Title: Video and Temporal Spatial Parameters Assessment of Gait after Dysport Treatment: A Pilot Study

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SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigator or Clinical Site Investigator:

Signed: _____ Date: _____

Name: Alberto Esquenazi, MD

Title: Chairman, Department of Physical Medicine and Rehabilitation;

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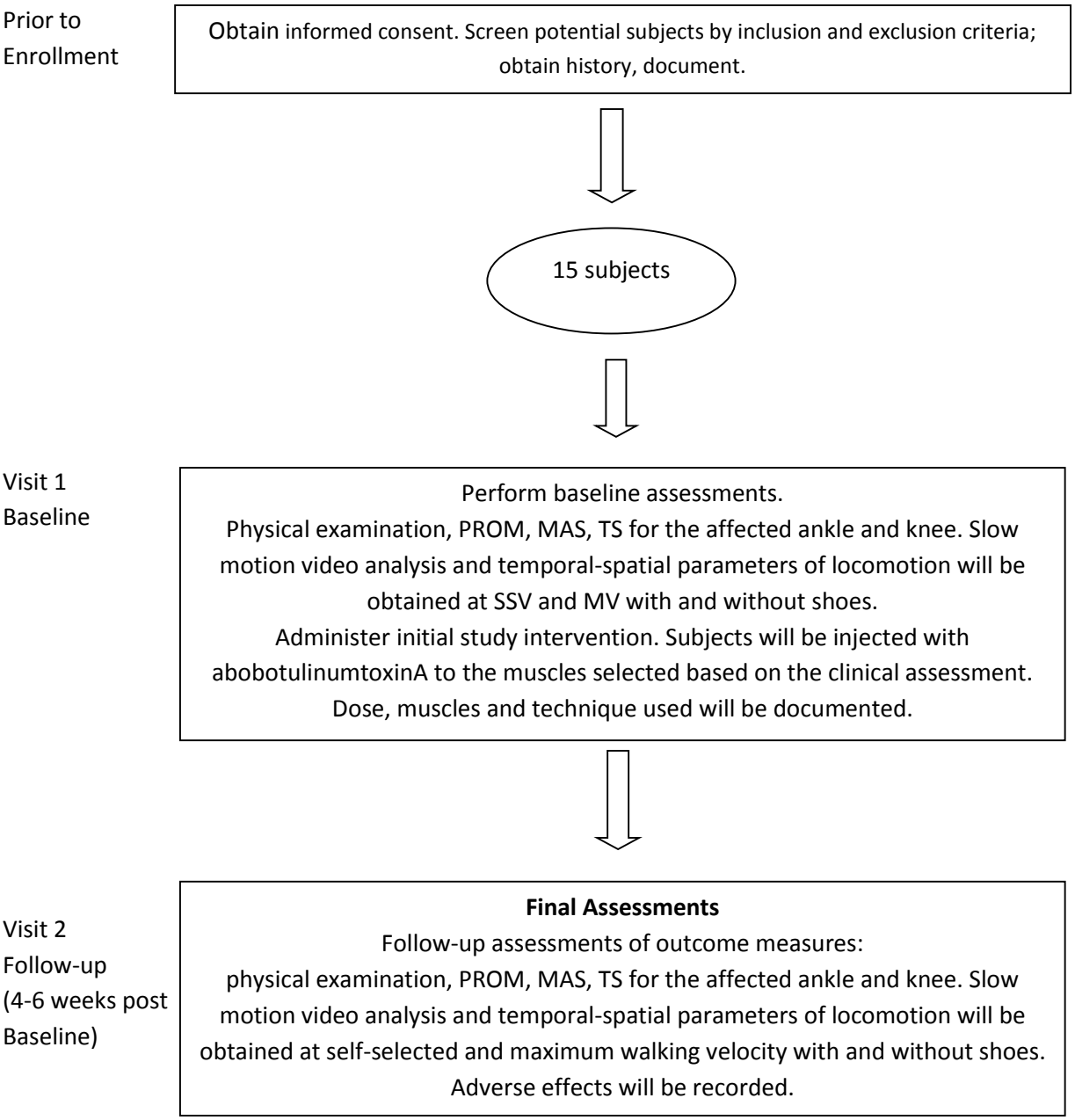
LIST OF ABBREVIATIONS

