Title : Measuring the efficacy of surgical and percutaneous neuroablative procedures in the management of plateaued or refractory upper-extremity spasticity patients.

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Protocol Title: Measuring the efficacy of surgical and percutaneous neuroablative procedures in the management of plateaued or refractory upper-extremity spasticity patients.

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Use of Study: This is a pilot study to test the current treatment with novel interventions for refractory patients. Achieved data will be presented at scientific meetings, for presentation and or scientific journal publication. Should a larger study stem from this pilot, the data from this pilot might be included with the larger dataset. If this occurs, pilot study participants would be asked for their consent to use the data in this way.

Background/Rationale:

This Center has developed a novel interdisciplinary approach to assessing and managing the plateaued or refractory patient with spasticity. This clinic implemented the, novel to North America, DNB to select the treatment pathway in the use of selective percutaneous and surgical nerve ablative procedures. This clinic's standard of care now includes weekly assessments for novel interventional and surgical care not offered anywhere else in Canada with the degree of access, frequency of assessments or choice of procedures. The present triage pathway was accepted as an academic poster and published abstract, "THE ROLE OF THE DIAGNOSTIC MOTOR NERVE BLOCK IN GUIDING NOVEL SPASTICITY TREATMENT: AN ALGORITHM" at the Canadian Association of Physical Medicine and Rehabilitation (CAPMR) Annual Meeting in Gatineau, Quebec in May 2019.

Many patients continue to live with disabling spasticity that negatively affects their health, independence and quality of life.[1] For these patients traditional therapies such as bracing, medications, and botulinum toxin have not achieved maximal outcomes. Up to one quarter of physicians have noted to be limited by maximal dosage of botulinum toxin allowed in their country.[2] Due to common complaints of pain, difficulty with limb positioning, and hygiene concerns there has been an increase in demand for novel adjunctive therapies, including surgery, to improve patient outcomes. Severely spastic patients often require total body and regional dosing of toxin therapy that exceeds formulary dosing and is considered "off label." This can lead to lack of insurance coverage, poor adherence and cessation of interventions and insufficient change in function. In most countries, there is rarely treatment for spasticity that forms a contracture, an immovable joint which can lead to skin break down, infection and hospitalization.

The investigators of this study have created Canada's first interdisciplinary spasticity clinic consisting of a physiatrist, plastic surgeon and anesthesiologist. In 2019 this group co-founded the Canadian Advances in Neuro-Orthopedics Congress (CANOSC) with UBC colleagues. CANOSC is dedicated to bringing the world leading spasticity interventions to Canada and developing Canadian techniques. This includes

cryoneurotomy and selective microfascicular neurectomy. Both of these techniques have been developed in our clinic and in the past three years and have been published as journal articles, academic posters or presented at international congresses. [3] [4] [5] [6]

The usual care in Victoria, has become a leading centre of neuro-orthopedic care in Canada.

The proposed patient selection pathway is based on the diagnostic lidocaine motor block (DNB). The DNB is practiced in Franco-European countries, with the la Société Française de la Médecine Physique et de Readapatation (SOFMER) group publishing their guidelines in Annals of Physical Medicine and Rehabilitation this year. [9] The DNB involves locating a selected branch of a peripheral nerve to an individual or group of spastic muscles using landmarks on the skin's surface. Using a percutaneous electric stimulator (e-stim) the nerve is stimulated with the lowest possible current to cause a muscle contraction, typically less than 1 mA. An anesthetic, usually 1-3 cc's of 1-2% lidocaine is injected to cause a nerve block and muscle paralysis for up to one hour. The patient is then examined to see if greater range of motion around the joint is achieved.[10] [11] The results can be divided into greater range of motion, fully reducible range of motion, or no change indicating contracture of the muscles and joints has occurred. The temporary procedure is the only procedure that can predict outcomes of definitive treatment for patients with spasticity to allow the patient to foresee the potential outcome of each procedure they are to undergo. "The blocks also allow to better define the therapeutic objective."[9] The DNB allows the full potential of a muscle's modulation to be explored. It can predict if altered or higher doses of toxin may be effective, or if a neurotomy procedure or tenotomy or more invasive surgery is needed to address the deformity.[12,1311] The DNB can inform if a patient uses their spasticity for a positive function, such as weight bearing, or a clawed hand or stiff elbow that is capable of carrying an object such as a shopping bag.

