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PII: S2590-1095(24)00023-5
DOI: https://doi.org/10.1016/j.arrct.2024.100333
Reference: ARRCT 100333

To appear in: *Archives of Rehabilitation Research and Clinical Translation*

Please cite this article as: Alexios Carayannopoulos DO , David Johnson MD , David Lee MD , Anthony Giuffrida MD , Kavita Poply MD, PhD , Vivek Mehta MD , Marco Amann MD , Douglas Santillo PhD , Yousef Ghandour DPT , Amy Koch PT , Meredith Langhorst MD , Robert Heros MD , Precision Rehabilitation following Neurostimulation Implantation for Multifidus Dysfunction in Nociceptive Mechanical Chronic Low Back Pain, *Archives of Rehabilitation Research and Clinical Translation* (2024), doi: https://doi.org/10.1016/j.arrct.2024.100333

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Running head: Multifidus Dysfunction Neurostimulation

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Material Presentation: Poster format for American Society of Regional Anesthesia and Pain Medicine (ASRA Pain Medicine) Annual Pain Medicine Meeting on November 10-11, 2023

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A. Carayannopoulos, D. Johnson, D. Lee, R. Heros, M. Langhorst, A. Guiffrida contributed to the development of the protocol. A. Carayannopoulos and D. Johnson drafted the manuscript. All authors reviewed and approved the manuscript before initial submission.

ABSTRACT

Chronic low back pain (CLBP) is a debilitating, painful, and costly condition. Implantable neuromuscular electrical stimulation targeting the multifidus musculature is growing as a non-pharmacologic option for patients with recalcitrant nociceptive mechanical CLBP who have failed conservative treatments (including medications and physical therapy) and for whom surgery is not indicated. Properly selecting patients who meet specific criteria (based on historical results from randomized controlled trials (RCTs), who diligently adhere to implant usage and precisely implement neuromuscular rehabilitation, improve success of significant functional recovery, as well as pain medication reductions. Patients with nociceptive mechanical CLBP who underwent implanted multifidus neurostimulation have been treated by physicians and rehabilitation specialists who have honed their experience working with multifidus neurostimulation.

They have collaborated on consensus and evidence-driven guidelines to improve quality outcomes and to assist providers when encountering patients with this device. Physicians and physical therapists together provide precision patient-centric medical management with quality neuromuscular rehabilitation to encourage patients to be experts of both their implants and quality spine motion to help override long-standing multifidus dysfunction related to their CLBP.

Keywords: implantable neurostimulators, chronic pain, low back pain, paraspinal muscles, patient-reported outcome measures, patient selection, rehabilitation

Abbreviations:

CLBP - chronic low back pain

ROM - range of motion

MRI – magnetic resonance imaging

IPG – implanted pulse generator

VAS – visual analog scale

ODI – Oswestry Disability Index

RCT – randomized controlled trial(s)

SCS - spinal cord stimulation

PNS - percutaneous neuromuscular stimulation

ADLs - activities of daily living

PT – physical therapy or physical therapist

INTRODUCTION

Chronic Low Back Pain Burden

Low back pain is a common and disabling condition that has significantly burdened individuals, healthcare systems, and society for decades without proven interventions to shift its trajectory.[1–4] While acute low back pain (existing for less than 12 weeks[5]) typically can resolve in a matter of weeks, Stevans, et al.[6] noted nearly a third of people presenting to primary care for acute low back pain could transition to chronic low back pain (CLBP). CLBP (pain for greater than 12 weeks and present for more than 50% of the time in the last six months[7]) has shown to negatively impact people's physical, psychological, and social functioning, subsequently decreasing quality of life.[8]

CLBP also has imposed substantial burdens on society. From a public health epidemic of opioid overdoses (with a large portion of consumers with CLBP)[9] to financial burdens of direct and indirect costs (i.e., healthcare disability costs, missed work) in the billions annually in the United States, CLBP has been challenging to curtail.[10] Furthermore, CLBP is projected to increase with population aging and risk factor prevalence rising, including obesity and sedentary lifestyles.[2] Addressing CLBP burdens requires a comprehensive approach encompassing prevention, early intervention, accurate diagnoses, and evidence-based treatment and management strategies.

With numerous multifactorial pain generators involved in CLBP,[11] the treating clinician typically conducts a thorough history and exam to distinguish management pathways for patients with CLBP, pathways which are not always clear. One decision pathway is to determine if patients need surgical intervention to avoid further detriment

to their condition. If this is the case, patients move on to surgery. If not, patients may be classified as either having neuropathic or nociceptive CLBP. Neuropathic CLBP is typically characterized by leg-dominant pain stemming from inflammatory or ischemic consequences involving the nerve root.[12] Nociceptive CLBP typically dominates the lumbar spine region and can develop from trauma or long-term structural tissue damage.[12] Recognizing these two broad classifications, which can occasionally overlap, essentially can help clinicians better align care for management planning, including adjunctive technologies to assist with their CLBP and improve function and reduce pain medication.[13]

This paper intends to focus on the more enigmatic nociceptive mechanical CLBP for which there has been little technological advancement until recently. An evolving evidence-based intervention, the implantation of a multifidus neurostimulation device, has shown through RCT and real-world evidence to have large impacts on pain, quality of life, and function for those in this classification. To improve the overall success for both providers and their patients with nociceptive mechanical CLBP who may undergo implantation with this newer technology, efforts have been made by rehabilitation providers with significant experience surrounding multifidus neurostimulation to develop general guidelines in caring for these patients. These guidelines, conceived for this article, are an evidence-based consensus by the authors, which includes comprehensive consideration of select aspects of musculoskeletal health known from the literature to be prevalent in this population (i.e., sleep disruption, movement dysfunction, etc.).