AE	Adverse Event/Adverse Experience
CRF	Case Report Form
eCRF	Electronic Case Report Form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
IRB	Institutional Review Board
MAS	Modified Ashworth Scale
MV	Maximal Velocity
N	Number (typically refers to subjects)
PROM	Passive Range of Motion (ankle)
PI	Principal Investigator
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
SSV	Self-Selected Velocity
TS	Tardieu Scale

PROTOCOL SUMMARY

Title:	**Video and Temporal Spatial Parameters Assessment of Gait after Dysport treatment: A Pilot Study**
Summary:	This pilot study will aim to understand the potential benefit of the assessment of walking using video slow motion for muscle selection and the development of an image catalogue guide of the potential results of injection of abobotulinumtoxinA by comparing foot postures before and after injection.
Objectives:	To evaluate the use of video assessment to improve muscle selection for the injection of botulinum toxin A to improve walking outcomes Primary: SSV, MV, symmetry of walking Secondary: PROM, MAS and TS
Population:	15 persons post stroke or TBI over age 18 with equinovarus foot deformity who are able to ambulate.
Description of Intervention:	Dysport 1000 to 1500 units to be distributed on the basis of clinical indication to ankle plantar flexors (gastrocnemius and soleus), knee extensors and flexors, tibialis posterior and long toe flexors
Study Duration:	Study set-up including IRB/EC approval: 9 months Final study report estimated by: March 2019
Subject Participation Duration:	4-6 weeks
Estimated Time to Complete Enrollment:	May 2018 to December 2018

Schematic of Study Design:



KEY ROLES AND CONTACT INFORMATION

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1 BACKGROUND INFORMATION

Post-stroke, ~40% of patients develop spasticity, with severe or disabling spasticity in up to 15% of patients. [1, 2] Of those who have sustained a traumatic brain injury, approximately 75% develop spasticity, with nearly 50% warranting anti-spasticity treatment. [3] Spasticity is a chronic condition defined as "disordered sensory-motor control, resulting from an upper motor neuron lesion, presenting as intermittent or sustained involuntary activation of muscles" with postural limb changes. [4] Spasticity is characterized by muscle stiffness, paresis, muscle spasms, muscle fatigue, and in some cases rheological change with abnormal lower limb postures. [5] Beyond the underlying primary disorder and disease, spasticity negatively influences patient function, quality of life and increases caregiver burden. [6]

Hemiparesis from acquired brain injury can also impair mobility, related to abnormal passive and active antagonist muscle resistance. [4] In chronic hemiparesis, walking speed stabilizes at a low plateau level, in most cases inadequate to sustain community ambulation. [7] Intramuscular injection of botulinum toxin type A (BoNT-A), produces muscle relaxation for 12–16 weeks or longer and is an effective treatment for lower limb muscle overactivity in spastic paresis. [8] While botulinum toxin reduces muscle tone and improves spasticity-related features in lower-limb muscles, muscle selection that results in improved walking outcomes have not been explored. [8]

Currently clinical evaluation of the patient with lower limb spasticity after TBI or stroke focuses primarily on physical examination, and in some instances visual assessment of walking. These data, supplemented by registries, illustrations depicting typical patterns, and the potential muscles involved are used to determine the selection of the potential muscles for the injection of botulinum toxin.

This pilot study will aim to understand the potential benefit of the assessment of walking using video slow motion for the muscle selection and develop an image catalogue of the potential results of injection of abobotulinumtoxinA by comparing foot postures before and after injection.