The traditional French approach involves localizing the nerve using anatomic landmarks. Our clinic utilizes ultrasound (US) guidance to improve localization, reduce unnecessary skin pricks and reduce the volume of injection. US guidance is long established in the anesthetic literature as an effective method to improve technique, reduce vascular puncture and reduced volumes of anesthetic, with several spasticity papers published recently supported its efficacy.[14–18] The Society of French Anesthesiologists (SFAR) 2016: ''recommend the use of ultrasound guidance for the achievement of a loco-regional anesthesia, etc.'' with a grade 1+ strong agreement.[19] It is of note that our group is leading an international consensus paper on the use of ultrasound guided nerve blocks in Spasticity.

Safety of nerve blocks:

The 2019 French Guidelines are the most comprehensive opinion on the safety of nerve blocks in spasticity. Contraindications to lidocaine nerve blocks are rare. The guidelines suggest a dose of 2mg per kg per patient. Patients will receive up to 4ml of lidocaine per treatment. Thus 2% lidocaine means 20 mg/ml or 80 mg/4ml. It is of note that Each 1 ml of lidocaine hydrochloride contains 20.0 mg of lidocaine hydrochloride, corresponding to 16.2 mg lidocaine. The toxic dose is 5 mg per kg or 350 mg in a 70 kg person. Our nerve blocks use 1-2cc's of 2% lidocaine per nerve block, up to three blocks per patient. Using 3 ml of 2% lidocaine is less than 1 mg per kg (0.897 mg per kg). There are rare

contraindications of lidocaine, this would include the rare allergy. All patients are asked about potential allergies. The French guideline address the issue of patients on anti-platelet and anti-coagulation noting that *"The American Society of Pain Medicine and Regional Anesthesia, the European Society of Regional Anesthesia and Pain Management, the American Academy of Pain Medicine, the International Society of Neuromodulation and the World Institute of Pain have recently published recommendations on how to deal with platelet and anticoagulant drugs when performing different procedures. The peri-nervous injection of an anesthetic drug is classified as a low-risk procedure for bleeding accidents."*

Need for multidisciplinary interventions:

In Canadian practice, most patients with spasticity are manage by PMR, Neurology or pediatricians with medical treatments such as oral anti-spasmodic, baclofen pumps, or injectable botulinum toxins. Bracing and physical therapies are adjunctive treatments that are unequally funded, and poorly accessible in provinces such as British Columbia as they are poorly funded by the province. The idea of a polyclinic with a medical-surgical-therapist collaboration, is rare in Canada. Neuro-orthopedics is the name now utilized to encompass such collaborations. Dr. Mary Ann Keenan, American professor emeritus authored many of the initial studies on neuro-orthopedics and is a mentor to our group. A growing body of literature, outlined below, notes the rising impact of surgical and collaborative intervention.

Improved upper extremity spasticity after surgical neurectomy or cryoneurotomy is currently reserved for patients who had otherwise maximized traditional therapies. For example, they remain with a tightly fisted hand with skin breakdown, have no ability to use their hand, have a tightly adducted shoulder against their chest which impairs not only usage, but daily activities such as hygiene and dressing. Severe pain remains an addition indication. Proper systematic patient selection for the appropriate surgical or invasive intervention is critical to ensure that the chosen procedure will produce a predictable improvement in function.