Mechanical CLBP and Implanted Multifidus Neurostimulation

Majority of patients with CLBP have no indication for spinal decompression or stabilization surgery[14] as most suffer from mechanically-driven, predominantly nociceptive pain.[15,16] CLBP prevalence continues to grow despite conventional nonsurgical symptom-based treatments (i.e., medications, exercise, tai chi, yoga, mindfulness-based stress reduction, psychological therapies, multidisciplinary rehabilitation, acupuncture, massage, spinal manipulation, and interventional procedures including medial branch nerve ablations).[17–20] Mechanical CLBP treatment success depends on symptom control, source identification and reduction, which requires integration of focused functional interventions and biopsychosocial influences to overall optimize recovery.

It has long been thought muscle dysfunction contributes to mechanical CLBP and that strengthening in conjunction with sensorimotor retraining is the ideal process. However, various exercise programs have been studied with inconstant results.[21–23] Specific exercises, including motor control and stabilization, aimed at focused activation of deep core muscles, seem to be more effective than other exercises in the short term.[24,25] Activating the critically-important deep stabilizing multifidus muscle system becomes challenging in the presence of lumbopelvic spine-muscle inhibition and movement dysfunction.[26,27] Consequently, long-term effectiveness of these specific exercises on disability is limited and the benefits of repeated rehabilitation bouts appear to be limited as well.[17,28] Additionally, structural muscle changes[29] and related cortical remodeling[30] may necessitate increased frequency, intensity, time, and individualized treatment approaches not readily available.[31] This may explain why dedicated exercise

and strengthening-centered rehabilitation programs provide unsatisfactory outcomes indifferent to “usual care” over the long-term for some patients.

Functional spinal instability (due to multifidus muscle dysfunction secondary to muscle inhibition and loss of neuromuscular control) has emerged as an important functional etiology in mechanical CLBP development.[32] When motor control entrenches acutely or chronically, multifidus muscle atrophy can typically contribute to spine segment micro-instability susceptibility and ongoing nociceptive pain.[33] Functional spinal instability with underlying multifidus muscle dysfunction may be an important driving factor in perpetuating mechanical CLBP and recurrence episodes or flares. Strengthening-focused rehabilitation strategies attempt to re-engage the deeper, more involuntary core muscle stabilizers, but the altered cortical mapping of these muscles in the motor cortex make this very challenging.[30,34]

As such, a proposal was made in 2015 to elicit multifidus muscle motor responses via electrical stimulation of the medial branch of the dorsal ramus nerve to facilitate restoration of segmental control and functional spine stability, thereby expediting pain reduction and restoring functional abilities.[35] Subsequent clinical studies have demonstrated long-term (three-year) improvements in participants who received an implantable multifidus neurostimulation device.[36] Results showed that 67% of participants reduced their CLBP to less than 2.5 on a visual analog scale (VAS), while 62% reduced their disability based on Oswestry Disability Index (ODI) by greater than or equal to 20 points. Quality of life also improved which included reduced opioid consumption[37–40] and reduced healthcare utilization.

Patient Selection Overview

Implanted multifidus neurostimulation is indicated for patients with mechanical CLBP (without neuropathic/radicular leg pain) recalcitrant to conservative treatments and presenting with clinical features of underlying multifidus dysfunction. Ideal candidates have history and examination findings suggestive of multifidus dysfunction as well as supportive magnetic resonance imaging (MRI).

Subjective history from these patients often includes reports of pain exacerbated by small motions (i.e., slight flexion/extension, prolonged sitting or standing, or changing positions) in everyday small-load tasks (i.e., brushing teeth, washing their face, doing dishes, or getting dressed). Patients may report their back feels “unstable” or intermittently “gives out”, and are often plagued by intermittent muscle spasms.[41] Physical examinations ideally include assessing for sagittal aberrant movements,[41] a Multifidus Lift Test,[42] and a Prone Instability Test,[43–45] (described elsewhere).

Briefly, the Prone Instability Test is most important as it recruits the deep fibers of the multifidus and will elicit pain relief with a positive test. It also was the test used as an inclusion criterion in RCTs using a multifidus neurostimulation device.[46,47] The Multifidus Lift Test includes palpation of the multifidus and qualifies the summed contraction of the multifidus response under a counterbalance demand. Positive responses indicate no multifidus contraction and/or an overcompensation of the global spine muscles, (i.e., the erector spinae).[48] Finally, aberrant movements can be qualitatively observed and matched with patients’ indications of their pain during small motions in their daily lives.[48] If all three of these tests are positive, it is very likely there is presence of underlying multifidus neuromuscular control issues, or multifidus dysfunction.