1.1 Rationale

Current FDA approved dosing for leg muscle injection with abobotulinumtoxina ranges from 1000 to 1500 units to be distributed based on clinical indication to ankle plantar flexors (gastrocnemius and soleus), tibialis posterior and long toe flexors at intervals greater than 3 months. The treatment algorythm may be improved by a dynamic walking visual guidance. We believe visual assessment will improve guidance to muscle selction for treatment, which may result in improvement in foot posture and walking.

1.2 Potential Risks and Benefits

1.2.1 Potential Risks

Lower limb spasticity injection most frequently reported adverse reactions (>2%) are: nasopharyngitis, muscular weakness, musculoskeletal pain, dizziness and falls.

1.2.2 Potential Benefits

Potential benefits of visual assessment during walking may improve functional outcomes. While it may not provide direct benefit to subjects, the importance of the knowledge that may result from the study such as improvement in muscle selection for treatment, patient outcomes and patient satisfaction.

2 OBJECTIVES

2.1 Study Objectives

Primary objectives: This is a prospective, single arm, non-randomized clinical study designed to evaluate pre-post walking velocity and symmetry with the use of Dysport in patients with equinovarus foot deformity.

Secondary objectives: The study will also a**ssess** impact of Dysport related to the following measures: ankle and knee PROM, MAS and TS.

2.2 Study Outcome Measures

Walking velocity will be collected at baseline and at the follow-up visit using the Gait Mat evaluation. Ankle and knee PROM, MAS and TS data will be collected at baseline and at the follow-up visit.

2.2.1 Primary

Primary endpoint: comparative walking velocity and symmetry of walking at baseline and follow-up visits.

2.2.2 Secondary

Secondary endpoint: ankle and knee PROM, MAS and TS as well as video observational analysis at baseline and follow-up Visits.

3 STUDY DESIGN

This is a prospective, single arm, non-randomized clinical study with pre-post assessment to include post-stroke and TBI outpatients with spastic ankle / foot muscles amenable to botulinum toxin injection. Subjects must be able to walk without braces.

abobotulinumtoxinA injection in a dose range of 1000 to 1500 units one time to be distributed on the basis of clinical indication to ankle plantar flexors (gastrocnemius and soleus), knee extensors, knee flexors, tibialis posterior and long toe flexors. Administration of the Dysport will be performed by the PI.

First patient expected to be enrolled will be May 2018 and last patient expected to be enrolled will be December 2018. Subjects will be enrolled for a duration of 4-6 weeks.

4 STUDY ENROLLMENT AND WITHDRAWAL4.1 Subject Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

- Provide signed and dated informed consent form
- Willing to comply with all study procedures and be available for the duration of the study
- Male or female, aged ≥ 18
- Equinovarus foot deformity appropriate for botulinum toxin treatment (naïve or non-naïve)
- MAS between 1 to 3
- Women of reproductive potential must use effective contraception for the duration of the study
- Able to walk a few steps without a brace for the purpose of the video observation

4.2 Subject Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

- Previous surgical intervention to affected/ankle/foot
- Uncontrolled seizures
- Pregnancy or lactation
- Known allergic reactions to Dysport
- Treatment with another investigational drug or other intervention in the past 4 months
- MAS 4
- Anything that would place the individual at increased risk or preclude the individual's full compliance with or completion of the study
- Lower motor neuron disorder
- < Four months post botulinum toxin or serial casting

4.3 Strategies for Recruitment and Retention

Subjects will be recruited from clinician referrals in the stroke and TBI outpatient clinics, the gait laboratory and patient charts. Subjects will receive the toxin free of charge.

4.4 Subject Withdrawal

Subjects may withdraw voluntarily from the study or the investigator may terminate a subject's participation.

4.4.1 Reasons for Withdrawal

Subjects are free to withdraw from participation in the study at any time upon request.

An investigator may terminate a study subject's participation in the study if:

- Any clinical adverse event (AE) or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the subject.
- The subject meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

4.4.2 Handling of Subject Withdrawals or Subject Discontinuation of Study Intervention

If a subject withdraws from the study, the Investigator will complete and report the observations as thoroughly as possible up to the date of withdrawal including the date drug treatment and the reason for withdrawal. If the subject is withdrawn due to an AE, the Investigator will follow the subject until the AE has resolved or stabilized. In all cases, the reason for and date of withdrawal must be recorded in the case report form and in the subject's medical records.