Surgical neurectomy is an established effective procedure to reduce spastic tone and improve function in the upper extremity.[20 21] Recently, neurectomy has been increasingly considered in upper extremity spasticity compared to tendon procedures in patients who either had poor response to botulinum toxin or who were not candidates for toxin therapy. Our clinic offers a newer approach for neurectomy by incorporating the knowledge from spinal cord injury transfer surgeries, known as microfascicular surgery. We have also independently studied and offered a novel treatment of spasticity, the cryoneurotomy that has only one published case from the 1990s, which we are offering on a routine basis.[22] We have published the first paper on the use of cryoneurotomy in spasticity and have offered over 50 patients this novel treatment. [3] Our patients' improved upper extremity spasticity after surgical neurectomy or cryoneurotomy has been widely presented at international congresses as posters, and cases studies, invited lectures and keynote addresses, but has not yet undergone prospective study[4–6].

In order to best assess potential, patient selection for the appropriate surgical or invasive intervention is critical to ensure that the chosen procedure will produce a predictable improvement in function. Our literature to date has found that the changes in the range of motion have been so drastic that multi-modal assessments are needed to document outcomes.

This study will assess the outcomes of current standard of care, which is to screen patients that remain with problematic spasticity after treatment for their candidacy for DNB and further treatments. They are triaged into optimal streams of increased BoNT-A dosage, which is the normal non-interventional approach and requires no further study. The intervention streams are surgery, cryoneurotomy, tenotomy or not a candidate. For those undergoing the interventional procedures, we will assess their change in function clinically and using dynamic range of motion.

The decision-making in spasticity treatment requires an interdisciplinary approach including the (DNB). The patient selection pathway for surgical neurectomy or muscle lengthening has been well established[23] [11] to predict candidacy for and predict outcomes from these procedures, mainly however, in the lower limb.

The principal of patient selection is contingent on the response to the DNB. The DNB allows the clinician to determine if greater range of motion or function is possible with a further intervention. Several pathways have been proposed. Such as the Mont Godine triage pathway using nerve blocks for the treatment of the spastic foot.[24] An upper extremity pathway has not presented in the same manner. In a triage, the patient without ongoing problematic spasticity is selected for nerve block for the upper extremity:

1. In a patient with milder ongoing going spasticity undergoes a DNB which restores the range of motion an assessment is made if botulinum toxin and bracing and therapy have been offered and in sufficient quantity. If not, then this treatment remains the standard of care. The maximal dosage for the three toxins available in Canada for an upper extremity of botulinum toxin varies widely but consensus suggests 300 units of onabotulinum or incobotulinum toxin or 500 units of abobotulinum toxin. In Canada, typically, total body doses are maximum 600 units in the first two subtypes (meaning clinicians routinely exceeded the formulary dose of 400 units all across the country) and 1500 of the latter. Increased or altered dose is reserved for those that have the least spasticity and just require a little more relaxation. The total body dose would not exceed the 400-600 total body dosage. The extra dose would be taken from another area if already at maximal dosage. This pathway requires no study as is the normal clinical care pathway.

2. In more severe cases, if a block increases active range of motion or allows for much greater passive range of motion, it implies the muscle has not contracted but the spastic drive it is too overactive for the toxin and therapy to overcome its pull. Thus, there is the consideration for a cryoneurotomy, radiofrequency or surgical neurectomy, will be explored. Each of which will have specific indications. Cryoneurotomy, is a percutaneous procedure targeting easily identified large motor branches that do not have a sensory component to avoid loss of sensation. Thus, only large motor nerve branches to specific muscles that can be identified are the target for this procedure. This includes, the branches of the musculocutaneous nerve to the brachialis and biceps, the radial nerve to the brachioradialis, the pectoral nerve to the pectoral muscles. A median nerve to the hand is possible if the patients reports no loss of sensation to successive blocks in a paralysis clenched fist. Surgical microfascicular neurectomy allows of

exquisite intra-operative dissection of most muscles of the upper extremity, including the muscles controlling wrist and finger function, shoulder and elbow. More individual muscles can be targeted with this option.

