NEURO 20
EFFICIENT HEALTH

Physical Rehabilitation Network Case Studies

1. **High level athlete attestation (D1 football ESPN 300 athlete with hamstring strain):** utilized the strength protocol to increase the load we had placed on him in squat, lunge, Bulgarian split squat, hex bar deadlift pattern, as well as eventual jogging/sprinting pre-programmed protocols. Pt week 1 was able to increase approximately 15-20% of capable lifting loads and subjectively as well as objectively had increased ease of coming out of the hole with heavy goblet squat and hex bar deadlift patterns. Used the jogging protocol for 50-75% subjective full speed work for 2-3 sessions followed by sprinting program for 2 sessions prior to HS playoff football game. Before the Neuro 20 suit, he wasn't able to jog, much less sprint without pain and his hamstring "grabbing" him. Using the suit and stim, he was able to produce improved motor recruitment as well as improved pattern of movement thus allowing him to sprint without pain and improve "confidence" levels as well. Pt even asked if he was allowed to wear the suit under his uniform during the game because he felt so strong; I politely told him it wasn't designed for that as well as the legality of that during play.

2. **High level athlete attestation (D1 female track athlete s/p ACL recon and partial meniscectomy):** utilized the strength protocol to increase the load we had placed on her in squat, lunge, Bulgarian split squat, hex bar deadlift pattern, as well as eventual jogging/sprinting pre-programmed protocols. Used the suit on the patient week 2 of rehab moving forward after her partial meniscectomy and was able to increase the recovery speed. She was done with PT in 3.5 weeks with full return to function as opposed to the typical 6 week return protocol for a high school sprinter/hurdler.

3. **Medicare R Rotator cuff repair**: Implemented approximately 7.5 weeks into program to enhance end range AROM into flexion and abduction. Pt had around 10 and 15 degrees respectively left of each direction to attain and the use of the suit per his report made it easier to reach end range, and what was thought to be primarily a capsular restriction turned out to be that only of a mild nature and more so due to weakness along with motor control/patterning issues we were able to correct. This patient felt "stronger" and had an easier time with his Keiser strength program while using the suit. It produced some soreness the following session, but no AROM limitations, and could also be due to the program selected by the PT more than the increased muscle fiber recruitment.

4. **MS and S1 radiculopathy with nerve damage into lower extremities**- Prior to using the suit we attempted to utilize electrical stimulation to improve motor function, but the patient was unable to perform 3 lunges with assistance without failure. After 2 sessions with the suit, he was able to perform 3-4 sets of 8 repetitions of lunges with no assistance. He states his radicular pain has almost completely

resolved and it has given him confidence and the ability to do more things he wants to at home.

5. **ACL reconstruction with developed a cyclops lesion**-Male, Patient prevented from being able to perform exercises and running. While utilizing the Neuro20 suit he was able to run, jump, and squat with increased resistance and weight to return to coaching soccer and feeling like he has a normal leg again.

6. **Thoracic fusion-** Female, mid 30s - used in a total strengthening manner around 8-10x and she was able to make significant gains in both strength, endurance during her regimen, and overall power output as measured by our Keiser strength machine and it's power meter. One of her screws broke, but she remained asymptomatic in her back, largely due to the strength she had built in PT, compounded we both believe by the use of the suit, and the suit totally eliminated pain during sit ups, plank positions, as well as running. She was not able to run without pain prior to the use of the suit.

7. **Achilles Tendon**- Female, for many months we worked with a former college basketball player who tore her Achilles tendon and had a reconstructive surgery. She was apprehensive with jogging, running, and dynamic tasks but while utilizing the Neuro20 suit she felt like she was a "superhero". You could see the confidence in her face as she realized she didn't have pain while running and was able to feel like an athlete again.

Synopsis Case Study D1 Collegiate Athlete

[redacted] Thursday, June 17, 2021 9am

B/D 11/30/00 [redacted]

S: 20yo. Left ACL surgery 4/1/21 by Dr J Locker at Orthopedic Institute in Ocala FL (352-620-1900). Caroline is a center fielder, lead-off hitter for women's softball heading to Univ of South Carolina-Upstate to play 3-4 years based on her eligibility. Caroline competed at College of Central Florida last year and this is where she sustained the injury while running to first base. Eric English is her AT at the University of South Carolina-Upstate in Spartanburg SC 864-279-4990 eenglish@uscupstate.edu

O: Biometric measurements.