In addition to a thorough patient history of CLBP with exacerbating/relieving movements, clinical indications of multifidus dysfunction (at minimum, a positive Prone Instability Test and history of pain with small movements), establishing an ideal candidate for a multifidus neurostimulation device may also include MRI findings with multifidus muscle fatty infiltration, indicative of muscular atrophy. These MRI findings are best appreciated on T1- or T2- weighted sequence axial cuts and are graded as none (Grade 0), slight (Grade 1), or severe (Grade 2).[49–52] These multifidus changes are highly correlated with the presence of back pain but not as well correlated with what kind of back pain nor with how the multifidus functions. Therefore, the entire presentation of an ideal patient first needs to include any exacerbations with small or sustained movements (i.e., brushing teeth over a sink) from the clinical history and a positive Prone Instability Test. The clinical impression of an ideal candidate is further clarified with presence of, or increasing changes, in multifidus fatty infiltration on MRI images.

Contraindications to an implanted multifidus neurostimulation device are similar to those for any implanted neuromodulation device, including active infection, inability to use the device, during pregnancy, etc. A history of prior lumbar surgery is currently considered a relative contraindication given a lack of evidence using the therapy in this cohort. Conversely, any history and diagnostic imaging suggesting a need for surgical intervention should be considered an absolute contraindication, which includes severe central canal stenosis, unstable spondylolisthesis, or disc herniation with nerve root compression and associated radicular symptoms.

MATERIALS and METHODS

Implant Overview

It is important to have an appreciation of the implant procedure to understand how to protect the leads, lead pathways, and placement early in the healing and rehabilitation process. Additionally, it is valuable to also teach patients how to protect the longevity of the leads and implant over time as this technology typically is used to gain long-term lasting effects. The multifidus stimulation implant procedure has evolved since Deckers et al.[35] with the current procedure now utilizing a lateral approach with a two-incision technique. One incision is made for the implantable pulse generator (IPG) while the second is for the lead wire introductions. This midline lead wire incision is now performed at L4 to avoid a critical overlap of thoracolumbar fascia at L3 which historically subjected the leads to repetitive shearing forces generated by two layers of fascia moving in opposing directions at this juncture.[35] Lastly, a straight relief loop is created and tucked in at the midline incision prior to tunneling leads to the IPG pocket site (Figure 1). This builds slack in the system to allow for lumbar multiplanar motion and to reduce unnecessary forces on the system.

Potential Complications

Potential complications following a multifidus neurostimulator implantation may typically occur immediately following the procedure. Types of complications with multifidus neurostimulation implantation are similar to that of spinal cord stimulation (SCS) and percutaneous neuromuscular stimulation (PNS) lead wire implantation, which are typically separated into device-related and biologic complications.[54–57]

Device-related complications associated with implantable multifidus neurostimulation, SCS and PNS may include lead migration, lead breakage, over- or under-stimulation, intermittent stimulation, hardware malfunction, loose connections, battery failure, and generator communication failure. Biologic complications include infection, seroma, pain over implant site, allergic reaction, and skin breakdown, but unlike SCS, do not include epidural hemorrhage, cerebrospinal fluid leakage, or anything related to the spinal cord region. Also, unlike PNS, the multifidus implanted neurostimulator lead wires and IPG are all within the body, instead of percutaneous and externally connected to a pulse generator.

Like traditional SCS and PNS, post-operative limitations on function should focus on minimizing disruption to the implanted system and soft tissue by limiting forces around the leads and IPG for SCS and implanted multifidus neurostimulator, and around the lead wire exit for PNS.[56] Lead migrations, one of the most common complications after SCS implant, and lead dislodges and fractures in PNS[58], have not been present with implanted multifidus neurostimulation due to distal tines on the IPG leads anchoring into the bilateral intertransversarii plus the creation of a strain-relief loop. To date, there are zero reported lead migrations from the ReActiv8-B randomized clinical trial.[37]

To remain conservative during the healing process, patients with an implantable multifidus neurostimulation device should be advised on post-operative activities, including activities of daily living (ADLs), post-operative physical therapy, and home exercise programs while wound healing and scar tissue formation proceed. This may also be the case for PNS and SCS, however, the PNS protocol is limited to 60 days and

the device is not meant be permanent. Contrast this with SCS, which remains internal permanently but is only palliative. Implantable multifidus stimulation is different from both SCS and PNS in that it promotes renewal of multifidus motor control, can remain implanted permanently, or be explanted for low back pain resolution. Contraindications are similar for all the devices, except with PNS, which is not indicated for patients with allergies or sensitivities to adhesives due to bandages protecting the wire exit site and pulse generator attachment to the skin.

Rehabilitation Overview

This rehabilitation overview was formulated through an evidence-based collaborative consensus among the physician and physical therapist authors who have developed their experiences while caring for patients with CLBP and multifidus neurostimulation implants. They included a comprehensive assessment of select musculoskeletal aspects known from the literature to be prevalent in CLBP, (i.e., sleep disturbances, movement dysfunction, functional deterioration, etc.) as well as key timing aspects (e.g., tissue healing).