3. In patients where no change is found, muscle and joint contracture are present which require more extensive surgery to either cut tendon (tenotomy), muscle lengthening, or capsular release of a joint.

4. Patients undergo the less invasive procedure of neurotomy or choose to next undergo a surgical procedure based on their outcomes as part of our clinics standard of care.

Power Over:

Patients involved in thus study have lived and managed their spasticity from years to decades. This clinic evolved after the sense of hopelessness that no more could be done with the traditional botulinum toxin centred plan. This multi-pronged treatment options offers the patient the choice and option to choose the treatment option they wish to undergo based on consultation with clinicians. The DNB clinic which occurs weekly is the only such clinic in Canada. The DNB is one of the rare instances where we can demonstrate what an intervention could look like. This study is not a clinical trial; thus, no patient is "enrolled" at random in a study arm. In fact, each patient is part of the decision-making tree. Patients and families may choose to forego surgery if it is the "best" option and undergo a cryo or radiofrequency neurotomy if they prefer to not undergo anesthesia, or surgical care. Patients may choose to have no change to their care pathway. Patients that do not participate in the study will undergo the same care as those that do not. All patients have the option of trying each of the options as a step wise approach to management is a typical surgical rehabilitation strategy. This study is an assessment of change from the selected clinical interventions. Finally, the patients will be enrolled after the decision to treat with a specific intervention has been selected.

Primary Objectives:

1-Degree of changes in spasticity as assessed by Modified Ashworth Scale[32] from baseline and in 1, 3, 6, 9 and 12 months after the intervention. The test will be done by the trained assistant which is not enrolled in providing medical care. It will be graded as 0 (no spasticity), 1, 1+, 2, 3 and 4 which the affect part is rigid in flexion or extention.

2-Degree of changes in range of motion of tested joints as assessed by Tardieu Scale[32] from base line and in 1, 3, 6, 9 and 12 months. The maximum of passive range of motion in slow movement(V1) and degree of catch in speed (V3) and active range of motion will be measured by goniometer.

3- Upper limb function changes as assessed by DASH[37] questionnaire (2006). It is a self-administered questionnaire that participants will be asked to fill out at baseline and in 1, 3, 6, 9 and 12 months. Final score will be calculated based on the provided formula and will be between (0), which means patient has no difficulty at all and (100) which means the worst outcome.

4- Patients satisfaction in achieving their goals after the procedure as assessed by Goal Attainment Scale[38]. Based on this scale participants will be asked for 3 main goals that they desire to achieve after the intervention. The baseline score will be (-1) and they will be interviewed again at 1, 3, 6, 9 and 12 months, to record how they reported their achievement. The scores of (-2), (-0.5), (0), (1) and (2) will be assigned if they feel that their condition is worse than before, better but not as good as expected, as expected, better than expected and much better than expected. All goals will be weighted equally, and final score will be calculated based on the available formula, in each session. The higher score is presenting of better outcome.

Secondary Objective:

1- Upper limb function changes as assessed by Box and Block test. Participants will be in sitting position and will be asked to move the cubes from one part to the other part in 1 minute. The test will be done in baseline and in 1, 3,6, 9 and 12 months.

2- Changes in pain as assessed by Brief Pain Inventory Questionnaire. This is a self-administered questionnaire that will be provided for participants for filing out at baseline and in 1, 3, 6, 9 and 12 months after the intervention. The Patient will ask to answer each question by choosing a number between 0 to 10, and the final score is calculating by adding these numbers together and then divided by 4. The result will show the severity of patient pain out of 10. (0 means no pain and 10 means the worst pain that can be imagine)

3- Changes in the Hand resting position as assessed by Keenan Scale (1987) [36]. Participants will be assessed by an independent examiner and based on available scale their hand position will be graded. Grade 1 is the minimum deformity while grade 5 Is the maximum deformity which is presented by clenched fist and palmar hygiene problem. The assessment will be done at baseline and in 1, 3, 6, 9 and 12 months.