5 STUDY INTERVENTION

5.1 Study Product Description

Product information can usually be obtained from package insert, for licensed drug or biologic (Appendix A).

5.1.1 Acquisition

An IMP may be supplied by the manufacturer or study sponsor.

5.1.2 Product Storage and Stability

Drug will be provided by IPSEN for subject use. Dysport will be stored in the refrigerator along other botulinum toxins available in the gait laboratory. The refrigerator is locked and only accessible to gait laboratory staff.

5.2 Dosage, Preparation and Administration of Study Product

Drug will be prepared in the gait laboratory by staff currently trained in preparing botulinum toxins for clinical use. The toxin will be reconstituted with 3 cc of NSS. All vials are closed by 13 mm freeze-drying with a center hole, crimped over. Dysport drug product will be stored at the recommended temperature between $2^{o}C/8^{o}C$.

The product does not contain any antimicrobial agent. It is therefore recommended that the product be used immediately after reconstitution.

5.3 Accountability Procedures for the Study Product

The PI, or other representative, will ensure that all IMP is stored in a secured area, under recommended temperature monitored storage conditions, in accordance with applicable regulatory requirements and will be reconstituted and dispensed by qualified staffed members.

All study treatments are to be accounted for Dysport accountability log.

5.4 Concomitant Medications/Treatments

The following concomitant medications are not permitted during this study:

- Other botulinum toxin for administration into any site of the body other than Dysport.
- Any investigational new drug or device or off label use of any drug.
- Aminoglycoside antibiotics or other drugs that interfere with neuromuscular transmission.

The following concomitant medications are permitted during this study but they must be monitored closely and every effort should be made to keep their dose and dose regimen constant throughout the course of the study.

- Changes in pain medication are acceptable if absolutely necessary and according to clinical judgement and will be recorded in the eCRF.
- Concomitant use of anticholinergic drugs (which may potentiate systemic anticholinergic effects) is permitted if the dosage has been stable for the six weeks prior to the study treatment and is expected to remain at this stable dose throughout the study.
- Concomitant treatment with dantrolene, tizanidine, gabaerigc, opiord or other antispasticity agents, including oal baclofen and benzodiazepines should be kept at the same dose throughout the study.

5.5 Administration of Intervention

The treatment dose will be administered by the PI to the targeted muscle at the baseline visit.

6 STUDY SCHEDULE

Details of the timing of each clinic visit, and the tests and procedures to be performed at each visit are located in Appendix B. Visits should take place as close to the visit time point as possible. Details on the performance of specific assessments or activities are presented in this section.

6.1 Screening

Screening Visit

Written informed consent should be obtained prior to enrollment. This visit may occur on the same day as the baseline visit at the discretion of the PI. The following assessments will be performed to check eligibility criteria:

- Demographics (sex, date of birth/age, ethnicity, race, height and weight)
- Medical/surgical history, including ongoing medical history
- Botulinum toxin history use
- Prior and concomitant medications. Prior medications will be all medications administered within 4 weeks before screening visit
- Measurement of ankle and knee PROM, MAS, TS and video and temporal-spatial parameters of walking
- Adverse event collection

6.2 Baseline

The screening visit and the baseline could occur on the same day at the PI's discretion. The following assessments should be performed at the baseline visit prior to administration of Dysport. If the screening and the baseline visits occur on the same day all assessments identified in the screening visit should also be done at the visit, recorded in the eCRF.