Following the implant procedure, patients are typically prescribed to be on relative rest for approximately two weeks. This includes simple engagement with low intensity and minimal range of motion (ROM) bending such as for manipulating objects below waist height, any ADLs, and transitions, such as stand-sit-stand. It is imperative patients demonstrate understanding of these minimized spine motions to allow proper healing to occur. Ideally, patients should physically show their best lifting and reaching techniques utilizing high quality hip-hinging while maintaining neutral spine awareness,

utilizing proper hip-centric rotation, and demonstrating motions powered by the posterior kinetic chain. These steps are necessary to begin processes of reprogramming motor planning and to avoid pre-surgery pain-adapted motions.[59] Most often, implanting physicians will put patients on conservative load, repetition, and speed restrictions to optimize healing and promote use of proficient movement performance. Additionally, walking may also be encouraged, within capabilities, to continue cardiovascular strengthening. If patients have sedentary jobs, they may typically return to work after a few days following surgery.

Two weeks after the implant procedure, multifidus neurostimulation implants are programmed with patients at an in-clinic visit. Amplitude and electrode configuration settings are set to produce strong, yet comfortable, multifidus muscle contractions with patients in prone or side-lying positions. The device is initiated with a handheld activator switch and each cycle of neurostimulation starts off with a ramp up to a 10-second multifidus contraction at the desired settings followed by a ramp down for a 20-second rest. Patients are typically educated on the specifics of how to turn on the device using the activator and use the implanted device at the recommended 30-minute twice-daily dosage.[36] Parameters can be adjusted as needed to continually achieve desired levels of muscle contractions long-term if and when patients accommodate to the stimulation. Repetitive multifidus contractions have gradual and longitudinal accrual effects over time and are thought to override the underlying inhibitions contributing to normalized neuromuscular control and functional spinal stability.

Typically, patients return for programming updates at 6-weeks, 3- and 6-months post-op where re-evaluations are performed, and any adjustments can be made. Early

treatment responses will typically be variable between patients, but at approximately two to three months post-op, most patients tend to report a percentage of functional improvement, particularly if functional movement instructions were specifically and distinctively delivered. If upon follow-up patients don't report substantial pain relief, they most often note functional improvements as their low back and deep core musculature motor control improves. Pain relief has been observed to typically follow functional improvements by approximately one to two months.

Studies utilizing an implantable multifidus neurostimulation device to date have not included formal rehabilitation as part of the treatment plan to avoid confounding cause and effect observations. In cases where implanted neuromuscular stimulation has been deemed appropriate, providing proficient movement-focused rehabilitation in tandem with the onboard neurostimulation tends to be a logical next step.

Referral to rehabilitation is typically based on many factors, including the number and magnitude of comorbidities, history and comprehension of exercise, fitness, nutrition, and other key aspects of healthy living. Additionally, a patient's individual goals and motivation for returning to function, desired activity levels, and work demands are factored in. We suggest providing education about movement dysfunction and task optimization in the perioperative period to optimize quality movements for everyday life activities. While some physicians suggest starting rehab for education and activity modification as early as two weeks post-implantation, most tend to start at about six weeks post-implantation when movement restrictions are typically lifted, and patients have had time to accommodate to the twice-daily stimulation sessions.

Shared rehabilitation goal setting, where patients and professionals contribute to valuable dialogue surrounding the patient's unique rehab goals, are highly recommended.[60] There is continued caution as patients build their individual goals, however. It is important to structure goals to consider how long the person has been in a chronic pain condition, particularly preparing them for more quality movement and eventual goal achievement. Some may have goals to return to gardening while others strive to return to running ultra-marathons. Regardless of functional demands, patients should understand movement tasks are to be performed with engrained movement proficiency to avoid a rebound of the "movement dysfunction-pain" cycle which underpins motion segment micro-instability development.

Patients undergoing multifidus neurostimulation device implantation have an accumulated history of CLBP and often have engrained patterns in their daily lives that could hinder optimized progress in healing. Providing any sources where patients can receive assistance on behavioral health,[61] nutrition,[62,63] and sleep,[64,65] in addition to their functional movement[66–68] and exercise/activity[69] could greatly improve their recovery toward their goals. Importantly, after multifidus neurostimulation implantation, patients must be screened to develop individualized comprehensive plans focused on rehabilitation and exercise incorporation long-term.

After implantation, initial rehabilitation typically transitions to a home exercise program which addresses underlying trunk bracing secondary to pain and weaknesses, major mobility deficits,[70] and underlying cardiovascular function. Simple aspects, such as diaphragm breathing[71,72] to help coordinate trunk control with ADLs, to larger integrated components, such as balance,[73–75] become critical components to return to

ideal function. As multifidus activation normalizes, restoration of core muscle function and neuromuscular control is achieved through an integrated functional movement exercise progression.[43,44,76–79] Criteria for patient discharge will vary based on individual desired goals and specific job demands. Typically, at 12-16 weeks post-implant, more advanced physical function testing can be performed. If testing criteria are met, return to work/full activity is encouraged as part of the rehabilitation program.