4- Changes in thumb deformity (position of thumb in relation to other fingers) as assessed by House Scale (1981)[35]. Participants will be assessed by an independent examiner and based on available scale their thumb position will be graded between 1 to 4. Grade 1 is the minimum deformity and 4 is the maximum deformity. The assessment will be done at baseline and in 1, 3, 6, 9 and 12 months.

5- Changes in hand function as assessed by House Functional Scale (1981) [35]. The test will be done by an independent examiner and participants will be asked to pick a cube on the table while they are in a sitting position. Based on the available scale (o= No movement and 8= spontaneous use, complete) their hand function will be graded in baseline, 1,3,6,9 and 12 months after intervention.

6-Changes in hand grip strength as assessed by dynamometer and will be recorded in KG in baseline and 1,3,6,9 and 12 months. The test will be done by Jamar Dynamometer and will be recorded as KG.

Hypothesis:

Surgical or percutaneous ablative procedures can improve range of motion, function and patient satisfaction in patients that have plateaued or are refractory to botulinum focused therapies after screening patients with an ultrasound (US)-guided electrical (e)-stimulation DNB with 2% lidocaine to determine the most responsible muscle(s) in the spastic upper extremity.

Study Design:

This cohort study has a prospective intensive repeated measures study design. Repeated measures design is a research design that involves multiple measures of the same variable taken on the same subjects either under different conditions or over two or more time periods. Intensive denotes more measurements over time. Patients diagnosed with spasticity vary widely in function and limb usage; thus, the benefit of using this design is that it allows participants to serve as their own control.

Design Details:

Patients with upper extremity spasticity will be recruited from the multidisciplinary spasticity clinic. All study patients will have been assessed in the interdisciplinary team consisting of a physiatrist, hand surgeon, and an interventional anesthesiologist. US-guided e-stimulation DNB with 2% lidocaine will be used as a screening tool to determine the most responsible muscle(s) for the spastic upper extremity. Pre- and post-block maximum active and passive range of motion in the spastic muscle group., and the presence of fixed joint contractures will be assessed.

Based on the results of the DNB, patients and their clinician selection the mutually selected most appropriate treatment streams: altered toxin dosage, surgical microfascicular neurectomy, percutaneous cryoneurotomy, radiofrequency neurotomy, surgical tenotomy, or unlikely to benefit from further procedures. The choice of which stream is based on the response of the nerve block. All patients with contracture will need a tendon or muscle surgery to improve range of motion. Patients with increased range of motion in isolated regions, such as the shoulder adductors, elbow flexors, can undergo cryoneurotomy on their isolated motor nerve. Patients with increased range of motion in the finger and wrist flexors require nerve surgery as well as possible muscle and tendon surgery to the motor fibres cannot isolated for nerve ablation in the region. The decision to not offer a procedure and increase toxin is reserved for the milder cases where range of motion is quite good, but the nerve block reveals even more loosening. This group will not be part of our study as that is the typical course of treatment.

Beginning of Study:

After surgical or percutaneous neuroablative procedures are selected patients will be invited to enroll in the study.

There will be no change in usual care after the procedures. Units of BoNT used will be tracked. All patients will be assessed at each stage by a single assessor to administer measurements and test scores. This study is not blinded. Blinding is not typical in surgical studies. It is too difficult to hide scars. The skin will need to be exposed to ensure proper measurements. The assessor would also intuitively guess by the deformity of the arms which procedures were most likely undertaken.

Initial Contact Letter:

Once a patient elects to undergo a nerve or surgical procedure they will receive a study information package at the time of decision. All patients have routine follow ups in clinic and the assessment will be done in the same days of their visits. All patients will be offered to take the package home to consider or fill out in clinic. Patients will receive one reminder phone call or email at their preference to determine if they will participate. All patients will be given a reminder call by our research assistant two weeks after unless they opt out.

Surgical Neurectomy Stream.

