program continues for this period of time, or the exercise duration.

Programming Tips

- In general, faster walkers have a shorter swing phase (stimulation) and a shorter stance phase (no stimulation).
- In general, slower walkers have a longer swing phase (stimulation) and a longer stance phase (no stimulation).
- Adjust settings to trigger the stimulation sooner, to help initiate swing closer to heel-off versus toe-off during the gait cycle.
- Shorten the stimulation duration if stimulation is staying on too long, into the stance phase of gait.
- Extend the stimulation duration if the patient needs assistance controlling the ankle or knee while transitioning from swing phase, through initial contact, for a stable foot position on the ground during stance.

Programming and Training Tips

- The enemy of good is perfect. Use a safe and effective program achieved efficiently and then adjustments can always be made later.
- Observation of the patient walking is the most important thing when making clinical decisions and adjustments to FES programs.
- Educate patients and set realistic expectations. FES is not an instant cure and it will take time for strength, endurance, balance, gait pattern, etc. to improve.
- Talk to patients about accommodation to the stimulation. With consistent and repeated use, the stimulation becomes more comfortable and less noticeable.
- Explain the wearing schedule, compliance and electrode care clearly.
- Ensure that patients understand how to operate and maintain the device.

Sample Wearing Schedule

- This wearing schedule includes walking, exercise and time the device is not providing stimulation but is still being worn on the leg.
- Wearing schedules should be customized for each patient, based on their activity level, tolerance for stimulation, health of their skin and/or sensation, etc.
- Patients, caregivers/parents and clinicians should continuously assess progress or issues that arise and adjust the wearing schedule as needed. For example:
  - Increase wearing time to promote strength, endurance and activity.
  - Decrease wearing time to inhibit undue muscle soreness, fatigue or skin irritation.

Day	On Time
1	1.0 hr
2	1.5 hrs
3	2.0 hrs
4	2.5 hrs
5	3.0 hrs
6	3.5 hrs
7	4.O hrs
8	4.5 hrs
9	5.0 hrs
10	5.5 hrs
11	6.0 hrs
12	6.5 hrs
13	7.0 hrs
14	7.5 hrs
15	8.0 hrs
16	unlimited

FES Skin Irritation
Risk Prevention & Treatment

Patient education is the key.

- A wearing schedule gradually increases the time spent with the stimulation powered ON.
- Removing the system from the leg every 2-3 hours for 15 minutes may inhibit skin irritation during the breaking-in period.
- Use the lowest intensity possible to get the desired response.
- Wet the electrodes prior to each use.
- If skin irritation occurs, STOP using the FES until the skin is completely healthy. Review, re-educate and re-adjust the treatment as needed to prevent future issues.

FES Skin Irritation
Risk Prevention & Treatment

- Hygiene
  - Use natural soap without lotion, deodorant or antibacterial agents that can leave a film on the skin which inhibits stimulation from passing efficiently through it.
  - Do not use lotion in the area of the electrodes unless the skin is extremely dry, and then use a light lotion at night followed by natural soap to clean the area before applying the electrodes.
- Drink plenty of water (8 glasses or more daily) to keep the skin and tissues hydrated so that the stimulation is efficiently conducted and skin preserved.

FES Skin Irritation
Risk Prevention & Treatment

- Use the lowest net charge possible to create the functional response.
  - More efficient stimulation requires less net charge to produce a response, thereby preserving the skin, muscle and nerve.
  - The patient controls the intensity and should use the lowest level of stimulation.
  - If the pulse width is decreased to enhance comfort, the intensity may need to be increased to produce the desire response.
  - It's a balancing act. These settings affect comfort and functional output.
- If a patient follows all instructions for hygiene, wearing schedule, electrode management, intensity, etc. and they still have skin irritation, try an alternative electrode when the skin is healthy.
- A patient with a true allergy to electrodes will have a reaction to an electrode placed anywhere on the skin (ie. lower leg), even without electrical stimulation. Alternative electrodes may be available for patients with allergies to adhesives or stainless steel.

Summary

- FES is a clinically proven tool that may help promote optimal functional outcomes for individuals with upper motor neuron lesions.
- Technologies today offer therapists efficient set-up and means for calculating objective measures, all while expediting patient recovery.
- Although patients benefit from using FES in therapy, today's technologies make it possible for many patients to continue their treatment outside the rehab setting.

THANK YOU!

For support please contact ACP FES Patient Solutions, or your local distributor

https://acplus.com/fes-patient-solutions

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