Overview/Goals of Rehab Phases

Pre-implant phase:

Education regarding the primary drivers of mechanical CLBP movement dysfunction ideally should be included, especially concepts of stability, key role of the multifidus, multifidus dysfunction, and atrophy driven by entrenched pain and dysfunctional movements. Mobility issues are typically screened to determine areas to be addressed after surgery. Education criteria for desirable and skillful movement performance typically are centered around hip-hinging for bending tasks. Additionally, the multifidus and core musculature co-contractions are emphasized in all desired movements (e.g., quadruped to half-kneeling, rolling from supine to side lying to sit), especially hip-hinging tasks, which are defined with the following lumbo-pelvic movement performance points:

1. Hip-centric rotation
2. Neutral spine maintenance
3. Posterior kinetic chain powered movement
4. Unloaded knee position (i.e., bodyweight supported mostly in the heels)

5. Proficiency-limited task performance ROM, load, speed, duration, repetitions must all be limited if any proficiency in points 1-4 are compromised)

High quality education about multifidus neurostimulation implants, surgical expectations, formal consent, and the post-op course remain integral to perioperative consultations and are best provided by the implanting physician. Twice-daily activation session compliance continues to be stressed to build awareness, and realistic expectations usually are discussed related to pain relief and functional improvements.

Protective Phase (0-2 weeks post-op):

Wound care education typically is guided by individual clinician preferences at this stage. Bodily movements are typically restricted in activity intensity to simple ADLs, performing only shallow bending tasks with quality hip-hinge kinematics. Assistance may be required for both overhead reaching to avoid loading and for larger hip ROM tasks such as putting on shoes and socks to avoid intra-lumbar flexion. Patients may also benefit from using modified or higher chair seats to permit greater adherence to movement proficiency. General activities (i.e., walking) for progressing cardiovascular strength are encouraged.

Initial Activation Phase (2-6 weeks post-op):

Initial device programming is performed at 2-weeks post-op. Goals, at a minimum, typically consist of comprehending proper 30-minute twice-daily usage, adhering to boundaries of low-level functional capacity, and reinforcement in

maintaining ADLs with proficient low-intensity lumbo-pelvic movements (e.g., when brushing teeth, to squat down with back straight, using hip-centric motion and unloaded knee positions to reach the sink). Goals should also include steadily increasing confidence with walking frequency and duration. Movements are restricted to protect the leads as it is thought to take approximately six weeks for the leads to scar and be secure.

Physical Therapy (PT) Phase 1 (may begin 6-8 weeks post-op at a maximum of 2 visits per week for 2 weeks):

PT initial evaluation:

Self-reported outcomes ideally are recorded for baseline assessment (i.e., ODI, VAS). Global movement assessments to identify major mobility or immobility typically should be performed. Areas of focus should include, at a minimum, hips, thorax, and ankles, as restricted movements in any of these areas can adversely affect functional movements.[80,81] Maximizing mobility includes any joint mobilizations, stretching and continual evaluation of these deficits in the broader scheme of activities. If reduced thoracic extension and flexion are limited, this increases the likelihood that motion must occur elsewhere, such as demanding more from the lumbar spine. Similar to lack of mobility at ankle dorsiflexion, which would demand more from the knees and hips. Additionally, recent evidence has suggested exercise programs for patients with CLBP that include hip and thorax mobility do enhance results.[82] Maximizing gains refers to professional judgement of when to accept that full “normal” ROM may not be

reasonable due to chronicity of the case (due to degenerative changes, etc.) but to gain what is possible to reduce the strain on the entire musculoskeletal system.

Attention to breathing quality is also important here.[83] A simple breathing screen can be utilized[71,72] to ensure patients achieve quality diaphragmatic breathing patterns paramount to overcoming compensatory, excessive superficial core muscle activity. Proper breathing sets the stage for proper core muscle function and associated functional movement pattern competency. As mobility and breathing improve, it is suggested to add individualized core motor control assessments,[31] to include volitional deep core muscle activation. Volitional activation of the transverse abdominis and multifidus muscles is well established as a key to core motor control and is easily integrated into rehab programs at this stage while patients are receiving twice-daily motor stimulation.

Next, a simplified hip-hinge is assessed by asking patients to demonstrate a seated hip-centric, neutral spine hip-hinge motor pattern. Expect patients to need correction of dysfunctional intra-lumbar flexion or excessive thoracic flexion while performing this task. These compensatory movements reflect chronically poor neural control of lumbar stability and multifidus dysfunction. Using motor learning principles, blocked training is initiated first with immediate feedback using verbal, tactile, and visual corrective cues. Goals focus to achieve desired motor patterns even if ROM, speed, and duration need to be limited. Once desired movements have been demonstrated, and patients practice 5-repetition sets satisfactorily, prescribing this level of motor pattern as homework every few hours daily is ideal. As movement quality improves, focus shifts to random training approaches to ensure long-term motor learning occurs.