In Europe, surgical treatment for spasticity is more commonly pursued by offering neurectomy of involved nerve branches to overactive muscles [12,20,21,25–27]. However, the small body of literature does not take into account the novel, cutting edge, nerve transfer techniques of pioneers, such as Susan MacKinnon in St. Louis. [28]

Since 2016, a single surgeon in Victoria has performed surgery on patients with spasticity to reduce the over-activity of spastic muscles and improve hand function (the microfascicular neurectomy). By applying an understanding of microfascicular anatomy of individual nerves, developed from and widely used in nerve transfer surgery, Dr Krauss has been performing neurectomies as recommended by European experts, but with a different surgical technique. Essentially surgical neurectomy can be performed with smaller incisions, without the need for intramuscular dissection, and to targeted nerve branches with less operative time and less dissection than the European techniques. We hypothesize the clinical results are comparable to older established techniques with reduced perioperative recovery and complications for the patient.

Cryoneurotomy Stream

Based on the results from our first two years using cryoneurotomy as adjunctive therapy for the management of limb spasticity we proposed the following approach to the use of cryoneurotomy of motor branches for spasticity management. This protocol was published in 2019. [3]

1. An in-depth knowledge of the motor peripheral nerves anatomy is required to understand where they can be targeted without affecting sensory peripheral nerves, thus minimizing the risk of dysesthesia as an adverse outcome. There are numerous references that describe optimal locations to target peripheral motor nerves. [11,23,29–31]

2. Selection of motor branches to be targeted should be confirmed with DNB on two separate occasions pre-cryoneurotomy to demonstrate expected clinical benefits and minimize potential of adverse events such as loss of function or sensory impairment.

4. Cryoneurotomy procedure: we perform cryoneurotomy using a Lloyd SL 2000 Neurostat (San Diego, California). There are different devices available on the market if used, should be capable of delivering the same electrical stimulation as the Lloyd provides.

Procedural details include:

I. A thermal insulating catheter (#16 angiocatheter) serves as a guide and thermocutaneous protection from cutaneous frostbite. [31] The catheter also serves as an insulator to provide optimal e-stim.

II. Small dose of local anesthesia for cutaneous and subcutaneous anesthesia; less than 1 ml of 1% lidocaine to avoid diffusion.

III. Cryoneurotomy lesions are performed juxtapositioned to the motor nerve branch using an in-plane ultrasound technique to optimally view and guide the cryoprobe tip.

IV. Two lesions are performed, either superior/inferior or medial/lateral to the motor nerve at a temperature of -60° for 3.5 minutes per lesion for a total of 7 minutes as per standard cryoneurotomy protocols. [31]

V. Should the patient experience a painful sensation, then the probe tip is re-adjusted immediately and the cryoneurotomy resumed.

VI. Care is taken to avoid any vascular structures; therefore, colour Doppler setting on the ultrasound is essential.

VII. Post-procedure, the percutaneous entry point is stabilized with pressure and sealed with skin glue and occlusive dressing applied.

5. Standardized outcome measures should be used to capture outcomes and adverse events. We recommend use the Tardieu scale 25 for documentation of maximal range in a joint with a slow stretch as V1 (maximal range of passive motion = XV1), and a power high velocity stretch as V3 (angle of catch = XV3), thus creating a spasticity angle denoted as V1–V3, the difference between the maximal slow stretch and rapid catch. The angle of paresis is calculated as V1 minus the patient's maximal active range of motion, indicating the patients active range vs the maximal range passively obtained.[32] Other outcome measures that may be used include the MAS.

6. Reassessment of the patient post-procedure to readjust the spasticity management strategy and goals. Redistribution of BoNT will likely occur. Ongoing follow-up as of the patient as needed, as there is a potential for nerve re-growth and repeat procedures as needed.