Left Involved		Right	
Relax	Contracted	Relax	Contracted

6” Inferior	12 1/3	12 1/3	12 ½	12 ¾
3”	12 ¼	12 ¼	12 ¼	12 ¼
Mid-patella	14	13 2/3	13 ¾	13 ½
3” Superior	13 ¼	13 ¼	15 ½	15
6”	15 ½	15 ½	15 ½	15 ¾

	Active	Passive	Active	Passive
Extension, Seated	0	-4	-4	-6
Flexion, Seated	134		144	

		Left,inv	Right
Surface temps	mid-patella	91.6	88.8
	VMO	92.0	92.0

non-antalgic gait, scars are healing well, paresthesia proximal/lateral compartment of Left lower leg, able to perform Quad Set and SLR, Involved VMO is atrophied, 2/5 Leg Extension

A: 11 weeks post ACL repair, Hamstring tendon

P: FU with Monica Joshi MAPT in NY and Jesus Villafane, strength and Conditioning Coach, in FL. Awaiting Fax from Dr Locker for ACL Protocol guidelines. Proceed according to protocol as established by Dr Locker. Will commence Neuro20 suit while exercising with Jesus in FL. I suggest she begins the workouts with the Neuro20 July 1 as it will allow me to see the physician guidelines. Until then Caroline can do Quad, Hamstring Adduction, Gluteal Medius and Gastrocnemius exercise’s pain free. Closed Chain exercises commence with caution and guidance from Monica Joshi. Biometric measurements to be repeated every other week. Functional progression not to be done until physician clears her to do so.

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Saturday August 14, 2021

S: Saw [redacted] this morning for a FU visit. She is ~ 19 weeks post-op and leaves for USC-Upstate this weekend.

O: Biometric measurements.

	Left Involved		Right	
	Relax	Contracted	Relax	Contracted
6" Inferior	12 7/8	12 7/8	12 ½	12 ½
3"	12 ½	12 5/8	12 ¾	12 3/4
Mid-patella	14	13 ½	14	13 5/8
3" Superior	15 ½	15 ¼	14 ¾	14 ½
6"	17 ¼	17 ¼	17 ½	17 3/8
9"		21		21

	Active	Passive	Active	Passive
Extension, Seated	0	-2	-4	-8
Flexion, Prone	No measure	142	No measure	145

A: 19 weeks post ACL Reconstruction with Hamstring

P: Average increase thigh circumference of 2" during her rehab. This is clinically significant for such a short time frame. I believe her personal trainer, Jesus and [redacted] work ethic contributed to this success. Go to USC-Upstate and work with AT, Eric English to continue her progress and eventually return to play he and Dr Locker release her to do so.

Note* [redacted] was cleared to return to full athletic activity in October, 2021- 6 months post-surgery.

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CASE ANECDOTAL RECORDS– BACK IN THE GAME THERAPY, NYC RESULT DRIVEN PRACTICE "Back in the Game Therapy" BITG

- 15 years of a small elite practice
- Age range - 3 months to 92 years finance, lawyers, celebrities, musicians, dancers, housewives, pharma
- Clinic goal is to help patients achieve their mutually agreed upon goals
- Patients interested in wellbeing, fitness and staying healthy
- Activities are running, triathlons, biking, yoga, hiking, weight training • Willing to try cutting edge technology that may assist them
- Determined and motivated-they trust us and know we are all about their wellbeing and getting them better

NEURO20 AT BITG - 4 patients 2x/wk. 20 min./session

- Low back pain
- Chronic hamstring strain
- Parkinson's
- IT band syndrome

MONICA JOSHI – "MY PERSONAL EXPERIENCE w/ NEURO20"

- Run, bike, yoga, strength training, HITT
- PT consult with my colleague
- Poor left glut firing, weak left hamstring, weak left oblique, tight left IT band, OVERUSE of bilateral piriformis, overall weak gluteal and hip abductors
- Program for me – 2X/week for 20 mins for 6 weeks - core, hip, scapula strengthening exercise ME- HNP L5 with referred pain on right side
- DJD L3-5
- Left hamstring tear
- Left chondromalacia patella

PERSONAL RESULTS

- System helped activate my gluts
- Improved left oblique as well
- After 3 weeks: more strength in LE, stronger core, able to run 4 miles again, riding bike faster and harder.
- After 6 weeks- much better in my side planks, left gluts and hamstrings • No knee pain and less back pain

PATIENT 1 RESULTS

• MS - 61 years- F- diagnosis of thoracic outlet syndrome with pain and left arm weakness, Parkinson's - had poor gait pattern, left hand tremors, no left arm swing during gait, rigid thoracic spine during gait, weak left arm, poor function, weak core and scapula muscles
• Dosage – x2/week 20 mins.
• Following 15 sessions-50-60% better with gait, started arm swing, better thoracic movement during gait, no arm tremors the day following Neuro20, more strength to do ADL