For patients who are more advanced in skill development, similar principles may be applied with marginally more demanding and functional standing hip-hinges. ROM, load, speed, duration, and repetitions are always proficiency limited.

Ancillary screening and education may be provided and individualized to patients wherever needed in matters relating to general health and wellbeing, including low-insulin, low inflammatory nutrition, proper hydration, sleep, and behavioral health. To move beyond this phase, achievements include maximizing mobility gains and adequate functional hip-hinging.

PT Phase 2 (may begin 8-10 weeks post-op, typically lasts 2-6 weeks):

Proficient functional movement integration:

Once fundamental mobility deficits have been addressed and quality hip-hinging movement pattern basics are being established, attention turns to core-focused progressions from functional rolling patterns through standing movements. Confirming functional rolling patterns,[84] which helps confirm normalized timing in the multifidus, serves as a base to progress to more advanced movement re-training and ensures patients have overcome compensatory excessive superficial core muscle movement strategies and maximize lumbar multifidus activation timing.[76]

Appropriate hip-hinging function is crucial and should continue to be highly emphasized for ADLs (e.g., stand-sit-stand, reaching below waist height at drawers, fridge shelving and other household tasks). Functional movement therapy for patients with movement dysfunction is defined by skill acquisition of quality movement. Under supervised functional movement therapy, twice per week ROM, speed, repetitions, and

duration of activity can be progressively increased in keeping with patients' skill acquisitions and capacities. Achieving quality movement (smooth neuromuscular control) should be the goal of this rehabilitation phase. Quantitative strength or ROM and other discretionary fitness elements will naturally develop over time on the foundation of movement proficiency. Patients should be guided to engage in any bending task with high quality hip-hinging kinematics maintaining neutral spine awareness, hip-centric rotation, and posterior kinetic chain powered movement.[77,85] Patients should demonstrate understanding the difference between knee-loaded kneeling (squatting fully with buttocks close to heels) and intra-lumbar flexion (posterior rotation of the pelvis simultaneously with lumbar flexion), both of which should be avoided at this stage because the fascia and soft tissues are still scarring and healing at six weeks.

Demands and challenges of expertly performing these relatively simple movement tasks should not be under-estimated considering the movement dysfunction background related to mechanical CLBP and multifidus muscle neural inhibition contributing to inadequate motor control. Achievements include pain-free and symmetrical functional movement patterns (e.g., segmental rolling from supine to any transition, hip centric bending to various levels, and global movements, like walking) with adequate balance to move to the next phase.

Back in Action Phase (may begin 10-16 weeks post-op, typically lasts 6-8 weeks and beyond, as determined by implanting physician and PT):

Functional capacity development phase:

Functional capacity can be considered as one of the ultimate metrics of health. Functional capacity determines what one can achieve and do in life. For some patients this may be athletic competitions and for others this may be comfortably enjoying light gardening. As always, management is individualized to patients' current abilities, movement skills, and desires. Regardless of the desired discretionary functional capacity levels, it must be achieved on movement proficiency foundations. Therefore, as elements of intensity evolve favorably with ROM, speed, duration, strength, and power, it is always appropriate to take scaling steps backward if functional lumbo-pelvic movement proficiency is compromised. Failure to recognize poor movements in loaded and unloaded positions in the pursuit of capacity (including the return of intra-lumbar flexion, de-activation of the posterior kinetic chain occurring in conjunction with knee-loaded hinging (or deadlifting), and/or poor squatting techniques) may result in re-injury or acute flare-ups of pain. We want to protect the spine when it is loaded, say, in a lift, while in the unloaded spine, we want to see smooth coordinated spinal motion that includes composite flexion that protects as well. Technique matters, and patients, ideally, arevery cognizant of defining proficient movement, self-correcting, and appreciating the feeling of moving well through the lumbo-pelvic spine at this stage.

Functional movement training should consist of short episodes of relatively intense exercise efforts (5-10 minutes) made up of a combination of two to three regularly varied and characteristic functional movements (e.g., deadlift, squat, row-erg, cycle-erg, ski-erg, kettlebell swing, lunge, shoulder press, wall-ball, ball-slam). All these movements express core muscle-integrated kinematics with extremity power, neutral spine position, posterior kinetic chain activation, unloaded knees, multi-joint compound

activities with wide ROM. Optimally, power is expressed by quickly moving larger loads greater distances.[86,87] The inherent intensity associated with functional movements means sustained efforts are limited to shorter time domains of efficient training and far greater neuro-hormonal stimulation necessary for physiological adaptation.[87]

Finally, with a safe buffer of functional capacity exceeding functional demands of task specific work requirements, training can transition to more specific and work-related functional or non-functional movement demands should they arise. Adaptation is time- and intensity-dependent but can be developed safely if patients have the functional capacity to maintain lumbar intersegmental stability.

Precautions/Contraindications

PTs often use different modalities and procedures to help with patient symptoms and functional restoration. There are no contraindications to using modalities such as moist heat and ice packs to manage post-operative pain and swelling (which have generally not been challenging given the low surgical procedure invasiveness). However, lumbar region ultrasound and diathermy are contraindicated in patients implanted with any device.