Baseline Visit

- Verify inclusion/exclusion criteria
- Adverse event collection
- Concomitant medications
- Results of physical examinations, ankle and knee PROM, MAS and TS
- Video assessment of temporal spatial parameters of with and without shoes at SSV and MV
- Study treatment administration

6.3 Follow-up Final Visit

The following tests and procedures will be performed/evaluated at Follow-Up Visit:

- Adverse event collection
- Concomitant medications
- Review medical and medication history
- Record results of physical examinations, ankle and knee PROM, MAS and TS

- Video assessment of temporal spatial parameters of with and without shoes at SSV and MV
- Record adverse events as reported by subject or observed by investigator
- Record subject's compliance with intervention

6.4 Withdrawal Visit

Early withdrawal for each subject, the following tests and procedures will be performed/evaluated:

- Adverse event collection
- Concomitant medications

7 STUDY PROCEDURES /EVALUATIONS

7.1 Study Procedures/Evaluations

Primary Evaluations:
SSV without and with shoes – Subjects will be advised to walk 10 meters with and without their shoes at their comfortable walking speed. Three trials of this test will be collected. SSV will be obtained prior to the study treatment at baseline and follow-up visits.

MV without and with shoes – Subjects will be advised to walk 10 meters with and without their shoes and their fastest walking speed. Three trials of this test will be collected. MV will be obtained prior to the study treatment at baseline and follow-up visits.

Secondary Evaluations:
Tone will be measured for the gastrocnemius and soleus muscles with the MAS – MAS will be used to assess muscle tone in the grastrocnemius and soleus muscles prior to the study treatment at baseline and at the follow up visit.

Spasticity in the gastrocnemius and soleus muscles measured with the TS - The will be used to assess spasticity in these muscles. Assessments will be made at slow (V1) and fast (V3) speed of stretch. The angle of arrest at slow speed (X_{v1}), the angle of catch at fast speed (X_{v3}) and the spasticity grade (Y) at fast speed will be recorded in the eCRF at each speed. The spasticity angle will be calculated by the difference between the angle of arrest at slow speed (X_{V1}) and the angle of each at fast speed (X_{v3}). The TS ratings will be obtained prior to the study treatment at baseline and at the follow-up visit.

PROM - will be used to assess treatment response. The ankle, knee flexed and knee extended measurements will be obtained prior to the study treatment at baseline and at the follow-up visit.

8 ASSESSMENT OF SAFETY

8.1 Adverse Events

An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

8.2 Serious Adverse Events

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect
- An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

8.3 Time Period and Frequency for Event Assessment and Follow-Up

Unanticipated problems will be recorded in the data collection system throughout the study.

The PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization. SAEs will be reported to DrugSafety.USA@ipsen.com.

8.4 Characteristics of an Adverse Event

8.4.1 Relationship to Study Intervention

To assess relationship of an event to study intervention, the following guidelines are used:

1. Related (Possible, Probable, Definite)
    a. The event is known to occur with the study intervention.
    b. There is a temporal relationship between the intervention and event onset.
    c. The event abates when the intervention is discontinued.

d. The event reappears upon a re-challenge with the intervention.

2. Not Related (Unlikely, Not Related)

   a. There is no temporal relationship between the intervention and event onset.

   b. An alternate etiology has been established.

8.4.2 Expectedness of SAEs

The Study PI will be responsible for determining whether an SAE is expected or unexpected. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention.

8.4.3 Severity of Event

The following scale will be used to grade adverse events:

1. Mild: no intervention required; no impact on activities of daily living (ADL)

2. Moderate: minimal, local, or non-invasive intervention indicated; moderate impact on ADL

3. Severe: significant symptoms requiring invasive intervention; subject seeks medical attention, needs major assistance with ADL

9 STATISTICAL CONSIDERATIONS

9.1 Study Hypotheses

The statistical analysis of the data obtained from this study will be performed using SPSS v. 19.0.

All data collected in this study will be documented using summary tables and subject data listings. Continuous variables will be summarized using descriptive statistics, specifically the mean, median, standard deviation, minimum and maximum. Categorical variables will be summarized by frequencies and percentages.