TESTIMONIAL: "*The first week of Neuro20 was exhausting with a lot of muscular fatigue and pain. However, by the third week this had dissipated. I am still stronger on my right side, but the discrepancy is far less. I recently skipped a full week of Neuro20 and I thought I might have an overall digression. If I did it was insignificant and when I resumed Neuro20 I found most exercises to be much easier with the biggest change and improvement being on the days off. There is great improvement and sustainability. I am finding a daily improvement and can now sustain fluid mobility on the days I am not doing Neuro20 Some exercises have become easy, the learning curve when given a new exercise is quicker and the down time is nonexistent. Since incorporating Neuro20 into my physical therapy I have seen a marked difference in my overall well-being. Most notably I am stronger, more fluid in my movements and have greater range of motion. Additionally, the resting tremor in my left arm has decreased, most significantly in my hand and fingers. I definitely have more stamina.*"

PATIENT 2 RESULTS
• RM -46 years-M- HNP, right knee and foot pain -running, biking, swimming x7/wk. - always pain in right knee and foot after 9 miles, limping for rest of day
• Dosage- x2/week for 20 mins.
• 8 sessions so far able to run 15 miles with no pain, bike trip for 7 days with no knee issues
TESTIMONIAL: "*Neuro20 has been an amazing experience! Monica and I have focused on building core strength, and I've seen a huge difference in my running ability after using it regularly for the summer 2x/week. I usually injure myself after running >13 miles, and I've successfully logged a 15 mile and 18 mile run in the last month and gearing up for a 20-mile run tomorrow!*"

PATIENT 3 RESULTS
• JB - 51 years- M- low back pain, right TA tendonitis - running, biking - pain in right foot after 4 miles, poor endurance on bike, training for marathon in November
• Dosage- x2/week for 40 mins.
• 7 sessions later - 7-day bike trip in France with no issues, ran 15 miles with no issues, stronger core and LE
TESTIMONIAL: *"I begrudgingly started using the suit and was very skeptical at first. However, after several sessions over the summer it is clear to me that I'm stronger and less*

injury prone. I've decided based on my results so far to train for the NYC marathon, which was far out of reach before."

PATIENT 4 RESULTS

• JR - 45-year-M- 8 weeks s/p spinal fusion for stenosis and DJD -back pain, pain on standing for more than 5 minutes
• Dosage- x2/week for 30 mins
• 4 sessions later -minimal back pain, able to stand for 15 minutes, tremendous increase in core and LE strength

MVP Research May 2019

SYNOPSIS OF PILOT STUDY AT THE UNIVERSITY OF TAMPA

Note on Validity

The preliminary result tables from the Human Performance Laboratory, University of Tampa pilot study 2019 are complete. The principal investigator stated that the pilot study will not reach the "Excellent" validity score benchmark that we want all research to reach. The issue was due to "the low sample size that caused a high level of variability (deviation outside the range) due to an outlier." The principal investigator stated this is a normal occurrence and an encouraging validity score in the pilot phase. This pilot validity will reach the "Very Good" range of 85%-90% (actual score is 89%), however the clinical trial must have a sample size large enough to account for variability and score in the 97% plus range.

Note on Confidentiality and Scheduled Clinical Trial-

The principal investigator and I unpacked the data, and we must await formal publication of the pilot study before public release. Our Research Agreement with the university states, that they own the data and we cannot publish until after their board approves publication. However, we may use the data for internal operations until the publication date. The date for publication will be approximately 6 months following the completion of the larger clinical trial. The University has scheduled and assigned personnel to conduct the trial from February 2020-May 2020 coinciding with their Semester schedule.

For the clinical trial the University of Tampa needs to secure more subjects to make formal finding statements, especially because there is "one outlier in the control group has created a high level of variability which is common in research but can only be offset if we had a larger sample size." What is common practice in low sample size research in the human performance area is that the outlier is identified as such and removed from the data table with a qualifying statement and then the numbers are recalculated, especially because of life load factors outside of the control of the study that effects validity scoring. This issue only highlights the stated need for more product to be available for them to conduct a full study with 50 plus participants.

Note on sharing data tables

The data tables may not be shared with anyone outside of our internal organization without a specific discussion on both the variability and the context of the protocols first along with written permission from the University of Tampa. Without understanding the protocols fully, the data table alone could appear unfavorable in some areas at first glance, however only through unpacking the data and understanding the protocols does the data become clear that we are onto something revolutionary.