Knowledge of the thoracolumbar fascial anatomy, noted previously, is important for the implant procedure as well as for the rehabilitation process. Fascial attachment, thickness, structure, and mobility play a major role in fascial stiffness and pliability. Connective tissue thickness reflects the amount of tensile stress applied on it, by way of tensile forces and increased fibroblastic response. Lariviere et al[88] discussed connective

tissue size and thickness, especially within CLBP, and increased tension from global bracing and guarding, neither of which are desired.

Considering the variety of manual therapy techniques used to inhibit/decrease pain, improve circulation, improve flexibility, and increase ROM, it is imperative to protect surgery sites, leads, and IPGs. Protecting IPG leads from shearing along the pathways to the dorsal rami medial branch nerves is important to allow scarring and healing. Therefore, up to 12 weeks post-op, manual therapy/fascial release in its different forms for elongating, stretching, and displacing fascia (i.e., manual, manipulative, stretching, instrument-assisted soft tissue mobilization, scar mobilizing, stretching especially in flexion, and neural tension mobilizing) are all contraindicated. Generally, it is suggested to avoid manual therapy or other treatments applied directly over the strain relief loop indefinitely (roughly L4 and superior and lateral of L3). If there is post-operative edema in the IPG area, on a case-by-case basis, it is appropriate to provide effleurage-type massage to encourage the lymphatic system. Lumbar region dry needling is contraindicated due to the uncertainty of lead wire paths. Puncturing the lead wire coatings risks interrupting conductivity, potential infections, and corrosion.

Typically, patients can begin to flex and rotate the spine between 6-8 weeks in unloaded conditions with muscular control emphasized. Then, after 8-12 weeks, the implanting physician typically allows a return to full desired activity. This can be done in conjunction with the rehabilitation professional based on unique progress, goals, and desired level of activity. Throughout the rehab process, the rehab provider should caution patients to avoid excessive lumbar spine flexion and rotation (for example, yoga positions that may emphasize end-range passive flexion or rotation without muscular

protection). This is precautionary as patients' unique movement patterns may dictate and help inform and progress spinal movements with exercises. For example, some patients utilize excessive lumbar rotation or flexion to often compensate for reduced motion elsewhere (like restricted hamstrings). Therefore, understanding their unique global and proficient functional movement performances as described, and associated motor control, will help to create safe, effective, and individualized rehabilitation programs.

In general, very strenuous, high force activities including extreme ROM of the arms should be performed with caution since it could impact the longevity of the leads: (e.g.: chopping wood, rowing, heavyweight lifting, and wrestling). A list of commonly implemented exercises and patient-reported outcomes is included in Table 1 to give readers a basis for each phase of recovery.

CONCLUSION

Implanted multifidus muscle neurostimulation has been shown to be a significant non-pharmacological adjunct for challenging cases with recalcitrant nociceptive mechanical CLBP. The effectiveness of implanted multifidus neurostimulation to slow and seemingly reverse the direction of this type of CLBP long term highlights a potential imbalance in the injury-recovery cycle that perpetuates the pain and dysfunction. Perioperative rehabilitation should be synergistic between patient's goals and with the implant goals, which are to optimize multifidus muscle contraction and restore lumbar intersegmental stability compromised by pain and movement dysfunction. Optimal rehabilitation includes proficient functional movement under various demands and

positions. Optimal rehabilitation programs should also consider addressing aspects of patients' lives which may have hindered healing from mechanical CLBP insults (i.e. repetitive injuries due to poor hip-hinging form when lifting, sleep disturbances, nutrition, proper aerobic activity) and encourage better management strategies post-operatively. Rehabilitation that enhances overall general well-being alongside implant-recruited multifidus muscle activity and upskills patients' default bending movements to protect lumbar spine segments from further accelerated biomechanical stress provides a reliable foundation to build a high-functioning capacity and quality of life.

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Manufacturer and product noted in manuscript:

[a]Mainstay Medical, Inc., San Diego, CA; ReActiv8® implantable restorative neurostimulator

Figure Legend:

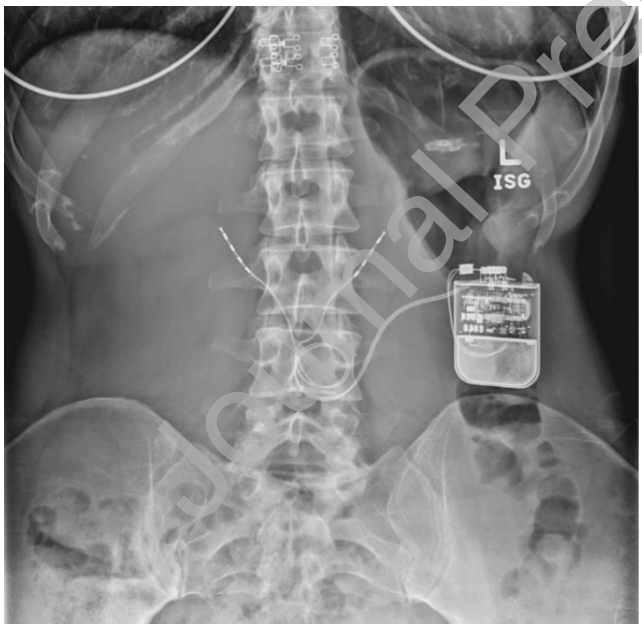

Figure 1. Radiographic anterior-posterior view with leads and implanted pulse generator (IPG).