Pulsed radiofrequency Stream

The protocol follows the same assessment and preparation as cryoneurotomy. Dr. Vincent has performed thousands of these interventions to nerves. They are also percutaneous nerve procedures. The protocol is quite similar as cryoneurotomy, with the exception of the probe. Pulsed radiofrequency (PRF), a technique introduced in the 1990's [33], is known to be safe and effective on nerve structures and particularly relieving pain. It delivers an electrical field and heat bursts to targeted nerves or tissues without damaging these structures. Previous studies have used continuous radiofrequency (CRF) [34] exposes target nerves or tissues to a continuous electrical stimulation and ablates the structures by increasing the temperature around the RF needle-tip. PRF does not produce sufficient heat to cause structural damage. The availability of cryoneurotomy is quite limited to the lack of machines in Canada, where as radiofrequency is widely performed in hospitals and clinics all across Canada. To date our availability of time on the cryoneurotomy equipment is limited, and pulsed radiofrequency will allow for shorter waits.

Sample Size Justification. Statistical Analysis

Sample Size: N = 50

This is a pilot study. A convenience sample of 50 patients is anticipated, based on the volume of patients that has been triaged in this clinic to date. Over 100 patients have been triaged in 18 months, so it is anticipated that 50 target patients to be fully completed treatment in 18 months. At 4-6 (divided between surgical and interventional) patients per month for 12 months, this is achievable based on this clinical experience. Analysis will be individualized per patient, as each will undergo a unique procedure. Statistical analysis will address each patient stream individually. The outcome measures that will used are standard clinical and functional measures, but effect sizes are not readily available from previous studies in order to formally calculate sample size. Furthermore, this study uses an exploratory prospective cohort design, rather than a parallel group trial design, limiting the rationale for providing a sample size calculation.

To confirm that improvements in outcomes are statistically significant a paired t-test on the difference of proportions, applicable to pre-treatment and post-treatment, will be performed. Pearson's correlation and logistic regression will also be used to determine whether any key predictors are associated with any of the outcomes at final visit. We will employ repeated measures or linear mixed (multilevel) models of change to analyze within-person trajectories in all key outcomes for the intensive repeated measures data spanning the 12-month study period. Such models derive individual parameter estimates for baseline function and change pursuant to nerve or surgical procedure, and will directly index the magnitude in improvement for each outcome (pursuant to treatment) with each individual serving as their own control (i.e., with change indexed relative to each individual's own personal baseline).

If normal distribution in the outcomes does not stand, McNemar's test and Spearman correlation will be calculated instead of paired t-test and Person's correlation, respectively.

We will rely on Island Health Statistic for this process, the data will not leave Island Health and will be analyzed through REDCap. (Statistics provided by Victor Espinosa, Island Health)

Inclusion Criteria:

- Adult patient ≥ 18 years old, with upper extremity spasticity causing functional impairment.
- Patients that have plateaued in outcomes in which the clinical examination suggests further interventions can be trialled.
- The clinical examination, including a V1 (maximal passive stretch) and V3 (Fast catch) on upper extremity examination that demonstrates further passive or active range may be possible, versus if contracture must be managed. For example, a fisted hand that can be forced open. This includes factors such as fluctuating tone or clonus interfering with assessment.
- The patient undergoes a diagnostic nerve block to determine if there is a reducible spasticity in the muscle versus contracture.
- The patient has been offered a neuroablative procedure or surgery and has elected to undergo the procedure. The patient has consented to undergo said procedure.

Exclusion Criteria:

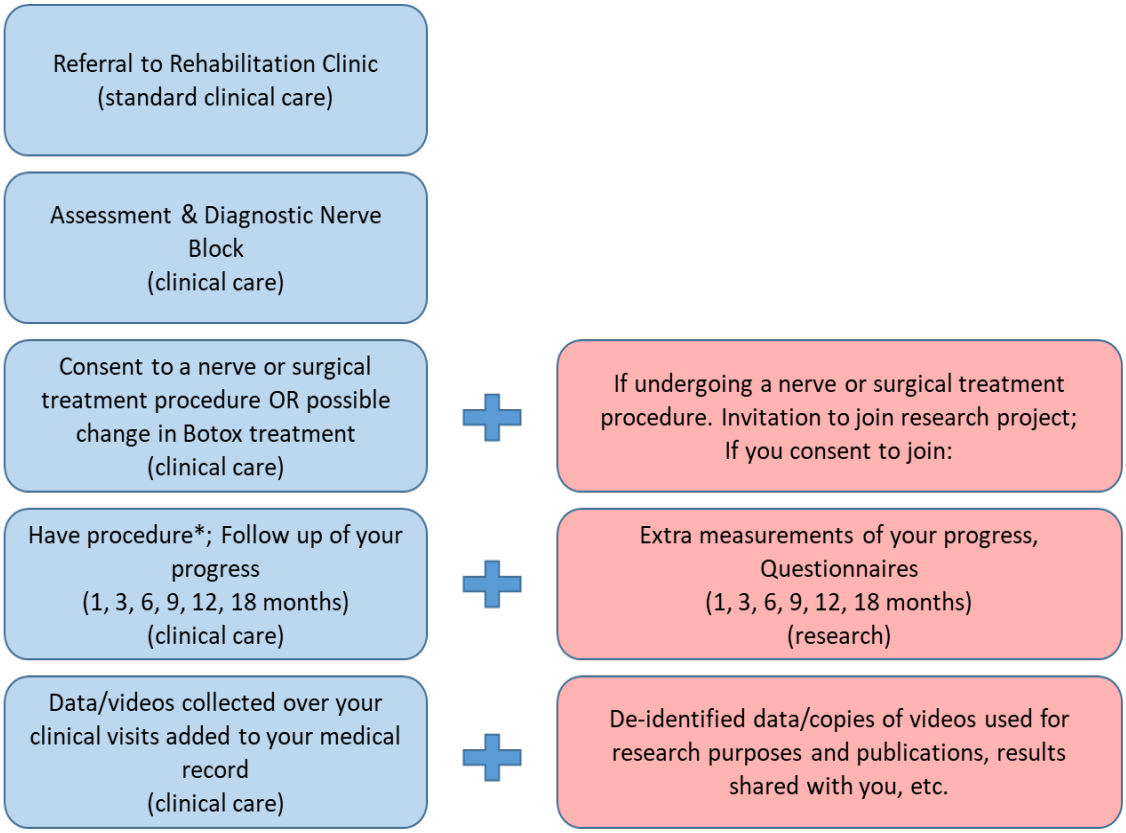
- Patients where no consent or Assent is obtained
- Unable attend treatment schedule

Efficacy Evaluation/Schedule/length of the study:

Patients will be recruited over a one-year period. All patients would have already been screened and elected to undergo one of the procedures with consent to procedure. All patients will require baseline measurements prior to their procedure. Efficacy will be measured by their assessments after the procedure using our outcome measures, including a twelve months follow up for the initial study but will remain for up to 24 months.

Visual Timeline:

Clinical Care and Research Activity Timelines



*Note, you may have more than one type of procedure, based on your response/recovery.
You and your doctor would discuss this as it is a clinical decision. (standard clinical care)

Time required to complete study (months):

24 months.

Access to Patient Charts:

As part of our usual standard of care. The charts will be accessed by the treating physicians. The research assistant will require chart access to plot demographics and contact patients.

Incidental Findings:

Incidental findings are not expected in the ablation procedures as this is percutaneous and the ultrasound of the limb would have been done on two previous occasions. While not expected in upper

extremity surgery, surgical incidental findings include, abnormal anatomy, tumours. Any incidental finding would be reviewed with the patients and investigated fully by the research team and or their primary care givers, with appropriate referrals and imaging found.

Stopping rules:

The study would be stopped by the clinical team in the advent of treatment failure, or adverse events in conjunction with the CEC. It would be stopped if the REB or Health Authority stops the trial over research concern. Loss of funding is an unlikely cause of stopping as the treatments are funded, it is only the data collection salary that provides the largest expenditure.

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