Subject Adverse Effect Reporting

There were no negative adverse effects associated with the use of the system and there were no adverse effects.

Discussion

The body sculpting numbers, i.e.: % of fat content, average power numbers, etc. are within the same to similar range of gains/loss as traditional workouts as considered by human performance specialists. Although the data table alone would be misleading and perceived a negative, this is actually a very positive indication due to the protocols. The data suggests that the claim that the technology can get greater results in less time could be true.

Although the system demonstrated slight gains in the Average Power category, if the removal of the outlier occurs then the technology would demonstrate a significant gain. Place the numbers in context with the study protocols and the technology greatly exceeds expectation.

Protocols- The control group proceeded with their traditional training methodology- 5 gym visits per week with a rotating training program for 1 hour with isolating muscle groups. This group was comprised of some members of the University Hockey Team who had additional training on ice.

The EMS group used the technology for two workouts 20 minutes per week. The population group was also from the hockey team, and they discontinued their traditional gym training regimen, however they continued with their on-ice training the same as the Control.

The EMS group fell within the range of change percentage of the Control group. This very promising because it indicates that the efficiency of the system lends to the EMS training being favorable to method of training due to the reduction of time, less need for equipment. This is a major concern for both the NCAA and professional sports organizations due to regulatory obligations placed on athletes' time. The general population will also be affected by improved efficiency both in athletics and physical therapy.

The research also noted that the fact that the EMS group obtained these results through training methods devoid of impact on the musculoskeletal system, as they only exercised through body movement and not with additional equipment such as weights is potentially a game changer. According to UT, and especially for those who may be injured, elderly, obese, or an athlete, achieving equivalent exercise results in less time with more limited injury risk is significant.

Since the EMS protocol was to exercise only through functional body movements, and body weight only exercise, they believe that if the clinical trials demonstrate the same results then a reduction in the risk to injury that allows for rehabilitation for injury in comparison to the physical impact of weights associated in traditional training could lead toward a Breakthrough designation by the FDA.

Whether healthy or injured, UT was confident that the EMS protocol if fully studied could lead to a conclusion that it be a far more safe and efficient exercise and rehabilitation protocol option for the public. The UT research team surmised that since repetitive stress injury is often the prevention of patient rehab or the cause of sports injury, the EMS protocols would indicate a de-risking for this to occur without significant performance variance thereby being the healthier protocol moving forward. They want to study this potential more fully.

Furthermore, the fact that this training may occur within the normal scope and movement of the desired kinetic action that the trainer wants the athlete or patient to perform is an essential difference than the control groups training regimen, therefore adding a factor for practitioners to make EMS the preferred protocol. For example, i.e. (Football snap drills, kicking a soccer ball, hitting a puck, baseball or golf ball requires specific technical movements, and rather than using a weight room to increase power each athlete can have individualized muscle performance within their normal scope of movement. The example in Physical Rehab- walking, running, bending over, etc... is the same, contractions rather than strapped on weights or resistance bands. UT is interested in the application difference in both occupational therapy and sports training that the flexibility that our tech provides with decreased risk for injury, to receive training within the functional rehab space. This is potentially a market differentiation and therefore can be disruptive and will be part of the Next Steps section of their research paper.

In terms of Medical Potential Applications there are Additional Positive Indications, especially in the Ortho/Osteo/Joint Replacement Space and Spinal Degeneration/Rehab Space, and for Increased Athletic Performance with Potential Reduction of Injury, because of these two important Indicators:

> Even with the control group outlier numbers included the Whole-Body Bone Mineral Content of the EMS group was +1.5% greater of that of the traditional workout control group, within the protocol framework of only 4 weeks of 8-EMS 20-minute workouts. Even more promising is that the Whole-Body Bone Mineral Density numbers were +9.63% even with the outliers included for the EMS group and under the same protocols when compared to the control. Again, these numbers bear further study due to the low sample size, but added to the context of years of well-established research on bone density increases from EMS, the supporting qualitative data gathered from our other studies, the already established use of FEMS and Inferential EMS in therapeutic practice and pain management by healthcare practitioners, and the well-established use of NMES and Burst Mode EMS (Russian Stim) for athletic performance and recovery, these numbers can be game changing for the technology upon confirmation with a wider data study achieving a higher validity score.

Note on Current Status- Unfortunately in March of 2020 the clinical trial plans were postponed due to the closure of the University due to Covid. The trial could not be rescheduled until Fall of 2022. By that time the Principal Investigator graduated and returned to India. The company decided to abandon the research and focus efforts in the medical market with clinicals scheduled for March 2023 in India.