Table 1. Multifidus Neurostimulation Implant Rehabilitation Recovery Phases

Phase	Time Period	Goals	Example Activities
Preoperative Phase	N/A	• Assess baseline functional status • Assess baseline psychosocial status • Patient and family education	Oswestry Disability Index (ODI) Pain Self-Efficacy Questionnaire (PSEQ) Fear Avoidance Beliefs Questionnaire (FABQ) If able, maintain/improve upper trunk, hip, lower extremity range of motion without exacerbation to the lumbar spine. If able, maintain aerobic capacity prior to surgery.
Protective Phase	Weeks 0-2	• Wound care and use of corset as instructed • Implant protection • Soft tissue healing (inflammatory stage) • Cardiovascular health maintenance	Daily wound care per physician instructions. Avoid repeated spine flexion, extension, rotation and overhead reaching. Lifting restricted to < 5 lbs; no overhead lifting. Progressive walking 5-10 minutes, 3-4 times per day.
Initial Activation Phase	Weeks 2-6	• Initial multifidus neurostimulation device programming • Patient education (device use parameters) • Regular use of device twice a day, 30 minutes each	Introduce slow and gentle pain-free spinal movements and reaching. Continue to avoid activities that require quick or maximum spinal movements. Lifting restricted to < 10 lbs. in overhead lifting. Increase lifting to up to 25 lbs. over the Phase. Increase walking duration.

PT Phase 1	Weeks 6-8	• PT Evaluation • Screen for major joint/soft tissue mobility deficits. • Manage superficial muscle tone/guarding. • Hip centric movements	Manual therapy and mobility exercises to treat identified impairments. Diaphragmatic breathing techniques and trigger point work. Hip hinging quality (sit-to-stand (beginning of Phase) squatting with no weight (end of Phase)).
PT Phase 2	Weeks 8-10	• Progressive core control • Functional movement competency • Normal balance	Core progression from segmental rolling, quadruped work, kneeling chops/lifts, to bilateral and unilateral hip hinging exercise (e.g., single leg deadlifts) Balance exercises
Back in Action Phase	Weeks 10-16	Activity specific strength/endurance*	Short episodes of intensity training with multiple actions (5-10 min) Progressive strength and cardiovascular training (i.e. deadlift, press, Turkish get-up, etc.) With proficiency, introduce work- and sport-specific activities as needed

*Avoid or be extremely cautious with very strenuous, high force activities, particularly long-lever functions involving extreme arm range of motion (e.g., chopping wood, rowing, heavyweight lifting, and wrestling).

Conflicts of Interest:

Outside the submitted work: Dr. Carayannopoulos reports consulting fees from Pain Spine and Rehabilitation Consulting, Inc., royalties from Springer Press, grants from Aspen Medical, NIH, DARPA, and Medtronic, expert testimony as PSR Consulting, Inc, meeting/travel support from ASRA, NBOME, AAOE, AOA, leadership/fiduciary roles for AAOE, and RISIPP; Dr. Johnson reports leadership roles as co-director of The Back Pain and Functional Movement Training

Centre, Brisbane, Queensland, Australia and co-director of the College of Functional Movement Clinicians; Dr. Giuffrida reports consulting fees from Gspine, LLC and personal consulting fees from Mainstay Medical; Dr. Poply reports an educational grant paid to employer from Pfizer, a patent (EEPIN: Executive Education Program in Neuromodulation), leadership roles as Section Editor of Pain Practice, Director of EEPIN, Program Lead PG Certification in Neuromodulation, and Examiner FFPMRCA at RcoA, NANS Education Committee member, and personal consulting fees from Mainstay Medical; Dr. Mehta reports a grant from Abbott, personal consulting fees from Boston Scientific and Medtronic, honoraria from Medtronic, Mainstay Medical, and Abbott, a patent (EEPIN: Executive Education Program in Neuromodulation), and a leadership role as Chair of the Faculty of Pain Medicine, United Kingdom; Dr. Amann reports personal consulting fees, honoraria, and meeting travel support from Mainstay Medical, and personal consulting fees Stryker; Dr. Santillo reports personal consulting fees and meeting support from Mainstay Medical; Ms. Koch reports personal consulting fees from Mainstay Medical; Dr. Langhorst reports personal consulting fees from Vivex and Mainstay Medical; Dr. Heros reports grants paid to his institution from Abbott, Ethos Laboratories, Mainstay Medical, Nevro, and Saluda, personal consulting fees from Abbott, Boston Scientific, Biotronik, Mainstay Medical, and Saluda, honoraria from Mainstay Medical and Boston Scientific, meeting support from Mainstay Medical and Relievant. The remaining authors have no conflicts of interest to disclose outside of the submitted work.