Demographics, Medical History and Baseline Characteristics:
The subjects will be summarized with respect to baseline demographics and baseline characteristics (e.g., age, gender, race, ethnicity, injury type and time since last injury, height and weight, etc.). These will be summarized by descriptive statistics including means, medians, standard deviations and ranges (for quantitative variables) and counts and percentages (for categorical variables).

Primary Endpoint:
The primary end point is to collect SSV and MV with and without shoes at Baseline and Follow-up Visits using the Gait Mat. Data will be reported descriptively and continuous data will be reported with the change from follow-up to baseline.

Secondary Endpoint:
The following are secondary endpoints:

- PROM will be presented descriptively as continuous data along with the change form baseline.
- The TS will be presented descriptively as continuous data along with the change from baseline.
- The MAS will be presented descriptively as rank data along with the change from baseline.

9.2 Sample Size

For this pilot study, no prospective calculations of statistical power have been made. The sample size of 15 subjects has been selected to provide information on safety, reliability and feasibility of video assisted muscle selection for Dysport injection.

10 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Study staff will maintain appropriate medical and research records for this study, in compliance with IRB requirements for the protection of confidentiality of subjects. Study staff will permit authorized representatives of the IRB to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

11 ETHICS/PROTECTION OF HUMAN SUBJECTS

11.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

11.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all subject materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any subject is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

11.3 Informed Consent Process

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and possible benefits of study participation will be provided to subjects and their families, if applicable. A consent form describing in detail the study procedures and risks will be given to the subject. Consent forms will be IRB-approved, and the subject is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the subject and answer any questions that may arise. The subject will sign the informed consent document prior to any study-related assessments or procedures. Subjects will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to subjects for their records. The rights and welfare of the subjects will be protected by emphasizing to

them that the quality of their clinical care will not be adversely affected if they decline to participate in this study.

The consent process will be documented in the clinical or research record.

11.4 Subject Confidentiality

Subject confidentiality is strictly held in trust by the investigators, study staff, and the sponsor and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to any study information relating to subjects.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor or other authorized representatives of the sponsor may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study subjects. The clinical study site will permit access to such records.

12 DATA HANDLING AND RECORD KEEPING

The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. The investigator will maintain adequate case histories of study subjects, including accurate case report forms (CRFs), and source documentation.

12.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the investigator. All source documents and laboratory reports must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems and adverse events must be reviewed by the investigator or designee.

12.2 Data Capture Methods

Data will be collected on paper and entered electronically on a password protected network computer. Data quality checks will be performed internally on a routine basis.

12.3 Types of Data

Subject medical history, demographics, concomitant medications will be collected. The following outcome data will be collected: ankle and knee RPOM, MAS, TS, Gait Mat data on temporal spatial data including SSV and MV without and with shoes.

12.4 Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol, Good Clinical Practice, or Manual of Procedures requirements. The noncompliance may be on the part of the subject, the investigator, or study staff. As a result of deviations, corrective actions are to be developed by the study staff and implemented promptly.

All deviations from the protocol must be addressed in study subject source documents and promptly reported to the local IRB, according to their requirements.

13 LITERATURE REFERENCES

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APPENDICES

Appendix A: Dysport (abobotulinumtoxinA) Dosing and Dilution Guide

Appendix B: Schedule of Events

APPENDIX A: DYSPORT (ABOBOTULINUMTOXINA) DOSING AND DILUTION GUIDE

APPENDIX B: SCHEDULE OF EVENTS

Procedures		Screening	Baseline	Final Visit Follow-up	Premature Discontinuation
Signed Consent Form		X	X		
Assessment of Eligibility Criteria		X	X		
Review of Medical History		X	X		
Review of Concomitant Medications		X	X	X	X
Study Intervention			X		
Physical Examination	Complete	X	X	X	
Assessment of Adverse Events			X	X	X
Drug Administration			X		
Other Procedures	PROM	X	X	X	
	MAS	X	X	X	
	TS	X	X	X	
	SSV with and without shoes	X	X	X	
	MV with and without shoes	X	X	X	
	Temporal spatial data	x	x	x	